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Smart Infusion Pump Technology: Don't Bypass the Safety Catches

Computerized prescriber order-entry and bar-code applications for drug dispensing and administration are capable of reducing medication errors. Yet, even if these technologies are fully implemented, serious medication errors remain possible, especially errors associated with the administration and titration of intravenous (IV) high-alert medications such as dopamine, heparin, and insulin. Even if the right drug and dosing information are at hand, a misprogrammed infusion pump can leave a patient only a button press away from harm. One study showed that the most common reason for the administration of wrong doses of intravenous medication was an error in programming IV infusion pumps (41%), and this step in the medication-use process was associated with the highest impact.[1]

A new technology, commonly referred to as "smart" infusion pumps, is beginning to play a role in reducing the risk of administering IV medications. There are several functions of a smart pump, including the ability to store dosing guidelines in a drug library and to apply those guidelines during pump programming to warn clinicians about potential unsafe drug therapy.[2] These drug libraries allow organizations to enter various drug infusion protocols with hospital-defined upper and lower dosing limits stored in the pump's memory. If a dose is programmed outside of established "soft-stop" limits, the pump sounds an alert, informing the clinician that the dose is outside the recommended range and requiring confirmation by the clinician that he or she intended to go outside this soft limit (see Figure). Organizations can also establish "hard-stop" limits that will not allow users to exceed the preset limits in the pump. Some pumps can integrate patient monitoring and other patient parameters such as age or clinical condition, and most modern pumps can generate logs of recorded data for doses that trigger dose limit warnings. A survey of hospital pharmacists by the American Society of Health-System Pharmacists in 2006 showed that 32% of hospitals reported using smart pumps.[3]

One example of an event submitted to PA-PSRS where the use of a smart pump could have prevented harm states:

> *A patient with a previous history of hemothorax was on a heparin infusion upon admission. The ambulance personnel relayed the drip was to infuse at 60 mL/hr. The nurse at the admitting facility set the pump to infuse 60 mL/hr. When the night shift nurse assessed the patient, she found that the heparin was infusing at 6,000 units/hr (60 mL/hr). The heparin infusion was stopped. The patient's PT result was 99.45, PTT was 240, INR was 43.4. and blood pressure was 78/40. At 11 p.m., the patient was found* [with agonal respiration]*. The patient was intubated and placed on ventilator. Protamine and vitamin K 10 mg IV push were given, and the patient was transferred to another facility.*

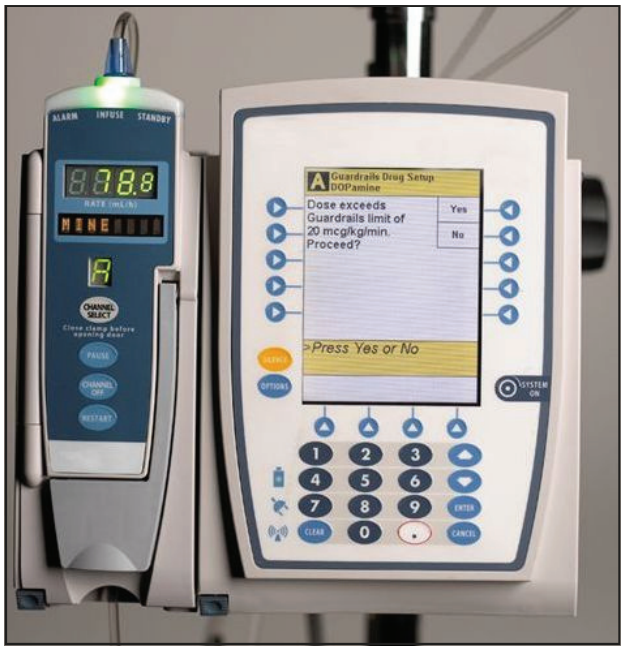

Figure. Example of "Soft-Stop" Limit. Image provided courtesy of ECRI Institute.

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An example that demonstrates the ability of smart pumps to prevent harm from misprogramming infusion pumps occurred in an emergency department (ED) where a physician wrote an order for **INTEGRILIN** (eptifibatide) but inadvertently prescribed a dose appropriate for **REOPRO** (abciximab).[4] The Integrilin infusion was initiated and continued for approximately 36 hours after the patient was transferred to a medical/surgical unit. During this time on the unit, the patient's mental status deteriorated. This infusion event occurred while the hospital was switching to a new smart infusion pump. As the nurse transferred the infusion parameters from the old infusion system to the new system, safety software incorporated in the device alerted the nurse that there was a "dose out of range."

The pump would not allow the nurse to continue until a pharmacist was called and the mistake was corrected.

In another case, a hospital's heparin protocol called for a loading dose of 4,000 units followed by a constant infusion of 900 units per hour. The loading dose was administered correctly, but the nurse inadvertently programmed the continuous dose as 4,000 units per hour. Since the pump limit for heparin as a continuous infusion was set at 2,000 units per hour, the infusion device would not start until the dose was corrected.

Unfortunately, errors may still occur when using this technology. Numerous reports sent to PA-PSRS include examples of errors associated with the use of smart infusion pumps. Some examples include similar types of errors that may occur with the use of general infusion pumps. For example, one contributing factor to the misprogramming of smart infusion pumps arises when organizations do not use standardized concentrations of high-alert medications.

> *Hospital policy dictates that the standard Levophed solution is 4 mg/500 mL. The pharmacy sent 4 mg/250 mL. The nurse programmed the smart pump incorrectly by entering the standard solution (4 mg/500 mL). The medication was titrated to achieve a systolic blood pressure of 90. Patient did not suffer any adverse effects as result of error.*

> *Patient had heparin infusing per standard protocol. On assessment, smart pump was found to be programmed incorrectly. The patient was to receive 1,000 units or 20 mL/hr. Pump was programmed for the 25,000 units in 250 mL concentration. Bag hanging was the 25,000 units in 500 mL concentration. Therefore, patient was receiving half the ordered dose. The patient's next* [activated partial thromboplastin time (aPTT)] *was subtherapeutic.*

There are many examples of "wrong rate" medication errors in reports submitted to PA-PSRS, involving general infusion pumps as well as smart infusion pumps when practitioners inadvertently switch IV lines between separate infusion pumps or dual-chambered infusion pumps.

> *This unit received the patient from the critical care setting with an insulin infusion 0.4 mL/hr and IV fluid at 100 mL/hr. When the patient was disconnected from the pump to reprogram the smart pump to the medical surgical profile, the infusion lines were inadvertently switched. When the pumps were restarted, the patient received the insulin at the IV fluid rate and the patient received approximately 40 units of insulin. The patient's blood sugar was immediately checked and was down from 200 to 100.*

Wrong-dose errors have been reported to PA-PSRS when inaccurate patient weights were used to calculate and program weight-based doses on smart pumps, because of mixups between weight in pounds and weight in kilograms.

> *Nurse set the dopamine infusion via smart pump at 170 kg as weight instead of 170 lbs. Corrected by the nurse and the doctor made aware.* [Vital signs were] *monitored.*

Because new types of information—more than just rate and volume to be infused—are entered into smart pumps, there is now an opportunity for new types of errors associated with these pumps. For example, practitioners may inadvertently choose the wrong drug or the wrong unit of measure in the smart pump's library.

Wrong Drug

> *The nurse incorrectly programmed the smart pump for a Lasix infusion instead of Brevibloc as was ordered. The rate was infusing at 5 mL/hr instead of the ordered 17.5 mL/hr dose.*

> *Upon assessment,* [staff] *found Levophed running on a smart pump programmed for neosynephrine infusion at 200 mcg/min. The Levophed solution was not scanned prior to administration and the wrong medication*

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was administered. The patient had orders for both vasopressors.

Wrong Unit of Measure

*Labetalol ordered to run intravenously at 5 mg/**hr**. The smart pump's library was set for mg/**min** and the medication was given at 5mg/min.* [emphasis added]

*Propofol was ordered at 80 mcg/kg/**hr** but was programmed at 80 mcg/kg/**min**. The rate was changed and the patient was overly sedated but there was no change in the vital signs. The medication was discontinued and the physician was made aware.* [emphasis added]

One Serious Event reported to PA-PSRS occurred when the smart pump was programmed at a 10-fold overdose because there was no preprogrammed dose limit in the library.

Nurse hung the patient's [total parenteral nutrition (TPN)] *to run at 625 mL/hr instead of the ordered 62.5 mL/hr x 24 hours. The infusion pump was incorrectly programmed at 625 mL/hr. Depending on pump library chosen, there is no hard stop for the TPN, which allowed the incorrect entry. Error discovered after 1 hour and 30 minutes when the patient became short of breath. The patient was treated appropriately for elevated potassium and glucose, but three hours later the patient coded and expired.*

Overridden Libraries

Equally important as the built-in safety capabilities of the smart pump is the role of the clinician to consistently use the technology to its fullest potential. As with other technologies, clinicians have sometimes bypassed its use, only to realize its true value after a serious error has occurred that could have been prevented with the technology.[5]

Rothschild et al. indicated that IV medication errors and adverse drug events were frequent and could be detected using smart pumps. However, violations during the intervention periods included 571 (25%) bypasses of the drug library. The authors concluded that there was no measurable impact found on the serious medication-error rate, likely in part due to poor compliance. The study concluded that although smart pumps have great promise, technological and nursing behavioral factors must be addressed.[6] It is noted that this study was conducted with an early-generation smart pump that required users to opt into the drug library. Most newer pumps encourage use of the drug library by presenting it to the user at startup and allowing the user to opt out if necessary.

The following account describes one instance of bypassing a drug library. A 19-year-old obese woman, who had recently undergone cesarean section delivery of a baby, presented in the ED with dyspnea. Believing the patient had developed a pulmonary embolism, the physician prescribed an IV heparin bolus dose of 5,000 units followed by a heparin infusion at 1,000 units per hour. After administering the bolus dose, a nurse started the heparin infusion but misprogrammed the pump to run at 1,000 mL per hour, not 1,000 units per hour (20 mL per hour). By the time the error was discovered, the patient had received more than 17,000 units (5,000 unit loading dose and about 12,000 units from the infusion) in less than an hour. A smart pump with dosing limits for heparin had been used, so the programming error should have been recognized before the infusion was started. However, the nurse had elected to bypass the dose-checking technology and had used the pump in its standard mode. Fortunately, the patient did not experience adverse bleeding, as her aPTT values were as prolonged as 240 seconds when initially measured and 148 seconds two hours later. Further investigation of this event uncovered that, like the nurse involved in this error, most nurses in this hospital were bypassing the dose-checking technology available with the smart pumps.[5]

There are many reports in PA-PSRS of clinicians who override the library to infuse medications, thus bypassing the built-in capabilities of the pumps.

*The smart pump was not programmed using guide rails and programmed as basic infusion. The rate was programmed 50 **mL**/hr for a 14-year-old patient receiving amiodarone. The order was for 50 **mg**/hr, which should have run at 27.7 mL/hr. The patient became short of breath. The nurse was notified, and incentive spirometry and nebulizer treatments were given. Patient stated he had relief with the treatments but not complete relief. The patient was unable to sleep overnight and had to sit straight up while in bed to breathe well. It was discovered the next day that amiodarone was infusing at too high a rate, and the rate was adjusted. The infusion dose corrected and the patient was able to breathe better after the dose corrected.* [emphasis added]

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> *Nurse hung a* [peripheral parenteral nutrition] *via pump but bypassed the drug library and programmed the rate at 417 mL/hr instead of the ordered rate 41.7 mL/hr.*
>
> *Nurse programmed smart pump to infuse heparin at 650* ***mL****/hour instead of ordered dose of 650* ***units****/hour. Drug library not used to program the heparin in the smart pump. The physician was notified and the heparin was discontinued. The patient's lab values checked and protamine sulfate administered.* [emphasis added]
>
> *The nurse found the patient's Lasix drip infusing at* ***100*** *mg/hour instead of ordered rate of* ***10*** *mg/hour. The correct drip rate was recorded on the pharmacy label, but the drug library in smart pump was not utilized to program the infusion and automatically compute dosage. The incorrect rate was infusing for 1.5 hours; no untoward reaction.* [emphasis added]

Studies about smart pump implementation have provided some answers about why clinicians have chosen to bypass the dose-checking technology, including

- falsely low perceptions of risk;
- failure to make adjustments in the drug library when alerts are not credible;
- extra work to use the technology, time pressures, distractions, interruptions;
- clinical emergencies; and
- a culture that inadvertently supports at-risk behaviors, including technology work-arounds.[1-3]

Smart pumps that turn on in standard mode (i.e., no dose checking) or default to standard mode can also discourage compliance, as it takes extra effort to switch the pump to the dose-checking mode and to access the library. Most pumps sold today (and all pumps that received a high rating in ECRI Institute's October 2007 evaluation of general-purpose pumps[7]) encourage use of the drug library by presenting the library to the user at start-up and allowing the user to opt out when necessary. In reviewing data from facilities that use modern drug library software, ECRI Institute found usage compliance rates above 90%, depending on whether the drug library includes most drugs and fluids used by each care area.[8] Data-mining tools such as software that parses through pump logs can be used to improve compliance by monitoring use of the drug library and telling nursing management which drugs see the most alerts in each care area.

Safe Practice Strategies

Healthcare providers can compare using smart pump technology to using a seatbelt. Unlike airbags, which are safety features that are not optional and not subject to being bypassed by the user, seatbelts are an *optional* safety feature. They can be bypassed, just like dose-checking technology, despite a policy that may require their use. Thus, it is not enough to purchase smart pumps, program the library once, distribute the pumps, educate users, and hope that the dose-checking feature will always be used. Facilities can prepare to maintain their systems by collecting and reviewing log analysis data on a regular basis and modifying drug libraries when necessary. Such activities can support a larger initiative to create a culture of safety that drives clinicians to avoid bypassing such a safety feature, or to report conditions that encourage work-arounds so they can be remedied. A culture of safety also promotes the critical thinking necessary to evaluate pump alerts from a clinical and safety perspective, significantly limiting overrides to situations that have been fully appraised. Thus, a culture of safety is fundamental to both compliance with using the smart pump technology as well as heeding the alerts that may arise. In addition, organizations may consider some of the following steps if they are considering purchasing and implementing smart infusion pumps in the near future:[9]

- Just like other forms of technology, a readiness assessment is essential with particular attention to the organizational culture when planning for the use of this technology.
- Establish a multidisciplinary team to determine best practices including IV-related policies and procedures and standardized concentrations, dosing units (e.g., mcg/min versus mcg/kg/min), and drug nomenclature, which should be consistent with what appears on the medication administration record, the pharmacy computer system, and other technology used in the institution.
- Determine dosage limits for infusions and bolus doses on the basis of current policy and practice, the literature, and consensus

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among the group. Also decide which dose limits require a hard stop versus a soft stop.

- Develop care-area-based dosage limits (e.g., for adult intensive care unit [ICU], adult general care, pediatric ICU, pediatric general care, labor and delivery, anesthesia) and procedures for nurses to follow when a drug is not in the software library or a nonstandard concentration must be used.

- Another important enabler of smart pump technology is the use of wireless connectivity. With the addition of a wireless card on each pump (similar to those used for laptop computers), wireless coverage in care areas, and a server to house and process information, a facility can regularly download event/alarm logs from the pumps and upload new drug libraries to them, all without the need to locate and touch each device. ECRI Institute considers the use of wireless technologies to be a critical part of maintaining a practical, flexible dose error reduction system and permitting further software upgrades and updates to devices over time.[7]

Additional measures for facilities to consider that can nurture compliance with smart pump technology and attention to the alerts include the following:

- Analyze pump logs, evaluate overrides (which can point to mismatches between limits and typical care practice) and reprogrammings (which indicate a "good catch"), and make necessary adjustments to the drug library.

- Monitor and measure compliance with the technology to identify and remove any barriers to the safe and appropriate use of these pumps.

- Publicize salient examples of "good catches" to frontline caregivers to underscore the utility of drug libraries.

- Conduct focus groups and satisfaction surveys to solicit nursing feedback.

Do not have healthcare clinicians view the dose-checking feature of smart pumps as an option that can be turned on or off. The alerts that arise from the system should not be allowed to be bypassed without serious consideration. For every error like those described above, there are many more that have been prevented because smart pump technology has been employed. There is little doubt that smart pumps can save lives if properly implemented *and* used.

Notes

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The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error ("Mcare") Act. Consistent with Act 13, ECRI Institute, as contractor for the PA-PSRS program, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority's Web site at www.psa.state.pa.us.

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