New Approaches to Improving Patient Safety:

Strategy, Technology and Funding

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For more information on Alaris Medication Safety Systems, see this article: www.longwoods.com/jobsite/HQ81HHSCprofile.pdf

In keeping with its commitment to provide practical medication safety solutions to hospitals throughout Canada, Cardinal Health brought together nationally recognized healthcare financial thought leaders to focus on the use of innovative technology to improve patient safety in Canadian acute care hospitals.

The consensus of the financial healthcare thought leaders was that improving patient safety is most importantly "the right thing to do"; a good business case is an added bonus. Avoiding adverse events (AEs), including adverse drug events (ADEs), may improve efficiencies by avoiding unnecessary costs and extended lengths of stay. This can be especially important while a "window of opportunity" exists to increase new funding for Canadian hospitals by improving efficiency ratings using the Integrated Population-Based Allocation (IPBA) methodology. Participants also explored various possibilities for funding safety technology. This Executive Summary details the Key Points that emerged from conference presentations and discussion.

Need for Improved Medication Safety

Length of stay – The Canadian Adverse Events Study showed that adverse events, including preventable adverse drug events (PADEs), are associated with increased length of stay. As described below, advanced technology is now available to avert high-risk medication errors – those most likely to lead to PADEs – and help avoid increased length of stay.

> "Given the IPBA formula, your best bet to increase funding is to reduce your cost per case while increasing or at least maintaining your number of weighted cases. Reducing length of stay would be a major driver to actually achieve that." *Dennis Biesaida, BBA, CMA Corporate Director of Finance and CFO, Grey Bruce Health Services*

High-risk medication errors – Several factors have increased the likelihood of error in Canadian hospitals. Along with higher patient acuity and lower staffing levels, recent years have seen dramatic increases in the numbers of medications used in treatment and the complexity of medication management. While some errors cannot be avoided, (e.g., an

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unexpected allergic drug reaction), many serious errors are preventable (Tables 1 and 2)*.[2,3] Medication safety uses best practices and technology to avert PADEs.

TABLE 1. Adverse drug reactions in Canadian hospitals[2]

- Adverse drug reaction (ADR) fatalities are the 7th leading cause of death in Canada, after cancer, heart disease, stroke, pulmonary disease and accidents, using 1995 Statistics Canada data.
- ADRs prolong Canadian hospital stay by an average of 4.6 days, costing Canada $300 million annually.
- One-third of adverse drug reaction deaths are preventable.
- Between 1999 and 2003, the rate of adverse ADRs for teaching and community hospitals increased from 12% to 22%

In the medication use process, the nurse at the bedside is the most vulnerable. Leape et al., in a 1995 study showed that 38% of medication errors causing PADEs occurred during administration, and only 2% of these administration errors were intercepted.[4] In general, 51% of all non-intercepted potential ADEs and PADEs occurred during the administration stage.[4]

Errors vs. harm – While it is important to work to reduce the frequency of all medication errors, the first priority must be preventing errors with the greatest potential for harm, that is, those involving high-risk medications.[5,6] Only a few oral medications are high-risk drugs, while a great number of IV medications pose a high risk of harm (e.g., heparin, insulin, morphine and propofol.) [7-9]

IV medications have been associated with 54% of potential ADEs,[10] 56% of medication errors,[11] almost 61% of the most serious and life-threatening errors (Bates DW, personal communication 2001), and often result in the most serious outcomes of medication errors.[12]

A nurse would never give one hundred pills to a patient; however, he or she can all too easily program a general-purpose infusion device to deliver a comparatively massive overdose (Table 3).[5] In addition to the tragic results for the patient and family, an infusion related PADE can be a career-ending mistake for the nurse and result in lost productivity for associated staff.

"The cost of medication errors goes beyond the direct costs such as legal settlements and loss of reputation. The effect of serious errors on the care team (nurses, pharmacists, physicians) can be profound and result in many additional supports for the team being required." *Rheta Fanizza, MBA, Vice President Diagnostic and Information Service , The Scarborough Hospitals*

In seeking to improve medication safety, the goal is to change the system, make it easier to do the right thing, prevent individuals from committing errors, and build high-reliability organizations. To achieve this goal, the use of technology is essential.[13] However, until recently, no technology has been able to safeguard against the type of medication errors most likely to cause harm – intravenous (IV) infusion delivery of high-alert medications.[13,14] New safety software with error-prevention, data-collection and networking capabilities (see Appendix) specifically targets high-risk infusion medication errors. A so-called "smart pump" (computerized infusion device) is a standalone infusion pump supported by dose error reduction software. A smart medication safety system is a more advanced technology that provides capabilities beyond those of smart pumps, as discussed in the Appendix.

"The health care change that we've lived through in the past five years is going to be a constant state, resulting from the expectations of the patient and clinicians need for innovative, quality health care. The flexible technology platform is a foundation that allows you to add components in the future to meet these types of requirements." *Altaf Stationwala, Site Executive and Vice President Patient Services, William Osler Health Centre*

TABLE 2. Canadian adverse events study[3]

Findings included the following:

- The rate of adverse events (AEs), including adverse drug events (ADEs), in Canadian acute care hospitals was 7.5 per 100 hospital admissions
- 24% were drug- or fluid-related events (the second most common AEs)
- AEs, including ADEs, resulted in increased length of stay (mean per patient):

Hospital	Additional days due to AEs/ADEs
Small	7.7 days
Large	3.6 days
Teaching	6.2 days

- 255 patients with AEs required an estimated additional 1,521 hospital days.

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Improved IV Medication Safety – Hospital Benefits

CIO concerns – Conference participants emphasized four concerns that every CIO has with regard to information technology that is being discussed: (1) Will the company ever build it? (2) Once it has been built, can it be implemented successfully or at all? (3) Will staff actually use that technology, which is seen as being primarily physician directed? (4) Will it eventually provide the result or the benefit that has been described in the very beginning?

TABLE 3. IV medication programming errors[6]

- A continuous insulin infusion for an adolescent patient was ordered in adult, unit-based dosing. The pediatric intensive care unit (PICU) nurse was accustomed to weight-based dosing and programmed 7 units/kg/hr instead of the intended 7 units/hr for the 67-kg patient, thereby inadvertently administering a 67-fold overdose
- In programming a nipride infusion for a 3.3-kg infant, a nurse incorrectly entered "205" instead of "2.5" and inadvertently administered an approximately 82-fold overdose.

Documented improvements in patient and clinician safety – Participants stressed the importance of published data to allow hospitals to make evidence-based decisions. Data from the CQI logs have documented immediate and continuing improvements in IV medication safety,[5,6,13-16] such as those shown in Figures 2-3.

> "It's all about patient and staff safety. Implementing the Alaris® System is an investment for our staff and patients, a purely strategic decision. Markham Stouffville has always supported a culture of safety and quality and progressive utilization of technology. So purchasing the Alaris® System was just in keeping with who we are and what we do." *Dr. James MacLean, President and CEO Markham Stouffville Hospital*

> "I agree with Dr. MacLean 100%, I think for almost every hospital, it is patient safety first, and if there is a good business case to back up the buy decision, that's a bonus." *Dennis Biesaida, BBA, CMA Corporate Director of Finance and CFO Grey Bruce Health Services*

Reduced risk – Prior to implementation of the safety system, a large community hospital conducted a failure mode and effects analysis (FMEA) to determine a risk priority score related to setting IV heparin infusion rates. At that time, without a reliable mode of error detection for drug infusions, the score was 210. Following implementation of a safety system and software, the score dropped from 210 to 56 – nearly a four-fold reduction in risk.[6] An IV Medication Harm Index has been developed to allow hospitals to quantify averted harm achieved by using advanced technology.[17]

Actionable data provide basis for best practice improvements – CQI reports provide:

- accurate information about clinical care
- time, date and care areas where most Guardrails® Suite alerts occur
- medications that trigger a high number of Guardrails® Suite alerts
- magnitude of error
- actions taken

TABLE 4. Key features of the Alaris®System

1. Ease of use
2. Internal, programmed drug calculations
3. Standardized drug programming with specific hard (cannot be overridden) and soft (can be overridden) dose limits
4. Programming that is intuitive; requires fewer key strokes
5. Standardization of medication concentration and dosing
6. CQI data–all programming errors and subsequent actions
7. Customizable patient care profiles
8. System platform adaptable for up to 4 detachable modules, including large-volume pumps, syringe pumps, patient-controlled analgesia (PCA), pulse oximetry, end-tidal CO2**
   and potential future infusion and patient monitoring modules**
9. Single interface for all modules–less training or opportunity for confusion
10. Expanded drug library containing up to a total of 1,000 drugs
11. Does not require, yet will have electronic interface with IS to facilitate use of CQI data
12. Modularity of infusion channels allows for maximization of the number of infusible lines across patients.

*** This product may not be made commercially available.*

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For example, time-based data revealed that during the first six months of a smart IV system being used in a pediatric hospital, infusion programming errors peaked at 10 am, 7 pm, 10 pm and midnight (Figure 4, darkened area). Analysis showed that these were especially busy times, when shift change, high admission volumes and activities such as drug distribution combined to distract nurses. As a result of these findings, the units were closed during shift change, and the timing of several elective activities was changed to reduce distractions. Since these changes, pump alerts are much less frequent and all of the former error peaks have been eliminated (Figure 4, lighter area).[18] This example shows how smart IV alerts can be the "canary in the mine"[19] to identify where nursing workload issues exist and to target quality improvement efforts to improve patient safety, best practices and nursing satisfaction.

Figure 1[16]

Improved safety culture – Improved communication among medical, pharmacy and nursing staffs results from the multidisciplinary work involved in the creation of the drug libraries. Greater communication continues with analysis of CQI reports. In addition, CQI data can help increase patient safety awareness and motivation, since they document what could have happened, if the system had not been in place. Since errors were averted, blame is not involved.

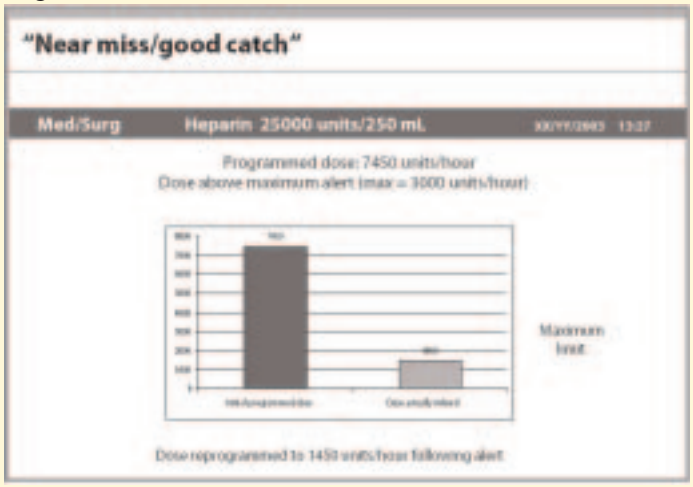
> "Once data are available – once we have direct evidence from the devices that show what has been averted, what may be going on throughout my whole institution – the whole call to action becomes very, very strong." *Rheta Fanizza, MBA Vice President Diagnostic and Information Services The Scarborough Hospitals*

Business Case

Cost avoidance – Medication errors are costly. Currently, no data are readily available for national costs of ADEs in Canada; however, examination of US data is instructive. Bates et al. found that for a 700-bed teaching hospital, the cost per PADE in 1993 dollars was US$4,685, with an estimated annual cost of approximately US$2.8 million.[20] These figures include costs related to extended patient stays, but do not include the costs of injuries to patients, malpractice costs, cost of admissions due to ADEs, or litigation. The cost per PADE inflated to 2004 dollars is US$6,500.[18] A three-year study completed at a major medical centre showed that the average incremental expense was approximately US$8,000 per PADE.[16]

Margins and working capital – Such costs become even more important in light of recent trends in hospital total margins and working capital. While small hospitals tend to fare better than community or teaching hospitals, total margins for all hospitals decreased between 1997 and 2002 and are now only about 1%.[21] Working capital shows a similar downward trend, with a negative percentage for all hospitals for the first time in 2002.[21] Thus, any patient safety initiative, including the use of medication safety technology, must be evaluated in terms of not only clinical benefits, but also financial and operational improvements.

Figure 2[15]



Length of stay – The Ministry of Health and Long-Term Care funding formula is based on performance. Efficient hospitals are rewarded. A key factor is length

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of stay. A recent study of the Alaris® System identified a statistically significant reduction in length of stay in the participating ICU.[22]

Additional benefits – In addition, improving patient safety by averting the highest-risk-of-harm medication errors can improve quality of care and patient throughput. Greater efficiency can help improve a hospital's efficiency rating. Moreover, averting medication errors can also avoid the lost staff productivity associated with PADEs. A single user interface for multiple types of devices simplifies training. CQI data can be used to identify opportunities to reduce drug costs (e.g., by avoiding propofol overdosing in the sedation of ventilated patients).[23] Finally, the cost to upgrade from a "smart pump" (computerized infusion device) to a smart medication safety system can be higher than the cost to implement a smart system initially.[15]

ROI – In an average 350-bed hospital, the typical time for payback after implementation ranges from 15 to 20 months, based upon the cost of PADEs.

Nationwide averages for a 350-bed hospital are 368 PADEs/year and $6,000 to $8,000 per PADE, compared with a $1.6 to $2.0 million investment in a complete system.[15] PADE costs do not include negative public relations, litigation costs or insurance costs.

Public relations/fundraising, balanced scorecard – Documented improvements in medication safety – that is, averted errors – make a good story to take to the community for a balanced scorecard and for fundraising. Consumers can readily understand the need to avert infusion programming "typos" that can lead to significant overdoses and appreciate the benefits of having a computerized "brain at the bedside" to double-check programming accuracy.

> "You can leverage investments into more fundraising. The more you do as a health care organization to provide better and safer care for your community, the more your community will support your fundraising efforts. So, there are opportunities to feature things such as the Alaris® System to help with fundraising." *Dr. James MacLean, President and CEO Markham Stouffville Hospital*

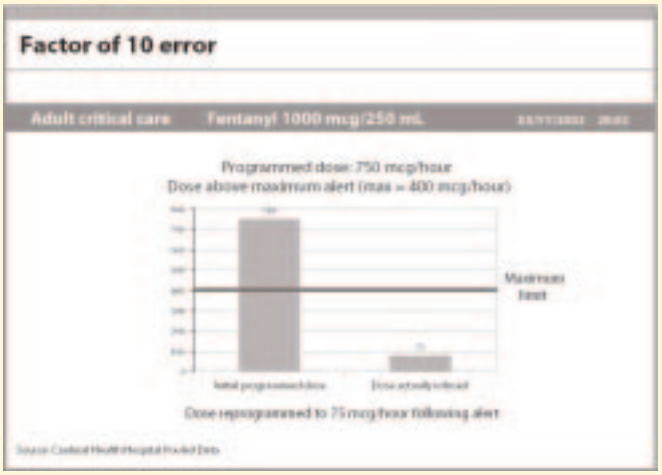
Partnering for performance

Improving best practices throughout the hospital requires that a company and a hospital become performance partners to go beyond the point-of-care "test of reasonableness" to be able to act on the data. Examples of hospital partnering include productive collaboration to:

- establish medication limits for different care areas
- standardize rule sets
- install on "go live" date
- upgrade software
- as a beta site, help identify needed innovations
- analyze data (e.g., correlate medication delivery alerts with shift, time of day and day of the week)
- help hospitals comply with regulatory mandates
- create new educational and safety campaigns focused on best practice changes

Hospitals have indicated that they want to know that the company's goals align with their goals. They want a partner that will work together with them to customize the safety software, train staff and install the systems quickly and without disruption according to timelines that a hospital can rely upon.

Figure 3[15]



Following installation, the hospital and supplier continue to work together to improve the system and infusion therapy best practices, to help with the production and analysis of measurable and actionable data, and help to communicate benefits that can be shared with the community for public relations and fundraising efforts.

Purchasing options – Purchasing the systems using a proof-of-concept model allows a hospital to forego payment on the software and the implementation services for three to six months following implementation, when the system's benefit to the hospital has been shown.

Strategic decision – Conference particip nts viewed purchase of a safety system and software as both an operational and a strategic decision. Infusion pumps need to be replaced on a regular basis. Those monies can be allocated to purchase of the IV medication safety system as the best investment for clinical,

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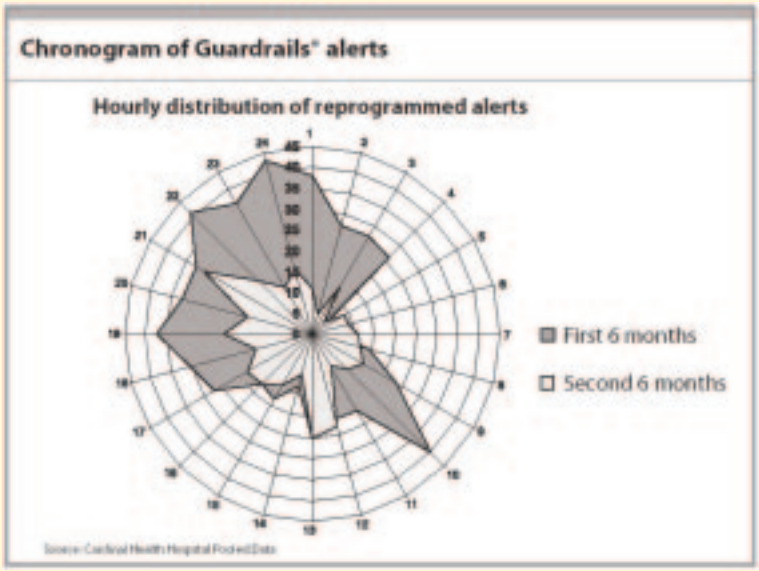
Figure 4[18]



financial and operational returns.

> "The decision to implement technology can't exclusively be driven by what the front-line providers say that they want. There has to be a balance between longterm strategy and making sure the basic needs are always met." *Ann-Marie Strapp, Manager, Health Systems Performance Unit Ministry of Health and Long Term Care*

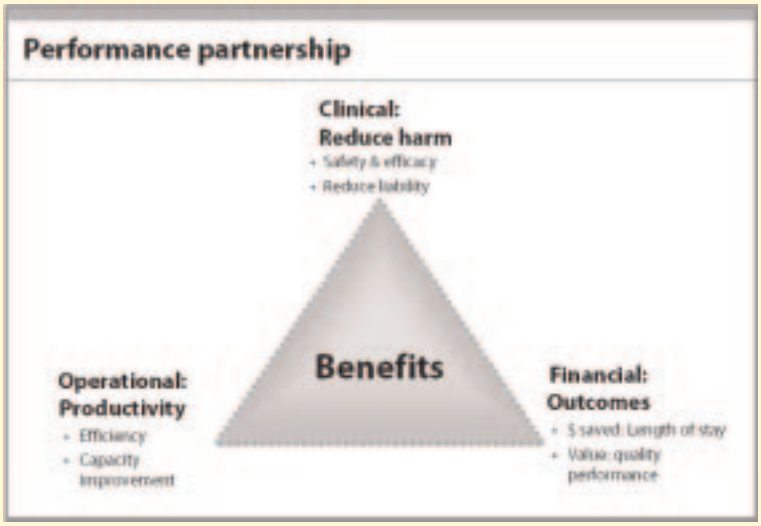
Conclusion

The creation of the institution-specific software data set, as well as the flexibility, effectiveness and auto-matic data gathering capabilities of available safety systems, allow a hospital to meet all four goals listed in the Canadian Adverse Events Study as leadership requirements for efforts to make patient care safer:

- encourage the reporting of AEs
  - the system automatically documents averted errors
- continued monitoring of the incidence of these events
  - CQI logs provide data to document decreased incidence
- judicious application of new technologies
  - safety systems with the safety software provide exceptional "speed to impact" in averting the most critical medication errors
- improved communication and coordination among caregivers
  - customization of the safety software increases interdepartmental collaboration and provides immediate feedback to caregivers on any medication being administered outside institution-established limits

Safety systems and software not only meets a hospital's immediate needs but position a hospital to be able to meet future developments, as well – with measurable and actionable results, timelines that a hospital can count on, and benefits that a hospital will be proud to share with their community.

Figure 5



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Note: Alaris® System formerly known as Medley™System

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Appendix

The Alaris® System with the Guardrails® Suite of safety software

A smart IV medication safety system –

- Integrated medication safety platform that offers dose error reduction safety software across all infusions on one platform and includes PCA, large volume delivery, patient monitoring and syringe delivery
- Integrates patient monitoring using a common user and IT networked interface
- Provides comprehensive CQI reporting and analytic tools that allow hospitals to more frequently improve best practices
- Speed to impact through CQI reporting and analytic tools that are networked, providing immediate access to the data and accelerating best practice and process improvements
- Networked for Safety and Workflow Efficiency – providing a single gateway into hospital systems from multiple modalities.

Dose error reduction software – The Alaris® System with the Guardrails® Suite of safety software incorporates dose error reduction software (DERS) that enables a hospital to incorporate their best-practice rules, including dosing limits, into the system to perform a final "test of reasonableness" at the point of care. This computerized IV medication safety system with both error-prevention and data-collection capabilities comprises a new technology that allows hospitals to specifically target high-risk infusion medication errors.

Averting high-risk medication errors – When infusion programming exceeds best-practice limits, the safety software provides an alert when the "start" key is pressed. Infusion cannot begin until the alert is addressed. Programming steps that previously would have led to a medication error are brought to a nurse's awareness and corrected as they occur, thereby improving patient safety and reducing the potential for harm.

Patient care area customization – The safety software allows an institution to create specific "profiles" with drug libraries and other parameters customized for different patient care areas or patient types: e.g., adult critical care, oncology, adult medical/surgical, obstetrics, pediatrics, etc. Clinical advisories can be included in the software to help ensure that clinicians use best practices.

Continuous quality improvement (CQI) logs. The safety software's CQI logs automatically record the programming errors ("near misses") averted by the new system, thereby providing clinicians with a previously unavailable tool to assess current practices and identify opportunities to improve medication administration. Aggregated data from 18 healthcare institutions for 425,000 patient days provide objective documentation of the frequency of infusion programming errors (Table 5).[13]

Modular design. The Alaris® System's modular design uses a single interface for various modules (large volume, syringe, pulse oximetry, end-tidal CO2 and future modules), which allows for future innovations and scalability. A single interface also simplifies training and decreases opportunity for error.

Rapid implementation. The average time for implementation of the Alaris® System from start to "go live" is 90 days.13 Installation in patient care units can be accomplished in less than a day. Implementation does not change workflow or require additional full-time equivalents (FTEs).[14,15]

Networked systems. After implementation, the Alaris® System can function as a stand-alone device or be networked to a hospital information system (HIS) with data communication by radio frequency in real time.

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