

ACCP GUIDELINE

Guidelines for Pharmacoeconomic and Outcomes Research Fellowship Training Programs

Joint Guidelines from the American College of Clinical Pharmacy and the
International Society of Pharmacoeconomics and Outcomes Research

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Pharmacoeconomics and outcomes research (PEOR) demonstrates the added value of health services and treatments and is used by a variety of individuals in numerous settings to optimize patient care. Currently, 51 PEOR fellowship programs are publicized on Web sites from organizations such as the American College of Clinical Pharmacy (ACCP), the International Society of Pharmacoeconomics and Outcomes Research (ISPOR), and the Academy of Managed Care Pharmacy. These programs demonstrate the diversity of PEOR fellowships, as they are offered by sponsors in a variety of environments (e.g., academia, industry, consulting services, United States managed care, and government). Although the program sponsors vary, all fellowships should have the common goal of providing directed, highly individualized postgraduate training designed to prepare participants to become independent PEOR researchers. Like any health discipline, advancements in knowledge and technology along with changes in health care systems require refinement of existing training programs, including PEOR fellowships. Members of ACCP and ISPOR developed a survey instrument to assess structure, educational objectives, and outcome measures of PEOR fellowship programs. The survey objectives were to determine PEOR researchers' beliefs regarding qualifications of the training site, program, and preceptor(s) as well as fellowship applicant requirements, research commitment, didactic coursework and evaluation of fellows' research skills; and to develop PEOR fellowship guidelines based on data obtained from the survey. Pharmacoeconomics and outcomes research fellowship guidelines were originally published in 1999; this document outlines the revised PEOR fellowship guidelines based on recent literature and results of the ACCP-ISPOR survey described above. These guidelines are intended to assist PEOR researchers design, refine, and self-assess their fellowship program and to serve as a tool for prospective PEOR fellowship candidates to evaluate programs.

Key Words: American College of Clinical Pharmacy, ACCP, International Society of Pharmacoeconomics and Outcomes Research, ISPOR, pharmacoeconomics and outcomes research, PEOR, fellowship and scholarship health services research.

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Fellowships in Pharmacoeconomic and Outcomes Research (PEOR), sometimes referred to as Health Economics and Outcomes Research (HEOR), have existed since 1989 and are increasing in number as a result of global health trends.¹ While pharmacoeconomics and health economics are slightly different, we will use the term PEOR throughout these guidelines.² PEOR demonstrates the added value of health services and treatments. PEOR is used by a variety of individuals in numerous settings to optimize patient care, including pharmacists, physicians, economists, academicians, hospital administrators, and industrialists. As such, individuals seeking advanced training in PEOR, particularly PEOR fellowships, often have diverse educational backgrounds and skill levels. Moreover, individuals who complete PEOR fellowships are employed in diverse environments. Like any health discipline, advancements in knowledge and technology along with changes in health care systems require refinement of existing training programs, including PEOR fellowships. Moreover, with increasing globalization, there is a need to address PEOR issues across multiple continents.

Currently, 51 PEOR fellowship programs are publicized on web sites from organizations such as the American College of Clinical Pharmacy (ACCP), International Society of Pharmacoeconomics and Outcomes Research (ISPOR), and the Academy of Managed Care Pharmacy. These programs demonstrate the diversity of PEOR fellowships, as they are offered by sponsors in a variety of environments (e.g., academia, industry, consulting services, United States managed care, and government).³⁻⁵ Although the program sponsors vary, all fellowships should have the common goal of providing directed, highly individualized postgraduate training designed to prepare participants to become independent PEOR researchers.^{3,6,7} ACCP and ISPOR worked collaboratively to revise the existing PEOR fellowship guidelines to reflect the different types

of programs, preceptors, and applicants involved in PEOR research today.

Since the publication of the 1999 ACCP Position Statement on Guidelines for Pharmacoeconomic Research Fellowships, a number of studies examining the structure, educational objectives, and effectiveness of existing programs from the perspective of current and former fellows and preceptors have been conducted.^{1, 8-10} Overall, PEOR fellowship programs are similar in terms of duration (2 years), sponsorship (pharmaceutical industry), facilities (medical library and database access), salary, research design and analytic skills, and learned software applications.¹¹ In terms of structure and educational objectives, fellows reported significant variation in preceptor qualifications and the amount of time devoted to PEOR experiential activities and didactic coursework.⁹ Program effectiveness or outcome assessment, particularly in terms of the fellow's knowledge (cognitive domain) and proficiency in PEOR skills (psychomotor domain), were susceptible to variability in subjective interpretation and were therefore difficult to quantify.¹⁰ Preceptor qualifications, didactic coursework, and outcome assessment were some of the areas where clear guidelines for PEOR fellowship programs are needed.

Members of the ACCP Publication Committee and core members of the ISPOR Fellowship Taskforce developed a survey instrument to assess structure, educational objectives, and outcome measures of PEOR fellowship programs. The survey objectives were as follows: 1) to determine PEOR researchers' beliefs regarding qualifications of the training site, program, and preceptor(s) as well as fellowship applicant requirements, research commitment, didactic coursework and evaluation of fellow's research skills; and 2) to develop PEOR fellowship guidelines based on data obtained from the survey. The survey was distributed to the members of the ACCP Outcomes and Economics Practice Research Network (PRN) and the ISPOR Fellowship Taskforce and was available online from December 31, 2006 until January 31, 2007 using survey research software (SurveyMonkey, 2006). In total, 117 out of 280 ACCP and/or ISPOR members responded to the survey, a response rate of 42%. Details of survey results are available on the ISPOR Web site.¹²

This document outlines revised PEOR fellowship guidelines based on the

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recommendations of ACCP and ISPOR members, the previous ACCP PEOR fellowship guidelines published in 1999, and existing ACCP guidelines for clinical research training programs.^{1,3} These guidelines are intended to assist PEOR researchers design, refine, and self-assess their fellowship program and to serve as a tool for prospective PEOR fellowship candidates to evaluate programs. These guidelines will also be used during the voluntary, peer evaluation process offered by ACCP.¹³

Training Program Requirements

1. A minimum of 3000 hours of the fellowship training time should be devoted to PEOR research-related activities over a minimum period of 2 years.

By definition, a fellowship emphasizes the development of research skills with the goal of becoming an independent researcher. For this reason, the majority of the fellow's time should be focused in research-related activities that will vary depending on the setting (e.g., academia, industry, consulting services, United States managed care, government).^{2,5,6} The research-related activities include those described in the Fellowship Experience section and the course work described in the Training Program Requirements below. The 2-year fellowship duration is recommended because this is the minimum time necessary to fulfill the requirements of the fellowship experience (outlined below). It is recognized that more time may be necessary if the fellow is simultaneously pursuing a graduate degree. The emphasis should not be to count the research-related hours accrued but instead to develop and accomplish programmatic research oriented goals and objectives.

2. The training program should develop and document a training plan with goals and objectives prior to initiating the fellowship.

The goals and objectives for a fellowship will vary depending on the setting (e.g., academia, industry, consulting services, United States managed care and government) since the experiences offered in these environments differ. For example, academia may develop objectives with greater emphasis on grantsmanship and the pursuance of external federal funding. These may not be a strong priority in industry or managed care since the sources of research are

different. Regardless of the setting, it is recommended that the goals and objectives follow the core competencies of a PEOR fellowship as described in the Fellowship Experience section. After including the core competencies, it is appropriate to make additions depending on the fellow's interests (e.g., health policy, patient-reported outcomes). Also, the fellow's previous educational training (e.g., Ph.D. prior to fellowship) may necessitate additional modifications.

3. The training program should provide formal instruction in PEOR-related topics.

The fellowship program curriculum should include formal instruction about pharmacoeconomic research, clinical research, and analytical/methodologic research techniques. Some of the PEOR concepts that are considered foundations for subsequent research should be obtained through didactic coursework. There may be greater emphasis on formal instruction in PEOR fellowships than other types of research fellowships. The importance of formal instruction exists regardless of the setting (e.g., academia, industry or consulting services, consumer services). It is recommended that the coursework be primarily undertaken during the first year of the fellowship, as this will be the basis for projects and analysis completed in the second year. Opportunities for formal coursework might include but is not limited to biostatistics and software, clinical trial design, data analysis, econometrics, epidemiology, health care systems, health services research methods, health technology assessment, patient reported outcomes research, and pharmacoeconomics.

The completion of a certificate program or an advanced degree would be one method of achieving this guideline. Furthermore, the opportunity to earn an additional credential or degree would likely to be valued by most fellowship candidates. As the field of PEOR advances in sophistication and the expectations for high-quality research increases, earning an advanced degree in a health outcomes-related discipline is likely to become increasingly important. Training programs and fellowship candidates should thoroughly evaluate the content and relevance of advanced degrees when offered as part of PEOR fellowship programs. Options for advance degrees during a PEOR fellowship include but are not limited to Masters of Science (M.S.) in Public Health, M.S. in

Pharmacy Administration, M.S. in Statistics, M.S. in Health Economics, M.S. in Pharmacoeconomics and Health Policy, M.S. in Health Outcomes Research, and M.S. in Clinical Research. Degree titles will vary depending on the academic institution, but obtaining a degree with one of the aforementioned educational themes is recommended.

4. The training program should have a team of preceptors. However, each fellow should be assigned a primary advisor who oversees and coordinates the fellow's training.

PEOR fellowship training requires that the fellow learn multiple clinical, economic, and humanistic concepts that are best provided by a variety of preceptors with varying expertise. However, the fellow needs to be assigned a primary preceptor or advisor who will provide individual guidance, assure adherence to the fellowship objectives, and maintain the integrity of the fellowship.

5. The training program should have ample resources for conducting research including the following:

- Personnel with demonstrated capabilities in performing PEOR through publications, presentation of PEOR data at scientific meetings, or through known collaboration with recognized organizations producing PEOR.
- Direct (e.g., to patients) and/or indirect (e.g., medical claims data, electronic medical records, survey data) access to health care information to provide fellows with data to perform PEOR.
- Administrative support for the preceptor's research program and the fellowship training program.
- Ready access to a medical library or electronic access to medical literature as well as computing facilities.
- A collaborative relationship with other organizations/institutions to provide the fellow with experience in multiple PEOR practice environments (e.g., collaborations of academic organizations with governmental organizations to offer insight into health policy that may not have been obtained in a solely academic experience).

Qualified personnel to train the fellow are the cornerstone of any training program. In

addition, sites need to have the support to facilitate the conduct of PEOR.

Issues regarding single versus multisite programs should be considered. Multisite PEOR fellowship programs with teaching collaborations between academia and industry are becoming commonplace. Multisite programs have the potential advantage of providing the fellow with a broader range of experiences, including exposure to a variety of work environments, as well as access to a larger group of PEOR scientists. With this approach, however, the fellow may be less able to gain an in-depth experience with specific projects. The selection of a multisite program should depend on the interests and career goals of the fellow.

6. The training program should have a systematic plan to evaluate the fellow, preceptors, and program as an integral part of the training process.

A structured, formal evaluation of the fellow's performance should occur at regular intervals throughout the fellowship; every 6 months is recommended as an appropriate timeframe. The fellow should be evaluated based on the goals and objectives set forth at the beginning of the fellowship.

The evaluation of the fellow's performance should be based on the following:

- Posters and/or oral presentations at a national meeting
- Seminars on PEOR-related topics
- Manuscripts submitted or published
- Research projects executed
- Motivation
- Professionalism
- Communication skills (verbal, e-mail, formal writing)
- Presentation skills (research ideas and findings)
- Collaboration/team work skills
- Ability to evaluate clinical, economic, and patient-reported outcomes literature
- Research skills (question development, process, management, analysis, etc.)
- Time management

A comprehensive assessment of these characteristics will likely require input from preceptor(s), co-workers, and a self-assessment.

The fellow should perform a preceptor and program evaluation every 6 months. The fellow and primary preceptor or advisor should use the

goals and learning objectives developed at the beginning of the fellowship to determine if the program is progressing as planned. This is an optimal time to discuss modification of the goals and objectives in case the fellow has altered his/her interests. The fellow should have a formal and non-punitive mechanism to express his/her opinions regarding the primary preceptor and contributing preceptors' abilities to support/accomplish the outlined goals and objectives.

Preceptor Qualifications

1. A preceptor should have an established and ongoing record of independent research accomplishments and expertise in PEOR, that may be exemplified by the following:

- a. Fellowship training, a graduate degree, and/or equivalent experience
- b. Principal or primary investigator on research grants and/or projects
- c. Published research papers in the peer-reviewed scientific literature on which the preceptor is the primary or senior author

Preceptor qualifications may vary in the academic, industry, consulting, and consumer setting. Based on the culture of the environment, a preceptor may not have the opportunity to have an ongoing record as an independent researcher (i.e., principal or primary investigator). For example, investigator-initiated studies are uncommon in industry, consulting, and consumer settings. Nevertheless, a preceptor in industry, consulting, or consumer settings should demonstrate a strong record of project involvement and have a leadership role on these projects. Also, the primary preceptor or advisor in an industry, consulting, or consumer setting should be well positioned to provide the fellow access to a variety of projects.

2. The preceptor should have received formal instruction in pharmacoeconomics and outcomes research.

Current PEOR preceptors may have a variety of educational backgrounds, some clinical and some non-clinical. The variation in training makes it difficult to assess the preceptor's qualifications based on educational experiences alone. However, PEOR preceptors should provide evidence that they have received formal instruction in pharmacoeconomics and outcomes research methods.

3. The preceptor should have prior experience training PEOR fellows and/or students.

This can be a catch-22 for new programs because new preceptors become experienced by training the fellow. However, in the absence of prior of experience training PEOR fellows, preceptors should have had prior experience training students or colleagues about PEOR.

4. The preceptor should have an active collaborative research relationship with other health outcomes researchers or organizations.

Other health outcomes researchers may include individuals in other departments. For example, in the industry setting, it might be the global versus national health outcomes department. In academia, it might be a health economist in a School of Public Health.

Fellowship Applicant Criteria

1. Ideal PEOR fellowship applicants should have an advanced degree such as a Doctor of Pharmacy (Pharm.D.), Doctor of Medicine (M.D.), Doctor of Science (Sc.D.), Doctor of Philosophy (Ph.D.), Doctor of Public Health (Dr.P.H), Masters in Public Health (M.P.H.), Masters in Pharmacy Administration /Pharmaceutical Economics (M.Sc.), or a Masters/Ph.D. in business, economics, life science, psychology, or epidemiology.

Fellowship applicants who do not have an advanced degree may be considered eligible for fellowship based on unique skills, training, or experience.

2. Prior clinical experience is preferred prior to starting PEOR fellowship training.

Ideally, the fellowship applicant should have previous practice experience either through residency or work experience as a means of demonstrating his or her familiarity with health care systems. However, it is recognized that applicants coming from non-clinical backgrounds may not have this type of work experience. Each applicant should be assessed individually regarding his or her familiarity of health care systems through personal communication about prior experiences and by evaluating the coursework he/she has completed.

3. The fellow applicant should have a strong interest in and aptitude for a career in health economics/outcomes research.

Interest and aptitude for PEOR can be demonstrated through letters of recommendation, prior coursework, and/or projects completed.

Fellowship Experience

1. The fellow should demonstrate proficiency in multiple aspects of a PEOR fellowship through participation in at least one but preferably multiple scholarly projects during his/her training. These may include the following:

- a. Literature reviews, including systematic assessments *and* meta-analyses
- b. Dossier development (e.g., AMCP, National Institute for Health and Clinical Excellence)
- c. Prospective studies (e.g., clinical trials, observational studies)
- d. Retrospective studies (e.g., claims database analyses, medical record reviews)
- e. Economic modeling

The primary goal of a fellowship is to prepare the fellow to become an independent researcher; the candidate should, ideally, serve as a lead investigator on at least one project that is completed during the fellowship. In the consulting and industry environments, however, there may be less opportunity for a fellow to serve as principal investigator, especially in the early phases of training. Working on various components of multiple projects is likely to be more feasible in these settings.

The types of studies performed during the program will likely be driven by the environment in which the fellow is placed. However, familiarity with key concepts across the broad range of PEOR studies is advised. For example, in the industry, consulting, and consumer settings, the skill to develop a dossier based on the AMCP format will rank higher in priority than in an academic environment. However, fellows in the academic setting should also be familiar with these requirements.

While many fellowships will likely focus on PEOR issues within their own countries or healthcare system, there is an increasing need to address PEOR questions across multiple countries and healthcare environments. This is particularly true in the industry and consulting practice settings.

2. The fellow should actively participate in all aspects of the research process through a combination of didactic and structured,

supervised experiences which includes the following:

- a. Study design (e.g., development and testing of study hypothesis, study protocol development, statistical analysis plan, submission to appropriate institutional review board, study budget, and timeline)
- b. Grantsmanship / proposal writing
- c. Study implementation
- d. Data collection
- e. Data analysis
- f. Research program management
- g. Reporting

The fellow should be able to identify sources of funding to support his/her research. However, the importance of grant writing may weigh more heavily in a fellowship based in an academic setting than in non-academic settings. Grantsmanship may be better described as a proposal for funding allocation within a department in the industry setting or a proposal to a client in the consulting setting.

3. The fellow should develop an understanding of multiple methods of measuring clinical outcomes through a combination of didactic and structured, supervised experiences that includes the following:

- a. Clinical markers of disease (e.g., blood pressure, LDL cholesterol, glucose)
- b. Impact of disease on patients
- c. Impact of drug on patients
- d. Patient safety (e.g., adverse events)
- e. Adherence
- f. Process and delivery of care

4. The fellow should demonstrate proficiency in multiple methods of measuring economic outcomes through a combination of didactic and structured, supervised experiences that includes the following:

- a. Costing
 - i. Direct medical costs (e.g., drug, office visit, hospitalizations)
 - ii. Direct non-medical costs (e.g., caregiver costs)
 - iii. Indirect costs (e.g., loss of work, productivity outcomes)
- b. Economic analyses
 - i. cost-benefit
 - ii. cost-effectiveness

- iii. cost-minimization
- iv. cost-utility

5. The fellow should demonstrate proficiency in multiple methods of measuring patient-reported outcomes through a combination of didactic and structured, supervised experiences that includes the following:

- a. Health-related quality of life
- b. Patient satisfaction
- c. Patient preference

6. The fellow should develop an understanding of multiple aspects of the health care delivery system through a combination of didactic and structured, supervised experiences that includes the following:

- a. Health care financing
- b. Managed care and integrated delivery systems
- c. Health technology assessment
- d. Clinical practice guideline development and use
- e. Disease state management
- f. Medication use policy analysis

The type as well as depth of information necessary will largely depend on the environment in which the fellow works. For example, knowledge of regulatory guidance and information (e.g., the FDA and Healthcare economic information communication - Section 114 FDAMA- and the FDA and PRO for labeling: Guidance to industry) will be important for those in the United States industry and consulting environments, although every fellow, regardless of setting, should be knowledgeable about these guidelines.

7. The fellow should develop excellent oral communication skills (e.g., through participation in professional and or public communication of PEOR) and written communication skills (e.g., through preparation of reports, abstracts, and manuscripts).

The ability to disseminate PEOR in a clear and concise manner is critical to ensure that the information reaches a wide audience that includes clinicians, economists, and epidemiologists, among other stake holders.

8. The fellow should regularly participate in journal clubs, research workshops, and/or seminars.

Throughout the fellowship program, the fellow should continually update his/her knowledge and skill in this continually evolving field.

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