

## Director's Forum

# Developing a Medication Patient Safety Program – Infrastructure and Strategy

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The Directors Forum series is written and edited by Robert Weber and Michael Sanborn and is designed to guide pharmacy leaders in establishing patient-centered services in hospitals and health systems. Another specific goal of this column is to address many of the key challenges that pharmacy directors face today, while providing information to foster growth in pharmacy leadership and patient safety. This month's Forum is co-authored by Scott Mark and focuses directly on the importance of a patient safety infrastructure.

### INTRODUCTION

Growing evidence of the number of medical errors that occur throughout the US health care system has prompted stakeholders' interest in hospitals' approach to improve safety. A significant concern of patients, health care organizations, and clinicians is medication errors that occur at an average of 19% to 36% in hospitals; in fact, every patient will experience at least one medication error during their hospital stay.<sup>1</sup> In the United States Pharmacopeial Convention's 2004 published report, almost 2% of all reported medication errors (approximately 4,000 yearly) resulted in significant harm to patients.<sup>2</sup>

The Institute of Medicine (IOM) recently released a report commissioned by the Center for Medicare and Medicaid Services titled *Preventing Medication Errors*. This report suggests a

national agenda for preventing medication errors including improving patients' understanding of medications using technology to improve information related to medication use, improving drug packaging and labeling, employing human factors engineering concepts to drug-related technologies, funding medication safety research, and providing monetary incentives for quality and safety in health care.<sup>3</sup> Patient safety experts Drs. Lucian Leape and Donald Berwick, in a commentary published a year before the IOM report was released, noted progress in the health care environment of patient safety that focused on a systems-based approach. However, they warned that significant improvement in patient safety would only be recognized by an ambitious national agenda.<sup>4</sup>

As a result of the call to action by the IOM and others, hospitals

and health care organizations must establish their own agenda to prevent medication errors based on collaboration among caregivers through an effective organizational culture of patient safety. Building a culture of safety remains a somewhat elusive construct, and health care organizations often struggle with how to develop a safety culture infrastructure that will result in continuous improvements in quality of care.<sup>5</sup> Additionally, most hospitals do not have sufficient infrastructure and a clear strategy for preventing medication errors.

When considering patient safety in hospitals, the goal is to create a strong safety culture throughout the organization, with everyone developing a sense of responsibility for patient safety rather than considering safety the primary responsibility of a separate committee like the Quality Assurance Department. Related to this concept, many health care workers may view patient safety efforts as "extra" work and not an integral part of their job function. Building a safety culture is not a sudden transformation; a culture emerges as a collective learning process from working together over a long period of time.<sup>6</sup> Finally, an organization's safety culture is often the product of individual and group values, attitudes, perceptions, competencies, and the hospital staff and leadership's patterns of behavior.<sup>7</sup>

Many organizations do not have a clear and focused strategic

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plan for patient safety, including the area of medication patient safety. In reviewing the literature, only one peer-reviewed publication was found that described the importance and process for developing an organizational strategic plan around medication safety.

This article begins a series in the *Director's Forum* describing the pharmacy director's role in implementing a patient medication safety program. Previous articles in the *Director's Forum* stressed the importance of the pharmacy director's thorough knowledge in core competencies of hospital pharmacy practice in order to promote a patient-centered pharmacy service. An example that relates to patient safety involves the pharmacy director having knowledge of essential department and hospital data, which are related to the types and causes of serious medication errors and adverse drug events. First-hand knowledge of this information will establish the initial steps in creating a strategy to improve medication safety. Regional and national data on medication errors may provide the pharmacy director with important strategies to establish a patient safety program. For example, the Pittsburgh Regional Health Care Initiative has identified important data related to medication errors and found four drugs that contribute to nearly 45% of all serious medication errors.

This first article will focus on practical considerations in developing a culture, strategy, and infrastructure for a medication patient safety program. A second article will focus on the examples of patient safety programs that can be implemented in a pharmacy department and have an organizational impact on patient safety.

Building a medication patient safety program requires a patient-

centered approach to develop a collaborative and comprehensive program. The goal of this article is to help hospital pharmacy directors understand their organization's patient safety culture and develop a strategic medication safety plan. The specific aims of this article are to (1) describe how to promote a blame-free medication error reporting system; (2) describe how to review essential department and hospital data to determine priorities for patient safety; (3) show how establishing a pharmacy medication safety officer will help establish an infrastructure for patient safety; and (4) outline the steps to establish a medication safety strategic plan. Given the critical nature of medication error prevention in hospitals, it is imperative that the pharmacy director be a leader in implementing and assessing the hospital's medication safety program.

#### **MEDICATION ERROR REPORTING SYSTEMS AND "BLAME FREE" CULTURE**

In order to design safer medication delivery systems, information on medication errors must be collected and analyzed. While it is essential that data be collected and trended for analysis, the difficulty in detecting errors has long been recognized as a barrier to studying the problem effectively. Medication errors should be identified and documented, and their causes must be studied in order to develop systems that minimize recurrence. Most hospitals and health systems use a variety of methods to gather information on medication safety, including computerized surveillance, voluntary reporting, and observing medication processes.

These systems identify errors and track a variety of information on the errors, including the person

who committed the error. Despite much rhetoric on the systems-approach to improving patient safety, the actions of individuals involved in an error are routinely reviewed. The perception and action taken regarding an individual's involvement in an error establishes the patient safety culture for that organization. The pharmacy director plays a key role in promoting blame-free analysis of medication errors within the organization by establishing a pharmacy department culture of open communication around medication errors.

One key cultural paradigm centers on blame-free reporting of errors. When people feel they can openly communicate about medication errors without fear of punishment or disciplinary action, then it is likely that they will share information about the actual contributing factors. To some, investigating an event implies a punitive direction as opposed to studying an event which implies learning. As a result, some hospitals have adopted standardized words for use when discussing medication-related events in an attempt to minimize any negative connotations. Importantly, conversations and information related to medication errors need to stay de-personalized and non-judgmental.

Hospital executives and physicians need to be personally involved if a culture of safety is going to be established.<sup>8</sup> This means educating the board of trustees and medical staff on the importance of patient safety while making a significant place for patient safety initiatives in the budget. For example, creating an economic analysis of the cost of an error can help to justify expense allocation. Importantly, involving physicians and leadership in root-

**Table 1. Strategies for Promoting a "Blame-Free" Organizational Culture for Reporting and Discussing Medication Errors**

Remove references to punitive consequences for committing medication errors from all performance appraisals; consider adding a performance standard to promote the reporting of medication errors

In collaboration with the medical staff, nursing staff, and hospital leadership, develop a statement promoting the open and honest discussion of medication errors

Educate hospital governance on the concept of establishing a "no blame" patient safety culture

Approve a policy by the hospital and medical leadership that empowers pharmacists to refuse to dispense unsafe orders until an appropriate review process is employed (eg, review by Chief of Medical Staff and Director of Pharmacy)

Review all medication sentinel events in the appropriate forum (eg, Medical Executive Committee) stressing the systems-based factors that contributed to the error

Publish a quarterly review of medication errors focusing on the types, severity, and causes of medication errors; distribute this report to all hospital and medical staff

Participate in a national medication error reporting system that provides additional information on errors across a broad scope of hospitals and patients to best establish safety priorities for the organization

**Table 2. Medications Commonly Associated with Serious Medication Errors<sup>11</sup>**

Insulin
Albuterol
Morphine sulfate
Heparin, warfarin
Potassium chloride
Cefazolin
Furosemide
Levofloxacin, vancomycin

severity of the error. While quality management processes should include programs to prevent all medication errors, effort should be concentrated on eliminating the causes of errors associated with greater levels of severity. There should be established mechanisms for tracking drugs or drug classes that are involved in medication errors. Correlations between errors and the method of drug distribution and dispensing should also be reviewed (eg, unit dose, floor stock, injectable medication, etc). A previous article of the Director's Forum stressed the importance of the director of pharmacy's knowledge and understanding of essential department data including medication error information.

From this information, the hospital can establish some targeted drugs or drug classes for safety efforts. If institution-specific data are not available, then national and regional data on problem medications are available through the United States Pharmacopeia (USP) and the Institute for Safe Medication Practices (ISMP). Table 2 lists the drugs most commonly associated with serious medication errors.

A similar list should be developed for each health system and a

cause analyses provides them with an insight that medication errors are multifactorial in nature.

It is also essential that it be culturally acceptable to question other health care professionals, orders, or situations. Too often, a root cause analysis conducted after a major error reveals that one or more health care professionals thought there was a problem, but they did not feel comfortable questioning it, or they were "scolded" for questioning and therefore did not escalate their concern. A well-established process for questioning a medication order needs to be outlined.

The pharmacy director plays an important role in establishing a "blame-free" and open environment in dealing with errors. First, the pharmacy director should remove any reference to punitive consequences of medication errors in performance evaluations and job descriptions. Second, the pharmacy director should establish a regular

forum to discuss medication errors with department staff. Third, the pharmacy director should educate the medical staff, through the hospital's Medical Executive Committee, on the medication order review process while gaining their support on pharmacists' questioning orders that may be unsafe. Finally, the pharmacy director should routinely publicize successes in medication patient safety to provide staff with tangible outcomes for their error-prevention efforts. Table 1 summarizes how the pharmacy director can promote a "blame free" process for reporting and discussing medication errors.

#### **ESSENTIAL DEPARTMENT DATA AND MEDICATION SAFETY**

Understanding the nature of medication errors and adverse drug events for a given hospital is critical to implement interventions that improve safety. Determining causes of medication errors should be coupled with assessment of the

**Table 3. Job Functions of a Medication Safety Pharmacist**

Identify and implement best practices for medication safety
Analyze current practices that may contribute to medication error occurrence and take proactive steps to prevent errors before they occur
Facilitate process and system changes and prevention activities to reduce the likelihood of occurrence/recurrence of error
Manage medication error reporting and investigation
Review reports and collect additional information to determine root cause
Manage medication error data entry into internal and external databases to provide reports to clinical staff and committees as appropriate
Educate pharmacy staff and other health care professionals to promote safe medication practices
Participate in departmental and interdisciplinary hospital, health system, and regional committees related to emergency medications, adverse events, medication errors, policy review, safe medication use, and patient safety
Assist in the development and review of medication use policies and adapt to current practice
Address issues of non-compliance and recommend corrective actions
Monitor compliance with medication control and security standards in the pharmacy and hospital patient care areas

concentrated effort made across all disciplines to eliminate the more common root causes, which attribute to each error involving a medication on this list. For example, as a result of an analysis of their internal data, it may be determined that insulin is the most common medication associated with a severe medication error.

**HOSPITAL AND DEPARTMENT INFRASTRUCTURE FOR MEDICATION PATIENT SAFETY**

A unified hospital vision for medication safety is critical to the institution's success. To drive change, hospital leaders must create organizational infrastructure to provide patient safety. Importantly, hospitals must also establish an infrastructure for communicating medication safety concerns. Quality Councils or Patient Safety Steering Committees are examples of the type of governing body created to evaluate medication safety concerns. Often such entities report directly to the hospital board to ensure that they can function autonomously and avoid conflicts of interest.

Many organizations have formed multidisciplinary groups designed to talk about frontline medication safety concerns. These Unit-Based Medication Safety Teams or Safety Action Teams then hold patient safety dialogues, which serve to define issues. Approaching the issues from the bottom up generally promotes an increased level of support. For example, this serves to engage the expertise of the people doing the work. It is important that these groups develop a common goal, such as the reduction of medication errors involving insulin within a given unit or patient population. Finally, the pharmacy department needs to establish a structure that allows them to participate in various medication safety programs throughout an organization.

The University of Pittsburgh Medical Center (UPMC) established a medication safety pharmacist position in 2001 to address the organization's need for direct pharmacist involvement in patient safety. The job functions of this position are listed in Table 3. This position has become an integral part of

the hospital's medication patient safety program and has positively impacted medication error reporting rates and implementation of medication safety initiatives.<sup>9</sup>

**DEVELOPING A MEDICATION SAFETY STRATEGIC PLAN**

The medication safety strategic plan is a collaboration of various departments and is primarily the champion efforts of the director of pharmacy and the chair of the Pharmacy & Therapeutics Committee. Although the strategy to prevent medication errors may be different for each initiative, a standard approach is suggested by the ISMP to address all patient safety initiatives (see Table 4).<sup>10</sup>

Whether the institution uses benchmark data received from other hospitals, comparative data from surveys such as the ISMP survey, internal data from variance reports, or information gathered from the flow diagrams, it should be possible to get a sense of the safety needs and the prioritization of the risk associated with each. Using a multidisciplinary team, solutions should be identified to

**Table 4. Medication Error Prevention Methods and Their Effectiveness**

<i>Method</i>	<i>Effectiveness</i>
Forcing functions and constraints	Most effective
Automation and computerization	Most effective
Standardization and protocols	Effective
Checklists and double-check systems	Effective
Rules and policies	Least effective
Education and Information	Least effective
Be more careful; be vigilant	Not effective

\*Adapted from recommendations by the Institute for Safe Medication Practices

reduce or minimize the identified risks. These proposals are then consolidated and mapped along a timeline to create a Medication Safety Strategic Plan. This Safety Plan then serves as the guide for decisions and sets the vision for upcoming years. Importantly, the plan integrates the many ways to improve medication safety, including incorporation of automation and technology, expansion of clinical pharmacy services, policy development, and formation of unit-based teams. Appendix I provides an example of a medication safety strategic plan for preventing insulin medication errors.

### SUMMARY AND CONCLUSION

Developing a systematic and strategic approach to preventing medication errors must be a 2007 organizational imperative for hospital pharmacy directors. A successful medication safety strategic plan must incorporate an effective use of hospital and departmental

data, be supported by an adequate infrastructure, and embrace a culture of “no blame” in reporting and analyzing medication errors. The pharmacy director plays a key role in this plan by providing expert advice on medication errors and supporting an open environment within the pharmacy department. Finally, a pharmacist position dedicated to medication patient safety activities may provide the necessary focus and resource to make significant improvements in an organization's patient safety outcomes.

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**Appendix A: Sample Medication Safety Strategic Plan for Preventing Insulin Medication Errors**

**GOAL: PREVENT MEDICATION ERRORS FROM INSULIN PRESCRIBING AND ADMINISTRATION**

**Intervention: Design and Implement Insulin Ordering Form**

**Cost:** Low – mostly staff time for form development, education

**Champion:** Dr. Blue

**Measurement of success:** All insulin orders received after June 30, 2007 must be written on an insulin order form. Those not received on this form will not be processed.

**Evaluation:** All insulin orders will be tracked for 1 fiscal year, and reports will be provided to each department head monthly. Data will also be reviewed at the P&T committee monthly.

**Intervention: Modify Insulin Warnings in Hospital Computer Systems**

**Cost:** Minimal internal programming costs

**Champion:** Dr. White

**Measurement of success:** Programming completed by June 30, 2007. All insulin errors will be compared to computer reports of warning acknowledgements

**Evaluation:** Incidence of insulin errors will be tracked.

**Intervention: Assess All Insulin-Related Procedures**

**Cost:** Low—possible costs might include education, forms development, buying alternative products, etc

**Champion:** Dr. Green

**Measurement of success:** Review of steps and processes, changes where needed, presentation and approval of Med Error Performance Improvement Team.

**Evaluation:** This task has been completed and for the most part felt to be in compliance.

**Intervention: Eliminate Abbreviations “U” and “IU”**

**Cost:** None

**Champion:** Dr. Purple

**Measurement of success:** Monitoring of all insulin orders for compliance.

**Evaluation:** All orders must comply.

**Intervention: Establish a Hospital-Wide Policy for Insulin**

**Cost:** Low—mostly time of drafters of policy

**Champion:** Dr. Black

**Measurement of success:** Approval of policy.

**Evaluation:** This policy was approved and has since been revised in order to keep pace with the changing process of medication delivery at the hospital.

**Intervention: Inservice all Staff on Insulin Handling and Prescribing**

**Champion:** Dr. Red

**Measurement of success:** Successful inservice of affected groups (75% attendance)

**Evaluation:** Reduction in insulin errors by 10% in the first month.

**Intervention: Implementation of Unit-Based Medication Error Reduction Performance Improvement Effort**

**Measurement of success:** Completion of at least one error reduction project per year, which is focused on insulin

**Evaluation:** A reduction of insulin errors by unit by 10%.

**Intervention: Reformat Medication Labels for Insulin**

**Measurement of success:** Successful implementation of new label formats and fewer label-related errors with insulin reported

**Evaluation:** Specific focus in root cause analysis on label information and contribution to cause.