From research to international scale-up: stakeholder engagement essential in successful design, evaluation and implementation of paediatric HIV testing intervention

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Abstract

Stakeholder engagement between researchers, policymakers and practitioners is critical for the successful translation of research into policy and practice. The Counseling and Testing for Children at Home (CATCH) study evaluated a paediatric index case testing model, targeting the children of HIV-infected adults in care in Kenya. Researchers collaborated with stakeholders in the planning, execution and evaluation, and dissemination phases of CATCH. They included a community advisory board, the national HIV programme, County health departments, institutional ethics review bodies, a paediatric bioethics group, facility heads and frontline healthcare workers. Stakeholder analysis considered the power and interest of each stakeholder in the study. All stakeholders had some power to influence the success of the project in the different phases. However, support from institutions with higher hierarchical power increased acceptance of the study by stakeholders lower in the hierarchy. During the planning, execution and evaluation, and dissemination phases, the study benefitted from deliberate stakeholder engagement. Through engagement, changes were made in the approach to recruitment to ensure high external validity, placing recruitment optimally within existing clinic flow patterns. Choices in staffing home visits were made to include the appropriate cadre of staff. Adaptations were made to the consenting process that balanced the child's evolving autonomy and risks of HIV disclosure. Dissemination involved delivering site-specific results in each HIV clinic, local and international conferences and sharing of study tools, resulting in the study approach being scaled up nationally. The deliberate engagement of stakeholders early in intervention development optimized study validity and accelerated adoption of the CATCH approach in nationwide HIV testing campaigns by the Ministry of Health and inclusion of paediatric

index-case testing in national HIV testing guidelines. Involving policymakers and frontline health-care workers throughout the study cycle builds capacity in the implementing team for quick adoption and scale-up of the evidence-based practice.

Keywords: Stakeholder engagement, community-based participatory research, stakeholder analysis, paediatric HIV testing, index-case testing

KEY MESSAGES

- Identifying key stakeholders in a research project and involving them in the design, implementation and dissemination of findings enables faster translation of the research into policy and practice.
- Stakeholder analysis is helpful in identifying the relative power and interest each potential stakeholder in a project has, and their relative contribution to determine effort required in engaging the stakeholder.

Introduction

Stakeholder engagement is critical in designing successful research projects and scaling the solutions they produce (Laura Esmail *et al.*, 2015). The involvement of patients, communities and policymakers as active collaborators beyond their roles as participants and consumers of research ensure that there are meaningful and culturally appropriate research procedures and material (Israel *et al.*, 2008; Amirav *et al.*, 2017; Goodman and Sanders Thompson, 2017). The Good Participatory Practice guidelines for stakeholder engagement developed by UNAIDS (UNAIDS and AIDS Vaccine Advocacy Coalition, 2011) established a framework for involving stakeholders in clinical trials and other HIV research. They recommend that stakeholder engagement be a continuous process throughout the life of the study from formulating research questions, protocol development, execution and dissemination of results.

Despite the importance of stakeholder engagement, researchers often struggle to systematically engage diverse stakeholders throughout the lifecycle of a research project (Hoffman *et al.*, 2010). Two systematic reviews noted that slightly less than half of studies involve stakeholders in the early stages of the study, including protocol development, (Day *et al.*, 2018) and only 10% involve them in the dissemination stage (Concannon *et al.*, 2014; Day *et al.*, 2018). Consequently, these research projects may be tested in conditions that do not take into account ‘real-life’ implementation challenges (Glasgow *et al.*, 2003). Even in settings where stakeholder engagement does happen, there are challenges in having well defined roles for each stakeholder that allow for meaningful contributions and avoid the risk of tokenism, where researchers are seen to be only interested in ‘checking a box’ (Harrison *et al.*, 2019). On the other hand, policymakers and practitioners who are not involved in research often do not have ready access to scientific literature about effective interventions, and researchers are often uninvolved in implementation through programmes (Haines *et al.*, 2004). As a result, there is often a long gap, averaging 17 years (Balas and Boren, 2000), in the time between high-quality trial results and widespread adoption of an intervention (Glasgow *et al.*, 2003; Haines *et al.*, 2004).

While many studies have documented stakeholder engagement, fewer expound on the methodology used to assess the importance and results of that engagement (Martinez *et al.*, 2019). One method of evaluating stakeholder engagement is using the ‘power and

interest’ model. In this model, the importance of any stakeholder is determined by the power they have to impact the success of a research project and the interest they have in the research (Chinyio and Akintoye, 2008; Horton and Pilkington, 2014; Colvin *et al.*, 2020). This model can be applied prospectively to guide the researchers on the stakeholders whose influence could impact feasibility of the research project. Retrospective analysis of the power and interest different stakeholders had in the study can explain the reach and acceptance of the study by the stakeholders and the target community. Researchers can also apply a role-based approach to determine the important stakeholders to engage (Horton and Pilkington, 2014). In this approach, the researchers rate the importance of different roles in the success of the study, and the stakeholders who perform the most important roles, regardless of their power, are engaged more purposefully.

Paediatric HIV has high morbidity and mortality, particularly when diagnosis is delayed (Wamalwa *et al.*, 2012). At the time when this study was conducted, prevention of mother-to-child transmission of HIV (PMTCT) programmes had scaled up widely in Kenya, resulting in a reduction in new infant infections [National AIDS and STI Control Programme (NASCOP), 2014]. However, ~60% of HIV-infected children remained undiagnosed [National AIDS and STI Control Programme (NASCOP), 2014] and many were first identified in hospital when seriously ill when they could not fully benefit from antiretroviral therapy (Njuguna *et al.*, 2016). Among adults in HIV care, only 45% ever tested their children [National AIDS and STI Control Programme (NASCOP), 2014]. This article shares lessons learned from stakeholder engagement in research design through national scale-up of a paediatric HIV index case testing model to address the aforementioned testing gaps in Kenya, the Counseling and Testing for Children at Home (CATCH) study.

Methods

CATCH study

The CATCH study was designed in 2012 and implemented in six health facilities in Nairobi County and one facility in Kisumu County in Kenya between the years 2013 and 2016. Caregivers in HIV care who had children aged 0–12 years of unknown HIV status were offered an opportunity to test their children either in clinic or at home (Wagner *et al.*, 2016). In 2012, when the study was

designed, index case testing as an approach to reaching children at high risk of being HIV infected was not widely used and was not explicitly included in the national HIV testing guidelines (Ministry of Public Health and Sanitation, 2010).

CATCH was a collaborative study between University of Nairobi (UoN) and University of Washington (UW) (Wagner *et al.*, 2016). The UoN/UW collaborative group had a longstanding collaboration in paediatric HIV prevention, testing and treatment research projects and bi-directional training programmes involving the universities, the largest referral and teaching hospital in Kenya [Kenyatta National Hospital (KNH)] and the Kenya Ministry of Health (MOH). The CATCH study adopted a research approach informed by community-based participatory research (Israel *et al.*, 2008), which included recognition of healthcare workers (HCW) expertise in HIV programming, building on existing strengths within community HIV programmes, involvement of community and government stakeholders in design, conduct and evaluation of the project and capacity building/knowledge dissemination through implementation of study tools into the national programme (Satcher, 2005).

Stakeholders in the CATCH study

The CATCH study engaged diverse stakeholders throughout the study lifecycle, including the UoN/Kenyatta National Hospital Ethics and Research Committee (ERC), UW Institutional Review Board (IRB) and Seattle Children's Hospital's Treuman Katz Center for Pediatric Bioethics. A community advisory board (CAB) was convened, comprised of HCW with experience working with persons living with HIV, community health workers (CHW), peer counsellors, HIV-infected caregivers and a child protection officer. Following constitutional changes in Kenya in 2010, county health departments managed the bulk of public health facilities and programmes including HIV prevention and treatment programmes. The National AIDS & STI Control Programme (NASCOP), housed in MOH, which previously managed the HIV programme country-wide, was tasked with policy development and monitoring (Barker *et al.*, 2014). This required that the study engage both county and national levels of government, along with heads of facilities and HIV care clinics and HIV clinic staff.

Data sources

Communications to and from the ethics bodies and the paediatrics bioethics centre were done through letters. Engagement with the CAB, County, NASCOP, facility heads and frontline HCW was documented through meeting minutes, presentations, field notes and reflections from the study coordinators, study nurses and the principle investigators. The CAB held a series of meetings prior to the study rollout and met every 6 months for the duration of the study. Meetings were held before the rollout of the study between the research team and NASCOP, the County HIV coordination teams, facility heads and frontline HCW. Thereafter, the study coordinator and study nurses had informal meetings with sub-County HIV programme managers, facility heads and frontline HCW at least monthly and formal meetings with the same stakeholders after completing study activities at each facility. Formal dissemination meetings with all stakeholders were convened after completion of the pilot study (year 1) and completion of the study in year 4. Discussions in all meetings were guided by presentations made by the research team. In addition, results were disseminated in local and international conferences through posters and oral presentations.

Analysis of stakeholder engagement

To describe the involvement of stakeholders in the CATCH study, we utilized a modified 'power-interest' stakeholder analysis model. While the original model classifies stakeholders as having high or low absolute power—where the stakeholder with the most power and influence is regarded as more important in the success of the project (Chinyio and Akintoye, 2008; Horton and Pilkington, 2014)—the context in the CATCH study was different. Given the decentralized but hierarchical structure of health service delivery within Kenya, we determined that all stakeholders had the power to enable or disable the project at any level, but there were institutions with higher hierarchical power and their support resulted in increased acceptance of the study by other stakeholders lower in the hierarchy. Moreover, we also applied the role-based model (Horton and Pilkington, 2014) to accurately describe the importance of the stakeholder engagement in the study. For example, engagement of the frontline HCW was instrumental in the successful execution of the study due to their role in adapting data collection tools and integrating study activities into clinic flow. However, their engagement was dependent on the study buy-in by the facility heads and sub-County HIV programme managers. Furthermore, the County HIV coordination team first required the research team to engage and receive approval from NASCOP and ethics teams, who only played a peripheral role in the actual execution of the study. The Kenya and US-based ethics bodies are mandated to determine ethical questions especially on consenting and study procedures. However, the contribution made by the bioethics centre and the CAB, despite not having hierarchical power, was pivotal, as described in the Results section.

In each phase of the study, the authors retrospectively determined which stakeholders were engaged and their roles using the aforementioned data sources. They then made a judgement via consensus on the interest each stakeholder demonstrated and the impact they had in each of the three phases of the study (planning, execution and evaluation, and dissemination). Finally, they considered the hierarchical position of each stakeholder.

Results

Roles of various stakeholders

Diverse stakeholders had evolving roles throughout the planning, execution and evaluation and dissemination phases of the study. The UW and UoN ethics reviewers and experts were heavily engaged during the planning phase of the study due to their regulatory responsibilities. The study design and study population targeted by CATCH made it critical to define how the study would protect children and their caregivers from potential psychological harms associated with paediatric HIV testing. After the ethics review committees reviewed and approved the protocol, their role shifted to oversight and compliance, with periodic monitoring and annual reports. The Treuman Katz Center for Pediatric Bioethics played a crucial role in designing the CATCH study during the planning phase. The study team sought input from the bioethicists on specific issues related to study participant consenting and assenting procedures. In the planning phase, MOH and CAB were engaged closely through a series of meetings due to their crucial role in ensuring acceptable and appropriate entry into facilities and client homes. In the execution and evaluation stage, The sub-County HIV programme managers and heads of facilities had substantive roles in the study, informing the integration of the study within existing HIV programme structures and in supervision, ensuring that study staff adhered to existing HIV testing protocols. The frontline HCW in the

Figure 1 Summary of contribution from stakeholders engaged in the CATCH study

HIV clinics were engaged in the execution and evaluation phase of the study and recruiting participants and, through regular meetings, helped optimize study procedures. MOH and the CAB were kept informed through regular brief communications but did not have a direct supervisory role. In the dissemination phase, MOH played a more significant role since they made decisions on how the study results influenced national HIV testing policy and made the dissemination forums available. The study team kept close contact with MOH through frequent meetings and developed packages that helped them interpret the results correctly. The frontline HCW, facility heads and county health departments were kept informed by presenting facility-specific or county-specific results to them, while the CAB received results from all facilities (Figure 1).

Aspects of the study most heavily impacted by stakeholder engagement

Consent and assent

During the planning stage, the study struggled with how to conduct appropriate consent and assent to balance the diverse needs and rights of children and adolescents aged 0–18 years. Kenya's HIV testing guidelines required parental consent for child testing, but no guidance on child assent was provided. The ERC and CAB noted that children in the Kenyan context were not routinely asked to assent for medical procedures and that requiring assent for children might make caregivers reluctant to enrol in the study, limiting generalizability. They also noted that an assent that explicitly mentioned HIV testing could inadvertently disclose either a child's or a caregiver's HIV status to their children, making enrolment unacceptable

to them. On the other hand, UW IRB and Trueman Katz Bioethics Center suggested that older children and adolescents had a right to receive their HIV test results. In view of the competing priorities, the bioethicists suggested that we restrict the study to include only children 0–12 years for testing and, further, offer an optional assent for children aged 7–12 years that did not mention HIV. The assent was offered to the child only if the caregiver agreed. They further suggested conducting a separate formative study to understand appropriate adolescent engagement approaches, which resulted in the development of the Developing Adolescent Strategies for HIV testing study (Wagner *et al.*, 2017; Wilson *et al.*, 2017).

Approach to home visits

During the planning phase, the study team considered which cadre of staff should conduct the home-based HIV testing visits, paying particular attention to the risk of stigmatizing families and potential for accidental disclosure, as well as the potential of programmatic scale-up. The CAB advised that a CHW should accompany study nurses during home visits to minimize stigmatization and to match with the role and scope of this cadre in programmatic care. The study engaged the CHW in charge of the community unit in which the household we visited for home-based testing was located. Since the standard scope of work for CHW did not already include HIV testing, transport reimbursement was important in successfully engaging this cadre and was provided by the study.

The MOH representatives were engaged to support appropriate study design, staffing and testing procedures to ensure that the intervention was operationalized in a way that could be integrated into

existing health systems. For example, children under 18 months who were tested at home required confirmatory polymerase chain reaction (PCR) testing; collecting this sample and returning results to the family at home or by phone would have competed with existing PMTCT systems and threatened appropriate linkage to care. MOH advised that these children should have their samples collected at home and immediately referred to their local PMTCT clinic to receive their PCR results.

Integration with existing health systems

The study aimed to leverage, and integrate into, existing systems for HIV test kit procurement and reporting. The study team engaged with sub-County HIV programme teams who supplied HIV test kits, allocated CHWs for home visits and kept the study team informed of other HIV testing activities in and around the study sites to improve scientific inference on intervention effectiveness. In turn, the study shared recruitment and testing data for reporting purposes and helped clinics diagnose historic gaps in service delivery. The study team also regularly engaged frontline HCW during execution and evaluation, providing regular updates and incorporating HCW feedback in operationalization. For example, HCW were instrumental in characterizing patient flow, identifying the optimal point of recruitment to maximize contact with all clients and refining study eligibility logs to meet the study objectives, but not be overly burdensome. In return, HCW were either reimbursed as individuals (\$2.50/day), as a group, or nominated a peer educator that was hired by the study for participant recruitment and referral; while this was deemed necessary in a research context, this would likely not be feasible at programmatic scale.

Dissemination

CATCH study results were disseminated widely. In addition to conventional international conferences, the study team presented site-specific results in each of the participating clinics, at county headquarters and at various national MOH and local scientific meetings. During presentation of the site-specific results, the HCW provided context and possible explanations for the results presented especially on the proportion of caregivers reached and test completion. The main study results were published after many of these dissemination meetings. Results interpretation in this manuscript incorporated local feedback from the dissemination meetings (Wagner *et al.*, 2016).

Impact of stakeholder engagement on study validity

Deliberate engagement of diverse stakeholders was instrumental in ensuring scientifically valid and pragmatic study findings and in enabling integration of the CATCH intervention in the national HIV programme. The study also benefitted from unique partnerships in staffing. Pairing CHWs with study nurses during home visits enhanced the completion of testing and linkage of HIV-infected children to HIV care. Strategic positioning of recruiting staff in the triage and pharmacy areas of HIV care clinics ensured that all patients in a day were approached about testing their children. Stakeholder engagement allowed the study to be culturally and locally informed. The optional child assent approach enabled the study to maximize external validity by not excluding a population who felt uncomfortable with child assent, and to balance respect for both parental and child rights regarding participation. Awareness of overlapping HIV testing mandates between research and programmes allowed quick adaptation to aid in achieving synergistic goals and helped to correctly interpret study results in the absence of a parallel control arm.

Figure 2 summarizes the contribution each stakeholder made across the three phases of the study (planning, execution and evaluation and dissemination), and the effect their contribution had on the conduct of the study or interpretation of study results.

Synthesis of stakeholder engagement using the modified power-interest framework

In the planning phase, the ethics bodies had high hierarchical power due to their position as regulators. The study was not considered high risk and so their interest beyond performance of their initial regulatory roles was low. The national Ministry of Health also had high hierarchical power due to their policymaking functions and were highly interested in the actual study since it would inform their policy on HIV testing. The CAB had lower hierarchical power but had an oversight role detailed in the study protocol. Due to the composition of the CAB, they had high interest in the conduct and outcome of the study. The paediatrics bioethics centre had low hierarchical power and little interest beyond advising the study on the consenting and target population questions.

In the execution and evaluation phase, the County Department of Health and facility heads had high hierarchical power since they managed the study sites and had a supervisory role on testing and referral procedures. They had high interest in the study outcome since the study was offering HIV testing services—one of their deliverables. Although the frontline HCW had lower hierarchical power than the facility heads and County, they had some power that they used to determine when and where to approach caregivers and refer them to study staff. HIV testing was an important deliverable of their usual role in the clinic, which made them have high interest on the study outcome. The ethics bodies, MOH and the CAB maintained their passive oversight roles and had no direct supervisory roles.

In the dissemination phase, MOH showed high interest in the study outcome due to the implications it had on HIV testing policy. Their position as the policymaking body conferred high hierarchical power to determine when and how the dissemination was done. The County, facilities, CAB and attendees of dissemination meetings showed high interest in the study outcome due to the potential to reach untested children and gaps in testing the study showed. The County and facility heads, however, had limited hierarchical power that enabled them to dictate where and when County- and site-specific dissemination was done (Figure 2).

Discussion

Preliminary CATCH study results were released in 2015 allowing MOH to document CATCH as a best practice in paediatric HIV testing and linkage to care. The study team shared scripts, data collection tools and training material with the programme. Within 5 months of tool sharing, the Kenyan national HIV programme adopted the CATCH approach in a nationally scaled Rapid Results Initiative, testing >500 000 children for HIV. Testing children in clinics following index case identification was also incorporated into national HIV testing guidelines 2015 (Ministry of Health, 2015). The same toolkit was shared with the World Health Organization Inter-Agency Task Team on paediatric HIV. Since completion of CATCH in 2016, in Kenya, the approach was utilized on a wider scale to close the gap in HIV testing for contacts of persons living with HIV. For example, for the period between October 2016 and March 2018, clinics supported by the US Center for Disease Control and Prevention completed >200 000 HIV tests for children

Figure 2 Illustration of stakeholder power and interest in the three phases of the CATCH study

<15 years of adults in care and identified over 1400 children living with HIV (Lasry *et al.*, 2019). Several African countries including Malawi and Zimbabwe (Ahmed *et al.*, 2017; Chikwari *et al.*, 2019; Lasry *et al.*, 2019) have since adopted a similar model to reach more children at high risk of being HIV infected with HIV testing.

There is limited literature about stakeholder engagement in research studies in low- and middle-income countries (Day *et al.*, 2018). Previous studies have suggested that engaging stakeholders in these settings may be more challenging due to communication barriers, fewer resources and a lack of trust of research by communities (Newman *et al.*, 2015); this is despite the appreciation that stakeholder engagement is even more important when conducting research in these contexts (Newman and Rubincam, 2014).

Previous literature on stakeholder engagement demonstrated that few studies rigorously engage government stakeholders (11%) and healthcare stakeholders (21–46%), and that study participants (80%) and community leaders and community advisory groups (71%) are more frequently engaged (Concannon *et al.*, 2014; Day *et al.*, 2018). Stakeholder engagement in the CATCH study was done throughout the study cycle, including dissemination, differing from other research studies that mostly engage stakeholders during the initial stages only (Concannon *et al.*, 2014; Day *et al.*, 2018). Furthermore, CATCH engaged several key stakeholders including patient and community representatives (CAB), research stakeholders (ethics bodies), healthcare stakeholders (HCW) and government stakeholders (MOH/County), which presented a learning opportunity of how to engage diverse stakeholders with varying power, interest and roles. The success of the stakeholder engagement for the CATCH study with government stakeholders could also be attributed to institutional culture. Kenya's HIV programme is regarded as an early adopter of evidence-based innovations in HIV prevention and treatment. It was among the first African countries to scale up the comprehensive prevention of mother-to-child transmission programme that included Option B (3-drug regimen of antiretroviral drugs during pregnancy) and Option B-plus (3-drug regimen of antiretroviral drugs for life) (Government of Kenya, 2012; du Plessis

et al., 2014). It is also among the first countries to scale up HIV self-testing (World Health Organization, 2015), testing of newborns at birth and pre-exposure prophylaxis (Ministry of Health Kenya, 2018). In the formulation of these guidelines, Kenya's HIV programme has routinely engaged researchers in academic institutions and other implementing partners.

The data sources used in this analysis, including meeting minutes, field notes and reflections of the research team, have been utilized in previous stakeholder analyses (Martinez *et al.*, 2019). The consideration of stakeholder's power in analysing the stakeholder's contribution, although widely used in stakeholder literature (Roome and Wijen, 2006; Thaler and Levin-Keitel, 2016; Colvin *et al.*, 2020), is rarer in health-related literature, and even rarer from low- and middle-income countries.

The CATCH study benefitted demonstrably from comprehensive and diverse stakeholder engagement by having a culturally sound intervention, buy-in from frontline HCW and adoption of the intervention in the national HIV care guidelines. The stakeholders had direct benefit (HCW, facility heads, County and MOH) due to the study helping them accomplish HIV testing, one of their core deliverable services and indirect benefit for patients who learned their children's HIV status. This demonstration of the benefits of stakeholder engagement has previously been noted as a gap in stakeholder literature (Laura Esmail *et al.*, 2015). This demonstration of sustained stakeholder engagement and its benefits to all parties should encourage researchers to invest time and other resources and to design studies that substantively include stakeholder engagement in their study procedures.

Conclusions

Engaging stakeholders early and frequently during intervention design and execution and evaluation ensures scientific validity, programmatic relevance and policy impact. This process should include parties at all levels of MOH, health facilities and the community targeted for research. Involvement of frontline practitioners in the

study improved morale and ownership of the intervention. It is also important to tailor compensation for research procedures to practitioners to what is most acceptable with the staff and management. Facility management can be engaged directly by offering supervisory roles in the study. This ensures experience is gained on how to run the intervention if adopted into programmatic practice. Active dissemination, including of preliminary results, methodology used in the research and data collection tools and material, is necessary to achieve scale. Using study designs that are more pragmatic in nature allow researchers to test 'real-life' scenarios, enhancing external validity and ensuring more rapid adoption of effective interventions..

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Author contributions

C.M., M.N., F.N., V.O., V.O., E.M., I.N., H.M., K.S., I.I., E.M.-O., D.W., G.J.-S., J.S. and A.D.W. were involved in data collection and dissemination activities and writing and review of this article. A.D.W., J.S., D.W., K.S. and G.J.-S. were involved in study design.

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