Baxa Corporation

Creating a Culture of Safety

Technical Paper

Understanding the health-system challenges in creating an environment that supports successful safety initiatives.

Dennis Tribble, PharmD – Chief Pharmacy Officer, Baxa Corporation

Baxa Corporation
14445 Grasslands Drive
Englewood, CO 80112

tel: 303-690-4204
fax: 303-690-4804
www.baxa.com

Overview: An Unresolved Problem

Ten years have passed since the publication of the 1999 Institute of Medicine report on patient safety ("To Err is Human").[1] In that time, a great deal has been written about what makes systems safe, in general; and what is needed to make our healthcare systems safer. Highly publicized incidents have further focused attention on medication safety with specific acknowledgement that intravenous administration of medications is both hazardous and poorly controlled.

The fact that a decade of focus on this subject has resulted in very little change in the overall incidence of medical error should cause us to ask, "What it is that we have not done to improve the overall safety of medical care?" and of more importance health-system pharmacy, "How do we impact the overall safety of medication use?" In his book "Why Hospitals Should Fly," John Nance identifies that hospitals have the safety profile they currently have *because they are designed to produce that result*[2]. Without changing the way work is done, the systems and procedures that support that work and even the attitudes of the professionals performing the work, the safety records cannot, and will not change.

Recognizing the challenges inherent in creating and sustaining the change necessary to support a culture of safety, Baxa Corporation convened a panel of pharmacist experts at the 2009 American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting[3] to discuss the concept of a culture of safety, to review the lessons that organizations have learned along the way to creating a culture of safety and finally, to attempt to define the pathway that leads to safer performance. This technical paper provides a review of the panel's conclusions, as well as other writings on the subject that provide an understanding of the challenges that health systems face in undertaking this environmental change, thoughts on how to influence success and some of the benefits that they can expect to see from their efforts.

To Err Really Is Human

Perhaps the starting point in any discussion of a culture of safety is the acknowledgement that human beings make errors. Research has demonstrated that, given the need to perform repetitive tasks, humans will tend to make some kind of mistake about 3% of the time. This rate is higher with more complex tasks and those requiring logic.[4] Yet systems in hospitals tend to be built around the notion of human infallibility. Indeed, it is not uncommon to hear seasoned providers make claims such as they have been practicing their profession for over 20 years and have never made a mistake. Significant bodies of behavioral research demonstrate the utter impossibility of that claim.

Knowing that working more than about 10 hours on a shift produces fatigue effects similar to being legally drunk, does not prevent us from permitting cognitive providers in our health systems to work double and triple shifts.[5] Relying on human end-process inspection flies in the face of long-standing manufacturing experience that you cannot

inspect quality *into* a process at the end. Quality must be built into processes at every key step for there to be quality results.

So, a culture of safety must begin with the understanding that people *will* make mistakes, and that procedures and processes must be in place that not only minimize the opportunities for errors to occur, but also provide safeguards against errors that cannot be avoided.

This approach is counterintuitive to healthcare providers, many of whom have evolved a strong sense of infallibility in their work. Part of establishing a culture of safety necessarily involves confronting the fact that each of us is human, and likely to err, and learning to accept that reality and still be able to come to work.

Safety Isn't Something We Do On Alternate Thursdays

If we accept the notion that we are likely to err, then safety has to be part of every operation associated with the medication-use process, and must be a constant part of our awareness as we both perform our daily functions and evaluate those functions.

Successful cultural change means that safety considerations must be a part of everything that we do, including:

- Purchasing decisions – placing safety issues regarding form, labeling and use of automated identification on a par with price when we decide to purchase drugs.
- Stocking and inventory processes – providing systems to ensure that items are stocked in ways that limit the opportunity for incorrect picking, and limit the opportunity for stocking incorrect items in an established location.
- Product repackaging/relabeling – providing systems and procedures that ensure that each inventory is properly and accurately labeled, and that bar codes, if used, can be scanned and result in the proper response from automated systems.
- Order review – medication order review is performed under appropriate conditions by adequate numbers of personnel who are supported with appropriate tools.
- Compounding – preparation of compounded doses is performed in standardized ways associated with properly documented procedures. Compounding personnel are trained and validated in their ability to perform compounding procedures.
- Labeling – labeling is clear and unambiguous, containing the information absolutely required without gratuitous additional information that may be confusing or misleading.
- Dispensing – appropriate in-process and final checks verify that product selection is appropriate for the order.
- Administration – medication doses are provided in as near to a "ready-to-use" format as possible, properly labeled including bar coding or other automated identification that assists in ensuring that the right dose reaches the right patient.

Beyond this, a culture of safety in health systems treats every 'near miss' as an opportunity for improvement. Again, if we accept the notion that humans will make errors, then we must also accept the notion that our systems can either facilitate safe

practice or facilitate error. Each near miss is an opportunity to fine tune those systems away from facilitating error.

In her discussion during the ASHP panel presentation, Rita Shane of Cedars-Sinai Hospital in Los Angeles talked about celebrating their near misses, and using them as anecdotes, or "stories" by which they communicate with each other on the subject of safe practices. Finding opportunities to tell these stories – and using them as an opportunity for learning vs. punishment – builds a common library of understanding about what does, and does not, constitute safe practice.

System Problems Versus Human Indifference

As true as it is that humans will make errors, it is also true that humans generally do not set out deliberately to make errors. Patti Kienle, Director, Accreditation and Medication Safety for Cardinal, pointed out in her presentation at the ASHP program that cultures of safety must recognize that the majority of errors are the result of systems, as opposed to human performance; and that there are things humans do that increase risk. A culture of safety is intolerant of individuals whose daily performance disregards what is known to be safe practice. This concept has become known as the concept of a "Just Culture," where errors are recognized to have systemic components, but humans are held accountable for the *proper* use of safe systems, and high-risk behavior is not tolerated.

Collaboration and a Culture of Safety

A culture of safety also recognizes that there are things that one provider does that may promote unsafe conditions for another. Seth Eisenberg, Professional Practice Coordinator for Infusion Services at the Seattle Cancer Care Alliance Ambulatory Clinic, pointed out that most nurses have little awareness of the amount of work that goes into preparing an IV in the or of the effect of their demands on the pressure under which the pharmacy operates. A culture of safety demands that providers consider the entire medication-use system, not just their portion of it.

Automation and a Culture of Safety

There is no easy answer. John Poikonen, Clinical Informatics Director at UMass Memorial Health Care, pointed out that the application of technology to the medication-use process is not a panacea. Automation of a flawed system may exacerbate the opportunities for error. The application of automation within a health system requires careful consideration of the impact of the technology itself, ensuring that the appropriate infrastructure is in place to support the use of the technology. Users must be able to manage the practice changes that the technology may bring, handle the training and ongoing maintenance of the technology and ensure that the purchased technology actually provides the benefits for which it was purchased.

Baxa Corporation and a Culture of Safety

Baxa Corporation maintains a strong commitment to helping its customers develop and maintain a culture of safety through the use of products and services designed to re-engineer medication-use processes within the pharmacy to support safe systems.

Among the products and services available to assist in the support of a culture of safety in health-system pharmacy are:

- Oral Dispensers designed to provide safe and accurate oral liquid dosing that cannot be used for administration by other, inappropriate routes of administration. The FDA published the safety alert, "Never Use Parenteral Syringes for Oral Medications," on this issue in January 2010.[6] on their Web site.
- Automated preparation devices that use bar coding and vision systems to provide in-process checks of key steps in dose preparation, reducing reliance on human vigilance and ensuring compliance to best practice in sterile compounding.[7]
- Workflow and dose management products that provide similar in-process checks and documentation for manually performed dose selection and preparation.[8]
- IV administration tools that are designed to be easy to use and hard to misuse.[9]

Summary

A culture of safety is not a one-time event, a philosophy or even a mission. Rather, it represents a continuous effort by an organization to improve its processes by minimizing or eliminating opportunities for error and recognizing and correcting performance that increases risk. Such a culture requires an ongoing recognition of *safety* as a key strategic element in all decision-making, including purchasing decisions, programmatic decisions, employee relations and the application of automation. It also requires commitment to safety at every level of the organization, with strong multi-disciplinary collaboration.

References

[1] Institute of Medicine: A consensus report. *To Err is Human: Building A Safer Health System*. November 1, 1999.
[2] Nance John J. *Why Hospitals Should Fly*. Second River Healthcare Press. 2008.
[3] www.baxa.com/webinars
[4] http://panko.shidler.hawaii.edu/HumanErr/Index.htm
[5] Williamson AM, Feyer AM (October 2000). "Moderate sleep deprivation produces impairments in cognitive and motor performance equivalent to legally prescribed levels of alcohol intoxication." *Occup Environ Med* 57 (10): 649–55.
[6] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=94#9
[7] http://www.baxa.com/PharmacyProducts/AutomatedFillingSystems/
[8] www.baxa.com/doseedge
[9] http://www.baxa.com/PharmacyProducts/IVAdministration/