Title: Comparative Safety of Smart Infusion Pumps with Standard Infusion Pumps

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Context and policy issues:
General-purpose infusion pumps are widely used to accurately deliver fluids via intravenous (IV) or epidural administration for therapeutic and/or diagnostic purposes. These pumps are used when greater accuracy or higher flow are needed than can be provided by manually adjusted gravity systems. However, lack of standardization for dosing methods and incorrect programming have led to serious adverse drug-related events. Between 1987 and March 2003, Health Canada received reports of 425 separate incidents involving infusion pumps. Of the 425 incidents, 23 resulted in death, 135 resulted in injury, and 127 could potentially have led to death or injury. Of these, 20 deaths and all 135 injuries were caused (or suspected to have been caused) by the infusion pump. Since these reports were voluntary, these figures likely underestimate the actual risk of injury or death associated with infusion pumps.

A national hospital survey conducted in 2003 by the Institute of Safe Medication Practices (ISMP) attempted to identify problems users have experienced with infusion pumps in Canada. Seventy-five percent of responding hospitals reported infusion pump problems. Majority of the incidents were associated with incorrect flow rate (58%) free-flow errors (47%), air sensor errors (47%), and overdose errors (36%). All of these problems can arise as a result of human error (e.g. in programming or improper placement of machinery) or as a result of software or hardware flaws. In light of these results, Health Canada now recommends the purchase of pumps with free-flow protection and a dose error reduction system (i.e. smart technology) that safeguard against dosing and infusion rate errors.

A drug error reduction system is a set of software tools that check programmed doses against preset limits specific to a drug and clinical care area (e.g. ICU, surgery, obstetrics, pediatrics). These systems alert clinicians to programmed doses that exceed the preset limits and either require confirmation before beginning delivery (soft limit) or not allow delivery at all (hard limit). Smart infusion pumps allow for the importation of institution-specific drug libraries. These libraries include drug name, diluent, drug concentration, lower and upper limits on dosage or...
infusion rate, units (for drug, diluent, or dosing), and clinical care area. Multidisciplinary teams including pharmacists, nurses, and physicians set up and update these drug libraries based on institution-specific best practice guidelines. Two-way wireless communication capabilities allow some pumps to send data to a server and receive new libraries without the need to locate and connect each pump to a computer. This data can then be used to help staff address previously unrecognized medication safety issues, refine the drug library, improve compliance, and identify opportunities for best practice improvements.

In selecting and implementing smart pump technology, an assessment of patient harm in comparison to current technology is needed to determine potential long-term clinical and economic benefit. In 2002, the ECRI Institute began reviewing general-purpose infusion pumps based on ability to enhance patient safety. This report will review evidence for the safety of Baxter Colleague smart pumps versus Baxter Flo-Gard pumps. A brief overview of other smart infusion pumps available in Canada will also be discussed.

**Research question:**
What is the evidence that the Baxter Colleague smart pump has less risk of infusion errors compared to the Baxter Flow-Gard Pump?

**Methods:**
A literature search was conducted on key health technology assessment resources, including PubMed, The Cochrane Library (Issue 3, 2007), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI’s HTAIS and Health Devices Gold, EuroScan, international HTA agencies, and a focused Internet search. Results include English language publications from 2002 to date. Links to online full-text are provided when available. Bibliographies of reports were scanned to identify other relevant evidence.

**Summary of findings:**
No meta-analyses, systematic reviews, or trials were retrieved specifically addressing the safety of Baxter infusion pumps. ECRI product evaluations for general-purpose infusion pumps were retrieved in the search. A detailed product comparison based on these reviews for smart pumps available in Canada as well as a useful checklist to help assess which smart infusion pump is best suited to a particular institution can be found in ECRI’s latest evaluation. ECRI findings show that factors that distinguish one pump from another are not performance issues, but patient safety considerations. Most of the currently available pumps perform reliably and accurately when properly used. However, not all models offer the same level of protection against pump programming errors (i.e. human error) and other events that can lead to IV medication errors as a result of software or hardware design flaws.

While the Baxter Flo-Gard 6201 and 6301 models both have free-flow protection, ECRI has rated them as “Not Recommended” for purchase because they lack a dose error reduction system. Furthermore, ISMP Canada has received reports involving over-infusion with the Baxter Flo-Gard 6201 infusion pump. Recently, ECRI has also rated the Baxter Colleague CX and 3CX smart pumps as “Not Recommended” for purchase. ECRI states that the Guardian software provided with the Colleague pumps does not compare favorably with the smart technology used in other pumps. Problems encountered with setting up the drug library include a process that is not user-friendly, reduced customizability, and drug names that cannot be displayed using TALLman lettering (e.g. DoBUTamine, DOPamine). Not defaulting to the dose error reduction system on power-up could potentially decrease compliance with this safety
function. Lack of a dedicated log for storing programmed doses that trigger alerts or re-programming activities hampers assessments of effectiveness or use toward improvements in clinical practice. In the last few years, the Colleague CX and 3CX pumps have also been subject to several recalls and product seizures due to the potential risk for serious injury or patient death. The reason for these recalls consist of several issues encountered with these pumps including hardware and software design flaws (battery under-charging, false air detection alarms, gearbox wear, under-infusion, non-detection of upstream occlusion, battery damage), and evidence of falsified repair, test and inspection sheets. A recent Health Canada advisory reports discontinued infusions encountered with Colleague triple channel infusion pumps as a result of a software irregularity. The Colleague CXE and 3CXE infusion pumps were cleared for marketing in February 2007 and represent an improvement over the CX and 3CX models. Improvements include a larger drug library, a spreadsheet tool for developing drug libraries, and modifications to help prevent battery damage. However, they are still rated as “Not Recommended” for purchase as the functionality provided by Baxter’s Guardian software is still limited compared to other models. The Colleague pumps also lack wireless capabilities and the keypad design could lead to inaccurate programming.

However, ECI RI rated the Cardinal Health Alaris system as “Preferred” for its easy to use and comprehensive safety features (including two-way wireless communication and a bar code scanner) as well as for its PCA module. Furthermore, several observational prospective studies have been published documenting improvements in patient safety following successful implementation of the Alaris system. Hospira’s Symbiq model was rated as “Acceptable” for purchase due to limited implementation experience but ECI RI states that this model is a good choice for hospitals that wish to use one drug error reduction system for both general-purpose and PCA pumps. The Sigma Spectrum pump was rated as “Acceptable” due to good safety features but limited implementation experience. ECI RI rated the B. Braun Outlook 300 and Alaris SE smart pump as “Not Recommended” for purchase based on the finding that the flexibility and safety features of their smart technology are inferior to other pumps.

Conclusions and implications for decision or policy making: Available evidence suggests that smart pumps help avert potentially serious and life-threatening medication errors. However, some smart pumps are clearly superior to the Baxter infusion pumps in terms of reliability in preventing infusion errors. An initial step in smart pump implementation is to determine the scope for smart pump use that is most appropriate for the institution’s patient population, technological capabilities, and budget. Supplier support for both initial implementation and ongoing system maintenance and development is an important consideration. Ideally, hospitals should choose suppliers with extensive implementation experience along with a good history of regular product upgrades and updates in response to customer feedback. The establishment of multidisciplinary project teams (including pharmacy, nursing, physicians, information technology, biomedical engineering, and pharmacy and therapeutics committee) is key in programming institution-specific drug libraries according to best practice guidelines. It is important to note that although smart technology is intended to improve patient safety, it may introduce new errors. Conducting a beta test (pilot study) should help identify new errors in advance and ease institution-wide adoption. Comprehensive training is needed to prevent possible barriers with acceptance of the new technology including falsely low perceptions of risk and time pressures in clinical emergencies. Finally, successful implementation of smart-pump technology should involve continuous collaborative efforts among all relevant disciplines. Interfacing smart pumps with other systems such as the electronic medical record, computerized prescriber order entry, bar coded medication administration systems and pharmacy information systems will help realize their full potential for improving patient safety. Further research is needed to confirm the impact of smart pumps on
length of hospital stay, quality of patient recovery, complications, and economic benefit over standard infusion pumps.

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References:


