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Canadian Pharmaceutical Bar Coding Project

Medication Bar Code System Implementation Planning

A Resource Guide

September 2013 (Final)

*This resource guide was developed as part of the **Canadian Pharmaceutical Bar Coding Project**, collaboratively led by the Institute for Safe Medication Practices Canada and the Canadian Patient Safety Institute.*

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For additional information or to provide feedback please contact: info@ismp-canada.org

The Institute for Safe Medication Practices Canada would like to acknowledge funding support from all those who contributed to the *Canadian Pharmaceutical Bar Coding Project*, listed in Appendix V.

About the Institute for Safe Medication Practices Canada (ISMP Canada)

ISMP Canada is an independent national not-for-profit agency committed to the advancement of medication safety in all healthcare settings. ISMP Canada works collaboratively with the healthcare community, regulatory agencies and policy makers, provincial, national, and international patient safety organizations, the pharmaceutical industry, and the public to promote safe medication practices.

ISMP Canada's mandate includes collecting, reviewing, and analyzing medication incident and near-miss reports, identifying contributing factors and causes, and making recommendations for the prevention of harmful medication incidents.

Link to the Institute for Safe Medication (Canada)

About the Canadian Patient Safety Institute (CPSI)

CPSI is a not-for-profit corporation, operating collaboratively with health professionals and organizations, regulatory bodies, and governments to build and advance a safer healthcare system for Canada. CPSI performs a coordinating and leadership role across healthcare sectors and systems, promotes leading practices, and raises awareness about patient safety by working in collaboration with partners, patients, their families, and the general public.

Link to the Canadian Patient Safety Institute

This resource guide is dedicated to the memory of Allan Reynolds, a member of our advisory Implementation Committee, whose enthusiasm and unceasing commitment to improving medication safety for Canadians were guiding beacons.

Foreword

This comprehensive resource document has been written for use by senior practice leaders involved with medication management and system development and by their executive leadership colleagues responsible for strategic funding and system acquisition.

The purpose of this document is to review the need for automated identification (e.g., bar coding) of medications within both community-based (e.g., nursing home) and institutional (e.g., hospital and ambulatory) care. It is hoped that a better understanding of relevant issues will accelerate the adoption of innovative and safer medication processes within the Canadian healthcare system thus creating a medication system that protects Canadian patients from preventable and potentially serious harm.

Its release represents the final phase of the Canadian Pharmaceutical Bar Coding Project, co-led by the Institute for Safe Medication Practices Canada and the Canadian Patient Safety Institute. Its development has incorporated input and received support from major Canadian healthcare practice organizations, such as the Canadian Nurses Association and the Canadian Society of Hospital Pharmacists.

This document has four sections:

A Bar Code Primer for Leaders
Section I provides an overview of how automated identification works using the GS1 global standard.

Building the Case for Automated Identification of Medications
Section II reviews evidence and principles, building a case for the acquisition and implementation of bar coding systems by reviewing current medication error rates, the potential for human error, available effectiveness studies, and important organizational leadership principles.

Implementation Considerations
Section III presents a high-level review of system implementation considerations, which may be used as the basis for developing a detailed plan.

References
Section IV provides a list of categorized references.

Document Navigation
Readers are encouraged to begin by reading the "Executive Summary", followed by the summary section entitled "Document Précis". These summaries may be most efficient for executive leadership review, and provide direct links to and from the detailed information and citations, as desired.

Additional detail is provided in the remaining document sections which may be most useful to managers who seek to develop a strategic funding argument and/or develop an implementation plan.

Some Words From Leaders …

From Richard Alvarez…

President and CEO
Canada Health Infoway
https://www.infoway-inforoute.ca/

Working together is key to reducing the potential for medication errors. Common standards and sharing of best practices can enable more effective use of technology in patient care environments so as to help Canadians and their healthcare providers to achieve safer medication practices. This resource guide reflects the collective input of experts from across Canada committed to using these tools to make care safer in community-based and institutional settings.

From Sam Shortt…

Director, Quality Initiatives
Canadian Medical Association
http://www.cma.ca/

The Canadian Medical Association (CMA) supports initiatives that increase patient safety and whose implementation is feasible within the fiscal parameters of Canadian healthcare. Adverse drug events, especially those that are preventable through improved healthcare systems, are an ongoing concern to the Association. For that reason, in 2010 the CMA provided written support for the Canadian Pharmaceutical Bar Coding Project, co-led by the Institute for Safe Medication Practices Canada and the Canadian Patient Safety Institute.

The current report, entitled Medication Bar Code System Implementation Planning: A Resource Guide, represents the principal deliverable in the final phase of the Bar Coding Project. It makes a compelling case that the introduction of information systems employing the GS1 global standard for Automated Identification of Pharmaceuticals will enhance patient safety. The use of this technology will allow consistent tracking and identification of medications from the process of manufacture to the hands of the patient in a way that human checking methods can not duplicate.

We encourage healthcare providers and managers in both community and institutional settings to explore this document and, in particular, to learn from the very practical advice on implementation. The report states that in 2010 bar code verification was employed for only 8% of institutional beds in Canada. In contrast, the figure in the United States is currently almost 50%, suggesting Canadian healthcare should accord greater priority to this important patient safety intervention.

From Barb Mildon…

President
Canadian Nurses Association
http://www.cna-aiic.ca

Patient safety has always been a key driver in the Canadian Nurses Association's efforts to advance excellence in nursing practice, whether in community, home or hospital care settings. The care systems we work in evolve through the interaction of highly developed sciences, human variability and technology. Under these conditions, using technology can be our most effective way of reducing preventable errors and improving the quality of health care. The nursing profession, which is responsible for delivering more care than any other group in the health system, fully supports the widespread adoption of medication bar coding technology. In terms of medication safety systems, bar coding offers a much needed series of checks and balances that will minimize the opportunities for error, cross-referencing several pieces of information as medications move along the supply chain to the nurse at the patient's bedside.

In order for bar coding to improve patient safety, nurses and other health-care providers also need a clear understanding of how the technology works and how to use it to support their practice. I think the new Medication Bar Code System Implementation Planning Resource Guide is a valuable tool in achieving this understanding. It presents the key activities to implement bar coding and step-by-step procedures, background information and system requirements, an overview of medication errors and how to design systems to weed them out, and responses to challenges we might meet along the way. This comprehensive guide brings us much closer to ensuring greater patient safety in the future for all patients.

From Myrella Roy …

Executive Director
Canadian Society of Hospital Pharmacists
http://www.cshp.ca/

The Canadian Society of Hospital Pharmacists (CSHP) welcomes the release by the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI) of the publication Medication Bar Code System Implementation Planning: A Resource Guide.

CSHP represents pharmacists who are committed to patient care through the advancement of safe, effective medication use in hospitals and other collaborative healthcare settings. One of our strategic programs is the CSHP 2015 initiative, launched in 2006. As a vision of pharmacy practice excellence by the year 2015, CSHP 2015 strives to improve patients' medication-related outcomes and safety. Two of the CSHP 2015 objectives address the use of bar-code technology:

- *75% of hospitals will use machine-readable coding to verify medications before dispensing.*
- *75% of hospitals will use machine-readable coding to verify all medications before administration to a patient.*

Medication bar code systems are associated with improved operational efficiencies and reduced preventable medication errors and potential adverse events. Despite a wealth of evidence supporting these systems, adoption of the technology is largely lacking in Canada. According to the CSHP 2015 section of the Hospital Pharmacy in Canada 2011/2012 Report, 20% of the survey respondents indicated that bar-code technology is used in their pharmacy dispensary operations and 4% use it to verify medications at the point of care before administration to a patient. Canadian hospitals are making progress, but most still have a long way to go. CSHP is confident that this Guide from ISMP Canada and CPSI will garner support for implementation of medication bar-code, and help build safer medication system infrastructure.

Medication Bar Code System Implementation Planning: A Resource Guide stands on the shoulders of an extensive collection of literature. This comprehensive Guide addresses a variety of topics of interest to pharmacy managers and leaders: how the different types of bar codes differ, how patient care benefits from bar-code systems, how to make the case for the strategic need for the system, and how to implement and assess such systems. The Guide is a must read not only for all those who want a medication bar-code system, but also for those who wish to upgrade their existing bar-code system.

CSHP congratulates ISMP Canada and CPSI on publishing this breakthrough guidance document!

From Elaine Orrbine…

President and CEO, Canadian Association of Paediatric Health Centres
http://www.caphc.org/

The Canadian Association of Paediatric Health Centres (CAPHC) is a recognized leader and advocate for advancing the improvement of healthcare for Canada's children and youth. In this capacity, our Board strongly endorsed the Canadian Pharmaceutical Bar Coding Project and has supported the work of the Institute for Safe Medication Practices Canada, the Canadian Patient Safety Institute, and all the partners behind this project throughout its development process. It is our pleasure to now stand behind the release of this bar coding resource guide, which is the product of many years of work and collaboration between the pharmaceutical industry and national health organizations. We are especially appreciative of the significance of the guide in helping members of the CAPHC community adopt the principles of automated patient identification and implement the systems needed to ensure safer care at the bedside for the thousands of children and youth who have to be accommodated daily, with countless recalculations of their medication because of the small doses in which they have to be administered.

From Michael Cohen…

President, Institute for Safe Medication Practices (U.S.)
http://www.ismp.org/default.asp

Bar code scanning is one of the most important technologies to assure patient safety. So completion of the bar code project serves as a seminal event for Canada. It ends a standoff that existed for many years where manufacturers were reluctant to invest in systems to produce bar-coded medication packages if hospitals and pharmacies weren't equipped to scan them. At the same time, hospitals and pharmacies wouldn't invest in scanning systems unless medications were available with bar-codes as repackaging the medications internally would be costly.

From Mark Neuenschwander ...

President, Neuenschwander Company, and co-founder of the TerraPharma Project
Producers of the unSUMMIT Conferences on Medication Bar Coding

http://twitter.com/hospitalrx
http://www.unsummitu.com/unsummit-u/

The Medication Bar Code System Implementation Planning resource guide is brilliant, thorough, and timely. This labor of love from the Canadian Pharmaceutical Bar Coding Project paves the way for hospitals, nursing homes and patients to benefit from state-of-the-art technologies, which have proven effective for industry and consumers across North America and around the world.

Utilizing bar-coding at all transfer points, Federal Express and UPS have demonstrated efficiency and accuracy in delivering packages to the correct address. Amazon.com fulfillment centers commit less than one error in a thousand transactions by scanning product bar codes against computer-generated orders. Big-box stores and super markets have enough data to trust the accuracy of customers scanning and weighing products at self-checkout kiosks.

Common sense suggests that bar-code driven clinical systems would assist caregivers in giving the right medications to the right patient and to prevent one patient's specimen from being confused with another's.

Arguably, the life-and-death benefits for healthcare are more important than the economic benefits to business and industry. So what if a blue baby blanket ordered on line arrives in pink? It's critical that heparin ordered by a physician for that little boy does not arrive in an adult dosage.

In the U.S., we could not scan drugs at the point of care until individual packages arrived from the manufacturer with bar codes. But manufacturers would not bar code product until the government required it. If we had this Resource Guide in the US when we first got serious about bar-coding in hospitals, we'd be ten years ahead of where we are today.

I hope and pray your government, drug manufacturers, and healthcare institutions will waste no time in capitalizing on this landmark guide and begin reaping the benefits of bar-coding experienced your neighbors to the south.

Oh, and did I mention how the literature[127] finally validated our common sense was correct—that what made business and industry more efficient and accurate would make hospitals less wasteful and, more importantly, safer at the point of care?

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127. Poon EG, Keohane CA, Yoon CS, et al. Effect of Bar-Code Technology on the Safety of Medication Administration. N Engl J Med. 2010; 362:1698-707.

Contents

Glossary

The following defined technical terms are italicized throughout this document. Organization names and healthcare terms used repetitively are defined and abbreviated within the document itself.

AIDC (Automated Identification and Data Capture) or Automated Identification
Automated Identification refers to the process of automatically reading a *data carrier*, separating and extracting the individual embedded *data elements,* using them to automatically obtain more information about the coded item from a computer database. The information obtained is then usually recorded (data captured) within a process document, thus indicating that the transaction (or that particular transaction step) has been accurately completed. Note that a complex process involving several steps may include a series of individual *AIDC* steps before the entire process is deemed to be fully completed.

Bar Code:
Refers to a specific type of *data carrier*, but performs the same function as other *data carriers*. There are many types of bar codes, which differ slightly in their ability to carry multiple *data elements* and which will be discussed later in this document.

Data Carrier:
Refers to any symbol or device capable of holding embedded data characters, and which can be read (extracted) by a reader/scanner. Examples include bar codes and data chips such as those found on charge cards, staff name badges, etc.

Data Element
Refers to a piece of information usually in the form of a short numeric, textual or alpha-numeric character string contained within a *bar code* or other *data carrier*. The characters can often not be interpreted by humans directly, and rely on an aligned *database* to provide additional data fields (information) about the data element.

DataBar:
Properly called *GS1* DataBar symbology family of bar codes, this term refers to a *GS1*-approved *one-dimensional* bar code family which has several variants. They generally allow additional characters compared with UPC codes.

Database or Data Registry:
Refers to a source of information accessible to a reader' software, and which allows the *data element* to be located within the database. Once located, the associated data record contains additional information about the coded/scanned item. The information extracted from the database is more descriptive to a human than the *data element* itself. The additional information possible is almost limitless, and can be used to assist a human to better identify or understand properties about the product, service or person scanned.

DataMatrix:
Properly called the *GS1* DataMatrix symbology, this term refers to a *GS1*-approved two-dimensional (2D) bar code. It has expanded capabilities and features, as outlined in Appendix 1.

Symbology:
Refers generically to a bar code type, such as UPC, DataMatrix, and others. Different bar code symbologies have different capabilities and, therefore, potential uses.

UPC Code:
UPC refers to a specific symbology: a *one-dimensional* (*1D* or *linear*) bar code known as a Universal Product Code (UPC), of several sub-types. The UPC code has a long history both within Europe and North America, particularly within the retail sector for point-of-sale transactions. It may be used within healthcare settings for a transitional period, but has some technical limitations which may limit its future usefulness.

About the *Canadian Pharmaceutical Bar Coding Project*

The following resource guide reviews bar coding and its value to community and institutional medication management. It was developed in partnership by the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI), as the *Canadian Pharmaceutical Bar Coding Project*, under the direction of a national advisory group, the *Implementation Committee* (*IC*). The document has been reviewed by a panel of front-line healthcare leaders and executives, some of whom also sit on the project's *IC* and/or *Technical Task Force*.

The need to adopt standards for processes related to *Automated Identification* of medications can be traced through the medical literature, which shows an overreliance on human checking methods. These legacy processes are now known to carry unacceptable error rates.

The purpose of the *Canadian Pharmaceutical Bar Coding Project* was to establish a national consensus on *Automated Identification* for pharmaceuticals. The specific project objectives were published in September 2008. The project continues to be supported by funding from both not-for-profit and for-profit organizations committed to improving medication safety for all Canadian patients, while optimizing system efficiencies within the healthcare supply chain.

The project has been widely endorsed by major Canadian healthcare practice organizations. Endorsements and other project documents are available at the following web page:
http://www.ismp-canada.org/barcoding/

The following is a synopsis of the four project phases:

Phase I: National Stakeholder Roundtable (January 2008)
The need for a pan-Canadian standard for bar coding of medications was affirmed by the National Stakeholder Roundtable, held in early 2008 under the sponsorship of ISMP Canada and the CPSI and subsequently documented in the roundtable proceedings (published in July 2008), which incorporated broad input from the healthcare industry.
http://www.ismp-canada.org/download/BarCoding_Roundtable_Proceedings.pdf

Phase II: Project Charter and Adoption of the GS1 global Automated Identification Standard
The IC approved the project charter and a national process to review and adopt a pan-Canadian bar coding standard for pharmaceuticals. It was envisioned that such a standard would provide a common basis for Automated Identification of medications at each stage of the medication-use process.

In April 2009, ISMP Canada and the CPSI issued a joint statement endorsing adoption of the GS1 global standard for *Automated Identification* of pharmaceuticals in Canada. In doing so, they recognized the importance of international integration of identification standards for pharmaceuticals, represented by the global collaboration established by GS1. The GS1 global standard has already been adopted by many Canadian and global manufacturers and by other healthcare-related organizations.

GS1's Canadian arm, GS1 Canada, a not-for-profit organization, has been working with the Canadian Pharmaceutical Bar Coding Project and the project's Technical Task Force to identify the requirements of users in each healthcare sector and thus to ensure that existing or planned GS1 global standards will meet identified needs for efficiency of the supply chain and patient safety.

Reporting to the IC and with technical support from GS1 Canada experts, a 34-member national Technical Task Force was formed. The Technical Task Force consisted of members from six Canadian healthcare sectors: pharmaceutical manufacturers, supply chain and group purchasing organizations, retail pharmacy professionals, institutional pharmacy professionals, integrated providers of healthcare information technology, and professional practice and healthcare quality organizations.

A technical statement entitled Joint Technical Statement on Pharmaceutical Automated Identification and Product Database Requirements (JTS) was originally released in January 2010 and was updated as Version II: 2012 in February 2012. The document describes the pan-Canadian integration of Automated Identification of pharmaceutical products and provides a basis for the coordinated transfer of each medication from the manufacturer to the patient-dose level with a single product bar code (identifier). The JTS (Version II: 2012) and its supplements are available for viewing or downloading at the following link: http://www.ismp-canada.org/barcoding/index.htm

The adoption of a global Automated Identification standard in Canada, with the availability of bar code reader technology connected to intelligent software, will allow the country's healthcare system to advance patient safety practices. In particular, *Automated Identification* of medications, as described in the JTS, will allow healthcare solution providers to meet public expectations for safer healthcare practice, through the development of automated software for identifying products and checking their safety. Such innovations will, in turn, also support busy healthcare providers by ensuring that medications are identified accurately, providing reliable access to standardized product descriptions from a common product data registry, and enhancing the quality of documentation in the patient electronic health record, thus making the Canadian healthcare system safer and more efficient.

Phases III and IV: Promotion of Improved Understanding and Adoption of Automated Identification

During Phase III of this project, the updated 2012 JTS was disseminated across all Canadian healthcare sectors, to encourage development of appropriate safety software and automated practice systems using a common *AIDC* standard and to promulgate a broad understanding of the safety benefits of bar coding among pharmaceutical manufacturers and technology providers.

During Phase IV, improved end-user and leadership knowledge and acceptance of bar coding methods are being pursued. The purpose of Phase IV activities is to accelerate the adoption into practice of Automated Identification strategies for medications. The current resource guide, which is a defined Phase IV objective, is directed to front-line healthcare providers and executive leaders, in both community and institutional practices.

Executive Summary

This medication bar code resource guide is part of the *Canadian Pharmaceutical Bar Coding Project,* a project co-led by the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). This multiyear project, which has received input from many individuals representing six Canadian healthcare sectors, has also generated a series of technical statements related to the use of a common bar coding standard for pharmaceuticals used in Canada.

The project has been endorsed by major Canadian healthcare practice organizations, for its objectives to create a pan-Canadian standard for pharmaceutical bar coding practices usable within all Canadian healthcare sectors and to increase patient safety through the avoidance of preventable medication errors by automated (bar code) verification methods. All project information, including downloadable documents, can be found at the ISMP Canada website: http://www.ismp-canada.org/barcoding/index.htm

Specifically, this medication bar code resource guide provides direction to end-user organizations within both community-based (e.g., nursing home) and institutional (e.g., hospital and ambulatory) care environments. It provides executives and practice leaders with simple yet important knowledge about bar code systems, develops strategic arguments for the acquisition and funding of such systems, and offers implementation guidance for the successful acquisition and adoption of the technology.

All of the organizations that have supported the project or endorsed its objectives hope that the project as a whole and this guide in particular will stimulate Canadian governmental and healthcare leaders to align behind this national initiative and more rapidly acquire and implement this critical medication-related patient safety technology.

Section I: A Bar Code Primer for Leaders

Section I introduces bar coding to leaders, showing in a simplified manner how bar codes work along the medication chain to ensure accuracy of medication verification and documentation, thereby significantly reducing the incidence of preventable medication errors.

Human error is a major cause of preventable medication errors. These errors constitute a major factor in elevated adverse drug event rates in healthcare, which in turn lead to substantial patient harm and wasted system resources. The introduction of automated verification technologies increases patient safety by reducing medication-related harm.

A global bar code standard for pharmaceuticals, known as the GS1 global Automated Identification and Data Capture (AIDC) application standard, has now been adopted for Canada. This global standard has also been adopted by many international healthcare organizations, including numerous regulatory authorities, and will continue to inform national automated identification practices in Canada. Its application in bar codes at the commercial pharmaceutical packaging level (by December 2012) allows individual units of medication to be safely and efficiently processed, with excellent documentation, along the complete medication chain from manufacturer to the patient's bedside.

Section I explains how these machine-readable bar codes work in front-line medication practices. It outlines, in simple terms, the basic components of the GS1 global standard, the various forms of one- and two-dimensional bar codes, and their inherent capacities for embedding essential *data elements* about drug products. These embedded *data elements* ensure accurate medication verification by bar code readers and improve the documentation accuracy of related the medication process in electronic health records.

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

It is imperative that senior leadership, including chief financial and information officers, understand not only that significant patient harm that is avoidable, but also the secondary cost-related and organizational benefits of automated medication-related processes. They must work closely with nursing and pharmacy practice leaders to create funded, multiyear strategic plans for medication safety. Such a process is found in the Ontario Hospital Association recommended benchmarking process for *Electronic Medical Record Adoption*. Failure to automate medication verification and achieve standard procedures with related processes may increasingly be viewed by external stakeholders as organizational failure.

High reliability organizations (HROs) are increasingly cited as models for many healthcare operations. HROs have several common characteristics upon which healthcare planning can be based, including the promotion of standardized processes for routine (but potentially harmful) processes. Such practices would be consistent with automated medication systems.

The medication-use process involves two intersecting chains: a four-step prescription process and a more complex pathway involving a series of product manipulations and transfers. Although study methodologies and definitions of "error" and "adverse drug event" (ADE) vary, current rates of preventable medication error are unacceptably high, in both community-based and institutional care. All practice organizations agree that significant system changes are required; changes that will support healthcare practitioners in routine medication processes known to be associated with inadvertent and significant patient harm.

Patient harm leads to large primary and secondary costs. In the U.S., estimates of direct costs to institutions exceed $6,000 to $8,000 per ADE based solely on a patient's increased length of stay (LOS). Studies in ambulatory care and community settings have shown equivalent error rates and costs probably exceeding $2,000 per ADE. The true costs to the healthcare system, once secondary economic impacts are taken into account, are thought to be much higher than the simple institutional costs. Errors also contribute to the "clogging" of healthcare system services and beds.

Evidence, principally from observational institutional studies, has shown that bar code verification at the patient's bedside reduces preventable errors by at least 50% and by more in pharmacy-based operations such as dispensing. Additional secondary benefits include many critical medication, patient, and dosing safety checks, improved accuracy of documentation, and direct healthcare provider links to secondary medication and procedural information.

Although few formalized return-on-investment (ROI) studies have been conducted, and their methodologies have not been standardized, early evidence from a few studies indicates that medication

bar coding systems have a positive ROI, beyond the prevention of needless patient harm. Some studies have found an ROI (based on 5-year full-system analysis) of 1 to 4 years, based solely on inpatient LOS. When broader advantages related to healthcare system economics and patient throughput within the healthcare system are considered, it is likely that a positive business case can be made for automated identification.

Finally, the cost of medication verification modules are low relative to the costs of other information-based modules such as computerized prescriber order entry and organizational health information systems. Medication bar code systems have good safety and cost ROI.

In 2010, bar code verification was employed for only 8% of institutional beds and 33% of dispensing/compounding practices within hospital pharmacies in Canada. In the United States, the figure is now approximately 50% at the bedside. Furthermore, it is suspected that bedside bar code verification is very low in Canadian community-based practice.

Canadian success stories are provided as case studies in the Section II appendix.

Section III: Implementation Considerations

High-level implementation considerations are provided looking first at external healthcare system factors influencing planning decisions, and then internal (cultural) factors such as safety-culture education and individual provider practices, touching also on HRO safety principles. Such foundational issues affect the implementation of any new technology, including bar code verification systems.

Experience in health centres has shown that implementation can fail as a consequence of myriad interrelated issues. System "failure modes" may relate to certain issues that are specific to bar coding (e.g., bar code readability, lack of internal facility standards), equipment or network problems, use or over-use of triggered alert warnings, problems with pharmacy support services, or noncompliance by the end user (e.g., low scanning rates or use of workarounds). Healthcare organizations should view new technologies as part of larger collaborative partnerships among care providers and administrative and practice leaders.

To reduce the potential for implementation failure, organizations should consider a number of pre-emptive planning strategies, most of which should be employed during the pre-implementation phase. These include developing implementation teams, applying prudent pre-decision RFP and testing techniques, and performing various other assessments. Failure to perform pre-implementation Usability (Heuristic) Testing of a new system very often results in non-compliance by end users and may even cause new forms of medication errors.

During implementation, a staged training process is recommended. Such an approach allows trainees to gradually increase their comfort with the system under increasingly challenging clinical situations. "Super users" can serve as mentors for newly trained staff members. User satisfaction is highly variable and must be gauged over the long-term, not just immediately after implementation.

A high-level, staged implementation map provided at the end of this section takes the reader through the knowledge, strategic planning, and implementation phases of bar code verification systems.

Document Précis

The "Document Précis" section summarizes the main content of the document, in bullet format. Refer to the complete sections in the body of the document for cited references and additional detail. Direct links to additional detail are provided beside each major section title to assist the reader.

Synopsis Section I: A Bar Code Primer for Leaders

Section I provides a simplified explanation of Automated Identification and Data Capture (AIDC) and the GS1 global AIDC standard, the uses and limitations of selected bar code types within the GS1 standard, and how bar codes can be used within healthcare to safely verify medications and accurately document health care practices.

A Review of Automated Identification (Link to Detail)

- *AIDC* is a term associated with an automated process of verifying objects or service steps, collecting key information about each as they are performed, followed by documentation of the process and verifications within an electronic record for future reference.
- *AIDC* is a generic term that incorporates a bar code, RFID tag or other carrier of encoded data, and that can be interpreted by a suitable scanner/reader.

Human Limitations within Complex Practices

- Medication systems have historically been founded on human methods, relying on well-trained providers who were assumed to be fully vigilant at all times.
- Changes in medications and medication systems are occurring at a pace that is taxing human limitations, potentially leading to differences in individual practices.
- These changes may lead to errors with the potential to cause serious patient harm.
- Systems should be developed to support healthcare providers in routine medication-related processes, while allowing them to more fully engage in cognitive (clinical judgment) and patient communication functions of care.
- Automating repetitive medication-related practices should ensure a higher level of practice standardization, greater safety, and benefits to patient care and the overall Canadian healthcare system.

Machine-Readable Codes and Automated Identification

- A machine-readable code, or *data element*, refers to a piece of information embedded within a bar code or *radiofrequency Identification chip (*RFID*)*.
- Bar codes may use different character types, usually such as numbers, letters, or a combination of the two.

- Data elements can be extracted, read and interpreted by a reader (scanner), which uses them to find additional information, perform process functions, and document the processes accurately (data capture).
- Data elements can denote a product or part, but may also be used to identify a person, location, service, or specific step within a process.

Bar Codes and How They Differ (Link to Detail)

Bar Code Types and Quantity of Stored Data

- *Bar codes*, which are one form of *data carriers*, come in different formats (*symbologies*).
- The most common bar code for retail and some health products is the Universal Product Code (UPC), which is often used for inventory and point-of-sale transactions.
- UPCs have significant character-type limitations, including the number of data characters that can be embedded as a data element.

Bar Codes Are Not Created Equal

- The GS1 global standard has approved several *data carriers* (e.g., *bar codes*) for healthcare.
- Common bar codes are UPC, GS1 DataBar, and GS1 DataBar Expanded, all of which are one-dimensional (or linear [1D]). Two dimensional (non-linear [2D]) bar codes include GS1 DataMatrix.
- These various types of bar codes have different capabilities or attributes, such as:
  - Number of and type of characters allowed in each bar code
  - Ability to carry numeric or alphabetical characters or both
  - Ability to be scanned in various orientations
  - Auto-correction if a portion of the bar code is obliterated
  - Use of application identifiers to differentiate between different data element types.
  - 1D versus 2D codes
  - Label space requirements
- The GS1 DataMatrix (a 2D code) is described as an improvement on the limited UPC (a 1D code).
- QR codes are approved for accessing product information, but not for product automated identification purposes.

RFID Explained

- Radio-frequency identification (RFID) is a system that uses an electronic “tag”, also known as an Electronic Product Code.
- Information (e.g., a *data element*) is stored within a “microchip” that is itself embedded inside a label, tag or package.
- Reading is accomplished by a scanner capable of reading an electrical signal.
- RFID allows reading of a single item or a batch of items.
- “Passive” and “non-passive” RFID chips are defined and their properties and uses are discussed.

- RFID is not yet approved for medication-related use and is still undergoing review by healthcare regulators such as the U.S. Food and Drug Administration, but not yet fully reviewed by Canadian agencies.

GS1 and AIDC Global Standards (Link to Detail)

International Consensus and the GS1 Global Standard

- Global standards for *AIDC* are now established, including standards for approved bar codes and embedded *data elements*.
- These standards facilitate efficient data flow between business partners through the use of such approved bar codes and data elements.
- Use of the GS1 *AIDC* global standards for Canadian medication practices by all healthcare sectors is discussed in a document entitled the *Joint Technical Statement on Pharmaceutical Automated Identification and Product Database Requirements* (Version II: 2012). http://www.ismp-canada.org/barcoding/index.htm

GS1 Services

- GS1 is a global not-for-profit standards organization with branches throughout the world, including GS1 Canada in Canada.
- GS1 Canada supports Canadian businesses and healthcare organizations in utilizing GS1 global standards such as *AIDC* to improve efficiency and health-related (patient) safety and documentation.
- GS1 Canada also works with healthcare stakeholders to further develop the global *AIDC* standard.

Some Key *GS1* Standardized Healthcare *Data elements*

- Illustrations of GS1 bar codes and process are shown.
- Among the wide variety of *data elements* in existence, some are *static* and so never change (e.g., product identification codes), whereas others are *variable* and are subject to change (e.g., lot numbers).
- Some bar codes can embed only a *static data elements* (e.g., UPC), whereas others can embed either static or variable *data elements* or both (e.g., DataMatrix).
- Different data elements are used for different types of information. Within a bar code, different data element types are separated by defined characters known as "Application Identifiers" (AI). The following are examples of data elements and their corresponding AIs:
  - AI 01 = Global Trade Item Number (GTIN)
  - AI 10 = lot or batch number
  - AI 17 = expiry date (YYMMDD)
- Packaging levels are also defined within the GS1 *AIDC* global standards, to allow readers to differentiate between bar codes for pallets, cases, boxes, and single units of inventory.
- The GTIN is an important *data element* that provides an internationally unique product code for each item. Using the GTIN, a *database* can store much additional product data.
- GTINs can be embedded in all GS1 bar code types, with some historical exceptions.

- Many other standardized GS1 data elements are available.
- Serial numbers will soon be used worldwide to identify individual healthcare products, including medications. The international impetus for the application of serial numbers is to reduce counterfeit products and to ensure a chain of ownership and authenticity, a process known as "ePedigree".

System Requirements for Bar Code Use (Link to Detail)

Types of Readers

- Readers (scanners) are required to read bar codes and extract key *data elements*.
- There are two types of readers, for 1D and 2D bar codes, respectively.
- Issues of concern related to reading bar codes or reading failure are discussed.

Software for Bar Code Medication Practices

- Software is required to fully utilize data elements for improving medication-related safety and business practices and for supporting healthcare providers. A list of functionalities is provided, such as auto-calculation and warnings.
- The medication chain and prescription process are discussed.
- The downloadable summary of functionalities of medication safety software available through the Canadian Pharmaceutical Bar Coding Project should be reviewed before any medication bar code system is acquired.

http://www.ismp-canada.org/barcoding/download/JTSv2/SupplB-MinFunctionality.pdf

- A simplified view of how bar coding functionality applies in medication dose administration is provided. A series of functionality groupings are briefly described:
  - Reminders and warnings
  - Automated calculations
  - Interoperability and accessing of relational databases

Data Capture (Link to Detail)

How a Bar Code Reader Finds Data

- After extracting a data element (e.g., *GTIN*) from a bar code, the bar code reader uses its aligned software to find additional product (or service) information. It finds the information within the data fields of an associated inventory or patient health record database. The extracted *data element* extracted acts as a key for finding the additional information within the assigned database.
- Medication databases may contain 50 or more data fields, many of which are increasing structured on GS1 global standards.
- The medication bar code software then transmits the necessary task information (based on these data) to the healthcare provider, who then sees the full information on a screen, and proceeds with the next step of the medication process. The next step, for example, may be automated dose and patient verification, or it may involve a triggered alert (warning).

- When the entire process is completed, the software then documents completion within the patient's electronic health record; or similar quality control documentation or requisitions used with other types of automated medication processes.

Documentation within the Patient's Health Record and Sharing of Information

- The increasing use of standardized data fields within locally-stored medication inventory files (e.g., in the community or hospital pharmacy) will assist in standardizing medication documentation in patient health records.
- Such data standardization will greatly assist in the seamless sharing of patient health information between future provincial and national patient health records (e.g., Canada Health Infoway) and will promote interoperability between healthcare systems.

Appendix I-1: Bar Code Types (Link to Detail)

- The appendix presents a brief comparative review of bar code types and their advantages and disadvantages.

Synopsis Section II: Building the Case for Automated Identification of Medications:

The Value of Bar Code Systems in Reducing Preventable Medication Errors

Section II provides a rationale for utilizing automated medication verification at various stages of the medication-use process. It offers a basis for understanding the problem of preventable medication errors, human accuracy issues related to routine but important medication-use functions, and the principles of enhanced support for such functions.

It also provides speaks to the important role of senior healthcare leaders in adopting strategies aligned with improved electronic and automated systems.

An Overview of Medication Errors and Their Causes (Link to Detail)

Prescription and Medication Management Pathways

- The full medication-use process involves two intersecting pathways: the four-step prescription pathway of prescribing, transcribing, dispensing, and administering doses, which is supported by a more complex medication pathway, which involves a series of product manipulations and service hand-offs related to the prescription itself.
- Preventable adverse drug events (ADEs) result from various causes, including all types of medication errors, whether errors of commission or errors of omission.
- Medication errors occur within both community-based and institutional care, but the exact rates from each setting are unknown.

Methodologies for and Findings of Error Rate Studies

- The methodologies and settings for studying ADEs and medication errors vary widely, which leads to difficulties in comparing studies and determining precise error rates.
- Incident reporting and chart review methodologies are not ideal for determining error rates; observational methods generate more accurate estimates.
- Appendix II-1 summarizes a selection of studies, largely based on observational methods, which show elevated rates of *ADE* and/or error rates, with a high degree of preventability.
    - Errors have been observed in as many as 14% of administered medication doses.
    - One major study in “skilled nursing” facilities showed no statistical difference in error rates between community-based and institutional care.
- The Canadian Adverse Events study (2004) and the U.S. Institute of Medicine’s update report on medication errors (2007) and) are notable studies of medication-related errors and associated adverse events.
- From the data summarized, it can be concluded that ADEs resulting from preventable medication errors are too high, and strategic safety planning is required to address this problem.

Causes and Preventability of Medication Errors

- The provision of advanced therapeutic care in all care environments, coupled with the requirements of complex medication regimens, has led to unprecedented demands on healthcare providers.
- The expectation of sustained human vigilance over all aspects of this complex care, while meeting multiple competing demands, may have exceeded the collective ability of healthcare providers to perform repetitive, routine, but important patient care tasks.
- Humans are susceptible to errors known as mistakes or slips, which, if not intercepted, can lead to significant patient harm.
- Many such errors could be prevented through automated support for healthcare providers, such as bar code verification systems.

The Impact of Failure (Link to Detail)

Patient and Caregiver Harm, Effect on Public Confidence, and Canadian Case Studies

- Studies have shown that a significant percentage of adverse events (including ADEs related to preventable medication errors) lead to serious patient harm, including permanent disability or death.
- A second victim of error is the healthcare provider involved in each ADE, who is not usually the primary "system" cause" of the error, yet can also be affected. Provider harm may manifest as severe remorse and reduced confidence, for which therapeutic intervention may be required.
- Public and governmental trust in individual centres of care, or Canadian healthcare in general, suffers when medications errors occur.
- Two Canadian case studies of medication errors causing death which were potentially avoidable with bar coding are summarized.

ADE Costs in Community and Institutional Settings

- The reported healthcare system costs of preventable *ADEs* are likely substantially understated because of incomplete assessment of the true cost implications.
- To date, institutional *ADE* costs have usually been quantified solely in terms of increased *Length of Stay* (*LOS*). The average estimated increase in *LOS* varies but is in the range of 5–7 days per *ADE,* including preventable medication errors that can be avoided through technology.
- Institutional costs have been estimated at $6,000 to $8,000 (2007 USD) per ADE, not including associated costs external to the institution.
- *Emergency* department visits associated with community-acquired preventable *ADEs* are estimated at over $1,400 per ADE (range $1,140 to $10,375) for admitted patients.
- Costs of ADEs in ambulatory and long-term care (e.g., nursing home) settings have not been well studied. One study from an ambulatory setting estimated a cost of $2,000 per preventable event.

Healthcare System Cost Continuum and Patient Access Time

- Current studies focus primarily on costs incurred within institutions; real healthcare system costs from preventable medication errors and other ADEs are much higher.
- *ADE*-related costs should also account for patient follow-up in the community, laboratory and clinic costs, loss of family and business income, travel, insurance, and legal costs, among others.
- Canadian patients' access to healthcare services is impeded by congestion and wastage partially caused by preventable adverse events, as measured in terms of waiting lists, hospital occupancy, emergency department over-crowding, and availability of support services such as laboratory testing. Reducing preventable errors should assist in making the healthcare system more accessible to Canadians.
- Inaccuracies in health documentation lead to duplication, delays, and related inefficiencies. Standardization of data capture associated with bar coding would greatly enhance the quality and transferability of health record information.

Silos of Care

- Community-based and institutional care planning strategies are often developed and implemented within "care silos", yet each setting can significantly affect the costs and operational efficiency of the other.
- More benefit could be achieved if the planning of automated medication verification and documentation strategies and anticipated system impacts were coupled between care environments.

Designing Out Errors (Link to Detail)

High Reliability Organizations

- *High reliability organizations (HROs)* are defined and their key organizational characteristics outlined.
- *HRO* practices typically include containment of unexpected occurrences (e.g., errors), anticipation of problems, safety education, equity between workers within a safety culture, definition of processes, and mindful leadership.
- *HROs* typically avoid unnecessary procedural complexities; however, they do not try to simplify processes or process reviews that are not inherently simple.
- *HROs* do not support individual procedural variation by staff (a typical "cottage industry" approach). Where possible and appropriate, employed systems should ensure procedural consistency with and conformity to established processes.

Reducing Human Practice Variability for Routine Tasks

- System changes based on "forced functions" and automated procedures supported by computer software are effective methods of reducing human practice variability and reduce error potential.
- Automation and computerization, such as medication bar code verification, are recommended for routine tasks that lend themselves to such processes and that will benefit from safety reminders to healthcare providers and quality documentation.
- Further customization of unique practice areas may be necessary, to ensure that the selected automated system conforms with the specialized care processes.

Automated Identification: Evidence of Effectiveness in Error Reduction (Link to Detail)

The Safety Evidence Dilemma

- Some reviewers of healthcare safety studies suggest that evidence is imperfect due to variation in the methodologies, criteria definitions, and results of published studies.
- The current evidence dilemma facing organizational leadership is discussed, where studies utilizing observational methodologies are highlighted.
- The impracticality of each organization establishing its own ideal study evidence is argued.
- The evidence available so far for many safety improvements (such as unit dosing, storage of concentrated medications, standardization of concentrations, and now bar coding) is limited but should be sufficient for decision-makers to gain a degree of comfort while planning strategically for long-term improvements in the medication safety system.

Functionality and Findings of Bar Code Verification Systems

- Appendices II-2 and II-3 summarize study results for bar code verification.
  - Appendix II-2 summarizes the results of observational studies of the effectiveness of bar code verification in reducing medication errors in institutional settings. The selected studies indicate a reduction in medication errors (excluding errors related to dose timing) of 50% or more.
  - Few data exist for community-based nursing home care; however, it seems logical to expect similar effectiveness, in light of the similarities in medication error rates and medication-related processes.
  - Appendix II-3 summarizes three literature reviews of published bar code verification studies. The reviews cite the known methodology deficits, but all conclude that most bar coding studies have demonstrated positive effects on error rates and on qualitative aspects of the medication-use process, including accurate documentation of medication-related events.
- The functionality of bar code verification at various steps along the medication chain, such as pharmacy operations, stocking, and bedside dose verification (a process known as *Bar Code Medication Administration* or *BCMA*) is briefly discussed.
- A link to a downloadable checklist of the minimum functionality of safety software is provided.
  http://www.ismp-canada.org/barcoding/download/JTSv2/SupplB-MinFunctionality.pdf
- The secondary patient care benefits of bar coding software, beyond basic verification and documentation of products and patients, are noted. Such secondary benefits include clinical monitoring reminders, allergy checks, drug and laboratory warnings, patient education material, and product images.

The Strategic Planning Imperative (Link to Detail)

The Importance of Leadership

- It can be difficult for healthcare leadership to balance needs for clinical and other system improvements with constrained resources.
- In the United States, hospital excellence and efficiency are increasingly being measured by a set of metrics related to Hospital-Acquired Conditions (HACs). These metrics include overall infection rates, as well as rates of hospital-acquired infections, readmissions, and other potentially avoidable comorbidities. Preventable ADEs constitute one such HAC.
- The future reputations and funding streams of U.S. institutions will be increasingly influenced by HACs.
- In Canada, future healthcare funding and organizational reputation may increasingly be linked to a similar HAC metric, forming part of governmental or health authority funding models.
- CEOs, CFOs, and CIOs must collaborate to fully understand the relative cost-related risks, to both patients and the organization as a whole, of preventable medication errors and to ensure effective strategic planning.
- Important *HRO* principles, including healthcare providers' conformance with established practices, apply to bar coding methods.
- Practice conformance must be balanced with flexibility on the part of technology providers (vendors) to address functional requirements. As well, the functionality of the bar code system must support customization in areas of specialized care needs.
- Vendor performance should be tested and confirmed. Ideally, the vendor will become a partner in achieving the organization's risk objectives and measuring its outcomes.
- Failure to address *HRO* issues of automation and staff conformance may increasingly be viewed by external stakeholders as organizational failure.
- Senior management should access benchmarking adoption models, like the Ontario Hospital Association's Electronic Medical Record Adoption Model.

Implementation Penetration of Bar Code Verification Practices

- Implementation of bar code verification in US hospitals is 50% (bedside BCMA).
- Canadian penetration lags:
    - approximately 8% at the bedside
    - approximately 33% full or partial verification of dispensed doses within pharmacy
- There is little indication of widespread community-based implementation in Canada.

The Value of Medication Bar Code Verification Systems (Link to Detail)

Hard versus Soft Cost Benefits

- Senior healthcare leadership may find it difficult to be certain that bar code verification will be beneficial, given the stated limitations of effectiveness evidence and the relatively high cost of acquisition.

- On the other hand, there is observational evidence of reduced rates of errors, and other positive impacts of medication bar code verification.
- Direct (hard) and indirect (soft) benefits are listed. Hard cost benefits include avoidance of extended patient *LOS*, inventory efficiencies, and reduced liability costs. The many soft benefits, including potential cost savings, include reduced system wastage, reduced drug treatment costs, improved patient throughput within the healthcare system, reduced emergency department visits caused by drug-related adverse effects in the community, and improved documentation in patients' electronic health records.

***Return-on-Investment* Studies**

- *Return-on-investment (ROI)* studies for any health-related information technology are few and suffer from methodology and criteria (metric) definition issues similar to those in many patient safety studies. This situation holds true for medication management technologies.
- An extensive *ROI* evidence base does not yet exist for bar code verification systems.
- Early *ROI* studies indicate that medication bar code verification modules within a *health information system* (*HIS*) project have the following investment attributes:
    - are fully cost-effective within 1–4 years, according to a multiyear *ROI* assessment based on reductions in medication error–related LOS
    - have shorter *ROI* and implementation timelines than the much larger *computerized prescriber order entry (CPOE)* modules

The Logic Stream: If A, then B, then C (Link to Detail)

- A stream of logic is presented to illustrate our project's positions on key issues related to the decision to acquire bar code systems.
- The issues include the preventability of medication errors, the impact and cost of patient harm, the reliability of available evidence of effectiveness, and the costs, benefits, and consequences of an organizational failure to implement bar coding technologies.
- This logic supports the contention that medication bar code verification systems represent an important aspect of both patient safety and innovation within the healthcare system and therefore should be included in organizations' strategic plans.
- Community-based strategic acquisition decisions may be considered to follow a similar logical flow.
- Beyond the cost considerations, it is known that patients suffer significant harm from current methods of medication management. This harm can and should be reduced significantly by application of medication bar code verification methods.

Recommendations from Key Organizations (Link to Detail)

- A list of published recommendations from key healthcare organizations is provided.
- A list of 13 Canadian practice organizations endorsing this project, including its objective to promote the adoption of bar code verification practices within Canadian healthcare, is also provided.

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

(Link to Detail)

- The appendix presents a number of summarized studies based on reported medication error or ADE rates.

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

(Link to Detail)

- The appendix presents a number of summarized bar code effectiveness studies based primarily on observational study methods.

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

(Link to Detail)

- The appendix summarizes reviews of bar code effectiveness studies from three healthcare quality organizations.

Appendix II-4: Canadian Case Studies

(Link to Detail)

- The appendix provides experience from Canadian institutions that have previously implemented bar code-enabled medication systems.

Synopsis Section III: Implementation Considerations

Successful Bar Code Implementation: Foundational and Specific Experiences

Successful implementation of new or modified healthcare systems depends on a number of external and internal factors. External factors are often not within the facility's control, but internal factors can often be foreseen and addressed. This section reviews both high-level external influences and a number of internal planning considerations and also suggests a structure for the implementation process.

The Foundation for Safety Culture Change

Facing External Factors (Link to Detail)

The following four external factors are influences over which managers will have little direct control, but they nonetheless affect the planning expectations of new healthcare systems:

- Clinical Risk Categories
  A wide range of patients' clinical needs and comorbidities influence how healthcare systems are built. To handle a broad range of such needs and comorbidities within a single setting, systems must be resilient. In such varied circumstances, implemented systems may be acceptable overall, yet may not ideal for specific conditions.
- Healthcare Economics and Governance
  High-level governmental or regional funding plans affect local budgets and hence local initiatives. On occasion, such economic factors affect planning for both physical structures and system planning.
- Public Expectations of the Healthcare System
  Public expectations for successful health outcomes may be difficult to achieve in light of planning constraints. Increased prioritization based on realistic objective, evidence-based health and safety outcomes is necessary.
- Definitions of Healthcare Outcomes
  Varied definitions of quality outcomes and their metrics may make it difficult to precisely define and demonstrate a successful and reasonable outcome for a new system, such as medication error reduction through medication system changes.

Facing Internal High Reliability Factors (Link to Detail)

Five levels of internal success factors affecting planning and implementation are provided, along with related individual provider barriers. Unlike external factors, these variables are usually within the influence of an organization's executive and project planners.

Acknowledging these factors and working to improve them is a preliminary project step, laying the foundation for technical and system modifications to come.

- Strategic and Budgetary Planning

  Aligning budgetary and strategic safety plans is important. Such alignment is usually the responsibility of the organization's administrators, especially its CFO and CIO. Full alignment of bar code modules with both the *MMIT* and *health information system* (*HIS)* plans is important.

  Failure to demonstrate leadership by ensuring such alignment is an early indicator of probable project failure.

- Staff Availability

  Chronic shortages of skilled staff affect an organization's overall ability to focus on higher-level safety initiatives, including new systems, and staff dissatisfaction and/or process workarounds may ensue. Conversely, a well-staffed operation sends a powerful message to healthcare providers that the organization is a high-quality care centre, which in turn may be a strategic recruitment advantage.

  A realistic assessment of clinical workload and an integrated staffing strategy should be undertaken.

- Collaborative and Balanced Safety Culture

  It is important to build a collaborative safety culture in which all participants are consulted and managed fairly.

  A 2005 statement from the American Association of Critical-Care Nurses on "healthy" work environments offered a well-rounded strategy for engagement of healthcare providers, which could serve as an example for other organizations. Such a strategy should have the full and visible support of an organization's executive.

  Organizations should endeavour to strike a balance between a "no blame" environment and "provider accountability".

  Realistic productivity expectations are a trait of *high reliability organizations* (*HROs)*. In particular, *HROs* place safety considerations above workload (output) achievements. In healthcare, it is often difficult to always achieve this balance, given that actions to address certain patient needs cannot be delayed or minimized. Organizations should attempt to address and reconcile these competing priorities.

- Response to Internal Barriers within Healthcare *HRO*s

  Five internal "barriers" to healthcare *HROs* are presented, relating primarily to changing provider attitudes toward personal (individual) objectives and teamwork, and moving toward practice conformance for identified tasks. These are presented in more detail within Appendix III-1.

- Acceptance of Limitations on Maximum Performance
  Some individuals are driven to achieve high personal objectives, an approach that may manifest as taking on unrealistic workloads or other individual practice methods. For *routine* tasks, such as most medication-related processes, standardized process activities should not incorporate (or expect) unique maximum performances.

- Refinement of Professional Autonomy
  Health professionals are expected to use clinical judgment. However, when utilizing a technical system, the system should minimize the ability of a single provider (or group of providers) to create and adopt individual patterns of technical use. This stipulation does not apply to truly specialized practice areas, or in areas of clinical patient assessment or treatment planning, where application of individual clinical judgment may be required for valid and approved patient care reasons.

- Transition from the Mindset of Craftsperson to That of Equivalent Actors
  Unique practices for standardized routine practices should be avoided. All "actors", (i.e., healthcare providers) within such processes should be replaceable without any effect on the quality of the outcome. All "actors" should agree to a mindset of conformance and not that of a unique "craftsperson".

- Need for System-Level Arbitration to Optimize Safety Strategy
  HROs accept and indeed encourage both internal and external arbitration of their processes.

- Need to Simplify Professional Rules and Regulations
  A careful approach to process simplification is needed. Although *HROs* typically make processes as simple as possible, they never oversimplify necessary steps, or the evaluation of near-miss events (system failures). Conversely, unnecessary complexities, such as "procedural patches" over time, should be avoided.

- Identify Processes for Change
  The final internal issue is the need to evaluate current systems and processes through a combination of *Root Cause Analysis (RCA)* (i.e., adverse event review) and *Failure Modes and Effects Analysis (FMEA)* tools. Such evaluations will expose those areas that most require process and/or technological change. Organizations should evaluate systems before deciding on the most appropriate changes to be implemented.

Implementation Failure (Link to Detail)

This subsection discusses the potential failure modes related to bar code implementation (summarized in Appendix III-2) and potential risk-mitigating strategies (summarized in Appendix III-3).

Some potential failure modes are applicable to most planned system changes (e.g., collaborative culture, communication skills), whereas others relate specifically to bar code systems (e.g., bar code readability, scanners).

System Failure Modes (Link to Detail)

- Technology
  Categories of potential technology failure modes are discussed, largely applying to both patient bedside bar code medication administration (BCMA) and pharmacy-based bar coding (dispensing and compounding).

  The complementary use of *FMEA* and *Usability Testing (Heuristic Evaluation)* is discussed. System changes, such as new technologies, entail new processes and, in the case of technologies, new human–machine interactions (*Usability Interfaces*). Many technologies have been shown to improve safety, but they may also introduce new preventable errors, which may be revealed during usability testing.

- Bar Code Standards
  Failure of an organization to select a limited number of bar codes formats for use my lead to degraded system functionality. Organizations must determine their own bar code standards for use in three categories of patient doses: commercial-based, patient-specific bulk or prepackaged, and patient-specific customized. Each category should use a specified bar code symbology containing designated *data elements* that are usable by the bar code software all along the medication and prescription pathways.

- Bar Code Scanners
  Bar code scanner selection is an essential decision for a successful bar code system due to their human/machine usability issues. Readers must be lightweight and transportable, have long-life batteries, retain programming if batteries run out, have a sufficient number of charging stations and sufficient number of back-up units, and be Wi-Fi enabled.

- Bar Code Readability
  Users often cannot differentiate between failure related to non-readability of a bar code and incorrect functioning of a bar code scanner. Bar code non-readability may relate to initial planning decisions such as dose label printer purchased, label and ink materials, and whether or not pre-emptive bar code readability testing was performed.

- Multiple Bar Codes
  The presence of multiple bar codes on a patient dose package (and the relative placement of such codes) is problematic and may lead to confusion and, possibly, workarounds. *Supplement A* of the *Joint Technical Statement on Pharmaceutical*

Automated Identification and Product Database Requirements (Version II: 2012) (*JTS*) provides guidance on bar code placement to pharmaceutical manufacturers, but system implementation planners may also find valuable information related to the creation and placement of bar codes on labels.

- Hidden Sources of Bar Codes
  Some users may apply various methods to bypass patient or dosing bar codes, including use of inappropriate bar codes from so-called "hidden sources". Such workarounds may be viewed by the practitioner as a method of increasing practice efficiency or batching work from several patients within a medication room. They may indicate poor system design or implementation. However, they represent potentially serious deviation from safe practices. Additional user education may be needed.

  Sources of codes used in workarounds include empty dose packages that have not been discarded, photocopies of legitimate bar codes, bar codes printed in the medication administration record, and duplicate patient wrist bands.

- Physical Infrastructure and Support
  Several infrastructure failures may occur once a system has been implemented, any of which may lead to user dissatisfaction with the system or workarounds.

  - Wireless Coverage
    A robust wireless network must be present in all patient care areas. Slow response rates represent efficiency decay and can lead to frustration on the part of users.

  - Maintenance and Technical Support (Computers and Bar Code Scanners)
    All equipment must be properly maintained, and sufficient units must be available to allow for maintenance without interrupting patient care. Qualified technical support must also be readily available.

  - Medication and Prescription System Delays
    Timely and accurate pharmacy services, such as prescription order entry, compounding, and dose dispensing, feed into *BCMA* functionality in patient care areas. Delays in these services, especially if not communicated to nurses and other clinical care providers, can lead to user dissatisfaction with the system or workarounds.

- Alert Fatigue
  Triggered system alerts (warnings) constitute an important element of a medication bar code system. However, setting up too few or too many alerts can diminish the effectiveness of the alert system and compromise patient safety.

  A multidisciplinary planning team should be convened to determine criteria for the type and number of system warnings to be employed. Warnings should be focused on *high-*

alert situations and certain other limited and well-defined situations, such as critical allergies, discontinued medication orders, and major overdoses.

Any organization that is planning a bar coding system is encouraged to consult with other organizations that have already implemented systems with automated alerts.

Records of triggered alerts in a system quality database can be audited to determine any patterns in the alerts being triggered, alert overrides being instituted by users, and the reasons for overrides. Before a decision is made to modify the alert system on the basis of such an audit, users should be interviewed for additional detail.

- Pharmacy-Based Bar Code Functionality
  A large number of pharmacy-based bar code functions are reviewed, such as contracting, purchasing, stock transfer, prescription order entry, compounding, repackaging, cart filling, and dispensing.

  These functions have several inherent failure modes falling into 3 categories: system-induced errors, errors related to user non-compliance, and residual human system errors. As noted above, delays in services are also a potential concern.

  Many medication errors occurring in pharmacy-based functions will be forwarded to the BCMA step but are unlikely to be caught by the BCMA system itself. The planning team should use *FMEA* and *usability testing* to identify critical potential failure points in pharmacy-based functions. High-alert medications and related processes should undergo particular scrutiny.

- User Compliance: A Manifestations of Poor System Design and Implementation
  Previously discussed "upstream" causes of user dissatisfaction with the system and causes of non-compliance are reviewed, including inadequate system design or implementation planning. A good portion of nurse time is associated with the medication process. For a nurse to conform fully to the new system procedures, she/he must also be comfortable with all aspects of the BCMA (bedside) functionality.

  Although the literature often attributes compliance problems to nurses, such problems may involve a user at any point of the medication system.

  Non-compliance during dose administration may take either of 2 forms: reduced scanning rates or workarounds.

  - Reduced Scanning Rates
    The scanning rate can be monitored through the system's database. Low rates may be caused by several factors, each of which should be assessed.

- Workarounds
  Workarounds involve users adding unapproved steps to the process or dropping or modifying approved steps. The potential causes of workarounds can be complex and interrelated.

If BCMA compliance problems arise after implementation, the entire bar code system should be reviewed, with input from front-line users and consideration of contributory upstream factors. Following the review, additional user training should be undertaken, if appropriate.

Reducing System Risks

Detailed planning, accompanied by consultation with other organizations that have successfully implemented a bar code system, is highly recommended. This subsection is divided into pre-implementation, system education and training, and post-implementation considerations.

- Before Implementation (Link to Detail)
  - Implementation Guidance Team
    A multidisciplinary bar code implementation team should be established to oversee planning and implementation of the bar code system. This team should have representatives from nursing, pharmacy, medicine, and administration and should be supported by the information technology and biomedical engineering departments, with some members who attend only for specific aspects of the planning. It should have a strong presence on the facility's medication management information technology (*MMIT)* committee.

    Community-based care organizations should include a representative from their contracted pharmacy provider on the implementation team.

  - Pre-Purchase Considerations
    The pre-purchase stage of system acquisition is critical, as it represents the organization's only opportunity to evaluate the proposed bar code system without fully committing to its purchase. Several key aspects of the system, as well as the vendor's other offerings, should be investigated thoroughly. In particular, functionality of the system's software must undergo detailed scrutiny.

    - Request for Proposal
      A formal request for proposal (RFP) should be developed and sent to prospective vendors. Important sections to include in the RFP are requirements of the vendor and organization prerogatives (e.g., *Usability Testing*). The RFP should contain a checklist of required software functionality, with an indication of the relative importance of each functionality requirement. *Supplement B* of the *JTS* provides a basic bar code functionality checklist as a starting point.

Requirements for educational materials and implementation support should also be included in the RFP. Skilled negotiators should be used.

- Site Visits
  Site visits to other institutions that have implemented the vendor's system should be undertaken during the vendor assessment phase.

- Evaluation of Vendor's Software
  An extensive discussion of staged evaluation of the vendor's software system is provided. Ideally, the software should be demonstrated, following which increasingly more thorough *usability testing* of the system in basic and complex tasks, urgent situations, and clinical simulations based on local care needs and organizational environment.

  Full *usability testing* should occur before a purchase decision is made. If such testing is not possible, the agreement to purchase should allow for further evaluation and possible system modification after implementation. Usability testing may need to be repeated after system modification.

  Negotiated contracts should include the cost of such system modifications, as well as end-user education and implementation.

- Infrastructure and Physical Evaluation
  As noted above, user satisfaction can also be affected by the facility's existing infrastructure and chosen auxiliary equipment. Detailed user-focused evaluation of the following requirements must be completed and any problems addressed: network and wireless suitability, computers and handheld equipment and their functionality, scanners and battery life, battery charging stations, network and wireless infrastructure, ancillary mobile carts, and scanner stands.

- Safety Education and Culture Priming
  Successful implementation relies on users' commitment to innovative system modifications, which will lead to improved safety. Providers who feel that they are "in the loop" and are being consulted will usually be more engaged with the system.

  Effort is required to establish a longstanding commitment to communication, including scheduled discussions and meaningful collaboration.

  - Collaboration and Communication Skills
    To convey the facility's commitment to joint efforts on behalf patient safety and to promote collaboration, group sessions involving both users and leaders should be held. These sessions should be used to establish communication and response channels and should also offer training in communication skills.

- Medication Safety Culture and Goals
  Creation of a medication safety culture and development of broad strategic plans for system improvement are important. Bar code systems should be seen to form part of the overall strategy.

- Network and Database Support and Redundancies
  A number of network infrastructure support issues are discussed. This infrastructure must remain functional at all times, and working groups should be assigned to review, design, and implement the necessary support. Issues for consideration by working groups include:

  - scheduled support and system down time
  - equipment maintenance and redundancy
  - unscheduled down time

  Of particular importance is the need for contingency plans for scheduled and unscheduled down time. Contingencies should include manual methods, use of data back-ups, and data catch-up strategies.

- Pharmacy and Formulary System Preparedness
  Pharmacy-based services that support seamless downstream bar coding (i.e., *BCMA*) must be reviewed and upgraded as necessary. These include a rationalized formulary and standardized concentrations, prepackaging repackaged and batched products, Group Purchasing Organization contracted items and bar codes, set-up of inventory (medication) database for both commercial and in-house pre-prepared (i.e., batched) products, prescription order entry, dispensing medications pursuant to stat and new medication orders, central intravenous admixture (CIVA), and other types of compounded preparations.

- Issues Affecting Bar Code Scanning Rates
  A prospective review of failure modes affecting user scanning rates should be conducted according to the potential failure modes listed above, especially bar code readability, scanner issues, delayed medication services, delayed network response rates, and alerts.

  A collaborative environment with established communication channels is beneficial.

- System Training and Implementation (Link to Detail)
  In this subsection, the stages of user training for a specific bar code system are discussed. Such training should be undertaken only after basic team collaboration has been established and safety culture education, *usability testing*, and any necessary system modifications are complete.

  - System Training and Follow-up

Training should precede live implementation by a period of only a few days. Three levels of training are recommended. Pharmacists should also receive BCMA cross-training to assist them in answering questions from users after implementation.

Basic Classroom Training
Initial classroom training combines demonstrations of the system and simple tabletop training on basic system operations. Communication pathways to services (such as pharmacy and technical support) should be emphasized.

Clinical Simulation Environment Training
A more advanced training session should cover increasingly complex clinical situations, tailored to users' actual practice environments, with classroom set-up to approximating live practices. A variety of orders (e.g., "as needed", stat, range orders) should be included. It is recommended that this session be led by a "super user", who will later become a system mentor to new users.

Live Integration and Mentoring by "Super Users"
Once trainees have begun to use the system in a live environment, they will not be fully efficient. Allow slightly additional staff to be scheduled to allow the trainees to gradually integrate the system into routine practices. Ward-based "super-users" (i.e., local system experts) can provide assistance, with their presence and availability being reduced over a period of weeks. Vendors should continue to provide support during these early live stages, with a staged decrease in service (e.g., transitioning from on-site presence to available on-call).

- After Implementation (Including Operations and Monitoring) (Link to Detail)
  - Staff Satisfaction and Workload
    Staff satisfaction and a balanced workload are very important. The bar code system must be seen to fit seamlessly into a new practice paradigm. The satisfaction of staff in all disciplines should be monitored over time, with recognition that issues of user concern may shift as familiarity with the system grows.

    It is important that any concerns voiced during team rounds or surveys be acknowledged and addressed in some fashion. Such concerns may represent system weaknesses. Even if no system weakness is identified, the concerns may lead to dissatisfaction and possible non-compliance. Ensuring user satisfaction and addressing any issues raised are not short-term strategies but must continue over time, to show that the facility values and fosters communication, collaboration, and interdisciplinary cohesiveness.

  - Auditing Practices
    Technical systems with software-based functionality will have a background database for collecting information about various events. These data will assist system managers in monitoring conformance with system practices. Audits are complementary to, not replacements for, team communications.

- Internal System Data
  Internal system *data element*s can be used to monitor overall activity in the medication-use system, such as number of "catches" (i.e., errors caught by the technology) during dose or patient verification. A rough calculation of activity rate can be generated and monitored using a denominator such as total doses administered or total number of patient days. It should not be assumed that each "catch" necessarily represents an error prevented.

  The number of triggered "alerts" or warnings may also be monitored, as can the number of times alerts are overridden. Any such information must be discussed with the group, as there may be good reasons for non-compliance, in which case alert settings may need adjustment. Non-compliance may also indicate an over reliance on alerts by the system planners.

  Data derived from internal databases can be helpful, but any trends observed should always accompany team discussions with users, and the generation of reports certainly will not replace these discussions.

- Incident Reports and Errors Related to New Technology
  Any new system, including new medication verification technologies, should decrease error rates, but new forms of errors may arise because of the system's inherent weaknesses in a practice environment. Incident reporting should be encouraged, including errors or near misses caused by the system. Key incidents should be followed-up, possibly by means of the *RCA* tool.

- Follow-up Training
  As the bar code verification system changes (including its software functionality or settings), additional communication and training are required. Larger changes may require a return to the structured training outlined above.

Implementation Process Maps

A simplified project activity map is presented in 3 parts (levels) in Appendices III-4.1 through III-4.3: gaining knowledge on bar code issues, strategic arguments, and implementation steps.

Appendix III.4.1: Technical Knowledge (Link to Detail)
Appendix III.4.2: Strategic Plan (Link to Detail)
Appendix III.4.3: Planning Implementation (Link to Detail)

The steps follow the general outline of this resource guide but must expanded into further project detail by the facility's implementation planning team.

Synopsis Section IV: *References provided.* (Link to Detail)

Detailed Resource Guide Sections I to IV

The following sections and associated appendices provide detailed information related to the understanding of medication bar coding technology using the GS1 global standard for automated identification, arguments for the acquisition and funding of medication bar code systems, implementation considerations and, finally, associated references.

These sections are primarily for the use of key practice managers and directors with delegated responsibilities for developing system strategic planning requests and/or system implementation.

The following discussions are summarized in the previous Document Précis section.

Section I: A Bar Code Primer for Leaders

The purpose of this section is to provide a simplistic explanation of Automated Identification and Data Capture (AIDC) and the global standard known as GS1, the use and limitation of some bar code types found within the GS1 standard, and how bar codes can be used within healthcare to safely identify medications and accurately document healthcare practices.

It is hoped readers will be provided with a rudimentary understanding of the AIDC technical process, and feel more confident in working with bar coded medication systems.

A synopsis of Section I is located in the Document Précis section of this document, above.

A Review or Automated Identification

AIDC is a term associated with an automated process of verifying objects or service steps, collecting key information about each as they are performed, followed by documentation of the process and verifications within an electronic record for future reference. *AIDC* is a generic term that incorporates a bar code, RFID tag or other carrier of encoded data, and that can be interpreted by a suitable scanner/reader.

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Human Limitations within Complex Practices

Healthcare delivery practices have been based traditionally on human methods passed from one healthcare provider to another. The most common and reliable medication system component was a well-trained healthcare provider exercising vigilance in the face of multiple simultaneous demands, relying heavily on individual human attentiveness usually within a set of written policies and procedures.

Past healthcare practices evolved at a relatively measured pace, so that changing methods could be taught and incorporated into slightly modified practices. More recently, however, the pace of healthcare innovation has become unsupportable by even the most capable healthcare providers. In such an environment of change, individuality of practice has caused a drift away from overall system predictability and reliability. A

higher degree of healthcare provider (HCP) conformity is required for some tasks to ensure standardization of safety practices. [3, 4, 149]

In its ideal form, individual healthcare provider application of cognitive skills should be limited to those clinical areas where such skills are based on knowledge decisions, such as with diagnosis, surgery, supportive and emergent care, and assessment of patient needs. Certain other aspects of healthcare practice are more routine and technical, and best performed within a more standardized practice structure. Simple repetitive medication processes include drug product selection, individual patient dose manipulation (e.g., compounding and calculation), and, importantly, dose administration.

Increasingly, studies have shown that even simple medication processes are error-prone. [17,18,21,23,77] The reasons for human error are common to all of us, often relating to unintended actions during moments of fatigue, distraction, stress, or multi-tasking. [49,67] Inadvertent medication errors result in serious harm to a patient, and also loss of confidence in the system and the healthcare provider involved. A more complete discussion of inadvertent error and rates is provided in Section II of this document.

Automating repetitive procedures can provide much needed support for busy healthcare providers. Properly implemented, technology has the ability to assist in the completion of routine important tasks, thus assuring an overall higher level of standardization, reliability and safety within an organization. Benefits accrue to patients, healthcare providers and organizations and, by extension, system-wide improvements to Canadian healthcare.

Machine-Readable Codes and Automated Identification

The term *machine-readable code* may also be referred to as a *data element* or a *key.* It refers to an embedded piece of information contained within a carrier of information known as a *data carrier* (e.g., a bar code). The *data carrier* can be read and interpreted by an automated device known as a reader or scanner.

The embedded *data element* may be in any character format as long as the reader can 'interpret' the characters used. Often the data characters will be numbers only (numeric code), but could also be letters only (alpha code), or a combination of numbers and letters (alpha-numeric code).

In most cases, there is no need for a human to read or interpret the *data element*. In fact, very often the *data element* by itself will be meaningless to a human. It will simply be seen as a string of characters. For example, your Social Insurance Number (SIN) is meaningless without looking up the SIN in an affiliated database or similar list of information. Only when found within that database will the SIN lead to essential information about you.

Reading *machine-readable codes* forms part of a larger quality process known as "*Automated Identification and Data Capture*", or *AIDC.* The *AI* and *DC* are often discussed as separate but highly interdependent steps of a process. Like the SIN example above, the first step in any *automated identification* process is for the reader/scanner to read (or "identify") a *data element* from within a *data carrier*, such as a bar code. Next, with the help of a software program that accompanies the reader/scanner, the system uses the extracted *data*

element to search for additional information about that scanned code ("*data capture*"). The information can be captured into a document usually as part of the process. Examples of *data capture* documents include a store's sales receipt, a store's record of sales, or a required quality control document.

Though many scanned bar codes are associated with a product or part, a bar code and its *data element* may also relate to other business aspects, such as a service being provided, a location, a single step in a process, or a person or animal. Business sectors today have the ability to place a data carrier with its embedded *data element* on almost anything for any reason!

In healthcare, bar codes may be used on medical devices, supplies, room locations, patients, staff members, medication containers, or individual patient doses. *Data capture* can refer to many quality control processes, such as requisitions, documenting a process, and, importantly, patient chart documentation. Figure I-1 shows how a bar code with a *data element* (e.g., GTIN) can provide additional information on a drug product for the purpose of data capture. Such access data elements are often "static" (unchanging) identification codes, which will be discussed later in this section.

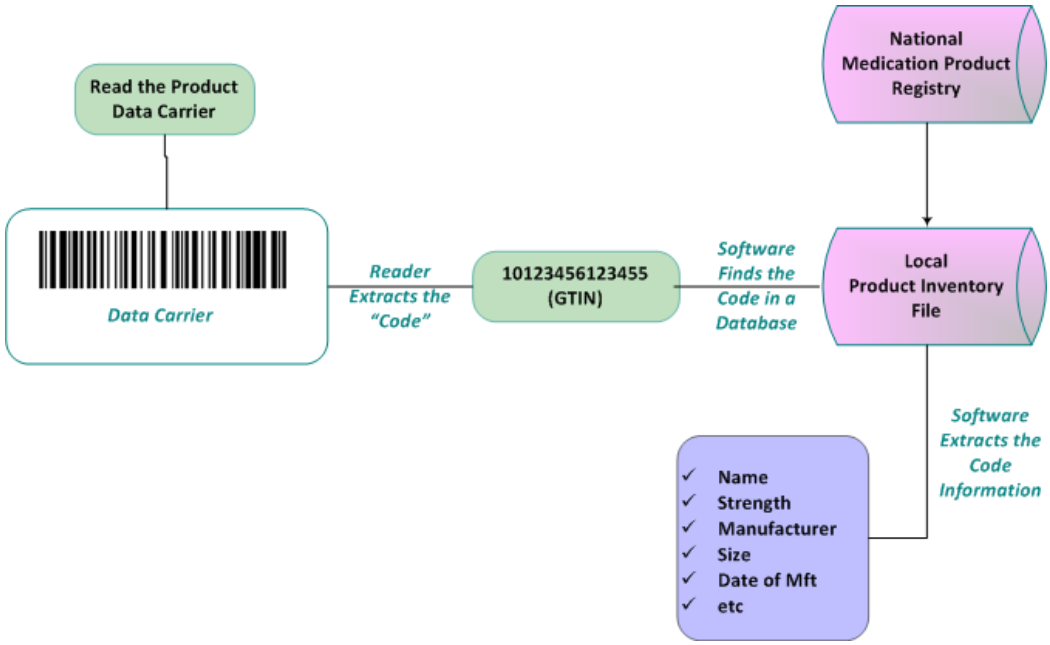

Figure I-1: Reading a Medication *Data element* and Capturing Product Data

Bar Codes and How Do They Differ

A bar code is one type of *data carrier*, and is currently the most common type used within business and healthcare practices. Different bar code types are known as "*symbologies*". The differences can be technically complicated; but suffice it to say, some are better in specific situations.

This section discusses some limitations of some common bar codes to fully accommodate future healthcare practice needs.

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Bar Code Types and Quantity of Stored Data

All bar code *symbolo*gies have the ability to carry one or more *data element*s in the form of a short numeric or alphanumeric strings of characters. However, symbologies have differing abilities to hold data, with some being limited in the number of characters.

Many retail operations use the well-known bar code called a "UPC", or Universal Product Code, that we see when we purchase items every day. UPC is an older style of bar code which often finds its main use in simple "sales" processes known as "*Point of Sale*" transactions. In such cases, an item's UPC code is scanned by a reader/scanner, which then places a textual description of the scanned retail product and its printed numeric code onto a printed sales receipt; a process which is repeated for each scanned item in your basket. The system software obtains product descriptions from the store's inventory files (database), and when the purchase basket is empty, the software totals the item costs, calculates sales tax, and provides a net total, a date, and prints (documents) the sales receipt.

The basic bar code *AIDC* process is not any more complicated in healthcare settings. For example, any medical supply item or medication can be scanned and documented. This process will be discussed in detail later.

In our example, the UPC code has limitations. This bar code symbology can only carry up to 12 numeric characters, and can only be scanned/read across the lines: left-to-right or right-to-left. It cannot be scanned top-to-bottom. The UPC is also a relative large bar code which takes up much space on a package, which is often acceptable for many retail items. More advanced bar code symbologies begin to alleviate some of these orientation and spatial constraints.

When a product's *data element* used for a product has only 12 numeric characters almost any symbology, like a UPC, can be chosen for the product's package. However, if additional *data elements* are required within the bar code, it will require that more characters are stored and, as a consequence, only certain symbologies can be used.

Bar Codes Are Not Created Equal

As noted, there are several types of bar codes, each with its own limitations and advantages. Some are more suited for certain segments of business, such as point-of-sale (retail sales), while others can add additional functions in more complex practices such as healthcare.

Healthcare will need additional product information within our healthcare product bar codes, to ensure an accurate and safe process. Additional information will include lot numbers and expiry dates, or other key medication or supply information. As we evolve automated systems to support patients' needs and related healthcare practices, there will be the need to consider other bar code symbologies.

Advanced bar code formats that alleviate some of the UPC constraints include *GS1* DataBar, *GS1* DataBar Stacked, *GS1* DataBar Expanded Stacked, as well as the two-dimensional *GS1* DataMatrix.

Although bar codes may look quite different, the differences among them relate to one or more of the following advancements. The basic function of reading a bar code's *data elements* is no more complicated than that of a simple UPC code.

- A*dditional character lengths* are allowed.
  This allows more and longer *data elements* to be stored directly within the bar code, including some human readable text (if scanned)
- Carry *both numeric and alphabetical* characters (*alpha-numeric*).
  This allows more complex codes to be developed by software programmers and, thereby, more sophisticated human practice needs can be supported.
- The ability to *scan the bar code in any direction* ("*omnidirectional*")
  The package does not need to be oriented to suit the machine reader/scanner; the bar code can be read up/down/left/right and still read properly.
- *Auto-correction of bar code reading.*
  A common frustration occurs when a code fails to be read by a reader/scanner. This is especially the case in mobile scanning devices. By adding auto-correction within a bar code's structure of lines or dots, even if some of the code is not visible (or has been inadvertently erased or rubbed off), the reader may often successfully read the necessary *data elements*.
- Ability to *utilize Application Indicators* to separate different *data element* functions within a bar code's character string. (See discussion later.)
- *One-dimensional and two-dimensional line/dot patterns* that possesses a combination of one and two dimensional parts to the code (a "*composite*" code).

Here is a brief comparison between the GS1 DataMatrix (two-dimensional) bar code symbology and the one-dimensional UPC code symbology described above:

- A DataMatrix can carry up to 3116 numeric, or 2335 alphanumeric, characters, while the UPC only has the ability to carry only 12 or 14 numeric (only) characters.

- A DataMatrix code also has the ability to utilize "*Application Indictors*" to separate multiple *data elements within the same bar code* (see later), while the UPC can carry only one Application Indicator.
- A DataMatrix has inherent auto-correction abilities to reduce failures in reading the bar code, while the UPC does not.
- A DataMatrix also can be printed in a very small print size to fit on small spaces and can even be laser-etched onto surgical instruments or other equipment parts, while the UPC is a large bar code requiring quite large labels for printing.

Appendix I-1 provides the reader with a synopsis of selected bar code symbologies currently approved by the GS1 global *AIDC* application standards organization, which will review later. For healthcare products, including medications, it is very likely that a product's bar code will come from one of the codes approved by *GS1* and shown in Appendix I-1. It is prudent to ensure software systems used in your nursing home care or hospital can read all of these *GS1* code symbologies, and also consider using them on your internal bar coding procedures for patient-specific prescriptions or products.

As a final note, patient-specific identification bar codes are critical to medication dose administration, as well as other delivered healthcare services. Patient identification can be addressed using one of the *GS1*-approved bar code symbologies, such as shown in the Figure I-2 using an in-house assigned unique patient code. As with medication products, a patient Identification identifier (e.g., patient number) can be uniquely assigned as a type of *data element within the patient's electronic health record.*

Figure I-2: Patient-Identification Bar Codes

The same bar code reader that scans a medication product should be able to read/scan the patient ID *data element* on the patient wrist band. The scanned patient *data element* will access a patient database, which will be separate from the medication or prescription database. There, the automated system will extract individual information related to a patient and his/her admission. The specific bar code symbology used on the patient bar code (wristband usually) may be the same or different to that used on his/her medication doses, laboratory blood tubes or requisitions.

It is not the direct purpose of this guide to develop strategies for patient identification coding. Several coding methods can be used. An example of both patient and provider IDs is the GS1 global *AIDC* standard known as the Global Service Relation Number (GSRN). This coding method can be used to establish a unique provider/recipient relationship, for example, between a healthcare provider delivering a service and a patient receiving the service. This particular standard can be applied within any business sector where a service or action is delivered by a provider to a "customer or client", where documentation of the transaction is desirable. Readers are encouraged to read on the application of GSRN, or other methods of identifying patients.

RFID Explained

We should here provide a brief comment on *Radio Frequency Identification* (RFID) chips (or "tags"), which you may also see referred to as "*Electronic Product Codes*" (*EPCs*). Although widespread RFID integration into healthcare product or process *AIDC* is probably several years away, the RFID process will almost certainly have a future within healthcare practices. In the interim, more study of the global health standard, process and cost is needed.

RFID is an electronic microchip that stores data in a method that can be emitted by electronic waves, which can actually pass through some external packaging. The reader (or "*antenna*") picks up the data emitted by the chip and processes the *data element* much like the reader process the code from a printed bar code. An added advantage is that the RFID chip and the *antenna* do not need to be in direct visual line-of-sight of each other. Reading an RFID chip is more "automatic" than reading a bar code, the latter requiring a decision and action by a human to read a bar code.

In theory, multiple items within a basket of items may be readable as a "batch", rather than one-by-one. This "batch reading" may be advantageous in some situations, for example as with healthcare kits. Also, RFID tags permit all *GS1 data elements* to be used, and, in particular, incorporate serial numbers of products easily.

Passive vs. Non-passive chips

Data elements are written onto the RFID chip electronically, by means of a writer. The code(s) can then be read at different points along a standard process. A passive RFID chip emits its data to a reader (antenna) only when it is irradiated with the reader's radio signal in range, whereupon it will respond with its embedded information code(s). Such a tag is referred to as a "passive" RFID chip because it responds only when it is targeted and asked for its code.

An active tag works differently. It carries an on-board battery. Active RFID chips periodically emit their information into the local surrounding environment.

Finally, RFID chips can of two types. They can be "read only" chips where, for example, a product's serial number is embedded once and never changes, or they can be of the "read/write" variety, where data can be written to, modified, and erased from the tag.

Current RFID Issues and concerns

The most common obstacles to RFID implementation are the need for specialized equipment capable of handling RFID processes, the current lack of a wide-spread use of such equipment in client healthcare facilities, and the cost of implementation. Medication products are not yet available with RFID tags, but studies are underway by major manufacturers.

The global regulatory community, such as the U.S. FDA, continues to study the safety and effectiveness of RFID on products, especially biological products. Also, the business integrity of using RFID tags requires further maturation, so that chips are read only when needed. Problems would

arise if, for example, multiple medications were placed in range of a reader (antenna) and more than one chip (or the wrong chip) was inadvertently read in a process.

In summary, the use of RFID for most medication practices has not yet taken root, but some aspects of healthcare practices are beginning to explore its use. The ISMP Canada Canadian Pharmaceutical Bar Coding Project will continue to monitor the global status of RFID technology in healthcare and the potential value of RFID integration into future practices.

GS1 and *AIDC* Global Standards

International Consensus and the GS1 Global Standard

In a world of global integration and international commerce flow there is a need to use an international language for business transactions. Both the vendor (e.g., manufacturer) and the purchaser (e.g., wholesaler, retail pharmacy, or hospital) must collaboratively ensure that business transaction information is linked efficiently and accurately to products, quantities and costs. It is to both parties' advantage to use the same bar code *AIDC* standard and, if possible, the same database data fields when transacting business.

Several international standards organizations have published *AIDC* standards which define and allow acceptable bar code symbologies, including the *data elements* that can be used within the approved bar codes. Each standards organization develops a method for creating a shared product information database.

The GS1 global *AIDC* standard was endorsed by the *Canadian Pharmaceutical Bar Coding Project*, as well as other Canadian healthcare projects, such as the national vaccine project coordinated by the Public Health Agency of Canada. The Pharmaceutical project's *Joint Technical Statement* (Ver II: 2012) recommends that all healthcare sectors, including pharmaceutical manufacturers, develop bar code (*AIDC)* processes aligned with the GS1 global *AIDC* standard.

The 2012 technical statement can be found and downloaded at the project web page:
http://www.ismp-canada.org/barcoding/index.htm

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GS1 Services

GS1 is a global non-profit *AIDC* standards organization that manages may international data standards, including *AIDC* standards. *GS1* standards are employed across a number of businesses ranging from grocery and clothing retailers, agricultural, equipment and healthcare products and processes. Its standard can be applied to many business processes, such as product transfer and sales, provision of services, equipment parts and repair, and document processing. The *GS1 AIDC* standard has begun to be employed within healthcare settings including on commercial medications, but also on vaccines, medical devices, medical/surgical items, and other products. The application of the standard will benefit supply chain and purchasing, as well as patient safety.

GS1 has branch offices in almost every country. Each branch office works with local business sectors to bridge their specific process needs with the global standards. In Canada, GS1 Canada has offices located in Toronto, Montreal and Calgary, offering bilingual services at all offices.

National branches convene as a global network several times annually, where they continue to evolve the global business standards, including *AIDC* standards, to meet the changing needs of business sectors. One such sector is the *GS1* healthcare group. As a result, the global standard evolves in a parallel manner for all international members. GS1 Canada is a member of the *Canadian Pharmaceutical Bar Coding Project's* national advisory committee and its technical task force. http://www.gs1ca.org/home.asp

It is essential for Canadian healthcare to be able to seamless transact between all healthcare sectors because products and services flow from manufacturers through supply chain outlets, to healthcare provider practices such as pharmacy compounding and dispensing, patient care services and, importantly, bedside care. At each step, both patient safety and electronic health record documentation must occur smoothly and accurately. A common *AIDC* standard will help ensure common and safe practices.

Some Key *GS1* Standardized Healthcare *Data elements*

Within the *GS1 AIDC* standard, several *data element* types are defined, some of which are used in healthcare. The following section outlines some key *data element* types.

The difference between static and variable data elements

Certain GS1 *data elements* found within bar codes are referred to as "static" elements. *Static data elements* rarely change for a given product, so that a product's label and bar code can be printed well in advance. In other words, the bar code never changes.

Another *data element* type is referred to as "variable". *Variable data elements* change each and every time an item is produced. An example of such a *variable data element* in your own home would be the serial number

on your home electronic devices (e.g., TV or DVD player). In healthcare, *variable data element* examples include a product's lot number, expiry date, date of manufacture, manufacturing or packaging location (if several plant locations exist), or, again, a product item's uniquely-assigned serial number.

Some of the bar code symbologies discussed above (e.g., UPC codes) can only handle *data elements* that do not change (i.e., *static data elements*), while other bar codes (e.g., DataMatrix) can accommodate both *static* and *variable data elements* occurring within an embedded data character string.

Common data elements and product "Application Identifiers"

There are very many *data elements* used in business; however few are likely to be found within a medication bar code. Each different *data element* type has a corresponding assigned "*Application Identifier*".

Application Identifiers (AI)

When multiple *data elements* appear within a single bar code, they appear as a long string of characters. To separate the individual *data elements*, and to make them readable as distinct and separate *data elements* by a reader/scanner, they are each preceded by a two or three digit flag called an "*Application Identifier*" (*AI*).

AI codes are also defined within the *GS1 AIDC* standard. In additional to telling a bar code reader where a *data element* begins within a sometimes long character string, the *AI* also informs the reader what type of *data element* it is about to read, and its format. For example, if a product's expiry date is located within a bar code character string, it will be preceded by the *AI* code 17. The following are just some *GS1* examples which may be used within a product's bar code:

AI 01 = *Global Trade Item Number* (*GTIN*)
AI 10 = Lot or Batch Number
AI 17 = Expiry Date (YYMMDD)
AI 21 = Serial Number
AI 30 = Quantity in the package

Packaging levels defined by *GS1*

The *GS1 AIDC* standard also defines and numbers four packaging levels:

Pallet
Case or Shipping Unit: A package/case of Secondary units
(e.g., a case of 12 boxes of 10 vials)
Secondary: A package of Primary units
(e.g., a box of 10 vials)
Primary: The unit of use level of a product.
(e.g., one vial)

Each level is assigned a *GS1* packaging level number, which is included in the product's identifier code, *GTIN*. (See *GTIN* description below.)

The *Global Trade Item Number* (*GTIN*) (Static Data Element)

Key among all product *data element*s is one known as the "*Global Trade Item Number*", or "*GTIN*". It is a globally unique identification code for any product produced, including its packaging level. In medication terms, *GTIN* is a more specific code than the Health Canada *Drug Identification Number* (*DIN*). Its length varies from 8 to the currently recommended 14 character length.

Inclusion of *GTIN* on all marketed pharmaceutical packaging levels in Canada has been recommended to pharmaceutical manufacturers since December 1, 2012.

Using the 14-character length example, the *GTIN* contains (Figure I-3):

- Product packaging level digit
- Company identifier (prefix)
- Company's Product Number Category
- Company's Internal Product Number
- Final "check digit" number to ensure GTIN number is read properly

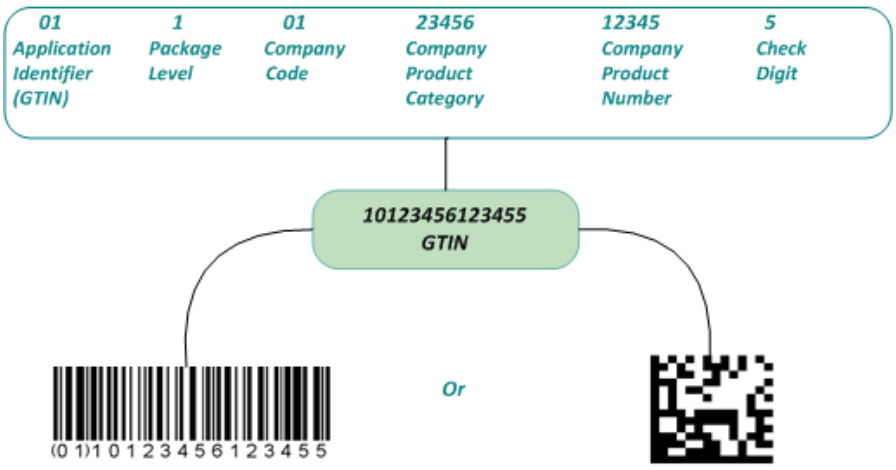

Figure I-3: GTIN-14 Composition

The *Global Location Number* (*GLN*) (Static *Data Element*)

This GS1 *data element* indicates the location of the product's origination, or last location, depending on the use of the *GLN* code. It can indicate the source of the product, and can be added as an additional *data element* within a bar code, but is not required at this time.

Expiry Date (Variable *Data Element*)

The product "Expiry Date" can be included in a bar code string and can thus be used to identify whether the product is usable or not. This *data element* is recommended in Canada by December 2017.

Lot or *Batch Number* (Variable *Data Element*)

The specific lot or batch number assigned by the company can be included within a bar code. This *data element* is recommended in Canada by December 2017.

Global "*Serialization*" Efforts

International healthcare jurisdictions are reviewing the future use of medication product serial numbers, which are seen as an important means of controlling and validating the safe medication chain. It is a future operational practice concept, but one which is already taking root in certain countries.

When serialization is fully developed it will create a continuous string of documented "ownership" of a medication from the manufacturer through warehousing, shipping companies, and, potentially, hospitals and pharmacies to the patient. Its use will greatly assist in the global endeavour to combat counterfeit medication practices. The product serial number will be unique to each vial or unit of medication, much like your home DVD player has a unique serial number. It should be noted that the initial serialization efforts may be limited to a case or secondary packaging level.

Various international healthcare jurisdictions are enacting laws entitled "ePedigree", which will require information to be submitted using a product's serial number to a database that will track and ensure that product distributed is not counterfeit, misbranded or diverted (stolen) product. Some drug products have been known to be susceptible to drug diversion and/or counterfeiting. The enactment of such laws should increase public confidence that their medication is effective and authentic.

The future use and application of medication product serial numbers will be reviewed in 2013 by ISMP Canada, after review of global regulation in this process.

System Requirements for Bar Code Use

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Types of Readers

It is not the purpose of this document to provide an extensive review of readers, their specific functionality, or utilization issues.

There are several basic types of bar code readers, but these can be divided into two categories: *light-based* readers and *camera-type* readers.

> *Light-based* readers work by illuminating the contrasting lines of a bar code, such as on a one-dimensional bar code. The contrasting optical density pattern of light (created from the contrast between dark lines and white spaces) returning into the reader is converted into electrical patterns within the reader. These are, in turn, translated into the data character string.
>
> Though some older 2D bar codes may be read by *light-based* readers, *camera-type* readers are required for newer two-dimensional bar codes (e.g., DataMatrix). *Camera-type* readers have an array of light sensors, like a matrix, which captures the pattern of dots within the 2D code. This pattern is converted into data character string.

It is noteworthy that smaller electronic devices, like digital phones, can be used as camera-type readers, and may play a part in the future of healthcare practice. However, currently the differing abilities to auto-focus on an image mean that only certain two-dimensional bar codes lend themselves to reading by such mobile 'cameras'. The *GS1* DataMatrix code can be used, as can a recently-approved *GS1* code called "QR code". (QR codes are popular for rapid access to marketing websites from printed journals, posters and advertisements. QR codes are included in *GS1*-approved symbologies for non-healthcare items purchased by consumers or hospitals.)

Most readers acquired today can read both one-dimensional and two-dimensional codes, but care should be taken to ensure any purchased reader can read bar codes reliably. And, with some readers, they may require that a certain bar code symbology be enabled prior to use. Also, system coordination can fail as a result of multiple reader types, some of which may be different in functionality or read capabilities.

Typical problems with readers and bar codes

The most common reader concern encountered by bar code users is the apparent inability to capture and utilize some bar codes on products. This can become frustrating to the user and potentially lead to user

dissatisfaction and non-compliance. Occasionally a bar-coded item may need to be passed several times under a reader, or the distance between the bar code and the reader face may need to be accurately maintained to keep the readable bar code image in focus.

In mobile practices such as with nursing care, as opposed to desktop practices, unsuccessful reads are a concern that point to the need for fine-tuning reader effectiveness and efficiency. Also, it is important that the reader is chosen carefully, and set-up to read the appropriate bar codes used within the medication system. During implementation, user comfort with reader vagaries should be addressed with the staff.

Unsuccessful reads can also be due to the bar code itself, not the reader. Such variability includes the background of the product label, or the reader's rate of bar code pick-up on certain packaging. Our project's technical statement and other similar standards recommend that pharmaceutical manufacturers ensure a product's bar code readability. Manufacturers follow international technical guidelines and perform standardized readability tests as part of their packaging approval requirements. Some bar codes may inadvertently be eroded due to treatment by solutions during healthcare practices, and labels are tested to reasonably resist such erosion.

Items with small radii or small labeling surfaces, such as a 1 to 5 mL medication ampoule or vial, have may be difficult to read due to the tight radius (bending) of the bar code. This problem can also occur with patient arm bands, especially of small weight neonates, but re-orientation of the bar code direction can often help.

Health and industry sectors continue to identify and collaborate on solutions to known issues. Organizations must ensure the readers utilized are appropriate, easy to use, and that there are not multiple types of readers such that the medication system bar codes cannot be utilized at all points of the medication chain.

Some additional bar code reader implementation issues related to poor reader set-up configuration and product labelling will also be provided in Section III.

Software for Bar Code Medication Practices

The Importance of Complementary Software

Just as a bar code cannot be used unless it can be read, a *data element* extracted by a reader cannot be used unless the reader can relay the *data element* via a software program which connects to a database of information. The software, in turn, used the *data element* to link to product descriptors, and then applies various functionality (safety) steps related to the medication process and health record documentation.

Software is the integrating engine linking the printed bar code (or RFID chip) with the practice functionality that supports patient needs and healthcare providers. Software can perform several important safety tasks along the medication chain and prescription process. For example, it will verify a product and access its product information as a basic minimum function. It can also seek and obtain important ancillary information about the safe use of the product or the appropriateness for that specific patient. Other functions include:

- Automated calculations
- Verification of the correct medication selection based on a patient's medication record (health record)
- Warnings of unsafe situations or patient monitoring requirements
- Confirmation of the completed and approved process
- Accessing patient education material
- Documentation of the process in the Electronic Health Record (EHR)
- Automatic notification of recalled or quarantined medication batches

The Medication Flow Chain and Prescription Process

To this point we have focused solely on medication verification at the patient dose administration level. In fact, the same bar code (or RFID chip) is utilized at every step in a long chain of events, as shown in Figure I-4. It sequentially enhances system conformity and efficiency, product verification, accurate quality documentation. In short, bar codes and software enhance patient safety by avoiding many preventable human errors.

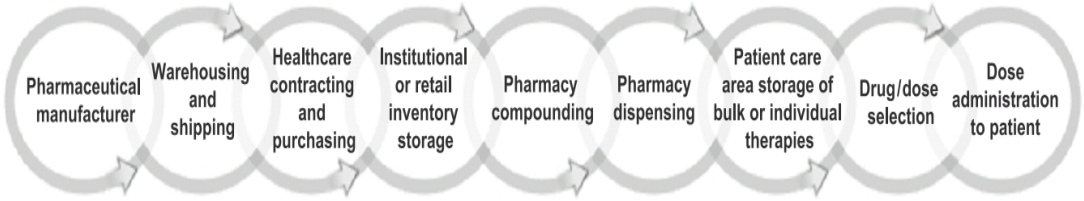

Figure I-4: Medication Flow Chain

Of course, bar code software functionality at each link in the chain is different and specific to the detailed process at that step. However, the basic *AIDC* process described earlier in this section is similar. It includes: product identification and documentation, automated calculations of when small portions inventory units are used, and safety verification against standardized patient records, standard recipes, or standard protocols.

The *Canadian Pharmaceutical Bar Code Project* in 2012 issued a *minimal software functionality checklist* to assist technology providers and healthcare providers to develop and acquire information and automated systems that optimize bar code system potential. The functional checklist is available at the ISMP Canada website, or by clicking on the document image below.

The figure below shows simplistically how software integrates practices at the medication dose administration stage, often referred to as the "*Bar Code Medication Administration*" stage, or *BCMA*. Figure I-5 demonstrates how a scanned medication item is verified and related data captured into the health record, whether within a community-based care facility or an inpatient/ambulatory facility.

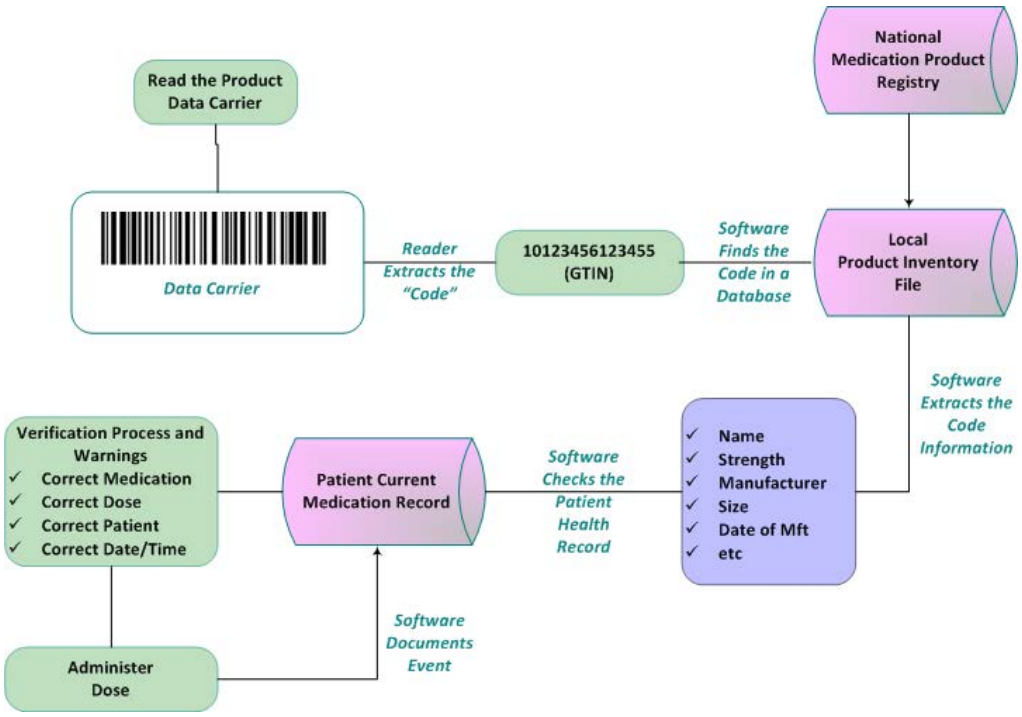

Figure I-5: Simplified *BCMA* System *AIDC* Functionality

Though it is not a primary focus of this resource guide, the establishment of a robust and reliable method of patient bar code identification is a precursor to an effective *BCMA* system. Organizations must ensure that the patient ID system is carefully chosen and implemented, as it is used for critical healthcare practices, or applied services, other than medication practices.

In Section II, a more detailed review of bar code safety functionality and effectiveness is described for points along the medication flow chain and prescription processes.

Reminders and Warnings

Software can selectively integrate reminders to healthcare providers based on known medication treatment plans and site policies. This process may remind a healthcare provider when a medication event is due, to avoid late or missed doses, or may remind healthcare providers of necessary checks prior to administering medication (such as the latest laboratory results). Routine required patient monitoring, such as checking a patient's blood pressure, respiration rates or hydration, may also be prompted.

Warnings related to wrong drug, wrong patient, allergies, dosage, etc can all be ranked or customized by an organization to include only those that are deemed essential for patient safety.

Of course, warnings must be handled carefully. Literature has reviewed the pros and cons of warnings. Though warnings can enhance patient safety, too many warnings may cause operator "alert fatigue", and may unnecessarily interfere with the flow of healthcare. It is not the purpose of this Primer to discuss warnings in great detail; however it is recommended that the reader review literature related to the appropriate use of warnings.

Automated Calculations

In pharmacy operations especially, complex recipes or formulae involving only part inventory units are common, and can quite often involve high-alert medications of concern. A recipe, for example, can be automated to ensure selection of correct ingredient(s), accurate calculation of the portion (volume) of the inventory unit required, and documentation of quality assurance information. These safety functionalities can also apply to nursing practices, where such practices are required.

This is especially critical in those recipes produced by pharmacy and that involve medications with the potential for catastrophic patient harm. These are often produced in pre-prepared batches, and represent an increasingly common safety practice in healthcare.

Interoperability and Accessing Relational Databases

An intriguing development concerns the ability of software to obtain ancillary information related to a medication product from distant, or "relational", databases. Software using the same medication *GTIN data element*, can access external databases, where the *GTIN* code is used to cross-link various databases. Such databases and information uses are potentially many:

- Health Canada product monographs and national "Black Box" warnings.
- Approved Clinical Information including Drug Interaction and Dosing Information.
- Laboratory Interactions or Warnings.
- Parenteral Policies and Infusion information.
- High Resolution product images.
- Approved locally-approved or commercial patient counselling information.
- Educational videos.

The term 'interoperability' is used to denote the ability of two software systems to exchange simple information for use by one system, or both.

Data Capture

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How a Bar Code Reader Finds Data

As indicated in the Figure 4, above, using *GTIN* allows system software to find detailed product information from a local product inventory file. The product data within this file can be obtained from a national standardized pharmaceutical product registry. GS1 Canada maintains such a database which complies with global data field standards. It is known as *ECCnet Registry,* and has been recommended by this Project as the primary medication product descriptor data repository. It contains a great deal of information on most marketed Canadian pharmaceutical products. Other similar databases also exist which may also comply with the global rules for standardized data fields.

Both the national and local product databases can contain as many as 50 or more product data fields. Which data fields are relevant to patient care practices are, of course, a local decision when setting up the local software/inventory system. However, it is comforting to know that data fields will increasingly become standardized to global standards, thus allowing more consistent data flow and quality documentation.

Documentation within the Patient's Health Record and Sharing Information

One exciting aspect of a pan-Canadian bar code and data standard is that information on a patient's health record will increasingly become more standardized in its structure. The alignment of both database data fields and product data descriptions between healthcare systems should greatly facilitate the transfer of important patient healthcare information.

This information, in turn, can more seamlessly flow upward into future regional, provincial and national patient health records (Canada Health Infoway), populated from many different healthcare sources within community and institutional settings.

A good start to help to build interoperability between healthcare systems, and the transfer of patient health records to provincial and national health records, is a the point of system procurement. The Project's Supplement B (Software Functionality) to its Joint Technical Statement (ver II: 2012) is a good place to begin. Discuss data synchronization and software safety functionality with your prospective technology providers.

Appendix I-1: Bar Code Types

(Excerpted from: http://www.gs1.org/barcodes/technical/bar_code_types/#ean_upc)

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Bar Code Symbology	Summarized Features
UPC A (GTIN 12) 	• One-dimensional • Omnidirectional • 12 Character (others exist for 8 and 13 character versions also) • Numeric characters Only • Allows GTIN-12 (12 character GTINs only) • Point of Sale
GS1 DataBar (GTIN 14) 	• One-dimensional • Omnidirectional • 14 Character (GTIN 12 or 13 character versions are also allowed, if the GTIN number is padded with zeroes (0) on the left to make up the full 14 character string) • Numeric characters Only • Allows GS1 Application Identifiers (GTIN and others)
GS1 DataBar Expanded 	• One-dimensional • Omnidirectional • 74 Numeric or 41 alphanumeric • Allows GS1 Application Identifiers (GTIN and others)
GS1- DataBar Composite 	• Mixed one-dimensional and two-dimensional • Allows GS1 Application Identifiers (GTIN and others)
GS1 Data Matrix 	• Two-dimensional, compact • Can be etched on metal • 3116 Numeric or 2335 alphanumeric • Allows GS1 Application Identifiers (GTIN and others) • Camera-based readers required
GS1 QR Codes 	• Approved for product or customer information (e.g., information websites) • Not approved yet for use in product automated identification.

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 I is located in the Document Précis section of this document, above.

An Brief Overview of Medication Errors and Causes

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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)

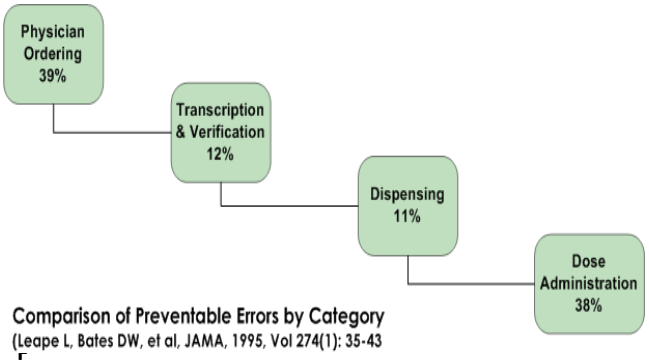

Figure II-1: The Prescription Flow Process

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.

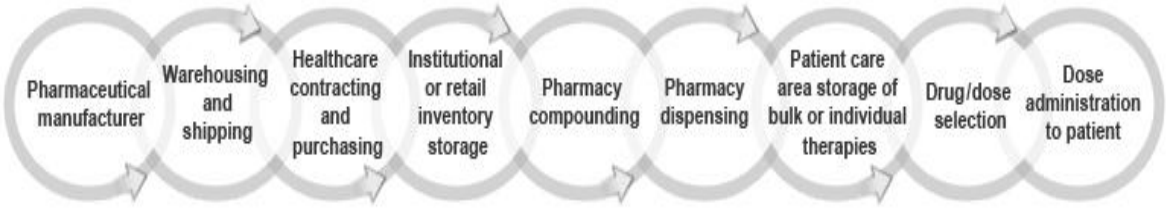

Figure II-2: The Medication Product Chain

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*).

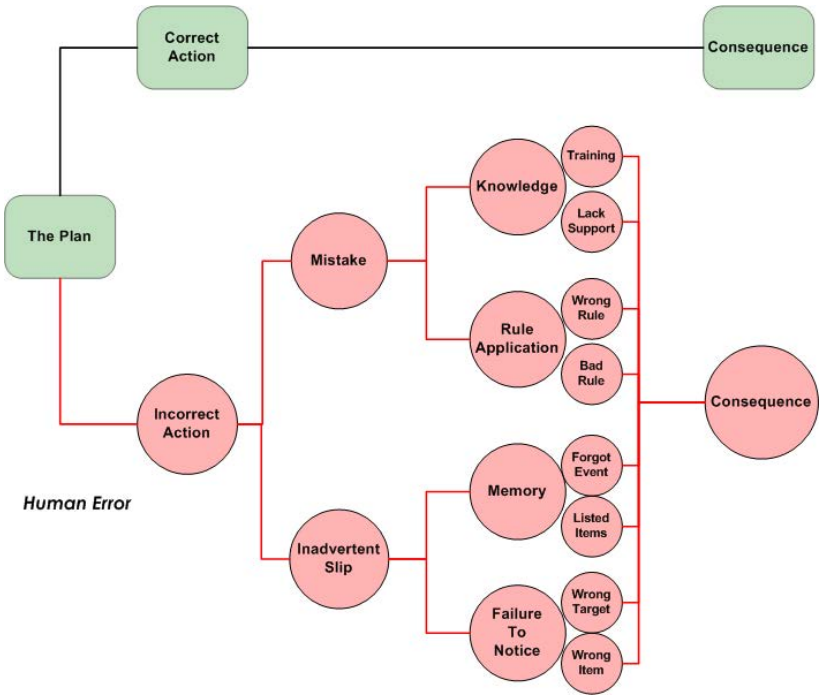

Figure II-3: Correct versus Incorrect Actions

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

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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

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.

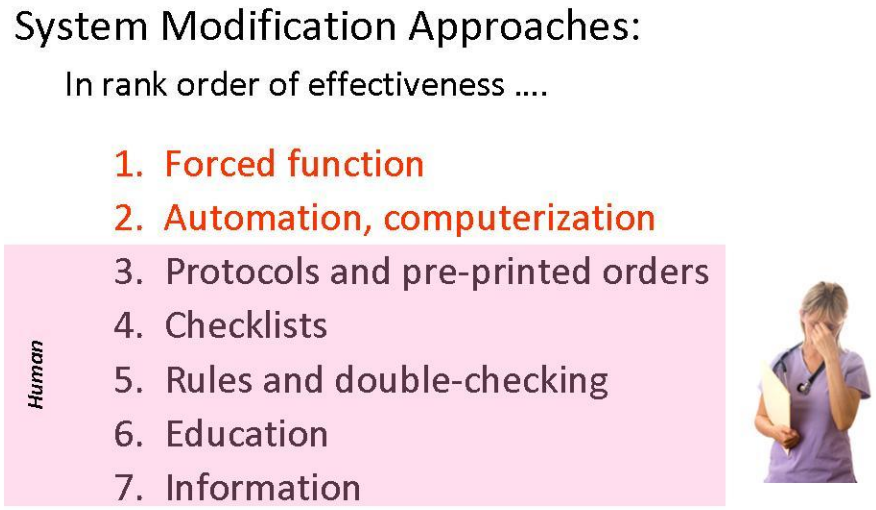

Figure II-4: Approaches to System Modification

Automated Identification:
Evidence of Effectiveness in Error Reduction

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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 c*omputerized 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 not 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 full 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

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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

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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.
  - Five (5) year full costs recovered by one year after full implementation.
  - Worst case model showed a *ROI* within 4-5 years.
  - 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:
  - Pre and post implementation: 87% reduction in medication administration errors, including timing errors, on pilot unit.
  - 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
  - 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]**
  - Kaushal (2006): 7 years. Net benefit >$10 million over 10 years
  - 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

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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;**
   - Over 8-15% of medication dose administration attempts are in error, depending on the patient care environment reviewed, excluding dose timing errors.
   - Errors occur in both institutional and community-based care at approximately the same rate.
   - Pharmacy dispensing and compounding errors also occur.
   - 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.
   - 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**;
   - 20-30% of all ADEs cause significant harm.
   - 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.

- Ambulatory costs are in the range of $2000 or greater per event.
- 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**;
   - 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

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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

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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

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

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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

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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
  - Qualitative (satisfaction and process changes)
  - Value of investment (financial, clinical and organizational)
  - 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*):**
  - Prescribers (physicians) are the most studied group.
  - Improvements were found in *process* in hospital (87% of studies), and ambulatory (68% of studies) settings. Community-based process improvements were not found.
  - Improvement in *errors* in hospitals (68% of studies). Ambulatory and community-based studies (not found).
  - 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**
  - 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.
  - 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

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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, Dépармente 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 preceded 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

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, Dépармente 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 preceded 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

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

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 preceded 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.

Section III: Implementation Considerations

In Section II, we reviewed an argument for the adoption of automated verification and documentation processes for routine medication functions as being consistent with the principles of High reliability organizations (HROs).

This section reviews aspects of system implementation; such as safety culture change in relation to HRO principles, possible internal system pre-conditions and barriers and, importantly, the need to collaborate with the healthcare providers most affected by the planned system change. It is also the most subjective part of this resource guide.

The overriding purpose is neither to provide a comprehensive review nor a proven method of bar code system implementation which will work within every organization. Indeed, issues vary greatly between settings and the "appropriate" steps cannot be etched in stone. Rather, our review is designed to provide the reader with principles that can be carried through a detailed implementation process, as well as an array of potentially problematic issues. Several issues introduced below will also apply to other forms of technology implementation.

Figure III-1 illustrates the flow of this section. It begins with observations related to safety culture change followed by potential implementation or new system "failure modes" and, finally, a high-level map of implementation flow. The report provides a process by which an organization can become more aware of issues and strategies and, thereby, develop its customized project plans, working closely with the organization's own Medication Management Information Technology plans (MMIT).

Many customized approaches to transformational change and change management exist. For example, John Kotter (Harvard Business School) has written extensively on the issue. The reader may wish to review this or other approaches to supplement their approach to planning.

- *Leading change. John P. Kotter, 1996, Harvard Business School Press, Boston, MA.*[177]
- *Leading change: Why transformation efforts fail. (John Kotter).* [178]
- *ASHP Foundation: Leading Change in a Complex Health Care System* [179]
- *Change Management Leadership Guide (2001): Ryerson University* [196]

A synopsis of Section III is located in the Document Précis section of this document, above.

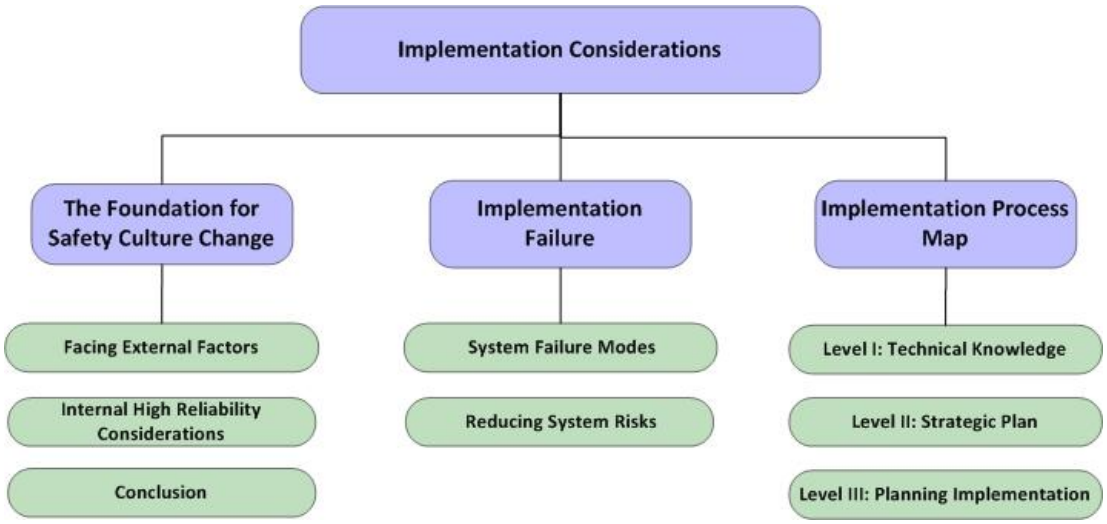

Figure III-1: Section III Flow

The Foundation for Safety Culture Change

It is not possible for an organization to achieve truly sustained safety system implementation without a parallel change to its underlying safety and quality foundation. The latter precondition is not an easily achieved yet should be in place before any new system is introduced.

Though it can be argued that a technology change can be implemented in a relatively short timeframe, operational harmony and healthcare provider support will not exist until the recipients both expect the altered practices and embrace progressive safety culture. This is the pre-condition on which the successful change may be built.

Intra-organizational change is affected by multiple external and internal environmental factors, each interdependent on others. Attention should be paid to these in a thorough and unhurried manner. The future operators of a planned system should embrace a common vision; a 'future state' built on a realistic foundation of public, patient care, and internal operational expectations.

Facing External Factors

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In a discussion paper on system evolution, Dr. Rene Amalberti mentions external structural pressures, which should be openly embraced before embarking on internal system factors related to safety planning and implementation.[4] Figure III-2 shows four pressures which arise largely outside of our direct healthcare influence, yet may greatly influence our ability to plan and implement improved systems.

Figure III-2: External Pressures

Patient Clinical Complexity and Risk

Healthcare needs of patients encompass a broad diversity of health problems and acuities. Clinical risks can range from minor to major and a patient may possess a number of additional risk factors. Individual needs can be complex, requiring transient or long-term needs whether the patient receives institutional or community care.[166] As a consequence, the systems we employ must be resilient enough to handle the clinical risk variation.

As with patient complexity, system planners cannot either fully customize the physical care environment or operations in which the care is given. In larger centres it may be possible to narrow the variation in care through clinical specialization and developing customized system environments such as on a cardiac or pediatric, or geriatric care unit. However, this is very often not the case in smaller communities where specialized care cannot be fully separated from other forms of care. This variation in physical needs may also be found in operating rooms or emergency care centres.

In such "blended" clinical risk and physical circumstances, it may not be possible to employ fully customized care processes to the ideal degree. Amalberti argues that it may impede us from achieving an optimum safety status known as an "ultra-safe" organization; at least not in all aspects of our care.[4] Industries that statistically

reach “ultra-safe” safety levels include the nuclear and commercial aviation industries. Amalberti further observes that some aspects of healthcare may be approach that desired level (anaesthesiology and radiotherapy, for example), while other aspects of healthcare, at least in the near future, may more realistically be aiming for a statistical level of safety he refers to as “High Reliability”.

Blended clinical risk needs and physical constraints will affect our ability to implement ultra-safe systems.

Healthcare Economics and Governance

The broader economics of healthcare funding by governments, and its limiting effect on local healthcare budgets, impacts our ability to plan and execute desired change. It may not be possible to significantly modify systems if support for such change is not forthcoming in the form of both higher level political and funding support. For example, cases of infection contamination rates can often be traced to structural defects found in older structures, despite the existence of well-planned and executed quality plans and staff commitment.

Local healthcare leaders are faced with the long-term prospect of either individual or group attempts to change the broader economic and governmental support in an effort to secure support for larger improved quality and safety plans. Failure of governing bodies to identify the required resources (with or without off-setting cost efficiencies or improved secondary quality) may stop any system innovation from proceeding.

Governmental and healthcare authority planners must understand the importance of system innovations and provide necessary policy, practice and funding support.

Public Expectations

An important healthcare partner is our patient and their family. Unfortunately, collectively expectations of a “successful” health outcome may at times be systemically unrealistic.

It is common to see organizations issue public statements on the provision the highest “quality of care” to patients. It is also important that healthcare manage public expectations of the clinical and safety outcomes; ones based on realistic evidence-based research, benchmarking, and overall system safety. It may be necessary to educate our public partners that health outcomes and life quality are relative to modern healthcare’s ability to treat specific conditions and to build reasonable, safe healthcare systems.

On a positive note, a significant reduction in medication errors is a safety outcome for which a higher bar of public expectation can reasonably be set.

Definitions of Medical Error and Quality

Fully aligned with outcome expectation is our ability to accurately measure quality. Terminology and definition of health outcomes requires improved standardization, in a manner that is understood and adopted by all. As reviewed in Section II, a major dilemma facing researchers and healthcare planners who attempt to

measure improvements is the variety of definitions of terms such as adverse event, error, patient harm, and, importantly, the appropriate method of error rate calculation or other quality indicator.

External organizations with national or international benchmarking responsibilities should provide improved definitions and indicators with which healthcare organizations can monitor quality against public or practice expectations. Until such time, it may be difficult to fully establish an organization's exact safety record.

Facing Internal High Reliability Factors

Several references refer to the characteristics of *HRO* organizations, many of which were discussed in Section II. [3, 4, 93, 149, 163, 164, 166] Though references vary somewhat, all have a common message that *HRO* principles and impediments must be addressed before real and sustained system safety improvement. The journey toward higher quality and safety depends not only on external factors which we cannot easily affect, but also internal factors that we can.

Internal success factors, or alternatively "system barriers", should be assessed prior to launching new system change. (Figure III-3)

The American Association of Critical Care Nursing (AACN), for example, has emphasized one important *HRO* principle: the importance of collaboration with all staff, including nurses.[166] Other references emphasize different principles such as staff accountability[149], or safety culture.

The salient point is that organizations which have successfully addressed prerequisite internal issues will have a greater chance of sustained system success. They will be more likely to achieve healthcare provider 'ownership' [195] of the system and its products, and demonstrate inherent fairness. Conversely, failure to address internal foundational issues could result in fragmented system change and, therefore, less than ideal organizational reliability. What follows is a discussion of some internal "deal-breakers".

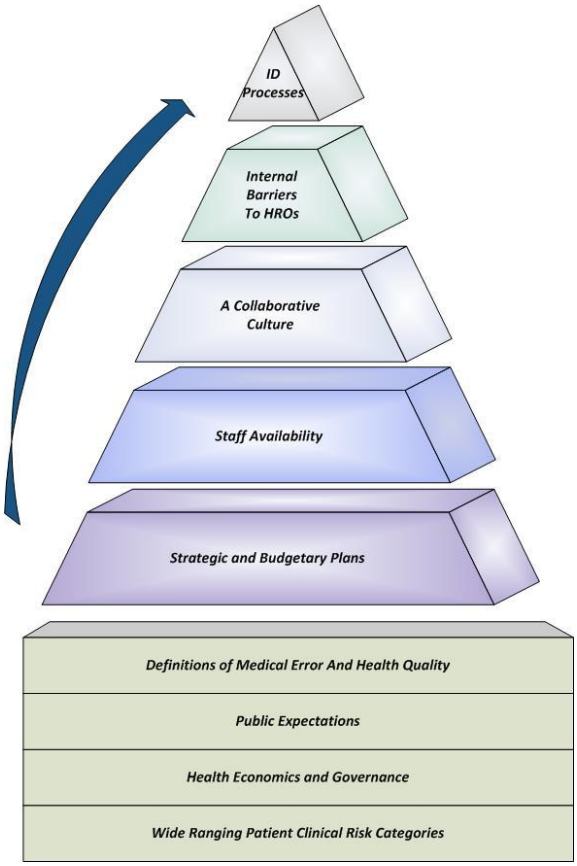
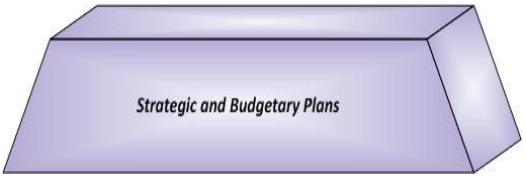


Figure III-3: Internal Pre-conditions for Change

Strategic and Budgetary Planning



Senior management leadership vision was discussed in Section II, including the importance of collaboration between an organization's executive, CFO, CIO, and practice leaders. Working together, strategic commitment to medication bar coding along the entire medication and prescription pathways are possible.

In most cases, integrated bar coding strategies should form an integral part of the overall organizational *health information system (HIS)* strategy, which includes *the Electronic Health Record (EHR), electronic medication administration record (eMAR)*, *Bar Code Medication Administration* (*BCMA*), and other modules. From a critical pharmacy services perspective, it should include medication purchasing, stock transfer, compounding and dispensing. Together, these modular components form an integrated *Medication Management Information Technology (MMIT)* strategic plan.

In the case of community-based medication care, an extra strategic planning step is required. A nursing home or residential care facility must work closely with its contracted pharmacy provider. It must ensure that bar codes on pharmacy-issued medications (ward stock and patient-specific dose packaging) can be read by, and can integrate with the facility's chosen EHR, eMAR and BCMA. Such Service provider integration must form part of the organization's strategic plan and any negotiated agreement with a contracted provider.

Change consultants working on behalf of the facility's strategic plan are also recommended. As we will discuss later, educational workshops for discipline leaders should occur which focus on HRO principles and internal change process, including safety and staff success issues. Later, the education and training can focus on specific (e.g., bar code) implementation challenges. Support for such education should also form a visible part of the overall strategic plan.

We recommend that an organization develop a multi-year funded, staged *HIS* and *MMIT* strategic plan. The absence of leadership sustained commitment toward a multi-year strategic plan may be an early indicator of organizational failure. Failure to secure the support of the uppermost executive office is a critical internal success factor.

Staff Availability

Consistent availability of educated and skilled providers at an appropriate patient-to-staff ratio is critical. Staffing shortages can occur locally and there may be competition between otherwise collegial sites. When shortages occur, they can result in multiple secondary system impacts.

Firstly, there may be a need to rush newly-hired staff members into assigned practice areas to maintain appropriate workload-to-staff ratios. Poorly trained staff will not have fully absorbed and committed to important concepts of care and safety. They may also still also be developing specific clinical practice skills and communication knowledge. Under such conditions, new staff may revert to rudimentary care to ensure all essential tasks are completed. This is not the environment under which new systems should be implemented and maintained, especially when new systems require altered practices. It becomes a fertile field for what will appear as healthcare provider "non-compliance".

The term "work-around", describes a process by which a healthcare provider may individually (or as a group) decide to modify the approved process by changing an approved procedure, change the timing or sequence of steps, or avoid the step entirely. A contributing factor is again a lack of time to fully complete the approved procedure, or poor system design and/or implementation.

On the positive side of staff availability is a safe health system's ability to attract staff. A well-functioning system sends a powerful message to individuals who are seeking career-orientated employment. Most healthcare professionals wish to work in environments which are safe for both patients and themselves professionally.

We recommend that, for new systems to be implemented successfully, and for potential work-arounds to be minimized, an organization should develop elaborated strategies. They should ensure appropriate recruitment of educated providers, appropriate training and patient-to-staff ratios. Staffing assessments should be based on the realistic complexity of practice and amount of clinical workload.

Failure to develop an integrated staffing strategy is an early sign of possible future implementation or staff compliance weakness, which will manifest itself as either operational "non-compliance" or, yet again, human error.

A Collaborative and Balanced Safety Culture

The 2008 Agency for Healthcare Research and Quality (AHRQ) review of HROs within healthcare discussed five important foundational concepts for HROs.[3] One such concept was "Deference to Expertise" wherein the requirement for consultation with staff members who work in a practice area is critical, especially in areas of truly specialized care. This concept has been repeated in many HRO resources.

Deference to Expertise ...
If leaders and supervisors are not willing to listen and respond to the insights of staff who know how processes really work and the risks patients really face, you will not have a culture in which high reliability is possible.

~ Becoming an HRO for Healthcare Leaders
(AHRQ Report, 2008)

The AACN extended the concept of enhanced collaboration into a well-rounded "healthy" work environment in its 2005 statement.167 The statement included the following criteria:

- Skilled communication between members
- Authentic leadership
- True collaboration
- Meaningful recognition
- Appropriate staffing levels
- Effective decision-making

In the AACN standard, along with other organizational elements, were the importance of provider education directed at developing collaborative skills, accountability of staff and leaders who embrace collaboration and, importantly, a practice environment wherein every team member uses the learned communication techniques.

Newly modified medication systems introduce revised processes and new technologies. For these to be effectively employed, concepts of teamwork must be in place; such as prior consultation and ongoing collaboration in both overall goals and detailed procedures. Not only should healthcare providers be conceptually aware of the planned process changes, but they must be both comfortable and skilled in the techniques of collegial exchange of ideas and feedback.

For a team-based exchange to be viable, the communication environment must be a safe one. In this respect, we mean not only the culture of patient safety, but also a culture of open and fair evaluation of ideas. This team collaboration must extend to the practice evaluation of new technologies, which we will discuss later as "usability testing".

There is a tricky "flip-side" to two-way collaboration between leadership and care providers. That is, the concept of personal responsibility of providers for compliance with standardized processes.

Balancing Accountability and 'No Blame'

… the urgency of the task also demands that we stop averting our eyes from the need to balance "no blame" with "accountability".

~ Wachter and Pronovost
N Engl J Med. 361; 14:1401-6.

An organization that fosters open and transparent input and focuses on system-related error potential ("No Blame") must also balance the healthcare provider's practice responsibilities. In a 2009 New England Journal of Medicine editorial, by R.M. Wachter and P.J. Pronovost, the concept of balancing a "No Blame" safety culture with a provider "Accountability" culture is explored.[149]

By way of example, the article cites the issue of hand hygiene and its role in reducing a Hospital-acquired condition (HAC); contamination and infection control. They suggest the ongoing low compliance rate is often a problem of healthcare provider self-accountability.

Conversely, the 1999 Institute of Medicine's sentinel report "To Err is Human", based on the theoretical error model proposed by James Reason, recognized the role of the overall "System" in creating many preventable human errors.[76] In the past, many healthcare providers have felt that an inadvertent error placed them at the "sharp end" of a blame stick, where they were inappropriately blamed for the error and resultant harm.

Clearly, an organization which commits to fair, open and meaningful collaboration with its care providers needs to seek a balanced expectation of provider compliance with approved systems and methods. (Figure II-4) In all but tightly-defined clinical circumstances, compliance with technical systems should be expected, while assuring errors occurring within approved procedures fall into "no blame" or system error categories. Though such balance may prove to be an elusive objective, open communication is the path forward.

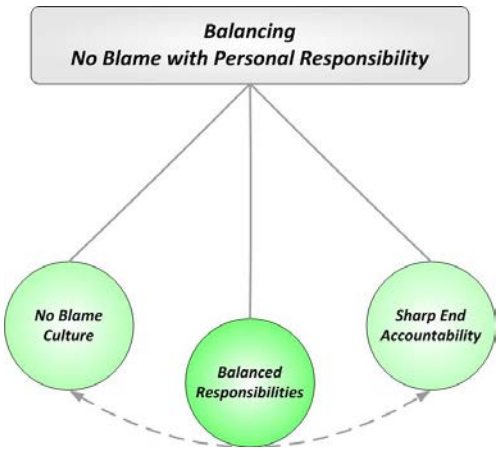


Figure III-4: Balancing Accountability with No Blame

Production Levels

An HRO places its need for production behind that of process safety. In true HROs, operations undergo an orderly shut down, or are severely scaled back, if the pre-determined safety outcome cannot be ensured. An airplane will not take-off when pilots cannot be found who meet pre-determined safety certification standards, comply with hours worked, or sleep duration. It is a standard we, as travelers, expect when we travel even if we are inconvenienced in some manner. But, commercial aviation has a level of safety that can be difficult to achieve in some aspects of Canadian healthcare.

When funding or staffing cannot keep pace with public clinical care needs and expectations of the healthcare system, unlike airlines, we are unable to completely scale back work production demands. Situations arise where healthcare providers are confronted by practice patient care demands, potentially including workload from medication systems, which overtake the time available to provide a service.

Where possible, a successful organization will proactively address these specific situations in an effort to minimize the impact of imbalances between workload (production) and provider time available. As much as possible, within our system we should define those hard limitations, like the airlines.

Failure to do so, yet again, may contribute to provider workarounds or non-compliance.

Internal Barriers to Healthcare *HROs*

System barriers exist beyond those already discussed. These are more deeply buried and relate to *individual* practice habits. They may be engrained within either a single individual's practice or a common ethic within a practice group.

Amalberti (et al) explored five such internal system barriers in an article which argues that true transition to an *HRO* status is not possible without a transformation of these *individual (or group)* human factors.[149] Their assertion is that an organization must work with its care providers, and seek to modify practices away from an individualistic approach and toward a commonly-accepted safety goal of conformance of practice, as was introduced in Section II. In other words, like the airline industry, where each pilot is functionally interchangeable and flies the airplane in an identical manner.

Organizations will find it difficult to both request and then later to ensure individuals conform to standardized processes, at least for most routine safety practices. Organizational pitfalls along the path to conformity may include:

- The request for conformance of practice may appear as non-collaborative or as dictating professional practice.
- Provider conversion may be transient and require periodic reinforcement.
- Conformity may be subjectively applied by the care provider, and not be evident in certain emergent situations, sometimes appropriately.
- Conformity may be gained one individual at a time, so that some individuals within a group have converted while others have not.

Conformed practice may best be applied in those practices which are routine high-risk technical tasks, such as, for example, most medication management steps. The reader is recommended to read Dr. Amalberti's (et al) discussion in detail.[149]

An important clarification regarding conformity and clinical judgment in healthcare practices:

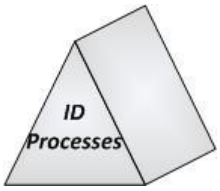
The strategy of conformity does not fit all clinical situations. One patient's clinical and social condition and co-morbidities will not match exactly with the next patient's. Therefore, it is difficult to achieve absolute conformity in all aspects of complex and ever-varying healthcare.

Health professionals are expected to use clinical judgment. However, when utilizing a technical system, the system should minimize the ability of a single provider (or group of providers) to create and adopt individual patterns of technical use. This stipulation does not apply to truly specialized practice areas, or in areas of clinical patient assessment or treatment planning, where application of individual clinical judgment may be required for valid and approved patient care reasons.

The barriers to provider conformance described in Amalberti's paper are dependent on an individual's response to five criteria, which are briefly described in Appendix III-1.

1. Acceptance of Limitations on Maximum Performance
2. Abandonment [sic] of Professional Autonomy
3. Transition from the Mindset of Craftsman to That of an Equivalent Actor
4. Need for System-Level Arbitration to Optimize Safety Strategies
5. The Need to Simplify Professional Rules and Regulations

Identifying Processes for Change



A final internal organizational consideration is the need to adopt a systematic approach to identify key safety processes requiring further design enhancement, simplification and/or standardization.

Two tools employed are *Failure Mode and Effects Analysis (FMEA)* and, for errors and near misses*, Route Cause Analysis* (*RCA*). These processes are complementary. Where *FMEA* primarily assesses key system processes and their inherent process weaknesses (i.e., Failure Modes), *RCA* usually dissects processes exposing those steps that may potentially be contributing to errors.

This document does not discuss these assessment processes however ISMP Canada and others provide a framework for such strategies.

Conclusions

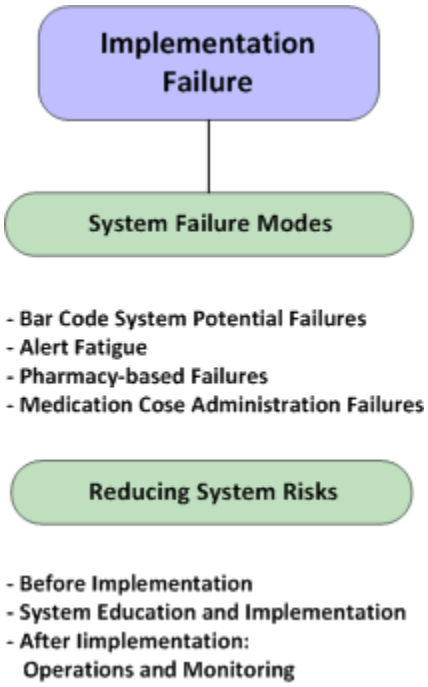
Prior to embarking on the process of system modification, including automated technologies, an organization should understand and assess the foundation upon which such changes will be constructed. Specific factors influencing success vary between literature sources. In this sub-section we have introduced interrelated external and internal factors that may affect the success of newly introduced technology change.

Organizational planners and local leadership will not usually be in a position to directly affect external factors, though groups of healthcare leaders or organizations may have an impact using a collective effort. Such issues usually are controlled at a public, provincial, or at least regional health level.

Factors more directly under organizational influence are internal factors. Such factors influence the achievement and sustainability of the intended system change, and, therefore, our efforts to achieve a higher reliability status. An engaged and enlightened leadership group which is willing to make strategic and budgetary commitments will be more successful. The commitments also include a plan for staff availability, a truly collaborative culture, consideration of both production and safety criteria, addressing various individual barriers to system change and, finally, the use of formalized tools to identify and assess the most critical processes for safety change.

The above considerations apply to many change system processes, and certainly apply to bar code medication system implementation. If an organization wishes to enhance its chances of successful new system implementation, these foundational assessments should be considered the first pre-condition for the anticipated change.

Implementation Failure



A newly introduced technology may fail for a number of reasons. Bar code verification and documentation systems are no different, and failure could occur any stage of the medication and prescription process from myriad causes. The specific cause(s) may be unique to the organization. This sub-section identifies a number of possible causes of failure and some potential planning resolutions.
A planning and implementation team should be vigilant and pursue a structured process for discovering and remedying potential system failure modes. They will need to utilize system evaluation tools, external resources and collegial networks to benefit from the experience of others.

The greatest effort should be placed in addressing as many known failure modes as possible prior to implementation. Also, use transformational learning, understanding the phases of change, and leveraging communication and teamwork as the system is evaluated.[179] And, never giving up …

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System Failure Modes

HRO Vigilance …
An elevated level of organizational vigilance is reflective of HROs as they generally support a cultural predisposition that prevents the materialization of adverse events.

~K.E. Weick and K. M. Sutcliffe (2001)
Assuring high performance in a range of complexity
Jossey-Bass, San Francisco (Publishers).

In general, we describe the "medication system" in relation to the entire medication process, inclusive of all procedures, human actions and intersecting technologies used within the process. It is a truly complex process which is therefore difficult to analyze in a single system evaluation.

Often, components of the medication system are assessed in isolation, such as an intravenous pump, a new medication cart, or a revised document and its related process. In reality, each component or sub-component influences the effectiveness of, or is reliant

on, other components. For example, the use and effectiveness of the *BCMA* component is reliant on preceding pharmacy components which, in turn, uses other technologies. For example, the efficiency of medication order entry and it accuracy into the *HIS*, dose dispensing accuracy and delays, product switches, or robotic packaging and label printing (including bar codes) all affect the *BCMA* system intended performance. The end-user's ability to use a new technology may indeed be greatly compromised by up-stream operational failures and, in turn, the overall user "system satisfaction" of the down-stream component may suffer. Some "failure modes" will relate directly to the vendor's technology design and development methods, or the performance of allied equipment components (e.g., scanners, monitors and carts). Other failure modes exist outside of the technology itself, yet are part of the system change. Often failure points will interrelate, and they may not be evident unless the system is put under stress (such as added clinical complexity, specialized needs, or time urgency).

In this document sub-section we discuss various points at which a bar code system may fail, and introduce methods that can be employed to prospectively assess where failures could occur.

Appendix III-2 (*Potential Bar Code System Failure Modes*) summarizes selected major potential failure modes.

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Bar Code System Potential Failures

Technology

Technology-related adverse events have been described in several papers related to *HIS* and *BCMA*.[25, 28, 85, 87, 88, 120, 123, 151, 168-172,184] Many early failure assessment reports were based on previously implemented systems, sometimes resulting in less-than-ideal experiences. When post-implementation assessment occurs, the discovered issues require, at best, system re-configuration or re-design or, at worst, a entire withdrawal of the implemented software, with re-implementation at a later date; both at a high potential cost impact.[151]

The U.S. Joint Commission (on Healthcare Accreditation), in 2008, issued an informative advisory that described potential technology-related safety issues and provided recommendations to assess technology prior to implementation.[85]

Many medication system weaknesses may be foreseen. *Failure Mode and Effects Analysis* (*FMEA*) is useful to evaluate overall medication system weakness, or failure points, typically related to existing procedural issues. It may isolate those points that require system re-engineering. But, *FMEA* methods alone are not sufficient to evaluate the technology itself.

New medication error forms may arise from technology, including those aspects of the technology which rely on preceding medication system components. Many of these technology weaknesses can be foreseen by specialized pre-implementation evaluation. To effectively assess a technology and its related software functionality, one must note evaluate the technology in isolation. The ability of technology to be operated by care providers under different conditions is known as the human

"usability interface" (UI). To measure this, a different type of evaluation is beneficial, called *Usability Testing.*

The complementary combination of *FMEA* and *usability testing* is a process described in a paper by Borycki and Keay[169]. It is most useful when it is applied during the acquisition and pre-implementation process, as noted.

Various definitions and methods of *usability testing* and "*heuristic evaluation*" exist, but it is not the purpose of this document to delve deeply into such differentiation. *Usability testing* models can be developed by accessing a consultant in this field. Human Factors and health informatics experts capable of conducting *usability testing* provide a good starting point for developing such testing plans. We provide hereunder resources which can provide readers with resources such as *usability testing*, human factors, tools, and organizational designs related to system evaluation and implementation. Some organizations also provide access to practice-related work groups and their findings.

- U.S. government (Department of Health & Human Services) http://usability.gov/index.html
- Canadian Nursing Informatics Association http://cnia.ca/
- Canada's Health Informatics Association http://www.coachorg.com/en/index.asp
- International Medical Informatics Association http://www.imia-medinfo.org/new2/

We strongly recommend planned bar code systems undergo prior *usability testing* in a manner that challenges the new technology's ability to function under stressed, complex situations, and also assesses its impact on healthcare providers. Such testing will expose possible problems that could directly or indirectly lead to patient errors.

Heuristic evaluation techniques, criteria and metrics vary. They include both objective and subjective criteria. At its very highest level, *heuristic evaluations* should assess the new technology's effectiveness, efficiency and user satisfaction.

Carvalho, Borycki and Kushniruk[172] prospectively evaluated a Veterans Administration (VA) *HIS* in a phased manner. They provided a detailed review of 38 heuristic criteria for an *HIS*, noting these fell into four testing categories:

- Workflow (steps of processes working well from beginning to end)
- Content (e.g., quality and applicability of information contained on the screens)
- Safeguards for active and passive decision support for humans (e.g., alerts, reminders)
- Functionality (e.g., the ability to move about a system, screen layout and screen options)

Again, it is not possible for this document to provide a full discussion of *FMEA* or *usability testing*. Rather, we recommend that planned medication systems, operational processes and technologies be evaluated using a combination of these two techniques, under the direction of a usability consultant working closely with process/content experts (healthcare providers). Graduates from some academic programs may have the knowledge to develop their own local tests, and the Information Technology

department may allow and facilitate such tests in the context of their own local programs. The methods and criteria can be developed in consultation.

Bar Codes Standards

It is important early in the planning process to ensure the bar coding modules utilize a defined set of bar code symbologies meeting recommended standards, including the information (*data elements*) contained within the selected bar codes.

There are two predominant sources of medication bar codes used in facilities: *commercial* and *in-house* (pharmacy-applied) bar codes. The following discussion provides a potential categorization of both the dose types and bar code requirements; however, each organization can modify these categories based on internal discussions between their pharmacy and chosen Technology Provider(s).

Commercial **Products**

Our *Canadian Pharmaceutical Bar Coding Project* has consulted with several Canadian healthcare sectors and GS1 Canada to promote the voluntary national compliance of Pharmaceutical Manufacturers and Technology Providers sectors with *the* GS1 global *Automated Identification and Data Capture (AIDC)* standard. This standard applies to all commercial products used in Canada.

Link to Joint Technical Standard for Pharmaceutical Bar Coding (ver II: 2012)

As of December 2012, *commercial* pharmaceuticals used in Canada should have predictable and readable bar codes at every level of packaging based on the GS1 global standard. In turn, these bar codes should be readable by the medication bar code verification software used at community and institutional facilities. The same bar code should be useable at each and every stage of the medication and prescription processes: purchasing, internal pharmacy compounding and dispensing operations, stock transfers, and, importantly, dose administration at the patient bedside.

In-house **Modified Products**

Non-commercial medication packages and labels are usually created within an institution's *in-house* (or regional) pharmacy, or within a nursing home's contracted pharmacy. *In-house* pharmacy operations, whether from institutional or retail pharmacies, repackage and/or compound a medication dose, followed by package labelling and dispensing to the patient care area.

These medication manipulations become necessary when bulk commercial products are modified into patient-specific dose packages (or containers). These packages include unit-dose blisters, multiple drug blister packs, or 30-day monitored dosage cards. They may also

include sterile bags, vials or syringes containing reconstituted solutions, or aliquots of commercial solutions. The pharmacy often may compound several ingredients into a single new mixture such as an ointment, oral solution or parenteral mixture, sometime involving ingredients which are high-alert medications.

The altered medication formats may be produced in bulk (i.e., batches) ahead of their need, or alternatively may be produced as specialized mixes for one patient only as needed.

Based on the above *commercial and in-house* categorization, in both institutional or community-based care environments, there are three types of medication dose bar codes possible for *BCMA* (Figure III-5):

1. *Commercial* dose bar codes:
   The dose bar code symbology complies with the GS1 global *AIDC* standard and minimally contains the product's *GTIN*.
2. *In-house pre-prepared "batched"* dose bar codes:
   The dose bar code symbology is chosen by the facility and minimally contains the local unique inventory ID code.
3. *In-house "patient-specific"* dose bar codes:
   Dose bar code uses a specialized patient-specific prescription-specific number code scheme to identify a prescription correct dose unit.

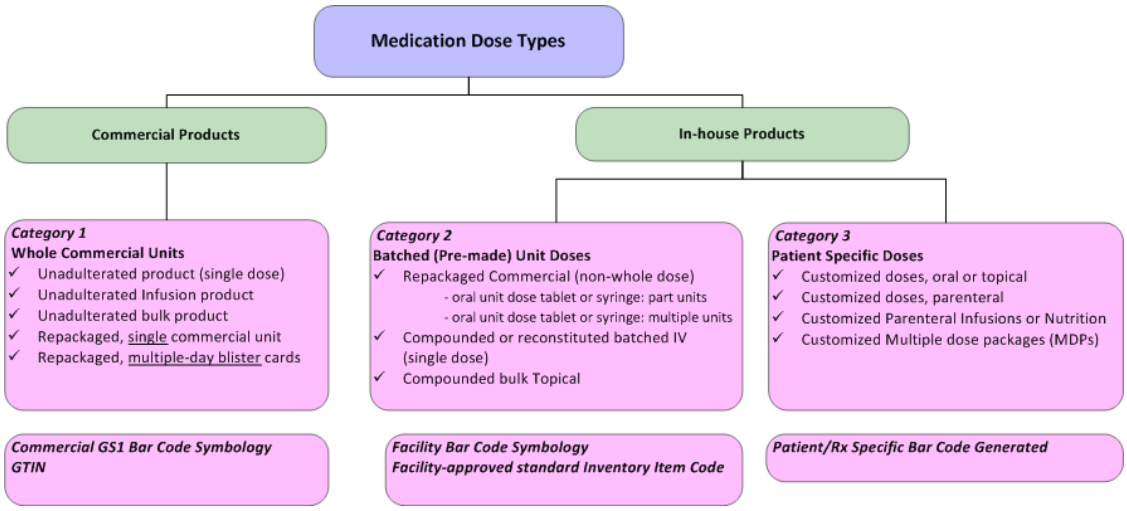

Figure III-5 Dose Types and Bar Code Categories

The following are potential *in-house* bar code options for organizations, based on the above patient medication dose categories:

1. *In-house Pre-prepared Batch Products:*
   - Consider utilizing a *GS1*-standard bar code symbologies. (*See Section I, Appendix I-1*)
   - Include essential information within the code, using *GS1* standard *data elements*, such as: Product inventory ID (minimally) (i.e., GS1 GTINs or other similar unique ID codes), Lot number, expiry date.
   - Use a printer/system that generates 1-D (e.g., UPC code) or, preferably, 2-D (e.g., DataMatrix).

2. *In-house Patient-specific:*
   - Develop in consultation with your software provider. Use a computer software logic that uniquely creates and prints a single **unique** bar code for the dose package. The bar code should include the following *data element*s necessary for the system to obtain the correct *EHR* prescription *data element*s from the active *EHR* prescription record for verification:

     Minimum bar code *data elements*:
     - Unique Patient ID or Medical Record number
     - Unique Patient visit number
     - Unique Prescription number.

     Again, the purpose of this concatenated patient/visit/prescription number (or equivalent single bar code) is to allow the bar code verification software to first scan the package bar code, then trace back to the specific patient prescription record to obtain essential other prescription safety information necessary for automated verification and *EHR* documentation. The system will ask/obtain:
     - Is the prescription still an active medication order?
     - Patient Name and patient ID
     - Drug Name and Drug ID Code
     - Dose and/or strength/concentration
     - Dose days and approved administration time(s)
     - Time of last dose administration
     - Confirmation of intended route
     - Additional details, as designed

It is not possible to discuss all possible bar code options in this resource guide. In summary, by establishing defined bar codes meeting data element standards for the three dose categories (commercial, in-house batch and in-house patient specific), it will allow a *BCMA* system to function seamlessly for all (or most) patient medication doses at the point of dose administration.

To avoid system failure, plan the following prior to implementation:
- Dose categories,
- Bar code symbologies for each category,
- Inventory file drug coding fields (for commercial and in-house batch products)
- Therapeutically interchangeable products and a system method for identifying interchangeable dose products.

Bar codes must be predictable, readable, and be usable bar code scanners and software. The systems may involve more than one bar code verification system, such as bedside *BCMA*, smart pumps, pharmacy dispensing systems and pharmacy compounding pumps. The single bar code designed for each dose type must be usable along the complete medication chain from purchasing through to the patient bedside.

Bar Code Readers

Bar code reader (scanner) types were briefly discussed in *Section I*. The attributes of specific scanner models are largely beyond the scope of this report. An organization must choose its scanner(s) based on their selected commercial and in-house bar code.

It is essential that the scanner works seamlessly with your computer module software, so consultation with your *MMIT* vendor and pharmacy-provider is required. Most probably your institution should select a scanner compatible with 2-D bar codes, most of which can read 1-D bar codes as well.

Additional user considerations for readers include:

- Light-weight and transportable
- Work with long-life batteries.
- Software is not lost if battery is drained
- Sufficient number of charging stations
- Sufficient number to allow staff to recharge and take another.
- Potentially Wi-Fi enabled with security

Proprietary application software that require readers to add a suffix or prefix to a medication or patient ID code, may result in a bar code reader that cannot be utilized across several functions (e.g., medication, laboratory, food/dietary verification modules). Ideally, no prefixes or suffixes should be configured into a reader's setup. Not doing so, may result in confusion for users, additional function-specific readers (i.e., multiple readers) and system cost.

Many reader-related failures can be traced to staff acceptance of the tool which will form a large part of their technical day. As we will review later, bar code scanner usability and reliability is an important factor in staff compliance and satisfaction, and therefore, system success.

Bar Code Readers and Code Readability

It is difficult for users to differentiate between a scanner that will not scan and a bar code that will not be read. In the end, both will cause user compliance issues.

System pre-implementation planning should also include an ongoing quality control process whereby both commercial and the in-house package bar codes are routinely tested for readability and

correctness. Test scans as a standard quality process within pharmacy will minimize the chance that nurses and pharmacy staff have difficulty reading the dose bar codes.

The readability of commercial pharmaceutical product bar codes is defined within *Supplement A* of our projects *Joint Technical Statement (ver II: 2012) (JTS)*, which cites an international standard that must be met. Regardless, problems may still occur with commercial labels or IV bag bar codes[189] within your facility's own operations for a number of reasons. It is important commercial labels are tested also.

Your implementation strategy must also include the printer systems used for in-house bar code printing. Carefully review the various printer types you plan to use, methods of printing (e.g., laser), label paper, label layout, and package placement. Ensure testing is done and that printers and toners are maintained regularly.

Although *Supplement A* has been written as guidance for commercial pharmaceutical manufacturers, various issues discussed in that supplement apply equally to in-house bar code planning, testing and printing. The supplement provides label planning considerations.

Multiple Bar Codes

It is advisable to limit the number of bar codes on a medication package to a single prominently displayed bar code, which can (in the future) incorporate several *data element*s and can be interpreted by the chosen bar code reader (scanner).

As much as possible, the bar code should be placed in a position that minimizes package manipulation by staff when scanning the code during activities. For example, the bar code should not be behind label flaps or non-transparent package covers. If the bar code is placed under a clear covering, such as perhaps a sterile over-pouch, the readability of the bar code must be ensured.

The point of this subsection is that, like readability, user compliance and satisfaction suffers greatly when multiple bar codes are used or a single bar code is not easily found and readable.

Hidden Sources of Bar Codes

An example of work-arounds is the use of 'hidden' sources of bar codes; ones that are not primarily intended for dose or patient verification. Such bar codes may have been cut, copied or extracted from 'legitimate' sources by staff. Users may also utilize alternative printed documents which also happen to contain the needed bar code, or old dose packages. Anything other than an actual dose container or a patient's attached identification bracelet is **not** legitimate and represents a major system compliance issue.

Legitimate sources of bar codes for the medication process include:

- Pharmacy
  - Medication dose packages dispensed
  - Computer fill lists

    - Compounding recipes
    - Purchase orders
- Patient care Areas
    - Patient wrist bands, on the patient's body
    - Medication dose packages dispensed
    - eMAR, or printed MAR

Non-legitimate sources, used for workarounds, include:

- Photocopies of labels or patient bar codes
- Cut out and scotch-taped to another surface (from old doses or lists)
- Duplicated patient wrist bands
- MAR document patient ID, instead of patient's actual wrist band
- MAR for medication dose, instead of actual medication dose package

There are likely reasons why the users resort to such workarounds. They may indicate poor system design or implementation. Pre-implementation planning of documents and printed bar codes must be thoroughly reviewed to assist users in their compliance and to avoid the temptation of non-compliance. Planners can design printed MARs to not contain duplicates of patient ID bar codes or medication bar codes. (Please note, however, that this decision must be made in conjunction with the planned contingency for system down-time.)

Users should be educated in the dangers of utilizing non-legitimate bar code sources to circumvent aspects of the approved medication verification system.

Patient Wrist Bands: An important failure mode is when patient wrist ID bracelets are removed from a patient and stored in various other locations (e.g., taped to cart, wall, bed headboard, or binder, or med room). This is often symptomatic of a more primary system problem, such as:

- Patient refusal to wear identification (i.e., stigmatization)
- Tight curvature of wrist band, causing non-reads (e.g., pediatrics)
- Neonatal skin cuts or abrasion
- Concerns about awakening sleeping patients
- Compliance or efficiency work-around issues

Physical Infrastructure and Support

Many system readiness issues may exist that outside of the technology itself and in the surrounding physical or support environments. These too are best addressed during pre-implementation planning. Failure to anticipate and test these potential inadequacies will contribute to individual user frustrations, compliance failures or, worse, complete project interruption in the affected areas.

There are two areas of planning that *FMEA* can be used to foresee areas of concern.

Wireless Coverage

A robust and secure wireless environment is required for the mobile aspects of your planned system. The system wireless environment should be developed in collaboration with your

information technologists. Although a wireless infrastructure may already be present, its robustness needs to be challenged.

Medication administration and documentation can often occur throughout the entire patient care area; down long hallways and inside rooms with various barriers. It is not sufficient for testing to include only the areas around a central workstation or medication room. Rather, extensive testing of the wireless coverage and performance under stress is needed. Grey areas of reduced coverage or slowed network system response (speed problems) are a potential cause of user non-compliance.

Specific testing (under extreme system load demands) should be completed. A relatively low additional resource outlay will ensure this aspect of the system will not become a major failure point.

Maintenance and Technical Support (Computers and Bar Code Scanners)
Pharmacy or nursing operations cannot be delayed by missing or malfunctioning equipment. There should be sufficient additional equipment (redundancy) to allow system technicians to remove a piece of equipment for maintenance or repair without compromising medication operations.

Coupled with equipment strategies, a thorough review of mobile equipment battery capabilities is necessary. Not only should there be sufficient chargers, there should also be additional mobile scanner units to allow user functions to continue on a 24x7 hour basis while discharged units are re-charged.

Medication and Prescription System Delays
Delays associated with obtaining required medication doses from pharmacy can cause nurses to seek alternative (workaround) sources for medication doses, by means of stock hoarding or 'borrowing' from other patients' medications. A "pharmacy" delay may occur as a result of prescription order entry (including safety verification), or the requirement for prescription clarification between a pharmacist and the prescriber.

It is important that the following issues are properly addressed during pre-implementation planning, and subsequent system user training:

- Accurate and timely prescription order entry[11]:
  - Order entry policies and procedures
  - Missed or modified prescription order entry
  - Visual orientation of medication orders on *MAR or eMAR*.
- Timely communicating with nurses about:
  - Delayed computer order entry or verification
  - Modified or clarified prescriptions (changed orders)
  - Stat or new urgent medication orders
- The use of verbal orders.

Alert Fatigue

The use of system-triggered user alerts (i.e., warnings or reminders) can become one of the most controversial decisions related to medication bar code implementation. There are no specific criteria associated with choosing which to employ, but the level of attention paid to alerts by busy healthcare providers can quickly become a hidden system failures.

Critical alerts are not only essential as practice reminders to healthcare providers, but their absence within automated systems could be viewed as a potential organizational liability.

Alerts can be used in many ways. They warn healthcare providers to be more attentive to medication safety steps; such as to obtain secondary safety checks, adhere to critical process steps or required laboratory tests, monitor patient clinical status, complete documentation, plus many other safety prompts. They can also pass information to the healthcare provider, such as patient allergies, interactions, common medication side effects, or key policy requirements.

The potential system failure mode is the over-use of alerts. As every person who drives on a busy road with too much signage knows, the over-abundance of signs leads a driver to potentially ignore all potential warnings, including the important ones. Attention to alerts may become individually subjective, where only some alerts have an impact.

Miller (et al) showed alert triggers on 17% of scanned medications, with 55% of those being for high alert medications with insulin, hydromorphone, potassium chloride and morphine being within the top agents.[101] Of the overridden alerts, only 23% were provided with reasons. Koppel (et al) reported nurses overriding 4.2% of *BCMA* alerts.[87]

The selective use of alerts is another important pre-implementation issue: one which requires the wisdom of a multi-disciplinary team in consultation with frontline providers and human factors consultants. Together, alert criteria can be developed for when alerts should and, equally important, should not be utilized. The resultant criteria can be applied through system software settings, usually by Pharmacy information staff.

It is recommended that alert wording be considered through the lens of human factors to avoid potentially confusing messages or abbreviations.

The following list provides some considerations for the appropriate use of automated alerts. Software functionality may also be flexible enough to allow customization of alert triggers which are based on the medication status and/or patient clinical risk circumstances:

- Designated *High Alert* medications
  - *Independent Double-checks* by a colleague, when required
  - Any pre-dose physiological or clinical observations
  - "Last Dose" warnings
  - Required pre/post dose laboratory tests or clinical observations
- "Repeated Dose" or "Daily Maximum" warnings
- Major overdose warnings
- Critical allergy conflicts

- "Wrong Patient", "Wrong Medication", "Wrong Dose" (or prescription), "Wrong Time" (+/- acceptable time variance allowance).
- "Discontinued" Medication Order
- "On-hold" Medication Order

Examples of information better provided as optional nurse viewing include:

- Documentation or policy information
- Drug information
- Side effects
- Toxicity symptoms and recovery treatments
- Normal dose ranges
- Patient education material access

The reader is encouraged to consult with other organizations who have implemented bar coding. Consults with ISMP Canada's interdisciplinary team can also be arranged.

Alert Compliance: Learning from Audits and Interviews

Auditing user system compliance and scan rates will be addressed later in Section III.

Alert auditing is possible. If repeated failures to comply with alerts are noted, they may be symptomatic of alert planning. Individual and group users who routinely ignore or override warnings should be identified and discussions held to investigate reasons why.

Look for signs of excessive number of alerts per shift, overall bar code system performance, clinical workload, or other environmental issues. Other possible causes of poor alert compliance are a system's use of multiple screens, loudness of the auditory alarm, blurred mobile or computer screens, small visual icon or text font, or ambient lighting conditions.

Lastly, nurses, pharmacy staff or physicians may disarm auditory alarms for many reasons, such as nuisance noises or a desire to not interrupt patient rest periods. Such actions should not be allowed to continue however, again, a review should be conducted with the group users and area leadership before any final decision is made.

Pharmacy-Based Bar Code Functionality

Retail and institutional pharmacies perform several process steps prior to transferring a medication to a patient care area for storage, retrieval and dose administration. The accurate and timely completion of these steps is critical to ensure the medication administered is accurately dispensed and labelled. Downstream system accuracy and efficiency is reliant on the quality of these earlier pharmacy processes.

If errors are made during Pharmacy-based functions, these may not be obvious to nurses at the bedside or caught by bar code verification, resulting in patient medication errors.

The following usual Pharmacy-based functions should also utilize bar code verification and documentation, to enhance downstream system quality:

- Contracting, purchasing, and inventory storage
- Stock transfer within Pharmacy and Patient Care areas
  - Automated Drug Cabinets
  - Re-packaging Robots
  - Area Satellite Pharmacies
  - Patient Care Area Ward stock
  - Emergency Kits
- Compounding oral and topical mixtures
- Compounding parenteral, spinal mixtures
  - Central Intravenous Admixture (*CIVA*)
  - Parenteral Nutrition
- Repacking *bulk commercial* products into *In-house* packaging
  - *Unit-dosed* tablets
  - *Unit-dosed* oral or topical solutions
  - Smaller bulk containers for patient care areas, or take-home medications
- Prescription order entry accuracy and Turn-around times for new prescriptions
- Dose dispensing,
  - Stat Doses: *CIVA* and *Unit-Dose*
  - Interim doses: *CIVA* and *Unit-dose*
  - Cart fill Doses: *CIVA* and *Unit-Dose*

Bar code verification processes and their failures modes within Pharmacy-based functions are quite similar to those in patient care areas, though the specific functions and documents are different. Pharmacy bar code verification usually occurs between a printed sheet with bar codes (or an electronic list) and a physical medication package which is being compounded or dispensed. Scanning problems may occur in any of the following specific functional steps:

- Filling the prepackaged unit-dosed tablets against a computer-generated "fill list".
- Mixing a topical or intravenous mixture by verifying the correct bar coded ingredients against a standardized recipe. (Ideally, the system should utilize auto-calculation of ingredient amounts and bar codes of intended products.)
- Re-loading a prepackaging robot to create new singe bar coded unit-dosed dose packages, where a bulk *commercial* container is validated against a robot's affiliated holding canister.
- Dispensing new patient-specific doses by verifying the chosen package against an entered computer prescription.

Potential bar code system failure modes from pharmacy-based functions may arise from three categories: system-induced failures, deliberate user non-compliance, or human-based errors. The first two, system-induced failures and user non-compliance, arise from issues similar to those discussed in more detail below.

Human-based pharmacy errors may occur despite having a bar code verification systems fully implemented. The following medication manipulations are steps where bar coding has limited impact:

- A correctly printed bar code label may be affixed to an incorrect medication package.
- A correctly printed bar code label may be affixed to the wrong IV bag or syringe.

- A correctly printed bar code label may be affixed to an incorrect strength package.
- A bar code label may be affixed to the wrong patient's dose(s)
- Workload delays in entering or validating new prescriptions in the facility's *EHR* medication record for nurses.

The purpose of outlining the fallibility of precursor pharmacy functions is to demonstrate that patient errors may still occur with bar code systems. These, in turn, may affect the overall system usability and compliance of others downstream.

It is important that pre-implementation planning address potential pharmacy failure modes, especially as they relate to *high alert* medications. The use of both *FMEA* and *Usability Testing of pharmacy operations will help*. Review should include assessments of pharmacy workload, staff conformance, and pharmacy environment issues. It should support the possible retention of secondary human *Independent Double-checks* for high alert medications. Failing to do address pharmacy functional issues may give facilities a false sense of medication safety security.

Appendix III-2 contains a list of potential pharmacy failure points.

User Compliance: A Manifestation of Poor System Design and Implementation?

The prescription and medication flow chains converge at the final step of the medication process, bedside medication dose administration. We have previously reviewed a number of system failure modes, including preceding support services. If any unresolved issues remain the result may be a non-administered or non-verified medication. Mitigating the negative impact of these contributing failure modes will be discussed in the next subsection (Reducing System Risks)

Attention also must be given to causes of non-compliance by users who choose not to use the system as it is designed. In this discussion we primarily view non-compliance through the lens of nurses during medication dose administration, because most bar code research is associated with those nursing practices. However, the same issues of non-compliance apply equally to other user disciplines such as pharmacy staff.

A failure of a nurse to be compliant with an implemented system usually indicates that the system has a perceived unaddressed weakness. These are often a result of inadequate system design or implementation planning. Several reports have investigated nurse work habits with BCMA systems.[58, 87, 101, 119, 120, 143, 186] Transgressions may take the form of reduced scanning rates or workarounds of approved processes. And, importantly, they may be key early signals of system or technology weakness.

Compliance is affected by any number of system or human reasons. A 2008 study in the Netherlands[143] found bar code verification was influenced by the "medical department" [sic] practices, variations between administered and prescribed dosing times, admission routes, the number of nurses available, and the age of the nurse. The five cited causes were:

- Difficulty in scanning the bar code,
- Lack of awareness of the bar codes,

- Delayed computer responses,
- Shortage of time, and
- The need to administer the dose before the prescription system was ready (e.g., Prescription not yet on the eMAR)

The study suggested a wide range of contributory factors, from system-related causes to educational awareness and personal reasons. It is therefore incumbent upon those planning bar coding systems that user practice requirements be fully assessed, and should:

- Not be overly simplified,
- Include front line staff consultation both before and after implementation,
- Include contributory system issues (i.e., Pharmacy), and
- Include nurse training, which addresses professional and personal considerations.

Reduced Scanning Rates

Scanning rates should be audited after implementation. Rates should approach 100%, however achieving this level may require several successive quality improvement cycles. Low scanning rates are affected by a number of factors, including:

- *Usability* of the technology:
  - Is it easier to scan than not?
  - Is there a slow system response rate?
  - Are the screens too full of information?
  - Are there too may alerts?
  - Is the system too complicated or confusing in complex clinical situations?
  - Does the system work during urgent situations?
- Non-availability of scanning equipment at patient bedside:
  - Do the scanners, alert and patient record screens, and doses all reach the bedside?
- Bar code readability, multiple bar codes, hidden or duplicated bar codes:
  - Are the bar codes fully strategized, easily read and not confusing?
  - Is there a single bar code, and is it located in an obvious location?
  - Are bar code symbologies and *data element*s standardized?
  - Is there a strategy for patient-specific custom doses?
- Drugs scanned are not in the computer system:
  - Are all inventory items included in the drug data file, with appropriate coding?
  - Are therapeutically interchangeable items cross-referenced for scanning?
- Scanner mobility, functionality and battery life?
  - Is the mobile scanner light weight and transportable?
  - Does it have the requisite multiple features that assist the user?
  - Are there sufficient numbers of scanners, including redundancy?
  - Is there a workable battery (re-charge) plan?

Workarounds

Workarounds involve providers adding unapproved process steps, or dropping or modifying approved steps. As with scanning non-compliance, the interrelated causes for work arounds are complex and inextricably tied to system design, performance and manner of implementation.

Up to 40% of a nurses time may be involved with medication-associated activities. Any real or perceived inefficiency of a bar code system causes nurses workload problems. *BCMA* may increase[105] or decrease[126] medication-related time and, thereby, influence both nurse satisfaction and the potential for workarounds. If other practice workload is co-incidentally elevated, the overall medication system inefficiency may further promote bar code system workarounds.

The causes of *BCMA* workarounds have been reviewed in great technical detail by Koppel (et al) [87], several of which appear in *Appendix III-2*, and *Reducing System Risks* subsection below. The Koppel (et al) review touches on over 38 causes, the details of which are beyond the scope of this guidance document. The issues noted in the Koppel report relate to many different system aspects: software functionality (e.g., the number of screens, the number of auditory warnings), the physical set-up (e.g., size, weight and location of equipment, time-out of screens), human issues (e.g., false sense of security, alert fatigue), and others. The reader is strongly encouraged to review the possible causes of *BCMA* work-arounds which appear in their article, as well as other similar implementation reports. (See *Reference Section IV*).

Reducing System Risks

This subsection provides a high-level review of planning steps designed to mitigate several failure modes of bar code verification systems; based on reported experiences from other organizations. The strategies are contained in the three subsections: pre-implementation, system education and implementation, and post-implementation.

Most strategies are applicable to bar coding implementation within any healthcare environment, and apply to both nursing-based and Pharmacy-based bar coding practices whether these practices fall within the community or institutional care.

It is wise to invest ample time reviewing pre-implementation issues. Planning is of paramount importance.

Appendix III-3 (*Mitigating New System Risks*) provides a summary of the reported recommendations

Before Implementation

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Implementation Planning Team

The foremost implementation strategy is to convene a formal interdisciplinary Bar Code Implementation Team (BCIT) that can oversee all aspects of pre-implementation assessments and the implementation progress. It should have effective representation on the facility's MMIT committee. BCIT members ideally should include leaders from pharmacy and nursing practices, a physician, an administrative representative, and front-line representation from pharmacy and selected patient care areas. The BCIT should receive technical support from the Information Technology and Biomedical Engineering, departments, if possible. For community practices, the BCIT may vary slightly, and should have representation from the contracted pharmacy provider, and outside technical support may be required through support consultants.

Pre-Purchase Considerations

A bar code system module will be acquired from a vendor, or *Technology Provider*, and contains proprietary software functionality. The chosen vendor may specialize in one aspect of medication management primarily (e.g., pharmacy operations) or the modules will co-exist within a larger h*ealth information system.*

Regardless of the source of the software, the modules functionality should be thoroughly vetted using a series of increasingly detailed evaluations which include input from the in-house healthcare providers. The approval of software should parallel the processes for acquiring any other bar code system components, such as necessary equipment, and computers and network infrastructure. At some point of the planning, several vendors will need to collaborate to ensure their systems can work together to fulfill the end user's needs.

In the case of community-based facilities, the nursing home will also need to contact its contracted pharmacy provider. It is best to first administratively meet with the pharmacy so that both parties agree the home's medication management requirements and the need for integration with the pharmacy's dispensed medications. In other words, the bar codes sent by a pharmacy must integrate seamlessly with the facility's medication bar code system software. Though this agreed alignment is an additional project step, it is not one which is insurmountable.

The following steps should be considered before software is considered for live trial.

Request for Proposal

A *Request for Proposal* (*RFP*) is important, followed by careful negotiation of a system contract, including any allied sub-contracts for equipment, databases or services.[176] Using documents such as the *Canadian Pharmaceutical Bar Coding Project* (*Supplement B* of the *Joint Technical Statement Version II: 2012*) (link below), a clear and detailed *Request for Proposal* (*RFP*) should be developed.

Link to Minimum Safety Software Functionality Checklist

The *RFP* may be part of a larger *HIS RFP.* Regardless, it should minimally include the following standard sections: description of purpose, available funding commitment, legal and liability responsibilities, required functionality, and a request for both direct and indirect cost estimates. If a facility does not possess a well-tested RFP template, it should acquire a template from a close institutional partner.

The RFP should contain a detailed appendix which provides a clear software and system functionality checklist of "must haves" and "nice to have" functions presented in a manner which allows weighted scoring of each respondent's product. The vendors should be clear on the most important aspects of the system. "Must haves" should be clearly marked. "Nice to haves" should be assigned a weighting to indicate the relative importance of each functionality item. Engage a skilled negotiator when creating and executing an RFP.[176]

It is important to state within the *RFP* that your facility's staff will assess the functionality during the assessment process, indicating how this will be achieved. If there are requirements of the vendor during the assessment process, these should be indicated also.

If you intend to conduct site visits to view of their products in a live environment, or require demonstrations; include this in the *RFP* and ask the vendor for site suggestions.

During the vendor's *RFP* response process:

- Allow the vendor to ask questions to better understand your organizations needs or limitations.
- Ensure the vendor has realistically noted any product software functionality gaps (i.e., when compared with the *RFP* listed bar code functionality. If there are gaps, ask whether the vendor has developed a software development plan, as requested in the Project's *Joint Technology Statement* (ver II: 2012).
- Ask about the software's ability to allow facility-controlled preferences, screen design, alerts, and highlighting. In other words, what is standard (unchangeable) versus what can be controlled through settings.
- Ask if the vendor will customize its software to meet the truly specialized clinical needs within your organization; and, if so, the costs of such changes? Are there any guarantees of the turn-around time for such re-programming (including vendor system re-testing).
- Seek vendor active participation in staff education and implementation "go-live".
- Discuss innovative vendor "risk participation" with the facility. For example, are they willing to put more "no cost" resources into ongoing education or software tweaking if staff are not satisfied or key system metrics do not improve over time?

Site Visits

As above, you will want to communicate with and visit a site that has previously implemented the vendor you are considering. Site visits, at least in part, should allow time alone with colleagues, without the presence of the vendor.

Prepare questions and consider including your original *RFP* functionality list as a verification checklist too. Ask if the system has undergone previous heuristic evaluation and, if so, if you can receive a copy of the findings and subsequent actions.

Evaluation of Vendor Software

It is essential that the vendor product is evaluated in a structured and progressive manner. Failure to properly assess the system features may progress to long-term medication system failure, such as medication errors arising from the technology itself, or staff compliance and satisfaction erosion.

***RFP* Process Demonstrations:**

Using the *RFP* list of "must have" and "nice to have" checklist, ensure that a preliminary assessment of each function can be demonstrated clearly to a fairly large number of users especially from nursing and pharmacy assessing collaboratively.

Not only should the product be demonstrated using a presentation but also in less formal "test" setting where attendees can use it "one-on-one" with the vendor representative assisting. Consider two sessions: one as a vendor overview presentation, followed by another with the product itself.

Pre-decision Trial:
It is difficult to withdraw from a signed agreement once a decision is made. So, a thorough pre-decision detailed trial may be one of the last practical chances you have to either reject the software, or come to agreement on significant system changes (customization) prior to the product agreement. This pre-decision assessment is usually only employed when a facility is down to a select few (or final preferred) vendor(s).

If a full heuristic evaluation can be managed before a decision, then attempt to do so. Otherwise, if this is the final assessment before there is a final agreement on terms and costs include the need for future trials in the contract, with allowances for system software modifications.

Don't be afraid to request multiple trial sessions using situations that are as close to a "live" system as possible. Again, engage different types of users with varying practice needs. It may be best to develop a staged approach. First demonstrate its basic functions to show standardized medication daily functions. Follow these assessments with increased complexity. Ensure each test scenario is designed to demonstrate realistic complexity in your facility, including standardized medication practices.

Include scenarios that represent truly specialized clinical care practices. Staff from chosen specialty areas should be included in the test planning. It may be necessary to create "dummy" patients and/or medication products to adequately perform some realistic testing. Add some "urgent need" scenarios to your testing to see how the system responds.

Post-decision Usability Trials
If full usability testing (or heuristic evaluation) is not possible before a decision, then it should be performed after a decision, but well-before implementation is planned. Especially for community care settings, enquire if collegial institutions have already performed such usability tests and might be willing to share, or, alternatively, work collaboratively with other organizations to complete an evaluation.

Heuristic evaluation as a concept has been discussed at the beginning of this section, above. Again, evaluations should involve an experienced consultant working closely with practice experts to design tests. Specific test designs and success metrics will vary but, in general, the tests should:

- Allow for both subjective and objective measures.
- Test:
    - Simple and straightforward processes
    - More complex processes
    - The same processes under severe time constraints, such as emergent care

- Use more than one evaluator.
- Be in a realistic healthcare environment which simulates clinical practice reality, as much as possible.
- Use an iterative process: Test, modify the system (or settings), then re-test.
- Assess the ease with which providers can use the system, and the ease of learning its nuances. Assess the user memory requirement to use the system, both short-term and long-term retention needs.
- Assess the performance of allied equipment, such as screens, scanners and carts, as these form part of the overall system also.

Be sure to disclose any concerns to the vendor. Seek collaborative solutions to modifying the system to meet user requirements. Note that initial usability testing may need to be repeated after any significant system modification.

As a system is tested, remember that it is not advisable to modify safe medication practices to conform to vendor software idiosyncrasies. In other words, software should adjust to critical practices (e.g., ICUs), not the converse. Too much practice patchwork to fit the software functionality could become unsafe.

Of course, remember that bar coding verification processes will fundamentally change medication practices.

Vendor Education Package Software Evaluations

Finally, the vendor's education package should be reviewed. A vendor should provide superior education material and instructors, while allowing for some customization of the package for your staff.

Later in the implementation process, a pre-implementation staff communication and education plan will be developed (see below). At this time, the basic education packages can be adjusted, based on collaborative input from frontline staff and a "super user" group who will ultimately be asked to understand the new system better than others in their areas of practice.

Infrastructure and Physical Evaluation

Once a vendor and software module has been selected pre-implementation work proceeds. Next planning steps include consideration of the system environment, auxiliary equipment, number of units required, back-up units, and similar reviews:

Computer and Mobile Equipment

- Cart-top versus tablet computers
- Screen sizes

- Weight and ergonomics
- Scanner (Readers), including auditory and screen size and lighting
- Scanner ergonomics
- Scanner battery life
- Scanner bar code symbology capability
- Scanner station holders and stability
- Compatible operating systems

Battery and Re-charging Systems
- Number and location of stations
- Re-charge time

Network and Wireless Coverage and Response Rates
- Hospital Infrastructure status and any additional network needs
- Hardwired Ethernet ports
- Wireless nodes, standards and security
- Passwords, as necessary

Carts and ancillary devices
- Mobile carts, if computers on wheels (COWs) are used
- Scanner stands
- Unit Dose Patient Dose bins and storage
- Bar coded bins and/or shelves

Safety Education and Culture Priming

Creating a common understanding among healthcare providers about the objectives of bar code verification and their place in an overall medication safety strategy is vital. An individual who feels they are 'in the loop' and being consulted about the progress will be a more engaged colleague.

It is also important that user engagement does not become a single event. Ideally, education on, and practitioner sensitivity to, fundamental patient safety principles, including HROs and systems, should occur first in academic and technical curriculums, but this may not always be available. Within institutional education plans, exposure to automated (e.g., bar code) systems should be part of a broader engagement related to overall safety culture and objectives. The bar coding effort, as with other systems, should incorporate a longstanding communication and response channel, involving routine discussions both with individuals and teams.

Collaboration and communication skill training might also be included to promote constructive interchanges, dove-tailing with collaborative efforts. If no such program exists, a facility should give serious consideration to creating a facility-wide effort, both for existing and new staff members.

The first level of education provided to providers should introduce your facility's commitment to ongoing collaboration on practices and patient needs. Early sessions should focus on methods for multi-level and multi-disciplinary collaboration and communication. Do not assume individuals are initially comfortable with these concepts, or that they are easily convinced with early attempts to demonstrate these commitments.

If built on the above principles of collaboration, all future patient safety system changes will be viewed in a 'safety' light. Ideally, bar code implementation will be seen as one of many steps toward the goal of improved patient safety and healthcare provider satisfaction.

Network and Database Support and Redundancies

Planning for adequate network and database system infrastructure is necessary. Medication administration and, to a large extent, pharmacy operations never cease, so it is important for the project planning team to assess a network's inherent ability to support bar coding practices during live operations. To do this, the team must enlist the help of Information System planners and support personnel.

Work groups should develop standard procedures and communication methods for each of the following scheduled "support" situations:

Scheduled Down-time or Support
These are often completed at pre-arranged times with the prior notification of all users. They should be completed during slow practice periods and, where possible, completed without interruption of the service.

- Data Backup
  System data back-ups should include both on-site and off-site back up storage.
- Operating System Upgrades
- Drive or other Equipment Replacement

Equipment Maintenance and Redundancy
Equipment requires scheduled maintenance and will occasionally malfunction. Equipment redundancy (swap out) should be discussed.

- Maintenance or Repair Situations
- Battery Problems
- Carts or Computer Shortage Situations

Unscheduled Down-Time
Though the above scheduled support issues will become part of an overall *HIS* plan, medication system recovery strategies for unscheduled service interruptions are required, including disaster response. The duration of interruptions may range from temporary to longer term.

The system recovery may take the form of a small amount of data catch-up after a short-term interruption. But, rarely, it could require a complete patient data rebuild followed by a longer period of recent data catch-up (from the point of the last back-up date).

The following three situations should each have a recovery plan:

- Temporary (Less than 3 hours), such as;
  - Once or twice daily database back-up periods
  - Unplanned network shut-down or maintenance
  - Network slowing (response times)
  - Power Surges.
- Long-term System Loss (2-24 hour)
- Catastrophic system shutdown (Greater than 24 hours)
  - Fire, system failure

To avoid catastrophic system data rebuilds, incorporate the following into your plans:

- Avoid the probability of unscheduled shutdown through routine maintenance and upgrades. Utilize "Universal Power Supplies".
- Use on-site "mirrored database drives".
- Ensure there are both on-site and off-site data back-ups for use during (on-site and off-site).

Manual Medication System Contingency

Note that ***manual*** medication verification and documentation systems may be required for system shutdown of longer than 3 hours. These may also be needed during larger facility 'disaster planning'.

Consider the retention of manual documentation systems designed for unscheduled events. Consider the use following paper-based fall-back options when required:

- Printed MARs with bar codes from PC-based patient records. These should include active medication orders, administration times, last scheduled dose, patient name, birth date and ID number. They should also be timed to note the time of printing, and allow room at the bottom for additional orders.
- Blank MARs for new patients and additional room for admitted patients
- Blank Medication order Forms
- Medication communication forms between areas
- In Pharmacy, plan how medications will be dispensed based on back-up prescription records and manual updates, and how labels might be produced.

Finally, plan for post-event data catch-up. After the initial event, the manually-collected data will need to be incorporated into the recovered *HIS*. This data entry catch-up phase needs to be foreseen.

Pharmacy and Formulary System Preparedness

Like a data network above, the importance of Pharmacy operations to support bar code verification systems cannot be understated. Pharmacy systems should be considered to be mission-critical components of the bar code system.

Pharmacy services should always be completed in an efficient manner and communicated when the expected turn-around times are not met. The potential impact of delayed (or absent) pharmacy services needs to be fully explored by the planning team. This should include discussions with the site administrator responsible, if additional workload support is required. Failure to meet these system support objectives may have a serious impact on the downstream provider (e.g., nurse) compliance and satisfaction.

The planning team should also review the standard times for services, looking from the perspectives of both internal pharmacy operations (order entry, compounding and dispensing) and the patient care areas (medication administration).

The key services to be reviewed include:

- A rationalized formulary, standardized concentrations, and dose strengths, including pre-packaged unit-doses intravenous, oral and topical dose units.
- *Group Purchasing Organization (GPO*) contracts and pharmaceutical labelling requirements.
- Purchasing and Inventory Stocking
- Drug Database Management:
    - Addition of new drug items
    - Creating identification codes and bar coding for both contracted and back-ordered medications
    - Determining therapeutically-equivalent products (interchangeable items), and cross-referencing theses with the software system
    - Standardizing product descriptions
- In-house re-packaging and labeling systems
- Prescription Order Entry and Verification Turn-around
- Stat Medication Dispensing
- New Order (dose) Dispensing
- Compounding Services (CIVA, parenteral nutrition and topical)

Issues affecting Bar Code Scanning Rates

Bar code verification relies on hundreds of individual scans daily. Many design and implementation issues affect user scan rates. Some are related to pre-implementation planning, while others fall into implementation and post-implementation actions. The reason for introducing low scanning rates at this point of the document is that there is opportunity to reduce known causes of low scanning rates during pre-implementation.

The ease and reliable of scanning affects the willingness of users to carry mobile equipment and integrate the scans into their daily work routines.[190] Reports of scanning rates range from approximately 50% to nearly 95%, and depend on how carefully a user's individual needs are met by the system. Busy nursing practices, perhaps above all others, are most affected.

Environmental factors affecting scan rates include clinical workload pressures, a high frequency of scans, ergonomics, challenged communications, and overall system and culture satisfaction. Specific causes of low rates include:

- Bar code readability problems:
  - Unreadable: missing, smudged, extreme curvature
  - Incorrect bar codes
  - Unrecognizable item
- Scanner not at beside:
  - Too few functioning
  - Battery problem
  - Ergonomic or mobility
- Poor medication system response rates

Still other scanning considerations relate to higher-level culture issues, such as communication, collaboration and education during the pre and post-implementation phases[194], all of which will be addressed below.

System Training and Implementation

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We have previously touched on pre-implementation staff safety culture education and communication methods as a foundation on which systems can be implemented. We also discussed system usability trials and their role in selecting and modifying the planned bar code system.
As bar code implementation itself approaches, a plan for more technical provider system training which is needed. This training builds on the foundation of safety, but is specific to the final operational functionality of the planned system. We noted that part of the vendor selection process included an assessment of the vendor's own system training resources; both educational material and as well their people resources.
This guide subsection provides an approach to planning detailed training.

System Training and Follow-up

System training should precede actual implementation only by a short period of time. It should include two or three levels, allowing a progressive path from the classroom to live operational training. The stages of training that may be considered are:

- **Basic Classroom work**
  It is ideal if additional staff can be scheduled for the early training steps. The additional staff allows trainees to have an uninterrupted orientation to the new system.

  Basic (Level 1) training should lead trainees progressively through multiple screens, providing a high-level system functionality overview. The sessions may include PowerPoint screen presentations, followed by hands-on table top training using medications and medication forms and simple simulated situations. Any known variations of practice, including special circumstances, should be discussed so that they are not a surprise to the trainee later.

  This basic level session should also include communication methods with pharmacies, interruption of service procedures, major down-time issues, or other known potential site issues. It may be prudent to include a reminder of incident reports for reporting any events that a practitioner feels has been caused by the newly implemented system, including how these reports will be reviewed.

  It is important that there be sufficient equipment so that each provider has ample opportunity with real equipment, software and simulated medication orders.

- **Clinical Simulation Environment Training**
  Previously we discussed clinical simulations as part of system acquisition and the RFP process. Clinical simulations can also be effective in training.

  After Level 1 system training is completed, the trainees are ready to be exposed to simulated clinical simulations (case studies) which reflect the circumstances found in their practice areas. Examples may include such circumstances as:
  - Medication "range" orders and "as required" orders
  - Medication "stat" orders
  - Emergent Care situations
  - Delayed or omitted therapy and the use of "reason codes" (if present in the software system)
  - Parenteral medication orders, including integration with pump systems.

  The chosen clinical simulations may best be conducted by the area "*super-user*", or mentor, as these will be the people who will support the trainees in the early days of implementation.

- **Live Integration and Mentoring by "Super Users"**
  The requirement for additional staffing can be reduced as the trainee progresses to the live practice environment. Remember, however, a newly-trained individual will not be fully up to usual efficiency. They will not be thoroughly knowledgeable in the new system, or its use in exceptional circumstances.

The use of "super users" during early stages of live operation process is desirable, and may require 24 x 7 scheduling of the super users temporarily. The super user of an area may later be a conduit for the communication of staff comments and suggestions.

The vendor should also provide a presence during early training, even if a super user is utilized. The vendor support may taper however to a 24 x 7 "on-call" support, or a circulating vendor contact.

To enhance the probability of long-term success, pharmacists should also receive *BCMA* cross-training[11], in addition to their training for pharmacy-based systems[107]. The ability for pharmacists to support nurses who have questions about the *BCMA* system, or be able to help troubleshoot is important to long-term success and communication.[11] Pharmacists should be able to explain why medications may or may not be present on a patient's eMAR or printed MAR, or to explain possible reasons why a bar code is not scanning properly.

In smaller care centres, it may not be possible to schedule sufficient staff to allow Level 1 classroom education during normal working hours. These centres might consider group education sessions and/or over-time shifts attended by vendor representatives.

A graded approach to system training and positive support immediately after go-live will pay down-stream dividends in staff compliance and comfort with the system. Encourage staff feedback during training, emphasize the facility's communication channels and collaboration systems, and schedule times when staff can individually and in groups provide informal feedback.

Training should reinforce the collaborative team effort to enhance local patient safety. Each trained healthcare provider hopefully understands that medication bar code verification is a progressive steps toward the larger movement of medication system safety reform, and better care for Canadian patients. Each successive system builds on the last.

Finally, don't forget to buy the doughnuts!

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After Implementation (Including Operations and Monitoring)

Staff Satisfaction and Workload

Nurse satisfaction should be tracked over time to determine at what point nurses are truly satisfied with a new medication system using bar code technology.

~ S.B. Fowler, P. Sohler, D.R. Zarillo
MedSurg Nursing 2009;1892:103-9

Beyond the technical functionality of any healthcare system another equally major consideration exists. In order that change be viewed in a positive light it must be seen to fit comfortably within a healthcare provider's practice, and not cause problems to either the patient or the caregiver's sense of safe practices.

Medication system users often share common concerns. They see a system in a more granular, practical way than many planners or administrators. Their chief concerns are

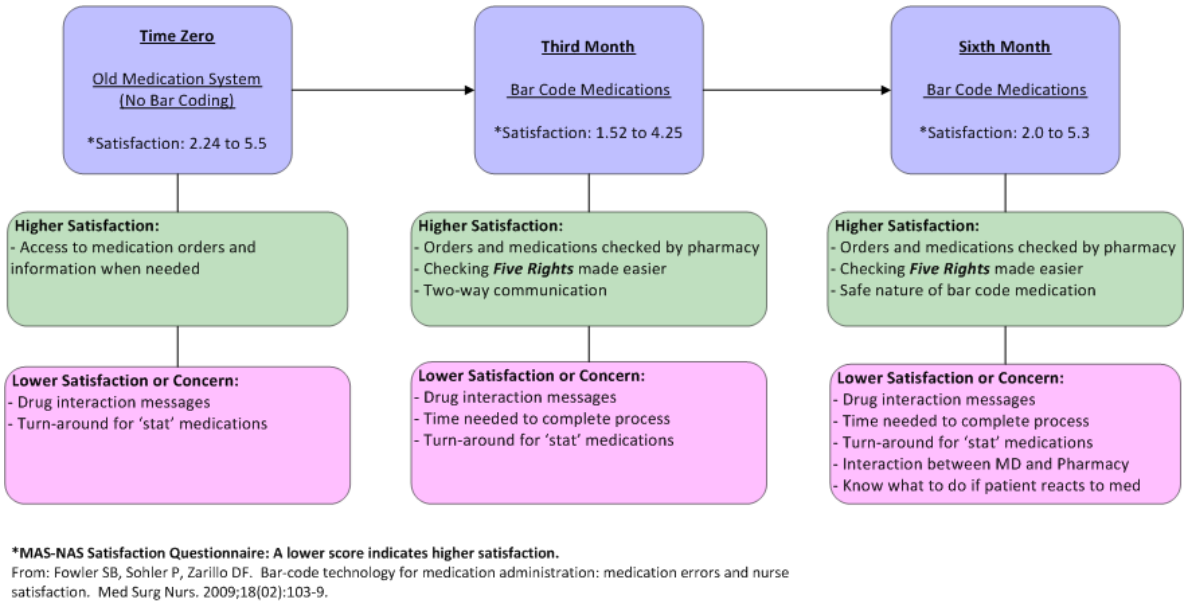
that a new system is safe for patients, easy to use, provides the necessary information at the point it is needed, and is timely yet not time-consuming.[105] Similar concerns will be found across the spectrum of disciplines who utilize bar code verification, along the medication chain.

When systems are introduced some major advantages may be initially uplifting professionally and noted in surveys[105.] At that point, respondents are able to easily compare the new system to the former recently replaced. Later, the observed differences may be taken for granted, as the users collectively move forward to focus on other more detailed aspects of the new system: ones that may require further attention.

Equally, but more concerning, major system weaknesses may follow the same subjective pathway of being initially tolerated and later taken for granted (ignored) if not improved. This change in focus should be concerning to safety engineers as the weaknesses would in theory become the new system's "latent errors", or manifest themselves as poor user compliance or work-arounds. In Figure III-6, a study utilizing structured nurse satisfaction questionnaires demonstrates how healthcare provider satisfaction and focus on a new system issues drift over time.[58] Though some feelings may remain, others come and go.

The overriding lesson from the study is that post-implementation satisfaction and system issue identification should be applied over a long period of time. Provider surveys should not be a single event, and certainly not only immediately after implementation. A longer term assessment, and re-assessment, allows the planning team to deal with a variety of issues in a prioritized manner, always communicating to the affected providers. These surveys, and related communications, signal important collaborative commitments to providers:

- Communication channels are open for business.
- Inter-disciplinary system cohesiveness and collaborations are working.
- Users are valued.
- Major safety or operational concerns will be identified before they become "latent errors".
- Subjective minor irritations, which have the potential to cloud overall user satisfaction or compliance, will be discussed.



***MAS-NAS Satisfaction Questionnaire: A lower score indicates higher satisfaction.**
From: Fowler SB, Sohler P, Zarillo DF. Bar-code technology for medication administration: medication errors and nurse satisfaction. Med Surg Nurs. 2009;18(02):103-9.

Figure III.6 Satisfaction and Issue Shifts

Staff satisfaction is not a purely objective process. Findings may be real or imagined, and may expose either implementation planning or valid medication system weaknesses. Major system attributes or weakness perceived by users may eventually be taken for granted (ignored). Surveys should be completed in a sustained manner. Findings should be carefully interpreted and most definitely discussed with the contributing user groups.

In summary, beyond initial reactions and observations, watch for the longer term subtle changes in opinions. When new issues arise on team meetings or surveys, this may indicate either a newly found clinical situation, or that users have moved their practice to a higher level of safety expectation with their attention now focused on details, but still important, issues. This shows an encouraging willingness to improve the system further.

Auditing Practices

Post-implementation quality databases monitor aspects of system user practice patterns and are important. Beyond team communications, they provide objective insight into system functionality, and user compliance and/or satisfaction. It is important that routine scheduled audits are seen to form part of the envisioned system from the outset, and are properly resourced as an important component of the system. Retrieving and analyzing critical system reports requires time and follow-up effort.

Vendor system databases, with their inherent reporting capabilities, are typically assessed during vendor *RFP* selection. The reports and report frequencies are usually established during pre-implementation planning.

Other complementary databases are also important, such as incident reporting, including near misses, as they view events from a different and important lens.

Internal System Data

Data captured by a bar code system can indicate the system's safety performance and user conformance. Over an extended period of evaluation, these data form an important source of overall system utilization that informs quality and operational managers' system activities.[123]

We trust medication errors will be prevented by a bar code system before reaching the patient. "Errors" may be in the form of a "wrong item" or "wrong patient" (i.e., *one of the five rights*), or it may be identified by a triggered alert warning. System medication "error" messages need to be viewed carefully however. The system data may not always indicate a valid error catch. Nurses or pharmacy personnel may override a warning with good reason.

Systems databases can also reveal user conformance issues with the system. Each process step can be captured into a database as they are completed, including associated data such as the date/time, hospital, area, user, etc. Data can be reported as totals for the facility, individual areas and, if desired, individual user or user-type.

If an error warning or alert is automatically triggered by the system, its resolution or non-resolution also can be captured, along with any "reason" provided by the user for their decision to proceed. Rates of alerts, or user non-conformance, also provide an important insight into the reliance or over-reliance of alerts, such as:

- The number of alerts and associated workload
- The medications causing alerts, including high-alert medications
- Alerts overridden, and reasons why.

As with technology error "catches" above, user compliance must also be analyzed carefully. An apparent trend (e.g., late or omitted doses) may appear to be user non-compliance, but, in reality, could relate to workload, or system design weaknesses, or system performance such as late system responses caused by a slow network, or delayed pharmacy order entry or dispensing. Reporting of such internal quality data should always be accompanied by team discussions before any conclusions or actions are considered.

Examples of medication system report estimates include:

- System activity (workload) by care area or user:
  - Number of doses scanned
  - Number of high-alert doses scanned
  - Number of alerts triggered
  - Percent of doses scanned
  - Percent captured preventable "errors"
  - Percent alerts per doses scanned
- User or area conformance:
  - Percent doses scanned

- Percent doses not scanned
- Acknowledged Alerts
- Overridden Alerts

Incident Reports and Errors Related to New Technology

As we have reviewed, new technology may give rise to new forms of error. Some errors may result from identifiable system or user practices that can be amended. Other errors may result from more structural issues such as the physical building or network issues which may be more difficult to modify easily.

Incident reporting related to medication errors should continue to be encouraged, including those potentially arising from new technologies. Reported errors and root cause analyses will provide insight into the entire medication system (i.e., the prescription and medication pathways) as well as any special circumstances. Such system analysis greatly complements the simple internal system quality data reporting described above.

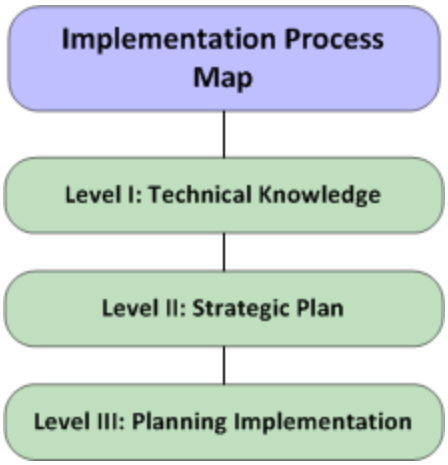
Follow-up Training

Information systems change almost constantly, sometimes involving sudden functionality leaps when new software releases are implemented. Organizations therefore must not look at initial system implementation training as a single, one-time event. Each system change is an opportunity for renewed communication and, sometimes, user re-training.

Small software or operational changes can be quickly demonstrated to users away from live patient care operations. Users can be allowed to become familiar with the change with out distraction. Larger changes may require a return to the more formal training environment, as described earlier, though perhaps not requiring as much concentrated mentoring.

Finally, group user comments and area system “rounds” are recommended. These will indicate if a refresher training session, or renewed collaboration, is required.

Implementation Process Steps



Appendices III-4.1 through *III-4.3* provide an overview for practice leaders of the stages of bar code implementation, as described in this guidance document. The process steps are largely applicable whether the organization is based in the community or institutional practice environment.

By using this resource document and following the appended process map, an organization, with its committed practice discipline leaders and staff, should be able to create a relatively simple structured approach to the successfully understanding, arguing, acquiring and implementing medication bar code verification systems.

The strategy for the use of *AIDC* (bar code verification and documentation) should touch on each step of the medication and prescription chains. If chosen well and implemented with care, the medication bar code system will provide patients added confidence in an innovative, safer healthcare system, and allow healthcare providers to work efficiently and accurately within the improved care environment.

Appendix III-1: Five Internal System Barriers

Based on:
Amalberti R, Auroy Y, Berwick D, Barach P. Five system barriers to achieving ultrasafe healthcare. Ann Intern Med. May 2005; 134(9):756-64.

Acceptance of Limitations on Maximum Performance

Maximum performance described here is related to individual decisions to push her/his clinical abilities to a maximum and, thereby, heightened risk. With higher risk potential, the probability of achieving *HRO* safety is lowered. An example of such individual risk is given; such as mountaineers, pilots of micro-light aircraft, or potentially daring physical feats. In such cases, an individual seeks to push her or his limits of performance, to achieve a pre-set goal, sometimes as a confirmation of one's individual abilities.

The situation rarely occurs in healthcare except in situations related to life-saving and emergent care. Most planned routine activities should not require an individual to display unique skills or levels of achievement (individual performances). Rather, these routine procedures should be controlled by process, and steps followed to reduce inadvertent risk and, thereby, maximizing the potential for a successful and predictable outcome.

Abandonment of Professional Autonomy

In many routine health-related procedures, it is desirable to remove the ability of healthcare providers to create individual processes (professional autonomy). While feedback and collaborative system changes are always to be encouraged, individual decisions to adopt new practices must not be.

In stating this, again, it is understood healthcare practitioners are required to exercise clinical judgment, and also that a normally routine procedure may become non-routine in an unforeseen way. In such cases, if an alternate contingency plan is not approved, it may require an individual to adopt non-standardized professional practices (autonomy) to cope with the specific situation for its duration.

Transition form the Mindset of Craftsman to That of an Equivalent Actor

Society often admires a product or performance from an individual, where the outcome displays the performer's unique talents. It may take the form of a modified procedure (e.g., creating a unique ceramic pot), the flare of the performer (e.g., a performing restaurant chef), or timing of some aspect of the performance (e.g., re-arranging a song, a painting or a scene in a play), or even streamlined aesthetics (e.g., simplified paintings or brevity of action). In such cases, the performer applies his or her interpretation to the event, and thereby feels the performance is improved.

For routine healthcare tasks, like most medication practices, each performer should be replaceable, and the technical performances should be indistinguishable from each other. The provider accepts beforehand that they will conform to approved processes and outcomes.

Need for System-Level Arbitration to Optimize Safety Strategy

One characteristic of highly accurate processes with statistically low error rates is that the responsible team accepts both external and internal scrutiny of their system. Rather than isolating their practices and system, diverse system-level scrutiny is openly encouraged.

Examples of an open process review include the use of multiple assessments from non-connected experts after a near-miss incident. This may include using both internal and external sources, using views from both biased (but knowledgeable) internal team members and unbiased (independent) assessors. These could include human factors, socio-technical or heuristic reviews using safety experts in these fields.

Amalberti (et al) point out that an unwillingness to adopt open assessment of practices may be an echo of the second internal barrier (excessive professional autonomy).

The Need to Simplify Professional Rules and Regulations

Simplification is a tricky issue, having both positive and negative implications.

It is often beneficial to simplify processes, rules and regulations where possible. Sometimes, it is possible to adopt technologies which simplify aspects for a human user, while the underlying complex system functionality is hidden within the software itself.

Unnecessary Complexity
Over time, successive quality review processes may add a patch-work appearance to any procedure. When this occurs, it appears as an excessively detailed process, and can lead to care provider confusion and, potentially, errors or work-arounds.

Necessary Complexity
Conversely, complex procedures should be reviewed, but should never be over-simplified. Over-simplification of a process that requires complexity may remove necessary steps and compromise safety or the desired outcome.

It is a principle of *HROs* that the ***review*** of safety incidents (errors) and causes should not be simplified. In other words, evaluation of contributory system processes should not lean toward simplistic analysis. After the review, the process should be re-constructed systematically as simply as safely possible.

Appendix III-2: Summarized Bar Code System Failure Modes

a) This table assumes a functional bar code verification system has been implemented.
b) This table does not include higher level internal factors such as staff availability, education and skill training, collaboration, workload or other environmental causes of errors.
c) The term "CPOE" refers to a human error made during computer prescription order entry while creating the patient's electronic or paper medication administration record (eMAR or MAR). It also includes omission of prescriptions from the patient eMAR

Automated Identification Failure Mode	Contributing Factors [a, b, c]	Pharmacy Operations	Stock Transfer or Repackaging	Medication Administration
Human Errors in Pharmacy Operation				
Attach a dose label to wrong medication product	▪ Look-alike, sound-alike (LASA) drug names or packages ▪ Repackaging bulk to unit dose process ▪ Central IV admixture (CIVA) process ▪ Medication formulary and concentrations not rationalized ▪ Incorrect Computer Prescription Order Entry (CPOE)	√	√	
Attach a dose label to wrong strength of medication	▪ LASA ▪ Repackaging bulk to unit dose process ▪ CIVA process ▪ Medication formulary and concentrations not rationalized ▪ Incorrect CPOE	√	√	

Automated Identification Failure Mode	Contributing Factors [a, b, c]	Pharmacy Operations	Stock Transfer or Repackaging	Medication Administration
Attach a dose label to wrong patient's dose package	▪ LASA ▪ Incorrect CPOE ▪ CIVA process	√		
Pharmacy Stock Transfer or Replacement	▪ LASA	√	√	
Alert-Mediated Failures				
Alert fatigue	▪ Too many alerts ▪ Irrelevant alerts for clinical area	√	√	√
Failure to notice alert	▪ Irrelevant alerts for clinical area ▪ Environment lighting ▪ Crowded device screens ▪ Device or screen too far away from activity ▪ Disabled audio	√	√	√
Ignore or overrides alert	▪ Too many alerts ▪ Irrelevant alerts ▪ User compliance	√	√	√
Disabled audio alarm, or low-light on screen employed	▪ Concern for sleeping patient (patient care) ▪ Irritating alarm ▪ Too numerous alarm ▪ User compliance	√	√	√

Compliance and Work Around Failures				
Automated Identification Failure Mode	**Contributing Factors [a, b, c]**	**Pharmacy Operations**	**Stock Transfer or Repackaging**	**Medication Administration**
Failure to Scan: Patient ID bar code	▪ User Compliance: ○ Does not scan ○ Scans bar code from unapproved source (i.e., printed alternate document) ○ Places wrist band on non-patient surface. ○ Scanner ergonomic issues ▪ No bar code on patient or a temporary ID given (e.g., Emergency Departments) ▪ Multiple Patient IDs exist ▪ ▪ Compromised bar code: won't scan ▪ Patient wrist curvature ▪ Patient or nurse removed wrist band and placed elsewhere ▪ Patient sleeping ▪ Scanner not easily available ▪ Poorly placed critical equipment components, or carts.			√
Failure to Scan: Medication bar code	▪ User Compliance: ○ Does not scan ○ Scans bar code from unapproved source (e.g., MAR, old package, list) ○ Scanner ergonomic issues ▪ Lack of bar code on package label ▪ Compromised bar code: won't scan ▪ Incompatible bar code symbology	√	√	√

	▪ Multiple package bar codes ▪ Scanner not easily available Poorly placed critical equipment components, or carts.			
Failure to visually check medication package text and package contents against the MAR or eMAR entry	▪ User compliance ▪ Poorly placed critical equipment components, or carts	√	√	√
Failure to notice screen icon which indicates additional medication administration information or reminders	▪ User compliance ▪ Ineffective scanner or computer screen resolution or light reflections ▪ Computer screen, if used, not in position to easily read. Poorly placed equipment or carts ▪ Small icon size	√		√
Failure to pursue a second human independent double-check when indicated on scanner screen	▪ User compliance ▪ Computer screen not in position to easily read. Poorly placed equipment or carts. ▪ No audio reminder for high alert	√		√
eMAR/MAR prescription errors or omissions	▪ CPOE error ▪ No order on eMAR/MAR) ○ CPOE Rx omission ○ Delayed CPOE ○ Stat or verbal order: (no eMAR order) ○ Prescription discontinued (auto-stops)	√		√
Failure to check physician records for new medication orders, not yet entered and/or verified through CPOE (pharmacy)	▪ User compliance ▪ Stat or verbal order: (no eMAR order)			√

Automated Identification Failure Mode	Contributing Factors [a, b, c]	Pharmacy Operations	Stock Transfer or Repackaging	Medication Administration
Early scanning of medication doses (or patient), followed by medication transport and intended action. Examples: ▪ Medications and/or patient scanned before medication is given and ingested ▪ Stock top-up processes (e.g., Automated Drug Cabinets (ADC)) ▪ Dispensing doses ▪ Ingredient checks during compounding	▪ User compliance, such as ward medication room scanning with eMAR/MAR and copies of patient IDs ▪ Cart/screen for charting will not fit into patient room. Scanning done in hallway or med room	√	√	√
Medication removed from package and package scanned later.	▪ User compliance	√	√	√
Medications scanned for more than one patient, then transported	▪ User compliance ▪ Medication or hallway scans performed due to lack of room space			√
Failure to split dose in package to correct dose (tablet, solution, vial portion)	▪ Dispensed non-exact dose in package ▪ Bulk ward stock or ADC stock ▪ Medication or hallway prior scans performed due to lack of room space.	√		√

Automated Identification Failure Mode	Contributing Factors [a, b, c]	Pharmacy Operations	Stock Transfer or Repackaging	Medication Administration
Early or late dose times	▪ User compliance ▪ Medication or hallway prior scans performed due to lack of room space.			√
Double dose or omitted dose	▪ User compliance: No scans performed ▪ CPOE errors/omissions ▪ Dispensing error delays process			√
Wrong Medication Error	▪ Poor system and/or user-interface design ▪ CPOE (Prescription entry) error ▪ Dispensing error: e.g., right label, wrong medication (See Pharmacy Human Errors above) ▪ Scanned medication bar code from printed document instead of actual dose package ▪ Time delay between dose scan and dose administration ▪ Missed system error alert (see alert section)			√
Wrong Dose Administered Error	▪ Poor system and/or user-interface design ▪ Dispensing error: - Right label, wrong strength - Right label, wrong concentration ▪ Range orders confusion ▪ Missed system error alert (see alert section) ▪ Not every package for a multiple package dose is scanned (e.g. prednisone doses). (i.e., Pharmacy does not dispense full dose in a single package) ▪ User scans the same package multiple times			√

Automated Identification Failure Mode	Contributing Factors [a, b, c]	Pharmacy Operations	Stock Transfer or Repackaging	Medication Administration
Wrong patient	▪ See user failure to scan section ▪ Patient bar code from printed document scanned ▪ Missed Alert ▪ User scans prematurely before actual; dose time, then enters wrong room with medications.			√
Unordered medication	▪ User compliance. Not using bar code scan system. ▪ Verbal order error			
Secondary System Failures				
Physician fails to review the eMAR before prescribing.	▪ User compliance ▪ Lack of Access to eMAR ▪ Lack of system training			√
Nurse fails to interact with patients in the same manner as before the technology.	▪ User compliance ▪ Lack of system/safety culture education			√
Nurse reduces vigilance regarding visualizing dose and/or medication package and text labels as a secondary system check.	▪ User compliance ▪ User compliance ▪ Lack of system/safety culture education			√
Communication between prescriber and nurse regarding patient medication needs, or responses, may erode.	▪ User compliance ▪ Lack of system/safety culture education			√

Appendix III-3: Summarized Methods of Reducing System Risks

a) *This table has been compiled using a variety of practice and literature information sources. Four references are cited.*
b) *Many recommendations are applicable to bar code applications used in either pharmacy and medication dose administration, or others, while others may be applicable in one application area only.*
c) *This table does not include issues related to the following issues. See document Section III for review of these foundational issues:*
   i. *External or internal barriers to implementation*
   ii. *Request-for-proposal (RFP) processes or usability testing*

Before implementation: Physical, Equipment and Bar Code Scanner Readiness
Risk Reduction Strategy [a, b, c]
Ensure a multidisciplinary bar code planning team is formed; involving pharmacy, and nurse, physician, leaders. Include Information Technology support, and a biomedical engineering consultant.
Ensure bar code team has strong representation on larger facility *Information Technology* team.
Ensure effective education modules are provided to users in the following cultural themes: team collaboration, patient safety and organizational care objectives. Create an environment of team excitement, commitment, and joint successes.
Ensure users are committed to the necessity of bar code verification as a key component of medication patient safety.

Risk Reduction Strategy [a, b, c]
Assess the physical environment in which bar coding will be used. Consider physical aspects of building, computer and network infrastructure.
Ensure network and Wi-Fi responsiveness of bar code scanners and computer and Wi-Fi system. Repeatedly test response rates under realistic situations of high or maximum system demands.
Ensure Wi-Fi coverage extends throughout the all patient care and movement areas.
Ensure component equipment such as carts, computers and mobile scanners are thoroughly investigated and function well in combination. Ensure particularly that mobile scanners are acceptable ergonomically to user group.
Ensure sufficient scanner, computer and cart equipment is available to provide ready access by users, including physicians during prescribing. Ensure sufficient additional equipment to allow units to be replaced when units are being repaired, or undergoing scheduled maintenance.
Test bar code scanner's ability to read bar codes, its ergonomics such as weight, mobility and ability to be tethered to user, for hands free-care. Also ensure battery life of scanner along with the scanner re-charging plan.
Review the battery/charging plan for all mobile equipment. Do not underestimate the importance of a robust a battery/re-charging strategy.
Review the software to ensure the minimum number of screens necessary to complete task. And, ensure screens contain only information that is important; with secondary (or supportive) information available on other screens accessible easily.

Risk Reduction Strategy [a, b, c]
Ensure auditory and visible screens alerts are easily heard and instantly accessible, and easily interpreted by user.
Rationalize bar code systems on auxiliary systems such as bar code-enabled smart pumps, ADCs, robotics, etc. Ensure linkages of all medication-related bar code systems to necessary safety and documentation aspects of the patient's electronic health record in HIS.
Ensure auditory and visible screens alerts are easily heard and instantly accessible, and easily interpreted by user.

Before implementation : Bar Code Formats and Related Bar Code Issues
Risk Reduction Strategy [a, b, c]
Ensure standardized bar code formats are used on packaging for the following groups of doses: ▪ Commercial bulk (multi-dose) containers (e.g., bottles of tablets, powders, bulk topical) ▪ Commercial unit-dosed ▪ Inpatient bulk (multi-dose) containers (Non-patient-specific) (e.g., bottles of tablets, powders, bulk topical) ▪ Inpatient unit dose (Non-patient-specific) ▪ Patient –specific oral non-unit dose ▪ Patient-specific unit-dose: oral and topical ▪ Patient-specific unit-dose: CIVA ▪ Patient-specific infusion containers
Utilize 2D GS1 DataMatrix bar codes where possible on patient and medication bar codes.
Ensure system scanners can read all chosen dose and package bar codes chosen for the site. Ensure testing includes readers for auxiliary systems such as bar code enabled smart pumps, PN or IV compounders, ADCs, and repackaging robotics.
Ensure selected vendor's product is thoroughly vetted, including clinical simulation. Consider revising software functionality (or system configuration settings) in areas with truly specialized medication system needs.

Risk Reduction Strategy [a, b, c]
Review possible hidden sources of bar codes, where a non-compliant user may scan either a patient or medication bar code, instead of the actual patient or medication dose package. If a bar code is printed on forms, attempt to make it unusable for direct patient, ingredient, or dose verification processes to avoid user workarounds. E.g., Printed MARs, Drug or Patient lists, etc.
Review placement of bar codes on dose and package containers, to avoid hidden codes.
Review and eliminate where possible multiple bar codes on doses, medication packages, lists or MARs.

Before implementation : Safety Alerts and Reminder Planning
Risk Reduction Strategy [a, b, c]
Use a clinical multi-disciplinary team approach to determining important alerts and reminders, being sensitive to user "alert fatigue". Consider "site-wide" and "program-specific alerts" separately to reduce the overall impact of alert fatigue. Focus on high alert medications. Discuss and test various alert audio alarms. Discuss any allowed user alarm override options and policies, and, if allowed, user limits. Include discussions related to resting or sleeping patients.
Review facility policy on patient wristbands, focusing on specialized situation such as; new patients, neonates or small children, psychiatric patients and the elderly. Examine procedures in Emergency Departments, especially when unidentified patient is admitted or a temporary patient ID is assigned. Does the system cross-reference a temporary patient ID to the permanent patient ID? Prohibit user copying of patient wristbands for medication rooms, or other unapproved locations.

Before implementation: Pharmacy Preparedness Strategies
Risk Reduction Strategy [a, b, c]
Ensure bar code label printers and actual printed labels are regularly assessed for bar code, bar code location, and text clarity. Test bar code readability of both in-house and commercial bar codes on a scheduled basis as part of ongoing quality control.
Institute a system that allows users to report to Pharmacy (or other assigned department) any scanning problems for rapid resolution.
Develop a system for repackaging bulk products into bar coded unit-dose packages. Discuss both robotic and extemporaneous repackaging methods and labels. Ensure there is a system to reduce potential of human error when doing bulk or extemporaneous repackaging and labelling.
Discuss adequate pharmacy resources for the following services to avoid downstream delays of medication administration: ▪ Computer Prescription Order Entry ▪ Patient-specific dispensing: oral ▪ Patient-specific: compounding and dispensing: CIVA ▪ Repackaging unit dosed packages ▪ Other
Ensure patient doses are dispensed in exact doses. Review the bulk unit dose tablets available on Wardstock or in ADCs.
Review areas of remaining human error within pharmacy operations, such as placing a package or dose label on the wrong product or dose. Utilize RCA and FMEA processes to identify pharmacy subsystems at risk, and specific risk-reduction strategies.

Before implementation: Other
Risk Reduction Strategy [a, b, c]
Review bar code two-way communication and user-feedback strategies, such as for: ▪ Delayed or missing patient doses on eMAR/MAR ▪ Non-scanning bar codes ▪ Verbal or stat orders ▪ Modified prescriptions
Select area "super-users" and allow them to become familiar with the project plans, including communication, planned safety education and system training, and other team feedback activities.
Review Formulary, standard medication packages and concentrations, and reduce storage of items to the extent possible in patient areas. Develop standard recipes and inventory coding (including bar coding) for standardized products.

Implementation: Education and Operational Strategies
Risk Reduction Strategy [a, b, c]
Avoid necessity of user double-documentation situations (documentation in two separate systems) wherever possible. Employ paper-based documentation only in cases of short-term cross-over conversion periods (1-2 weeks), or during periods of required redundancy.
Ensure system training of staff by super –users, as appropriate. Include clinical scenarios in training modules that are applicable to user practice area(s). Ensure "super-users" are identified to trainees, and include training related to communication for issue follow-up.
Cross-train pharmacists from each patient care area, include one or more key physician leaders also.
Prominently display support contact information to resolve issues.
Ensure a method of communicating system functionality updates, which may include aspects of re-training for large changes.
Ensure users feel free to collaborate and input into the functionality of the system, and representatives are part of the initial (pre-implementation) system testing, modification and guide implementation plans.
Communicate known system issues to staff. Attempt to develop a "community of knowledge" between user areas.

After Implementation: System Operational Strategies and Avoiding Common Workarounds
Risk Reduction Strategy [a, b, c]
Limit number of patients without wrist bands.
Replace wristbands as needed, on a scheduled basis in long term care situations to assure their presence and readability.
Allow RNs method to enter secondary code and patient ID if primary bar code is missing, but ensure two patient identifiers are used.
Scan the patient wristband prior to each medication dose administration. If patient is not acknowledged correctly by the automated system, resolve patient by using approved alternative methods. Report verification problem.
Provide method of using medication product number entry for non-scannable dose bar codes.
Ensure documentation of all medications administration immediately by all users whether or not the automated bar code verification system is utilized. (RNs, Respiratory, etc)
Cross-verify any displayed bar code-generated allergy information with a second reliable source (e.g., allergy bracelets) before administering medications.
Develop and maintain a process for notifying nurses of any “stat” or “urgent new” orders. Electronic Bar code systems may not have the capability of notifying RNs of urgent doses which may have been entered without their prior notice.
Each patient care area should print and reconcile “missed medication” reports at least daily, but preferably specific times daily. This lessons the potential for omitted doses.

After Implementation: Quality Monitoring and Support
Risk Reduction Strategy [a, b, c]
Schedule planned maintenance and back-up system down-time. Avoid busy clinical workload times, and minimize disruptions to workflow.
Replace malfunctioning equipment during its servicing or repair. Do not leave the area short of normal equipment levels.
Risk Reduction Strategy [a, b, c]
Establish a bar code equipment support and cleaning program. Consult infection control, particularly with mobile equipment and isolated patients.
Audit "Alert Warning" overrides; by area and individual. Meet to discuss. Create trend graphs.
Audit non-scanned patients and doses; by area and individual. Meet to discuss. Create trend graphs.
Discuss all non-compliance reasons with individual staff members and conduct periodic scheduled focus groups. Modify processes or software, as necessary.
Conduct Executive Bar Code rounds.

Appendix III-4.1: Level I Implementation Map (Technical Knowledge)

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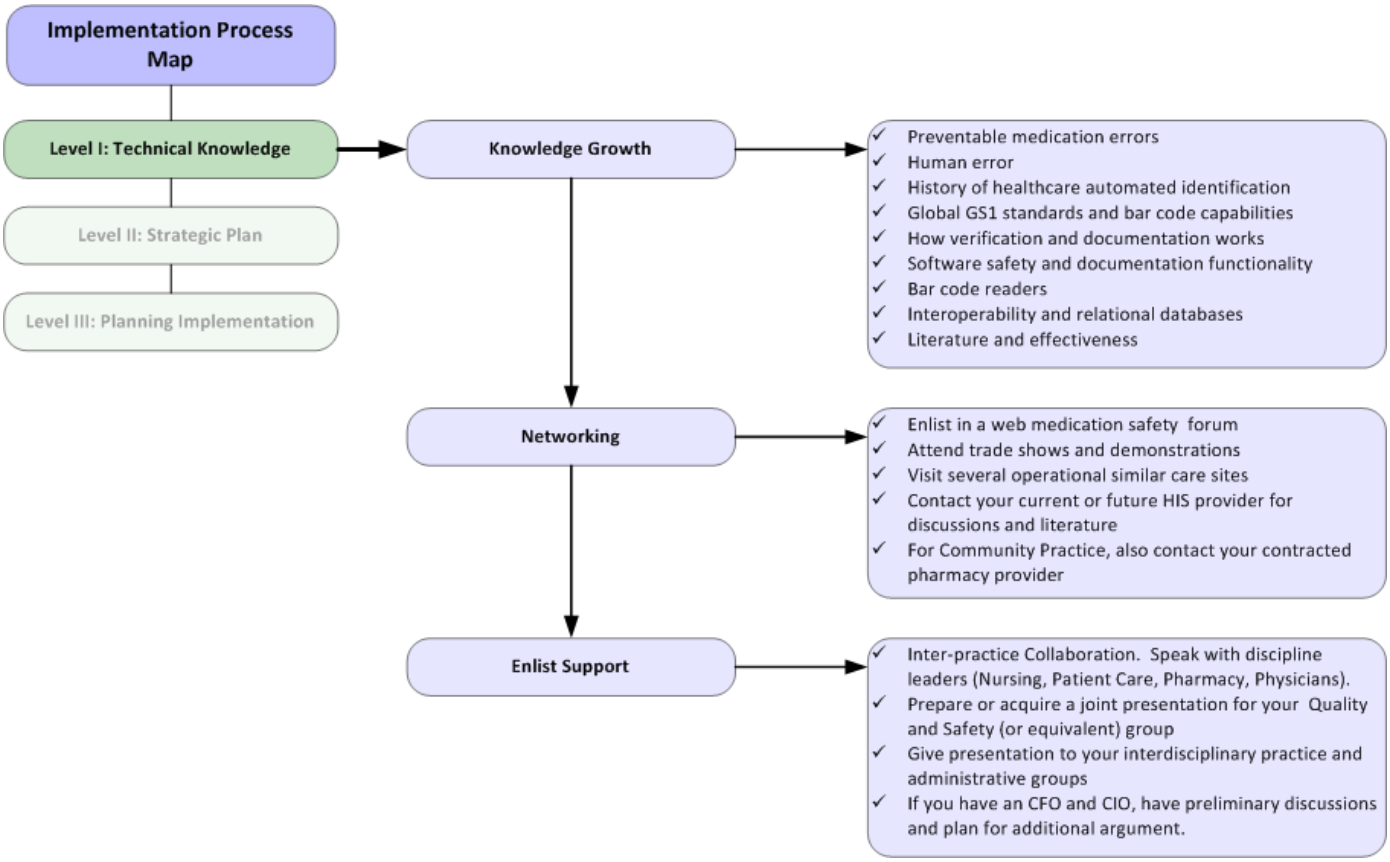

Appendix III-4.2: Level II Implementation Map (Strategic Plan)

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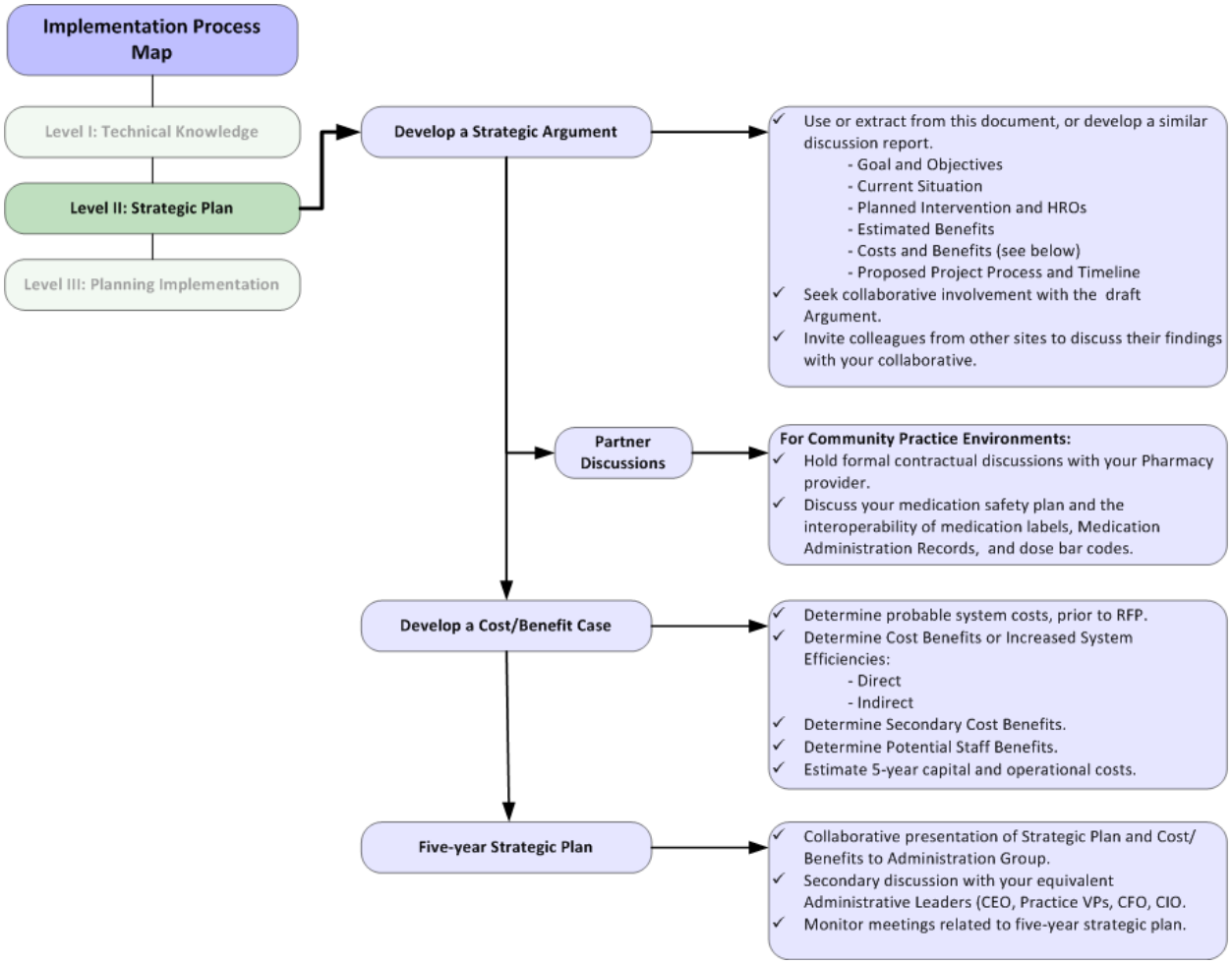

Appendix III-4.3: Level III Implementation Map (Planning Implementation)

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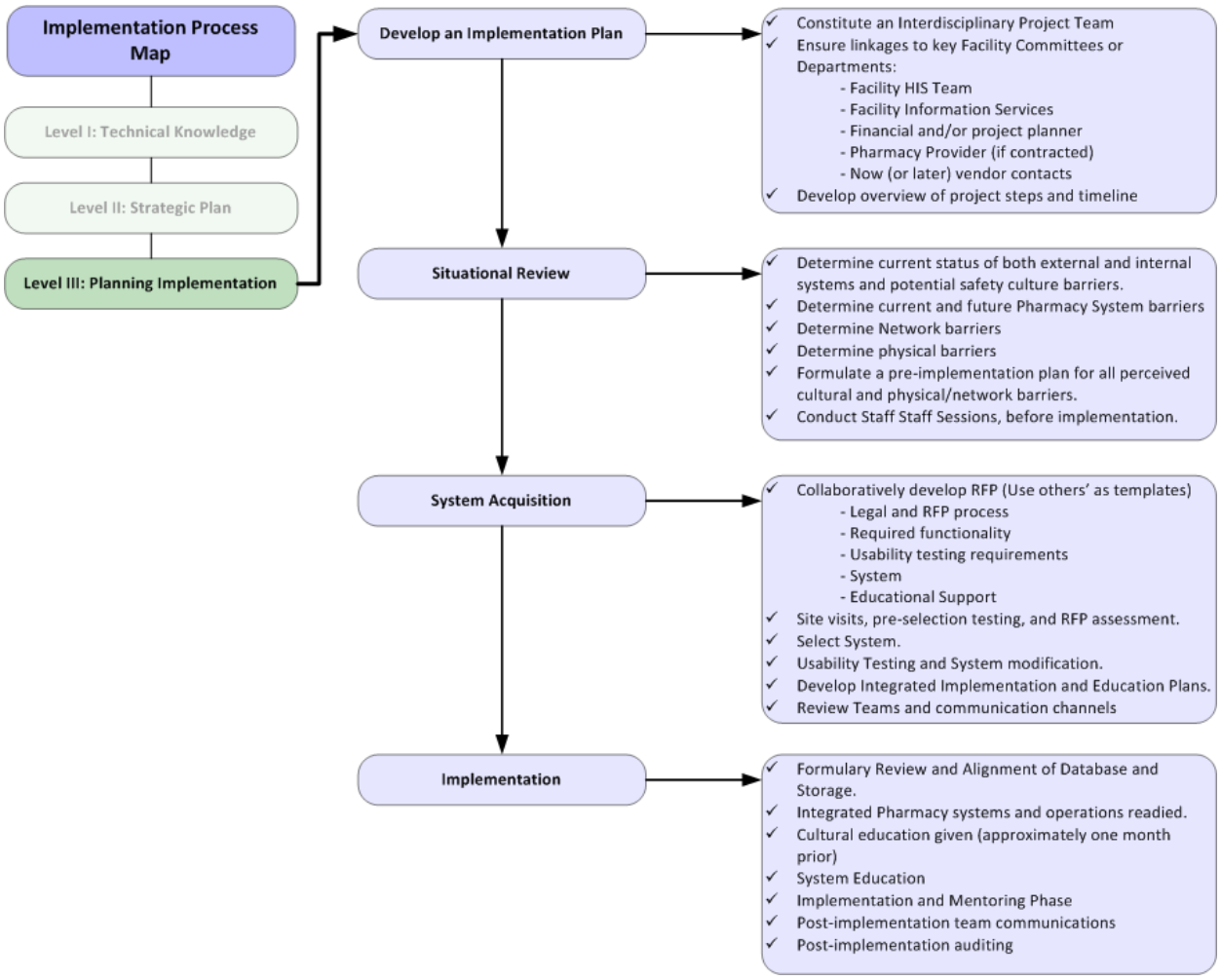

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