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What can we learn from smart-pump infusion data analysis?

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In this issue of *British Journal of Anaesthesia*, Webster and colleagues¹ discuss the limitations of error analyses in the peri-operative space, and cite modern aviation industry strategies that anaesthesiologists should adopt instead. The salient feature of these modern techniques is the jettison of observational protocols and patient chart review in favour of the collection and analysis of the reams of data that are now routinely uploaded into electronic health records (EHRs) from traditional monitoring devices (e.g. ECG, pulse oximeter, etc.), combined with tracked back incident reports that may lead to a root cause analysis (the authors call these Tier 1 and Tier 2 approaches, respectively). The authors highlight the example of medication safety, wherein previous attempts to evaluate root causes and prevention strategies have fallen short, mainly because of costly and inaccurate data collection processes.

Manually administered bolus drug injections are difficult to monitor, record, and analyse in retrospect, primarily because errors are more common than we realise and may not be readily apparent.² Automated medication infusions also have potential for harm because of the inherent susceptibility to infusion pump errors. From 2005 through 2009, the US Food and Drug Administration received ~ 56 000 reports of adverse events associated with use of infusion pumps, including numerous injuries and deaths.³

A 'smart' pump is the commonplace term given to a programmable computerised drug infusion device that contains a drug library, also known as a dose error-reduction system. Smart pumps enable the delivery of i.v. fluids and medications within the bounds of preset parameters, such as drug concentration and dose. They can also be programmed to deliver a bolus dose over a preset time interval, and can calculate weight-based dosing schemes automatically. Most important is the decision support capabilities of a dose error-reduction system, which are composed of institution-specific ranges for each drug.

The user is alerted when the programmed dose (or concentration or duration of infusion) differs from the preset minimal or maximal limits. Depending on the drug and institutional preference, these alerts are divided into 'soft limits', that are manually overridable, and 'hard limits', that cannot be overridden. Drug libraries can also be divided into different clinical care areas. For example, anaesthesia care providers can have different soft and hard limits than other types of clinicians. Smart pumps are thus able to provide real-time feedback to reduce medication infusion errors, and improve patient safety.

Although there is now widespread use of smart pumps, their data analysis capabilities are used inconsistently. Every action of a smart pump has the ability to be recorded and uploaded to a central server where it can then be subject to aggregate analysis to determine patterns of use, some of which may represent errors or unsafe use that were not previously known. We can determine how often the drug library is being bypassed, and use that metric to make improvements. It is also possible to analyse individual programming events to show how often the library limits prevent potential errors. For example, a review of infusion pump data could show that an insulin infusion was programmed at 705 units h⁻¹, which resulted in a reprogrammed correction to 7.5 units h⁻¹ when it triggered an upper hard limit alert.

A recent survey indicated that smart pumps are in use in about 80% of US hospitals.⁴ When used in isolation, the safety limits are effective when the correct drug is programmed by the provider and when the alerts prompt changes in programming, but they do not prevent errors when programming the wrong drug. Ideally, there should be bidirectional communication between the pump and the patient's EHR, known as 'smart pump–EHR interoperability', which enables the medication order to be transmitted to the pump and the pump's activity to be transmitted to the record. Transmission of the order directly to the pump eliminates multiple potential sources of error. However, smart pump–EHR interoperability is not currently supported with most anaesthesia information management

systems. To reach full potential to enhance patient safety, these integrations are essential throughout the hospital, including the operating room, but are costly and will require institutional commitment.⁵

Taking this concept even further, smart pump–EHR integration in the operating room may expand the type of interaction between Tier 1 and Tier 2 data discussed by Webster and colleagues¹ because pump errors can be tracked to patient outcomes. Without this trackback, it will be difficult to determine meaningful outcomes based on aggregate data only. To illustrate, we can analyse drug infusion data (Fig. 1) to determine how often pump users exceeded a certain dose, and what dose range was associated with the need for, say, atropine or phenylephrine, to support HR or BP, respectively. This relationship may not be apparent from EHR data alone, because it relies on manual user input that may not reflect actual use. Unsafe practices can also be uncovered, such as unconventional dilution practices or use of extremely high doses in lieu of a manual or programmed bolus, among others. These analyses can guide the creation of systematically engineered solutions within the pump software to prevent those types of errors in the future.⁶

In May 2018, we (RL, SO, JWB) participated in the Institute for Safe Medication Practices (ISMP) Second National Smart Infusion Pump Summit, sponsored by educational grants from Baxter, B. Braun, Becton-Dickenson, ICU Medical, and Ivenix. The purpose of the summit was to ‘develop an updated and expanded compendium of expert- and evidence-based best practices to maximise the intended safety benefits of this important technology and better position organisations for interoperability of smart infusion pumps with the electronic health record.’⁵ The process began with a nationwide survey of safe practices by healthcare workers to frame the key safety issues and technology challenges. Although survey respondents ($n > 1000$) indicated that 97% use some type of smart pump in at least one area of their

hospital, more than 700 respondents commented on their barriers to use, which included alarm fatigue, deficiencies in drug libraries, insufficient pump availability, slow pump programming that interrupted workflow, confusion about secondary infusions, pump malfunctions, difficulty reading the pump screen, and inability to access and analyse their pump data, among others.⁵ The survey was followed by a live summit featuring extensive discussion from a wide variety of stakeholders to reach initial recommendations. By the end of the consensus process, which continued beyond the dates of the summit, ISMP created guidelines and recommendations in several broad areas including pump infrastructure, drug libraries, continuous quality improvement, clinical workflow, and bi-directional pump interoperability with the EHR.⁵ This document was published in 2020 and is freely available on the ISMP website (<https://www.ismp.org/guidelines/safe-implementation-and-use-smart-pumps>). Most relevant to this discussion are the recommendations to pursue smart pump–EHR interoperability and to expand the use of smart pumps in procedural locations including the operating room.

In 2010, the Anesthesia Patient Safety Foundation (APSF; apsf.org, Rochester, MN, USA) published their recommendations for improving perioperative medication safety.⁷ They recommended a four-pronged approach consisting of standardisation of concentrations of high-alert drugs and their infusion with smart pumps, use of technological advances (e.g. barcoding labels), delivering prefilled, premixed medication syringes to anaesthesia providers, and establishing a culture of safety to assess errors. Since then, the APSF has published additional recommendations for medication safety, including the development and use of technologies that can identify drugs and their administered doses and directly link these to documentation in EHRs.⁸ Besides error analysis, aggregate smart pump data analysis can provide information about novel or unexpected clinical uses of medications, opioid diversion, or

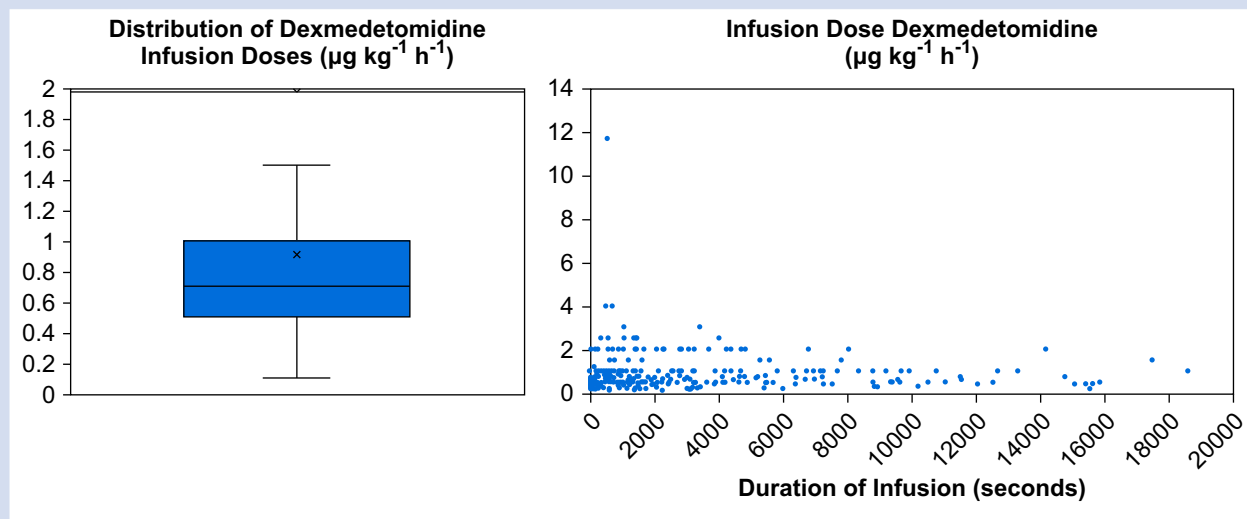


Fig 1. Example of aggregate drug infusion analysis. Left: box and whisker plot of dexmedetomidine infusion dose ranges over a 6-month period. The box represents the 25th–75th percentiles, whereas the whiskers represent the maximum and minimum values. The median is represented by the horizontal line going through the box. Right: scatter plot indicating duration of dexmedetomidine infusion(s).

even predictions of drug shortages.⁹ For example, during the peak of the coronavirus disease 2019 (COVID-19) crisis in April 2020, analysis of medication utilisation in one institution provided visibility of the dramatic increased use of critical care medications, and enabled that institution and drug manufacturers to anticipate increasing demand.

Aggregate data derived from medication infusion smart pumps is underutilised to enhance patient safety. The use of built-in institution-specific decision drug library support capabilities greatly diminishes accidental programming errors, but analysis of aggregate data from thousands of pumps has the potential to determine how often these safety mechanisms are bypassed. Electronic bidirectional functionality between the infusion pump and the anaesthesia electronic record has the potential to further reduce errors and provide tracking back to the patient in the event of a clinical complication. In addition to error reduction, analysis of aggregate pump data allows one to determine patterns of clinical care that might not otherwise be evident by individual chart review. Although anaesthesia has a long way to go to implement all aspects of the medication safety paradigms described above, analysis of aggregate infusion pump data represents another line of attack in the multifaceted approach that is the future of perioperative medication safety.

Authors' contributions

Contributed to the ideas and written words contained within this editorial, and were involved in the editing and final approval: all authors.

Declarations of interest

RSL and the Institute for Safe Medication Practices have no financial conflicts of interest. Children's Hospital of Philadelphia has equity stake in Bainbridge Health. SO has ownership equity in Bainbridge Health, which analyses medication data for healthcare facilities. JWB is an employee and shareholder of ICU Medical, which manufactures smart infusion pumps and data analytic software.

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A call to action: evaluation of perioperative neurocognitive disorders in low- and middle-income countries

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