

## RESEARCH ARTICLES

### Pharmacoepidemiology Education in US Colleges and Schools of Pharmacy

Esmond D. Nwokeji, PhD, Karen L. Rascati, PhD, Leticia R. Moczygemba, PharmD, and James P. Wilson, PhD

University of Texas at Austin

Submitted December 15, 2006; accepted February 8, 2007; published August 15, 2007.

**Objective.** To examine the type and extent of pharmacoepidemiology education offered by US colleges and schools of pharmacy.

**Methods.** An electronic Web-survey was sent to all 89 US colleges and schools of pharmacy between October 2005 and January 2006 to examine the type and extent of pharmacoepidemiology education offered to professional (PharmD) and graduate (MS/PhD) students.

**Results.** The response rate was 100%. Of the 89 schools surveyed, 69 (78%) provided pharmacoepidemiology education to their professional students. A mean of 119 ( $\pm 60$ ) PharmD students per college/school per year received some pharmacoepidemiology education (range 1-60 classroom hours; median 10 hours). Thirty-five schools (39%) provided education to a mean of 6 ( $\pm 5$ ) graduate students (range 2-135 classroom hours; median 15 hours).

**Conclusions.** A majority of US colleges and schools of pharmacy offer some pharmacoepidemiology education in their curriculum. However, the topics offered by each school and number of classroom hours varied at both the professional and graduate level.

**Keywords:** pharmacoepidemiology, epidemiology, curriculum

## INTRODUCTION

Pharmacoepidemiology is the “study of the use and effects of drugs in large numbers of persons.”<sup>1</sup> It was first described in 1984 when it was proposed that a new discipline was necessary to integrate epidemiology and drug-related events (Figure 1).<sup>2</sup> Since then, pharmacoepidemiology research has evolved into an important discipline that analyzes information pertaining to areas such as adverse drug events, drug utilization patterns, drug efficacy, and post-marketing surveillance research.<sup>3,4</sup>

Pharmacoepidemiology contributes to the body of knowledge that supports the optimal use of medications and helps clinicians make better-informed drug therapy decisions.<sup>5</sup> This field of research also plays a fundamental role in the drug-approval process within the United States with regard to drug safety. Recent withdrawals of marketed medications due to adverse events were primarily due to findings from pharmacoepidemiological research. In a recent editorial, Hartzema points to new roles for pharmacoepidemiology, including the development of work on quality indicators (eg, the Centers for Medicaid and Medicare 8th Scope of Work using drug use quality of care indicators) and risk management of medication

errors (eg, the FDA RiskMAP).<sup>6</sup> The significance of pharmacoepidemiology is also demonstrated by its inclusion in one of the objectives of Healthy People 2010.<sup>7</sup> In this document, published by the US Department of Health and Human Resources, Objective 17-1a highlights pharmacoepidemiologic databases as resources that can be used by health care organizations to monitor and report adverse events related to medical therapies.<sup>7</sup>

As the discipline enters into its third decade, a need exists for properly trained pharmacy professionals who are capable of understanding and utilizing fundamental pharmacoepidemiological concepts and methods in their day-to-day practice. Patients and health care providers increasingly rely on pharmacists to appropriately evaluate the benefits and risks of drug therapy, thus indicating a need for pharmacoepidemiology training and education in pharmacy schools.<sup>3,4,6,8</sup> Although epidemiologic terms and statistics often appear in the clinical literature, pharmacy students may not have adequate preparation to accurately understand these terms or interpret statistical results about drug risks and benefits.<sup>4,9</sup>

The Accreditation Council for Pharmacy Education (ACPE) concluded that education in US pharmacy programs should provide students with the sufficient background in understanding biostatistical and clinical epidemiological concepts.<sup>10</sup> Specifically, the 2006 ACPE standards and guidelines recommend the inclusion of

---

**Corresponding author:** Esmond D Nwokeji, PhD, Research Associate, The University of Texas at Austin, 1 University Station, A1930, Austin, TX 78712-0127

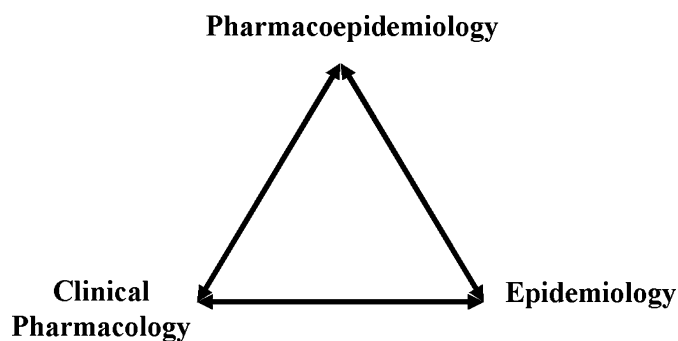


Figure 1. Schematic representation of the relationship between pharmacoepidemiology, clinical pharmacology and epidemiology.

pharmacoepidemiology in the social, behavioral, and administrative sciences component of the pharmacy curriculum. Pharmacoepidemiology topics include:

- application of principles of epidemiology to the study of drug use and outcomes in large populations
- studies that provide an estimate of the probability of beneficial effects in populations, or the probability of adverse effects in populations, and other parameters relating to drug use benefit
- methods for continual monitoring for unwanted effects and other safety-related aspects of drugs<sup>10</sup>

The ACPE's recommendations are likely to increase the extent of pharmacoepidemiology education provided by US colleges and schools of pharmacy in the future.<sup>10</sup>

Pharmacoepidemiology is emerging as an important component of pharmacy education. While the ACPE has adopted new standards for pharmacoepidemiology curricula taught in US colleges of pharmacy, they have only provided general guidelines for incorporating pharmacoepidemiology topics into pharmacy curricula. A literature search conducted by the authors found no data on the number of US pharmacy programs that provide pharmacoepidemiology education or any information about the extent of this type of education in US pharmacy programs. The purpose of this study was to examine the level of pharmacoepidemiology training/education being offered in US colleges and schools of pharmacy, as well as examine the pharmacoepidemiology topics covered by these programs.

## METHODS

An online web-survey was designed to assess the extent of pharmacoepidemiology training/education being offered in colleges and schools of pharmacy throughout the United States. The questionnaire was adapted from a previous survey instrument used to assess pharmacoeconomic education being taught in US pharmacy programs.<sup>11</sup>

The electronic survey instrument was created using html and *ColdFusion MX 6.1* software (Macromedia, San Francisco, Calif). The following definition of pharmacoepidemiology was provided at the beginning of the questionnaire: "Pharmacoepidemiology is the application of epidemiologic reasoning, methods, and knowledge to the study of the uses and effects (beneficial and adverse) of drugs in human populations."<sup>12</sup> The questionnaire assessed 5 areas: (1) whether the pharmacy college or school offered pharmacoepidemiology education and at what degree level (professional or graduate), (2) the number of clock or classroom hours the program devoted to pharmacoepidemiology education, (3) whether pharmacoepidemiology was part of the required curriculum or the elective curriculum, (4) the number of students enrolled in the course(s) each year, and (5) the types of pharmacoepidemiology topics being taught. Schools offering pharmacoepidemiology training at the PharmD degree level were categorized as providing professional-level pharmacoepidemiology education. Those offering pharmacoepidemiology courses at the MS and/or PhD degree levels were categorized as providing graduate-level pharmacoepidemiology education. The following explanation of how to calculate clock hours was provided: "if your school offers 2 lectures that are 90 minutes each, your response would be 3 clock hours. If your school offers a class that meets 3 hours per week for 15 weeks, your response would be 45 clock hours." A list of pharmacoepidemiology topics were provided to participants. Based on 2006 ACPE guidelines listed above, these topics were supplemented with more specific topics found in 2 pharmacoepidemiology textbooks.<sup>12,13</sup>

The survey was conducted between October 2005 and January 2006. One faculty member was selected from each of the 89 colleges and schools of pharmacy who were listed in the 2005-2006 AACP Roster.<sup>14</sup> A pre-notification e-mail was sent to each of these faculty members explaining the purpose of the study and asking for the name and e-mail address of the most appropriate person at their institution to complete the questionnaire. Names and e-mail addresses of these contacts were collected and recorded in a spreadsheet. One week later, an e-mail cover letter was sent to each contact with a hyper-text link to the online questionnaire. A follow-up e-mail was sent to non-responders 2 weeks later. For the 10 contacts who had not replied to the follow-up e-mail, telephone calls were made and in some cases a print version of the survey instrument was faxed to those who did not respond via e-mail. After all questionnaires were completed, some respondents were contacted to clarify and validate specific responses.

Data collected for this study were descriptive, so no inferential statistical tests were conducted. An online database was designed using Microsoft Access to capture and analyze survey responses. The online questionnaire and database were hosted on a computer server at the University of Texas at Austin.

## RESULTS

A faculty member from each of the 89 accredited US colleges and schools of pharmacy listed in the 2005-2006 AACP directory responded to the survey, resulting in a 100% response rate. Of the 89 schools, 74 (83%) indicated that they provided some level of pharmacoepidemiology education (Figure 2). Among these schools, 69 PharmD programs indicated that they provided pharmacoepidemiology training. Among the graduate programs, 35 schools indicated that they provided pharmacoepidemiology to their MS or PhD students.

The total number of classroom or clock hours offered to PharmD students ranged from 2 to 60. The mean number of classroom hours was  $14.6 \pm 13.9$  (median = 10 hours). At the graduate level, classroom hours ranged from 2 to 135, with a mean of  $36.7 \pm 34.8$  hours (median = 15 hours).

Of the 69 pharmacy programs offering pharmacoepidemiology at the PharmD level, 65 (94%) reported that the subject was part of their required course curriculum. Among the master of science (MS) and doctor of philosophy (PhD) degree programs, just over half (N=18) indicated that pharmacoepidemiology was being taught as part of their required curriculum, while 17 (49%) programs offered it as part of an elective course.

The mean number of PharmD students receiving pharmacoepidemiology education or training was  $119 \pm 60$  per school year (median = 110 students). The average number of MS and PhD students was  $6 \pm 5$  per school (median = 6 students).

Frequency results for each pharmacoepidemiology topic surveyed among pharmacy programs are presented in Table 1. For those schools that offered pharmacoepidemiology at the graduate level, all of the topics listed on the survey were taught by at least 80% of the graduate programs. For the PharmD programs, the most frequently listed topics (86% and above) included: “general application of epidemiological methods to drug use,” “estimating probability of drug effects,” “pharmacoepidemiology study design,” and “bias and confounding.” About three-fourths of the PharmD programs covered the topics of “quality-of-life measures” and “monitoring of unintended drug effects.” Just over half indicated that they covered “meta-analysis of pharmacoepidemiological studies.” Further, only one third of PharmD programs offered their students training on the use of databases used in pharmacoepidemiology research (eg, Medicaid, Veterans Administration, and industry databases).

Respondents from 28 schools recorded additional comments in a section located at the end of the questionnaire. Sixteen schools indicated that pharmacoepidemiology topics were covered in other courses (eg, drug literature evaluation, health policy, pharmacoconomics, and research methods). Four respondents reported that these topics were included in courses taught outside the school of pharmacy, such as in the school of public health or school of medicine.

Several respondents felt that the list of topics provided in the questionnaire did not represent all of the relevant subjects taught in pharmacoepidemiology. For example, one respondent stated that “population based pharmacoepidemiology” should have been included as a topic. Another respondent commented that they would not consider “quality-of-life measures” as a pharmacoepidemiology topic. Another respondent indicated that the survey did not clearly differentiate between coursework in epidemiology (which could easily be applied to the drug use

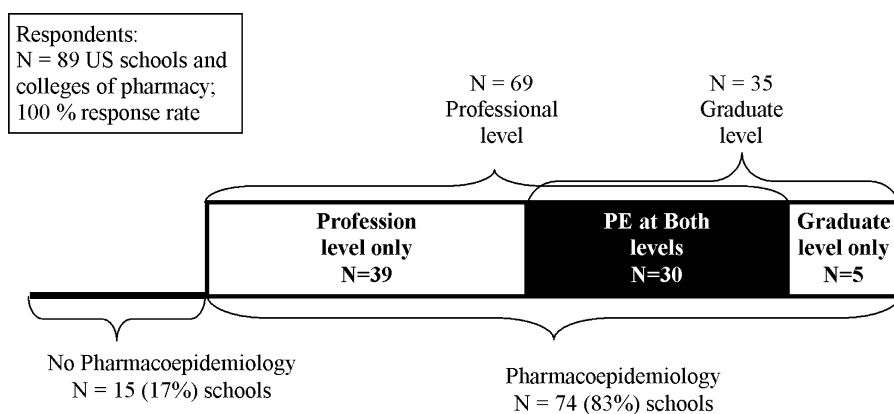


Figure 2. Number of professional and graduate programs offering pharmacoepidemiology at US schools and colleges of pharmacy.

Table 1. Frequency of Pharmacoepidemiology Topics Taught In US Schools and Colleges of Pharmacy (n = 89)\*

Topics	Number of Programs Teaching Pharmacoepidemiology at the:							
	PharmD Level (N = 69) <sup>†</sup>				MS/PhD Level (N = 35) <sup>‡</sup>			
	Required Curricula No.	Elective Curricula No.	Combined No. <sup>§</sup>	%	Required Curricula No.	Elective Curricula No.	Combined No. <sup>§</sup>	%
Application of Epidemiological Methods to Drug Use	59	4	63	91	16	16	32	91
Estimating Probability of Drug Effects (eg, incidence, prevalence, risk ratios)	58	4	62	90	15	16	31	89
Bias & Confounding	55	4	59	86	17	17	34	97
Study Design (eg, cohort, case-control)	57	4	61	88	18	17	35	100
Quality-of-Life Measures	51	2	53	77	16	16	32	91
Monitoring of Unintended Drug Effects (eg, spontaneous reporting, post-marketing surveillance)	49	4	53	77	16	12	28	80
Role of Regulatory Agencies	47	3	50	72	15	14	29	83
Meta-Analysis	36	1	37	54	16	13	29	83
Use of Databases (eg, Medicaid, Veterans Administration, Industry)	18	4	22	32	17	16	33	94

\*Total number of schools/colleges of pharmacy (N = 89) surveyed

<sup>†</sup>Schools reported a total of 69 PharmD level programs providing pharmacoepidemiology

<sup>‡</sup>Schools reported a total of 35 Masters (MS) and/or Doctor of Philosophy (PhD) level programs providing pharmacoepidemiology

<sup>§</sup>Percentage of combined programs

process) versus coursework in pharmacoepidemiology. Several faculty members indicated that they planned to enhance their pharmacoepidemiology curricula in the near future by introducing new courses or additional topics.

## DISCUSSION

This study was subject to a number of limitations. First, a limited number of questions were asked. Since this was an exploratory study, the investigators believed keeping the number of questions to a minimum was important to avoid a low response rate. Second, the list of topics used to evaluate the extent of pharmacoepidemiology being taught among the schools was not extensive or exhaustive. No expanded definitions were provided for the list of topics that appears in Table 1; therefore, these items may have been interpreted differently among the respondents. Third, clarification may have been needed on what constituted pharmacy students receiving pharmacoepidemiology education specifically within their school of pharmacy versus receiving this type of education in outside departments or schools (ie, school of medicine and public health). This leads to the fourth limitation: we surveyed only US colleges and schools of pharmacy. Pharmacoepidemiology education is also provided through other venues (eg, medical schools,

health policy schools, economic schools, continuing education courses, and seminars).

## CONCLUSION

Since the ACPE has incorporated pharmacoepidemiology as a required component of pharmacy curricula, it is important to obtain some consensus on the minimum number of classroom hours that should be offered and more specific recommendations concerning what topics should be included. Future research should focus on a more comprehensive assessment of pharmacoepidemiology education in order to develop a standardized approach to teaching pharmacoepidemiology in US colleges and schools of pharmacy. Pharmacoepidemiology is an important component of pharmacist education and training as the pharmacists' role in drug therapy decision-making and monitoring expands. This study revealed that most colleges and schools of pharmacy provide some pharmacoepidemiology education in their curriculum, but the number of classroom hours devoted to this discipline as do the topics covered varies from school to school.

## ACKNOWLEDGEMENT

This study was presented at the International Conference for Pharmacoepidemiology (ICPE) 7th Annual

European Congress in Lisbon, Portugal, August 2006, and at the American Association of Colleges of Pharmacy (AACP) meeting in San Diego, Calif, in July 2006.

## REFERENCES

1. Strom BL, Tugwell P. Pharmacoepidemiology: current status, prospects, and problems. *Ann Intern Med.* 1990;113:179-81.
2. Lawson DH. Pharmacoepidemiology: a new discipline. *Br Med J.* 1984;289:940-1.
3. Stewart RB. Drug surveillance – epidemiology: role of the clinical pharmacists. *Am J Pharm Educ.* 1986;50:468-70.
4. Draugalis JR, Plaza CM. Emerging role of epidemiologic literacy. *Ann Pharmacother.* 2006;40:229-33.
5. Etminan M, Gill S, Fitzgerald M, Samii A. Challenges and opportunities for pharmacoepidemiology in drug-therapy decision making. *J Clin Pharmacol.* 2006;46:6-9.
6. Hartzema AG. The beginnings of pharmacoepidemiology in The Annals. *Ann Pharmacother.* 2006;40:1647-8.
7. Healthy People 2010. 2nd ed. With understanding and improving health and objectives for improving health. 2 vols. Washington, DC: U.S. Government Printing Office, November 2000. Available at: <http://www.healthypeople.gov/Document/pdf/Volume2/17Medical.pdf>. Accessed October 10, 2006.
8. Hammer DP, Sauer KA, Fielding DW, et al. White paper of best evidence pharmacy education (BEPE). *Am J Pharm Educ.* 2004;68:1-12.
9. Lee CM, Soin HK, Einarson TR. Statistics in the pharmacy literature. *Ann Pharmacother.* 2004;38:1412-8.
10. American Colleges of Pharmacy Education (ACPE). ACPE Accreditation standards and guidelines for the professional program in pharmacy leading to their doctor of pharmacy degree (Appendix B). Adopted January 15, 2006. American Colleges of Pharmacy Education, Chicago, Ill.
11. Rascati KL, Draugalis JR, Conner TM. Pharmacoeconomic education in U.S. schools of pharmacy. *Am J Pharm Educ.* 1998;62:167-9.
12. Hartzema AG, Porta M, Tilson HH, eds. *Pharmacoepidemiology: An Introduction.* 3rd ed. Cincinnati, Ohio: Harvey Whitney Books; 1998.
13. Strom BL. *Pharmacoepidemiology.* 4th ed. New York, New York: Wiley & Sons; 2005.
14. American Association of Colleges of Pharmacy (AACP). AACP Roster of faculty and professional staff 2005-2006. AACP, Alexandria, Va.