

WORKSHOP 1:**Developing and Implementing a Strategic Plan for Medication Safety***Patricia C. Kienle, M.P.A., FASHP*

A strategic plan for medication safety has become essential. Many hospitals and health systems already have such a plan but believe it needs validation; others are seeking to develop one. During this interactive workshop, Ms. Kienle, Medication Safety Manager for Owen Pharmacy Management, presented key elements of such a plan and challenged participants to brainstorm and present to the group the issues that should be considered in planning for each of these elements.

Starting Out

The model for a strategic business plan, Kienle noted, is often portrayed as a triangle with three components—finance, market, and operations. A strategic plan for medication safety likewise has three components: (1) resources, not only financial but also human; (2) operations, which pertain to the procedures associated with medication safety; and (3) patients.

The three questions typically asked when a business strategic plan is being developed might be applied to a strategic plan for medication safety. These questions and the answers to them are as follows:

- What are you selling?
Medication safety.
- Who are the target customers?
Health care providers and consumers.
- How can you beat the competition?
By “selling” medication safety as the “product” that gives your institution a competitive edge.

A business plan is built on an institutional vision. A strategic plan for medication safety is no different. Developing this vision entails the following steps:

1. Involve stakeholders.
2. Identify a strategic objective.
3. Identify relevant aspects of old ideas.
4. Link the vision to core competencies.
5. Determine metrics and measuring agents (particularly failure mode and effects analysis [FMEA]).
6. Create a sense of urgency.
7. Keep people informed.

Once stakeholders have agreed on a vision, planning can begin. Steps involved here include identifying facilitators and barriers to change and building a broad coalition of supporters. True “change agents” should occupy leadership positions, but a broad-based task force should oversee the effort. It’s a good idea to aim for a dramatic change early on in the project. This will grab people’s attention and boost support.

Elements of a Strategic Plan for Medication Safety

Planning for medication safety, Kienle proposed, is a bottom-up activity that may be illustrated as a pyramid. At the base are an institution’s leaders, organizational structure, and culture. At the next level are reporting and analysis techniques, methods of system assessment, and planning. Nearing the top of the pyramid one must deal with issues such as education and competence, information management, and technology. Strategies are needed for dealing with each of these elements in order to effect the systemwide change required to implement a strategic plan for medication safety.

Leadership

A plan for medication safety must have the support of the facility’s informal as well as formal leaders. This support must go beyond lip service; financial resources will be needed.

Acquiring such support may entail negotiations with administrators who have their “heads in the sand.” As an example, Kienle cited results of a recent study by the New Jersey Hospital Association. Although 98 percent of administrators interviewed agreed that adverse drug events (ADEs) were of concern to them overall, only one third believed that ADEs were a concern at their institutions. Developing leadership buy-in entails identifying each of the categories of individuals involved and framing the issues in a way that is most important to each. Physicians may demand evidence-based models relating to specific medication safety strategies, while nurses may be more concerned with practical issues.

Other leadership issues, suggested by participants, include the need for board-level involvement, for a physician “champion,” and for leaders’ assurance that sufficient resources will be allocated to the plan. If a chief operating officer (COO) remains unconvinced, one participant noted, “Grab them by the hand and have them walk around the hospital with you . . . Let them see what folks are doing.”

Organization

A key consideration here is the composition, role, and function of the medication safety team. Should it be led by a physician? Should the hospital’s COO be its medication safety officer? The scope of services of this team, as well as oversight responsibility for it, must be considered. Its makeup is important. It should not be domi-

nated by management staff. It should include people from the trenches. If this is not possible, a means should be in place for regularly securing their input.

Participants pointed to the need for interdisciplinary and interdepartmental communication. Make sure there is a feedback loop so that information on all activities being conducted by the task force is relayed back to staff as well as conveyed to administrators, they urged. Another strategy is to conduct safety rounds and spend time talking with frontline staff about areas where medication safety is at risk.

Culture

Kienle ran a short video, “Beyond Blame,” to illustrate the importance of culture in safe medication use. In it, physicians, nurses, and pharmacists who have been involved with serious medication errors talk about the experiences and their aftermath. The message is the need to confront problems openly and to implement a systemwide, nonpunitive approach to error prevention that focuses on shared accountability. A strategic plan cannot be governed by a fear of litigation.

Workshop participants mentioned such things as valuing and demonstrating the importance of working together, awareness of the prevalence of errors, and of recognizing how system problems help create errors. The need to ensure that the individual who has filed an occurrence report receives feedback on the outcome of the incident was stressed. There is a need for an anonymous reporting system that will yield actionable results. Strategies for increasing reporting are of critical importance.

Reporting and Analysis

A plan for medication safety requires the existence of benchmarks by which progress can be measured and areas for improvement identified. The National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) definitions, or a “massaging” of them, will suit this purpose. The greatest effort should be focused on errors that have the greatest consequences on the NCC-MERP system.

There are no national metrics against which individual hospitals can assess their performance. Efforts to make comparisons are hampered by inconsistent benchmarks; for example, some systems are based on dosages dispensed, others on patient days.

Reporting may be required or voluntary. In some cases, it is required by federal or state regulations. Even when state laws do exist, they are not always rigorously followed.

The need for easier, more consistent, and more thorough reporting of errors was stressed. Hospitals have the choice of developing their own forms or using a form developed by a commercial vendor. Whether the report is called in by phone, entered online, or submitted in writing, ease of use is essential. Timeliness is also important, with respect both to filing the report and to forwarding it to the appropriate place. Timeliness may be

enhanced by computer analysis. Pharmacy technicians may also assist with data analysis. A multidisciplinary team should be established to determine reporting parameters.

Trends in error monitoring must be reported to hospital officials and others. Annual reports might suffice for the board of directors, but administrative officers need more frequent reports.

System Assessment

The tool developed by the Institute for Safe Medication Practices (ISMP) is generally agreed to be essential for systemwide assessment of medication safety procedures. Hospitals that have used this instrument possess valuable baseline data, but it may be advisable to redo the assessment, at least in part, in order to track progress or identify areas where more work is needed. ISMP now has a tool for ambulatory care settings.

Some health systems also find it helpful to perform a gap analysis that is based on an external document such as the recent Institute of Medicine report on medication safety.

Planning

The goals, objectives, and time lines of the medication safety plan must tie in to the institution’s strategic business plan.

These objectives may be sufficiently broad to apply to more than one institution, and collaboration in the interest of safe medication use may have merit. For example, a group of hospitals in the Delaware Valley (Pennsylvania) area has banded together to form a “culture of safety” and has jointly adopted the following objectives:

- To create an institutional culture under which every staff member is aware of medication safety issues and receives education and training on the subject.
- To provide the infrastructure needed to support safe medication use (e.g., appointment of a medication safety coordinator).
- To promote good clinical practice with respect to medication use.
- To ensure safe practices in the use of current and future technology (e.g., computerized prescriber order entry).

Education and Competence

Education must focus on whom to educate, what to cover, when to teach, and how to teach it. Both orientation programs and ongoing professional development opportunities must be considered.

Ensuring competence begins by defining it; the next step is to define the educational experiences needed to help staff attain the competencies in question. Methods for evaluating competence (skill based as well as written tests) are needed, as is a system for helping those who fall short of goals. The newest edition of ASHP’s Competency Assessment Book, *Competence Assessment: Tools for Health-System Pharmacists*, includes materials relating to medication safety.

Orientation should not be confined to a lecture hall. For example, a hospital may have new nurses come to the pharmacy during their orientation to meet staff and get an idea of how things work. After such a visit, the pharmacist is more than just an anonymous voice on the phone. The “Beyond Blame” video is an excellent resource for orientation. Continuing education must cover such areas as new medications as well as new drug devices and technology.

Education can take place through a variety of methods, including newsletters (check with risk management staff, however, before citing actual examples from the hospital and e-mail messages, as well as more traditional techniques. Issues related to credentialing and privileging fall into this category and must be considered in developing the strategic plan.

Information Management

Gathering, documenting, and recording information is important, but ensuring that the information is available and used appropriately is also essential. A major challenge is to standardize how documentation is handled. Not all departments document information the same way, and important data may fall through the cracks at the time a patient is transferred from one service or facility to another. The value of facilitating access to information must be weighed against confidentiality concerns and Health Insurance Portability and Accountability Act regulations.

Computerized prescriber order-entry systems, touted as a means of greatly reducing a key source of medication errors, are not

without faults. Many practitioners now believe that they simply lead to a different set of errors. The challenge is to avoid information overload as well as underload. Systems integration is key.

Technology

A strategic plan for medication safety must not only cover current technology but also provide for the integration of new technology. Issues of compatibility and training must be considered. A plan for evaluating the technology must be in place. Any plan must be based on the premise that technology per se is neither good nor bad; it can hamper as well as help if not properly used. The short half-life of technology, its potential complexity, and the need to use it to its optimum extent must be borne in mind.

Tools and Suggestions for Plan Development

Root-cause analysis and FMEA are two tools that health systems can use in developing a strategic plan for safe medication use. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) now requires that institutions select a high-risk process each year and apply FMEA to it. The processes to be studied do not have to be medication related; however, such processes are obviously good candidates for such a review. Kienle noted that pharmacists are ahead of the curve with respect to FMEA, and others in the organization should look to their expertise in this area.

As hospitals look toward improving their plans or creating new ones, it is important to be on the lookout for items to include in the plan. Kienle suggested distributing and using a template such as the one below for this purpose:

Priority	Description	Leader	Time Anticipated	Resources Needed	Date Started	Date Completed

Ranking issues in order of priority is essential. Kienle suggested a grid such as the following:

Not as important; easy to fix	Important; easy to fix
Not as important; hard to fix	Important; hard to fix

To build support for the plan and to create momentum, Kienle suggested, one might begin in the upper-right quadrant with the “Important and easy to fix” issues. Once the project has gained support, the team can take on the harder issues.

Conclusion

Other take-home points suggested by Kienle include the following:

- Write an executive summary of your strategic plan for your COO.
- Make sure the strategies you suggest are SMART (specific, measurable, attainable, realistic, and time-sensitive).
- Make sure that responsibility and time lines are clearly set forth.
- Create a sense of urgency.
- Keep everyone informed.
- Expect midcourse corrections.

Published Resources

Voelker R. Hospital collaborative creates tool to help reduce medication errors. *JAMA*. 2001;286(24):2067-9.

Hickson GB et al. Patient complaints and malpractice risk. *JAMA*. 2002; 287:2951-7.

Leape LL et al. What practices will most improve safety? *JAMA*. 2002; 288:501-7.

Solana KG et al. Safe but sound: patient safety meets evidence-based medicine. *JAMA*. 202; 288:508-13.

Web Sites

www.ashp.org: Information on best practices

www.jcaho.org: Information on root cause analysis

www.nccmerp.org: Definitions and taxonomy