Institutions need to pay attention to pre- and post-smart pump implementation recommendations if they are to reap the benefits from this technology.
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About the Healthcare Technology Safety Institute (HTSI)
Founded within the AAMI Foundation, the 501(c)(3) charitable arm of AAMI, the HTSI is a community of leaders throughout the healthcare system that are dedicated to one common vision, “No patient will be harmed by medical technology.” HTSI’s mission is “To engage the entire healthcare community in multi-disciplinary safety initiatives that strengthen the development, management, and use of medical technology for improved patient outcomes.” HTSI engages the healthcare community in research, education, consensus, and partnerships related to the challenges facing healthcare technology industries, regulatory and accrediting bodies, clinicians, caregivers, and patients.

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Introduction

The purpose of this document is to guide healthcare institutions through the purchasing and implementation phases of smart infusion pumps and to help institutions that are currently using this technology to assess successful adoption.

Smart infusion systems function similarly to traditional general-purpose infusion pumps with the added feature of a built-in dose error reduction system designed to detect programming errors before reaching the patient. Smart infusion systems provide either a “soft” limit warning that allows a nurse to override the limit and continue infusing or “hard” limit warning that requires a nurse to reprogram the pump within acceptable parameters. The main differences between programming a smart infusion system and a traditional infusion pump include the following: selecting a drug library for the specific clinical care area, selecting the drug and concentration to be administered, and responding to pump alerts.

The Ontario Health Technology Advisory Committee (OHTAC) engaged the University Health Network’s (UHN) Health Technology Safety Research Team (HTSRT) to collect evidence on the effectiveness, and safety of smart infusion systems. To this end, HTSRT conducted both lab and field evaluations. This document presents a summary of recommendations based on results from these evaluations. There is clear evidence to show that the full benefit of this technology can only be realized by a structured approach to implementation. While this report presents a summary of the recommendations, a comprehensive report containing lab study results, field study results, and a roadmap to successful migration can be accessed using the following link: www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_smd_20090401.pdf.

Other reports on this topic can be accessed at: www.hqontario.ca/en/mas/mas_field_eval_report.html#2010.

It is clear that smart medication delivery systems have the potential to dramatically improve patient medication safety. The purpose of these recommendations is to ensure that this full benefit is achieved.

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I. Preparation Phase

**Formation of multi-disciplinary steering committee**
The key to a successful implementation of a smart pump system is to view the change as an institutional undertaking as opposed to a departmental undertaking. It is essential to involve a team of physicians, nurses, pharmacists, biomedical engineers and IT system experts. Thus, implementation of smart infusion pump systems requires a formal process that involves many stakeholders, and should not be viewed as a pump replacement initiative but rather as a patient safety initiative.

**Standardization of drug concentrations and dosing units**
Smart IV infusion systems require the use of drug libraries and connections to wireless servers. Therefore, a comprehensive readiness assessment is required for smart pump system implementation. Standardization of drug concentrations and dosing units is critical to ensuring (a) synchronicity of information contained on physician orders and in smart pump drug libraries, and (b) compliance with use of the Dose Error Reduction System (DERS). Thus, standardized drug concentrations and dosing units are a “must have” prerequisite to smart pump implementation.

**RECOMMENDATIONS**
- Establish standardized concentrations and dosing units prior to smart pump implementation to ensure full safety benefits.
- Establish drug libraries that are tailored to specific areas of the hospital, to meet physician prescribing needs.

**Drug library development**
Optimized smart pump adoption requires the creation, customization and maintenance of drug libraries for different clinical care settings to create library subsets for specific groups of patients.

**RECOMMENDATIONS**
- Establish standardized concentrations and dosing units.
  - Policies and guidelines must be updated according to changes made to standardized concentrations and dosing units.
- Create Clinical Care Area (CCA) specific drug library subsets.
  - Drug library subsets should be grouped by patient populations that require similar medication concentrations. Neonatal and pediatric patients should be grouped by weight.
- Set dosage limits for different types of infusions, especially for bolus vs. maintenance drug administrations.
  - Both soft and hard limits must be set.
  - Protocols must be established for each dosing guideline.
- Consider the use of clinical advisories to synthesize information and notify clinicians of important issues.
  - Clinical advisories must be highly specific and should be used infrequently to reduce “alert fatigue.”
**Figure 1.** Example of a potential closed-loop medication administration process

**Description of a closed-loop medication administration process:**
First, a physician's order can be transmitted to a smart pump server after being approved by pharmacy. The nurse at the bedside uses a scanner on the smart pump (or a third party scanner) to scan the patient's armband, the medication label, and his/her nursing badge (in the case where a third party scanner is used, the nurse would also scan the smart pump). This information is sent wirelessly from the smart pump to the pump server. The pump server, which is electronically linked to the Computerized Physician Order Entry (CPOE), the Pharmacy Information System (PhIS), the Positive Patient Identification system (PPID), and/or the electronic Medication Administration Record (eMAR), tethers the administration to the medication order. If the scanned information matches the physician order, the pump server populates the smart pump's parameters according to the stored doctor's orders. The nurse reviews the entries and starts the infusion. The automated system transmits the infusion with the associated clinician and patient ID to the eMAR.
Planning for integration of key systems

Benefits achieved through smart pump use will depend on the extent to which the smart pump has been integrated with other systems. Many institutions lack a systemic approach to addressing medication safety issues, leading to fragmented solutions that can introduce new, unintended issues. Once the fundamental requirements of a medication drug library containing standardized concentrations and dosing units are met and wireless network-based uploading and downloading of information is prioritized, smart pump implementation can follow an adaptable approach that allows incremental benefits while progressing towards a fully integrated system. Institutions should make a long-term plan that includes the eventual integration of related IT systems and the use of bar coding and radio frequency identification (RFID) tagging for patient and medication identification (Figure 1 provides a description of a potential closed-loop medication administration process).

Identification and preparation for cultural shift and process changes resulting from smart pump implementation

Prior to implementing smart pumps, institutions must prepare for the cultural shift and process changes that result from smart pump implementation. The migration from traditional IV infusion pumps to smart infusion systems brings about changes to practice in nursing and in pharmacy. For example, given that smart infusion systems require the standard concentration platform, there may be changes in who mixes the drugs (e.g., shift from nursing to pharmacy). Furthermore, the steps involved in programming a smart pump differ from those involved in programming a traditional pump, and this may include a shift from flow rate to dose rate.

RECOMMENDATIONS

- Assess the extent to which smart pump system can integrate with other safety technology initiatives.
- Use a common database management system or data exchange standards (e.g., HL7 in healthcare) that will allow the sharing of data.
- Establish a formal process to ensure that changes made to information that is shared across multiple stakeholders are reflected throughout the corresponding departments. For example, institutions must ensure synchronicity between standard concentration and dosing units contained in smart pumps and in physician order entry systems (whether computerized or paper-based).

Food for Thought

Institutional leaders must recognize that implementing smart infusion systems involves more than simply replacing the traditional pumps. Successful implementation requires a multi-disciplinary medication safety program and often may necessitate a cultural change to reflect that commitment. Are you and your organization ready for change, including being committed to standardization, and establishment of a culture of learning as opposed to a culture of blame? Are you ready to allocate sufficient personnel and financial resources for drug library upgrades, integration with other systems, and wireless infrastructure maintenance?

CONSIDERING HUMAN FACTORS

Conduct a human factors evaluation by applying human factors assessment principles such as heuristic analysis and simulated use studies.
Implementation of wireless infrastructure
A wireless-ready pump and wireless network environment is necessary for frequent drug library updates and for continuous quality improvement. Many institutions do not ensure wireless connectivity prior to implementing smart pumps. Consequently, these institutions cannot reap the benefits that smart pumps can offer (e.g., ability to rapidly update drug libraries and download use data to assess compliance with drug templates during programming).

RECOMMENDATIONS
- Implement wireless network infrastructure, and integrate with smart infusion pump system. If this is not possible at start up, it should be done as soon as possible afterwards.
  - Wireless infrastructure is necessary for regular Continuous Quality Improvement (CQI) downloads, drug library uploads, and pump tracking. Drug libraries must be updated on a regular basis to ensure compliance.
  - Regardless of an institution’s wireless network readiness, a connectivity strategy for information upload and download to smart pumps must be defined.

Smart pump system evaluation and acquisition
There are many variations in the functionality and ease of use of both pumps and their associated software across suppliers. When evaluating the shortlisted products, the steering committee must assess all components of smart infusion systems (e.g., drug library software, continuous quality improvement software) rather than focusing solely on the pumps themselves.

RECOMMENDATIONS
- Evaluate all components of smart pump system (including drug library and continuous quality improvement software). Vendors’ CQI data analysis software is still immature and difficult to use and should therefore be assessed carefully when selecting the smart pump manufacturer.
- Conduct a Human Factors evaluation. (see page 6 sidebar)

Training/policy development
In planning training, institutions must consider the technical skills and process changes required for adopting the new smart pump system.

RECOMMENDATIONS
- Address technical and behavioural factors associated with the effective use of technology and user acceptance, and conduct hands-on training for each user.
- Establish a process to coordinate training and troubleshooting before, during and after implementation.
- Establish ongoing communication and education about new processes and policies regarding smart pump system use.

Food for Thought
The increased complexity of smart infusion systems makes ease of use an important evaluation and selection criterion. Have you considered incorporating a Human Factors evaluation in your institution’s smart infusion system evaluation and acquisition process?
III. Ongoing Optimization Phase

Compliance with use of Dose Error Reduction System (DERS)
User entry into the Dose Error Reduction System (DERS) is critical to achieving safety benefits of the smart pump. Bypassing the DERS by programming in the generic mode leads to a negative return on investment and an absence of safety benefits.

**RECOMMENDATIONS**
- Select pump design that encourages entry into DERS.
- Mandate use of DERS.
- Conduct post go-live follow-ups to assess compliance.
- Regularly update drug libraries based on pump system user reports.
- Promote a culture of safety urging nurses to evaluate alerts, and limit overrides to circumstances that are clearly defined.

Maintenance/monitoring
Compliance with the complete system should be assessed and barriers to successful adoption should be identified and removed.

**RECOMMENDATIONS**
- Assign the task of analyzing CQI data to specific individuals and provide them with necessary training.
- Plan for the allocation of significant time and resources into CQI data analysis to produce quality reports.
- Evaluate CQI data to (a) assess drug library compliance, and (b) identify and remove barriers to adoption.

Food for Thought
For smart infusion systems to be useful, it is critical that institutions evaluate compliance with the use of Dose Error Reduction System (DERS) through analysis of pump log data. Does your institution have a process in place for regular evaluations of log data?
Conclusion

Supporting the use of smart pump systems can improve the quality of patient care, and institutions’ culture of safety. Institutions’ project managers and their multidisciplinary task force face a difficult, but attainable, goal demonstrated by healthcare organizations that have already adopted smart infusion systems. The key is to recognize that smart infusion systems are only a subset of a longer patient safety journey which requires ongoing consideration and commitment.

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Has your healthcare organization implemented any of the strategies discussed in this publication?
Do you know of a healthcare facility that has dealt with a technology-related issue and has a story to share?
If so, we would love to hear from you! Please email slombardi@aami.org.