Implementation Research

The Fourth Movement of the Unfinished Translation Research Symphony

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> "This is the next frontier for the World Bank Group—helping to advance a 'science of delivery.' Effective delivery demands context-specific knowledge. It requires constant adjustments, a willingness to take smart risks, and a relentless focus on the details of implementation"
>
> —World Bank Group President Jim Yong Kim, October 12, 2012 Annual Meeting Plenary Session, Tokyo, Japan

Paradigms play fundamental roles in the evolution of science and are often viewed as "universally recognized scientific achievements that, *for a time*, provide model … solutions to a community of practitioners" [1]. This perspective signals that paradigms have shelf lives and raises an important question vis-à-vis translational science. Has the shelf life of the prevailing paradigm(s) for translational science expired? Many commentators and editorialists have expressed skepticism about the sustainability of the current status quo, such that the arch of reason now bends toward the notion expressed by Dr. Francis Collins [2] that the time is right for re-engineering translational science.

Of note, paradigms are inextricably linked with the apprehension of the crisis or challenges of an era. Thus the realities of the times and the *direction* sought by a "community of practitioners" are critical in determining the birth of new model solutions. The response to the emerging consensus to re-engineer translational science would therefore benefit from a clear understanding of the fundamental direction we seek. Herein, the eternal question becomes very pertinent: *Quo Vadimus*? (Where are we going?) Or in colloquial iteration: Where are we coming from? Attempts to answer this question warrant the evaluation of present understanding of translational research, our successes and failures (where we have come from), and thereby elucidate a path forward.

AN UNFINISHED SYMPHONY

The spectrum of translational research

The National Institutes of Health (NIH) defines translational research as the process of applying ideas, insights, and discoveries generated through basic scientific inquiry to the treatment or prevention of human disease [3]. However, there is no consensus on the definition of translational research. For example, the NIH perspective is only shared by about 44% of the readers of *Nature Medicine*, which is a reflection of considerable variation in how the scientific community interprets translational research [4]. Similarly, the definition and classification of the steps of translational research have evolved over the years, and they are likely to continue to evolve catalyzed by the continued quest to optimize the pipeline from discovery to application. In this regard, the introduction of the NIH Roadmap for Biomedical Research by the former NIH Director Dr. Elias Zerhouni was a significant milestone [5]. The Roadmap was aimed at accelerating scientific discovery and its translation to patient care by eliminating growing barriers between clinical and basic research.

The Roadmap recognized 2 translational steps from "bench to bedside" and "bedside to practice" (T1 and T2, respectively). However, Westfall et al. [6] cogently argued that the NIH Roadmap was devoid of the blue highways needed to connect the interstates of academic scientific discoveries to the patients that receive care at tree-lined ambulatory practice sites. Thus they proposed an expansion of the T1 and T2 model to include a third step (T3), wherein both T2 and T3 are practice-based research, but they explicitly referred to T3 as dissemination and implementation research. Although the expansion to a T3 step was recognized as important for implementation in practice, Woolf [7] correctly critiqued that the 3-step model was incomplete because implementation is not limited to the domain of health care practitioners. Woolf [7] argued that all consumers of evidence—for example, policy makers, public health administrators, regulators, clinicians, public health professionals—play a role in the translation of research findings to practice. Furthermore, he pointed out that the T3 model needs further expansion to recognize the reality that successful health interventions require more than the translation of biotechnological insights and novel therapies, but of equal importance is the translation of other "basic sciences" such as epidemiology, behavioral science, psychology, communication, cognition, social marketing, economics, and political science [7].

Perhaps a more contemporary model (Figure 1) should recognize the complex circular (iterative/recursive) nature of the translational research process, the feedback loops and intersections that can occur between various steps in the process, as well as the nonlinear progression from

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fundamental discovery science to population health impact in real-world settings. For example, the issues of preclinical replication were revealed in part because phase II trials were not able to produce findings that would be predicted from phase I trials. Furthermore, some lines of research might allow us to skip translational steps. For example, do we need all of the translational steps to show that placing signs next to elevators to encourage taking the stairs is effective? Would it not be enough to do a pre-/post—real-world test (T4)? Nonetheless, the pedagogical delineation of translational steps informs our understanding of what each step represents. Fundamental discoveries mark a possible but not obligatory initial entrance into the translation roadmap. Subsequent steps in the spectrum aim to bridge different stages of research: T1, between fundamental discoveries and human research; T2, between human research and patient research; T3, between patient research and clinical practice research; and T4, between clinical practices and real-world settings. An important distinction that sets T4 translation apart from other steps in the translational research spectrum is that it focuses on implementation research with emphasis on the contextual factors relevant for successful population-level intervention using evidence-based cost-effective treatments.

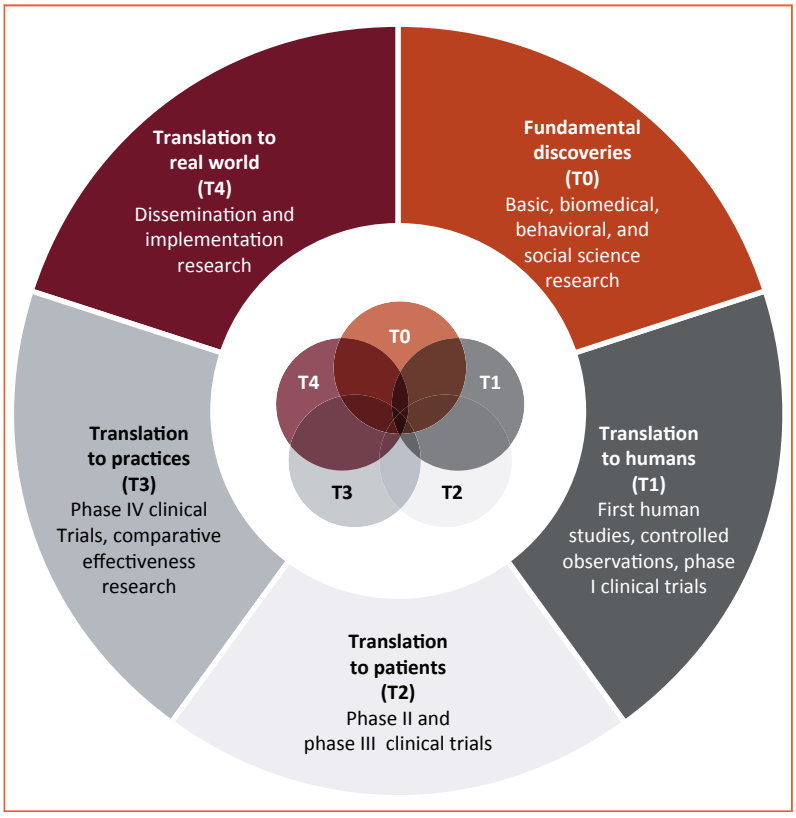

FIGURE 1. Translation research paradigm: fundamental research discoveries and translational steps toward implementation. The figure depicts the complex circular (iterative/recursive) process from fundamental discovery science to population health impact in real-world settings. The center of the donut demonstrates feedback loops and intersections that indicate progression is nonlinear and that translational steps may be skipped in some lines of research. The steps in the translation research spectrum are delineated. T0 represents fundamental discoveries in basic, biomedical, behavioral, and social science research. T1 translation is the initial translation of fundamental discovery to humans. T2 translation is the translation to patients and usually involves well controlled efficacy trials. T3 translation is the translation to clinical practices and centers on effectiveness (external validity). T4 translation is the final step, which focuses on translation of findings to real-world settings. Each translation step in the spectrum aims to address a different knowledge gap: T0, basic, foundational, or theoretical knowledge; T1, proof of concept knowledge, T2, efficacy knowledge; T3, effectiveness knowledge; and T4, context-specific applied knowledge.

Our successes and failures

The ultimate goal of research translation is to generate and deliver evidence for decision making in health. According to the *New Oxford American Dictionary*, "evidence" is defined as "the available body of facts or information indicating whether a belief or proposition is true or valid" [8]. Brownson et al. [9] describe 3 types of evidence available for decision making in health. Etiologic and/or epidemiologic evidence tells us that an action is required by defining the magnitude and severity of a health outcome and the preventability of its etiology [9,10]. Clinical trial evidence indicates what should be done by providing information on the comparative impact of specific interventions relevant to a health condition [9,10]. It is apparent that we have been very successful in amassing etiologic and clinical trial evidence. For example, the literature is replete with information on the incidence and prevalence of diseases and risk factors. Similarly, more than 1 million randomized controlled trials of medical interventions have been conducted over the past 50 years [11], a number of which have been distilled into clinical practice guidelines that are routinely updated and disseminated via various channels. For example, the National Guideline Clearinghouse contains over 2,000 individual guideline summaries [12]. However, we have performed poorly in the generation of implementation evidence that should guide decisions on how to implement evidence-based interventions by providing information not only on how to do so, but also the contextual elements of implementation [13].

Regarding health decisions, less attention has been paid toward late-state translation research. The bulk of the little attention that exists has been focused on components of T3 translation research (e.g., comparative effectiveness studies) with abysmally poor attention to T4 translation (implementation) research. The gravity of our poverty in implementation science is palpable in the case of hypertension, a health condition for which an array of well established, evidence-based treatment options exists. It is important to note that we have had treatment guidelines for hypertension since 1977 [14]. After more than 35 years

of hypertension treatment guidelines, the report card on their public health impact shows that a lot more could be done. Between 1980 and 2008, the global mean systolic blood pressure (SBP) decreased by only 0.8 mm Hg in men and 1 mm Hg in women, per decade [15]. Male SBP fell the most in high-income North America, by a modest 2.8 mm Hg per decade, but SBP rose in regions such as Oceania, East Africa, South Asia, and Southeast Asia for both sexes [15]. Furthermore, according to the Global Burden of Diseases, Injuries, and Risk Factors Study, hypertension is now a leading risk factor for mortality and disability adjusted life years (DALY) worldwide [16]. In the United States, recent reports indicate that the prevalence of hypertension, including uncontrolled hypertension remains high in some regions [17]. However, it is important to acknowledge that the modest 2.8 mm Hg decrease per decade in mean SBP in North America demonstrates progress in the efforts to control hypertension. It also suggests that there is a lot of room for improvement. Perhaps improving our fundamental knowledge about the implementability of guidelines may increase the return on investment for the millions of taxpayers' dollars spent on generating new evidence, rigorously reviewing and synthesizing existing evidence, and developing and updating clinical practice guidelines.

The jump from T3 to T4 appears to be the biggest leap and our failure to jump ranges from things we can control easily—such as fluoridation of water and iodination of salt—to problems that require real creativity, money and political will—such as establishing access to health systems, addressing health disparities, economics, poverty, and behavior change. These are really difficult dynamic, adaptive, and multiscale issues that require a research agenda because they are critically important for society, involve interventions that physicians do not do well or understand fully, and call for some unusual solutions such as getting society to exercise, stop smoking, build cleaner cities, or use cleaner fuels. Some of these T4 activities might fall in the area of public health—dealing with population health and ensuring the greatest health for the greatest number. Public health research has traditionally been the field that addresses some of these issues, and much of public health research attempts to figure out behaviors and obstacles that need to be changed to improve delivery of services and coverage with programs. The failure of T4 programs often falls in the realm of the social determinants of health and issues of health equity. Much of global health equity relates to where one is born; for instance, research into why sickle cell disease (SCD) patients die at an early age of 3 years in Ghana compared with at 53 years in the United States is not biologic but could be considered T4 translation.

Contributory factors

Thoughts about dissemination and implementation research largely began in the 1990s. It is fair to say that prior to this time the biomedical research enterprise predominantly assumed that the consumption of scientific literature by clinicians was sufficient for integrating interventions into clinical practice. The early 2000s ushered in organized calls for evidence-based strategies for dissemination and implementation, which has led to the current visibility and growth of the field of dissemination and implementation research. Simultaneously, there has been increasing awareness that the goal of discovery should also be to improve the human condition as opposed to satisfying scientific curiosity alone.

A path forward

From a public health perspective, the value proposition in funding biomedical research is to maximize the population health impact of the invested resources. Failure to achieve that value proposition is akin to a symphony left unfinished, which leaves the theater audience dissatisfied. Therefore, the path forward requires emphasis on the late stages of translation, especially T4 translation. Complete execution of the research translation spectrum is required to realize full benefits from the resources invested in preceding stages of the spectrum. Additionally, poor knowledge about highly effective implementation strategies in diverse populations contributes to health inequities. Consequently, implementation research platforms will be invaluable in addressing health inequities. In this context, such platforms can deal with multiple diseases and maximize impact while creating economies of scale. For example, a major academic health center in active partnership with its Clinical and Translational Science Award (CTSA) program, School of Public Health, Local or State Health Department, and network of Federally Qualified Health Centers, or other safety-net care centers can address a spectrum of chronic conditions such as asthma, sickle cell disease, and hypertension using a unified platform to accelerate implementation research in these priority diseases. We may benefit from "sustainable integration of interventions within dynamic health care delivery systems and the implementation of evidence-based systems of care rather than individual interventions" [18]. In addition, we should consider how to "embrace the increased globalization of health care research and encompass the application of dissemination and implementation across the world" [18]. This represents a viable path forward, which constitutes a paradigm shift and an answer to the eternal question, where are we going?

A PARADIGM SHIFT

Training programs, implementation research platforms, and context

The acceleration of growth in implementation science requires fundamental ingredients, 1 of which is the availability of research and theory on the principles and practice of effective implementation. In this regard, the recent book by Brownson et al. [19] is an invaluable tool that brings

together much of what is currently known about implementation research and captures the information growth that has taken place within the field. Another ingredient is the availability of well trained workforces capable of executing implementation research studies. The development and growth of training programs for implementation science needs to be catalyzed. Two multiyear efforts are prime examples worthy of recognition. The NIH-funded Implementation Research Institute (IRI) at Washington University [20] and the NIH-funded Training Institute for Dissemination and Implementation Research in Health (TIDIRH) at Harvard University [21]. The IRI has provided 2 years of training in implementation science related to mental health, principally supported by the National Institute of Mental Health and the Department of Veterans Affairs. Trainees attend 2 annual weeklong trainings provided through a rigorous curriculum, local and national mentoring, and exposure to a federally funded implementation research project, pilot research, and grant writing [20]. The TIDIRH is a 5-day annual training program developed and organized by multiple NIH offices and institutes, including the NIH Office of Behavioral and Social Sciences Research, in collaboration with the National Cancer Institute, the National Institute of Mental Health, National Institute of Diabetes and Digestive and Kidney Diseases, National Heart, Lung, and Blood Institute (NHLBI), and the Department of Veterans Affairs [21]. The growth of workforce for implementation research will be aided by the proliferation of programs similar to IRI and TIDIRH with emphasis on core knowledge for cross-disciplinary implementation research. One approach would be to incentivize various CTSA-funded institutions to develop implementation research training programs as a commitment toward broad and maximum societal impact. There is synergy between workforce training and the development of implementation research platforms. Arguably, in addition to stand-alone implementation research programs, existing robust research programs such as CTSA can be retrofitted to incorporate unified implementation research platforms that will address priority diseases, injuries, and risk factors.

Successful platforms will serve as epitomes of implementation science that truly capture what implementation research is and how to do it [22], by demonstrating the importance of modern quantitative methods and design (e.g., pragmatic designs [23]) as well as the relevance of integrating qualitative methods and metrics, which help us unwrap the answers to the complex contextual questions that quantitative methods cannot address. The quest to achieve optimal health outcomes requires that we understand how context interacts with health care interventions. To this end, implementation research employs context-sensitive study designs to evaluate what works, for whom, and in what context. This includes both adapting or modifying an intervention to a new context and testing it within that context. Contextual fit in implementation research is of primary importance and requires attention to sociostructural determinants to achieve effective integration of interventions into complex heterogeneous environments. However, we can improve implementation by not just accepting the current context but by changing the context. Thus, it is equally important to have a better understanding of how to change contexts that are modifiable to increase the likelihood of adoption. This is a particular problem for public health interventions, which often get pressed to fit within the dismal resources that are available instead of addressing headlong that the resources are inadequate and studying how to change the context in a cost-efficient way to make the resources adequate. Context is indeed paramount because some health inequities are a simple logical consequence of inadequate infrastructures to facilitate care and inadequate incentives (both for providers and patients) to implement empirically supported treatments. For instance, health outcomes and inequities may be adversely impacted in settings where medical practitioners are reimbursed the same whether they deliver empirically supported treatment or just nod their heads empathically. Thus in an effort to maximize population health impact we need to understand how to test interventions modified for specific contexts and how to change contexts to improve implementation.

Response from the NHLBI

Over the past 50 years, the NHLBI has provided global leadership in the funding and advancement of heart, lung, and blood research, which has resulted in effective diagnostic, preventive, and therapeutic interventions [24]. However, there remains ample room to speed up the translation of research evidence in an effort to achieve greater population impact [4,6,25]. For instance, ischemic heart disease remains the leading cause of mortality and DALY in the United States and globally [26–28]. In addition, the well known inequities in cardiovascular health outcomes have not only persisted, but they are worsening in some regions domestically and globally [29,30]. These realities led to the recent commitment by the NHLBI to renew emphasis on T4 translation research [31]. There are resulting developments that demonstrate the seriousness of the NHLBI's commitment. The first is the refocusing of the institute's agenda on generating rigorous evidence synthesis for the development of cardiovascular prevention guidelines. The NHLBI will now channel its effort toward a "public service leadership role in promoting health education by taking responsibility for generating the systematic review dataset and evidence syntheses that other organizations will use to develop cardiovascular guidelines" [32]. However, an equally important reason for undertaking systematic evidence review and syntheses is to guide the institute's agenda for addressing evidence and implementation gaps [33]. In addition, there is an overall response from the NIH as evidenced by the creation of various centers dedicated to improving research translation and implementation science [2,34] and increasing interest in dissemination and implementation research [35]. To facilitate further innovation and

accelerate knowledge dissemination and implementation science that enhances public health, the NHLBI has identified research translation as 1 of the 4 goals of its strategic visioning agenda [36].

RATIONALE FOR DOMESTIC AND GLOBAL LEADERSHIP

Starting in 2005, a trans-NIH multi-institute program funded a robust set of projects that reflect the growth and evolution of dissemination and implementation research and that signal future directions for advancement [35]. In a review of grants submitted through this program from 2005 to 2012, Tinkle et al. [35] highlight that it is paramount for future dissemination and implementation research efforts to include a focus on low-resource settings and high-risk populations such as low-income, minority, and low-health literacy groups. However, it is important to acknowledge that there are multiple contributors to health inequities, and that a differentially or inappropriately applied successful dissemination and implementation research agenda could similarly perpetuate or exacerbate current challenges in domestic and global health and health inequities. Nonetheless, a poor report card for implementation research is certainly of no benefit in addressing health inequities and global health. Recently, the U.S. Council on Foreign Relations (CFR) called for more robust U.S. global health involvement, especially regarding noncommunicable diseases (NCD) [37,38]. The task force commissioned by CFR found that NCD were largely responsible for premature burden of death and disability in many of the countries that receive significant U.S. health assistance [37]. The CFR concluded that NCD undermine the effectiveness of existing U.S. global health investments and represent an opportunity for the U.S. government to build on existing U.S. global health platforms to achieve sustainable reductions in premature death and disability, which disproportionately affect the poor.

Furthermore, the recent report on the state of U.S. health indicates that in 2010 ischemic heart disease, stroke, and chronic obstructive pulmonary disease were 3 of the 4 top-ranked contributors to the burden of diseases in the United States [27]; similarly, in 2010, they were the top 3 contributors to the global burden of diseases [26]. These findings suggest that efforts targeted at reducing the burden associated with chronic obstructive pulmonary disease, ischemic heart disease, and stroke will have significant domestic and global impact. Of note, these are disease conditions for which there exist formidable evidence-based prevention and treatment strategies. Thus improved implementation of existing evidence-based strategies may have far-reaching beneficial effects in reducing the burden of diseases domestically and globally. This potential beneficial scenario should provide impetus for leadership toward its realization. Similarly, recent reports on asthma and SCD provide additional rationale for concerted leadership. Asthma is a well characterized disease condition that affects as many as 334 million people [39], with rising burden in some regions as evidenced by increases in the prevalence of asthma symptoms in Africa, Latin America, and parts of Asia [40]. Similarly, the pathology and genetic-underpinnings of SCD have long been well understood; however, its associated death and disability in Sub-Saharan Africa has remained disproportionately high compared with the rest of the world. In 2010, the global age-standardized DALY per 100,000 population associated with SCD was 80.09 (60.00 to 102.40) compared with 281.16 (196.70 to 368.44) in Sub-Saharan Africa, which was in excess of the estimated 77.86 (58.01 to 98.96) for other developing regions [41]. These trends in global epidemiology call for global response in the dissemination and implementation of evidence-based prevention and treatment strategies.

SUMMARY

Although a universally accepted definition of translational research does not exist, it is widely accepted that the spectrum of translational research begins with fundamental scientific discoveries and ends with discovery of new knowledge for implementation of proven-effective interventions that, when applied will improve population health. Within this broad spectrum, various translational research steps have been identified. Current evidence shows that the biomedical research enterprise has been highly successful in early translational research, whereas much less success can be demonstrated for late phase translational research, especially T4 translation research. To maximize the population health impact of fundamental research discoveries, we have to endeavor to complete the execution of all steps in the translational research spectrum. In this regard, the stakes for T4 translation research and implementation science are very high. However, ongoing trans-NIH efforts provide reassurance that there is a path forward for success in confronting the challenges in the arena of implementation science. There is a growing symphony of activity within dissemination and implementation research as evidenced by funding announcements, annual meetings, trainings, publications, and studies; perhaps this is less a symphony than it is an instrument group burgeoning in vibrancy and in membership. Regardless of the viewpoint, the symphony of research discovery and impact requires this group—perhaps the string instruments—to sit beside the other translational groups and create the ultimate masterpiece.

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