

Stakeholder Engagement in Late-Stage Translation Phase 4 Research for Noncommunicable Diseases in Low- and Middle-Income Countries

What Works and Why—The Vietnam Experience (UMMS—Vietnam Team)

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ABSTRACT

Background: Stakeholder engagement is crucial for conducting high-quality implementation research as well as for the incorporation and adoption of health interventions and policies in the community.

Objectives: This study sought to build a mutually rewarding collaboration between stakeholders in Vietnam and investigators in the United States.

Methods: A collaboration was established between investigators from several institutions in Vietnam and the University of Massachusetts Medical School that was built on mutual trust, cross-cultural learning, and shared experiences. This collaborative arrangement has led to sustainable stakeholder engagement in Vietnam. We formed a multidisciplinary transnational research team and maintained regular contact both online and in person. We also conducted a needs assessment study, in which several focus group discussions and in-depth interviews of stakeholders in Vietnam were carried out.

Results: The formal collaboration between investigators in Vietnam and the University of Massachusetts Medical School began in 2011 and has strengthened over time. The U.S. team provided expertise in study and intervention design, data collection and analysis, and trial implementation, whereas the team in Vietnam brought a deep understanding of local health care delivery systems and expertise in the delivery of health care interventions at the grassroots level. Our initial partnership has now grown to include committed individuals at the government, academic, and community levels including the Vietnam Ministry of Health, key governmental and nongovernmental research institutions and agencies, medical and public health universities, and communities in rural settings. The needs assessment study found that there are important gaps in the delivery of hypertension management practices in many rural communities in Vietnam and that stakeholders are fully engaged in our ongoing, community-based, hypertension-control project.

Conclusions: Multiple layers of stakeholders and communities in Vietnam are fully engaged with, and have contributed significantly to, our ongoing hypertension control research project in Northern Vietnam.

Vietnam, a low-to middle-income country (LMIC), is currently facing a high and growing burden of morbidity and mortality associated with noncommunicable diseases (NCD) [1,2]. In 2012, it was estimated that approximately three-quarters of all deaths and two-thirds of the total burden of disease in Vietnam were due to NCD, including cardiovascular disease (CVD), cancer, diabetes, and chronic respiratory disease [2]. The changing epidemiological profile of disease in Vietnam can be

attributed to changes in the sociodemographic characteristics of the population, predisposing factors, and to increases in life expectancy [1–5]. Major risk factors for NCD are either on the rise or at levels of major public health concern in Vietnam, including elevated blood pressure, hyperglycemia, dyslipidemia, overweight, smoking, excessive use of alcohol, unhealthy dietary practices, high salt intake, and a lack of regular and vigorous physical activity [6,7].

The authors report no relationships that could be construed as a conflict of interest.

This work is supported by the National Heart, Lung, and Blood Institute of the National Institutes of Health under award #U01HL138631-01.

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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GLOBAL HEART
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VOL. 14, NO. 2, 2019
ISSN 2211-8160/\$36.00.
<https://doi.org/10.1016/j.ghheart.2019.05.003>

LATE-STAGE (T4) TRANSLATION RESEARCH FOR NCD AND THE PRESENT SITUATION IN VIETNAM

The translational research spectrum includes 5 stages: T0 represents fundamental discoveries; T1 denotes the initial translation of fundamental discovery to humans; T2 covers the translation of research findings to patients, usually involving well-controlled efficacy trials; T3 denotes the translation of these research findings to clinical practice with a focus on external validity; and T4 represents the final step in this research and translational spectrum that focuses on the incorporation of research findings to real-world settings and populations [8].

Late-stage research tackles complex real-world settings with innovative study designs and analytic methods primarily focused on evaluating the implementation strategies utilized for delivering proven effective interventions [9]. At the latter stages of translational research, implementation science provides methods to promote the adoption and integration of evidence-based interventions, strategies, and policies into routine health care and population settings [10]. The National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) recently emphasized the importance of promoting late-stage research in NCD in LMIC. This federal governmental agency emphasized the need for improving research capacity and building a cadre of T4 researchers who can conduct high-quality research within the local context and environment [11,12].

Despite the magnitude and impact of NCD in developing countries, there are extremely limited epidemiological data available describing this increasing cause of morbidity, mortality, and loss of functional status in LMIC such as Vietnam, especially from the more generalizable perspective of population-based investigations and during recent years. Similarly, there are a limited number of later phase studies examining the implementation process and effectiveness of community-based interventions and/or health strategies to improve the management and control of NCD and their major predisposing factors in Vietnam. There remains a compelling need for high-quality implementation and dissemination research, including large-scale epidemiological studies and community-based intervention trials, to provide better evidence for the formulation, planning, and eventual dissemination of regional and national health policies in Vietnam and other LMIC to reduce the magnitude and impact of NCD and their major risk factors.

This paper describes our experiences in building a mutually rewarding collaboration between stakeholders in Vietnam and investigators in the United States during the past several years, particularly in the context of the *Đường đi với bệnh Tăng huyết áp ở Việt Nam: Giải pháp từ tế cơ sở* (Conquering Hypertension in Vietnam: Solutions at Grassroots Level) (U01) project, which is currently funded by the NIH/NHLBI.

METHODS

The collaboration between investigators from several institutes, universities, and governmental agencies in Vietnam and the University of Massachusetts Medical School (UMMS) has been built on mutual trust, cross-cultural learning, and shared experiences, and has led to considerable and sustainable stakeholder engagement in several NCD-related research projects. We formed a multidisciplinary transnational research team and maintained regular contact both online and in person. We also conducted a needs assessment survey in which we conducted several focus group meetings and in-depth interviews with several key personnel in Vietnam, including leaders from the departments of health and provincial and district hospitals in Hung Yen province, in 2018.

RESULTS

From the beginning of our collaboration, the Vietnam Ministry of Health has provided guidance about overall direction on matters such as topics to be addressed and intervention approaches that can be pursued in this LMIC. We have prioritized our research agenda to respond to the local health issues raised in these discussions, with high blood pressure and cigarette smoking being 2 pressing public health issues of contemporary importance. The Ministry of Health expressed its full commitment to the nationwide dissemination of any effective evidence-based strategies emerging from our ongoing work. Furthermore, the Ministry of Health emphasized the importance of strengthening international cooperation with different countries, research institutes, medical and public health universities, and professional associations in the region and worldwide to improve capacity for Vietnam in NCD research, in the training of future scientists, and in fostering present and future prevention and control efforts.

COLLABORATION AMONG UMMS, BAYLOR SCOTT & WHITE HEALTH, AND VIETNAM IN THE HYPERTENSION PROJECTS

First NIH funding grant experience

Chúng ta nói về bệnh Tăng huyết áp (We Talk About Our Hypertension) study (R21). Hypertension is a well-established risk factor for NCD, in general, and CVD in particular. As more than 40% of adults 50 to 69 years of age in Vietnam have been diagnosed with hypertension (HTN), the Ministry of Health has sought to find more effective strategies to cope with this major NCD risk factor and disease condition [7]. To this end, we received initial funding support from the NIH Fogarty Center to carry out a pilot feasibility study using a storytelling intervention to improve HTN control among 160 patients with uncontrolled HTN (2014 to 2016). Details of this study have been published previously [13,14].

Receipt of this federal grant was extremely important because it catalyzed and further strengthened the effective

collaboration between investigators from these 2 countries. We formed a multidisciplinary transnational research team and maintained regular contact both online and in person. We set up regular e-mail exchanges, monthly Web-based conference calls, and made the first visit to Vietnam in March 2016. In addition, several Ministry of Health officials visited with a number of faculty at UMMS and discussed future collaborations and possible research projects with investigators from UMMS in August 2016. Through regular contact and subsequent site visits, we have established a strong personal and professional relationship between the U.S. and Vietnam study teams. The U.S. team became familiar with officials from the Ministry of Health in Vietnam, and their support for our ongoing projects, and obtained a greater understanding about the health care system in Vietnam and how future NCD prevention and control efforts and policies could be incorporated nationwide.

The team of investigators from UMMS has significant clinical and methodological expertise in developing, implementing, and evaluating programs to control HTN in different population settings. Complementing this expertise, the investigators from Vietnam have a deep understanding of local and regional health care delivery systems and expertise in the delivery of health care interventions at the grassroots level. We have engaged members of our research team with committed individuals at the government, academic, and community levels including the Vietnam Ministry of Health, key governmental and nongovernmental research institutions, medical and public health universities, and communities in rural settings to develop a plan of action and design a randomized controlled trial to enhance the treatment of middle-age and older Vietnamese men and women with uncontrolled HTN.

During a visit to Vietnam in 2016, we visited Hung Yen province, a typical rural setting in northern Vietnam, where the study team met with a number of leaders at the Provincial Department of Health, physicians, nurses, community health workers, and patients and discussed our proposed storytelling intervention, which would be adapted to local cultural needs. During our discussions, each of these groups expressed their full support of our work and highlighted the potentially positive impact of our intervention to their community. One head of the local community health center stated “the Storytelling intervention is very new to us; we like it a lot and we believe that it will help our patients to better manage their blood pressure.” Through these numerous meetings and subsequent discussions, we understood deeply the needs of the population and health care system at the grassroots level in Vietnam. In these highly informative sessions we have been able to design and implement more appropriate intervention strategies for the enhanced management and control of NCD and their major predisposing factors, including HTN and tobacco use, in the Vietnamese population through funding support provided by the NIH.

Subsequent NIH funding support

Đương đầu với bệnh Tăng huyết áp ở Việt Nam: Giải pháp từ Y tế cơ sở (Conquering Hypertension in Vietnam: Solutions at Grassroots Level) study (U01). Building on our encouraging results from the feasibility trial of HTN control [13], we are currently 1 of 5 LMIC projects to receive recent funding support in the form of a U01 grant from the NHLBI-supported Global Health Program (Hy-Trec program) to conduct a large-scale clinical trial of HTN control in Vietnam. We have proposed to evaluate the implementation and effectiveness of 2 multifaceted community- and clinic-based strategies for the control of HTN among adults residing in rural Hung Yen province.

In brief, a total of 16 communities will be randomized to either an intervention (8 communities, 300 patients with uncontrolled HTN) or comparison group (8 communities, 300 patients with uncontrolled HTN). Both comparison and intervention groups will receive a multilevel intervention modeled after the Vietnam National Hypertension Program, a program jointly developed by the Vietnam Ministry of Health and the Vietnam Heart Association. Components of this program include education and practice change modules for health care providers, easy-to-read brochures for patients with HTN, and a community awareness multimedia program. In addition, the intervention group will receive 3 carefully selected enhancements integrated into routine clinical care: 1) expanded community health worker services; 2) home blood pressure self-monitoring; and 3) a storytelling intervention, previously developed and pilot tested for feasibility and effectiveness in Vietnam by our research team [13,14]. The Health Strategy and Policy Institute, a key research institute that is part of the Vietnam Ministry of Health, is the primary recipient of this grant. The institute's functions include the following: 1) conducting research to provide evidence for the Ministry of Health and related stakeholders for health policy development in Vietnam; 2) serving as an advocate or adviser on health policies and strategies for the Ministry of Health; and 3) providing training in health policy and in the strengthening of health care systems.

We have strengthened our collaboration with Ministry of Health officials and the Health Strategy and Policy Institute through numerous online meetings and a recent visit to Vietnam in May 2018. During that visit, we met with officials from the General Department of Preventive Medicine, Division of Non-Communicable Diseases, at the Ministry of Health to discuss our current study and potential for future collaborative activities. A Ministry of Health official said that “NCDs account for 3 quarters of all deaths in Vietnam, CVD is the leading cause of these deaths, and hypertension is the most important risk factor for CVD in Vietnam. We urgently need effective interventions to combat the NCDs, in general, and CVD in particular. We fully support the ‘Conquering Hypertension

TABLE 1. Challenges and solutions

Challenges for Stakeholder Engagement	Structural Barriers
<ul style="list-style-type: none"> • Identifying necessary stakeholders. • Defining appropriate approaches to targeted stakeholders. • Language barriers. • Low willingness to participate in the study. 	<ul style="list-style-type: none"> • Low capacity in carrying out T4 research leading to limited late-stage and high-quality research. • Limited training curriculum in NCD research at medical school. • Limited mechanisms and collaboration in bringing scientific evidence to policy makers that could be translated to effective health recommendations.
Overcoming Challenges for Stakeholder Engagement	Overcoming Structural Barriers with Facilitators
<ul style="list-style-type: none"> • Get policy makers involved from the beginning. • Work with officials at the Ministry of Health to define solutions to overcome stakeholder engagement challenges. • Identify key individuals necessary for execution and success of research projects. • Obtain support documents from the Ministry of Health to send to provincial departments of health to carry out the projects. • Partner with research institutions affiliated with the Ministry of Health. 	<ul style="list-style-type: none"> • Develop effective communications such as regular e-mail exchanges, monthly Web-based conference calls, and direct visits to build trust. • Visit research sites to discuss and interact with stakeholders about the research projects in a culturally appropriate manner. • Conduct focus group discussions and in-depth interviews with key personnel to explore needs and willingness to participate in the study. • Empower local researchers with financial and mentoring support. • Establish a research and training center at the most well-known medical university. • Identify and recruit researchers and stakeholders from various sectors. • Establish a track record of peer-reviewed publications initially.

NCD, noncommunicable disease.

in Vietnam: Solutions at Grassroots Level' study, and are committed to implementing it nationwide if it is shown to be effective. Moreover, we would like to work with members of the U.S. team to conduct more research studies in NCDs and CVD."

As part of this project, we performed a needs assessment study in which we conducted several focus group discussions and in-depth interviews with a number of key personnel in 2018; these included leaders from the Department of Health and provincial and district hospitals in Hung Yen province. We found that there are some gaps in the delivery of HTN management practices in Hung Yen province. These included limited roles of commune-level health facilities in providing HTN treatment, a lack of financial support resources, limited capacity of community health workers (village and commune), and a lack of coordinated and continuity care for HTN management across varying levels of care. Each of the respondents expressed their high willingness and strong commitment to support and participate in our HTN-management research project. Health care workers desired to have more targeted training to improve their knowledge and skills in HTN treatment and management.

When we asked these diverse individuals about the approaches that we should consider in designing community-based interventions for HTN control, a leader

from a district hospital shared this comment: "An effective hypertension control strategy should be implemented at the grassroots level with community engagement. Hypertension should be detected at an early stage, and the community health workers will play important roles in this process as they have a deep understanding about their community members and their needs." When asked about their willingness to participate in the study, a program coordinator at the Centers for Disease Control at the provincial level stated "Our office is responsible for organizing and coordinating all health project activities at the provincial level. In your project, I will serve as a focal point at the provincial level to facilitate the project implementation. We will provide guidance for local staff and carry out various monitoring activities as part of your research project." In summary, stakeholders are fully engaged in our HTN research project, which will greatly facilitate the implementation and success of this ongoing project.

Challenges and solutions to overcome these challenges

Table 1 presents the challenges that we have faced during the HTN project, and our proposed solutions to these challenges.

DISCUSSION

Our activities and project portfolio in conducting meaningful community-based translational and implementation research in NCD in Vietnam continues to grow. This collaborative effort has strengthened over time as we maintain close contact between members of the Vietnam and UMMS teams via conference calls, meetings, exchange visits, and shared publications. Multiple layers of stakeholders and communities in Vietnam are fully engaged with, and have contributed significantly to, our ongoing community-based HTN-control project.

There are several lessons learned that we would like to share. First, these collaborations take time to build and require the establishment of trusting relationships that come with time spent together. Bidirectional travel and Skype-type meetings can be extremely beneficial for solidifying these associations as well as establishing project momentum. Second, collaborations should often start with small projects, establishing a track record of peer-reviewed publications that can provide a strong initial foundation. Third, the LMIC should provide the primary guidance about overall direction on matters such as topics to be addressed and intervention approaches to be utilized, with the research-intensive institution providing support to integrate the principles of translational research and implementation science. Fourth, the collaboration should include researchers and stakeholders from a number of sectors, including academic and governmental agencies. Lastly, policy makers should be involved from the very beginning to achieve buy-in and ensure that research findings will be sustained through national buy in and efforts of dissemination of worthwhile programs at the level of the community and its individual members.

CONCLUSIONS

Key community, health care, and governmental stakeholders are fully engaged in our HTN research project and our collaboration has strengthened significantly over the past several years. Our research and training collaboration aims to find and subsequently promote evidence-based health policies and improve clinical, public health, and translational research and project management for Vietnam. The ultimate goal of these shared experiences and developing portfolio of primary and secondary prevention NCD research projects is to improve the general health status of the Vietnamese population and reduce the magnitude and impact of the major risk factors for NCD. This collaboration is an excellent opportunity for

investigators in the United States and Vietnam to exchange knowledge and ideas, strengthening a bilateral and mutually satisfying relationship between the 2 countries. This exchange will continue to provide important points of connection for clinical and public health research and for facilitating the efficient and productive exchange of study protocols, data, and disseminable scientific and training results, thereby increasing the research output and capacity of both countries.

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