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Canadian Patient Safety Institute
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Canadian Pharmaceutical Bar Coding Project

Medication Bar Code System Implementation Planning

Section III: Implementation Considerations

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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.

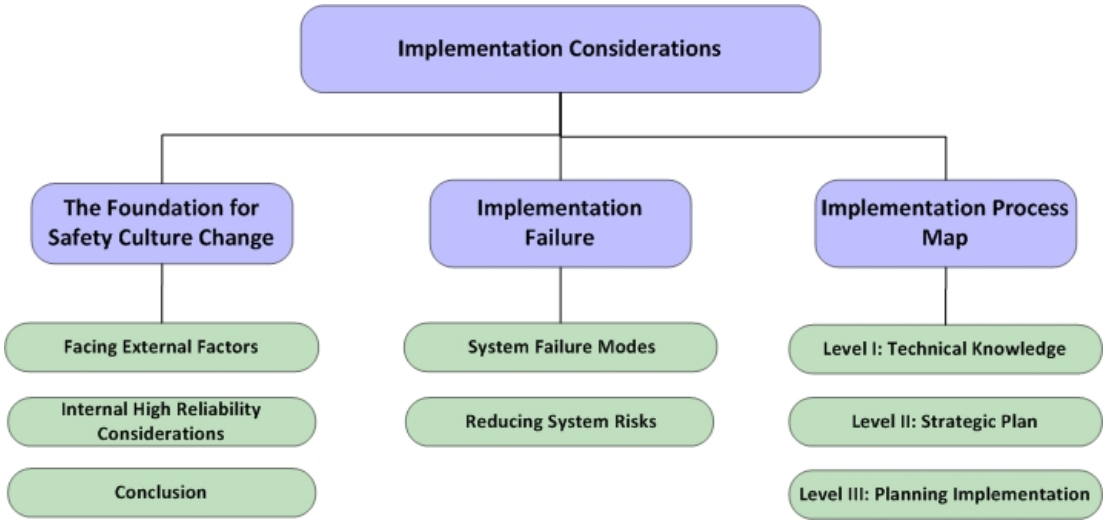

Figure III-1: Section III Flow

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.

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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".

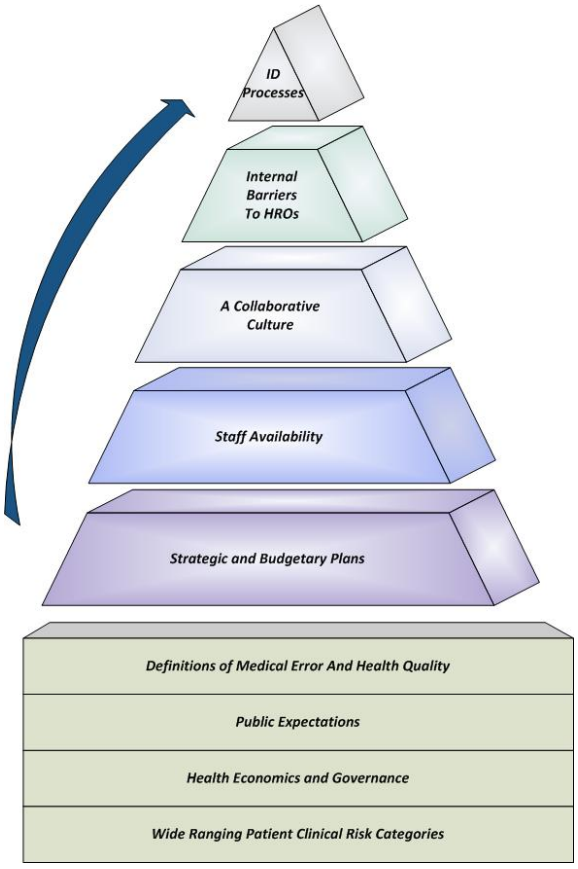
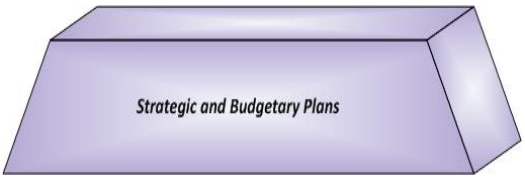


Figure III-3: Internal Pre-conditions for Change

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.

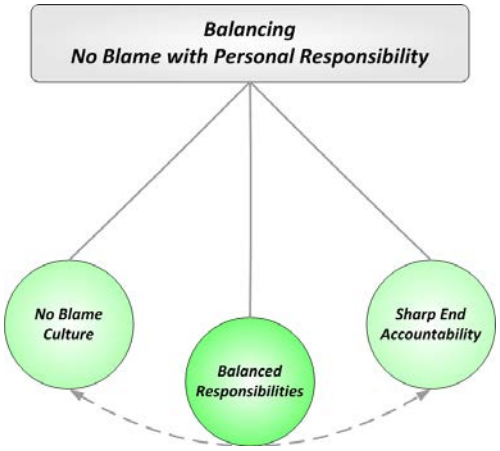


Figure III-4: Balancing Accountability with No Blame

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:

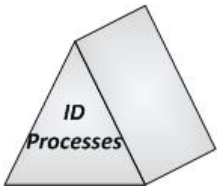
The strategy of conformity does not fit all clinical situations. One patient's clinical and social condition and co-morbidities will not match exactly with the next patient's. Therefore, it is difficult to achieve absolute conformity in all aspects of complex and ever-varying healthcare.

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.

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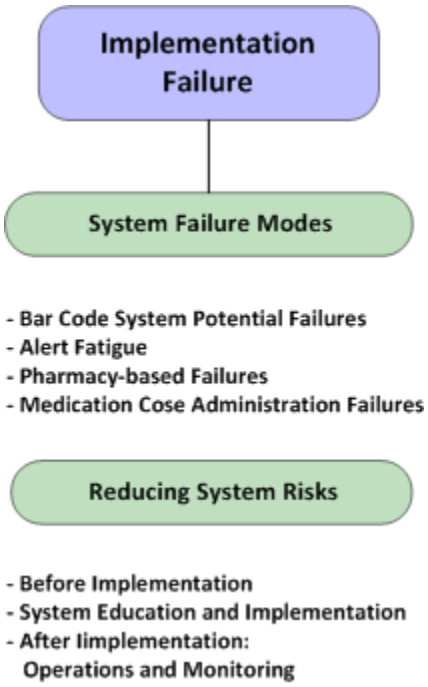
Implementation Failure



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.

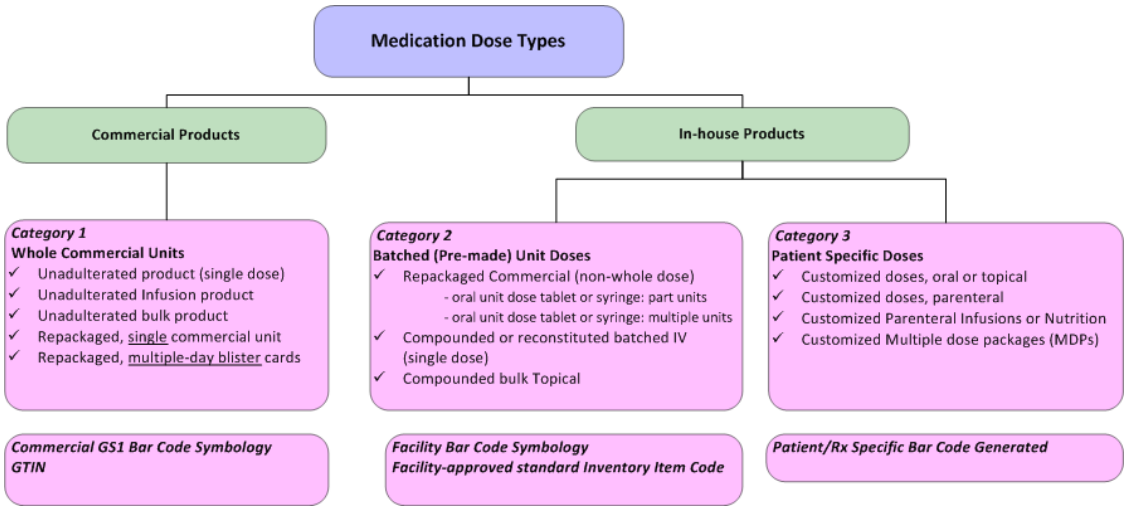

Figure III-5 Dose Types and Bar Code Categories

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

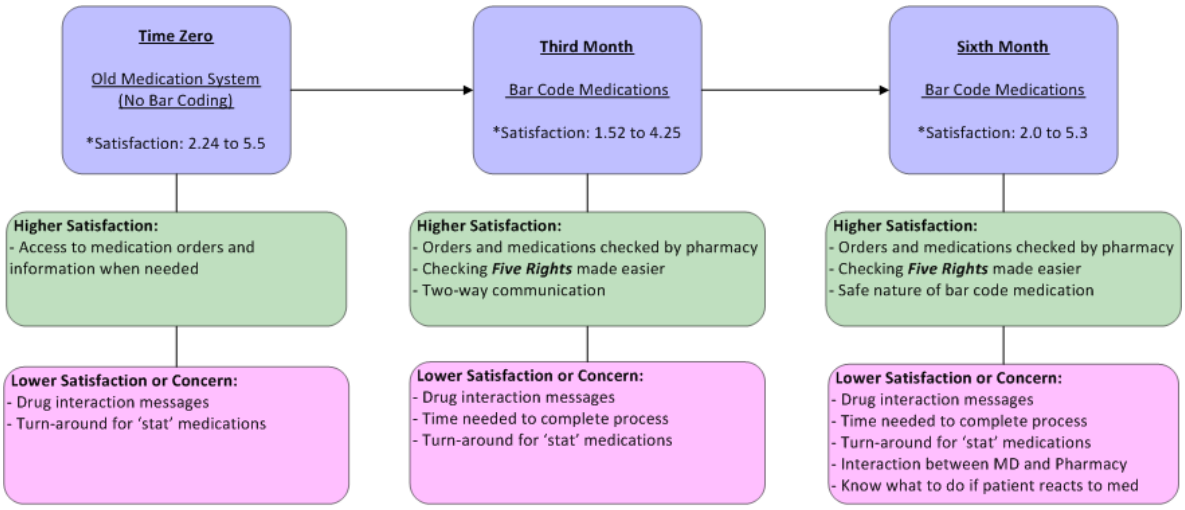
that a new system is safe for patients, easy to use, provides the necessary information at the point it is needed, and is timely yet not time-consuming.[105] Similar concerns will be found across the spectrum of disciplines who utilize bar code verification, along the medication chain.

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.

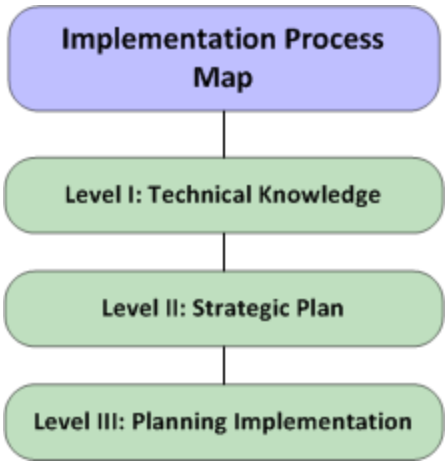
Follow-up Training

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

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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: o Does not scan o Scans bar code from unapproved source (i.e., printed alternate document) o Places wrist band on non-patient surface. o 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: o Does not scan o Scans bar code from unapproved source (e.g., MAR, old package, list) o 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) o CPOE Rx omission o Delayed CPOE o Stat or verbal order: (no eMAR order) o 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

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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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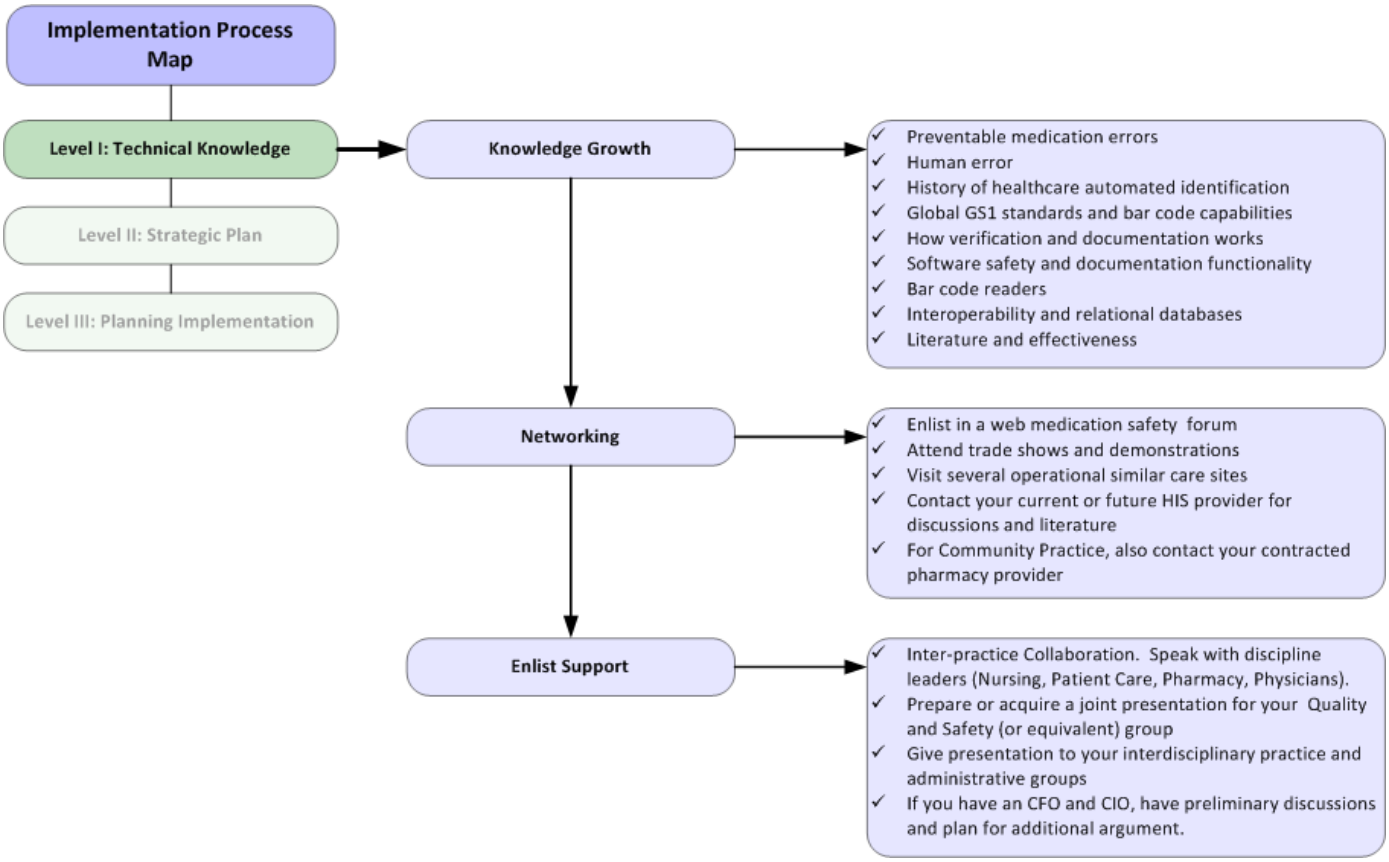

Appendix III-4.2: Level II Implementation Map (Strategic Plan)

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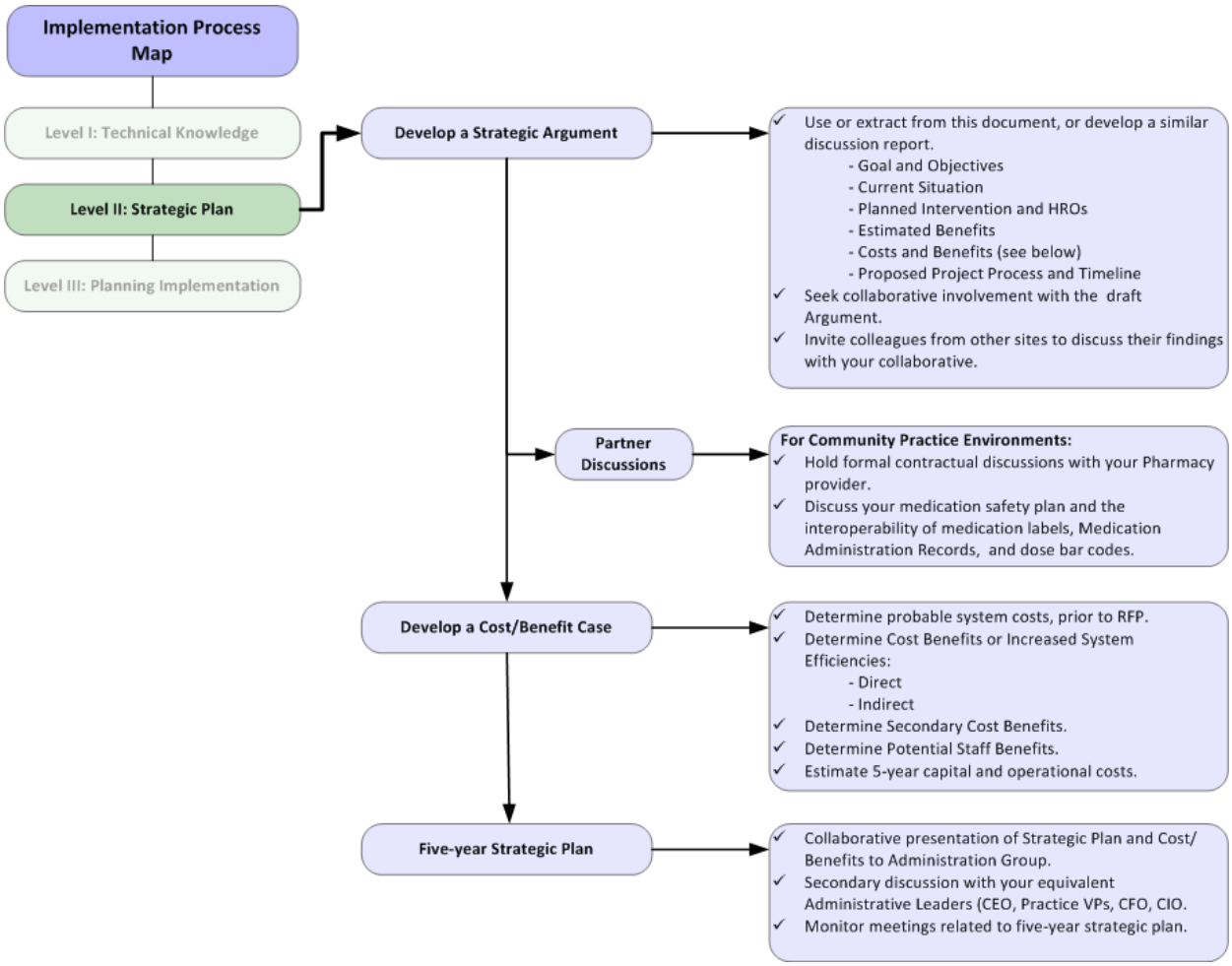

Appendix III-4.3: Level III Implementation Map (Planning Implementation)

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