

# Stakeholder Engagement in Late-Stage Translation Research and Implementation Science



## Perspectives From the National Heart, Lung, and Blood Institute

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### ABSTRACT

Stakeholder engagement is crucial for turning discovery into health. Although it is a highly effective approach for research in general, it is an essential component in late-stage translation research and implementation science in which the central objective is to accelerate the sustained uptake and integration of proven-effective interventions into routine clinical and public health practice. Where the stakeholder is an entire community, the term *community engagement* has often been used and has traditionally been defined as “the process of working collaboratively with groups of people who are affiliated by geographic proximity, special interests, or similar situations with respect to issues affecting their well-being.” More recently, this definition has been expanded to specifically incorporate pre-study needs assessment, shared decision making about study themes and specific aims, data collection and analysis, interpretation and dissemination of research findings, and plans for scale-up and spread of research findings. In this article, the authors explore the scientific foundations of stakeholder engagement in biomedical research and public health practice. They highlight the strategic vision goals and objectives of the National Heart, Lung, and Blood Institute and the commitment to advance dissemination and implementation research and community-engaged participatory research. The authors conclude with comments on the stakeholder engagement efforts in the National Heart, Lung, and Blood Institute—funded TREIN/Hy-TREC consortium’s work published in this issue of *Global Heart* and their perspectives on the challenges and opportunities as we chart the future together.

As one of 27 Institutes and Centers of the National Institutes of Health (NIH), the National Heart, Lung, and Blood Institute (NHLBI) is committed to the NIH goal of turning discovery into health [1]. We recognize that successful translation of scientific discoveries into proven-effective interventions that enable people to live longer and more fulfilling lives cannot be optimized without the active engagement of stakeholders. This is particularly important in late-stage translation research and implementation science in which the central objective is to accelerate the sustained uptake and integration of proven-effective interventions into routine clinical and public health practice. We also recognize that the public we serve, including patients, their families, and whole communities, represents our most important stakeholders. Our other stakeholders include research investigators, health care providers, other allied health professionals, policymakers, science and technology innovators, and health research trainees.

In this article, we first explore the historic perspectives of stakeholder engagement and its scientific foundations in biomedical research and public health practice. We address

the important contributions of several agencies and organizations in our understanding of stakeholder engagement. We then highlight the strategic vision goals and objectives of the NHLBI and our commitment to advance late-stage translation research and implementation science using community-engaged participatory research. We conclude with comments on the stakeholder engagement efforts in the NHLBI-funded TREIN/Hy-TREC consortium’s work in the global health arena published in this issue of *Global Heart*. It is important to note that, in this review, we focus predominantly on community engagement as our prototype stakeholder engagement and highlight other stakeholders when their engagement is considered crucial for addressing the challenging implementation research outcomes of acceptability, affordability, reach, and sustainability of interventions and implementation strategies for communities.

### HISTORICAL PERSPECTIVES

In 1997, the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry published the *Principles of Community Engagement* that

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defined community engagement as “the process of working collaboratively with groups of people who are affiliated by geographic proximity, special interests, or similar situations with respect to issues affecting their well-being” [2]. In 2011, the Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry were subsequently joined by the NIH, Health Resources and Services Administration, U.S. Department of Veterans Affairs, and other federal agencies, academic institutions, and community partners in publishing the second edition of the principles to further advance knowledge about community engagement [3]. Since then, community engagement has been seen as a vital component of efforts to expand access to quality care, prevent disease, and achieve health equity [2–4].

In 2006, when the NIH launched its Clinical and Translational Science Award program to transform the research enterprise at academic medical centers in the United States, the principles of stakeholder engagement were part of the central organizing constructs and seen as key in facilitating research and its translation to real-world settings [5]. For example, active involvement and engagement of the community was considered essential to the success of appropriate trial design, participant recruitment in research, and overall success of the Clinical and Translational Science Award program [5]. As the NIH director noted, the shift of disease burden “from acute conditions to chronic conditions primarily seen in community rather than tertiary centers,” requires active engagement of local and regional community stakeholders [6]. These community stakeholders importantly include patients, their health care providers, health systems, caregivers, family members, and civil society.

In November 2012, the Patient-Centered Outcomes Research Institute held its inaugural merit review of research applications that ushered in a focused appreciation of stakeholder engagement in clinical research at the patient level [7]. This event was the outcome of a deliberative process in which Patient-Centered Outcomes Research Institute leveraged its broad-based stakeholder community including especially patients, caregivers, and their clinicians, not only in the generation of topics for clinical research but also in the critical merit review of what applications to fund [7]. As summarized by Fleurence et al. [7], 363 scientists scored 480 applications in the first phase of the review. In the second phase, 59 scientists, 21 patients, and 31 stakeholders provided a “pre-discussion” score and a final “post-discussion” score after an in-person meeting for the review [7]. What became apparent in this process is that patient and stakeholder reviewers brought different perspectives that enriched the review process. Consistent with what others have noted, the involvement and active engagement of patients as stakeholders can change the types of research questions that are considered and their relative priority [8]. However, as the authors admit, additional data collection for long-term evaluation of the effect on the funded research is needed [7].

Most recently, the NIH has further highlighted the importance of stakeholder engagement in its *All of Us* research program, the flagship component of the U.S. Precision Medicine Initiative [9]. This research program seeks to create one of the world’s largest and most comprehensive precision medicine research platforms. As articulated in a recent funding opportunity announcement, the program is defined by impactful stakeholder engagement that comprises a “bidirectional, co-equal relationship between the program and its participants” and intended to “delight, educate, inspire, and establish a long-lasting connection with the communities they have been designed with” [10]. These stakeholder engagements are also intended to be customizable for many different communities to reflect the diversity of those living in the United States, including communities historically under-represented in biomedical research.

#### SCIENTIFIC FOUNDATIONS AND CHALLENGES IN STAKEHOLDER ENGAGEMENT

These historic perspectives paint a favorable and encouraging picture of stakeholder engagement and the number of publications on the subject has increased significantly, especially in the last decade (Figure 1). However, a rigorous assessment of how these principles should be applied, operationalized, or translated into real-world experiences and what constitutes best practices for adoption and implementation remain poorly understood. For example, as Cottrell et al. [11] point out, there have been few efforts to measure the benefits and tradeoffs of specific stakeholder engagement processes or different approaches for selecting and engaging different stakeholder types. How should research investigators evaluate the impact of their stakeholder engagement efforts based on the specific benefits they desire for their programs and their stakeholders. What is the evidence supporting best practices in stakeholder engagement?

In another rigorous assessment, Concannon et al. [12] conducted a systematic review of stakeholder engagement in comparative effectiveness and patient-centered outcomes research published in the peer-reviewed literature for the decade since 2003. They reported that stakeholder engagement was highly variable in content and quality. Additionally, they noted that engagement was frequent with patients and modestly frequent with clinicians; however, there was infrequent engagement with stakeholders in other key decision-making groups across the health care system [12]. Importantly, stakeholder engagement was also less frequent in implementation and dissemination research in comparison with earlier stages of research [12]. Based on these findings, Concannon et al. [12] recommended 3 directions for future research that include improvements in descriptive research on stakeholder-engagement in research; evaluative research on the impact of stakeholder engagement on the relevance, transparency, and adoption of research; and development

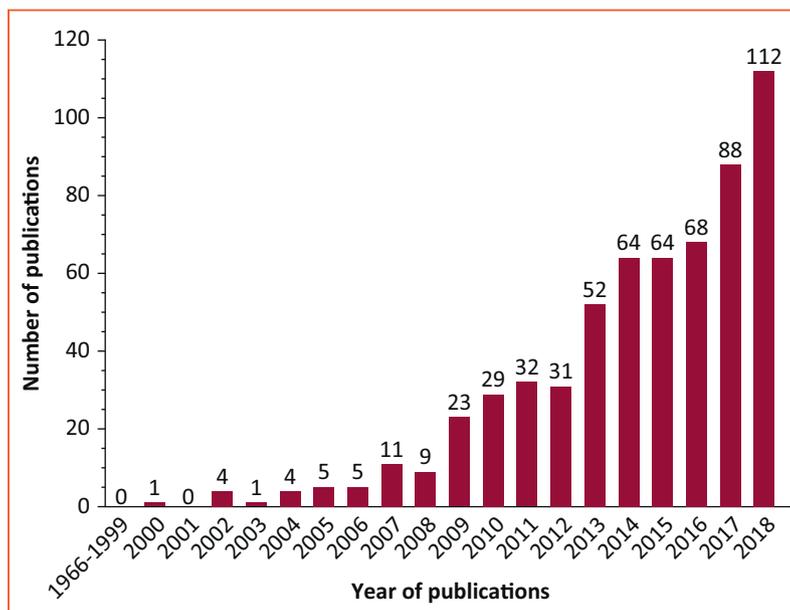
and validation of tools to support further research in stakeholder engagement. It is noteworthy that the 7Ps Framework for Stakeholder Engagement upon which Concannon et al. based their work is the same framework used in the report from Nepal [13] in the collection of articles published in this issue of *Global Heart*.

### LESSONS FROM THE TREIN/Hy-TREC CONSORTIUM

The articles on stakeholder engagement published in this issue of *Global Heart* represent the work of the NHLBI-supported TREIN/Hy-TREC Consortium investigators [13–24]. The articles highlight the consortium's commitment to “forging a path forward through partnerships and meaningful engagement with individuals, communities, public interest groups, and governments to conduct innovative research that will generate the impact necessary to reduce avoidable and premature death and illness from NCDs for all patients and people,” as articulated in the Kathmandu Declaration [14]. Importantly, they highlight a spectrum of strategies used for active stakeholder engagement and related opportunities for fostering peer to peer learning and sharing best practices as fostered by the NHLBI [13,15–18].

For example, stakeholders at the national level will be invaluable for successful implementation research and need to include Ministries of Health; key national and regional institutions, health systems, and networks; and health care providers and their national and regional professional organizations. Similarly, engaging clinical and public health thought-leaders at the national, regional, and local community levels, including those in rural, urban, and periurban settings, will be invaluable. The human immunodeficiency virus (HIV) and other communicable disease experts also represent crucial stakeholders whose expertise, resources, and infrastructure for health care and research could be leveraged to advance implementation research in cardiovascular and other chronic diseases, especially when they manifest as comorbidities in people living with HIV. Efforts in Malawi have engaged the national HIV program and leveraged its resources, models, and platforms for implementation research. Their focus has been on integrated chronic care for hypertension, diabetes, asthma, and epilepsy as well as screening, diagnoses, and treatment of hypertension, and is quite instructive [22,23].

Stakeholder engagement at the subnational and local community levels is the soul of successful community-participatory implementation research and has been highlighted in these articles. For example, Rwanda has engaged and trained multiple stakeholders with their focus on regional infrastructure needs to study dissemination and implementation strategies for hypertension and cardiovascular disease control [19]. In Tripura State, India, multiple levels—including political leadership, health administrators, and health professionals—are engaged in effective delivery of a new health system intervention [17]. The program recognized that success will require patients,



**FIGURE 1. Number of publications with stakeholder engagement or community engagement in the title, from PubMed, National Library of Medicine, 1966 to 2018.**

health care providers, health system, and leadership to recognize the immediate and long-term benefits of the new intervention. In Ghana, stakeholders are identifying facilitators and barriers to the adoption of evidence-based task-shifting strategies for hypertension management [20,21]. Stakeholders include community health officers, administrators, policymakers from the Ghana Health Services, researchers, and community health officers in community-based regional health planning services [20,21]. In Guatemala, patients, family members, community members, health care providers, and Ministry of Health officials from 5 districts in Guatemala City are being engaged to help define details of the planned evidence-based interventions to be studied [16]. In Vietnam, the study team has engaged leaders of provincial Departments of Health, physicians, nurses, community health workers, and patients and gained support for a storytelling intervention to help control hypertension, which is adaptable to local cultural needs [15].

### CHARTING THE FUTURE: OPPORTUNITIES AND THE PATH FORWARD

With consistent and ubiquitous community engagement and an enduring principle to support implementation science that empowers patients and enables partners to improve health, NHLBI is charting a path forward. The 2016 NHLBI Strategic Vision was developed with the participation of stakeholders from 50 states and 42 countries and inputs in the form of 42,000 votes from close to 4,500 participants. Implementation of the NHLBI Strategic Vision goals and objectives calls for a continuing

engagement of diverse stakeholders that include the research investigators, health care and allied health professionals, patients and their advocates, communities, professional organizations, policymakers, and members of the general public [25]. Following suit, the TREIN/HYTREC Consortium members have robustly and proudly embraced the importance of stakeholder engagement for health research in low- and middle-income countries, as published in this issue of *Global Heart*.

As we chart the path forward for 2020 and beyond, we uphold a commitment to continue to foster “ongoing dialogue through different forums, to solicit and incorporate in our research program the best ideas of our community while keeping our strategic research priorities nimble and adaptive to scientific advancements and opportunities” [25].

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