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AT RISK

Pathways **for** **MEDICATION SAFETY**SM

Strategies for
LEADERSHIP

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PATHWAYS FOR MEDICATION SAFETY: LOOKING COLLECTIVELY AT RISK

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Section 2 —

EXECUTIVE SUMMARY**Summary**

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.

The risk assessment tools in *Looking Collectively at Risk* can be applied by individuals on a daily basis and can also help direct the efforts of committees to reduce medication errors.

The tool is organized in a modular format to suit different organizations and individuals. This way, organizations at various points on the medication continuum can select the portions that are most relevant to them. Also, different health care professionals can focus on the sections that are customized for their perspectives.

Goals

- To raise awareness of error-prone processes in the medication delivery process.
- To maximize appropriate application of system redundancies.
- To build awareness of the medication error issue.

Context

This is one of three related tools designed to help hospitals reach the broader objective of

creating nonpunitive, systems-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.
- **Assessing Bedside Bar-Coding Readiness.** 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 move towards an effective implementation.

Contents

Section 2.1 provides a brief background on risk assessment and how it is currently applied to assist in medication error reduction.

Section 2.2 presents an overview of Failure Mode and Effects Analysis (FMEA) and the roles of the individuals in the five disciplines listed above as members of the team providing this analysis, including professional insights they might glean from the process.

Section 2.3 looks at risk using the Institute for Safe Medication Practices (ISMP) *Ten Key Elements of the Medication Use System*.

Questions for individuals to ask and subsequent actions to take are presented for the five disciplines to initiate constructive conversations exploring risk. In keeping with the modular design of the tool, a separate, customized set of questions is provided for each of the five primary audiences.

Section 2.4 provides several examples of ways that flow diagrams, charts, and case scenarios can be used to illustrate the system processes to explore risk. This section includes:

- Information on how to create a process flow diagram that can be used by an organization to identify the steps in the medication process.
- Case scenarios of possible errors that occur in your organization, how to use the medication process flow, and the ten key elements to identify where breakdowns in the system occurred and/or where system changes could be incorporated.

Process

1. **BUILD AWARENESS:** Help the organization recognize the role of risk assessment via staff education and information sharing. **Sections 2.1** and **2.2** can be useful in this regard. Obtaining and disseminating key articles listed in **Attachment 2.B** may also be of some assistance. The first *Pathways* tool—*Leading a Strategic Planning Effort*—may help in presenting tools to engage hospital leaders and managers in the process assessment project.
2. **BRAINSTORM:** Gather and engage a multidisciplinary team of clinical and nonclinical staff to creatively and openly share ideas. New directions are developed by asking questions to help team members view risk differently both in their own section of

health care delivery as well as in others.

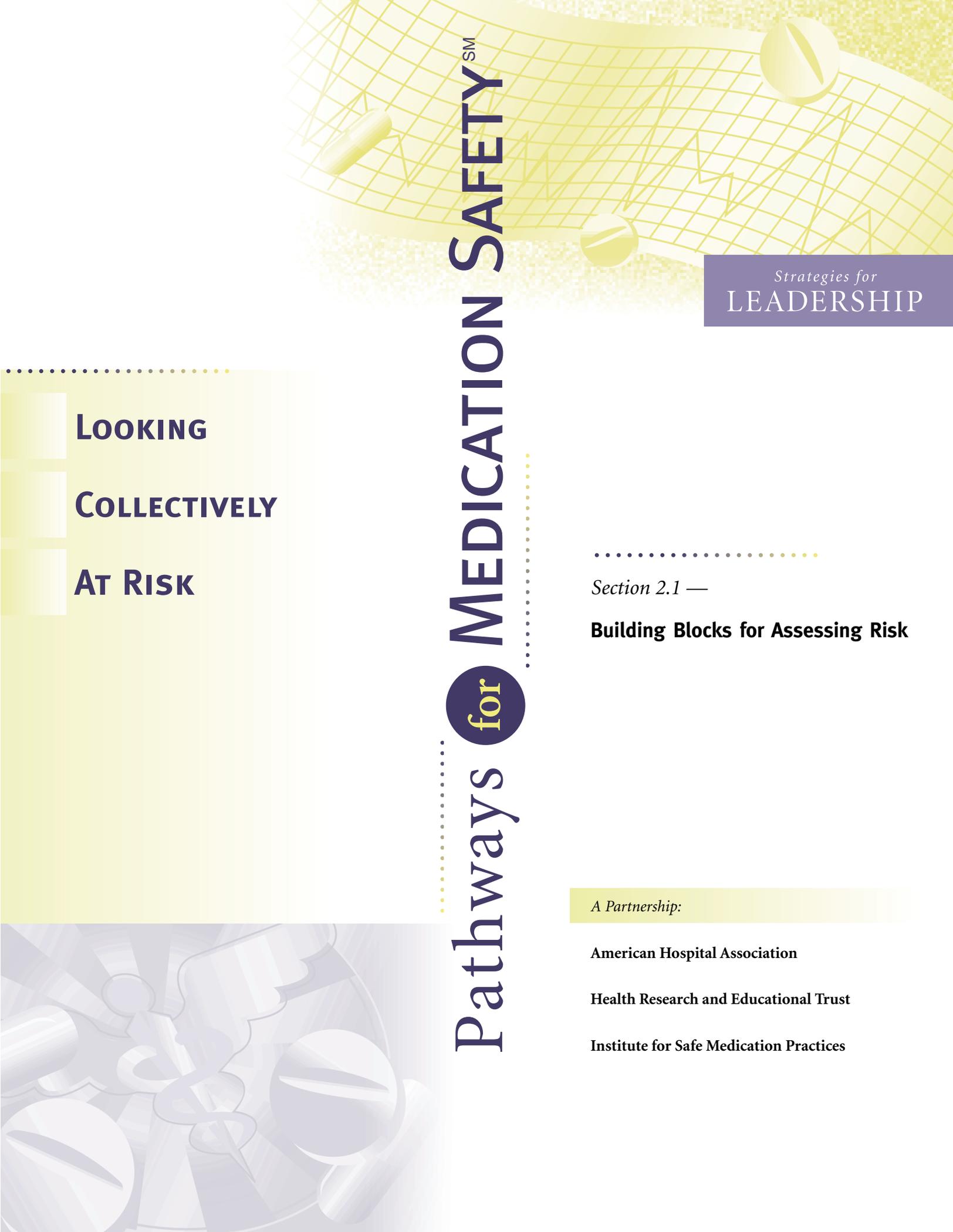
Section 2.3 provides questions relevant to five primary segments of the workforce.

3. **ESTABLISH PRIORITIES:** Prioritize candidate ideas for risk assessment.
4. **MOBILIZE TEAM:** Assemble a team of experts and practitioners who are knowledgeable about the candidate ideas. Include one outsider with a novice view of the process, as distance from a process can be very helpful.
5. **IDENTIFY RISKS:** Apply strategies contained in this document in **Section 2.4** to identify issues, causes, and failure modes.
6. **DEFINE SOLUTIONS:** Design a strategy to reduce failure modes and causes. **Section 2.3** provides suggested actions to generate improvements.
7. **ASSESS PROGRESS:** Evaluate the process used and determine what improvements have been made.

Outcomes

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

- Initiate process assessment to seek medication safety improvements at the institution.
- Understand what administrators/managers, physicians, nurses, pharmacists, and risk managers will offer and learn from participating in process assessment.
- Comprehend ISMP's *Ten Key Elements of the Medication Use System* and how they can be used in their daily practice and promoted throughout the organization to help identify and prevent risk.
- Use a flow diagram or flow chart of the medication process to identify risk assessment questions.
- Construct a case scenario of a medication error or near miss and use the ISMP's *Ten Key Elements* to identify breakdowns in the system.



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Section 2.1 —

Building Blocks for Assessing Risk

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Section 2.1 —

BUILDING BLOCKS FOR ASSESSING RISK

Introduction

The purpose of *Pathways for Medication Safety: Looking Collectively at Risk* is to provide a variety of tools to help five disciplines—administrators/managers, physicians, nurses, pharmacists, and risk managers—view and assess risk in their daily activities, while participating on committees and interacting with other health care personnel in their working environment.

These five disciplines are of course not the only groups of professionals or individuals involved in the medication use process. All health care personnel within hospitals impact risk assessment and can learn from tools presented in this document. It is hoped that this material, focusing on just a segment of the health workforce, will provide examples that lend themselves to adoption by the broader health care community, including patients.

Change Is Imperative

The release of the Institute of Medicine's (IOM) report *To Err is Human*,¹ in November of 1999, was a turning point in health care. The community of providers devoted to delivering medical care was faced with an opportunity to create, from within, systems that reduce medical error and improve patient care. Would the community step forward and acknowledge that there are deaths from medical errors? Would the community identify causes and support change in the name of improved

patient care? Or would it shy away from the results and continue practicing as usual? In a follow-up report, *Crossing the Quality Chasm*, the IOM Committee presented a set of principles for change with the caveat that “Trying harder will not work. Changing systems of care will.”²

Leadership: Promoting a Culture of Safety

Since the release of these reports, organizations have struggled to address two questions: how to initiate and sustain a process for improvement, and how to identify where improvements are needed. The first question has been discussed in numerous publications including a previous *Pathways for Medication Safety* tool called *Leading a Strategic Planning Effort*.³

Change must start with a commitment from the leaders, and safety must be incorporated into the organization's strategic plan. Certainly, if patient safety was not a regular agenda item before *To Err is Human*, it began appearing more frequently thereafter. From the executive suite to the front lines, a culture of safety was taking root—in some communities more quickly than in others.

Identifying Error-Prone Processes

Once a culture of safety is launched in an organization, the need for processes, tools, and teams to help identify where change is needed must be supported. There are many different

“Trying harder will not work. Changing systems of care will.”
— *Institute of Medicine*

Once a culture of safety is launched in an organization, the need for processes, tools, and teams to help identify where change is needed must be supported.

tools and approaches that can be employed to identify risk and to bring about common understanding of goals. Clarifying what the current situation *is* will be critical to understanding and moving toward what *can be*. Taking time to learn how to identify risk within an organization and what can be done to minimize risk will lead to improvement.

Health care organizations focused on improving patient safety must first identify, ascertain the causes of, and employ strategies to reduce risk. Everyone on staff in an organization has responsibility for risk assessment and, therefore, risk management. This includes involving patients in their care and seeking their help to identify risk in the system. Assessing risk in an organization is important to understanding and prioritizing areas of highest risk and for discovering which improvements will have the greatest overall impact on patient safety.

There are a number of methods that have been created, adapted, and employed in health care to assess and minimize risk including root cause analysis (RCA) of errors, near misses, and sentinel events; clinical risk mapping; human factors analysis; threat and error management model; self-assessment surveys; and failure mode and effects analysis (FMEA).⁴ The application of these and other methods should allow for culture-specific process mapping and analysis.

Adaptation and Application

It's not surprising that the health care community looks outward for opportunities to address internal challenges. In doing so, health care has begun to adapt best practices from manufacturing, including RCA, FMEA, ISO 9000, Six Sigma, and Crew Resource Management.

Because of regulation, some tools have been more successfully integrated than others have. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has integrated RCA and FMEA into its patient safety standards. RCA—an after-the-fact process that teaches us what went wrong—can be considered one end of the spectrum while FMEA—a prospective look at what could go wrong—is the other.

The basic definition of the RCA process is simply a tool designed to help:

- describe *what* happened during a particular occurrence;
- determine *how* it happened;
- understand *why* it happened; and
- recommend actions to *prevent* it from happening again.⁵

Root cause analysis is an important process when an error or sentinel event has occurred. However, providers and clinicians realize that when they're dealing with human life, a prospective strategy is preferred. FMEA is a proactive tool that can assist organizations in identifying, preventing, or minimizing the severity of potential or actual risks that threaten patient safety and organizational liability. It has been widely accepted by many health care organizations. Because of its proactive nature, FMEA and other process assessment tools are the focus of **Looking Collectively at Risk**.

Getting Started and Spreading the Word

Everyone on the staff of an organization has responsibility for risk assessment: it is not just a task for the risk manager or the role of only one committee. A good risk assessment program begins by orienting all the staff members to the organization's commitment to safety and by outlining their roles to help assess

risk either formally as a member of a committee or task force or individually during their daily practice. Assessing risk can be done in many different ways, and the approach to risk assessment may vary depending on the individuals' roles in an organization.

The goal of this tool is to help outline several methods that can assist in facilitating assessment effectively. For example:

- Administrators or managers may view the organization more globally and look at how all medications are ordered and administered in the entire hospital or for specific patient units.
- Physicians may come to understand how their workaround of a computerized prescriber order entry (CPOE) system affects those who respond to their directions.
- Frontline nurses may view their job responsibilities as a process—from medication ordering to administration for a particular patient.
- Pharmacists may realize how the lack of accessibility to patient information can lead to delays in treatment and possibly medication errors.
- Risk managers may see where staff teamwork is fractured in such a way that mishandling of medications could result.

No matter what the perspective, the important aspects are that the medication process is a team effort and that all participants of that team must continually assess the process for risk so they can recommend changes in the system.

The following text provides strategies for empowering staff members in risk assessment. Readers who are not familiar with Failure Modes and Effects Analysis should start with **Section 2.2**. Others can skip directly to **Section 2.3**. Read the introduction on the key elements of medication use safety and then find the relevant set of questions, i.e., for administrators/managers, physicians, nurses, pharmacists, or risk managers.

Finally, move on to **Section 2.4** for an example of how process diagrams and case scenarios can help uncover risk.

Endnotes

1. *To Err is Human: Building a Safer Health System*, eds. Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson. (Washington: National Academy Press, 1999). <http://www.nap.edu/books/0309068371/html>. Accessed October 25, 2002.
2. Committee on Quality of Health Care in America, Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. (Washington: National Academy Press, 2001). <http://www.nap.edu/books/0309072808/html>. Accessed October 24, 2002.
3. American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices. *Pathways for Medication Safety: Leading a Strategic Planning Effort*. (Chicago: Health Research and Educational Trust, 2002).
4. Fay Rozovsky, Jeffrey Driver. *Patient Safety Tools in Clinical Risk Management—Module III of the American Society for Healthcare Risk Management*. (Chicago: American Society for Healthcare Risk Management, 2002).
5. ABS Group. *The Root Cause Analysis Handbook: A Guide to Effective Incident Investigation*. (Knoxville, TN: ABS Group, 1999).



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Section 2.2 —

Failure Mode and Effects Analysis

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It is important to not only identify the locations and mechanisms of potential failures but also to assign the effects, severity, and probability of the failure as well as the actions to reduce or eliminate failures.

Section 2.2—

FAILURE MODE AND EFFECTS ANALYSIS

Effective July 2002, the JCAHO requires health care facilities to select at least one high-risk process for risk assessment each year (Standard LD.5.2). One of the processes the JCAHO cites that involve risks or may result in a sentinel event (PI.4.2) is medication use.¹ FMEA is the tool that has the potential to be an integral part of any risk assessment and, therefore, the risk management process.

The Failure Mode and Effects Analysis (FMEA) process is a “systematic method of identifying and preventing product and process problems before they occur.” FMEAs focus on identifying and removing defects, enhancing safety, and increasing customer satisfaction.²

Several different terms have been used to identify this concept, including Failure Mode Effect and Criticality Analysis (FMECA), which has been used by product development engineers, particularly in the aerospace industry, because of the lack of data but the abundance of expertise during product development.³ The Veterans Affairs’ National Center for Patient Safety uses the term Healthcare Failure Mode and Effect Analysis™ (HFMEA) in referring to its risk assessment program.⁴

In this *Pathways* document, FMEA will be the general term used to describe these related risk assessment processes.

Process Assessment and Teamwork

The first step in preparing for an FMEA is to gather a multidisciplinary team to conduct the process. It is important not only to identify the locations and mechanisms of potential failures but also to assign the effects, severity, and probability of the failure as well as the actions to reduce or eliminate failures. For this reason the team should include members from at least the medical staff, nursing, pharmacy, risk management, and administration.

Everyone on the team need not be close to the process being examined. Indeed, many veterans of FMEA suggest that an “outsider” to the process is very important. Frontline staff—or those on the “sharp end”—are important components as they have the knowledge and expertise to critically evaluate the elements that contribute to the occurrence of a system failure.

Other disciplines—such as information technology (IT) and management—can provide input into the processes and give support to the actions that must be taken to reduce the risk. Whatever the system(s), meaningful, organization-wide processes that identify and promote response to adverse patient occurrences are the backbone of an effective risk management program.

The purposes and value of any system must be clearly identified for *all* members of the health

care team. Below are examples of team member input into the processes of FMEA:

- Pharmacists, nurses, and physicians could provide subject matter expertise on a medication topic.
- Clinicians who have frontline or daily responsibility for the processes could contribute explorations of what might happen by defining failure modes.
- Clinicians working with information technologists, biomedical engineers, human factors experts, and others could identify the causes of failure.
- All team members would be involved in the process of identifying the effects on the patient of a failure, the severity of failure should it occur, and the probability of the failure occurring.
- Clinicians, IT, managers, risk managers, and others could be responsible for crafting an action to prevent the failure.
- Representative members of various groups could monitor progress of the learning after the assessment.

However, the roles of various participants are not exclusive; multiple parties may have an interest in or experience with another discipline's role in the process. For example, physicians, nurses, and pharmacists all obtain patient histories. It may be useful for a trained facilitator to help guide this process.

Evaluation Tools

The intent of this section of *Looking Collectively at Risk* is not to review the entire FMEA process. Instead, this section provides insight into what each discipline—administrators/managers, physicians, nurses, pharmacists, and risk managers—can contribute to and learn from the process. Sample examples of different approaches to perform actual FMEA's can be found in the following two attachments: **Attachment 2.A**

details an FMEA on of the use of intravenous patient-controlled analgesia (PCA). In **Attachment 3.A** a slightly different approach is provided on how to explore the impact of bar coding in a hospital. These two examples illustrate how the questions and actions provided in *Looking Collectively at Risk* can be incorporated in the process resulting in different visual products but similar learning experiences for the evaluation team.

Administrators'/Managers' Role

Risk assessment should play an important role in the daily activities of everyone from senior administrators to frontline supervisors. To assess risk, managers must know what to look for and what questions to ask. One way to learn the risk assessment process is to participate in an FMEA being conducted within the organization. FMEAs are often performed for new medications, procedures, or devices and may be conducted at the committee level or as a task force or committee subgroup.

A good place to start may be with the Pharmacy and Therapeutics Committee. This committee will often perform an FMEA on a new medication or treatment that is being considered in the organization. If the FMEA were done on a new medication, administrators and managers could learn a great deal about the processes in their organization. For example, they would:

- Learn the processes and subprocesses involved, from medication prescription to administration.
- Hear firsthand from frontline clinicians what could go wrong in their current system and why.
- Appreciate some of the effects to patients when a system breakdown occurs.
- Participate in suggesting actions or system changes that could be made to prevent something from going wrong.

Administrators and managers could use the information learned from the FMEA to support changes that should be made in the system. They will also be in a better position to help educate other administrative, medical, and health care staff on the proper safeguards that should be followed and to seek their help in promoting these safeguards. Having a better understanding of the processes in their system, senior administrators will have a better context for explaining financial considerations for system safeguards to board members. Finally, administrators and managers will become much more knowledgeable when they are discussing errors, their causes, and their prevention to all hospital employees.

Physicians' Role

Physicians are often in the position to help advocate for system change as well as bring about change from their example. The problem in most health care settings is that the medical staff may not be fully informed of why modifications are needed and hence will not be supportive of instituting the change themselves, let alone help enforce the change throughout the organization. This is not a case of stubbornness or disregard for safety, but of a lack of information on the reasons for altering the status quo.

This is why the medical staff's participation in risk assessment is important. Members of the medical staff are short on time as are all health care professionals, but they should still help in the organization's commitment to prevent errors. It is important that administrators seek—and possibly offer incentives for—physicians' participation in risk assessments. Only through participation in FMEAs will members of the medical staff truly appreciate the processes that occur “behind the scenes” to provide care to their patients.

Consider the example of a new medication being discussed for use in the hospital. The educational benefits for physicians who participate in FMEAs is similar to that of administrators and other managers but it's from a different perspective. By taking part in the assessment physicians will:

- Gain a better appreciation of the many steps involved, from medication prescription to administration.
- Hear firsthand from frontline clinicians what could go wrong in the current system and why, as well as also offer some of their experience in system breakdowns.
- Participate in discussions regarding the effects on patients when a system breakdown occurs.
- Offer their experiences in other organizations, which could help in instituting actions or system changes that could be made to prevent errors.

The most important aspect of involving physicians and other medical staff in FMEAs is that they become engaged in helping make changes in the organization. Participants in the process will learn firsthand what steps occur after a medication is prescribed for a patient. The experience of exploring risk with their colleagues will illustrate that certain checks and balances fail to occur as medication is being delivered because of inadequacies in the system—not the staff—that were until that time unidentified. The individuals will then be in a better position to offer valuable suggestions for system improvement and will advocate the change to their fellow practitioners.

Nurses' Role

The nurses' role in risk assessment is extremely important. This is especially true for medications in an acute care setting

because nurses are often the ones who administer medications to patients. It would be difficult to perform any FMEA on medications without nurse participation in the process. Frontline nurses who participate in a medication FMEA will:

- Gain a better appreciation of processes that they may not be directly aware of or involved in (such as procurement, preparation, and profiling of medications).
- Acquire more knowledge in the failure modes for the processes that they may not participate in as well as add their experiences and expertise in failure modes that may occur.
- Help identify the causes of system breakdowns in their departments as well as appreciate system causes of errors in pharmacy or other departments.
- Evaluate the effects, severity, and probability of errors.
- Offer insight into system changes that are needed to prevent errors.

When frontline nurses participate in FMEAs, the experience and knowledge they gain on the entire medication use process is invaluable for their everyday practice. Nurses will gain a better appreciation of the needs of both prescribers and pharmacy staff in the medication use process. The prevention of medication errors is a team effort, and all members of the team must be cognizant of the entire process. In support of that philosophy and to further incorporate the nursing perspective, FMEA teams should also include nurse assistants, nursing aides, unit secretaries, and so on, as needed.

Pharmacists' Role

Pharmacists are often assumed to be the “guardians” in ensuring that medication errors do not occur. This expectation is unrealistic, because avoiding error is a health care team

effort. It has, however, been suggested that pharmacists should assume a leadership role in implementing safe medication use efforts in their organization. There are many ways that pharmacists should assume this responsibility, but one that is paramount is active participation in medication-related FMEAs. The pharmacist and other pharmacy staff who participate in the assessment process will:

- Explain the important processes and subprocesses of medication use from prescription through administration.
- Participate in identifying failure modes throughout the entire medication process, especially in information that should be available to the prescriber and nurse, as well as describing the steps in the process that occur after the medication order is transferred to pharmacy.
- Offer possible causes for medication errors because of breakdowns in the prescription-to-administration process.
- Identify effects, as well as their severity and probability, when a system failure occurs.
- Offer suggestions—along with all team members—for actions that should be taken to prevent medication errors.

Pharmacists are an integral part of any medication safety assessment process. They not only offer information—as do the other disciplines discussed here—they can also expand their knowledge through participating in this initiative. Pharmacy participation should include frontline staff, pharmacists, pharmacy technicians, and pharmacy support staff. It is important to have multilevel involvement so that all system enhancements are discussed and identified.

Risk Managers' Role

The risk manager's responsibility as part of any risk assessment team is to address the types of issues that typically arise in claims and

litigation. In assuming this position, the risk manager is well prepared to facilitate the mapping process from one stage to the next. Besides asking pertinent questions, as well as mapping out processes for the team, the risk manager's experience with loss prevention can contribute to the brainstorming of actions to reduce the failure mode. As risk managers contribute to the assessment process, they will:

- Investigate and analyze claims and litigation experience to identify what might happen and how and use that experience to identify possible effects.
- Prevent losses by identifying actions to reduce the failure mode.
- Monitor compliance by employing appropriate standards (JCAHO, HIPAA, CMS, ISMP, organizational policies and procedures, staffing, patient education, and maintenance tools) and by using the actions agreed upon by the team to do so.
- Evaluate effectiveness of the actions established to reduce the failure mode.
- Communicate findings of monitoring and evaluation.
- Improve facilitation and follow-up skills.
- Gain purposeful access to subject experts and expand their knowledge of clinical operations.
- Establish themselves as team players for safety.

Endnotes

1. Joint Commission on Accreditation of Healthcare Organizations, *Hospital Accreditation Standards* (Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations, 2002).
2. Robin E. McDermott, Raymond J. Mikulak, and Michael R. Beauregard, *The Basics of FMEA* (Portland, OR: Resources Engineering, 1996).
3. Ellen Williams and Ray Talley, "The Use of Failure Mode Effect and Criticality Analysis in a Medication Error Subcommittee," *Hospital Pharmacy* 29 (1994): 331-37.
4. VA National Center for Patient Safety, *Healthcare Failure Mode and Effects Analysis Course Materials* (Ann Arbor, MI: VA National Center for Patient Safety, 2002). www.patientsafety.gov/HFMEA.html. Accessed October 22, 2002.

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Section 2.3 —

**Use of the Ten Key Elements
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Section 2.3—

USE OF THE *TEN KEY ELEMENTS* TO ASSESS RISK

Background

In the spring of 2000, the ISMP in cooperation with the American Hospital Association (AHA) sent a medication safety self assessment to every hospital in the United States.¹ The purpose of the self assessment was to help organizations assess the safety of medication practices in their facilities, identify opportunities for improvement, and eventually compare their experiences with those of demographically similar hospitals.

These *Pathways for Medication Safety* tools were developed using results of these aggregate data. A multidisciplinary group of administrators/managers, physicians, nurses, pharmacists, and risk managers completed the assessment at each organization.

The *ISMP Medication Safety Self Assessment*^{TM 2} is divided into sections that represent the key elements of medication use safety:

1. Patient information.
2. Drug information.
3. Communication of drug orders and other drug information.
4. Drug labeling, packaging, and nomenclature.
5. Drug standardization, storage, and distribution.
6. Medication delivery device acquisition, use, and monitoring.
7. Environmental factors.
8. Staff competency and education.

9. Patient education.
10. Quality processes and risk management.

Assessing Risk with the *Ten Key Elements*

This section illustrates how these elements can be used to evaluate risk from the perspective of five distinct disciplines: administrators/managers, physicians, nurses, pharmacists, and risk managers. Each review contains questions that individuals should answer and actions they may take to ensure medication safety within their institutions.

The medication use process is an interdisciplinary process, and the entire team must be involved for long-lasting improvement in the system. This includes involving patients in the process. For this reason it should not be assumed that looking at the system should be different for each discipline, but that each professional group may view the same information from its unique perspective.

For example:

- Administrators may ask if the information system in the hospital is adequate to provide patient information to all employees and medical staff when they need it.
- Nurses may ask if the information they are reviewing is adequate for a particular patient.
- Pharmacists may ask if they can seamlessly obtain laboratory information for a patient who may need a dose adjustment of renally excreted medications.

Members of each discipline can use the following lists to evaluate the key elements in everyday practice. Practitioners can become familiar with these questions and use them daily to assess risk when they're ordering, dispensing, or administering medications. The questions may also be used in a group setting for individual disciplines to share their thoughts on risk assessment for the key elements. For example:

- Administrators and managers may use these questions when they're making department visits to query employees on safe system changes that may be needed for their hospital. The use of administrative "walkarounds" has been promoted as a way for administrators and managers not only to promote their commitment to safety but to evaluate how their efforts for improvement are working. See **Attachment 1.B** for information on this process.
- The questions could be used as checklists for process improvement projects and as information to give to all current and new employees. The checklists should be used to continually evaluate the medication system in the hospital.
- Employees will be reminded of the administrators' commitment to safety if these questions are routinely asked by their managers. This effort will indicate to staff that medication safety is an important element in the hospital's strategic plan.
- The charting processes outlined in **Section 2.4** can also be used to help

answer questions when the hospital is performing an RCA on a near miss or actual error. Staff could ask:

- "What if I had more patient information?"
- "What if I had up-to-date and immediate access to drug information on this medication?"
- "What if the medication order was entered into a computer with alerts and rules to prevent overdosing or automatically check the patient's weight and height with the dose?"

The *ISMP Medication Safety Self Assessment™* contains 194 questions within the *Ten Key Elements*. The following lists are not comprehensive, but they should help get each discipline to ask consistent questions when the medications system in their hospital is reviewed. Individuals may develop more or different questions to ask under each category. But in the long run, all disciplines will be asking basically the same type of questions to improve the medication system within their environments.

Endnotes

1. Judy L. Smetzer, "Preliminary Key Findings from the ISMP Medication Safety Self Assessment™ Will Be Used to Determine Provider Training Needs," (article in development).

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Section 2.3—

EVALUATION TOOL FOR ADMINISTRATORS/MANAGERS

The questions on the following pages should be asked when you're evaluating the safety of medication use within your organization. They should be used as points of discussion when you participate in a multidisciplinary review of the medication use process and serve on hospital committees that set standards and policies for improving patient safety (Pharmacy and Therapeutics, Quality Committee, and so on).

*These questions may also be used to stimulate discussion regarding day-to-day safe practices when you meet with frontline staff during safety (executive) walkarounds. View **Attachment 1.B** for information on one walkaround program.*

The recommendations that follow are designed to standardize quality processes and to reduce the risks that are commonly associated with medication use. Administrators should fully support these actions and promote their acceptance with hospital employees, the medical staff, fellow hospital administrators, and the board of trustees.

Evaluation Tool for Administrators/Managers

● KEY ELEMENT 1: PATIENT INFORMATION

To guide appropriate drug therapy, health care providers need readily available demographic and 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.

Questions to Consider

- Is bar-coded medication administration used on all patients?
- Is the pharmacy computer system interfaced with the laboratory system?
- Does the pharmacy computer system, or CPOE system, contain hard stops so it won't process any medications that a patient is allergic to?
- Do pharmacists routinely adjust medication doses for patients with renal or liver impairment?
- Do all patients have bar-coded name bracelets and colored allergy bracelets?
- Does the IT system provide physicians, nurses, and pharmacists with easy and electronic access to all patient information (history, allergies, laboratory values, diagnostic tests, medications, and so on) at any terminal with password entry?
- Does patient information include both inpatient and outpatient medications and laboratory results?

- Are allergies clearly visible on all order forms, medication administration records (MARs), and patient charts?
- Can physicians and nurses readily view a patient's current medications by accessing the pharmacy system on any patient unit?

Suggested Actions

- Create a strategic information technology plan that includes electronic access to patient information for all health professionals caring for the patient.
- Support policies and procedures that help physicians, nurses, and pharmacists share and document patient information.
- Implement a system-wide CPOE that is interfaced with pharmacy and point-of-care bar-coded drug administration, if feasible.

Evaluation Tool for Administrators/Managers● **KEY ELEMENT 2: 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, MARs, and regular clinical activities by pharmacists in patient care areas.

Questions to Consider

- To the extent possible, are pharmacists available on patient care units to assist prescribers with medication selection, answer questions for nurses, and participate in patient education?
- Except in emergencies, does a pharmacist screen all medication orders before they are administered?
- Do the pharmacy computer system and/or the CPOE system contain software to alert pharmacists and prescribers of drug interactions, minimum and maximum dose checks, disease state dosing modifications, etc.?
- Are special precautions (dosing charts, auxiliary labels, protocols, preprinted order sets, and so on) used for high-alert medications and/or high-alert treatments and procedures?
- Is the software for computer alerts and checks updated at least monthly?
- Are online drug information resources (such as MICROMEDEX) available on all terminals in the hospital?
- Do key personnel have access to the Internet so they can obtain timely drug information when necessary?
- Is there a process to evaluate and update all reference texts, medication dosing charts, and other drug information on an annual basis?
- Is there a process to evaluate all preprinted order sets and protocols before they are used? Is there a process to update this information at least annually?

Suggested Actions

- Support system-wide online drug information access throughout the hospital.
- Ensure that proper staffing exists to have pharmacists review medication orders before they are dispensed.
- Support the need for staff and software to maintain updated drug information resources.
- Support a clinical pharmacy program with the goal of having pharmacists available on patient units to follow high-risk patients or patients receiving high-risk medications.

Evaluation Tool for Administrators/Managers

● KEY ELEMENT 3: COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION

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

Questions to Consider

- Does the pharmacy provide the MAR for nurses (pharmacy computer-generated MAR)?
- Am I supportive of any plans to implement a CPOE?
- Do we have and do I support a policy for a clear and effective path that staff can follow to resolve conflicts stemming from disagreement regarding a medication order?
- Am I supportive of the hospital drug formulary?
- Are protocols and standard order sets used in the hospital?
- Are verbal orders accepted from prescribers who are in the hospital? Is there a policy and procedure on the safe acceptance of verbal orders?
- Does the hospital have a list of dangerous abbreviations that should never be used?

Suggested Actions

- Support a strategy for CPOE. Recommend and support the use of protocols and standard order sets by the medical staff.
- Attend Pharmacy and Therapeutics Committee meetings and support their decisions.
- Support policies and procedures for the safe communication of drug information.
- Do not allow unsafe communication (such as dangerous abbreviations, nonemergency use of verbal orders) in the organization.
- Meet privately with medical staff, if needed, to support safe communication within the hospital.
- Review publications that offer recommendations on safe communication and share the information with the medical staff.

Evaluation Tool for Administrators/Managers

● KEY ELEMENT 4: DRUG LABELING, PACKAGING, AND NOMENCLATURE

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

Questions to Consider

- Is information on unsafe labeling and packaging shared with the Pharmacy and Therapeutics Committee?
- Are decisions on what medications to stock in the hospital made with safety in mind?
- Do IT personnel take into account safety in displaying or printing dangerous medication designations on computer screens and printed material?
- Is auxiliary labeling used to decrease the possibility of confusion with look-alike and sound-alike drug names as well as confusing labeling of products?
- Do I support the use of different manufacturers, even if the cost is higher, to help differentiate look-alike and sound-alike products or dangerous labeling?
- Are all medications labeled (even in the OR) until the time they are administered?

Suggested Actions

- Support pharmacy decisions on changing drug manufacturers, even if against purchasing group bids, when a safety issue is identified.
- Inform all employees, including the medical staff, that medications must always be properly labeled.
- Ensure that pharmacy and IT review medication presentation on computer screens and printed material for safety.

Evaluation Tool for Administrators/Managers

● KEY ELEMENT 5: 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 drugs from the pharmacy in a timely fashion. Whenever possible, health care organizations also should use commercially available solutions and standard concentrations to minimize error-prone processes such as IV admixture and dose calculations.

Questions to Consider

- Are all doses of medications in the hospital available only in unit-dose form?
- Does pharmacy purchase commercially available premixed IV solutions and prefilled syringes whenever they are available?
- Are sample drugs permitted within the hospital? Are pharmaceutical representatives allowed in patient care areas?
- Are concentrated electrolytes properly stored inside the pharmacy?
- Does your organization have a list of high-alert medications that is known by physicians, nurses, and pharmacists? Are these medications properly stored inside the pharmacy? If they are stored outside the pharmacy, are they secured and in limited quantities? Except for emergencies, are all orders screened by pharmacy before they are obtained?
- Are all neuromuscular blockers properly labeled as “paralyzing agents” and segregated from other drug storage? If neuromuscular blockers are stored outside the pharmacy or OR, are the type and quantities limited?
- Does your organization have established time frames for medication delivery when stat or urgent medications are needed? Are these times adhered to?
- Are dosing windows used to standardize drug administration times?
- Is nonpharmacy staff allowed in the pharmacy when a pharmacist is not physically present in the hospital?

Suggested Actions

- Support the purchase of commercially available premixed IV solutions and prefilled syringes.
- Prohibit the use of sample medications in the hospital.
- Support staffing requirements and automation to ensure the timely and safe availability of medications when they are needed.
- Ensure that high-alert medications are safeguarded and that known safety requirements for storage, availability, and labeling are followed.

Evaluation Tool for Administrators/Managers● **KEY ELEMENT 6: MEDICATION DELIVERY DEVICE****ACQUISITION, USE, AND MONITORING**

To avoid errors with drug delivery devices, health care organizations must assess the devices' safety before purchase; ensure appropriate fail-safe protections (such as free-flow protection, incompatible connections, and safe default settings); limit variety to promote familiarity; and require independent double checks for potential device-related errors that could result in serious patient harm.

Questions to Consider

- Is there a policy that all pump settings for high-alert medications must be checked by two independent practitioners?
- Do all infusion devices used in the hospital have free-flow protection?
- Do we limit the type of infusion devices and medication equipment used?
- Is all tubing for the administration of medications, nutritional products, irrigations, etc., properly labeled?
- Does the hospital have an interdisciplinary team that reviews the purchase of all infusion devices and medication supplies?

Suggested Actions

- Support the use of the newest safety features in automation.
- Prohibit the purchase of multiple types of infusion pumps or pumps that allow free flow.
- Ensure that staffing can accommodate the double check of pump settings for high-alert medications.
- Do not approve the purchase of new equipment or devices unless an interdisciplinary group that includes frontline practitioners has reviewed it for safety.

Evaluation Tool for Administrators/Managers
● KEY ELEMENT 7: ENVIRONMENTAL FACTORS

Environmental factors such as poor lighting, cluttered work spaces, noise, interruptions, high patient acuity, and nonstop activity contribute to medication errors because health care providers are unable to remain focused. Staffing pattern deficiencies and excessive workloads also underlie a broad range of errors and present unique challenges to health care organizations today.

Questions to Consider

- Are all critical work environments monitored for safety? For example, are they uncluttered and clean with minimal distractions, and do they provide adequate lighting?
- Does pharmacy have adequate space to safely prepare and dispense medications?
- Are critical workload shifts reasonable with adequate rest between shifts and scheduled breaks and lunches?
- Are areas where medications are stored outside the pharmacy secure, and do they allow enough space to properly store and retrieve medications?

Suggested Actions

- Monitor areas within the hospital where medications are stored, prepared, and dispensed to ensure a safe environment.
- Review human resource policies and current practice to ensure adequate staffing patterns.

Evaluation Tool for Administrators/Managers

● KEY ELEMENT 8: STAFF COMPETENCY AND EDUCATION

Although staff education is a weak error-reduction strategy by itself, it can play an important role when it's 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, nonformulary medications, high-alert medications, and medication error prevention.

Questions to Consider

- Are orientation programs for personnel involved in medication prescribing, dispensing, and administration adequate, and do they take place in all areas where the medication use process is performed (patient areas, pharmacy, etc.)?
- Are all employees trained in the safe use and storage of medications within the hospital?
- Do all personnel involved in the medication use process have access to new drug information?
- Is the professional staff trained in responding to a medication error?

Suggested Actions

- Support a comprehensive training program for all staff on safe medication use—orientation for new hires and ongoing education for staff clinicians.

Evaluation Tool for Administrators/Managers● **KEY ELEMENT 9: 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.

Questions to Consider

- Are all staff members instructed to follow up on all patient and caregiver questions on medications?
- Are patients offered an opportunity to speak with a pharmacist about their medications?
- Does a program exist to educate patients and their caregivers that they are an important part of safe medication use?

Suggested Actions

- Support a program for pharmacist counseling of high-risk patients or patients receiving high-risk medications.
- Support programs to encourage patients to identify themselves to hospital personnel and ask questions about their medications.

Evaluation Tool for Administrators/Managers

● KEY ELEMENT 10: QUALITY PROCESS AND RISK MANAGEMENT

Health care organizations 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, to stimulate productive discussions, and to identify effective system-based solutions. Strategically placed quality control checks are also 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.

Questions to Consider

- Is the culture in the hospital blame-free when it involves committing an error? In the post-event process, is there a policy that prohibits disciplinary action against practitioners who make an error, unless malicious or illegal activity is present?
- Does a policy exist for disclosure of all medication errors that reach the patient?
- Are staff, administrators, and the board aware that error rate reporting is not used for benchmarking comparisons or as employee competency tools?
- Is psychological counseling provided for employees who are involved in serious errors that cause patient harm?
- Does the organizational strategic plan contain medication safety objectives?
- Are incentives and positive feedback provided for individuals who report errors?

Suggested Actions

- Create and support a blame-free environment and allow for the open discussion of error for the education of the staff.
- Do not use error reporting to establish rates or to make comparisons between units or individuals.
- Provide psychological counseling for employees who are involved in serious error that causes patient harm.
- Establish medication safety objectives in the organization's strategic plan. (Refer to *Leading a Strategic Planning Effort* for more information on this process.)
- Conduct patient unit rounds to ask employees about safety issues they may have concerns with.

Section 2.3—

EVALUATION TOOL FOR PHYSICIANS

The following questions should be asked when you're assessing medication safety in your daily practice. They should also be used as points of discussion when you participate in interdepartmental or multidisciplinary review of the safety of the medication use process in your organization (participation on the Pharmacy and Therapeutics Committee, Quality Committee, and so on).

The recommendations that follow are actions you should perform daily or promote to hospital employees, other medical staff, and hospital leaders to enhance safety within the organization.

Evaluation Tool for Physicians

● KEY ELEMENT 1: PATIENT INFORMATION

To guide appropriate drug therapy, health care providers need readily available demographic and 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.

Questions to Consider

- If I'm using an electronic order entry screen, am I immediately notified of a potential safety issue with the medication that I prescribed?
- Do I have access to patient laboratory, medication, and other information to make a decision on a change in medication or to add a new medication?
- Do paper order forms, if used, contain prompts for entering allergies, height, weight, and disease conditions?
- Are allergies clearly visible on all order forms, MARs, and patient charts?
- Do I have access to outpatient medications and laboratory results?
- Do I always list allergies and other patient information that I may be aware of (comorbid conditions, height, weight) on all initial medication order forms or in the electronic record?
- Do I include indications on medications, especially for look-alike and sound-alike medications?

- Do I inform nursing personnel and pharmacy of any changes in patient information that I may be aware of?
- Can I access the current online pharmacy profile on the patient care unit?
- Do I have access to the hospital information system from my office? Can I enter orders from my office?

Suggested Actions

- Champion the use of a computerized order entry system.
- Always place allergies and other important patient information on each initial order sheet.
- Include indications for medications to guard against inadvertent dispensing or administration of look-alike or sound-alike medications.

Evaluation Tool for Physicians● **KEY ELEMENT 2: 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, MARs, and regular clinical activities by pharmacists in patient care areas.

Questions to Consider

- To the extent possible, are pharmacists available to me to assist with medication choices, answer questions, and participate in patient education?
- Does the MAR contain the same information that is on the pharmacy profile?
- Do I order medications only on the hospital formulary unless it is medically necessary?
- Are special precautions (dosing charts, auxiliary labels, protocols, preprinted order sets, etc.) available to me for high-alert medications and/or high-alert treatments and procedures?
- Do I receive a copy of the *ISMP Medication Safety Alert* and other publications to keep myself informed about medication safety issues?
- Does the hospital drug formulary contain very little duplication of therapeutically equivalent products?
- Do I have access to drug information on any computer terminal in the hospital?
- Does each nursing unit have up-to-date texts of drug information when I need it?
- Do I have ready access to the medications that are on the hospital formulary?

Suggested Actions

- Prescribe available approved facility formulary medications whenever possible.
- Support the use of protocols and dosing guidelines for high-alert drugs (such as chemotherapy, opiates, or anticoagulants).
- Champion the availability of clinical pharmacists on patient care units.
- Support the decisions of the Pharmacy and Therapeutics Committee.
- Promote systems that ensure ready access to drug information throughout the facility.

Evaluation Tool for Physicians

● KEY ELEMENT 3: COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION

Because failed communication is the cause of many errors, health care organizations must eliminate communication barriers between health care providers and standardize the way that orders and other drug information is communicated.

Questions to Consider

- Does the CPOE system contain alerts for unsafe orders?
- Do prescribers enter orders directly into the CPOE that is linked with pharmacy and my MAR?
- Is there a hospital-wide policy and procedure to resolve conflicts on potentially unsafe medication orders?
- Is the nursing MAR easy to read and follow?
- Do I use protocols and standard order sets whenever they are available?
- Do I give verbal orders for high-risk medications and chemotherapy?
- Do I ask nurses, pharmacists, and others taking verbal orders to repeat back to me the spelling of drug names and doses?
- Do I use any dangerous abbreviations and dose expressions in any of my written orders, notes, or progress notes?
- Do I notify nursing personnel when I write or enter a new order and ask if any clarification is needed before I leave the unit?

Suggested Actions

- Never use dangerous abbreviations or dose expressions in any written communication.
- Never use expressions such as “resume meds as at home,” or “resume pre-op medications.”
- Notify nursing personnel of all new orders and ask if any clarification is needed before you leave the hospital.
- Avoid verbal medication orders whenever possible. If you do give verbal orders, however, be sure that you require a verification process such as a “readback” of the complete order by the person receiving the order.

Evaluation Tool for Physicians

● **KEY ELEMENT 4: DRUG LABELING, PACKAGING,
AND NOMENCLATURE**

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

Questions to Consider

- Do I notify the pharmacy when I read about drug name mix-ups and/or unsafe labeling and packaging of medications in the hospital?
- Do I always make sure that medications are properly labeled before I administer them?

Suggested Actions

- Notify the pharmacy and other staff members if unsafe labeling and packaging is observed or known from reading the literature.
- Always label any medications unless they are drawn up at the patient bedside and administered immediately.

Evaluation Tool for Physicians

● KEY ELEMENT 5: 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 drugs from the pharmacy in a timely fashion. Whenever possible, health care organizations also should use commercially available solutions and standard concentrations to minimize error-prone processes such as IV admixture and dose calculations.

Questions to Consider

- Is medication delivery and administration timely?
- Do I order medication as “stat” or “now” only in the case of emergencies as defined by hospital policy?
- Do I order sample medications for inpatient use?
- Do I meet pharmaceutical representatives in restricted areas of the hospital (i.e. patient care units)?
- Do I bypass formulary process by writing orders for patients to take their own medications?
- Do I notify nursing and pharmacy if I observe unsafe drug storage?

Suggested Actions

- Use “stat” and “now” only on medication orders that must be given within the time frame selected by hospital policy.
- Notify nursing and pharmacy staff if there are delays in medication delivery and administration times.
- Never order sample medications for inpatient use.
- Don’t write orders for patients to use their own medications while they’re in the hospital unless it’s an emergency.

Evaluation Tool for Physicians

● **KEY ELEMENT 6: MEDICATION DELIVERY DEVICE ACQUISITION, USE, AND MONITORING**

To avoid errors with drug delivery devices, health care organizations must assess the devices' safety before purchase; ensure appropriate fail-safe protections (such as free-flow protection, incompatible connections, and safe default setting); limit variety to promote familiarity; and require independent double checks for potential device-related errors that could result in serious patient harm.

Questions to Consider

- Am I familiar with the use and types of infusion devices used in the hospital?
- Does a member of the medical staff sit on a committee to review new medication devices and equipment?

Suggested Actions

- Volunteer if possible to attend new medication and equipment reviews.

*Evaluation Tool for Physicians***● KEY ELEMENT 7: ENVIRONMENTAL FACTORS**

Environmental factors such as poor lighting, cluttered work spaces, noise, interruptions, high patient acuity, and nonstop activity contribute to medication errors because health care providers are unable to remain focused. Staffing pattern deficiencies and excessive workload also underlie a broad range of errors and present unique challenges to health care organizations today.

Questions to Consider

- Is there a space on the patient unit for the medical staff to write medication orders without distractions and noise?
- Do I feel that staffing levels for nurses and pharmacists are adequate for safe patient care?

Suggested Actions

- Notify administrators if there is a need for more space and/or quiet work space on patient care units.
- Notify administrators of any concerns with staffing levels in the hospital.

Evaluation Tool for Physicians

● KEY ELEMENT 8: STAFF COMPETENCY AND EDUCATION

Although staff education is a weak error-reduction strategy by itself, it can play an important role when it's 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, nonformulary medications, high-alert medications, and medication error prevention.

Questions to Consider

- Are medication safety programs offered at medical staff meetings? Do I try to attend lectures and in-service programs on medication safety?
- Do I feel that the nursing staff receives enough education on medications, especially timely information on nonformulary medications if they are needed?
- Are pharmacists involved in providing in-service programs to the medical staff?
- Do I offer my services to help in conducting safety programs for the hospital staff?

Suggested Actions

- Ask that pharmacists become involved with medical staff education.
- Request that programs on medication be presented at least annually to all medical staff.

Evaluation Tool for Physicians● **KEY ELEMENT 9: 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.

Questions to Consider

- Is a pharmacist available for patient education, especially for high-risk patients and patients receiving high-alert drugs? Do I consult pharmacy for these services?
- Do I encourage patients to ask questions about their medications while they are in the hospital? Do I investigate their concerns and questions?
- Do I tell my patients to bring their medications into the hospital for verification?

- Do I provide drug information to my patients before they are discharged from the hospital?

Suggested Actions

- Encourage patients and their caregivers to freely ask questions about their medications.
- Consult pharmacy to help educate patients who represent high risks or are receiving multiple medications.
- Support expanded pharmacy programs such as an anticoagulation clinic.

Evaluation Tool for Physicians

● KEY ELEMENT 10: QUALITY PROCESS AND RISK MANAGEMENT

Health care organizations 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, to stimulate productive discussions, and to identify effective system-based solutions. Strategically placed quality control checks are also 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.

Questions to Consider

- When errors or near misses are reported, are system changes made to help prevent similar future instances?
- Do I disclose all medication errors that reach the patient?
- Are reports of errors and near misses freely exchanged among the hospital staff? Is there a fear to report errors because of embarrassment or reprisal?
- Is support provided for staff members who have been involved in an error?
- Are medication errors discussed at medical staff meetings? Are suggestions for system improvement made and sent to the administrative staff?
- Do I offer to double-check a medication, calculation, dose, or pump setting for a nurse if I am available?
- Do I assist in focus groups and committees to identify, educate, and perform RCA on real and potential medication error in the hospital?

- Do I order pediatric medications as total dose and mg/kg dose? Do I order chemotherapy as total dose and mg/m² dose?
- Do I always wash my hands before I examine any patient?

Suggested Actions

- Support the need for system changes that will help prevent medication errors.
- Notify administrators if system changes are needed within the organization.
- Always include total dose and mg/kg for pediatric orders and mg/m² dose for oncology orders.
- Participate on medication safety committees and RCA groups.

Section 2.3—

EVALUATION TOOL FOR NURSES

These questions should be used as a guideline to assess the safety of medication use in your everyday practice. They should also be used as points of discussion when you participate in interdepartmental or multidisciplinary review of the medication use process. The recommendations that follow are actions you should perform daily and/or promote to your coworkers, supervisors, and hospital administrators to encourage safety.

Evaluation Tool for Nurses

● KEY ELEMENT 1: PATIENT INFORMATION

To guide appropriate drug therapy, health care providers need readily available demographic and 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.

Questions to Consider

- Is bar-coded medication administration used on all patients?
- Does pharmacy provide the MAR for nurses (pharmacy computer-generated MAR)?
- Do pharmacists routinely adjust medication doses for patients with renal or liver impairment?
- Does our IT system provide easy and electronic access to all patient information (history, allergies, laboratory values, diagnostic tests, medications, etc.) at any terminal with password entry?
- Does patient information include both inpatient and outpatient medications and laboratory results?
- Do paper order forms contain prompts for prescribers to enter allergies, height, weight, and disease conditions?
- Are allergies clearly visible on all order forms, MARs, and on patient charts?
- Do all patients have bar-coded name bracelets and colored allergy bracelets?
- Can physicians and nurses readily view a patient's current medications through the pharmacy system on any patient unit?

Suggested Actions

- Place allergies on all medication order sheets as well as in the MAR and on the front of charts.
- Use allergy brackets for all inpatients and outpatients being treated with medications.
- Support policies and procedures that back physicians', nurses', and pharmacists' documentation of patient information.
- Notify pharmacy of any new allergies or changes in a patient status.
- Request that MARs be printed by the pharmacy.
- Request that nurses and physicians have access to view the current pharmacy medication profile.

Evaluation Tool for Nurses

● KEY ELEMENT 2: 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, MARs, and regular clinical activities by pharmacists in patient care areas.

Questions to Consider

- To the extent possible are pharmacists available on my patient care unit to assist prescribers and nurses with medication choices, answer questions, and participate in patient education?
- Unless it's an emergency, does a pharmacist screen all medication orders before medications are available to me for administration?
- Are special precautions (dosing charts, auxiliary labels, protocols, preprinted order sets, etc.) available to me for high-alert medications and/or high-alert treatments and procedures?
- Do I have access to online drug information resources (such as MICROMEDEX) on all terminals in the hospital?
- Do I have (and do I need) access to the Internet so I can obtain timely drug information when necessary?
- Are only the most current drug references available on my unit?
- Are all preprinted order sets and protocols current and updated at least annually?
- Does the hospital drug formulary contain very little duplication of therapeutically equivalent products?

Suggested Actions

- Request online drug information at all patient care unit terminals.
- Support the establishment and/or growth of a clinical pharmacy program with the goal of having pharmacists available on patient units to follow high-risk patients or patients receiving high-risk medications.
- Support the drug formulary by notifying physicians when medications are not on the formulary and which medications are available for emergency use.
- Support the use of protocols and standard order sets to prescribers.
- Ask that pharmacists inform all nurses of new medications that are added to the formulary and provide information on any nonformulary medication that may be used.

Evaluation Tool for Nurses

● KEY ELEMENT 3: COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION EVALUATION

Because failed communication is the cause of many errors, health care organizations must eliminate communication barriers between health care providers and standardize the way that orders and other drug information is communicated.

Questions to Consider

- Does the CPOE system contain alerts for unsafe orders?
- Do prescribers enter orders directly into a CPOE system linked with pharmacy and my MAR?
- Are time frames established for “stat,” “now,” and routine medication delivery?
- Is the nursing MAR produced by pharmacy, and does it match the pharmacy profile?
- Is there a hospital-wide policy and procedure to resolve conflicts on potentially unsafe medication orders?
- Do I immediately contact the prescriber if I have a question on any new order, even if it’s about handwriting?
- Do I always take the MAR to the patient’s bedside before I administer medications?
- Do I use any dangerous abbreviations and dose expressions in any of my written material (MARs, notes, progress notes)?
- Do I accept verbal orders for high-risk medications and chemotherapy?
- Do I immediately write down all verbal orders and repeat them back (spelling drug names)?
- Are medication times standardized throughout the hospital and are dosing windows used?

Suggested Actions

- Support and enforce the use of a list of prohibited abbreviations and dose expressions.
- Adhere to policies to resolve conflicts stemming from disagreement regarding a medication order.
- Contact prescribers for any questions on orders.
- Accept verbal orders only in an emergency and repeat back the order, spelling the drug name and sounding out any doses.
- Take MARs to the patient bedside before administering medications.

Evaluation Tool for Nurses

● KEY ELEMENT 4: DRUG LABELING, PACKAGING, AND NOMENCLATURE

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

Questions to Consider

- Are all medications dispensed to me in unit-dose form?
- Do I label all syringes with the name and strength of the medication?
- Are medications that sound or look alike separated in storage areas, including automated dispensing cabinets?
- Do I keep all oral medications in their original packaging until the point of medication administration at the bedside?
- Do I notify prescribers to include indications for medications that may be associated with look-alike or sound-alike mix-ups?
- Are auxiliary warning labels included on medications that contain odd strengths (such as “2 tablets” or “1/2 tablet”) for the dose?
- Are the labels on medications, including those prepared by the pharmacy, easy to read? Do I notify pharmacy if they are not, and does pharmacy immediately make changes in the appearance of the label?
- Do I always check medication labeling for any unsafe conditions and notify pharmacy immediately?

Suggested Actions

- Ensure that all medications contain a label until the time of administration.
- Request that all medications be dispensed from pharmacy in unit-dose form.
- Ensure that pharmacy labels and manufacturer labels are easy to read and contain the proper information for safe drug administration.
- Notify pharmacy of any problems with labeling of medications and expect that someone will get back with an answer and/or remedy.

Evaluation Tool for Nurses

● KEY ELEMENT 5: DRUG STANDARDIZATION, STORAGE, AND DISTRIBUTION EVALUATION

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

Questions to Consider

- Does pharmacy prepare the majority of parenteral, IV push medications, oral solutions, and oral tablets and capsules in unit-dose form?
- Are all orders reviewed by a pharmacist before the medication is available from automated dispensing cabinets?
- Are the majority of medications prepared for use by the manufacturer?
- Are high-alert medications restricted to the pharmacy or, if available on the patient unit, are they secured?
- Have all concentrated forms of electrolytes been removed from patient care units?
- Is medication stock on my unit routinely reviewed by nursing staff and pharmacy?
- Are stock medications in unit-dose form (i.e., no bulk supplies)?
- Are only standard concentrations available for high-alert medications?
- Are pharmaceutical representatives allowed on the patient units?
- Are sample medications allowed for inpatient use?
- Am I notified when medications are delivered to the unit?
- Does a process exist to remove discontinued medications in a timely manner?

- Are stock medications for internal use separated from external-use medications and from testing solutions and other nondrug substances?
- Are nurses or other nonpharmacy personnel allowed in the pharmacy at times when the pharmacy is not staffed by pharmacy personnel?

Suggested Actions

- Request premixed, manufacturer-prepared solutions whenever available.
- Support the pharmacy in obtaining enough staff to prepare all medications in unit-dose form.
- Prohibit nonpharmacy personnel from entering the pharmacy when pharmacy staff is not available on-site in the hospital.
- Ensure that automated dispensing cabinets contain software to allow pharmacy review of orders before medications are obtained.
- Request that all medications, including IV push medications and oral solutions, are dispensed in unit-dose form.
- Request that concentrated electrolytes are removed from areas outside the pharmacy.
- Separate internal and external use medications and nonmedication supplies.

Evaluation Tool for Nurses

● KEY ELEMENT 6: MEDICATION DELIVERY DEVICE ACQUISITION, USE, AND MONITORING

To avoid errors with drug delivery devices, health care organizations must assess the devices' safety before purchase; ensure appropriate fail-safe protections (such as free-flow protection, incompatible connections, and safe default settings); limit variety to promote familiarity; and require independent double checks for potential device-related errors that could result in serious patient harm.

Questions to Consider

- Do I always get another practitioner to check IV solutions and pump settings for all high-alert medications?
- Do all infusion devices used in the hospital have free-flow protection?
- Do I normally examine new devices and supplies for an error potential? Do I notify my manager and others when I think a safety problem may exist with supplies or equipment?
- Are oral syringes that can't be connected to IV tubing or ports available on my unit (including the ED) for oral solutions?
- Do I routinely label all infusion lines (i.e. IV, gastric, arterial)?
- Am I and/or are fellow staff asked for our opinion before new medication equipment and devices are used in the hospital?
- Is the variety of infusion devices limited within the hospital?
- Is adequate training for nursing staff provided for the use of new infusion devices and medication administration equipment?
- Are there adequate infusion devices for the patients who need it?

- When unsafe equipment is noted and reported, is the equipment removed or changed?

Suggested Actions

- Notify administrators if pumps without free-flow protection are still available on patient units.
- When mistakes in programming infusion pumps are made, fill out an error report and ask managers to look into the problem.
- Devote time, even if off shift, to participate on committees that evaluate safety in devices and equipment.
- Request that oral syringes and labels to identify tubing are available on all patient care units.
- Always ask a fellow practitioner to double-check IV line hookups and IV solutions and pump settings for high-alert medications.
- If you're unsure how to operate infusion devices, ask for training and request that charts or cards are available with each pump.

Evaluation Tool for Nurses

● KEY ELEMENT 7: ENVIRONMENTAL FACTORS

Environmental factors such as poor lighting, cluttered work spaces, noise, interruptions, high patient acuity, and nonstop activity contribute to medication errors because health care providers are unable to remain focused. Staffing pattern deficiencies and excessive workload also underlie a broad range of errors and present unique challenges to health care organizations today.

Questions to Consider

- Am I and is other frontline staff informed of new services or expanded clinical programs well before they are instituted? Am I offered an opportunity to address any staffing or environment concerns with new services or programs?
- Is an area free of distractions available to me when I am transcribing medications and charting patient vital signs and other important information?
- Is there adequate space and lighting in the area where I obtain stock medications?
- Am I required to work shifts longer than 12 hours except in an emergency?
- Do I have at least 10 hours rest between shifts and have an opportunity to take a rest and meal break during every shift?
- Is staffing adequate on my unit for the number of patients and the level of patient acuity?

- Does staff (including pharmacy, prescribers, and so on) interrupt me when I am administering medications?

Suggested Actions

- Notify managers and administrators if there are unsafe environmental conditions.
- Request that interruptions are kept to a minimum—only for emergencies—when you're administering medications.
- Notify nurse managers when you experience or observe unsafe staffing patterns or unsafe work shifts.
- Request notification when any changes in staffing patterns or additions of new programs or services are being considered.

Evaluation Tool for Nurses

● KEY ELEMENT 8: STAFF COMPETENCY AND EDUCATION

Although staff education is a weak error-reduction strategy by itself, it can play an important role when it's 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, nonformulary medications, high-alert medications, and medication error prevention.

Questions to Consider

- Did I receive orientation on prescribing, dispensing, and administration of medications?
- Have I had an opportunity to spend time in the pharmacy and with pharmacy staff to learn their processes for medication preparation and dispensing?
- Are all employees oriented to the safe use and storage of medications within the hospital?
- Am I and is other staff trained on how to respond to a medication error?
- Does pharmacy staff present in-service programs on new medications and medication protocols to nursing staff?
- Am I offered opportunities to attend off-site educational programs to enhance my skills?
- Am I provided with information on new medications prescribed for my patients?

- If I am asked to train new staff, are my staffing duties curtailed so I can adequately perform this function?

Suggested Actions

- Request pharmacy to conduct in-service programs on new medications and dosing protocols.
- Request to spend time in the pharmacy to observe their procedures for medication preparation and dispensing.
- Request decreased staffing requirements when you're asked to train new staff.

Evaluation Tool for Nurses● **KEY ELEMENT 9: 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.

Questions to Consider

- Do I always follow up on questions from patients regarding their medications?
- Do I always encourage patients and caregivers to ask questions about medications?
- Do I provide patients and their caregivers with written, easy-to-understand information about their medications?
- Are patients offered an opportunity to speak with a pharmacist about their medications?
- Does a program exist to educate patients and their caregivers that they are an important part of safe medication use?

Suggested Actions

- Request that pharmacists be available to counsel high-risk patients and/or those receiving high-alert medications.
- Support programs to encourage patients to identify themselves to hospital personnel and to freely ask questions about their medications.
- Request that current, easy-to-read drug information is readily available on the patient unit.
- Always listen to patients and their caregivers when they have questions about medications or offer information on past experience in taking medications.

Evaluation Tool for Nurses

● KEY ELEMENT 10: QUALITY PROCESS AND RISK MANAGEMENT

Health care organizations 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, to stimulate productive discussions, and to identify effective system-based solutions.

Strategically placed quality control checks are also 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.

Questions to Consider

- Is the current culture in the hospital one that is blame-free when it involves committing an error? In the post-event process, are practitioners who make an error disciplined in cases when malicious or illegal activity is absent?
- Is there an individual in my institution whom I view as an advocate for preventing medication errors?
- Do I disclose all medication errors that reach the patient?
- Do administrators regularly visit my unit and seek staff input on ways to help prevent medication errors?
- Am I notified of errors and near misses that others have been involved in to learn from the experiences?
- Do I freely report medication errors and near misses without any fear of retribution?
- Are error rates used for benchmarking comparisons or kept in employee files?
- Is psychological counseling provided for employees who are involved in serious error that causes patient harm?
- Are incentives and positive feedback provided for individuals who report errors?
- Do prescribers order pediatric medications in total dose plus mg/kg dose and chemotherapy in total dose and mg/m² dose?
- For high-alert medications, do I ask another practitioner to double-check my calculations and the medication I am about administer and to document it?
- Do I wash my hands before I prepare or administer any medications to patients?

Suggested Actions

- Practice and support a blame-free environment and allow for the open discussion of error for staff education.
- Support personnel who have been involved in a medication error.
- Report medication errors and near misses.
- Ask a fellow practitioner to double-check all calculations and the medication before administering high-alert medications.

Section 2.3—

EVALUATION TOOL FOR PHARMACISTS

These questions should be used as a guideline to assess the safety of medication use in your everyday practice. They should also be used as points of discussion when you participate in interdepartmental or multidisciplinary review of the medication use process. The recommendations that follow are actions you should perform daily and/or promote to your coworkers, supervisors, and hospital administrators to encourage safety.

Evaluation Tool for Pharmacists

● KEY ELEMENT 1: PATIENT INFORMATION

To guide appropriate drug therapy, health care providers need readily available demographic and 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.

Questions to Consider

- Is bar-coded medication administration used on all patients?
- Does pharmacy provide the MAR for nurses (pharmacy computer-generated MAR)?
- Does the pharmacy system prohibit me from entering medication orders on patients who do not have an allergy listed?
- Do I routinely check patient diagnosis and comorbid conditions before I dispense medications?
- Do I routinely adjust medication doses for patients with renal or liver impairment?
- Do I routinely seek the height and weight of patients who may require high-alert medications?
- Does our IT system provide easy and electronic access to all patient information (history, allergies, laboratory values, diagnostic tests, medications, etc.) at any terminal with password entry?
- Do I have direct access to inpatient and outpatient information including laboratory results?
- Do paper order forms contain prompts for prescribers to enter allergies, height, weight, and disease conditions? Is this information always contained on new orders?
- Does the pharmacy computer system screen and detect the drugs that a patient is allergic to?
- Are allergies clearly visible on all order forms, MARs, and patient charts?
- Can I access a patient's medication profile from any terminal within the hospital?
- Does the pharmacy keep logs on all patients receiving chemotherapy, and does it track lifetime doses?

Suggested Actions

- Request that all order forms contain patient allergies.
- Unless it's an emergency, do not enter medication orders on patients for which an allergy is not documented.
- Provide pharmacy-generated MARs to nurses.
- Request that nurses and physicians have access to the current pharmacy medication profile.
- Request that the pharmacy computer system is directly interfaced with the laboratory system. If the system is not interfaced, check vital laboratory values for medications that require renal dosing adjustments.
- Obtain the height and weight for patients who may be receiving critical-dose medications.

Evaluation Tool for Pharmacists

● KEY ELEMENT 2: 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, MARs, and regular clinical activities by pharmacists in patient care areas.

Questions to Consider

- Do I have adequate time to routinely assist prescribers with medication choices and assist nurses with medication selection, answer questions, and participate in patient education?
- Unless it's an emergency, do I screen all medication orders before medications are available to nurses for administration?
- Are special precautions (auxiliary labels, protocols, preprinted order sets, etc.) available to me and on all patient care units for high-alert medications and/or high-alert treatments and procedures?
- Does the pharmacy computer system offer alerts for maximum and minimum doses of medications plus drug interactions, allergies, abnormal laboratory values, and other important medication screening?
- Do I always check the patient's profile before I make changes in medication therapy?
- Am I able to enter look-alike and sound-alike warnings into the pharmacy computer system?
- Do I have access to online drug information resources (such as MICROMEDEX) on all terminals in the pharmacy and throughout the hospital?
- Do I have access to the Internet so I can obtain timely drug information when necessary?
- Are only the most current drug references available in the pharmacy and on every patient care unit?
- Does the hospital drug formulary contain very little duplication of therapeutically equivalent products?
- Do I routinely notify prescribers when nonformulary medications are ordered?
- Am I routinely updated on the activities of the Pharmacy and Therapeutics Committee?

Suggested Actions

- Request online drug information at pharmacy and patient care unit terminals.
- Support the establishment and/or growth of a clinical pharmacy program with the goal of having pharmacists available on patient units to follow high-risk patients or patients receiving high-risk medications.
- Support the drug formulary by notifying physicians when prescribed medications are not on the formulary and by letting them know what medications are available for emergency use.
- Support the use of protocols and standard order sets to prescribers.
- Ask that all pharmacy staff be given updates on Pharmacy and Therapeutics Committee activities.
- Educate all nurses on new medications that are used in the hospital.

Evaluation Tool for Pharmacists

● KEY ELEMENT 3: COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION

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

Questions to Consider

- Does the CPOE system contain alerts for unsafe orders?
- Do prescribers enter orders directly into the CPOE system that is linked with the pharmacy system and nursing MAR?
- Are all preprinted order sets and protocols current and updated at least annually?
- Is the nursing MAR produced by pharmacy, and does it match the pharmacy profile?
- Is there a hospital-wide policy and procedure to resolve conflicts on potentially unsafe medication orders?
- Do I immediately contact the prescriber if I have a question on any new order, even if it's about handwriting?
- Do I provide dosing instructions and other drug information to nurses and instruct them to place it on the MAR? Do I assist nurses by placing important drug information on the MAR?
- Do I use dangerous abbreviations and dose expressions in any of my written material (notes, progress notes)?
- Do I accept verbal orders for high-risk medications and chemotherapy?
- Do I immediately write down all verbal orders and repeat them back (spelling drug names)?
- Do I accept orders for “resume previous meds” or other incomplete orders?

Suggested Actions

- Support and enforce the use of a list of prohibited abbreviations and dose expressions.
- Adhere to policies to resolve conflicts stemming from disagreement regarding a medication order.
- Contact prescribers for any questions on orders.
- Accept verbal orders only in an emergency and repeat back the order, spelling the drug name and sounding out any doses.
- Provide nurses with important drug information and assist them by placing it on the MAR if applicable.

Evaluation Tool for Pharmacists

● KEY ELEMENT 4: DRUG LABELING, PACKAGING, AND NOMENCLATURE

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

Questions to Consider

- Do I dispense all medications in unit-dose form whenever possible?
- Do I always check medication labeling for any unsafe conditions and notify my manager or buyer?
- Are medications that sound or look alike separated in storage areas throughout the pharmacy and hospital, including automated dispensing cabinets?
- Do I dispense all oral solutions in oral syringes that can't be connected to IV tubing? Are the syringes labeled for oral use only?
- Do I notify prescribers to include indications for medications that may be associated with look-alike or sound-alike mix-ups?
- Do I include auxiliary warning labels on medications that contain odd strengths (such as "2 tablets" or "1/2 tablet") for the dose?
- Are the labels on medications, including those prepared by the pharmacy, easy to read? Do I ask nurses to notify the pharmacy if they are not, and does pharmacy immediately make changes in the appearance of the label?
- Do all IV solution labels contain the total volume of solution, the concentration, and total amount of drug additives?

Suggested Actions

- Ensure that all medications are properly labeled and request that different manufacturers be used if labels are ambiguous or unsafe. Dispense all medications in unit-dose form whenever possible.
- Ensure that pharmacy labels and manufacturer labels are easy to read and contain the proper information for safe drug administration.
- Notify other pharmacy personnel and your manager of any problems with the labeling of medications.
- Always include auxiliary labeling on medications that may contain odd strengths or must be diluted.

Evaluation Tool for Pharmacists

● KEY ELEMENT 5: 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 drugs from the pharmacy in a timely fashion. Whenever possible, health care organizations also should use commercially available solutions and standard concentrations to minimize error-prone processes such as IV admixture and dose calculations.

Questions to Consider

- If available, do automated dispensing cabinets contain software to allow a pharmacist to check the order before it can be obtained from administration?
- Does pharmacy buy the majority of medications as commercially available premixed solutions and prefilled syringes whenever they are available?
- Are concentrated forms of electrolytes removed from patient care areas?
- Does pharmacy prepare the majority of parenteral, IV push medications, oral solutions, and oral tablets and capsules in unit-dose form?
- Are time frames established for “stat,” “now,” and routine medication delivery?
- Are high-alert medications restricted to the pharmacy or, if they are available on the patient unit, are they secured?
- Does pharmacy routinely review stock medications with nurses on the patient care units?
- Are only standard concentrations available for high-alert medications?
- Does a process exist to remove discontinued medications in a timely manner?
- Are pharmaceutical representatives allowed on the patient units? Must representatives

check into the pharmacy before they are allowed anywhere in the hospital?

- Are sample medications allowed for inpatient use?
- Are nurses or other nonpharmacy personnel allowed in the pharmacy at times when the pharmacy is not staffed by pharmacy personnel?

Suggested Actions

- Request that the pharmacy purchase premixed, manufacturer-prepared solutions whenever available.
- Request that floor stock of high-alert drugs that can be harmful if given in error are not available outside the pharmacy.
- Prohibit nonpharmacy personnel from entering the pharmacy when pharmacy staff is not available in the hospital.
- Ensure that automated dispensing cabinets contain software to allow pharmacy review of orders before medications are obtained.
- Dispense all medications, including IV push medications and oral solutions, in unit-dose form.
- Ensure that concentrated electrolytes are removed from areas outside the pharmacy.
- Do not allow pharmaceutical representatives on patient care units.

Evaluation Tool for Pharmacists

● KEY ELEMENT 6: MEDICATION DELIVERY DEVICE ACQUISITION, USE, AND MONITORING

To avoid errors with drug delivery devices, health care organizations must assess the devices' safety before purchase; ensure appropriate fail-safe protections (e.g., free-flow protection, incompatible connections, and safe default settings); limit variety to promote familiarity; and require independent double checks for potential device-related errors that could result in serious patient harm.

Questions to Consider

- Do I offer to double-check IV solutions and pump settings for all high-alert medications when I am on the patient unit?
- Do all infusion devices used in the hospital have free-flow protection?
- Do I normally examine new devices and supplies for an error potential? Do I notify my manager and others when I think a safety problem may exist with supplies or equipment?
- Are oral syringes that can't be connected to IV tubing or ports available in all patient care areas (including the ED) for oral solutions?
- Am I and/or are fellow staff asked for our opinion before new medication equipment and devices are used in the hospital?
- Is the variety of infusion devices limited within the hospital?
- Have I been trained on how to use infusion devices?
- When unsafe equipment is noted and reported, is the equipment removed or changed?

Suggested Actions

- Notify administrators if pumps without free-flow protection are still available on patient units.
- When mistakes in programming infusion pumps are made, fill out an error report and ask managers to look into the problem.
- Devote time, even if off shift, to participate on committees that evaluate the safety of devices and equipment.
- Request that oral syringes and labels to identify tubing are available on all patient care units.
- Always ask a fellow practitioner to double-check IV line hookups, IV solutions, and pump settings for high-alert medications.
- If you are unsure how to operate infusion devices, ask for training and request that charts or cards are available with each pump.

Evaluation Tool for Pharmacists

● KEY ELEMENT 7: ENVIRONMENTAL FACTORS

Environmental factors such as poor lighting, cluttered work spaces, noise, interruptions, high patient acuity, and nonstop activity contribute to medication errors because health care providers are unable to remain focused. Staffing pattern deficiencies and excessive workload also underlie a broad range of errors and present unique challenges to health care organizations today.

Questions to Consider

- Is staffing adequate in the pharmacy for the number of patients in the hospital and the services provided by pharmacy?
- Is there an area free of distractions available to me when I am entering new medication orders into the computer or calculating doses of medications?
- Are phone calls to the IV preparation area screened before they are put through?
- Am I and/or are other frontline staff informed of new services or expanded clinical programs well before they are instituted? Am I offered an opportunity to address any staffing or environment concerns with new services or programs?
- Is there adequate space and lighting in the area where I prepare medications?
- Am I required to work shifts longer than 12 hours except in an emergency?
- Do I have at least 10 hours rest between shifts and have an opportunity to take a rest and meal break during every shift?
- Am I frequently interrupted when I am entering medication orders or preparing or checking medications before they are dispensed?
- Do I often call the nursing unit and interrupt nurses for questions that could be answered by visiting the unit myself?

Suggested Actions

- Notify managers and administrators if unsafe environmental conditions are encountered.
- Request that interruptions be kept to a minimum when new orders are entered or medications are being prepared.
- Notify managers when you experience or observe unsafe staffing patterns or unsafe work shifts.
- Request notification when any changes in staffing patterns or the addition of new programs or services are being considered.

Evaluation Tool for Pharmacists

● KEY ELEMENT 8: STAFF COMPETENCY AND EDUCATION

Although staff education is a weak error-reduction strategy by itself, it can play an important role when it's 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, nonformulary medications, high-alert medications, and medication error prevention.

Questions to Consider

- If I am asked to train new staff, are my staffing duties curtailed so I can adequately perform this function?
- Are all employees oriented to the safe use and storage of medications within the hospital? Does pharmacy participate in this orientation?
- Did I receive orientation on prescribing, dispensing, and administration of medications?
- Have I had an opportunity to spend time in the patient care areas and with nursing staff to learn their processes for medication preparation and administration?
- Am I and are other staff trained on how to respond to a medication error?
- Am I offered opportunities to attend off-site educational programs to enhance my skills?
- Do I routinely provide nurses with new drug information and information on nonformulary medications?

- Do I present in-service programs to nurses and prescribers on new medications and medication protocols?

Suggested Actions

- Request that pharmacy conduct in-service programs on new medications and dosing protocols.
- Provide nurses with orientation to the pharmacy and medication preparation and delivery. Request to spend time in the patient care areas to observe procedures for medication prescribing, preparation, and administration.
- Request that your staffing duties be curtailed when you're asked to train new staff.

Evaluation Tool for Pharmacists

● KEY ELEMENT 9: 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.

Questions to Consider

- Do I follow up on patients who are considered high risk or are taking high-alert medications?
- Do I always follow up on questions from nurses and/or patients regarding medications?
- Are patients offered an opportunity to speak with a pharmacist about their medications? Do I have an opportunity to provide direct patient education?
- Is written medication information that is current and easy to understand available for patients?
- Does a program exist to educate patients and their caregivers that they are an important part of safe medication use?
- Do I always encourage patients and their caregivers to ask questions about medications?

Suggested Actions

- Request that pharmacists be available to counsel high-risk patients and/or those receiving high-alert medications.
- Support programs to encourage patients to identify themselves to hospital personnel and to freely ask questions about their medications.
- Request that current, easy-to-read drug information is readily available on the patient unit.
- Always listen to patients and their caregivers when they have questions about medications or offer information on their past experience in taking medications.

Evaluation Tool for Pharmacists

● KEY ELEMENT 10: QUALITY PROCESS AND RISK MANAGEMENT

Health care organizations 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, to stimulate productive discussions, and to identify effective system-based solutions. Strategically placed quality control checks are also 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.

Questions to Consider

- Is the current culture in the hospital one that is blame-free when it involves committing an error?
- Is discipline used in cases when malicious or illegal activity has occurred?
- Is there an individual in my institution whom I view as an advocate for patient safety?
- Do administrators regularly visit hospital areas and seek staff input on ways to help prevent medication errors?
- Do I freely report medication errors and near misses without any fear of retribution?
- Am I notified of errors and near misses that others have been involved in to learn from the experiences?
- Are error rates used for benchmarking comparisons or kept in employee files?
- Do I receive and routinely review publications to become aware of medications with error potential?
- Are incentives and positive feedback provided for individuals who report errors or hazardous conditions?
- Do prescribers order pediatric medications in total dose plus mg/kg dose and chemotherapy in total dose and mg/m² dose?
- For high-alert medications, do I ask another practitioner to double-check my calculations and the medication I may have prepared and to document it?
- Do I wash my hands before I prepare or handle any medications?
- Do I perform drug use evaluations on medications that have a heightened error potential?

Suggested Actions

- Practice and support a blame-free environment and allow for the open discussion of errors for staff education.
- Support personnel who have been involved in a medication error.
- Report medication errors and near misses.
- Ask a fellow practitioner to double-check all calculations and the medication before dispensing high-alert medications.

Section 2.3—

EVALUATION TOOL FOR RISK MANAGERS

The following questions should be asked when you're assessing organizational risk and medication safety practices within your hospital. They should also be used as points of discussion when you participate in interdepartmental or multidisciplinary review of the medication use process (participation on the Pharmacy and Therapeutics Committee, Quality Committee, and so on).

The recommendations that follow should be promoted to frontline practitioners, the medical staff, and hospital leaders to minimize identified organizational risks often associated with the medication use process.

Evaluation Tool for Risk Managers

● KEY ELEMENT 1: PATIENT INFORMATION

To guide appropriate drug therapy, health care providers need readily available demographic and 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.

Questions to Consider

- Is bar-coded medication administration used on all patients?
- Is the pharmacy computer system interfaced with the laboratory system?
- Does the pharmacy computer system or CPOE system contain hard stops so that it will not process a medication if a patient is allergic to it?
- Does pharmacy provide the MAR for nurses (pharmacy computer-generated MAR)?
- Do pharmacists routinely adjust medication doses for patients with renal or liver impairment?
- Does the IT system provide physicians, nurses, and pharmacists with easy and electronic access to all patient information (history, allergies, laboratory values, diagnostic tests, medications, and so on) at any terminal with password entry?
- Does patient information include both inpatient and outpatient medications and laboratory results?
- Do all patients have bar-coded name bracelets and colored allergy bracelets?
- Are allergies clearly visible on all order forms, MARs, and patient charts?
- Can physicians and nurses readily view a patient's current medications by accessing the pharmacy system on any patient unit?

Suggested Actions

- Support a strategic IT plan that includes electronic access to patient information for all health professionals caring for the patient.
- Support policies and procedures that back documentation of patient information by physicians, nurses, and pharmacists.
- Support implementation of a CPOE system that is interfaced with pharmacy and bar-coded drug administration, if feasible.
- Conduct audits of order forms, MARs, and charts to ensure that important patient information for medications (allergies, height, weight, etc.) is easily visible for physicians, pharmacists, and nurses.
- Check the pharmacy computer system for allergy alerts.
- Support implementation of bar-coding technology.
- Audit orders transmitted to pharmacy to ensure that basic information (patient name, location, birth date, etc.) is easily visible on the pharmacy copy.

Evaluation Tool for Risk Managers● **KEY ELEMENT 2: 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, MARs, and regular clinical activities by pharmacists in patient care areas.

Questions to Consider

- To the extent possible, are pharmacists available on patient care units to assist prescribers with medication selection, answer questions for nurses, and participate in patient education?
- Does the pharmacy computer system (and/or the CPOE system) contain software to alert pharmacists and prescribers of drug interactions, minimum and maximum dose checks, disease state dosing modifications, and so on?
- Unless it's an emergency, does a pharmacist screen all medication orders before they are administered?
- Are special precautions (dosing charts, auxiliary labels, protocols, preprinted order sets, and so on) used for high-alert medications and/or high-alert treatments and procedures?
- Is the software for computer alerts and checks updated at least monthly?
- Are online drug information resources (such as MICROMEDEX) available on all terminals in the hospital?
- Do key personnel have access to the Internet so they can obtain timely drug information when necessary?
- Is there a process to evaluate and update all reference texts, medication dosing charts, and other drug information on an annual basis?

- Does the hospital use standardized printed order forms, and is there a process to evaluate all preprinted order sets and protocols before they are used? Is there a process to update this information at least annually?

Suggested Actions

- Support system-wide online drug information throughout the hospital.
- Support a clinical pharmacy program with the goal of having pharmacists available on patient units to follow high-risk patients or patients receiving high-risk medications.
- Check patient care areas for standardized charts and dosing information for high-alert medications.
- Seek membership on the Pharmacy and Therapeutics Committee.
- Ensure that pharmacists review all medication orders (except in an emergency) before medications are administered.
- Ensure that before medications are added to the hospital formulary the safe use of the medication is reviewed.
- Present loss experience from the hospital to support drug information needs.

Evaluation Tool for Risk Managers

● KEY ELEMENT 3: COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION

Because failed communication is the cause of many errors, health care organizations must eliminate communication barriers between health care providers and standardize the way that orders and other drug information is communicated.

Questions to Consider

- Am I supportive of any plans to implement a CPOE system?
- Are protocols and standard order sets used in the hospital?
- Am I supportive of the hospital drug formulary?
- Do we have and do I support a policy for a clear and effective path that staff can follow to resolve disagreement regarding a medication order?
- Does the hospital have a list of dangerous abbreviations that should never be used?
- Are verbal orders accepted from prescribers? Is there a policy and procedure on the safe acceptance of verbal orders?

Suggested Actions

- Support a strategy for prescriber order entry.
- Support the use of protocols and standard order sets to the medical staff.
- Attend Pharmacy and Therapeutics Committee meetings and support their decisions.
- Support policies and procedures for the safe communication of drug information. Audit patient charts, MARs, and other written material for the use of dangerous abbreviations.
- Ensure that MARs are taken to the patient bedside before medications are administered.
- Audit patient charts, MARs, and other documentation for legibility problems.

Evaluation Tool for Risk Managers

● KEY ELEMENT 4: DRUG LABELING, PACKAGING, AND NOMENCLATURE

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

Questions to Consider

- Is information on unsafe labeling and packaging shared with the Pharmacy and Therapeutics Committee, and are decisions on which medications to stock in the hospital made with safety in mind?
- Does pharmacy have alerts in the computer system for look-alike and sound-alike medications? Is this information (auxiliary labeling, warnings on MARs, and so on) also shared with nursing?
- Does the pharmacy have the ability to purchase “off contract” for medications that have labeling and packaging concerns?
- Are all pharmacy-prepared labels easy to read, devoid of abbreviations, and containing information needed for appropriate drug administration (patient name, drug name, strength, dose, etc.)?
- Are all medications labeled—even in the OR—until the time they are administered?

Suggested Actions

- Support pharmacy decisions on changing drug manufacturers, even if against purchasing group bids, when a safety issue is identified.
- Inform all employees, including the medical staff, that medications must always be properly labeled.
- Audit medication labels for ease of reading and to ensure that important patient and medication information is included and visible.
- Conduct audits of the OR to ensure that all medications are properly labeled, including those in the sterile field.
- Audit drug administration to ensure that all medications remain in their unit-dose packaging until the time of administration.

Evaluation Tool for Risk Managers

● KEY ELEMENT 5: 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 drugs from the pharmacy in a timely fashion. Whenever possible, health care organizations also should use commercially available solutions and standard concentrations to minimize error-prone processes such as IV admixture and dose calculations.

Questions to Consider

- Are all doses of medications in the hospital available only in unit-dose form?
- Does pharmacy purchase commercially available premixed IV solutions and prefilled syringes whenever they are available?
- Are sample drugs permitted within the hospital? Are pharmaceutical representatives allowed in patient care areas?
- Are concentrated electrolytes stored outside the pharmacy?
- Do we have procedures that addresses the delivery time of medications ordered as “stat” or “now”?
- Do we have a list of high-alert medications that is known by clinicians? Are these medications stored only in the pharmacy? If they are stored outside the pharmacy, are they secured and in limited quantities? Unless it’s an emergency, are all orders for these high-alert medications screened by pharmacy before they are obtained?
- Are dosing windows used to standardize drug administration times?
- Is nonpharmacy staff allowed in the pharmacy when the pharmacy is not staffed by a pharmacist?

- Are all neuromuscular blockers properly labeled as “paralyzing agents” and segregated from other drug storage? If neuromuscular blockers are stored outside the pharmacy, are the type and quantities limited?

Suggested Actions

- Support the purchase of commercially available premixed IV solutions and prefilled syringes.
- Prohibit the use of sample medications in the hospital.
- Support staffing requirements and automation to ensure the timely and safe availability of medications when they are needed.
- Ensure that high-alert medications, concentrated electrolytes and neuromuscular blockers are safeguarded and that known safety requirements for storage, availability, and labeling are followed.
- Support the requirement that nonpharmacy personnel are not allowed in the pharmacy when pharmacy staff is absent.
- Ensure that a policy exists for timely delivery of “stat,” “now,” and routine medication orders.

Evaluation Tool for Risk Managers

● KEY ELEMENT 6: MEDICATION DELIVERY DEVICE ACQUISITION, USE, AND MONITORING

To avoid errors with drug delivery devices, health care organizations must assess the devices' safety before purchase; ensure appropriate fail-safe protections (such as free-flow protection, incompatible connections, and safe default settings); limit variety to promote familiarity; and require independent double checks for potential device-related errors that could result in serious patient harm.

Questions to Consider

- Do all infusion pumps in the hospital have free-flow protection?
- Is there a policy that all pump settings for high-alert medications must be checked by two independent practitioners?
- Are oral syringes that can't be connected to IV tubing or ports available in all patient care areas (including the ED) for oral solutions?
- Do we keep the type of infusion devices and medication equipment limited?
- Is all tubing for the administration of medications, nutritional products, irrigations, etc. properly labeled?
- Does the hospital have an interdisciplinary team that reviews the purchase of all infusion devices and medication supplies?
- Is agency nursing staff adequately trained on the use of infusion devices?
- Does the biomedical department inspect all infusion devices at least yearly?

Suggested Actions

- Support the use of the newest safety features in automation.
- Prohibit the purchase of multiple types of infusion pumps or pumps that allow free flow.
- Ensure that staffing levels are adequate for the double check of pump settings for high-alert medications.
- Do not approve the purchase of new equipment or devices unless an interdisciplinary group that includes frontline practitioners has reviewed it for safety.
- Participate in product evaluation committees.
- Audit patient units to ensure that oral syringes are available and used for oral solutions.

Evaluation Tool for Risk Managers

● KEY ELEMENT 7: ENVIRONMENTAL FACTORS

Environmental factors such as poor lighting, cluttered work spaces, noise, interruptions, high patient acuity, and nonstop activity contribute to medication errors because health care providers are unable to remain focused. Staffing pattern deficiencies and excessive workload also underlie a broad range of errors and present unique challenges to health care organizations today.

Questions to Consider

- Are all critical work environments monitored for safety? Are they uncluttered and clean, with adequate lighting and minimal distractions?
- Does pharmacy have adequate space to safely prepare and dispense medications?
- Are critical workload shifts reasonable, with adequate rest between shifts and scheduled breaks and lunches?
- Are areas where medications are stored outside the pharmacy secure, and do they allow enough space to properly store and retrieve medications?

Suggested Actions

- Monitor areas within the hospital where medications are stored, prepared, and dispensed to ensure a safe environment.
- Review human resource policies and current practice to ensure safe staffing patterns.
- Visit all areas of the hospital to review safe medication storage and to ensure that proper space is available to prepare and administer medications.
- Interview nurses and pharmacists for their views on environmental safety issues for medication storage and use.

Evaluation Tool for Risk Managers

● KEY ELEMENT 8: STAFF COMPETENCY AND EDUCATION

Although staff education is a weak error-reduction strategy by itself, it can play an important role when it's 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, nonformulary medications, high-alert medications, and medication error prevention.

Questions to Consider

- Do orientation programs for personnel involved in medication prescribing, dispensing, and administration contain adequate time and cover all areas in which the medication use process is performed (patient areas, pharmacy, etc.)?
- Do nurses spend time in the pharmacy and do pharmacists spend time on the nursing units during orientation?
- Are there specific nurse staff competencies for administering chemotherapy, caring for pediatric patients, and so on?
- Are all employees oriented to the safe use and storage of medications within the hospital?
- Are educational programs directed to all staff when a medication error occurs?
- Do pharmacists provide in-service programs to nurses on new medications and provide information on nonformulary medications?
- Is the professional staff trained in responding to a medication error?
- Are pharmacy and nursing personnel offered an opportunity to attend continuing education programs on safe medication use?
- Do all personnel involved in the medication use process have access to new drug information?
- Are employees informed that they can report medication errors without fear of reprisal?

Suggested Actions

- Support an orientation program for all new staff on safe medication use and support ongoing training for clinicians.
- Never use errors as a way to evaluate staff competency.
- Ensure that all nursing personnel involved with the administration of chemotherapy and caring for pediatric patients have additional training and certification.
- Support the interdisciplinary education of new personnel with time allotted for nurses and pharmacists to spend time outside of their respective areas.
- Support the availability of funds for nurses, pharmacists, and other health care personnel to attend continuing education programs.

Evaluation Tool for Risk Managers● **KEY ELEMENT 9: 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.

Questions to Consider

- Are staff instructed to follow up on all patient and caregiver questions about medications?
- Are patients offered an opportunity to speak with a pharmacist about their medications?
- Does a program exist to let patients and caregivers know that they are an important part of safe medication use?
- Are patients and caregivers given a brochure detailing their role in safe medication use?

Suggested Actions

- Support a program that allows pharmacists to counsel high-risk patients or patients receiving high-risk medications.
- Support programs to encourage patients to identify themselves to hospital personnel and ask questions about their medications.
- Review patient information material to ensure that it is understandable for the majority of patients and their caregivers.

Evaluation Tool for Risk Managers

● KEY ELEMENT 10: QUALITY PROCESS AND RISK MANAGEMENT

Health care organizations 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, to stimulate productive discussions, and to identify effective system-based solutions. Strategically placed quality control checks are also 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.

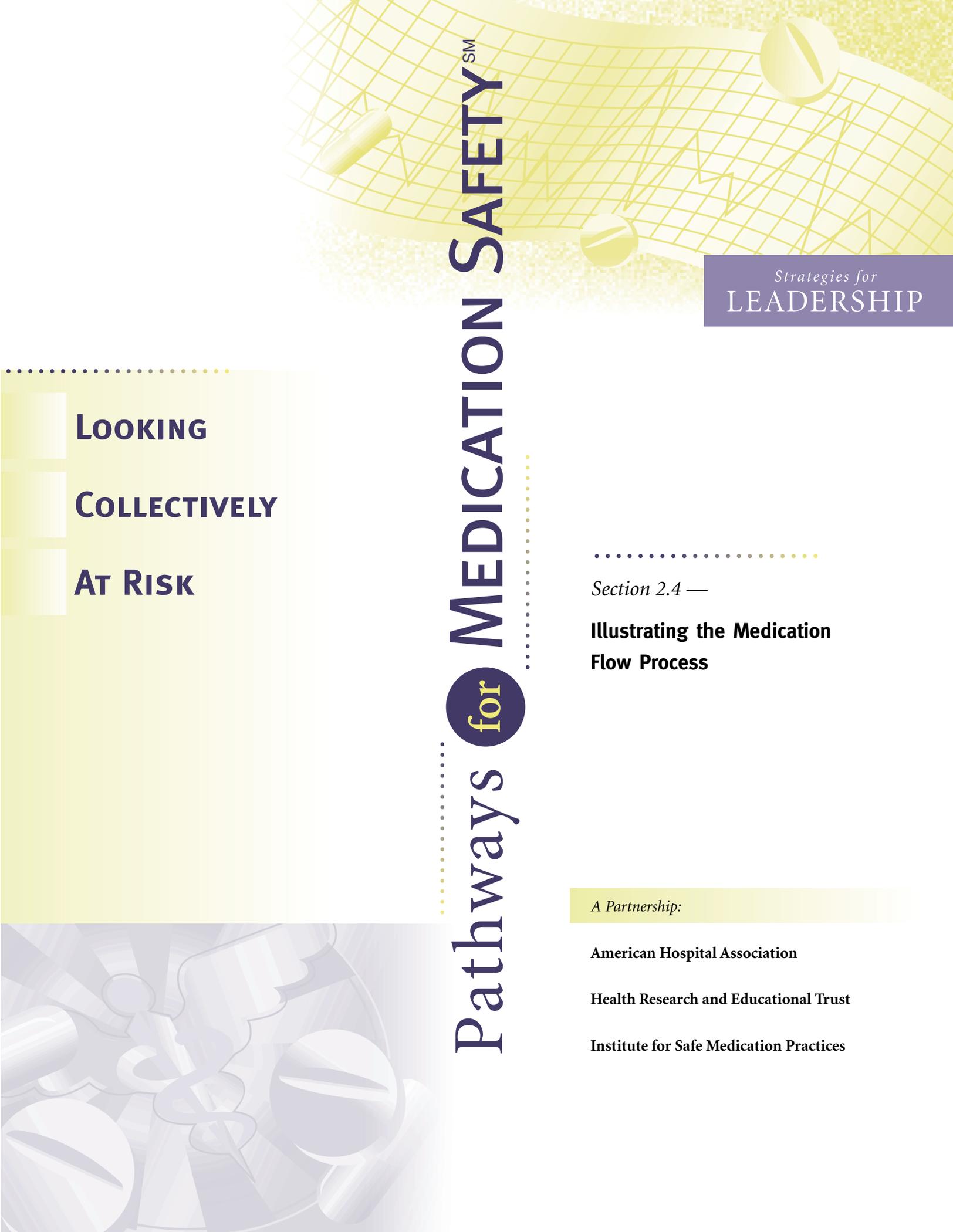
Questions to Consider

- Is the current culture in the hospital one that is blame free when it involves committing an error?
- Is discipline used in cases when malicious or illegal activity has occurred?
- Does a policy exist for disclosure of all medication errors that reach the patient?
- Does the hospital have someone or some department that all personnel recognize as a person or group that they can contact, without retribution, regarding errors or hazardous conditions and receive feedback on progress for improvement?
- Are reports of internal errors and near misses shared with all hospital personnel?
- Are staff, administrators, and the board aware that error rate reporting is not used for benchmarking comparisons or used as employee competency tools?
- Is counseling provided for employees who are involved in a serious error that causes patient harm?
- Does the organizational strategic plan contain medication safety objectives?
- Are external publications on error reports and safety issues distributed to employees?
- Are incentives and positive feedback provided for individuals who report errors?

- Do nurses perform double checks on all pump settings for high-alert medications?
- Do all personnel wash their hands before preparing medications?

Suggested Actions

- Create and support a blame-free environment and encourage the open discussion of error.
- Do not use error reporting to establish rates or comparison between units or individuals.
- Ensure that actual errors as well as hazardous conditions are freely reported.
- Share with personnel information on errors and hazardous conditions within the hospital as well as publications on external errors.
- Provide psychological counseling for employees who are involved in error that causes harm.
- Establish medication safety objectives in the organization's strategic plan.
- Conduct patient unit rounds to ask employees about safety issues they may have concerns with.
- Audit patient units and pharmacy to ensure that double-check mechanisms are in place for the preparation and administration of high-alert medications.



Strategies for
LEADERSHIP

LOOKING

COLLECTIVELY

AT RISK

Pathways **for** **MEDICATION SAFETY**SM

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Section 2.4 —

**Illustrating the Medication
Flow Process**

A Partnership:

American Hospital Association

Health Research and Educational Trust

Institute for Safe Medication Practices



Section 2.4—

ILLUSTRATING THE MEDICATION FLOW PROCESS

*There are several methods of implementing or illustrating the use of the risk assessment questions and actions presented in **Section 2.3** of this document. They can be used for a retrospective look at an actual error, root cause analysis (RCA), which was briefly described in **Section 2.1**, or they can be used to perform a Failure Mode and Effects Analysis (FMEA), as described in **Section 2.2**. Two other ways to use the risk assessment in **Section 2.4** are to develop a flow diagram or present a case scenario utilizing the information. This section presents an example of a flow diagram and two case scenarios to illustrate how the risk assessment thought process can be used to further help your organization in medication error prevention.*

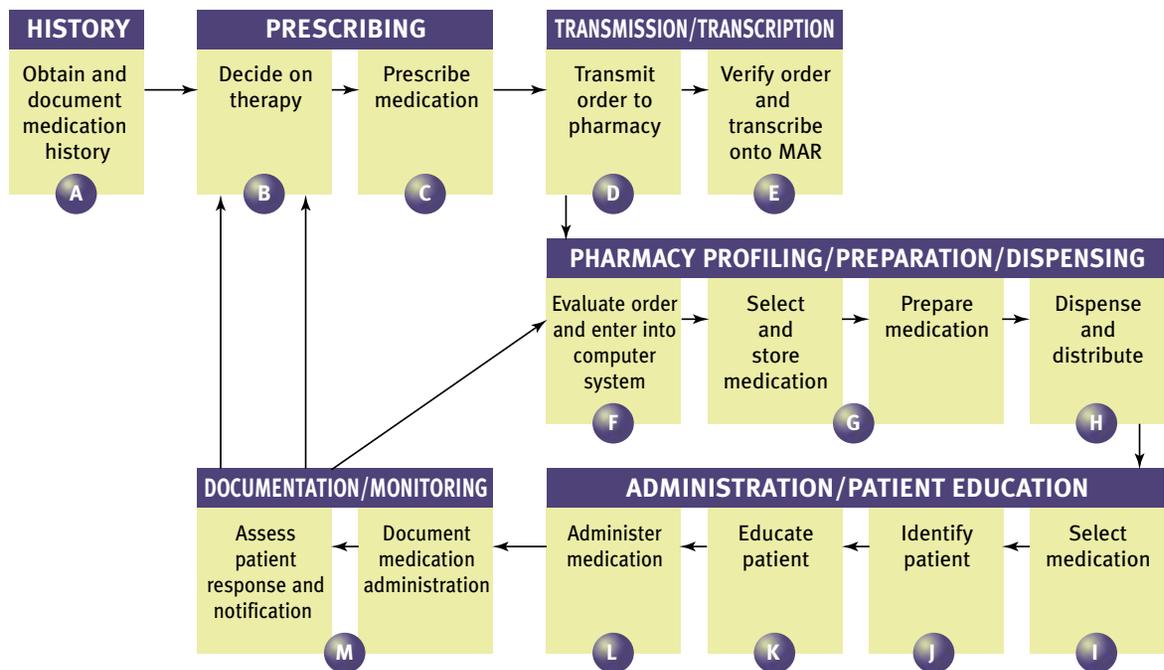
● PROCESS FLOW DIAGRAMS

An easy method to help identify the steps in a hospital's medication use system is to develop a process flow diagram of the system.

The diagram should be put together with the help of all the individuals involved in the medication use process (physicians, nurses, unit secretaries, transport personnel, pharmacists, pharmacy support staff, and so on). The diagram can be very detailed or may include just the basic steps in the process.

Below is a sample diagram constructed by ISMP. The letters A through M represent a 13-step sample medication administration process. Each step is listed below with suggested questions that can be asked when assessing safe practices within the system. Depending on the level of detail deemed appropriate for the institution, this process can be used in a variety of environments.

Figure: Sample Medication Process Diagram. Source: 2002 © Institute for Safe Medication Practices. Reprinted with permission



● QUESTIONS FOR EXPLORING THE PROCESS

The questions used below are not meant to be all-inclusive, but they should help the assessment team begin thinking of safety characteristics that should be incorporated in their process. The questions within each process may be directed to all health care practitioners or to the health care personnel

who are most actively involved in the process being described. This is not meant to imply that certain questions are only for physicians, nurses, or pharmacists; they are intended to help all practitioners assume the perspective of each other's discipline.

History

STEP A: OBTAIN AND DOCUMENT MEDICATION HISTORY

- Is a complete medication history taken on all new patients that includes prescription and over-the-counter medications, vitamins, herbal products, and any use of illicit drugs? Is the information easily obtainable online or are there prompts on written materials to guide in asking questions?
- Are outpatient laboratory studies and other test results that are pertinent to the medications the patient may be taking readily available and accessible?
- Are allergies verified by a health care professional and documented in the written and electronic record, as well as on the front of the chart?
- Is information on the patient's diagnosis and comorbid conditions shared with pharmacy?
- Is a pharmacist readily available to assist in medication history taking?

Prescribing

STEP B: DECIDE ON THERAPY

- Do I have ready access to all patient information, including laboratory studies? Does this include studies performed as an outpatient?
- Is computerized up-to-date drug information available on all the patient units? Are all reference texts current and up to date?
- Are standardized drug protocols, guidelines, dosing scales, and so on readily available where prescribing occurs?
- Is the hospital formulary readily available?
- Am I kept informed of formulary decisions and provided information on new medications added to the formulary?
- Is a pharmacist readily available to answer questions that I may have on medications?
- Do I ask patients for input into what I may prescribe and educate them about the medications they will be taking?
- Do I have access to a computerized order entry system that will warn me about unsafe orders (allergies, drug interactions, and so on) and offer decision rules for the use of formulary medications and laboratory testing?

STEP C: PRESCRIBE MEDICATION

- Do I use electronic prescribing to enter new orders?
- Do standardized preprinted orders exist for common diagnoses, and are they available on all patient units?
- Are preprinted order forms that include maximum doses for high-alert drugs available?
- Do I use dangerous abbreviations when writing orders?
- Do I include the total dose and mg/kg dose for children or mg/m² dose for chemotherapy orders?
- Am I uninterrupted when I am writing medication orders?
- Do practitioners ask me to repeat back and spell out all verbal medication orders?
- Do I rewrite all orders when patients are transferred from different levels of care?
- Are orders written for “resume pre-op medications,” “take medication from home,” “discharge on current therapy”?

Transmission/Transcription**STEP D: TRANSMIT ORDER TO PHARMACY**

- Are pharmacists available on patient care units to check on new orders before they are sent for preparation and dispensing?
- Are orders electronically transmitted to pharmacy?
- Does pharmacy have important patient information (allergies, diagnosis, height, weight, comorbid conditions, etc.) before orders are sent?
- If addressographs are used, are they easy to read and clearly visible with patient information?

STEP E: VERIFY ORDER AND TRANSCRIBE ONTO MAR

- Are orders electronically entered into a computer system that is interfaced with the nursing MAR and the pharmacy computer system?
- Are all orders legible and free of dangerous abbreviations and dose designations?
- Do medication orders contain the trade and generic name of drugs when necessary and include the total dose and mg/kg dose for children and mg/m² dose for chemotherapy?
- Is pharmacy immediately notified of any legibility, spelling, dosing, and other issues with medication orders?
- Does a policy exist for conflicts that may arise when orders are questioned?
- Does an area free from noise and activity exist for transcribing orders onto the MAR?
- Are standardized dosing times and dosing windows used for all medications except for medications that must be given immediately?
- Does pharmacy provide the MAR on at least a 24-hour basis?

Pharmacy Profiling/Preparation/Dispensing

STEP F: EVALUATE ORDER AND ENTER INTO COMPUTER SYSTEM

- Are pharmacists available on the patient care units to assist prescribers and nurses on new medication therapy decisions and questions?
- Are orders entered electronically and transmitted directly to the pharmacy computer system?
- Are preprinted standardized order forms used for high-alert medications and common diagnoses?
- Are medication orders free of dangerous abbreviations and dose expressions?
- Do orders contain an indication for the medication, especially those that have been identified as having look-alike or sound-alike errors reported?
- Do prescribers write “resume previous medications” or “take medications from home”?
- Are nonformulary medications used only when necessary?
- Does a policy exist for conflicts in dealing with prescribers if a medication question is encountered?
- Is important patient information readily available and easily accessible when reviewing medication orders?
- Does the computer system automatically screen for allergies, drug interactions, maximum doses, and so on etc?
- Does the pharmacy computer system contain warnings and alerts for look-alike and sound-alike drug products?
- Is the laboratory system seamlessly interfaced with the pharmacy computer system?
- Is outpatient medication and laboratory information available to me electronically?
- Do all pharmacy order entry terminals have electronic drug information available, and are they updated at least quarterly?
- Are labels generated for medication orders that will be used to check against the original order?

STEP G: SELECT, STORE AND PREPARE MEDICATION

- Does the hospital buy products with potentially confusing names and packages?
- Are the majority (greater than 90 percent) of all medications obtained or prepared in unit-dose form?
- Does the pharmacy purchase premixed IV solutions and syringes whenever they are available?
- Are oral solutions obtained in unit-dose containers or, if unavailable, are they prepared in oral unit-dose syringes?
- Is the workspace and lighting adequate for medication storage and preparation?
- Are medications with look-alike and sound-alike names and packaging stored separately within the pharmacy?
- Are bulk chemicals and external medications and products stored with internal medications within the pharmacy?
- Is appropriate infection control followed for the preparation of compounded oral and intravenous products?
- Are all medications properly labeled with the drug name, strength, dose, route of administration, and the patient’s name and location?
- Are independent double checks performed on all high-alert medications both on dose calculations and preparation?
- Are quality control measures in place for end-product testing of preparations such as TPN solutions, cardioplegic solutions, or dialysis solutions?

STEP H: DISPENSE AND DISTRIBUTE MEDICATION

- Are medications checked against the label and original order copy before they are dispensed from the pharmacy?
- Are standardized concentrations used for all high-alert medications?
- Is medication delivery under the control of pharmacy?
- Does medication delivery follow established turnaround times for “stat,” “now,” or routine medication orders?
- Are areas where medications are delivered safe and secure?
- Are nurses notified when a delivery is made to the patient care unit?
- Are discontinued medications retrieved from the patient care units in a timely manner?
- Are nonpharmacy personnel prohibited from entering the pharmacy when it is closed?

Administration/Patient Education**STEP I: SELECT MEDICATION**

- Are medications contained on the unit in a secure and safe area?
- Is the space where medications are stored (such as stock cabinets, cassettes, refrigerators) clean and of adequate size for proper storage?
- Is floor stock available on the unit specific for the patients who are treated in that area?
- Are all medications provided in unit-dose form (includes oral tablets and solutions, intravenous push medications, etc.)?
- Is there a direct interface of automated dispensing cabinets with the pharmacy computer system?
- Does pharmacy have the ability to check medication orders before the drugs are available from stock?
- Do I check patient allergies before I prepare to administer any medications?
- Do I obtain a double check of high-alert medications before I remove them from stock or prepare them for administration?
- Do I have ready access to drug information on all medications that I must administer?
- Are infusion devices readily available to me when I need them?

STEP J: IDENTIFY PATIENT

- Is bar coding used to verify patient identity?
- Do I ask patients to identify themselves before I administer any medications?
- Do alert patients identify themselves to me before they accept any medications?

STEP K: EDUCATE PATIENT

- Is drug information readily available to help educate patients?
- Do I provide understandable written information to patients and their caregivers?
- Are patients informed about look-alike and sound-alike drug products that could be confused with their current medication?
- Do I encourage patients to ask questions about their medications and to notify me of any problems they may be experiencing?
- If a patient or a caregiver questions me regarding a medication, do I try to get an answer before I administer the medications?
- Are pharmacists available on the unit to assist in patient education?
- Are there certain medications or patient criteria that automatically trigger a consult with a pharmacist for patient education?

STEP L: ADMINISTER MEDICATION

- Have I used appropriate hand washing and other infection control procedures before I administer this medication?
- Is the medication I am about to administer in a unit-dose package that is properly labeled? If the medication is for IV administration, is it labeled?
- Do I have to “manipulate” the medication (such as split a tablet, draw up a parenteral dose, measure an oral solution from a stock bottle) before I administer it?
- Have I checked for allergies before I administer this medication?
- Do I have the MAR at the bedside while I administer this medication?
- Am I aware if the medication I am about to administer is a high-alert drug or has heightened error potential (does it have auxiliary labels, notation on the MAR), and am I aware of any extra precautions to take?
- If the medication is intended for administration that is intravenous (peripheral, central, and so on), nasogastric, or through a feeding tube, is it noted clearly on the MAR and are the “ports” properly labeled?
- Is bar coding used to verify patient identity and verify drug selection before I administer them?
- Is another health care professional available to double-check any high-alert medication I may be administering or to check my pump settings?
- Am I properly trained on the use of any infusion devices that I may be using to administer medications?
- Do I have ready access to an antidote if needed for any severe adverse effects from this medication?
- Have I explained to the patient adverse effects of the medication and told him/her to notify me in case any occur?

Documentation/Monitoring

STEP M: DOCUMENT MEDICATION ADMINISTRATION, ASSESS PATIENT RESPONSE AND NOTIFICATION

- Is bar coding available to document the patient, time, and medication that I just administered?
- Do I have the MAR at the patient's bedside to document the time and medication administered?
- Does the MAR contain patient assessment parameters that should be monitored with the medication that I just administered?
- Am I able to electronically record my assessment (such as through vital signs, glucose reading) before or after medication administration?
- Is a pharmacist available on my unit to answer drug information questions that I have following my assessment?
- Am I able to easily contact the pharmacy and/or prescriber for any questions that I have following medication administration?

● CASE SCENARIOS

Another mechanism to explain risk assessment to all hospital personnel is case studies. The case could involve an actual medication error or near miss that occurred, one obtained from the literature (such as reports in the *ISMP Medication Safety Alert* and *JCAHO Sentinel Event Alerts*, or an error or near miss that could happen (for example, one discussed while performing an FMEA). One well-publicized error that occurred involved the death of a newborn infant. This case shows where system breakdowns occurred in many of the *Ten Key Elements* of the medication use system.¹ This error is presented in the first case below to help identify failures in the medication use process.

The second case is a report of another serious error; it uses the ten key elements of the medication use system to show where system breakdowns occurred. By reviewing these cases and others, the reader will be able to relate how the use of some of the risk assessment tools presented earlier can play a role in proactively identifying risks that existed in these systems. These examples are not meant to present an RCA of the event but to illustrate how FMEA, the review of the ten key elements, or review of medication flow diagrams could be used to prevent errors from occurring.

Case One

THE ERROR

In 1996, a newborn infant died after receiving penicillin G benzathine intravenously. An order for penicillin G benzathine 150,000 units was written for the infant after it was discovered that the mother had contracted syphilis while residing in another state. Laboratory tests were also ordered, but a decision to treat the infant before results were available was made due to a

fear that the mother may not return with the infant for follow-up treatment. The order was misinterpreted by pharmacy as 1.5 million units. Subsequently, two prefilled syringes of 1.2 million units/2 mL were dispensed with directions to administer 2.5 mL of the drug by the intramuscular route. Due to the volume that would have to be administered to the infant, two nurses investigated if the medication could be given intravenously. After misinterpreting information about the drug in reference texts and via oral communication with the Department of Health, the medication was administered by the intravenous route, which ultimately caused the infant's death.

REVIEW OF THE ERROR

Described below are the system risks and failures revealed in a review of the medication administration process. The system risks and failures are explained in context of the *Ten Key Elements* of medication use safety explained in **Section 2.3**.

PRESCRIBING PHASE

1. Patient Information (Key Element 1)

- Past medical information, which would have revealed that the mother was treated for syphilis in the past, was not readily available.
- Treatment was initiated before laboratory results were available.

2. Communication of Drug Orders and Other Drug Information (Key Element 3)

- There was a lack of efficient means to communicate with the patient's mother, who spoke only Spanish.
- The letter "U" was used for units in the medication order, which added to the confusion between 150,000 units and 1,500,000 units.

3. *Drug Information (Key Element 2)*
- Complete information on dosing obtained from the Health Department was not documented in the medical record.
 - Medication prescribed was nonformulary and seldom used.

4. *Patient Education (Key Element 9)*
- The patient's mother and spouse were not adequately instructed in the treatment options for their infant.

ORDER PROCESSING PHASE

5. *Drug Information (Key Element 2)*
- Insufficient drug information was available on a nonformulary, rarely used medication.
 - Recommendations from the Department of Health and drug reference resources were misinterpreted.

6. *Staff Competency and Education (Key Element 8)*
- There was a lack of pharmacy staff with training in neonatal/pediatric pharmacy.

7. *Quality Processes and Risk Management (Key Element 10)*
- No maximum dose warnings were in the pharmacy computer system.

MEDICATION DISPENSING PHASE

8. *Drug Information (Key Element 2)*
- There was insufficient drug information regarding the volume of medication that can be given intramuscularly to infants.
9. *Drug Labeling, Packaging, and Nomenclature (Key Element 4)*
- No unit-dose system existed for all medications.
 - Syringes should have been labeled as 1,200,000 units rather than 1.2 million units.

- No auxiliary labeling was on the pharmacy label or syringe (i.e., "for IM use only").

10. *Staff Competency and Education (Key Element 8)*

- The staff was not adequately educated prior to dispensing a nonformulary drug.

11. *Quality Processes and Risk Management (Key Element 10)*

- The double-check policy for dispensing high-alert medications or medications to high-risk patients was inconsistent.

The above review is not meant to be an inclusive list of all the causes or risks that were involved in this case. It is meant to stimulate thought on the risks involved in an actual case. Hopefully, it can be used to appreciate how the preceding tools on assessing risk can be used to help identify inadequacies in the system before they lead to serious errors.

Case Two

THE ERROR

In 1993, mivacurium (Mivacron) instead of metronidazole was accidentally administered to several patients at a large hospital. Three patients went into respiratory arrest, and one died. A multidisciplinary team was assembled to analyze the event and determine actions that could be taken to prevent similar errors from recurring. Here's what they found:

A technician pulled several bags of foil-wrapped intravenous items from the bulk intravenous storage area. At the time, it was thought that metronidazole was the only medication in the pharmacy that was packaged in foil outer wraps. However, the anesthesia department had ordered samples of mivacurium from a drug representative without notifying the pharmacy. A shipment

of sample products had been delivered to the pharmacy the previous day and placed into stock without notice. The technician placed pharmacy-generated labels that said “metronidazole” on the foil outer wrap of each bag. The pharmacist checked the bags and the computer-generated labels against the physician’s order. No one noticed that the foil-wrapped bags actually contained mivacurium. The mivacurium was sent to the nursing unit, mislabeled as metronidazole.

When the nurses received the bags, they noted the pharmacy label for metronidazole on the outer foil wrap. They verified the drug name on the pharmacy label with the transcribed order on the patient’s MAR. The medication was administered intravenously to four patients, still packaged in the foil outer wrap. All four patients went into respiratory arrest, and one died several days later as a result of the error. The incident resulted in the termination of a pharmacist and a pharmacy technician and the suspension of several nurses.

REVIEW OF THE ERROR

The following review will identify many of the failure points in the *Ten Key Elements* that were involved in this error. By using the tools provided in the previous sections of this document you should be able to prospectively review your system to help prevent a case like this from happening in your organization.

1. *Communication of Drug Orders and Other Drug Information (Key Element 3)*

- The Pharmacy and Therapeutics Committee failed to communicate that mivacurium was added to formulary on a trial basis for the anesthesia department.
- The stickers from the manufacturer to be placed on the bags were not used (this was due to a lack of a clear drug warning from

the manufacturer and lack of clear directions to the pharmacy technician on how to place the stickers).

2. *Drug Labeling, Packaging, and Nomenclature (Key Element 4)*

- The foil packaging was used on another medication and not identified as a possible look-alike problem.
- The drug name was not printed on the outer wrap and not identified as a labeling issue. Nor was the visibility of the drug name within the foil container identified as a labeling issue.

3. *Drug Standardization, Storage, and Distribution (Key Element 5)*

- The mivacurium was stored in the bulk intravenous storage area that had drugs listed alphabetically, which placed it next to the metronidazole.
- The cartons of the two products looked similar.

4. *Quality Process and Risk Management (Key Element 10)*

- There was a failure to report a previous incident when a technician found mivacurium and metronidazole mixed in the same storage bin.

The above review is not meant to be inclusive of all failures identified in this error. Hopefully it can be used to help identify risk in your system and prevent an error like this from occurring.

Endnote

1. Judy L. Smetzer and Michael R. Cohen, “Lessons from the Denver Medication Error/Criminal Negligence Case: Look Beyond Blaming Individuals,” *Hospital Pharmacy* 33 (1998): 640-57.

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LOOKING

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Pathways **for** MEDICATION SAFETYSM

Strategies for
LEADERSHIP

.....
Attachments —

- 2.A — **Health Care Failure Mode and Effects Analysis for Intravenous Patient-Controlled Analgesia**
- 2.B — **Readings Related to *Looking Collectively at Risk***

A Partnership:

American Hospital Association

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Attachment 2.A —

HEALTH CARE FAILURE MODE AND EFFECTS ANALYSIS FOR INTRAVENOUS PATIENT-CONTROLLED ANALGESIA (PCA)

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Key

HAZARD SCORE

Hazard score = Severity Score multiplied by Probability Score

HAZARD SCORING MATRIX

Failure modes with scores that fall in the color area (8 and greater) should be given highest priority

Probability	Severity of Effect			
	<i>Catastrophic</i>	<i>Major</i>	<i>Moderate</i>	<i>Minor</i>
Frequent	16	12	8	4
Occasional	12	9	6	3
Uncommon	8	6	4	2
Remote	4	3	2	1

Scoring Guidelines

KEY FOR SEVERITY RATING:

Severity Score	Description
1	Minor patient outcome: No injury, nor increased length of stay, nor increased level of care
2	Moderate patient outcome: Increased length of stay or increased level of care for 1 to 2 patients
3	Major patient outcome: Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients
4	Catastrophic patient outcome: death or major permanent loss of function (sensory, motor, physiologic, intellectual), suicide, rape, hemolytic transfusion reaction, surgery/procedure on the wrong patient or wrong part of body, infant abduction or discharge to wrong family

KEY FOR PROBABILITY RATING:

Probability Score	Description
1	Remote: Unlikely to occur (may happen sometime in 5 to 30 years)
2	Uncommon: Possible to occur (may happen sometime in 2 to 5 years)
3	Occasional: Probably will occur (may happen several times in 1 to 2 years)
4	Frequent: Likely to occur immediately or within a short period (may happen several times in one year)

Note: *Scoring method adapted from: VA National Center for Patient Safety, Healthcare Failure Mode and Effect Analysis (HFMEA)

Note: Hypothetical FMEA for typical hospital using patient-controlled analgesia. Specific hospital issues and hazard scores will differ at each practice location.

EXAMPLE OF A HEALTH CARE FAILURE MODE AND EFFECTS ANALYSIS FOR IV PATIENT-CONTROLLED ANALGESIA (PCA)

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Processes & Subprocesses	Failure Modes (what might happen)	Causes (why it happens)	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
PRESCRIBING							
Assess patient	Inaccurate pain assessment	Cultural influences; patient unable to articulate	Poor pain control	2	4	8	Standard scale to help assess pain; training on cultural influences
Choose analgesic/mode of delivery	Wrong analgesic selected	Clinical situation not considered (age, renal function, allergies, etc.); tolerance to opiates not considered; standard PCA protocols not followed (or not available); concomitant use of other analgesics not considered; drug shortage; knowledge deficit; improper selection of patients appropriate for PCA	Improper dosing; improper drug; allergic response; improper use of substitute drug	4	3	12	CPOE with decision support, clinical pharmacy program; standard PCA protocol with education on use; point-of-use access to drug information; feedback mechanism on drug shortages with information on substitute drugs available; selection criteria for PCA patients
Prescribe analgesic	Wrong dose (loading, PCA, constant, lock-out), route, frequency	Knowledge deficit; mental slip; wrong selection from list; information about drug not available	Overdose; under-dose; ADR	4	3	12	CPOE with decision support; clinical pharmacy program; standard PCA protocols
	Proper patient monitoring not ordered	Knowledge deficit; mental slip	Failure to detect problems early to prevent harm	4	3	12	Standard PCA order sets with monitoring guidelines
	Prescribed on wrong patient	Similar patient names; patient identifier not clear; name does not appear on screen when ordering medications	Wrong patient receives inappropriate drug and dose; ADR; allergic response	3	3	9	Match therapy to patient condition; alerts for look-alike patient names; visible demographic information on order form or screen
	No order received	Unable to reach covering physician	Poor pain control	2	2	4	Proper physician coverage and communication channels

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Processes & Subprocesses	Failure Modes (what might happen)	Causes (why it happens)	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
DISPENSING							
Send order to pharmacy	Order not received/processed in pharmacy	Unaware of order on unit; medication used from floor stock, so order not sent; order entered onto wrong form or screen; verbal orders not documented	Drug therapy omitted; overdose; under-dose; ADR; allergic response if wrong drug used	3	3	9	Flagging system for new orders; policy to send all orders to pharmacy; physician review of new orders with unit staff; shift chart checks; standard verbal order receipt/ documentation process
	Delay in receiving/ processing order	Order not flagged; inefficient process for sending orders to pharmacy; order not seen/misplaced after reaching pharmacy	Delay in dispensing drug; use of floor stock before pharmacy order screening; delay of drug therapy	3	4	12	As above; standard, efficient process for pharmacy order receipt; timely review and triaging of orders received in pharmacy
Enter order into computer	Order misunderstood	Illegible order; use of abbreviations, trailing zeroes, naked decimal doses; verbal orders; look-alike drug names; order copy unclear	Overdose, under-dose; allergic response; ADR; delay in therapy; poor pain control	3	4	12	CPOE; preprinted orders; prohibit dangerous abbreviations, dose expressions, non-urgent verbal orders; fax original order to pharmacy; seek clarification directly with prescriber
	Order entered incorrectly	Design of software; computer mnemonics; look-alike drugs; failure/absence of double check	Same as above	3	3	9	User-friendly order entry process; look-alike drug alerts; double check process for order entry
	Order entered into wrong patient profile/wrong encounter	Poor presentation of patient demographics (fax interference, light imprint, order copy unclear); look-alike names	Same as above	3	3	9	CPOE; vivid demographics on order forms/screens; high quality fax machines, routine maintenance; view only access to prior patient encounters; alerts for look-alike names

EXAMPLE OF A HEALTH CARE FAILURE MODE AND EFFECTS ANALYSIS FOR IV PATIENT-CONTROLLED ANALGESIA (PCA)

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Processes & Subprocesses	Failure Modes (what might happen)	Causes (why it happens)	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
DISPENSING (continued)							
Enter order into computer (cont.)	Standard directions (concentration, mixing instructions) in computer wrong	Use of substitute drug due to shortage; overlook default directions in computer when changing processes	Overdose, under-dose; poor pain control	3	2	6	Checklist/testing to ensure revisions in electronic/print when changing processes/ drugs; quick access to information on substitute drugs
Produce label	Label inaccurate	Inaccurate order entry	Overdose, under-dose; wrong route; ADR	3	3	9	As above under “order entered into computer” section
	Label unclear	Ambiguous information; poor quality of printer	Same as above; delay in therapy; poor pain control	3	3	9	High quality laser printer; improve presentation of label information with nursing input
	Label not printed	Equipment malfunction; improper interface with pharmacy computer	Missed therapy; delay in therapy; poor pain control	2	1	2	Routine equipment maintenance and performance testing
	Label lost	Inefficient process for printing/retrieving labels; remote location of printer	Same as above	2	2	4	Reorganize workflow and placement of printers to improve efficiency
Prepare medication	Wrong drug	Look-alike products stored near each other; drug shortage; knowledge deficit	ADR; overdose; under-dose; allergic reaction; poor pain control	4	3	12	Separate look-alike products; PCA protocols; feedback mechanism on drug shortages with information on substitute drugs available; readily available mixing protocols; compounding log of ingredients with lot numbers; independent double check
	Wrong diluent	Same as above	ADR; toxicity from diluent	3	3	9	Same as above

EXAMPLE OF A HEALTH CARE FAILURE MODE AND EFFECTS ANALYSIS FOR IV PATIENT-CONTROLLED ANALGESIA (PCA)

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Processes & Subprocesses	Failure Modes (what might happen)	Causes (why it happens)	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
DISPENSING (continued)							
Prepare medication (cont.)	Wrong dilution/ concentration	Knowledge deficit; calculation error	Overdose; under-dose; poor pain control	4	3	12	PCA protocols; independent double check for all calculations
Check medication before distribution	Check not completed	Inadequate staffing patterns	Potential error not detected	3	3	9	Adequate staffing patterns
	Check inadequate	Same as above; environmental factors (distractions, space, lighting, noise); inefficient workflow; human factors	Same as above	3	3	9	As above; environmental and workflow improvements; mental warm-ups before checking to increase task focus; use of verbal checks
Deliver medication to patient care unit	Delay in distribution	Inadequate staffing patterns/equipment used for delivery of drugs; inefficient drug delivery system; delivery equipment mechanical failure; shared delivery system	Delay in drug therapy; use of floor stock before pharmacy order screening	3	4	12	Establish dedicated delivery system under direct control of pharmacy; use dedicated staff/equipment for medication delivery; routine maintenance and update of equipment
	Delivered to wrong unit	Inadequate, untimely interface with admission/transfer information	Same as above; omitted doses; unneeded doses on wrong unit possible (administration to wrong patient)	3	3	9	Timely and seamless communication of admissions/transfers to pharmacy
ADMINISTRATION							
Receive order/ transcribe onto MAR	Order/MAR misunderstood	Illegible order; use of abbreviations, trailing zeroes, naked decimal doses; verbal orders; look-alike drug names; knowledge deficit	Overdose, under-dose; allergic response; ADR; delay in therapy; poor pain control	3	4	12	CPOE; preprinted orders; prohibit dangerous abbreviations dose expressions, non-urgent verbal orders; seek clarification directly from prescriber/chart; staff training for typical drugs used for PCA

EXAMPLE OF A HEALTH CARE FAILURE MODE AND EFFECTS ANALYSIS FOR IV PATIENT-CONTROLLED ANALGESIA (PCA)

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Processes & Subprocesses	Failure Modes (what might happen)	Causes (why it happens)	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
ADMINISTRATION (continued)							
Receive order/transcribe onto MAR (cont.)	Order transcribed onto MAR incorrectly	Same as above; too many sections/pages of MAR; lack of support staff training; distractions; failure/absence of double check; knowledge deficit	Same as above	3	3	9	Same as above; pharmacy computer-generated MAR; staff training; environment free of distractions; user-friendly MAR; consistent double check process
	Order transcribed onto wrong MAR	Look-alike patient names; poor presentation of patient demographics on MAR; order transcribed before patient identifier added	Same as above	2	3	6	Look-alike name alerts; vivid demographics on MAR forms; high quality imprint machines
Obtain PCA infusion pump	No pump available	Inadequate supply; hoarding; bottlenecks with cleaning process	Delay in therapy; poor pain control; use of improper pump/no pump; overdose, under-dose	3	3	9	Purchase adequate supply of pumps; central distribution center; efficient cleaning process
	Wrong pump selected	As above; knowledge deficit	Delay in therapy; poor pain control	2	2	4	As above; staff training
Obtain PCA medication	Cannot find dispensed medication	Pharmacy delivery problem; no communication to nurse that medication delivered	Delay in therapy; poor pain control	2	2	4	Efficient pharmacy delivery process and communication
	Wrong drug	Look-alike products stored near each other (automated dispensing cabinets, floor stock, refrigerator); drug shortage; knowledge deficit	ADR; overdose; under-dose; allergic reaction; poor pain control	4	3	12	Separate look-alike products; PCA protocols; feedback mechanism on drug shortages with information on substitute drugs available; independent double check

EXAMPLE OF A HEALTH CARE FAILURE MODE AND EFFECTS ANALYSIS FOR IV PATIENT-CONTROLLED ANALGESIA (PCA)

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Processes & Subprocesses	Failure Modes (what might happen)	Causes (why it happens)	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
ADMINISTRATION (continued)							
Obtain PCA medication (cont.)	Wrong concentration	Same as above; unnecessary multiple concentrations available; knowledge deficit; calculation error	Overdose; under-dose; poor pain control	4	3	12	Same as above; use one standard concentration (use auxiliary warning labels if using different concentration and have pharmacy dispense the drug); PCA protocols; independent double check
	Error during compounding (wrong drug, wrong diluent, wrong concentration)	Unfamiliarity with IV admixture; no pharmacy service at night; failure of double check	ADR; overdose; under-dose; allergic reaction; poor pain control	4	4	16	Full pharmacy IV admixture service; purchase prefilled syringes/cassettes from manufacturer
Program pump	Pump mis-programmed (flow rate, concentration, lock out, loading dose)	Design flaw in pump (e.g., Abbott LifeCare PCA pump) which makes programming error-prone; lack of standard concentrations; failure to limit variety of products used; knowledge deficit; confusion between units of measure (mg vs. mcg); mechanical failure	Overdose; under-dose; poor pain control	4	3	12	Purchase pumps that are easy to program: use FMEA process to determine potential failure modes of pumps to guide purchasing decisions; limit variety of pumps; train staff on use of new pumps; minimize variety of products used for PCA; standardize concentrations used; PCA protocols; independent double check at bedside
Check medication/pump settings before administration	Check not completed	Inadequate staffing patterns; lack of making the check a priority; previous successful violations; check process not integrated into the way care is delivered	Potential error not detected and likely to reach the patient	4	3	12	Adequate staffing patterns; engaging staff in culture of safety; understand causes for prior successful violations and take action to eliminate barriers to consistent checks; build check processes into the care delivery model in use

EXAMPLE OF A HEALTH CARE FAILURE MODE AND EFFECTS ANALYSIS FOR IV PATIENT-CONTROLLED ANALGESIA (PCA)

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Processes & Subprocesses	Failure Modes (what might happen)	Causes (why it happens)	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
ADMINISTRATION (continued)							
Check medication/pump settings before administration (cont.)	Check inadequate	Same as above; environmental factors (distractions, space, lighting, noise); inefficient workflow; human factors; check not completed at bedside (to ensure check of pump settings, patient, line attachments)	Same as above	4	3	12	As above; environmental and workflow improvements; mental warm-ups before checking to increase task focus; use of verbal checks; check performed at bedside
Administer PCA	Wrong patient	Failure of double check at bedside; failure to check/absent name bracelet; ordered on wrong patient; /transcribed on wrong MAR	Overdose, under-dose; allergic response; ADR; delay in therapy; poor pain control	3	3	9	As above under “medication/pump settings checked” section; match patient therapy with condition; patient education
	Wrong route	Catheter attachment confusion; failure of double check at bedside	ADR; poor pain control	4	2	8	As above under “medication/pump settings checked” section; label proximal ends of lines near insertion ports
	Wrong dose	Failure of double check; family/nurse activation instead of patient activation; Inadequate patient/family education before use; improper use on patients who cannot activate their own PCA; patient/staff/family tampering (drug diversion, criminal intent); patient misuse (accidental activation due to confusion with call-bell, etc.)	Overdose, under-dose; ADR; poor pain control	4	3	12	As above under “medication/pump settings checked” section; patient selection criteria for appropriate use of PCA; staff education; patient education before use (surgical preadmission processes, etc.); inaccessible medication in locked pump with electronic recording of transitions; clear differentiation between call bell and activation button

EXAMPLE OF A HEALTH CARE FAILURE MODE AND EFFECTS ANALYSIS FOR IV PATIENT-CONTROLLED ANALGESIA (PCA)

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Processes & Subprocesses	Failure Modes (what might happen)	Causes (why it happens)	Effects	Severity	Probability	Hazard Score	Actions to Reduce Failure Mode
ADMINISTRATION (continued)							
Administer PCA (cont.)	Wrong flow rate	Failure of double check; pump not protected from free flow; mechanical failure; insufficient preventive maintenance of pump; inaccurate pump calibration; insufficient power source for pump	Same as above	4	3	12	As above under “medication/ pump settings checked” section; proper selection and maintenance of pumps; use of pumps protected from free flow; back-up power source for pump
Document PCA	Drug administration not documented	Human factors; environmental distractions; workload; inefficient process; multiple MAR pages/screens	Inability to properly evaluate pain management; duplicate therapy	3	2	6	Establish user-friendly MAR; review documentation before end of each shift to ensure complete; use flow sheets at bedside to document PCA (and patient monitoring parameters)
MONITORING							
Monitor effects of medication	Insufficient monitoring of effects of PCA	Workload; knowledge deficit; monitoring parameters not ordered; ineffective communication between caregivers; cultural influences	Failure to recognize the consequences of an error before patient harm occurs; inability to evaluate pain management; poor pain control	3	3	9	Standard order sets with monitoring guidelines; standard scale to help assess pain; training on cultural influences; proper staffing patterns and safe workload; use flow sheet at bedside to document PCA and patient monitoring parameters

Attachment 2.B —

READINGS RELATED TO LOOKING COLLECTIVELY AT RISK

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