

**PROCEEDINGS FROM THE
ISMP SUMMIT ON THE USE OF SMART
INFUSION PUMPS: GUIDELINES FOR
SAFE IMPLEMENTATION AND USE**



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BACKGROUND ON INFUSION PUMP SAFETY

General information

Intravenous infusion pumps are used to deliver parenteral medications at precise rates or in specific amounts. This technology is not new, but for several years, infusion pumps have been manufactured with software that can alert users to potential errors. The pumps with this additional software are often referred to as “Smart Pumps” or “Intelligent Infusion Devices.” This software allows an organization to create a library of medications that provides medication dosing guidelines, by establishing concentrations, dose limits, and clinical advisories.

The medication library in the smart pump can be tailored for the specific needs of an organization and for different patient groups within the facility, based on patient location, acuity, or weight (2, 9-11). In addition to continuous infusions, these libraries can often be programmed for bolus and intermittent doses as well.

Alerts provided by this type of technology can include clinical advisories, soft stops, and hard stops (11). Clinical advisories contain relevant information about a specific medication that is displayed on the smart pump screen when the drug is selected from the library. For example, a clinical alert may prompt the practitioner to utilize a filter with the medication they have selected for administration. Soft stop alerts notify the user that the dose selected is out of the anticipated range for this medication. However, soft stops can be overridden by the user, and the medication can still be infused without changing the smart pump settings. Hard stops will notify the user that the dose is out of the institution-determined safe range and will not allow the infusion to be administered unless the pump is reprogrammed within the acceptable range.

Smart pumps can provide a great deal of data that is useful in driving safe practices. Data collection can include the number of infusions programmed using the drug library, the number of soft stop overrides, or the number of times that an alert, soft stop, or hard stop resulted in the reprogramming of an infusion (11). The data allows organizations to evaluate smart pump use, identify opportunities to enhance safe use, and take action to correct problems. The interventions based on the data can be tailored to the specific needs of the organization and can focus needed resources on those areas identified.

Benefits of utilizing smart pumps

Many intravenous medications are also classified as *high-alert medications* and thus more likely to cause harm if an error occurs during administration (1-4, 8-11). One of the benefits of smart pump technology is that they can reduce administration errors associated with miscalculated doses. Smart pumps can provide a check of manual calculations, and ensure that the dosing formula selected is appropriate to the medication and the patient (e.g. mcg/kg/hr vs. mcg/kg/min) (10). Alerts and stops provided by the infusion pump allow clinicians to recognize programming errors and miscalculated doses that could have otherwise resulted in patient harm (8, 10). Another benefit of using these devices is the availability of data captured when practitioners program the pumps. Analysis of this information can guide quality improvement efforts.

These infusion devices are not fool proof, and thus there is still a risk of choosing the wrong medication from stock or selecting the wrong medication from the smart pump's drug library.

Ideally, to reduce the potential for these errors, smart pumps should possess bar-code functionality that will access the patient drug profile, identify if the medication has been ordered for the patient and then select the appropriate medication and concentration from the drug library when a bar-code label on the IV bag or other container is scanned (2).

Limitations of smart pump technology

Smart pump technology is also not without limitations. If the smart pump drug library is bypassed, and the infusion rate and volume is manually entered, 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 (1, 6, 7, 9, 10).

The software also cannot replace independent double checks. The accuracy of information entered into the smart pump (patient identity, selection of medication, patient weight, etc.) is dependent on correct data entry (2, 3, 5). These data entry errors can be exacerbated if medication concentrations have not been standardized within an organization (1, 3, 7, 8, 10, 11). An independent double check is warranted for certain identified high alert medications. Too many concentration options for each drug increase the potential for the wrong concentration to be selected.

User alerts have limitations as well. Soft stop alerts can be easily overridden, often with one key stroke. Hard stops that aren't set appropriately can create a barrier to care delivery and may result in nurses using work arounds such as programming the infusion device using the rate / volume mode rather than using the drug library. Failure of users to understand or critically evaluate the information provided by the alert can also result in an error.

As mentioned previously, data collected from smart pumps can also be extremely useful to guide practice change and performance improvement efforts (2, 4, 6, 9, 10). However, reviewing the data stored in the pump often does not enable the reviewer to identify which patients or users may have been involved with a potential error (12). Manually updating and collecting data can also be very time consuming without the benefit of a reliable wireless network (11, 12). A manual system places practical limits on the frequency of data retrieval and analysis, thus delaying the implementation of quality improvement interventions and observing their impact.

Other considerations

Organizational resources must be considered when implementing smart pumps. Significant time must be allocated for developing, maintaining, and updating drug libraries, clinical alerts and advisories, and reviewing the alert data, i.e., overrides and edits, recorded and stored in each smart pump. Consistent monitoring and support for process change is necessary to maximize the safety benefits of smart pumps. Reviewing information collected from near misses and work arounds reported voluntarily, and information gathered from the smart pump data, is extremely valuable. Data analysis is imperative to attain the greatest benefit from this technology (3).

Smart pumps will impact practitioners in many ways. Ensuring that staff has the appropriate tools to utilize the full benefit of this technology as well as the resources to assist with the transition, will directly impact the compliance use rates.

Examples of Desirable Functionality / Features of Smart Infusion Pumps

The following features may enhance medication safety with these devices:

- Wireless technology that can integrate with computerized prescriber order entry (CPOE), bar-code medication administration (BCMA), and electronic medication administration record systems
- Functionality that prohibits practitioners from bypassing drug libraries for selected medications
- Default rate settings for certain drugs that must be manually overridden, with the override reason required
- Rate settings that default to zero when an infusion is complete
- Libraries with the capacity to include all of the drugs that will be administered with these devices
- Routing practitioners directly to the drug library when the device is turned on
- Ability to update the drug library in the background while the pump is in use
- Ability to extract data stored in the device while the pump is in use

STAKEHOLDER COLLABORATION

In 2007, the Institute for Safe Medication Practices (ISMP) formed a steering committee that included smart pump vendors and the ISMP staff to discuss the impact of this technology. Representatives from five different vendors participated in this meeting. The steering committee agreed that guidelines for the implementation and use of smart pumps would be beneficial for organizations considering this technology. Three primary topics, in which facilities consistently need direction, were identified: implementation of smart pumps, drug library development and use of information and clinical practice.

The vendors also identified facilities that had experienced successful implementation of smart pump technology. Representatives from these facilities, as well as infusion pump vendors, and ISMP practitioners were invited to attend a national summit. Representatives from all groups included pharmacists, nurses, physicians, and biomedical engineers.

The participants of the summit were charged with sharing experiences, opinions, and ideas to help develop a set of guidelines that support the safe and effective implementation and use of smart pump technology.

PROJECT GUIDANCE

The ISMP Smart Pump Summit was held in suburban Philadelphia over two days. Topics discussed included implementation, drug libraries, and clinical practice. The panel was randomly divided into small interdisciplinary groups to discuss each of the topics, which were then presented to the full panel for consensus. ISMP analyzed the consensus recommendations and utilized their expertise to develop the guidelines based on those recommendations.

DISCLOSURE

All participants were volunteers and received no compensation other than travel and meeting expense reimbursement. ISMP acknowledges the expertise of these volunteer practitioners and appreciates their assistance in developing these guidelines. The summit and production of this guidance document was funded by the generous support of Baxter, B. Braun, Cardinal Health, Hospira, and Smith's Medical.

ABOUT ISMP

The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents more than 35 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. ISMP is a federally certified patient safety organization (PSO). For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit www.ismp.org. For access to our consumer website, please visit www.consumermedsafety.org.

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Additional Sources for Information

American Society of Health-System Pharmacists - Statement on the Pharmacist's Role with Respect to Drug Delivery Systems and Administration Devices 1992,1998.

American Society of Health-System Pharmacists Policy Position Medication Therapy and Patient Care, Organization and Delivery of Services - Standardization of Intravenous Drug Concentrations

I. IMPLEMENTATION OF SMART PUMPS

Many organizations recognize the safety advantages of employing smart infusion devices and are replacing the infusion pumps they currently utilize. Organizational leaders need to understand that implementing smart pumps involves more than simply replacing the currently employed infusion devices. Successful implementation goes beyond selecting the right devices and right technology. It requires a commitment to a comprehensive medication safety program and often may require a cultural change to reflect that commitment. Implementation also involves departments that have not previously been involved with traditional infusion pumps, e.g., information technology or clinical informatics. Corporate policy, organizational processes, and unit-based audits of systems and clinical practices must be evaluated to ensure that they are consistent with the organizational safety goals.

A. Ownership of the Process at the Executive Level

- Assess the culture of the organization to determine if there is a readiness for change, including the commitment to standardization, and the establishment of a culture of learning versus a culture of blame.
- Incorporate the culture of learning into the error reporting system and adopt a systematic approach to error analysis.
- Expect that frontline practitioners utilize the advanced technology provided by smart pumps, with limited exceptions, (see section II-Drug Library).
- Develop a process, including, but not limited to, reviewing data captured by the pump, for identifying at-risk behaviors exhibited by practitioners that could compromise medication and patient safety.
- Consider the legal liabilities associated with the deployment of smart pumps and not fully utilizing the safeguards they offer, (i.e. drug library with hard stop dose limits to prevent catastrophic events.)
- Budget for smart pump implementation providing ample funds for indirect costs associated with additional staff time for drug library development, staff training, troubleshooting problems, and the provision of super users who are available 24/7 for an extended period of time after implementation.
- Provide for ongoing budget resources to be allotted for library upgrades, integration with other systems such as BCMA, and infrastructure maintenance, e.g., wireless technology.
- Provide budgetary support for risk management, quality improvement or other appropriate departments who will be collecting and analyzing the data from the infusion pumps.
- Develop a process and schedule for the timely review and response to the data captured by the smart pumps.
- Form an interdisciplinary team to guide the development of the drug library and the implementation and use of smart pumps. Members (at a minimum) should include:

- Identified champions in nursing, pharmacy and other appropriate clinical areas
 - Information Technology (IT) management
 - Biomedical engineering
 - Infection Control
- Define the groups or departments with ownership of software, oversight over process decisions, protocol development, drug library revision requests, and maintenance. There may be several departments and/or committees with individual responsibility for one or more of these items (e.g., Pharmacy and Therapeutics Committee or other committee with medication safety oversight, Bio-medical engineering and IT departments).
 - Evaluate components of the medication-use system and their compatibility and integration with this new technology. Prior to implementation, perform a Failure Mode and Effects Analysis (FMEA), to identify potential barriers to programming the pump, accessing and using the drug library, or the presence of other conditions that could drive practitioners to bypass safety features or to develop work arounds as a means of dealing with any difficulties they encounter.

B. Technological Readiness

- Ensure the ability of current organizational IT systems to interface with the pumps as these devices evolve to link with CPOE, BCMA, robotics employed to prepare sterile dosage forms for IV administration, pharmacy information system, and an electronic medication administration record (eMAR).
- Ensure that staff levels in IT and Biomedical Engineering are able to support the increased workload that smart infusion pumps will require from development through post-implementation.
- Update the drug libraries and download medication safety information stored in each pump efficiently and in a manner that permits all pumps to be updated in a short period of time. This is best achieved through the utilization of a wireless network.
- Consider wireless network communication as a future upgrade of the organization's technology plan if it is not available prior to the implementation of smart pumps. Ensure that sufficient bandwidth is available to support all wireless devices used in the organization.
- Identify and address network security concerns to permit wireless technology to be utilized throughout the organization.
- Do not delay implementation of smart infusion pumps if BCMA or wireless technologies are not presently available.

C. Physical Environment and Equipment

- Purchase a sufficient number of pumps to ensure that enough devices are available to meet the needs of the organization.
- Develop policies to address the cleaning, storage, and distribution of the pumps.
- Develop procedures for the short term rental of smart infusion pumps from outside vendors to supplement capacity. Ensure that the rental pumps provide the same protection as the pumps owned by the organization. Biomedical Engineering inspection of these devices should include deleting any drug libraries existing in the pump when delivered and programming the organization's drug library into the rental pumps.
- Provide a sufficient number of electrical outlets that must be available for pump operation when they are used in patient care areas, and for recharging the pump's internal battery when not in use.

D. Staff Education

- Plan for the training of super-users, using vendor support for the initial group.
- For the initial implementation, plan for a minimum of 6-12 weeks of ongoing staff education.
- Develop additional super-users as the pumps are implemented throughout all areas of the organization, and ensure the presence of one or more super-users on all work shifts.
- Educate the frontline staff users as close to the actual implementation date as possible.
- Ensure that education is mandatory and is an ongoing process, provided at periodic intervals for all staff and at a minimum during annual skill or competency evaluations or updates.
- Incorporate device training into the orientation curriculum for all staff working in clinical areas.
- Include the purpose of soft and hard stops, procedures to follow for each, an explanation of the data stored in the pump, and how this data is utilized to improve practices and enhance patient safety.
- Distribute information to all staff members as new policies and procedures are developed and each time the drug libraries are updated.
- Develop policies and procedures for training staff members who work in multiple patient care areas and temporary staff members, e.g., per diem and traveling/agency nursing staff.
- Develop champions in each clinical area who are committed to the culture of safety. Have them share with staff members the "good catches" identified through the use of safety

software and safety-related stories as the pumps are implemented and thereafter on a regular basis. Publicize these good catches throughout the organization.

- Incorporate simulation exercises into smart pump training. Use sample medication orders, MARs, protocols, and IV drug infusion bags with pharmacy-prepared labels and have staff program the pump. Include examples of routine and error prone practices, (e.g., administration of secondary IV infusions, bolus dosing) plus examples of errors that have occurred in the institution, along with errors reported in the literature. Provide guidance to practitioners for safely handling these practices.
- Emphasize during training the benefits associated with administering drug infusions using smart pump technology with dose error reduction software versus the risk associate with traditional rate-based programming and infusion.

F. Specialized Patient Care Areas

- Dispel any misperceptions that certain areas are unique and cannot standardize practices, procedures, or drug libraries.
- Establish a plan to address the needs of certain patient care areas or specific therapies and plan to invest additional effort in these areas:
 - Pediatrics/NICU/Nursery
 - Drug concentrations may differ from adult care areas
 - Lack of commercially-available standardized products
 - Weight and age ranges for pediatrics are wide and may require more than one standard concentration for some drugs
 - Doses are administered in small amounts – device with syringe capabilities will be required
 - Patients often are fluid restricted
 - Pain Management
 - IV patient-controlled analgesia (PCA)
 - Epidural PCA
 - Continuous infusions
 - OR/PACU
 - Anesthesiologists must be part of the implementation plan in these areas
 - Medications, concentrations, and specific doses may be administered in these areas that should never be used in other patient care areas
 - Oncology
 - Sequential chemotherapy regimens may require additional planning
 - Doses vary based on different protocols
 - ED
 - Combination of adult and pediatric populations
 - May need access to multiple libraries

- Patient Transport (Pre-hospital Care and transfer to other facilities)
 - May require a unique drug library due to different concentrations
 - Adult and pediatric concentrations required
 - Infusion devices used by transport or the other facility may differ from those used in the hospital

G. Vendor Support

- Request and maximize the use of support personnel and information provided by vendors including:
 - assistance in defining implementation timetable
 - sample drug libraries that can be used as a template from which organizations can customize their library
 - provision of online tutorials
 - super-users from vendors should be available around the clock for an specified duration, but at least the first week of implementation
 - live telephonic assistance
 - follow-up visits at regular intervals post implementation
 - assistance in evaluating initial smart pump data and understanding what it represents
 - external support groups

H. Rollout

- Prioritize the sequence of patient care areas where pumps will be deployed.
- Consider the major service lines and the size of the unit.
- Select patient care areas with adequate staff and resources for the rollout.
- Plan to use carefully selected staff members from the pilot units as staff educators and champions for subsequent units if possible.
- Staff support from the vendor or internal “super-users” should be readily available during the rollout phase.
- During the rollout, use simulated scenarios, rounding on patient care units by super-users, and in-depth analysis of any events to evaluate the current process.

II. DRUG LIBRARY

The establishment of a safe, practical, and effective customized drug library is critical to the successful utilization of smart infusion pumps. Building a drug library can be difficult, and there are few easy answers to questions such as where to begin and what are the “right” decisions for a facility. The institution should evaluate their current policies and procedures to have a thorough understanding of their clinical practice prior to creating the library. The process may take 2-6 months, depending on the size of the organization, and the complexity of the library, before the library is ready to “go live.” Using a library from another organization as a reference source is useful, but the information in libraries obtained from other facilities must be thoroughly reviewed to ensure that the drugs, concentrations, volumes, and nomenclature match those used in the institution importing the library.

To maximize the library’s ability to improve medication safety, at a minimum, it should include all high-alert drugs with standard concentrations, hard and soft stops for each identified drug dose, and policies that address changes to the library and library maintenance. Over time, plan to include all infusions (both continuous and intermittent infusions) in the drug library.

A. Policy Development

The leadership group responsible for drug library development should:

- Be fully established prior to policy development and include at a minimum, pharmacy and nursing (as project co-chairs) and physician representatives.
- Determine the method for defining drug libraries, e.g., defined to reflect the type of care or therapy required, or the patient care unit where the pump will be used.
- Prior to implementation, ensure that issues unique to each patient care area and service line have been addressed satisfactorily during creation of the drug libraries for each area.
- As defined by executive leadership, set the overarching expectation that the safety software should be used in every situation except for emergent needs when a delay in initiating therapy could have a deleterious effect on patient care (being cognizant of the system barriers to full use). Drug infusions should be reprogrammed using the safety software when the emergent need has passed.
- Define the workflow such that practitioners are directed to the drug library with the error-reduction software when the pump is activated.
- Provide guidance to the practitioner, e.g., use of dose titration charts, independent double checks, to promote the safe administration of those medications not contained in the drug library. Monitor the frequency of infusions programmed outside the drug library to drive future library updates.
- Define the consequences of not using the safety software.
- Establish a defined process for changes to the drug library that includes identifying the appropriate level of approval for any requested change and the expected timelines for implementing urgent and non-urgent changes.

- Validate the accuracy and functionality of all drug entries in a newly created library *and* all updates to existing libraries, in several devices prior to placing these libraries in service.
- Establish a review process for investigational drugs, off-label uses of drugs, and non-drug products administered via the pumps, e.g., administration of breast milk enterally, or blood products.
- Create a policy that requires an independent double-check for the administration of organizationally selected high-alert drugs that are not in the drug library at the time of administration.
- As previously discussed, develop procedures for the rental of smart infusion pumps, as necessary, from outside vendors.

B. Standardization

Successful implementation of smart pumps depends significantly on the organization's commitment to standardize and limit the number of concentrations programmed in the drug library.

Standardization requires examination of organizational dynamics including how people agree or disagree on clinical issues, and how they arrive at consensus. Maintenance of the drug library is simpler and easier to manage when standardization has been given high priority.

- Develop standard concentrations for IV drug infusions to the maximum extent possible as the initial step in building the drug library.
- Limit the number of different standard concentrations to no more than two for each drug included in the library for a specific patient care area.
- Use commercially-prepared, premixed drug infusion products as the basis for standardizing library entries.
- Standardize dosing nomenclature for each drug within each library, e.g., do not include multiple dosing methods for the same drug in the drug library, such as mcg/min and mcg/kg/minute for the same drug. Choose only one that will be used in the institution.
- Develop standard definitions for terms used in intravenous drug administration, e.g., IV Piggyback, bolus, intermittent infusion "keep open" and continuous infusion.
- Obtain consensus from those prescribing IV drug infusions, for a single concentration for each drug if possible, (but not more than two) for inclusion in the drug library.
- Ensure that the drug library or libraries reflect current institutional practices. If a drug library is obtained from another organization or a smart pump vendor, use it as a reference source but do not attempt to force-fit it into the institution.
- Encourage the understanding that a successful drug library is the result of careful consideration of safe practice and compromise between practitioners.

- Design the drug library and information displayed on the pump screens such that there is harmonization between the language in protocols, physicians' orders or CPOE order screens, pharmacy labels, and the medication administration record (MAR). If necessary make changes to the pharmacy label, CPOE, and/or MAR.
- Review every prescriber order set prior to implementation to ensure that orders for IV infusions reflect the standard concentrations used in the organization and that the sequence of information on the orders directly correspond to the sequence of data entry into the infusion pump.

C. Communication

- Communication channels must be established prior to the drug library development process.
- Effective, frequent communications must occur between frontline staff and the group responsible for drug library development and maintenance. As frontline practitioners identify problems or specific barriers to the programming of drug infusions, these issues must be readily communicated to the group. If possible, the group should make changes necessary to circumvent these barriers prior to the deployment of the pumps.
- Medical staff members, anesthesia practitioners, and practitioners representing specialty populations should be engaged in the early phase of library development to identify their specific needs and to cultivate an understanding of the measure of safety achieved through use of the drug library.
- Establish a variety of mechanisms for obtaining feedback from frontline staff through routine, ongoing communication to support drug library maintenance functions.
- Develop a process to ensure a timely response to information received from the frontline practitioners.
- Create a mechanism to ensure that staff are informed in timely manner of any changes to the drug library.

D. Drug Administration Limits

Initial drug dose limits incorporated into the drug library should reflect a blend of actual institutional practice, internal error report data and the limited amount of clinical literature that has been published on establishing soft and/or hard stops. Hard stops can be difficult to establish, therefore to avoid workarounds, carefully deliberate how these will be employed. Evaluate the risk of setting versus not setting a hard dose limit, taking into consideration the patient care area involved. Drug libraries for areas providing care for high-risk patients and high-alert drugs may require more hard stops than other patient care areas or drugs to avoid catastrophic errors. Experience obtained through use of the pumps and data management should assist in guiding dose limit changes over time.

Organizations should:

- Determine the best practices related to IV drugs in the organization through discussion with physicians, frontline staff and various care committees, and reviewing information available in the literature. Use this information along with internal error/near miss information to set soft and hard dose limits for the medications in the drug library.
- Initially, set hard dose limits to avoid catastrophic events. Reset the alerts over time to prevent the programming of potentially dangerous doses (although less than catastrophic doses) that could result in patient harm.
- Consider the impact of excessive user alerts, which may result in alert fatigue, when soft limits are established. Use internal data to establish soft and hard limits around current practice.
- Examine each drug for the applicability of bolus dosing. Determine the drugs for which the bolus feature will be active and in which patient care areas a given drug can be administered as a bolus.
- Ensure that the ability to selectively block the administration of bolus doses on specific patient care units is available.
- Develop and incorporate into the drug library, clinical advisories that provide staff members with information that should be considered during programming of the drug infusion.
- Use data captured by the infusion pump logs (overrides, reprogramming attempts), continuous reviews of the literature, internal and external medication error reports, and clinical practice experts to modify dose limits previously established.
- Include in staff education the purpose of the drug library and the potential consequences of not using the library when programming drug infusions.
- Ensure that staff members understand the concept of soft and hard stops and what they should do if they receive alerts when these limits are exceeded.
- Develop policies and procedures for handling drug library changes when a patient is transferred from one care area to another and monitor compliance with converting from one drug library to another.

E. Updating the Drug Library

If wireless communication technology is not available in the organization when smart pumps are purchased, the institution should make the implementation of wireless technology a priority. Wireless communication with the smart pump devices will allow the organization to easily make drug library adjustments across the facility. In the absence of wireless technology, each pump must be physically retrieved to make any changes to the error reduction software. Because manual pump manipulation is a tedious process it often results in less frequent updating of the drug library, and thus diminishing its safety potential.

- Perform updates to the drug libraries periodically as needed but not less than quarterly (unless there are no updates for that quarter)

- In a wireless environment, create a mechanism to ensure that available updates are downloaded into each device by staff members when alerted that an upgrade is available.
- Define urgent versus routine library updates and develop download procedures accordingly.
- Determine the frequency and committee responsibility for review of the entire drug library, and outline the approval process for all changes.

III. USE OF INFORMATION & CLINICAL PRACTICE

The data captured and stored in smart infusion pumps provides a window into clinical practices. Thorough analysis of this data can result in the refinement of the drug library as well as contribute to positive changes in practice. Organizations must have a plan for timely review of the data and determining how it will be used to improve medication safety throughout the facility.

Wireless technology permits timely downloading of usage data from each device. In the absence of wireless technology, each pump must be physically retrieved to extract data stored in the pump. Because manual pump manipulation and data collection is a time-consuming, tedious process it often results in less frequent downloading of data and thus a delay in addressing the need for changes to the drug library and/or additional staff education.

Organizations should:

- Define a process for downloading data from smart infusion pumps, ensuring that this process describes who is responsible for this activity and the frequency at which it should occur.
- Enlist a multidisciplinary group to translate data analysis to practice. The information retrieved from the devices may not make sense until clinicians provide the contextual explanation of events revealed by the data.
- Define the organizational group that has responsibility for data management as well as additional persons or committees that can utilize the data to improve safety, (e.g., nursing leadership, Pharmacy and Therapeutics Committee, biomedical engineering).
 - These pathways should be identified prior to the generation of data reports.
- Establish a consistent feedback loop for the organization to fully reap the benefits of the information.
 - Pump log data must be considered as valuable feedback and reviewed regularly.
- Develop a budget that provides for the human resource needs associated with data collection and analysis.
- Create a mechanism for associating a patient identifier with medication data extracted from the device. This will assist in developing context when an error occurs and a process for making changes necessary when the need for change is discovered.
- Use the information from the smart pump devices for process improvement to:
 - identify necessary changes to drug libraries
 - make changes to soft or hard stops based upon override data
 - identify, analyze and report errors, including those associated with at-risk behaviors or specific patient populations for the purpose of improving processes for use of the devices

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- create opportunities for drug-specific education
- encourage compliance with smart pump usage
- develop a curriculum for staff education
- Plan for the adoption of bar-code technologies associated with the use of smart pump devices, as they become available.

Vendor Assistance

- Vendor should encourage clients to reach out to each other to share data management policies, including data collection and analysis techniques, and ideas on how the data may be used to drive process improvement.
- Use vendor provided support, if available, at least initially to review the data. The vendor may identify trends that might not be apparent to new users. They may be able to offer practice solutions for certain areas of need based on experience with other users.