

This section of the Annals brings you current activities and comments from the American College of Epidemiology. The first is a policy statement that addresses the role of epidemiologists in a current NIH initiative that promotes clinical and translational science. The second is a letter that ACE has addressed to the Director of the Center for Scientific Review at the NIH urging changes in the key aspects of the grant review process. The third is a Letter to the Editor expressing concerns about a proposed NIH policy to permit multiple Principal Investigators on a single grant.

The Annals welcomes the thoughts and comments of readers on these issues.

The Role of the Epidemiologist in Clinical and Translational Science

AMERICAN COLLEGE OF EPIDEMIOLOGY POLICY COMMITTEE

INTRODUCTION

The National Institutes of Health (NIH) released a new Roadmap RFA on October 12 entitled Institutional Clinical and Translational Science Award (RFA-RM-06-002). It seeks to “forge a uniquely transformative, novel, and integrative academic home for Clinical and Translational Sciences; the NIH envisions the emergence of a specific discipline of clinical, translational research.” The RFA implies that this new discipline should have specific academic and physical housing and this entity would issue degrees, manage its faculty’s time, and make appointments and promotions. The new Award will subsume existing Roadmap K-12, K-30, T-32, and General Clinical Research Centers into one entity that can be a department, center, or institute. The scope of the resulting award to an institution would be large. The NIH will put \$30 million into this RFA in fiscal year 2006 and expects to make five initial awards. However, during the next few years, it will issue additional solicitations for CTSA until the nation’s health sciences centers are following this new paradigm for training and research. The train is on the track, and, undoubtedly, institutions across the country will attempt to be in the first wave of CTSA or seek developmental funding.

As the CTSA “train” inevitably moves forward, a major question is which seat the epidemiologist should take. We propose that epidemiologists should be conductors. The new vision for clinical and translational research is familiar to epidemiologists; it stretches not just from “bench to bedside,” but from “bench and bedside to population.”

Why is it critical for translation to stretch beyond the bedside to the population? The greatest gains in life

expectancy in the 20th century were caused by prevention. Led by reductions in mortality from cardiovascular causes, the reduction in tobacco smoking and control of hypertension and diabetes made more of a difference than all of interventional cardiology. In the area of infectious diseases, sanitation, water purity, personal hygiene, and population-based approaches to vaccination have had as much or more impact on major causes of infection-related deaths than the widespread use of antibiotics. These and many more examples like them (not the least of which is population-based planning for a bird flu epidemic) underscore the import of translating from bench to population.

Why should epidemiologists have such a critical role in the emerging agenda for translation research? Epidemiologists have a long history of providing the evidence base for showing the efficacy and effectiveness of clinical and community interventions moved into practice. The history of this evidence base shows that smaller and/or less rigorously conducted clinical research can lead to false impressions. Clarity may be achieved best by evidence from population-based prospective studies and clinical trials, generally by epidemiologists. There are numerous examples of the pivotal role of such studies, including understanding the usefulness of hormone replacement therapy, health claims with vitamin E and beta carotene, and the need for coronary artery bypass grafting. The population perspective puts a wider (and proper) scope on translational science, and epidemiologists have the expertise needed to work jointly in the domains of clinical and population science. The platform of the CTSA and the push for clinical and translational science should embrace epidemiology as the core discipline underlying this “new” line of health research.

Advancing this role for epidemiology and epidemiologists may prove challenging in many academic health centers. For those having schools of public health, there often is a divide between the population scientists in such schools and their clinical research colleagues in adjacent buildings.

From the American College of Epidemiology.

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Selected Abbreviations and Acronyms

NIH = National Institutes of Health
RFA = Research focus announcement
CTSA = Clinical and Translational Service Award

In some larger institutions, clinical departments, particularly departments of medicine, have many well-trained clinician/epidemiologists, and liaisons with a school of public health may seem unneeded. For the many academic health sciences centers without schools of public health or relevant departments, there will be a need to add capacity in epidemiology and biostatistics. Across these scenarios, we see opportunities to forge new links between population health disciplines and clinical science in a new integrated fashion so that the needed multidisciplinary research teams can be formed. The academic structure for establishing the CTSA's will vary from institution to institution, but it can only be implemented fully if interdisciplinary interactions are facilitated. Epidemiologists should have a central role, particularly those with strong clinical backgrounds. The epidemiologist/clinician almost uniquely can understand the causes and distributions of diseases in populations, how

sick people get into hospitals and clinics, determinants of outcome of care, and predictors of well-being and survival.

This and subsequent RFAs for CTSA's and the push for a science of clinical and translational research offer a long-needed opportunity to break down the disciplinary silos that prevent long-term success in creative innovative interdisciplinary or transdisciplinary science. With the proposed capacity of the CTSA's for internal training and career advancement and the uniformity of the paradigm across the land, more young scientists are likely to move into clinical and translational research while maintaining a core discipline. We submit that epidemiologists already cross this disciplinary divide with facility and should be prime players in this new enterprise.

By the time this goes to press, the first round of applications likely will be in to have met the March 27 deadline. At least all the moving parts and leadership will be decided. Undoubtedly, there will be problems, misunderstandings, and false starts, but we think this is a new vehicle for team science in which epidemiologists can and should have a major role. Therefore, we urge everyone to get those epidemiologists onto the outbound trains and to get them on board if they are not already on the train.