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The Essential Research Curriculum for Doctor of Pharmacy Degree Programs

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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 impact a pharmacy student well beyond the completion of the coursework. Research experience will not only benefit a student that is pursuing a career in this field, but will also provide all students with critical-thinking, analytical and lifelong learning skills, which will enable them to handle challenges and situations as they arise.¹⁻³ With the pace of technology evolution and changes in the

profession of pharmacy, future pharmacists must 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 their accreditation standards for Pharm.D. degree programs, a guidance document detailing elements of the basic biomedical, pharmaceutical, social/behavioral/administrative and clinical sciences that ACPE stakeholders identified as being “essential to the development of pharmacists”.⁴ This guidance recommended that education regarding research should be addressed via 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.

The critical need for pharmacy graduates to understand and apply fundamental research principles has also been reflected in the current strategic plan⁵ and research agenda⁶ of ACCP, reports from the American Association of Colleges of Pharmacy (AACCP)^{7,8} and the mandatory training requirements for PGY-1 residencies accredited by the American Society of Health System Pharmacists (ASHP).⁹ To date, however, specific recommendations regarding how to develop, integrate, deliver, and evaluate a core research curriculum within professional degree programs have not been developed. 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 curriculum content, the student 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 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 drug literature evaluation courses, faculty should expand content on investigational drugs to discuss

requirements of institutional review boards. In ethics classes, students could be given an exercise to critically evaluate a patient consent form for its readability and comprehension. In a pharmacotherapeutics course, after discussing a landmark clinical trial, the faculty could then have students identify additional research questions that still need to be addressed based on the limitations of the trial. In a pharmacoeconomics class, the students could be asked to use data sets to analyze prescription drug benefit programs. On clinical rotations, students should be encouraged to identify knowledge gaps in the primary literature when responding to drug information question, and then 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 to participate in journal clubs, so that they develop 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 the student describe treatment efficacy using humanistic outcome measures for a published clinical trial that used laboratory test results as an outcome measure, or have the student 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 (CITI) public access course in Responsible Conduct of Research (available at www.citiprogram.org).

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

For those 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 who are able to participate. For example, in the proposed essential curricular content, some students could go on to collect data, conduct statistical analysis of results, interpret data results, deliver a formal verbal presentation or poster, and/or prepare a manuscript which can be submitted to a peer-reviewed journal. This is considered the highest level (ultimate) experience and hopefully would motivate some students to pursue additional education and training beyond the Pharm. D. degree.

Current Status of Research Curricula and Challenges to Incorporating the Essential Research Curriculum at Colleges of Pharmacy

Current pharmacy school curricula provide variable 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 credits hours of such coursework spanned a wide range. Of the 77 responding schools, 53% and 38% offered a research methods course as a required or elective course, 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 + standard deviation). In addition to research-related courses, these authors also evaluated the number of schools that offered research-related experiences. 25% and 57% of schools had required and elective research experiences, respectively. These research experiences were widely variable and included full projects, institutional review board submissions, written proposals, oral presentations, etc. The low number of class hours

and variability in research exposure makes interpretation of these data difficult, but indicates inconsistent research exposure at schools of pharmacy.¹⁴

There may be several challenges to incorporating the essential research curriculum at many colleges of pharmacy. A culture of scholarship may be absent in the college.⁸ To foster a culture of scholarship, college administration must provide an adequate infrastructure and support services to assist faculty in this endeavor. Services include grantsmanship training; assistance 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 among other essential university and college offices, e.g., information technology, business office, etc. Funding student research assistants, and sabbaticals or mini-fellowships for faculty for the purposes of developing new or unique research skills may also be useful. The majority of the faculty may be comprised of pharmacy practice faculty who may not have formal research training. For the most part, these individuals have a Pharm. D. degree and one 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 curriculum initiative because they do not perceive such courses as directly impacting on 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 curriculum 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 Area	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 – common measurement tools – 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"> • Application of 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"> • Institutional review boards and informed consent • HIPAA (covered entities)² • Good Clinical Practice • Ethical principles of research • Animal research regulations • FDA³ regulations (drug & device) • Special populations (children, women, prisoners) 	<ul style="list-style-type: none"> • Identify when IRB¹ approval is required • Delineate required from optional consent elements • Discuss inappropriate research conductance

¹ IRB-institutional review board

² HIPAA-Health Insurance Portability and Accountability Act

³ FDA-Food and Drug Administration

Table 2

Examples of Successful Strategies to Deliver Research Content

Strategy	Description
Capstone projects <ul style="list-style-type: none"> • Self-directed study • Supervised by 2-3 member faculty committee • Enhanced learning through communication and application 	Course description: In conjunction with research specific didactic coursework, students assigned to faculty facilitator (1 primary, 2 secondary) to assist in the development of the research project. Spanning entire curriculum period, students formulate research question, develop and design 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.
Pharmaceutical outcomes course <ul style="list-style-type: none"> • Didactic coursework • Team teaching • Therapeutic specialists interpret in own area 	Sample lectures: Integrating humanistic, and economic data into drug therapy plan, determining therapeutic endpoints for monitoring medication regimens, applying new knowledge to clinical situations, communicating recommendations.
Biostatistics and drug literature evaluation course <ul style="list-style-type: none"> • Didactic coursework • Generally one faculty Could be one or two separate courses	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.
Clinical research and design (research methods) course <ul style="list-style-type: none"> • Didactic coursework • Team teaching Enhanced learning through communication and application	Sample lectures: clinical research terminology, principles of research design, methodology, and biostatistics needed for development of research proposals. Final exam: Complete a research proposal, including study design and analysis techniques.
Research ethics course <ul style="list-style-type: none"> • Didactic coursework • Team teaching • Enhanced learning through communication and application 	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. Final exam: Essay incorporating course objectives applied to published research within last year.
Applied research elective course <ul style="list-style-type: none"> • Experiential • One faculty • Enhanced learning through communication and application 	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 (alternately). Degree of project involvement and magnitude of credit dictated by primary faculty. Must include some formal communication output at end of experiential.
Clinical research elective clerkship <ul style="list-style-type: none"> • Experiential • One faculty • Enhanced learning through communication and application 	Course description: A full time, 4 – 8 week experience in a research-only environment. Student is primarily engaged daily in routine operations of a clinical research center (including physical assessments, subject consenting, randomization, source documentation and query resolution, etc.) or service (i.e., investigational drug service). Minimal outcome objectives analogous to entry level study coordinator performance measures.
PharmD Paper and/or Seminar <ul style="list-style-type: none"> • Self-directed • Course coordinator 	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, Practice Insights) or have abstract accepted at major medical conference for presentation

Strategy	Description
<ul style="list-style-type: none"> Enhanced learning through communication and application 	
Summer research programs <ul style="list-style-type: none"> 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: PharmD + (PhD or MPH or MS) <ul style="list-style-type: none"> Graduate committee Enhanced learning through communication and application 	General description: Institution specific, advanced training program run (potentially) simultaneously with standard PharmD curriculum. Second degree requirements vary extensively and may lengthen year(s) of study. Final: dissertation or governing body approved standards

¹ IRB-institutional review board

² HIPAA-Health Insurance Portability and Accountability Act

³ FDA-Food and Drug Administration