Please see below for a link to the webinar recording for the Trials Methodology Research Partnership:

Clinical research in low resource settings

Elizabeth Allen (University of Cape Town), Arancha De La Horra Gozalo (University of Oxford), James O'Donovan (University of Oxford), Sangeetha Paramasivan (University of Bristol), Wigilya Mikomangwa (MUHAS, Tanzania)

23 March 2021

On behalf of the Global Health Network

The slides are also available below.

For any queries, please contact uktmn@nottingham.ac.uk

Part 1: https://www.youtube.com/watch?v=5WU3eGgPyX4

Part 2: https://www.youtube.com/watch?v=MYwYQyT93MU

Trials Methodology TMRP Research Partnership

Global Health Working Group

MRC Medical Research Council

NIHR National Institute for Health Research

University of Cape Town · Universiteit van Kaapstad · iYunivesithi yaseKapa · Universiteit van Kaapstad

LSTM Liverpool School of Tropical Medicine

University of Oxford

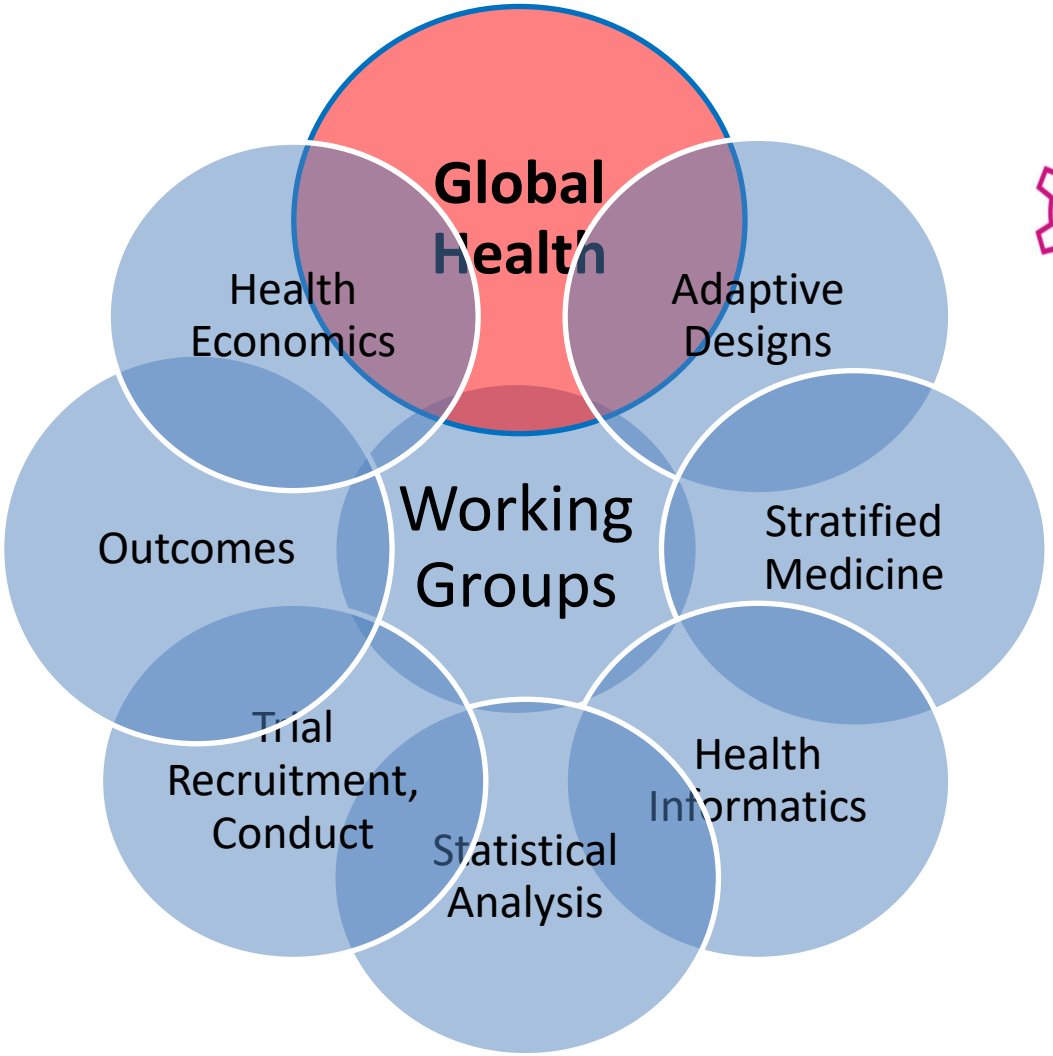
The Global Health Network
Enabling research by sharing knowledge

A global community of practice for Trials Methodology Research

Improving design, conduct, analysis of trials everywhere

- Trialists in all roles finding optimal methods
- Generating evidence for & implementing the most effective, appropriate methods
- Reflecting local context, internationally relevant

⟶ Trials benefit from insight & experiences of those working in both HICs & LMICs



Trials Methodology TMRP Research Partnership

MRC Hubs for Trials Methodology Research

UKTMN Trial Managers' Network

HDRUK Health Data Research UK

Health Research Board TMRN Trials Methodology Research Network

UKCRC Registered Clinical Trials Units

THE GLOBAL HEALTH NETWORK

MRC Medical Research Council

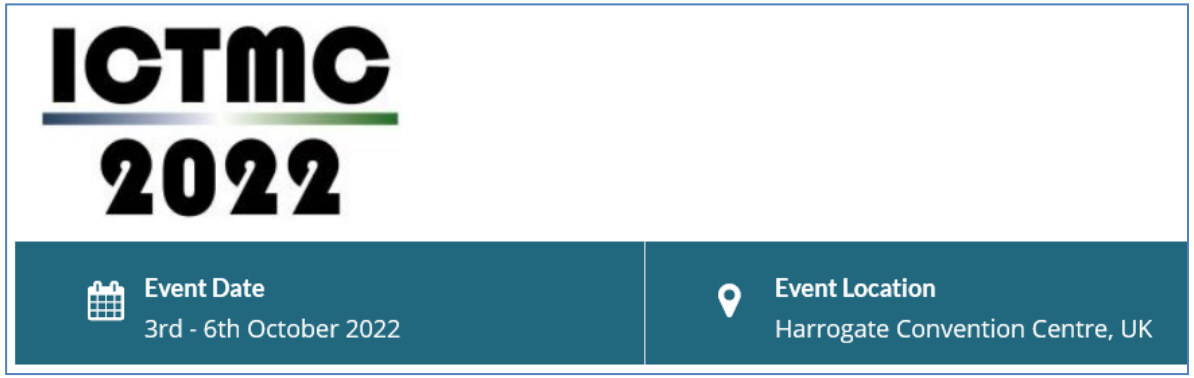
NIHR National Institute for Health Research

Remit of the Global Health WG

- Raise awareness of the field of trials methodology research in LMICs
- Signpost to other working groups of the TMRP
- Promote freely accessible resources, training
- Encourage networking
- Facilitate small grants for LMICs

What we've been up to

- Membership @ approx. 80
  - NB welcome to also join topic-specific WGs
- Integrated with the Global Health Network's online Global Heath Methodology Research hub
  - Competition to win attendance at ICTMC 2019
- TMRP Annual Meeting (recorded sessions)
- Twitter takeover @MRCNIHRTMRP
- Pump priming awards 2020



MRC-NIHR TMRP Webinar series 2

Previous recorded topics: adaptive trials, routine data, electronic study management systems, implications of COVID-19 for trials, involving the public with CTMR, using Twitter, CONSORT & SPIRIT guidelines updates

14th April HRB-TMRN

- **Recruiting to clinical trials in pregnancy**: using a behavioural lens to explore perceptions & experiences of recruiters

5th May: UK CRC Registered CTU Network

- **Wishing you a lightbulb moment in clinical trial monitoring** (ways of improving monitoring)

www.methodologyhubs.mrc.ac.uk
https://globalresearchmethods.tghn.org/

UKTMN Trial Managers' Network

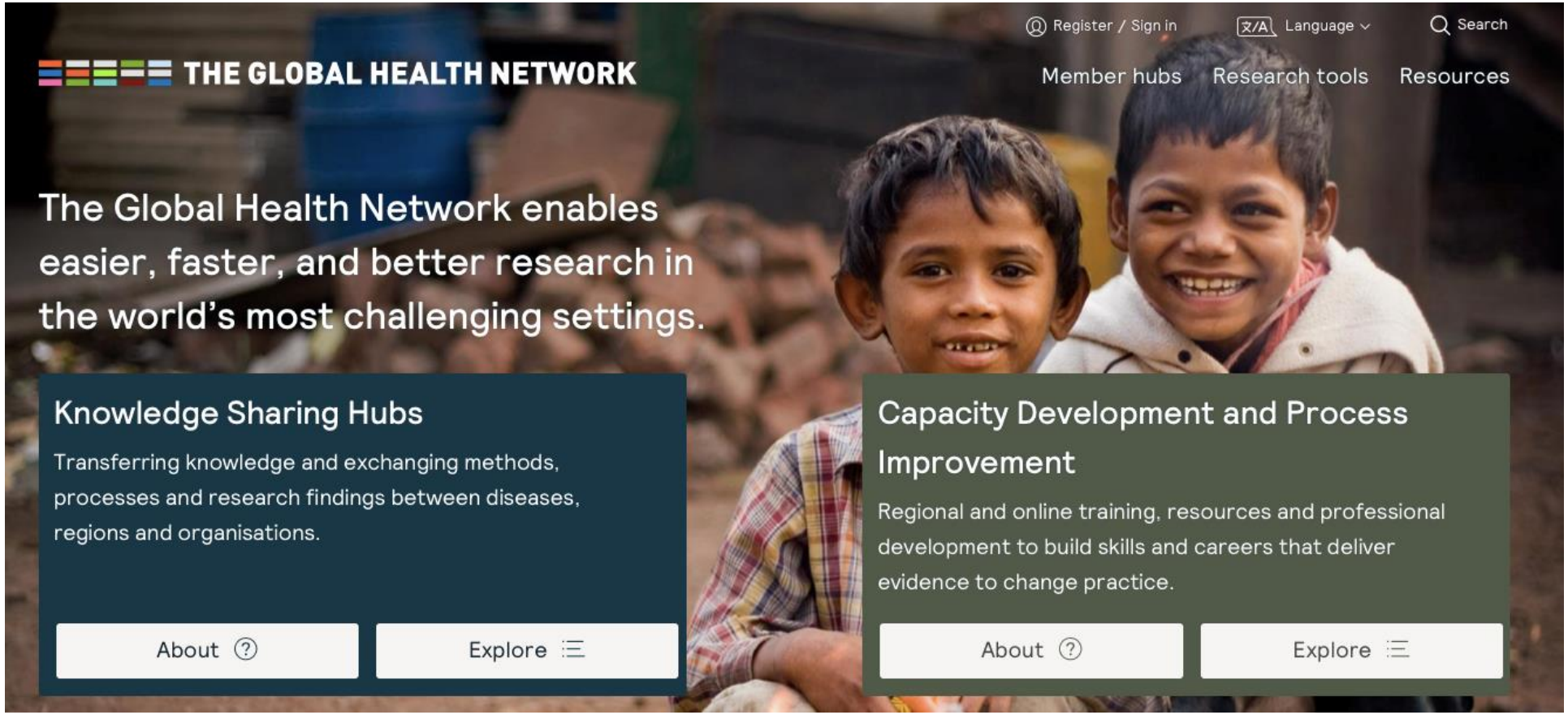
Pump priming awards

Uganda	The practice of **pilot studies** in informing the conduct of HIV clinical trials in sub Saharan Africa: a review of study protocols
Kenya	Pilot implementation of **Short Message Service for randomisation** in a multisite pragmatic factorial clinical trial in Kenya (PRISMS Study)
Uganda	**Photovoice to explore community members perspectives** regarding health and healthcare challenges in Mukono District, Uganda
Tanzania	Assessment of the **challenges encountered in implementing vaccine clinical trial** methodologies in low income countries
UK/India	**Optimising Informed CONsent** in clinical trials in low- and middle-income settings: feasibility of an adapted QuinteT Recruitment Intervention (QRI) in India (OrION-I)
Thailand	Exploring **barriers to data reuse**
South Africa	**Cultural competence in trial design and conduct**

Better Research for Better Health

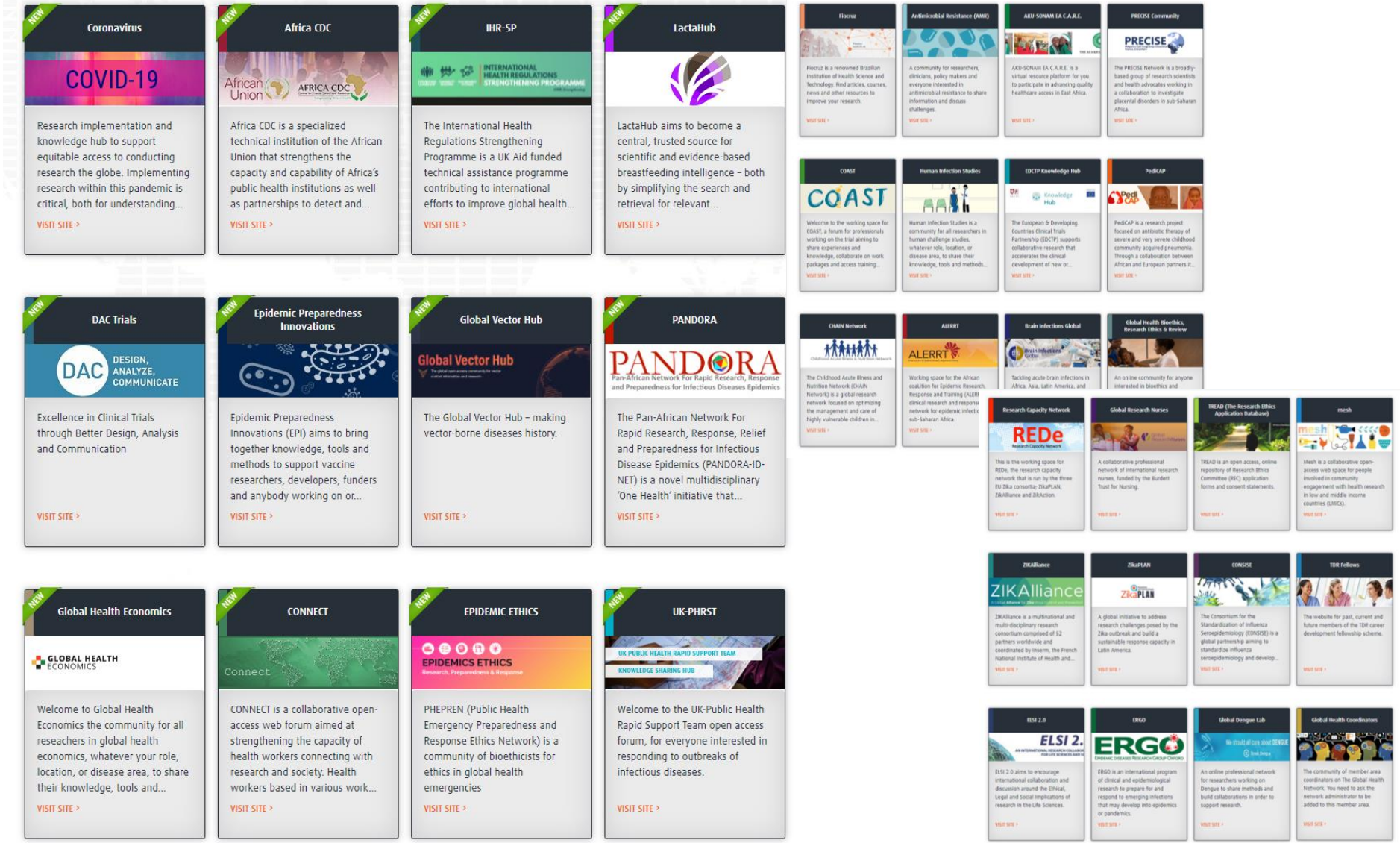
THE GLOBAL HEALTH NETWORK
Enabling research by sharing knowledge

Facilitating health research & delivering research capabilities



58 Member areas

THE GLOBAL HEALTH NETWORK
Enabling research by sharing knowledge



Research resources

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Global health Methodology Research Hub

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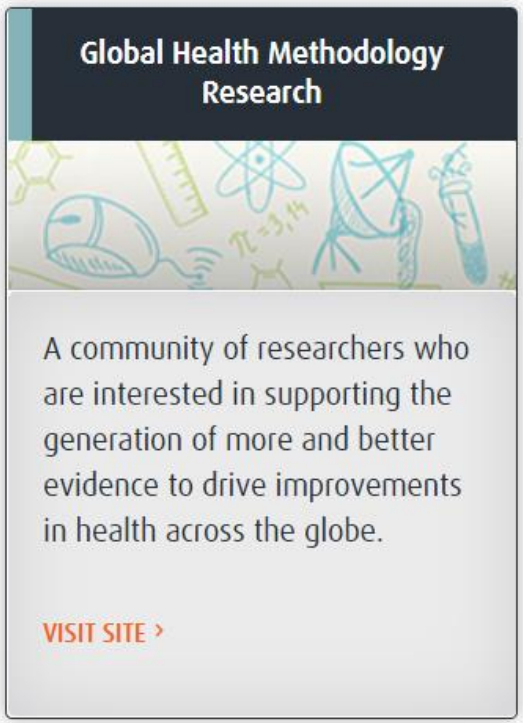


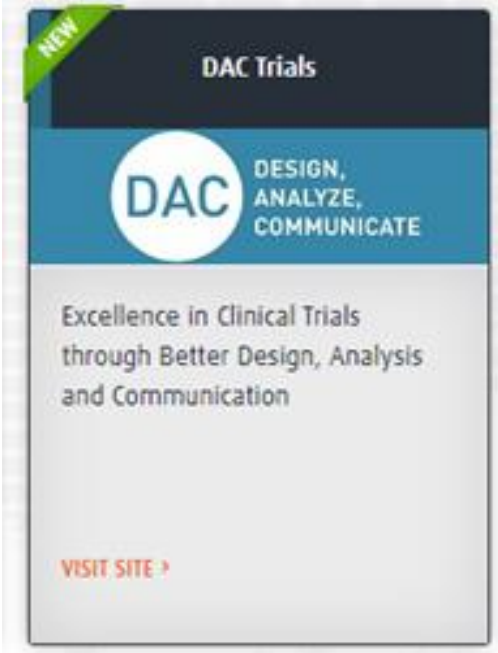
@GHWG_TMRP

https://globalresearchmethods.tghn.org/

For any other queries about the Global Health Working Group please contact Elizabeth Allen elizabeth.allen@uct.ac.za

DAC

THE GLOBAL HEALTH NETWORK
Enabling research by sharing knowledge

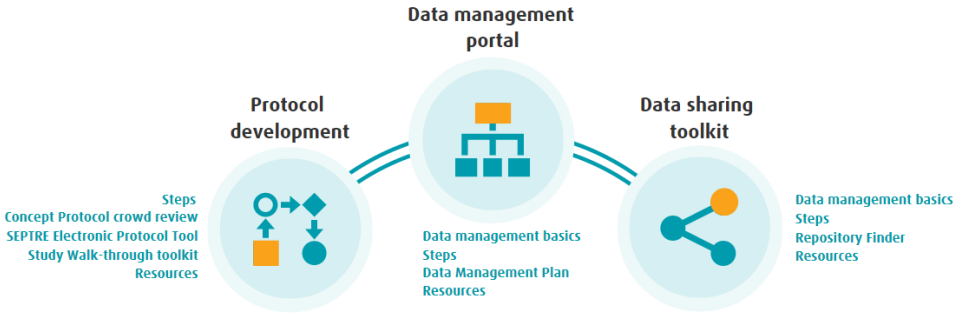


https://dac-trials.tghn.org/

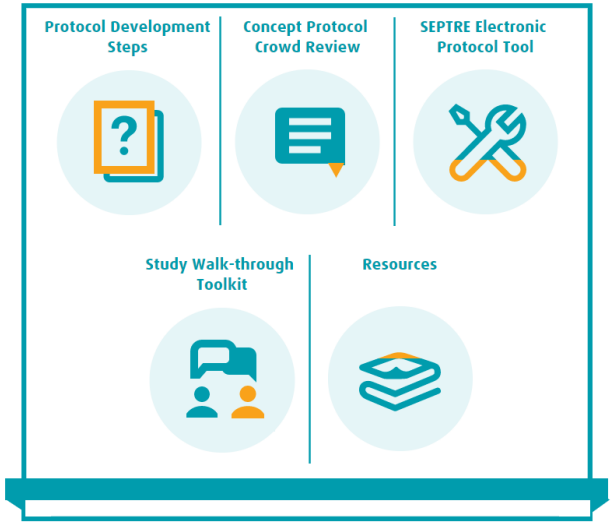
BILL & MELINDA GATES foundation

EDCTP knowledge hub

THE GLOBAL HEALTH NETWORK
Enabling research by sharing knowledge



Click on the icons to view the guide, resources, go directly to the protocol tools or learn about the Study Walk-through method

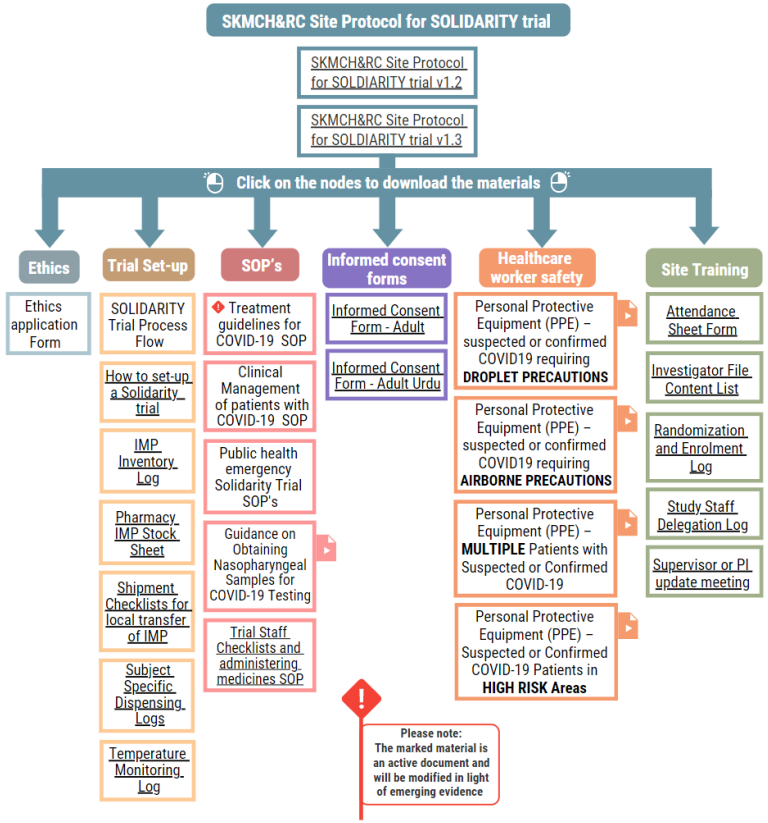


https://edctpknowledgehub.tghn.org/

Other resources

THE GLOBAL HEALTH NETWORK
Enabling research by sharing knowledge

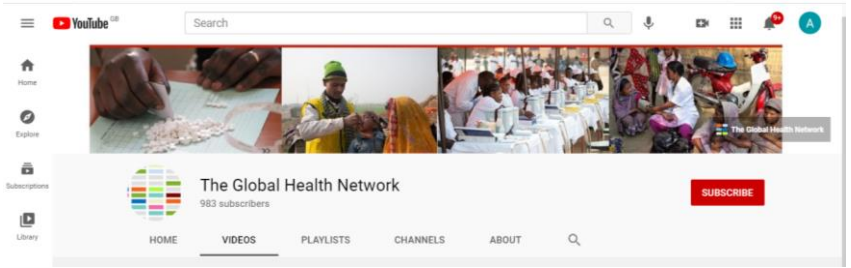
COVID-19 Research Implementation and Knowledge Hub



TGHN webinar events calendar

https://hub.tghn.org/event-tghn/

YouTube channel



New collaborations

- HeLTI – Healthy Lives Trajectories Initiative
- IBRN - International Blast Injury Research Network

For any other queries about the Global Health Working Group please contact Elizabeth Allen elizabeth.allen@uct.ac.za

THE USE OF PHOTOVOICE TO INFORM CLINICAL TRIALS IN GLOBAL HEALTH - A CASE STUDY FROM UGANDA

Dr James O'Donovan - DPhil, MBBS, MRes - Study Co-PI

Dr David Musoke – Lecturer, Makerere University School of Public Health – Study Co-PI

Miss Rebecca Hamala – Omni Med, Uganda

Mr Allan Namanda – Omni Med, Uganda

Mr Filimin Niyongabo –Makerere University School of Public Health

OUTLINE

- Rationale for our study
- Background to Photovoice
- Research questions
- Study setting
- Methods
- Preliminary Results
- Unanticipated challenges

RATIONALE FOR STUDY – THE PROBLEM

- It is essential that clinical studies in low- and middle-income countries (LMICs) **explore locally identified areas of concern**, in order **to ensure clinical trials are contextually relevant and incorporate local knowledge.**

- However, there is a relative **paucity in community members involvement in healthcare related research projects in LMICs.**

- A systematic review by George et al. pertaining to community involvement in health systems research in LMICs found that from 260 articles, 95% supported community's in implementing interventions but **only 18% involved communities in identifying and defining problems**.

Reference

George AS, Mehra V, Scott K, Sriram V (2015) Community Participation in Health Systems Research: A Systematic Review Assessing the State of Research, the Nature of Interventions Involved and the Features of Engagement with Communities. PLOS ONE 10(10): e0141091. https://doi.org/10.1371/journal.pone.0141091

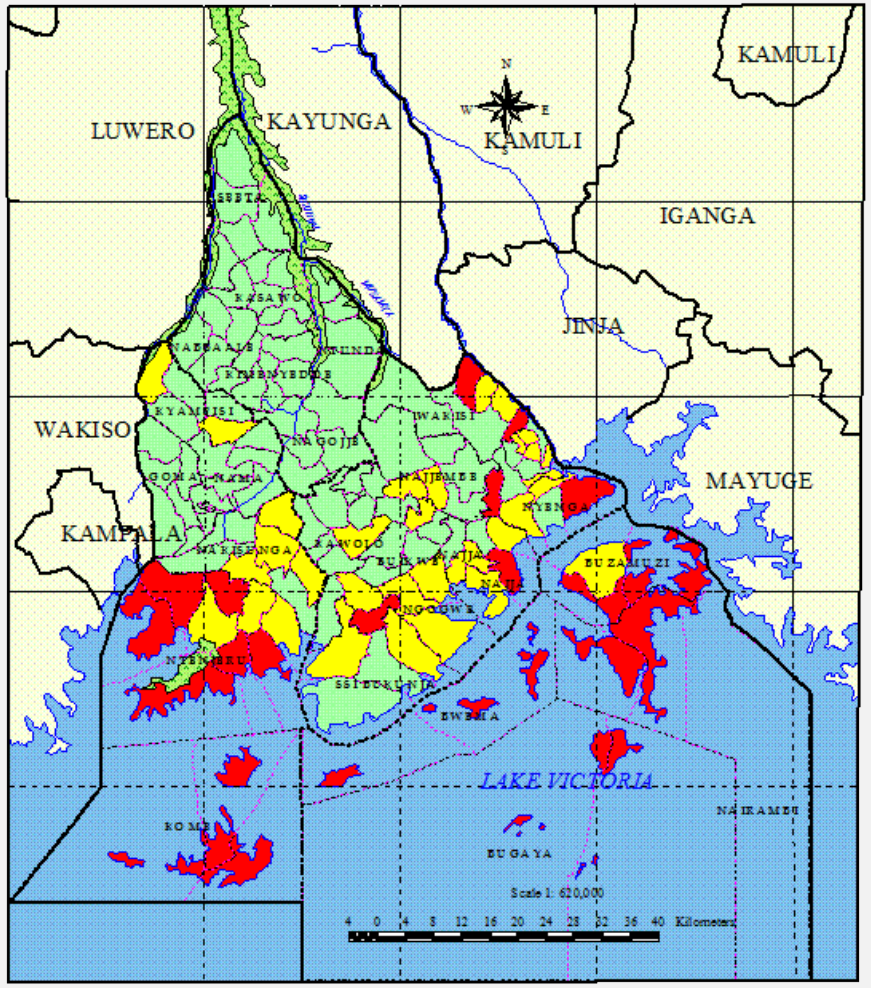
RATIONALE FOR STUDY – A PROPOSED SOLUTION

- Community Based Participatory Research (**CBPR**) is a useful approach to address this challenge.
- CBPR involves local stakeholders **being central** to the research process.
- CBPR can be a valuable way of helping to ensure research remains contextually relevant, and helps to better understand the lived experiences of a community.
- Specific to clinical trials CBPR has consistently been suggested as a means **of increasing and diversifying participation**, as well as their **relevance and quality to end users** (i.e. patients or community members).

PHOTOVOICE

- **Photovoice** is a Participatory Visual Method.
- In a photovoice study cameras are given to individuals in order to **capture photographic images around a central theme which is normally of community importance or concern**.
- These photographs are then used to facilitate interview-style discussions to explore the theme further.
- The photographs and findings from the discussions are then shared with the wider community with the aim of **action and change**.

STUDY SETTING



STUDY AIMS

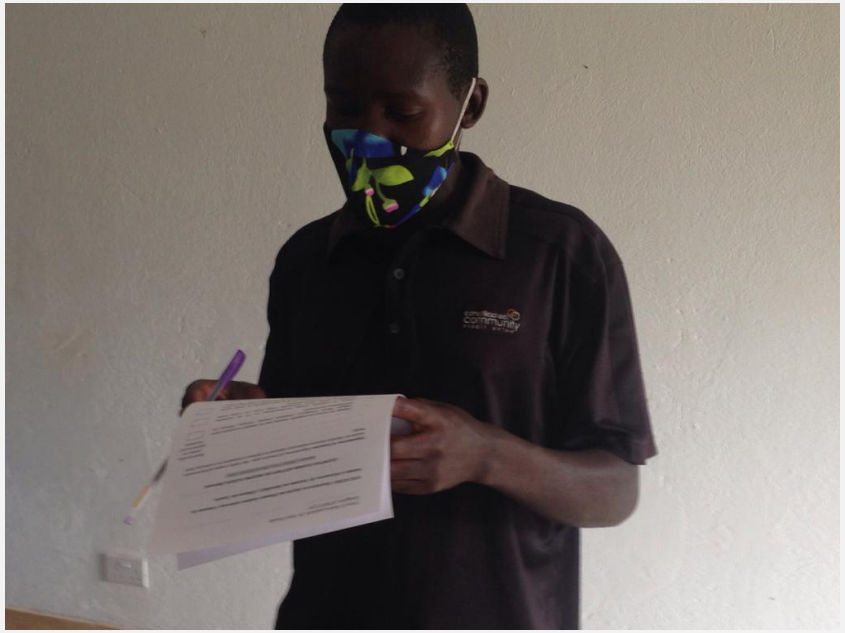
- In Mukono District, it is unclear as to how community members perceive the delivery of healthcare, local disease burdens, and the barriers they face in accessing care.

- The aim of this study is to **explore the feasibility and acceptability** of **using photovoice** with **community members** to understand their experiences and perspectives of health and healthcare in the region.

METHODS

- **14 community members** from the Seeta Nazigo Parish, Mukono were **purposively selected** to participate in the photovoice project.

- There was no restriction placed on sex, gender, language, religion or tribe.



METHODS CONTINUED…

- Community members were provided with cameras to capture images relevant to health issues and challenges that they face
- A 2-day training workshop was held covering: use of the cameras, obtaining consent

METHODS CONTINUED…

- Participants have been interviewed by the study research facilitators once each month at the local health centre, using the photographs as central discussion points and using the SHOWED acronym:

- What do you ***See*** here?
- What is really ***Happening*** here?
- How does this relate to ***Our*** lives?
- ***Why*** does this concern, situation, or strength exist?
- How can we become ***Empowered*** through our new understanding?
- And, what can we ***Do***?

- We are analysing the data using Braun and Clarke's 6-stage framework for thematic analysis.

References

Liebenberg L. Thinking Critically About Photovoice: Achieving Empowerment and Social Change. International Journal of Qualitative Methods. December 2018. doi:10.1177/1609406918757631
Virginia Braun & Victoria Clarke (2006) Using thematic analysis in psychology, Qualitative Research in Psychology, 3:2, 77-101, DOI: 10.1191/1478088706qp063oa

PRELIMINARY FINDINGS

- 53 relevant photos captured in the first month

THEME ONE –THE HIDDEN BURDEN OF CHILDHOOD DISABILITY

That is a young lady with her first born child. She gave birth to her baby when he is very normal, but after some time, the baby just stopped talking

“I took a photo of this child because of how helpless her situation is. She can neither shower nor eat on her own”

“Her wheel chair is broken and her family can’t afford a new one. She needed that wheel chair for daily movements including going to the health centre in case she falls sick.”

“Also, a place can be built for such children to be taken care of so that they feel safe. That place can also offer them free treatment whenever they need it because their needs are many. Being a girl who is now 17 years, she is undergoing changes in her body like menstruation”

That boy was affected by cerebral malaria which affected his brain…he shouts a lot and talks alone, he lives with his mother, the challenge his mother has is how to get medication from Butabika (mental health facility) that helps to calm him down. The facility is far and his mother has no transport to take her there.

Why is this important?

- It demonstrates the high and hidden burden of disability in the local area and the impact it has on parents and carers

- This finding is important for the future clinical trials given that this could be the primary focus of the clinical trial

- Disability is an underexplored area, especially in Ugandan and sub-Saharan Africa more broadly

- The community have been able to identify specific areas for clinical trial focus such as a holistic models of support including increased sensitization and training, provision of medications and the creation of formal links to specialist support and assessing the effectiveness of different aspects of this model

THEME TWO – CHALLENGES FACED BY THE ELDERLY

THEME THREE – LOCAL INFRASTRUCTURAL CHALLENGES AS A BARRIER TO GOOD HEALTH

What is the challenge?

"Someone is fetching water from a dirty jerry can…for drinking…It is an unprotected water source that people actually use"

Why is this a particular challenge?

"Our population have low incomes and cannot afford to build protected water sources. It is too expensive for us. Also, they do not understand the dangers of drinking un-boiled water since they have grown up watching people around them doing so. Those who are aware of the dangers are lazy and reluctant."

How this could be addressed?

"We need support from an organization or district leaders. We could create awareness and provide clean jerry cans to people."

What is the challenge?

"The poor condition of the roads hinders our ability to access the health centre"

Why is this a particular challenge?

"In terms of health, we don't have a nearby government health centre so we have to go to Seeta and that's the road that takes us there. I personally fell on that same road with my dad when we were heading to the health centre. It's the reason I took this photo"

How this could be addressed?

"Community mobilization… The first responsibility should be us since we are the ones directly affected.The local government also has a role to play "

FEASIBILITY AND ACCEPTABILITY OF PHOTOVOICE

Challenges with the camera (n=2) → Two community members were unable to capture appropriate photos for the initial set of interviews and so required further training

Challenges with the method (n=8)

→ Initial suspicion about the use of cameras & capture of photographs (n=6)

"After the training, it was challenging because people in my village were wondering when I became a qualified health worker for me to begin asking them questions about health. I kept explaining to them that there's an organization that trained and asked us to take photos so that they can identify the health needs of our area. On hearing that, many started trusting and confiding in me… all is well now"

→ Community members not wanting to discuss their problems openly (n=1)

"Most of them don't want to share their challenges, they are not straight forward yet sometimes we to know the difficulties they go through but they don't want to talk about them".

→ Challenges with children articulating their challenges (n=1)

"In most cases I find children who can't talk. Their parents or grandparents have to explain the problems they face but I don't think they tell the full story of the problems they are having"

UNANTICIPATED CHALLENGES RELATED TO THE STUDY

- **Pandemic related issues** → procurement of hardware for the study e.g. cameras / solar chargers
- **Ethical review delays** → in-person IRB meetings were delayed
- **Funding challenges** → money was sent to wrong division at School of Social Sciences

ACKNOWLEDGEMENTS

Collaborators

- Dr Kenneth Kabali – Chief Medical Officer, Omni Med, Uganda
- Mrs Margaret Nalubwama – Community Health Worker (CHW) supervisor, Omni Med, Uganda
- Mr Kiyingi Herbert – CHW supervisor, Omni Med, Uganda
- Mr Isaac Ddumba – Deputy District Health Officer, Mukono District, Uganda

Funders

Feasibility of an adapted QuinteT Recruitment Intervention to Optimise Informed cONsent in clinical trials in India: OrION-I study

Sangeetha Paramasivan

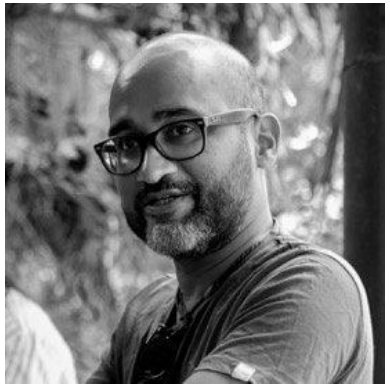
Population Health Sciences, Bristol Medical School, University of Bristol

On behalf of the study team

Team





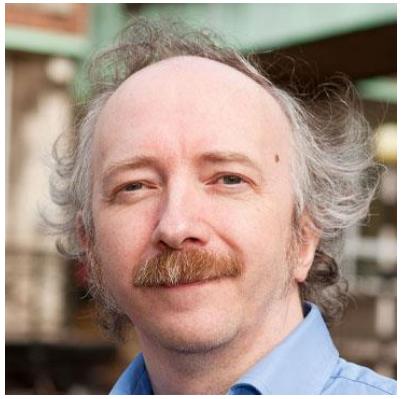




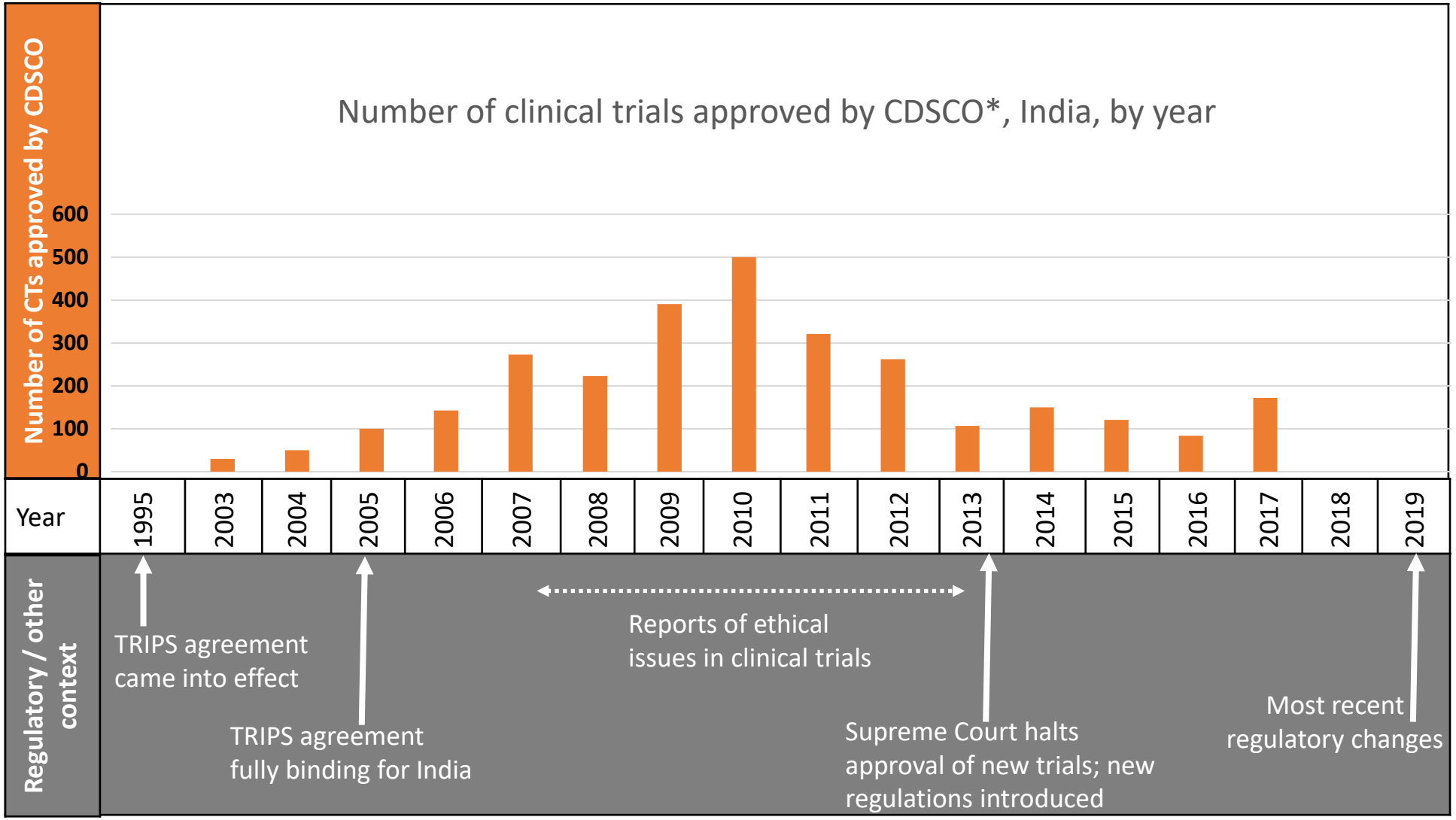








Background



Singh, 2013; Chawan et al, 2015; Jeffery et al, 2018; Gogtay et al, 2017; Jesani et al, 2019

* CDSCO – Central Drugs Standard Control Organisation – National Regulatory Authority in India

Background

- Increase in the number of clinical trials approved by the regulatory authorities after 2005 (when TRIPS agreement became fully binding)
- Sharp decline after 2010, to about 2013 – but picking up again
- Possible reasons for decline:
  - Reports of ethical misconduct, predominantly in relation to informed consent
  - Concerns for patient safety and autonomy
  - Robust health activism – public interest litigations from non-governmental organisations
  - Supreme Court halted approvals for new trials in 2013
- Current evolving context
  - Newest regulations – New Drugs and Clinical Trial (NDCT) Rules, 2019
  - Indian Council for Medical Research's (ICMR) guidelines
- **Some unique features…**

Systematic scoping review

- **Aim:** To obtain an overview of empirical research pertaining to the ethics of clinical research in India
- **Methods**
  - 9 databases; until Nov 2019; all peer-reviewed research with any stakeholder groups
  - Evidence map, narrative synthesis, research gaps, consultation exercise
- **Key findings**
  - 9699 screened, 282 full texts obtained, 80 included
  - Wide range of topics covered; studies often conducted with little to no funding
  - Studies predominantly examined knowledge of lay and professional participants on topics such as research ethics or their understanding of information given to obtain consent for research participation
  - Easily accessible groups, namely ethics committee members and healthcare students, were frequently researched
  - A range of research gaps identified, including the need to better understand the recruitment-informed consent process

Systematic scoping review

- **Aim:** To obtain an overview of empirical research pertaining to the ethics of clinical research in India

BMJ Global Health

What empirical research has been undertaken on the ethics of clinical research in India? A systematic scoping review and narrative synthesis to map the evidence

Paramasivan S,[1,2*] Davies P,[1,3] Richards A,[1,3] Wade J,[1] Rooshenas L,[1,2] Mills N,[1,2] Realpe A,[1,2] Raj JP,[4] Subramani S,[5] Ives J,[6] Huxtable R,[6] Blazeby JM,[2,7] and Donovan JL[1, 2]

- A range of research gaps identified, including the need to better understand the recruitment-informed consent process

What is the QuinteT Recruitment Intervention (QRI)?

To understand and optimise recruitment and informed consent

- Embedded in feasibility or main trial

- At outset or if struggling to recruit

Donovan *et al. Trials* (2016) 17:283
DOI 10.1186/s13063-016-1391-4

Trials

RESEARCH Open Access

Optimising recruitment and informed consent in randomised controlled trials: the development and implementation of the Quintet Recruitment Intervention (QRI)

Jenny L. Donovan[1,2*], Leila Rooshenas[1], Marcus Jepson[1], Daisy Elliott[1], Julia Wade[1], Kerry Avery[1], Nicola Mills[1], Caroline Wilson[1], Sangeetha Paramasivan[1] and Jane M. Blazeby[1]

Intensive Triangulation of Qualitative Research and Quantitative Data to Improve Recruitment to Randomized Trials: The QuinteT Approach

Qualitative Health Research
1–8
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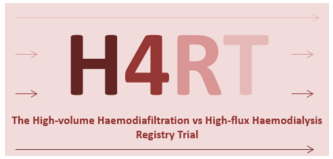
DOI: 10.1177/1049732319828693
journals.sagepub.com/home/qhr
SAGE

Leila Rooshenas[1], Sangeetha Paramasivan[1], Marcus Jepson[1], and Jenny L. Donovan[1], on behalf of the QuinteT Research Group

MRC Hubs for Trials Methodology Research
ConDuCT-II Hub

QuinteT
Qualitative research Integrated within Trials



- Began in 1999 with the ProtecT trial
- Integrated in about **70 RCTs**

QuinteT Recruitment Intervention: methods

Phase I: Understanding recruitment obstacles (rapid)

- Mapping recruitment pathways, assessing screening and eligibility procedures
- Interviews with trial staff (and sometimes patients)
- Audio-recordings of 'recruitment consultations'
- Document analysis (protocol, patient information, screening logs)
- Observations of investigators meetings

'Real time'

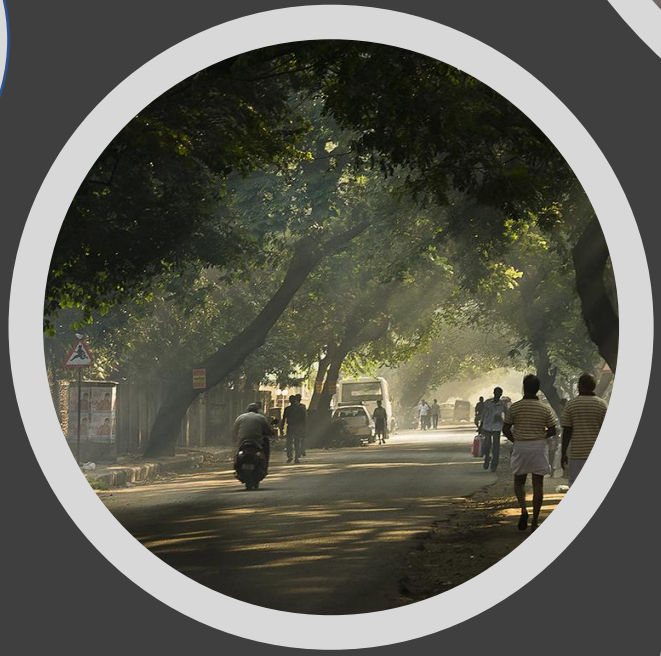
Findings discussed with CI/TMG and 'Plan of action' agreed

Phase II: Addressing recruitment obstacles

- Feedback/training
- Written guidance and information
- Changes to trial literature to improve clarity
- Adjustments to trial pathways and processes

Personal context: India-UK-India

- International Strategic Fund, UoB



Site: King Edward Memorial Hospital, Mumbai

- Department of Clinical Pharmacology

OrION-I study

Aims: To investigate the feasibility of audio-recording (AR) trial consultations & acceptability of using them to provide recruiter feedback in one centre in India, to facilitate scaling up in a larger study

- Objective 1: To explore feasibility of obtaining recruiter-patient consent for ARs and successfully implementing ARs in selected trials

- Methods: AR of trial consultations after informed consent from recruiters and patients (n=15)

OrION-I study

Aims: To investigate the feasibility of audio-recording (AR) trial consultations & acceptability of using them to provide recruiter feedback in one centre in India, to facilitate scaling up in a larger study

- Objective 2: To examine recruiters and patients views on acceptability of ARs and for providing feedback to recruiters

- Methods
  - In-depth semi-structured interviews with recruiters and patients (n=10)
  - Suggestions to adapt QRI components

OrION-I study

Aims: To investigate the feasibility of audio-recording (AR) trial consultations & acceptability of using them to provide recruiter feedback in one centre in India, to facilitate scaling up in a larger study

- Objective 3: To formulate processes for translation/transcription of ARs, data analysis and mechanisms for data management/sharing across India and UK

- Methods: Develop data management/sharing mechanisms and guidelines on:
  - Transcribing and translating from Marathi/Hindi
  - Measures to anonymise, label, securely store ARs/transcripts
  - Collaborative analysis across KEM-India and UoB-UK
  - Data transfer
  - Measures to facilitate future secondary analysis

To inform main grant with additional centres

Progress

Since June 2020…

- Contracts and research agreements ✓
- Protocol, participant information sheets and consent forms ✓
- Ethics application (Institutional Ethics Committee, KEMH, Mumbai) Outcome: Conditional approval granted subject to approval from the Health Ministry Screening Committee (HMSC) in India ✓
- **Final approval:** HMSC application submitted mid-December 2020 - **awaiting review**

Acknowledgements

Co-applicants:

1. Dr. Nithya Gogtay, Additional Professor, Clinical Pharmacology, KEM, Mumbai, India

2. Professor Urmila Thatte, Head of Clinical Pharmacology, KEM, Mumbai, India

3. Dr. Jeffrey Raj, Senior Resident, Clinical Pharmacology, KEM, Mumbai, India

4. Professor Jenny Donovan, Bristol Medical School, QRI founder/pioneer, UoB, Bristol, India

Collaborators:

1. Professor AS Ramakrishnan, Surgical Oncologist, Head of Research, Cancer Institute, Chennai, India

2. Dr. Abhijit Nadkarni, Founder and Co-Director of Addictions Research Group, Sangath, Goa, India and London School of Hygiene and Tropical Medicine, UK

3. Dr Anant Bhan, Adjunct Professor, Centre for Ethics, Yenepoya University, Mangalore; President, International Association of Bioethics; Lead, Sangath-Bhopal hub

4. Dr. Jennifer Van Ilo Nuil, Medical Anthropologist, Research Fellow, Oxford University Clinical Research Unit (OUCRU), Ho Chi Minh, Vietnam

5. Dr. Nguyen Than Ha Quyen, Ethics Team Leader, Senior Clinical Research Associate, OUCRU, Ho Chi Minh, Vietnam

6. Ms Nguyen Thi Hong Yen, Anthropologist, Social Science Research Assistant, OUCRU, Ho Chi Minh, Vietnam

Advisory panel:

1. Dr Roli Mathur: Head of Bioethics Unit, Indian Council of Medical Research, Bangalore

2. Ms Sarojini Nadimpally: Executive Director, SAMA Resource group for women and health, New Delhi; public health researcher/social scientist

3. Dr Amar Jesani: Founder/Editor Indian Journal of Medical Ethics; Faculty member, Centre for Ethics, Yenepoya University, Mangalore

4. Ms. Evelyne Kestelyn: Head of Clinical Trials Unit, OUCRU, Vietnam

5. Dr Susan Bull: Senior Researcher-Ethics of Genomics and Global Health, Ethox Centre, University of Oxford

6. Dr Jonathan Ives: Reader-Empirical Bioethics, UoB

7. Professor Usha Menon: Professor-Gynaecological Cancer, University College London, UK; Strategy Lead-Clinical Development Services Agency/Adjunct Professor-Translational Health Science and Technology Institute, New Delhi

8. Professor Mike Clarke: Director of MRC Methodology Hub, Queen's University Belfast

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“If you have come here to help me, you are wasting your time.

But if you have come because your liberation is bound up with mine, then let us work together.”

—aboriginal activists group, Queensland, 1970s

Through Lilla Watson, Aboriginal educator, artist and activist

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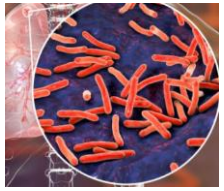
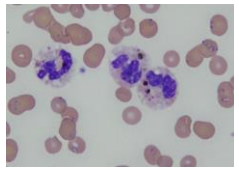
CHALLENGES ENCOUNTERED IN IMPLEMENTING VACCINE TRIALS IN LOW MIDDLE INCOME COUNTRIES: EXPERIENCES FROM TANZANIAN INVESTIGATORS

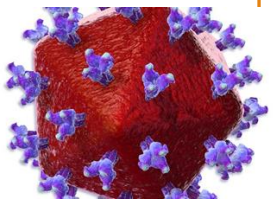
WIGILYA MIKOMANGWA (BPharm, Msc)

Background 1/2

- LMIC is the house of the disease of the poor (HIV, Malaria, TB and NTDs)







- TB
- Malaria
- HIV

Natural history of disease

Treatment/prophylaxis

- Anti-TB
- Anti-Malaria
- ARVs

- Vaccines
- TB (BCG,1920s), new?
- Malaria
- HIV

Elimination

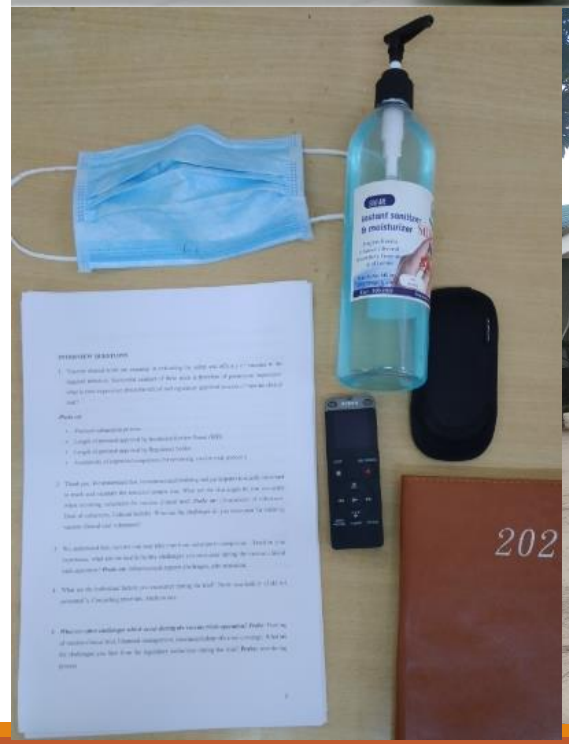
Background 2/2

- Only few vaccines are in clinical trial phases
- Lack of documented methodological challenges encountered by vaccine trialists in LMICs like Tanzania
- We intended to explore challenges experienced by Tanzanian investigators when conducting HIV, TB and malaria vaccines

Methodology

- Explorative design
- In-depth interview involving investigators of vaccine trials in Tanzania
- HIV and TB trials at MUHAS and Malaria vaccine at IHI (Bagamoyo)
- Analysis is still ongoing to explore the challenges encountered by investigators during the conduct of vaccine trial designs in Tanzania.
  - Protocol approval
  - Recruitment of volunteers
  - Retention
  - Enabling environment

Malaria vaccine center-IHI (Bagamoyo)



HIV vaccine center-Muhimbili

Preliminary findings

Challenges encounted during protocol approval, volunteer recruitment, retention and enabling environment

Protocol approval

P2
"…now days we submit electronically, however, the system is not user friendly, it is unnecessarily long and repetitive…"

Application

- Submission process is not user friendly
- Poor communication between the NatREC and applicant
- High application Fee;
  NatREC-500USD
  NRA-3000USD

Ethical review

- Inadequate number of reviewers with expertise in vaccine trials
- Delay in approval >6months
- Ethical approval time is shorter than requested (short expiry)

P1
"…I think reviewers are not experienced because once you apply for ethical clearance, there are lot back forth comments, which if the reviewer were experienced they would understand what we mean"

Volunteer recruitment

P4
"…volunteers are like sheep to be sacrificed, you will be infertile and male sperms are destroyed… if you agree to volunteer I will curse you…."

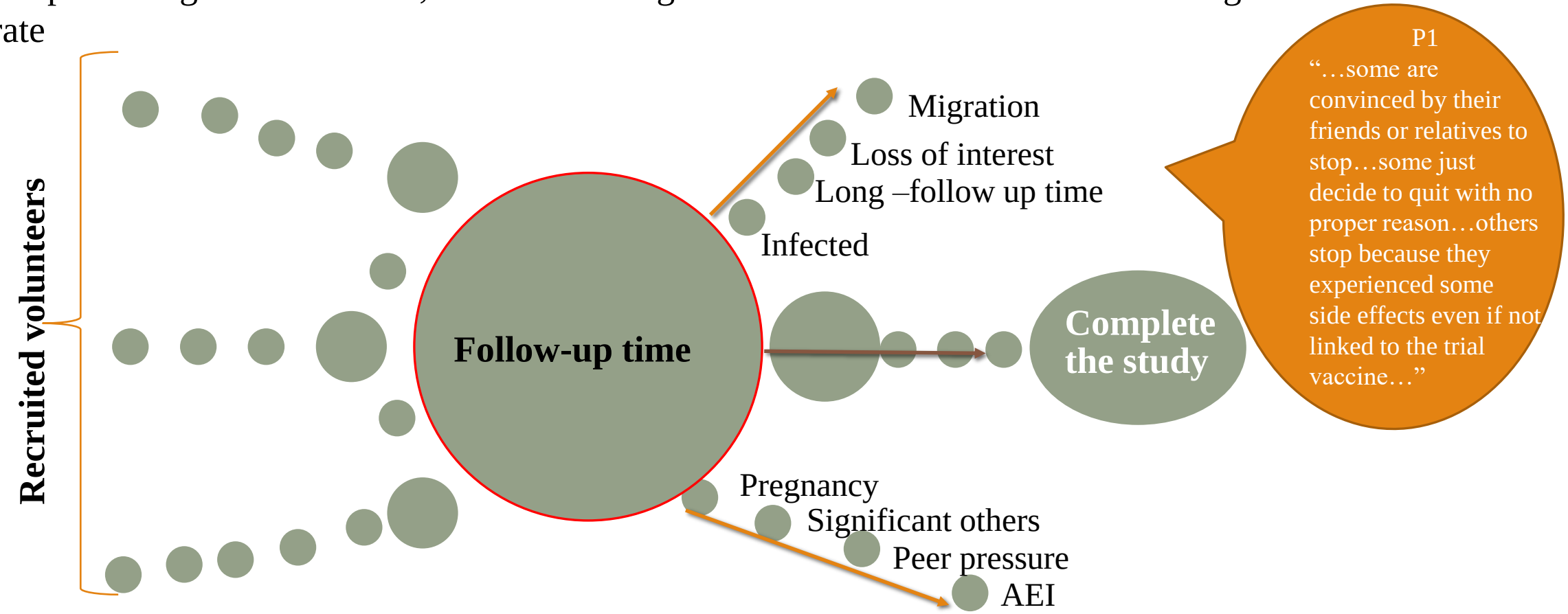
- Inadequate community and potential volunteer's awareness on the vaccine trial
- False beliefs
- Takes a lot of time and resources to raise community awareness
- The significant others phenomenon

The need to engage or involve community in the design of vaccine trials

P3
"…it is not difficult to recruit volunteers if are aware of the trial vaccine but is not easy to recruit them if the community is not well informed of the trial vaccine…It was very difficult initially but nowadays we do community sensitization.."

Retention

Despite of high retention rate, several challenges have been noted to contribute to high attrition rate



Enabling environment

- Lack of skilled personnel to conduct vaccine trials
- Lack of curriculum for training vaccine trials
- Lack awareness not only in the community but even in the scientific community
- Lack of reliable of Power supply
- Competing interest

P2
"…availability of skilled personnel is still a challenge, as vaccine trial is a new field in our country… the same people who were trained since the introduction of this vaccine in 2008 are still the same up to now.. may be because there is no accredited course on vaccine clinical trials…"

Challenges faced in this project

- Slow rate of recruitment. This have affected the estimated time of study completion.
- Coordinators of vaccine trials refused to provide contact and list of trial participants due to fear of breach of confidentiality, so they were not included in the study as was proposed.
- The findings rely on experiences from investigators and regulators
- Some potential key informants refused to participate because of fear from political leaders

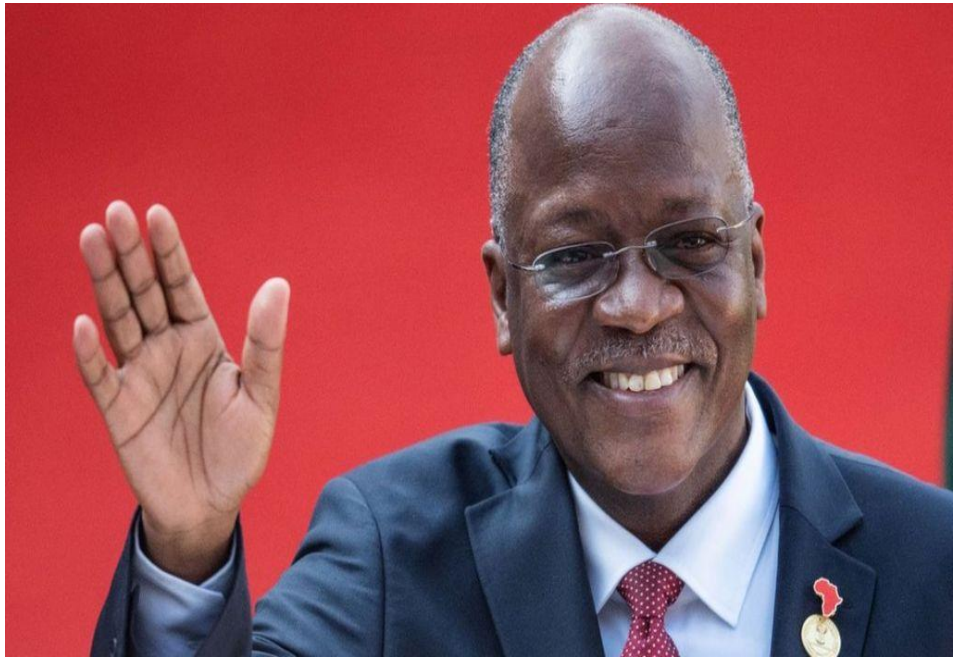
Acknowledgement

- Research assistant for their tireless effort to ensure that data are collected even in the challenging time of COVID-19
- Investigators of vaccine trials in Tanzania for their participation understanding their busy schedule
- Thanks to the MRC-NIHR Trials Methodology Research Partnership (MR/S014357/1 Global Health Award for funding this research

Welcome to Tanzania, the land of mount Kilimanjaro

THANKS

AHSANTENI



R.I.P Dr. John Pombe Joseph Magufuli