Chapter 6. Smart Pumps and Other Protocols for Infusion Pumps: Brief Review (NEW)

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Introduction

Medication errors represent a serious issue affecting the U.S. health care system, accounting for the largest category of patient safety incidents within the larger category of medical errors. One report estimated that at least 1.5 million preventable medication errors occur in the U.S. each year.¹ A list of high-alert medications (those with the highest potential for patient harm if used in error) published by the Institute for Safe Medication Practices (ISMP) includes several medications delivered by intravenous (IV) infusion (e.g., insulin, propofol, heparin).²

Because IV delivery is more rapid and leads to higher systemic concentrations of drugs compared with other delivery methods, adverse drug effects tend to be more rapid and severe when associated with IV infusion. Because traditional infusion pumps are typically programmed in milliliters per hour (mL/hr) and volume-to-be-infused (VTBI) in mL, they are particularly vulnerable to errors in drug administration and monitoring.¹ Such errors include administration of the wrong dose or the wrong drug as well as erroneous infusion to the wrong patient.

What Are the Practices for Reducing IV Medication Errors?

To address the shortcomings of infusion pumps, manufacturers have added technology to recent models of general-purpose (large volume),³ syringe,⁴ and patient-controlled analgesia (PCA) pumps⁵ specifically designed to prevent medication errors. Smart pumps include a software program (also referred to as a dose error reduction system [DERS]) that provides a customized drug library alerting users to predetermined minimum and maximum dose limits for each drug.

The program provides soft alerts (also known as soft stops) that prompt users to reconsider a given drug dosage but allow them to administer that dosage if they choose, as well as hard alerts (or hard stops) that prevent users from going beyond the stated dose limits.¹ These systems permit the development of dosing limits for continuous and bolus deliveries, as well as clinical advisories (point of care notifications) and area-wide default settings for alarm thresholds.

In addition, some smart pumps have incorporated barcode technology that allows verification of patient identity, thereby preventing delivery of the wrong drug or delivery to the wrong patient.⁶,⁷ One PCA pump offers an integrated bar code scanner for automatically locating the correct drug entity (e.g., drug name and concentration), and a handful of hospitals have created interfaces between their general purpose pump servers, barcode-enabled point of care (BPOC) systems, and documentation systems to make sure that the pump is programmed according to the medication order and that administration is automatically documented.⁶

Unlike traditional infusion pumps, smart pumps can alert health care workers when they have selected inappropriate dosages for a given drug. Soft alerts have the shortcoming that they are merely reminders that can be overridden by the user although overrides are captured in a DERS log and can frequently be associated with a user. Hard alerts have the potential to be more effective because they do not allow easy circumvention, although they can still be circumvented by determined users (e.g., by bypassing the drug library and entering the infusion rate and
volume manually). A significant drawback is that inappropriately programmed hard alerts may impede delivery of care, and circumvention of hard alerts can lead to serious errors.9

Smart pumps with DERS plus BPOC can additionally prevent drug delivery to the wrong patients.10,11 As long as users comply with such alerts and prompts, smart pumps have the potential to reduce the number of infusion errors. Compliance with safety features can be improved by programming prompts that increase ease of use, and by emphasizing a culture of safety within the organization. Smart pumps also contain a data log that can be used to identify programming errors or show that the pump prevented adverse events.9

However, the basic limitation of smart pumps is that they can correct only errors of administration; other types of medical errors can occur during ordering or prescribing, dispensing, transcribing, and monitoring of patient response.10 For this reason, smart pumps function best not as standalone devices but when integrated into a larger medication safety system that connects them with computerized provider order entry (CPOE), BPOC, and electronic medication administration records (eMARs).9 Such interconnected systems can target not only errors of administration but also errors of ordering, dispensing, and transcription.10

How Have These Practices Been Implemented?

A recent systematic review by Hertzel and Sousa (2009) identified nine studies published from 2003 to 2008 that assessed the use of smart pumps for prevention of medication errors. The majority of studies evaluated smart pumps with soft alerts. The review summarized the study findings and identified lack of user compliance with soft alerts as an important factor that compromised the efficacy of smart pumps in the majority of studies. The authors concluded that “well-designed research is still lacking with respect to the effectiveness of smart pumps in preventing medication errors.”1 The most relevant studies mentioned in this review are summarized in more detail below, along with more recent studies published subsequent to the review’s publication date.

Smart Pumps With Soft Alerts

Nuckols et al. (2007) performed a retrospective review of 4,604 critically ill patients in ICUs at two hospitals to determine how often preventable IV adverse drug events (ADEs) matched smart pump safety features. These consisted of drug libraries with dose limits that triggered soft alerts, which could be addressed or overridden. The study evaluated ADEs before and after smart pump implementation. Of 100 preventable ADEs, only four (two before and two after smart pump implementation) matched the safety features of smart pumps.12

Rothschild et al. (2005) performed a prospective time series study of smart pumps with intervention (decision support on) and control (decision support off) periods to determine the impact of integrated decision support on the incidence of medication errors and adverse drug events in 735 cardiac surgery patients. Preventable adverse events (11 intervention, 14 control) and non-intercepted potential adverse events (82 intervention, 73 control) did not differ significantly between groups. Serious medication error rates were 2.41 and 2.03 per 100 patient-pump days in the intervention and control periods, respectively (P = 0.124). Caregivers violated infusion practice 25% of the time (571 infusions) by bypassing the drug library during the intervention periods. Medications were administered without physician documentation 7.7% of the time (intervention and control periods combined). The smart pumps were not programmed to give hard alerts, which cannot be easily overridden; therefore, it was easy for caregivers to override alerts or bypass the drug library. Poor caregiver compliance with the drug library and
dosage limits may have explained the lack of advantage of smart pump decision support in this study. This study used an early version of smart pump technology that was opt-in rather than opt-out, which made it easier for users to skip the library rather than look for it.

Larsen et al. (2005) performed a retrospective before-after study in pediatric patients that compared medication infusion errors 12 months before and 12 months after adopting a new protocol using a combination of smart pumps, standard drug concentrations, and human-engineered (user-friendly) medication labels. The smart pumps included a modifiable drug library and provided soft alerts to users who attempted to use doses that exceeded the safety limits. The infusion error rate dropped from 3.1 to 0.8 per 1000 doses from the pre-intervention to the post-intervention period, a risk reduction of 2.3 (95% CI 1.1-3.4, P <0.001). However, since this was a combination of three interventions, it is unclear what percentage of the error reduction can be attributed to smart pumps alone. Data were obtained from the hospital-wide-incident-reporting system, which tends to underreport errors, but the reported pre- and post-intervention error rates should be representative of the relative number of errors.

Adachi and Lodolce (2005) conducted a retrospective before-after study (one year pre-intervention, one year post-intervention) to determine whether a new intervention (revised standard order sets and smart pumps with soft alerts) could reduce IV dosing and administration errors. Although they found that only a small reduction occurred in overall dosing errors (59 to 46), a larger reduction occurred in pump-related errors (24 to 10, or from 41% to 22% of dosing errors). Standard concentrations eliminated errors related to the wrong drug concentration. Nine out of the 10 post-intervention pump programming errors occurred because users did not use the pump software.

Three uncontrolled studies illustrate compliance issues associated with smart pump soft alerts. Eckel et al. (2006) reported a high frequency of programmings (44.4%) due to users bypassing the drug library when selecting a drug. Furthermore, users overrode 88.5% of soft alerts. Fields and Peterman (2005) reported 506 medication errors due to users overriding soft alerts. However, a third study (Breland 2010) reported that a community hospital was able to improve compliance with pump alerts from 33% (when smart pumps were first introduced) to 97% three years later.

**Smart Pumps With Soft and Hard Alerts**

Schilling and Sandoval (2011) performed a retrospective before-after study (4 months pre-and 4 months post-intervention) of smart pumps with soft and hard alerts in a community hospital setting. Use of rescue medications and heparin infusions decreased substantially from pre- to post-intervention, and length of stay in patients receiving antimicrobial agents also decreased substantially. Regarding dosage alerts, 86.2% were soft alerts and 13.8% hard alerts. About 61% of soft alerts were overridden by users and 39% were modified to comply with accepted rates; users complied with every hard alert.

Fanikos et al. (2007) conducted a retrospective before-after study evaluating the impact of a smart pump with soft and hard alerts in an academic medical center. After reviewing anticoagulation errors in 3,674 patients, the authors found no significant decrease in errors post-intervention (49 pre vs. 48 post). This lack of difference may reflect the fact that only a relative minority of events were infusion-related errors (19/97 total events). Infusion errors were substantially higher in the period prior to smart pump implementation (15 errors) compared with the post-intervention period (4 errors).
Smart Pumps With Soft and Hard Alerts Plus Barcode Technology

Trbovich et al. (2010) conducted a simulation study comparing nurses’ ability to avoid medication errors using a traditional pump, a smart pump, and a pump with an integrated barcode scanner (the latter two had soft and hard alerts). The study was conducted in a laboratory setting using patient mannequins with bar-coded wristbands and medication bags with bar-coded labels containing patient ID; errors were assessed by type. Wrong drug errors did not differ significantly by pump type. Patient ID errors were remedied by significantly more nurses using pumps with barcode scanners (88%) than with the smart pumps without barcode scanners (58%) or traditional pumps (46%). Significantly more nurses remedied critical overdose errors when using pumps with barcode scanners (79%) and smart pumps without barcode scanners (75%) due to hard alerts than with traditional pumps (38%). Wrong dose soft alerts did not result in significant differences in fixing overdose errors among different pumps (errors remedied by 75% of nurses using pumps with barcode scanners, 63% with smart pumps without barcode scanners, and 50% with traditional pumps). This was because many nurses overrode soft alerts.7 While this study provides perspectives on error rates, it does not faithfully simulate a clinical environment: auto-programming in a clinical setting is limited at this time but is typically accomplished through interfaces with BPOC systems instead of through printing medication labels with patient ID.

Smart Pumps With Soft and Hard Alerts Integrated With Barcode Technology and eMARs

Prusch et al. (2011) conducted a prospective before-after study evaluating a program integrating intelligent infusion devices (IIDs) with a BPOC system and an eMAR system.21 Monthly compliance with the telemetry drug library increased from 56.5% pre to 72.1% post intervention (p<0.001) and the number of telemetry manual pump edits decreased (56.9 to 14.7; p<0.001). Pump programming errors related to i.v. unfractionated heparin occurred at a rate of 16.9 events/10,000 opportunities pre-implementation and 11.3 events /10,000 opportunities post-implementation, but the rate decrease was not statistically significant (P = 0.17). However, smart pumps were used before and after the implementation period, the only difference being that the smart pumps became fully integrated with BPOC and eMAR in the post-implementation period. Therefore, the true impact of smart pumps on infusion error rates is unclear from this study.

None of the studies described above identified harms to patients that could be attributed specifically to the use of smart pumps in place of traditional infusion pumps.

What Have We Learned About These Practices?

Implementation of smart pump technology by health systems and hospitals generally requires considerable planning, including identification of stakeholders, evaluation of software capabilities, evaluation of hospital-specific practices, decisions regarding standard operating systems and procedures, building of drug libraries, and education of staff before the pumps can be deployed.22 Successful implementation usually involves multidisciplinary teams that include pharmacists, nurses, and physicians. With minor variations, this overall process has been described in several published studies.17,18,23,24

In their guidelines for safe implementation and use of smart infusion pumps, ISMP identifies several key steps necessary for implementation. These include:
• Ownership of the process at the executive level (assessment of culture and budget resources, forming a multidisciplinary team, performing a Failure Mode and Effects Analysis [FMEA] to identify barriers to compliance)

• Technological readiness (ensure that information technology [IT] systems can interface with pumps and that IT staff levels are sufficient, update drug libraries and download medication safety information efficiently [preferably via a wireless network], consider wireless network communication upgrade if it is unavailable prior to smart pump implementation)

• Physical environment and equipment (ensure sufficient number of pumps, policies for cleaning, storage, and distribution, short-term pump rental from outside vendors [if necessary], ensure rental pumps are programmed with the renting facility’s drug library and dose limits, ensure sufficient number of electrical outlets for pump operation in patient areas and for recharging internal batteries when not in use)

• Staff education (plan for several weeks of staff education, train super-users, ensure ongoing education, explain purpose of and procedures for soft and hard stops, inform staff about drug library updates, develop champions in each clinical area devoted to safety culture, do smart-pump simulation exercises, emphasize benefits of smart pump technology)

• Specialized patient care areas (make plans to address needs of specific therapies or patient care areas such as pediatrics/nursery, pain management, operating room, oncology, emergency department, and patient transport)

• Vendor support (to help define implementation timetable, provide sample drug libraries, online tutorials, live telephone assistance, post-implementation follow-up visits, assistance in data evaluation, and external support groups)

• Rollout (prioritize sequence of patient care areas receiving pumps, select areas with adequate staff and resources, select educators and champions from pilot units, vendor support should be available, evaluate rollout process)\(^8\)

Creation of safe and effective customized drug libraries is essential for proper utilization of smart pumps. Institutions must evaluate their clinical practice when determining what drugs and dosage limits to select for their library. Drug libraries should at least include all high-alert drugs with standard concentrations as well as soft and hard stops for various dosage limits. Once drug libraries have been developed, considerable time must also be devoted to maintaining and updating the libraries. Wireless communication technology in an organization’s infrastructure allows easier adjustment or updating of drug libraries, which otherwise would require manually updating each pump separately.\(^8\)

Breland (2010) reported that a community hospital was able to increase compliance rates with pump alerts from 33% at baseline (when smart pumps were first introduced) to 97% three years later. This was done by having nursing directors and managers stress the importance of the safety software and how it could improve patient safety. Compliance data were shared with staff nurses and unannounced twice-weekly inspections were performed by pharmacy to determine why safety software was not being used in individual cases. Continual reeducation and customization of drug libraries for the needs of specific critical care areas (CCAs) also helped to improve compliance. Compliance rates for individual CCAs were distributed to nursing directors, who also emphasized to the staff the legal liability entailed in noncompliance. In addition, a review of edits and overrides led to a drug library revision to eliminate unnecessary
alerts by changing some dosage limits to reflect actual dosing practices (which were determined to be safe).  

Conclusions and Comment

The evidence supporting efficacy of smart pumps for prevention of medical errors is limited by the relatively small number of studies and the use of observational study designs with inherent susceptibility to bias (Table 1). In addition, most published studies have evaluated only smart pumps with soft alerts; study findings are somewhat variable, ranging from suggesting no effect to a limited effect of soft alerts in reducing the rate of medical errors. This appears to be partly due to user compliance, which although somewhat variable among different institutions, is usually low because users can easily override soft alerts. Hard alerts and barcode technology should theoretically have more impact on error rates, but too few studies have evaluated these features to judge their relative effectiveness. Smart pumps have the most potential to reduce medication errors when integrated into a larger medication safety system that connects them with CPOE, BPOC, and eMARs.

Implementation of smart pump technology by health systems and hospitals generally requires considerable planning, including identification of stakeholders, evaluation of software capabilities, evaluation of hospital-specific practices, decisions regarding standard operating systems and procedures, building of drug libraries, and education of staff before the pumps can be deployed. Successful implementation usually involves multidisciplinary teams that include pharmacists, nurses, and physicians. Once drug libraries have been developed, considerable time must also be devoted to maintaining and updating the libraries. Wireless communication technology in an organization’s infrastructure allows easier adjustment or updating of drug libraries, which otherwise would require manually updating each pump separately.

Table 1. Chapter 6. Summary table

<table>
<thead>
<tr>
<th>Scope of the Problem Targeted by the PSP (Frequency/Severity)</th>
<th>Strength of Evidence for Effectiveness of the PSPs</th>
<th>Evidence or Potential for Harmful Unintended Consequences</th>
<th>Estimate of Cost</th>
<th>Implementation Issues: How Much do We Know?/How Hard Is it?</th>
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References


