Community engagement and Good Participatory Practice: lessons learned and existing tools

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Outline

1. What is GPP-EP and why do it?
2. How to do it and what tools are available?
3. Implications for the Lassa vaccine trial protocol development
What is GPP-EP and why do it?
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) 2016

- Provide trial sponsors and research team members with principle-based guidelines on how to effectively engage stakeholders in the design and conduct of prevention and treatment trials for emerging and re-emerging pathogens.

- Principle based guidelines: respect, fairness, integrity, transparency, accountability, and autonomy.

- Strengthen mutual understanding, collaboration and trust when implementing clinical trials -- ensure that research is relevant and that research processes are acceptable and sensitised to the context in which the research is being delivered.
Our success begins and ends with communities – Samba Sow

Patience, time and tact – Andre Bita

Think local, act local ...

Don’t leave us out, our voices must be heard – Stephen Kennedy
How to do it and what tools are available?
Good Participatory Practice for Emerging Pathogens

Good Participatory Practice for Emerging Pathogens (GPP-EP): a principle-based approach to effectively engage stakeholders in the design and conduct of prevention and treatment trials for emerging and re-emerging pathogens.

Clinical trials of medical countermeasures for new emerging pathogens produce significant breakthroughs in discovering lifesaving medicines, diagnostics, and vaccines during public health emergencies. These trials are delivered in tough emergency contexts with accelerated timelines to produce results as quickly as possible. Multistakeholder engagement throughout the lifecycles of clinical trial development, deployment and dissemination ensures trial implementation is understood, acceptable, relevant, and trusted. Learning lessons from HIV prevention trials, in 2016, WHO developed guidelines for Good Participatory Practice to normalise and standardise this work for clinical trials of emerging pathogens (GPP-EP).
Milestones guiding GPP activities

**Before site selection**
- Set up internal engagement and communications group
- Plan engagement activities
- Context scan
- Map stakeholders
- Identify resources
- Identify or set up a CAB
- Review protocol and anticipate concerns
- Establish clear communications channels
- Establish media contacts
- Engage with global coordination

**Before recruitment**
- Finalize engagement plan
- Include engagement plan in protocol
- Engage CAB
- Plan and conduct engagement activities
- Develop tools and materials including FAQs
- Feedback outcome of consultation to trial team
- Establish mechanism for public information and communications

**During recruitment**
- Establish mechanism for continuous input from local stakeholders
- Establish a system for monitoring anxieties, concerns, rumours
- Proactively engage in activities to foster trust
- Share experiences ad troubleshoot with global coordination.

**End of the trial**
- Prepare and communicate closure and exit strategies in advance
- Get feedback from CAB re: sharing trial outcomes
- Ensure sufficient resources for engagement and feedback activities at the end of the trial.
Solidarity Trial Vaccines: lessons learned and existing tools

- an international, individually randomised controlled trial to rapidly evaluate promising new vaccines for COVID-19
- led by World Health Organization (WHO) and co-sponsored by WHO and Ministries of Health

Key features of STV GPP coordination

- Bespoke onboarding for new teams
- Suite of tools and resources
- Global coordination
Implications for the Lassa vaccine trial protocol
1. Rapid formative research on key questions
   • Focused on key questions, scoping for trial, alongside existing clinical trials, vaccine acceptance for trials not same as acceptance for roll out.

2. Mechanism for end user input to protocol development
   • Advisory group, including people who have had Lassa fever, people who are at risk. Be clear on where the input can happen – clear expectations.

3. Plan for and invest in GPP-EP throughout the trial
   • Plan, budget, staff: community engagement focal point, engagement plan before, during and after, engage national PIs
National Principal Investigators, GPP-EP leads and GPP-EP teams in countries delivering the Solidarity Trial Vaccines (Colombia, Philippines, Mali, Sierra Leone, Kenya)

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