Strategies for
LEADERSHIP

Pathways for Medication Safety℠

Assessing Bedside Bar-Coding Readiness

A Partnership:

American Hospital Association

Health Research and Educational Trust

Institute for Safe Medication Practices

Pathways for Medication Safety: Assessing Bedside Bar-Coding Readiness

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Section 3 —

Executive Summary

Summary

This tool will help hospitals better understand what is required to apply this emerging technology in health care and how to best implement a bedside bar-coded drug administration system. The materials will help organizations understand the issues related to bar coding in health care, assess their readiness, and take the initial steps toward an effective implementation. Please keep in mind that this particular tool does not include specific tasks for the actual implementation of a bedside bar-coded drug administration system.

Like the other ***Pathways for Medication Safety*** tools, ***Assessing Bedside Bar-Coding Readiness*** is designed in a modular format, making it easier for health care professionals and organizations to locate and use the materials most relevant to their goals and circumstances.

Goals

- Increase awareness about current issues associated with bedside bar-coded drug administration systems.
- Explore the readiness of health care organizations for implementation of a bedside bar-coded drug administration system.
- Facilitate an efficient transition into a bedside bar-coded drug administration system in organizations that have made the implementation of this technology a short-term or long-term goal.

Context

This is one of three related tools designed to help hospitals reach the broader objective of creating nonpunitive, system-based approaches to reduce adverse events and errors. The other ***Pathways*** tools are:

- ***Leading a Strategic Planning Effort.*** This tool is designed to help hospital leadership and their staff implement an effective medication safety strategic plan at their hospital. The tools include a model strategic plan, comparative data, culture surveys, budget templates, timelines, staff questionnaires, policy guidelines and many other materials.
- ***Looking Collectively at Risk.*** This tool is designed to help hospital personnel identify potential medication safety risks. Administrators/managers, physicians, nurses, pharmacists, and risk managers can use the materials in this tool to pinpoint specific areas of weakness in their medication delivery systems. This initial process can provide the foundation for a multidisciplinary effort to design and implement system improvements.

Contents

Section 3.1 provides a brief background on bar-coding technology. It opens with a short explanation of bar coding within the larger context of technology in health care. The focus then moves more specifically to exploring the benefits and challenges of implementing

bar-coding technology for drug administration in health care. A list of supplemental reading also is included.

Section 3.2 presents a self-assessment tool for evaluating a health care organization's readiness for implementing a bedside bar-coded drug administration system. The self-assessment tool helps organizations evaluate specific elements that are most closely associated with successful implementation of a bedside bar-coded drug administration system. The size and complexity of each organization will vary and should be considered when discussing the prerequisites to successful implementation.

The tool is accompanied by several attachments that serve as examples of elements described in the self assessment:

- A template for a technology vendor request for proposal (RFP).
- A worksheet to estimate the cost savings associated with implementing technology.
- Examples of cause and effect diagrams and a Failure Mode and Effects Analysis (FMEA) for a bedside bar-coded drug administration system that demonstrates anticipated failure points and their causes.

Process

1. Establish a multidisciplinary team with broad representation. This tool includes specific recommendations about the composition of the team, but each hospital needs to carefully consider what constituencies should be represented at their organization. Consider areas that will be using the system, such as interventional radiology and nuclear medicine, and determine the appropriate level of their involvement. Information technology professionals need to be included in the early stages of assessment.
2. Disseminate **Section 3.1** to team members and also to others who will influence or eventually implement a bedside bar-coded drug administration system. Where appropriate, disseminate the list of supplemental readings for staff to seek out additional information.
3. Assess the status of the organization using the elements provided in **Section 3.2.**
4. Identify organizational strengths and weaknesses related to the organization's readiness for implementing a bedside bar-coded drug administration system.
5. Develop an action plan to improve the organization's readiness level. Review the attachments to determine their usefulness as a template or learning tool.
6. Execute the action plan and evaluate progress.

Outcomes

At the conclusion of a review of the materials the reader should be able to do the following:

- Understand the issues related to bar-coding technology and how it's used in health care.
- Gauge the scope of implementing a bedside bar-coded drug administration system—the technical requirements, resources, and costs.
- Evaluation of organizational readiness for future implementation of a bar-coded drug administration system.
- Contribute to the development of an action plan to best prepare for future implementation of a bar-coded drug administration system.
- Identify process and outcome measures to evaluate the effectiveness of implementing a bar-coded drug administration system.

Pathways for Medication Safety℠

Strategies for
LEADERSHIP

Assessing Bedside Bar-Coding Readiness

Section 3.1 —

Putting Bar Coding into Context

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Section 3.1

Putting Bar Coding into Context

With heightened concern about medical errors, many organizations are looking to information technology (IT) as a means to enhance patient safety, with specific emphasis on medication-use safety. Such technology may also help an organization meet accreditation requirements related to patient safety (see ***Figure 1****). **Figure 1** shows how various forms of technology might be used to help address the medication safety component of The Joint Commission on Accreditation of Healthcare Organization's (JCAHO) patient safety requirements.*

"Bar-code scanning is to medication safety what wearing seatbelts is to automobile safety. It is not the only thing, but it is a salient thing."[1]

— Mark Neuenschwander, Editor, CQInfo

Figure 1. The medication safety section of The Joint Commission on Accreditation of Healthcare Organization's (JCAHO) patient safety standards. Source: ©2002 Bridge Medical Group, amended and used by permission.

JCAHO has also adopted as one of several patient safety goals for 2003, "improvement in the accuracy of patient identification." One of JCAHO's recommendations for achieving this goal is for providers to "use at least two patient identifiers (neither to be the patient's room number) whenever taking blood samples or administering medications or blood products. Acceptable identifiers may be the patient's name, an assigned identification number, telephone number, or other patient-specific identifier."

JCAHO has subsequently determined that bar coding including two or more patient-specific identifiers will comply with this recommendation and thus provides organizations with one option for meeting this requirement.

"Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with an institutionally developed patient safety strategy."

– Carl W. Armstrong, M.D.
Senior Medical Advisor
Virginia Hospital and Healthcare Association and American Hospital Association

Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with an institutionally developed patient safety strategy. Technology offers a wide range of systems to be used in conjunction with other aspects of a safety program. To name a few, such systems include computerized prescriber order entry (CPOE), pharmacy information systems, electronic medical records (EMR), and bar-code–enabled point-of-care (BPOC) technology.

A comprehensive discussion of all forms of technology currently available in health care is beyond the scope of this document. Ideally, a hospital would integrate multiple technologies for other clinical systems to achieve maximum safety benefit for the patient and efficiency for the organization. This might include CPOE, a pharmacy system to aid in dispensing, a laboratory system to monitor patient status, and technology-supported medication administration process. Practically speaking, most hospitals will have to adopt an incremental approach to technological improvements.

As technologies are added incrementally, it is important that the organization follow a carefully planned, long-range strategy. Organizations should consider the logical sequence for adding various technologies. It must also anticipate whether to follow a "best of breed" approach (which requires interface solutions to enable disparate technologies to "speak" with one another) or a modular integrated approach from a single vendor.

In either case, it is generally accepted that for technologies related to medication safety, an optimized pharmacy information system would form the nucleus of an interconnected system and represent the first order of business in most hospitals. Integration of the laboratory and pharmacy systems might well be a second order of business. Then other modules, such as CPOE and BPOC medication administration systems, can be added to this nucleus.

There are several reasons for focusing on bar coding in this tool. To begin with, market forces and regulatory trends suggest that BPOC will become a strategic and compliance imperative (see Regulatory and Market Environment below).

Additionally, data from the *ISMP Medication Safety Self Assessment* completed in 2000 by nearly 1,500 hospitals demonstrated clear interest in this technology. But while 43 percent of respondents had discussed the possibility of implementing bar codes to verify patient identity during drug administration, only 2.5 percent actually used the technology in some areas and only one percent had fully

implemented it throughout the organization. It has also been suggested in the literature that the cost and time associated with implementing BPOC technology is generally less than the cost and time required for CPOE implementation.

Yet, very little guidance is available on how to go about preparing to implement BPOC technology. Within this context, then, the following discussion will focus specifically on bar-coding systems and the issues an organization should consider to determine readiness for implementation. This attention is not meant to imply that this form of technology should take precedence over others.

A comprehensive discussion of all forms of technology currently available in health care is beyond the scope of this document.

What Does a Bar-Coding System Look Like?

In the ideal system, all single-unit packages would come from the manufacturer with a pre-printed bar code containing the National Drug Code (NDC) number or some other unique identifier, lot number, and expiration date. Patients would be issued a wristband with a bar-coded unique patient identifier on admission to the hospital. The hospital would have bedside scanners linked to: the admission, discharge, and transfer (ADT) database; the pharmacy information system; the laboratory information system; the personnel system; and software to supply active decision support (i.e., a rules engine).

When a patient is to receive a medication, the nurse would scan his/her bar-coded employee identifier, the patient's wristband to confirm patient identity, and then each package of medications to be administered at the bedside. The system would verify the dispensing authority of the caregiver, confirm the patient's identity, match that identity with his/her medication profile in the pharmacy information system, check the rules engine for any alerts or reminders for the nurse, electronically record the action in an online medication administration record (MAR), and store data for later aggregate analysis. Note that the bar code itself serves primarily as a pointer to the organization's databases. It contains no patient information, which is only acquired through linkage to those databases.

Benefits of Bar Coding

Bar-code-enabled point-of-care systems offer several levels of functionality. At the most basic level, they help to verify that the right drug is being administered to the right patient at the right dose by the right route and at the right time (see **Figure 2**). Such systems also create an online MAR that is likely to be more accurate than traditional MARs generated manually. The increased administrative efficiencies realized through the use of bar codes will result in improved inventory control, billing accuracy and reduction of rework. "Smart" systems can also support the nurse by providing drug reference information and various alerts (e.g., look-alike/sound-alike) and reminders (e.g., important clinical actions that need to be taken when administering certain medications). Finally, data capture allows for

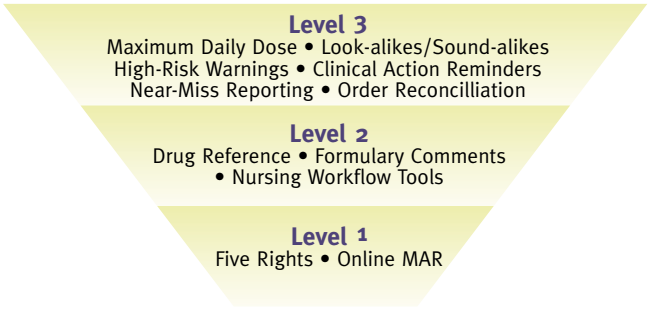

Figure 2. Levels of functionality in bar-code–enabled point-of-care technology for medications. Source: ©2002 Bridge Medical Group, amended and used by permission.

retrospective analysis of aggregate data to monitor trends (e.g., percent of doses administered late and errors of omission). Such analysis should not, however, be used to assess employee performance, especially if it could lead to punitive action.

The principles behind bar coding suggest that errors leading to patient harm could be significantly reduced through the effective use of this technology. Although the goal is perfection, the reality is that humans are expected to err. It is unreasonable to think that any technology is going to produce a totally fail-safe environment. Even the best-designed system (people, process, and technology), using the best strategies to identify potential failures (FMEA), is going to fall short from time to time.

For example, there could be an error in the application of the correct bar-code label, particularly with in-house labeling operations. Or users could circumvent the normal procedures (i.e., perform an unauthorized work-around) by scanning a surrogate bar code rather than the one on the medication or wristband or the employee's identification badge.

"Technology is just one tool, among many, that needs to be consistently and effectively used by organizations striving for fail-safe medication use."

– Judy Smetzer, RN Vice President Institute for Safe Medication Practices

Technology is just one tool, among many, that needs to be consistently and effectively used by organizations striving for fail-safe medication use. Ultimately, these systems will only perform well when the interfaces between people and technology are well managed through the understanding of human factors elements.

Current Challenges in Bar Coding

In general, BPOC systems tend to present fewer implementation challenges than other types of clinical technology (e.g., CPOE). Challenges do exist, however, and include the following:

- Only about 35 percent of drugs currently contain manufacturer's bar codes. In the future, regulation should cause this percentage to increase.
- There is a growing trend of fewer medications being made available by manufacturers in unit-dose form.
- There is no uniform standard for bar coding medications.
- No standard exists for relabeling/bar coding in-house. In the absence of such standards, hospitals are left to follow whatever commercial standards exist.
- In-house repackaging of medications and bar coding result in unreimbursed costs and, especially if done manually, may introduce new sources of error.
- Interfacing the bar-coded medication administration system with legacy IT systems may prove difficult and costly.
- Bar code scanners need to be readily available and set up to be user-friendly (e.g. placed in convenient locations) so as to minimize any disruption of a nurse's workflow.
- During times of nursing staff shortage, temporary "agency" or "floating" nurses may be unfamiliar with the system and its proper use. Time and effort must therefore be expended to orient these practitioners to the systems within each hospital.
- Vendor BPOC products often lack one or more desirable features. (see levels 2 and 3 in **Figure 2**).
- Patient-specific medications, such as multi-additive intravenous solutions, most pediatric dosage forms, and pharmacy-compounded products, will always require bar coding by in-house pharmacy departments.

Selecting the Right System

Once an organization has determined that it is ready to move forward with a BPOC medication administration system, it still faces the daunting task of evaluating the products

offered by various vendors. An evaluation of those products is beyond the scope of this tool, but readers may wish to review a suggested template for a request for proposal (RFP) to IT vendors. Doing so will help the organization ask the right questions pertaining to vendor stability, product capabilities, and the levels of service and support that can be anticipated.

One such template from the California HealthCare Foundation, provided as **Attachment 3.B**, is part of a larger document entitled *Addressing Medication Errors in Hospitals: A Practical Tool Kit.* (The full document is available online at: http://www.chcf.org/documents/quality/addressingmederrorstentools.pdf.)

Costs Associated with BPOC

As a general guide, hospitals can expect a BPOC system to cost between $500,000 and $1 million and require up to one year to implement.

Attachment 3.A provides a template that can be used to calculate the approximate cost savings from implementing technology that will reduce medication errors. However, the assessment process must also include an analysis of the financial, system, and human resources needed to develop and implement a BPOC system. Many of the items in the assessment (**Section 3.2**) are related to resource allocation such as 11, 22, 40, 45, 94, 95, 105, 119, and 135.

Preparing for the Unexpected

Before embarking on a BPOC implementation, it's critical to anticipate potential failures and develop contingency plans for unexpected results. Of course, a stringent testing phase should also be built into the system roll-out.

Regulatory and Market Environment

The U.S. Food and Drug Administration (FDA) on December 3, 2001, announced that it was considering proposing a rule requiring that the National Drug Code (NDC) be bar coded on all pharmaceutical and biological products. The FDA announcement stated that the agency was also examining the requirement for lot number and expiration date to also be included in the bar code. On July 26, 2002, the FDA held a public meeting to solicit comments for the development of a regulation on bar-code labeling for human drug products, including biological products.

At least two group purchasing organizations for hospitals have announced contract requirements for bar codes on unit-dose products, and several pharmaceutical manufacturers have already agreed to put bar-code labels on their products.

The recently formed National Alliance for Health Information Technology (NAHIT) seeks to "improve quality and performance through standards-based information systems." NAHIT intends to promote voluntary standards to facilitate the interoperability of information systems. The alliance will focus, in the short term, on standardizing and uniformly applying bar codes on products for use in health care organizations.

Conclusion

Information technology, such as BPOC, holds the promise of preventing medication errors at

the point of administration. It is, however, just one of many important forms of technology. Bar code–enabled point of care is reviewed here because of emerging issues surrounding its application in hospitals. Hospital leaders need to approach BPOC within the context of an overall plan for information technology infrastructure and with the realization that IT alone will not solve all problems related to medication safety.

The following readiness self assessment is designed to provide a pathway for an organization and its staff to explore preparedness to implement BPOC technology in the context of the environment described above. Although some influences are beyond a health care organization's control, other elements of readiness can be improved just through thinking about the process. It also helps to be receptive to change—to make the necessary adjustments to meet the challenges ahead.

Endnote

1. Mark Neuenschwande, "Special Expanded Edition: CQInfoAutomation," *CQInfoAutomation*,(Quarter 4, 2000): 1-11.

Pathways for Medication Safety℠

Strategies for LEADERSHIP

Assessing Bedside Bar-Coding Readiness

Section 3.2 —

Readiness Assessment for a Bedside Bar-Coded Drug Administration System

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Section 3.2

Readiness Assessment for a Bedside Bar-Coded Drug Administration System

Instructions for Conducting the Readiness Assessment

The following readiness assessment is divided into nine distinct elements related to successful implementation of a bedside bar-coded drug administration system. These nine elements are based on the ISMP *Ten Key Elements of the Medication Use System.* Each element includes multiple items to help an organization evaluate its readiness for implementing this technology. The items are divided into two categories:

Prerequisites: These are items that *must be in place before* attempting to implement a bedside bar-coded drug administration system.

Facilitators: These items are *not required, but would make it easier* to implement a bedside bar-coded drug administration system.

To Complete the Readiness Assessment:

1. Establish a multidisciplinary team consisting of, or similar to, the following:
   - Senior administrative leader
   - Physician leader
   - Nurse executive
   - Director of pharmacy
   - Clinical informatics representative
   - Risk management/quality/ safety representative
   - Nurse educator
   - At least two staff nurses from inpatient units
   - At least one nurse from an outpatient unit
   - At least one staff pharmacist
   - Pharmacy technician/unit secretary
   - Board member (optional)

   Although the composition of the multidisciplinary team will vary between hospitals, it should include adequate representation from senior leadership, management, and frontline staff.

   This team should be provided with sufficient time to complete the readiness assessment. Because implementation of a bedside bar-coded drug administration system is a complex, interdisciplinary process, the value and accuracy of the readiness assessment is significantly reduced if only a single discipline involved in the process completes it. Completion of the readiness assessment has been estimated to take two to three team meetings, with variable additional time between meetings based on the volume of items requiring further investigation.

2. Read and review the readiness assessment in its entirety before beginning the assessment process. If possible, make copies of the readiness assessment and send them to team members for review before the first meeting.

3. Discuss each item in the readiness assessment and evaluate the organization's success with implementing it. As necessary, investigate and verify the level of implementation with other staff outside of the team. When a consensus on the level of implementation for each item has been reached, place a check mark in the appropriate column using the following scoring key:

   KEY
   A = Not implemented
   B = Partially implemented
   C = Fully implemented

   As applicable, review the examples provided in **Attachments 3.A**, **3.B**, and **3.C** to assist in evaluating the associated items.

4. Repeat the process for all items in the readiness assessment.

5. Identify strengths (items that scored C) and weaknesses (items that scored A or B) related to the organization's readiness for implementing a bedside bar-coded drug administration system.

6. Based on the team's analysis of strengths and weaknesses, develop an action plan to improve the organization's readiness for implementing a bedside bar-coded drug administration system. Prioritize the action plan based on whether the weakness is a **PREREQUISITE** or **FACILITATOR**.

   When appropriate, consider using **Attachments 3.A** and **3.B** as templates or learning tools for specific items in the action plan.

7. Execute the action plan and evaluate the organization's progress in paving the way for successful implementation of a bedside bar-coded drug administration system.

Nine Elements of Assessment

I. Drug Labeling, Packaging, and Nomenclature

To facilitate proper identification of drugs, health care organizations should provide all medications in clearly labeled, unit-dose packages and should take steps to prevent errors with look-alike and sound-alike drug names, ambiguous drug packaging, and confusing or absent drug labels.

ITEM #		MANUFACTURER LABELING AND PACKAGING OF MEDICATIONS	A	B	C
1	**P**	A list of the most frequently prescribed medications that cover 80% of all drug administration is available for the purpose of determining priority medications that need to be bar coded.			
2	**F**	A list of high-alert drugs used in the organization has been established for the purpose of determining a list of products that should be bar coded at the unit-dose level.			
3	**P**	Single-unit medication packages with a bar code are purchased from source manufacturers, whenever available, or from wholesalers or other entities that repackage the medications.			
4	**F**	The *ISMP Medication Safety Alert* and/or other current literature is reviewed regularly to identify drug labeling, packaging, and nomenclature problems, and alerts are built into the pharmacy computer software to remind practitioners. (Point-of-care technology can be interfaced with the bar-code system to provide nurses with relevant alerts).			
		HOSPITAL LABELING AND PACKAGING OF MEDICATIONS			
5	**P**	An automated packaging solution (single-hopper machines, multi-cassette packagers, over-packagers, etc.) to apply bar codes to unit-dose medications is available for use.			
6	**P**	The pharmacy computer system has the capability of printing labels with bar codes that describe the content of IV admixture solutions and other parenteral medications.			
7	**P**	The pharmacy computer system has the capability of printing labels with bar codes for pharmacy-prepared, patient-specific unit doses (e.g., pediatric doses, oral solutions, extemporaneous medications).			
8	**P**	The printers in the pharmacy that are used for labels have the capacity to produce a high-resolution bar code that can be read easily. (The print quality of the bar code should be at the C or better ANSI [American National Standards Institute] standard).			

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KEY
P = Prerequisite
F = Facilitator

I. Drug Labeling, Packaging, and Nomenclature

		HOSPITAL LABELING AND PACKAGING OF MEDICATIONS (cont.)	A	B	C
9	**P**	Unit-dose oral medications remain in the manufacturer's (or pharmacy's) packaging up to the point of actual drug administration at the point of care so that a final check of the drug against the MAR and patient information can be accomplished.			
10	**P**	If nurses must prepare an injectable medication or flush solution (draw the medication/solution into a syringe), the medication is brought to the bedside in the original container, drawn into the syringe, and administered immediately. (Following this practice is necessary to avoid circumventing the process of scanning the medication at the point of care.)			
11	**P**	Resource allocation plans for a bar-coded drug administration system have factored in the costs associated with repackaging medications with a bar code for distribution (including staffing needs).			

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Nine Elements of Assessment

II. Drug Standardization, Storage, and Distribution

Many errors are preventable simply by minimizing floor stock, restricting access to high-alert drugs and hazardous chemicals, and distributing unit-dose packages of drugs from the pharmacy in a timely fashion. Whenever possible, the use of commercially available solutions and standard concentrations can also minimize error-prone processes, such as IV admixture and dose calculations.

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ITEM #	UNIT DOSE DISPENSING		A	B	C
12	P	Drugs stocked in patient care units (including automated dispensing cabinets) are in ready-to-use unit doses. Exceptions: topical products, nasal or throat sprays, ophthalmic solutions/ointments, otic solutions/ointments, vaginal creams.			
13	P	Manufacturer's prefilled syringes or single-dose vials/ampules (rather than multiple-dose vials) are used for at least 90% of the injectable products that are commonly stored in patient care units (e.g., narcotics, saline and heparin flushes).			
14	P	Multiple-dose vials of insulin are dispensed from the pharmacy for individual patients.			
15	P	Commercially available, premixed IV solutions are used whenever they are available on the market.			
16	P	IV solutions that are unavailable commercially are prepared in the pharmacy unless needed in emergent, lifesaving situations (to allow application of a bar code to the label and restrict the need for nurses to mix IV solutions in patient care units).			
17	P	At least 90% of all IV push medications used in inpatient units are dispensed in unit-dose form to patient care units as ordered.			
18	F	For rare exceptions when the pharmacy cannot dispense a medication in a patient-specific unit dose (e.g., drug with a significant stability problem after reconstitution), an independent double check of the drug and dose calculation is performed and documented. (This safeguard is needed for the few medications that will not be administered using the full advantages of a bar-code system).			
19	F	For oral solid medications that are available in different strengths, the inventory is sufficient to avoid unnecessary splitting of tablets or use of multiple tablets/capsules for patient-specific doses (to maximize the bar-code system's effectiveness and reduce the amount of repackaging).			

II. Drug Standardization, Storage, and Distribution

		UNIT DOSE DISPENSING (cont.)	A	B	C
20	**P**	Pharmacy dispenses oral liquid medications in labeled, unit-dose oral syringes (with "oral use only" labeling) or unit-dose cups/bottles and avoids dispensing bulk bottles to patient care units.			
21	**F**	Typical doses of oral liquid pediatric antibiotics have been standardized to minimize the workload of preparing unit-dose oral syringes of liquid medications.			
22	**P**	Resource allocation plans for a bar-coded drug administration system have factored in the costs associated with a full unit-dose dispensing system and a full pharmacy IV admixture service for products not commercially available as premixed solutions (including staffing needs).			
		DRUG PROCUREMENT AND STORAGE			
23	**P**	The pharmacy procures and dispenses all pharmaceutical products. Exceptions: radioisotopes used in nuclear medicine, plain IV solutions dispensed (not procured) by material management staff.			
24	**P**	The use of patients' personal store of medications is avoided whenever possible and permitted only when the product cannot be obtained by the pharmacy. Exceptions: metered dose inhalers, birth control pills, eye drops.			
25	**P**	The use of medication samples is prohibited for inpatients.			
26	**P**	First doses of high-alert drugs are not removed from floor stock or an automated dispensing cabinet and administered until a pharmacist reviews and screens the specific patient for safety. Exceptions: per hospital policy in urgent situations where the risk of delayed administration outweighs the safety benefit of pharmacy review of the order before administration; and during periods when a pharmacist is not on the premises.			
27	**F**	Turnaround time for medications dispensed from the pharmacy is consistent with established time frames for emergent, urgent, and routine medications.			

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F = Facilitator

Nine Elements of Assessment

III. Environmental Factors

Environmental factors, such as poor lighting, cluttered work spaces, noise, interruptions, high patient acuity, and non-stop activity, contribute to medication errors when health care providers are unable to remain focused on medication use. Staffing pattern deficiencies, excessive workload, and complex work processes also underlie a broad range of errors. In addition, building an infrastructure into the environment that supports advances in technology presents unique challenges to health care organizations today.

ITEM #	TECHNOLOGY ENVIRONMENT		A	B	C
28	F	The organization has successful experience with integrating/interfacing various information system technologies used throughout the organization.			
29	F	Automated forms of information technology (computers, laptops, palm-held devices, etc.) are available in patient care units and are well utilized by clinicians (nurses, pharmacists, physicians).			
30	F	Inpatient and outpatient information technology systems are integrated.			
31	F	Various clinical applications of information technology are available at point of care and are well-utilized by nurses.			
32	F	Bar-code technology is available and used for various functions in the hospital (e.g., central supply distribution, blood bank).			
33	F	A computer-based patient management system is in place to capture and maintain patient demographic information and patient location within the facility as appropriate.			
34	F	Hospital interface systems are capable of handling the HL7 standard.			
35	F	A network to support information transfer via radio frequency is available in patient care areas.			
36	F	An application interface engine is available that would allow future information systems to be fully integrated into the current technology infrastructure (important for integrating clinical rules-based bar-code systems).			
37	F	An up-to-date compendium of information system capabilities and all clinical functionalities currently driven by automated technology is available.			
38	P	Information systems are protected with security and access control systems, which include a logging mechanism.			

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P = Prerequisite
F = Facilitator

III. Environmental Factors

		TECHNOLOGY ENVIRONMENT (cont.)	A	B	C
39	**P**	There are an information back-up process and a business recovery plan to handle technological failures. These plans cover the hospital's bar-coded drug administration system and are regularly tested.			
40	**P**	Resource allocation plans for a bar-coded drug administration system have factored in the costs associated with hardware and software (including interface costs).			
		PHYSICAL ENVIRONMENT			
41	**P**	There is adequate space in patient care units for medications, equipment, and hardware (including computer terminals) associated with bar-coded drug administration.			
42	**P**	There is adequate space at the patient's bedside (point of care) for the equipment and hardware associated with bar-coded drug administration (including adequate width of doorways to enter patient rooms with equipment and medication carts).			
43	**P**	There is adequate space in the pharmacy for repackaging of medications into unit doses with a bar code, as necessary. This includes space to prepare 90% of the IVs and to store unit-dose medications once they are prepared.			
44	**P**	There are sufficient electrical outlets in nurses' stations and medication rooms for charging electrical equipment associated with a bar-coded drug administration system.			
45	**P**	Resource allocation plans for a bar-coded drug administration system have factored in costs associated with changes needed in the physical environment.			
		WORKFLOW OF MEDICATION ADMINISTRATION			
46	**P**	The processes associated with medication administration have been thoroughly examined through flowcharting or process mapping to promote detailed understanding of caregiver needs and the current workflow.			
47	**P**	Nurses consistently follow existing processes for medication administration.			
48	**F**	Little or no variation exists with how medications are administered on each inpatient care unit.			
49	**P**	Nurses prepare and administer only one patient's medications at a time.			

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III. Environmental Factors

		WORKFLOW OF MEDICATION ADMINISTRATION (cont.)	A	B	C
50	**F**	The impact of a bar-coded drug administration system and anticipated changes in nursing processes, work rhythm, time requirements, and job responsibilities have been examined initially by comparing a hypothetical flow chart of medication administration with bar coding against a flow chart of the current medication administration process.			
51	**F**	Pharmacists routinely spend time in patient care units to observe the drug administration process and understand the barriers to safe medication practices that nurses face. (Such knowledge facilitates pharmacy distribution of medications in a way that promotes safety and matches the way nursing care is delivered.)			
		WORKFLOW OF PHARMACY DISPENSING			
52	**P**	The processes associated with medication dispensing have been thoroughly examined through flowcharting or process mapping to promote detailed understanding of caregiver needs and the current workflow.			
53	**P**	Pharmacists consistently follow existing processes for medication distribution.			
54	**F**	The impact of a bar-coded drug administration system and anticipated changes in pharmacy processes, work rhythm, time requirements, and job responsibilities have been examined initially by comparing a hypothetical flow chart of medication dispensing with a bar-coded drug administration system against a flow chart of the current medication dispensing process.			
55	**F**	Nurses routinely spend time in the pharmacy to observe the drug dispensing process and understand the barriers to safe medication practices that pharmacy staff faces. (Such knowledge facilitates nursing confidence in the drug distribution process and promotes more effective communication between nurses and pharmacy staff.)			

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Nine Elements of Assessment

IV. Patient Information

To guide appropriate drug therapy, health care providers need readily available demographic information (such as patient identity and location), clinical information (such as age, weight, allergies, diagnoses, and pregnancy status), and patient monitoring information (such as laboratory values, vital signs, and other parameters that gauge the effects of medications and the patients' underlying disease processes).

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ITEM #		PATIENT IDENTITY	A	B	C
56	P	Upon admission to the hospital, a bar-coded name band is applied to all inpatients.			
57	P	Upon registration, a bar-coded name band is applied to all outpatients. This is a prerequisite if bar-code technology will be used in outpatient settings, such as the emergency department, oncology clinic, or ambulatory surgery.			
58	P	The bar code on all name bands includes a unique patient identification number.			
59	P	Patient name bands have been tested for durability. Bands should be able to withstand typical abuse without rendering the printed information or bar code unreadable.			
60	F	Patient name bands can be printed in patient care areas to facilitate reapplication in the event that the band has been removed or rendered unreadable.			
61	F	Policy prohibits printing multiple name bands for patients unless a replacement is needed and applied immediately to the patient. (Extra name bands on the unit can lead to unsafe workarounds and potential mix-ups if a replacement is needed.)			
62	F	Bar-coding technology is used to verify patient identity in clinical applications, such as blood administration or collection of laboratory specimens (which promotes experience with bar-coding technology).			
		CLINICAL INFORMATION AND ALERT SYSTEM			
63	F	The computer system used for medication order entry interfaces directly with the laboratory system. (Similar technology may be integrated/interfaced with a bar-code system to alert nurses to drug-lab problems at the point of care.)			

IV. Patient Invormation

		CLINICAL INFORMATION AND ALERT SYSTEM (cont.)	A	B	C
64	**F**	The medication order entry computer system automatically alerts practitioners to the need for potential drug therapy changes based on current laboratory values. (Similar technology may be integrated/ interfaced with a bar-code system to alert nurses to an unsafe dose at the point of care.)			
65	**F**	A timely and reliable system is in place to link information about patients' allergies with the pharmacy computer system. (Similar technology may be integrated/interfaced with a bar-code system to alert nurses to drug-allergy problems at the point of care.)			
66	**F**	A timely and reliable system is in place to link information about patient weights with the pharmacy computer system. (Similar technology may be integrated/interfaced with a bar-code system to alert nurses to an unsafe dose at the point of care.)			

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V. Drug Information

To minimize the risk of error, the drug formulary must be tightly controlled, and up-to-date drug information must be readily accessible to health care providers through references, protocols, order sets, computerized drug information systems, medication administration records, and regular clinical activities by pharmacists in patient care areas.

ITEM #	HOSPITAL FORMULARY		A	B	C
67	**P**	Medications listed in the pharmacy computer system database include National Drug Code (NDC) numbers or a unique drug code. (A code system facilitates downloading of the hospital formulary when creating a bar-coded drug administration system formulary).			
68	**F**	The hospital formulary contains almost no duplication of generic equivalents and very minimal duplication of therapeutically equivalent products. (Extensive formularies slow implementation of bar-coded drug administration systems.)			
69	**F**	The use of non-formulary products is limited to situations where they are therapeutically necessary and appropriate. (Frequent use of non-formulary products will limit the organization's ability to administer these products using a bar-coded system.)			
70	**P**	Non-formulary products are entered into the pharmacy computer system with an NDC number or unique drug code before use. (Non-formulary drugs that lack a unique drug code limit the organization's ability to administer such drugs using a bar-coded system.)			
71	**F**	Formulary decisions are based in part upon whether a product is available from the manufacturer in unit-dose packages with a bar code.			
72	**F**	Vendor contracts reflect preferential purchasing of products packaged in unit doses with a bar code.			
73	**P**	Drug information updates for pharmacy computer systems are received from a database vendor and loaded at least quarterly.			
74	**F**	Maximum doses for high-alert drugs, such as chemotherapy, electrolytes, and opiates, have been established and are available in the pharmacy computer system to perform dose-range checks and warn practitioners about an unsafe or subtherapeutic dose. (Similar technology may be integrated/interfaced with a bar-code system to alert nurses to an unsafe or subtherapeutic dose at the point of care.)			

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Nine Elements of Assessment

VI. Communication of Drug Orders and Other Drug Information

Because failed communication is at the heart of many medical errors, health care organizations must eliminate communication barriers between providers and standardize the way that orders and other drug information are communicated to avoid misinterpretation.

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ITEM #		MEDICATION ADMINISTRATION RECORDS (MARS)	A	B	C
75	**P**	Drug administration is guided and documented by computer-generated or electronic medication administration records (MARs) that share a common database with the pharmacy system.			
76	**P**	Nurses in all inpatient units use the same MAR format to guide and document medication administration.			
77	**F**	All inpatient medication administration is documented on a single MAR (which includes respiratory therapy medications but may exclude intraoperative medications).			
78	**P**	Pharmacists who enter medication orders into the pharmacy computer system consider how each order will appear on the MAR to avoid possible misinterpretation (e.g., eliminate unnecessary information important only to the pharmacy, provide safety alerts and special directions for administration as necessary).			
79	**P**	MARs are available at (or taken to) the patient's bedside for point-of-care reference during drug administration.			
80	**F**	Standardized times for routine drug administration have been established and are followed consistently on all inpatient units. Exception: some medications for neonates in intensive care.			
81	**P**	A password or bar-coded name badge is provided to all nurses upon employment to allow an appropriate level of access to information systems. (A password or bar-coded name badge is needed to document medication administration electronically when using a bar-coded drug administration system.)			
		COMMUNICATION OF PRESCRIBED THERAPY TO THE PHARMACY			
82	P	All prescriber orders for inpatients are forwarded to the pharmacy, including those that do not specifically include medication orders.			

Nine Elements of Assessment

VII. Staff Competency and Education

Although education in itself is a weak error-reduction strategy, it can play an important role when combined with system-based error-reduction strategies. Activities with the highest leverage include ongoing assessment of health care providers' baseline competencies and education about new medications, non-formulary medications, new technologies related to medication use, high-alert drugs, and medication-error prevention strategies.

ITEM #	COMPETENCY		A	B	C
83	**P**	The information technology (IT) staff includes personnel with specialty training in clinical informatics, not just general computing support for finance and business operations. (This level of specialization facilitates the cross-disciplinary application of information technology with the clear thought processes, decision-making abilities, and problem-solving rigor of clinicians.)			
84	**P**	IT staff with specialty training in clinical informatics hold leadership and decision-making roles in the hospital, not just an advisory or academic role.			
85	**F**	Frontline nurses have experience using some form of computerized information technology (e.g., computerized drug information databases, electronic medical records, automated dispensing cabinets, electronic medication administration record).			
86	**F**	Physicians have experience retrieving information from computerized information systems (to facilitate retrieval of information from electronic medication records).			
87	**F**	The use of periodic nursing and pharmacy agency staff who have little or no hospital-specific orientation to clinical functions is minimized.			
	EDUCATION				
88	**P**	In the past year, educational programs and interactive discussions have been held with frontline clinical staff about bar-coded drug administration and other forms of technology. Periodic technology orientation will enhance their comfort and gain their commitment to future automation of the medication-use system.			
89	**P**	In the past year, educational programs and interactive discussions have been held with senior leaders and the board about bar-coded drug administration and other forms of technology.			

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VII. Staff Competency and Education

		EDUCATION (cont.)	A	B	C
90	**P**	In the past year, interactive discussions have been held with frontline clinical staff (including physicians) about potential anxieties and job dissatisfaction related to the use of technology, in order to reduce the risk of circumventing or ignoring technology. (Examples include anxieties and job dissatisfaction related to loss of control over aspects of the job that were previously important to clinicians, degradation of clinical skills that are replaced by technology, the impact of technology on the clinician's work life, suspicions about technological capabilities, concern about potential tracking of individual nurses' medication error, untoward use of tracking data, and unchecked optimism and complacency due to reliance on technology.)			
91	**P**	Qualified hospital personnel are available for ongoing staff training and support after a technology vendor leaves the facility.			
92	**F**	The educational needs and methods of delivering education to physicians who may use a bar-coded drug administration system have been considered.			
93	**P**	Training plans for bar-coded drug administration include instruction on how to handle a technological failure (e.g., documentation of drug administration).			
94	**P**	Resource allocation plans for a bar-coded drug administration system have factored in the costs associated with training clinicians to use the system (including indirect costs associated with staff replacement during training).			

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Nine Elements of Assessment

VIII. Patient Education

Patients can play a vital role in preventing medication errors when they have been educated about their medications and encouraged to ask questions and seek satisfactory answers. Because patients are the final link in the process, health care providers should teach them how to protect themselves from medication errors and seek their input in related quality improvement and safety initiatives.

ITEM #			A	B	C
95	**F**	Resources are available to create educational materials to explain the bar-coded drug administration system to patients and advise them how they can help facilitate use of this technology.			
96	**F**	Patients are provided with a list of medications that they are receiving in the hospital for reference during the drug administration process (to facilitate patient review of an electronic MAR during drug administration with a bar-coded system).			
97	**F**	Plans to implement new technology in the hospital are shared with the community through the local media.			
98	**F**	Teams that evaluate technology to improve patient safety include representation from a lay community member.			

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Nine Elements of Assessment

IX. Quality Processes and Risk Management

Health care organizations need strong leadership, planning, and multidisciplinary collaboration to improve medication safety. They need systems for identifying, reporting, analyzing, and reducing the risk of medication errors. A nonpunitive culture of safety must be cultivated to encourage frank disclosure of errors and near misses, stimulate productive discussions, and identify effective system-based solutions. Strategically placed quality control checks also are necessary. Simple redundancies that support a system of independent double checks for high-risk, error-prone processes promote the detection and correction of errors before they reach and harm patients.

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ITEM #		LEADERSHIP AND PLANNING	A	B	C
		(See ***Leading a Strategic Planning Effort*** for additional information related to this topic)			
99	**P**	The board actively demonstrates its commitment to patient safety by approving a safety plan, encouraging practitioner error reporting, and supporting system enhancements, including technology, that are likely to reduce errors.			
100	**P**	Senior leaders and the board are committed to expanding use of clinically proven technologies to improve medication safety.			
101	**P**	A bar-coded drug administration system fits well into the organization's overall clinical information system planning strategy.			
102	**P**	The scope of the business case for a bar-coded drug administration system has been defined and agreed upon by senior leaders and the board. (For example, will the business case that drives the implementation be based upon specified enterprise performance—that is, financial terms—specific organizational mission and values, societal values, or a defined combination of all?)			
103	**F**	A needs assessment has been conducted and a business case for bar-coded drug administration has been prepared and articulated to senior leaders and the board. (See **Attachment 3.A** for an example of an *Estimated Cost Savings Worksheet* related to implementation of technology.)			
104	**P**	Goals related to the initiative of bar-coded drug administration are part of the hospital's strategic plan and are clearly articulated by the board and senior leaders in specific terms to all hospital staff.			
105	**P**	The board and senior leaders are committed to allocating the resources necessary to implement a bar-coded drug administration system.			
106	**F**	Senior leaders have taken steps to ensure that the expenditure and implementation of bar-coded drug administration technology will not create relationship problems with other departments in the hospital or the medical staff.			

IX. Quality Process and Risk Management

		LEADERSHIP AND PLANNING (cont.)	A	B	C
107	**F**	Senior leaders have taken steps to ensure that the implementation of bar-coded drug administration technology will not create problems with labor unions if job responsibilities change.			
108	**P**	Senior leaders have involved frontline nurses and pharmacists in initial discussions and planning meetings. Frontline input is essential to designing a bar-coded drug administration system that will improve patient safety and enhance workflow efficiency.			
109	**F**	At least one staff member has been assigned responsibility to monitor licensing and regulatory bodies (e.g., U.S. Food and Drug Administration), accrediting bodies (e.g., Joint Commission on Accreditation of Healthcare Organizations), national organizations (e.g., Institute for Safe Medication Practices, American Hospital Association), and the pharmaceutical industry for up-to-date information about changes that would affect the implementation of a bar-coded drug administration system.			
110	**P**	State licensing regulations have been examined to ensure compliance with medication repackaging standards (for the purposes of applying a bar code to a unit-dose package).			
111	**P**	Criteria for evaluating potential vendors' stability, experience, service, and specific technological characteristics for a bar-coded drug administration system have been compiled. (See **Attachment 3.B** for a sample *Request for Proposal Template*.)			
		MULTIDISCIPLINARY TEAMS AND COMMITTEES			
112	**P**	The hospital utilizes teams or committees comprised of nurses, pharmacists, physicians, and information technology staff who work together successfully to improve the safety or quality of patient care services.			
113	**P**	Several clinicians and a clinical informatics staff member have been identified as champions for bar-coded drug administration.			
114	**P**	A multidisciplinary team comprised of frontline clinicians, clinical informatics staff, clinical managers, risk managers, and senior leaders has been identified to select a vendor and address the clinical support and technology issues associated with implementing a bar-coded drug administration system.			
115	**P**	The multidisciplinary team charged with facilitating implementation of a bar-coded drug administration system has the authority to set timelines, define specifications and processes, and work closely with the users of the system to elicit feedback and remedy technology and workflow issues.			

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IX. Quality Process and Risk Management

		MULTIDISCIPLINARY TEAMS AND COMMITTEES (cont.)	A	B	C
116	**F**	Clinical and clinical informatics representatives plan to visit other hospitals that have implemented a bar-coded drug administration system to learn firsthand about their systems' strengths and challenges to implementation.			
117	**P**	A team of frontline nurses and pharmacists has examined the potential failure points and associated risks of a bar-coded drug administration system through some form of proactive risk assessment (e.g. Failure Mode and Effects Analysis, cause and effect diagramming). (See **Attachment 3.C** for an example of cause and effect diagrams and an FMEA related to implementation of a bar-coded drug administration system.)			
118	**F**	Trained staff perform regular, ongoing literature searches to learn about potential sources of error with new technology, including bar-coded drug administration. (A medical librarian could serve as a resource.)			
119	**P**	Resource allocation plans for a bar-coded drug administration system have factored in the costs associated with staff time spent on the multidisciplinary team charged with facilitating implementation of a bar-coded drug administration system.			
		CULTURE			
120	**P**	Clinicians and other staff report and openly discuss errors without undue embarrassment or fear of reprisal from peers and hospital/organization leaders.			
121	**P**	In the post-event process, no disciplinary action is taken against clinicians who made an error. (Exceptions: malicious or illegal behavior that results in an error, drug diversion, chemical dependence, intentional breach of confidentiality, other egregious behavior.)			
122	**P**	Data related to medication errors are not used as a measure of employee competence or vigilance during performance evaluations.			
123	**F**	Reportable events include both hazardous situations that could lead to an error and actual errors, including those that have been detected and corrected before they reach a patient.			
124	**F**	Near misses and hazardous situations that have the potential to cause patient harm (but score low on a patient outcome severity scale) are given the same high priority for analysis and error prevention strategies as errors that actually cause patient harm.			
125	**F**	Discussions have been held with frontline nurses and pharmacists to prepare them for the increase in error detection that will occur with a bar-coded drug administration system in order to prevent defensive attitudes when the data are available and reviewed.			

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IX. Quality Process and Risk Management

		FEEDBACK MECHANISMS	A	B	C
126	**F**	Trusted nurse, pharmacist, and physician representatives facilitate periodic, announced focus groups of frontline practitioners for "off the record" discussions to learn about perceived problems with the medication-use system.			
127	**P**	Nurses feel comfortable reporting and frankly discussing any barriers they encounter to following existing processes related to medication administration.			
128	**P**	Pharmacists feel comfortable reporting and frankly discussing any barriers they encounter to following existing processes related to medication dispensing.			
129	**F**	Effective mechanisms are in place (i.e., RCAs or FMEAs) to provide regular, meaningful reports to frontline clinicians about progress with medication safety objectives. (See ***Pathways for Medication Safety: Looking Collectively at Risk*** for strategies on implementing these feedback methods.)			
130	**F**	Effective mechanisms are in place to provide regular, meaningful reports to senior leaders and the board about progress with medication safety objectives.			
131	**F**	Medication safety objectives are celebrated and widely communicated when met.			
		USING DATA TO IMPROVE MEDICATION SAFETY			
132	**P**	The board, senior leaders, and clinicians (nurses, pharmacists, and physicians) demonstrate strong interest in being able to intercept potential medication errors in "real time" to prevent adverse drug events that harm patients.			
133	**P**	The board, senior leaders, and clinicians (nurses, pharmacists, and physicians) demonstrate strong interest in detection of medication errors that may otherwise remain undetected without bar-coding technology.			
134	**F**	The board, senior leaders, and clinicians (nurses, pharmacists, and physicians) desire a means of measuring medication safety during drug administration for the purpose of demonstrating improvement over time.			
135	**P**	Time and resources have been allocated to analyze and use averted error data generated by a bar-code system.			

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Pathways for MEDICATION SAFETY℠

Strategies for
LEADERSHIP

Assessing Bedside Bar-Coding Readiness

Attachments —

3.A — **Estimated Cost Savings Worksheet**

3.B — **Request for Proposal (RFP) Template**

3.C — **Cause and Effect Diagrams and Failure Mode and Effects Analysis (FMEA)**

3.D — **Readings Related to *Assessing Bedside Bar-Coding Readiness***

A Partnership:

American Hospital Association

Health Research and Educational Trust

Institute for Safe Medication Practices

Attachment 3.A

Estimated Cost Savings Worksheet

The following link provides a worksheet to guide the hospital in calculating the potential savings resulting from the implementation of technology to reduce medication errors. The amount of savings will vary, depending on organizational characteristics and the technologies under consideration. Suggested users include senior management and department leaders involved with product evaluation, selection, and purchase. See tool #9 in http://www.chcf.org/documents/quality/addressingmederrorstentools.pdf

The results of this worksheet can help to direct the hospital toward technologies that offer the most value for the organization in terms of medication safety and financial return. Sources of information would include the results of the organizational assessment and IT vendors. Sample calculations are provided as a guide for the user; please substitute organization-specific data as available.

This document was developed by Protocare Sciences for the California HealthCare Foundation and has been linked to here with permission. For additional information on Addressing Medication Errors in Hospitals: Ten Tools *(the source of this worksheet), please see www.chcf.org/topics/view.cfm?itemID=12682*

Attachment 3.B

Request for Proposal (RFP) Template

The following link suggests criteria to consider when requesting a proposal from a technology vendor. Include these criteria in a Request for Proposal (RFP) to a technology vendor so that you gather appropriate information. The information learned can help you make the best-informed decisions regarding technology purchases. Suggested users include senior management and department leaders involved with product evaluation, selection, and purchase. See tool #8 in http://www.chcf.org/documents/quality/addressingmederrorstentools.pdf

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Attachment 3.C

Cause and Effect Diagrams and Failure Mode and Effects Analysis

The following attachment presents examples of actual Cause and Effect Diagrams and Failure Mode and Effects Analysis performed by Metropolitan Methodist Hospital, San Antonio, Texas, before successfully installing a bedside bar-coded drug administration system.

The attachment consists of multiple parts:

- Part I (page 3.C.3) is a Cause and Effect Diagram that displays possible reasons why the hospital may not produce accurate, scannable bar codes on all medications. The possible causes are sorted into five categories: People, Materials, Equipment, Methods, and Environment. The diagram takes the shape of a fishbone and hence may be called a Fishbone Diagram. This well-defined list of potential failure points for producing accurate, scannable bar codes on medications was then used as the basis for a Failure Mode and Effects Analysis (found in Part II).

- Part II (pages 3.C.4 – 3.C.11) is one example of a Failure Mode and Effects Analysis (FMEA) performed by the hospital for producing an accurate, scannable bar code on all medications. This FMEA takes each potential cause, or failure point, identified in the Cause and Effect Diagram and determines the potential:

  - ❍ Effect of the failure.
  - ❍ Severity of harm to the patient.
  - ❍ Frequency of occurrence.
  - ❍ Ability for detection.
  - ❍ Root causes of the failure.

Each failure point was assigned a Hazard Score (see **Key** for more information), and a determination was made whether to accept, control, or eliminate the risk of the potential failure. Finally, error prevention strategies were suggested for the failure points that could not be accepted.

To begin the FMEA process, the potential failure points were first grouped into the five categories in the Cause and Effect Diagram (People, Materials, Equipment, Methods, and

Environment). After the FMEA was completed, the failure points could be sorted from high to low Hazard Score to assist with prioritization of the strategies.

More detailed information on performing a Failure Mode and Effects Analysis can be found in ***Pathways for Medication Safety: Looking Collectively at Risk.***

- Part III (pages 3.C.12 – 3.C.15) consists of Cause and Effect Diagrams for four of the most serious failure points identified in the FMEA (failure points with the top-scoring Hazard Scores). For each of the four failure points, additional root causes were explored to help ensure that the strategies selected for action would be most successful.

Based on this analysis (and other risk assessments and analyses not provided as examples), the hospital developed an effective action plan to reduce the risk of failures (and errors) after installing a bedside bar-coded drug administration system.

Attachment 3.C, Part I

Cause and Effect Diagram

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

Effect: Failure to Produce Accurate, Scannable Bar Codes on Medications in a Hospital

People

1. Technician labels package incorrectly.
2. Technician packages wrap that is empty.
3. Technician packages two items in one bag.
4. Pharmacist checks packaging incorrectly.
5. Technician/pharmacist sends medication to floor without bar code.
6. Nurse opens package before scanning
7. Not enough staff to bar code.

Materials

1. Ink does not adhere and bar code will not scan.
2. Initial bar code is scannable, but after handling, it becomes unscannable.
3. Bar-coding materials are not available when needed.
4. Small items are difficult to bar-code, as reduced bar codes are unreadable and larger bar codes obscure readability of drug name, strength, lot number, expiration date, and warnings.
5. Overwrapped, multi-dose items do not retain their bar code once opened; staff have to reinsert medication into an open-sided bar-code wrapper.

Equipment

1. Equipment fails to operate.
2. Equipment fails to print scannable bar code.
3. Package produced does not meet USP standards for unit-dose packaging.

Methods

1. NDC number is not in database for scanning.
2. Drugs are needed for patients prior to bar coding.
3. Drugs are substituted due to unavailability from wholesalers.
4. Drugs expire when removed from overwrap in short timeframe (e.g., Xopenex = 7 days).
5. Areas without bedside scanning will be opening bar-coded bags without benefit.
6. Rx-generated IV, IVPB, compounds have only Patient name and Rx #. What if account or Rx changes? (e.g., Rehab treatment, Copy and Edit, Limited Edit, ASO).
7. Home medications are not bar coded.

Environment

1. Not enough space in pharmacy for bar-coding equipment and supplies.
2. Narcotics and floor stock will require additional space on nursing unit.

Attachment 3.C, Part II

Failure Mode and Effects Analysis

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

Key

Hazard Score

The Hazard Score determines the criticality of the failure mode and helps determine whether the risk of failure should be:

- Accepted (do nothing about the potential failure).
- Controlled (take action to enhance detection or reduce the risk of the potential failure).
- Eliminated (prevent the potential failure).

The Hazard Score is obtained by multiplying the severity rating, probability rating, and the detectability rating scores. For example: 3.C, Part IV, the Hazard Score was derived from the analysis in the "People 1." row of the FMEA.

Scoring Guidelines

Scores for severity, probability, and detectability are based on a ten-point scale using the following anchors:

Attribute	Score #1	Score #10
Severity	Non-discernible to patient	Failed without warning and could cause serious harm to patient.
Probability	Unlikely (1 in 100,000).	Likely (1 in 10).
Detectability	Cannot occur so detection unnecessary.	Could occur but cannot be seen.

Failure Mode and Effects Analysis

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

Category	Failure Modes (what might happen)	Effects	Severity	Probability	Detectability	Hazard Score	Analysis[1]	Causes (why it happens)	Actions to Reduce Failure Mode
People 1.	Technician labels package incorrectly.	Patient receives wrong medication.	10	8	4	320	Control	1. Not enough time to eliminate mistakes. 2. Not enough staff assigned to task.	
People 2.	Technician packages wrap that is empty.	Delay in obtaining additional medication from pharmacy.	2	8	1	16	Accept	N/A	N/A
People 3.	Technician packages two items in one bag.	Patient receives twice as much medication as ordered.	3	8	6	144	Control	1. Inattention during packaging process. 2. Malfunction of equipment.	
People 4.	Pharmacist checks packaging incorrectly.	Patient receives wrong medication.	10	8	7	560	Control	Inattention during packaging process.	1. Rotation of staff assigned to task. 2. Triple check developed as quality assurance monitor.
People 5.	Technician/pharmacist sends medications to floor without bar code.	Scanning unavailable; all manual medication errors possible.	10	9	1	90	Control	1. Inadequate lead time in ordering medications. 2. Less than 24-hour coverage of packaging technicians.	

1-Analysis = Eliminate, Control or Accept Failure Mode Cause

Failure Mode and Effects Analysis (cont.)

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

Category	Failure Modes (what might happen)	Effects	Severity	Prob-ability	Detect-ability	Hazard Score	Analysis	Causes (why it happens)	Actions to Reduce Failure Mode
People 6.	Nurse opens package before scanning.	Medications become mixed and patient receives correct medication but at wrong administration rate, dosage, frequency, route, etc.	10	9	8	720	Control	1. Inadequate training on new processes. 2. Inadequate time allotted to perform new process.	
People 7.	Not enough staff to bar code.	Medications go to floor without bar code and bypass scanning; all manual medication errors possible.	10	9	1	90	Eliminate	Inadequate staff assigned to bar coding of medications.	1. High priority in department in scheduling of adequate packaging technicians. 2. Frequent monitoring of productivity of packaging with established standards. 3. Frequent monitoring by operations manager of adequacy of volume of packaging.
Materials 1.	Ink does not adhere and bar code will not scan.	Medications are without bar code and bypass scanning; all manual medication errors possible.	10	5	1	50	Eliminate	No scanning performed after bar coding of medications.	1. Medications scanned by pharmacist as double check with visual check. 2. Monitor of daily scanning logs to identify any batches with scanning difficulty.

Failure Mode and Effects Analysis (cont.)

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

Category	Failure Modes (what might happen)	Effects	Severity	Probability	Detectability	Hazard Score	Analysis	Causes (why it happens)	Actions to Reduce Failure Mode
Materials 2.	Initial bar code is scannable, but after handling, it becomes unscannable.	Medications are without bar code and bypass scanning; all manual medication errors possible.	10	5	1	50	Accept	Repeat handling of bar-coded medications renders bar code unscannable.	Monitor of daily scanning logs to identify any batches with scanning difficulty.
Materials 3.	Bar-coding materials are not available when needed.	Medications are without bar code and bypass scanning; all manual medication errors possible.	10	5	1	50	Control	Inadequate process for inventory and reorder of supplies.	Weekly monitor of inventory levels of supplies with back-up supplies stored on-site.
Materials 4.	Small items are difficult to bar code as reduced bar codes are unreadable and larger bar codes obscure readability of drug name, strength, lot number, expiration date, and warnings.	1. Medications are without bar code and bypass scanning; all manual medication errors possible. 2. Medications are not humanly readable; medications that are labeled incorrectly or expired are not detected.	10	9	2	180	Control	Inadequate process for bar coding of small items due to space constraints and unreadability of reduced symbology technology.	Develop bar-code solutions for each type of product, such as insulin, topicals, ophthalmics, otics, etc.

Failure Mode and Effects Analysis (cont.)

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

Category	Failure Modes (what might happen)	Effects	Severity	Prob-ability	Detect-ability	Hazard Score	Analysis	Causes (why it happens)	Actions to Reduce Failure Mode
Materials 5.	Multi-dose items do not retain their bar code once opened; staff have to reinsert medication into an open-sided bar-code wrapper.	1. Medications are reinserted into incorrect bar-code wrappers. 2. Medications become mixed and patient receives correct medication but at wrong administration rate, dosage, frequency, etc.	10	10	8	800	Control	1. Inadequate training of personnel. 2. Inability to develop a bar code for some multi-dose items that are scannable and patient administerable (e.g., eye drops).	1. Purchase unit-dose products whenever possible. 2. Repackage medications into unit-dose whenever possible.
Equipment 1.	Equipment fails to operate.	Medications are without bar code and bypass scanning; all manual medication errors possible.	10	7	1	70	Eliminate		Have alternative solutions (equipment, software) to all bar-coding needs.
Equipment 2.	Equipment fails to print scannable bar code.	Medications are without bar code and bypass scanning; all manual medication errors possible.	10	7	1	70	Eliminate	No scanning performed after bar coding of medications.	1. Medications are scanned by pharmacist as double check with visual check. 2. Monitor daily scanning logs to identify any batches with scanning difficulty. 3. Frequent quality control checks on equipment and routine preventive maintenance schedule implemented.

Failure Mode and Effects Analysis (cont.)

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

Category	Failure Modes (what might happen)	Effects	Severity	Prob-ability	Detect-ability	Hazard Score	Analysis	Causes (why it happens)	Actions to Reduce Failure Mode
Equipment 3.	Package produced does not meet USP standards for unit-dose packaging.	Inadvertent dissolution of medication resulting in subtherapeutic dosing.	3	2	9	54	Control	Unavailability of testing process and equipment for USP standards.	1. Explore outside laboratory for periodic analysis. 2. Destroy packages with obvious integrity flaws.
Methods 1.	NDC number is not in database for scanning.	Medications are scanned but do not match in database; scanning is bypassed; all manual medication errors possible.	10	8	1	80	Control	All products must be manually entered into "Alt #ID" field after initial data upload.	Process to have technicians hit "print screen" when NDC number is added to new product and have pharmacist verify 100% of all new entries by technicians.
Methods 2.	Drugs are needed for patients prior to bar coding.	Medications are without bar code and bypass scanning; all manual medication errors possible.	10	8	1	80	Control	New line items are available when ordered on a patient.	1. Secondary wholesaler availability. 2. Closed formulary. 3. All new items are entered into Meditech in advance of formulary status. 4. Purchase bar-code label software and generate label in advance of entry of item into Meditech.

Failure Mode and Effects Analysis (cont.)

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

Category	Failure Modes (what might happen)	Effects	Severity	Prob-ability	Detect-ability	Hazard Score	Analysis	Causes (why it happens)	Actions to Reduce Failure Mode
Methods 3.	Drugs are substituted due to unavailability from wholesalers.	Medications are without bar code and bypass scanning; all manual medication errors possible.	10	10	1	100	Control	1. Wholesaler unavailability. 2. National drug shortages.	1. Secondary wholesaler availability. 2. Closed formulary.
Methods 4.	Drugs expire when removed from overwrap in short timeframe (e.g., Xopenex=7 days).	1. Medications are administered after shortened expiration date, resulting in subtherapeutic dosing. 2. Medications are destroyed when unused within shortened expiration date, resulting in increased cost to the hospital.	3	9	8	216	Control	USP packaging requirement demands shortened dating when removed from overwrap to perform unit level bar coding.	1. Development of shortened dating tracking process. 2. Inservice on Xopenex for RTs for Xopenex (and other personnel if additional categories identified) on process and need to carefully check shortened expiration dates prior to administration.
Methods 5.	Areas without bedside scanning will be opening bar-coded bags without benefit.	Additional workload on areas not involved with eMAR may decrease labor resources for other activities on unit.	1	10	1	10	Accept	N/A	N/A

Failure Mode and Effects Analysis (cont.)

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

Category	Failure Modes (what might happen)	Effects	Severity	Prob-ability	Detect-ability	Hazard Score	Analysis	Causes (why it happens)	Actions to Reduce Failure Mode
Methods 6.	Rx-generated IV, IVPB, compounds have only patient name and Rx number. What if Rx changes? (e.g., Rehab treatment, copy and edit, limited edit, ASO).	Medications are bar-coded but unrecognizable in system and bypass scanning; all manual medication errors possible.	10	9	1	90	Control	1. Rehab patients are admitted to a new account number due to billing regulations. 2. Pharmacy utilizes copy-and-edit routines and updating of ASO renewals to generate a new Rx number. IV solutions, IVPB and compounds only have patient name (account number) and Rx number so computer will not recognize correct drug if Rx number is different.	1. Retrain pharmacists to preserve the Rx when Rx numbers are utilized for scanning. 2. Training of nursing staff to recognize if IVPB and IV solution do not scan that Rx number may not match. 3. Training of rehab staff that IV, IVPB and compounds issued during inpatient hospitalization will not scan.
Methods 7.	Home medications are not bar coded.	Medications are without bar codes and bypass scanning; all manual medication errors possible.	10	10	1	100	Accept	Home medications are not processed through normal ordering, receiving, and bar-coding processes in the department.	Consider printing an Rx number, patient account-specific bar-code label to be affixed to the patient's home medication during admission stay.

Failure Mode and Effects Analysis (cont.)

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

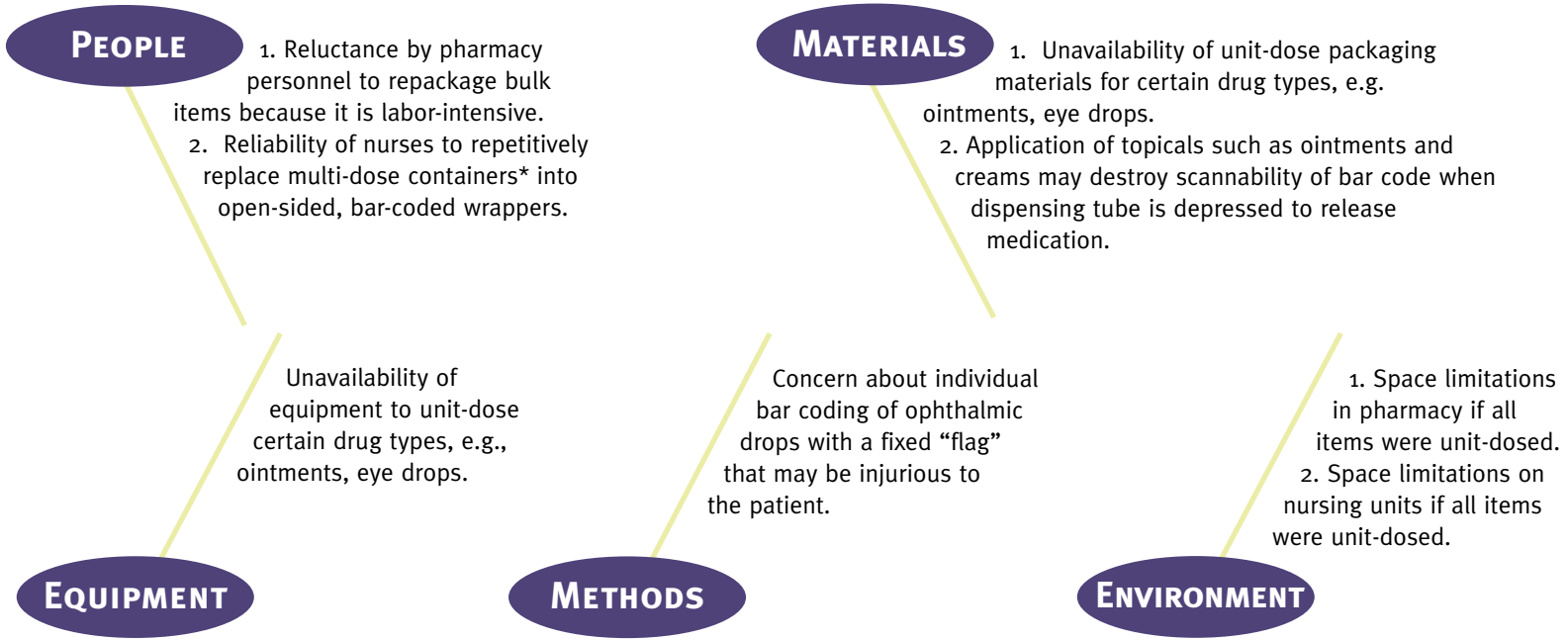
Category	Failure Modes (what might happen)	Effects	Severity	Prob-ability	Detect-ability	Hazard Score	Analysis	Causes (why it happens)	Actions to Reduce Failure Mode
Environment 1.	Not enough space in pharmacy for bar-coding equipment and supplies.	1. Higher rate of errors than expected due to inadequate workflow. 2. Higher rate of unchecked drugs to nursing units due to lack of space for bar coding, checking, and storage.	10	7	1	70	Eliminate	Space limitations for all departments at Metropolitan Hospital (MHS).	1. Redesign of main pharmacy. 2. Explore options with State Board of Pharmacy to perform bar coding off-site under common control for all MHS facilities. 3. Explore outside vendors to supply medications with bar-coded labels prior to arrival at institution.
Environment 2.	Narcotics and floor stock will require additional space on nursing unit.	Reduction in inventory levels may cause delays in drug availability, resulting in medication administration delays.	3	7	4	84	Accept	Space limitations for all departments at Metropolitan Hospital.	1. Explore feasibility of increasing narcotic storage capability on nursing units. 2. Consider changing workflow patterns to re-supply narcotics and floor stock from pharmacy more frequently than every 24 hours.

Attachment 3.C, Part III

Cause and Effect Diagram (Hazard Score=800)

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

Effect: Overwrapped, Multi-Dose Items Do Not Retain Their Bar Code Once Opened



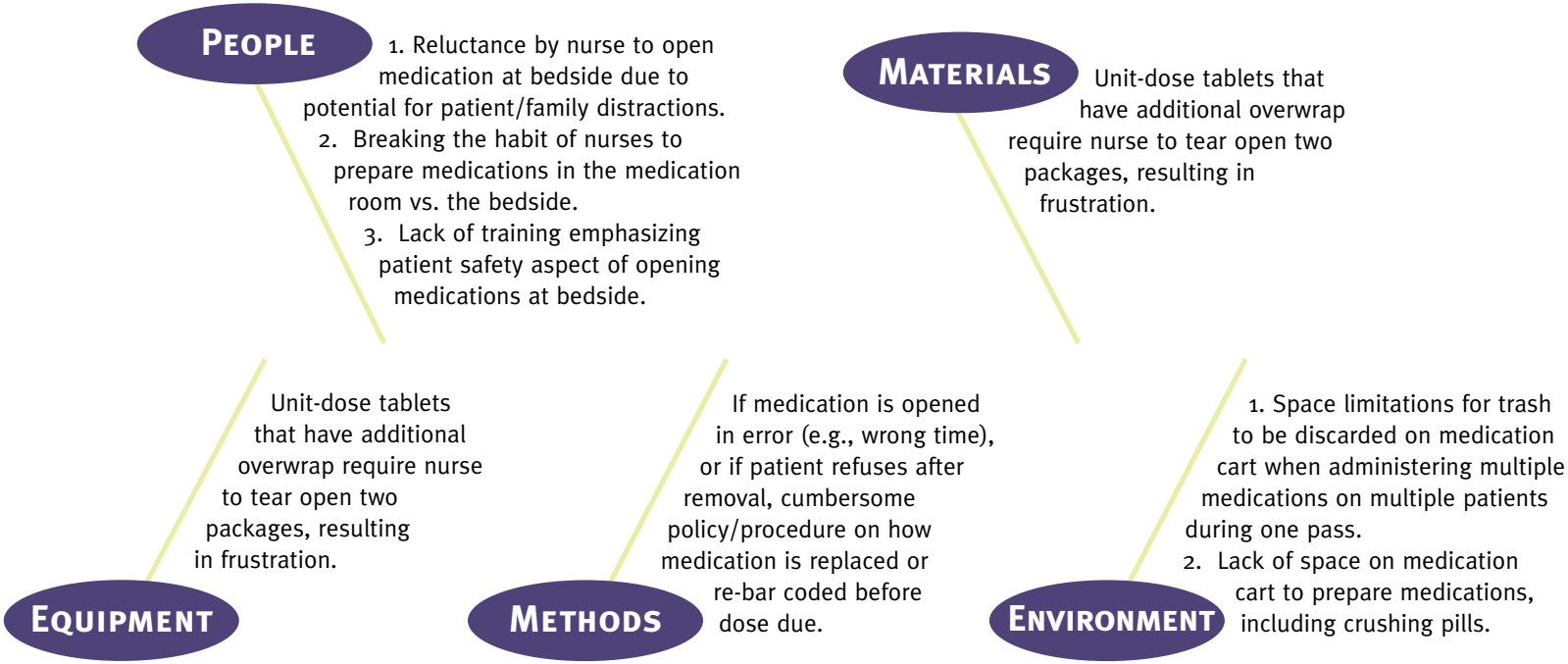
*Multi-dose containers include: ointments, creams, ophthalmics, otics, inhalers, sprays, shampoos, topical liquids, nasal sprays, powders, heparin, syrups, suspensions, drops, packs (medrol, ovral-28), and vaginals.

Attachment 3.C, Part IV

Cause and Effect Diagram (Hazard Score=720)

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

Effect: Nurse Opens Package before Scanning

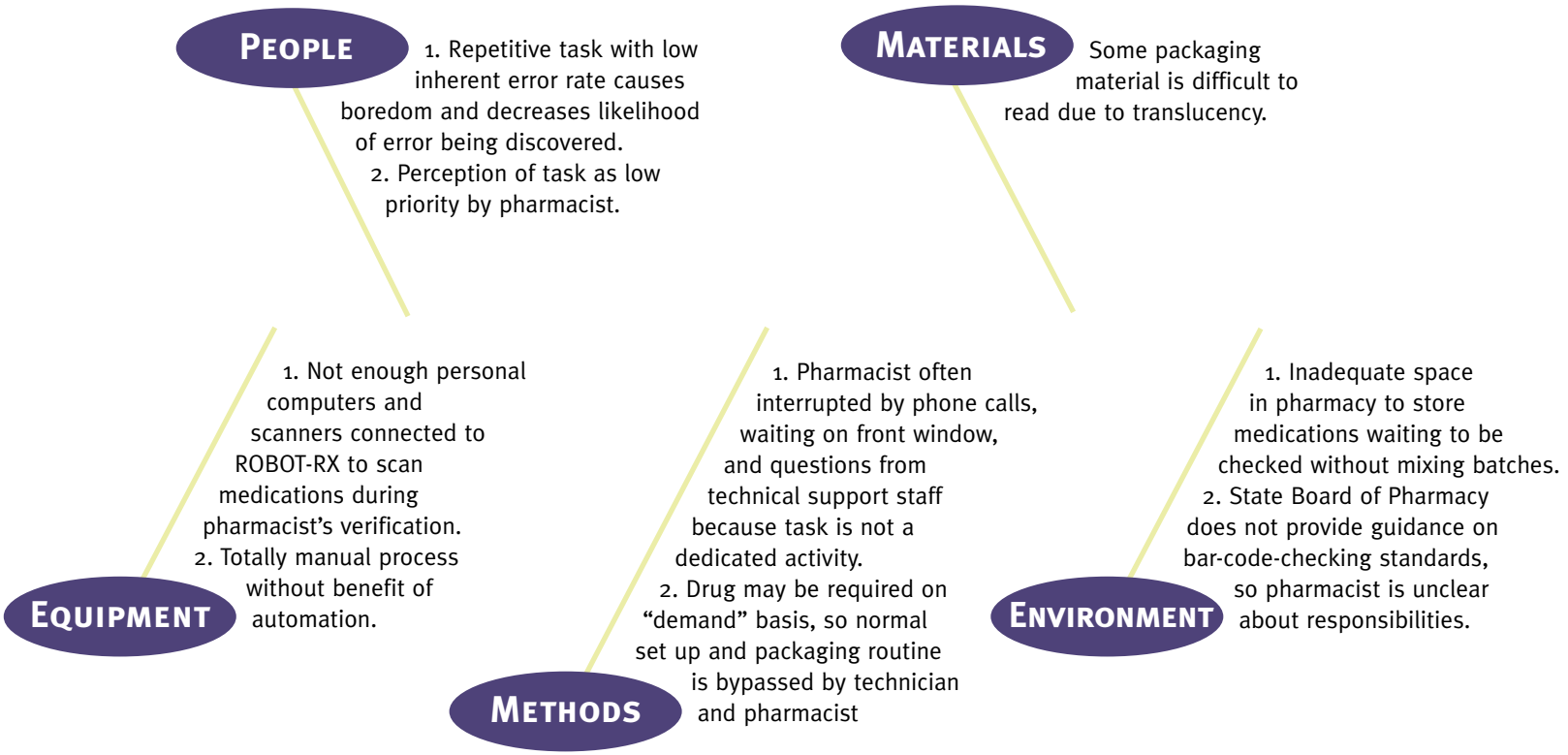


Attachment 3.C, Part V

Cause and Effect Diagram (Hazard Score=560)

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

Effect: Pharmacist Checks Packaging Incorrectly

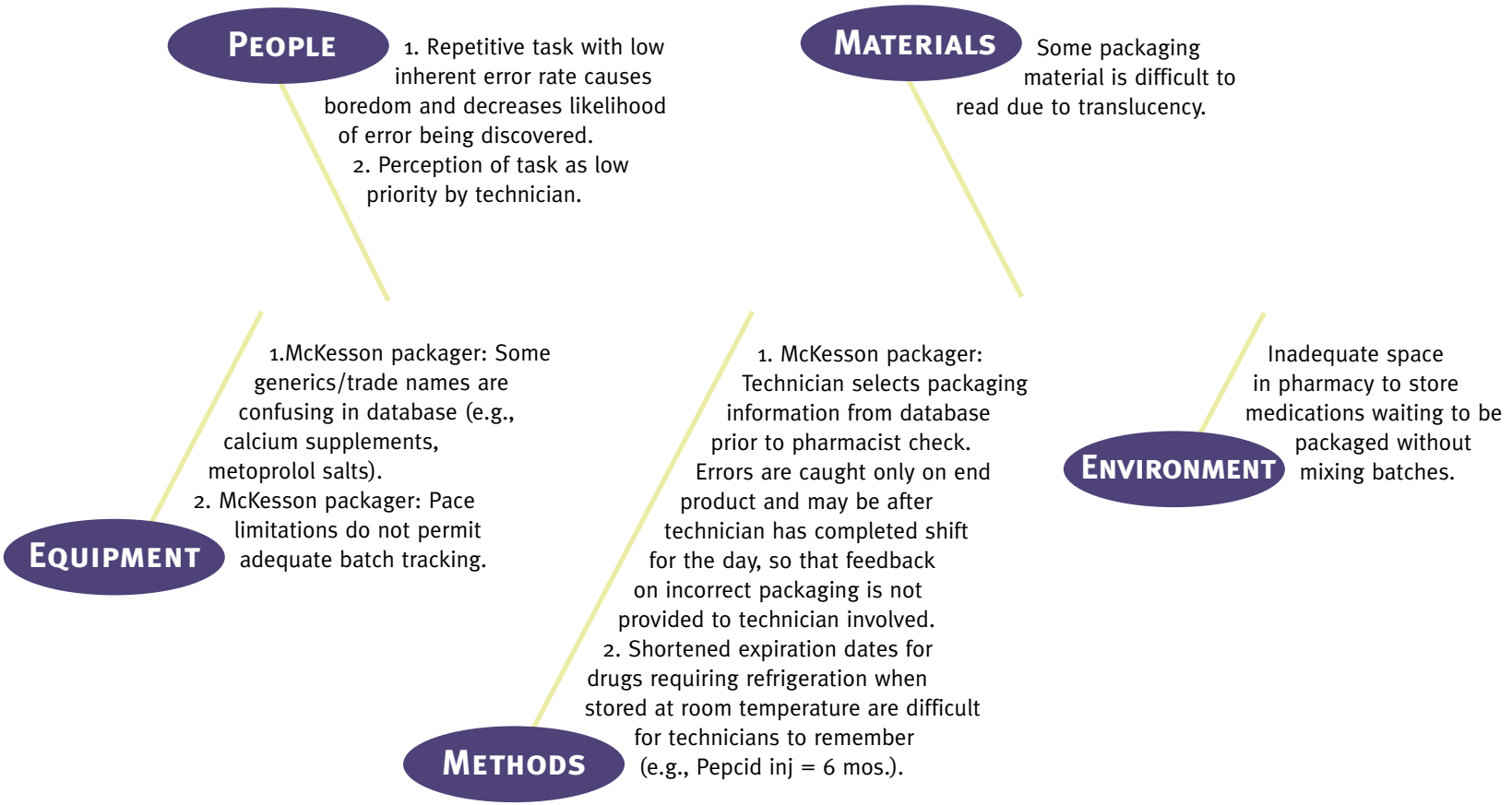


Attachment 3.C, Part VI

Cause and Effect Diagram (Hazard Score=320)

Prepared by: Agatha L. Nolen, M.S., D.Ph., FASHP Director of Pharmacy, Metropolitan Methodist/Northeast Methodist Hospitals

Effect: Technician Labels Package Incorrectly



Attachment 3.D

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