

INNOVATION IN STAKEHOLDER ENGAGEMENT: PILOTING A MONITORING AND EVALUATION TOOLKIT

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BACKGROUND

WIDELY ACCEPTED BEST PRACTICES FOR STAKEHOLDER ENGAGEMENT IN HEALTH RESEARCH HAVE BEEN IMPLEMENTED FOR MANY YEARS ACROSS DISEASE AREAS.

Examples of practices include community advisory boards (CAB), community education and research literacy, and development of networks for patient and community leader support. Such activities have become an expectation of donors as well as stakeholders in trial communities and countries.

The *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials* (GPP) were adapted for TB drug trials and are being used generically in additional settings. As practices expand, increasing focus rests on GPP impact.

Existing guidelines and policies, however, provide little insight into expected outcomes, indicators of success, or effective monitoring and evaluation (M&E) mechanisms for assessing impact of engagement on clinical trials and communities.

OVERVIEW OF M&E TOOLKIT

To better understand impact, a cross-field, cross-disease M&E toolkit was developed. It was piloted widely with clinical research sites conducting novel combination TB drug trials and biomedical HIV prevention trials using a variety of methodologies, research settings, and respondents.

The M&E toolkit is intended for use by research staff and clinical trial sponsors for assessment within a trial or over a given time period. Although initial intended audience included infectious disease research staff, it is applicable for diverse disease, research, geographical and population-based settings.



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The toolkit includes guidance for program management, indicators of impactful activities, and a comprehensive set of data collection tools. The indicator framework includes four sets of recommended CSE indicators according to community benefits and to three stages of the research cycle—planning and preparedness, trial conduct, research outcomes. Table 1 contains an excerpt from planning and preparedness.

The set of tools (Table 2), based on the indicator framework, include self-directed log forms, interview guides, surveys, and focus group discussion guides. Tools encompass both quantitative and qualitative data, such as the frequency and type of engagement, knowledge, understanding and perception over different stages of a clinical trial.

A database accompanies the toolkit for analysis. A web-based program allows implementers to collect and analyze data with ease, either in the field at the point of data collection, or logged in after data is collected manually.

RESULTS

The piloting process improved the toolkit's relevance to ongoing engagement programs. Indicators of success, relevant data points and data collection methodology were refined. The tools were revised, for example, according to respondents' practical input on key areas of engagement work, such as: CAB activities, consultation with individual stakeholders and small groups, media and communications work, and outreach to stakeholders outside the trial community at national and broader levels. Practical input also included a realistic frequency for data collection, particularly regarding community and advisory board member interviews, as well as PI and engagement coordinator self-assessments. Indicators of success were revised to improve on linkages between engagement efforts and participant-focused outcomes such as recruitment and participant adherence to trial regimens. Once finalized, the toolkit and database will be made widely available to interested research organizations.

PILOT PROCESS

The set of tools and web-based analysis database were piloted in various stages by community engagement program staff from clinical trial sites in sub-Saharan Africa.

Piloting occurred in three key stages

1. Consultations with clinical site staff to assess relevance of tools to typical program activities.
2. Workshop and focus group discussion with implementers from 15 research sites in Kenya, South Africa and Tanzania for in-depth content review across a broader spectrum of disease and research types.
3. Implementer test of web-based analysis database to inform software development on accuracy, usability at point of data collection, effectiveness in documenting ongoing activities at various trial timepoints; this step also reviewed data entry across various sites working on one trial.

Pilot sites were identified both from centers conducting novel combination TB drug trials and those conducting biomedical HIV prevention trials, all with significant history of engagement programs. Example pilot sites included the Aurum Institute and FACTS Consortium, both in South Africa, and the Kenya Medical Research Institute in Kilifi, Kenya.

TOOL SET

Table 2

M&E Tool	Purpose
AA. Stakeholder ID and Analysis	Compile list of stakeholders, for reference throughout toolkit
A1. Engagement Log	Document engagement as it takes place, such as form of engagement, type and number of stakeholders reached, and location of engagement
A2. Compilation of Clinical Trial Data	Collect information about clinical trial recruitment and retention progress, and extract potential linkages with implemented engagement activities
B1. Community Stakeholder Interview	Evaluate knowledge, level of engagement, and perception of community members in relation to research
B2. Community Advisory Group Member or Community Representative Interview	Evaluate knowledge, level of engagement and perception of advisory group or other trial community members in relation to research
B3. Broader Stakeholder Interview	Evaluate knowledge, level and perception of engagement of stakeholders outside of trial community
C1. Trial Participant Exit Interview	Evaluate value and level of engagement throughout participation in clinical trial
C2. Prospective Trial Participant Interview	Evaluate level of knowledge and perception about trial, including prior to screening
D1. Self Assessment: Community Engagement Manager/Community Liaison Officer	Assess progress of planned activities throughout trial process; evaluate level of engagement with key stakeholder groups
D2. Self Assessment: Principal Investigator or Senior Researcher	Evaluate level and quality of engagement throughout trial process from investigator perspective

INDICATOR FRAMEWORK

Table 1

Area of Desired Impact	Indicators	Measurement methods/ source document
Disease risk perception issues	Proportion and type of community members/stakeholders consulted	Brief survey of community members and/or stakeholders
	Number and type of community member/stakeholder suggestions incorporated	
Avoidance of volunteer harms	Perceived value added of community member/stakeholder engagement efforts on the part of research staff	Brief survey of research staff
	Extent issues were addressed through community member and stakeholder engagement efforts	Interviews with research staff
High levels of participant understanding of informed consent	Number of participants reporting high levels of understanding of informed consent	Management data/records
	Perceived level on the part of researcher of participant understanding of informed consent	Brief survey of research staff
	Number and type of education mechanisms/initiatives focused on relaying information to participants on informed consent	Clinic exit survey Interviews with research staff
Participant access to quality package of products and services	Number of participants reporting access to quality package of products and services	Clinic exit survey
	Perceived satisfaction of participants regarding access to quality package of products and services	
Avoidance of external misconceptions/rumors about trial	Number and type of high quality information resources distributed externally	Management data/records
	Number and type of education mechanisms/initiatives to address misconception/rumors	Community survey
	Number of stakeholders who report negative messages in community	Press/Media opinion pieces

CONCLUSIONS

Incorporation of feedback from sites with leading GPP experience led to development of an effective, relevant, user-friendly toolkit for monitoring and evaluation of community and stakeholder engagement activities. Wide use of the toolkit is needed to build an evidence base and to better understand the impact of engagement on research and stakeholder-related outcomes.