



MRC-NIHR Trials Methodology Research Partnership: Webinar recording

## **Engaging non-researchers with clinical trials**

*Presented, on behalf of the Global Health Network, by:*

Alun Davies (University of Oxford) and Salim Mwalukore

**14 February 2024**

The slides are available below.

For any queries, please contact [uktmn@nottingham.ac.uk](mailto:uktmn@nottingham.ac.uk)

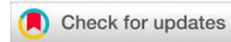
<https://youtu.be/u5eqoRDDKBg>

# Drawing lessons on engagement and involvement for Adaptive and Alternative trial designs from Ebola and Covid-19

14<sup>th</sup> February 2024





## Alun Davies





SYSTEMATIC REVIEW

## A rapid review of community engagement and informed consent processes for adaptive platform trials and alternative design trials for public health emergencies [version 1; peer review: 2 approved]

Alun Davies <sup>1</sup>, Ilja Ormel<sup>2</sup>, Alexe Bernier <sup>3</sup>, Eli Harriss<sup>4</sup>, Noni Mumba <sup>5</sup>, Nina Gobat<sup>6</sup>, Lisa Schwartz<sup>2</sup>, Phaik Yeong Cheah <sup>7,8</sup>

Commentary

BMJ Global Health

## Ethical priorities for international collaborative adaptive platform trials for public health emergencies

Katharine Wright <sup>1</sup>, Joseph Ali <sup>2</sup>, Alun Davies <sup>3</sup>, Paul Glasziou <sup>4</sup>, Nina Gobat <sup>5</sup>, Tanja Kuchenmüller <sup>6</sup>, Katherine Littler <sup>7</sup>, Chelsea Modlin <sup>2</sup>, Lee-Anne Pascoe <sup>7</sup>, Andreas Reis <sup>7</sup>, Jerome Amir Singh <sup>8</sup>

- Community Engagement and Consent in public Health Emergencies
- Contrasting approaches in Ebola and COVID-19 trials

# Guidelines for engagement with clinical trials

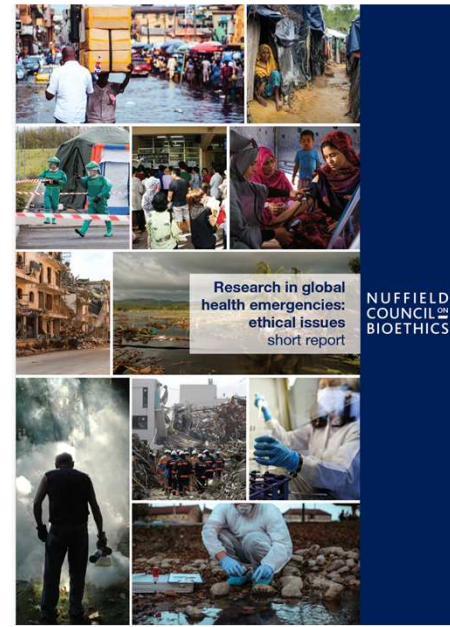


Good participatory emerging (an that are likely to cat future and fo coun!

Outcome docume



Prepared by Dr Catherine Hankins for the World Health Organization December 2016



NUFFIELD COUNCIL ON BIOETHICS



UK policy framework for health and social care research

Better public involvement for better health and social care research

Supported by the UK Public Involvement Standards Development Partnership



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1. Briefing note one: introduction
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  1. Democratic principles
  2. Provide a different perspective
  3. Improve the quality of the research
  4. Making the research more relevant
  5. Interests of research funders and research organizations
  6. Ethics

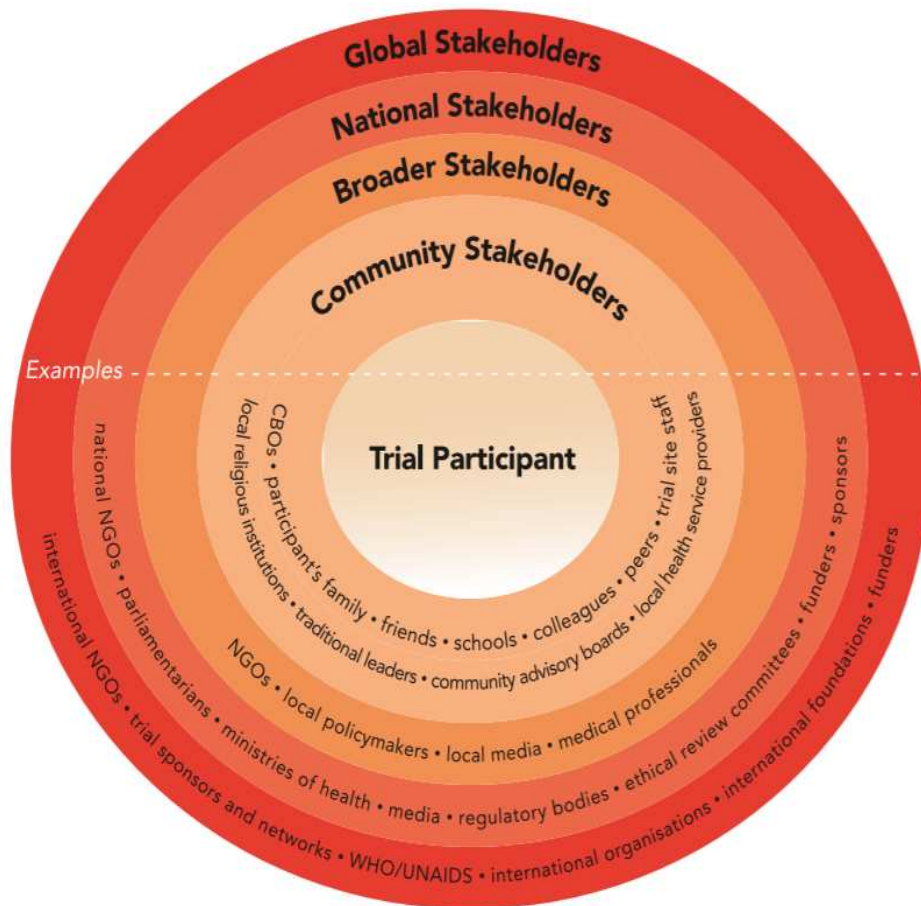
Published: 05 April 2021      Version: 1.0 - April 2021      [Print this document](#)

**Briefing note one: introduction**

This guidance is for researchers new to public involvement in research and just starting to consider how best to involve members of the public in their work. It will also be of interest to researchers with experience of public involvement in research who are looking to update and refresh their knowledge and skills. And it will be helpful to others interested in public involvement in research. Including involvement leads. This guidance explains the different ways that members of the public are involved in research. It will help you to plan, resource and support public involvement in research.

You can find more involvement resources and guidance on [Learning for Involvement](#).

# What is Good Participatory Practice

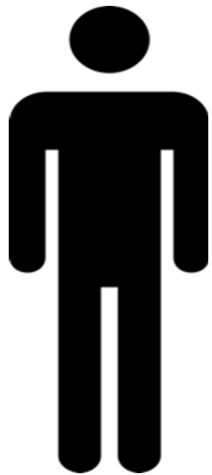


- Engage with a range of stakeholders
  - International, National and Broader, stakeholders
  - Community/Public
  - Patients – with lived experience
- Engagement at the beginning of the trial
  - Agreements, Social value, discuss risks and concerns, acceptability, feasibility,
- Engagement during the trial
  - Inform implementation, address concerns
- Engagement at the end of the trial
  - Dissemination, giving feedback, ensuring long-term collaborative partnerships

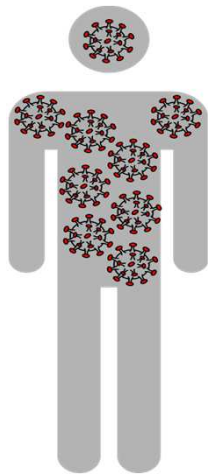
# Explanatory trials vs Adaptive/Alternative trials

## Explanatory RCT

- Fixed sample size
- Strict inclusion/exclusion criteria
- Trained research clinicians



Uninfected



Infected

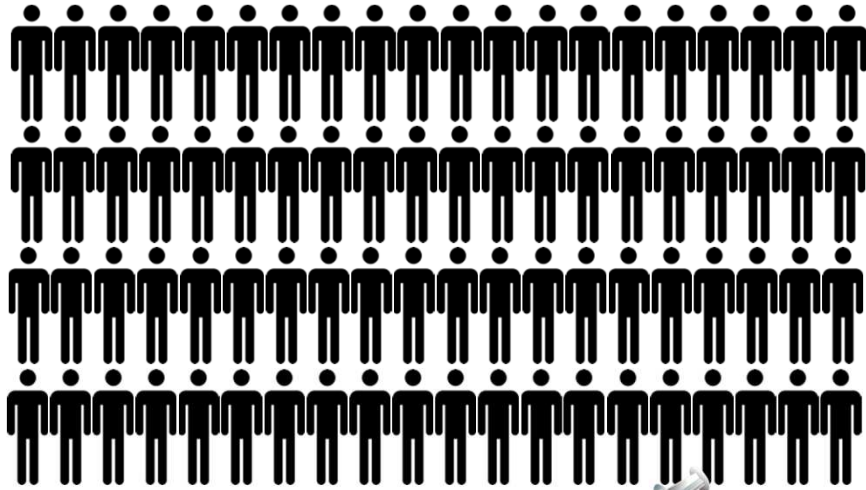
## Adaptive platform trials

- Final sample size determined by the number of outcomes (Bayesian statistics)
- Arms can be dropped or added
- Pragmatic trials – drawing on hospital networks eg NHS
- Often managed by treating clinicians

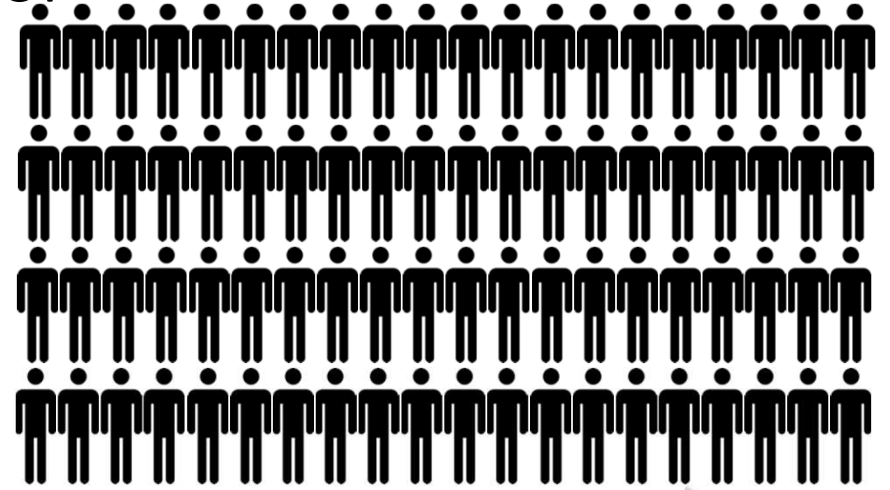
## Alternative design Trial

- Cluster randomized ring vaccination

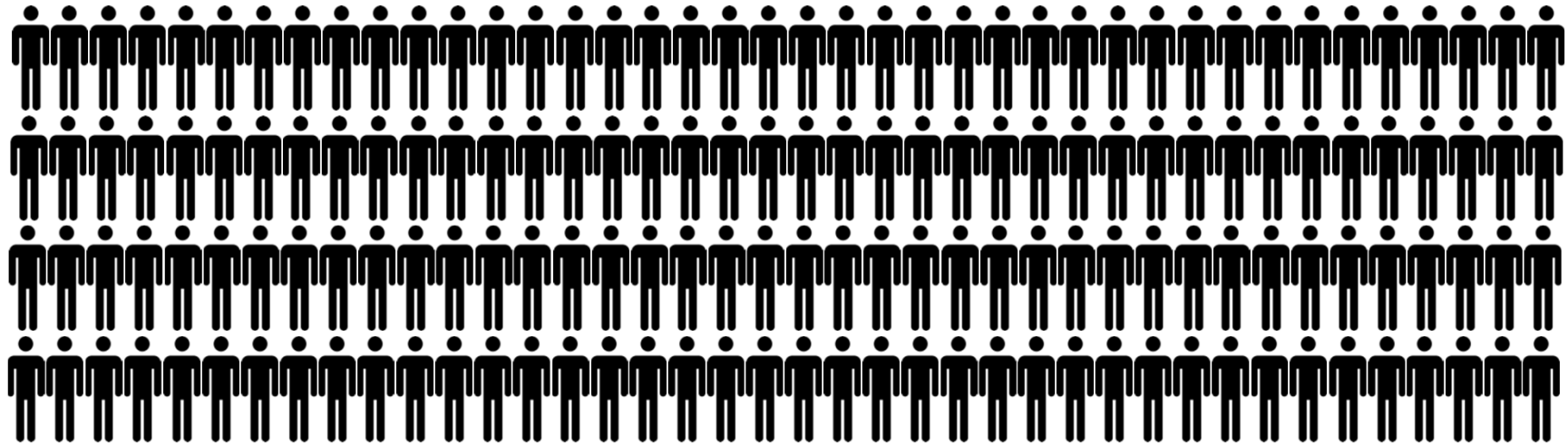
'Explanatory' RCT



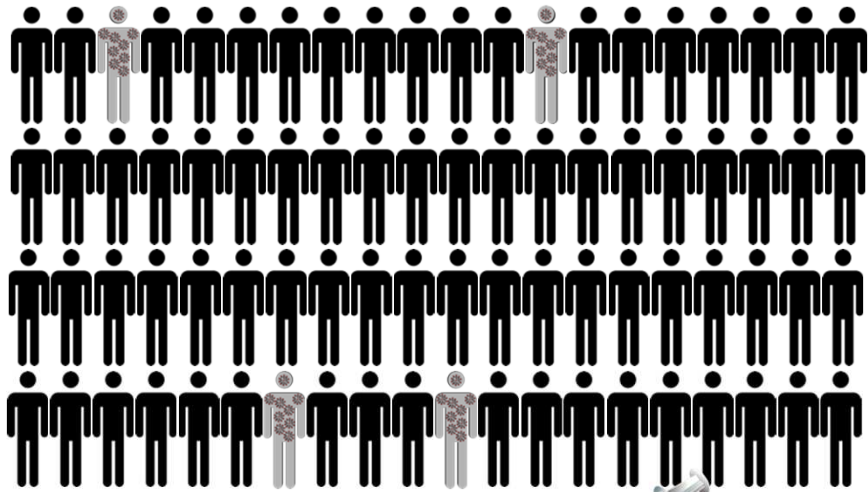
Vaccine A



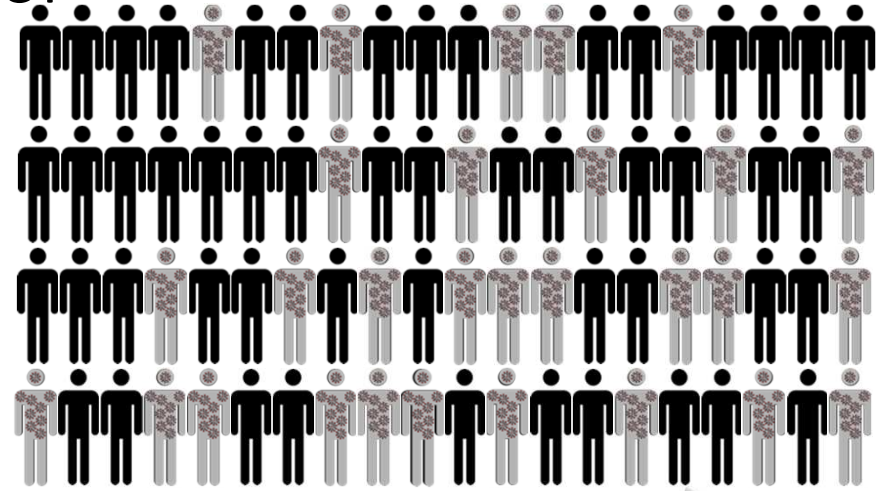
Vaccine B



'Explanatory' RCT



Vaccine A



Vaccine B

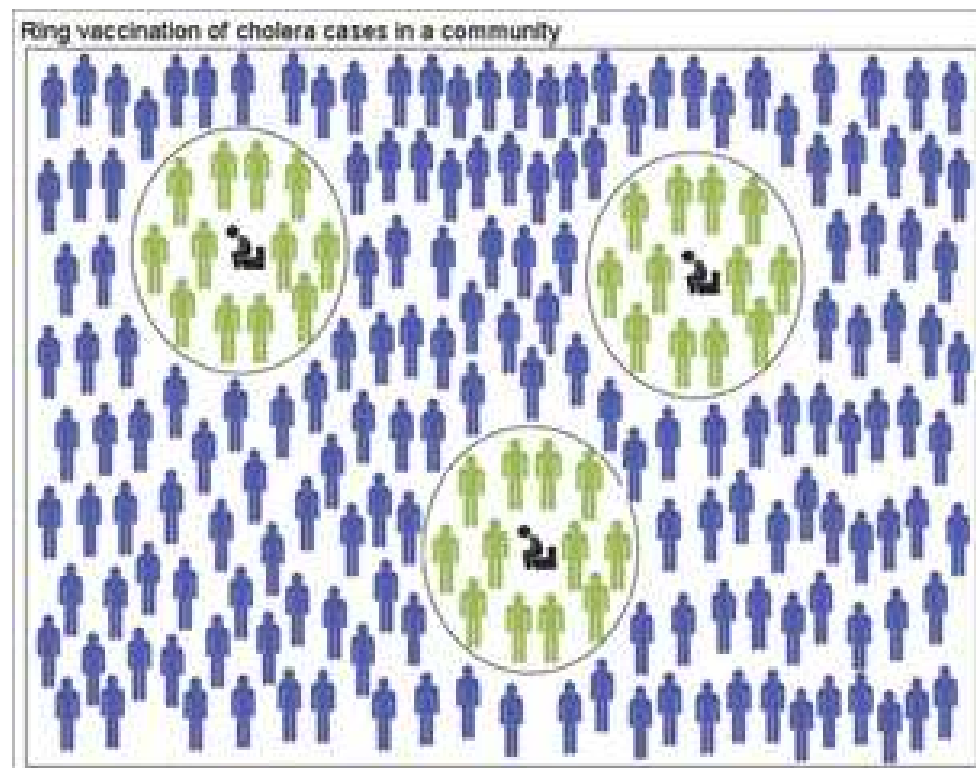


Month  
12



## Alternative Design Trial: Cluster Randomized Ring Vaccination (CRRV)

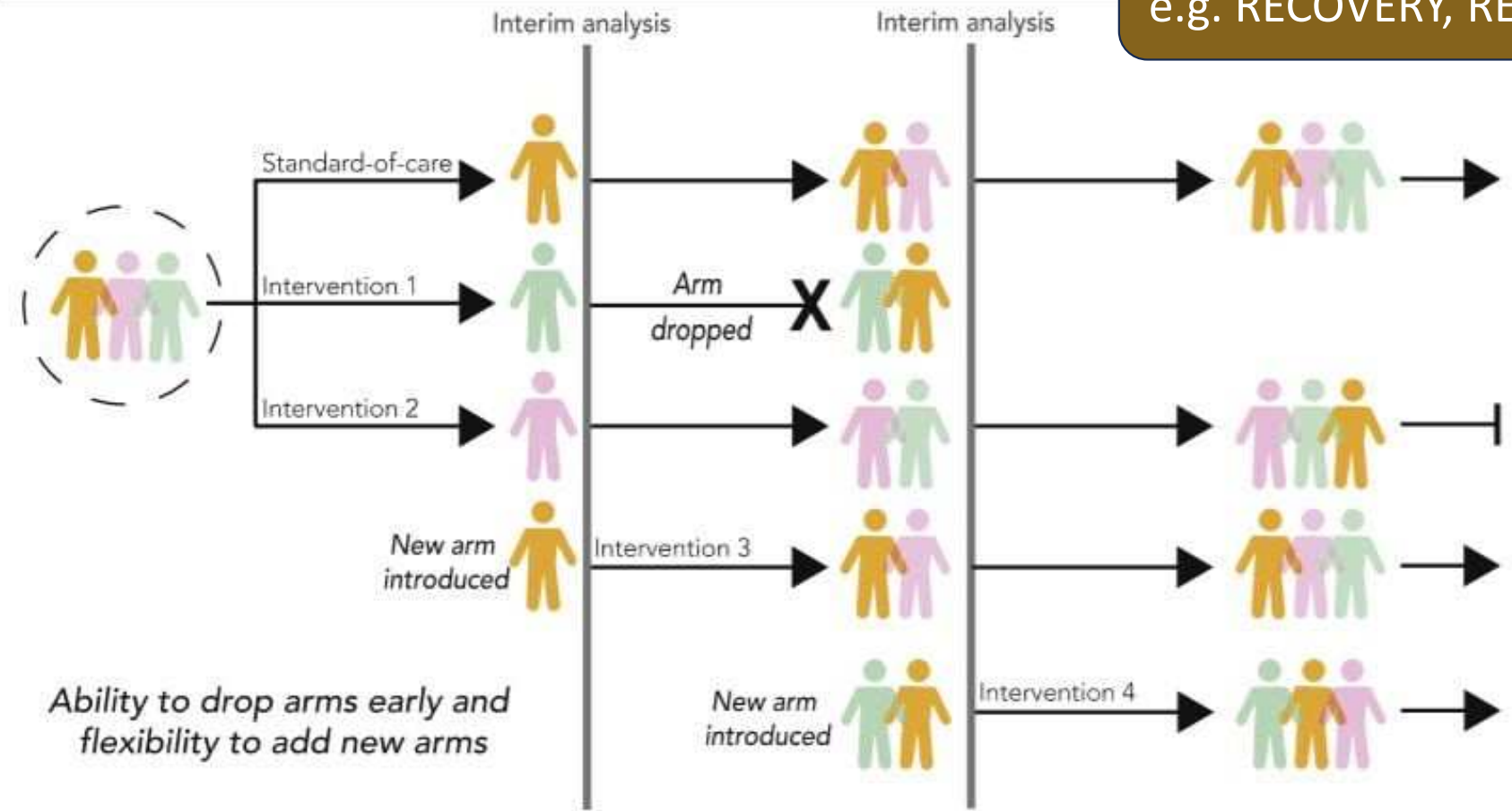
- Ebola Ca Suffit Ring vaccination cluster randomised trial Guinea
- Randomisation of clusters into 'immediate' or 'delayed vaccination'
- No placebo



Deen and von Seidlein. "The case for ring vaccinations with special consideration of oral cholera vaccines." *Human vaccines & immunotherapeutics* 14.8 (2018): 2069-2074.

# Platform trial

Covid-19 Treatment trial  
e.g. RECOVERY, REMAP-CAP



Ability to drop arms early and flexibility to add new arms

Park JJ, Harari O, Dron L, Lester RT, Thorlund K, Mills EJ.  
An overview of platform trials with a checklist for clinical readers.  
Journal of Clinical Epidemiology. 2020 May 13.

# Engagement before the trial

## **Ebola ca Suffit – CRRV**

- Both contexts – no existing treatment, fear and need for speed
- Field based vaccine trial – West Africa
- Context mistrust of researchers
- Stakeholder engagement – determine acceptability - shift from Placebo Control to CRRV
- Huge community engagement efforts – raising awareness and building trust – “key to the trial’s success”

## **APTs e.g. RECOVERY, REMAP-Cap,**

- Hospital-based COVID-19 treatment trial – UK, Europe etc.
- Very high-level stakeholder engagement
- *“A standard contract was issued to sites with a “take it or leave it” approach, allowing no room for local negotiation or adaptation.” Goosens et al, 2021*
- Sparse pre-trial Patient and Public Involvement in the literature

# Engagement during the trial

## **Ebola ca Suffit – CRRV**

- Described well in the literature – though no empirical studies on engagement
  - Raising awareness, addressing public concerns and building trust Epidemic surveillance
  - Identification of index cases and contacts
  - Recruitment

## **APTs e.g. RECOVERY, REMAP-Cap,**

- Very sparse description in the literature
- Web-based engagement described on trial websites
- PPI activity – inform comms and consent materials – sparsely described in the literature
- Huge Public Communication – though not described in academic literature

# Engagement after the trial

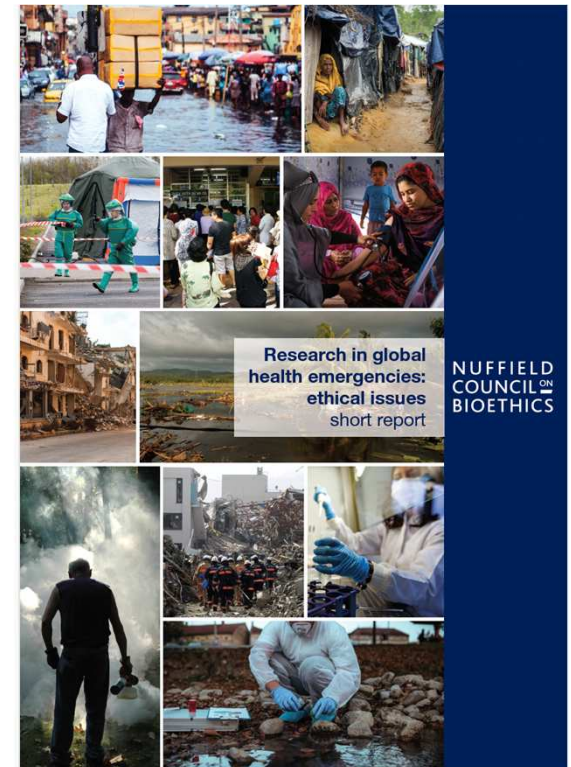
**Ebola ca Suffit – CRRV**

**APTs e.g. RECOVERY, REMAP-Cap,**

- No Descriptions of post trial engagement were found in this literature review
- In general – very sparse description of any PPI or engagement for Covid-19 Trial

# Guideline documents – some potential gaps?

- Some guidelines had a focus on challenges associated with PHEs
  - Mitigate infection
  - Addressing fear
- Very little guidance for adaptive/alternative trials
  - No guidance on engagement for dropping/adding arms
  - Assessing social value as new treatments/vaccines emerge
- Guideline documents gave limited differentiation of engagement approaches for vastly different trial contexts:
  - Field based vaccine trials vs hospital treatment trials (healthy vs sick)
  - Conducting vaccine trial during national roll-out – placebo?
  - Different trial designs



# The value of Stakeholder engagement

- Ebola ca Suffit – Stakeholder input trial design and acceptability
  - Engagement leading to substantial changes in trial design
- PRINCIPLE – UK based Covid-19 treatment trial
  - Innovative approaches to reach diverse audiences and ethnic minorities – diversity in recruitment
  - Online public survey to assess public acceptability of using contact data derived from COVID-19 tests to recruit participants



# Many thanks

- Alexe Bernier (McMaster University);
  - Ilja Ormel (McMaster University);
  - Nina Gobat (University of Oxford, GOARN-Research);
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  - Noni Mumba (KEMRI-Wellcome Trust Research Programme, Kenya);
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- This work was supported by Wellcome 214711





# Placing Communities at the Centre of Research Planning and Implementation



**Community Engagement at the KWTRP**

**Salim Mwalukore**

# Defining Engagement

Terms used inter-changeably:

Community Engagement (**CE**); Public Engagement (**PE**); Participant-Patient Involvement (**PPI**); Stakeholder Engagement (**SE**)

1. Process of working collaboratively with relevant partners who share common goals and interests (*Tindana et al, 2007*)
2. A set of activities aimed at **building mutual understanding** and **respect** between communities/publics and researchers (*KWTRP Communication strategy, 2005*)

# At Present Community Engagement

- A set of activities undertaken to create **mutual understanding and appropriate levels of trust** between the communities that participate in research activities and the KWTRP research programme
- Activities undertaken to create community awareness on planned or ongoing studies in the community and at the KWTRP research programme

**Our Engagement has since expanded;**



# The Engagement has since expanded in response to views and expanding work of the programme



**Engagement with  
local communities  
and stakeholders**



**Engagement with  
Schools/Univ.,  
Media, public**



**Engagement with  
Policy makers**



# Our Broad Engagement Goals



**Building, sustaining and deepening respectful relations and mutual understanding between communities/publics and researchers/research institutions**



**Sustaining and deepening values, policies and practices for CPE at KWTRP to support responsive, mutually beneficial and ethical research**



**Contribute to strengthening regional and global CPE policy and practice through collaborative initiatives**



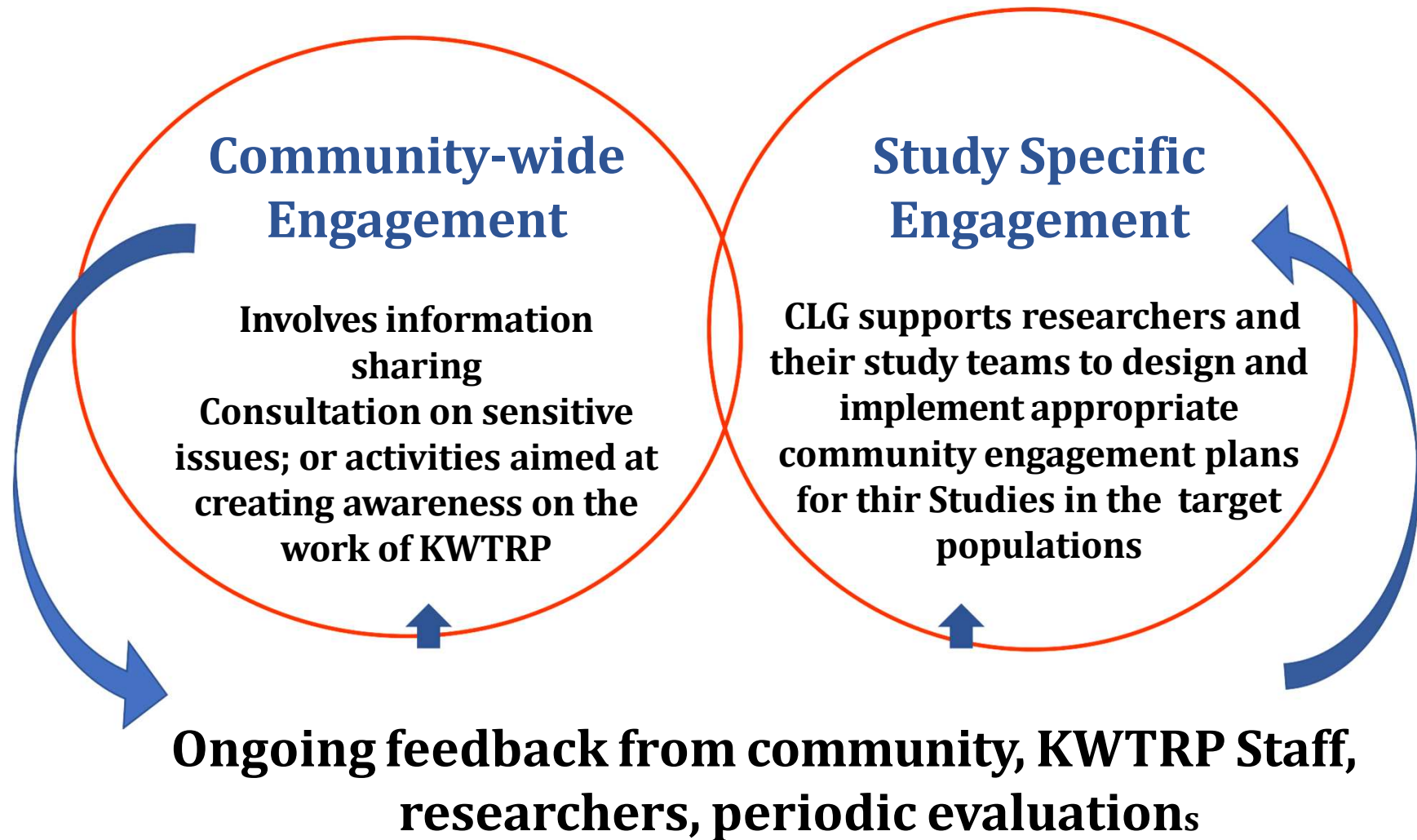
**Strengthen the translation of research findings into health policy**

# Why Community Engagement?

- **Ethical** requirement
- Building bridges; **respect**; collaboration
- Building and **maintaining trust**
- Inclusion of **community voice** in research agenda; processes
- Direct input into **study procedures**
- Representing **interest of** research community; participants

A good in itself

# Structure of our core engagement





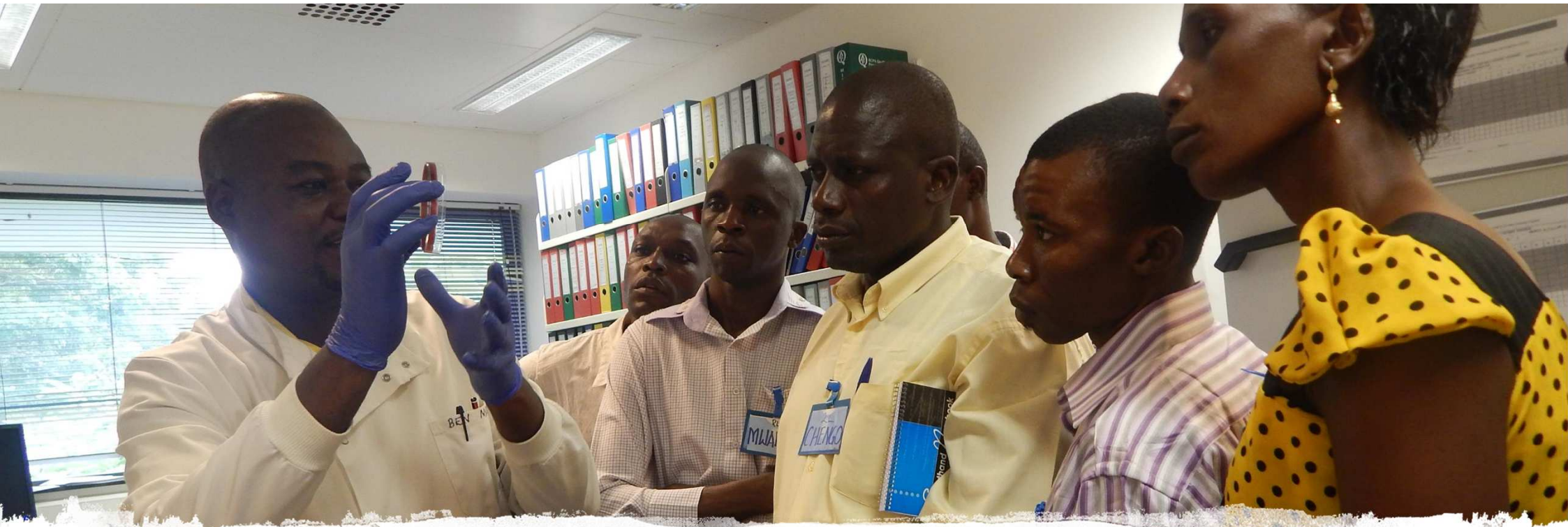
# What Engagement Entails

## Community-wide Engagement

- KEMRI Community Representatives Network
- Open Days for Community and Staff
- Community meetings
- Magnet Theatre (Drama) sessions for difficult topics
- Community Exhibitions

## Study Specific Engagement

- Review of research protocols
- Joint planning of engagement
- Joint Implementation of CE plans
- Training Interface Research staff
- On going support to interface research Staff and response to concerns

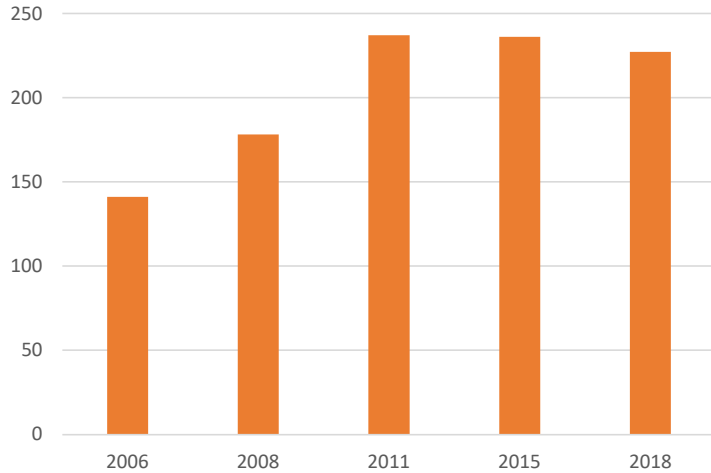


## Open Days

- Approach used to reach very **specific gatekeepers**: internal (KWTRP staff); external (religious leaders, Ward Administrators, MCAs...)
- Lab staff very supportive, and see this as a very important activity
- Various community groups reached with this activity

# KCR Network

KCR Network Members



- So far have had about **1,019** community members as KCRs
- **Network an important link** to KHDSS community; relationship and trust building
- **KCRs consultation:** Contributed to policies the KWTRP

- **Network set up in 2006:** every 3 years conducting sub-location level elections;
  - **KCR Important Channel for Community Consultations** as we increasingly conduct complex research: e.g. human infection studies
- e.g. of consultations:** Shigella HIS, Biobanking, Research in Children, Data Sharing, Benefits & Payments
- **KCRs want to do more;** have more active roles; reluctant to retire when term ends

# Study Specific Community Engagement

## **Objectives**

- To consult the community on study specific procedures and processes
- Get feedback from communities on ongoing and planned research
- Create awareness on study specific activities to opinion leaders/gate keepers
- Sensitize the community on planned or ongoing studies
- To respond to community concerns during the implementation of research activities
- To feedback results of research findings to various stakeholders

# Study Specific Support Processes

- CLG support through CCC and protocol development Meetings (PDM)
- CCC review of Informed Consent and other Participants' Materials
- Translations of Informed Consent to local languages
- Constituting of Community engagement Advise for Studies Team (CAST)
- Development of Community Engagement Plan
- Implementation of the Engagement targeting different stakeholders
- Reacting to Study Specific Concerns from the Community

# Embedded Monitoring and Evaluation



**Community and Public Engagement  
2016-2021 Evaluation Report**

**REPUBLIC OF KENYA**



**MINISTRY OF HEALTH**



# Acknowledgements

