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Keeping Clinicians in Clinical Research: The Clinical Research/ Reproductive Scientist Training Program

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Abstract

In recent years the need for translational and clinical research has increased while the number of physicians involved in clinical research has diminished. There is clearly a need for formalized academic training in the quantitative and methodological principles of clinical research in reproductive medicine. The Clinical Research/Reproductive Scientist Training Program (CREST), a program supported by the National Institute of Child Health and Human Development, the Clinical Research Training Program (CRTP) at Duke University, and the American Society for Reproductive Medicine (ASRM) meets this existing need. In addition, this program is specifically designed for physicians in private or academic clinical practice in reproductive medicine. Innovative programs such as CREST encourage the practicing physician to engage in clinical research while maintaining an active role in clinical practice. Participants in the program receive didactic on-line training from the CRTP, attend intensive weekend seminars at the National Institutes of Health (NIH) and CREST seminars at the annual meeting of ASRM. Successful participants in the program receive a Certificate in Clinical Research from the CRTP. The program's goal is to provide practicing physicians with the tools and research credentials that will facilitate collaborations with investigators involved in large clinical trials.

Keywords

physician-scientist; clinical research

There have been many challenges in the area of translational research.(1) Fewer physicians have National Institutes of Health (NIH)-supported research careers; in fact the total number of physician-scientists involved in NIH-related research has decreased. In 1980 there were approximately 15,000 physicians involved in NIH-related research and in 2004 that number

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was 14,000. In contrast, the number of Ph.D. scientists applying for NIH grants for the first time has increased by 120% in the past 30 years.(2) Although the success rates for M.D.s and Ph.D.s are comparable, the number of M.D. applicants has decreased in the past decade. In addition, the decrease in M.D. applicants has not been compensated for by an increase in M.D./Ph.D. applicants.(3) There are many reasons for this concerning trend, and some possible explanations include:

Difficulty in obtaining funding

Shortening of review cycles

Complex grant process

Increasing competition from Ph.D.s

A perceived bias against clinical applications versus basic science grant proposals

An equally concerning trend is the increasing number of physicians who start a career path in research and subsequently leave the field. Unfortunately there is not a great deal of data examining the etiology of this troubling trend, but some authors suggest a lack of career security as a result of the difficulty in finding and maintaining research dollars, while others identify a lack of adequate training and mentoring.(3,4)

The shrinking research dollars have become a significant impediment to entering a career in clinical research.(4,5) Although all of these factors are important, and contribute to the declining numbers of clinical researchers, the focus of this discussion will be on the role of training in recruiting and retaining physician-scientists in the field of Reproductive Medicine.

There is a paucity of data about the number of fellows in Reproductive Endocrinology and Infertility that take an academic position following graduation. Individual program directors maintain statistics about their institution's graduates, and an informal survey of program directors suggests that more graduates are not only choosing private practice, but in many cases, they are also choosing to end their involvement in clinical research. Although precise numbers are not available, many of those involved in fellow education would estimate that a third to a half of graduates choose an academic position. What is even more difficult to estimate is the number of recent graduates who choose to stay involved in clinical research in some capacity. Unfortunately many recent graduates view participation in clinical research as an all or none proposition. Far too frequently these young physicians feel that the inability to obtain a NIH R01 grant precludes any involvement in research.

What are the other barriers to a career as a physician-scientist? Debt as a result of medical school, residency and fellowship training is a significant disincentive to taking a salaried academic position. In 1984 the average debt for public school graduates was \$22,000 and \$26,500 for private school. In 2004 the average debt soared to \$105,000 for public school and \$140,000 for private school, with only 20% of students graduating with no debt.(2,6) The National Institutes of Health has attempted to address this problem with a series of loan repayment programs. These NIH programs were created to encourage physicians with large medical school debts to enter clinical research careers in the following areas: pediatrics, contraception and reproductive health, health disparities, and clinical research for disadvantaged backgrounds. (<http://www/lrp.nih.gov>)

Another potential barrier to continued involvement in clinical research is a lack of training. Although a university-based statistics course is a fellowship requirement, the rigor and relevance of this training is variable. Many fellows also do not receive instruction in study

design, grant writing and other essential skills needed for clinical research. Several universities have recognized this problem and have created clinical research programs that offer degree and non-degree options. The Clinical Research and Training Program (CRTP) at Duke University, for example, provides academic training in the quantitative and methodological principles of clinical research. The program is designed for clinical fellows who are training for academic careers, and offers formal courses in research design, research management, medical genomics, and statistical analysis. The University of Pittsburgh also has a Clinical Research Training Program which was founded in 1999 with support from the NIH. The core curriculum includes instruction in clinical research methods, biostatistics, and computer methods for clinical research and measurement in clinical research. Like Duke University, the University of Pittsburgh offers degree and non-degree (certificate) options. The online training which is available makes this an invaluable resource for practitioners who want to obtain additional skills in clinical research. (www.crtp.mc.duke.edu, www.icre.pitt.edu/crtp)

In an effort to address the growing attrition of physician-scientists in Reproductive Endocrinology and Infertility, two senior respected academicians, Dr. Robert Rebar of the American Society for Reproductive Medicine and Dr. Phyllis Leppert of the National Institute of Child Health and Human Development developed a partnership among partnered the National Institute of Child Health and Human Development, the American Society for Reproductive Medicine and Duke University to create the Clinical Research/Reproductive Scientist Training Program (CREST). Unlike other university programs which are designed for fellows pursuing careers in academic medicine, CREST is designed for physicians in private or academic clinical practice in reproductive medicine. In order to make this valuable training opportunity available to providers in general obstetrics and gynecology practice as well as other physicians in related fields such as Urology and Internal Medicine, the eligibility criteria have recently been expanded. (www.asrm.org/Media/misc_announcements/CREST.html) Completion of a fellowship in Reproductive Endocrinology and Infertility is no longer required. Applicants must be members of ASRM, have an M.D. degree and must have completed a residency in any specialty. They also must have clinical experience, a demonstrated interest in reproductive medicine and they must be eligible for Intergovernmental Personnel Act (IPA) funding. CREST scholars receive didactic on-line training from the CRTP at Duke University, attend intensive weekend seminars at the NIH and CREST seminars at the annual meeting of ASRM. Financial support is provided for tuition and fees, as well as transportation and housing for the required seminars. Admission to the program is competitive and requires submission of an application and letters of reference. At the completion of the program, participants receive a Certificate in Clinical Research from Duke University School of Medicine.

Since its inception there have been a total of 10 graduates of the program. The average grant for each scholar is approximately \$10,000–\$12,000. The differences in totals are primarily related to differences in travel costs for each of the scholars. Although the first graduates completed their training in 2006, they have already shown evidence that they are utilizing the skills obtained through their participation in CREST. The scholars not only had an impressive number of abstracts at recent annual meetings, they have authored a number of manuscripts. One of our first graduates has been first or senior author on ten published manuscripts, while engaged in a full time clinical practice in a large IVF clinic. His research has included prospective clinical trials as well as basic science investigations conducted with the embryologists at his institution.(7,8). Another graduate of charter class has focused on medical education and is now the Residency Program Director at the University of Colorado. (9,10). A third member of this class has now joined the faculty at Stanford University, after remaining active in clinical research while in a full time practice. (11,12)At their final seminar at NIH in 2006, they developed a research grant proposal which was submitted and approved by the Society for Assisted Reproductive Technologies (SART). This collaborative project will

examine a number of variables and their importance in predicting IVF outcomes. As a result of the initiative and hard work of the charter class, the program now plans to offer a formalized second year experience which will focus on a group clinical research project.

The physician-scientist has become an “endangered species”, but the CREST program and other similar initiatives can provide the resources and training necessary to make important contributions to clinical research in Reproductive Medicine. Support for physician scientists in our discipline is crucial, as eloquently stated by Dr. Leon Rosenberg, “In the absence of physician scientists, the bridge between bench and bedside will weaken, perhaps even collapse.” We have a professional and an ethical obligation to continue to train and support clinical researchers.

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