SPECIAL ARTICLES

Teaching the Science of Safety in US Colleges and Schools of Pharmacy

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This paper provides baseline information on integrating the science of safety into the professional degree curriculum at colleges and schools of pharmacy. A multi-method examination was conducted that included a literature review, key informant interviews of 30 individuals, and in-depth case studies of 5 colleges and schools of pharmacy. Educators believe that they are devoting adequate time to science of safety topics and doing a good job teaching students to identify, understand, report, manage, and communicate medication risk. Areas perceived to be in need of improvement include educating pharmacy students about the Food and Drug Administration's (FDA's) role in product safety, how to work with the FDA in post-marketing surveillance and other FDA safety initiatives, teaching students methods to improve safety, and educating students to practice in interprofessional teams. The report makes 10 recommendations to help pharmacy school graduates be more effective in protecting patients from preventable drug-related problems.

Keywords: safety, curriculum, pharmacy education, FDA, quality

INTRODUCTION

Since 2000, a series of publications have argued for change in healthcare and healthcare education. These include the Institute of Medicine's (IOM's) report "To Err Is Human: Building a Safer Health System," which defined the economic and clinical consequences of medication error and misuse¹; "Crossing the Quality Chasm: A New Health System for the 21st Century," which called for fundamental changes in the structure and provision of healthcare²; and "Health Professions Education: A Bridge to Quality," which identified gaps in healthcare education and general recommendations for change.³ "Roadmap to 2015: Preparing Competent Pharmacists and Pharmacy Faculty for the Future,"⁴ made an argument for pharmacy education to serve as a resource and catalyst for furthering research in the areas of patient safety and quality. In 2006, IOM released "The Future of Drug Safety — Promoting and Protecting the Health of the Public," which recommended how the FDA might improve the nation's drug safety and how other elements of the federal government might help ensure the safe use

of medical products.⁵ One key recommendation in this report was an appeal to improve the science of safety.

This paper presents the findings of the report "A Baseline Evaluation of the Integration of the 'Science of Safety' into the Curriculum of the Doctor of Pharmacy Degree in US Colleges and Schools of Pharmacy." The concept of science of safety is introduced and recommendations are presented for improving the science of safety curricula in US colleges and schools of pharmacy. Detailed description of the methodology used to develop the report is presented in the final report.⁶

What Is the Science of Safety?

The FDA describes the science of safety as an emerging discipline that seeks to understand and prevent adverse events.⁷ This explicit definition should have a common meaning for various disciplines within the field of pharmacy. However, initial discussions with educators and others did not find this to be the case. One reason was because pharmacists and scientists/health science professionals tend to view the construct, science of safety, within the framework of their own discipline. Therefore, toxicologists commonly view science of safety as the study of toxic substances in animals, pharmacoepidemiologists see it as exploring the risk of drugs used in populations, and clinicians perceive it as identifying and preventing adverse drug events in practice settings. The concept of

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science of safety also can be confused with issues like equipment safety, laboratory safety, occupational safety, and consumer product safety. Because the science of safety can mean many things, it was important to clearly define the term for educators.

This research defines *science of safety* as the systematic study of the negative impact of drugs and devices on humans at all stages of the drug product lifecycle (Figure 1). This definition is based on source documents from the IOM⁷ and FDA.⁸ Key elements of science of safety include the following:

- It deals with the systematic exploration of the safety of medications and devices
- Its purpose is to help scientists and practitioners understand, explain, and predict physical risk from exposure to medications and devices
- It examines risk throughout the entire product lifecycle, from drug discovery to postmarketing

Thus, science of safety can refer to knowledge learned at any step of the product development and marketing process including in preclinical animal toxicology and safety studies, clinical studies in humans, safety studies needed for FDA approval, and postmarketing epidemiological research. It includes translational research enabling health-care professionals and other individuals to better identify, understand, report, manage, and communicate the risk of drugs and devices in patient populations. It also includes advances in the molecular origins and progression of disease, adverse consequences of treatments, and patient-

specific and population-specific causes and responses. Figure 2 presents subject matter potentially associated with science of safety.⁹

FDA'S Interest in the Science of Safety

In September 2007, the Food and Drug Administration Amendments Act (FDAAA), HR 3580, was signed into law giving the FDA greater authority over regulation of medication safety.¹⁰ The FDAAA gave the FDA more authority to require pharmaceutical companies to conduct postmarketing studies and trials, make safety-related medication labeling changes, and develop risk evaluation and mitigation strategies (REMS). In addition, the act instructed the FDA to develop a systematic plan to better manage the risks versus the benefits of drugs as they progress through their lifecycles.

The FDA's strategic plan had objectives to strengthen the science and systems that support medication and device safety.¹¹ Part of that plan was to develop collaborations with bodies involved in maximizing patient and consumer safety. Colleges and schools of pharmacy and faculty members were identified as important partners in the science of safety because of their contributions to the science and to the teaching of that science to students.

The FDA strategic plan included 4 main goals in which pharmacists might have some role:

- (1) Strengthen the FDA for today and tomorrow. Pharmacy professionals and academic research can collaborate with FDA by participating in programs such as Sentinel Initiative, Critical

Figure 1. Science of safety domains within the product lifecycle.

Figure 2. Safety topics associated within the product lifecycle.⁹

Path Initiative, and the Adverse Event Reporting System (AERS).

- (2) Improve patient and consumer safety. Pharmacy faculty members and pharmacists can further the science of best methods and development of tools for communicating risk associated with medications, devices, and biologics.
- (3) Increase access to new medical and food products. Pharmacists can facilitate access to new, safe, and effective medical products by improving the monitoring, reporting, and management of risk associated with medications.
- (4) Improve the quality and safety of manufactured products and the supply chain. Because of their knowledge of pharmacoepidemiology, familiarity with adverse event-reporting programs, and effective communication skills, pharmacists can help detect and report sentinel events that occur in their community.

To achieve the goals of the strategic plan, the FDA wanted to better understand how pharmacists are educated in the science of safety in order to identify ways to partner with pharmacy professionals in improving medication safety. That interest led to a collaboration between the FDA, the American Association of Colleges of Pharmacy (AACP), and the Pharmacy Services Support Center (PSSC) at the American Pharmacists Association to conduct this research. The purpose of the collaboration was to conduct a baseline assessment to identify ways to improve the teaching of the science of safety in colleges and schools of pharmacy in support of FDA medication safety initiatives to support implementation of Title IX of the FDA Amendments Act. The results from this project provided the FDA with information necessary to con-

struct a plan to accomplish the agency's strategic goals and legislative mandates. In addition, this baseline assessment of the pharmacy curriculum provides a platform for continued collaboration between the AACP and the FDA. Expected benefits of this collaboration to pharmacy academia include the following:

- A better understanding of FDA expectations of partners in the science of safety
- A baseline understanding of how the pharmacy professional curriculum matches the expectations of the FDA
- Provision of baseline data to guide program development and policy in the area of medication safety
- Guidance and recommendations that can support collaboration between pharmacy academia and the FDA in promoting the science of safety.

METHODS

Specific research domains were developed during consultations between representatives of the AACP, PSSC, and FDA, and the study investigators (Table 1). A model science of safety curriculum developed by the FDA⁹ formed the basis of many of the identified research domains and questions.

This project consists of a literature review, key informant interviews, in-depth case studies, and a nationwide survey. A multi-method approach to data analysis was used to synthesize data collected by qualitative and quantitative methods. Multiple methods allowed triangulation of results (ie, cross-checking findings for consistency and contrast) and offered greater potential for insight and understanding. The project was conducted by a team of researchers from colleges and schools of pharmacy at

Table 1. Science of Safety Domains and Questions of Interest

Domains	Questions of Interest
Science of safety	How does the pharmacy profession and academia define science of safety? What science of safety topics are covered in colleges and schools pharmacy? What competencies are expected? Who teaches it?
Needs	What are the perceived gaps in the curriculum, leadership, and expertise; future plans; and barriers to teaching?
Pedagogy	What strategies for instruction are used to teach science of safety? What role does experiential education, integration of topics across the curriculum, and multidisciplinary teaching have? What level of interprofessional education exists? How do educators collaborate with safety net healthcare providers for underserved populations?
Organization	What is the relationship between organizational factors (eg, Clinical and Translational Science Awards [CTSAs], Centers for Education and Research on Therapeutics [CERT], and the teaching of the science of safety)?
Students	What is the role of pre-pharmacy and postgraduate training on the teaching of science of safety?
Outcomes	Are graduating students perceived to have achieved desired training in risk understanding/appreciation, identification, management, communication, and reporting?

Virginia Commonwealth University, the University of Arizona, and the University of Mississippi. Methods and design were approved by the institutional review board of each university. A brief overview of the literature review, key informant interviews, and in-depth case studies is provided here as background. A detailed description of the methodology for all 4 research approaches is described in the final report.⁶

Literature Review

Prior to primary data collection, a review of the current literature on the education of the science of safety in US colleges and schools of pharmacy was conducted. Investigators reviewed published and unpublished literature relating to pharmacy education and safety-related topics. Scans were conducted of the PubMed and International Pharmaceutical Abstract databases of biomedical and life sciences literature and of pharmacy organization and association Web sites (eg, Institute for Safe Medication Practices, National Association of Boards of Pharmacy). Titles and abstracts of articles in the *American Journal of Pharmaceutical Education* also were reviewed for relevance to science of safety.

Keyword searches were used to link the terms *pharmacy education*, *pharmacy teaching* and *pharmacy curriculum* with other keywords including *safety studies*, *toxicity*, *biomarkers*, *institutional review boards (IRB)*, *Protection of Human Subjects*, *drug interactions*, *pharmacokinetics*, *pharmacology*, *pharmacogenomics*, *personalized medicine*, *adverse events*, *Physician Labeling Rule*, *ClinicalTrials.gov*, *quality improvement / assurance*, *Titles VIII and IX of FDA Amendments Act (FDAAA)*, *post-marketing safety*, *pharmacovigilance*, *MedWatch*, *sentinel events*, *medication safety / patient safety*, *FDA Advisory Committee for Drug Safety and Safety Risk Communication*, *market withdrawal*, and *risk communication*. Titles and abstracts of articles generated from the search were reviewed for relevance to the proposal objectives. English-language papers from January 1, 2000, to March 31, 2010, were reviewed. References of key articles also were searched for seminal papers prior to 2000, allowing the inclusion of earlier papers. More than 100 articles were read in the first review of the literature.

Of these articles, further analysis was done to identify papers that surveyed pharmacy school curricula, provided key commentaries and reports relating to the teaching of safety within a curriculum, or provided detailed descriptions of courses or educational experiences in the teaching of science of safety topics. Twenty-six papers were analyzed and used to provide support for the findings of the literature review.

Key Informant Interviews

Thirty key informant interviews were conducted with individuals by study investigators. The purpose was to understand current thinking and practices in pharmacy education about the science of safety from the perspective of educators and safety experts. In-depth interviews were conducted with educators at pharmacy colleges/schools across the United States from a mix of small and large institutions and safety experts from institutions and associations engaged in safety-related topics [eg, Institute for Safe Medication Practices (ISMP), Pharmacy Quality Alliance (PQA), AACP].

An interview protocol was created and used to collect descriptive information and obtain viewpoints about the topic. When relevant, findings from the literature were used to guide the interview. Trained investigators conducted the interviews via phone or e-mail. Interviewers took notes during interviews or afterwards from recordings of interviews. Content analyses of interview summaries were conducted to assess and organize themes, ideas, and practices. These content analyses were used to summarize the findings of the interviews.

Case Studies

Colleges/schools of pharmacy at 5 universities (Temple, University of Arizona, Midwestern University – Chicago College of Pharmacy, University of Southern California, and Virginia Commonwealth University) were identified for case studies and asked to provide in-depth insight into curriculum development and effective processes that integrate and elevate the science of safety in pharmacy education. Case studies consisted of review of the college's/school's Web site and telephone interviews with faculty members. Supplemental documents not available on the Web, like course syllabi, also were requested and reviewed. Specific questions of interest include the following:

- Does the doctor of pharmacy (PharmD) program:
 - Offer standalone courses teaching medication safety?
 - Offer specialty elective track of courses in drug safety?
 - Have faculty who champion safety in the professional curriculum?
 - Offer an Advanced Pharmacy Practice Experience (APPE) emphasizing medication safety?
- Do the postgraduate programs in quality assurance, regulatory affairs, and/or medication safety offer:
 - Certificate, master of science (MS), doctor of philosophy (PhD), distance education, combined degree options?

FINDINGS

This section provides a brief summary of the results from the literature review, key informant interviews, case studies, and survey. A detailed summary of the findings of this research is in the final report.⁶

There appears to be general agreement from the various methods that pharmacy education should include the following broad topic areas related to science of safety:

- Educate students in interprofessional teams that are systematically grappling with quality and safety issues
- Teach communication skills; specifically, how to communicate with patients when an error occurs
- Teach about computing, data and information, and communication technology; technology's benefits and limitations
- Teach about new evolving disciplines including bioinformatics, genomics, proteomics, and metabolomics
- Provide opportunities for student research in safety that requires application of skills to complex situations
- Promote a culture of safety in the minds of students

In general, respondents at colleges and schools of pharmacy believe that they are devoting adequate time to science of safety topics. A few topics that are of interest to the FDA but were not covered well included the colleges'/schools' use of clinicaltrials.gov, use of electronic decision support tools, teaching of methods to improve safety, and understanding of the role of the FDA's Advisory Committee for Drug Safety and Safety Risk Communication. Several respondents indicated that they plan to begin teaching these topics.

Similarly, respondents believed that their college/school was promoting the role of pharmacists in minimizing risks associated with medication products. Individuals indicated that their graduates are able to accomplish many of the abilities associated with the science of safety. However, there is some room for improvement in educating pharmacy students about the FDA's role in product safety and the future of postmarketing surveillance, pharmacoepidemiology, and other population-based safety efforts. The new Accreditation Council for Pharmacy Education (ACPE) guidelines include more requirements related to population-focused care, informatics, pharmacoepidemiology, and research processes and future curricula likely will reflect many of these changes.

There were various opinions among respondents about how to best teach science of safety topics and how to integrate science of safety topics into the curriculum. There was some interest in the development of a model science of safety curriculum for colleges and

schools of pharmacy that is modular in nature so colleges and schools can adopt portions depending on their needs.

Finally, few respondents indicated that their college or school of pharmacy was interprofessional in its approach to teaching the science of safety. Given that medication safety requires teamwork between pharmacists, technicians, nurses, physicians, and other professionals, this finding was disappointing. Some interprofessional education is provided in many schools, but it is not done in a systematic manner for all professional students. Opportunities typically occur in advanced practice experiences, but chances to work in team-based settings depend on a student's luck in being assigned to the right practice site and faculty mentor.

DISCUSSION

Both the FDA and the pharmacy profession seek to positively impact patient health by ensuring appropriate use of medications toward a goal of achieving desired health outcomes. The FDA and pharmacy professionals seek to minimize risk to patients by identifying, understanding, reporting, managing, and communicating risk. Consequently, many of the FDA's concerns regarding the safety of medication use parallel those of the pharmacy profession and pharmacy educators.

In general, the product lifecycle approach used by the FDA to frame the science of safety is not an explicit approach to curricular design in colleges and schools of pharmacy. Rather than viewing safety in terms of the FDA's product approval process where medications progress from preclinical to clinical to postmarketing phases of their lifecycle, the pharmacy profession and academics tend to characterize science of safety by how it relates to patient care, emphasizing domains relevant to postmarketing stages of the medication product lifecycle. The curriculum related to premarketing stages of the product lifecycle is not typically framed in terms of medication safety.

Nevertheless, the product lifecycle approach is well-suited for pharmacy education because much of the coursework in colleges and schools of pharmacy matches the FDA's model curriculum.⁹ Although earlier phases of the product lifecycle do not typically come to mind when discussing science of safety, they are important elements of a student's education at most colleges and schools of pharmacy.

Most safety competencies expected of pharmacy graduates are consistent with those recommended by the "IOM Report on Health Professions Education: A Bridge to Quality." Competencies expected of graduates include the adopting of a safety philosophy, developing the ability to work in teams, incorporating best evidence in decision

making, applying quality improvement and systems approaches to problems, using technology, managing risk, and refining communication skills. Some safety competencies, like the ability to use databases in pharmacoepidemiology research, are not considered priorities; possibly, these skills are not often used in pharmacy practice settings.

Colleges and schools of pharmacy are exerting significant time and effort toward the teaching of science of safety topics. Even so, there appears to be gaps in content and competencies achieved. Some schools are already taking action to address these gaps while others are not. Addressing these gaps may help support full implementation of new federal laws relative to medication safety and aid pharmacists advocating for greater roles as therapeutic safety management experts.

Report Recommendations

Based upon the findings of the report, a list of 10 recommendations is provided to guide the FDA and the pharmacy profession. These recommendations are intended to encourage dialogue and action inside and outside of academia about pharmacy's role in science of safety and its needs. In addition, we desire/hope that the results of this research will provide opportunities for collaboration between US colleges and schools of pharmacy and the FDA. These opportunities include improving the teaching of the science of safety to improve our healthcare delivery system in all practice settings including those sites serving underserved and underinsured populations.

- (1) The AACP should convene a conference to discuss the findings of this report. Attendees should comprise a diverse group including educators, scientists, clinicians, practitioners, pharmacist employers, and FDA representatives. Participants at the conference should confer and seek agreement on various questions including:
 - (a) What elements of the FDA Science of Safety Model Curriculum should be a part of the education of all graduates of colleges and schools of pharmacy in the United States?
 - (b) What educational outcomes relating to the science of safety should be achieved by all graduates of US pharmacy colleges and schools, and how would these outcomes be measured?
 - (c) What steps should be taken to achieve the educational outcomes in science of safety identified in the conference?
 - (d) What is the role of academia in promoting the science of safety within the profession?

- (2) Studies need to be conducted to quantify exactly what science of safety outcomes are being achieved at colleges and schools of pharmacy in the United States. This report highlights some potential gaps in basic student safety competencies including those relating to human factors research, medical errors, medication errors, quality or process improvement, root cause analysis, failure mode and effects analysis, and safety organizations (eg, ISMP). A better understanding is needed of the types and extent of gaps in student safety competencies in order to respond with educational interventions.
- (3) More education resources should be developed and made available to colleges and schools of pharmacy to address faculty needs in the science of safety. Resources exist for faculty members but may only address pieces of the medication safety puzzle. No comprehensive works exist on the subject where science of safety experts share their expertise with fellow educators. One model of training for faculty members is the Educating Pharmacy Students and Pharmacists to Improve Quality (EPIQ) program available through the PQA (www.pqaalliance.org/). The EPIQ program is a complete educational curriculum that can educate pharmacy students, pharmacists, and other stakeholders about measuring, reporting, and improving quality in pharmacy practice. It contains PowerPoint slide sets with lecture notes, case studies, student-centered activities, student readings, faculty readings (ie, a list of suggested readings to hone faculty knowledge of core content), class discussion questions, examples of outside-of-class projects for additional hands-on experience, an example syllabus, recommendations for achieving differing levels of knowledge and skill development for various audiences, and more. Other models are offered by the Institute for Healthcare Improvement (IHI) (www.ihl.org/IHI/) and the ISMP (www.ismp.org/). The IHI provides educational tools for improving health care delivery, measures to track improvement, educational materials, and links to professionals with similar interests. The ISMP provides educational materials, tools, guidelines, newsletters, alerts, and consulting services to promote patient safety.
- (4) Educational materials should be developed that target pharmacy students' learning gaps (eg, appropriate use of medication guides) related

to the science of safety. The FDA could provide the material on their Web site or content could be made available on the Web sites of the AACP and other organizations. For instance, modules might be designed to educate students either in the classroom or in an e-learning format via the Web. Testing achievement of defined learning outcomes also could be conducted. Modules could be developed for topics including REMS, history of medication risk regulation, clinical pharmacogenomics, and others.

- (5) Interprofessional education and training in patient safety and related topics should be encouraged at schools of medicine, nursing, pharmacy, and other health professions. One way would be to link some federal research funding to efforts to provide interprofessional education at schools. For instance, one criterion for funding Clinical and Translational Science Awards could be that the institution has plans to implement interprofessional education within its curriculum. Certain skills and topics are better learned using an interprofessional teaching approach, especially adopting a safety philosophy, developing the ability to work in teams, applying quality improvement and systems approaches to medication safety issues, and communication. Not all pharmacy schools are located on medical center campuses; therefore, interprofessional education may require innovative teaching approaches. For example, didactic training could be provided online, mixing professions in case-based exercises or via telemedicine conferences.
- (6) Support should be provided by HRSA to expand the number of PSSC experiential learning sites for pharmacy students with the goal of providing patient-centered, team-based approaches to identifying, understanding, reporting, managing, and communicating medication risk. The Health Resources and Services Administration (HRSA) Pharmacy Services Support Center (PSSC) has the potential to increase interprofessional education of pharmacy students in medication safety through its support of student practice experiences at health care sites caring for underserved populations. PSSC healthcare sites work under team-based practice models not typically seen in many community pharmacy practice settings.
- (7) Institutions, associations, and/or organizations should conduct studies that examine the role of pharmacy employers on the science of safety. This research illuminated some assumptions in academia that the current pharmacy practice environment may lower expectations in students about the relevance of some science of safety topics. Concern also was expressed that the work environment in some pharmacy practice settings did not promote a culture of safety. There is little evidence to support or counter these opinions. Research needs to be conducted to better understand this issue. Some questions that might be answered by this research include:
 - (a) To what extent do pharmacists in practice settings deviate from standards of practice that put patients at unreasonable safety risks? For example, are pharmacists adequately fulfilling their roles in REMS?
 - (b) What expectations do employers have of pharmacists in the areas of science of safety?
 - (c) What kind of socialization occurs in practice settings to encourage or discourage safe medication practices? How do organizational norms influence the adoption of safe medication use?
 - (d) To what extent does the socialization of pharmacy students in practice settings influence their commitment to medication safety?
 - (e) To what degree do employers establish and maintain a culture of safety in workplaces?
 - (f) What technology and management systems are in place to identify, understand, report, manage, and communicate medication risk?
 - (g) How can employers support the teaching of science of safety in the curriculum? What real life experience can they provide to encourage student commitment to medication safety?
 - (h) To what extent do employers incentivize or sanction practices related to safety? Are these approaches effective?
 - (i) What occurs when a pharmacist's professional norms with respect to safety are in conflict with organizational norms?
- (8) Funding should be raised to support postgraduate training in the science of safety. This funding could support residencies, fellowships, and graduate degrees in patient safety.
- (9) The AACP Council of Deans should address the issue of science of safety. At minimum,

the Council should make a statement about their assessment of the relevance and importance of the topic to pharmacy education. A statement from the Council of Deans would provide some leadership to educators about where science of safety should fit within the pharmacy curriculum.

- (10) Colleges and schools of pharmacy should consider adopting the product lifecycle approach to teaching the science of safety. The product lifecycle approach views the science of medication safety as an interconnected sequence of events that begins with the creation of a drug; continues with its development, testing, and introduction to the market; and ends when the drug is removed from the market. The lifecycle approach views problems of medication safety using an interdisciplinary and interprofessional approach instead of a compartmentalized method that is dealt with by separate scientific disciplines or professions. This systems approach to medication safety can harmonize all of the disciplines toward a single conceptual framework and provide explicit linkages between basic and applied sciences. The lifecycle can be used to coordinate the various sciences associated with pharmacy – medicinal chemistry, pharmacology, pharmaceuticals, clinical sciences, social/behavioral/administrative sciences, and others – with the common goal of better identifying, understanding, reporting, managing, and communicating risk in a way that protects patients.

CONCLUSION

This paper summarizes the findings of a report providing baseline information on how the science of safety is taught in professional programs at US colleges and schools of pharmacy. The report indicates some room for improvement in teaching students to identify, understand, report, manage, and communicate medication risk. Many of the deficiencies revolve around areas of interest to the FDA. Another concern surrounds the need

for improving interprofessional training with physicians and other health professionals. Ten recommendations are provided to encourage future discussions about helping pharmacy graduates be more effective in protecting patients from preventable drug-related problems.

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