

## TRANSLATIONAL RESEARCH: MOVING SCIENTIFIC ADVANCES INTO THE REAL-WORLD SETTING

Keith C. Norris, MD, FACP  
Editor-in-Chief  
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Despite remarkable advances in biomedical sciences and medical therapeutics in recent decades, the anticipated improvements in patient outcomes have not been realized due to the inability to translate scientific advances into clinical practice.<sup>1</sup> Indeed, as many as one half of Americans with major chronic diseases do not receive care that meets recommendations for acceptable practice.<sup>2,3</sup> This is particularly true for a disproportionately high percentage of women, racial and ethnic minorities, and other high-risk groups in the US healthcare system. Although incentives and funding are in place to foster research that addresses the disparities in health suffered by women and ethnic minorities, the need for information and intervention remains unmet.<sup>4</sup>

In 2000, the US Department of Health and Human Services (DHHS) spearheaded by David Satcher, MD, PhD, the then US Surgeon General, released its 10-year health objectives for the nation, *Healthy People 2010*. The two main objectives of *Healthy People 2010* are to: 1) increase quality and quantity of healthy life; and 2) eliminate health disparities.<sup>5</sup> A key component of addressing not only health disparities in disadvantaged populations, but also the overall health of our nation, is the recognized need to re-engineer the traditional approach to health sciences related research. The gap between the promise of science and the realities of clinical practice has prompted urgent calls for broad changes in the health science-health care continuum.<sup>6</sup> To further address this issue, the NIH initiated a strategic planning process that culminated in a roadmap that promotes the integration of intra- and inter-disciplinary research and expanding research partnerships and integrated research networks with a focus to improve patient outcomes.<sup>7</sup> Critical to this approach is the understanding of, and commitment to, the premise that basic science, clinical discovery, and patient-oriented research (clinical trials, bio behavioral, etc.) are interdependent and not necessarily successive steps.<sup>8</sup> The new *NIH Roadmap* outlines the translation of research advances in the context of a patient-centered approach, consistent with the recent recommendations from the Institute of Medicine.<sup>9</sup> This approach to health science will hopefully provide the necessary building blocks to support the evolving approach to healthcare delivery.<sup>10</sup>

Briefly, the translation of research advances to improve health outcomes occurs in two continuous phases.<sup>11</sup> The first phase is from laboratory research to clinical research application; the second phase is from the clinical research setting to the real-world practice. Reviewing Figure 1, one can see the potential advances of the emerging disciplines of genomics, proteomics, glycomics, metabolomics, bioinformatics, and others for establishing readily identifiable biomarkers to assess disease risk, disease severity/activity, and clinical outcomes. These advances will be bolstered by their interpretation in the setting of robust phenotypic profiles that will include clinical, physiological, socio-cultural, biobehavioral, environmental, geo-spatial, and other community-level factors. This will enhance the validity of the interpretation of data and improve the relevance of the translation of these findings to healthcare providers and the communities we serve. Finally, the dissemination of evidence-based information in a culturally and linguistically appropriate manner to providers, consumers, and other stakeholders is critical for optimizing high-quality healthcare delivery, but can only be effective in the setting of access to care. Thus, the implementation of effective healthcare policies is needed to ensure effectiveness and equity in the delivery of evidence-based recommendations.

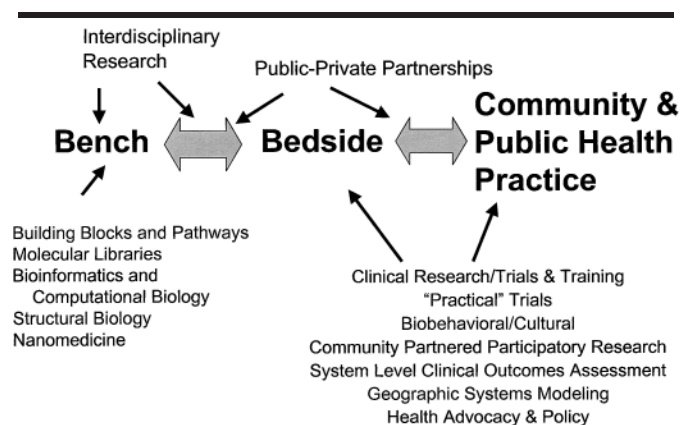


Fig 1. Translational research in the 21st century

To ensure translation of scientific advances into public gain, leading science groups have called for increases in the numbers of clinical investigators and in capacity of the clinical research enterprise to field multiple clinical studies.<sup>12-16</sup> The field of clinical trials will also be affected as we see a transition from narrowly focused, randomized, double-blind studies with restricted inclusion and exclusion criteria to a new, more-encompassing design model termed "practical trials."<sup>17</sup> Trials may be considered practical if they yield findings that practitioners, consumers, or the public can use or apply. Characteristic features of practical trials include: 1) selection of clinically relevant alternative interventions to compare; 2) inclusion of a diverse population of study participants; 3) recruitment of participants from heterogeneous practice settings; and 4) collection of data on a broad range of health outcomes.

Even given practical utility, research findings may not result in community health improvements if stakeholders do not perceive them as relevant and if they do not utilize them. The problem of relevance may be particularly acute for community clinics or populations, such as ethnic minorities, who are historically under-represented in clinical research. Through the development of community partnerships and the inclusion of community participation in all phases of research, there will be an improvement in the relevance of, and trust in, research among multicultural and under-served groups.<sup>18,19</sup> As the intellectual and physical capacity of communities to partner in research are enhanced, the ability to design practical trials more efficiently and with flexibility to fit community needs and perspectives, as well as to conduct trials with deeper public participation, will usher in a new era of research excellence to more effectively advance clinical research findings to real-world practice.<sup>20,21</sup>

I look forward to the work of many scientists contributing to *Ethnicity & Disease* leading the way for creating the rigorous standards for the needed phenotypic profile assessment that will integrate diverse community and individual characteristics, allowing a more informed interpretation of emerging biomarkers, genetic markers, and pharmacogenomic analyses. Ultimately, these contributions will pave the way toward addressing the moral imperative to achieve efficacy and equity in healthcare delivery.

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