

ACCP POSITION STATEMENT

Guidelines for Pharmacoeconomic Research Fellowships

American College of Clinical Pharmacy

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Pharmacoeconomic research has evolved as a significant and important field of research in an era of cost-conscious health care delivery. As the focus on providing quality, cost-effective health care intensifies, it is becoming critically important to evaluate new treatments in three dimensions—safety, efficacy, and *value*. Because pharmacists have an obvious role in evaluating alternative drug therapies, it is important that they gain an understanding of basic pharmacoeconomic principles. In addition, some pharmacists now are seeking advanced training in pharmacoeconomic research to pursue a career in this field or to augment their clinical skills in ways that will broaden their expertise.

Several training programs have emerged to meet these growing educational needs, mostly in the form of pharmacoeconomic research fellowships. The *1999 Directory of Residencies and Fellowships*, published by the American College of Clinical Pharmacy (ACCP), lists twelve residency or fellowship training programs with pharmacoeconomics as their primary area of emphasis. Fourteen additional programs note pharmacoeconomics as a secondary or tertiary

area of concentration. In particular, the number of fellowships related to pharmacoeconomic research has grown from one in 1989 to eleven in 1999.

Although the availability of many fellowship programs provides more options to pharmacists seeking training in the field, it is difficult to evaluate and compare them in the absence of training guidelines specifically relevant to pharmacoeconomic research training. The ACCP guidelines for clinical fellowship training programs¹ are clearly relevant to pharmacoeconomic research programs as they relate generally to any research fellowship experience. The guidelines presented here augment existing ACCP guidelines by providing more specific criteria that are particularly relevant to pharmacoeconomic research training programs.

Whereas each pharmacoeconomic research fellowship experience will vary in some way, it is important to ensure that they all provide an environment for fellows to acquire a core set of pharmacoeconomic research skills and experiences. The purpose of this document is to offer guidelines that should be useful in evaluating and comparing pharmacoeconomic research fellowship programs. It is envisioned that these guidelines will:

- assist candidates in evaluating and comparing training programs,
- assist preceptors in establishing rigorous training programs, and
- assist pharmacoeconomic fellows in establishing core learning objectives.

Pharmacoeconomic research fellowship programs should meet the training program criteria put forward in the ACCP guidelines for

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clinical fellowship training programs.¹ These criteria, adapted for pharmacoeconomic programs, are divided into five categories: general training program criteria, applicant criteria, preceptor and site criteria, didactic criteria, and research experience criteria.

General Training Program Criteria

Guideline

1. The fellow shall have a primary commitment during the fellowship to research activities. Although it is understood that there is often overlap between research and patient care activities, ideally the fellow shall have no more than 20% of fellowship training time devoted to teaching and clinical practice; the remainder should be spent on research activities over a period of at least 2 years.

Interpretation

A fellowship has been defined as a "...training program designed to prepare the participant to become an independent researcher."² Thus, to allow the fellow to concentrate on gaining research skills necessary to become an independent researcher, the fellow should enter this training program having completed a residency or equivalent experience.

Although the ideal length of a fellowship training program will depend on the program and the fellow, a fellowship of at least 2 years is considered necessary for most fellows to accomplish their research objectives. During this time the fellow will be involved in many activities and, in general, these can be grouped into three categories—research, teaching, and clinical practice. As the fellow will have completed a residency or will have equivalent experience, the amount of time involved in providing direct patient care should be minimized. Rather than focusing on the exact percentage of time spent in research, teaching, and practice, emphasis should be placed on the attainment of observable research outcomes accomplished by the fellow (e.g., grants prepared, abstracts presented, papers published) and the research skills acquired.

During the training experience, research skills must be developed that will enable the fellow to become an independent investigator. Training settings for pharmacoeconomic research scientists might include a clinical research center at which pharmacotherapeutic studies in humans

are conducted, a biomedical modeling laboratory for analysis of data from clinical studies, a pharmacoepidemiology or pharmacoeconomics research center, or a clinical practice setting involved in patient-based research. Regardless of the specific setting, all fellowship training experience must include development of a scientific hypothesis and methods to test the hypothesis, grant proposal preparation, data collection, data analysis, and presentation and publication of results.

Guideline

2. There shall be evidence of administrative institutional support for the preceptor's research program and the fellowship training program.

Interpretation

The stability of administrative support of the preceptor's research program is important and can be demonstrated by evidence of grant funding for several years, institutional funding for the fellowship, a letter of support from the preceptor's institution, or other institutional support.

Guideline

3. The training program should provide clinical and technical facilities to conduct research.

Interpretation

Facilities must be available to conduct scientific research. Realizing that fellowship experiences are diverse, these facilities may be clinical research centers, drug development programs, computer centers, or other environments. These facilities may be available in the preceptor's setting, shared with others, or available through collaborative arrangements.

Guideline

4. The preceptor should assure availability of qualified personnel to teach pharmacoeconomic research skills.

Interpretation

On completion of the fellowship, the fellow must have acquired sufficient research skills to become an independent pharmacoeconomic investigator. Preceptors and others providing

training may have received their research skill training through formal (e.g., fellowship, sabbatical) or informal (e.g., hands-on) programs. The qualifications of those providing training should be evidenced by grant applications, abstract presentations, and manuscript publications.

Guideline

5. The training program should provide ready access to a medical library and computer facilities.

Interpretation

Access to library holdings, computerized search methods, and any other resources necessary to enhance the ability of the fellow to search and stay current with the literature should be provided.

Computer facilities to support the research and training needs of the fellow should be readily available. The fellow should be encouraged to attend classes or seminars on the use of computers in biomedical research as necessary.

Preceptor Criteria

Guideline

1. The primary preceptor of a pharmacoeconomic research fellowship should be a clinician or scientist with relevant training and experience in pharmacoeconomic research. Preceptors should have an established and ongoing record of research accomplishments in this field of research.

Interpretation

The preceptor should have significant training in pharmacoeconomic research in the form of relevant graduate training, fellowship training, or an established record of research experience in the field. Preceptors should have a record of published research papers in peer-reviewed journals and presentations at scientific meetings. Other evidence of achievement includes previous precepting experience, a track record of funded research, and participation in other relevant training activities (including precepting students and lecturing on topics related to the field).

Guideline

2. The preceptor should demonstrate active collaborative relationships with other scientists.

Interpretation

Preceptors should be actively involved in collaborative research programs with other scientists. This allows fellows the opportunity to work with and learn from other researchers at the fellowship site. These collaborative activities may be demonstrated by ongoing collaborative research projects and joint publications in peer-reviewed journals.

Fellowship Applicant Criteria

Guideline

Individuals applying for fellowships in pharmacoeconomic research should fulfill the following criteria:

- Pharm.D. or equivalent post-graduate training,
- pharmacy practice residency or clinical work experience is preferable, and
- demonstrated interest in or an aptitude for a career in research.

Interpretation

Fellowship applicants should complete thorough clinical training before beginning a fellowship program. Fellows should possess a Pharm.D. or an advanced degree that encompasses clinical training in the use of pharmaceutical products. The ideal candidate will have completed additional training in the form of a clinical or administrative residency or will have clinical work experience. The successful candidate will demonstrate previous or current involvement in a research project or will demonstrate a high level of motivation and aptitude for a career in research. Specific training in economics, statistical analysis, and research methods is desirable but is not a specific requirement for pharmacoeconomic research fellowships. Selection of successful candidates can be demonstrated by productivity in a research position after completion of the fellowship. The fellow should not be a full-time graduate student in the preceptor's or an affiliated institution.

Didactic Criteria

Although fellowships, by definition, are flexible, experience-based training programs,² the availability of relevant, graduate-level coursework is essential to augment the knowledge base of fellows, enhance their research capabilities, and complement their ongoing research

activities. Typically, a fellow's course load will taper over the first year as their primary research responsibilities increase.

Guideline

The institution should ensure that relevant, graduate-level coursework is available to the fellow.

Interpretation

The institution must ensure that appropriate coursework is available to the fellow. This coursework should include classes in areas including biostatistics, research methods, economics (including health economics), epidemiology, and pharmaco-economic research (including quality of life assessment).

Adequate flexibility should be allowed to tailor a fellow's course load based on experience and previous graduate-level work. Regardless, fellows should receive significant grounding in each of these areas during the first year of the fellowship program.

Decisions regarding coursework audited or taken for credit should be left to the joint discretion of the preceptor and the fellow. The fellow should not be a full-time graduate student during the fellowship program.

Research Experience Criteria

The minimum requirements for competency in the research component of a pharmaco-economic fellowship program include exposure to an appropriate mix of didactic coursework and experiential training. Given that this is a research-focused fellowship, a large portion of the fellow's time and effort (80%) should be devoted toward skill building and achieving proficiency in pharmaco-economic research methods.

At a minimum, the fellow should have primary responsibility for conceptualizing, developing, and conducting at least one research project. In addition, over the course of the 2-year program, the fellow should be involved with several more research projects that will provide general experience with pharmaco-economic research.

Specific areas within which a reasonable competency should be achieved through project-related experience and mentorship by the preceptor include clinical research design, pharmaco-economic research design, pharmaco-economic research analysis, and research dissemination.

Guideline

1. The fellow should acquire practical experience in clinical research study design with biomedical applications.

Interpretation

The fellow should be exposed to experiential situations in which the following topics are discussed and/or completed as a part of a research project: (1) formulation of the clinical research question; (2) development of a research protocol; (3) sample size determination, power, and significance; (4) outcome measurement and sources of error and bias; (5) experimental research methods; (6) observational research methods; (7) human subjects, informed consent, and ethical issues in clinical research; (8) application for study funding; (9) questionnaires and secondary data; (10) pretesting, case report form development, and quality control; and (11) study implementation.

Within this area, the preceptor should make certain that the fellow is properly prepared to develop and evaluate a clinical research protocol along with the appropriate data collection materials. Additionally, the fellow should learn how to incorporate economic or quality of life research questions alongside clinical trial protocols.

Guideline

2. The fellow should acquire knowledge in research designs for economic evaluation and quality of life studies.

Interpretation

The fellow should be exposed to experiential situations in which the following topics are discussed and/or completed as part of the fellow's research project: (1) formulation of the pharmaco-economic and/or quality of life research question; (2) development of a research protocol; (3) instrument development and properties of measurement scales; (4) sample size determination and power; (5) outcome measurement and sources of error and bias; (6) clinical protocol-induced bias; (7) statistical, clinical, and economic significance; (8) pretesting, case report form development, and quality control; (9) study implementation; and (10) observation or assistance with collection of patient self-assessed data.

Guideline

3. The fellow should acquire experience in conducting and analyzing economic and quality of life evaluations using various methodologies.

Interpretation

The fellow should participate in all aspects of the following: (1) cost of treatment estimation; (2) cost of illness determination; (3) disease outcome and economic modeling; (4) cost-effectiveness and cost-benefit analyses; and (5) utility, satisfaction, quality of life, and health status evaluation. The fellow should be exposed to conceptualization of the analytic plan; complete data collection (e.g., practice pattern surveys, utilization, and unit cost estimation) from secondary sources as well as from clinical trials; model building; and specification of assumptions, statistical analyses, and ascertainment of results and sensitivity analysis.

Guideline

4. The fellow should acquire experience in the preparation and submission of abstracts and manuscripts for presentation at meetings and publication in peer-reviewed journals.

Interpretation

Successful completion of a research project requires submission of the methods and results for peer review, with subsequent publication of abstracts and manuscripts. Fellows should be required to disseminate the methods and results of their research project at a peer-reviewed scientific meeting.

References

1. American College of Clinical Pharmacy. Guidelines for clinical fellowship training programs. *Pharmacotherapy* 1988;8:299.
2. American Society of Health-System Pharmacists. Definitions of pharmacy residencies and fellowships. *Am J Hosp Pharm* 1987;44:1142-4.