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Building research readiness for a future filovirus outbreak
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Community engagement during trials: Overview

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Introduction

• Community engagement is a decision to involve the community in acting together.

“a process of developing relationships that enable stakeholders to work together to address health-related issues and promote well-being to achieve positive health impact and outcomes” (WHO, 2020)

• Community engagement in research, including public health related research, is acknowledged as an ethical imperative.

Aim: Empowerment of communities to engage and take ownership
Speaking impact of CE during trials

- **Be community-led**: Facilitate community-led solutions through the improvement of the quality and consistency of CE approaches

- **Be data-driven or evidence-based**: Generate, analyse and use evidence about community’s context, capacities, perceptions, and behaviours

- **Reinforce/strengthen local capacity and solutions**

- **Be collaborative**: Strengthen coordination of stakeholders to increase quality, harmonization and integration
Introduction

• WHO, 2016 R&D Blue Print

Overview

Good participatory practice guidelines for trials of emerging (and re-emerging) pathogens that are likely to cause severe outbreaks in the near future and for which few or no medical countermeasures exist (GPP-EP)

The primary audience for the good participatory practice guidelines for emerging pathogens (GPPEP) is all those involved in designing, financing, and implementing prevention and treatment trials of emerging or re-emerging pathogens. These are pathogens that are causing or are likely to cause severe outbreaks in the near future and for which few or no medical countermeasures exist. They include diseases such as Ebola virus disease, Crimean Congo haemorrhagic fever, Marburg, Lassa fever, MERS and SARS coronavirus diseases, Nipah, Rift Valley fever, Chikungunya, severe fever with thrombocytopenia syndrome, Zika, and other known and as yet unknown pathogens.

This guidance specifically addresses good participatory practices during trials conducted in health emergency contexts where accelerated research processes are needed.

GPP-EP is the only set of global guidelines that directly address how to engage stakeholders in the design, conduct, and conclusion of emerging pathogen prevention and treatment trials. When applied over the trial life cycle, the GPP-EP guidelines enhance both the quality and outcomes of research.
The context of the clinical trial

- Sudden threat, death, fear, denial, social disruption, etc.
- Low risk perceptions
- Low/Inadequate knowledge
- Mistrust, religious beliefs
- Infodemics (Mis-/dis-information, rumours)
- Complacency, anxiety, searching of an escape goat
- Community resistance/reticence?
- Uncertainties & Fear

Community Engagement to

- Building TRUST
- Building confidence
- Engaging the audience
- Demonstrating respect, humility and empathy
- Co-construct the clinical trial
The process to engage communities (co-construction)

Community engagement strategies
Knowing the audience

- **Involve social scientists** at the early stage to facilitate the understanding of the protocols, conduct operational research, and build bridges between communities and trials’ **teams**

- **Conduct Rapid Assessment “in-depth and quick studies”** for social and behavioral data, including qualitative research to understand communities’ perceptions and beliefs related to the trial, and use this insights to orient CE and the overall trial’ strategies

- **Map community engagement partners** (tools available/ Online kobo)

All of this leads to building **TRUST**
Listen actively: understand and respect community concerns (2-ways)

- Facilitate community engagement meetings (Focus Groups discussions, etc.)
- **Community dialogues with experts**: Encourage questions and provide thoughtful responses to enhance audience participation
- Establish **social listening mechanisms** (2-way communication) to manage infodemics (online and offline): feedbacks,
- **Use live polls or surveys to gather audience opinions**, promoting engagement and making sure the audience feel involved
- **Share community feedback & perceptions** with health care workers in the Treatment centers

All of this leads to building **TRUST**
Plan and implement with the community (co-creation)

- Ensure participation in all levels and in all steps of the trials

- Involve the community in decision-making that affects the trials for ownership & sustainability

- Ensure to communicate and discuss the overall steps of the trials with the communities (beginning to end, including use of results)

- Ensure fairness (EQUITY)

- Ensure fundings to implement CE operational plans

- Ensure accountability with communities

- Ensure feedback and iterative collaboration (sharing and discussion of the results with the communities) from the beginning to the end of the clinical trial

All communication products and actions aimed at the community must be adapted to:

- **Settings** in which the population is found e.g., workplace, learning institutions, health facilities, prison, religious institutions

- **Level of education, age, sex, socio-economic status, etc.**

- **Common languages and/or dialects**

- The most appropriate means of communication for them (e.g., oral, written, visual, etc.)

- **Trusted and accessible channels and stakeholders.**

- The materials (posters, leaflets, messages...) must also be pretested before use and before mass production.

All of this leads to building **TRUST**
Build capacities

• Inform and train the communities in the clinical trial (translate scientific knowledge into an easy-to-understand language)

• Hold stakeholders’ meetings to listen to and understand the community leaders’ concerns and respond

E.g; of worries about the clinical trial
• Level of risk (individual, family and community)
• Benefits
• Payment of the cares
• Post-trial cares/side effects
• The stigma/family trust and social disruption

• Train community health workers/community volunteers to communicate on the clinical trials in their communities

All of this leads to building TRUST
M&E, accountability, documentation, and publication

- Hold evaluation and follow-up meetings with the community to give feedback

- Document the process and activities to capture both best practices and challenges/gaps of the engagement of the communities

- Go back to the communities to present the results of the clinical trials

- Ensure to thank communities for their engagement in the scientific publication of the results of the trials (if possible, share a copy of the paper with the communities/health authorities/health care center/community library)
Challenges

- Insufficient/inexistence of ethical guidance and regulatory oversight both at national and community levels

- Lack/insufficient engagement of local, social, administrative, civil society organizations and political structures in the research during « peace time » for preparation/readiness for trial enrollment

- Insufficient understanding and implementation of community engagement' timely operational research (during clinical trial)

- Insufficient up to date literature/guidance/operational frameworks for Community engagement for trials; and/or existing guidance differ across settings

- Resources/financial

- Insufficient/lack of will to engage communities
Build on experience, and existing literature

- Ebola vaccine introduction in West Africa (2014-2016)
- COVID-19 related clinical trials

Association of community engagement with vaccination confidence and uptake: A cross-sectional survey in Sierra Leone, 2019

Mohamed F. Jalloh, 1 Paul Sengoh, 2 Noobeh Ibrahim, 2 Shibani Kulkarni, 1 Tom Sessay, 3 Victor Eboh, 4 Mohammad B Jalloh, 2 Samuel Abu Prati, 2 Nance Webber, 2 Harold Thomas, 5 Reinhard Kaiser, 6 Tushar Singh, 6 Dimitri Prybylski, 1 Saad B. Omer, 1 Noel T. Brewer, 8 and Aaron S. Wallace 1

Abstract

The aim of this study is to determine how stakeholder engagement can be adapted for the conduct of COVID-19 related clinical trials in sub-Saharan Africa. Nine essential stakeholder engagement practices were reviewed: formative research; stakeholder engagement plan; communications and issues management plan; protocol development; informed consent process; standard of prevention for vaccine research and standard of care for treatment research; policies on trial-related physical, psychological, financial, and/or social harms; trial accrual, follow-up, exit trial closure and results dissemination; and post-trial access to trial products or procedures. The norms, values, and practices of collective societies in Sub-Saharan Africa and the low research literacy pose challenges to the conduct of clinical trials. Civil society organizations, members of community advisory boards and ethics committees, young persons, COVID-19 survivors, researchers, government, and the private sector are assets for the implementation and translation of COVID-19 related clinical trials. Adopting ethics guidelines to the socio-cultural context of the region can facilitate achieving the aim of stakeholder engagement.
Final tips & takeaways

TRUST
PERCEPTION
EMPATHY
EMPOWERMENT
Ressources


• WHO, 2020, Community engagement: a health promotion guide for universal health coverage in the hands of the people


THANK YOU