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?

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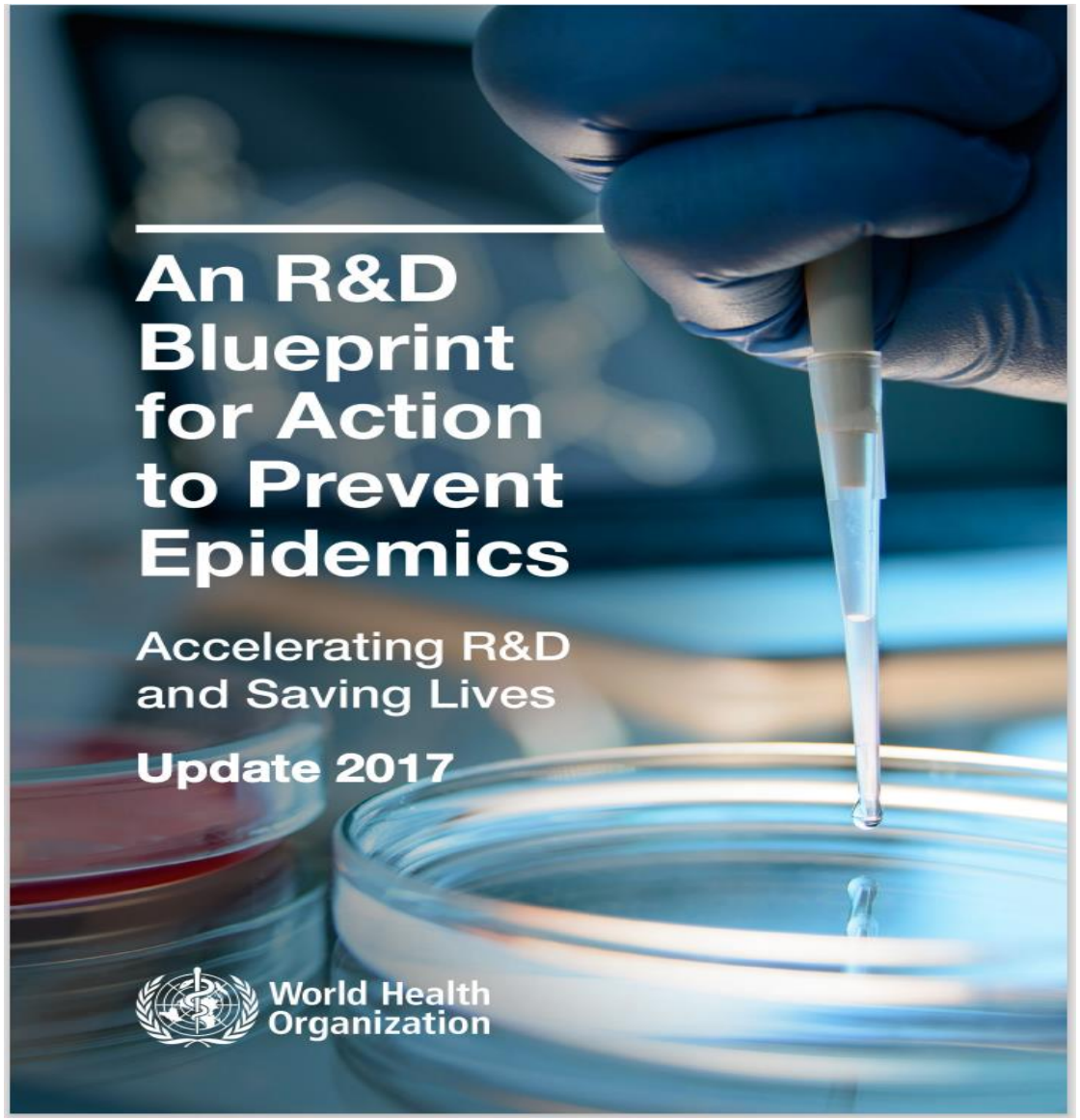
Good Participatory Practice for clinical trials of (re-)emerging pathogens (GPP-EP)



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.

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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?

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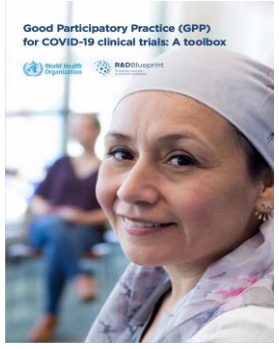
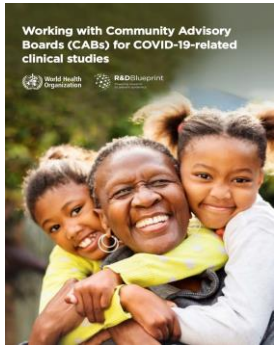
Good Participatory Practices

← Solidarity Trial Vaccines

Credits +





What is 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 clinal 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).

Key documents

- Good Participatory Practice (GPP) with trial populations for the Solidarity Trial Vaccines (STV)
- Good Participatory Practice for trials of (re-)emerging pathogens (GPP-EP): Guidelines
- Working with Community Advisory Boards for COVID-19 clinical studies
- R&D Good Participatory Practice for COVID-19 clinical trials: a toolbox

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

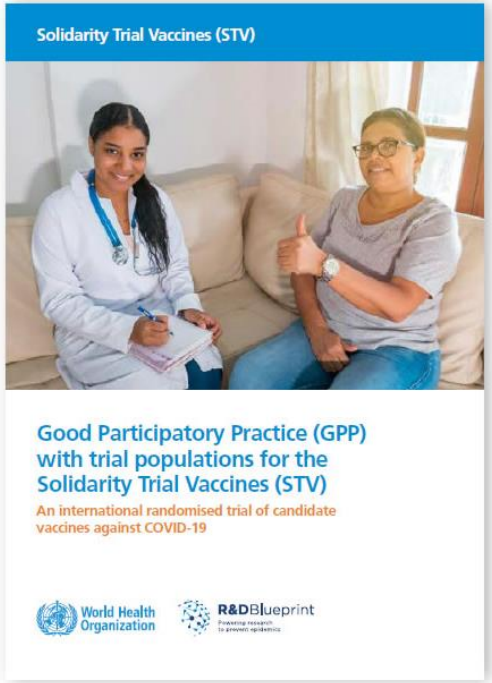
- Prepare and communicate closure and exit strategies in advance
- Get feedback from CAB re: sharing trial outcomes
- Ensure sufficient resources for engagement and feedback activities at the end of the trial.

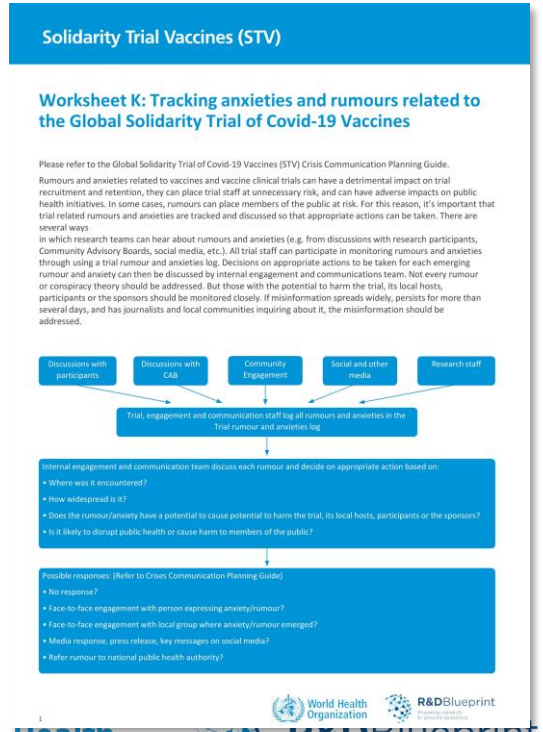
Solidarity Trial Vaccines: lessons learned and existing tools

- 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**





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Implications for the Lassa vaccine trial protocol

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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

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Acknowledgements

National Principal Investigators, GPP-EP leads and GPP-EP teams in countries delivering the Solidarity Trial Vaccines (Colombia, Philippines, Mali, Sierra Leone, Kenya)

WHO COVID-19 Research Roadmap Good Participatory Practice technical advisory group: Lisa Schwartz (McMaster University), Alun Davies (KEMRI-Wellcome Trust, University of Oxford), Alex Bernier (McMaster University), Anna Buhrmann (McMaster University), Eugenia Canas (University of Western Ontario), Phaik Yeong Cheah (MORU Tropical Health Network, University of Oxford), Joanna Howard (Institute of Development Studies), Shelley Lees (London School of Hygiene and Tropical Medicine), John Marshall (University of Toronto), Sassy Moluneaux (KEMRI-Wellcome Trust, University of Oxford), None Mumba (KEMRI-Wellcome Trust, University of Oxford), Srin Murthy (University of British Columbia), Elysee Nouvet (University of Western Ontario), Zoha Salaam (McMaster University), Beatriz Thome (Federal University of Sao Paulo).

Audience Social Marketing (design/editing): Ed Gyde and Andrew Pate with Becky Owens, independent communications consultant.

WHO: Nina Gobat, Sayyorra Esser, Patrick Lydon, Ximena Riveros Balta, Odile Leroy, Alhassane Toure, Abourahamane Diallo, Ana Mara Henao Restrepo

Resource development was supported by German Federal Ministry of Health (BMG) COVID-19 Research and development funding to WHO

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