



Canadian Pharmaceutical Bar Coding Project

Medication Bar Code System Implementation Planning

Document Précis

August 2013 (Final)



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 (*symbolologies*).
- 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.



Medication Bar Code System Implementation Planning: Précis

- 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 *HROs***

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 may 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**



Medication Bar Code System Implementation Planning: Précis

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 elements* 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 be 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.