

COMMENTARY

National Institutes of Health Eliminates Funding for National Architecture Linking Primary Care Research

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With the ending of the National Electronic Clinical Trial and Research Network (NECTAR) pilot programs and the abridgement of Clinical Research Associate initiative, the National Institutes of Health Roadmap presents a strategic shift for practice-based research networks from direct funding of a harmonized national infrastructure of cooperating research networks to a model of local engagement of primary care clinics performing practice-based research under the aegis of regional academic health centers through Clinical and Translational Science Awards. Although this may present important opportunities for partnering between community practices and large health centers, for primary care researchers, the promise of a transformational change that brings a unified national primary care community into the clinical research enterprise seems likely to remain unfulfilled. (J Am Board Fam Med 2007; 20:229–231.)

In order for the National Institutes of Health (NIH) to realize its potential for improving the nation's health, medical knowledge generated from relevant clinical research must be translated into practical applications and incorporated into the nation's health care delivery systems. Over the course of a year, visits to primary care providers in the United States exceed the total of all other physician visits. The broad range of care provided by primary care physicians intersects with the disciplines of many NIH Institutes, making the community-based primary care office a clearly important site for the integration of new NIH clinical research findings across its Institutes.

Unfortunately, the potential of NIH to engage the national primary care research community and to facilitate better tools to provide care was signif-

icantly diminished with the apparent elimination of the NIH commitment to develop a national infrastructure for integrating research and practice. On December 6, 2006, at an NIH Roadmap meeting, Dr. Barbara Alving, the Director of the National Center for Research Resources, announced the decision to end funding for the development of a National Electronic Infrastructure for Clinical Research (NECTAR) that would integrate community investigators. This announcement represents a strategic shift from direct funding of a harmonized national infrastructure of cooperating research networks to a model of local engagement of primary care clinics under the aegis of regional academic health centers (AHC).

Historically, the NIH recognized moving new knowledge from the laboratory bench to the academic bedside (aka translation) as an important step in the introduction of new research findings. More recently however, NIH has appreciated that translation does not stop at the AHC bedside. Too often the transfer of new research from laboratory bench to the hospital bedside is followed by a transfer from the bedside to the academic bookshelf. Implementation of the findings into community practices can be delayed by an additional 17 years.¹

New methods of efficient information exchange between academic research centers and the primary

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care community are essential to reduce the inefficiencies and even the dangers of the delay in translating research into community practice. Termed “type 2 translation,” the development of successful practice integration strategies in the community requires a partnership between providers and researchers.² This partnership provides for bidirectional information exchange. Most would agree that current research can improve clinical care, yet it is sometimes overlooked that the development of good research is also best served when informed by clinical acumen. Novel clinical observations about the nature and progression of disease can stimulate important investigations in the basic science laboratory.

From the perspective of the primary care physician, the rapid expansion of knowledge and the explosion of medical literature has overwhelmed the ability of textbooks to provide up-to-date and balanced treatment recommendations. As information becomes available at an even faster pace, family physicians lack time to critically evaluate the volumes of published research and instead rely on systematic evidence-based reviews to inform practice. But evidence-based reviews rely on the existence of good evidence, and the true effectiveness of innovation can only be judged in appropriately designed clinical trials conducted in the setting in which the innovation is to be applied. Research on the effectiveness of new treatments in health care delivery settings and new “practical” clinical trials in primary care are necessary if we hope to improve the health of the nation.³

For more than 25 years, practice-based research networks (PBRNs) of dedicated primary care clinicians, operating on shoestring budgets and in-kind support, have investigated common clinical problems and tested practical treatments in the primary care setting. More recently, PBRNs have captured the imagination and interest of many primary care providers and researchers. In 1998, PBRNs were noted by the Institute of Medicine to be “the most promising infrastructure development that [the committee] could find to support better science in primary care.”⁴ By 2003, with funding primarily from the United States Department of Health and Human Services Agency for Healthcare Research and Quality and the Robert Wood Johnson Foundation, 54 regional and national PBRNs spanned the nation, assisting more than 6500 community-based clinicians to conduct research in their prac-

tices. In 2005, the Association of Family Medicine Organizations unanimously endorsed that “participation in the generation of new knowledge must become integral to the activities of all family physicians and, . . . should be incorporated into family medicine training. In addition to incorporating practice-based research into the values, structures, and processes of family medicine practices. . . .”⁵

Funded by the Office of the Director by the transinstitute NIH Roadmap initiative, the Inventory and Evaluation of Clinical Research Networks (IECRN) released a report in June of 2006 identifying 7 primary care PBRNs among their 29 “best practice” clinical research networks from more than 248 research organizations nationwide. The IECRN recognized the stability of funding for PBRNs as a “pressing concern.”⁶

It seemed that NIH was beginning to understand the importance of partnering with primary care on a national basis to establish an infrastructure for integrating clinical research and practice. In particular, 2 major programs were announced that involved the primary care community more closely than ever before. First, in a unique feasibility study, 3 primary care practice-based research groups were funded to pilot the construction of NECTAR. These pilot projects involved many PBRNs and thousands of primary care investigators. Second, the Rand Corporation was asked to investigate the development a Clinical Research Associate (CRA) initiative that would train and work with 50,000 investigators in a wide variety of community settings.

Unfortunately, with Dr. Alving’s announcement, it is now clear that the NECTAR pilots will not continue, and the CRA initiative has also been discredited. Although the findings of the Rand report were never made public, presumably the cost of their proposed model was too high and the initiative was instead relegated to a small supplemental grant to AHCs.

The instrument that NIH is promoting instead to speed the translation of research into practice and to improve the health of the country is the Clinical Translational Science Award (CTSA) that funds the development of new institutes for multidisciplinary clinical research within existing AHCs. Promising \$1.5 billion dollars to 50 AHCs over the next 5 years for infrastructure development in clinical research, the NIH Roadmap has committed nearly all its eggs to this one basket. At the foun-

dation of that commitment is the tenuous presumption that AHCs will learn how to engage in productive dialogue with the community if they are promised enough money. That sounds very similar to the academic model we have used for the last 60 years.

AHCs face many similar problems across the country. Although primary care has made important inroads in some universities, many AHCs have too few experienced primary care investigators to assure that any new “partnership” will provide for a bidirectional exchange of information or provide enough sharing of resources to stabilize the primary care research infrastructure. Although the CTSA program may stimulate the development of locally strong translational centers, and some of these centers will provide a pathway for participation of local or regional communities, the promise of a transformational change that brings a unified national primary care community into the clinical research enterprise seems likely to remain unfulfilled.

Regardless of this bad news, I strongly encourage all primary care PBRN investigators to continue to work together. As primary care clinicians, our strength is in our cooperation with each other and with our patients. As we test the effects of expert recommendations in real settings, develop better access to clinical data, and inform and provide our patients with the latest scientific advances, we will continue to advance toward our goal of providing the best care possible. In the meantime, I advocate that the primary care community encour-

age NIH to use Roadmap funds to establish a national backbone for existing and emerging primary care PBRNs to promote the development of a harmonious national architecture for the translation of research into community practice and to provide the beginning of a long overdue partnership between the national community of primary care investigators and the NIH.

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