Pathways for Medication Safety℠

Strategies for LEADERSHIP

Leading A Strategic Planning Effort

A Partnership:

American Hospital Association

Health Research and Educational Trust

Institute for Safe Medication Practices

Pathways for Medication Safety: Leading a Strategic Planning Effort

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Section 1 —

Executive Summary

Summary

This tool is designed to help hospital executives work with various members of their institutions to formally identify specific medication safety strategic initiatives. By incorporating medication safety objectives into the organization-wide strategic plan, hospital leadership sends a clear message—that this is an important goal, a goal that all members of the organization should strive to attain. By enumerating specific initiatives, the strategic plan also establishes a framework for tracking progress toward the medication safety goal.

Goals

The primary goal of ***Leading a Strategic Planning Effort*** is to promote the fact that medication safety should be a critical component in any hospital's overall strategic plan. The tool also provides guidance for how to incorporate medication safety into the strategic planning process.

Context

In November 1999, the American Hospital Association (AHA) Board of Trustees identified patient safety as a strategic priority and established measurable medication safety improvement goals as its first objective. To accomplish that objective, AHA formed a strategic partnership with the Institute for Safe Medication Practices (ISMP). In May 2000, AHA and ISMP together distributed the *ISMP Medication Safety Self Assessment*™ to all hospitals in the United States.[1]

The results of the self-assessment showed that specific medication safety objectives were included in the Chief Executive Officer's strategic plans in only 12 percent of responding hospitals. Furthermore, about half of all respondents did not feel that their Boards of Trustees demonstrated a commitment to patient safety by approving a safety plan, encouraging practitioner error reporting, or supporting system enhancements, including technology, that were likely to reduce errors.[2] As a result, the ***Pathways for Medication Safety: Leading a Strategic Planning Effort*** was developed to provide organizations with a model strategic plan for medication safety.

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

- ***Looking Collectively at Risk***. This tool is designed to help hospital personnel identify potential medication safety risks. Administrators/managers, physicians, nurses, pharmacists, and risk managers can use the materials in this tool to pinpoint specific areas of weakness in their medication delivery systems. This initial process can provide the foundation for a multidisciplinary effort to design and implement system improvements.

"Only 12 percent of the hospitals that were part of the self assessment actually had specific medication safety elements in their strategic plan. This tool will help more hospitals adopt and develop specific medication safety objectives as part of their strategic planning process."

—Mary Pittman, Dr. P.H. President, Health Research and Educational Trust

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- ***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 1.1 provides a brief background on strategic planning for medication safety, which answers two basic questions:

1. Why is strategic planning for medication safety important to every hospital?
2. Why should every hospital devote significant resources to medication safety?

Section 1.2 is a **Model Strategic Plan for Medication Safety**, which includes examples of seven long-term goals and suggested activities to achieve each goal.

Section 1.3 guides hospitals though a process to use the model plan to design an organization-specific strategic plan for medication safety.

The tool is accompanied by numerous attachments and references that may be helpful during the strategic planning process or during the implementation of the plan. In some cases, the attachments have been provided by organizations that have successfully implemented one of the suggested activities in the **Model Strategic Plan for Medication Safety**.

Process

1. **Involve Key People:** Establish a core team to review the model strategic plan and develop an organization-specific strategic plan for medication safety. Multidisciplinary representation on the core team is essential to the success of the strategic planning process.
2. **Review Materials:** Distribute ***Pathways for Medication Safety: Leading a Strategic Planning Effort*** to each member of the core team as well as to others who will influence or implement the plan. Ask them to familiarize themselves with the introductory material and **Sections 1.1-1.3** to any planning sessions.
3. **Map a Strategy for the Future:** Follow the guidelines provided in **Section 1.3** to develop your organization's strategic initiatives. When necessary, refer to **Section 1.2** for information regarding the long-term goals, boundaries, enduring advantages, etc.
4. **Select Change Projects:** For each long-term goal, have the core team select change projects that are most likely to lead to achievement of the goal.
5. **Implement the Strategic Plan:** Have the core team establish a communication plan to effectively disseminate the strategic plan to everyone who needs to know about it and to secure a commitment to making it happen.
6. **Monitor Performance**: Have the core team work out a timetable to periodically review the medication safety strategic plan and monitor the progress toward achieving each goal.

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Outcomes

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

- Why a medication safety component is critical to any hospital's strategic plan.
- Who should be involved in the process.
- What processes will assist participants in making appropriate judgments and decisions.
- How to identify goals, communicate relevant changes in processes and procedures, and evaluate progress toward goals.

Endnotes

1. *ISMP Medication Self Assessment*™ (Huntingdon Valley, PA: Institute for Safe Medication Practices, 2000). Available at: www.ismp.org.

2. 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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Pathways for Medication Safety℠

Strategies for LEADERSHIP

Leading A Strategic Planning Effort

Section 1.1 —

Why Hospitals Need a Strategic Plan for Medication Safety

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Section 1.1 —

Why Hospitals Need a Strategic Plan for Medication Safety

A strategy defines the organization's intent — where it wants to be in the future — and encourages everyone to work together to achieve common goals. Its focus reflects the organization's values and priorities.

Why is *strategic* planning for *medication safety* important to every hospital?

- While the hectic pace of health care often forces immediate patient needs and priorities to take precedence over planning for the future, the strategic planning process allows an organization to strike a much-needed balance between managing the short-term needs of patients and planning the long-term goals of the organization to *ensure* patient safety.
- Safe medication use requires careful planning and cannot be achieved if all of the organization's resources are spent meeting the patient's immediate needs.
- Errors involving the use of medications comprise the largest single cause of medical errors in hospitals.[1]

Why should every hospital devote *significant resources* to medication safety?

Considering the fundamental mission of any hospital—to provide patients with the best possible care—arguing the case in favor of reducing medication errors is hardly necessary from a human compassion standpoint. However, the extent to which a hospital commits resources toward this effort could be determined in part by the strength of the economic case for reducing medication errors.[2] Rest assured, a sizable body of evidence suggests that medication errors are *bad business* because they are costly in both human and financial terms.

For example, in one study: [3]

- Two serious medication errors that caused patient harm occurred with every 100 admissions.
- An average of 4.6 days were added to these patients' lengths of stay.
- An extra $5,857 per event was added to these patients' costs.
- In a 700-bed teaching hospital, the extrapolated cost of preventable adverse drug events over the course of a year was $2.8 million dollars. This staggering number does not include costs associated with investigating the adverse events, mounting a defense for associated claims, and paying settlements or awards.

Other organizational costs associated with serious medication errors include:[4,5]

- Increased malpractice insurance premiums.
- Marketing costs associated with minimizing

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the impact of negative news media coverage.
- Higher employee turnover.
- Decreased operational efficiency due to practicing defensive medicine.

Patients also bear some of the financial burden from serious medication errors. Additional care may be required due to long- or short-term disability and a loss of income may result, not just for the patient, but also for their caregivers.[6,7]

New external pressures to improve patient safety also make a strategic focus on medication safety good business. Consumers' lack of confidence in the health care industry spurred the Institute of Medicine's report, *To Err is Human: Building a Safer Health System*.[8] In that report, the committee suggested that the best strategy for improving safety is to exert external pressure on the health care industry to make errors so costly in terms of maintaining market share and reputation that organizations would be compelled to take action and invest appropriate resources to improve safety. As a result:

- Employers are now questioning how much money they spend on health benefits. [9]
- Employers also want to know how much money spent on health benefits is due to recovery from preventable events.
- Coalitions of private and public purchasers of health care have been created to put pressure on the health care industry to do more about patient safety. For example, the Leapfrog Group, a coalition of large employers, plans to reward hospitals that use effective computerized prescriber order entry (CPOE) systems.[10,11]

A final approach to determine if a strategic investment in medication safety is good business is to conduct a cost-effectiveness analysis.[12] This approach goes beyond understanding and measuring the direct and indirect costs associated with medication errors and their prevention in monetary terms. It expands the perspective in human terms, taking into consideration important societal standards, such as freedom from accidental injury.

In the end, the successful business model for health care must focus on medication safety, not just because it makes sense financially, but also because it is the right thing to do.

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, 2000).

2. J.E. Turnbull, and James Mortimer, "The Business Case for Safety," *In Lessons in Patient Safety*, eds. Lorri Zipperer and Susan Cushman (Chicago: National Patient Safety Foundation, 2001), 21-26.

3. David Bates, Nathan Spell, David Cullen, et al., "The Cost of Adverse Events in Hospitalized Patients," *Journal of the American Medical Association* 277, no. 4 (1997): 307-311.

4. William B. Weeks, Julia Waldron, Tine Foster, Peter D. Mills, and Erik Stalhandske, "The Organizational Costs of Preventable Medical Errors," *Joint Commission Journal of Quality Improvement* 27, no. 10 (2001): 533-539.

5. Philip Schneider, Maja Gift, Yu-Ping Lee, Elizabeth Rothermich, and Bruce Sill, "Cost of Medication-Related Problems at a University Hospital," *American Journal of Health System Pharmacies* 52, no. 21 (1995): 2415-2418.

6. Eric J. Thomas, David M. Studdert, Joseph P. Newhouse, et al., "Costs of Medical Injuries in Utah and Colorado," *Inquiry* 36 (Fall 1999): 255-64.

7. Diana Brahams, "Medical Errors: A Costs Burden on Society," *Medico-Legal Journal* 68 (Part 1 2000): 1-2.

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8. *To Err is Human: Building a Safer Health System*, eds. Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson (Washington: National Academy Press, 2000).

9. William B. Weeks, Julia Waldron, Tine Foster, Peter D. Mills, and Erik Stalhandske, "The Organizational Costs of Preventable Medical Errors," *Joint Commission Journal of Quality Improvement* 27 (No. 10 2001): 533-539.

10. Jane Metzger and Fran Turisco, *Computerized Physician Order Entry: A Look at the Vendor Marketplace and Getting Started* (Washington, DC: The Leapfrog Group, 2001). Available at: http://www.informatics-review.com/ thoughts/cpoe-leap.html. Accessed November 6, 2002.

11. Peter Kilbridge, Emily Welebob, and David Classen, *Overview of the Leapfrog Group Evaluation Tool for Computerized Physician Order Entry* (Long Beach, CA: First Consulting Group, 2001). Available at: http://www.leapfroggroup.org/CPOE/CPOE%20 Evaluation.pdf. Accessed November 6, 2002.

12. William B. Weeks, Julia Waldron, Tine Foster, Peter D. Mills, and Erik Stalhandske, "The Organizational Costs of Preventable Medical Errors," *Joint Commission Journal of Quality Improvement* 27, no. 10 (2001): 533-539.

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Section 1.2 —

Model Strategic Plan for Medication Safety

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Section 1.2 —

Model Strategic Plan for Medication Safety

The **Model Strategic Plan for Medication Safety** is comprised of seven long-term goals:

1. Create, communicate, and demonstrate a leadership-driven culture of safety.
2. Improve error detection, reporting, and use of the information to improve medication safety.
3. Evaluate where technology can help reduce the risk of medication errors.
4. Reduce the risk of errors with high-alert medications prescribed and administered to high-risk patient populations or at vulnerable periods of transfer through the health care system.
5. Establish a blame-free environment for responding to errors.
6. Involve the community in medication safety initiatives and medication self-management programs.
7. Establish a controlled formulary in which the selected medications are based more on safety than cost.

Each long-term goal is followed by a brief description of:

- **Boundaries** – Definite parameters based on current limitations and capabilities that help clarify exactly what should be accomplished.
- **Enduring Advantages** – Sustained, positive influences on the system that benefit patients, staff, and the organization.
- **Potential Barriers/Threats** – Conditions or situations that could impede progress in achieving the desired goal.
- **Change Projects** – A specific tactic, activity, program, or action plan that will help achieve the strategic long-term goal.

The suggested long-term goals and change projects are provided as examples only. They are not intended to represent a comprehensive list of all possible endeavors related to medication safety that merit attention. However, the goals and change projects were selected as prime examples because:

- Most are widely applicable in hospitals regardless of size or financial capabilities.
- The potential for improving medication safety is high if the suggested change projects are implemented and the long-term goals are achieved.
- An expert advisory panel of health care leaders agreed that they represent best practices.

Likewise, the enduring advantages and potential barriers and threats that accompany each long-term goal are not intended to represent a comprehensive list of all possibilities. In fact, hospitals are likely to uncover additional advantages and more specific barriers based on their unique circumstances.

"Leading a Strategic Planning Effort **will have special relevance for hospital leadership in that it is designed to help hospital executives work with various members of their institution to formally identity specific medication safety strategic initiatives."**

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

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Model Strategic Plan for Medication Safety

Long-Term Goal # 1

Create, communicate, and demonstrate a leadership-driven culture of safety.

Boundaries:

- The selected change projects will be directly related to medication safety.
- Staff dedicated solely to medication safety will be limited to 0.5 FTE for the first year, with further evaluation of expanded hours thereafter.

Enduring Advantages:

- Ongoing executive commitment to and participation in patient/medication safety initiatives.
- A culture in which staff/board members at all levels of the organization clearly understand that patient safety is the top priority and patients recognize that all are committed to translating that goal into action.
- Strong commitment and momentum maintained for patient/medication safety regardless of budgetary and human resource constraints.
- Enhanced public perception of the hospital's commitment to patient safety.
- Potential to become the hospital of choice for patients, employers, and other purchasers of health care.

Potential Barriers/Threats:

- National shortage of qualified personnel who may fill any positions necessary to accomplish the goal (e.g., patient safety officer).

Change Projects:

- Revise the hospital mission statement to accurately reflect the strategic emphasis on patient safety and ensure that all staff members understand its importance.
- Widely communicate the organization's commitment to patient safety, in specific terms and with concrete examples, to staff, patients, visitors, vendors, and others involved in the provision of health care.
- Conduct anonymous staff surveys to discern the hospital culture as it relates to medication/patient safety and staff's level of anxiety and fear over making and reporting errors. (See **Attachments 1.A1-1.A6** for sample surveys.)
- Carry out weekly executive *WalkRounds*™ (by the CEO and other senior leaders) in all areas of the hospital and during all three shifts to demonstrate leadership's commitment to a culture of safety and obtain frontline staff and patient feedback about medication/ patient safety issues. (See **Attachment 1.B**, which describes the process for executive *WalkRounds*™.)
- Disseminate the *ISMP Medication Safety Alert*[1] to all staff involved in medication use.
- Establish medication safety as a standing agenda item for discussion at monthly Medical Executive Committee meetings, Board of Trustees meetings, and other executive level committee meetings.
- Recruit and train a patient safety officer who will spend about 0.5 FTE on improving medication safety. (See **Attachment 1.C** for a sample job description for a patient safety officer.)
- Create a "business case" template to help the staff, executives, and board members understand the financial impact of medication errors and other medical errors. (See **Attachment 3.A** for a cost savings worksheet.)
- Develop a dashboard report for the Board of Trustees to keep them informed about the status of medication safety in the organization.

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Model Strategic Plan for Medication Safety

Long-Term Goal # 2

Improve error detection, reporting, and use of the information to improve medication safety.

Boundaries:

- Primary focus will be on medication errors and adverse drug events.

Enduring Advantages:

- Ongoing process of focused and open learning from medication errors so that they can be prevented in the future.
- Enhanced staff awareness about conditions that could jeopardize patient safety (e.g., staff more likely to notice and report hazardous conditions).
- Proactive use of information about hazardous conditions to prevent errors.
- Improved outcomes for patients.
- Reduced legal liability for poor patient outcomes due to adverse drug events.

Potential Barriers/Threats:

- Staff fear of reporting errors due to mandatory requirements that hospitals report all adverse events that cause patient harm to professional licensing bodies, which may, in turn, take action against the practitioner's license.
- Blaming culture.
- Legal limits on the protection of medication error information.

Change Projects:

- Hold quarterly focus groups of frontline staff for "off-the-record" discussions to learn about perceived problems with medication use.
- Establish a system of rewards for staff members who report medication errors, participate in identifying system-based causes, make recommendations to improve the system, and facilitate the necessary changes.
- Create a method to capture pharmacy interventions electronically (e.g., using palm-held devices and the pharmacy computer system) and use the data to identify additional opportunities to improve medication processes.
- Streamline the reporting process and obtain only the most important information about proximate and system-based causes of errors with a minimal amount of staff effort. (See **Attachment 1.D** for a sample medication error reporting format.)
- Establish a feedback mechanism to keep frontline staff, managers, and senior leadership informed about medication safety problems and error reduction strategies.
- Establish a system for using triggers and markers to enhance detection of patient harm from adverse drug events. (See **Attachment 1.E** for a sample list of triggers and markers.)
- Investigate use of the observational methodology[2] to enhance medication error detection during drug administration.
- Educate members of the medication safety team about the principles of error reduction (e.g., standardize, simplify, restrict access or limit use, improve access to information, automate, and create fail-safes) so that recommended remedies have the greatest chance of sustained impact.

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Long-Term Goal #3

Evaluate where technology can help reduce the risk of medication errors.

Boundaries:

- Initial focus will be on a bedside bar-coded drug administration system and CPOE.
- Financing for implementation of a CPOE system will have to be included in the budget cycle, and will require up to an 18-month lead time.
- Financing for implementation of bar-coding applications in patient care settings will require lead time of up to 12 months and coordination with external vendors and agents.
- Enduring Advantages will accrue only if adequate time and resources are committed, and only if the current technological foundation is sound.

Enduring Advantages:

- Enhanced technology will improve patient care and business processes.
- Enhanced technology will improve public perception of quality health care services.
- A hospital that effectively uses advanced technology is more likely to become the provider of choice for patients, employers, and other purchasers of health care.
- Pre-implementation planning can reduce implementation errors and cycle time.

Potential Barriers/Threats:

- Lack of a single source of reference for all internal information system capabilities and clinical functionality.
- Difficulty interfacing new technology with current information systems.
- Failure of manufacturers to place a standard bar code on each unit dose package of medication.
- External marketplace pressure to implement technology.
- Introduction of new errors with technological solutions.
- Staff resistance to incorporate new technology into the present workflow.

Change Projects:

- Prepare an up-to-date compendium of information system capabilities and all clinical functionalities currently driven by automated technology in the hospital.
- Investigate bar coding applications in patient care settings to determine feasibility for implementation.
- Undergo a readiness assessment for application of a bar-coded drug administration system. (See ***Pathways for Medication Safety: Assessing Bedside Bar-Coding Readiness: Section 3.2.***)
- Investigate and compare CPOE systems currently on the market to inform a subsequent decision about which vendor to select.[3,4]

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Model Strategic Plan for Medication Safety

Long-Term Goal # 4

Reduce the risk of errors with high-alert medications prescribed and administered to high-risk patient populations or at vulnerable periods of transfer through the health care system.

Boundaries:

- Focus for high-alert medications includes: opiates and narcotics, anticoagulants, chemotherapy, insulin, concentrated electrolytes, neuromuscular blocking agents, thrombolytics and adrenergic agents.
- Focus for high-risk patient populations includes: elderly and pediatric/neonatal populations.
- Focus for periods of transfer includes: admission and discharge from the hospital.

Enduring Advantages:

- Reduction of errors that have the greatest risk of causing harm to patients.
- Valuable use of resources since impact on patient safety high.

Potential Barriers/Threats:

- National shortage of pharmacists and nurses.
- Staffing shortages for qualified technical support in the pharmacy.
- Decreased availability of medications packaged in unit doses.

Change Projects:

- Expand clinical pharmacy consultation services for high-risk patients and patients receiving high-alert medications.
- Initiate an outpatient warfarin monitoring program that is coordinated with community physicians' offices.
- Establish maximum safe doses for high-alert medications and enter them into the pharmacy computer system to electronically alert staff to potentially toxic doses. (See **Attachment 1.F** for a template to use for maximum dose limits of parenteral chemotherapy.)
- Evaluate the storage and use of high-alert medications in the hospital and initiate safe practice recommendations as published in the literature. (See **Attachment 1.G** for a sample checklist/action plan for the management of high-alert medications.)
- Establish a process to verify the medications the patient has been taking before admission.
- Implement a full pharmacy IV admixture program 24 hours a day, 7 days a week.
- Increase the percentage of high-alert medications dispensed to patient care units in unit dose packages from 75 percent to 95 percent.
- Where appropriate, establish standard order sets for the use of high-alert medications (pain management, anticoagulants, chemotherapy, concentrated electrolytes, etc.).
- Use a Failure Mode and Effects Analysis (FMEA) process to determine possible failure points associated with patient-controlled analgesia (PCA) and take action to reduce the risk of errors or over-sedation of patients. **See Attachment 2.A** for an example of an FMEA for PCA.
- Standardize the types of IV infusion pumps used in the hospital to administer high-alert medications (PCA, drug infusions, epidural infusions, etc.).
- Establish a consistent process for a cognitive, independent double check of all high-alert medications before administration.

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Model Strategic Plan for Medication Safety

Long-Term Goal # 5

Establish a blame-free environment for responding to errors.

Boundaries:

- A blame-free environment will not preclude appropriate disciplinary or legal action for intentionally malicious or illegal acts that may lead to a medical error.

Enduring Advantages:

- Acceptance of human fallibility, leading to improved systems that will make it more difficult for staff to err.
- Open discussion of human error without fear of reprisal, so that problems can be identified and remedied.
- Enhanced job satisfaction, staff morale, and trust among staff and leaders.
- Improved creativity because fear of failure is reduced.
- Organizational culture will be aligned with the desired organizational values, vision, and patient safety goals.

Potential Barriers/Threats:

- Staff fear of reporting errors due to mandatory requirements that hospitals report all adverse events that cause patient harm to professional licensing bodies, which may, in turn, take action against a practitioner's license.
- Pressure to impose disciplinary sanctions when handling people who make errors associated with a policy violation, pattern of frequency, or patient harm.
- Prior, long-standing blame culture and the practice of using the absence or presence of errors to evaluate staff performance and competency.
- Inconsistencies with desired behavior for handling people involved in errors due to individual attitudes.

Change Projects:

- Survey the staff regarding the level of anxiety and fear associated with making and reporting errors. (See **Attachment 1.A4-1.A6** for sample questionnaires.)
- Provide training for all staff and board members regarding the benefits of a blame-free environment and the hazards of a blaming culture.
- Establish a blame-free, non-retaliatory, error reporting policy that is fully supported by hospital leadership, human resources, risk management, and legal services. (See **Attachment 1.H** for a sample blame-free error reporting policy.)
- Hold an educational session for all levels of clinical staff, management, senior leaders and the board to describe how and why human error occurs, regardless of competency, experience, and vigilance.
- Incorporate patient safety tenets in evaluation of employee competence during the initial three-month probationary period, and in annual performance evaluations for all employed staff. (Patient safety tenets should not include the absence or presence of errors as a criterion.) Include similar patient safety tenets in the board's self evaluation.

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- Provide training for management on ways to effectively evaluate competency and performance, supervise and mentor staff's clinical skills, and handle difficult staff behavioral issues without allowing the presence or absence of medical errors to be a factor.
- Establish a mechanism to routinely review literature (e.g., *ISMP Medication Safety Alert*™, NPSF's *Patient Safety Literature Current Awareness Alert*, and AHA's *Improving Medication Safety* web page and *Prescriptions for Safety* series)[5-8] about medication errors that have happened in other organizations to stimulate non-threatening, blame-free group discussions about errors.
- Promote a model of shared accountability for errors based on realistic expectations (promoting safety, not perfect performance) and a clear understanding of the role leaders and frontline staff play in patient safety. For example, having leaders accountable for making safety a priority and understanding and acting on the barriers to safe practice. Holding frontline staff accountable for reporting errors, facilitating system-based changes, and safe professional practices such as asking for help when needed and a willingness to change practices to enhance safety.
- Conduct system-based analyses of medication errors and remove all focus on who made the error.
- Hold open discussions with all levels of staff about the pressure points associated with maintaining a blame-free environment (e.g., policy violations, individual pattern of frequency, patient harm).
- Create and use an employee/medical staff/board orientation program to engage staff and trustees in the culture of patient/medication safety. Reorient existing staff on a regular basis.

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Model Strategic Plan for Medication Safety

Long-Term Goal # 6

Involve the community in medication safety initiatives and medication self-management programs.

Boundaries:

- Exclude sharing specific evidentiary materials with patients, which could be used against the hospital in the event of a lawsuit.
- Proper medical supervision is required for patient self-management programs.

Enduring Advantages:

- Patients reassured that the hospital is taking effective steps to reduce the risk of medication errors.
- Allows patients to play an important role in their own safety.
- Allows consumers to make more informed decisions about their health care.
- Enhanced public perception of hospital's commitment to patient safety.
- Potential to become the provider of choice for patients, employers, and other purchasers of health care.

Potential Barriers/Threats:

- Lack of media and community interest in proactive, non-sensational, medication safety information.
- Lack of sufficient reimbursement for medical supervision of medication self-management programs for patients.

Change Projects:

- Submit quarterly (or more frequent), proactive medication safety information (editorials, feature articles, appearances on radio talk shows) to the local media to educate patients about medication safety, actions taken to reduce the risk of medication errors, and ways that patients can help prevent medication errors.
- Communicate the hospital's medication safety initiatives to patients and visitors through internal resources such as videos, televisions in patient rooms, and storyboards in the lobby.
- Establish patient responsibilities regarding medication use in the hospital and review the policy with all patients and families upon admission or during the preadmission process. (See **Attachment 1.J** for a sample medication safety pledge for patients.)
- Invite community representatives to quarterly meetings with nurses, pharmacists, and physicians so that their input on medication safety issues can be solicited regularly.
- Hold an annual community health fair specifically to raise awareness of medication safety issues (e.g., poison prevention, safe use of herbal products, safety tips for self-administration of over-the-counter medications) and to describe medication error prevention efforts at the hospital.
- Establish self-management programs in the community using hand-held monitoring devices for patients with diabetes or taking warfarin.

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Model Strategic Plan for Medication Safety

Long-Term Goal # 7

Establish a controlled formulary in which the selected medications are based more on safety than cost.

Boundaries:

- Hospital formulary is not applicable to outpatient prescriptions.

Enduring Advantages:

- Limited variety of drugs available in the hospital through a clear and systematic formulary process focused on patient safety. Cost containment is often an added benefit.
- Enhanced staff familiarity with the medications used in the hospital.

Potential Barriers/Threats:

- Group purchasing requirements and managed care contracts may limit choices for formulary medications.
- Frequent changes in managed care formularies.

Change Projects:

- Establish an initial and ongoing process to review all therapeutic categories of drugs currently available in the hospital and eliminate unnecessary therapeutic (or generic) duplication.
- Establish an automatic therapeutic interchange policy that is authorized in the medical staff rules and regulations and approved by the medical staff.
- Include error potential as a standing item for discussion and evaluation on all medications being considered for formulary addition.
- Develop a tickler system to search the literature for at least six months after adding a new drug to the formulary in order to identify errors or adverse drug reactions that may have been reported since product launch.
- Publish and distribute an up-to-date, pocket-sized hospital formulary and/or make it available in electronic format in patient care areas.
- Develop and enforce a clear procedure for ordering a non-formulary drug, which requires the prescriber to provide a compelling reason before dispensing the medication.
- Review all standard order sets to limit the choices of drugs, and ensure that only formulary medications and approved therapeutic substitutions are included for selection.

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Endnotes

1. *ISMP Medication Safety Alert*™ ed. Judy Smetzer (Huntingdon Valley, PA: Institute for Safe Medication Practices). Available at: www.ismp.org.

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Pathways for Medication Safety℠

Strategies for
LEADERSHIP

Leading A Strategic Planning Effort

Section 1.3 —

Creating an Organization-Specific Strategic Plan for Medication Safety

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Section 1.3 —

Creating an Organization-Specific Strategic Plan for Medication Safety

Follow the directions in this section to use the ***Model Strategic Plan for Medication Safety*** *to guide the design of an organization-specific strategic plan for medication safety. If your organization's strategic plans currently include long-term goals related to medication safety, consider following the process to reevaluate the goals, stimulate discussion, organize activities, and widen the scope of efforts related to improving medication safety.*

"The success of the core team—and the strategic plan itself, once established—depends on multidisciplinary representation."

–*Peter M. Senge, Art Kleiner, Charlotte Roberts, Rick B. Ross, George Roth, and Bryan J. Smith,* The Dance of Change

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Creating an Organization-Specific Strategic Plan for Medication Safety

Involve Key People

An effective strategic plan has committed people at its core.

Establish a core team to review the model strategic plan and develop an organization-specific strategic plan for medication safety. The success of the core team—and the strategic plan itself, once established—depends on multidisciplinary representation from the following staff types:[1]

- Informal leaders from the front line who have intimate knowledge of the medication-use process and can undertake meaningful tests of the practical impact of new ideas and approaches.
- Senior administrative leaders who can lead by example, not to drive compliance with the plan, but to garner support and enthusiasm from the entire organization to move the strategic ideas forward.
- Physicians and high-level managers who typically move about the organization so they can nurture broad networks of alliances and provide feedback to the core team about the level of support needed to move ideas into action throughout the organization.

Some organizations may have a medication safety team of similar composition that can take on the role of reviewing the model plan and developing an organization-specific strategic plan for medication safety. Also consider a representative from the information systems department, quality/risk/safety management, and the community at large for membership on the core team.

Distribute **Section 1.1** to the core team (and key staff as appropriate) to gain support for establishing, funding, and carrying out a strategic plan for medication safety.

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Creating an Organization-Specific Strategic Plan for Medication Safety

Assess Your Current Position

A strong strategic plan is based upon an assessment of internal processes and capabilities.

Have the core team discuss the organization's current strengths and weaknesses related to medication safety by reviewing information gleaned from reliable sources, including but not limited to:

- Medication error reporting systems.
- Interventions by pharmacists, nurses, or physicians that correct medication errors before they reach patients.
- Surveys (e.g., *ISMP Medication Safety Self Assessment*, surveys that assess staff perceptions and leadership commitment to a culture of safety).
- Failure Mode and Effects Analysis and other risk assessment processes related to medication use.
- Root Cause Analysis of serious medication errors.
- Staff or patient focus groups.

A word of caution. Do not have the core team spend so much time assessing the organization's current position that it leaves insufficient time and energy for reviewing the model plan, mapping an organization-specific strategy, implementing it, and monitoring the progress.

Hospitals are already data rich and, at some point, a successful strategic initiative will need to stop gathering and reviewing information and move forward. Even if the core group doesn't have everything it needs, it should be able to determine some strengths, weaknesses, and opportunities related to medication safety in a relatively short period of time.

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Creating an Organization-Specific Strategic Plan for Medication Safety

Review the Model Strategic Plan

Specialized knowledge from experts and review of external influences establish a strong starting point for the strategic planning process.

Have the core team review the model strategic plan and compare the suggested long-term goals to the organization's strengths and weaknesses. Consider whether each long-term goal in the model plan:

- Matches an organization-specific opportunity for improvement.
- Offers real value to patients and the organization by improving medication safety.
- Is robust enough to survive for several years despite anticipated changes in the organization and in the health care marketplace.
- Matches the organization's capabilities and culture.
- Is measurable to allow tracking of progress and modifications as appropriate.
- Could integrate well into the organization as a whole and its overall strategic plans.

Use the suggested boundaries, enduring advantages, and potential barriers/threats in the model plan to stimulate discussion around these critical issues. Also examine the external influences that may jeopardize success with reaching each long-term goal, including the following:

- Current and anticipated economy.
- Health care reimbursement systems.
- Trends in technology.
- The political and legal climate.
- Regulatory and accreditation requirements.
- Applicable laws.
- Other health-related industry trends and problems such as professional staffing shortages.

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Creating an Organization-Specific Strategic Plan for Medication Safety

Map a Strategy for the Future

A strategic plan captures a series of goals that form the basis for change. Attainment of those goals will move the hospital closer to its overall mission.

After review of the model plan, have the core team select long-term goals related to medication safety that are most applicable to the organization. This may include one, several or all of the long-term goals provided in the model plan. The core team also may suggest alternative or additional long-term goals related to medication safety that have not been provided in the model plan.

For each long-term goal selected, have the core team document the enduring advantages, potential barriers/threats, and boundaries. Remember, planning what not to do is just as important as planning what to do. While it is difficult to reject the full scope of long-term goals that have the power to reduce medication errors, it is crucial to decide up front where the boundaries lie to make each goal manageable and achievable within the organization's capabilities.

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Creating an Organization-Specific Strategic Plan for Medication Safety

Select Change Projects

Bringing about effective change is vital to achieving the long-term goals.

For each long-term goal, have the core team select change projects that are most likely to lead to achievement of the goal. To stimulate discussion, refer to the model plan for suggested change projects for all applicable long-term goals. Also have the team review the surveys, checklists, worksheets, and other materials provided in **Attachments 1.J** that may be useful in implementing the change strategies suggested in the model plan.

Keeping in mind the boundaries previously set for each long-term goal, the change projects should:

- Challenge the organization.
- Facilitate achievement of the long-term goal.
- Be measurable and realistic.

With innovative new ideas from staff, suggestions in the model plan, and a large array of best practice recommendations published in the literature, the list of potential change projects to improve medication safety is likely to be long. Thus, a system for setting priorities should be applied to achieve focus and select a workable series of robust change projects that have a high likelihood of improving medication safety. See **Attachment 1.K** for a list of criteria to assist with the prioritization process.

After selecting a manageable number of change projects for each long-term goal, have the core team (and other key individuals as needed):

- Use Force Field Analysis or an FMEA process to predict potential problems, assess their impact, and develop contingency plans as needed to maximize success.[2] For additional information on these processes, see ***Pathways for Medication Safety: Looking Collectively at Risk***.
- Set a realistic budget for each change project.
- Allocate oversight responsibility (not sole responsibility) for each long-term goal and change project to the staff member with the most relevant experience.
- Set time targets to help avoid distraction by operational issues.
- If applicable, set milestones—small achievements along the way—to help monitor progress and keep the change project on track. (See **Attachment 1.L** for a sample Gantt chart, which provides a visual display of a proposed timeline for the **Model Medication Safety Strategic Plan**.)

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Implement the Strategic Plan

A new strategy brings fresh challenges and opportunities as change projects are set into motion.

Have the core team establish a communication plan to effectively disseminate the strategic plan to everyone who needs to know about it and to secure a commitment to making it happen. Most importantly, have the core team or other key leaders answer staff questions and explore what the medication safety strategic plan means to them and the way they do their jobs. To do that, the core team should:

- Review new roles and responsibilities with affected staff.
- Invest in training staff in new skills that may be needed to achieve the goals.
- Establish a feedback mechanism and encourage comments and suggestions from staff and patients.

After the plan has been communicated fully, begin the implementation process.

Monitor Performance

An army general once said, "No plan survives contact with the enemy."

Have the core team work out a timetable to periodically review the medication safety strategic plan and monitor the progress toward achieving each goal. Although short-term operational issues should not be used as an excuse for missing target dates, realistic assessments and flexibility to modify targets are needed to adapt to unforeseen changes. While the aim is to be proactive and anticipate changes in the health care marketplace, be prepared to adapt the plan and move ahead if circumstances create surprises.

Obtaining and using feedback from staff about each of the change projects is equally vital. Staff perceptions and insight into the strategies being used to implement each change project will result in improvements that will increase the chance for success. Likewise, staff feedback is needed about how the change project is affecting jobs and patients. Without this information, the medication safety strategic plan may move ahead blindly, without due consideration of unforeseen issues that may later cause it to unravel.

Endnotes

1. Peter M. Senge, Art Kleiner, Charlotte Roberts, Rick B. Ross, George Roth, and Bryan J. Smith, *The Dance of Change*, (New York: Doubleday, 1999): 10-33.

2. D.H. Stamatis, *Failure Mode and Effect Analysis: FMEA from Theory to Execution* (Milwaukee, WI: American Society for Quality, 1995).

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Pathways for MEDICATION SAFETY℠

Strategies for
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Leading A Strategic Planning Effort

Attachments —

1.A1-A6 – **Culture Surveys and Staff Questionnaires About Error Reporting**

1.B – **Creating a Culture of Safety Through Executive *WalkRounds™***

1.C – **Patient Safety Officer Job Description**

1.D – ***Medication System Analyze-ERR™***

1.E – **Triggers and Markers**

1.F – **Guideline for Maximum Adult Dose Limits of Parenteral Chemotherapy**

1.G – **Checklist/Action Plan for the Management of High-Alert Medications**

1.H – **Policy for a Nonpunitive, System-Based Adverse Drug Event Reporting Program**

1.J – **Medication Safety Pledge for Patients**

1.K – **Prioritization Criteria for Selecting Medication Safety Change Projects**

1.L – **Timeline for Implementing a Strategic Plan for Medication Safety**

1.M – **Readings Related to *Leading a Strategic Planning Effort***

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Attachments 1.A1-1.A6

Culture Surveys and Staff Questionnaires about Error Reporting

The first steps toward changing the culture of an organization are to identify and understand the attitudes and beliefs held by individuals in the organization, as well as the activities that reflect these values. The nature of these perceptions and activities can be gathered in a variety of ways, including staff meetings, focus groups, and survey tools.

In this section you will find a variety of survey tools designed to gather information from health care professionals. Some tools are specifically designed to solicit general perceptions about the punitive nature of the current environment from frontline practitioners and staff. Another survey tool is for executives and leaders that can be used initially and intermittently as a basis for personal reflection, strategic discussion, or to guide priority setting within a larger group.

Additional questionnaires, designed for each of the three main practitioner groups, solicit information about the current state of error reporting in the organization. Each questionnaire contains scenarios specific to each practitioner type and asks the practitioner to decide whether an actual error has occurred, and whether or not the error would be reported. Practitioners should be instructed that there are no right or wrong answers but rather that the questionnaires are designed to give the organization an understanding of the barriers associated with error reporting.

Each of these tools, whether used individually or collectively, will provide a baseline understanding of the perceptions of the members within your organization. Once this initial information is known, organizations should use it to prioritize the introduction of new ways of thinking about error, handling people who've made errors, specific safety activities that should be accomplished, or other means of changing behavior and attitudes to embrace a blame-free culture of safety. When used over time, these surveys also can be used to measure the transformation of attitudes and related activities in the organization.

Attachment 1.A1 – **Survey on Perceptions Regarding a Nonpunitive Culture in Health Care**

Attachment 1.A2 – **Survey to Solicit Information About the Culture of Reporting**

Attachment 1.A3 – **Conway, James. *Strategies for Leadership: Hospital Executives and Their Role in Patient Safety***

Attachment 1.A4 – **Nursing Staff Questionnaire Regarding Error Reporting**

Attachment 1.A5 – **Pharmacist Questionnaire Regarding Error Reporting**

Attachment 1.A6 – **Medical Staff Questionnaire Regarding Error Reporting**

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Attachment 1.A1

Survey on Perceptions Regarding a Nonpunitive Culture in Health Care

From: *ISMP Medication Safety Alert*™ June 27, 2001.

Despite a growing awareness of the system-based causes of errors, many in health care are still struggling to come to terms with the role of individual accountability in a nonpunitive culture. Please take a few minutes to complete this survey to anonymously express your personal beliefs on this issue. Please note there are no right or wrong answers – only your honest perceptions about a nonpunitive culture in healthcare.

1. Please indicate whether you agree or disagree with the following statements (1 = strongly disagree; 5 = strongly agree).

	Strongly Disagree ←				→ Strongly Agree
Statements	1	2	3	4	5
1. A nonpunitive approach to errors provides excuses for poor performance.					
2. A nonpunitive approach to errors absolves staff of personal responsibility for patient safety.					
3. A non-punitive culture may increase carelessness as individuals learn that they will not be punished for their mistakes.					
4. A non-punitive culture benefits those who make errors, but the organization suffers.					
5. A non-punitive culture tolerates failure.					
6. A non-punitive culture inhibits the necessary task of identifying and weeding out "bad apples."					
7. There is no such thing as human error - only system error.					
8. A policy that grants amnesty to staff who report errors is indicative of a non-punitive culture.					
9. A staff member's history of making errors can be used as a valid measure of performance.					
10. A staff member's history of making errors can be used as a valid measure of competence.					
11. Sanctions for mistakes will produce more careful individuals and reduce the risk of errors.					
12. After an error, one of the most effective non-punitive remedies is remedial education for involved staff members.					
13. People who make frequent errors while performing a specific function are usually error prone in other tasks as well.					
14. People who make more frequent errors are less motivated to perform well and/or less concerned about patient safety than those who make less frequent errors.					

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Statements (cont)	Strongly Disagree 1	2	3	4	Strongly Agree 5
15. Errors caused by violations of policies and procedures warrant disciplinary action.					
16. Employees who make repeated or fatal mistakes must be disciplined and/or terminated to protect the safety of our patients.					
17. Failure to terminate the employment of an individual involved in a serious error will be a public relations and legal nightmare for the organization.					
18. The public will view a non-punitive culture as the healthcare industry's reluctance to take action when a serious error occurs.					

2. Please indicate your professional/nonprofessional background:

__ Physician
__ Nurse/Nurse Practitioner
__ Executive/Administrator
__ Quality Improvement Staff
__ Other: _____
__ Pharmacist
__ Pharmacy Technician
__ Risk Management Staff
__ Patient/Consumer

3. Health professionals - please indicate your major area of responsibility within your practice site:

__ Administration
__ Staff
__ Management
__ Other

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Attachment 1.A2

Survey to Solicit Information about the Culture of Reporting

2002 © Allina Hospitals and Clinics, Minneapolis, Minnesota

Hospital (circle one) ANW Mercy PEI United Unity

Department/Unit _____

Occupation (circle one) Nurse Physician Pharmacist Other _____

Please rate the following: (circle one number on each line)	Strongly Agree	Agree	Disagree	Strongly Disagree	Not Applicable
1. Senior managers at my hospital communicate to me that patient safety is a high priority.	1	2	3	4	NA
2. My department/unit acts on reported information related to medical errors (near miss, incident, sentinel event) to improve patient safety.	1	2	3	4	NA
3. Individuals are supported for reporting medical errors.	1	2	3	4	NA
4. My department/unit places blame on individuals when an error is reported.	1	2	3	4	NA
5. I fear there will be negative consequences associated with reporting medical errors.	1	2	3	4	NA
6. My workload interferes with my ability to practice patient safety.	1	2	3	4	NA
7. I feel comfortable reporting medical errors made by co-workers.	1	2	3	4	NA
8. The medication protocols in my hospital are too complex.	1	2	3	4	NA
9. The process of reporting errors at my hospital is cumbersome.	1	2	3	4	NA
10. I believe that a medical error is the result of a failure of a complex system.	1	2	3	4	NA
11. New technologies, such as electronic medical records or Pyxis, are creating a safer environment for patients in my hospital.	1	2	3	4	NA
12. New technologies available in my hospital are fully utilized to help prevent medical errors.	1	2	3	4	NA
13. I work in an environment where I can openly communicate my opinions about patient care practices.	1	2	3	4	NA

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Attachment 1.A3

Strategies for Leadership: Hospital Executives and Their Role in Patient Safety.

This tool was developed by James B. Conway, chief operations officer at the Dana-Farber Cancer institute in Boston, MA. It was developed specifically for executives' personal use and reflection on their efforts to develop a culture of safety. Available at http://www.hospitalconnect.com/aha/key_issues/patient_safety/contents/conwaytool.pdf

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Attachment 1.A4

Nursing Staff Questionnaire Regarding Error Reporting

Authors: Karen Bussone, R.N. & Steven Belknap, M.D.
Institutions: University of Illinois College of Medicine at Peoria & OSF Saint Francis Medical Center, Peoria, Illinois

Scenario #1

You misread a doctor's prescription, written for a 50 year old man who has been admitted with congestive heart failure. You mistakenly prepare for administration Inderal 10 mg TID instead of Isordil 10 mg TID.

Please indicate your opinion by circling a number 1 to 5 for each of the following questions.

A. Another nurse detects the error before you administer the wrong medication to the patient.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

B. The error is detected by fellow nursing staff after the patient receives the wrong medication for 24 hours. The patient suffers no adverse outcome resulting from this error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

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C. The doctor detects the error after the patient becomes hemodynamically unstable and is transferred to the ICU. The patient suffers no permanent adverse outcome resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

D. The doctor detects the error after the patient becomes hemodynamically unstable and is transferred to the ICU. The patient dies several days later resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

Scenario #2

You misprogram an infusion pump for a heparin infusion. The misprogrammed dose is 10 times greater than the prescribed dose.

A. You detect the error prior to the patient receiving the wrong infusion.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

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B. Same scenario, but a fellow staff member detects the error after the patient receives the wrong dose for 24 hours. The patient suffers no adverse outcome resulting from the error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

C. The error is detected when the doctor questions the nursing staff, due to the patient having a large gastrointestinal hemorrhage and increased aPTT ratio. The patient is being transferred to the ICU. The patient suffers no permanent damage resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

D. The error is detected when the doctor questions the nursing staff due to the patient having a gastrointestinal hemorrhage and increased aPTT ratio. The patient is transferred to the ICU. The patient dies several days later resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

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Please briefly explain below why, in your opinion, medication errors are gathered and investigated.

_____

_____

_____

_____

_____

_____

Will you be "praised" by your peers for reporting errors? Yes No

Will you be "praised" by your hospital administration for reporting errors? Yes No

How long have you been employed as a nurse? _____ (in years)

How long have you been employed as a nurse in our organization? _____ (in years)

Do you work in: ❑ an inpatient nursing unit? ❑ an outpatient nursing unit?

Do you work in: ❑ adult services? ❑ pediatric services?

Have you ever reported a medication error? Yes No

If yes, please comment on any action taken regarding the error.

_____

_____

_____

_____

_____

_____

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Attachment 1.A5

Pharmacist Questionnaire Regarding Error Reporting

Authors: Karen Bussone, R.N. & Steven Belknap, M.D.
Institutions: University of Illinois College of Medicine at Peoria & OSF Saint Francis Medical Center, Peoria

Scenario #1

You receive a prescription, written for a 50 year old man who has been admitted with congestive heart failure. You mistakenly dispense Inderal 10 mg TID instead of Isordil 10 mg TID. (The correct label is placed on the box, but the wrong drug is placed inside).

Please indicate your opinion by circling a number 1 to 5 for each of the following questions.

A. The nurse administering the drug detects the error prior to the patient receiving the wrong medication.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

B. The error is detected by nursing staff after the patient receives the wrong medication for 24 hours. The patient suffers no adverse outcome resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

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C. The error is detected by the doctor after the patient becomes hemodynamically unstable and is transferred to the ICU. The patient suffers no permanent adverse outcome resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

D. The error is detected by the doctor after the patient becomes hemodynamically unstable and is transferred to the ICU. The patient dies several days later resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

Scenario #2

You receive a telephone call on a Saturday morning to prepare a high-dose methotrexate infusion for a pediatric patient. In producing the labels and worksheet you choose the incorrect regimen and hence an incorrect infusion rate. The infusion rate is 10 times greater than the prescribed rate.

A. The error is detected by you prior to the patient receiving the wrong infusion.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

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3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

B. Same scenario, but the error is detected by a staff nurse after the patient receives the wrong dose for 30 minutes. The patient suffers no adverse outcome resulting from the error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

C. The error is detected by the doctor after four hours. The patient has gone into renal failure and is being transferred to the ICU. The patient suffers no permanent damage resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

D The error is detected by the doctor after four hours. The patient has gone into renal failure and is being transferred to the ICU. The patient dies several days later resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

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Please briefly explain below why, in your opinion, medication errors are gathered and investigated.

_____

_____

_____

_____

_____

_____

Will you be "praised" by your peers for reporting errors? Yes No

Will you be "praised" by your hospital administration for reporting errors? Yes No

How long have you been employed as a pharmacist? _____ (in years)

How long have you been employed as a pharmacist in our organization? _____ (in years)

Do you work in: ❑ adult services? ❑ pediatric services?

Have you ever reported a medication error? Yes No

If yes, please comment on any action taken regarding the error.

_____

_____

_____

_____

_____

_____

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Attachment 1.A6

Medical Staff Questionnaire Regarding Error Reporting

Authors: Karen Bussone, R.N. & Steven Belknap, M.D.
Institutions: University of Illinois College of Medicine at Peoria & OSF Saint Francis Medical Center, Peoria, IL.

Scenario #1

You are clerking in a 50 year old man who has been admitted with congestive heart failure. In transcribing from his list of drugs on admission you prescribe Inderal 10 mg TID instead of Isordil 10 mg TID.

Please indicate your opinion by circling a number 1 to 5 for each of the following questions.

A. The nurse administering the drug detects the error prior to the patient receiving the wrong medication.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

B. The error is detected by your registrar after the patient receives the wrong medication for 24 hours. The patient suffers no adverse outcome resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

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3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

C. The error is detected after the patient becomes hemodynamically unstable and is transferred to the ICU. The patient suffers no permanent adverse outcome resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

D. The error is detected after the patient becomes hemodynamically unstable and is transferred to the ICU. The patient dies several days later resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

Scenario #2

You misprescribe the rate for administering heparin. The incorrect rate is 10 times greater than the correct dose.

A. The error is detected by you prior to the patient receiving the wrong infusion.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

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3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

B. Same scenario, but the error is detected by a fellow staff member after the patient receives the wrong dose for 24 hours. The patient suffers no adverse outcome resulting from the error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

C. The error is detected when the patient experiences a large gastrointestinal hemorrhage and increased aPTT ratio. The patient is being transferred to the ICU. The patient suffers no permanent damage resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

D. The error is detected due to the patient having a gastrointestinal hemorrhage and increased aPTT ratio. The patient is transferred to the ICU. The patient dies several days later resulting from *this* error.

1. How likely do you think that you will be blamed and criticized due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

2. How likely do you think that you will receive disciplinary action due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

3. How likely do you think that you will be discharged from employment due to *this* error?

(Unlikely)				(Likely)
1	2	3	4	5

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Please briefly explain below why, in your opinion, medication errors are gathered and investigated.

_____

_____

_____

_____

_____

_____

Will you be "praised" by your peers for reporting errors? Yes No

Will you be "praised" by your hospital administration for reporting errors? Yes No

How long have you been employed as a doctor? _____ (in years)

How long have you been working as a doctor in our organization? _____ (in years)

Do you work as:
- ❑ Medical staff member
- ❑ An attending physician or dentist
- ❑ A consultant physician

Do you work in:
- ❑ adult services?
- ❑ pediatric services?

Have you ever reported a medication error? Yes No

If yes, please comment on any action taken regarding the error.

_____

_____

_____

_____

_____

_____

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Attachment 1.B

Creating a Culture of Safety through Executive *WalkRounds*™

Excerpted from: *Creating a Culture of Safety Through Executive WalkRounds*™: a HRSA Grant Application proposal submitted: July 26, 2001 by HRET. Project participants: American Hospital Association, Health Research and Educational Trust, Massachusetts Hospital Association, and Partners HealthCare System.

For the health care industry to promote patient safety, the leaders of health care organizations must become intimately involved in patient safety science, and they must carry the banner of patient safety for all to see.

Purpose

The purpose of our project is to develop a patient safety culture using choreographed executive *WalkRounds*™ that promote open discussion of adverse events and harm; where information gathered during the rounds directs change; and where the relationship between open discussion and change is celebrated.[1] "Effective reduction of medical/health care errors and other factors that contribute to unintended adverse patient outcomes in a health care organization requires an environment in which patients, their families, organization staff and leaders can identify and manage actual and potential risks to patient safety."[2]

This combination of *WalkRounds*™ supported by an information-to-action feedback loop will lead to a decrease in adverse events and patient harm. This may only be accomplished by improving leadership knowledge of patient safety concepts and increasing their awareness of the issues faced by their employees and enhance dialogue and communication between leadership and clinical staff and students about these issues. The *WalkRounds*™ are ideally suited to accomplish this, and in so doing will lay the groundwork for improvements in patient safety education and the implementation of safety-based clinical practice.

Rationale

Institutional culture is determined by its leaders. For the health care industry to promote patient safety, the leaders of health care organizations must become intimately involved in patient safety science, and they must carry the banner of patient safety for all to see. The tool we have developed, which we have called *Executive Patient Safety WalkRounds*™, educates leadership to openly promote patient safety while teaching all those exposed to the rounds about the underlying concepts. The rounds are multi-faceted in their ability to teach and inculcate patient safety into clinical care. Information obtained during the rounds can be analyzed systematically for the antecedent and contributing factors that lead to patient harm, and actions designed to address those factors. An effective debriefing following a *WalkRounds*™ is a 3-4 hour process. Thinking about the changes to be made can enlighten those involved, allowing them to develop a new perspective on the health care environment. Participants in the rounds will include health care leaders, clinicians, pharmacists, nurses in all phases of training and medical students.

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New insights to be gained include:

1. Learning to think about system versus individual involvement in adverse incidents.
2. Understanding and applying the concepts from cognitive psychology on how we think and how we make errors.
3. What encompasses good teamwork.
4. What encompasses effective communication.
5. How we define high reliability organizations.
6. When we should use protocols in place of reminders.
7. Learning to design interdisciplinary in-service training as well as medical and nursing school curricula.
8. As appropriate, how to address adverse events and near misses in a nonpunitive way.

Goal:

To improve the culture of safety and systems that support the practice of safe and high quality care of patients by bridging the separate practice cultures of the administrator, physician, nurse, and pharmacist.

Endnotes

1. Allan Frankel, Erin Graydon-Baker, Camilla Neppl, Terri Simmonds, Michael Gustafson, and Tejal Gandhi. "Patient Safety Leadership WalkRounds ™." *Joint Commission Journal on Safety and Quality,* 29 no 1 (2003): 16-26.

2. "LD5.2". *2002 Hospital Accreditation Standards*, (Oakbrook Terrace, IL: Joint Commission Accreditation of Healthcare Organizations), 2002, p.200-201.

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Attachment 1.C

Patient Safety Officer Job Description

The content herein was developed under a project supported by the Delaware Valley Healthcare Council and is subject to the copyright of ECRI, ISMP, and DVHERF.

The following sample job description provides a brief position summary, a list of essential functions, and basic qualifications for a Patient Safety Officer. While each hospital may have differing functions that may fall under the role of patient safety officer, the sample job description covers essential clinical patient safety functions and should be used as a starting point when creating a more detailed job description for the position.

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Patient Safety Officer

The content herein was developed under a project supported by the Delaware Valley Healthcare Council and is subject to the copyright of ECRI, ISMP, and DVHERF.

Position Summary:

The designated Safety Officer will have primary oversight of the facility-wide patient safety program. This leadership role will direct others within the facility towards process improvements that will support the reduction of medical/health care errors and other factors that contribute to unintended adverse patient outcomes. This practitioner provides leadership for safety assessments, coordinates the activities of the patient safety committee, educates other practitioners on the system-based causes for medical error, consults with management and staff, and communicates literature-based ideas regarding effective patient safety strategies to others within the organization.

Essential Functions: The Patient Safety Officer will...

1. Oversee the creation, review, and refinement of the scope of the Patient Safety Program within the facility on an annual basis.
2. Coordinate the activities of the Patient Safety Committee.
3. Serve as liaison between the CEO, the Board of Trustees and the Safety committee.
4. Oversee the management and use of medical error information. Review internal error reports and utilize information from external reporting programs (e.g., *ISMP Medication Safety Alert*™ and *ECRI Health Device Alerts.*
5. Investigate (along with risk management if a separate position) patient safety issues within the facility. Participate in Root Cause Analysis of internal error reports.
6. Recommend and facilitate change within the organization to improve patient safety, based on identified risks.
7. Collaborate the development of policy and procedures effecting organizational safety.
8. Develop a mechanism for internal communication of patient safety related information.
9. Design and implement educational presentations that facilitate the understanding and implementation of patient safety standards within the organization.
10. Serve as a resource for clinical departments on issues of patient safety.
11. Support and encourage error reporting throughout the organization through a nonpunitive error reporting system.
12. Support the development of a recognition program aimed at improving patient safety.
13. Report to the governing body on the occurrence of known medical and health care errors and identified near misses and dangerous conditions within the facility, as well as actions taken, either proactively, or based on occurrences. Barriers to the implementation of safety programs should be addressed.

Qualifications:

1. An advanced degree in a health care related field is desirable. A Bachelor's degree with appropriate prerequisite knowledge, experience and skills should also be considered.
2. Experience with the organization's identified Quality Improvement model/program
3. Knowledge of risk management principles and issues regarding patient safety
4. Superior interpersonal skills
5. Strong leadership qualities (task completion, motivation)
6. Effective change agent

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Attachment 1.D

Medication System Analyze-ERR™

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This tool has been designed as a medication error reporting form (or format for electronic reporting) to collect and analyze information about actual and potential medication errors. Using a systems-based approach, the format is designed to help staff focus on identifying the underlying causes or contributing factors to the error. This shifts the focus of the error investigation from "Who did it?" to "What allowed it to happen?"

After an initial learning curve, the prompting questions asked on the Medication System Analyze-ERR™ *can be answered in just a few minutes.*

The Medication System Analyze-ERR™ *can take the place of an event form for medication errors and hazardous conditions related to medication use. Or it also can be used by unit managers, department heads or risk managers to supplement an existing event form to facilitate investigation of the event. In addition, the information gathered through the* Medication System Analyze-ERR™ *can be collected and used to identify problematic trends and patterns and direct robust system-based process improvements.*

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Medication System Analyze-ERR™

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Patient MR# _____ Incident # _____ (if error reached patient)

(Model from the Institute for Safe Medication Practices) ✔ if no callback identified:_____

Date of error: _____ Date information obtained: _____

Patient age: _____

Drug(s) involved in error:

_____

Non-formulary drug(s)? ❑ Yes ❑ No

Drug sample(s)? ❑ Yes ❑ No

Drug(s) packaged in unit dose/unit of use? ❑ Yes ❑ No

Drug(s) dispensed from pharmacy? ❑ Yes ❑ No

Error within 24 hours of admission, transfer, or after discharge? ❑ Yes ❑ No

Did the error reach the patient? ❑ Yes ❑ No

Source of IV solution:

❑ Manufacturer premixed solution ❑ Pharmacy IV admixture ❑ Nursing IV admixture

Brief description of the event: (what, when, and why)

_____

_____

_____

_____

_____

_____

_____

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Medication System Analyze-ERR™ (cont.)

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Possible causes	*Y/N*	*Comments*
Critical patient information missing? (age, weight, allergies, VS, lab values, pregnancy, patient identity, location, renal/liver impairment, diagnoses, etc.)		
Critical drug information missing? (outdated/absent references, inadequate computer screening, inaccessible pharmacist, uncontrolled drug formulary, etc.)		
Miscommunication of drug order? (illegible, ambiguous, incomplete, misheard, or misunderstood orders, intimidation/faulty interaction, etc.)		
Drug name, label, packaging problem? (look/sound-alike names, look-alike packaging, unclear/absent labeling, faulty drug identification, etc.)		
Drug storage or delivery problem? (slow turnaround time, inaccurate delivery, doses missing or expired, multiple concentrations, placed in wrong bin, etc.)		
Drug delivery device problem? (poor device design, misprogramming, free-flow, mixed up lines, IV administration of oral syringe contents, etc.)		
Environmental, staffing, or workflow problems? (lighting, noise, clutter, interruptions, staffing deficiencies, workload, inefficient workflow, employee safety, etc.)		
Lack of staff education? (competency validation, new or unfamiliar drugs/devices, orientation process, feedback about errors/prevention, etc.)		
Patient education problem? (lack of information, noncompliance, not encouraged to ask questions, lack of investigating patient inquiries, etc.)		
Lack of quality control or independent check systems? (equipment quality control checks, independent checks for high-alert drugs/high-risk patient population drugs etc.)		

Did the patient require any of the following actions after the error that you would not have done if the event had not occurred?

❑ Testing ❑ Additional observation ❑ Gave antidote
❑ Care escalated (transferred, etc.) ❑ Additional LOS ❑ Other_____

Patient outcome: _____

_____

_____

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Attachment 1.E

Triggers and Markers

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The uses of certain medications or other specific conditions or events (e.g., death, certain laboratory values, changes in patient status) often provide a clue that an adverse drug event has occurred. These medications and conditions/events are often called triggers and markers because they signal the need for further investigation.

This list provides examples of some of the more common triggers and markers. Organizations can increase the detection and documentation of medication errors and other adverse drug events if there is a process in place to consistently evaluate patient care when a trigger or marker event has occurred. Trigger and marker events can be identified through automated systems (e.g., pharmacy or laboratory computer systems) or accomplished by those who routinely review patient records.

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Triggers and Markers

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Triggers and Markers	*Possible Adverse Reactions*
DRUGS	
Antidiarrheals	Antibiotic-induced diarrhea
Antiemetics	Drug toxicity or overdose
Antihistamines	Hypersensitivity reactions, drug rashes
Atropine	Bradycardia
Benztropine	Extrapyramidal reactions
Blood transfusions	NSAID-induced gastric bleeds
Calcium chloride	Calcium channel blocker overdose
Calcium gluconate	Calcium channel blocker overdose
Dextrose 50% in water	Hypoglycemia from insulin overdose
Diazepam	Drug-induced seizures
Digoxin immune fab (Digibind)	Digoxin overdose
Diphenhydramine	Hypersensitivity reactions, drug rashes, extrapyramidal reactions
Epinephrine	Hypersensitivity reactions
Flumazenil	Benzodiazepine overdose
Fosphenytoin	Drug induced seizures, arrhythmias
Glucagon	Hypoglycemia, beta blocker overdose
Hyaluronidase	Chemotherapy extravasations
Lorazapam	Drug-induced seizures
Naloxone	Narcotic overdose
Nitroglycerine	Dopamine extravasations
Phenobarbital	Drug-induced seizures
Phentolamine	Dopamine extravasations
Phenytoin	Drug-induced seizures, arrhythmias
Physostigmine	Anticolinergic overdose, belladonna alkaloids overdose
Protamine	Heparin overdose
Kayexalate	Hyperkalemia
Steroids (injectable)	Hypersensitivity reactions
Steroids (topical)	Hypersensitivity reactions, drug rashes
Vitamin K	Warfarin overdose, bleeding
LABS	
aPTT greater than 100 seconds	Overuse of anticoagulation
INR greater than 6	Overuse of anticoagulation
WBC less than 3,000	Drug-induced leukopenia
Serum glucose less than 50	Hypoglycemia
Drug levels	Over- or under-use of medications
Creatinine levels rising	Drug-induced renal impairment
OTHER	
Lethargy	Oversedation
Falls	Drug-induced confusion or lethargy
Rash	Drug-induced rash
Transfer to higher level of care	Possible adverse drug event
Death	Possible adverse drug event
Abrupt discontinuation of medications	Possible adverse drug event

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Attachment 1.F

Guideline for Maximum Adult Dose Limits of Parenteral Chemotherapy

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This guideline is intended as a template to assist organizations in developing maximum adult dose limits and guidelines for chemotherapy within their own facility. Establishing institutional, therapy-specific dose limits is one way to reduce the chances of an improper dose reaching a patient.

Each institution must gather its own panel of chemotherapy experts, including physicians, pharmacists and nurses, to develop a maximum dose list to meet facility needs. Limits must be communicated to all health care workers involved in ordering, dispensing and administering chemotherapy agents, and an easily retrievable list should always be available for referral. You may even decide to post such information as a wall chart in the pharmacy and in medication rooms in appropriate units. As software programming allows, enter maximum doses into all pharmacy computers and prescriber order entry systems. Once a maximum dose list is agreed upon, any dose exceeding the established limit may not be dispensed or administered under any circumstances unless it goes through a review process. This review should include input from expert clinicians other than the prescriber, nurse, and pharmacist involved.

Institutions have unique formularies and may conduct more specialized chemotherapy such as bone marrow transplant therapy. The attached guidelines include only a small number of medications to illustrate how such a guide may be created and organized. It is recognized that cancer chemotherapy is an ever-evolving science and that ongoing research and publication perpetually results in new recommendations and ideas about how therapy should be carried out. As such, the doses listed are for informational purposes only and must not be used as the sole data source when making a therapeutic decision.

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Guideline for Maximum Adult Dose Limits of Parenteral Chemotherapy

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Generic Name *Brand Name*	*Single Dose*	*Course Dose*	*Lifetime Dose*
Carboplatin PARAPLATIN®	Use Calvert formula (gives total dose in mg not mg/m2). • Use AUC 2 - 7.5 Dose = (desired AUC) * (GFR + 25) (Max. dose in mg/m2 = 400 mg/m2 IV)	Use Calvert formula (gives total dose in mg not mg/m2) • Use AUC 2 for weekly dose. • Use AUC 4-7.5 for single dose every 21-28 days. Dose = (desired AUC) * (GFR + 25)	
Cisplatin PLATINOL® PLATINOL AQ®	120 mg/m2 IV as a single dose* *Patient must be adequately hydrated.*	20 mg/m2 IV daily for 5 days every 21 days. *Patient must be adequately hydrated.*	
Doxorubicin (conventional) ADRIAMYCIN PFS® ADRIAMYCIN RDF® RUBEX®	60-75 mg/m2 IV as a single dose as a single agent once every 3-4 weeks*	No more than 30 mg/m2 per week every 2 weeks with a week rest. OR Total recommended 75 mg/m2 per cycle	550 mg/m2 with normal cardiac function 450 mg/m2 with cardiac disease, hypertension, over 65 years of age, under two years of age or if had prior radiotherapy to the chest
Doxorubicin (liposomal) DOXIL®	50 mg/m2 IV once every 3 weeks	50 mg/m2 IV once every 3 weeks	550 mg/m2 with normal cardiac function 450 mg/m2 with cardiac disease, hypertension, over 65 years of age, under two years of age or if had prior radiotherapy to the chest
Ifosfamide IFEX®	5 gm/m2 IV as a single dose *Must give Mesna to prevent hemorrhagic cystitis. Total Mesna dose is 60% - 100% of ifosfamide dose. Give 20% immediately before ifosfamide dose then 40% at 4 and 8 hours after ifosfamide dose.*	2.5 gm/m2/day as intermittent IV infusion for 5 days *Must give Mesna to prevent hemorrhagic cystitis. Total Mesna dose is 60% - 100% of ifosfamide dose. Give 20% immediately before ifosfamide dose then 40% at 4 and 8 hours after ifosfamide dose.*	

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Guideline for Maximum Adult Dose Limits of Parenteral Chemotherapy

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Generic Name *Brand Name*	*Single Dose*	*Course Dose*	*Lifetime Dose*
Rituximab RITUXAN®	375 mg/m2 IV as a single dose. *Do not administer as IV bolus or push*	375 mg/m2 as IV infusion once weekly for 4 doses. *Do not administer as IV bolus or push*	
Vincristine ONCOVIN® VINCASAR PFS®	2 mg IV as a single dose *IV only. Fatal if given intrathecally.*	1.4 mg/m2 usually capped at 2 mg with protocol driven exceptions for non-Hodgkin's lymphoma. *IV only. Fatal if given intrathecally.*	

Approved by:_____

Date: _____

*See additional reference for non-IV routes

Disclaimer: The information contained in this document has been provided as a sample template and does not represent ISMP's recommendation for drug therapy. Any information from this document should be reviewed and approved for accuracy and applicability by your organization prior to its use.

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Attachment 1.G

Checklist/Action Plan for the Management of High-Alert Medications

(adapted from "High-Alert Medications: Safeguarding Against Errors" by Michael Cohen and Charles Kilo, In: *Medication Errors*; edited by Michael Cohen, American Pharmaceutical Association, 1999)
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The following document provides organizational guidance for the safe use of high-alert medications. Included is a list of more common high-alert medications, common problems associated with each medication, and basic principles or elements for safeguarding the use of such drugs that should be considered. Each medication category is coupled with a checklist of key improvement projects designed specifically to reduce the risks often associated with the use of these medications.

Organizations should systematically evaluate each high-risk medication and establish an action plan to improve the safe use of these medications based on the suggestions provided. When other high-alert medications are added to the formulary, apply the appropriate steps as outlined in this document to promote safe use.

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Checklist/Action Plan for the Management of High-Alert Medications

(adapted from "High-Alert Medications: Safeguarding Against Errors" by Michael Cohen and Charles Kilo, In: *Medication Errors*; edited by Michael Cohen, American Pharmaceutical Association, 1999)
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Nearly all drugs have a wide safety margin, a few drugs have a higher risk of causing harm when an error involving these agents occurs. These are referred to as "high-alert medications". Although errors may not be more common with these drugs than with others, their consequences may be much more devastating. High-alert medications can be, and should be, targeted for specific error reduction interventions.

High-alert medications commonly include:

Adrenergic agents (epinephrine, isoproterenol, and norepinephrine)	Cancer chemotherapeutic agents	Benzodiazepines
Intravenous calcium	IV Heparin, thrombolytics, thrombin inhibitors Warfarin	Drugs used for ambulatory pediatric sedation including chloral hydrate, ketamine, midazolam, etc.
IV Digoxin	IV Magnesium	Hypertonic saline
Insulin	Phosphate salts	Potassium chloride
IV Lidocaine	Neuromuscular blocking agents	Narcotics and opiates (including PCA)

Three principles may be used to safeguard the use of high-alert medications:

1. **Reduce or eliminate the possibility of error** (for example, reducing the number of high-alert medications stocked by the hospital; reducing the available concentrations and volumes; and removing high-alert drugs from clinical areas).
2. **Make errors visible** (for example, having two individuals independently check infusion pump settings for high-alert drugs is one way to make errors visible and thus caught before reaching the patient).
3. **Minimize the consequences of errors** (for example, fatal errors have occurred when the contents of 50mL vials of 2% lidocaine were injected instead of mannitol, which has a similar appearance – had lidocaine 2% been only available in the clinical area in a 10mL vial, if administered erroneously in place of another drug in a 10ml vial, the amount of lidocaine injected would likely not have been fatal).

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Steps in the Ideal Medication Use Process

1. Physician enters a drug order into the computer system.
2. The computer checks for drug interations, allergy interactions and dosing.
3. A pharmacist verifies the order, reviewing system generated alerts and screens for issues not caught by the computer system.
4. The system-generated label moves to the filling area, where a technician fills the order in the pharmacy.
5. A pharmacist checks the technician's work.
6. A nurse receives the drug and checks the nursing record against the medication sent.
7. The nurse administers the drug to the patient after checking the patient's name-band against the order, telling the patient the name of the drug, the dose, and its purpose, thereby allowing the patient to also serve as a double-check (where possible).
8. Unused drugs are returned to the pharmacy, where a pharmacist/technician reviews them for mistakenly unadministered drugs.
9. Extra (missing doses) doses requested are reviewed by a pharmacist/technician to understand why the doses are not where the nurses expect.

Key Change Concepts for Safeguarding High-Alert Medications

1. **Build in System Redundancies** (e.g. unit dose drug distribution).
2. **Use Fail-safes** (e.g. pumps with electronic fail-safe clamping mechanisms to prevent free flows).
3. **Reduce Options** (e.g. instead of having the option of ordering heparin in various concentrations, like 20,000 units/250mL and 20,000 units/500mL and 25,000 units/500mL - only one option should be available).
4. **Use Forcing Functions**, which are techniques that reduce the possibility that a medication can be administered in a potentially lethal manner (e.g. using oral syringes, for oral liquid doses, that will not fit with IV tubing and to which needles cannot be attached; and computer order entry which can be used to 'force' the physician to order standardized products).
5. **Externalize or Centralize Error-Prone Processes** (e.g. centralizing all IV solution preparations).
6. **Use Differentiation** (e.g. identify and isolate look-alike and sound-alike products; use generic names which do not tend to sound alike as often as brand names).
7. **Store Medications Appropriately** (e.g. separate potentially dangerous drugs with similar names or similar packaging).
8. **Screen New Products** (e.g. Pharmacy and Therapeutics should inspect all new drugs and drug delivery devices for poor labeling and packaging).
9. **Standardize and Simplify Order Communication** (e.g. minimize verbal orders and the use of abbreviations).
10. **Limit Access** (e.g. high-alert medications should only be stored in the pharmacy where only a pharmacist can access them).
11. **Use Constraints** (e.g. pharmacy screening of all orders for high-alert medications prior to preparation and administration; automatic stop orders and dose or duration limits).
12. **Use Reminders** (e.g. use auxiliary labels on high-alert medications; computer screens with warning information about high-alert drugs).
13. **Standardize Dosing Procedures** (use standard dosing tables or charts, rather than calculate doses based upon weight or renal function which is error-prone).

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High-Alert Medications – Problems and Key Improvements

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High-Alert Medication	Common Problems *(Check if you have experienced similar problems)*	Key Improvements *(Check if the suggested Key Improvement should be included in an Action Plan)*
Adrenergic Agonists **Epinephrine** **Isoproterenol** **Norepinephrine**	❑ In the OR, these items are often drawn up into unlabeled syringes or put unlabeled or incorrectly labeled cups or pans ❑ These items come in varying concentrations (e.g. epinephrine comes 1:1000 and 1:10,000) ❑ Isoproterenol comes in 1 mg and 0.2 mg ampuls (if ordered as 1 ampul, the wrong amount may be administered)	❑ Communicate orders in a standard fashion ❑ Label all containers ❑ Remove phenylephrine and other adrenergic agents from the formulary if not absolutely needed and use prefilled syringes whenever possible ❑ Use premixed solutions, standardized preparation instructions and dosing charts ❑ Before administering any of these agents use a second nurse to independently check the drug and dose and pump settings ❑ Use cardiac monitors on all patients with a central line
Dopamine and Dobutamine	❑ Subject to mixup due to similar names, settings in which they are used and the types of patients which receive them, similar concentrations ❑ IV flow rates are often confusing because they are based on calculations of micrograms per kilogram per minute ❑ Extravasation is a problem when dopamine is given via a peripheral vein	❑ Use labels that differentiate critical parts of the names (e.g. "DOBUTamine" and "DOPamine") ❑ Use premixed solutions from different manufacturers to make sure they look different ❑ Differentiate packaging (e.g. purchase dobutamine in 250mL bags and dopamine in 500mL bags) ❑ Use order sets to standardize ordering and dosage and IV rates ❑ Use standard concentrations to facilitate the use of dosing charts and eliminate possibility of calculation errors and base dosing titration against clinical factors ❑ Label IV bags and pumps with dosage charts and equivalent delivery rates for these dosages

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High-Alert Medications – Problems and Key Improvements

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High-Alert Medication	Common Problems *(Check if you have experienced similar problems)*	Key Improvements *(Check if the suggested Key Improvement should be included in an Action Plan)*
IV esmolol and propranolol (cont.)	❑ Esmolol comes in both vials (100 mg/10mL) and ampuls (2.5 g/10mL) and there are reports of fatal errors from confusing the ampul/vials ❑ Most common error with propranolol is the unintentional administration of an IV dose equal to the standard oral dose when a patient is switched from oral to IV. The IV dose is much smaller than the oral.	❑ Minimize the need for esmolol by promoting alternative agents ❑ Standardize order communication – do not allow esmolol to be ordered by "amp" or "vial" ❑ Store esmolol only in the pharmacy and prepare drips and IV syringes only in the pharmacy ❑ Have all IV orders of propranolol double-checked by a pharmacist and second nurse prior to administration
Benzodiazepines (midazolam or Versed)	❑ Misunderstanding about the time of onset of midazolam's sedative effect often leads to errors. Many believe the onset is immediate – however, it usually takes 5 – 10 minutes to reach peak effect. If dosed more frequently than 5 – 10 minutes, respiratory arrest, from toxic levels, can and has occurred ❑ Overdoses have been associated with confusing labels. The concentration is displayed on the front panel as "1 mg/mL or "5 mg/mL". Users have erroneously assumed that these numbers refer to the total amount in the vial. Depending on the package size, the amount varies from 2 mg (1 mg/mL in a 2 mL vial) to 50 mg (5 mg/mL in a 10 mL container)	❑ Provide appropriate monitoring during the use of midazolam (e.g., use pulse oximetry, have resuscitation equipment in the area) ❑ Restrict access – do use midazolam for preop sedation except in the OR, since appropriate monitoring equipment may not be available ❑ Limit packaging options – use only one concentration and use the smallest package size possible
IV calcium (as Gluceptate, Gluconate or Chloride)	❑ Prescribers often fail to specify the salt when order IV calcium even though the amount of elemental calcium varies: gluconate contains 4.5 m Eq of Ca++ per gram; calcium chloride contains 14 meq per gram. ❑ Calcium chloride IM is extremely irritating to tissue and should never be given by the IM route ❑ Prescribers may not be aware of the factors affecting serum calcium – including serum phosphorus and albumin	❑ Make certain that all calcium orders specify the salt ❑ Standardize IV salts – but still insist that orders specify the salt ❑ Standardize all preparation of calcium solutions in the pharmacy to provide a check for calcium-phosphate incompatibilities ❑ Have protocols (like for potassium and magnesium) for administration and monitoring

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High-Alert Medications – Problems and Key Improvements

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High-Alert Medication	Common Problems *(Check if you have experienced similar problems)*	Key Improvements *(Check if the suggested Key Improvement should be included in an Action Plan)*
IV calcium (as Gluceptate, Gluconate or Chloride) (cont.)	❑ Other adverse events associated with calcium include: (1) interactions with digoxin (rapid injection of calcium may cause bradyarrhythmias, especially in patients taking digoxin); (2) antagonism to calcium-channel blockers and elevations in blood pressure; (3) hypocalcemia or hypercalcemia resulting from inefficient monitoring of calcium levels; (4) incorrect calcium-phosphorate ratios in IV solutions resulting in precipitation and end organ injury or death; and (5) tissue necrosis caused by extravasation of calcium chloride	❑ Order calcium *only* in milligrams
Chemotherapeutic Agents	❑ Frequently associated with errors and due to toxic nature, errors often have catastrophic results	❑ Require certification before allowing practitioners to prescribe, dispense or administer chemotherapy ❑ Use carefully designed computer order sets for all chemotherapeutic agents ❑ Make sure all orders include the patient's current height and weight so that the BSA can be calculated and double-checked by all caregivers ❑ Standardize dosing and delivery protocols ❑ Establish and enforce dose limits: ceiling for dose of a single drug; daily dose ceiling; total dose ceiling for a course of therapy; and total lifetime dose ceiling ❑ Require two independent calculations for all orders. Make sure orders include calculated dose and mg/BSA or mg/kg on which the dose was based. ❑ Have two individuals independently check all chemotherapy pump settings before a drug is administered ❑ Develop a standard administration procedure that includes the use of checklists ❑ Avoid confusing terminology (e.g. do not allow the use of terms such as 'platinum' which may refer to cisplatinin or carboplatin)

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High-Alert Medications – Problems and Key Improvements

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High-Alert Medication	Common Problems *(Check if you have experienced similar problems)*	Key Improvements *(Check if the suggested Key Improvement should be included in an Action Plan)*
Chemotherapeutic Agents (cont.)		❑ Identify look-alike and sound-alike medication pairs and implement methods to differentiate ❑ Develop protocols that require peer review in cases of disagreement between prescribers and clinical staff ❑ Never use "U" for units ❑ Do not use an IV pump if only a bolus is needed ❑ Use only premixed solutions ❑ Make sure pumps are protected from 'free flow'
Chloral Hydrate and Drugs used for Pediatric Ambulatory Sedation	❑ Often used for sedation in ambulatory seeting and overdoses are possible due to two strengths available (250 mg/5mL and 500 mg/5mL); also another major cause of overdose is that it is ordered in terms of volume (mls) and not milligrams ❑ May be ordered "as needed" for agitated patient – patient may receive multiple doses before it reaches it full effectiveness resulting in overdose ❑ Often administered by personnel unfamiliar with proper dosing ❑ Often given by parents before bringing child in – if errors occur in home, adequate treatment may be unavailable in the event of overdose and if the exact dose is not clear, additional doses may be given by nursing staff potentially resulting in an overdose	❑ Educate all staff involved about the *potential* for error ❑ Allow only properly trained staff to administer chloral hydrate ❑ Do not allow home use – if a child is to undergo a procedure, administer it after the child has arrived at the facility ❑ Stock and order only *one* concentration (ketamine, midazolam) ❑ Order *only* in milligrams, never in volume ❑ Dose child by weight, following a protocol for milligrams per kilogram ❑ Do not order on as needed basis. If such orders are essential, provide a maximum total allowable dosage (e.g. up to 500 mg) ❑ Monitor all children who have received chloral hydrate for preoperative sedation before and after the procedure. Have a resuscitation plan and equipment available
Digoxin	❑ Digoxin has a narrow therapeutic range and has a number of drug interactions; those at particularly high-alert include the elderly on a high dose and those also taking quinidine	❑ Provide patient education by trained staff on the importance of compliance with dosing and follow up blood tests and on the warning signs of potential overdosage ❑ Increase patient monitoring through more frequent clinic visits and serum level tests ❑ Improve frequency of digoxin blood testing ❑ Monitor use of Digibind and develop a protocol for the appropriate use of Digibind

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High-Alert Medications – Problems and Key Improvements

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High-Alert Medication	Common Problems *(Check if you have experienced similar problems)*	Key Improvements *(Check if the suggested Key Improvement should be included in an Action Plan)*
Heparin	❑ Dose errors, concentration errors and mix-ups of heparin with other drugs are common ❑ Labeling of small volume parenteral vials is a problem – the vial may be labeled 10,000/mL but the user may believe that the vial contains 10,000 units total (if a 10mL vial, then a 10-fold error can occur) ❑ Both heparin and insulin are measured in units and both are stored in medication floor stock areas ❑ Heparin has been confused with vaccines where prefilled syringes are used since they can look alike ❑ Heparin is associated with drug allergies and thrombocytopenia ❑ If heparin is ordered with only a "U" and not the word "units" the potential for the "U" to be interpreted as a "0" exists and thus a 10 fold dosage error ❑ In newborns, heparin that is not preservative free may contain benzyl alcohol ❑ Heparin solutions are often made throughout institutions and stocked in regular floor stock – potential errors	❑ Standardize heparin solutions – use premixed and reduce the number of concentrations available ❑ Standardize administration procedures – place dose stickers on heparin bags and double check all rate changes. If a bolus is ordered, give it from a syringe, rather than modifying the rate of the infusion ❑ Differentiate all look-alike products ❑ Separate the storage of all drugs ordered in units ❑ Standardize the dosing using weight-based protocols ❑ Have infusion pump rate settings and line placement on dual-channel pumps checked by two persons ❑ Develop and follow standard treatment protocols ❑ Do *not* use "U" for units ❑ Use only 'free flow' protected pumps
Hypertonic Saline	❑ Rapid changes in serum sodium concentrations caused by administration of nonisotonic, and especially hypertonic, saline are dangerous. Yet, hypertonic saline is floor stocked in many areas. Five percent saline has been confused with D5W/NS. Three percent saline has been confused with 0.3% saline. ❑ Pediatric ICUs may stock 23.4% saline for use in preparing enteral feedings ❑ Dialysis units may use hypertonic salines to increase blood volumes and reduce cramping	❑ Allow only commercially available, standard (e.g. isotonic) concentrations of sodium chloride outside the pharmacy ❑ Limit options – do not stock the 3% sodium chloride injection ❑ Develop a protocol for administering sodium chloride for use in treating hyponatremia – covering the rate and volume of administration and the frequency of serum sodium monitoring ❑ Limit addition of sodium to enteral feedings to the pharmacy ❑ In dialysis units, stock a single hypertonic concentration and store in a locked area with limited access and affix special hazard labeling

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High-Alert Medications – Problems and Key Improvements

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High-Alert Medication	Common Problems *(Check if you have experienced similar problems)*	Key Improvements *(Check if the suggested Key Improvement should be included in an Action Plan)*
Insulin	❑ IV insulin is lethal if given in substantially excessive doses or in place of other medications (insulin and heparin are often mistaken for one another since both are ordered in units and typically stored near each other on nursing units) ❑ Problems may arise if pumps are programmed incorrectly ❑ If insulin is ordered with only a "U" and not the word "units" the potential for the "U" to be interpreted as a "0" exists and thus a 10-fold dosage error ❑ Mix-ups may occur because of sound-alike names (e.g. Humalog and Humulin), multiple types of insulins (e.g. animal source and human source) and varying concentrations (U500 and U100) ❑ Insulin has reportedly given to the wrong patient	❑ Use "units" instead of "U" ❑ Store heparin and insulin separately ❑ Require two independent checks of all pump settings ❑ Take extra precautions when writing and interpreting orders for insulin mixtures (Mixtard 70/30 premixed insulin) ❑ Standardize preparation and administration (e.g. never prepare U100 insulin doses in tuberculin syringes – always use insulin syringes; use only a tuberculin syringe for U500 insulin) ❑ Do not use slash marks to separate NPH and regular insulin doses (e.g. NPH 10/12 regular has been confused with 10 NPH and 112 regular because the slash mark was read as the numeral one ❑ After dispensing/using insulin do not return to the box it came in – this increases the risk that a vial might be placed in the wrong box and the next person may automatically select the wrong product ❑ Nurses should inform the patient that they are to receive insulin – patients not expecting this will immediately question the need
Potassium Chloride (KCl) (see also Phosphate Salts)	❑ If potassium chloride (KCl) is injected too rapidly (i.e. at a rate exceeding 10 mEq/hr) or in too high a dose, it may cause cardiac arrest. KCl should never be given as an IV push and initiation of an infusion is not an emergency. Therefore, there is no need to store concentrated KCl outside of the pharmacy. ❑ Some MDs use the term "bolus" when ordering potassium at a rapid rate to treat hyperkalemia. This term has been interpreted to mean IV push.	❑ Remove all KCl vials from floor stock. Centralize KCl infusion preparation in the pharmacy. Use premixed containers. ❑ Use protocols for KCl delivery, including: • indications for KCl infusion • maximum rate of infusion • maximum allowable concentration • guidelines for when cardiac monitoring is required • stipulation that all KCl infusions must be given via pump • prohibition of multiple simultaneous KCl solutions (e.g. no IV KCl while KCl is being infused in another IV) • allow for automatic substitution of oral KCl for IV KCl when appropriate

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High-Alert Medications – Problems and Key Improvements

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High-Alert Medication	Common Problems *(Check if you have experienced similar problems)*	Key Improvements *(Check if the suggested Key Improvement should be included in an Action Plan)*
Lidocaine	❑ Lidocaine mix-ups have occurred when lidocaine and heparin are obtained from the same manufacturer – the labeling is similar. Errors have also occurred when 50mL vials of lidocaine were confused with other drugs also available in 50mL vials. ❑ Multidose vials of lidocaine used as a local anesthetic may be contaminated as a result of poor aseptic technique ❑ Problems may arise because of misunderstanding how topical lidocaine is absorbed ❑ The use of topical (viscous) lidocaine in the oral cavity for painful mouth lesions has caused aspiration due to oropharyngeal anesthesia and loss of sensation of food bolus that may be present in the oral cavity	❑ Use lidocaine only in single-dose vials. Do not place vials that hold more than 500 mg in patient care areas. Single-dose vials reduce the risk of overdose and eliminate the risk of contamination. ❑ Use premixed, adequately labeled solutions for all cardiology patients.
Intravenous Magnesium	❑ Errors have resulted from mix-ups between the abbreviations "MS" or "MSO4" for morphine sulfate and "MgSO4" for magnesium sulfate ❑ Other terminology problems have also led to errors; for example "mg" (milligrams) and "mL" (milliliters) are confused, as are "mg" and "mEq" (milliequivalents) ❑ Infusion pump settings have led to fatal overdoses with free-flow intravenous solutions ❑ Health professionals are often unaware that an excessive dose has been ordered and administer an overdose	❑ Require protocols for the use of magnesium ❑ Educate staff about proper dosing ❑ Establish and publicize maximum doses ❑ Do not permit the use of abbreviations for morphine and magnesium ❑ Store containers containing more than 2mL only in the pharmacy ❑ Use only premixed containers for patients on IV magnesium replacement therapy and for women with preeclampsia ❑ Standardize ordering methods (i.e. either in grams or milliequivalents) ❑ Require independent, redundant checks of all calculations, dose preparations, and infusion pump settings
Narcotics and Opiates including Patient-Controlled Analgesia (PCA)	❑ Narcotic accidents are among the most frequent of all serious incidents reported. One reason for errors with these drugs is that parenteral narcotics are usually stored in nursing areas as floor stock. They are often identified, prepared, and administered by a single nurse; no redundant checks are performed.	❑ Educate staff about the potential for mixing up hydromorphone and morphine ❑ Standardize concentrations of intravenous solutions ❑ Minimize the amount of drug in a single container

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High-Alert Medications – Problems and Key Improvements

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High-Alert Medication	Common Problems *(Check if you have experienced similar problems)*	Key Improvements *(Check if the suggested Key Improvement should be included in an Action Plan)*
Narcotics and Opiates including PCA (cont.)	❑ Mix-ups between hydromorphone and morphine are common; hydromorphone is five times more potent than morphine ❑ Oral liquid morphine is available in much more concentrated forms – errors have been reported resulting in overdoses ❑ PCA accidents may involve errors in concentration, rate, drug and route. PCA use by patient and their families may be problematic when, believing that the patient is in pain, families may activate the PCA ❑ PCA and epidural lines are sometimes confused, leading to errors in route of administration ❑ Allergic reactions are common ❑ Pump-related errors have occurred	❑ Ensure that naloxone or an equivalent is available in all areas where narcotics might be used ❑ Limit oral liquid items available as floor stock to conventional concentrations. Limit concentrated oral morphine and hydromorphine only in areas where chronic pain is treated ❑ Do not use potentially confusing abbreviations such as "$MgSO_4$" and "MSO_4" ❑ Implement protocols for the use of PCA and epidural medications that ensure independent double-checks of the appropriateness of drug, dose, pump setting and line placement ❑ Label the distal ends of epidural lines and intravenous lines to differentiate them ❑ Question all patients receiving opiates about allergies ❑ Use only generic names
Neuromuscular Blocking Agents	❑ Outside of the operating room (e.g., in the ED, radiology, ICU) neuromuscular blocking agents (NMB) have been inadvertently used in patients who are not receiving proper ventilatory assistance – patients who have then suffered respiratory arrest and, in some cases, death ❑ Patients have been extubated while an order for one of these agents still exists ❑ Vials of NMBs have been mixed up with other agents, such as vaccines	❑ Educate staff about the potential for problems ❑ Standardize ordering; never allow "use as needed for agitation" orders; never refer to NMB as "relaxants" ❑ Develop protocols to ensure proper storage and administration. These protocols should stipulate that NMBs must be automatically discontinued when the patient is extubated and removed from the ventilator ❑ Implement warnings to staff of potential adverse effects. For example, some hospitals place signs near where these products are stored. Some place labels reading "WARNING: PARALYZING AGENT" on these drug vials. Some manufacturers place these warnings prominently on package labels. Use these brands whenever possible ❑ Limit access – NMBs are best handled by anesthesia personnel ❑ Do not store these agents outside of critical care areas

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High-Alert Medications – Problems and Key Improvements

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High-Alert Medication	Common Problems *(Check if you have experienced similar problems)*	Key Improvements *(Check if the suggested Key Improvement should be included in an Action Plan)*
Phosphate Salts (Sodium and Potassium)	❑ Phosphate is often given intravenously as potassium phosphate. The person ordering the phosphate may fail to consider the amount of potassium in the product. ❑ Some prescribers order phosphate in terms of "amps" or "vials" rather than amount (expressed in millimoles).	❑ Administer phosphate replacement therapy via the oral route whenever possible. ❑ Use sodium phosphate instead of potassium phosphate whenever possible ❑ Store intravenous potassium concentrated solutions in the pharmacy only ❑ Use guidelines for administration of potassium phosphate based on the patient's level of inorganic phosphate and other clinical factors. The normal dose should not exceed 0.32 mmol/kg over 12 hours, repeated until serum phosphate is greater than 2 mg/dl. ❑ Use strict criteria for delivery rates when administering intravenous phosphate. Always deliver via a pump.
Warfarin	❑ Dosages are often improperly adjusted ❑ Drug-food interactions are not appreciated. ❑ Monitoring via prothrombin time/INR is not consistently appropriate	❑ Use pharmacy-run anticoagulation clinics ❑ Provide patient education by certified staff in a structured setting ❑ Increase monitoring (e.g., more frequent clinic visits or home testing)

Thanks to Greg Prouty, PharmD, Director, Pharmacy Services, UC Irvine Medical Center, for his assistance in abstracting the information from "High-Alert Medications: Safeguarding Against Errors" by Michael Cohen and Charles Kilo, in *Medication Errors*, edited by Michael Cohen.

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Attachment 1.H

Policy for a Nonpunitive, System-Based Adverse Drug Event Reporting Program

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This attachment provides an example of a policy that details a blame-free reporting program. Clear definitions, severity classifications, and steps for staff to follow when reporting an error are included as well as guidelines for trending the information and using it to improve the medication use systems.

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Policy for A Non-Punitive, System-Based Adverse Drug Event Reporting Program

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These guidelines are intended to assist in the delivery of patient care or management of hospital services. They are not intended to replace professional judgment.

Policy Title

Adverse Drug Events

1.0 Purpose

To provide a standardized mechanism for identifying, reporting, and monitoring adverse drug events (ADEs) and to provide a consistent mechanism for improving the medication use process.

2.0 Scope

This policy applies to medication therapy for all patients cared for in hospital departments, main campus outpatient services, and physician practices regardless of where the medication was originally prescribed.

3.0 Definitions

Adverse Drug Event (ADE) - a deviation in the medication use process (prescribing, dispensing, administering, monitoring) or undesirable clinical manifestation that is consequent to and caused by the administration or omission of medications, or IV fluids as outlined in hospital policies and procedures or within the scope of accepted medical practice.

Significant ADE – An ADE categorized with severity category 6 or 7 (see below). It should be considered a sentinel event by hospital policy.

Adverse Drug Reaction (ADR) - is a subset of ADEs that includes any clinical manifestation that is undesired, unintended, or unexpected that is consequent to and caused by the administration of medications or IV fluids.

Preventable ADR - An ADR that resulted from a deviation in the medication use process that could be reasonably anticipated based upon existing policies and procedures, patient data, medical literature or accepted medical practice.

Medication Safety Improvement Committee - a subcommittee of the Pharmacy and Therapeutics (P&T) Committee that reviews errors, trends, and significant ADEs and makes recommendations for system-based changes to improve the medication use process (ie Fredrick Memorial's "Saf-Med Committee").

ADE Hotline - phone line to report possible ADEs.

ADE Report Form - Form completed by any member of hospital staff to document a possible ADE.

ADE Review Form - Form used by ADE Reviewers to assess and document to identify causative factors in preparation for entry into data base.

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ADE Reviewer - Member of clinical staff (pharmacist, nurse, radiology technologist, respiratory therapist, physician) appointed by the P&T Committee who reviews/assesses reported ADEs, completes documentation, and serves on the Medication Safety Improvement Committee.

Clinical Interventions - Routines in the Pharmacy computer system that allow pharmacists to document interventions made to clarify or optimize medication therapy, such as, dosage adjustments, or nonformulary requests.

Severity:

Category 1: Circumstances or processes that have the potential to cause an adverse drug event.
Category 2: An event occurred but the patient was not harmed.
Category 3: An event occurred that resulted in the need for increased patient assessments but no change in vital signs and no patient harm.
Category 4: An event occurred that resulted in the need for treatment and/or intervention and caused temporary patient harm.
Category 5: An event occurred that resulted in initial or prolonged hospitalization, affected patient participation in an investigational drug study, and/or caused temporary patient harm.
Category 6: An event occurred that resulted in permanent patient harm or near death event, such as anaphylaxis.
Category 7: An event occurred that resulted in patient death.

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4.0 Policy

4.1 Fredrick Memorial Healthcare System (FMH) encourages the reporting of adverse drug events, and potential adverse drug events as a means to assess and improve the medication use process and provide a safe environment for patient care. Thus, the focus of the program is quality improvement, not punishment. FMH assumes that practitioners are doing their very best and that errors and ADEs are not the result of gross negligence. Therefore, employees are not subject to disciplinary action when making or reporting errors except in the following circumstances:

- The employee consistently fails to participate in the detection, reporting, and the system-based remedies to prevent errors.
- There is reason to believe criminal activity or criminal intent may be involved in the making or reporting of an ADE.
- False information is provided in relation to the ADE report or investigation.

4.2 The reporting program is coordinated through the Pharmacy and Therapeutics Committee, as part of the hospital's performance improvement and peer review function, with participation by Nursing and Pharmacy departments and the medical staff.

4.3 Pharmacists report ADRs to the FDA if they are serious, associated with a new drug, or not mentioned in the drug's labeling.

4.4 ADEs are reported by physicians, nurses, pharmacists, patients, medical records/QA personnel or any member of the FMH staff. An ADE report form is completed or a call is made to the ADE Hotline within 24 hours of the event's identification.

4.5 Staff members identifying an ADE in severity category 6 or 7 above or classified as a sentinel event reports the event, contacts the Administrator on call and follows the steps outlined in the FMH Sentinel Event Policy and Procedure. A Root Cause Analysis is conducted in these cases as outlined by standing FMH procedures.

5.0 Procedures and Responsibilities

5.1 Identifying an ADE

- Staff who receive a report of or suspect an ADE notify prescriber immediately if the event is significant or may alter the patient's plan of care.
- Staff assess the patient.
- Staff collaborate with clinical and supervisory resource personnel if unsure how to proceed.
- Staff implement adjustments in patient's treatment as ordered.
- Staff document the factual description of the ADE, notification of physician and subsequent monitoring in the progress record.

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5.2 Reporting an ADE

- Staff calls the ADE hotline, completes the ADE reporting form or enters an ADE clinical intervention in the Meditech Pharmacy-module within 24 hours of the ADE identification. ADE forms are mailed, confidentially, to the Saf-Med Committee in the Pharmacy or put in an ADE drop box. Pharmacy staff take ADE reports off Hotline seven days a week and complete ADE Report forms.
- No copies are made of the ADE forms. Clinical interventions are migrated into a secure database. Forms and data are secured in the Pharmacy and accessed by key or password.

5.3 Reviewing ADEs

- Supervisor/manager completes timely evaluation of the circumstances surrounding the event.
- ADE Reviewers assess all reports, to verify and collect additional data, and assign severity level. In the case of significant ADEs or medication-related sentinel events, reviewers confirm notification of department director or manager, as well as compliance with sentinel event policy. (see above 4.5).
- ADE reports are reviewed using published criteria and categorized by: location, severity, product information and therapeutic classification, type, causes and contributing factors.
- ADR's get an additional level of review. ADR's are evaluated to determine: 1) appropriateness of medication for patient's condition; 2) predisposing contraindications to medication; 3) appropriate documentation of allergies; and 4) appropriate management and monitoring of ADR.

5.4 Trending/Reporting/Improving the Medication Use Process

- The Pharmacy Department performs the data entry, trending, and report distribution. The Pharmacy prepares a quarterly analysis of ADE's.
- The Pharmacy forwards quarterly ADE trending reports to FMH managers. Managers are responsible for analyzing their department data and responding with performance improvement activities.
- ADEs are tabulated monthly and reported to the Saf-Med Committee. Reports include ADE and ADR rates.
- The Saf-Med Committee reviews the monthly report, significant events, results of root cause analysis and completion of consequent recommendations and makes recommendations for improvements to the medication use process.
- Saf-Med Committee reports and recommendations are made to the P&T Committee. Minutes are distributed to the Safety Committee, P&T Committee Chair and Nursing management. P&T Committee recommendations are forwarded to the medical staff Quality Assurance Coordinating Committee.
- Medication use improvements and recommendations are communicated to FMH staff via e-mail, P&T minutes, Pharmacy Newsletter, educational offerings at medical staff and other department meetings.

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6.0 Documentation

Use ADE Report and Review forms.

7.0 Quality Assessment

ADE reports are trended monthly and reviewed at the Pharmacy and Therapeutics Committee and Saf-Med Committee. The Committees make recommendations on surveillance, formulary changes, educational efforts, and policy changes as necessary.

8.0 Exceptions

Adverse reactions that occur following the administration of investigational drugs are reported according to the specific protocol for that drug by contacting the principle investigator. A probationary employee may be terminated if basic competencies related to the medication use process are not demonstrated.

9.0 The following resources were used to prepare the above policy:

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Attachment 1.J

Medication Safety Pledge for Patients

The content herein was developed under a project supported by the Delaware Valley Healthcare Council and is subject to the copyright of ECRI, ISMP, and DVHERT.

The following tool (provided in both English and Spanish versions) was developed for use in admission brochures and other introductory information to help inform patients of their rights and responsibilities regarding safe medication use. Nurses, patient representatives, or other health care professionals involved in admission processes should review this pledge with patients upon admission. In addition, the medication safety pledge can be distributed to the community via quarterly newsletter publications, at local health fairs, schools, and to community service groups.

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Medication Safety Pledge for Patients

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Medications may be needed to improve my health. By working as a partner with my health care team, I can learn to use these drugs safely. I promise to:

- Tell all caregivers (doctors, nurses, pharmacists, etc.) about my allergies (food and drug).
- Learn about all of my drugs including the name, strength or dose, why I am taking the drug and how to take it.
- Tell all caregivers when new drugs are ordered for me by a different caregiver.
- Talk with my caregivers about my use of herbal products, vitamins, food supplements, or other over-the-counter drugs I may be taking.
- Identify myself before taking any type drugs given to me by a nurse, physician, pharmacist, or caregiver.
- Question my caregiver about any drug with which I am not familiar.
- Tell my caregivers if I have any problem taking the drug for any reason including the cost.
- Check with my caregiver before changing the way I take my drugs.
- Faithfully renew my prescriptions on time.
- Never share medications with others, or use drugs prescribed to someone else.
- Store drugs properly and safely, away from children and pets.

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Compromiso del paciente de que utilizará los medicamentos de forma segura

The content herein was developed under a project supported by the Delaware Valley Healthcare Council and is subject to the copyright of ECRI, ISMP, and DVHERT.

Los medicamentos que me prescriben son necesarios para mejorar mi salud. Colaborando con los profesionales sanitarios que me atienden puedo aprender a utilizar los medicamentos de forma segura. Me comprometo a:

- Informar a todos los profesionales sanitarios que me atienden (médicos, enfermeras, farmacéuticos, etc.) de mis alergias (a alimentos y medicamentos).
- Conocer los medicamentos que tomo, incluyendo su nombre, concentración o dosis, porqué estoy tomando cada uno y cómo los debo tomar.
- Informar a los profesionales sanitarios que me atienden cuando me sean prescritos nuevos medicamentos por otros profesionales.
- Comunicar a los profesionales sanitarios que me atienden si utilizo hierbas medicinales, vitaminas, suplementos alimenticios u otros medicamentos sin receta.
- Identificarme ante las enfermeras, médicos, farmacéuticos o cuidadores antes de que me administren cualquier medicamento.
- Cuando un medicamento no me resulte familiar, pedir al profesional sanitario que me atiende que confirme si corresponde realmente a mi tratamiento.
- Solicitar que me proporcionen las instrucciones escritas para tomar correctamente todos los medicamentos que necesite utilizar.
- Informar al personal sanitario que me atiende si tengo cualquier problema que me impida tomar la medicación incluyendo problemas para pagarla.
- Confirmar con el personal sanitario que me atiende si es posible realizar cualquier cambio en la forma de tomar la medicación, antes de hacerlo por mi cuenta.
- Renovar mis prescripciones justo en el momento que me corresponda.
- No compartir mi medicación con nadie ni utilizar por mi cuenta medicamentos que esté tomando otra persona.
- Almacenar los medicamentos de forma correcta y segura, fuera del alcance de los niños y de los animales de compañía.

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Attachment 1.K

Prioritization Criteria for Selecting Medication Safety Change Projects

Selecting a valuable yet workable change project is key to initial success. Use the following criteria to evaluate each one of the possible change projects and prioritize those that will have the greatest impact on medication safety and the highest chance for sustained improvement in the medication use process.

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Prioritization Criteria for Selecting Medication Safety Change Projects

Change projects should match as many criteria as possible to offer the highest leverage for success:

- High impact regarding severity
  - Prevent errors with high-alert medications that have the greatest potential to cause patient harm
  - Safeguard high-risk patient populations
- High impact regarding frequency
- Possible to accomplish/make significant progress within 3 years
- Contributes to profound learning about error reduction
- Balanced impact on institutional resources
- Fixes the system, not the human condition
- Does not rely heavily on human memory and vigilance
- Scientific evidence demonstrates that it is effective in reducing serious medication errors
- Obvious evidence shows that it needs to be accomplished
- Solves several medication-error-related problems at the same time
- Applicable to multiple care settings
- Simplifies complex, error-prone processes

Characteristics of prioritizing well:

- Puts emphasis where needed, even if changes are difficult
- Proactively handles high impact issues
- Takes external influences into account without losing focus
- Takes considered risks

Characteristics of prioritizing poorly:

- Carries out only those changes that are easy to make – low hanging fruit only
- Waits for bad results before making changes
- Makes external influences the main drivers of the plan
- Chooses the safest option

The following resources were used to develop the above criteria:

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2. Haraden, Carol, Terri Simmons, Alan Frankel, Roger Resar,, and W Rupp. *Practical Strategies for Hospital Patient Safety*. Audioconference. Boston, MA: Institute for Healthcare Improvement, November, 2001. Audioconference.
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Attachment 1.L

Timeline for Implementing a Strategic Plan for Medication Safety

Task

Goal #1: Culture of safety
Milestones: 1. complete survey, 2. begin executive *WalkRounds™*, 3. recruit/train patent safety officer

Goal #2: Improve error detection
Milestones: 1. capture pharmacy interventions, 2. revise error report, 3. use triggers

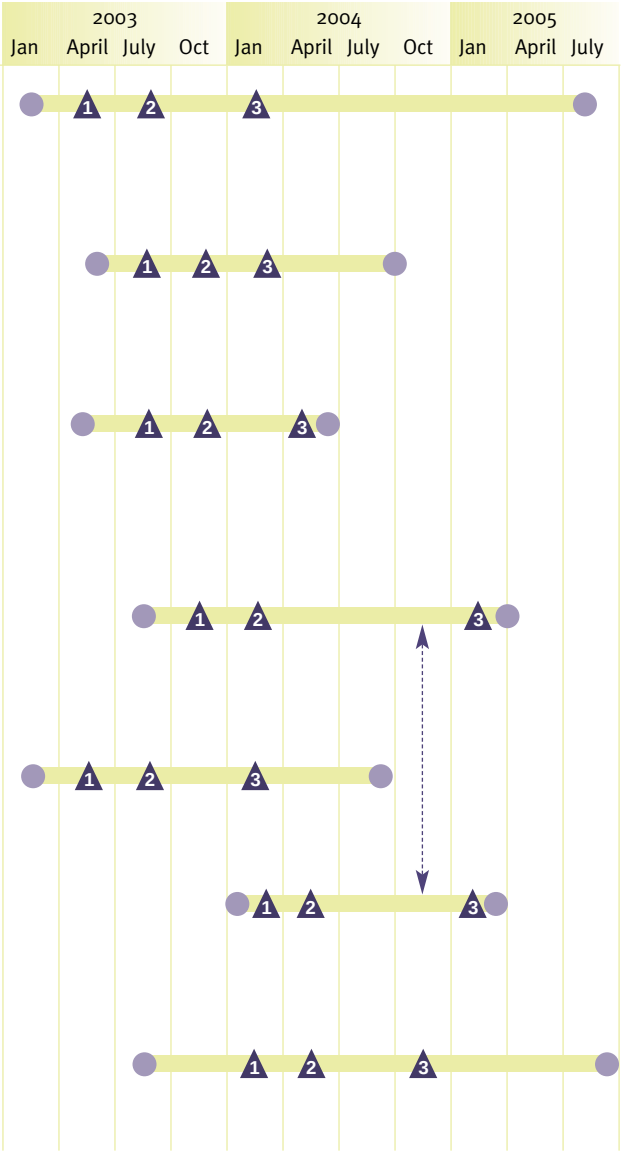
Goal #3: Technology
Milestones: 1. prepare compendium of information system capabilities, 2. readiness assessment for bar coding, 3. compare CPOE systems

Goal #4: High-alert medications
Milestones: 1. expand clinical pharmacy 2. full IV admixture service, 3. warfarin monitoring

Goal #5: Blame-free environment
Milestones: 1. policy, 2. review mechanisms, 3. management training

Goal #6: Involve community
Milestones: 1. patient bill, 2. community meetings, 3. self management program - warfarin

Goal #7: Formulary
Milestones: 1. therapeutic review, 2. non-formulary process, 3. publish formulary



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