AAMI FOUNDATION

QUICK GUIDE

What You Need to Know About Smart Pump Compliance and Drug Libraries

Acknowledgements

This document was produced by the members of the AAMI Foundation's National Coalition for Infusion Therapy Safety. The coalition, launched in 2015, is made up of clinicians, industry partners, researchers, and national patient safety organizations. It addresses ongoing patient safety issues identified at the AAMI/FDA Infusion Device Summit (2010):

- Improving drug library compliance
- Reducing non-actionable pump alarms
- Promoting multiple-line education

Link to the coalition website:
www.aami.org/foundation/infusion/coalition

The AAMI Foundation is proud to be partnering with Purdue University's Regenstrief National Center for Medical Device Informatics (REMEDI) Central on this important infusion therapy safety work. A special thanks to Richard Zink from REMEDI Central for his help and guidance on this project.

REMEDI Central is a collaborative community of pharmacists, nurses, researchers, and others working to improve patient safety through the development and exchange of infusion pump medication administration knowledge and best practices. REMEDI Central currently includes a pump vendor-neutral analytics and reporting package, allowing hospitals to perform self-analysis and comparison of Dose Error Reduction Software (DERS) programming alerts, smart pump compliance, and drug limit libraries.

For more information: **https://catalyzecare.org/remedi/about#learnmore**.

About the AAMI Foundation

The AAMI Foundation is a 501(c)(3) charitable organization.

It's mission is to drive reductions in preventable patient harm and improvements in outcomes associated with the use of health technology. The AAMI Foundation creates synergy between clinicians, researchers, regulators, biomedical and clinical engineers, industry, and patients, leading the nation to share and disseminate critically important information, building a body-of-knowledge addressing emerging and long-standing complex issues related to health technology. The Foundation accomplishes this by convening diverse expert stakeholders and engaging them in a collaborative, team-based approach to tackle specific issues in the development, management and use of health technology. The intended outcome is reduced preventable patient harm and improved patient outcomes.

To learn more about the Foundation and ways to become involved, visit **www.aami.org/foundation**.

To make a tax-deductible donation to the Foundation, visit **my.aami.org/store/donation.aspx**.

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Executive Summary

The Institute of Medicine (IOM) has estimated that medical errors cost $17 billion to $29 billion per year, with much of it due to adverse drug events (ADEs).[1] The Agency for Healthcare Research and Quality (AHRQ) estimates that hospitals can save $500,000 annually in direct costs by using computerized systems, like smart infusion pumps, to avoid ADEs.[2] Many hospitals have invested in smart infusion pumps with dose error reduction software (DERS) that provide clinicians with the ability to identify the medication to be administered to the patient, to control concentration and dose rates (as defined by literature and hospital staff), and to alert the clinician to potential under and overdoses of intravenous (IV) fluids and drugs. The smart pumps, however, increase patient safety and reduce costs only if the clinicians choose to use the smart pump software.

In addition to avoiding ADEs, the optimized use of smart infusion devices can support, shape, and drive best practices around IV medication administration. These will have further financial impact, such as reduced length of stay and the avoidance of medication administration practices that have limited clinical effect.[3] This strongly reinforces the need for the drug library to both support and frame clinical practice within a facility.

The purpose of this report is to inform hospital staff on the importance of supporting efforts to improve patient safety, ultimately increase efficiency—and reduce costs—through the use of smart pump technology. The report was developed by infusion therapy safety experts from hospitals, infusion pump manufacturers, national healthcare organizations, academia, and consultants who volunteered to participate in the AAMI Foundation's two-year effort, entitled the *National Coalition for Infusion Therapy Safety*.[4]

The format of the report is question and answer, which allows for the introduction of key concepts and identifies the requirements for a successful infusion therapy safety program. In each response, the importance of the topic is explained, metrics are defined to measure progress, and best practices are identified. The questions that hospital executives, managers, and clinicians should be asking about their smart pump usage, policies, and practices include:

1. **What is our current compliance rate?**

2. **What is our process for analyzing compliance data and alerts generated during pump programming?**

3. **What is our process for training and educating staff on compliance?**

4. **What is our process for ongoing drug limit library management?**

5. **What is our process for ensuring the pumps have the latest drug limit library?**

[1] **Institute of Medicine** (IOM) To Err Is Human: Building a Safer Health System. Washington, DC: National Academy Press, Institute of Medicine Committee on Quality of Health Care in America; 2000.

[2] **Agency for Healthcare Research and Quality (AHRQ).** http://archive.ahrq.gov/research/findings/factsheets/errors-safety/aderia/ade.html. Viewed June 28, 2016.

[3] **M. Bland Schilling, MD, Steven Sandoval.** Hospital Practice, Volume 39, Number 3, August 2011. "Impact of Intelligent Intravenous Infusion Pumps on Directing Care Toward Evidence-Based Standards: A Retrospective Data Analysis".

[4] **The AAMI Foundation.** http://www.aami.org/PatientSafety/content.aspx?ItemNumber=1781&navItemNumber=3084 Viewed October 25, 2017

Key Takeaways

Main recommendations for compliance and drug library management include:
- Creation of an Executive Infusion Safety Team
- Senior-leadership defined dynamic and priority driven smart infusion pump goals
- Ongoing staff communication and training plans
- Regular analysis and review of smart infusion pump data, including:
  - Compliance rates
  - Programming alerts
  - Overrides
  - Edits/reprograms
- A clearly defined process for drug library management
- A focus on keeping the smart pumps up-to-date with the current drug library

We hope executives, managers, and clinicians read this report and assess how they are in compliance with the suggested best practices for all five topics in the report.

Question #1: What is our current compliance rate?

Importance

The 2006 IOM report notes that many medication errors resulting in patient harm involve infusion devices, with the most common cause of these errors being incorrect programming of infusion pumps.[5] Healthcare organizations can utilize specific technologies, including smart infusion pumps, as a way to deliver safer care. "Smart" infusion pumps use dose error reduction software (DERS) to guard against infusion pump programming errors through customized data sets, which alert the user when programmed parameters (e.g., drug dose, drug concentration, etc.) are outside of the pre-established range.

The ability for users to bypass DERS remains a primary risk point identified in process Failure Modes and Effects Analysis (FMEA). Bypassing the DERS is not recommended, but occasionally required, for patient treatment. As such, healthcare organizations should *measure and monitor* smart pump compliance to ensure that DERS is being appropriately used to reduce the risk of patient harm.

Some smart infusion device manufacturers offer infusion devices that auto-default the clinician into the drug library. However, even when defaulting to the drug library, compliance monitoring is required as users still have the option to select "basic infusion" instead of a specific drug, exit the drug library feature in the case of an emergency and for a drug not in the drug library (e.g., research protocols). When auto-default is available, consider starting the pump in this mode and provide warning prompts when exiting the drug library feature. In addition, IV clinical integration of your smart infusion devices with your existing electronic medical record (EMR) vendor helps close the safety gaps between computerized physician/provider order entry (CPOE), the EMR, and the smart devices at the bedside.

Best Practices

- Establish a multidisciplinary team (including but not limited to pharmacy, nursing, risk management, quality assurance, and IT) responsible for routinely monitoring and improving compliance.

- Determine how you will define and measure compliance.[6] An example is to identify a target compliance rate, ideally greater than or equal to 95%, for all primary and secondary infusions. Measuring the compliance rate alone is not sufficient. Monitoring of the infusion administration process (e.g., selecting the correct care area library and correct drug) is also an important measure of safety and compliance.

- Both high-level and more granular reports should be generated and distributed at least quarterly. Unsatisfactory compliance rates should be investigated further through drill-down report analysis, direct observation, and communication and/or training with staff members to determine why DERS is not being utilized.[7]

- Have staff conduct unit-based audits in real time to identify barriers to DERS use and provide reinforcement of DERS use. *See Appendix A for a sample Drug Library Compliance Audit form on page 16.*

- Pumps and equipment should be evaluated for design and operation that make it easy to access and use DERS.

- Drug libraries should be well-designed, comprehensive, and perpetually maintained so that they are easy to navigate and use. Positive results and examples of errors prevented by DERS should be publicized and shared throughout the healthcare organization to drive behavior.

[5] **Institute of Medicine.** Preventing Medication Errors: Quality Chasm Series. Washington, DC: The National Academies Press, 2007. doi:10.17226/11623.

[6] **Ruhl, C.** Get smart with smart pumps. Nursing Management, 44(11), 17-20, 2013.

[7] **Ruhl, C.** Get smart with smart pumps. Nursing Management, 44(11), 17-20, 2013.

Measurement

Compliance rate is generally calculated as follows:

$$\frac{\text{(Number of pump events utilizing DERS)}}{\text{(Total number of pump events)}} \times 100\%$$

Compliance rate is often easy to obtain as most smart pump vendors provide tools and reports to help healthcare organizations aggregate data, measure, and track smart pump data, particularly when pumps are equipped with wireless communication technology.

Compliance rate is not calculated the same way by all vendors. Most vendors define a pump event as an infusion given or started. Other vendors define a broader pump event as any programming activity where there is an opportunity for error. Drug library compliance may also be measured by the number of individual programming attempts *that occurred in the drug library* divided by the total number of individual programming attempts. This will provide a different view of compliance than number of infusion starts within the drug library divided by the number of overall infusion starts.

To fully understand what is actually being measured in the compliance calculation, it is important to understand how the safety software defines infusions. An individual infusion may have multiple programming attempts as the infusion rate is titrated up or down in response to the patient's clinical state. Each titration occurring outside of the drug library is an opportunity for human error to occur, without being detected by DERS. These titrations need to factor into the compliance calculation. If individual titrations are not counted as new infusions, then drug library compliance may be overestimated (and patient risk underestimated) since the individual titrations are not counted in the infusion-based compliance calculation.

It is important to realize that a high compliance rate alone does not guarantee high quality outcomes. Compliance also entails selecting the proper care area, choosing the correct patient profile, and changing the care area when the patient moves to a new unit. The overall quality of a drug library is also an important consideration as the design of the library must align with clinical practice at the pump. A robust library is an important piece when assessing compliance. For example, if a drug is missing from the library, then the user may choose a different drug when programming the pump than the actual drug being infused. While this workaround uses the drug library, and would be counted by the vendor's software as an infusion using DERS, it is not considered in compliance and has the potential for patient harm.

The target is to optimize both compliance rates and the characteristics or quality of the drug limit library. In other words, the design of the library must align with bedside practice and hospital policies. Errors can still occur within DERS as well. For example, a user might select an incorrect library entry or the library entry may not be built with dosing limits designed to confer safety, match order sets, or clinical practice. In addition to routine monitoring of compliance rate and other metrics, direct observation of pump practices and staff behavior is necessary. Monthly rounds looking at in-process infusions and corresponding pump programming is an effective method of measuring compliance as well as providing an opportunity to reinforce the value of the safety technology.

Question #2: What is our process for analyzing compliance data and alerts generated during pump programming?

Importance

The monitoring of compliance data provides a metric for improving patient safety and quality. In addition to monitoring compliance rate, regular analysis of the alerts generated at the pump by the clinician while programming also help to improve patient safety and quality. These alerts are generated when the clinician programs an infusion outside the smart pump's drug library, or Dose Error Reduction Software (DERS). An example of a programming alert is when the programmed dose exceeds the limits defined in the DERS. The analysis of programming alerts allow for the identification of opportunities to improve compliance. Analyzing the alerts against DERS is important because nurses may become frustrated by a large number of programming alerts and choose to avoid generating more alerts by switching to basic infusions—those delivered without leveraging DERS software.

To be most effective, organizations need to analyze pump programming practices (as-used) and analyze the data to understand compliance to the pump drug library (as-designed). The smart pump's DERS is designed to protect against infusion programming errors that could cause patient harm. The difference between the potential for error prevention and actual error prevention is primarily DERS compliance, or consistently programming infusions using a thoroughly built and meticulously maintained drug library.[8] Analyzing alerts, overrides, and edits gives the facility the unique opportunity to hear and understand the voice of their medication administration system. It also provides an opportunity to continuously improve how the drug library fits into and supports clinical practice as practice continuously evolves.

Best Practices

The key practices for managing compliance are:

• An organization-wide commitment to encouraging the safest infusion programming practices, including the use of DERS

• Creation of an Executive Infusion Safety Team, with members who possess corporate oversight, who are empowered to make decisions, drive initiatives and provide direction. This team will define dynamic and priority driven goals and expectations around process/practice changes, program metrics, and compliance-defined infusion safety goals

• A dedicated cross-functional team, with authority to implement and train to changes, composed of representatives from pharmacy, nursing, risk management, informatics, and anesthesia (these users are often overlooked and typically have issues with the drug library content and are known for workarounds)

• A well-managed drug library

• Development of ongoing staff communication plan that includes: performance goals, performance metrics, process improvements, and patient safety outcome initiatives

[8] Hoh, T and Krueger, P. AAMI Analyzing Drug Library Compliance 112015. Data on file, Baxter Healthcare Corporation. November 20, 2015.

- Development of progress communication tools for staff, such as scorecards

- Analysis and review of smart infusion devices data using a clear process repeated on a regular schedule (e.g., monthly or quarterly)

- Communication on progress to key leaders (e.g., to the Quality Board, Board of Directors, etc.)

- A commitment to implement and measure improvements

Measurement

There are two categories of data to measure: drug library compliance data and the alert data generated during pump programming.

Drug library compliance rate is: See Measurement Section under Question 1 (page 6).

Analysis of the alert data requires generating a summary of the total number of alerts, the override data, and the alerts that resulted in edits/corrections/reprograms. With this information, make a determination of more detailed medication and care area specific data requiring further analysis. This will allow for comparison between timeframes and care areas to ultimately determine the reason for alerts and to utilize these analyses for continuous quality improvements (CQI).

Clinicians respond to alerts by either overriding the alert, if allowed, or editing their initial programming entry. A useful metric is the override to reprogram ratio defined as the proportion of alerts that result in an override divided by the number that are edited or reprogrammed. This ratio should be calculated hospital-wide, for individual care areas, and for medications that are alert-prone. This provides useful insight on how effective the drug library is at driving change during user programming. For example, a facility may identify 50% of the alerts coming from the drug library result in an override of the alert and 50% result in an edit of the programming

parameters overall (i.e., a 1-to-1 override-to-reprogram ratio). Put another way, every other alert results in a change in user programming at the bedside.

Once a summary of alerts for a given time period is reviewed, the alerts can then be further analyzed to determine the top medications producing alerts, overrides, and edits/corrections, and to pinpoint possible reasons for the alerts. Particular attention should be given to Institute for Safe Medication Practices (ISMP) High Alert Medications as these represent unique risks to patients. [11] If patterns have been identified by drug and care area, it is important to review findings with clinical users to gain an understanding of possible reasons for their pump programming decisions (i.e., drug library limits don't match their current clinical practice or re-education on dose titration and/or drug library limits are needed).

Analysis of edits/corrections should include reviewing not only the alert but also the programming steps around the alert to determine how the user proceeded after the initial alert response. This analysis may provide information on good catches (i.e., cases where the clinician initially programs a dose beyond the limit and then edits the infusion to be within the drug library limits). Good catches are important to note and provide an opportunity to determine how and why near misses occur. Having the user double check an order/dose and then proceed with the override, without analyzing the how and why, is a missed improvement opportunity. It is important to identify good catches, sometimes called near misses, as they provide the most opportunity for initiatives to improve safety.

Analysis of drug library alert information can provide valuable insight on the magnitude of variation between IV administration practices and drug library parameters, either overall or within a care area. An overall determination of alert, override, and edit rates provides a useful comparative information. Alert, override, and edit rates (i.e. the nurse determines that the alert is signaling a programming error, so the error is corrected) can be calculated for individual care areas or by specific medications to determine the magnitude

[9] **Institute for Safe Medication Practices (ISMP).** https://www.ismp.org/Tools/highAlertMedicationLists.asp. Viewed October 25, 2017.

of variation occurring between user programming practices and drug library parameters. This information may be used to determine medications that are particularly problematic for staff programming the devices and provides an opportunity to hone in on ordering and programming practices around specific medications.

Now, if a highly alerted medication has 98% of the alerts resulting in an override (i.e., a 49-to-1 override-to-reprogram ratio), then that drug library entry is relatively ineffective in driving change in clinician user programming activity. That means 49 alerts are being ignored before one is acted upon. This is a very useful way to identify drug library entries that are not effective in driving change or where clinicians have been desensitized to the alerts themselves. Additionally, this may be monitored after a change in drug library limits or clinical practice has occurred to determine if the drug library entry has improved effectiveness in driving change during user programming.

Careful analysis of edit/reprogram data provides useful information on the number and types of events being averted by the drug library. Analysis of these edits for a pattern within a medication or care area may provide useful insight into the types of human errors commonly identified in the data. While clearly pointing to the effectiveness of the drug library, this information has the ability to provide information for a near miss analysis. Common patterns of errors may be identified. Careful analysis of these patterns may provide insight on upstream system changes or staff training that may mitigate the error from occurring in the first place. This type of analysis also provides useful information on how the drug library is redirecting staff back into the standard of care during user programming as identified by drug library parameters.

Once measurement and analysis are completed, select the problems you want to address (e.g. make changes to drug library, reinforce to staff the importance of using DERS, etc.).

Design your action and communication plans. Ensure manager buy-in and implement the plans. Carefully monitor roll-out to ensure the staff understands the changes and have been well trained and are implementing the changes correctly.

This is an interative process, so after any changes the process begins again with the measurement phase. Celebrate successes!

Note: *A portion of the information in this section is derived from a detailed document provided by Baxter.[12] The complete document, Analyzing Compliance Data, is available in Appendix B on page 16.*

[10] **Hoh, T and Krueger, P.** Analyzing Drug Library Compliance. Data on file, Baxter Healthcare Corporation. November 20, 2015.

Question #3: What is our process for training and educating staff on compliance?

Importance

For hospital staff to fully leverage the investment in smart infusion pumps with dose error reduction software (DERS), provide them with training to understand why they should use the smart pump features, how to use the safe pump features, and how to provide feedback to improve the process. Since IV drugs and fluids are among the most potent—and often high alert as defined by ISMP—medications administered to patients, a decision not to start the infusion pump programming by selecting the medication before programming the infusion rate or dose leaves patients potentially unprotected from programming errors. Conversely, initiating the IV therapy by identifying the medication enables the appropriate concentration and dose programming and alerts the clinician to potential under and overdoses of IV fluids and drugs. As an added benefit, working to improve compliance will often lead to a reduction in programming alarms.

Best Practices

Staff training on how to use the smart pump features should be provided to all clinicians involved in infusion therapy administration. The training can be provided by the pump vendor or hospital personnel. Pharmacists should also be trained to be aware of the impact of modified drug orders on library settings and library changes on the nursing staff. Training should include an overview of the importance of compliance, a review of relevant policies that support the use of smart pump technology, instructions on how to use the smart pump features, hands-on activities to practice programming the pump,

and a description of the feedback process that allows clinicians to provide feedback to the pharmacy team on drug library settings. Training should be provided to all new clinicians as part of the orientation program and all clinicians should be provided with annual refresher training. However, It is critically important to have a process for regularly scheduled ongoing training: these pumps are complex and not all features can be learned during one training session. Providing available "super users" on all shifts in all areas where the pumps are used will enable nurses to have guidance available when needed. To help with improving compliance, visual aids (e.g., table tents, signage hung on the pumps, etc.) should be utilized to maintain visibility of the need to drive improved compliance and to remind staff to use the smart pump features. Hospitals are urged to test clinicians' competency levels on the use of the pumps; not only the functions that are used routinely, but also the functions that may be used only in emergency situations.

Measurement

Many of the vendor analytic packages allow for analyzing compliance rates at the organization level, at the facility/hospital level, and by care unit or profile. Develop new or focused training for clinical areas with the lowest compliance rate. Use your hospital's training software to keep track of those that have completed the required compliance training classes. And, as noted above, remember that learning complex technology takes time, and assistance at the bedside may be needed by staff nurses.

Question #4: What is our process for ongoing drug limit library management?

Importance

Drug library limits must support appropriate drug administration while avoiding catastrophic overdoses and sub-therapeutic drug delivery. If this balance is not achieved, the purpose of dose-limiting software may be defeated by workarounds.

Best Practices

Optimize the use of the drug limit library.

See Appendix C for a list of the Top 10 Questions to Optimize Drug Library Use on page19.

Additional best practices include:

- Assign a team to manage drug library limit maintenance
  Example: see Patient Safety seminars and peer reviewed papers on the AAMI Foundation website: www.aam.org/foundation/NCITS

- Assess the organizational resources required and secure organizational commitment
  Example: see Patient Safety seminars and peer reviewed papers on the AAMI Foundation website: www.aam.org/foundation/NCITS

- Define intervals (e.g., monthly, quarterly) for drug library updates

- Define processes for planned versus urgent drug library updates

- Establish organizational policies on hard and soft drug library limits
  Example: Use current drug information from authoritative resources to develop recommendations for smart pump drug library limits, which should be approved by the organizations medication policy generating body. A discussion of factors that should be considered when establishing limits can be found in the American Society of Health-System Pharmacist (ASHP) publication *Smart Infusion Pumps.*[11]

- Use pump CQI data to establish baseline drug library limit compliance

- Determine the type of data (reports) to be collected and analyzed for routine monitoring

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[11] **Phelps, PK.** Smart Infusion Pumps – Implementation, Management, and Drug Libraries. 2011. American Society of Health-System Pharmacists, Inc. Print.

- Establish metrics for drug library limit compliance

  Example 1: A health system with 14 facilities launched a CQI initiative utilizing smart pump data. The CQI findings were made available to employees via the hospital's internal computer systems. Monitored metrics included compliance rates, the drugs that alarmed the most, and many others. The practice of reprograming or canceling infusions can be an indication of averted or IV medication errors.[12]

  Example 2: Intermountain Health created and monitored an infusion pump safety score which resulted in a score improvement from 6.41 to 7.57.[13] This is an example of using a metric for regular and effective monitoring of smart infusion pumps and the drug limit library.

- Establish a process to manage dosing limits

- Communicate findings to staff on a regular basis

  Example 1: A nurse manager is concerned about whether the unit staff is using the latest version of the safety software and the number of limits that are being overridden. She disseminates a real-time report to the staff at the beginning of each shift and conducts pump rounds to determine what is causing nurses not to stay within smart pump safety limits. This serves to identify and get rid of the nuisance alerts, educate and instruct nurses about pump safety features that affect patients in real-time, and conveys the overall expectations for compliance with safety software.

  Example 2: A hospital system issued scorecards to provide an aggregate view of smart pump compliance rates, number of alerts, overrides, and edits, which included reports of critical catches or serious adverse events prevented and estimated cost avoidance.[14]

- Solicit feedback on established limits. Drug library benchmarking may be used to provide perspectives on how drug library entries are constructed across many different facilities. This may provide useful information on where latent drug library errors exist in a facility's library. Additionally, drug benchmarks may be useful when facilities have identified significant, and unwanted, variation between clinical practice and the drug library parameter for specific medications. This variation may be due to the drug library being out of step with clinical practice. Clinician workarounds are often an indication that clinical practice is out of step with the drug library. Comparing a facility's drug library parameters to benchmarks from many other sites will provide useful perspective as appropriate strategies are developed to reduce the unwanted variation.

Measurement

Establish a consistent policy and process for evaluating and maintaining current relevant drug library limits.
Example: Appropriate drug dosing limits are established and monitored to ensure current practice is supported, patient care needs are met, and catastrophic dosing errors are prevented. Data collected from smart pumps and other sources are analyzed to identify areas for improvement.

[12] **Skledar et al.** Quality-improvement analytics for intravenous infusion pumps. American Journal of Health-System Pharmacy April 15, 2013 vol. 70 no. 8 680-686.

[13] **Carlson, R., Johnson, B., Ensign, RH.** Development of an infusion pump "safety score." American Journal of Health-System Pharmacy —Vol 72 May 15, 2015.

[14] **Using Smart Pumps to Understand and Evaluate Clinician Practice Patterns to Ensure Patient Safety.** http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3875117/. March 19, 2016.

Question #5: What is our process for ensuring the pumps have the latest drug limit library?

Importance

If the pumps do not have the latest version of the dose error reduction software (DERS), then there is the possibility that a clinician can properly program the infusion using the DERS software, but unknowingly put the patient at risk because the DERs in the pump isn't up to date. Pump stewardship—making sure all the pumps in a hospital have the latest library—is required to reduce risk to patients.

Best Practices

The ideal method for keeping your pump fleet up to date with the latest drug limit library is to use wireless technology. Most hospitals have wireless capabilities, but there are some hospitals that are still wired. Accordingly, a process is defined for both cases.

Hospitals that do NOT have wireless capability to upload new drug libraries

Develop a plan to communicate to all staff that new drug libraries will be put on pumps and outline the key changes made to the drug library file. Collaborate between pharmacy, biomedical, and clinicians to plan the best approach for the organization. It is key to have adequate staff resources to achieve the update on all pumps in the desired timeframe. Establish a plan that is the least disruptive to patient care, such as a period that typically has a lower census. If patient stability and acuity allows, have pumps available with the new DERS to replace pumps that are currently on patients. When pumps are updated, have a way to identify that a new version of DERS has been loaded, such as a small colored sticker to ensure no pumps were missed.

Hospitals that have wireless capability to upload new drug libraries

Develop a plan to communicate to all staff that new drug libraries will be sent out on a specific date and time, and include an outline of the key changes made to the drug library file. The communication plan should also include a refresher on how to accept and activate the file on the pump, along with the institutional policy for updating pumps that are currently on patients. Consider how to identify pumps that have or have not been updated— does the pump continually or intermittently remind the clinician that a new file is available? Use the vendor-provided software to track pumps that have been updated to determine compliance with accepting the new file. Collaborate between pharmacy, biomedical, and nursing to plan the best approach for the organization. The approach depends on how your software functions (e.g., is the file always available until all pumps receive it, or does it need to be sent out again and again until all pumps have the new file?). Your vendor-provided software should track which smart pumps are up to date and which have yet to be upgraded to the latest version of DERS.

Additional best practices include defining the process and communication plans for planned versus urgent pump upgrades, keeping in mind your device update options, for example, auto-push versus clinician accepting download, wired versus wireless.

Measurement

Percentage of pumps with the latest drug limit library is calculated by:

$$\frac{\text{(Number of pump with current DERS)}}{\text{(Number of pumps)}} \times 100\%$$

Appendix A: Drug Library Compliance Audit Form

Drug Library Compliance Audit

Use in conjunction with DoseTrac® Real Time View to track compliance and identify barriers to use

Date: Unit: Auditor:

	Room/ Bed #	# of Pumps in Use	# in Drug Library	# in correct Care Area	# in Basic Mode	Comments Basic Mode drug name, rationale for use, drug library suggestions
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						

The AAMI Foundation wishes to express its appreciation to B. Braun for making this document available.

Appendix B: Analyzing Compliance Data

DRUG LIBRARY COMPLIANCE

Purpose
The purpose of this document is to describe the process of analyzing pump programming practices, compliance to using the pump drug library to program infusions, and identifying opportunities to improve compliance.

Prerequisites
The scope of this document assumes that a facility is using a wireless smart pump system that transfers infusion programming data to the system's Gateway with Continuous Quality Improvement (CQI) reporting capabilities. Analysis is possible on non-wireless systems as well, and can follow a similar process; however, analysis on non-wireless pump use has many more (and very cumbersome) steps.

Introduction
Drug library compliance is defined as the number of infusion starts programmed using the smart pump's drug library divided by the total number of infusion starts programmed, expressed as percentage (e.g., 97%).

DERS can reduce infusion programming errors, but only if you use it
A smart pump's drug library (or Dose Error Reduction Software – DERS) is designed to protect against infusion programming errors that could cause patient harm. The difference between the potential for error prevention and actual error prevention is DERS compliance, or consistently programming infusions using a thoroughly built and meticulously maintained drug library.

Because the drug library is the key safety feature of a smart pump, many facilities set a DERS compliance target rate—commonly a percentage in the mid-to-upper 90s. A 90% compliance rate still leaves 1 in 10 infusions at risk of a programming error that could be caught by the drug library/DERS, so the higher the rate, the safer the infusion programming.

Continuous Quality Improvement (CQI) insight supports high DERS compliance
Regular CQI analysis on infusion programming data allows facilities to understand two key measures:

1) the ratio of infusions programmed using DERS vs. those programmed outside of DERS' safe dosing ranges, and

2) Other infusion programming behaviors that can indicate areas for drug library improvement to support increased DERS compliance

Valuable CQI analysis requires: an organization-wide commitment to encouraging the safest infusion programming practices, defined infusion safety goals, a dedicated team with authority to implement changes, a clear process repeated on a regular schedule and a commitment to implement and measure improvements.

Committee Members and Responsibilities
The team should comprise representatives from pharmacy, nursing (management and education), risk management, and informatics. All members should have adequate knowledge, authority and influence to develop insights from the CQI data and other inputs, and to effectively enact and communicate changes.

Responsibilities
Establish drug library compliance targets for:

a. Integrated Delivery Network (IDN)

b. Individual hospital sites

c. Individual care areas/care area type/care unit/profile

Establish CQI analysis interval
Set a regular schedule for this committee to conduct the analysis and to implement improvements. Depending on the frequency of the committee's meeting schedule, for instance if the committee only meets quarterly, an occasional ad hoc meeting may be required to address med incident

The AAMI Foundation wishes to express their appreciation to Baxter Healthcare Corporation for making this document available.

involving infusion pumps, significant staffing changes or any other disruptive occurrence that necessitates a review of data and practices.

Examples of CQI analysis interval

• 1 to 2 weeks after smart pump implementation go-live

• followed by monthly or quarterly analysis

Determine documentation, reporting and communication process.

Develop documentation templates to ensure consistency of analysis. Identify various stakeholders that need regular reporting on the findings, the actions taken and the implementation communication. Communication should be timely, clear and concise.

Step 1 – Understand your current DERS compliance

All pump vendors offer a DERS compliance report. Run the DERS compliance report for a select timeframe (the timeframe should support your overall CQI analysis schedule and can be used for benchmarking improvements from analysis-period to analysis-period) for all important levels of your organization. Analysis may be performed for entire IDN, by individual hospital sites or by specific care areas or care area types.

Whatever the results of the reports are—even if they indicate a perfect 100% in all areas—the effort to achieve true infusion programming safety improvements has only begun.

Step 2 – Understand how the drug library is being used

a. Meet your gaps
If a care area has a DERS compliance number that falls below the stated target, do the following:

i. Review the Top Ten drugs most frequently programmed and verify if the data reflects actual drug usage.

ii. Review BASIC mode programming details to understand common dosing units used, common concentrations and doses programmed. This may help identify drug(s) that are not in the drug library or have concentrations that are not consistent with current practice.

iii. In addition to reviewing reports, one of the best ways to understand drug library gaps is to conduct targeted observation audits (drug rounds). Note, for any infusions running outside the drug library, ask the nurse why the infusion was programmed the way it was.

iv. Review soft/hard limit reports and identify Top Ten drugs with the most programming limit alerts and review common doses programmed against preconfigured safe dosing ranges. *See Phase 3 below for more details.*

Low DERS compliance may be corrected with training or a drug library update or both. The drug rounds will help identify gaps in the drug library that drive DERS compliance down. The preconfigured safe dosing range for each drug must be meaningful and reflect current practice, otherwise it may cause the clinician to program outside of the drug library.

b. Meet your phantoms
If a care area's DERS compliance number meets or exceeds the target, review the Top Ten drugs report to verify that the drug library is being used properly.

If data does not reflect actual usage:

i. Nurses who are required to program in DERS but have to do so without a drug library that fully supports their infusion practices sometimes program many infusions using a 'phantom' drug in the drug library (for example a drug like IV Fluids that has broad safe dosing ranges and is unlikely to trigger any alerts). This occurs when nurses can't find the actual drug, dose, or concentration in the drug library but need to maintain a high drug library compliance rate.

ii. Conduct targeted observation audits (drug rounds) to verify the drug programmed on the infusion pump is the actual drug being delivered.

iii. Review pharmacy drug utilization reports for the care area and compare with drug utilization reports from pump CQI data.

If you only look at the DERS compliance rate, you will not see the phantoms and your CQI analysis will not achieve the desired improvements in infusion programming safety.

If data does reflect actual usage, understand how that care area supports and reinforces consistent drug library use for programming so you can share knowledge, best practices and successful behaviors with other care areas.

Step 3 – Understand frequency of alerts and any occurrence of errors

DERS compliance is driven by many variables: training, facility expectation, ease-of-access to the drug library, ease-of-drug-library-search, availability of the drug, dose and concentration in the care area's library, and an overall annoyance factor.

If your drug library is complete (meaning it has a drug record for every IV infusion drug used), but the drug configurations are inconsistent with how the drug is ordered in a specific care area, nurses will have to manage unnecessary alerts, upping the annoyance factor and potentially resulting in alert fatigue which can drive nurses to program outside the drug library.

Regardless of the DERS compliance rate, investigate the Top Ten drugs that get soft limit alerts and hard limit alerts to understand if safe dosing ranges need to be adjusted to more effectively support infusion practice and reduce forced overrides. Data-driven, continuous refinements to the drug help support consistent programming in the drug library.

In addition to looking at the pump CQI reports, it is a best practice to review hospital med incident reports to look for drug library or training improvements that can help reduce a recurrence.

Step 4 – Define the problem(s)

Define the problems to be addressed (incomplete drug library, drug library inconsistent with practice, training needs reinforcement) with the answers to these questions:

a. What is our DERS compliance?

b. Are infusions programmed in DERS being programmed properly? If not, why not?

c. Are we missing any drugs, dose modes, or concentrations in the library? If yes, which drugs, dose modes, or concentrations need to be added?

d. Are there drugs in the library that are no longer ordered? If yes, list the drugs to remove and which care areas to remove the drugs from.

e. Is the drug library consistent with how infusions are ordered? If not, which drugs require dosing range edits to the safe dosing range in order for them to be consistent with common infusion orders?

f. Are order sets consistent with current practice? If not, identify order sets that need to be updated.

Step 5 – Design the action and communication plans

Necessary corrections flow easily from a well-defined problem statement. Also, note if your analysis revealed any best practices that can be shared system-wide to improve DERS compliance and add that to a training plan. Specify an action (correction) for each identified training opportunity or issue, including implementation method. Assign actions and timelines to team members.

Step 6 – Implement the correction(s) and communications

Team members complete their assignments: the drug library is updated and transferred to the pump fleet, and training takes place.

Each change implemented should be communicated to everyone the change will affect. Notify users to any changes in the drug library, explaining why the change was made. This is another opportunity to reinforce the importance of DERS compliance and the organization's commitment to supporting safe infusion programming. Ensure communication on the actions and training and implementation dates occurs.

Step 7 – Document and report

Document and report on the findings to all stakeholders previously identified. Communication should be timely, clear and concise.

Step 8 – Measure

Phase 8 is a repeat of Phase 1—run the reports you ran the first time to assess the effect of the implemented changes. Compare your current DERS compliance data as well as your alerts data to the previous set. Has your DERS compliance had the anticipated increase? Are you seeing fewer programming alerts? With subsequent analyses, you will have the comparison data from the previous effort to compare current data to, so you can measure how effective your corrections were.

Also for the time between implementing the corrections and beginning the CQI analysis again med incidents may have occurred, new nurses may have come on-board who need additional training, which can drive DERS compliance down, or drugs may have gone on (or come off of) shortage, drug protocols may have changed or there may be new IV drugs in the facility's formulary which might require additional drug library updates. Because there are endless variables in play that can affect drug library comprehensiveness and DERS compliance, each review interval requires a full CQI analysis through all of the phases.

Appendix C: Top 10 Questions to Optimize Drug Library Use

Citation: Vitoux, R., DoseTrac® Insights, June 2016. B.Braun Medical, Inc.

B|BRAUN
SHARING EXPERTISE

DoseTrac® Insights
Top 10 Questions to Optimize Drug Library Use

Analysis of DoseTrac Infusion Data has shown key themes that contribute to increased incidence of alerts.[1] Ask the following questions to assess your opportunity to reduce non-credible alerts, avoid clinical work-arounds and optimize drug library use.

1. Do you have a policy that addresses infusion pump drug library use and care area selection?

2. Do you have multiple entries, preparations and/or dosing units for the same drug?

3. Do the dosing limits reflect current clinical practice for your care area?

4. Do you have soft minimum limits for drugs that are titrated or weaned to patient effect?

5. Do you have hard maximum limits that could inhibit care delivery (e.g. IV fluids, oxytocin)?

6. Do you have a nursing bolus dosing policy that reflects current clinical practice?

7. Has the bolus feature been activated for all appropriate drugs and fluids?

8. Are your clinical advisories relevant and address specific hospital medication issues?

9. Does your infusion pump library, formulary and CPOE all match?

10. Do you have defined targets and a process for measuring alerts and drug library use?

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