Canadian Pharmaceutical Bar Coding Project

Medication Bar Code System Implementation Planning

Section II: Building the Case for Automated Identification of Medications

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Section II: Building the Case for Automated Identification of Medications: The Value of Bar Code Systems in Reducing Preventable Medication Errors

The purpose of this section is to provide the reader with a thorough understanding of the need for improved medication systems utilizing automated medication verification for all stages of the medication process. It provides a basis for preventable medication error problems, human accuracy related to routine but important medication functions, and principles of enhanced support for such functions.

The section also reviews the current literature evidence for bar code medication verification effectiveness, by reviewing the reduction in medication errors. Finally, it discusses the importance of healthcare leadership and strategic planning in this area of patient safety investment.

A synopsis of Section II is located in the <u>Document Précis</u> section of this document, above.

An Brief Overview of Medication Errors and Causes

Adverse Drug Events and Error Rates

Institute of Medicine (2007)
Preventing Medication Errors:
Quality Chasm Series

The frequency of medication errors and preventable medication-related injuries represents a very serious cause for concern.

Before entering into a review of automated identification and its effect on improved patient safety, a brief review of the medication management systems, the current study methods and rates associated with Adverse Drug Events (ADEs), and the causes of errors may be helpful.

Prescription and Medication Management Pathways

It is generally accepted that medication misadventure occurs along a series of interrelated steps. A high-level prescription process, described in 1995 by Leape, et al involves four steps: prescribing by physicians, prescription translation (interpretation) and verification, pharmacy dispensing and compounding, and, finally, dose administration. [91] (Figure II-1)

Physician Ordering 39%

Transcription & Verification 12%

Dispensing 11%

Dose Administration 38%

Comparison of Preventable Errors by Category
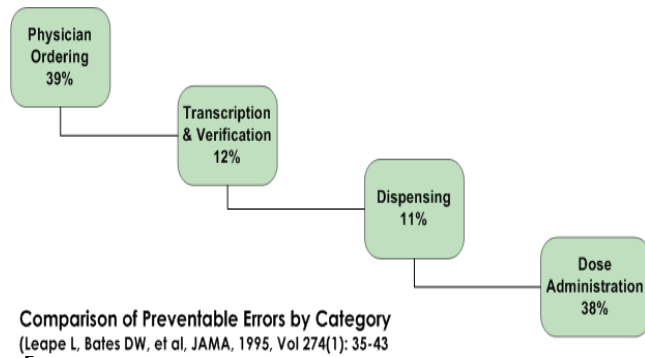(Leape L, Bates DW, et al, JAMA, 1995, Vol 274(1): 35-43

Figure II-1: The Prescription Flow Process

Beyond the simple prescription flow process itself, an aligned medication process involving intricate product handling and service hand-offs occurs with very high frequency and rapidity. A medication product systematically moves along an interrelated pathway where it is sequentially transferred and stored and possibly manipulated, each stage involving verification decisions and actions by separated caregivers. (Figure II-2) This medication chain describes a similar practice in both institutional and community care.

Pharmaceutical manufacturer → Warehousing and shipping → Healthcare contracting and purchasing → Institutional or retail inventory storage → Pharmacy compounding → Pharmacy dispensing → Patient care area storage of bulk or individual therapies → Drug/dose selection → Dose administration to patient

Figure II-2: The Medication Product Chain

International and Canadian studies have investigated the rate of healthcare Adverse Events (AEs), including a subset known as Adverse Drug Events (ADEs). Adverse Drug Events result from a myriad of unintended treatment actions. The majority of error and ADE studies have been completed within hospitals; however several have also been completed for community practices within long-term care facilities, and outpatient care.

Healthcare systems, patient acuity and care needs are widely variable, as are study methodologies used to assess quality improvement. So varied are the practice and study environments, the precise number or rates of preventable ADEs associated with medication errors is unknown. [77, 148]

Later in Section II, we will look at the potential for bar code verification to reduce errors at several points along the medication process.

Methodologies and Findings of Error Rate Studies

For a study to validate the effect of an intervention, it should seek to develop a direct and statistically observable correlation between the 'before' system and the 'after" (post-intervention) system; thereby quantifying the invention's impact by comparing the rates before and after. Though this ideal may be reasonably achievable in controlled 'laboratory-like' study environments, it is exceedingly difficult to achieve in studies involving disparate clinical systems with ever-varying patient co-morbidities, acuity and staff schedules and turnover.

The absence of a single medication error operational taxonomy is unfortunately not the only impediment to comparable studies.

Varying definitions of non-performance terms (e.g., Adverse Events (AE), Adverse Drug Events (ADE), *preventable medication error, etc.)*, myriad sub-systems, procedural and training methods, and chronically inconsistent incident data reporting, all contribute to the difficulty of studying causes of medication system failure and related patient harm.

For example, *ADE* reporting to determine safety rates can be conducted by at least three methods: individually-completed incident (event) reports, retrospective chart reviews or, concurrent observation of activities. Many literature reports of error rates are based on data derived from individual healthcare provider incident reporting, yet the number of incidents reported may be only a fraction of the actual number of AEs, ADEs or errors, for a number of reasons.[20,56,77,128,148] Retrospective chart reviews are reliant on the quality of the original documentation performed. Even when an observational study method is employed, errors will be missed, but it is probably the most accurate method of the three.[56]

Rate findings: Evidence of the Problem

Despite valid arguments of some researchers and academicians, who argue that the literature is lacking in ideal methodology and consistency, quality literature reports do exist. Those studies indicate a common patient safety thread: a correlation between the type of medication system used and the rate of preventable ADEs, and medication errors.

We provide a brief summary of some of the rates found using observational studies from pharmacy, hospital, residential (long-term care) and ambulatory settings (Appendix II-1). Though Appendix II-1 exposes a variation in calculated preventable *ADE* and medication error rates, they are clearly higher than acceptable.

> Bates, et al, in 1995, demonstrated an overall rate of ADEs of 6.5 per 100 admissions and 5.5 potential ADEs per 100 admissions. They employed a combination of ADE discovery methods at different stages of the prescription process, and used an expert review panel to assess preventability and harm of each ADE.[20] It was found that many ADEs were either serious or life-threatening (over 40%), and many in this harm category were found to be preventable (42%). The authors also concluded that the more serious the *ADE*, the more likely it was to have been preventable.

In a Canadian study, Baker and Norton (2004) reviewed overall AEs within hospital admissions. Using a two-stage chart review, the study showed an overall *AE* rate of 7.5 per 100 hospital admissions, with 24% of these attributable to medication and fluid therapies.[15] Overall, greater than 20% were judged to have caused a degree of permanent disability or death, and over 36% were believed to be preventable.

Several ambulatory care studies have been performed. Gurwitz et al (2003)[63] projected greater than 500,000 annual preventable ADEs within U.S. ambulatory care Medicare based on findings from a large ambulatory facility. A 2008 U.S. review of medication errors related to cancer outpatient treatment showed a rate of 7.1% and 18.8% of administered doses compared with ordered medications, in adult and pediatric visits, respectively[150].

For long-term care (nursing homes), Gurwitz et al (2005)[64] projected 800, 000 annual ADEs in all U.S. facilities. A U.K. (Welsh) National Health Services published a summary report which cited *ADE* rates ranging from 8.4 to 25.9% of administered doses.[112] Barker et al (2002) compared the medication error rates of "skilled nursing" facilities to acute care institutions and found that the error rates of administered doses were similar: 14.7% versus 14.4%, respectively.[18]

The U.S. Institute of Medicine (IOM) in its 2007 summary report on preventing medication errors[77] provides an exhaustive review of available studies by various study methods, as well as by stages of the prescription and medication-handling process, and in various healthcare settings. The report states that the collective results probably underestimate the real rates of preventable ADEs and *errors*, and, notably, the related increased healthcare cost implications. The evidence particularly understates the problem in the ambulatory and community care setting. The U.S. IOM report projections are summarized as follows:

- There are about 1.5 million preventable ADEs each year
- Hospital error rates are at least one error per patient day, projected at 380,000 to 450,000 annually
- Long-term care setting projections are 800,000 medication errors annually
- Ambulatory care setting projections are 530,000 annually, for Medicare patients

Canadian-based Adverse Drug Events in hospitalized patients are estimated in the Canadian Baker Norton study[15] at 185,000 AEs (including *ADEs*) annually, with an overall 70,000 AEs potentially preventable.

General conclusions

While further analyses should be attempted to define improved study methods for the determination of preventable *ADE* and medication error rates and associated patient harm, there is also a growing belief that unacceptable error rates have been effectively demonstrated beyond reasonable doubt.[77] Error rates in both international and Canadian care environments are unacceptably high. As a consequence, patients within all healthcare environments are suffering significant harm; and medication errors create an additional understated burden on already constrained financial resources.

Leading healthcare organizations have concluded that the medication systems employed are the primary cause of preventable errors. There is a global call for improvements to systems by the further study and adoption of improved operational methods.

Healthcare senior leadership is urged to undertake strategic system investment and modification, as will be addressed later in this section.[38,48,109]

Causes and Preventability of Medication Errors

Medication treatment plans in all care settings are increasingly complex. Healthcare resources continue to be constrained, while public expectations increase for positive outcomes, personal safety, and healthcare system access. Yet, healthcare providers are asked to deliver exacting care, consistent efficiencies, improved communication and documentation, and, most importantly, unwavering patient care vigilance. The combined impact of these realities is that all healthcare providers, including even families within their own homes, are becoming stretched to cope with the healthcare system's new demands.

Process complexity alone can lead to a decline in successful outcomes, but other factors also negatively contribute. Fatigue is common in different disciplines where continued attention to safety is required. Distractions, workload, noise, stress, and lack of adequate system orientation are all known to contribute to human error. The simple volume of repetitive tasks found within medication processes will dictate that, even in systems of high accuracy, any human will eventually take an action (or inaction) which can have serious consequences.[49,76]

When faced with repetitive tasks in complex demanding environments, all humans are susceptible to losing focus on even simple routine tasks. Even well-educated, well-intentioned providers can fall innocently into error traps, which fall into two broad categories; each capable of causing very serious consequences. (Figure II-3) An error may result from either actions (*errors of commission*) or inactions (*errors of omission*).
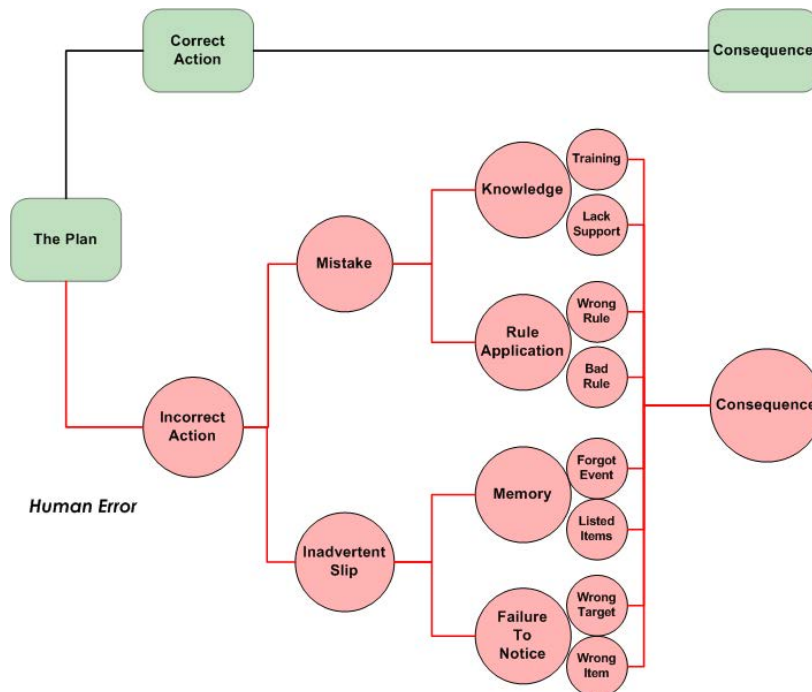
Figure II-3: Correct versus Incorrect Actions

Categories of inadvertent human errors (fallibility) within a broader system were described in paper a by James Reason.[130] For the purposes of this document:

- ‘Slips’ refer to an action that is either forgotten or the action is performed using an incorrect product or on the wrong target. These often involve someone who is distracted by events or thoughts and who is functioning on “auto-pilot”, a pre-learned (memorized) schema.

  Examples include choosing the wrong medication by not reading a label carefully, choosing a wrong patient, or omitting a scheduled dose.

- ‘Mistakes’ refer to an error in execution where a human is generally alert, but consciously chooses the wrong action in the incorrect manner. These often involve the incorrect application, or lack of, knowledge; or may involve information biases related to that knowledge.

  Examples include a calculation mistake, incorrectly setting a pump rate, selecting an incorrect medication, choosing incorrect information to apply to the clinical situation, and, potentially, double-checking a colleague’s work.

When such unintended errors occur in our normal lives the results are often inconsequential, or may sometimes be amusing. However, when healthcare providers are tasked with critical patient safety functions, the same 'slip' or 'mistake' may have more dire patient consequences.

Our chances of re-programming human evolutionary tendencies in a sustained manner are slight. Rather, it is more prudent to develop our future medication systems so that they support healthcare providers in routine and repetitive functions; those activities which are more susceptible to inadvertent human error. In providing support, a system should ideally maximize healthcare provider time for human cognitive and communication functions: those at which humans excel, such as patient assessment, treatment, planning and clinical monitoring, and patient interaction.

As we noted above, the final two steps of Lucian Leape's prescription process relate to the "dispensing" (including compounding) and "dose administration". The 1995 Bates study found almost 50% of the known preventable medication errors occurred at these two stages. They also found the 'system' interception rate of errors from these two steps (presumably based on a human-based double-check system) was only 34% for pharmacy-generated errors, and 2% for dose administration errors. These findings suggest that human vigilance alone is insufficient, and therefore is not a promising strategy on which to solely build future medication system innovation.

In conclusion, routine medication process tasks can be best supported by carefully-planned automated support; reducing the potential for inadvertent human error, while maximizing their opportunity for patient-focused care. Later we will look at the use of bar coding as a form of automated care to mitigate error potential.

The Impact of Failure

When preventable ADEs occur, both patient harm and healthcare system inefficiencies will result, manifesting as loss of timely and efficient human resources, increased reliance on clinical and pharmacy support services, and related medications and materials.

The following sections discuss how the judicious application of principles of standardization within the medication distribution system will assist in avoiding unnecessary wastage of healthcare resources.

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Patient Harm

As noted earlier, a considerable portion of ADEs lead to significant patient harm. Baker and Norton (2004)[15] reported that over 20% of all AEs lead to permanent disability and/or death. If moderate harm is included, with patient recovery in 1 to 12 months, the rate increases to over 32% of all AEs. Bates et al (1995)[20] studies of *ADE*, including 'potential' ADEs, using their definitions of harm, showed that 42% of ADEs were fatal, life-threatening or serious events.

Beyond the obvious harm to the patient, there are many less well recognized sequelae. Families of patients are severely affected and must be considered within the inner circle of unintended harm. These families are left not just with their original cause of concern (admission to care), but now also with new concerns for their loved one's wellbeing, and very probably an increased suspicion of the local healthcare system and its healthcare providers.

A medication error causing a preventable secondary 'iatrogenic' impact should be considered in the same light as a hospital-acquired infection, or any other medical error. Each has the potential for permanent tissue or organ damage. In particular, errors in 'at risk' populations (pediatric, elderly or severely compromised patients) may significantly affect the outcome of the primary admission disorder. And, lastly, permanent damage caused by errors will significantly compromise the quality of life for the patient and may greatly affect the entire family's future in many ways.

Caregiver Harm and Effect on Public Confidence

The Rights of the Second Victim

If the first victims are the patients and their families who are harmed, then the second victims are the caregivers and staff who sustain psychological harm …

~ Charles R. Denham, MD

Medical and medication error causing significant harm should be considered serious and traumatic incidents for staff. In a British Medical Journal article, Dr. A.U. Wu introduced the term, "the second victim" to denote the impact of an error on healthcare providers involved with a medical error.[153] Committed, well-educated healthcare providers will suffer loss of self-confidence, as may their colleagues in them. The involved providers may require expert intervention to cope with the psychological impact wrought by a simple error, much like that required by first-responders or military personnel.[49] Years of exemplary practice may be irrelevant.

Charles Denham (2007) also describes the third victims: the facility reputation and the healthcare system itself.[49] Each time a specific medication error becomes known outside of the facility, public trust declines commensurately. Strained public and/or political trust may affect future strategic direction for individual facilities, governance, as well for the healthcare system overall.

Canadian Case Studies

Publicized Canadian cases illustrate several points related to the value of automated processes in supporting the work of busy healthcare providers.

During a high-risk pharmacy admixture process involving multiple high-alert ingredients, a hospital technician inadvertently selected an incorrect, look-alike bulk electrolyte ingredient. The incorrect product was used to mix a number of bags of solution, which resulted in two fatalities almost immediately.[84] Though human double-checks had been performed during the process, the error was undetected until after the product had been released from pharmacy and serious patient harm had occurred.

This tragic case demonstrates that human errors and patient harm can happen even within institutions with well-planned operations. This centralized pharmacy service was one of high quality. The system, which met and exceeded existing practice standards, relied upon human detection of error performed during the mixing process.

In another Canadian case, an emergency room nurse inadvertently injected an opioid narcotic analgesic that was ten-times the potency of the prescribed narcotic, leading to the death of the patient. The offending ampoule resembled another product in the storage location, and the medication administered in error was similar to the prescribed medication in therapeutic category, drug name, and general appearance.

In both these cases, the institutions and the healthcare system in general were held accountable by the public and press. They questioned how such devastating errors could be made despite previous system improvements and prior knowledge of system error potential. The cases show the potential of a healthcare provider to make an unintended *slip*, with serious consequences.

In the first case, bar coding verification used with automated (standardized) recipes during compounding would force verification of ingredients. Automated compounding systems using standard or non-standard recipes can be employed which:

- Validates correct ingredients
- Ensures the correct ingredients are on the correct pump line and spike
- Confirms ingredient volumes infused into the product (mixture) bag

In the second case, the use of bar coding medication administration (BCMA) software would verify the medication selected by the nurse (or other caregiver) against the computerized prescription order, thus assuring correct medication was selected. Evidence of BCMA effectiveness will be discussed below. Such systems can, if programmed by the centre, provide important patient allergy, clinical monitoring requirements, and document the process.

The cases provided here relate to incorrect medications being selected. There are as many as 2,500 to 3,000 medication products on the shelves of most acute care hospital pharmacies, and ten-fold more available on the Canadian market. In retail environments the number is also high. It is not possible to clearly differentiate all marketed products visually, though considerable effort has been made by some pharmaceutical manufacturers since the above-mentioned cases; such as using distinctive visual clues using colour or text variation on labels, and/or, occasionally, tactile methods. Yet, errors continue to occur when systems rely on human visual differentiation alone.

ADE Costs in Community and Institutional Settings

Institutional Costs

Most cost studies on the cost impact of preventable ADEs have been conducted within hospitals silos, and are now somewhat dated. Like medication error rate assessments, the scope and methodologies vary. Published studies principally limit the effect of AEs or ADEs on patient LOS. Yet, additional flow-through inefficiencies occur in the form of extended and more complex patient, 'recovery' care plans, additional clinical monitoring, and possible follow-up discharge care. Few studies have been conducted on the broader healthcare system impact.

The 2004 Baker Norton study on Adverse Events in hospitals demonstrated an increased LOS which varied by the size of the institutions, showing a mean increase of 3.6, 7.7 and 6.2 days in large, small and teaching hospitals, respectively.[15] A cost assessment study by Bates in 2007 calculated an adjusted U.S. cost per preventable *ADE* of $5857 due to prolonged *LOS* (4.6 days), based on 1993 cost data (USD)[21], which has been updated to an estimated $8000 (2007 USD) using inflationary factors.[78]

In a 2001 US study, institutional costs associated with preventable community *ADE*-related emergency room (ER) visits were estimated at $10,375 (2001 USD) per event[157]. Lower costs were previously reported: a 1999 study estimated $1444 per *ER* event; a 1996 study showed $2752 per *ER* event for patients admitted for follow-up care[158] and $308 for non-admitted *ER* patients.[159] Again, these costs reports are thought to be conservative assessments of the real costs to the entire healthcare system.

Community and Ambulatory Error Rates and Costs

While acute care costs studies are more prevalent, a few studies have reported on both the *ADE* rate and costs for non-acute care settings. Rarely, however, have studies investigated the cost impact of under or over-utilization of prescribed medication; which represents a form of preventable medications error causing costs, and which could be improved by system innovation.

As noted earlier, Gurwitz, et al (2005)[64] estimated 800, 000 ADEs (U.S. data) for nursing home patients, but the report did not estimate a fiscal impact. The U.K. (Welsh) National Health Services published a summary report which cites *ADE* rates ranging from 8.4 to 25.9% of administered doses, again however these did not estimate associated medication error costs.[112]

Ambulatory care studies by Gurwitz, et al (2003)[63] projected greater than 500,000 ADEs annually occur in Medicare clinics for older patients, while Field et al (2005) estimated the cost per preventable ambulatory care *ADE* event at $1983 for adults greater than 65 years of age.[160].

The Healthcare System Cost Continuum and Patient Access Time

The broader healthcare system costs of preventable error to the healthcare system, families, and general society are far greater than currently acknowledged, whether from institutional or community-based errors. The 2007 Institute of Medicine report on medication error prevention[77] states the related *ADE* costs cited by most studies are very conservative and incompletely reported.

Calculated human resource and economic losses should also include time associated with related documentation and follow-up, patient or family wage losses, ambulatory, community or emergency room costs, travel costs, school interruption and/or general family expenses. Even more rarely considered are costs resulting either from legal actions or increased facility or group insurance premiums.

Significant improvement to our healthcare system's throughput could be gained through a collaborative approach to reducing ADEs resulting from preventable medication error. Broader collaboration is needed to better assess the impact of preventable errors on patient access to an overcrowded Canadian healthcare system, and its various support services. Current patient access delays for clinically-necessary interventions, such as hospital admissions, surgeries, emergency room waits, clinic appointments, and laboratory requisitions, can be partially attributed to system crowding resulting from preventable errors. [156-159]

Lastly, inaccuracies in health record documentation can also cause of inefficiency, resulting in duplication of assessment, treatment, and additional service expenditures. Accurate documentation (i.e., data capture) from an automated identification system in an information feeder system, ensures more transmittable standardized information. Standardized information can be better shared between care providers and thereby contribute to system efficiencies, and ultimately to the public goal of provincial and national electronic patient health records.

Silos of Care

Unfortunately, the historical primary focus on hospital-based cost implications may continue to skew our understanding of true and varied impacts of preventable ADEs on our interdependent Canadian healthcare system. In-patient facilities almost solely focus on their internal operational silo, and only for the duration of a patient's admission, as consequence of their independent budgetary structure. It follows that safety investment strategies are usually also aligned solely within their specific facility, or regional facility network.

Similarly, community care agencies may only plan for their own internal care operations. This silo of care usually involves only the needs of clients, and the capabilities of their specific contracted pharmacy provider. Their medication system's inadvertent impact on other points along the healthcare continuum may be ignored.

Increasingly, institutions, ambulatory and community-based care facilities need to include the secondary impact of their systems on the entire healthcare systems, both in terms of real cost avoidances and system inefficiencies. Governments and healthcare organizations, in turn, should also acknowledge broader healthcare impacts when supporting *Automated Identification and Data Capture* (*AIDC*) investments. *AIDC* methods can have a significant positive impact on the entire healthcare system costs and efficiencies by error reduction, and fully support the concepts of interoperable patient electronic health record systems.

Finally, the impact an individual's home-based medication management on the healthcare system unknown; particularly that of the elderly patient. There is potentially much benefit to be obtained by employing an *AIDC* approach to medication error reduction and accurate documentation within this very large component of our society. This is not a segment of the healthcare system we should ignore in our automation planning.

Designing Out Errors

High Reliability Organizations

> **Canadian Institute for Health Information: System Performance is the Real Problem**
>
> *If we wish to reach a standard of performance quality that prevails in other industries there will be a need to transform the healthcare system from a "cottage industry" to one in which quality is taken seriously.*
>
> *~ Dr. John Millar, Vice-President (2000)*

Bar code verification, as with other technical innovations, will assist an organization in its journey toward improved quality and reliability. Several attributes of automated identification and documentation are consistent with the ideals of h*igh reliability organizations* (*HROs*). [163, 164, 166]

High reliability organizations are found in several high risk industries, often as a result of a need to ensure public safety from significant internal system failures. Such industries include nuclear, aeronautics and chemical operations, and each have records of non-failure that are both impressive and necessary. *HROs* exhibit consistent characteristics in that they attempt to avoid catastrophic events by adopting advanced safety strategies despite having a high number of system outputs (i.e., transactions), each with a potentially devastating outcome should an event occur. They integrate an unusually high level of safety culture and standardization, safety assessments, and adoption of error-impact mitigating strategies.

HROs have been described as closely adhering to five key principles; leading to excellence.[180, 181] Aspects of these permeate *Section III* discussions (Implementation Considerations).

1. ***A preoccupation with failure.***
   Successful HROs track small changes in their results and, when found, are viewed as opportunities for learning, not indications of unwanted worker compliance or system failures. Rather, they demonstrate additional insight into a functioning system, allowing the system to be modified to reduce the potential or similar events.

   Surveillance incorporates many forms of event exposure, from staff to leadership contributions, to more formal system analysis and audits. Each time, the pros and cons of causes and solutions are reviewed, as well as the potential implications of such a failure.

2. ***A reluctance to simplify.***
   Though simplification of processes where it does not affect quality is generally a positive step, an HRO will not rush to simple solutions for potentially complex problems. Instead, an HRO will go out of its way to investigate a potential failure in great depth, complicating the assessment by bringing

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different views, interpretations and resources. The end solution may or may not be simple, but the assessment is not.

An example of this HRO principle can be seen in Section III, when *usability testing* is undertaken and complex clinical testing simulations are devised by knowledgeable healthcare providers along with experts in human factors. The testing will deliberately challenge the system to discover hidden potential failure modes. Similarly, RCA processes will often increasingly add layers of factors for investigation, to uncover the relationships between factors within the event being studied.

3. *A keen sensitivity for operations.*
   HROs, like any progressive organization have long term strategic goals. They do not, however, lose sight of the detailed operations that are ongoing today. Many HRO managers will assure that frontline colleagues are educated to scrutinize operations, and managers will assure that they are close touch with both the operations and the staff who work in the operational field. HRO managers do not rely from a distance on paper reports or committee discussions. Rather, they are often found talking directly to, or observing, detailed functions of the system; either discussing past system failures (or near failures), and attempting to identify latent system failure modes.

   HROs are open to modification of a systems functionality, without compromising their long-term objectives.

   In Section III again, we spend time discussing how there must be planned and persistent follow-up with staff who use a medication bar coding system. Individual and small group pre and post implementation discussions are vital on a number of levels, but keep their eye on the eventual integration of the system into daily practices, and further system enhancements.

4. *Maintaining a strong commitment to resilience.*
   HRO organizations plan for unexpected responses or outcomes from their systems, yet do not allow these often rare events to derail their ability to adapt, solve the issue, and continue operations. Because the events may rarely happen, or may manifest itself in unique ways, HROs teach their staff to be aware of such events and, if one should occur, to develop and adaptive approach to solve the issue, albeit within standardized processes for evaluating actions and problem-solving. In other words, they allow for resilient operations in cases of unexpected events.

   HROs are often organizations whose output is depended upon by many others, so they will develop contingencies pre-designed to shunt operations to other operational processes. In the case of bar coding, patient medication therapy must be maintained. Communication between sectors within an institution's system is required when an event occurs and, under some circumstances the problem can be solved within the system itself. If necessary, pre-determined manual by-pass systems, such as delayed or manual medication records, can be employed until the situation is resolve. Section III speaks of developing systems to communicate unexpected situations, and to plan for system contingencies.

5. *A deference to different levels of expertise.*

    An HRO recognized the value of expertise from different levels of and organization. They do not rely solely on a single person, and certainly do not allow a structure wherein one level near the top of a hierarchal organization is presumed to be the most knowledgeable. Rather, HRO will seek the advice from the level of the system that best understands the situation, potential system options, and consequences, and is often below the level of management. This does not mean, however, that decisions are made by one person alone, unless it is to stop operations when extremely unsafe situations are found and serious harm is imminent. Decision-making is adapted to the type of problem that is found.

    For such a multi-layered system of experts to function, an organization needs to have in place levels of communication and trust, and education, that promote a common welfare and understanding of roles amongst the levels of the system. Such an understanding can only be achieved in advance of system implementation, and must form part of the pre-implementation planning and education, as is reviewed in Section III.

> *Managing the Unexpected …*
> *As a collective whole, we [have] concentrated on what we expected to see happening, instead of paying attention to the many small and sometimes counterintuitive surprising observations that would have allowed different conclusions and decisions to arise.*
> *~ Dr. Annette Gebaier. ICL Berlin*

An organization's adherence to HRO principles can often be shown through its operational practices, many of which can into group into categories [3, 93], such as:

- **Containment of Unexpected Results**
    - Refer to expertise at different levels of the system
    - Redundancy of systems through back-up systems
    - Cross-checking between results/audits to expose system flaws
    - Staff training in well-defined roles and procedures, including self evaluation of systems
- **Problem Anticipation**
    - Pre-occupation with failure, including system audits and follow-up on implemented changes.
    - Reluctance to simplify interpretations of process failures
    - System simulation testing
    - Sensitivity to operations and its potential problems
    - Documented procedures
- **Learning Orientation**
    - Open communication between levels of an organization
    - Teaching team members to be observant for even small unexpected system events
    - Teaching the use of Root Cause Analysis of incidents
    - Continuous operational training

- **Just Safety Culture**
    - Encourage internal reporting
    - Open discussion of errors and solutions
    - Abandonment of work upon safety grounds, when necessary
- **Definition of Processes**
    - Tight coupling between people, equipment and processes
    - Thorough analyses of systems, including assessing the interactive complexity among system components
- **Mindful Leadership**
    - Proactive leadership supporting HRO principles
    - Investment of resources to support system evaluation
    - Balance between safety and production costs
    - Engagement with front-line staff

Healthcare is generally a high risk industry organized into discrete, yet interdependent, components. Each component has a varying degree of complexity and risk, and possesses several *HRO* public risk characteristics[16]. The entire healthcare system needs to consider *HRO* safety practices to knit together component parts and, thereby, decrease the overall system.

At times procedural variation is necessary to meet individual and sometimes unique client needs, making *HRO* aspirations challenging in some aspects of healthcare. There are, however, many common processes where reduced variability should be considered. Yet, in such processes we are daily witness to unnecessary variation in individuals' procedures. This includes most medication processes. An increased application of the above-noted *HRO* principles in routine medication practices will result in sustained patient risk reduction.

Reducing Human Practice Variability for Routine Tasks

Some key system obstacles have become operational barriers to improvement within healthcare[4] and, therefore, a goal of becoming an *HRO*. In routine medication tasks, selected human practices should be reviewed in an effort to identify and reduce unnecessary variability.

Using *HRO* principles, recommended reviews should look at:
- Limiting a person's ability to set individual performance limits.
- To the extent possible, limiting personal autonomy by promoting system-orientated procedures, while not limiting individual or collective input into system design.
- Simplification and standardizing of processes where possible, so that system risks and variation from normal procedure become more noticeable.
- Expanding audit reviews of hazards, thus allowing problem resolution and safety development strategies using expert intervention.
- Involvement of senior leadership to optimize safety strategies

Several of these obstacles support the adoption of standardized practices, including medication bar code verification and related documentation.

Different approaches to system safety modifications have varying probability of success. Those modifications that continue to rely fully on individual sustained human vigilance or procedural compliance will have a lower probability of success. Figure II-4 shows possible approaches to system change, indicating that automated or forced functions will have improved chances of success, and certainly meet many of the *HRO* objectives of standardized practices.

System Modification Approaches:

In rank order of effectiveness ….

1. Forced function
2. Automation, computerization
3. Protocols and pre-printed orders
4. Checklists
5. Rules and double-checking
6. Education
7. Information

Human

Figure II-4: Approaches to System Modification

Automated Identification:
Evidence of Effectiveness in Error Reduction

The Safety Evidence Dilemma

> ***Tracking Progress in Patient Safety***
>
> *If a hospital's reported incidents per 1000 discharges decreased from 100 last year to 70 this year, is that hospital safer?*
>
> *~ P.J. Pronovost MD, et al*
> *JAMA 2006; 296(6); 696-699*

We earlier touched on the issue of healthcare study methodologies. We noted that researchers seek more reproducible methods for determining preventable medication error rates and harm, comparing both before and after a system change.

It has been argued that, without additional evidence, it may be difficult for senior leadership to support strategic decisions on system reform, including committing the operational and financial costs necessary.[14, 36] Notwithstanding the bar coding and system reform recommendations of major organizations (below) and the *HRO* concepts of standardization of process, the appearance of a lack of ideal evidence data creates a dilemma for healthcare decision-makers:

> *In the absence of ideal safety and cost-return evidence of bar coding, at what point, should we make system investment decisions?*
>
> *If we delay our acquisition decision, we place patients at continued risk and we underuse a technology that may be effective. However, if we evaluate further, we may discover the intervention is less effective than expected.*

In theory, to satisfactorily answer the evidence dilemma, additional studies with improved methodologies would needed to validate the effect of bar coding on error rates. But, creating this methodological ideal will not be easily achieved.

The creation of reliable research data sets to fully evaluate evidence in theory would be required within each individual hospital or community care facility: a major research investment.[128] For example, an organization would need to establish expensive 'observational' research activities to accurately measure and compare 'pre' and 'post' medication error rates. The proposed system technology would need to be acquired and implemented at a significant cost, to achieve 'pre' and 'post' comparisons. And, finally, to ensure relevancy of the findings across varied patient care settings, a study design would need to assess multiple arms of patient care to ensure applicability of results to specialized areas of practice.

Instead, it is now accepted in health informatics literature that smaller clinical assessments using pre/post assessments, plus evaluations using local interviews and focus groups, *usability testing*, and clinical simulations can be effective in evaluating system usefulness. Qualitative assessments are more less-expensively employed.

Reasonable, if limited, evidence therefore now exists. Selected studies have utilized observational methods to determine medication error rate and have also compared rates before and after system implementation and are discussed later.

Functionality and Findings of Bar Code Verification Systems

Evidence of Effectiveness

Historically, important medication system modifications have been successfully implemented with 'limited' evidence of patient harm reduction; the same level as now exists for bar coding verification[77]. These include:

- Unit-dosed, patient-specific dispensing,
- Prescribing rule and abbreviations,
- Look-alike sound-alike (LASA) strategies,
- Storage of concentrated solutions of hazardous medications, and
- Standardizing and limiting drug concentrations available within an organization.

Practice targets for automated identification often include reference to the "Five Rights" (right patient, right medication, right dose, right time, right route), and some include two more targets to make "Seven Rights", adding "right documentation, and right reason". Evidence of improvements in routine verifications and documentation is important.

Appendix II-2 summarizes results of specific studies shown to have a positive impact on patient medication safety. Most studies have shown a significant reduction in medication error rates; though it should be noted one or two studies have shown small increases in error rates most probably from "dose timing" error types.

Appendix II-3 summarizes the findings of three literature reviews of studies: the U.S. Institute of Medicine (2007)[77], the Canadian Agency for Drugs and Technologies[30], and the U.S. Agency for Healthcare Research and Quality[2]. It outlines general impressions of the evidence, knowledge and gaps, and qualitative issues.

These Appendices demonstrate that medication bar code verification processes are effective at reducing preventable error, in both pharmacy-related processes and at the point of bedside dose administration.

Specific safety strategies should target the different prescription steps in the 4-step Leape prescription process and the medication product chain, described earlier. Bar code medication verification and documentation impacts predominantly the stock transfer, pharmacy compounding and dispensing, and dose administration

steps. It would have no or limited effect on prescribing and prescription verification/translation steps, where *computerized prescriber order entry* (*CPOE*) or standardized order sets would logically have a greater impact.

The sections which follow describe bar code verification application more detail.

Where Medication Bar Coding Can Be Used

Bar code verification will have application on the following routine medication processes:
- Inventory acquisition, monitoring, and stock movement
- Compounding of mixtures (especially high alert bulk mixtures)
- Dispensing
- Transfer of stock to patient care areas
- Patient care stock selection
- Patient and dose verification at the bedside

Support software applications aligned with the above basic bar coding module functions would provide additional important direct and indirect patient safety features, such as:

- Health Record documentation
- Clinical monitoring reminders
- Drug and laboratory warnings (i.e., Clinical Decision Support)
- Forced patient allergy checks
- Assisted pump programming with *Smart Pumps*
- Health Canada black box warnings
- Instant access to clinical drug information or patient education material
- Incident reporting of various types

The *Canadian Pharmaceutical Bar Coding Project*, in its 2012 *Joint Technical Statement,* developed a *Minimum Software Safety Functionality checklist* (*Supplement B*). The reader is directed to this downloadable document for detailed recommendations related to assessments of new medication automated system functionality along the medication chain and prescription pathway. Click on document image to access and download.

The following descriptions of medication bar code verification apply equally in community and institutional pharmacy and nursing practices. Similarities between practice objectives and methods continue to grow between these two care environments, despite somewhat varied patient acuity.

Safe medication practices require that the various stages of the overall medication process can function and communicate using the bar codes that are selected. In other words, the bar codes chosen for a given medication

must work equally for pharmacy inventory functions, compounding and dispensing, as well as for nurse functions at the point of care. Therefore, coherent bar code strategies for both commercial and patient-specific (in-house) medication bar codes are necessary.

Pharmacy dispensing and inventory operations

Based on limited cited studies, bar coding reduces pharmacy dispensing error rates by greater than 80% (range 85-96%) for "targeted medication" dispensing events involving those medications which allow bar code functionality to be employed. Bar code verification and documentation would have particular application during the filling (or refilling) of patient prescriptions from previously re-packaged and labelled unit-dose, blister packs, or directly from commercial packaging.

The bar codes must also integrate with the local inventory activities such as purchasing and restocking, thereby providing both safety and additional advantages such as increased inventory turns, reduced stock outages and wastage.

As noted, bar codes employed within pharmacy-based functions must seamlessly integrate with crucial medication verification steps at the patient care level, such as bedside dose administration verification.

Parenteral and high risk compounding

Bar code verification systems has been widely integrated into the automation used by pharmacies employed in parenteral nutrition compounding, as well as during intravenous solution compounding. In the U.S. especially, many batched large volume (500-1000 mL) and small volume (25-250mL) IV bags are now filled using ingredient verification, and bar code bag labelling.

Additional work is required by major software providers within pharmacy compounding processes. Pharmacy considering new or upgraded software systems should discuss these needs with their vendors. Bar code verification and calculation modules for standardized recipes should be available as part of basic pharmacy information systems. Such software modules should force automated ingredient checks and quality documentation against pre-programmed recipes. They should also incorporate automated calculations for ingredients when non-standard amounts (volumes) are compounded. Such software would be especially useful for retail or institutional pharmacies that participate in central IV admixture (CIVA) services, but cannot afford fully automated admixture robotics.

Stock transfer functions

Bar code verification also exists within *Automated Dispensing Cabinet* (*ADCs*) systems, often as an "add-on" function for stocking these units. These should be utilized at all times for stock replenishment to avoid potentially catastrophic errors involving high risk look-alike medications. Vendors who sell *ADCs* should provide this functionality as a part of their base functionality.

Additional work is required by retail and institutional *Information System* software providers to integrate bar code verification re-stocking functions; for use in nursing homes and those hospital locations <u>not</u> serviced by automated drug cabinets.

Patient care area operations

Bedside Dose Verification

Well-designed studies have shown reductions of approximately 50% in preventable medication errors at this important stage of the prescription process, usually with accompanied reduction in dose time errors. When aligned with an electronic health record (medication administration record), an improvement in documentation accuracy and dose scheduling has been widely observed.

We see no reason that the practice improvements obtained from the study of institutional practice should not be transferrable to community care settings. Nursing homes would need to work in concert with their contracted pharmacy provider to align the bar codes utilized on patient doses, and the software used within the nursing home.

As bar code verification practices represent a significant change in dose administration practices for nurses and their colleagues, system implementation processes should monitor aligned aspects of their practices to ensure there is no, or limited, impact on other aspects of patient care or staff compliance. (See Section III of this report.)

Operating Room Drug Verification

Operating Rooms are also now increasingly using bar coding to assist practitioners in identifying and documenting many high-alert medications used during surgery, usually by an Anaesthesiologist. Later in this document a case study is provided of this use at the University Health Network site in Toronto.

Smart Pump Programming

Smart Pumps are a recent important advancement which supports the nursing practice of safe administration of parenteral medications.   They utilize drug libraries and user-assisted infusion rate programming to reduce the risk of high alert medication errors in several ways. Firstly, these pumps promote the use of standardized IV/spinal concentrations and infusion rate checks. This is achieved by the nurse scanning a bag (or syringe) label's bar code, which automatically selects the correct drug and concentration from the on-board drug library. The pump then verifies the infusion rate input by the nurse falls within a safe dosage range. Secondly, when coupled with a printed or electronic *Medication Administration Record*, the patient can be verified using a patient bar code, ideally followed by electronic patient health record documentation (for those pump systems integrated with the electronic health record).

It is essential that *Smart Pump* providers increasingly ensure their pump systems integrate seamlessly with an organization's chosen *health information system's* (*HIS*) medication and its patient health record modules.   The same bar code used for the aforementioned pump programming and patient verification must seamlessly integrate with the electronic *HIS*

record, providing <u>full</u> safety and documentation functionality, including any secondary features such as alert warnings and reminders from the *HIS*.[191] *Smart Pump* system providers must also ensure their bar code reader system recognizes the bar codes found on all dose units from an pharmacy's *CIVA* program (patient-specific doses) or from commercially available products (e.g., IV fluid bags or pre-filled syringes).

Finally, it is important that the *Smart Pump* automated system not require care providers duplicate scanning or documentation efforts by the nurse. Further, the system must not require multiple bar codes to be placed on patient-specific doses or commercial products, but rather must be adaptable to the facility's base medication software system's use of medication bar codes.

The Strategic Planning Imperative

The Importance of Leadership

> ***Green Light Issues …***
>
> *Adverse events have predictable economic consequences. Knowledge about adverse events in medication management, information transfer, infections, and leadership failure is exploding.*
>
> *~ Charles Denham MD*
>   *J Patient Saf. 2010; 6(1); 52-56.*

Decision-makers must weigh the need to improve medication management systems against myriad competing resource demands. While it is difficult to determine which clinical, diagnostic or other system improvement strategies to pursue, focus will remain on the impact of known avoidable system failings, such as medication errors.

In a March 2010 article, Charles Denham investigated the strategic advantages of investing in patient safety; especially in those areas where harm and its impact on system efficiency are known.[47] He particularly cites the increasing role of financial executives in determining key areas of system improvements. In the U.S., funding agencies are beginning to look relatively less at metrics related to increased activity volumes, such as admissions, overall patient days, or service activities. They are now increasing their performance focus on their payments for events resulting from preventable system failures.

On the radar of funding agencies and insurance payers are costs for preventable adverse events, also known as Hospital Acquired Conditions (HAC).[47, 48] Included are harm and costs arising from hospital-acquired infections, re-admissions, and many ADEs. Pay-for-performance metrics may soon influence where a patient is sent for care; thus benefiting the revenue streams of institutions with superior clinical and preventable *Adverse Event* outcomes. One may also reasonably envision the increased use of 'default options' applying to patient admissions, whereby patients are automatically diverted to designated care and practice streams known to be in the best overall public interest.[47,65]

The per diem funding of Canadian healthcare organizations is not presently comparable to U.S. models or funding drivers. However, it is perhaps not unreasonable to foresee healthcare budgetary rationalization, or institutional or executive performance measurement, linked to similar assessments of overall clinical outcomes, including the avoidance of preventable HACs.[166] Historical service cost-cutting methods, or avoidance of innovative protective systems shown to prevent harm, may no longer be prudent strategic business decisions.

Arguably, the movement in Canada may have begun. The Province of Ontario has enacted its "*Excellent Care for All Act*", linking patient safety, patient access and quality to "accountability agreements" with facility and to executive performance. In addition, the Ontario Hospital Association has made available a benchmarking

model for the adoption of electronic medical records by member hospitals, which includes the adoption of key technologies, such as eMAR, CPOE and BCMA.
http://www.oha.com/CurrentIssues/keyinitiatives/eHealth/Pages/GaugeyourHospitalseHealth.aspx

In addition to an organization's senior executives, the roles of the Quality and Safety Lead and the Chief of Information Officer (CIO) are also important.[47,48,109] Communication between these offices is essential to fully formulate prudent, forward-looking strategies. In particular, the CIO is responsible for the overall *HIS* strategic plan, usually implemented as a coordinated multi-year project.

Should the CIO not have a comprehensive knowledge of harm reduction systems, as well as their key role in improved information transfer (documentation) methods, opportunities for integrating essential modules into the overall *health information system (HIS)* strategic plan may be missed. Importantly, medication bar coding modules at the bedside and within critical pharmacy operations have a relatively small impact on the overall *HIS* cost, yet their absences may have significant impact on the overall organizational cost, performance metrics, and the facility's public and governance reputation. Their absences may well also adversely affect future staff recruitment of highly skilled healthcare providers in a competitive job market.

> *It is particularly important that the CFO and CIO work closely with Nursing and Pharmacy practice leadership to understand the safety effectiveness and secondary financial benefits of medication bar coding systems so that effective strategic plans can be made.*

The pervasiveness of medications as a treatment modality and their attendant complexities and costs should be seen as administrators as both an opportunity for, and a risk to, sustainable operational and financial security.

> ***Financial Risk …***
> *The greater risk to finance teams is to be timid, not embrace safety as an opportunity to improve care while improving the financial strength because inaction will be visible, embarrassing, and painful to them.*
> *- Charles Denham MD*
> *J Patient Saf. 2010; 6(1):52-56.*

The Importance of Conformity

As we noted, one of the five hallmark traits of *HROs* is service provider consistency and compliance with approved practices. While it is imperative that the collective Executive leadership adopt effective acquisition strategies for medication risk mitigation in heath *HROs*, it is also a requirement that healthcare provider conformity to approved system methods and institutional policies is ensured. Providers must be fully supported in their daily practices by the systems that promote such conformity. The systems must be intuitive to healthcare providers and support, not interfere with their practices, while simultaneously averting most

technology-related secondary errors.[4,16,88,107] Section III of this report will outline some issues related to staff adoption and conformity.

The Importance of Vendor Flexibility

We noted above the need for healthcare provider conformity, on the basic functionality of any medication system. It follows that institutions should adapt its practices to the degree reasonably appropriate to the HIS Technology Provider's (Vendor) software module.

However, it is also essential that a selected *HIS* technology provider also conform to key specialized functionality required by an institution to ensure successful clinical outcomes. Truly critical organizational practices should not be compromised by inappropriately modified or unduly simplified vendor software. In critical instances, software should be customized or have an intrinsic ability to be tailored (by internal settings) to the required critical aspects of specialized care. Failure to do recognize truly specialized needs, and to adapt the acquired system functionality to these needs, will result in non-compliance by providers of care and/or possible risk to the patient. The balance between critical specialized organizational practices and simple provider non-compliance with basic medication practices must be fully discussed during implementation with the various clinical teams.

Prior to acquisition, Technology Providers (Vendors) should be required to review their system functionality in detail, perhaps starting with the basic safety functionality outlined in the aforementioned *Supplement B* of the *Joint Technical Statement*. Vendor bar coding functionality should extend to each link of the prescription and medication product chains in a seamless process.

Assessing the performance of a vendor's software with respect to safety functionality, staff education needs and compliance is a must. The importance of a thorough validation of the system with advanced staff input and communication, and follow-up, cannot be understated.[47,88] Finding methods of making the chosen vendor a legitimate business partner in risk outcomes and healthcare provider support and compliance within an organization is ideal.

In summary, in this section arguments have been provided that delayed executive action on known issues of preventable patient harm may result in future poor organization safety and quality performance metrics.[164] Lack of support for staff needs, coupled with evidence of non-conforming medication system practices, are indicators of organizational or implementation failure. The future holds the prospect of increased scrutiny of an organization's ability to function as an *HRO* whilst supporting healthcare provider needs, all in an efforts to minimize public harm, reduce cost wastage, and maximized system efficiency.

Implementation Penetration of Bar Code Verification Practices

Currently, approximately 50% of U.S. acute care facilities report operational bar code assisted medication administration (*BCMA*) systems, and 34% report partial or full pharmacy dispensed dose verification (ASHP Survey: 2011).[12] Of the 78 hospital respondents in Canada, only 6% report scanning patients' ID at the bedside (all hospital types), 8% are using bar codes to verify medication selection and 33% report partial or full dose verification prior to pharmacy dispensing (Hospital Pharmacy in Canada Report: 2009/10).[55]

There is sparse assessment of *BCMA* uptake within community practices. Though many retail pharmacies utilize bar codes for point-of-sale and inventory operations, it is unclear how many are utilizing bar codes for either pharmacy dispensing accuracy verification (against a computerized prescription record), or bedside *BCMA* within nursing homes or other similar community practice environments using a pharmacy-generated (or commercial) bar coded label.

The Value of Medication Bar Code Verification Systems

We have addressed the need of healthcare leadership to balance risks: the risk associated with continuing human-based medication systems with known safety issues against the risk of redirecting scarce resources away other operational priorities.

It is understandable for leadership to desire conclusive cost-return evidence prior to determining its best course of action. Indeed, some opinion-based articles have taken the position that further study is necessary.[14] Some literature reviews of bar code economic impact studies state that they do not collectively form a base of conclusive value/cost evidence, despite often describing safety, qualitative or process improvements to medication systems.[2]

On the other hand, we possess good knowledge of *components* of the medication error problem argument; such as preventable error rates and their effect on patient harm and costs. We also have reasonable indications of the positive impact of bar code verification systems, including secondary system benefits such as qualitative medication process improvement and documentation. Taken together, these may lead to reasonable assumptions about harm reduction and operational efficiencies.

Importantly, it is important to note that medication bar code verification modules form only a part of a larger *HIS* plan and costs. *Medication Management Information Technology* (*MMIT*) modules, and bar coding modules specifically, represents a relatively smaller incremental financial outlay, especially when compared to *CPOE* implementation costs.

This section outlines aspects of operational costs which will be affected by the introduction of bar code medication verification systems in both community and hospital practices.

Hard versus Soft Cost Benefits

Bar code medication verification systems can be considered to have both direct (hard cost) and indirect (soft cost) advantages. These benefits may be 'reinvested' in the healthcare system, leading to increased time for caregiver/patient interaction, reduced system wastage, and, by extension, increased patient access to clogged healthcare resources. It is unlikely that the resultant efficiencies would manifest themselves as simple budgetary savings.

> Direct cost enhancements include:
> - Reduced patient days in hospitals and care costs.

- Reduced inventory carrying costs and wastage, as appropriate for care.
- Reduced liability premiums.

Indirect cost enhancements include:
- Reduced follow-up monitoring costs (laboratory, ambulatory or community visits).
- Reduced harm-associated drug and support costs.
- Increase throughput (e.g., reduced waiting times) through hospitals, clinics, and ancillary services.
- Probable additional care-giver time for direct patient care activities.[54]
- Probable reduced ER admissions from outside care agencies.[156]
- Improved provider compliance and reporting.
- Improved Electronic Health Record accuracy and availability.

One particularly interesting growing value of bar code-assisted verification is its contribution to improved documentation of the healthcare process and, in turn, the value of the resultant increased physician access to a higher quality, organized patient health record. Schiff and Bates wrote on the issue, concluding that a re-designed EHR documentation process will improve physician diagnosis and patient care assessment greatly. [174]

Schiff and Bates note a significant portion of physician's time is spent assessment a patient's response to previously prescribed care. Both the care events and the patient's clinical response must be clearly documented to allow for timely and appropriate diagnosis, assessment and revisions to care. A properly designed EHR will allow improved access to key patient information for physicians and other prescribers. Schiff and Bates suggest that a documentation process (including BCMA) should allow:
- Readily available organized patient care findings, capable of user filtering requests.
- Entry of both automated data capture and free text notes.
- Facilitate the evolution of care, as treatment progresses.
- Patient "problem lists", as an annotated sortable list of current issues to resolve, including actions taken on each item.
- Ordering and integration patient exams, tests and results, including the high-lighting of critical tests or abnormal results, linking to patient clinical responses, and the current problem list.
- Automated findings with possible diagnoses or follow-up actions, to assist practitioners in considering diagnostic or treatment options.

The contribution of an automated bar coded medication process will be integral to a achieving an innovative, accessible, accurate and integrated EHR, leading to improved practitioner diagnosis and treatment decisions.

Return-on-Investment Studies

ROI studies are few in number and suffer from methodology challenges similar to those found in many of the medication error rate studies. These include:

- Determining the precise number of preventable ADEs that would be negated by bar code verification.
- Quantitative measurements of reduced, serious patient harm.
- Consistent definitions of study terms and assessment criteria.
- Assessment of direct (hard cost) and indirect (soft cost) advantages, both within an organization and beyond, including reduced liability costs.

It is not possible to conclusively state a probable *Return-on-Investment* (*ROI*) on hard cost economic grounds alone, but a growing number of reviews are being published.[2,36,147,183] Few *MMIT* studies have attempted a full economic evaluation. Those that have indicate a positive cost return, relative to five-year system implementation and maintenance costs. It has been estimated that the *CPOE ROI* timelines will be considerably longer than those for *BCMA* or Pharmacy-based bar code system *ROIs*.[140, 27]

Three *MMIT* articles relating to economic issues are cited here. Other commercial organizations with possible vested interest have also described *ROI* issues related to bar coding and *CPOE*.[27, 155]

- **Brigham and Women's Hospital (2007)[97]**
  The hospital demonstrated the ROI of a pharmacy-based bar code system by comparing before and after errors.
  o Five (5) year full costs recovered by one year after full implementation.
  o Worst case model showed a *ROI* within 4-5 years.
  o Full net five-year benefit of $3.5 million. Based on Bates et al and Leape et al 1995 study rates. Adjusted for inflation and preventability and probability of harm ADEs.

- **The University of Wisconsin Hospital and Clinics (UWHC)[140]**
  UWHC compared the relative costs of a bar code medication administration (*BCMA*) system and a *computerized prescriber order entry* (*CPOE*) system at their site. They state:
  o Pre and post implementation: 87% reduction in medication administration errors, including timing errors, on pilot unit.
  o Relative *CPOE* and *BCMA* costs, based on HIMSS 2006 information
    ▪ Initial costs $8 million versus $0.4-2 million
    ▪ Time to Implement: 1-4 years versus 4-6 months
  o Calculated *ADE* savings using UWCH model: Annual savings of $1.3 million

- **Report on *CPOE Return on Investment* estimates, based on the Leapfrog Quality and Safety Group Recommendations[94]**
  o Kaushal (2006): 7 years. Net benefit >$10 million over 10 years
  o Adams (2008): 2.2 years (26 months). Net benefit >$10 million over 10 years

Importantly, in a recent public statement, the FDA (Health and Human Services Branch) stated that it will review its federal 2004 bar code regulation (medications), and will update the savings and impact of bar coding. The FDA had previously issued a public statement that, when the bar coding rule is fully implemented, bar coding systems would prevent nearly 500,000 *ADE* and transfusion errors over 20 years, and save the U.S. healthcare system $93 billion over the same time frame.[141]

The Logic Stream: If A, then B, then C

The absence of conclusive economic studies related to automated medication verification does not necessarily imply a lack of value proposition. Indeed, this relative lack of economic study likely applies to most or all healthcare information technologies.[2] It would therefore be inconsistent to apply an economic metric only to medication system automation, especially as a sole criterion for acquisition.

While this discussion paper cannot fully overcome the question of the current level of *ROI* evidence, it is possible to summarize the issues we have presented, and hopefully form a basis for reasonable strategic action. In doing so, let us for the moment set aside the compelling clinical and societal arguments related to preventable *ADE-related* patient harm and its impact on patients and family, caregivers, and others.

Error Prevalence, ADE Cost and Preventability
Based on the 2007 Institute of Medicine report on medication errors[77] and other cited reports[15,105,66,77,78,105,127,134]:

A. **Medication error rates are higher than acceptable;**
- o Over 8-15% of medication dose administration attempts are in error, depending on the patient care environment reviewed, excluding dose timing errors.
- o Errors occur in both institutional and community-based care at approximately the same rate.
- o Pharmacy dispensing and compounding errors also occur.
- o Up to 50% of medication errors have been shown to occur at the pharmacy dispensing/compounding (11%) and medication dose administration (38 %) stages, often involving human error.
- o 30-40% of medication errors are preventable based on good study methodology.

B. **The institutional and broader healthcare system cost arising from preventable medication errors is real and very likely understated;**
- o 20-30% of all ADEs cause significant harm.
- o Preventable ADEs cause an extension in hospital care of approximately 6-8 days per event, or $6000 (or greater) per event, which includes only hospital costs.

- o Ambulatory costs are in the range of $2000 or greater per event.
- o The full costs associated with ADEs and medication errors are significantly underestimated.

C. **Bar coded medication systems have shown a consistently significant reduction in medication errors**;
- o Well-designed technologies, including bar coding, should reduce errors and the number and severity of ADEs, while simultaneously improving health record documentation and system conformity, consistent with the principles of *HROs*. For bar coding:
  - ▪ Greater than 80% reduction in dispensing-related errors, with additional efficiencies related to inventory practices.
  - ▪ Approximately 50% reduction in bedside administration errors.

Healthcare System Investment:
D. A precise medication system strategy to reduce all error-related costs has yet to be determined, but the answer likely lies in more than one system intervention.[48,73,36]
E. Reduction in medication errors, both at the pharmacy and medication administration stages of the prescription process, will lead to both hard and soft cost efficiencies. Minimally, it will result in a reduction in the system wastage associated with increased patient *Length-of-Stay* in hospitals, and reduced follow-up in Ambulatory Clinics. Community-based long-term care facilities show similar system-related problems, and will likely benefit from similar system interventions.
F. Failure to act upon a known major source of Hospital-Acquired Conditions (HACs*)*, or Adverse Events*,* against which certain technologies (*CPOE* and bar code medication verification) have been demonstrated effective, will represent an organizational failure to address.

It should logically follow that healthcare system cost inefficiencies arising from medication errors can be harvested and/or re-invested to meet the costs of bar code verification investment, while enhancing the Canadian healthcare system efficiency and preserving public and staff confidence in our systems.

Recommendations from Key Organizations

Finally, a number of international and Canadian organizations have already accepted the current evidence and logic related to preventable medication errors and the resultant patient harm.

These organizations have promoted a move toward the use of machine-readable codes (bar codes, RFID, etc) as a method of increasing patient safety, documentation quality, and healthcare efficiency.

A list of such organizations and statements and statement dates include:

Agency for Healthcare Research and Quality (U.S.)(AHRQ) [1, 193]

American Society for Health-System Pharmacists (ASHP) [10]

Canadian Society for Hospital Pharmacists (CSHP) [37]

International Pharmaceutical Federation (FIP) [83]

UK NHS [110]

Food and Drug Administration (U.S.)

(FDA: Regulation 2004)

(FDA): Executive Order Response 2011) [141]

The following national and provincial practice organizations have formally recognized this national initiative's objectives. These include the development of strategies for pan-Canadian standardization of medication bar coding, and enhanced end-user knowledge and adoption of bar coding practices, both in community and institutional care.

B.C. Patient Safety and Quality Council

Canadian Anaesthesiologists' Society

Canadian Association of Paediatric Health Centres

Canadian Healthcare Association

Canadian Medical and Biological Engineering Society

Canadian Medical Association

Canadian Nurses Association

Canadian Society of Hospital Pharmacists

Health Quality Council of Alberta

Health Council of Canada

Healthcare Insurance Reciprocal of Canada

Manitoba Institute for Patient Safety

Ontario Hospital Association

Appendix II-1: Summary of Medication Error and ADE Rate Studies

Pharmacy Practice Studies				
REF	**CITED STUDY**	**ESTIMATE**	**PREVENTABILITY**	**NOTES**
124	Poon, et al: Ann Int Med: 2006	- Average 0.37% filling error rate of dispensed doses to patient care area. (i.e., after final pharmacist check)	- greater than 90% reduction in dispensing errors for "target" doses when all doses bar code scanned.	- 0.17% ADE rate for all target doses dispensed (i.e., Significant, serious or life-threatening).
38	Cina, et al: Jt Comm J Qual Patient Safety: 2006	3.6% filling error rate overall. 0.75% error rate (i.e., after final pharmacist check).	Not Measured	- Potential for ADE in 23.5% of dose errors; of which 28% were serious and 0.8% life-threatening.
23	Beso et al: Pharm World Sci: 2005	- 2.1% overall pharmacy errors intercepted by pharmacist final check. - No measure of rate after final pharmacist check.	Not Measured	- No accurate evaluation of missed pharmacy errors sent to patient care areas.

| *Institutional/Hospital: Prescribing AEs and Errors* |

REF	*CITED STUDY*	*ESTIMATE*	*PREVENTABILITY*	*NOTES*
15	Baker, Norton, et al: CMAJ: 2004 Canadian: All AEs Hospital patients	- 7.5 AE per 100 admissions	36.9%	Retrospective chart review of AEs 24% Medication/Fluid
77	IOM, 2007 (Compiled Estimate) U.S. Preventable ADEs: Hospital	- 1 Error per patient day	25%	Compilation of studies 380,000 to 450,000 per year U.S.

18	Barker KN, et al: Arch Intern Med: 2002	- Hospital Error: 9.9% (excluding timing errors)
		- Hospital Error: 16.4% (all errors)
			NA	- Observational Method
				- Of errors:
				  - 43% Timing Error
				  - 30% omission
				  - 17% wrong Dose
				  - 4% unauthorized medication
				- 10% deemed potentially harmful
				- Error rates between accredited and non-accredited hospitals were not different statistically.

REF	CITED STUDY	ESTIMATE	PREVENTABILITY	NOTES
20	Bates, et al: JAMA: 1995	- ADE: 6.5 % admissions	28%	- Retrospective chart review
56	Flynn, et al: Am J Health-Syst Pharm: 2002	- 17.9% of doses	Not assessed	- Observational method compared to other methods of review.
116	Paoletti, et al: Am J Health-Syst Pharm: 2007	- 1.6% of doses on area with many order sets, and independent double-checks of transcriptions - 6.3% of doses on area with varied medications, and relatively fewer order sets or independent double-checks	See Results below.	- Observational Method
59	Franklin, et al: Qual Saf Health Care: 2007	- % of non-IV doses	Not assessed	Medication Administration errors.

Long-term Care Studies

REF	CITED STUDY	ESTIMATE	PREVENTABILITY	NOTES
18	Barker KN, et al: Arch Int Med: 2002	- 14.7% (excluding timing errors) - 20.6% (including timing errors)		US Study: Six skilled nursing facilities - Observational Method - 12 facilities
44	Crespin DJ, et al: Am J Geriatr Pharmcother: 2010	- 37.3% of errors were repeated more than one time.		- 15,037 errors from 294 nursing homes analyzed for repeated errors in the same patient. - repeated errors caused more harm than non-repeated errors.
77	IOM, 2007 (Compiled Estimate) U.S. Preventable ADEs: Long Term Care	- 800,000 per year (0.1 ADE per patient month)	42%	Gurwitz Study Cited: 2005
112	NHS: Public Health Wales, 2010: (Barber ND, et al: 2009)	- 8.4% of dose administration	NA	UK study: 55 residential care homes - observational method - 49.1% omissions - 21.6% wrong dose

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REF	CITED STUDY	ESTIMATE	PREVENTABILITY	NOTES
112	NHS: Public Health Wales, 2010: (Van den Bernt, et al: 2009)	- 21.2% dose administration (including timing errors)	NA	Dutch study: 3 Nursing homes - Disguised observational method
112	NHS: Public Health Wales, 2010: (Haws, et al: 2007)	- 25.9% dose administration	NA	UK Study: Geriatric Psychiatry Hospital: 2 elderly long-stay wards - observational method - Includes charting omissions
19	Barker KN, et al: Am J Health-Syst Pharm: 1982	- 12.2 % of ordered doses in LTCF - 8% if unsigned and out-of-date orders are excluded		US study: 58 Long Term Care facilities (LTCF) - Observational method - compares with 11% error rate in 10 hospitals also studied for comparison.

Ambulatory Care and Other

REF	CITED STUDY	ESTIMATE	PREVENTABILITY	NOTES
77	IOM, 2007 (Compiled): Expert Opinion U.S. Preventable ADEs: Ambulatory	- 530,000 per year	27.6%	Gurwitz Study Cited:2003 - Medicare Patients Only
150	Walsh, et al: J Clin Oncol: 2009	- 7.1% visits (adult) - 18.8% visits (pediatric)	NA	- Chart review retrospective - 64/112 potential for harm - Most common in dose administration stage (56%)
60	Ghandi, et al: N Engl J Med: 2003	- 25% of respondents	20% overall	Enrolled Patient Survey, with chart reviews. - 13% serious harm - 87% significant harm
33	CIHI (2007 newsletter): Commonwealth Health Policy Survey 2005: Canadian Patients	- 10% received wrong medication or dose - 15% reported an Adverse Drug Event	NA	-Patient Survey: within last 2 years

Appendix II-2: Summary of Selected Bar Coding Error Reduction Studies

Pharmacy Dispensing

REF	CITED STUDY	ERROR REDUCTION	METHOD	NOTES
124,125	Poon, et al: AMIA Symp: 2005 Ann Int Med: 2006	- greater than 85% reduction in dispensing errors for "target" doses when all doses bar code scanned.	Observational Method	- "target" drug refers to those dose production lines where bar coding was specifically implemented to improve quality. - Best results when every dose is scanned, as opposed to random scanning of doses within a batch of doses.
129	Ragan, et al: Am J Health-System Pharm: 2005	- 96% reduction in dispensing errors.	Not stated	- Aligned Inventory efficiencies were noted.

Bedside Medication Dose Administration				
REF	**CITED STUDY**	**ERROR REDUCTION**	**METHOD**	**NOTES**
116	Paoletti, et al: Am J Health-Syst Pharm: 2007	- 54% reduction in medication administration errors.	Observational Method	- Results shown on study cohort with varied medications (i.e., not standardized by order sets).
127	Poon, et al: N Engl J Med: 2010	- 41.4% Reduction in non-timing errors. - 27.3% reduction in dose timing errors	Observational Method	- 50.8% reduction in Potential ADEs related to non-timing medication errors. - Of reduced errors: Reduction by error category were: 57.4% wrong medication; 41.9% wrong dose. - Documentation errors on chart reduced by 80.3%. - Of reduced errors: Reduction by practice area were: 44.9% Surgical; 42.5% ICU; Medical 25.1%.
106	Morriss, et al: Healthcare Quarterly: 2009	- 47% reduction in ADEs	Daily Medical Health Record Review Method	- Neonatal ICU - Increase in medication error rate, including medication timing.

REF	CITED STUDY	ERROR REDUCTION	METHOD	NOTES
59	Franklin, et al: Qual Saf Health Care: 2007	- 39% Reduction Non-IV Doses	Observational Method	- Predominantly Wrong Drug and Dose Admission errors avoided. - Transcription errors also measured using before/after CPOE and electronic MAR, but beyond the scope of this document. (100% reduction)
50	DeYoung, et al: Am J Health-Syst Pharm: 2009	- 56% reduction in medication errors. - 60% reduction in dose timing errors	Observational Method	- Conducted in an adult intensive care unit
147	Johnson, et al: J Healthcare Inf Mgt: 2002	- 86.2% reduction in medication errors (including timing errors)	Incident Reporting	- one hospital, within the Veterans Affairs medication hospital system. - 1993 through 2001 data analysis
70	Helmons, et al: Am J Health-Syst Pharm: 2009	- 58% reduction, excluding timing errors in Med/Surg areas. - no decrease in ICU area	Observational	- Med/Surgical areas: - With timing errors, no change in calculated error rate. - increase in wrong time errors observed.

Appendix II-3: Bar Code Effectiveness Studies: Reviews from Major Healthcare Organizations

AHRQ Review (2011)[2]

In a thorough 2011 review of technology studies released by the U.S. Agency for Healthcare Research and Quality (AHRQ), and prepared by the McMaster Evidence-based Practice Centre, 40,582 studies were screened and 789 were fully evaluated. These were categorized by the stages of the medication process outlined earlier in this document, plus patient monitoring and medication reconciliation. The reader is directed to this excellent review of information technology studies for several "key" *MMIT* decision-analysis questions, including:

- Effectiveness
  o Qualitative (satisfaction and process changes)
  o Value of investment (financial, clinical and organizational)
  o Error impact
- Knowledge and Evidence Gaps
- Value Propositions
- Sustainability

Overall, the AHRQ review concluded the following,:

- That the literature represents a challenge, and that, although good studies exist, they do not form a broad base of support for any of the major steps within the medication prescription process. Additional work would be required with improved definitions, study budgets, and improved research skills.
- Current studies form a base of encouraging qualitative 'hope', such as qualitative improvement of the process of care, including patient safety.
- **Prescribing (*CPOE*):**
  o Prescribers (physicians) are the most studied group.
  o Improvements were found in *process* in hospital (87% of studies), and ambulatory (68% of studies) settings. Community-based process improvements were not found.
  o Improvement in *errors* in hospitals (68% of studies). Ambulatory and community-based studies (not found).
  o Improved prescriber adherence to prescribing guidelines, reminders and recommended practices was found in hospitals (in 83% of studies) and ambulatory (in 64% of studies).
- **Order communication**
  o Least number of studies with varied study goals in this medication process area, such as effect on errors, time, and work flow. All showed positive results.
  o Two-way electronic data interchange (EDI) shows promise in studies using quantitative observational methods.

- **Dispensing Medications**
  - Few studies exist, and only three Randomized Controlled Trials studies.
  - Evidence is shown, but is limited.
- **Medication Administration Process**
  - Many studies were only descriptive in nature
  - All reviewed studies were completed in hospitals
  - Error reduction goals were met in most studies (61% of studies). Four studies showed no change in errors, and one showed an increase (mostly due to timing of errors).
- **Economic Analysis**
  - Some studies have demonstrated economic return, based on various efficiencies (reduced ADEs and patient stays, drug costs, etc).
  - Evidence is inconclusive that *MMIT* can be justified on economic grounds alone.

Institute of Medicine Review (2007)[77]

Individual studies involving medication implementation are many. In its 2007 study on medication error, the IOM (Appendix D) cites evidence related to "technology interventions". It lists *CPOE* evidence as "medium strength", while BCMA evidence as "limited evidence", and the use of medication dispensing devices as "lower strength". Yet, even current mainstays of medication management processes were listed as challenged by evidentiary inconclusiveness, such as pharmacist review of medication orders before first dose ("limited evidence") or the storage of concentrated solutions on patient care areas and standardized concentration ("limited evidence").

The problem of evidence lies not necessarily in the validity of the safety measures, but quite possibly in the lack of standardized randomized controlled trials, as performed in other aspects of clinical care. Such an ideal state of evidence-based certainty may never be reached as such studies are exceedingly difficult and costly.

CADTH Review (2011)[30]

In a 2011 Canadian Agency for Drugs and Technologies in Health (CADTH) review of studies of dispensing and automation, a positive impact on medication errors was cited, however it also indicated that the reviewed studies had "lower internal validity".[30] The CADTH review covered both "automated dispensing" and "medication administration" [sic] systems (e.g., automated drug cabinets), and was not an extensive review of bar code medication administration studies. It did not attempt to differentiate study methodologies used.

Appendix II-4: Canadian Case Studies

Several Canadian institutions have shown early leadership, developing improved medication systems, based on the principles of automated identification and data capture. Their stories provide us with both encouragement and important information, and follow below.

Site Report: Centre Hospitalier Universitaire Sainte-Justine

Montreal, Quebec
Contributed by:
Denis Lebel (Phamacien, Unite de recherché, Déparmente de Pharmacie)
Jean-François Bussières (Chef, Départmente de Pharmacie)

System Modifications: Bar code-assisted Verification of Oral Syringes and Visual Images
Date of Project: 2009 and ongoing

What medication system was in place prior to the automation upgrade?

> Prior to our system re-engineering, we prepared approximately 400 oral liquid syringes daily for our pediatric population. Each syringe was drawn from the bulk medication container and placed with the original container for validation of product selection and volume.

What important organizational investigations or strategic activities <u>preceded</u> your decision to pursue medication system bar coding?

> We knew that the need for oral syringes for the entire institution was around 600 syringes per day. We also knew there were safety risks in the current system. As an example, the containers had to be utilized for a lot for stat orders and, therefore, were moved. Also, since most oral liquids are of similar white colour suspensions, pharmacists were not very comfortable with this validation step.

> We needed to develop an in-house solution to address the issue. The system solution we selected would need to guide pharmacy technicians in the selection of the correct product. They would be aided in the selection by visual feedback (using a picture of the product to be selected and a scaled representation of the filled syringe), automated identification (bar code verification), and voice alert (an audible sound/voice when risk situations were present and discovered by the scan).

What were the objectives of the upgrade project?

> We designed our solution with patient safety in mind. Though the syringe preparation time would be a little longer, the automated validation step would be very fast. Overall we felt it would take the

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same time. We wanted to combine bar coding with the dose dispensing from our pharmacy system using the bar code on the medication container and photographs of product containers and liquid.

The final application was to be a web-based application capable of displaying both the required medication and an image of the syringe to be prepared once the bar code related to the dispensation would be scanned. The application would then authorize the preparation when the barcode of the needed product was scanned and the lot number expiration date was confirmed.

What was the process for your new system's assessment and acquisition?

The project was developed over a summer with the help of a pharmacy intern who built the barcode and image database, and a pharmacist/programmer who built a web-based application which was interfaced with the Pharmacy Information System data. The development process was inspired by AGILE methodology.

How did you approach implementation across the site?

We started with a prototype system that evolved to the final application over a period of a few months. The pharmacy users were presented with small iterations of the technology several times a week in order to develop the right tool.

Can you characterize the pharmacy and/or nursing staff satisfaction related to the system changes?

The pharmacy technicians and the pharmacists were very satisfied with the safety improvement resulting from this development project. Though the new system took a little more time to prepare the syringes using the revised verification methods, we adapted the tasks of the pharmacy technician slightly over a few weeks.

What has the system upgrade benefitted, if anything?

Having the wrong product in a syringe rarely occurs now. Wrong volume errors also occur less often now that automated verification focuses on this element of our dispensing process. We were now able to produce more than 600 oral syringes each day, with confidence.

What three pieces of advice would you give to others who are contemplating a major system upgrade?

As time passes, training tends to focus on how to do things procedurally. Why we do things in this manner may be de-emphasized or skipped entirely. This may, in turn, lead over time to procedures being followed in a less strict fashion, and therefore the risk of a dispensing error going up. We have to stay vigilant at all times that processes are followed, and re-educate staff as needed.

Site Report: Centre Hospitalier Universitaire Sainte-Justine

Montreal, Quebec
Contributed by:
Denis Lebel (Phamacien, Unite de recherché, Déparmente de Pharmacie)
Jean-François Bussières (Chef, Départmente de Pharmacie)

System Modifications: Online Status of Prescription Preparations: Nursing Look Up
Date of Project: 2009 and ongoing

What medication system was in place prior to the automation upgrade?

> Prior to our system change, nurses often called the pharmacy whenever they could not find a medication in its expected storage location on the patient care area, which could result in searches within both the care area and pharmacy.

What important organizational investigations or strategic activities <u>preceded</u> your decision to pursue medication system bar coding?

> A significant proportion of the calls we received from patient care areas was to obtain information about the status of a prescription sent for dispensing and/or compounding. We wanted to find a way to eliminate this kind of system interruption and inefficiency for nurses and pharmacy staff.

What were the objectives of the upgrade project?

> We wanted to make the status of a prescription available on ward online. Many prescription statuses could be pulled from our pharmacy system. However, the most significant, occurred after dose validation by a pharmacist. The status points available to choose from included the following prescription process stages: in-preparation, final validation completed, sent through pneumatic tube system, and picked-up at the pharmacy. We needed to read the prescription bar code using a traceability application, which would monitor the progress of each prescription.

What was the process for your new system's assessment and acquisition?

> We developed a web-based application allowing data capture based on the dispensing number for each prescription. We also developed web reports that allowed nurses to obtain the status of a prescription for a patient.

How did you approach implementation across the site?

> We started with a design prototype that evolved to the final application over a period of a few weeks. The system users were presented small iterations of the system in order to develop the right tool. We are still evolving the application, capturing more process data points and improving the display for the ward. The data capture application has now been developed and integrated in our Pharmacy Information System.

Can you characterize the pharmacy and/or nursing staff satisfaction related to the system changes?

It was a simple project, easy to implement, and with immediate benefits for the nurses and the pharmacists.

What has the system upgrade benefitted, if anything?

Interruptions for both nurses and pharmacy staff have significantly decreased. Improvement will be made regularly.

Site Report: North York General Hospital

North York, Ontario
Contributed by:
Thomas Chan (Pharmacy Systems, Manager)
Edith Rolko (Pharmacy Director)

System Modifications: CPOE, EHR, BCMA, CIVA, Ward Stock Management
Date of Project: 2007 through 2010

What medication system was in place prior to the automation upgrade?

> Prior to the automation upgrade at North York General Hospital (NYGH), pharmacy was preparing oral medication in unit dose format using a manual unit dose machine. Pre-packaging of oral medication was subsequently upgraded to utilize an automated pre-packager, which could print a bar code on the unit dose package. Oral liquid was supplied in bulk bottles to nursing units. Pharmacy didn't have CIVA service prior to eCare.

What important organizational investigations or strategic activities <u>preceded</u> your decision to pursue medication system bar coding?

> NYGH leadership decided to invest in a corporate multi-year initiative called "eCare" in 2006. The eCare project aimed to revolutionize patient care with full electronic medical record (EMR), which utilized Clinical Provider Order Entry (CPOE) with evidence-based order sets, medication reconciliation and decision support tools, electronic medication administration record (eMAR), electronic clinical documentation, and barcode medication administration (BCMA). As a whole, eCare is a complete solution which can provide a seamless, efficient close-loop medication process in the hospital, and can significantly improve patient safety.
>
> This project was strongly supported by interdisciplinary collaboration between physicians, nurses, pharmacists and other allied health team members. A core team was working daily to plan, design, build, test, and implement the EMR systems using comprehensive consultation with front line staff.

What were the objectives of the upgrade project?

> As literature states, about 38% of medication errors occur at the stage of medication administration. Since dose administration is the last step in the medication process, any incident (sic) committed at this point can cause significant harm to the patient, resulting in prolong hospital stay or even lead to death. BCMA involves scanning medication a bar code at patient bedside, which can effectively minimize unintentional errors during dose administration by confirming the 5 rights (right drug, dose, time, route, and patient) as well as improve documentation on the eMAR. In order for medication scanning to occur, pharmacy required a system that could produce barcode on each unit dose of medications.

What was the process for your new system's assessment and acquisition?

The medication bar code system must work with the hospital information system. It is necessary to ensure that the bar code symbology and content is readable and compatible between the two systems. Another important fact is that the bar code requirements in US and Canada are very different. In US, JCAHO has mandated manufacturers to bar code each unit/single use dose, and thus made bar code scanning an easier process to implement in institutions. However, we don't have similar requirements in Canada, and medication bar code was quite a "novel" practice in hospitals, especially back in 2006. As a result, the pharmacy department didn't employ a consultant or visit other sites, due to the fact that no one had implemented it in Canada and the difference in bar code requirements with our US counterparts. The number of commercial (vendor) bar code systems available at that time was very limited, if not sole source, and there was therefore was no need to create a Request for Proposal (RFP) to source comparative systems.

How did you approach implementation across the site?

After the purchase of the bar code system, a bar coding team was formed, which consisted of one pharmacist and one pharmacy technician. Their tasks were to build the medication database with the bar code information, plan and design the bar coding process, develop policies and procedures, prepare training materials for pharmacy and nursing staff.

One month before the day of implementation for bar code scanning, the pharmacy technician team started to ensure that there were bar codes on all unit doses (in addition to oral medication packaged by an automated machine), and converted bulk oral liquid bottles into unit/single dose containers with bar code. This occurred throughout the hospital. In addition, the bar coding team provided education sessions designed to increase nurses' awareness with regard to both bar codes on medications and the scanning process at patient bedside, before the implementation of eCare.

Can you characterize the pharmacy and/or nursing staff satisfaction related to the system changes?

All disciplines were aware of the benefits of medication bar code scanning in improving patient safety. However, it was still a new process introduced to nurses during medication administration, and would require a change of practice. The most common nursing comment was "it took more time to administer a medication", especially on the first day of implementation when nurses had a steep learning curve. However, as nurses started to learn the new process and to realize the benefits of scanning medication, the bar code process was naturally accepted as part of the required workflow. The NYGH leadership was fully supportive of bar code scanning at patient bedside and established it as the best practice for medication administration.

What has the system upgrade benefitted, if anything?

Our hospital's bar code scanning results shows that, on an annual basis, approximately 1200 medication administrations are prevented from being given at the bedside, including to approximately 750 wrong patients. In addition, thousands of potential medication errors were identified and prevented even before the drugs reached the patients' bedside, because the handheld scanner would first verify the scanned medication bar code and match with patient's medication profile, thus alerting nurses immediately with "non-match" results.

What three pieces of advice would you give to others who are contemplating a major system upgrade?

- It is important to procure a bar code system that is compatible with the hospital information system, pharmacy system & other equipment.

- Ensure dedicated human resources are available to develop the bar code system with revised policies and procedures in place.

- Last but not the least, it is important that hospital staff team (e.g., nurses, physicians and leadership) understand the benefit and value of medication bar code scanning at patient bedside and provide full support of BCMA implementation.

Site Report: St. Michael's Hospital

Toronto, Ontario
Contributed by:
Janice Wells (Pharmacy Director)

System Modifications: CPOE, EHR, eMAR, Procurement, Packaging, Dispensing, BCMA,
Ward Stock Management
Date of Project: 2009 through 2012

What medication system was in place prior to the automation upgrade?

Our previous medication system was based upon paper-generated medication orders which were entered by pharmacists in the Pharmacy Information System. The Pharmacy distribution system was semi-automated unit dose and CIVA to 95% of the beds in the hospital. Pharmacy automation, introduced in January 2009, was an integrated robotics dispensing system for approximately 1.6 million oral solid doses, although some liquids were still issued in multi-dose containers.

At the patient dose administration level, RNs used manually transcribed MARs to guide medication administration. Several physical space and logistical barriers resulted in several procedural variances: RNs removing medications from unit-dose packages well in advance of taking them to the bedside, RNs not taking medication carts closer to the bedside, or performing documentation of medication administration out of sequence with actual time of administration.

What important organizational investigations or strategic activities <u>preceded</u> your decision to pursue medication system bar coding?

Our hospital was in the preliminary stages of a multi-year project to implement Computer Prescriber Order Entry (CPOE) and an Electronic Medical Record (EMR) when it became apparent the vendor application also required implementation of bar-code assisted bedside medication verification and administration (BMVA) to enable viewing of an electronic MAR (eMAR) from the EMR. This development considerably enlarged the EMR project scope and therefore required and received endorsement at the Executive Leadership level. Executive support included all of Medicine, Nursing and Pharmacy and was based largely on the anticipated improved quality and safety outcomes.

Pharmacy readiness to provide all medication in individual unit-doses labeled with a unique bar code was required within a one year timeframe during the period 2009-10, prior to CPOE go live on the pilot patient care unit. Development and implementation of CPOE and BMVA on patient care units throughout the hospital was part of a larger multi-year strategic initiative over the period March 2010 through February 2012

What were the objectives of the upgrade project?

The bar code-assisted bedside medication verification component was primarily pursued for the

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anticipated quality and safety benefits to the medication system. Experience at organizations that had introduced similar systems indicated that providing RNs with BMVA enabled identification of potential [preventable] medication errors and thus enabled the RN to correct errors prior to administration to the patient.

What was the process for your new system's assessment and acquisition?

The hospital partnered with a specific vendor to build and implement CPOE, eMAR and the EMR, and used a combination of consultants and vendor implementation consultants, along with in-house leadership, development and informatics teams to build and implement the system. Site visits within Canada and the US occurred as part of the RFP process and very early development stages for the EMR project.

Preparation for the Pharmacy and Nursing aspects of the bar-code assisted medication verification and administration system required:
- RFPs for additional semi-automated packaging and labeling equipment as well as mobile devices for RNs to perform bar code-assisted medication verification and administration at the bedside.
- Pharmacy consultant to manage pharmacy readiness for bar-code medication procurement and dispensing.
- Vendor implementation consultants to assist with adaptation and implementation of the BMVA application.
- In-house teams to guide selection and implementation of mobile medication delivery carts and devices and to redesign medication delivery and administration processes
- Site visits were not employed for this stage

How did you approach implementation across the site?

Implementation of the barcode-assisted bedside medication verification process was concurrent with implementation of CPOE which was performed in a phased patient unit cluster approach, following a similar sequence for each.

The approach included unit engagement approximately 6 weeks prior to CPOE go-live to identify and resolve unique issues on each unit, and RN and MD education in the last 2 to 3 weeks. The most common approach was that both CPOE and BMVA went live the same day or BMVA followed in less than 1 week. After go-live, each unit was supported 24/7 for 3 weeks by on site education team members. The planning and implementation team involvement for the entire CPOE /BMVA project included executives, inter-professional leadership, an operations group, and informatics and education support.

The Pharmacy team aspects were integrated with the larger project team. Key steps led by a pharmacy manager included unit by unit preparation and implementation of new mobile cart equipment, storage units for narcotics and individual patient unit-dose bins, bar coded packaging of all medications needed by a patient care unit and replacement of all wardstock medications with only barcode-labeled medication. Education and communications to pharmacists and pharmacy technicians occurred prior to each unit go live to ensure ongoing awareness of unique issues.

Can you characterize the pharmacy and/or nursing staff satisfaction related to the system changes?

Prior to the project's start, anticipation ranged from neutral to positive. Project leadership emphasized the patient safety benefits and how the tools and systems would enable more complete fulfillment of professional practice expectations, especially for RNs in fulfilling the Eight Rights of medication administration.

Within a week of go-live, adoption of the new tools and practices by RNs was very high and positive as they experienced catching and preventing errors, as well as the efficiency of documenting medication administration in an automated manner. For pharmacy staff, recognition of their contribution to prevention of medication errors resulted in positive acceptance of the new system.

What has the system upgrade benefitted, if anything?

The barcode assisted medication verification system has resulted in prevention of medication errors. The system has enabled RNs to align their medication administration practices with professional practice standards, to achieve more complete medication administration, and has also saved them the time formerly spent on transcribing manual MARs. Moving to an automated system also expanded use of unit-dose medications to approximately 50,000 liquid doses annually.

Unexpected outcomes:
- Perspectives of patients who perceived the safety and error prevention benefits and reinforced RN adoption
- The need to exactly align specific narcotic dose package strengths on wardstock with electronic orders which flow to the BMVA application, in order to prevent systematic mis-matches which, in turn, result in many system overrides by RNs. Also, individual bar code labeling of narcotics meant no longer using 'control packs' and therefore negative impacts on time for RNs to count these doses at shift change.
- The significantly higher degree of complexity that Pharmacy must manage on an ongoing basis. This includes drug inventory database management and stock alignment, medication contract/supplier changes and their ability to provide barcode labeled product, readability of barcode labels, to name a few.

What three pieces of advice would you give to others who are contemplating a major system upgrade?

- Ensure all planning and implementation is conducted by an adequately resourced inter-professional team that meets regularly. Accountabilities and workflows among the health disciplines are significantly impacted and development of new workflows and problem resolution requires an integrated approach.

- Utilize a structured and systematic 'project management' approach; assess and define strategies for categories of drugs (e.g., oral solids, injectables, narcotics, other) and fully leverage automation and pharmaceutical manufacturer bar coded labels where possible.

- Be vigilant for emergence of new types of system errors, and ensure to have a robust process for reporting and review of such errors to enable "rapid improvement cycles". A strong 'culture of safety' among staff will make this more successful.

Site Report: Trillium Health Partners – Credit Valley

Mississauga, Ontario
Contributed by:
Allan Mills (Pharmacy Program Director)
Lina Ranieri (Clinical Informatics Coordinator)
The eMAR-BMV Team

System Modifications: EHR, BCMA, CIVA, Ward Stock Management
Date of Project: 2007 through Present

What medication system was in place prior to the automation upgrade?

> The medication system that was in place at our organization in 2007 was a unit-dose cart exchange with automated dispensing cabinets (ADCs) for ward-stock and narcotic items. There was an IV additive program (CIVA) in place and computer generated (paper) MARs were used throughout the facility at the time of this project.

What important organizational investigations or strategic activities <u>preceded</u> your decision to pursue medication system bar coding?

> The early appointment of an Electronic Health Record (EHR) executive leadership team in 2006, whose purpose was to develop an implementation strategy for a full EHR, preceded the decision to pursue a medication bar coding system. Our investigations indicated that medication errors are a leading cause of preventable adverse drug events (ADEs) and a major threat to patient safety. Studies estimated that a large percentage of medication errors occur at the point of dose administration. Virtually all potential medication errors would get through to the patient bedside since there was no consistently effective double check system between the nurse and the patient dose administration. A closed-loop medication process was recognized to be the gold standard for patient safety.
>
> The final step in this quality improvement process was to implement Bar Coded Medication Administration (BCMA). All programs and leaders strongly supported this decision and endorsed opportunities of piloting this patient safety initiative.

Was the plan (decision) added to a multiple-year institutional strategic plan, or was it a single and somewhat isolated endeavor?

> The neonatal special care nursery unit was chosen as an independent pilot site for (BCMA) implementation. Rationale included: a uniform patient population, minimal patient transfer to other units, broad range of tests (e.g., clinical laboratory, imaging, cardiopulmonary), critical care components (e.g., monitors, ventilators, complex medications), and having a Nurse Practitioner practicing in the area. There were also some standard pre-printed physician orders and positive staff attitudes, coupled good program leadership. This local initiative was added to the site strategic plan for the organization with further roll out to adult populations.

Question: What were the objectives of the upgrade project?

The overarching objective was to reduce medication-related risk to patients. In order to assess progress, several indicators of success were identified and measured including: rate of medication errors and "near misses", patient identification [scan] rates, adherence to medication administration times, and staff satisfaction rates.

What was the process for your new system's assessment and acquisition?

The process for EMAR BMV assessment and acquisition included engaging an external consultant to perform a readiness assessment as part of our larger EHR strategy. Since the EMAR BMV solution was identified as a priority, it was made into a strategic investment by the organization. The hospital's main computer administration program was originally purchased to include the additional bar code module and support for future implementation of EMAR BMV, therefore further procurement of software was not required. Hardware and equipment deployed supported selection criteria and new BCMA policy and processes.

A custom [software] application for a pharmacy bar coding cart fill was developed, a technology provider (vendor) was selected, and this system was installed in pharmacy. Usability testing was successful for EMAR BMV hardware and other related support systems.

How did you approach implementation across the site?

Project leads were identified who obtained detailed training on the EMAR BMV module at the vendor's training facility. The development was informed by stakeholder buy-in [sic] and the need to align with other EHR projects and organizational goals and objectives.

A test system was established to confirm the functionality of the program and learning materials were developed to emulate EMAR BMV processes. Inventory, or drug file, bar code tables were created using a specific material management number or the product DIN number as a basis for the bar code. We tested for all potential scenarios for administering medications to confirm that the system was effective and developed the learning material for the staff from the results of this testing.

Staff training was carried out two weeks prior to roll out. "Super-users" were trained extensively on the eMAR-BMV system functions and nuances and acted as champions for both the system and its implementation roll out. These Super-Users were actively involved in training their colleagues, which contributed greatly to our success and user [staff] comfort with the system. Finally, it was confirmed that 24/7 support was required for the first two weeks immediately after an implementation.

Ongoing project team and issue monitoring and resolution meetings were held pre and post project implementation. The need to embrace the change management and strong communications processes was essential to accomplishing the project vision.

Can you characterize the pharmacy and/or nursing staff satisfaction related to the system changes?

A pre-eMAR-BMV survey found that 95% of respondents were satisfied with the traditional medication administration process. The remaining 5% were somewhat satisfied with the process, mainly because they felt it was too time-consuming. Of the respondents, 82% believed that

technology allows them to enhance patient care. Additionally, 50% of respondents believed that aspects of the traditional medication administration process could be improved.

A repeat survey was conducted during the 1-2 month period following implementation revealed that 80% of respondents were satisfied with the new protocols; however the staff response rate for the post survey was only 13%. The project plan includes a further evaluation after 6 months when new medication documentation processes have stabilized. Despite the overall satisfaction with the new system, a number of challenges with the protocols were identified, primarily from nurses:

- Difficult to scan patient armbands because many of the barcode tags began to curl after a few days.
- Concern over the inherent safety of the laser scanner itself.
- Difficultly in remembering medication times, since no overly obvious visual cues were present to indicate when a medication was due.
- eMAR/BMV protocols were potentially more time consuming compared to the traditional medication administration process.

Again, lack of sufficient survey respondents is a limitation of this portion of the study. As such, it is difficult to determine whether the responses represent the overall perception of the Special Care Nursery (SCN) unit.

What has the system upgrade benefitted, if anything?

The most significant impact of this project is the enhanced patient safety in the SCN and Adult Mental Health Unit.

- Patient identification rates have increased significantly and the data related to near miss counts are now objective rather than dependent on self-reporting by care providers.
- Following eMAR-BMV implementation, point of care safety warnings provide clinicians with an objective second check of their medication and patient, and also alert them to potential errors before the error was committed.
- Computerized access to patient medication administration records in real time, from any desk top allowed for increase in patient care coordination and clinical decision-making.

Pharmacy practice also benefited with an accurate check of all bin-filled medications and first doses before they left the department. Efficiencies in time and cost were also realized with the reduction in the printing and filing of paper medication administration records.

Overall we were able to identify specific patient cases were potential harm was prevented by implementing this system.

What three pieces of advice would you give to others who are contemplating a major system upgrade?

Based on our pilot sites, lessons learned from the automated system implementation include:

- Some staff had difficulties interacting with the new technology and the modified medication administration process.
- Specialized practice areas, such as SCN and pharmacy, have medication processes and protocols that may not align with the new electronic medication administration system

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requiring a fulsome review of our inherent practices before moving towards the new technology. We concluded that we could not allow technology to impinge on or dictate practice, but rather should design the system to compliment these practices. From bar coding to medication administration challenges, we found that many of these variations were addressed before the go-live date but even more were encountered after implementation. Proactive rigorous review of all medication administration processes must be conducted to ensure that eMAR-BMV processes do not introduce new risks.

- The method of training used in our SCN was effective and would be an excellent model for future projects. Having "Super Users" as system champions and utilizing just-in-time training techniques for implementation was highly effective and supported the multidisciplinary team members in the operation of the new system.

Site Report: University Health Network

Toronto, Ontario
Contributed by:
Edith Fung (Pharmacy Director)
Dr. Ludwik Fedorko (Anaesthesiologist, UHN)

System Modifications: Procurement, Anaesthesiology Medication System, Operation Room
Date of Project: 2009 through Present

What medication system was in place prior to the automation upgrade?

Prior to the automation upgrade in our operating room (OR) environment, anesthesiologists were responsible for dispensing, premixing/repackaging, re-labelling, and administering medications without any verification support system.

What important organizational investigations or strategic activities <u>preceded</u> your decision to pursue medication system bar coding?

Operating rooms are the only places in the Canadian health enterprise where the vast majority of administered drugs are "High Risk" medications (e.g., paralyzing agent, potent narcotics, and anesthetic agents). Drugs in the OR are administered without benefits of independent verification from the point of dispensing to injecting into the patient's intravenous line, which occurs up to 10,000 times per year by a single anesthesiologist. Eighty per cent of medication errors occur in peri-operative setting. Although the majority of errors are reversible and less than 10% are estimated to be serious, few of them are reported and all errors pose significant risk of patient harm. Approximately one to two critical medication errors were reported annually at our institution prior to our automation upgrade. The main sources of medication errors in anaesthesia practice were: unintentional swaps of ampoules, labels or syringes during medication selection, preparation, and administration.

Given the potentially serious implications of high risk medication errors in the peri-operative setting, the pharmacy and anesthesia teams committed to work together to find an effective solution to reduce the anesthesia-related drug errors linked to human factors.

What were the objectives of the upgrade project?

Our main objective was to implement and assess the impact of a cost-effective automation process, capable of providing a barcode-aided independent verification tool for anesthesia care providers throughout the perioperative process.

Other key deciding factors included: (1) potential for easily scalable implementation to other OR units both within and outside UHN; (2) readily acceptable by healthcare providers; and (3) contribution to improved overall medication delivery workflow.

What was the process for your new system's assessment and acquisition?

> At the time of this project, there was no market-ready barcode-aided software solution for patient care in the OR. There was also no implemented process in the market which would cover 100% of medication process flow, and which would not require extensive and very costly satellite pharmacies.

> We worked with an in-house project development team to create a point-of-care bar code-aided medication process, in line with Accreditation Canada specific guidelines for administration of "high-alert" medications in hospital. It included verification of ampoule dispensation, the production of accurate syringe labels, and aid in syringe verification prior to patient administration.

How did you approach implementation across the site?

> Collaboration among anesthesiology, nursing and pharmacy staff was key to the success of this project. Lectures and in-service rounds were held to educate all OR staff teams about the nature of the project, problems of peri-operative medication errors: issues which the new system expected to address.

> The responsibility of the pharmacy team was to ensure 100% unit dose bar coding of all drugs supplied to OR, by purchasing products with bar code labels on the "unit-of-use" medication package format. If the product did not have a label with the bar code on the unit-of-use, pharmacy staff would manually place the label on the package.

> The nursing team was educated about the new hardware and software in the OR and taught how to care for this equipment during the routine case preparation. The anesthesia team and anesthesia assistant team were the direct end-users of the technology, and were educated on how to prepare medications, administer and chart medications using bar code-aided work flow. Full support and collaboration with senior corporate [executive] management was critical.

Can you characterize the pharmacy and/or nursing staff satisfaction related to the system changes?

> The new automation process was enabled in January 2010. Although use was voluntary, within the first two weeks of implementation, all anesthesiologists had fully adopted the new process. High user acceptance of the new process was due to ease-of-use and minimum workflow interference.

> After 5 months of clinical usage, over 60,000 syringes were prepared and administered for 4,000 patients using the new process. At that time, a survey was conducted among TGH anesthesia providers. Forty-one anesthesiologists participated in the survey. 21 (52%) respondents reported 29 potential medication errors which were intercepted by the bar code-aided process during the first 5 month period.

> After 15 months of use and over 150,000 doses there was no critical drug identity errors reported, which is well below published data and previous years' experience at the Toronto General Hospital.

What has the system upgrade benefitted, if anything?

> This bar code-aided medication verification process has demonstrated to be safe and effective to intercept and prevent potential medication errors during the anesthesia medication administration

process. It is also cost -sustainable and possible to implement in the OR environment at a relatively lower cost compared to a satellite pharmacy and other OR automation technologies. It has a very high user acceptance rate. It has been in use voluntarily by 100% of anesthesia providers at the University Health Network with no major drug error incidents related to ampoule, label or syringe swap.

We believe it is a process that can be easily implemented in any size surgical facility. We recommend this process as a standard of safe medication practice in the operating room environment, as it is the only process which allows for bar code aided verification for 100% of medications used.

The new automated process has since become a new standard of practice at all 20 Operating Rooms located at the Toronto General Hospital site, and minimal ongoing technical support required. The process still continues with much success and has also expanded to all perioperative units at the University Health Network - Toronto Western Hospital site as well.

What three pieces of advice would you give to others who are contemplating a major system upgrade?

- Interdisciplinary collaboration including leadership and frontline staff is key during all stages of the planning, implementation and evaluation process.

- Timely education and in-service for new personnel rotating through the affected practice area is essential both before and during the implementation of any major system upgrade.

- Designing a new workflow process based on the natural workflow associated with the delivery of care will allow easier adaption of a new automated process.