

ACCP COMMENTARY

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The Essential Research Curriculum for Doctor of Pharmacy Degree Programs

American College of Clinical Pharmacy

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Abstract

In 2008, the American College of Clinical Pharmacy appointed the Task Force on Research in the Professional Curriculum to develop a commentary on the essential research curriculum to include in doctor of pharmacy (Pharm.D.) degree programs. The essential research curriculum provides all students with critical and analytical thinking and lifelong learning skills, which will apply to current and future practice and stimulate some students to pursue a career in this field. Eight key curricular competencies are as follows: (1) identifying relevant problems and gaps in pharmacotherapeutic knowledge; (2) generating a research hypothesis; (3) designing a study to test the hypothesis; (4) analyzing data results using appropriate statistical tests; (5) interpreting and applying the results of a research study to practice; (6) effectively communicating research and clinical findings to pharmacy, medical, and basic science audiences; (7) interpreting and effectively communicating research and clinical findings to patients and caregivers; and (8) applying regulatory and ethical principles when conducting research or using research results. Faculty are encouraged to use research-related examples across the curriculum in non-research courses and to employ interactive teaching methods to promote student engagement. Examples of successful strategies used by Pharm.D. degree programs to integrate research content into the curriculum are provided. Current pharmacy school curricula allow variable amounts of time for instructional content in research, which may or may not include hands-on experiences for students to develop research-related skills. Therefore, an important opportunity exists for schools to incorporate the essential research curriculum. Despite the challenges of implementing these recommendations, the essential research curriculum will position pharmacy school graduates to understand the importance of research and its applications to practice. This perspective is

provided as an aid and a challenge to those in leadership and teaching positions within schools and colleges of pharmacy.

In 2008, the American College of Clinical Pharmacy (ACCP) appointed the 2008–2009 Task Force on Research in the Professional Curriculum to develop a commentary regarding the essential research curriculum that should be included in professional programs leading to the doctor of pharmacy (Pharm.D.) degree. This commentary describes the recommendations of the Task Force, as reviewed and approved by the Board of Regents.

Rationale for an Essential Research Curriculum: Training in the scientific method and research design can affect a pharmacy student well after the completion of his or her coursework. Research experience will benefit a student pursuing a career in this field as well as provide all students with critical and analytical thinking and lifelong learning skills, enabling them to handle challenges and situations as they arise.¹⁻³ The pace of technology evolution and changes in the profession of pharmacy require that future pharmacists be equipped with such knowledge and skills.

Academic, professional, and administrative pharmacy organizations continue to emphasize the importance of integrating research into the Pharm.D. curriculum. In 2007, the Accreditation Council on Pharmacy Education (ACPE) released, in conjunction with its accreditation standards for Pharm.D. degree programs, a guidance document detailing the elements of the basic biomedical, pharmaceutical, social/behavioral/administrative, and clinical sciences that ACPE stakeholders had identified as “essential to the development of pharmacists.”⁴ This guidance recommended that education regarding research be addressed by core coursework in the areas of literature evaluation and research design. Coursework in the evaluation, interpretation, and practical application of statistical tests is also recommended. The standards do not stipulate minimal hours or credits of course content, the proportion of credits

that should be delivered through didactic instruction versus practical training, or specific outcome measures as they relate to research.

This critical need for pharmacy graduates to understand and apply fundamental research principles has also been reflected in ACCP's current strategic plan⁵ and research agenda,⁶ as well as in reports from the American Association of Colleges of Pharmacy^{7,8} and in the mandatory training requirements for PGY1 residencies accredited by the American Society of Health-System Pharmacists.⁹ To date, however, no specific recommendations have been made with respect to developing, integrating, delivering, or evaluating a core research curriculum within a professional degree program. The objective of this commentary, therefore, is to propose a core research curriculum that should be included in professional programs leading to the Pharm.D. degree.

Essential Curricular Competencies and Research Content in Pharm.D. Programs: Table 1 details the essential research curriculum for Pharm.D. degree programs as recommended by the Task Force. After completing the essential curricular content, students will be able to:

1. Identify relevant problems and gaps in pharmacotherapeutic knowledge.
2. Generate a research hypothesis.
3. Design a study to test the hypothesis.
4. Analyze data results using appropriate statistical tests.
5. Interpret and apply the results of research study to practice.
6. Effectively communicate research and clinical findings to pharmacy, medical, and basic science audiences.

7. Interpret and effectively communicate research and clinical findings to patients and caregivers.
8. Apply regulatory and ethical principles when conducting research or when using the research results.

To reinforce the importance and application of research content across the curriculum, faculty are encouraged to use research-related examples across the curriculum in non-research courses.¹⁰ For example, in a pharmacy management course, faculty could use illustrative examples of formulating budgets for research projects. In courses on drug literature evaluation, faculty should expand the content on investigational drugs to include the requirements of institutional review boards. In ethics classes, students could critically evaluate a patient consent form for its readability and comprehension. In a pharmacotherapeutics course, after discussing a landmark clinical trial, the faculty could have students identify additional research questions still requiring attention based on the limitations of the trial. In a pharmacoeconomics class, students could be asked to use data sets to analyze the benefits of prescription drug programs. On clinical rotations, students should be encouraged to identify knowledge gaps in the primary literature when responding to drug information questions and thereafter develop a research hypothesis and study design appropriate to evaluate the research question. Students should also be encouraged to prepare case reports of novel clinical findings and participate in journal clubs to assist in their development of facile skills in interpreting statistical tests.

In addition, pharmacy faculty are encouraged to use interactive teaching methods, such as a lecture plus an online, commercially available component. For example, faculty could have students describe treatment efficacy using humanistic outcome measures for a published clinical trial that used laboratory test results as an outcome measure, or faculty could have students

design a patient survey to test recently published research findings. Alternatively, a course on research methods could require a student's successful completion of modules and tests from the Collaborative Institutional Training Initiative public access course in the Responsible Conduct of Research (www.citiprogram.org).

Examples of Successful Strategies Used by Pharm.D. Degree Programs to Integrate

Research Content into the Curriculum: Table 2 includes selected examples of successful strategies used by some Pharm.D. programs to deliver content on research. The Task Force provides these examples to stimulate faculty at colleges to consider new or different ways to deliver research-related content more effectively to students.¹¹⁻¹³

At colleges with the faculty, staff, and space resources to support hands-on research experiences for students, such programs are encouraged to initiate or expand the number of students able to participate. For example, in the proposed essential curricular content, some students could go on to collect data, conduct a statistical analysis of results, interpret the data results, deliver a formal verbal presentation or poster, and/or prepare a manuscript that could be submitted to a peer-reviewed journal. This is considered the highest level (ultimate) of experience, and the Task Force is hopeful that it would motivate some students to pursue education and training beyond the Pharm.D. degree.

Status of Research Curricula and Challenges of Incorporating the Essential Research

Curriculum at Colleges of Pharmacy: Current pharmacy school curricula provide variable amounts of time for instructional content in research and may or may not include hands-on opportunities to develop research-related skills. A recent survey of Pharm.D. degree programs

showed that the content and credit hours of such coursework spanned a wide range. Of the 77 responding schools, 53% and 38% offered a research methods course as required or elective, respectively, whereas 15% of programs did not offer either type. The number of credit hours in a research methods course was 1.7 ± 1.0 hours (mean \pm standard deviation). In addition to research-related courses, these authors evaluated the number of schools offering research-related experiences. A total of 25% and 57% of schools had required and elective research experiences, respectively. These research experiences varied considerably and included full projects, institutional review board submissions, written proposals, and oral presentations. The low number of class hours and variability in research exposure make interpretation of the data difficult. Nevertheless, these data indicate inconsistent research exposure at schools of pharmacy.¹⁴

There may be several challenges to incorporating the essential research curriculum into many colleges of pharmacy. A culture of scholarship may be absent in the college.⁸ To foster such a culture, college administration must provide an adequate infrastructure and support services to assist faculty in this endeavor. Services include grantsmanship training; assistance in navigating the requirements of institutional review boards; securing funding for research equipment, research assistants, or other supportive personnel; and fostering supportive collaborations among faculty and other essential university and college personnel and offices (e.g., information technology, business office). Funding student research assistants and sabbaticals or mini-fellowships for faculty to develop new or unique research skills may also be useful. Most of the faculty may consist of pharmacy practice faculty without formal research training. For the most part, these individuals have a Pharm.D. degree and 1 year of residency training, neither of which may have included a research requirement. Low productivity in

scholarly activity among faculty at colleges of pharmacy has been documented, which suggests that scholarly activity is not a priority among a large number of faculty.¹⁵ Students may lack interest in a research-based curricular initiative because they do not perceive such courses as directly affecting their ability to provide patient care.

Conclusion: This commentary provides a brief overview of the essential knowledge, skills, and outcomes of a research curriculum for Pharm.D. degree programs. These curricular components will position pharmacy school graduates to understand the importance of research and its applications to practice. This perspective is provided as an aid and a challenge to those in leadership and teaching positions within schools and colleges of pharmacy.

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Table 1: Essential Content in Doctor of Pharmacy Curricula

Content Areas	Knowledge Areas of Focus	Skill Areas of Focus
Research methods	<ul style="list-style-type: none"> • Study types and limitations: <ul style="list-style-type: none"> ○ prospective, retrospective, experimental, observational • Steps in designing a research project: <ul style="list-style-type: none"> ○ defining the research question ○ stating the hypothesis ○ obtaining IRB¹ approval ○ using common measurement tools ○ using accepted surrogate markers. 	<ul style="list-style-type: none"> • Define a study question • State a research hypothesis • Conduct a comprehensive literature review • Assess the appropriateness of published research methods
Biostatistics	<ul style="list-style-type: none"> • Levels of measurement/data types • Descriptive / Inferential / Non-parametric statistics • Hypothesis testing • Power analysis • Commercially available programs • Advanced statistics (correlation / regression, survival curves) 	<ul style="list-style-type: none"> • Interpret statistical analyses from primary literature • Assess appropriateness of applied tests
Literature evaluation	<ul style="list-style-type: none"> • Types of published literature • Systematic method of evaluating primary literature • Criteria for assessing cause-effect relationship for adverse drug reactions • Criteria for assessing literature on efficacy of drug treatment 	<ul style="list-style-type: none"> • Apply research methods and biostatistics to a patient case • Identify knowledge gaps based on interpretation of the literature • Interpret data in figures and graphs
Research ethics	<ul style="list-style-type: none"> • IRBs and informed consent • HIPAA (covered entities) • Good Clinical Practice • Ethical principles of research • Animal research regulations • FDA regulations (drug & device) • Special populations (children, women, prisoners) 	<ul style="list-style-type: none"> • Identify when IRB approval is required • Differentiate required from optional consent elements • Discuss inappropriate research conduct

FDA = U.S. Food and Drug Administration ; HIPAA = Health Insurance Portability and Accountability Act; IRB = institutional review board

Table 2. Examples of Successful Strategies to Deliver Research Content

Strategy	Description
<p>Capstone projects</p> <ul style="list-style-type: none"> • Self-directed study • Supervised by two or three faculty or by a faculty committee • Enhanced learning through communication and application 	<p>Course description: In conjunction with research specific didactic coursework, students assigned to faculty facilitator (one primary, two secondary) to assist in developing the research project. Spanning entire curricular period, students formulate a research question, develop and design a study to answer the question, collect and analyze data, present results at institutional research day, and prepare a manuscript suitable for submission to a peer-reviewed journal.</p>
<p>Pharmaceutical outcomes course</p> <ul style="list-style-type: none"> • Didactic coursework • Team teaching • Therapeutic specialists interpret in own areas 	<p>Sample lectures: Integrating humanistic, and economic data into drug therapy plans, determining therapeutic end points monitoring medication regimens, applying new knowledge to clinical situations, communicating recommendations.</p>
<p>Biostatistics and drug literature evaluation course</p> <ul style="list-style-type: none"> • Didactic coursework • Generally one faculty member • Could be one or two separate courses 	<p>Sample lectures: Key terms and concepts in statistics that are used in the medical literature, appropriate use of various statistical tests for data sets. Parts of a research article are identified, and the elements that need to be included for the reader to confidently interpret the findings are discussed.</p>
<p>Clinical research and design (research methods) course</p> <ul style="list-style-type: none"> • Didactic coursework • Team teaching • Enhanced learning through communication and application 	<p>Sample lectures: Clinical research terminology, principles of research design, methodology, and biostatistics needed for development of research proposals.</p> <p>Final examination: Complete a research proposal, including study design and analysis techniques.</p>
<p>Research ethics course</p> <ul style="list-style-type: none"> • Didactic coursework • Team teaching • Enhanced learning through communication and application 	<p>Sample lectures: History of clinical research ethics, historical and current regulatory considerations, and professional standards of human and animal research, FDA submission requirement and IRB policies and procedures.</p> <p>Final examination: Essay incorporating course objectives applied to published research within last year.</p>
<p>Applied research elective course</p> <ul style="list-style-type: none"> • Experiential • One faculty • Enhanced learning through communication and application 	<p>Course description: In accordance with institutionally allowed credit/hours, student participates in an ongoing research project of an established faculty member(s). May include bench or bedside activities (preferentially) or literature reviews (alternatively). Degree of project involvement and magnitude of credit dictated by primary faculty. Must include some formal communication output at end of experience.</p>
<p>Clinical research elective clerkship</p> <ul style="list-style-type: none"> • Experiential • One faculty 	<p>Course description: A full time, 4- to 8-week experience in a research-only environment. Student is primarily engaged daily in routine operations of a clinical research center (including physical</p>

- Enhanced learning through communication and application
 - assessment, subject consent, randomization, source documentation, and query resolution) or service (i.e., investigational drug service). Minimal outcome objectives analogous to the performance measures of an entry-level study coordinator.

- Pharm.D. Paper and/or Seminar
 - Self-directed
 - Course coordinator
 - Enhanced learning through communication and application

Course description: Student selects topic to prepare a critical analysis of available published data. Course facilitator serves as guide and liaison between student and faculty in that specialty area.
Final: Manuscript suitable for submission (i.e., Therapeutic Frontiers or Practice Insights) or abstract accepted at major medical conference for presentation

- Summer research programs
 - Self-directed/salaried
 - Program director
 - Enhanced learning through communication and application

Course description: This competitive, 8-week full-time (40 hrs/week) program engages students to conduct formal (IRB approved, if applicable) independent research projects (generally tangential to faculty mentor's work) between spring and fall semesters.
Final: Institutional research day presentation (poster or platform) as well as manuscript suitable for submission.

- Dual-degree programs:
Pharm.D. + (Ph.D. or MPH or M.S.)
 - Graduate committee
 - Enhanced learning through communication and application

General description: Institution specific, advanced training program occurs (potentially) simultaneously with standard Pharm.D. curriculum. Second degree requirements vary extensively and may lengthen year(s) of study.
Final: Dissertation or governing body approved standards

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