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"Global Health in the Dominican Republic: Progress and Obstacles to Scale Up and Implementation of Successful Programs"

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GLOBAL HEALTH IN THE DOMINICAN REPUBLIC:

PROGRESS AND OBSTACLES TO SCALE UP AND IMPLEMENTATION OF SUCCESSFUL PROGRAMS

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Abstract

Implementation science is a powerful framework, promoted by the WHO and the Global Fund, to adopt and integrate evidence-based health interventions and change practice patterns within specific settings. It takes into consideration specific characteristics of the setting, the intervention, and the individuals implementing the intervention to help understand why some interventions succeed while others fail. The framework is inherently multidisciplinary, incorporating qualitative and quantitative data, as well as cultural, political, and socioeconomic factors.

We apply this framework to help understand successes and challenges encountered during two implementation efforts in the Dominican Republic: 1) Roll out of Community Health Clubs to improve water, sanitation and hygiene practices in rural Dominican communities, 2) Efforts to provide evidence to support the expansion of the Dominican national HIV treatment program to include treatment for those failing second-line medical treatment.

The discussion highlights the importance of interventions that account for setting, including: inner setting including the need for buy-in within community-based organizations or clinic/providers implementing new programs, and outer setting, including governmental willingness to receive input from outsiders and the international funding environment. Characteristics of individuals involved in implementation that lead to success will be outlined: highly motivated, persuasive, persistent, and willing to prove long-term commitment to the project. Finally, we will emphasize the necessity of continuous process improvement, including early detection and correction of missteps for successful implementation.

Background

Implementation science is a highly effective and increasingly utilized lens with which to understand successes and failures of global health interventions. The World Health Organization defines implementation research as 'the scientific study of the processes used in the implementation of initiatives as well as the contextual factors that affect these processes.'¹ It exists at the intersection of research and the real world, where interventions that have proven effective in clinical trials are scaled up and implemented in other contexts. It is specifically useful for the appropriate adaptation of interventions, frequently developed in high-income settings, to low- and middle-income countries.¹⁻⁴

The Consolidated Framework for Implementation Research (CFIR) provides guidance for successful implementation of interventions, and is useful in analysis and adaptation of interventions when unanticipated challenges arise.⁵⁻⁷ The CFIR argues that five major domains interact to influence implementation effectiveness: the intervention itself; the inner setting: often immediate community or clinic; the outer setting: the institution as a whole, the community, even policy and politics; the individuals involved in implementation; and the process by which implementation is accomplished.⁵

Understanding how interventions can be successfully scaled up or implemented is critical for improving global health, particularly considering the history of lack of success in many of these efforts. Some studies indicate that up to two thirds of organizations' efforts to implement change fail.⁸ Here, we use the CFIR to examine two efforts to implement change in the Dominican Republic: 1) roll out of Community Health Clubs to improve water, sanitation and hygiene practices in rural Dominican communities, and 2) efforts to provide evidence to support the expansion of the Dominican national HIV treatment program to include treatment for those failing second-line medical treatment. The CFIR framework sheds light on the challenges and successes of both efforts, and can be used as a model to anticipate barriers to future programs in these settings.

Case 1: Adapting community health clubs to improve water, sanitation, and hygiene in rural Dominican Republic

Context. In October 2010, a cholera outbreak began in Haiti's Artibonite valley and within three months had affected the entire country.⁹ By February 2011, 426 confirmed cases had been reported in the Dominican Republic, affecting 23 of 32 provinces.¹⁰ The risk for transmission was greatest in high density urban centers and rural, agricultural communities where access to water and sanitation were low. This included *bateyes*, former and current company settlements where migrant Haitian and impoverished Dominican laborers live while working on agricultural plantations. Due to the high poverty rates, low education and health care access, and limited autonomy, the estimated 500,000 *batey* residents were at a higher risk for morbidity and mortality from preventable disease such as diarrhea.¹¹

In 2011, 86% of the total Dominican population had access to an improved water source and 78% had access to an improved sanitation facility.¹² However, these national averages mask urban and rural disparities. Only 80% of rural households had access to improved water, mostly public taps, tanks and rain water of varying quantity and quality.^{12,13} For sanitation, 68% of rural households had access to an improved sanitation facility and 13% openly defecated.¹² But even these rural data excluded *bateyes*. The only data specific to *bateyes* estimated that 25% had access to a public tap, 57% did not treat their drinking water, and 30.9% did not have access to a toilet.¹¹ This situation provided the opportunity to implement an innovative community-based health education and behavior change program to prevent cholera, particularly in high risk *bateyes* along the Haitian border.

Intervention. The Community Health Club (CHC) strategy is a participatory health education and behavior change model pioneered in Africa to address water, sanitation and hygiene (WASH) and prevent diarrheal diseases.¹⁴ CHCs provide the venue for disseminating preventive health information, discussing common health threats, and identifying localized solutions. The curriculum spans six months, where a new topic is introduced each week for 23 weeks by a trained peer facilitator, which builds on previously learned lessons. The lessons are picture-based and participatory, accommodating low levels of education and high rates of illiteracy. After each meeting, members apply the lessons learned in their households and communities through homework assignments.

Positive peer pressure reinforces new behaviors, creating "common unity" and a new "culture of health." All who complete the 23 week curriculum are invited to graduate and receive a certificate.

Until 2011, the CHC model had been proven effective in a variety of social and cultural contexts across Africa, including rural and urban communities, informal settlements, post-conflict environments, and internally displaced people's camps.¹⁵⁻¹⁹ This Dominican program was the first adaptation of the model in the Caribbean and the lessons learned from this pilot program have been applied to a successful and ongoing program in Haiti.²⁰ This pilot project was implemented in five communities (2 urban and 3 rural) by a local NGO providing child welfare and education programs, with technical oversight and research provided by the Center for Medical Humanities & Ethic's (CMHE) global health program.

Barriers aligned with the CFIR framework

<u>The Intervention</u>: At the time, the CHC model had never been adapted and utilized in the Caribbean, and it was unknown whether the model would be acceptable and appropriate for *batey* communities.

Inner Setting: The implementing NGO's primary mission was to provide food, education and health care to vulnerable children living in the five communities, and it had no previous experience executing a community-based project of this nature. As a result, it was difficult to obtain full buy-in for the project. While the NGO's international support team in the US championed the project, the in-country team saw the project as parallel to, rather than aligned with, their mission. The NGO's community-health nurses were ideally suited to support the trained peer facilitators with the more complicated or technical topics on parasites and malaria. However, they only participated in the training workshops and they did not meaningfully engage with the project or support the peer-facilitators afterwards. As a result, the one individual tasked with coordinating the project was isolated and the project was not integrated into the NGO's wider mission.

This lack of institutional support led to a lack of community buy-in. Although the CHC model is community-based and designed to thrive with little external support, the outside support motivates people to participate. Since the NGO did not prioritize this initiative, the community members did not either. Participation was also affected by the choice of peer facilitators. Many of the NGO's community liaisons were youth leaders. These leaders had limited social networks and only mobilized their friends, family and peers. Without additional support from the NGO during mobilization and recruitment, the wider population remained unaware of the project or chose not to participate.

<u>Outer Setting</u>: Each community faced specific structural barriers that limited participation. Although door-to-door recruitment is commonly utilized early on, the fun and excitement generated during the weekly meetings serves to draw people in throughout the six months. However, the pre-schools and primary schools where the Clubs chose to meet were oftentimes on the fringes of the community. In one urban community, the school was isolated on the side of the mountain above the community, and the Club activities were virtually unknown to the wider community below.

Geography and demographics also affected recruitment and participation. In the Dominican Republic, Haitians have always lived with tenuous legal status and have faced a long history of institutionalized racism, resulting in the social, economic and political isolation of Haitian economic migrants and Dominican's of Haitian descent. In the three rural communities, there were both permanent and migrant Haitian families living in deeper poverty than their neighbors. Although these families were at greatest risk for diarrheal diseases, they were not aggressively recruited because of their ethnicity and not viewed as permanent residents.^{11,21} Finally, a lack of time due to employment, schools and access to other forms of entertainment made it difficult to recruit people in the two urban communities.

This project was also implemented by the NGO in isolation from governmental agencies. The Ministry of Public Health and Social Assistance did not provide any oversight, guidance or financial support. As a result, there was no strategic integration with governmental plans or activities for community health and development in the region. A common

outcome of the CHC strategy is an increased demand for safe sanitation. But without strategic partnerships to address this need, the demand went unmet. This lack of strategic integration also limited the scope for scaling. Since the NGO only worked in the five intervention communities, there was no path towards scaling the project in the surrounding communities or wider province.

<u>Individuals</u>: The NGO's country director supported the program in principle and hired a coordinator to manage the project, but little else was done to encourage wider staff or organizational engagement. This left the project officer isolated, a fact that was further compounded by the fact that he lived three hours away in Santo Domingo. The peer facilitators were therefore left to mobilize, recruit, and lead the weekly health education sessions without consistent support and mentorship. As a result, the peer-facilitator's facilitation and leadership skills, which were low to begin with, were never developed. Although the facilitators were given a training manual with detailed instructions on how to lead the weekly sessions, poor facilitation and a lack of engaging activities created Club environments that were school-like and boring.

Implementation process, outcomes, and lessons learned

Process:

Material Development: Prior to implementation, the WASH curriculum and health education materials were developed to be culturally and contextually appropriate over a ten-month period. Three students from the CMHE collected data to assess the WASH context and common WASH practices. These data informed the content of the picture-based curriculum, which was drawn by three local artists.

Training: Between February and March 2012, the five communities were introduced to the project and invited to participate via community meetings. Community leaders subsequently identified literate and respected peer facilitators who were willing to volunteer 4-6 hours per week. The peer-facilitators then attended the first four-day training workshop, after which they began mobilizing, recruiting, and implementing the first two months of health education sessions. The second four-day training workshop was

held in June 2012, but was stopped short due to a medical emergency with the CMHE trainer. As a result, the facilitators never received feedback on their facilitation techniques or training on the last eight topics of the curriculum.

Health Education Sessions: The 23 weeks of health education were implemented as intended for 8 months from May 2012 to December 2012. The project concluded in May 2013.

Evaluation: The CMHE conducted the evaluation in collaboration with a medical school in Santo Domingo. Baseline data was collected in March 2012 via a household survey and final data was collected in April 2013, two months after the health education sessions finished. Key informant interviews with the peer facilitators and focus group discussions with Club members and non-Club members were also used to assess the process of implementation.

<u>Outcomes:</u> In total, 6 peer-facilitators were trained, who formed 5 Clubs with a total of 241 members. Half of the members completed the entire 23 week curriculum and the associated homework. Club member's WASH knowledge increased significantly from baseline to final and Club member's WASH knowledge was significantly greater than non-members at final.²² However, there were minimal observable changes in WASH behaviors from baseline to final and little difference between members and non-members at final. Ultimately, CHCs were not continued in the five communities.

<u>Lessons Learned</u>: Despite the fact that minimal behavioral changes were observed and that CHCs were discontinued in these five communities, the overall lesson learned was that the model is appropriate and acceptable for underserved and impoverished communities in the Caribbean. This pilot project had results similar to those seen in Sub-Saharan Africa, although on a much smaller scale. This was encouraging considering the weak facilitators and overall lack of support and supervision from the implementing NGO. Those that participated reported that CHC membership was highly regarded and that they enjoyed the health education sessions, emphasizing that that this project was better than what was provided in the past.

This model requires the creation of a strong social identity and community leadership, which depends upon strong facilitators with institutional support. A key component of this is a motivated, enthusiastic, and charismatic project officer who regularly visits the Clubs to support and mentor the facilitators & members. This was especially important in this setting where the facilitators were generally weak. The facilitator's limited mobilization, poor facilitation and incomplete knowledge of the curriculum contributed to limited participation from the beginning of the project and a decline in participation over time. However, considering the significant lack of supervision and inconsistency of the facilitators in this project, it is impressive that this model was still able to spark a latent desire to organize and learn.

Case 2: Addressing multidrug resistant HIV in Santo Domingo, Dominican Republic

Context. Since 2003, the Dominican national HIV treatment program has provided antiretroviral therapy (ART) free of charge to people living with HIV who qualify at multiple treatment centers throughout the country. The concern for emerging resistance to ART was raised early on in the Dominican Republic (DR) and in other low and middle income countries in the process of scaling up access to ART.²³ At the time, the DR offered first-line therapy, consisting of three medications from two different drug classes: two nucleoside reverse transcriptase inhibitors (NRTIs) and one non-nucleoside reverse transcriptase inhibitors (NRTIs) and one non-nucleoside reverse transcriptase inhibitors (NRTIs) and one protease inhibitor (PI).²⁴ If patients developed resistance to both classes within the first line therapy (NRTIs and NNRTIs), only one drug class, PIs, remained. Since three medications from at least two classes are needed for effective treatment, an effective regimen could not be constructed for these individuals. Without ART, HIV is a fatal illness, and many providers feared for patients failing second line therapy in the DR.

From 2007-2009, we conducted antiretroviral resistance testing within the Dominican HIV Cohort, in a cohort of approximately 400 individuals receiving treatment for HIV at two sites in Santo Domingo, Dominican Republic. Of 24 cohort patients experiencing failure of

their current HIV treatment who had HIV-1 genotypes (resistance tests), 6 still had options for an effective ART regimen within the anti-retroviral medication available in the DR at the time. However, 18 patients had multiclass resistance, rendering many of them untreatable in the Dominican national program.²⁵ Without treatment, these patients faced death from AIDS.

Intervention. In the United States and other high-income settings, three new types of antiretroviral treatment had become available that would effectively treat Dominicans with multidrug resistant HIV.²⁶⁻²⁸ These medications were new to the market, not available in generic form, and needed to be used in combination. Combined, they could cost over U.S.\$20,000 annually per patient.^{29,30} They were not available as a "third-line" therapy option for the patients failing treatment because of multidrug resistant HIV in the DR. Our goal was to achieve access to these medications for patients receiving treatment through the Dominican national HIV treatment program.

Barriers aligned with the CFIR framework

The intervention: The primary barrier to access to third-line treatment for HIV in the DR was the cost of the intervention itself. Third-line treatments, if purchased at cost, would be approximately 100 times that of the cost of first-line treatment (~\$200 annually per person).³¹ In 2007, the Dominican national HIV program was funded through a combination of grants from the Global Fund to Fight AIDS, Tuberculosis, and Malaria, the World Bank, the President's Emergency Plan for AIDS Relief, and other international entities, and resources were limited.

<u>The inner setting</u>: At the time, the HIV treatment centers had limited structure to monitor treatment outcomes, recognize treatment failure, and assess for drug resistance. HIV-1 plasma RNA level testing, a key component to monitoring treatment success or failure, was intermittently available, and HIV genotype testing, the test for drug resistant HIV, was unavailable. There were also few systems in place to monitor for treatment failure, and no standardized protocols for how to address treatment failure. Without this capacity, even if third-line therapy were available it would be unclear who should receive it.

<u>The outer setting</u>: The Dominican governmental agencies responsible for the national HIV treatment program had many priorities competing with the need for third-line antiretroviral therapy. International funders judged programs scale up by the number of patients initiating antiretroviral therapy, not on whether treatment was successful. As subsequent rounds of funding were contingent on successful scale up, the national program was understandably very focused on increasing the number of individuals receiving antiretroviral therapy.

The structure of the governmental agencies was also confusing and possibly redundant. In 2007, the national treatment program was organized and managed by the Dirección General de Control de las Infecciones de Transmisión Sexual y el Síndrome Inmunodeficiencia Adquirida (DIGECITSS) within the Dominican Ministry of Health. However, the Consejo Presidencial para Control de Síndrome Inmunodeficiencia Adquirida (COPRESIDA), a special office established by the Dominican president and outside of the Ministry of Health structure, received the international funding for HIV care and prevention from the sources mentioned above (Global Fund, PEPFAR, and others).

<u>The individuals</u>: The initial data on the need for third-line therapy in the Dominican Republic was generated by an external research team from the US, in collaboration with Dominican HIV care providers. It is difficult to speculate, but some of the difficulties in dissemination of these data may have been that they were perceived as criticism coming from an external source. Once Dominican providers and people living with HIV had joined in advocating for third-line therapy, the momentum built for implementation of this intervention.

Patients, providers, and program administrators all had limited understanding of or training in multidrug resistant HIV at the initiation of the project, creating a significant barrier to recognizing and responding to this emerging threat. The directors of the responsible governmental agencies were commonly political appointees with limited prior experience with HIV and high turnover.

Process, outcomes, and lessons learned

<u>Process</u>: Our implementation strategy had three main components. First, we addressed individual barriers by educating patients, providers, and administrators regarding the threat of multidrug resistant HIV and the need for third-line treatment. We incorporated the 18 cases of multidrug resistant HIV found within the Dominican HIV Cohort into educational sessions for patients and clinic providers to increase knowledge and encourage clinics to develop strategies to monitor for and respond to treatment failure. We also presented our results, along with education regarding treatment failure monitoring and drug resistance, to program leadership in DIGECITSS. We did this annually for multiple years (2008-2012), as staff and leadership changed frequently.

As the structure of the national HIV treatment program changed, we also presented our data and the need for third line therapy to COPRESIDA (now the Consejo Nacional del Virus Inmunodeficiencia Humana y el Síndrome Inmunodeficiencia Adquirida, CONAVIHSIDA) and the local CDC, PEPFAR, and UNAIDS offices. These outreach meetings took place in multiple formats, including multiple one on one meetings with various administrators at each organization, presentations to panels, and convened research meetings.

Second, we enlisted members of the community, including clinical providers and activist organizations, to help raise awareness of the need for third-line therapy. Unsurprisingly, other HIV treatment sites within Santo Domingo were faced with the same problem of individuals failing second-line treatment and needing third-line antiretroviral therapy, though they did not always have HIV genotypic testing to prove that this was due to multidrug resistant HIV. These clinics also presented cases of second-line treatment failure to DIGECITSS and COPRESIDA, adding their influence to the growing requests for a thirdline treatment option.

Finally, we explored additional avenues through which clinics could obtain third-line therapy. These included international and local charitable organizations, which could import third-line therapy for a few individuals on a case-by-case basis, and pharmaceutical trials providing access to new medications through clinical research. Neither of these alternative avenues had long-term sustainability. Because of the dangers of generating further antiretroviral resistance by stopping and starting medications, most providers chose these alternative routes for third-line therapy only as a last resort for patients who were ill.

Outcomes and lessons learned: By 2014, the Dominican national HIV program developed a process by which, on a limited basis, third-line antiretroviral therapy was available to patients who qualified. Considering the challenges at multiple levels of the CFIR described above, we believe that several barriers were addressed prior to this change in governmental policy. Our group and many others, including key advocates living with HIV, played a role in educating individuals within the government and the community on the dangers of multidrug resistant HIV and the need for third-line therapy, decreasing barriers to adoption amongst individuals. This was in parallel with changes in the outer setting, as international funders became more aware of the need to measure treatment outcomes, rather than just numbers of individuals enrolled in treatment, and adopted more rigorous outcome metrics to evaluate programs. Currently, Dominican providers in our collaborating clinics report that they are able to

However, significant barriers to full implementation of third-line antiretroviral treatment remain. There is still limited infrastructure for treatment failure monitoring within HIV treatment centers, and little data to guide appropriate switching in low and middle income countries.³² Cost of third-line therapy remains prohibitively high in many of these settings, and are unsustainable unless the price of treatment decreases.³³ Despite these challenges, this case illustrates how addressing even a few of the barriers at the individual and outer setting level can lead to dramatic changes in implementation.

Discussion

The application of the CFIR to these two cases of implementation in the Dominican Republic highlights common barriers found in many low and middle-income countries. The CFIR provides the structure or framework through which to organize information separate from the specific implementation plan, allowing for more direct comparisons between different programs such as these.

In these cases, commonalities include the need for buy-in from community organizations and individuals. In the case of the CHC model, commitment from the implementing organization and individuals was less strong, and diminished the efficacy of the intervention. In the case of third-line HIV treatment, it took time and continuous results dissemination to engage community leaders, activists, and members of governmental institutions. Once they were engaged, they were essential in the process of lobbying governmental entities for the provision of third-line therapy. The characteristics of individuals involved in implementation are also critical. For success, individuals must be highly motivated, persuasive, persistent, and willing to prove long-term commitment. This is particularly important when a leader external to the inner setting is championing any component of the intervention. For the CHCs, the coordinator came from Santo Domingo, three hours from the intervention site, which created both geographic and communityspecific barriers. In the second case, much of the initial data supporting the need for thirdline therapy came from a US based research team, which may have impacted how it was received within the DR. Finally, neither case had a built-in mechanism for continuous process improvement, something that the CFIR highlights as an essential component for adaptation and uptake of interventions. These challenges are not unique to these cases, and could be experienced by many implementation efforts in low and middle-income countries.

The authors have incorporated lessons learned from these two cases in their continued work in implementation in the Caribbean. The CHC model has been successfully rolled out in Haiti, and that program's emphasis on local implementing partner buy-in and continuous training for facilitators, the project officer, and staff has helped ensure its success. The lessons from the second case have been applied to a newly launched HIV and sexually transmitted illness screening project, Estudio de la Prevalencia de Infecciones de transmisión sexual en poblaciones Claves (EPIC), by incorporating an extensive initial needs and capacity assessment into the planning phase of the project. This has allowed the investigators to generate awareness and buy-in for the project with multiple community and governmental stakeholders prior to project launch, and should facilitate the eventual dissemination of findings and process improvement suggestions.

The application of the CFIR, as demonstrated in these two cases, can serve to strengthen ongoing implementation initiatives and provide guidance prior to implementation for new projects. This systematic, implementation science approach to work in low and middleincome countries should be applied more frequently, and can play a significant role in the successful adoption of new processes and technologies in these challenging settings where intervention is most needed.

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