Building a Smart Infusion System Drug Library

Introduction

A smart infusion system is designed to minimize programming errors and the related risk of patient harm. Each facility develops a customized infusion system drug library, which includes dosing ranges and other safety limits for individual drugs. During infusion programming the pump checks the entries against the drug library and alerts the clinician when a drug library limit is exceeded, preventing the patient from receiving an incorrectly programmed infusion.

A comprehensive drug library is critical for the effective and safe use of any smart infusion system. The effectiveness of a smart pump system's ability to detect programming errors before an infusion is delivered to a patient is dependent on how well the drug library is built and maintained.

Infusion systems with Electronic Health Record (EHR) system interoperability provide additional programming safety and facilitate clinical documentation.

Figure 1 is an overview of the process to build an infusion system drug library, including steps to consider for EHR integration.

Design Phase

Step ONE – Establish the Team

One of the success factors for a well-built drug library is collaboration from all stakeholders.

Figure 1 Phases



DRUG LIBRARY CONFIGURATION Regular scheduled reviews for each Care Area





Building a drug library is a team approach and is not to be undertaken by one individual. Consider including the following key stakeholders:

Pharmacy

- Pharmacy admixing/compounding representative
- Clinical pharmacist representative for each unique clinical care setting
 - Pediatrics/neonatology
 - o Oncology
- Pharmacy & Therapeutics (P&T) committee representative
- Pharmacy representative for the EHR system (pharmacist informaticist)

Nursing

- Nurse educators
- Nursing manager/representative for each clinical care area
- Nursing representative for EHR system (nursing informaticist)

Prescriber

- Prescriber representative from a critical care unit
- Prescriber representative from a general medicine unit

IT resource

• IT representative with knowledge of the organization's wireless infrastructure

The Team

Pharmacy drug library leader

The leader for the drug library build should be a pharmacist with in-depth knowledge of the organization's drug formulary and intravenous infusion policies and procedures. The pharmacy leader must have readily accessible current drug reference materials and an understanding of pharmacy admixing practices and procurement. The leader should also be familiar with using Microsoft Windows software. This individual leads the development of the drug library, is responsible for entering drug records into the software provided by the pump vendor, and facilitates review meetings with stakeholders.

Nursing drug library leader

The nurse leader must have current clinical experience in infusion therapy and will serve as the lead nurse resource for the pharmacy drug library build.

Pharmacy admixing/compounding representative

This pharmacy team member provides expertise in how IV drugs are prepared, common formats for each IV medication, typical container fill volume, stability data, clinical care settings where medications are used, and label information affixed to the container. This person is instrumental in supporting the standardization of concentrations during the drug library build process (see section on Drug Concentration).

Clinical pharmacist representative for each care area

This pharmacy team member provides information on indications for drugs prescribed, common dosing and dosing methods and references to dosing limits. He or she confirms consistency to formulary and policies and procedures.

P & T Committee pharmacy representative

This individual serves as a liaison for the drug library development team, provides progress updates to the P&T Committee and ensures consistency between infusion practice and drug library setup.

Pharmacy representative for EHR system

This individual provides knowledge of the organization's formulary, preset drug admixtures and commercially available premixed IV products, and knowledge of prebuilt order sets within the EHR system. This person supports consistency between the organization's formulary and the infusion system drug library and ensures all drug entries are consistent with order sets in the EHR. Additionally, this individual is responsible for mapping (associating) all IV medications from the EHR to the infusion system drug library and ensures alignment with systems such as automated dispensing cabinets and IV workflow management system.

Nurse educator

This critical member provides expertise in current infusion delivery practices and ensures that all affected policies and procedures are updated. This individual is responsible for organizing hands-on education for nurses, anesthesia providers, and pharmacists during the implementation of the new infusion system.

Nurse managers/representative for each clinical care area

These members provide insight into current infusion practices and are directly involved with the drug library build in providing input and participating in drug library reviews.

Nurse representative for EHR system

This individual provides expertise for nursing workflow between the EHR system and infusion system programming and ensures that all clinical scenarios related to drug orders and other related interaction with the EHR system are considered. This individual provides detailed understanding of required clinical documentation in the EHR for infusions delivered using an infusion pump.

Prescribers

Prescribers provide insight into prescribing practices such as intended therapy, route of administration, drug and concentration selection and dosing methods. They are critical in supporting standardization of concentrations during the drug library build process in addition to standardization of order sets within the EHR system.

IT representative

This member provides expertise on the IT infrastructure to support the secure connection of the infusion pumps to the hospital wireless network, as well as ensures the appropriate server architecture is in place for wireless distribution of the drug library to the infusion pumps. In addition, this person will support the technical aspects of Bedside Barcode Medication Administration (BCMA) for integration of the infusion pump into the EHR.

Step TWO – Formalize the Process

It is important to establish formal processes for approving the drug library as well as managing *change requests* (CR) and *new requests* (NR) for any drug library revisions, both for the EHR system and the infusion system drug library. Changes to one system need to be aligned to ensure consistency and patient safety. This will ensure a robust history file and audit trail for all edits to the drug library.

Step THREE – Defining the Scope

Identify all medications that will be delivered using the infusion system. Consider taking a broad approach first and then reviewing specifically for each drug or classes of drug and care area setting (see Figure 2).

All medications and fluids should be delivered using a smart infusion system whenever possible.

Your assessment may be based on the following:

Drug format / container

- Chemical and physical properties
- Fill volume and container type and size
- Intended therapy and patient population
- Other ancillaries required for administration

Delivery of infusion

- Route of administration
- Dosing units
- Dosing method
- Flow rate and accuracy requirements
- Continuity of flow requirements
- Drug compatibility with approved pump administration sets

Figure 2 Defining the scope



External environment

• Identify clinical care area settings where this drug is intended to be infused

Figure 2 offers some examples to consider when evaluating drugs to be used with the infusion pump system.

In addition, each drug must be reviewed for how it is currently being infused, the safety and effectiveness of the current infusion method and the potential impact of any changes to the current delivery method.

Step FOUR – Collecting Relevant Information

Gather the necessary information to initiate a drug library build that is consistent with current practice and hospital policies and procedures.

The following are suggestions of data to collect:

Medication ordering/administration

- Standard order sets for each medication and/or therapy
- EHR interoperability workflow; autoprogramming initial dose and dose changes
- List of IV medications admixed by nursing and admixing chart used by nursing
- Medications administered as a bolus via continuous infusion bag, separate product, via syringe pump
- Medications administered via patient-controlled analgesia (PCA)
- Hospital's IV Manual
- Hospital's Policy and Procedures Manual
- Hospital's Formulary

Pharmacy

- IV admixing/compounding chart
- Drug library/formulations/drug label/usage data from your Pharmacy IV Workflow management software (DoseEdge, BD Cato[™], ScriptPro[®], I.V. Soft[®], Pyxis[®] IV system etc.)
- Drug library/formulations/drug label/usage data from your Automated IV Compounding system (RIVA[™], I.V. Station[™])
- List of commercially available premixed medications purchased
- List of medications purchased from outsourced compounding suppliers
- Back order status and history for IV medications

Medication Safety Committee

- Sentinel events and medication error reports
- Trending data and specific case reports related to medications

References (suggested)

- Manufacturer's Prescribing Information
- American Hospital Formulary System (AHFS) for US region
- British National Formulary (BNF) for UK region
- Australian Pharmaceutical Formulary and Handbook (APF) – Australia region
- Lexicomp[®] drug information
- Micromedex[®] drug information
- Pediatric Injectable Drugs (The Teddy Bear Book)
- First Databank Infusion Knowledge[™] content
- Standards or guidelines from recognized professional organizations, e.g. Institute for Safe Medication Practices (ISMP), American Society of Health-System Pharmacists (ASHP), and Association for the Advancement of Medical Instrumentation (AAMI)

How to use the data collected – Overview

Medication ordering/administration

Reviewing order sets is critical to ensure each drug is configured appropriately in the drug library. It is important that the way a drug is prescribed matches exactly the way the drug can be programmed on the pump. This also provides an excellent opportunity to review and confirm that current practice is consistent with your hospital IV Manual, Policy and Procedures and EHR prescriber ordering system.

Pharmacy

The information collected from pharmacy provides important data on drug formats, concentrations, dosing units and commonly prescribed dosages. Usage data may help in identifying opportunities for standardization. The drug library from your pharmacy compounding system must be consistent with the infusion pump drug library, ensuring all drugs prepared match exactly what is available on the pump, allowing the clinician to select the correct drug name and to program the infusion correctly.

A review of drug shortages is important to determine if additional drug concentrations are required to be included in the drug library to manage these situations.

Medication Safety Committee

It is important to review and understand sentinel reports and medication error reports and take these into consideration to ensure mitigations are incorporated into the drug library, where applicable.

References

Create a datasheet to document references used for each drug record in the drug library. Your organization's IV Manual, Policies and Procedures Manual and Formulary should be your primary sources as these reflect your facility's current, approved practices. Other references used should be current clinically and professionally recognized references.

Drug Library Configuration Phase

Step FIVE – Drug Setup

Depending on your infusion system's drug library software, you may be required to complete certain steps in sequence.

Here are a few options to consider:

Example 1:

- Create a master drug list
- Create clinical care area profiles
- Associate drugs to a care area profile and customize settings

Example 2:

- Create the clinical care area profiles
- Create records for all drugs in one care area and customize settings
- Copy drugs from one care area profile to another and customize
- Copy a care area profile to create a new care area profile with an identical drug list, and then customize the drug parameters for the new care area

Container Type / Pump Delivery Module

If the infusion system includes more than one type of delivery module, determine how each drug is to be delivered, the container type and size. If a drug can be delivered using more than one module, ensure that this drug is set up accordingly.

Drug Name

Entering the correct drug name into the drug library is critical to minimizing confusion during pump programming. Drug name consistency throughout the medication order/administration pathway is crucial to minimizing medication errors.

Things to consider when determining drug name setup:

a) IV Fluids

IV fluids should be entered into the drug library by chemical name and composition (e.g., NaCl 0.9%, Dextrose 5%, Lactated Ringers) to provide appropriate identification and accurate selection when programming a fluid therapy infusion. Names used in the drug library should be consistent with the names used in the EHR system. The composition, volume and rate of administration are critical attributes for administering each fluid therapy safely and as intended.

b) Generic Name vs Brand or Trade Name

Typically, a drug's generic name is used for the name in the drug library. Brand or Trade names may change when hospital's purchasing agreements change or during interim supply issues. ISMP recommends that all medicationrelated products be listed by generic name using all lowercase (unless using tall man letters as mentioned below) as the primary expression of drug nomenclature, ensuring that each matches US Food and Drug Administration (FDA)approved nomenclature and consistent with electronic health records and packaged labels.

Upper and Lower Case Letters (Tall man lettering)

Incorporate ISMP and Food and Drug Administration (FDA) tall man lettering (a combination of upper and lower case lettering for drug names) to differentiate look-alike and sound-alike drug names. Review sentinel events and medication incident reports to determine if any incidents occurred that may have been related to how the drug name is displayed.

c) <u>Label on Admixture, Premixed or Outsourced</u> <u>Compounded Product</u>

Review how the drug name is displayed on the label that is applied to the admixture or the label on commercially available premixed or outsourced compounded product. The drug name in the drug library should match exactly how it is displayed on the label. This will minimize confusion for the clinician and allow the selection of the correct drug when programming the infusion pump.

d) Preprinted Order Sets or EHR Order Sets

Review the order sets for each drug and ensure the drug name displayed is consistent with the drug name in the infusion pump drug library. This will support correct drug selection during pump programming.

e) Number of Characters Exceed Drug Name Limit

In situations where the full drug name exceeds the character limit in the drug library software, ensure that the condensed drug name is clear, consistent and easily recognizable.

Infusion Type

For most infusion pump systems, there are two general infusion types that may be configured, continuous or intermittent.

Things to consider when determining the infusion type for the drug:

a) Intermittent infusion

Infusions that are delivered over a specified time, at prescribed intervals in small volumes of parenteral fluids. Typically, a drug volume ranging from 25 mL – 250 mL, and infused over 15 – 90 minutes at prescribed intervals. b) Continuous infusion

A drug that is prescribed with a dose rate. The infusion continues until therapy is no longer required. Dose changes may be programmed during the infusion.

Evaluate each drug to ensure consistency with how the drug is prescribed and the dosing information included on the admixture/product label.

Delivery Method

Depending on infusion type, there are different methods to programming and delivering an infusion with an infusion pump. The three (3) general methods are:

- a) Primary Infusion
- b) Secondary Infusion (Piggyback)
- c) Multi-Step (ramping)

It is important the drug record is configured to allow clinicians to program the pump with the correct delivery method. Review your organization's IV Manual/Formulary, Policies and Procedures Manual, and EHR order sets to ensure compliance and consistency.

Primary Infusion

These are typically continuous infusions such as titratable medications and IV fluids that are delivered through the primary administration set.

The drug library software may allow for various custom options for primary infusions such as:

o Primary or Secondary

Allows drug to be delivered as primary or secondary infusion.

- Primary only, secondary not allowed
 - Drug can only be programmed as a primary and cannot be interrupted by a secondary infusion (e.g. high-alert drugs).

• Primary only, secondary allowed

Drug can only be programmed as a primary and a secondary is allowed to interrupt this infusion (e.g. IV fluids such as NaCl 0.9%).

Secondary Infusion (Piggyback)



Secondary (piggyback) infusions are delivered through an established pathway of a primary infusion.

Most large volume infusion pumps require a minimum height differential between the secondary and primary bag (Figure 3). No secondary infusions should be connected to high-alert primary continuous infusions. Consult your infusion system user manual for correct setup procedures for secondary infusions.

Note:

- Refer to the drug manufacturer's full prescribing information to confirm drug compatibility, volume and delivery rates are suitable for secondary delivery.
- Certain infusion pumps may allow for concurrent delivery of primary and secondary infusions.

Multi-Step Infusion

This allows the drug to be programmed on the pump to run at sequential dose rates. The infusion pump transitions from one dose rate to the next as programmed.

A callback option that alerts the clinician when a step in the infusion is completed may be available or the multi-step infusion may transition from step to step without an alert. Refer to your organization's formulary and drug manufacturer's full prescribing information to determine if multi-step use is appropriate.

Note: Consider if patient monitoring is required to confirm if a dose change is appropriate.

Clinical Application

Your drug library software may have an option for labeling drugs with multiple concentrations to differentiate how each concentration is used or how it is programmed on the pump. This information can provide further guidance for the clinician during pump programming. This clinical application feature for known infusion systems is referred to as <u>Clinical</u> <u>Use, Modifiers or Therapies</u>.

The typical drug selection workflow on the pump with clinical application is:



Determine if a drug has specific uses for certain concentrations. If available, you may consider using the clinical application feature to help guide programming of this drug on the pump. For infusion systems with EHR integration, confirm that the clinical application configured is consistent with order sets in the EHR.

Drug Concentration

Drug concentrations should be standardized to minimize the number of concentrations required for each drug. Reducing variability in concentrations minimizes the risk of pump programming errors.

Things to consider when determining concentrations: (Figure 4)

Figure 4 Determining drug concentration



a) Review order sets and prescribing method for the drug

- b) Review how drug is prepared:
 - Commercially available premixed
 - Outsourced admixed
 - Pharmacy admixed
 - Nursing admixed

There are different ways to configure a drug concentration.

i. Drug Amount and Volume

The total Drug Amount and the total Volume of the admixture is defined. This method standardizes drug amount and volume and eliminates variability. Select the correct unit of measure for both the drug amount and the concentration to be displayed. The drug amount and volume should be consistent with the labeled information on the admixture or premix. If volume overfill needs to be included, you may include this in the total volume or default starting Volume To Be Infused (VTBI) for the drug (*see section on VTBI*). Ensure that this is consistent with labeled information on the container and EHR order sets.

ii. X mg/1 mL

This option is available for drugs where the concentration is fixed but no specified drug amount and volume is available. Select the correct unit of measure for the concentration.

iii. Undefined concentration

This option can be used when the drug concentration is based on patient variables and therapy, and is therefore not standardized. The clinician is required to enter the drug amount and volume during pump programming. Upper and lower concentration limits may be configured in the drug library. Select the correct unit of measure for the concentration. This feature for known infusion systems is referred to as <u>variable</u> or <u>units only</u>. Note: Consider configuring a lower hard concentration limit to prevent misprogramming, particularly for high-alert drugs. (See ISMP Medication Safety Alert! 2012. Smart Pump Custom Concentrations Without Hard "Low Concentration" Alerts. Also, ISMP Medication Safety Alert! 2008. Misprogramming PCA concentration leads to dosing errors.)

iv. Volume based modes

This option is available for drugs or fluids that are delivered based on a volumetric rate and are not concentration dependent. Example mL/hr.

Dosing Unit

Select the dosing unit by which the drug will be prescribed. The dosing units available will be dependent on the unit of measure selected for the concentration in the previous step. It is critical that the dosing unit be consistent with EHR order sets for this drug and for the care area profile. Ensure the dosing unit is standardized for each concentration of the same drug.

Dosing Ranges and Limits

Upper and lower dosing limits provide the user with guidance during pump programming on the acceptable dosing range configured for the drug. Review the dosing limits in the EHR for each drug and ensure that limits are aligned between the EHR and infusion system drug library.

Upper and lower soft dose limits

- Provide common dosing range for the drug
- These limits may be overridden upon acknowledging the alert and confirming the dose entered

Upper and lower hard dose limits

 These are the maximum and minimum dose allowed Hard drug library limits cannot be overridden or exceeded at the pump

Time Duration Limits (Intermittent infusions)

Time duration limits are applicable to intermittent infusions and provide the user with guidance during pump programming on the time duration for delivering the drug.

Lower Soft and Hard Time Duration Limits

 Alert the clinician if the time duration programmed is shorter than allowed. Lower time limits determine the maximum rate the infusion can be delivered.

Upper Soft and Hard Time Duration Limits

 Alert the clinician if the time duration programmed is longer than allowed. Upper time limits determine the slowest rate the infusion can be delivered.

Soft and hard limits provide maximum safety benefits during pump programming. Limits should be based on your organization's formulary and practice as well as clinically- and professionally- recognized references for the drug.

Document all references used for traceability.

Volume To Be Infused (VTBI)

The drug library software may have an option to set a default starting VTBI for the clinician during pump programming. If the drug amount and total volume are defined for the drug, the VTBI is typically equal to the total volume defined. If required, the volume overfill may be included in the VTBI value. The VTBI should not exceed the labeled total volume on the IV container.

Loading Dose / Bolus Dose Limits

A loading dose is a comparatively large dose given at the beginning of treatment to rapidly achieve a therapeutic level of the drug. A bolus dose is similar, but it may be given at any time during the infusion. Depending on your infusion system, these two terms may be used interchangeably.

Loading dose and bolus dose programming may be enabled for continuous infusions. When enabled, the loading and bolus dose are intended to be delivered from the same primary IV drug container.

The use of the bolus feature provides safety by specifying the amount given over a defined time duration. Enabling the bolus dose feature in the drug library prevents the unsafe practice of manually increasing the infusion rate to administer a bolus.

Loading Dose/Bolus Dose Unit

- Dosing units are available as weight based or non-weight based
- Select the dosing unit by which the loading or bolus dose will be prescribed

Loading Dose/Bolus Dose Limits

Limits for loading and bolus dose may be configured with the following:

- Amount limits Lower and Upper hard and soft limits for the total amount of load or bolus dose to be given at any one time
- Time limits Lower and Upper hard and soft limits for the time duration of delivering the load or bolus dose
- *Dose rate limits* Lower and Upper hard and soft limits for the administration rate

Certain infusion systems allow separate limits for loading dose and bolus dose.

Line Flush Limit

The line flush feature may be available with your infusion system. This feature provides the clinician with the option to deliver the remaining volume in the IV container or tubing at the completion of an intermittent infusion. If available, set the maximum volume allowed for a line flush for each intermittent drug.

Drug Configurations

Your drug library software may allow these settings to be configured for each specific drug or these may be available in the care area profile settings.

Dose or Rate Change (Titration) Limits

A limit may be configured for the incremental dose or rate change for each titration programmed during an infusion. *Percent Change limits* are based on the percentage of the dose increase or decrease from the current dose programmed.

Example, a 101% change limit will allow a dose change from 2 mg/hr to 4 mg/hr without triggering an alert. However, a dose change from 2 mg/hr to 5 mg/hr will trigger an alert notifying the user that the dose change limit has been exceeded.

Review titration protocols for all titratable medications for the following:

- Initial or starting dose
- Maximum dose to be given
- Dose increment by which to adjust and specific time interval for assessment/adjustment
- Therapeutic outcomes that are measurable to determine dosage adjustment

For all titratable medications set the percent change limit appropriately to ensure meaningful alerts during dose or rate changes.

Keep Vein Open (KVO) Rate (mL/hr)

At the completion of the programmed infusion, the pump will infuse at the KVO rate configured for the drug or at the current infusion rate if it is lower than the configured KVO rate. KVO rate is intended to prevent clotting of the catheter when the programmed volume to be infused has been delivered. It is not intended as a therapeutic dose. Your drug library software may provide configurable KVO options specific to each drug. Some examples are:

- Custom KVO rate for the drug
- Allow infusion to maintain the current flow rate when the programmed volume to be infused (VTBI) has been completed
- Do not allow a KVO rate, so the infusion is stopped once the programmed volume has been delivered

Alarm audio settings

The volume of alarms may be configurable for specific drugs to help clinicians prioritize their response to an alarm based on the drug that is being infused.

Delayed Start

An infusion may be programmed to start after a certain time has elapsed. Enabling this feature would allow the clinician to program an infusion to automatically start after the entered time delay has elapsed, without further clinician interaction.

Bag Near End of Infusion Alarm

This alarm may be configured to provide a notification at a set time prior to the end of the programmed infusion. It may be used for critical medications to provide the clinician with an opportunity to obtain or prepare a new infusion for continuation of therapy. Your drug library software may allow custom settings for the notification time prior to the end of infusion or may be fixed at a certain time.

Call Back Alarms

These alarms require the clinician to acknowledge and respond during an infusion. Callback alarm options that may be available are:

Secondary Callback

 Notifies the clinician when a secondary infusion is completed. The clinician will need to respond and manage the infusion and determine next steps. It may be enabled if specific monitoring or action is required when the secondary infusion is completed. The pump does not transition to the primary infusion automatically.

Delay Start Callback

 Notifies the clinician when the programmed delay start time has elapsed. The clinician will need to respond and initiate the infusion as intended.

Multi-Step Callback

 When a multi-step infusion is programmed, the callback will notify the clinician after each step has been delivered. The clinician will be required to respond and initiate the next infusion step.

Drug Setup Summary

It is important that each drug is setup in the drug library to be consistent with how the drug is intended to be given, how it is prescribed and how it is labeled for the clinician (see Figure 5)

Figure 5 Drug setup summary



Step SIX – Care Area Profile Setup

A care area profile is a method of grouping drugs that are typically associated with a specific hospital area, nursing unit or patient population. Examples are Critical Care, MedSurg, etc.

Care Area Name

Setting up appropriate care area names in the drug library is critical to minimizing confusion during pump programming. The care area name should be easily recognizable and consistent with hospital naming conventions and EHR profiles. Consistency is crucial to minimizing risks of medication programming errors as drug setups may be customized for a specified area. Accurate care area names will support the analysis of infusion pump data.

Care Area Settings

Care area settings are required for the infusion system and applicable to infusions programmed within that care area, whether manually or via autoprogramming. These settings are not specified in, nor sent from, the EHR system. Different infusion systems offer different configuration capabilities for setting up a care area profile. Settings at the care area level will apply to all infusions that have been programmed from the selected care area.

Depending on your infusion system, care area settings may include the following:

Patient Weight and Body Surface Area (BSA) Limits

Configurable patient weight and body surface area (BSA) lower and upper limits provide additional safety during programming for care areas with specific patient populations or for drugs that are dosed based on patient proportions.

An alert will display during pump programming notifying the clinician when a patient weight or BSA value entered exceeds the limit configured.

Patient Weight/BSA value confirmation

Enable this feature, where available, to confirm weight or BSA entry before running the infusion.

Air in Line Sensitivity

If available, use this feature to select the threshold size of an air bubble to trigger an air-in-line alarm during an infusion. An air-in-line alarm will trigger for a single air bubble size that is greater than the set threshold. Select the appropriate sensitivity for the patient population within the care area.

Keep Vein Open (KVO) Rate (mL/hr)

Your infusion system may allow drug specific KVO settings or it may be set at the care area level. The pump will infuse at the KVO rate when the programmed infusion is completed, or maintain the current programmed rate if it is lower. Enter the desired KVO rate for all drugs in the care area.

See *Drug Configurations* section for more information.

Downstream Occlusion Pressure

The downstream occlusion pressure sensitivity may be configurable for each care area profile. This is the pressure threshold that will trigger a downstream occlusion alarm during an infusion. The lower the value, the more sensitive the pressure detection.

Maximum Rate (mL/hr) Limit

The maximum infusion rate (mL/hr) may be configured for each care area profile. This is the maximum delivery rate allowed for any drug programmed within this care area.

Maximum Volume To Be Infused (VTBI) Limit

The maximum volume for a single infusion may be configurable for a specific care area. If configured, an alert will notify the clinician during pump programming if the VTBI entered for the infusion exceeds the maximum VTBI limit configured for the care area. Certain patient populations may require a limit on the volume of fluid to be administered for a single infusion.

Auto Keypad Lock

If available, this feature provides the option for the pump to automatically lock the pump keypad after the infusion has started to prevent tampering. The keypad may only be unlocked with the assigned code.

Priming Volume Feature

Enabling this optional feature for primary intermittent infusions (if available) allows the clinician to subtract the volume of fluid used to manually prime the administration set and automatically adjusts related infusion parameters during pump programming.

Step SEVEN – General Pump Settings

These configurable settings apply to all pumps, regardless of the care area profile selected. The following options may be available:

Keypad Lock Code

This security code is used to lock the keypad manually and unlock the keypad when locked.

Wireless Options

Battery and AC Sleep Mode (if available)

Select the time interval for the infusion pump to automatically check for drug library updates. The drug library check will occur at these intervals when the pump is off and plugged into AC outlet or on battery. Note that the pump will continuously check for drug library updates when the pump is on.

Location Services (if available)

When a location system is used, you may select the time interval of when the pump will report its location and pump status information to the location system.

Step EIGHT – Review, Verify and Document

It is important that each drug setup and configuration be reviewed, verified and documented with appropriate supporting references to ensure compliance with current accepted clinical practices. This provides evidence-based data and traceability for each drug setup and will help in evaluating potential change requests.

Step NINE – Stakeholders Review

Once the drug library build has been completed, the next step is a review by key stakeholders. Nursing, Pharmacy and Physician representatives for each care area should review all drugs and parameter settings configured for their care area. Any change request or new drug requests should follow the formal process that was established earlier on. This important review step will help support and expedite the drug library testing phase.

Test Phase

Step TEN – Clinical Scenario / Drug Testing

Once the drug library is completely built and reviewed by the drug library development stakeholders, it needs to be tested on pump in a non-patient environment. Clinicians should program each drug in each care area to assess the library for completeness and accuracy. Common clinical scenarios as well as alternate workflows and edge cases such as limit violations should be performed.

Preprinted order sets and EHR order sets should be available for all drugs to be test programmed on the infusion pump. Examples of how each drug admixture is labeled should also be available to ensure consistency with the information displayed on the label and how the drug is setup in the infusion pump drug library.

Clinical scenarios, along with order sets and drug labels should be specific to each care area profile to be tested.

Representative clinicians for each care area should be involved in test programming care area-specific clinical scenarios.

It is important that each drug configured in each care area is tested for accuracy and consistency with order sets and information on the admixture label. All parameters should be evaluated, including but not limited to:

- 1. Primary or secondary infusion
- 2. Continuous or intermittent
- 3. Concentration(s) configured
- 4. Dosing units and safe dosing limit range
- 5. Starting default values
- 6. Availability of loading or bolus programming
- 7. Titration programming

Step ELEVEN – Change Requests

Revisions to the drug library should comply with the established process of managing change requests and new requests for additions to the drug library. This will provide the necessary documentation and audit trail for any revisions to the drug library.

Step TWELVE – Re-testing

All changes and new additions to the drug library need to be tested to ensure changes were made as intended and new additions were configured correctly. Follow steps TEN for testing.

Step THIRTEEN – Sign-off and Approval

Once testing has been completed successfully, the drug library is now ready for final approval. Follow the established approval process to ensure all key stakeholders are involved and accountable.

Go-Live and Rollout Considerations

Verify with the organization's IT resources and pump vendor regarding the following:

- Readiness of the wireless infrastructure
- Pump server's capacity to manage all infusion pumps within the organization
- Secure wireless connectivity between infusion pumps and pump server
- Transfer of drug library to full pump fleet

ISMP has identified the following key considerations for successful rollout of new infusion pumps:

- Prioritize sequence of patient care areas receiving the infusion pumps
- Select patient care areas with adequate staff and resources
- Select educators and champions from pilot units for subsequent units
- Super-users rounding on patient care areas to review any issues and evaluate process

EHR Integration Phase

EHR interoperability with infusion pumps requires detailed planning and collaboration between multidisciplinary stakeholders, the pump vendor and the EHR vendor. A readiness assessment should be conducted to assess the technology infrastructure as well as the organization's competency with the use of the EHR system and the infusion pump system.

In this document, EHR integration refers specifically to integrating the IV administration/documentation process between the electronic health record system and infusion system. This interoperability between infusion pumps and the EHR allows for autoprogramming the infusion pump with an infusion order from the EHR system and auto-documenting this infusion back into the EHR system. The following steps prepare your infusion system drug library for EHR integration.

Step ONE – Drug Mapping of EHR/Pump Drug Library

It is critical that each drug in the infusion system drug library is linked to an identical drug from the EHR system. Each drug that is setup in the pump drug library must consider all aspects of the same drug in the EHR system, including drug naming convention, drug amount and volume (concentration), dosing units, rate and the patient care location of where this drug will be prescribed. Depending on the EHR system mapping criteria, each drug in the pump's drug library is required to be mapped to a corresponding EHR drug with the following key attributes; drug name, drug amount and volume (concentration) and dosing unit. Accuracy in mapping is critical to ensure safe and successful transfer of the patient infusion order from the EHR to the infusion pump in addition to compliance with auto-programming of infusion orders.

Step TWO – Auto-programming Workflow Validation

It is critical to identify specific instances (with clinical use scenarios) when a pump can be autoprogrammed and when it cannot. Each clinical use scenario should be documented to include the expected workflow and any potential variability that could affect programming. Clinical use scenarios should include, but not be limited to:

- Initial programming
 - $\circ\quad \text{Continuous infusions}$
 - o Intermittent infusions
 - Weight-based, non-weight-based, BSA based
 - Loading dose
 - o Manual edits to auto-programmed fields
- Mismatch drug order
- Safety dose limits violations
- Primary infusions and secondary infusions
- Bolus dose
- Dose/rate changes (titrations) during infusions
- Bag changes during infusions
- Back association of pump connecting the infusion pump with an infusion in progress to patient's order in the EHR for documentation.

Step THREE – Integrated Drug Order Testing

The goal of this testing is to verify the accuracy of each drug record that is mapped between the EHR drug library and the pump drug library. This testing involves sending an infusion order for each drug from the EHR system to the infusion pump and verifying that all parameters are transferred correctly. In addition, once the infusion has started, the infusion data is sent back to the EHR's flowsheet and any infusion dashboard accurately (Figure 6). This testing must be performed for each drug that is mapped.

In addition, testing should be performed whenever software updates or IV medication orders changes are introduced for the EHR system or for the infusion pump system.

Figure 6 Integrated drug order testing



Step FOUR – Clinical Scenario Testing

It is critical that all clinical use scenarios established in step two are tested thoroughly in a non-patient environment.

Representative clinicians for each care area should be the involved in executing their care area specific clinical use scenarios by performing all necessary steps required for auto-programming, including all interactions with the EHR system.

Testing of expected workflows and deviations will help identify failure modes that may occur and mitigations that are required. This testing will also help in designing the training program for all end users.

Step FIVE – Sign-off and Approval

Once testing has been successfully completed and identified issues are addressed, the infusion system drug library is now ready to be implemented and integrated with the EHR system. Follow the established approval process to ensure all key stakeholders are involved and accountable.

Prior to going live with the system, full end-user training is required.

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