

## EDUCATING FOR SAFETY

### Educating for Safety in the Pharmacy Curriculum

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This overview of the Educating for Safety supplement issue explores the context and urgency of the problem of unsafe care, what we have learned about improving both safety and quality in health care, and the implications of this for educators. This supplement issue is a response to the charge of the AACP Council of Deans (COD) and the Council of Faculties (COF) Medication Safety Task Force to address the role of colleges and schools of pharmacy in responding to the national patient safety agenda. The articles included are intended to serve as a nexus for pharmacy education in developing curricula and promoting best practices as they relate to the importance of medication safety.

**Keywords:** medication safety, patient safety, quality improvement, curriculum

*Knowing is not enough; we must apply.*

*Willing is not enough; we must do.*

-Goethe

#### INTRODUCTION

The AACP Medication Safety Task Force was formed in July 2007 and consists of medication safety experts in pharmacy education and practice. This joint task force was charged to address the role of colleges and schools of pharmacy in responding to the national patient safety agenda. The task force divided into 3 panels to work on (1) the scholarship of medication safety; (2) curricular content in medication safety; and (3) medication safety awareness. The articles included in this supplement issue flow from these task force panels and are intended to both stimulate and advocate for the integration of safety concepts into the pharmacy curriculum.

Pharmacy educators have the responsibility to provide doctor of pharmacy (PharmD) students with the knowledge and competencies to hold their practice accountable to the profession's highest quality standards. According to Donald Brodie, "The ultimate goal of the services of pharmacy must be the safe use of drugs by the public."<sup>1</sup>

While our service aspirations are high with a strong emphasis on quality and safety, health care in general and

medication use in particular can still be unsafe. Harvard University professor, Lucian Leape, MD, the acknowledged founder of the modern day patient safety movement, and Donald Berwick, MD, current Director of the US Centers for Medicare and Medicaid, conclude that our progress in reducing error has fallen far short and that "many patients continue to fear, justifiably, that they may be harmed when they enter a hospital."<sup>2</sup> Increasingly and alarmingly, more medications are consumed outside of clinical settings, with little professional oversight. An analysis of death certificates from 1983 to 2004 found that the overall fatal medication error (FME) death rate increased by 361% and domestic FMEs (combined with alcohol and/or street drugs) increased more than 3000%.<sup>3</sup> Based on these findings, the Pharmacy Foundation of California's Safe Medication Use Alliance, concluded that more than 34 Americans die in their home each day because of a preventable medication problem.<sup>4</sup>

A 2006 prospective cohort study in 4 adult Boston primary care practices found that out of 661 outpatients who responded to a survey on medication use, 162 had experienced an adverse drug event (ADE), with 181 events having occurred within a 4-week period. The researchers concluded that ADEs are common in primary care and many are preventable or amenable. Twenty-four of the events (13%) were serious, 51 (28%) were amenable, and 20 (11%) were preventable. Thirty-two (63%) of the amenable events were attributed to the physician's failure to respond to medication-related symptoms and 19 (37%) were attributed to the patient's failure to tell the physician of their symptoms.<sup>5</sup>

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While errors in the outpatient setting are still largely estimates, the Agency for Healthcare Research and Quality (AHRQ) reported that medication side effects and injuries resulting from taking or being given the wrong medication or dosage increased dramatically (52%) from 2004 to 2008, from 1.2 million to 1.9 million. Over the same 4-year time period, more than 838,000 people were taken to emergency departments (and subsequently released) as a result of taking 1 of 5 categories of medicine: unspecified (261,600), pain killers (118,100), antibiotics (95,100), tranquilizers and antidepressants (79,300), and corticosteroids and other hormones (71,400). More than half (53%) of the patients who were hospitalized due to side effects or other medication-related injuries were age 65 years or older.<sup>6</sup> These numbers corroborate previous AHRQ and National Institute on Aging (NIA) data indicating that Medicare patients treated in the outpatient setting may suffer as many as 1.9 million drug-related injuries a year because of medical errors or adverse drug reactions (the latter may not be caused by error per se). About 180,000 of these injuries are life-threatening or fatal, and more than half are preventable, based on the estimates of a study of over 30,000 Medicare enrollees followed from 1999-2000.<sup>7</sup>

**Safety is a fundamental element of quality care but it is not a standalone element.** Patient safety in general and medication safety in particular are deeply embedded within a complex system. The Institute of Medicine Report, *Crossing the Quality Chasm*, defines quality health care as care that is safe, effective, patient centered, timely, efficient, and equitable.<sup>8</sup> Since the 1999 publication of the landmark IOM Report *To Err is Human*, health care leaders across the country (and internationally) have conducted an aggressive campaign to address both quality of care and patient safety.<sup>9</sup> Three major messages of this campaign are:

- Health care organizations can learn much from other high performance/high reliance industries that understand how to reduce error and improve quality;
- It is time for all of us to move beyond a “blame” mentality so that we can learn from error; and
- All stakeholders (health care providers, payers, and patients) need to be involved in the system redesign to improve system quality and patient safety.

## WHAT WE HAVE LEARNED ABOUT SAFETY EDUCATION

National leaders from academic medicine, government, health care providers, and payers point out that the 2005 Joint Commission initiative to promote the intro-

duction of patient safety education and training into the curricula of medical, nursing, pharmacy, and health care administration schools has failed to gain any traction within any of these disciplines. At least some aspects of patient safety are taught in over half of the nation’s medical schools; however, most medical schools are lagging behind.<sup>10</sup> A critical 2003 IOM report on health professions education outlines 5 core competencies that all health professionals should be able to demonstrate: the provision of patient-centered care; the ability to work in interdisciplinary teams; the employment of evidence-based practices; the application of quality improvement concepts; and the use of informatics.<sup>11</sup> We have identified 4 core educational safety concepts from the evolving science of safety (SoS) education that are fundamental to these 5 practice competencies.

### Core Educational Safety Concepts

**Create learning organizations.** A safe organization (or system) is one that is always listening and acting on the signals that it hears—a concept borrowed from the public health epidemiology model. This assumes the ability to generate accurate, usable data, whether voluntarily or through mandates. Learning from error and system breakdown data (as well as success) is the hallmark of a quality organization. High performance/high reliability industries like aviation and nuclear power have created continuous learning organizations that support and promote a culture of quality and safety through role modeling by their leadership and reinforce it with positive recognition and rewards for data generation.<sup>12</sup>

**Thought for pharmacy educators.** Are colleges and schools of pharmacy continuous learning organizations? Is appropriate data generation (eg, classroom assessments, evaluations) promoted and is it acted upon?

**Move beyond blame.** In order to improve the quality of a system, accurate and timely data and information are needed. However, a safe environment for everyone operating within the system is imperative to ensure access to complete and truthful information. “Speaking truth to power,” a phrase long associated with pacifism and the Quaker community, is finding new application in system and safety reengineering, which requires honest communication up and down the traditional hierarchical ladders—a model prevalent in both our medical and educational systems.<sup>13</sup> Another aspect of quality and safety improvement in high reliability organizations is the call for the creation of a “just culture” that values individual accountability and importantly differentiates human error from at-risk or reckless behavior.<sup>14</sup> The call has gone out to all health professionals (and educators) to speak up and hold one another accountable for their actions.

**Thought for educators.** Are classrooms safe and nurturing environments for speaking truth? Have pharmacy educators moved beyond blame to create a learning environment that recognizes the inevitability of human and system errors, while still holding individuals accountable for at-risk behavior?

**Understand the nature of complex adaptive systems.** Health care providers are beginning to understand how faulty system design (often complicated by outmoded policies and protocols usually developed at the “blunt end” of the system) helps to set people up for error at the “sharp edge” of the system where they are interacting with patients or students. Unlike mechanical systems that are highly predictive in their performance, health care systems are composed of human beings, often operating under the stress of tight schedules, hurried demands, and high patient volume. By recognizing the interplay of the various microsystems and silo operations, and understanding the system of work and the system of managing the work, a healthier system that provides consistent quality outcomes can be created.<sup>15</sup> Can pharmacy educators teach the key elements of a continuous quality improvement process (CQI) such as the Six Sigma business model<sup>16</sup> that analyzes the process that produces a quality product? Can pharmacy educators learn and teach how to foresee the active failures or unsafe acts, as well as the latent conditions within a system? For example, Joint Commission advocates conducting a root cause analysis to understand and correct system breakdowns in the delivery of healthcare, and the Institute for Safe Medication Practice advocates the benefits of failure mode and effects analysis (FMEA), particularly in the pharmacy setting. Generally root cause analysis *reviews* while failure mode and effects analysis *previews* and *predicts* actual and latent system conditions. These are the holes in British psychologist James Reason’s Swiss cheese model of system accidents often referenced in the safety literature.<sup>17</sup> The presence of holes in any one “slice” does not normally cause a bad outcome. However when the holes in many layers momentarily line up, they can permit a trajectory of accident opportunity and connect with a victim: a patient at the “sharp edge” of the system. This event also has created a “second victim” which is the health provider, who is also caught at the system’s “sharp edge.” How care and support are provided for the “second victim” is an emerging discussion within health care.

**Thought for educators.** Are pharmacy educators teaching and modeling quality system design in the curriculum? At both the micro (class) and macro (school) level? Are pharmacy educators preparing students for the numerous processes and innovations in quality and

safety improvement (ie, documentation of care and the federal, state, and quality assurance tracking and reporting methodologies) they will encounter in pharmacy practice experiences?

**Promote the value of interdisciplinary learning.** Teamwork is best learned while actually working within a team that is cooperating, coordinating, and communicating.<sup>18</sup> Typically, health care professionals are trained in separate disciplines and educational programs that do not adequately prepare them for entering the complex world of practice. An enormous amount of knowledge has been accumulated about team creation and management, including effective communication from other high performance industries, ie, aviation.<sup>19</sup> There are examples of high performance teams in health care, such as surgical teams, emergency room teams, and emergency response teams, where team members consistently and effectively work interdependently toward a shared goal.<sup>20</sup> Yet, there are too many examples in patient care where deference is given to rank and few are willing to question the actions or decisions made by the “longest white coat.”

Interdisciplinary and interprofessional education is generally accepted to mean “Occasions when (students) from 2 or more professions learn with, from, and about each other to improve collaboration and quality of care.”<sup>21</sup> By learning together early in their professional development, students have an opportunity to first be themselves, expose their vulnerabilities, and share a mutual excitement for learning before they take on their discipline-based professional persona. To be effective, preference should be given to case-based learning in small groups rather than large multidisciplinary classrooms. Case-based learning encourages shared problem-solving where team members have equal access to information and a shared situational awareness, much like the high-performance emergency room team that exchanges information freely and shares a singular goal to stabilize the patient. Traditional teaching methods may need to give way to greater problem-based learning and role playing. Simulations provide opportunities for students to see the same or slightly modified scenarios over and over until they achieve competency with every procedure that involves risk to the patient. The use of standardized patients in objective structured clinical examinations (OSCEs) could be easily adapted to emphasize competencies in medication safety.

**Thought for educators.** If pharmacy educators are promoting interdisciplinary professional practice, are they providing the opportunities for optimal team building and team maintenance in the classroom as well as in practice experiences?



## **ADDRESSING THE CHALLENGE**

### **Are We Preparing Students Who Can Lead Complex Organizational Quality and Safety Efforts?**

In January 2010, the National Quality Forum updated its “Safe Practices for Better Healthcare.” Safe Practice 18 states “Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization.”<sup>22</sup> The 10 actions outlined in this document include the systematic identification and mitigation of medication management risks; establishing pharmacy leadership structures and systems to ensure medication safety gaps; supporting a safety culture within the pharmacy staff with feedback to leadership; working across interdisciplinary teams to ensure evidence-based medication regimens; daily/24-hour safety and quality checks; establishing medication safety committees to review medication errors; medication safety walk-rounds with frontline staff input; staff skill building, establishing a central role in the planning and implementation of computerized prescriber order entry, bar-coding, smart infusion technology and other medication safety technology; the reporting and monitoring of ADEs and near misses; and responsibilities for medication reconciliation and patient counseling.<sup>23</sup> This national and international call for pharmacy to take responsibility for the quality of our care is not constrained to inpatient care. To address the critical and unmet need for improving and reporting quality performance with medication processes in all healthcare settings (primarily ambulatory and community), the Pharmacy Quality Alliance (PQA) was established in 2006 as a public/private consensus partnership. The alliance’s goal is “to identify, test and promote quality pharmacy measures nationwide as similar alliances of hospitals and physicians have successfully done.”<sup>24</sup> If pharmacists as professionals want to be recognized (and rewarded) as health care providers meeting and exceeding evidenced-based quality standards of care, they need to actively participate and be at the leading edge in these quality improvement and safety efforts.

**Thought for educators.** In their Analysis of the Pharmacist Supply Model, Knapp and Cultice observe that the workforce is projected to become younger, on average, by about 4 years by 2020, and they caution that the loss of experienced pharmacists could accelerate the rate at which younger (inexperienced) pharmacists are moved into positions demanding greater responsibility “Ongoing monitoring of work patterns and maintaining pharmacist supply with attention to leadership issues are of utmost importance.”<sup>25</sup> Pharmacy leaders have the need and unprecedented opportunity to meet and manage the demands

of complex medication systems, continuous quality improvement designs, and reporting requirements for the growing number of review organizations (eg, accreditation bodies, state pharmacy and public health regulatory boards, as well as the increasing number of local, regional and national peer review and quality review agencies). If pharmacists are to be included as an integral part of a leadership and safety program, pharmacy students will need to learn how to quickly adapt to performance improvement, streamline operations, grow clinical care services, integrate technology, and create and monitor organizational medication safety programs.<sup>23</sup> How well are pharmacy educators teaching these vital professional, personal, and organizational change and adaptation skills?

### **What Will the Delivery of Healthcare Look Like in the Near and Long Term?**

On March 31, 2011, the US Department of Health and Human Services (HHS) released proposed rules for Accountable Care Organizations.<sup>26</sup> An accountable care organization is a group of “providers who are jointly held accountable for achieving measured quality improvements and reductions in the rate of spending growth.”<sup>27</sup> The major system drivers for accountable care organizations, a product of President Obama’s Patient Protection and Affordable Care Act of March 23, 2010, are improved access to primary care, improved quality of care and, ultimately, payment reform. Understanding and implementing safe systems is an essential key to improving quality while reducing costs, including reducing hospital admissions.<sup>28</sup> Providing further impetus to address safety and quality in primary care, the Centers for Medicare and Medicaid Services (CMS) Center for Innovation has announced that their new Community-based Care Transition Program “will provide \$500 million in funding to community-based organizations partnering with eligible hospitals for care transition services that include timely, culturally, and linguistically-competent post-discharge education, medication review and management, and patient-centered self-management support within 24 hours of discharge.”<sup>29</sup>

**Thought for educators.** While professional organizations and regulators are sorting through the explicit and implicit roles of pharmacists in accountable care organizations and transitional care models that are emerging in the health care reformation, how are pharmacy administrators and educators educating students and faculty members about these opportunities? How are pharmacy educators teaching students, who in turn, will need to educate hospital and health-system administrators, health plan payers and other decision and policy makers, particularly in the ambulatory care sector, about the need – and value added - to incorporate pharmacists’ expertise in

medication safety and optimization in chronic disease management as well as product delivery?

### **How Can Educators Be More Accountable for Preparation in Safety?**

Leaders in health care have observed that we have just scratched the surface of the possibilities for improving safety for patients. They advise health care providers to “celebrate our successes, be clear-eyed about our failures and get on with the job of improvement.”<sup>30</sup> The challenge to pharmacy educators is to learn how we can better prepare pharmacy students to be both competent and accountable, as practitioners and as health care leaders, in providing quality patient care.

### **THE EDUCATING FOR SAFETY SUPPLEMENT**

The articles in this supplement describe the efforts of pioneer pharmacy educators in addressing critical interventions in patient and medication safety. A sampling of patient safety educational efforts in the United States and United Kingdom are presented. West and colleagues describe an exploration into the integration of the Science of Safety (SoS) in the PharmD curricula in the United States. In this first collaboration with the Food and Drug Administration (FDA), they provide a baseline look at the content and teaching methods used to present SoS topics in the pharmacy curriculum. The SoS is a broad view of drug safety that considers appropriate methods to study and report the safety of a drug product from its preclinical development through its use as an approved drug product. Developed as part of the FDA’s Response to the Institute of Medicine’s 2006 Report, the proposed SoS curriculum is described in some detail in the 2009 Report to the AACP.<sup>31</sup> West and coworkers found that 11 of the 17 SoS topics were covered by more than 75% of schools surveyed. The topics covered by the majority of schools ranged from those used in practice (How to report a drug safety problem to MedWatch, 92.3% covered) to those providing a background (How results of Phase II clinical trials are used to establish a basis for appropriate and safe product use, 81.3% covered). Six topics relating to recent developments in how drug product safety is monitored and communicated were covered by less than 75% of colleges and schools of pharmacy. Curriculum committees may find the list of SoS ability-based outcomes useful in their deliberations about the need for a comprehensive Patient Safety curriculum at their school.

Warholak and colleagues follow this overview of the SoS with a focused look at the issues that impact the delivery of medication safety education in US colleges and schools of pharmacy. Based on interviews with “key in-

formants” they identify curricular gaps, barriers, and the need for minimum standards and “hands-on” student engagement with SoS topics.

The importance of educating pharmacists about quality improvement to our mission in academia is illustrated well by Bradley and colleagues’ study of the influence of the hidden curriculum in patient safety education. Using an in-depth, case-study approach, Bradley and colleagues examine the impact of the formal planned, presented, and received curricula in patient safety at 3 schools of pharmacy in the United Kingdom, and the hidden curriculum experienced by students in practice settings with pharmacist role models. They found that among the patient safety topics missing from the formal curricula were the epidemiology of adverse drug events and medication errors, learning from and reporting adverse incidents, root cause analysis, and building a safety culture.

Kiersma and colleagues provide the academic pharmacy audience with a well-crafted review of the research published on patient safety instruction in the health professions. Medical curricula appear to be ahead of nursing, pharmacy, and dentistry in addressing patient safety content. The instructional methods include lecture as well as case-based and active-learning exercises and discussion. Many investigators used student opinion or self-assessment to determine the effectiveness of instruction, but a small number used knowledge examinations or objective structured clinical examinations to assess student performance.

Warholak and colleagues investigate the usefulness of a quality improvement curriculum recently developed for pharmacy students and pharmacists and pilot tested at the University of Arizona. The Educating Pharmacy Students and Pharmacists to Improve Quality (EPIQ) curriculum is organized into 5 modules designed to permit users to adapt the material for different teaching styles and audiences: status of quality improvement and reporting in US health care system, quality improvement concepts, quality measurement, quality-based interventions and incentives, and application of quality improvement to the pharmacy practice setting. The curriculum developed by a group of pharmacy faculty members, practitioners and industry scientists assembled by the Pharmacy Quality Alliance is described in more detail at [www.japha.org](http://www.japha.org) and [www.pqaalliance.org](http://www.pqaalliance.org).<sup>32</sup> Warholak and colleagues shared the EPIQ curriculum with 97 individuals who asked to review it. Eighty-one percent of the reviewers rated the curriculum as valuable or extremely valuable and a similar percent (81.5) indicated they had or were planning on using content in pharmacy management or medication safety courses.

William Fassett explores the essential performance outcomes for patient safety training: performing root cause analyses and healthcare failure mode effects analyses, and the ability to generate effective safety communications using structured communications. Through an extensive analysis of the health provider education literature, he recommends that all doctor of pharmacy students be able to perform both retrospective (RCA) and prospective (FMEA) analyses of error prone practice activities upon graduation, and that the situational briefing model (SBAR) for communication of patient safety concerns to other healthcare providers be taught throughout the curriculum alongside the more familiar SOAP note framework.

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