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The many faces of translational research: a tale of two studies

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Abstract

Translational research can take many forms: bench to bedside, across cultural groups, across geographical boundaries, among others. This case study will share how we addressed all three "translational" issues using two evidence-based studies (USA, Zambia) to illustrate these "roads less traveled." Our implementation and dissemination efforts were anchored by the "train the trainer" strategy, and the Glasgow RE-AIM model provided programmatic guideposts and direction. Keeping all stakeholders (scientific, community, political) involved in the implementation and dissemination process was an essential, perhaps determining factor in the success of the translation process.

Keywords

HIV prevention; Sexual risk reduction; Training of trainers; RE-AIM; Translational research; Women and couples living with HIV

The term "translational research" typically refers to "bench to bedside" whereby researchers attempt to convert evidence-based scientific findings into practical clinical service or public health prevention programs [17]. Another form of translation concerns enhancing the portability of a successful program from one cultural setting to another. Finally, there are translation programs combining the abovementioned forms for translation, both within and across geographical boundaries. In this case study, we will consider the process whereby behavioral interventions from two National Institute of Mental Health (NIMH)-supported clinical studies underwent the various transformations alluded to above, including lessons learned in one study providing guidance to the second and subsequent studies. The two translation studies are evaluated within the framework of Glasgow's RE-AIM model, and in closing, recommendations for long-range planning using the model are provided.

The first study, the SMART/EST Women's Program (SWP) (e.g., [3–5, 7, 18, 19, 22, 24]) began in 1996 as an effort to improve the quality of life and health status of ethnically diverse disadvantaged women living with case-defined AIDS. The initial program included ten weekly 135-min group sessions based on cognitive behavioral stress management principles combined with an expressive–supportive therapeutic component [23]. Successful findings from this research program, combined with major pharmacologic treatment advances led to the expansion of the study population to include *all* women living with HIV, and broadened the scope of the intervention to include a healthy lifestyle program specifically tailored to the needs of HIV+ women. The number of weekly sessions was

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increased from ten to 16 to accommodate the additional health promotion content. In addition, the entire program was translated from English into Spanish and Creole, to make the program accessible to monolingual women from Latin America and Haiti. The linguistic translation became the starting point rather than the conclusion of the translation process. Extensive formative efforts were required to establish “cultural” as well as “linguistic” equivalence to the original version of the intervention. A cultural brokerage committee chaired by an anthropologist and composed of members of the respective cultural and subcultural groups as well as psychologists, recruiters, and case workers exhaustively reviewed all elements of the intervention for cultural equivalence.

The positive findings from this study resulted in a successful application to the Center for Disease Control and Prevention to translate our evidence-based research program into five community health centers (CHCs) in Florida, New York, and New Jersey (2007–2011). Before proceeding further, let us take a brief look at our companion program in Zambia.

Following a 1998 Grand Rounds presentation of the results of the SWP, a Fogarty scholar visiting from Zambia approached us to request that we consider piloting the sexual risk component of the study in Zambia. The subsequent collaborative grant supplement was funded in 1999 and allowed us to undertake a feasibility study designed to reduce sexual risk behavior, HIV reinfection, and transmission among Zambian women living with HIV. Again, extensive formative efforts were required to adapt the intervention to the cultural context of women from the various Zambian ethnic groups. Based upon our experience to date, we determined that four weekly 2-h group sessions would be required to engage participants in the informational and experiential content as a “stand alone” program.

Data from this pilot [6] provided the foundation for a larger-scale NIMH-supported clinical study to confirm and extend the findings from the feasibility studies in both Zambia and USA. In tailoring this group intervention for the Zambian populations, we were acutely aware of the importance of accurate translation into Zambian languages, a process which continued to evolve across both the pilot and the original NOW project. We utilized certified translators from the University of Zambia and performed back translations by our study team, in which back translators were bilingual in English/Nyanja and English/Bemba. However, nuances of translation, e.g., the use of “town Nyanja” versus “rural Nyanja” required the team to make additional revisions to the materials.

The Zambian pilot study data provided the foundation for culturally guided revisions of the original intervention. The US SWP had been developed within a cognitive behavioral stress management (CBSM) plus expressive–supportive therapy (i.e., CBSM + EST) theoretical framework. Within this framework, increasing self-efficacy, problem-solving coping responses, perceptions of social support, and medication adherence while reducing anxiety, depression, and sexual risk behavior were “mechanisms” for improving overall quality of life and health. The intervention sessions were modified to address Zambian issues (e.g., using culturally tailored role plays), and the EST components that focused on HIV themes that were salient to the Zambian context, e.g., HIV stigma, spirituality, domestic violence, and gender issues, were highlighted. The application of the SWP CBSM+ theoretical framework to the Zambian context also required the adaptation of the materials related to gender-specific self-efficacy and assertiveness. These issues were tailored to be congruent with the role of women within the more male-dominant Zambian society, e.g., provision of consent and permission to participate by male partners, respecting reluctance to engage in covert use of female sexual products.

Inquiries about the program from male partners of the study participants suggested the possibility of improving study outcomes by including these partners in a “couples” version

of the intervention. Pilot interventions including both women and men led to NIMH- and National Institute of Child Health and Human Development (NICHD)-supported larger scale studies in Zambia and USA with couples [8–11, 13–16, 20, 21]. The findings from these couple studies confirmed the desirability of working with both partners concurrently, albeit separately, in gender concordant groups, and a pilot translation to a community health center was successfully conducted [12]. A funded application to NICHD to translate the intervention into the community through six CHCs in Zambia led to extensive groundwork to optimize the introduction and uptake of the program, including criteria for the selection of CHCs, clinic staff sensitization and "buy in," and support from the Ministerial and Provincial Health Department leadership to the local community advisory boards (CABs) at each community health center. The CABs became the principal source of adapting program components to the unique circumstances of the community, serving as advisors, participants, and recruiters of program participants from the community.

In both the Zambian and the US studies, the "translation" model involved the selection, training, and technical support of qualified CHC staff using the "train the trainer model [1] to ultimately assume independent leadership of the intervention program. Health care providers, counselors, and health educators in these studies were trained to teach other providers who then returned to their community health centers to disseminate the training to additional staff members. The goal of the translation studies was to use this "train the trainer" strategy to expand the reservoir of competent trainer/facilitators, as the backbone of the dissemination and implementation process.

Sharing the interim findings of this translation effort with the Center for Disease Control and Prevention program staff in Zambia led to their request to further develop the dissemination program to include *all* community health centers in the nine provinces of Zambia, a current "work in progress." The program is being systematically disseminated to provinces across Zambia with the support of the Ministry of Health, and the leadership in the Provincial Health Offices, the District Health Offices within the provinces, and the directors of Community Health Centers. Thus, the "train the trainer" model is the key translation mechanism for this large-scale endeavor, whereby a qualified CHC staff is identified by the CHC leadership and participates in an initial 2-day intensive workshop. Following the workshop, the trained CHC staff receives one-on-one supervision during the first two cycles of the intervention, after which the CHC staff conducts the intervention themselves with oversight and "on call" support from our project staff.

So, how did all of this come about? What was planned? What was "being in the right place at the right time?" What was sheer luck/circumstance? Looking over one's shoulder is always a chancy proposition as "selective recall" can certainly bias recollection, but there were certain "choice points" and opportunities which provide some guidance from a "lessons learned" perspective. By keeping our Zambian scientific colleagues, the CHC leadership and community advisory boards completely involved and engaged as partners at each step of our scientific "journey," our role as advisors and "coaches" kept the agenda and rhythm of the program in their court. Visiting the various academic and Ministry of Health officials in the company of our Zambian colleagues on each of our semiannual visits ensured that the funders were apprised of the study's progress and enlisted their support for forthcoming activities. Routine meetings with the University Ethics Committee (IRB) ensured that any concerns regarding study procedures were rapidly addressed. Mindful of certain cultural sensitivities, e.g., Zambian citizens being used as "guinea pigs," all studies conducted in Zambia were matched by having identical studies concurrently conducted in the USA.

The purpose of this case study is not to dwell on the details of these studies, which are described in the publications referenced above, but to consider and illustrate how the RE-AIM model [2] served as the theoretical framework for translating these evidence-based interventions into community clinical practice. The RE-AIM model describes five major components associated with effective translation from academic to community health care settings: reach, effectiveness, adoption, implementation and maintenance. This model posits that efficacy in the "laboratory" must be substantiated by effectiveness and consistency in real world settings. Reach is the number, proportion, and representativeness of individuals willing to participate in the program. Effectiveness describes the impact of the intervention on specified outcomes. Adoption represents the number, proportion, and representativeness of CHCs that are willing to incorporate the intervention into their health care delivery program. Implementation is the fidelity to the various elements of an intervention, including consistency of delivery. Maintenance is the extent to which a program becomes institutionalized as part of the routine "standard of care" within the CHCs.

Both the US and Zambian translations began with the assessment of CHCs available and able to conduct the intervention, and included formative and process assessments of clinical as well as site outcomes, e.g., participant attendance and clinical outcomes, facilitator participation in intervention training, staff turnover, and clinic uptake. Similarly, both studies assessed the number of sites willing to integrate the intervention into their regular program of services and utilized measures of fidelity to the intervention components. Finally, both studies assessed the maintenance of the program within and following the study period. Thus, the RE-AIM model provided a comprehensive framework to gauge organizational as well as clinical success of the translational process. However, both studies also found that program *maintenance* was dependent, in large measure, on the proactive identification of sources of funding to sustain the program beyond the research and demonstration phases of the program. Therefore, this model for translation needed to be expanded to include strategies for continued program support through existing health care reimbursement structures. Within this framework, it appears essential to include the financial as well as clinical requirements in long-range planning in order to achieve successful program translation.

SUMMARY

Translating evidence-based interventions from academia to the real world of service delivery is not for the faint of heart; additional challenges arise when adapting programs across geopolitical boundaries as well. A consideration of cultural and subcultural values in the context of the prevailing health care infrastructure of the host country requires extensive and intensive involvement of the host country stakeholders from the Ministry of Health to the CHC program facilitators and CAB members. The centerpiece of the translation effort, the "training of trainers" model, provided the vehicle for the systematic transition from "outside experts" to on-site facilitators capable of training their CHC colleagues, thereby enabling new health care interventions and services to become self-sustaining, the final step in the RE-AIM model.

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Implications

Practice

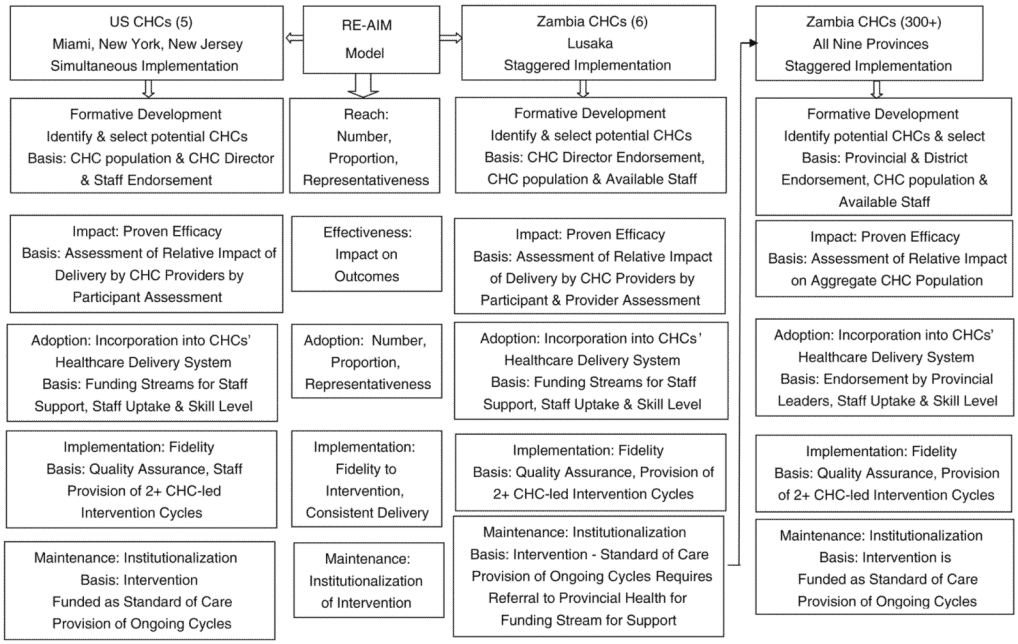
An evidence-based HIV prevention strategy based upon cognitive behavioral stress management principles can be disseminated to community health centers using a “train the trainer” model to facilitate translation at the national level.

Policy

Keeping all stakeholders involved in program dissemination is essential to an effective translation process.

Research

Further study is required to better understand the “mechanisms” involved in the translation process, particularly how the various clinical, administrative, community, and policy-maker stakeholders may contribute to the success (or lack thereof) of the process.



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