Medicare beneficiaries face tough obstacles

HURDLE #1

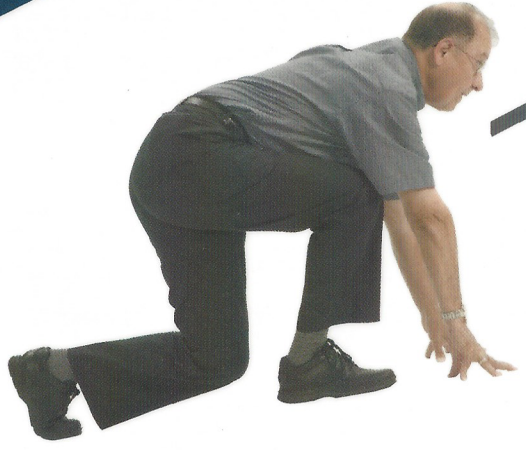
FIND A DOCTOR WHO ACCEPTS NEW MEDICARE PATIENTS

HURDLE #2

WAIT WEEKS OR MONTHS FOR AN APPOINTMENT

HURDLE #3

TRAVEL GREAT DISTANCES TO GET CARE



Laws that place cost control ahead of excellence in medicine threaten the Medicare promise. Help keep the Medicare promise. Go to www.FixTheFormula.org or call toll-free (877) 774-6337. Ask for Leslee.


CONGRESS
BALANCES THE
BUDGET
ON THE BACKS
OF AMERICA'S
SENIORS.
Laws that place cost control
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threaten the Medicare promise.
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Q: **Medicare patients are waiting longer and traveling farther to see their doctors. Why?**

A: **Doctors are being forced away from the Medicare program because payment for services does not cover the costs of providing care.**

The government announced it will cut physician payments each year through 2007, driving payments almost 20% below where they are now. These cuts will drive more and more doctors away from Medicare and force more and more patients to struggle to find the quality, timely health care they need and deserve.

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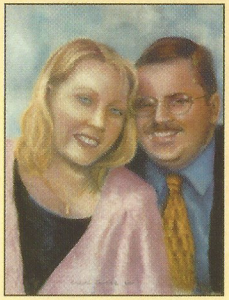
Portraits by Christa Lawrence



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ADVOCACY, LEGISLATIVE AFFAIRS, PAC

Bush Allows Research Funding for Existing Stem Cell Lines

Volker Sonntag, MD
President, North American Spine Society
Phoenix, AZ

On Thursday, August 9, 2001, President Bush announced his long-awaited decision on federal funding of embryonic stem cell research. While private dollars have supported and will continue to support embryonic stem cell research in its quest to uncover breakthrough therapies for spinal cord injuries and other debilitating diseases and conditions, the president's decision has a profound impact on the future of this ground breaking research. In his remarks, President Bush clearly defined the essential value of federal funding of any research. "Federal dollars help attract the best and brightest scientists. They ensure new discoveries are widely shared at the largest number of research facilities and that the research is directed toward the greatest public good."

While private dollars have supported and will continue to support embryonic stem cell research in its quest to uncover breakthrough therapies for spinal cord injuries and other debilitating diseases and conditions, the president's decision has a profound impact on the future of this ground breaking research.

President Bush, who declared as a candidate that he was opposed to embryonic stem cell research, is allowing federal funding only on existing stem cell lines. "As a result of private research, more than 60 genetically diverse stem cell lines already exist. They were created from embryos that have already been destroyed and they have the ability to regenerate themselves indefinitely, creating ongoing opportunities for research. I have concluded that we should allow federal funds to be used for research on these existing stem cell lines, where the life and death decision has already been made."

According to Health and Human Services Secretary Tommy Thompson and White House chief of staff Andrew Card, President Bush will stand by his decision to limit federal funding for embryonic stem cell research regardless of what scientific breakthroughs may occur.

NASS is grateful that President Bush did not close the door on federal funding for embryonic stem cell research. NASS is also pleased that the government will spend $250 million this year on adult stem cell research. All stem cell research, both embryonic and otherwise, will make a remarkable leap forward once scientists are able to control the survival and propagation of the stem cells. Presently, researchers are looking at possible approaches to this vital step in the process. While there is no exact evidence that the hopes of stem cell research will be fulfilled, it is the single most promising avenue scientists have in the seemingly endless battle against devastating diseases and conditions.

There are concerns, however, that the limits President Bush has placed on embryonic stem cell research will impede this research from fulfilling its promise.

According to Dr. John Gearhart of Johns Hopkins University Medical Center, a leader in the isolation of embryonic stem cells, "We know that there is a shelf life to these.... And I do think it will be sooner rather than later."

In addition, several of the organizations who possess these existing stem cell lines hold patents on them, creating possible access and cost issues for the scientists hoping to conduct this research. Patent holders can and do charge researchers fees for using their stem cell lines. Further, according to an August 2, 2001 Reuters Medical News article, the NIH, has "faced situations in which the patent holder was willing to allow basic research to continue only under terms that were inconsistent" with NIH policies. This situation parallels the concerns associated with restricting embryonic stem cell research only to the identified existing lines.

It is illogical to fund research only on existing stem cell lines in the name of protecting precious embryonic life without taking a stand against in-vitro fertilization, the process through which so many embryos are created only to be destroyed. A survey

conducted by the American Infertility Association found that nearly half of couples with frozen embryonic stem cells left over from infertility treatment would donate them to medical research. A small number of these "leftover" embryos are adopted out to other infertile couples, but the majority of them are discarded. If we, as a society, are willing to embrace and celebrate the creation (and ultimate destruction) of embryos to treat infertility—an often psychologically painful, though never fatal, condition—it seems counterintuitive that the same embryos that were knowingly created in excess of the need to treat infertility should be discarded rather than used to treat crippling and fatal diseases and conditions.

It is the couple alone—not the fertility clinics and not the researchers—who must give their informed consent before their embryos can be used for research. They determine whether the embryos will ever have an opportunity to fulfill their potential for life. Like the organ donation program, where family members donate their deceased loved one's organs for someone else's benefit, the owners of the embryos can make the choice to contribute their unused embryos for research.

NASS members overwhelmingly responded in support of a legislative call-to-action issued in March and again in May to let our elected officials know that this decision could decide the fate of hundreds of thousands of people crippled by spinal cord injuries and millions of people suffering with other acquired or inherited conditions.

The couple's decision not to use the embryos for procreation makes the leftover embryos – slated to be discarded – the fundamental equivalent of the embryos used to create the 60 existing stem cell lines. The "life and death" decision about these embryos has also already been made. Absurdly, the resources required for the most important scientific and medical breakthroughs are disposed of in the name of respecting human life.

NASS Efforts to Support Federal Funding

One of NASS' legislative priorities for the 107th Congress has been the protection of federal funding of stem cell research. As NASS' president, I wrote to President Bush urging him to allow continued federal funding of stem cell research in accordance with strict National Institute of Health (NIH) guidelines. The exacting NIH guidelines allow the use of stem cells culled only from embryos created through in-vitro fertilization that are otherwise destined for disposal. NASS members overwhelmingly responded in support of a legislative call-to-action issued in March and again in May to let our elected officials know that this decision could decide the fate of hundreds of thousands of people crippled by spinal cord injuries and millions of people suffering with other acquired or inherited conditions. A special thanks to all who took the time to contact their representatives.

Ensuring Optimal Smart Pump Use Through Augmented User Interface

Tim Hoh, Idal Beer, and Pamela Krueger

Infusion devices are intended to prevent programming errors through the use of a dose error reduction system (DERS). Smart pumps, which are infusion devices with DERS and a drug library (two terms often used interchangeably), protect infusions from programming errors by checking programming entries against drug- and care area–specific safe dosing ranges. If a programming entry is outside of the preconfigured dose range, the pump alerts the clinician to either confirm (override) or reprogram the entry. A DERS catches errors and prompts clinicians to correct entries before the infusion is started, protecting patients from potential adverse events.

Smart pumps were introduced to the market in 2001 shortly after the Institute of Medicine released its 1999 report documenting the number of medication errors faced by hospital patients.[1] Smart pumps were designed to decrease intravenous infusion programming errors and the patient harm that can result. The theory is that the drug library will guide programming within a safe range, with correct dosing units and high and low limits, preventing potentially dangerous programming and protecting patients from infusion programming errors.

To ensure that dosing units and dosing ranges are appropriate and that the alerts are effective, each facility develops a drug library unique to its patients and practices. When this painstaking effort is complete and the drug libraries are running on every pump, a nurse in the pediatric intensive care unit and a nurse in an adult care unit can program insulin with the dosing guidelines appropriate to their respective patients.

Nearly all U.S. hospitals have adopted smart pump technology and developed a unique drug library to match their infusion practices. Because of this, one might assume that every infusion programmed is checked before it starts. However, despite widespread hospital adoption of smart pump technology, drug library programming is inconsistent.[2–4]

The drug library is the defining smart pump safety feature. It is what differentiates smart pumps from their predecessors. If a user programs the pump outside of the drug library, it is no safer than programming an infusion pump circa 1999. There are no safe dosing limits to guide correct programming, which leaves the infusion vulnerable to programming errors and potential patient harm.

Two published studies from different facilities with smart pumps report drug library usage rates of 46% to 48% and 37% to 70% up to six months after going live.[5,6] A recent systematic review also described that compliance rates reported in the studies varied widely.[7]

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It is simple: If a hospital has a 70% drug library compliance rate, three of every 10 initial infusions are unprotected. At 46%, more than one-half are programmed without safe dosing limits and related alerts to catch a potential error. Inconsistent use of the drug library for programming leaves the infusion safety promise of smart pumps unfulfilled.

So why aren't smart pump users consistently using the drug library? We have observed two key reasons: 1) the pump programming workflow is not intuitive and 2) the hospital's drug library is incomplete or doesn't support current clinical practice.

Why aren't smart pump users consistently using the drug library? We have observed two key reasons: 1) the pump programming workflow is not intuitive and 2) the hospital's drug library is incomplete or doesn't support current clinical practice.

This article explores infusion safety from a DERS/drug library compliance perspective, specifically how both device design and the facility's ongoing management of the system factor into the success of this key patient safety technology.

To achieve the promise of reducing programming errors through the use of smart pumps, we need to increase the consistency of programming in the drug library (DERS compliance). The devices must encourage the use of the safety feature, and hospitals must commit to regular drug library updates to ensure adherence with changing clinical practice.

Pump Design: Programming Workflow

Simply having a drug library on a pump is not enough to protect infusion programming from errors. The devices themselves must encourage the use of the safety feature. Pumps must start up in the drug library, rather than expecting clinicians to opt into the safety feature before programming. Clinicians often skip extra steps in the urgency and complexity of bedside patient care. According to internal Baxter data, pumps with automatic startup in the drug library consistently show high DERS compliance rates.

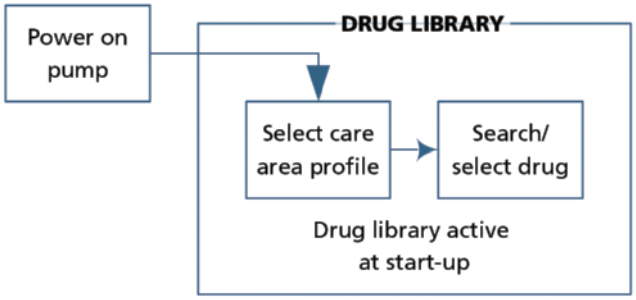

Figure 1. Workflow for Baxter's SIGMA Spectrum Infusion Pump

To optimize proper use, Baxter sought to augment ease of use and further advance the infusion safety protections offered by the next generation of its infusion system (Figure 1).

Baxter implemented human factors testing and engineering to achieve improved ease of programming. Extensive human factors formative testing revealed that test clinicians did not follow select programming workflows consistently, identifying the workflows that were not optimally intuitive. The human factors teams engineered improvements to increase workflow intuitiveness after observing tests and interviewing participants to understand their thought processes while programming.

With the help of Interface Analysis Associates, Baxter conducted a human factors simulated-use validation study on the next-generation test devices with the workflow improvements to determine if specific aspects of the system, labeling, and instructions for use lead to confusion, failures, high-risk errors, or patient safety risks. The findings from this study are on file at Baxter but have not been published in any independent journals. Additional information is available upon request from the corresponding author (Tim Hoh).

A total of 45 healthcare practitioners participated in the study, conducting 1,230 programming steps. This included 15 anesthesia users (anesthesiologists and certified nurse anesthetists), 15 critical care nurses, and 15 non–critical care nurses. Human factors testing was conducted under clinical simulation, representing real users and use environments, to determine user response and behavior in normal conditions.

The overall success rate was 99.1%, and participant DERS compliance was 100% (Baxter data on file). These solid summative test findings were supported when the next-generation devices launched; the first four sites achieved and maintained an average drug library compliance rating of 97% in fewer than four weeks after going live.

CQI Analysis: Drug Library Refinements

Consistently high DERS compliance rates are a product of two equally important factors: 1) the

pump's effortless access to the drug library and 2) the alignment of the hospital's drug library to clinical practice. For example, one of the four hospitals referenced above (hospital A) achieved a 94.3% DERS compliance rate on day 1. The director of pharmacy set a goal of 98% drug library compliance for this new system, so pharmacy and nurse managers conducted drug rounds after implementation to identify when and why pumps were running outside of the drug library. In each case, the infusion order specified a drug name, concentration, or dose mode that was not available in the facility's drug library. Pharmacy implemented additions and corrections and transferred an updated drug library file to the full fleet of pumps. Four days into use of the new system, this hospital reported a 98.1% drug library (DERS) compliance rate.

Rapid activation of an updated drug library file is an infusion safety critical function of a wireless smart pump system. Pumps that require the clinician to take the extra step to "OK" the activation of a new drug library file slow the complete transfer of the file to the full fleet. Pumps that require a complete power cycle to activate the new drug library file further prolong the transfer process. Rapid activation, when the pump is not in use, supports the

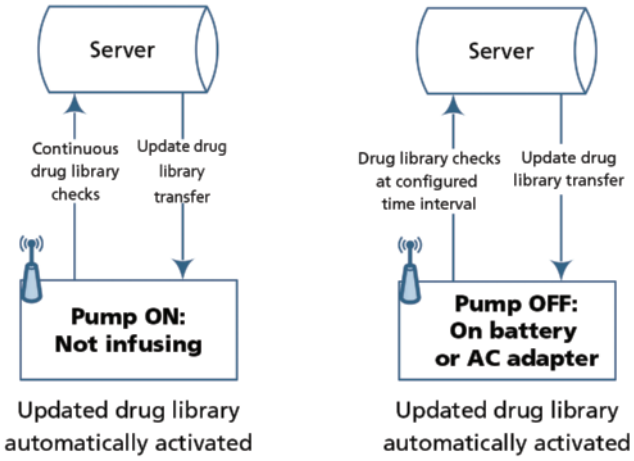

Figure 2. Baxter SIGMA Spectrum Drug Library transfer and activation

safest infusion programming by providing consistent access to the current drug library on all infusion pumps in all care areas (Figure 2).

The hospital A example illustrates the critical nature of a comprehensive, up-to-the-minute drug library that is regularly examined and refined to meet changing needs and practices. Newly available drugs, drug shortages, changing patient demographics, and other changes can necessitate a drug library update. Regular analysis of DERS compliance reports can identify drug library gaps to be corrected. A culture of improvement, fueled by regular analysis, also can support continuous communication on and reinforcement of the safety-critical importance of programming using the drug library.

When workflow is frequently interrupted by alerts that are not valuable to the proper programming or use of the device, bypassing safety systems or overriding the alerts without paying them proper attention becomes more likely.

CQI Analysis: Meaningful Alerts

A systematic approach to infusion data continuous quality improvement (CQI) analysis offers benefits even beyond drug library comprehensiveness. The Joint Commission (TJC) issued a National Patient Safety Goal, effective Jan. 1, 2014, to make clinical alarms systems safer, stating, "Alarms are intended to alert caregivers of potential patient problems, but if they are not properly managed, they can compromise patient safety."[8] Although this goal is focused primarily on the alarms that occur while a device is running, alarm fatigue can occur or be intensified in the programming of devices.

As an example, one healthcare system consisting of three facilities focused its CQI analysis on increasing the meaningfulness of alerts, specifically to minimize alarm fatigue. When workflow is frequently interrupted by alerts that are not valuable to the proper programming or use of the device, bypassing safety systems or overriding the alerts without paying them proper attention becomes more likely.

This healthcare system's infusion data were analyzed from an initial one-month and subsequent three-month period to identify 1) the frequency of soft dose limit overrides and the most common dose(s) that are overridden, 2) the top 10 drugs with the most soft limit overrides for each facility, and 3) the most common doses that were overridden.

The Baxter analysis revealed that vasopressin had the most soft limit overrides, with 42 overrides in the initial one-month period. A total of 17 overrides were at a programmed dose of 0.04 units/min and 14 overrides at a programmed dose of 0.02 units/min. All overrides occurred for programming below the lower soft limit configured in the drug library (0.1 units/min). This analysis identified that the drug

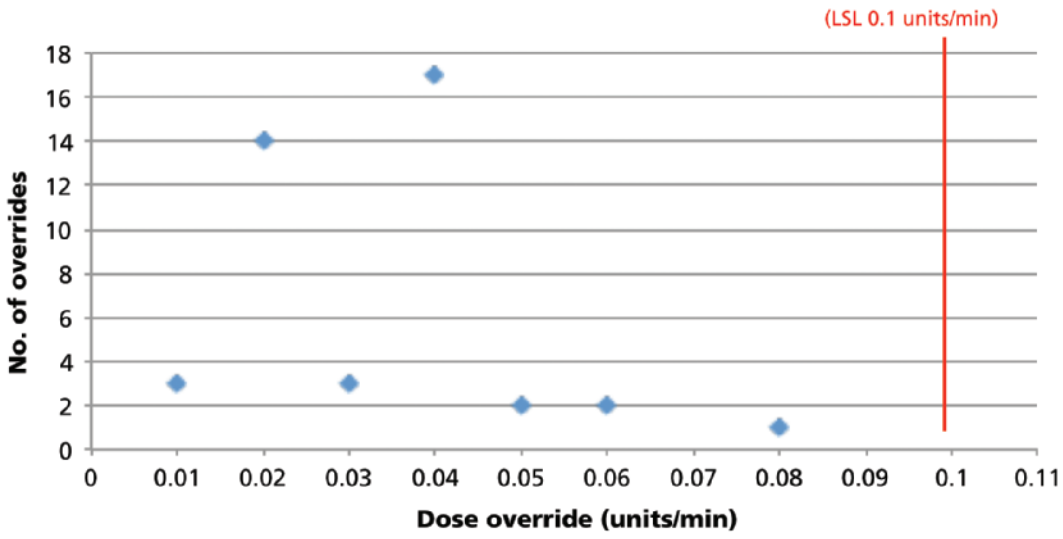

Figure 3. Vasopressin lower soft limit (LSL) overrides: Initial one-month period

library lower dose limit was inconsistent with prescribing practice, so they reconfigured the lower soft limit to 0.01 units/min to be consistent with practice (Figure 3). This change resulted in a substantial decrease in the number of soft limit overrides for vasopressin, down to four in the subsequent three-month period, according to the Baxter data on file.

This tenfold reduction in alerts will diminish potential desensitization to programming alerts, which can cause imprudent and unsafe overrides or avoidance of the safety systems.

Ongoing, rigorous CQI analysis of infusion pump data increases infusion safety by improving the drug library, which increases DERS compliance, and by ensuring meaningfulness of alerts, which allows clinicians to interact more effectively with their infusion devices. The overall result is improved consistency in the use of the smart pump safety systems.

Pump Design: Meaningful Alerts

Pump design also plays a role in the meaningfulness and clinical actionability of alerts and alarms. Both are fundamental to the consistent proper use of an infusion pump.

Alarms should be configurable to allow for meaningful notification. Adjustable audio levels can help identify and prioritize more critical infusion alarms or alarms on more critical medications. Users should have the ability to enable or disable certain alarms, such as an infusion completion alarm or "bag near empty," depending on whether the alarm is necessary for the drug that is being infused.

Finally, the pump must guide the user to be able to recognize and resolve an alarm correctly, preventing a recurrence of the alarm and potential related delays of therapy.

Conclusion

The advent and widespread adoption of smart pumps has created the potential for nearly eliminating the infusion programming errors that can cause patient harm. Inconsistent use of the drug library—the key safety feature of smart pumps—impedes the potential for safe infusions. Clinicians bypass safety systems when the device makes it easy to do so. They also bypass the safety systems when the drug library does not match clinical practice. Intuitive infusion pump design and a systematic approach to CQI analysis to iteratively improve drug library functionality are critical to achieving the promise of smart pump infusion safety. The AAMI Foundation's National Coalition for Infusion Therapy Safety is intended to address patient safety issues related to infusion therapy with infusion pumps.[9] ■

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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.

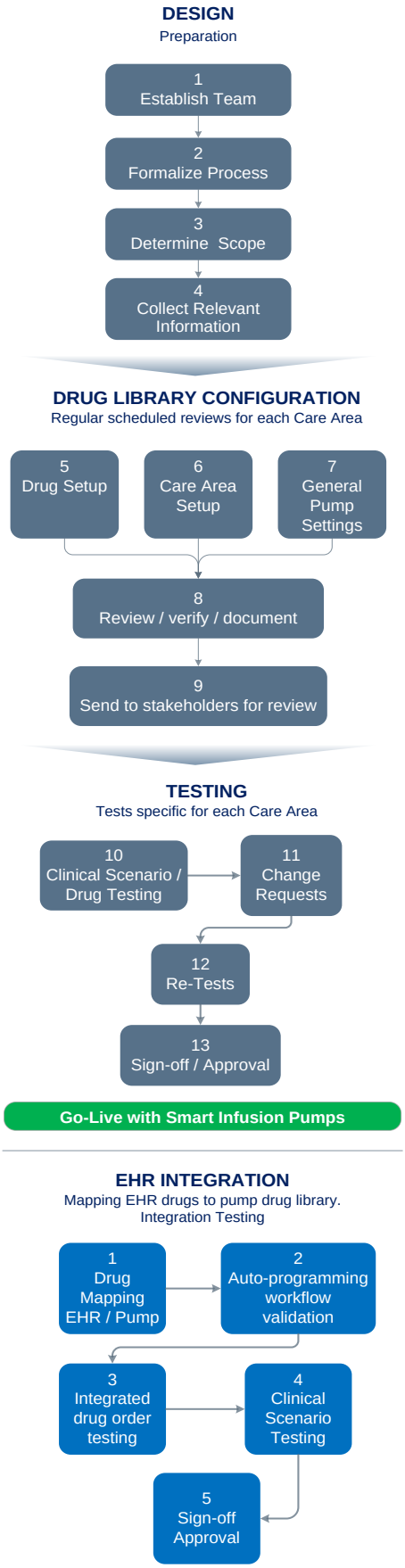
Figure 1 is an overview of the process to build an infusion system drug library, including steps to consider for EHR integration.

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



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
    - 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:

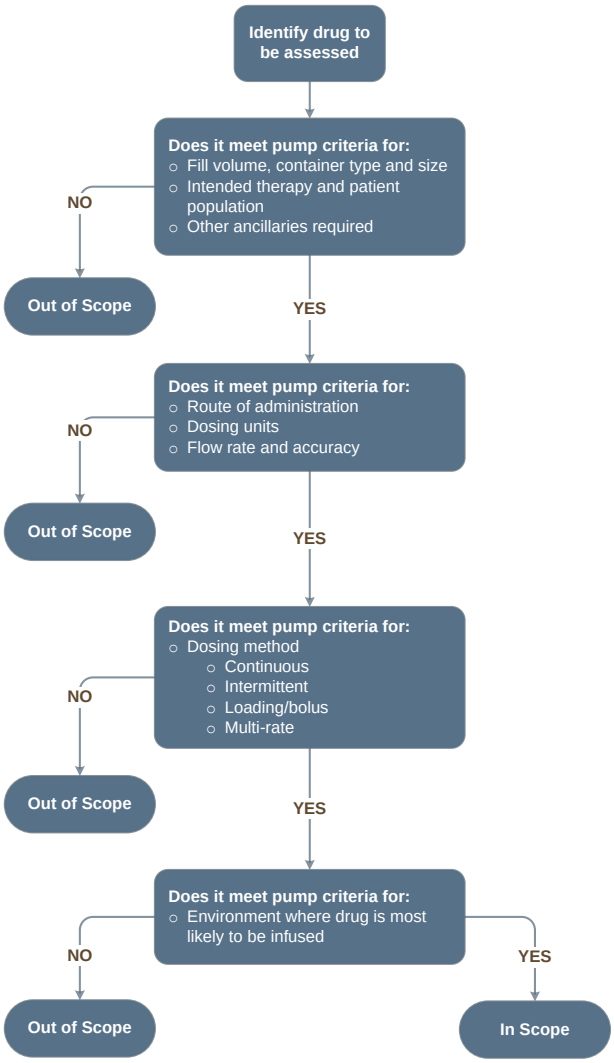
Drug format / container

- 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; auto-programming 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 medication-related 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) Label on Admixture, Premixed or Outsourced Compounded Product

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:

- Primary or Secondary

  Allows drug to be delivered as primary or secondary infusion.

- Primary only, secondary not allowed

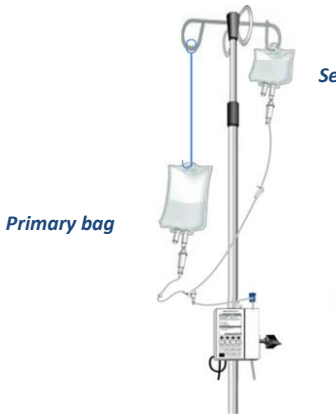
  Drug can only be programmed as a primary and cannot be interrupted by a secondary infusion (e.g. high-alert drugs).

- 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)

Figure 3 Secondary setup



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.

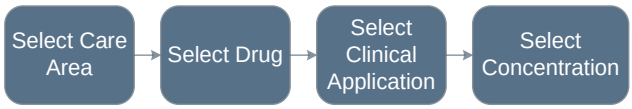
A callback option that alerts the clinician when a step in the infusion is completed may be available or the multi-step infusion may transition from step to step without an alert. Refer to your organization's formulary and drug manufacturer's full prescribing information to determine if multi-step use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

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



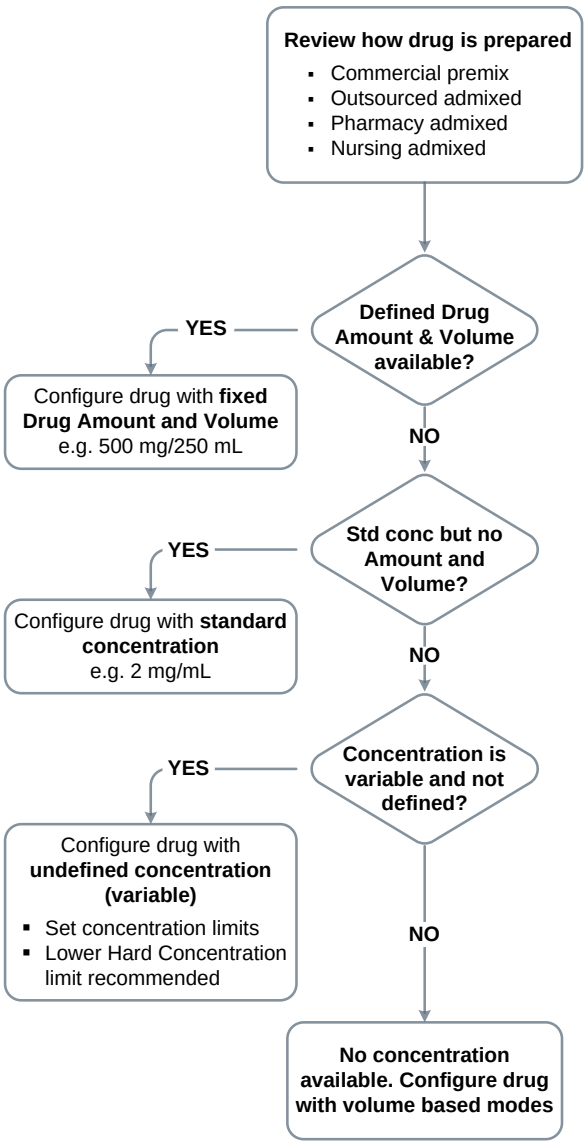
Determine if a drug has specific uses for certain concentrations. If available, you may consider using the clinical application feature to help guide programming of this drug on the pump. For infusion systems with EHR integration, confirm that the clinical application configured is consistent with order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

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.

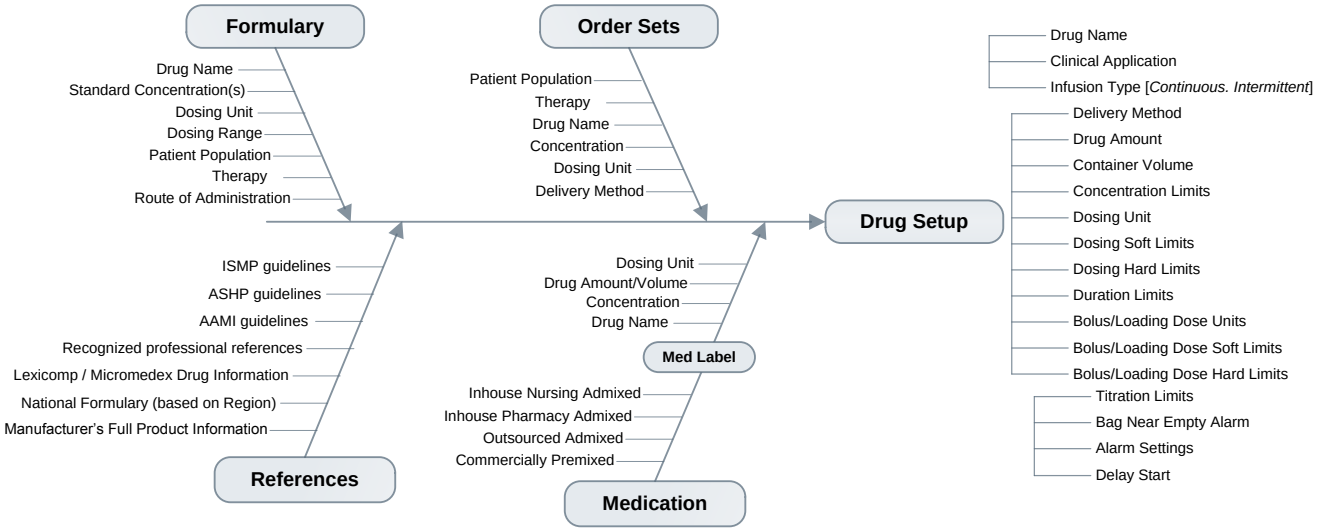
Multi-Step Callback

- 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 auto-programming. 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:

<u>Patient Weight and Body Surface Area (BSA) Limits</u>

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 auto-programming 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 auto-programmed 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:

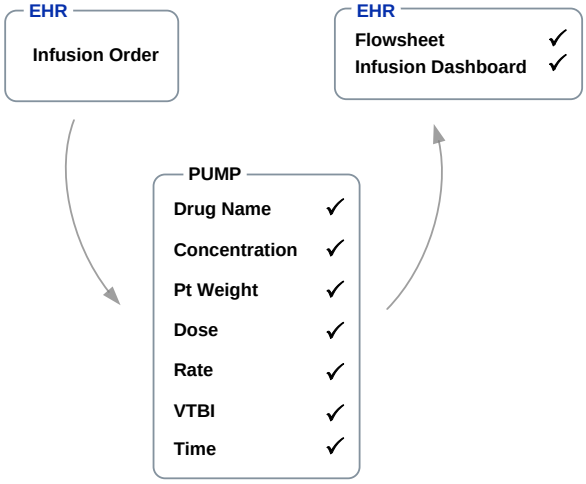
- Initial programming
    - Continuous infusions
    - Intermittent infusions
    - Weight-based, non-weight-based, BSA based
    - Loading dose
    - Manual edits to auto-programmed fields
- Mismatch drug order
- Safety dose limits violations
- Primary infusions and secondary infusions
- Bolus dose
- 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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Editorial

Strategies for successful advocacy

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Who could have predicted that one of the most important things we could ever do for our patients is to be politically active? It seems counterintuitive that a critical step in protecting your patients' access to the high-quality health care you provide would be to call your elected officials. It seems hard to believe that contributing to a political action committee will make a difference in the way you practice medicine every day. But it is a fact that medicine is now the single most regulated industry in this country (I suspected this was true and read the tax code to verify it). And there can be no doubt that physicians now find themselves in a position of political weakness because for many years every other group in health care developed focused lobbying efforts while physicians sat on the sidelines. We left the politics to our adversaries, and we did so at our own, as well as our patients', peril.

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I mentioned in my last editorial that the only rule in politics is that there are no rules. Although that is irrefutable, there are strategies that organizations and individuals can employ to further their communications with the decision makers who direct the delivery of health care in the United States. And that is the key to these efforts. The 535 men and women in the United States Senate and House of Representatives have countless issues, large and small, to consider and to act on. No small number of these issues is health-care related. Without the physicians' and the patients' perspective, health-care–related legislation will always bow to budgetary compromise and the interest of other for-profit players in the health-care delivery system rather than excellence in medicine. For our patients and our profession, we must ensure that this does not continue.

Strategy 1: tell them what you want, what you really, really want

The key to this, of course, is knowing what you really want. For example, let us consider the Medicare reimbursement issue. Before President Bush signed the Prescription Drug and Medicare Improvement Act into law, physicians faced a 4.4% Medicare fee cut for 2004 and similar cuts through 2008 until reimbursement decreases almost 20% below where it is today. In the face of this looming disaster, the new law's provision allowing for a 1.5% increase in physician reimbursement for 2004 and 2005 looks great. An increase always beats a cut, right? Not necessarily.

Whether the law had passed with the positive physician payment update or not, Medicare physician reimbursement will plummet precipitously beginning in or by 2006. The new law delays and, in fact, compounds the physician payment problem in the long term. The problem is in the formula that calculates the Medicare physician fee schedule. This formula's purpose is to restrict the growth of Medicare physician spending. Each year Congress sets a target allowable spending amount for Medicare physician reimbursement. If physician spending falls under that target amount, physicians will see an increase in their Medicare reimbursement in the following year. If physician spending exceeds the allowable target, physician reimbursement is cut the following

year to "pay back" the government for what it deems to be "overpayments" to physicians. The provision in the new law that allows for 1.5% increases for 2004 and 2005 presumes that this money is a loan to physicians to be paid back to the government in addition to the $8.9 billion Congress believes that physicians owe the government for previous years' "overpayments." The paybacks would begin in 2006 with cuts in reimbursement so steep they are referred to as a "cliff."

The problem with Medicare physician reimbursement lies in how the target is determined. Congress determines the target based on many variables, one of which is the gross domestic product (GDP), the measure of the USA's output of goods and services, rather than specific morbidity measures of the Medicare population and the related costs of treating patients themselves. For example, there is no obesity index, or smoking index, or cancer index to predict changes in the health status of the US public as a whole and therefore reasons for increased utilization. The lack of such indexes also puts physicians in the unpopular position of being blamed without reason for increased costs to the system without explanation. Further, the Medicare program increases the services available to Medicare beneficiaries, which serves to increase utilization without budgeting extra funding to cover this predictable increase in the spending target. So what Congress calls "overpayments" to physicians are, actually, payments for allowable services rendered to the patients for whom the government has promised coverage. In addition, we know that the payment the physician received for the service provided in many cases covers only 70% of the cost of providing the service (Marshfield Clinic study, June 2001, Marshfield, WI). The provision in the House bill delays the "debt repayment" 2 years but at an incredible cost to physicians and patients.

So what do physicians want? Physicians need a Medicare physician fee formula that establishes the annual spending target based on the size and health of the Medicare population, separate from the GDP (the new law modifies the use of GDP in the physician formula to a 10-year rolling GDP instead of measuring it year to year, which will reduce the stark payment drops each year). The problem with this request is that a formula that accounts for the size and health of the Medicare population will likely be unable to restrict the growth of physician spending, which presents Congress with some very unpleasant choices. Which leads to …

Strategy 2: know what you will settle for

Although it is important to know exactly what you want, it is equally important to know what you will accept instead. The problem with insufficient Medicare reimbursement is that it does not cover the cost of providing care to our nation's elderly. Many physicians have had to reduce their participation in the Medicare program in an effort simply to stay in business. Deeper cuts in physician reimbursement lead to deeper cuts in available services or appointment times for seniors (NASS member surveys reveal a strikingly upward trend in limiting Medicare program participation: September 2001, 26%; February 2002, after the 5.4% fee cut, 49%; January 2003, 57%). Physicians recognize that, ultimately, not only Medicare patients will suffer because of this budgetary crisis. Knowing what you will settle for comes from knowing what is most important. First and foremost in this case, it is protecting access to health care—for more than just our nation's elderly, as you will see later.

NASS survey numbers from September 2001 show that before the 5.4% physician fee cut that took effect January 1, 2002, 26% of NASS members had limited their participation in the Medicare program (limiting appointment times or services available to Medicare patients). One month after the 5.4% physician fee cut, the number limiting participation in the program jumped to 49%, an increase of 23 percentage points, directly attributable to the fee cut. By January 2003, 57% of NASS members had reduced their participation in the Medicare program. If the predicted 4.4% physician fee cut had taken effect on January 1, 2004, more and more physicians would have been forced away from the Medicare program with obvious negative effects on the health of US senior citizens.

As the guardians of health care, it is our responsibility to prevent the further erosion of access to care. Health care competes with national security, education and countless other interests for federal dollars. Knowing what we will settle for comes from knowing what is possible. The 1.5% increases buy physicians 2 years without further Medicare physician fee cuts to urge Congress to fix the formula. So, in this case, the 1.5% increase for 2 years is not what we want in the big picture, but it is what we will accept in the short term to stave off a decrease in pay that would jeopardize seniors' access to health care.

Strategy 3: embrace your special interest

Special interest groups are often spoken of with derision. The truth is that each time a citizen writes a letter to his elected official, he is representing his special interest. In our system of government, all interests vie for lawmakers' limited time and the federal government's financial resources by applying pressure on key decision makers. The only group guaranteed to lose in this game is the one without a voice.

Physicians have been without a voice in the legislative arena for far too long. In fact, political inaction is why we have our current health-care system. Conversely, insurance companies, health maintenance organizations, hospitals, device companies, pharmaceutical companies—every other group in health care—all have well-funded, expertly directed lobbies. In the end, when physicians lose, it is the patients who end up paying the price. So our special interest is indeed the patients' special interest as well. It is something we cannot afford to shy away from or, even worse, ignore. We owe it to our patients and our profession to have our voices heard in the halls of Congress.

Physicians must carry the brunt of the fight for fair Medicare reimbursement. There are powerful interests lined up

against us. Third-party payers that commonly key off of Medicare's physician fee schedule when they create their own physician fee schedules have a vested interested in seeing Medicare physician reimbursement drop. As Medicare reimbursement drops, so will reimbursement from third-party payers. Adding to the problem is many states use the Medicare fee schedule to set the workers' compensation physician payments, limiting injured workers' access to complete treatment. Physicians cannot—and our patients (seniors, employees and injured workers) cannot—afford to take a back seat on this issue.

Talk to your patients about the issue. NASS has created a Web site that provides you and your patients with a detailed but easily readable description of the problem and its effects on patient care: www.FixTheFormula.org provides all physicians with the tools necessary to urge Congress to create a Medicare physician reimbursement schedule that reflects actual costs of providing care.

Strategy 4: engage your elected officials on the federal level

Write to your congressional representative about how the Medicare cuts threaten your ability to provide the highest-quality, most timely care to your patients. Detail for your lawmakers how the skyrocketing professional liability premiums, combined with declining reimbursements, threaten your ability to provide the care you are uniquely skilled to provide. Develop an ongoing communication with your representative and senators so that when they or their staffers have a question about how pending legislation might affect patient care, you are on their speed dial. Keep abreast of the changes in health-care legislation. Join the NASS Congressional Liaison Program for updates and urgent action alerts to assist your efforts.

Strategy 5: engage your elected officials on the state level

This is especially important on such issues as professional liability in which states have more control than does the federal government. As you know, certain states, such as California, have enacted legislation that caps noneconomic damages at $250,000, limiting the "jackpot" jury awards that insurance companies claim are driving professional liability premiums skyward. While this fight has been taken up in Congress, the most immediate and effective campaigns are being fought and won on the state level. In July 2003, tort reform legislation failed to receive cloture on the US Senate floor to limit debate on the bill. Without limits on the debate, the Senate will not be able to have a vote because of a filibuster by opponents of the bill. This failure to receive cloture essentially killed the House-passed tort reform legislation in the Senate.

Given the current makeup of the Congress, even proponents of this legislation admit that the chances of enacting this proposal in the current Congress are slim. In the meantime, doctors and other providers are successfully enacting laws to limit jury awards in formerly pro-plaintiff states, such as Texas and Mississippi.

Strategy 6: multiply the message

Expanding on the idea that we must do together what we cannot do alone, NASS has joined forces with 13 other medical specialty associations through the Alliance of Specialty Medicine to amplify our voice in Congress. NASS, as a member of the American Medical Association (AMA) House of Delegates, also works with the AMA where appropriate to support its legislative efforts. NASS has recently joined another coalition of medical associations to launch a public media campaign to make the professional liability crisis a key issue of the 2004 elections.

Strategy 7: fuel the fight machine

You knew this was coming, right? The appropriate resources are necessary to fuel all effective lobbying efforts. NASS has been working closely with the spine industry to secure underwriting (although not direction) from the companies that understand that our struggles are their struggles. If Medicare reimbursement plummets and professional liability premiums continue to increase, more and more patients are going to find great difficulty in accessing specialty care. If patients cannot see physicians, then the products, devices and services the companies exist to sell cannot make their way to the patients. But only NASS members can fund SpinePAC.

So, I will say it again, who could have predicted that one of the most important things we could ever do for our patients is to be politically active? It seems counterintuitive that a critical step in protecting your patients' access to the high-quality health care you provide would be to call your elected officials. It seems hard to believe that contributing to a political action committee will make a difference in the way you practice medicine every day. But it is a fact that medicine is now the single most regulated industry in this country. And there can be no doubt that physicians now find themselves in a position of political weakness because for many years every other group in health care developed focused lobbying efforts while physicians sat on the sidelines. We left the politics to our adversaries, and we did so at our and our patients' peril.

Remember, if you don't step up, you cannot complain when legislation and regulations wreak havoc on your practice and your ability to provide care to the patients you are uniquely qualified to treat. There is no "someone else" to carry the bag for you. If you're going to complain, go ahead and do so directly to your elected officials to continually advance the dialogue on the issues plaguing health care in the United States. You will begin to solve the problems plaguing US health care.

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Maximizing Smart Infusion Technology

Best Practices for Drug Library Use
Hospital Case Study

Introduction

Approximately 90 percent of hospitalized patients receive IV medications.[1] Medication errors can occur with any route of administration; however, patients receiving IV medications are at particular risk, since many high-alert medications are administered intravenously.[2] Smart pumps operate using a facility's drug library (with dose limits, concentrations, and clinical advisories) to help reduce IV administration errors by alerting clinicians to potential programming errors that could possibly result in patient harm.[3] If the smart pump drug library is bypassed, the dose error reduction software will not be in place to prevent a potential error. Engaging in this at-risk behavior reduces the likelihood that an error will be identified, since no alerts will be triggered.[3]

What makes a smart pump "smart"?

All smart pumps use a drug library with facility-defined dosing parameters for IV fluids and medications. The drug library is the main feature of the smart pump's safety software—sometimes referred to as Dose Error Reduction Software, or DERS. It checks the drug library to confirm that infusions are programmed within preset safe dosing limits. When programming an infusion (or titrating an infusion that is already running) above or below the drug library's preset dosing limits, the smart pump issues an alert before the infusion is started. This notification prompts the clinician to review the order and either confirm the programmed infusion or reprogram the pump.

Consistent use of a complete and accurate drug library is the key to minimizing the risk of infusion-related Adverse Drug Events.

Use of the Drug Library Matters

Smart pumps have become the standard for infusion pumps within the United States. A survey of pharmacy practices conducted in 2010, which included a stratified random sample of pharmacy directors at 1,968 general and children's med-surg hospitals in the United States, showed that 65 percent have adopted this type of infusion technology.[4] Despite widespread adoption of this technology in hospitals, clinicians can bypass the smart pump's key safety feature—the drug library—when programming an infusion.[5] Failure to consistently use the drug library increases the potential for infusion-related medication errors.[5]

Drug Library Use Best Practices

Safety shouldn't be optional. Ensuring consistent use of the drug library for IV infusion programming and maintaining a drug library that is up-to-date and clinically relevant are both key to minimizing the risk of infusion-related medication errors. Two published reports from different facilities with smart pumps requiring a user to actively select (opt into) the drug library have average usage rates of 46 to 48 percent and 37 to 70 percent up to six months after going live.[6,7] This means that potentially up to half of these infusions were at risk for a programming error that could cause a medication error.

Baxter's **SIGMA Spectrum** Infusion System is designed to help avert infusion programming errors that could potentially lead to patient harm by automatically defaulting to the drug library when powered on. Baxter collected drug library usage data (November 2011 to April 2012) from 22 facilities operating the wireless **SIGMA Spectrum** Infusion System. Across the 22 hospitals, **SIGMA Spectrum** Infusion System users showed an average drug library compliance rate of 96 percent.*[8]

Baxter identified three facilities using the **SIGMA Spectrum** Infusion System that recognize consistent drug library use as a critical success factor for increasing infusion safety. Each of the facilities interviewed averaged a drug library use rate of 94 percent or higher (see table below).[8]

Pharmacists and nurses from these facilities were interviewed about what led to their high rates of drug library compliance. The following factors were identified by this group as essential to meeting the challenge of new technology acceptance and consistent infusion programming using the drug library:

- Automatic default to the drug library and DERS safety technology
- Expert drug library training and support
- Maintaining an updated drug library in the full pump fleet
- Reviewing Continuous Quality Improvement (CQI) reports to improve clinical education and the quality of the drug library
- Comprehensive pump training for clinicians

*Standard deviation: 2.89%, based on 1,485,414 infusions reported between November 1, 2011 – April 30, 2012, across 22 facilities.

Parameters	Sherman Hospital Elgin, IL	Yale-New Haven Medical Center New Haven, CT	St. John Medical Center Westlake, OH
Number of wireless infusion pumps	400	1,400	294
Drugs in library	392	792	267
SIGMA Spectrum Infusion System go-live date	June 2011	2010	May 2011
Drug library use rates from October 1, 2011 to March 31, 2012	**96.6%**	**94.9%**	**96.7%**

Automatic Default to the Drug Library

A 2010 *International Journal of Medical Informatics* article reports how acceptance of a new technology is strongly influenced by the users' perception of performance and usability.[9] When converting from one technology to another, some reluctance is common. Resistance to change can result in the tendency of clinicians to program infusions outside of the drug library.[9]

In a 2009 *Journal of Infusion Nursing* article, one clear cause cited for unacceptably high infusion-related medication error rates among medical facilities using smart pump technology was the failure to program infusions using the drug library.[7]

Some smart pump systems require users to actively select (opt into) the drug library. This extra step complicates programming and reduces the likelihood of infusions being delivered within the drug library's dosing limits, which would negate the pump's important infusion safety potential.

The **SIGMA Spectrum** Infusion System addresses challenges presented by the reluctance to accept new technology. Instead of requiring a user to take the additional step of actively selecting (opting into) the drug library, the pump automatically defaults to using the drug library when powered on before programming.

When using the **SIGMA Spectrum** Infusion System, conscious and deliberate action must be taken by the clinician to bypass the drug library.

Michele McPhie, critical care clinical educator with St. John Medical Center in Westlake, Ohio, believes that automatic default to the drug library supports safer infusion programming. "I like the fact that it takes the choice out of it, especially when it is a new product and you are moving from a non-smart pump to a smart pump," she said.

> *Although smart pumps have great promise, technological factors and nursing behavioral factors must be addressed if these pumps are to achieve their potential.*[9]

When a smart pump's DERS safety technology is bypassed, it reverts to "basic" mode. When a pump is in basic mode, there is no access to the drug library or its preprogrammed dosing parameters. "We question anything that is in basic mode," stated McPhie, "because our policy is that we shouldn't be using it. [St. John] stresses that high DERS compliance is important to patient safety."

Nilesh Amin, Yale-New Haven Hospital's clinical pharmacy specialist, agreed. "The nurses know how to search for the word 'basic,' rather than push a button, to program infusions outside of the drug library."

Twenty-one states have enacted laws stating that nurses and other healthcare professionals are responsible for acting with the general skill and operating standards ordinarily found in the profession.[10] As such, if a healthcare facility has a smart pump with a drug library, and proper training is provided, a nurse is responsible for using the device to help avoid drug programming errors. Legal consequences can ensue if a patient is harmed when a nurse does not use available technology which could have caught a pump-related programming error.[10]

An Accurate Drug Library Is Critical

An improperly maintained drug library within the pump fleet may fail to provide the appropriate drug parameters and configurations required for clinical practice, forcing clinicians to operate outside of the drug library.

Baxter's pharmacy and clinical experts provide comprehensive training and guidance to help support a facility's development of a drug library that meets the specific needs of each care area. The Baxter team coaches the facility through comprehensive drug library testing before the pumps are used on patients.

Efficient drug library updates ensure that all wireless pumps in the fleet are quickly updated. The wireless pump, configured to the network, searches for updates and downloads the drug library at the following times: 1) when powered on before the clinician begins programming, 2) after an infusion is cleared, and 3) during sleep-mode when the pump is powered off and plugged in. The clinicians Baxter interviewed cited the SIGMA Spectrum Infusion System's wireless updates of the drug library as one of the key factors ensuring consistent use of this safety feature.[8]

Efficient drug library updates ensure all pumps within a facility are using the same, most up-to-date, and clinically relevant dosing parameters. Rick Uplegger, Director of Pharmacy for Sherman Hospital, observed, "With wireless, [drug library] changes can be made and sent efficiently out to all pumps. There is now the ability to quickly set or change limits and change or add a care area whenever [needed]. As soon as it is determined there is a need for an update, it happens immediately. Overall, this is going to improve compliance and the safety of the patient."

Ongoing updates to the drug library are essential to meeting changing clinical practices and changes to the formulary. "We went live during a drug shortage," McPhie explained. "In our training, we emphasized that if you can't find something in the drug library, you must call me to report the missing substitute so we can keep a running list of substitutions and get the drug library updated quickly. As soon as we learned of necessary additions to the drug library, our pharmacist updated the drug library and pushed it out to all the pumps so the nurses could find the substitute drugs in the drug library and would not program the infusions using basic mode."

Continuous Quality Improvement Drives the Increase in Drug Library Use

"Information is education; education drives compliance," stated Uplegger, explaining why Sherman Hospital runs the DERS compliance Continuous Quality Improvement (CQI) report weekly. "We expect the reports to produce evidence, which will increase compliance and maximize benefits of the pump, helping us meet standards and increase safety."

The SIGMA Spectrum Infusion System CQI reports provide drug library compliance data by care area, and identify when soft limit overrides and hard limit attempts have been made. By analyzing this information, pharmacists, nurses, and safety and risk managers are able to make data-driven decisions about drug library updates and clinical education enhancements.

CQI report review can help **SIGMA Spectrum** Infusion System users improve their drug library safety technology compliance over time.[11] Amin, Clinical Pharmacy Specialist for Yale-New Haven Hospital described how analysis of CQI data works. "We review data on drug library usage by each care area to determine which are having problems," he said. "After that, we met with those that had low drug library compliance to determine the reasons—whether drugs were missing from the drug library or if nurses were unfamiliar with the selection of the drugs in the library."

Uplegger also acknowledged the benefits of regular CQI report review. "95 percent compliance was the goal at go-live; now it is 97 percent," he said. "We want to take advantage of the drug library and have the right limits in the right library to be able to make [infusion therapy] safer for the patient."

*Drug library updates occur automatically on wireless **SIGMA Spectrum** Infusion Systems configured to the network:*

- *When powered on before programming*
- *After an infusion is cleared*
- *During sleep-mode when powered off and plugged in*

According to McPhie, St. John Medical Center runs CQI reports with the same goal in mind. "Updated drug libraries are really important in maintaining your compliance," she said. "You have to have the information in the pump to use it correctly."

Comprehensive Training Supports Drug Library Use

Clinician training is an important aspect of smart pump implementation. Baxter's training goal is to ensure that 100 percent of **SIGMA Spectrum** Infusion System users are fully trained and understand its full complement of safety features. Additionally, Baxter trains clinicians within the facility as "super users" who are available to train others on an ongoing basis. This helps ensure that only fully trained clinicians use the **SIGMA Spectrum** Infusion System on patients.

"We spent a lot of time in setup and education to assure that everyone knew this was for patient safety," McPhie said. "And we let them know this was set up to make it easy for nurses; we made the drug library workable from their perspective. We were provided hands-on training, including specific scenarios and care area training to be certain everyone was competent in every situation.

"We had several instructors that came from Baxter. They worked with me to schedule the right number of training sessions. Baxter was very willing to work with us to set up training times, either just before a shift started or at the end of the shift. That really helped compliance, because people couldn't leave in the middle of a shift to get training. Classes were about one hour, but the resource nurses (or super users) were there longer, because they were on-the-floor resources for other nurses."

Comprehensive clinical training promotes consistent programming using the drug library and can strengthen the quality of the drug library before going live.

McPhie stated further, "I know that when we were going live at the main facility, nurses would come up with questions that were relayed back to the Baxter pharmacy consultant, which led to the good status of our drug library."

Uplegger confirms the connection between comprehensive clinical training and consistent drug library use. "We ran the DERS compliance report three days after going live and compliance was already at 95.5 percent," he said. "This was the result of having a comprehensive and accurate drug library and extensive nurse training."

Delivering on the Promise of Smart Pump Technology

Safety shouldn't be optional. The safety features of the **SIGMA Spectrum** Infusion System maximize the full potential of smart infusion technology, support best practices, and make it easy for caregivers to continuously foster infusion safety goals.

The difference between a smart pump's potential for error prevention and actual error prevention is compliance with consistently using an up-to-date drug library.

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Rx only. For safe and proper use of this device, refer to the complete instructions in the Operator's Manual.

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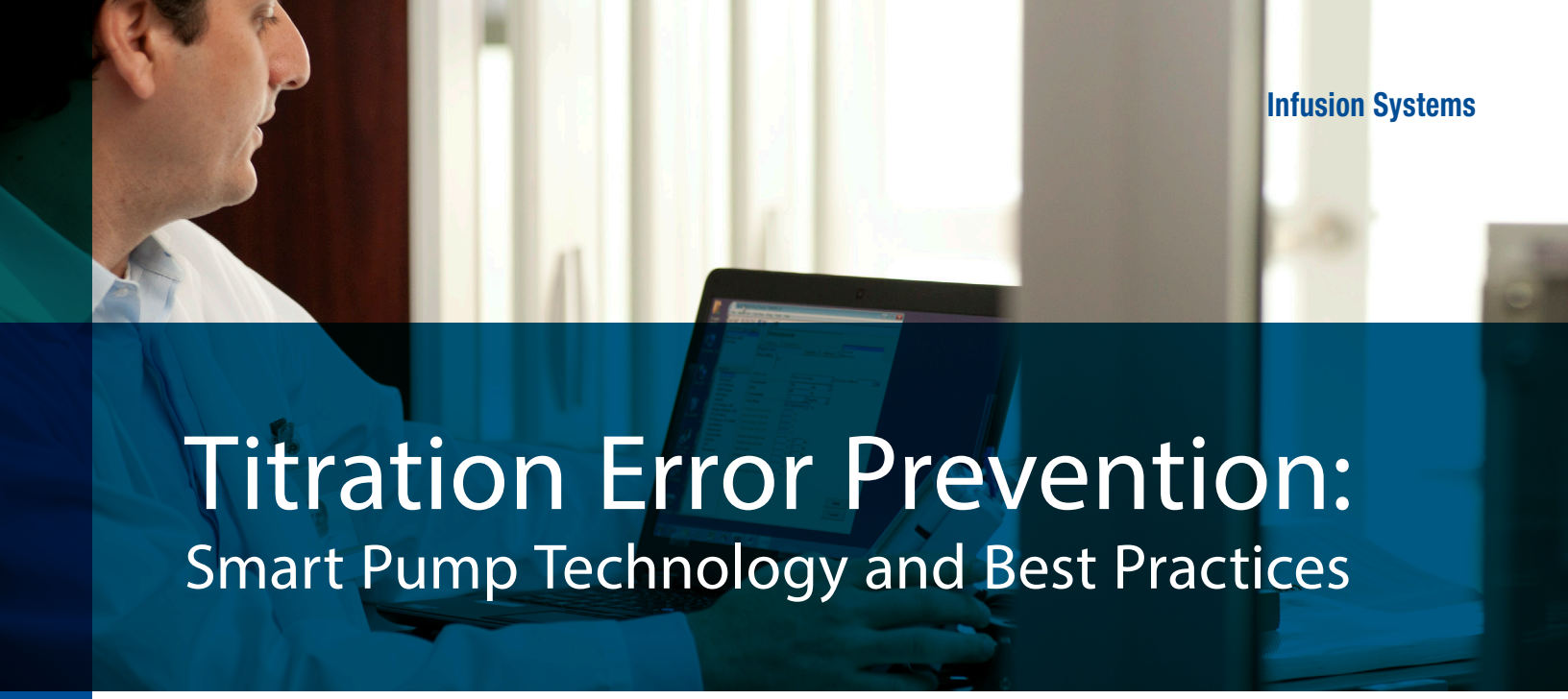

Titration Error Prevention:
Smart Pump Technology and Best Practices

Importance of Drug Dose Titration

High-alert medications carry a significant patient safety risk if not administered correctly, especially when given intravenously (IV).[1-2] These medications, which may include antithrombotics, antihypertensives, neuromuscular blockers, opioids, sedatives, analgesics,[2,3] and vasopressors are typically given to critically ill patient groups[4] and are often titrated to achieve a therapeutic effect.[5] Due to their potential for harm, careful monitoring and titration of these medications is essential.[5] For example, it has been estimated that 80% of deaths due to medication errors are correlated with just 20 high-risk drugs.[5]

High-alert medications are often titrated multiple times throughout an infusion. The risk of programming errors and IV infusion pump-related adverse drug events (IV-ADEs) increases as the number of changes increases.[5,9] In patients receiving more than one high-alert medication, the risk is compounded with each additional medication.

In the ICU patient encounters covered in the EHR database examined, 83% of patients receiving a high-alert medication (53,002) received two or more such medications over the course of their ICU stay, and 41% (26,038) received six or more high-alert medications (Figure 1).[6]

Correct dosing and titration of high-alert medications, especially in the ICU setting, is critical to avoid severe complications.

Of 64,260 ICU patient encounters involving high-alert medications identified in a US electronic health record (EHR) database covering 114 hospitals from 2008 to 2013, the most commonly administered high-risk medications class in the ICU were sedatives and analgesics (including opioids).[6] These drugs, if not administered correctly, may cause adverse events.[7]

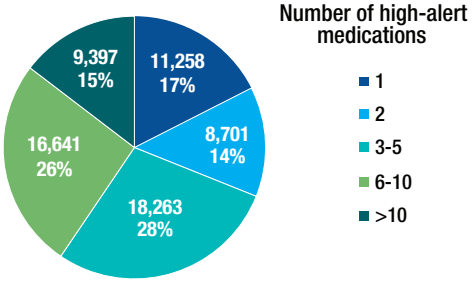

Figure 1. Distribution of high-alert medication use (number of drugs/patient) in ICU patients from a US EHR database covering encounters from 114 hospitals from 2008 to 2013.

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Titration Errors: Scope of the Problem

The prevalence of medication errors is well-known[9] and the administration stage of medication delivery is particularly prone to error[1] – especially incorrect dosing of titratable drugs in critically ill patients.[9]

The most important risk factor for ADEs in ICU patients is the higher number of medications ICU patients receive, including more high-alert medications.[4] A retrospective medical record review by Nuckols et al., published in 2007, analyzed two hospitals for adverse events with IV medications both before and after implementing smart pump technology. The analysis included 4,604 ICU patients and 20,559 bed days.[8] The study found that 44% of the adverse events that occurred were associated with four titratable high-alert IV medications.[8] Critically ill patients are particularly susceptible to ADEs and frequently receive potent intravenous drugs with narrow safety margins that require careful titration of dosage.[9] This could mean that this patient population is often exposed to multiple opportunities for medication errors, and that there is an opportunity for infusion technology to help address this source of medication errors.[3]

Error Rates and Potential Adverse Drug Events; An Ongoing Concern

Despite implementation of safety related technologies, including smart pump technology, medication error rates and rates of preventable IV pump-related ADEs are still unacceptably high.[4]

In the 2007 retrospective medical record review, by Nuckols et al., only 4% of the preventable IV-ADEs could be intercepted by the smart pumps' features included in the study (detecting duplicate and continous infusion doses outside of hospital defined ranges)[8]. The authors concluded that "expanding smart pump capabilities might prevent more IV-ADEs."[8]

One reason for titration errors may be the need to perform several tasks at once (i.e. programming doses for several IV medications). As explained in a set of 2012 guidelines created by the San Diego Patient Safety Council for the administration of high-risk medications, "The action of programming an infusion pump is complex. Humans performing complex behavior with many interruptions have a higher rate of failure."[3]

Titration alerts may help minimize this problem. As stated in these same guidelines, "Titration increment limits could be used in medications with standard protocols and provide additional safety benefits.[3] In circumstances when a clinician is titrating a drug up, yet has entered an incorrect dose into the infusion pump, limits to the titration increment could exist and trigger an alarm."

A smart infusion pump that could recognize potential titration errors would represent significant value to clinicians and could help support infusion safety.[4]

Titration Error Prevention

Importance of Titration Error Prevention

IV Pump-ADEs occurring when innaccurately changing a dose or rate can potentially be avoided with the use of a titration error prevention feature that provides alerts when defined limits are exceeded. Some high-alert medications, such as opioids, have the potential to cause harm even within common soft dosing limits.[1] For example, a vasopressor can have varying effects depending on the dose: at lower doses the vasopressor can cause vasodilation, at higher doses the effect is vasoconstriction. An incorrect adjustment of the infusion rate could therefore lead to serious unintended consequences. This is especially important in the ICU, where many patients receive high-alert, titrated medications, and in many cases receive more than one such medication. As stated by Dennison, in the ICU "many drug dosages are titrated based on the patient's changing condition, and the more dosage changes a nurse keys in, the greater the risk of error and patient harm."[5]

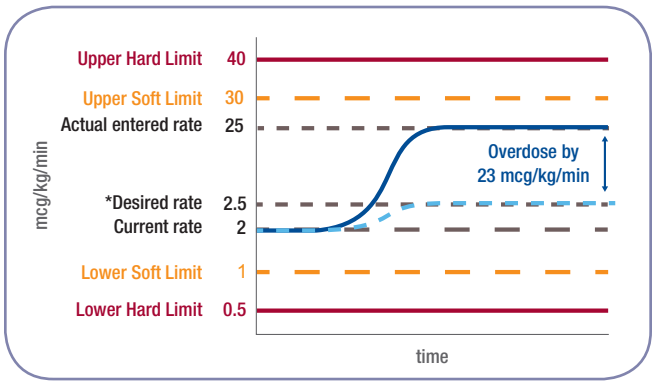

Figure 2. Example of a simple titration programming error (missing a decimal point), which could lead to a more than 10-fold overdose. Y axis not to scale.

Potentially harmful misprogramming of dose or rate changes – within each drug's soft limits – may be 'caught' and avoided with the use of a single-step titration error prevention feature that prompts the clinician to verify the programming or cancel and reprogram. For example, as shown in Figure 2, a clinician has accidentally keyed in a dose increase from 2 to 25 mcg/kg/min, when the desired rate was actually 2.5 mcg/kg/min. This is an overdose of 23 mcg/kg/min, however because the dose increase is still within the upper soft limit for this particular medication (30 mcg/kg/min), no "soft limit exceeded" alert is triggered by the smart pump. Undetected programming errors may lead to IV ADE's.

Most Smart Pumps Lack Titration Error Prevention

Titration error alerts are not a feature in all smart pumps.[10] All smart pumps include a DERS which includes a customizable drug library[10] that triggers alerts when programmed values exceed facility-defined limits. Soft dosing limits identify potential medication errors during initial programming of the drug, however they may not be applicable to subsequent dose change (titration) programming.

Baxter's SIGMA Spectrum Infusion Pump

Novel Dose/Rate Change (Titration) Error Prevention Safety Feature

Baxter's **SIGMA Spectrum** infusion pump is the only smart pump that alerts the clinician to potential programming errors in dose or rate changes. The titration error prevention feature can help identify potential titration programming errors within the facility-defined soft dosing limits. This feature alerts the clinician if the percentage change exceeds limits set to match the facility's titration protocols.

These alerts are configurable for all medications to meet each Care Area's clinical practice. For example, the default alerts will warn the clinician programming the change if the programmed increase is greater than 101% (or the decrease is greater than 51%) of the previously programmed dose. These percentage limits are editable by drug (exception Anesthesia and OR Care Areas where percentage increase limit is 500%). In the case of the example shown in Figure 2, the Dose/Rate Change Alert would alert the user of the programming error (25 instead of 2.5 mcg/kg/min).

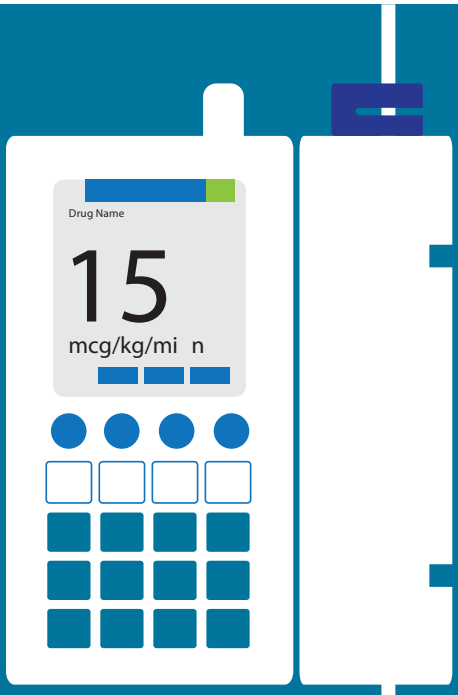

Figure 3. The **SIGMA Spectrum** Pump's Titration Error Prevention Feature alerts clinicians to dose increases or decreases exceeding defined limits, which can help identify potential medication titration errors.

Conclusion

Despite advances in smart pump technology, medication errors still occur frequently in the hospital setting. Errors in titrating high-alert medications can be particularly dangerous due to their prevalence in the ICU and usage in vulnerable patient groups.

The importance of accurate titration has been described in several articles and guidelines.[3,5] Though all smart pumps offer DERS functionality, **SIGMA Spectrum** Infusion Pump can identify dose/rate change (titration) programming errors, even within the soft limits.

The Dose/Rate Change Alert is designed to help reduce titration programming errors even within the drug library's soft limits. The Dose/Rate Change Alert feature is only available with the **SIGMA Spectrum** infusion system.

Dose/Rate Change (Titration) Error Prevention Feature

Employ best practices to maximize the patient safety feature of titration error prevention.

Hospitals with the **SIGMA Spectrum** Infusion System can customize single step rate change/ titration alert thresholds based on the IV medication and care area - this safety feature can be adapted to your hospital's IV medication policies. This feature enables an addtional safety check during doses/rate change (titration).

Suggested Steps:

+ Identify titratable IV medications
+ Review dosing protocols for each titratable medication
+ Adjust the SIngle Step infusion rate increase percentage accordingly to ensure meaningful alerts

The **SIGMA Spectrum** Infusion Pump with Master Drug Library is intended to be used for the controlled administration of fluids. These may include pharmaceutical drugs, blood, blood products and mixtures of required patient therapy. The intended routes of administration consist of the following clinically accepted routes: intravenous, arterial, subcutaneous, epidural or irrigation of fluid space.

The **SIGMA Spectrum** Infusion Pump with Master Drug Library is suitable for a variety of patient care environments such as, but not limited to, hospitals and outpatient care areas.

Rx Only. For safe and proper use of this device, please refer to the appropriate operator's manual.

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AAMI FOUNDATION

QUICK GUIDE

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

The AAMI Foundation is grateful to its collaborating partners in the National Coalition for Infusion Therapy Safety:

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NACNS
Clinical Expertise Nursing Practice Systems Innovation
National Association of Clinical Nurse Specialists

REMEDi
CENTRAL

Appendix B: Analyzing Compliance Data

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

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.

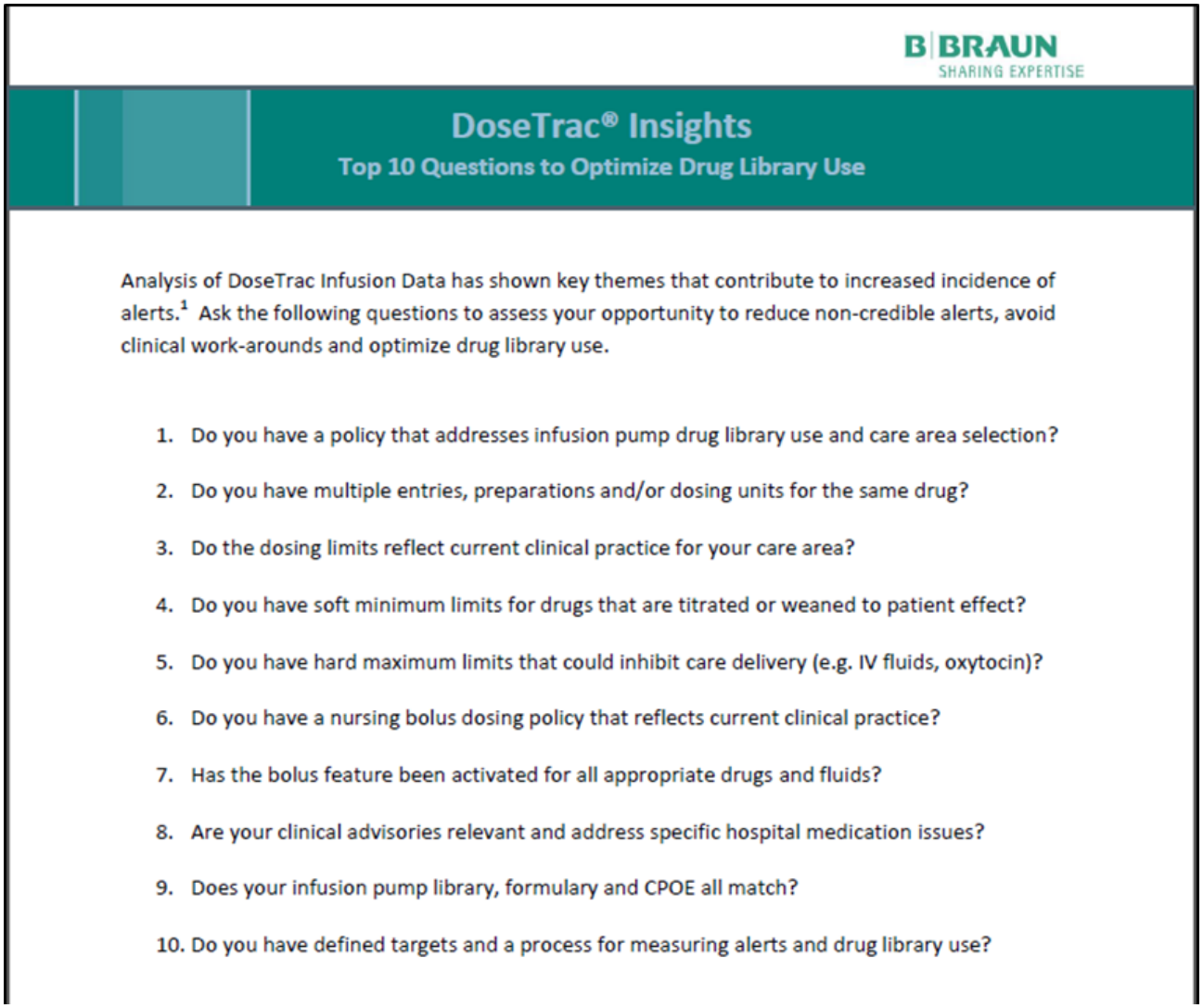
Step 8 – Measure

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.



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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?

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

AAMI Foundation is grateful to the industry sponsors of the National Coalition for Infusion Therapy Safety

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90% of pump programming events for High-Alert I.V. drugs are titrations

Authors: Tim Hoh, RPh; Idal Beer, MD, MBA, MPH; Shannon Kayler BSN, RN; Pamela Krueger, MS;
All affiliated with Baxter Healthcare Corporation, Deerfield IL.

ABSTRACT

High-alert I.V. medications are intended to be titrated during an infusion to achieve a targeted response. Each titration creates an opportunity for a programming error; however, there is no published data on the frequency of titration programming.

A retrospective analysis of infusion pump data from 45 hospital sites over 6 months indicates that 90% of programming events for high-alert I.V. medications are titrations. Understanding titration frequency can guide more effective infusion safety protocols and systems.

METHOD

Infusion pump data from **45 hospital sites** were analyzed for the frequency of titration programming vs. initial infusion start programming for high-alert I.V. drugs.

Infusion pump data info:

- **6 months of data** per hospital site (Oct. 2014 to July 2015)
- Adult patient care area types: **Critical Care**, **OR** and **Anesthesia**
- High-alert I.V. drugs with > 2000 initial infusion programming starts
- Data from 20,542 SIGMA Spectrum infusion pumps

1. Institute of Safe Medication Practices. ISMP List of High-Alert Medications in Acute Care Settings. 2014. https://www.ismp.org/tools/highalertmedications.pdf (accessed March 25, 2016)
2. Schnock KO, et al. BMJ Qual Saf 2016;0:1–10. doi:10.1136/bmjqs-2015-004465

RESULTS

Fig. 1

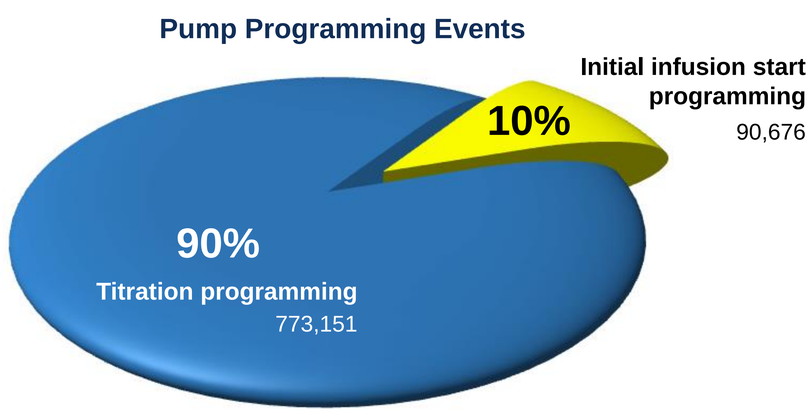
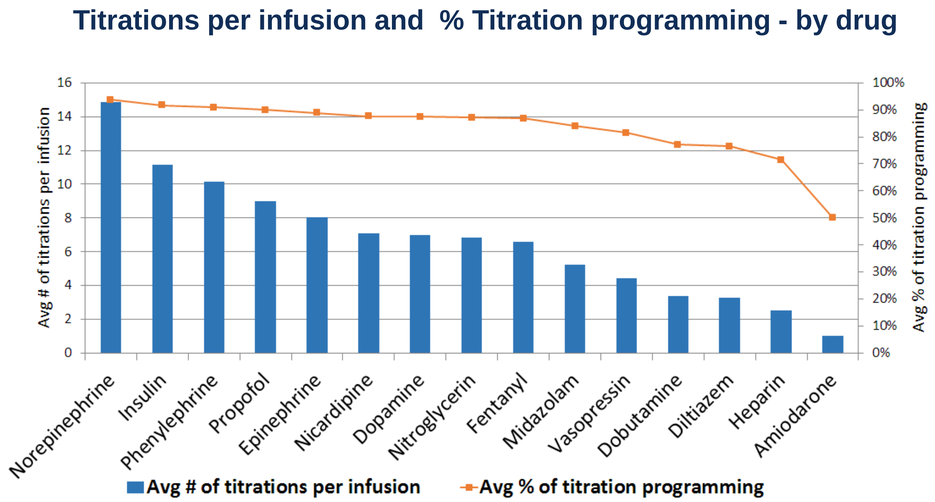


Fig. 2



CONCLUSIONS

High-alert medications bear a heightened risk of causing significant patient harm when used in error[1].

Up to 90% of pump programming events on infusions of high-alert drugs are dose or rate changes after the infusion has started (**Fig.1**).

This indicates the potential for programming errors to occur during a single infusion of a high-alert drug. For example, **Fig. 2** indicates that norepinephrine was titrated an average of 14.9 times. This represents an opportunity for 14.9 programming errors to occur for each infusion started.

DISCUSSION

This finding reveals that 90% of programming events on high-alert drugs may be unprotected by standard smart pumps and EMR systems. These unprotected programming events could help explain why one recent study found: 'Intravenous medication errors persist despite the use of smart pumps'[2]. Consider:

- Hospitals configure drug library dosing limits focused only on the safety of starting doses. Standard drug libraries provide no titration parameters to catch potential programming errors within soft limits.
- EMR integration auto-populates initial infusion programming parameters only; titration programming remains manual entry and susceptible to mis-programming.

Protocols and systems should be designed to protect against all pump programming events, especially for high-alert drugs. Further research is needed to determine the incidence of pump programming errors at all stages of an infusion.

Human Factors Study validates improvements to Infusion Device

Authors: Tim Hoh, RPh; Idal Beer, MD, MBA, MPH; Jim Martucci, MSBME, BSEE; Colleen Wibbe, RN; Pamela Krueger, MS;
All affiliated with Baxter Healthcare Corporation, Deerfield IL.

Introduction

Infusion devices are intended to provide safer infusion therapy by preventing programming errors with Dose Error Reduction Systems (DERS) and a user interface that encourages correct programming.

A Human Factors Simulated-use validation study, implementing Human Factors engineering to achieve improved patient safety through increased ease-of-programming, was conducted to validate thirty–five enhancements for usability, safety, and effectiveness. This presentation focuses on the following ***three high-patient-safety-impact improvements*** :

- **Time entry** during programming
- **Confirming values** entered
- **Loading Dose** programming workflow

Method

This study was conducted to validate design enhancements that resulted from findings in two previous Human Factors formative studies.

- Forty five (45) participants consisting of:
  - Fifteen (15) Anesthesiologists/Certified Nurse Anesthetists
  - Fifteen (15) Critical Care Nurses
  - Fifteen (15) Non-Critical Care Nurses
- Time entry tasks included 150 potential failure opportunities
- Confirm value tasks included > 800 potential failure opportunities
- Loading Dose programming tasks included 90 potential failure opportunities

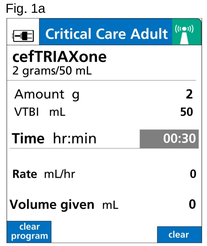
Refer to manufacturers' Prescribing Information for Ceftriaxone Sodium Injection
Refer to manufacturers' Prescribing Information for Dobutamine HCl Injection
Refer to manufacturers' Prescribing Information for Esmolol HCl Injection

Design

Time entry

Previous

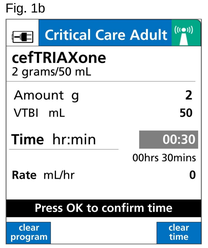
Fig. 1a



Time entry in hours or minutes not obvious

Enhancement

Fig. 1b

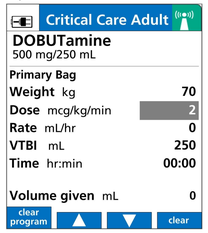


Time units displayed below the entry field as the time value is entered

Confirming values

Previous

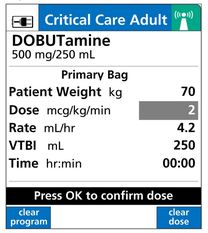
Fig. 2a



Up and down arrows may be used to navigate to next field without confirming entry

Enhancement

Fig. 2b

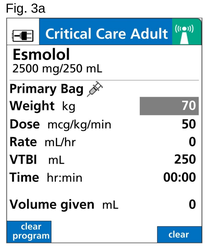


An **on-screen prompt** guides the user to press <OK> to confirm each entry

Loading Dose

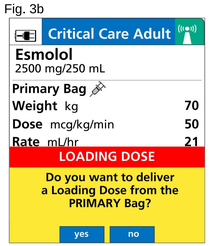
Previous

Fig. 3a



Primary programming is entered first

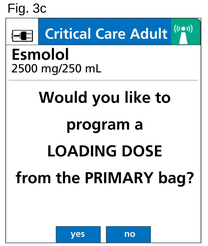
Fig. 3b



Loading Dose option appears after primary programming is completed

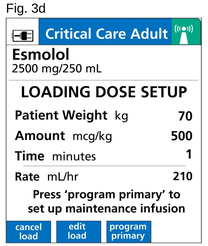
Enhancement

Fig. 3c



Loading Dose programming option appears first

Fig. 3d



Primary programming occurs after Loading Dose programming is completed

Results

Time entry (Fig. 1a, 1b)

- Previous design: 27/59 (46%) participants experienced at least one use error, close call or operational difficulty
- New design: 2/45 (4.4%) participants committed a use error when entering a time value

Confirming values (Fig. 2a, 2b)

- Previous design: 21/59 (36%) participants experienced at least one use error, close call or operational difficulty
- New design: 0/45 participants committed a use error

Loading Dose (Fig. 3a, 3b, and 3c, 3d)

- Previous design: 11/59 (19%) participants experienced at least one use error, close call or operational difficulty
- New design: 0/45 participants committed a use error

Conclusions

Standard infusion pump Dose Error Reduction Systems (DERS) alone are not sufficient to support safer programming, given the increasing complexity of intravenous medication protocols and other bedside technologies competing for nurse attention. Infusion pumps must be designed to support correct use. Human Factors engineering and testing of high risk infusion programming is required to validate the safety, effectiveness, and usability of the system to meet user needs and improve patient safety.

The Human Factors approach resulted in an overall summative testing success rate of 99.1%, (1219/1230), which contributed to the successful FDA clearance of an infusion system.

Baxter

Best practices for maximizing safety technology benefits through CQI data analysis

Authors: Tim Hoh, RPh; Idal Beer, MD, MBA, MPH; Pamela Krueger, MS;
All affiliated with Baxter Healthcare Corporation, Deerfield IL.

Introduction

Smart pump technology is intended to reduce programming errors using a Dose Error Reduction System (DERS). Facilities define soft and hard dose limits to guide clinicians during pump programming.

Soft dose limits must be meaningful and consistent with clinical practice to prevent alert fatigue, which can diminish the safety of the infusion technology by leading to nurses ignoring alerts or bypassing safety systems.

Method

Infusion pump Continuous Quality Improvement (CQI) data for one US Integrated Delivery Network (IDN) were analyzed for:

1. Frequency of soft dose limit overrides and the most common dose(s) that are overridden
2. The top 10 drugs with the most soft limit overrides were queried for each facility
3. The most common doses that were overridden which were reviewed against the configured soft limits

Time periods studied

- *Initial*: February 2012
- *Follow up*: July to September 2012

The IDN is 3 facilities with a total of 648 pumps analyzed for February and 717 pumps for July to September.

Refer to manufacturers' Product Information for Vasopressin Injection.
Refer to manufacturers' Product Information for Phenylephrine HCl Injection.

Analysis

Initial Analysis – Feb. 2012

Fig. A

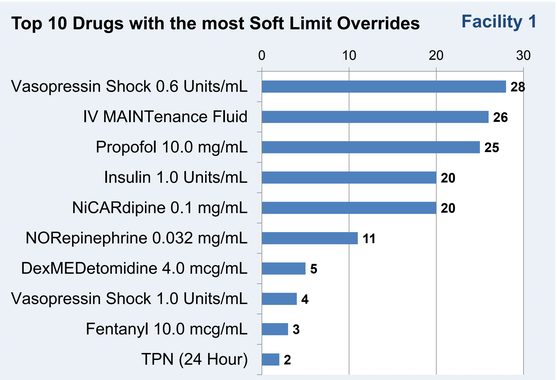
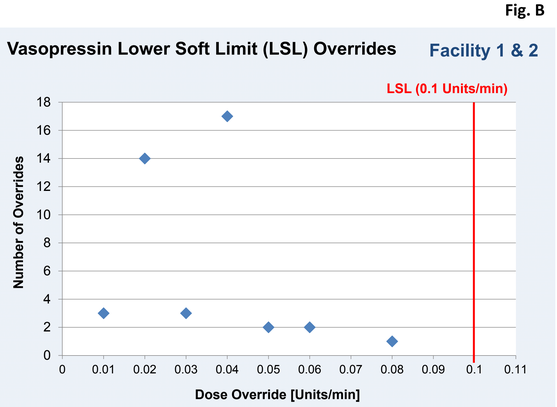


Fig. B



- **Vasopressin** had the most soft limit overrides for Facility 1 and was in the Top 10 in Facility 2
- Total of **42** lower soft limit overrides.
- **17** overrides at dose of **0.04 Units/min** and **14** overrides at dose of **0.02 Units/min**
- The drug library's configured dose limits for Vasopressin:

  Lower Soft Limit (LSL): 0.1 Units/min
  Upper Soft Limit (USL): 1 Units/min

Follow-up Analysis – July to Sept. 2012

Fig. C

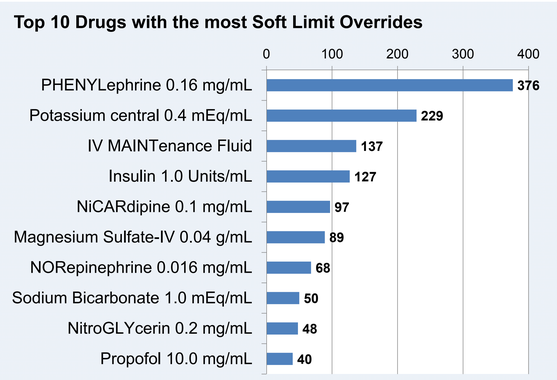
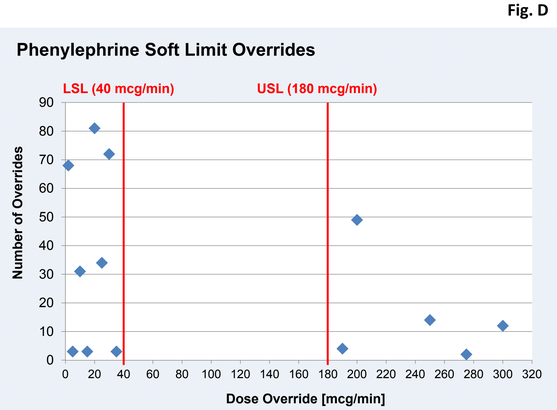


Fig. D



- **Phenylephrine** had the most soft limit overrides for all facilities with a total of **376**
- High number of lower soft limit overrides include: **81 (20 mcg/min), 72 (30 mcg/min), 34 (25 mcg/min)**
- Highest number of upper soft limit overrides include: **49 (200 mcg/min)**
- The drug library's configured dose limits for Phenylephrine:

  Lower Soft Limit (LSL): 40 mcg/min
  Upper Soft Limit (USL): 180 mcg/min

Results

Initial Analysis - Vasopressin Fig. A & B

- **Vasopressin** (2 concentrations) had the most soft limit overrides for two facilities
- All overrides were for programming below the **lower soft limit** configured (**0.1 Units/min**)
- Analysis identified that configured dose limits were inconsistent with prescribing practice
- Soft limits were re-configured to (**0.01 to 1**) **Units/min** to be consistent with practice

Follow-up Analysis - Vasopressin

- Soft limit overrides for Vasopressin reduced to 4 over a 3-month period (10x improvement)

Follow-up Analysis - Phenylephrine Fig. C & D

- 63% of common dose overrides were close to the LSL (40 mcg/min) and USL (180 mcg/min)
- Safety committee was tasked to review the limits and their consistency with clinical practice to determine how soft limits should be adjusted to ensure meaningful programming alerts

Conclusions

Ongoing, rigorous CQI analysis of infusion pump data improves infusion safety by ensuring meaningfulness of alerts, which prevents alert fatigue and accidental overrides.

A Best Practice for CQI Analysis is to focus on the most frequent soft limit alert overrides, assessing the appropriateness of the configured limits. This approach allows CQI review teams to identify and implement high-impact drug library improvements that support safer infusion programming and practice.

Baxter

Every infusion counts: A more complete measure of infusion safety

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PURPOSE

Infusion safety is most commonly measured by the drug library compliance rate or the frequency of clinicians programming an infusion using the pump's drug library versus programming outside the protections of the drug library.

Although recommendations for consistent use of the drug library persist, there are no industry performance standards for drug library compliance; each facility must set its own target.

This study looks at the number of infusions left unprotected at different compliance rate levels to help hospitals establish a more informed compliance rate target.

METHOD

Infusion pump data for **18 hospitals**, ranging from **287 to 3,417 pumps**, from **October 2014 to July 2015**, were analyzed to identify **1) drug library compliance rates** and **2) the number of unprotected infusions** (or those programmed outside the drug library). Data from **21,454** infusion pumps were analyzed with a total of **12,862,416** infusions delivered.

The study measured the number of infusions programmed outside of the drug library at different drug library compliance rates with the goal of helping hospitals quantify the patient safety impact of their drug library compliance and targets.

The study also considered the correlation between drug library compliance rates and hospital size (based on number of pumps) and between drug library compliance rates and number of infusions delivered.

RESULTS

Fig. 1 **% Compliance vs Unprotected Infusions**

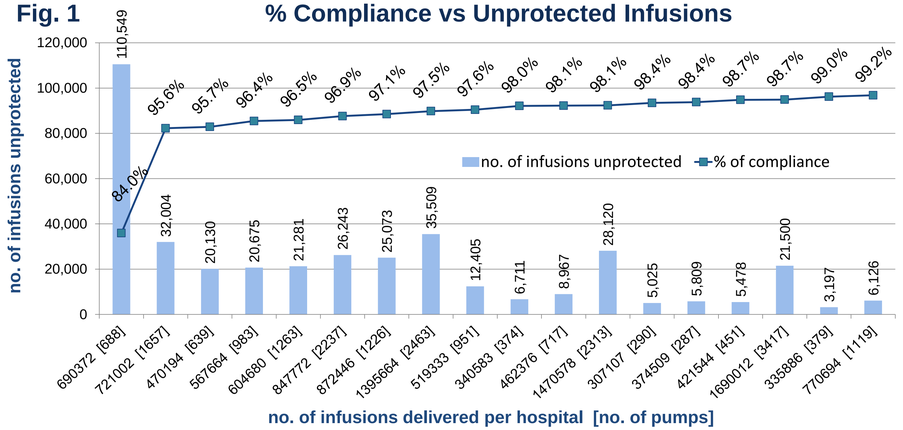
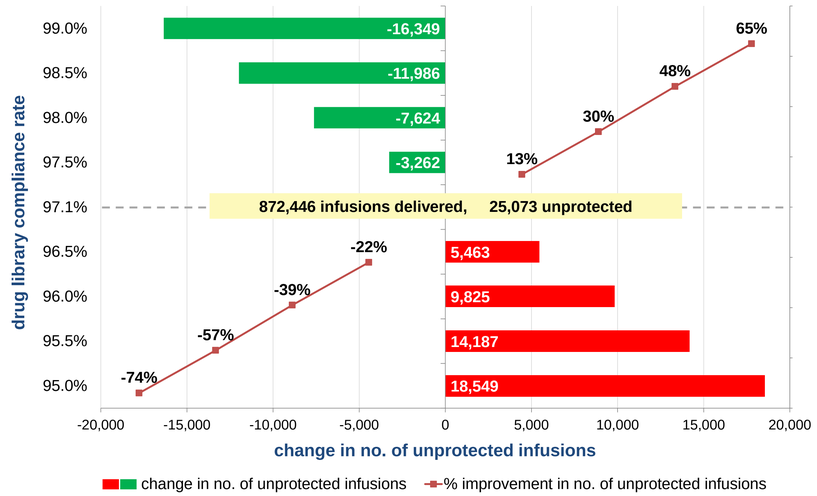


Fig. 2 **Affects of change in compliance to the no. of unprotected infusions**



CONCLUSIONS

The hospitals in the study had drug library compliance rates with a mean of 96.9%, and a median of 97.8%. The high drug library compliance rates did not consistently correlate with a low number of unprotected infusions (Fig 1). The number of unprotected infusions is a function of each individual hospital's drug library compliance rate and the number of infusions delivered .

Further analysis of one hospital with 97.1% compliance rate and 872,446 infusions delivered showed that even a single percentage point increases in the compliance rate would significantly reduce the number of unprotected infusions (Fig. 2).

Drug library compliance rates are consistently high (mean 96.9%) regardless of hospital size (based on number of pumps) or number of infusions delivered (Fig. 1).

DISCUSSION

A 97% drug library compliance rate is well above industry average and is a measure of an impressive infusion safety program. However, the drug library compliance rate does not convey the whole story. More telling is the number of infusions (and patients) left unprotected when the key smart pump safety feature is bypassed.

Hospitals can establish an informed drug library compliance rate target by quantifying the potential patient impact of different rates. By understanding the number of infusion delivered over a select time period and determining an acceptable maximum number of unprotected infusions, hospitals can establish a meaningful and patient-centric compliance rate target.

Disclosures: All authors affiliated with Baxter Healthcare Corporation, Deerfield IL.