Commentary: **Challenges and Pathways for Clinical and Translational Research: Why Is This Research Different From All Other Research?**

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Abstract

Three related articles in this issue addressing clinical and translational (C/T) research suggest four simple questions about such research that should be considered by policy makers at a national level, by academic institutions, and by individual scientists: What, who, how, and why. The author of this commentary posits that ambiguity in answering these questions means that policy makers are not providing a clear target for institutions and researchers. The vagueness of the definitions may also obscure accountability with regard to assessing whether the rhetoric matches actions—for instance, what is the distribution of research activities and funding across the different phases of C/T research? Given the rapid evolution of new tools and methodologies in C/T research, it is important to consider each of these issues across the full developmental pathway of a C/T researcher. Overcoming these challenges and rapidly advancing along the pathway of creating knowledge to enhance the health of our communities and the nation depends on coherence and agreement by all players involved in C/T policy, funding, and participation.

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Editor's Note: This is a commentary on the following articles: Heller C, de Melo-Martín I. Clinical and translational science awards: Can they increase the efficiency and speed of clinical and translational research? Acad Med. 2009;84: 424–432; Goldhamer ME, Cohen AP, Bates DW, Cook EF, Davis RB, Singer DE, Simon SR. Protecting an endangered species: Training physicians to conduct clinical research. Acad Med. 2009;84:439–445; and Teo AR. The development of clinical research training: Past history and current trends in the United States. Acad Med. 2009;84:433–438.

At the Passover Seder, Jewish tradition obligates all participants to ask and respond to four questions regarding the unique attributes of the holiday. Although typically recited by the youngest (and, thus, most naïve) child at the table, these questions are intended to be a focus of serious discussion and thought for the broader community, the family, and the individual because they represent important, larger issues.

In a similar manner, the articles in this issue relating to clinical and translational (C/T) research suggest four simple, yet profound questions regarding such research that should be considered by policy makers at a national level, by academic institutions, and by individual scientists: What, who, how, and why.

What is C/T research? Each of the three articles related to this commentary focus on a somewhat different part of the elephant. Heller and de Melo-Martín[1] note the two types of "translational research" defined in the National Institutes of Health (NIH) Clinical and Translational Science Awards (CTSA) Request for Application: (a) Applying basic discoveries to clinical applications and (b) enhancing adoption of best practices in the community. However, they focus their attention primarily on barriers to (a). For his historical analysis of clinical research training, Teo[2] applies the official NIH definition of "clinical research": "Patient oriented research, epidemiological and behavioral studies, and health services research." A significant portion of this article examines training programs that seem to be more closely linked to (b)—that is, those that offer an MPH degree or that focus on health services and quality research, such as the Robert Wood Johnson Foundation Clinical Scholars Program and the Harvard Program in Clinical Effectiveness (also described by Goldhamer et al[3]). Moreover, multiple other commentators have suggested alternative models of C/T research (e.g., Woolf[4] and Dougherty and Conway,[5] among others), and the CTSA Consortium Evaluation Committee is also developing a framework for defining C/T research.

The problem with all this ambiguity is that policy makers are not providing a clear target for institutions and researchers. The vagueness of the definitions may also obscure accountability with regard to assessing whether the rhetoric matches actions—for instance, what is the distribution of research activities and funding across the different phases of C/T research—(a) versus (b), T1 versus T2 versus T3, and so forth?

Who will be the future C/T researchers? Critical to answering this question are issues of recruitment, training, mentoring (and menteeing), social supports, the institutional reward system, and the impact of federal and other programs. Heller and de Melo-Martín's first-listed set of barriers and solutions are training and mentoring. Teo, as well as Goldhamer and colleagues, focus on training primarily at the fellowship level and also note the importance of

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List 1
Roles and Tasks of the Clinical/Translational Researcher

- Core professional functions: Conducting research to ultimately enhance the health of the individual, the community, the nation, and the world
- Intellectual orientation: Creative and disciplined thinking
- Technical skill: Systematic, objective investigations
- Management skills: Organization, maintenance, and efficiency of research efforts
- Values and integrity: Scholarly processes that adhere to the highest standards of ethical conduct
- Understanding interdisciplinary perspectives: Collaboration and integration across silos of investigative activity

mentorship. However, given the rapid evolution of new tools and methodologies in C/T research, it is important to consider each of these issues across the full developmental pathway of a C/T researcher—that is, from undergraduate experience (or, perhaps, even birth) to retirement.

Moreover, as Heller and de Melo-Martín note, academic rewards and incentives are generally not under the control of CTSAs but require leadership and action at higher institutional levels. In a recent article, Keyser et al[6] suggest how such leadership can be exercised and assessed with regard to research mentorship. In addition, just as a clearer notion of the "what" is needed, there also should be a clear set of expectations for the "who." An overarching description of the roles/tasks of a C/T researcher, adapted from an article by Burke et al,[7] is suggested in List 1, and a more detailed set of C/T research competencies is being developed by the CTSA Consortium Education Committee.

How are we going to overcome these challenges and rapidly advance along the pathway of creating knowledge to enhance the health of our communities and the nation? Obviously, answering this third question is beyond the space and scope of this commentary. Nonetheless, it is worth noting some of the multiple "subquestions" that are embedded in this complex question: Where should C/T research activities take place? (It can't be *just* the CTSAs.) How can the practical and regulatory barriers be overcome (and still maintain oversight, accountability, and adherence to the highest ethical standards)? How much funding will be needed (and where will it come from)? How can we best evaluate these strategies (and change them if expectations are not being met)?

There is, finally, the fourth question: Why is this research different from all other research? The answer is simple and, perhaps, can be summed up by paraphrasing Bill Clinton's Presidential Campaign War Room: "It's the patient, stupid!"

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