

A series of stylized human figures in various shades of red and orange, arranged in a line that recedes into the background. The figures are simple silhouettes with rounded heads and rectangular bodies.

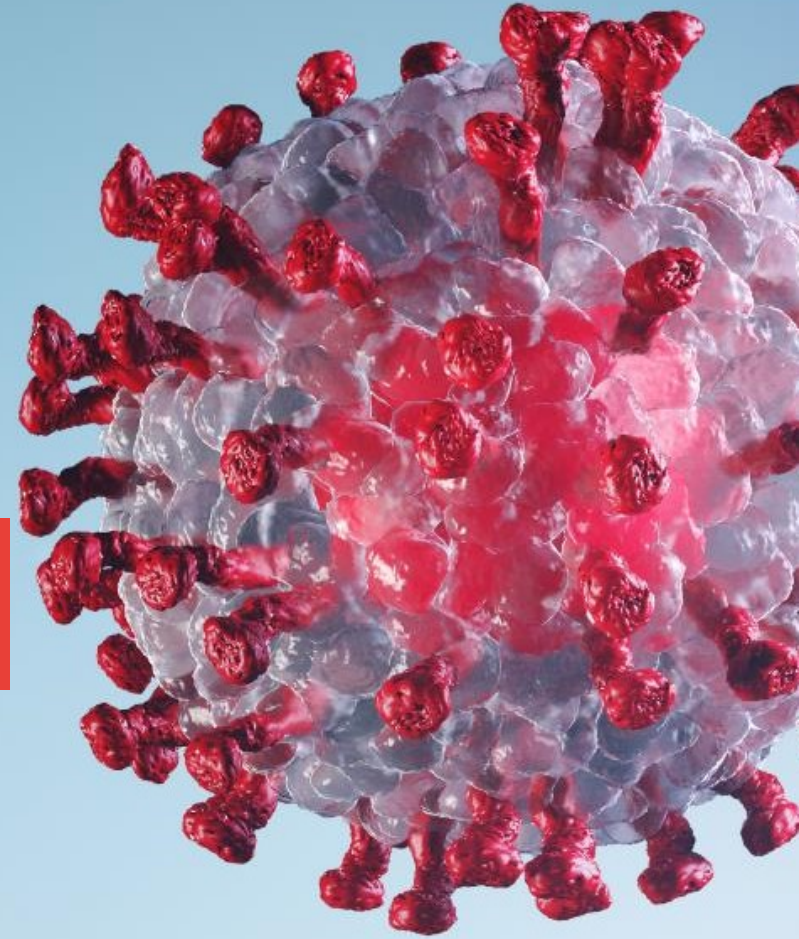
1st MEMBERS ASSEMBLY

*Collectively Advancing COVID-19 Research in
Resource-limited Settings – One Year On*

2 June 2021 | 14:30 CEST

A simple red icon of a hand with the index finger pointing to the right.

THE MEETING WILL BEGIN SOON



PART 1

14:30 – 14:45 (CEST)

AGENDA

WELCOME AND INTRODUCTION

Prof. Sir Nick White, Steering Committee Chair | Thailand & UK

REVIEW OF THE COALITION AT ONE YEAR

Prof. Helen Rees, Steering Committee Member | South Africa

WELCOME AND INTRODUCTION

DURATION: 5 minutes



PRESENTER(S):



Prof. Sir Nick White, Steering Committee Chair | Thailand & UK

Housekeeping Announcements (1/2)



Today's meeting is being **recorded** and the link will be shared on the coalition website.



Please send an email to adminIT@covid19crc.org if you have any **technical difficulties** and would like some help.



After the assembly, you will be asked to fill out a **short survey**. Many thanks in advance for providing your feedback on this event!



Please use #COVID19crc to tweet about the coalition and this assembly!

Housekeeping Announcements (2/2)



During the Q&A sessions, please **raise your hand to indicate that you would like to speak** and unmute yourself (and ideally turn on your camera) if the moderator calls you. You can also write your questions using **Slido** – more on that in a moment.

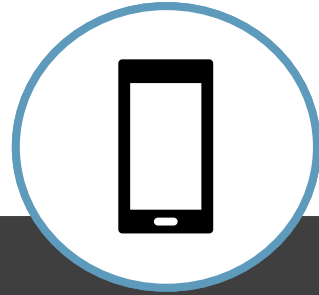


If we run out of time in the Q&A sessions, please provide your comments or questions in our special “**Comments, questions & your interest in project participation**” form. We will post the link in the chat after each session! And we will aim to answer all questions after the Assembly that we weren’t able to respond to during the meeting.



We are using **Slido for the Q&A management and polls** (*please don’t use the MS Teams chat function to ask questions*). You can use Slido to ask questions, and to upvote and comment on questions. The next slide shows you how to use this simple tool.

How to use **slido** (for Q&A and polls) – very simple and nothing to download!



MOBILE PHONE



Please scan the QR code!

Best option!

OR



INTERNET BROWSER

(on laptop or smartphone)

Go to [slido.com](https://www.slido.com) and insert
the code **#CRC**

Joining as a participant?

CRC





In one word, what is your biggest challenge as a researcher?

Join at
slido.com

#CRC



Early recognition of the threat to hard-won gains in global health



Global coalition to accelerate COVID-19 clinical research in resource-limited settings

Published Online

April 2, 2020

[https://doi.org/10.1016/S0140-6736\(20\)30798-4](https://doi.org/10.1016/S0140-6736(20)30798-4)

There is no available vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections and no drug with proven clinical efficacy, although there are several candidates that might be effective in prevention or treatment. Encouragingly, the response from the research community to the pandemic of coronavirus disease 2019 (COVID-19) has been vigorous. A review of clinical trial registries, as of March 24, 2020, identified 536 relevant registered clinical trials.¹ Of the 332 COVID-19 related clinical

trials, 188 are open for recruitment and 146 trials are preparing to recruit.^{1,2} The distribution of these clinical trials is centred in the countries most affected by COVID-19 in the past 2 months, particularly China and South Korea, with high-income countries in Europe and North America planning most of the forthcoming trials. Very few trials are planned in Africa, south and southeast Asia, and central and South America.

The number of confirmed COVID-19 cases reported in resource-poor settings is still relatively small,³ but

www.thelancet.com Vol 395 April 25, 2020

Leveraging global expertise for high-impact COVID-19 research

Promoting open sharing of research knowledge & data

Championing equitable & affordable access to COVID-19 vaccines, diagnostics & treatments

A GLOBAL RESEARCH RESPONSE TO COVID-19 DRIVEN BY THE NEEDS OF LOW RESOURCE SETTINGS



MEMBERSHIP

- 224 institutional members (408 representatives) from 65 countries
- 294 individual members whose institutions have not joined yet (75 countries)



13 TOPIC-SPECIFIC WORKING and ADVISORY GROUPS in ethics, data management & sharing, clinical epidemiology, etc. to address pressing needs in and identified by low-resource settings



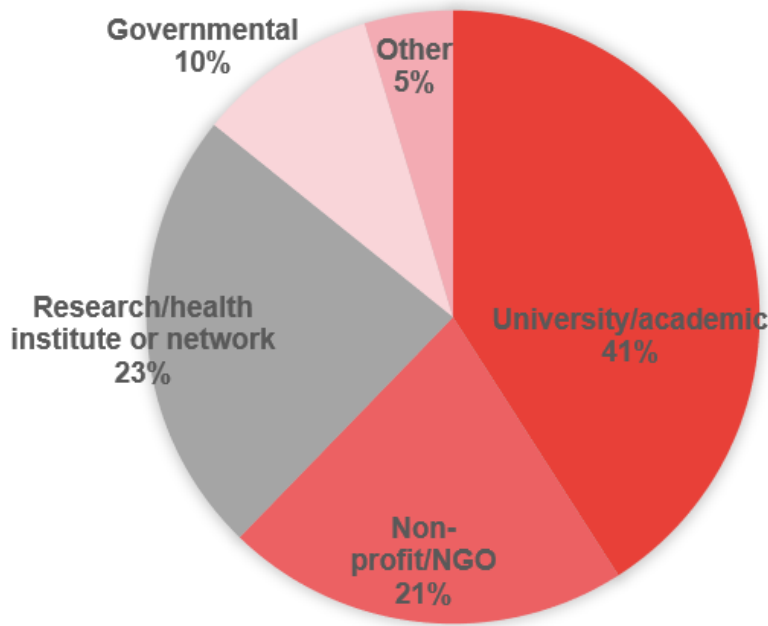
COALITION OUTPUTS

1. Webinars/workshops
2. Priority research questions
3. Working group projects
4. Op-eds, comments & articles
5. Protocol repository

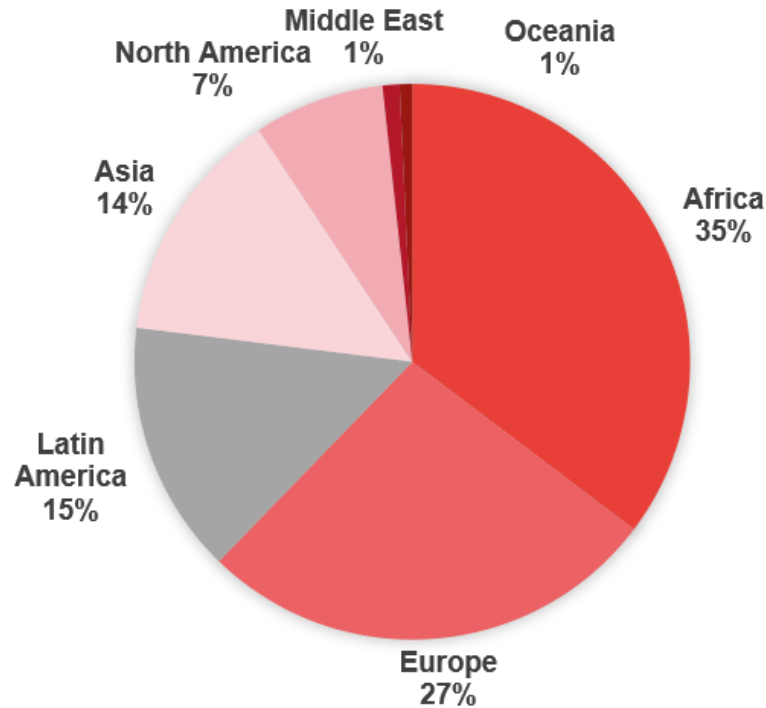
Membership

- In one year, the number of institution representatives has almost doubled.
- The number of individual members has been multiplied by 3.5.

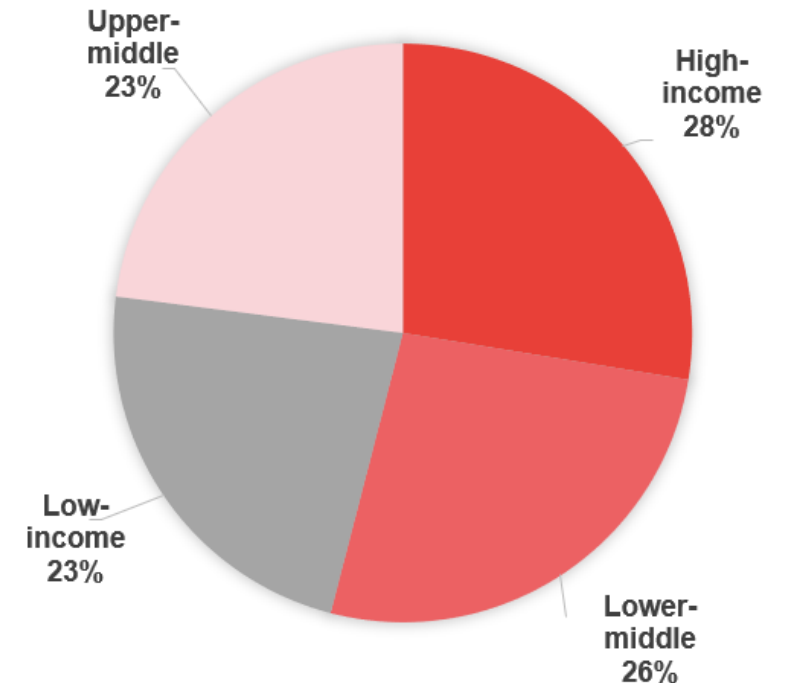
MEMBER INSTITUTION TYPE



INSTITUTIONAL REPRESENTATIVES BY REGION



MEMBER COUNTRIES INCOME CLASSIFICATION



Governance: Steering Committee members



Dr Gail Carson

Director of Network Development, ISARIC Global Support Centre
(UK)



Prof. Mohammad Abul Faiz

Professor of Medicine
(Bangladesh)



Prof. Patricia García

Universidad Peruana Cayetano Heredia
(Peru)



Prof. Philippe Guérin*

Director of the Infectious Diseases Data Observatory
(UK)



Prof. Gagandeep Kang

Professor, The Wellcome Trust Research Laboratory Christian Medical College, Vellore
(India)



Dr Jenniffer Mabuka-Maroa

Representative of the African Academy of Sciences
(Kenya)



Prof. Francine Ntumi

Leader of the PANDORA consortium
(Republic of Congo)



Prof. Helen Rees

Founder & Executive Director, Wits Reproductive Health & HIV Institute of the University of the Witwatersrand
(South Africa)



Dr Nathalie Strub-Wourgaft*

NTD and COVID Director & Member of the Executive Team of the Drugs for Neglected Diseases initiative
(Switzerland)



Ms Akhona Tshangela

Lead for Science, Innovation and Research, Africa CDC
(Ethiopia)



Prof. Sir Nicholas J. White*

Chairman of the Wellcome Trust's South-East Asian Research Units
(Thailand & Vietnam)
Chair of the Steering Committee

* Representatives of instigating organizations

The coalition secretariat



Julie Archer
Secretariat Coordinator

✉ Julie.Archer@covid19crc.org

📍 Geneva, Switzerland

🦠 Since April 2020, 90%



Laila Harras-Pelletier
Project Associate

✉ Laila.harras-pelletier@covid19crc.org

📍 Paris, France

🦠 Since October 2020, 80%



Dr Brenda Okware
Scientific Coordinator

✉ Bokware@extern.dndi.org

📍 Kampala, Uganda

🦠 Since February 2021, 60%



Maureen Kristin Thiele
Project Manager

✉ Maureen.Thiele@covid19crc.org

📍 Chamonix-Mont-Blanc, France

🦠 Since April 2020, 100%



Nebu
Canine Ambassador

✉ Info@covid19crc.org

📍 Kampala, Uganda

🦠 Since February 2021, 10%

Questions to reflect on for later discussion

1. Given the strengths & achievements of the coalition shared today, what do you think we should be trying to do **MORE OF**? (*Slido: one word*)
2. Is there anything we should be doing **LESS OF**? (*Slido: one word*)
3. What should we as a coalition be aiming to achieve? (*use “raise hand” function*)

REVIEW OF THE COALITION ONE YEAR ON

DURATION: 10 minutes



PRESENTER(S):



Prof. Helen Rees, Steering Committee Members | South Africa

Leveraging global expertise for high-impact COVID-19 research

Promoting open sharing of research knowledge & data

Championing equitable & affordable access to COVID-19 vaccines, diagnostics & treatments

A GLOBAL RESEARCH RESPONSE TO COVID-19 DRIVEN BY THE NEEDS OF LOW RESOURCE SETTINGS



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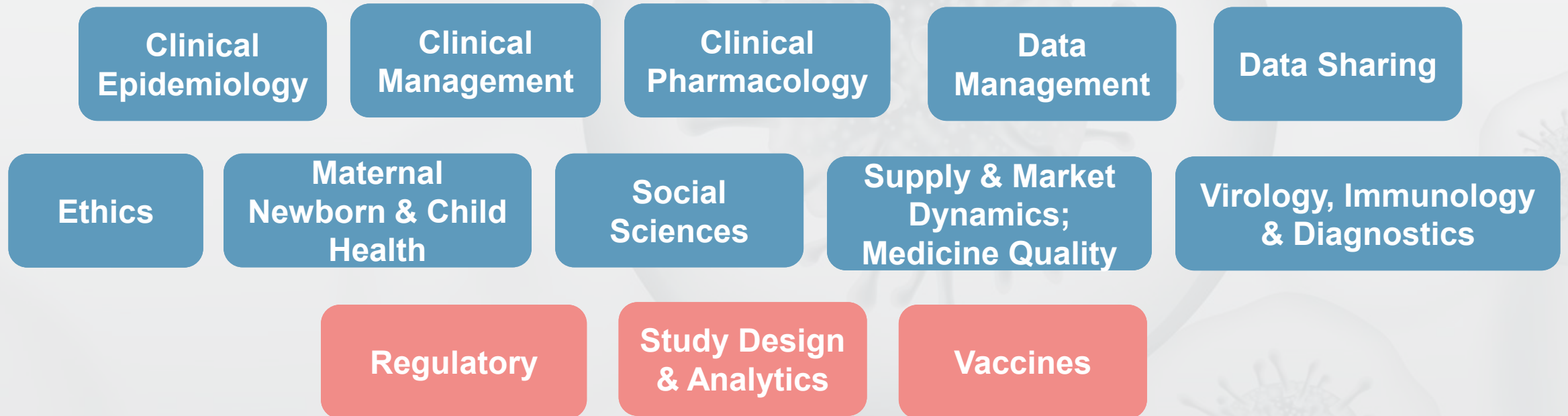


COALITION OUTPUTS

1. Webinars/workshops
2. Priority research questions
3. Working group projects
4. Op-eds, comments & articles
5. Protocol repository

The coalition's working groups

- **Key engine** for the mission of the coalition
- **Wealth of global expertise** in areas critical for research
- **10** expert working groups; **3** expert advisory/support groups



Working group feedback: strengths

- **Cross-functional, complementary expertise** with experience across different contexts
- **Geographical representation** from all regions → **Global perspective**
- Platform to **share experiences**, foster new partnerships and link to existing networks, discuss strategies & solutions.
- In the case of two working groups, ability to **attract resources/funding** for relevant projects; **quick response to calls** for projects leveraging on expertise and networks.

Working group feedback: challenges & proposed solutions

Challenges

- **Underutilization of expertise** within WGs by researchers from LMICs: pool of experts available for e.g., queries, protocol & analysis plan review
- **Time challenges:** time zones, competing priorities, cross-functional experts unable to participate in more than one WG
- **Low visibility** of coalition and WGs
- **Maintaining participation** of members: virtual interaction, cohesion sometimes difficult
- Finding **resources/financing** for projects/research ideas

Proposed solutions

- **Increase visibility**
 - E.g., international forums
 - Use of listservs
 - Greater clarity on website
- **Wider dissemination of working group resources, outputs**
 - Tool repository on website
- **Greater collaboration across working groups**

Working group feedback: next steps

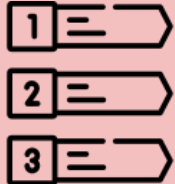
- **Better support researchers** in LMICs: Find best channels to share relevant advice & guidance, and increase visibility of WGs to clinical research communities in low-resource settings
- **Publish**, publish, publish...
- **Expand the network** – more members from more regions – and build lasting research networks
- Develop and share **collaborative ideas for research** and attract **funding**
- **Collaborate** on common areas of research interest and **across working groups**
- Contribute to methodological analyses.

Coalition achievements & outputs (1)



Advocacy

- To **increase representation by researchers from LMICs** in global decision-making & priority-setting bodies such as the Access to COVID-19 Tools Accelerator (ACT-A)
- For **responsible scientific communication**



Priority research questions

- Identified in: **social science; maternal, newborn & child health; clinical epidemiology; and virology, immunology & diagnostics**
- Now being translated to **project proposals**

Coalition achievements & outputs (2)



Partnerships

- **Global networking** within & outside WGs → Collaboration, communication
- **External collaboration** opportunities, with e.g., TGHN, WHO, others
- Platform to **highlight and discuss members work**



Capacity building *(resource & skills sharing)*

- **Online workshop:** To assess LMIC early career researchers' needs, and test a proposed e-course model and content
- **Data sharing course:** <https://globalhealthtrainingcentre.tghn.org/data-sharing>
- **Tools & info:** Protocol & SOPs library, recommendations for crisis oxygen management



Evidence generation & evaluation

- **Live Systematic Review** conducted by IDDO for the coalition to **highlight clinical research gaps**
- **Surveys** (completed & planned)
 - E.g., challenges in accessing and using data; data management tools in use.

Coalition achievements & outputs (3)



Webinars

- **8 webinars** on a range of topics
- E.g Challenges conducting research in LMICs, community engagement in vaccine trials, trial protocol relevance for LMICs, COVID-19 diagnostics, research ethics...



Articles

- Fegan G et al. **Solutions to COVID-19 data sharing.** *Lancet Digital Health.*
- White NJ et al. **Guidelines should not pool evidence from uncomplicated & severe COVID-19.** *The Lancet.*
- Coalition, GloPID-R & UKCDR. **Global COVID-19 research agenda still missing the priorities of low- and middle-income countries.** *The Lancet.*
- **Recently submitted:** manuscripts from Data Sharing, MNCH, Virology, Immunology & Diagnostics, and Clinical Pharmacology Working Groups



Funded projects

- Thanks to project funding from WHO:
 - Ethics WG – **2 projects**
 - Data Sharing WG – **4 projects**

PART 2

14:45 – 15:45 (CEST)

MODERATED BY:



Dr Nathalie Strub-Wourgaft
Steering Committee Member | Switzerland

AGENDA

1 CLINICAL EPIDEMIOLOGY WG & PROJECT PLAN

Prof. Juan Carlos Villar, Working Group Co-Chair | Colombia

Including Q&A

2 SOCIAL SCIENCE WG & PROJECT PLAN

Working Group Co-Chairs: Prof. Shelley Lees | UK & Dr David Kaawa-Mafigiri | Uganda

Including Q&A

3 DATA SHARING WG UPDATE

Dr Phaik Yeong Cheah, Working Group Chair | Thailand

Including Q&A

4 MATERNAL, NEWBORN AND CHILD HEALTH WG & PROJECT PLAN

Dr Melanie Etti, Working Group Coordinator | Uganda & UK & Dr Kirsty Le Doare, Working Group Co-Chair | Uganda & UK

Including Q&A

1 CLINICAL EPIDEMIOLOGY WG & PROJECT PLAN

DURATION: 15 minutes



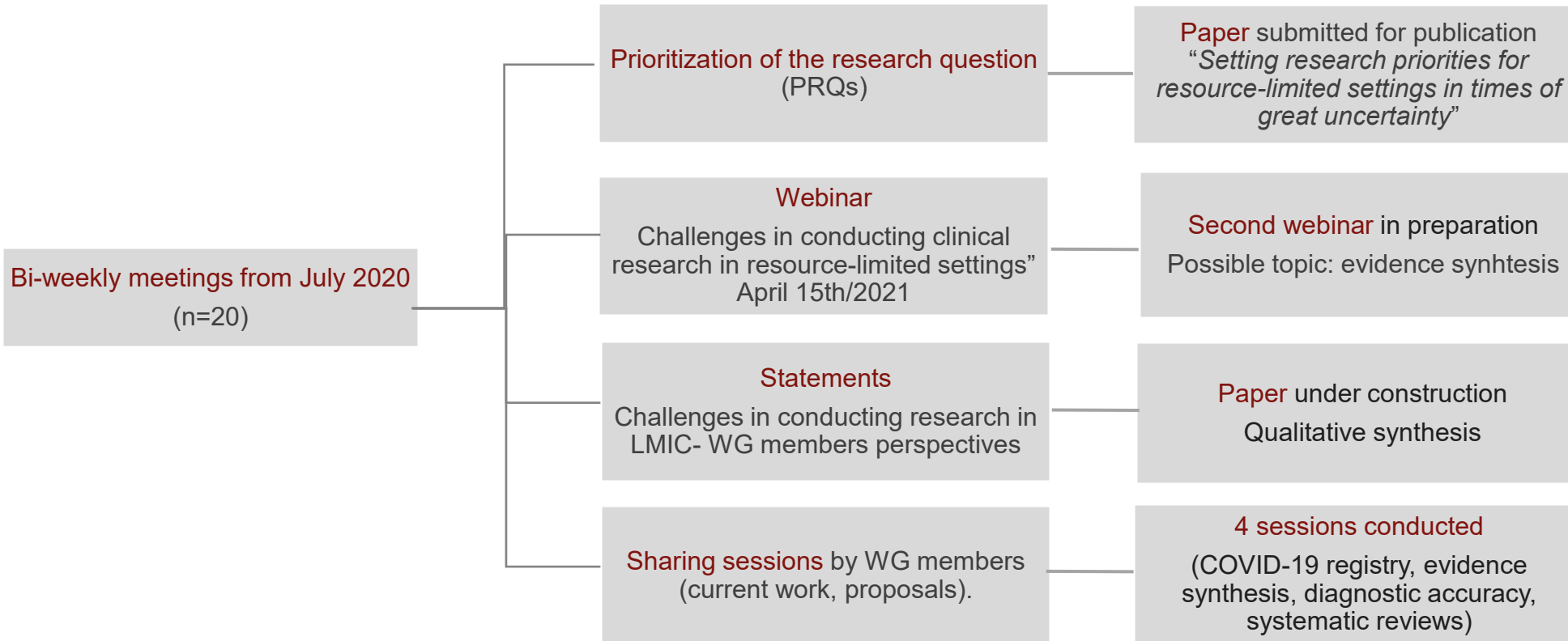
PRESENTER(S):



Prof. Juan Carlos Villar, Working Group Co-Chair | Colombia

WG members/activities

15 members from Latin America (6), USA (2), Africa (3), Europe (2), Asia (2)



Priority Research Questions

1. What clinical findings (signs, symptoms, biomarkers and imaging) are associated with a worse prognosis in COVID-19?

2. What signs and symptoms could confirm the clinical diagnosis of COVID-19?

3. What is the best strategy to achieve treatment goals in patients with NCDs during the pandemic?

4. What is the COVID-19 Infection Fatality Rate in low and middle countries +/- stratified by age?

5. What is the excess mortality non-COVID-19 in LMIC during the pandemic?

6. What are the short/mid and long term post-infectious sequelae in COVID-19?

Priority Research Questions

1. What clinical findings (signs, symptoms, biomarkers and imaging) are associated with a worse prognosis in COVID-19? **16**

2. What signs and symptoms could confirm the clinical diagnosis of COVID-19? **30**

3. What is the best strategy to achieve treatment goals in patients with NCDs during the pandemic? **26**

4. What is the COVID-19 Infection Fatality Rate in low and middle countries +/- stratified by age? **24**

5. What is the excess mortality non-COVID-19 in LMIC during the pandemic? **24**

6. What are the short/mid and long term post-infectious sequelae in COVID-19? **17**

Priority Research Questions

1. What clinical findings (signs, symptoms, biomarkers and imaging) are associated with a worse prognosis in COVID-19? **16**

6. What are the short/mid and long term post-infectious sequelae in COVID-19? **17**

Priority Research Questions

Final research question

What clinical findings (signs, symptoms, biomarkers and imaging) are associated with a worse prognosis and short/mid and long term post-infectious sequelae in COVID-19?

PRQ- Project proposal

What clinical findings (signs, symptoms, biomarkers and imaging) are associated with a worse prognosis and short/mid and long term post-infectious sequelae in COVID-19?

Approach:

- Stand-alone cohort (retrospective or prospective cohort study).
- Nested within a clinical trial.

It can:

- Facilitate implementation and organization of clinical care.
- Make KT easier in the LMIC context.
- Strengthen south-south collaboration.
- Facilitate research on therapies and/or social implications of long COVID.

Proposed roadmap



To participate in an ongoing registry (ISARIC, WHO- long-COVID Global COVID-19 Clinical Data Platform) AND/OR **clinical trials** (ANTICOV).

To support social sciences / implementation research
*Vaccine acceptance, attitudes, preferences.
*HCQ prescription for COVID-19 in Africa, clinical practice patterns, adherence to recommendations.

We envision an **international prospective clinical study** of over 10K patients followed for at least a couple of years with different (continental) coordination sites performing different measurements, integrating several strengths from research centers at LMICs.

Potential work beyond this pandemic



2 SOCIAL SCIENCE WG & PROJECT PLAN

DURATION: 10 minutes



PRESENTER(S):



Prof. Shelley Lees
Working Group Co-Chair | UK



Dr David Kaawa-Mafigiri
Working Group Co-Chair | Uganda

Working Group Update

- Robust membership from all geographic areas
- Bi-weekly meetings and offline collaboration
- Webinar series:
 - Webinar 1. Vaccine development: Lessons learned from social science research and community engagement in clinical trials in the Global South (Jan 2021)
 - Webinar 2. Operational experience in vaccine clinical trials: Lessons from the field (Mar 2021)
 - Webinar 3. The context of COVID-19 vaccine deployment (Planned)
- Written commentaries on social science in COVID-19 policy, practice, and research

Priority Research Questions

Research Question	Rationale
Project 1 Explore the political and social aspects of COVID-19 vaccine deployment across multiple sties	<ul style="list-style-type: none">• Vaccine inequity, vaccine hesitancy, lack of understanding of long COVID in LMICs, social science research in clinical trials• Improved uptake of vaccines
Project 2 Explore the impact of Long Covid on individuals and health care systems in LMICs	<ul style="list-style-type: none">• Understanding the social and political impacts of the pandemics
Project 3 (with Clinical Epi WG) Explore the social impact of COVID-19 on individuals who are participating in cohort studies	<ul style="list-style-type: none">• Improved knowledge about the long-term impact of COVID-19 on everyday lives

Partnerships and Approach

- Multi-year, multi-sited social science research, attentive to local context and political-economic dynamics
- Enablers: funding for fieldwork, research teams, analysis, report/briefing writing, community engagement, dissemination
- Partnerships – establish long-term social science research sites
 - Additional human resources and support for funding applications
 - Role of the Coalition in research updates, disseminating findings
 - Lead organization TBD
- Human resources involved: within and external to the WG – research leads and research teams at sites
- What can be done by whom in the WG? – Research leads



3 DATA SHARING WG UPDATE

DURATION: 10 minutes



PRESENTER(S):



Dr Phaik Yeong Cheah, Working Group Chair | Thailand

Objective

To facilitate and promote effective, ethical and equitable data sharing across geographies and disciplines

Achievement I

- Obtained funding from WHO to:
 - Map the current practices on data sharing
 - Map compliance to data sharing policies by authors and funders
 - Characterise data sharing requirements and practices across trial registries
 - Assess needs of researchers to share and use data – online workshop
 - Understand concerns around broad consent for future use in the absence of national guidelines in Columbia – qualitative interviews

Achievement II

Launched survey to understand if and how shared clinical research data is used; what challenges are experienced with accessing and using the data (led by Naomi Waithira with input from the WG members)

Data Reuse



20% complete

Have you used clinical research data that has been shared by other researchers?

- Yes
- No



Achievement III

- Launched e-course on Dec 2020
- 4 modules available (includes existing ethics module) - written and/or peer-reviewed by members of the WG

 THE GLOBAL HEALTH NETWORK

Email

Pass

Global Health Training Centre

Home eLearning Courses Professional Development Webinars and Workshops

Data Sharing

About this course

Module name	Launched	Total times taken	Total Users	Certificates awarded
Data governance, policies, and Data Access Committees	15/02/2021	1142	374	314
Data Quality	17/03/2021	795	300	245
Introduction to data management	18/12/2020	3661	1965	1206

Proposed plans I

- To collaborate with clinical management and clinical pharmacology working groups who are leading IPD analyses
- Priority drug identified by the Clinical Pharmacology working group
 - First priority: **ivermectin for early treatment**
- Data Sharing working group aims:
 - To help approach investigators
 - To ensure that process is ethical and equitable
 - To ensure meaningful participation from primary investigators
 - To explore ways of increasing incentives for academic data contributors

Proposed plans II

Data Reuse Survey

20% complete

Have you used clinical research data that has been shared by other researchers?

- Yes
- No

Scan to access the survey



- Now only in English
- Funding required to expand
- Translations to other major languages

Proposed plans III

- Data sharing course – POPULAR
- Other modules
 - Costing for data management and sharing
 - Data repositories
 - Advance concepts in data management
 - Data reuse principles
 - Preparing datasets for sharing
 - Sharing of qualitative data
- To seek funding for new modules
- Seeking authors and reviewers for new modules

Publications

- Fegan G, Cheah PY and the Data Sharing Working Group of the Covid-19 Clinical Research Coalition. Solutions to COVID-19 data sharing. *Lancet Digital H* 2021: 3, e6
- Maxwell L, Gilyan R, Chavan SA *et al.* Guidance for ensuring fair and ethical broad consent for future use. A scoping review protocol, *F1000Research* 2021, 10:102
- Several in preparation/submitted

Funding

- World Health Organization and TDR (the Special Programme Research and Training in Tropical Diseases) under grant P20-00060, P20-00007
- Wellcome Trust Research Enrichment, Open Research (106698/Z/14/J)

Working group members – Ken Awuondo, Susan Bull, Phaik Yeong Cheah (Chair), Greg Fegan, Philippe Guerin, Calvin Ho, Oommen John, Sharon Kaur, Lauren Maxwell, Laura Merson, Brian Mutinda (Coordinator), Duduzile Ndwandwe, Francine Ntoumi, Robert Terry, Naomi Waithira, Helena Wilcox





**4 MATERNAL, NEWBORN AND CHILD HEALTH WG
& PROJECT PLAN**

DURATION: 15 minutes

PRESENTER(S):

Dr Melanie Etti

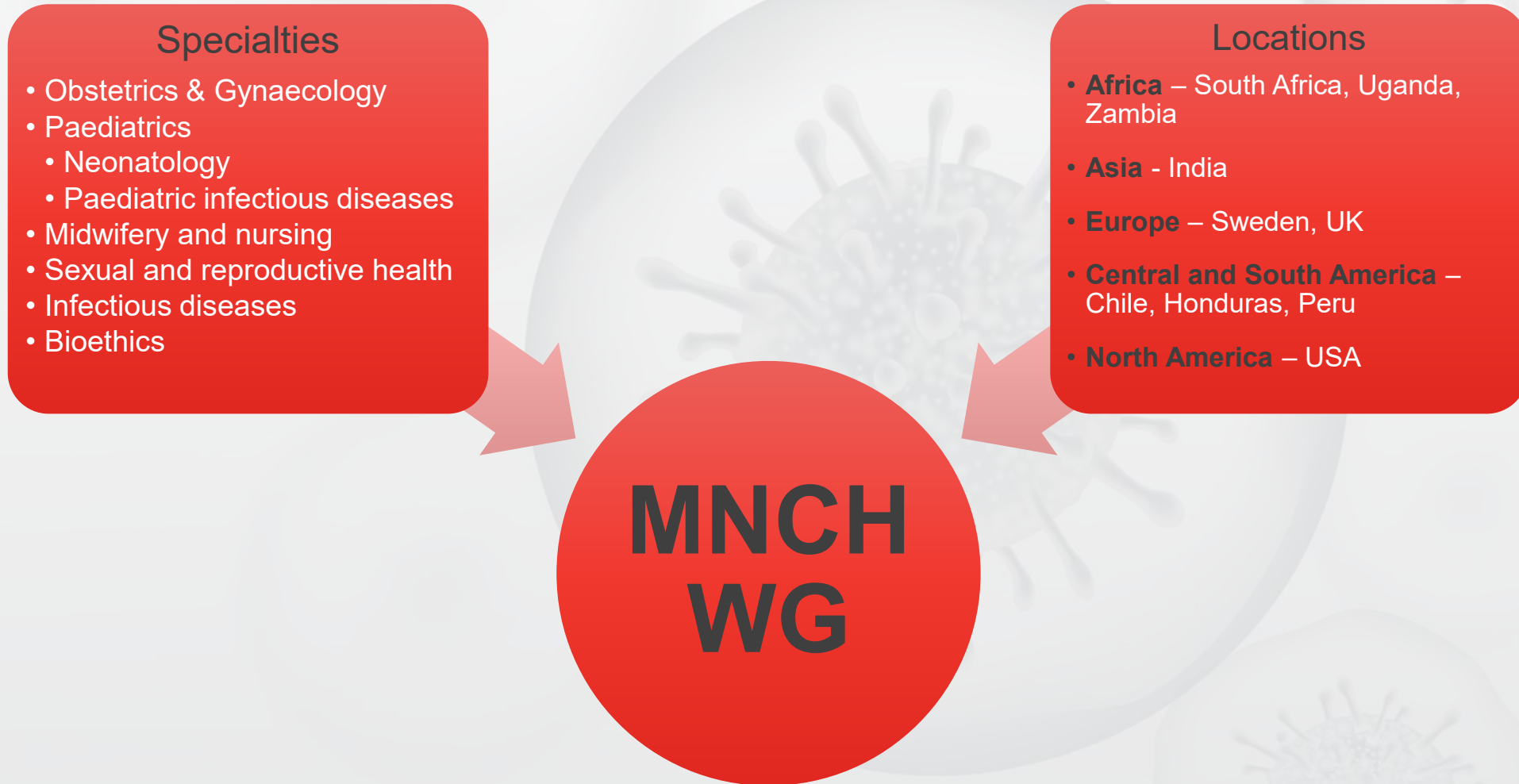
Working Group Coordinator | Uganda & UK



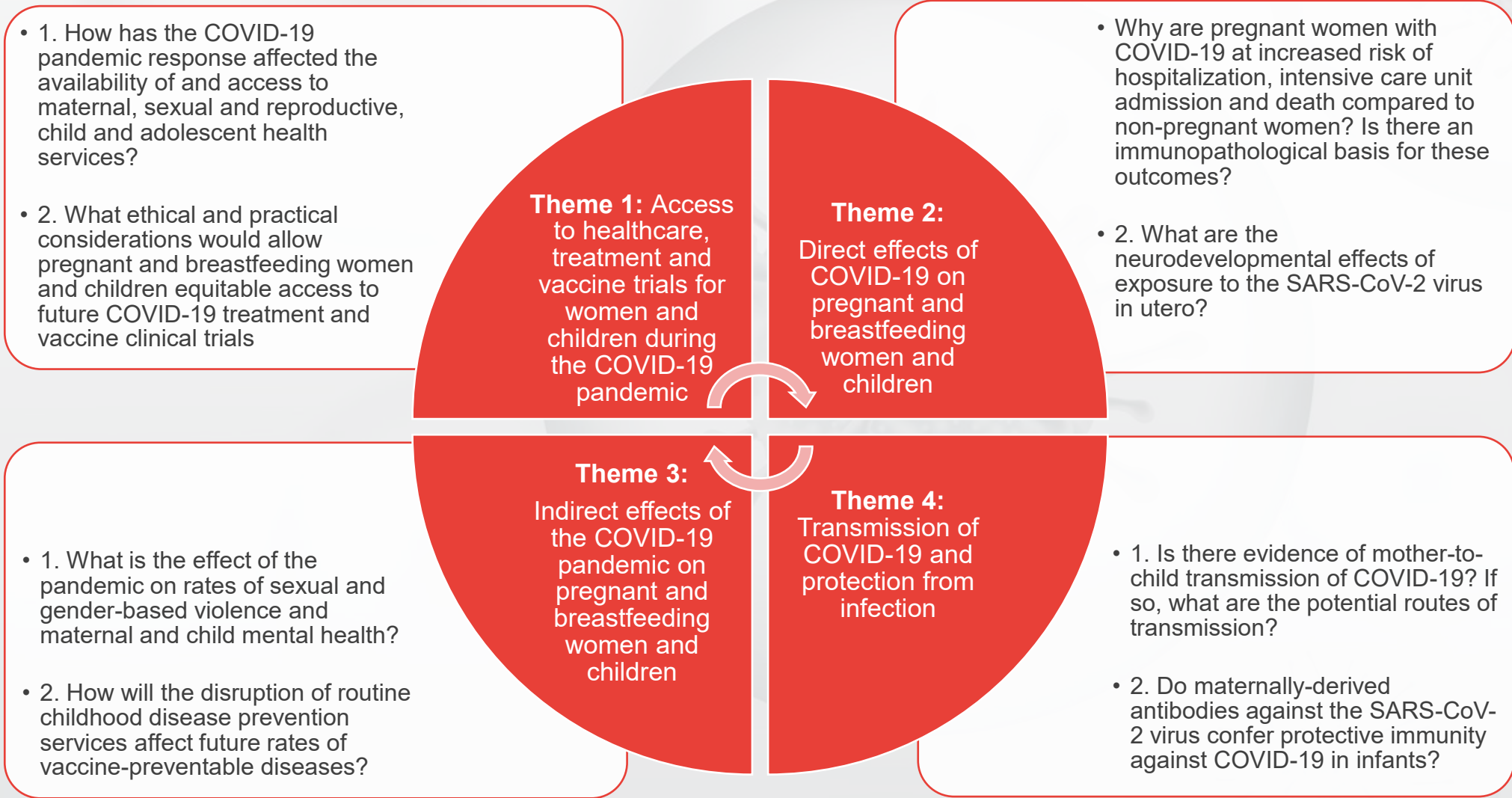
Dr Kirsty Le Doare

Working Group Co-Chair | Uganda & UK

MNCH WG composition



Research priorities



Summary of WG activities

- Research priorities research paper
 - Currently undergoing peer review
- Webinars
 - ORAS –CONHU
 - Research priorities webinar (hosted by the Coalition)– over 600 registrants
- Networking sessions
 - External speakers from the International Perinatal Outcomes of the Pandemic (iPOP) consortium and the SINEPOST study
- European Congress of Tropical Medicine and International Health session
 - Organised session: “*The ethical and practical considerations of the inclusion of pregnant women in public health emergency vaccine trials*” produced in collaboration with Ethics WG (expected September 2021)

Looking forward

- Expanding membership - Asia
- Refine and develop research questions within priority research themes
- Work with COVAX group for maternal vaccine safety assessments
- Formalise cohorts within the Coalition to start to develop grant applications for research questions
- Identify research champions in each region to lead research areas



PART 3

15:45 – 16:35 (CEST)

MODERATED BY:



Prof. Patricia J. Garcia

Steering Committee Member | Peru

AGENDA

5 VIROLOGY, IMMUNOLOGY AND DIAGNOSTICS WG & PROJECT PLAN

Dr Wilber Sabiiti, Working Group Member | UK

Including Q&A

6 ETHICS WG & PROJECT PLAN

Working Group Co-Chair/Mem.: Prof. Cheryl Macpherson | Grenada & Prof. Jantina de Vries | South Africa

Including Q&A

7 CLINICAL PHARMACOLOGY WG UPDATE

Dr Colin Pillai, Working Group Chair | South Africa

Including Q&A

8 SUBSTANDARD & FALSIFIED COVID-19 VACCINES (SUPPLY & MARKET DYNAMICS WG)

Prof. Paul Newton, Working Group Member | UK

Working Group Co-Chairs: Mr Paul Lotay | Kenya & Prof. Andrew Farlow | Brazil, Germany & UK

Including Q&A

**5 VIROLOGY, IMMUNOLOGY AND DIAGNOSTICS
WG & PROJECT PRESENTATION**

DURATION: 15 minutes



PRESENTER(S):



Dr Wilber Sabiiti, Working Group Member | UK

Working group summary

- Current membership is 16
- Membership spans all continents
- Multidisciplinary membership
- Holds biweekly meetings

Objectives of the WG

- Regularly update on list, prices, & availability of validated tests
- Review, adapt, endorse, &/or validate laboratory check lists & SOPs, including sample collection, handling, & analysis
 - This working group is transversal, to discuss and provide information on validated diagnostic tools and relevant SOPs, checklists, etc.

Priority Research Questions

The group came up with 5 Priority research questions. These were developed through:

1. Brainstorming
 - ✓ The WG members suggested several unanswered topics/questions for consideration
 - ✓ Thereafter, through a series of biweekly meetings, the topics were refined and consolidated
2. Consensus
 - ✓ Once a final list was made, the members of the WG agreed on the priority topics/questions from the list

The 5 Priority research questions include;

1. What is the feasibility and performance of “alternative” samples (nasal/saliva/oropharyngeal) for self-administered collection?
2. What is the impact on serological test performance of different disease backgrounds (e.g., malaria, HIV, TB)?
3. What is the role of antigen tests in different populations and settings?
4. Are PCR testing results (e.g., cycle threshold) associated with infectivity?
5. **What are the various approaches to setting up biobanks of COVID-19 samples?**

INCREASED BIOREPOSITORY AND SEQUENCING CAPACITY FOR LOW- AND MIDDLE-INCOME COUNTRIES (I-BIC)

Rationale

- Biobanking question is central to the mandate of the WG
- Its evident we'll face another pandemic threat long after COVID-19 is gone
- **There is need to learn from this pandemic & improve global preparedness**
- Basic and applied research is central to the learning process
 - The role of biorepositories in supporting this research are well known
 - There is need for with well annotated samples to answer pertinent biomedical questions
- **Challenges around access to specimens has been highlighted as a key barrier**
 - Barrier to development & evaluation of diagnostics
 - These are critical in pandemic response
- Furthermore, disparities in research infrastructure & capacity exist in many LMICs
- Repositories are difficult to establish & operate
 - They are thus beyond means of most LMIC institutions, especially during crisis situations

The Proposed Project

We propose to boost scientific response to COVID-19 in LMICs by enhancing **biobanking capacity of LMICs** through **setting up sentinel sites & creating linkages with biorepositories in HICs**.

Objectives

➤ The main aim of the project is to build capacity of LMICs in biobanking & bio preservation

Primary objectives

1. To establish a network of sentinel biorepository sites in LMICs
2. To develop a COVID-19 responsive biobanking training program for scientists in LMICs
3. To develop biobank collaborations between LMICs & HICs to promote capacity building for LMIC personnel

Secondary objectives

1. To enhance sequencing capacity for LMICs laboratories
2. To support research on the effect of variants on COVID-19 diagnostics, therapeutics, & recurrent & vaccine breakthrough infections

The Approach

Establishment of sentinel sites

- We shall set up sentinel sites in each of the African regions as well as South East Asia
- We shall link then establish collaborations
 - Intersentinel site collaborations
 - HIC-LIC collaborations
- The collaborations will
 - Strengthen research capacity at the sentinel sites
 - Build up sequencing capacity of the established sites

Development of a COVID-19 responsive biobanking training program

- Leverage current biorepositories in HIC to develop a training program
 - The training program will be COVID-19 specific
 - Will include both researchers & lab. technologists
 - Will also cover ethical aspects as well as sample accession aspects
 - How to leverage routine sample testing to support biobanks
- Off shoot research projects
 - Sentinel sites generated & run research projects using stored COVID-19 biospecimen
 - E.g. Effect of variants on COVID-19 diagnostics, therapeutics,
 - Recurrent & vaccine breakthrough infections

Approach continued

- ❑ To support the program we shall
 - Leverage all networks & resources
 - Reach out to to institutions eg Africa CDC
 - Leverage the Coalition to identify working group collaborations
- ❑ Funding
 - Respond to funding calls
 - Reach out to funders for unsolicited proposals
 - Funding needed for infrastructure (eg space, freezers, IT etc) as well as training program
 - We shall leverage the HR base of sentinel sites to support the program
- ❑ Implementers
 - Institutions of members of WG in each of the identified regions
 - Reach out to funders for unsolicited
 - A scientific advisory board (SAC) with coalition as convener will be formed
 - SAC will support the investigators on scientific aspects of the project
 - SAC will also be involved in resource mobilisation
 - Membership of SAC (biomedical research scientists, experts in biorepository, representatives of Ministries of health)



6 ETHICS WG & PROJECT PRESENTATION

DURATION: 15 minutes



PRESENTER(S):



Prof. Cheryl Macpherson
Working Group Co-Chair | Grenada



Prof. Jantina de Vries
Working Group Member | South Africa

Ethics Working Group members *(as of May 2021)*

- **Jennyfer Ambe** *(co-chair)*
- Caesar Atuire
- Anant Bhan
- Elizabeth Bukusi
- Phaik Yeong Cheah
- **Cheryl Cox Macpherson** *(co-chair)*
- Leonardo de Castro
- Jantina de Vries *(co-chair May 2020-Apr. 2021)*
- Deborah Diniz
- Sarah Edwards
- Shymaa Enany
- Melanie Etti
- Rita H Giacaman
- Anastasia Guantai
- Dorcas Kamuya
- Patricia Kingori
- Shai Linn
- Katherine Littler
- Vicki Marsh *(co-chair May 2020-Dec. 2020)*
- Elysee Nouvet
- Ricardo Palacios
- Michael Parker
- Sofia Salas
- Paulina Tindana
- Aissatou Toure
- Wangari Waweru Siika
- Katharine Wright

- ❖ **Range of ethics research expertise**
- ❖ **Representing Africa, Asia, Latin America, Europe & North America – 17 countries**

First coalition working group, launched in May 2020

Objectives & activities:

- **Support investigators on request** by answering ethics questions re protocols
 - Returning serology results to study participants
 - Responsibilities of research teams to allocate ventilator access/allocation at study sites.
- **Advance ethics capacity building**, including through WHO funded-projects:
 1. *Ethics equivalence for research ethics committee review in multi-country protocols*
 2. *Ethical compass consultation in Guinea*
 - Conducted by WG member Dr Elysée Nouvet, March 2021
 3. Preparing International Recommendations for Ethics Committees (IECs/IRBs)
 - WG conceptualized and initiated *Reviewing Vaccine Clinical Trials During Public Health Emergencies*

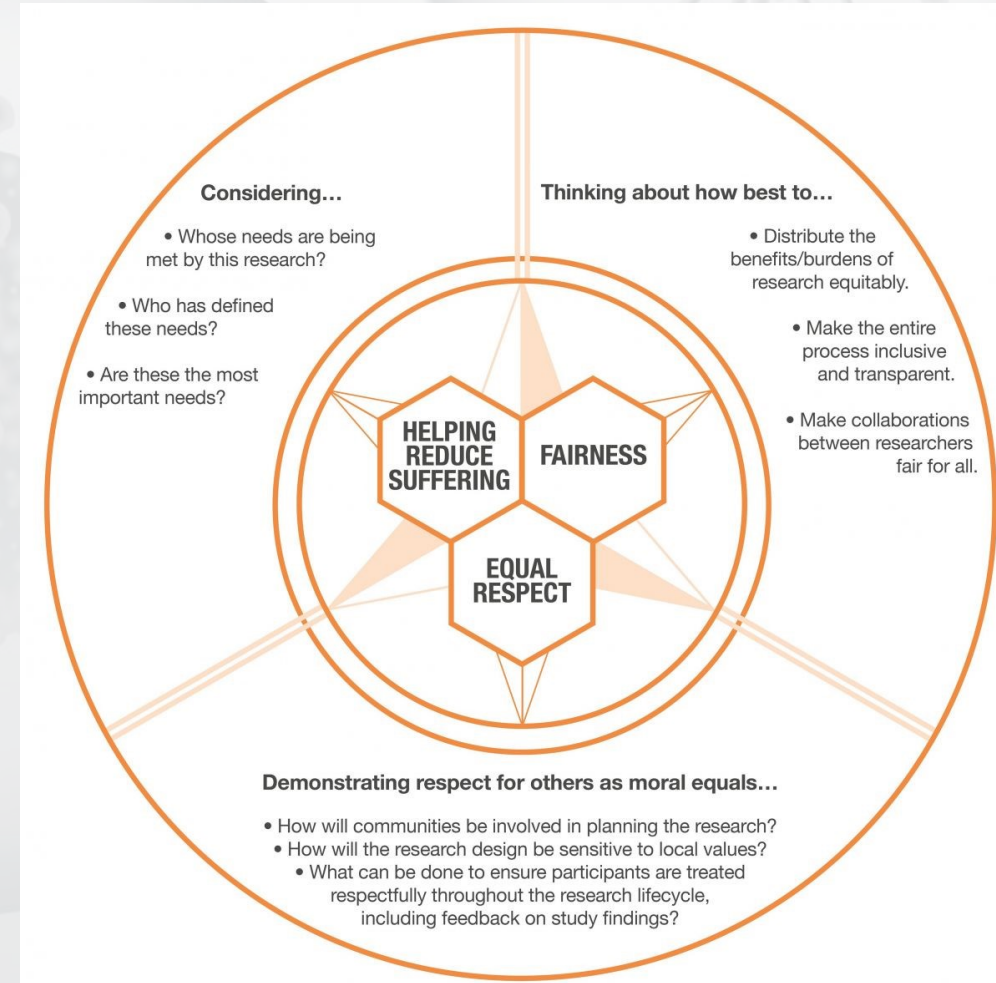
Project: Utility of Nuffield Council ethical compass for ethics review in public health emergencies

WHY? Research in public health emergencies (PHEs) raises challenging ethics questions

- Can lead to violations of individual rights and threaten research, public health interventions & public trust – with long-term consequences.

WHAT? Multi-country consultations on NC ethical compass

- **Ethical compass** – can inform policy and aid navigation of ethical challenges during PHEs of international concern.
- **Multi-country consultation** – explore utility of ethics compass for COVID-related research (build on Guinea consultations).
- Opportunity for **knowledge-sharing & capacity building** in low-resource settings today.



Multi-country consultations on Nuffield Council ethical compass – how & where?

Approach

- Conduct **country consultations**
 - **Model after Guinea project** (Elysée Nouvet, Oumou Younoussa Bah-Sow & Julian Sheather)
 - **Adapt approach to the landscape of each country** (WG partnership with a PI in each country)
 - Interested partners: Cameroon, Grenada, India, Kenya, Mexico, New Zealand, Nigeria, Philippines, and others
 - Explore possible consultations with members of other WGs

NEXT STEPS FOR WORKING GROUP:

- Interact with other coalition WGs and initiate communication with Social Science WG, others
- Renew relationship with Epidemic Ethics WG to collaboratively strengthen capacity in research ethics





7 CLINICAL PHARMACOLOGY WG UPDATE

DURATION: 10 minutes

PRESENTER(S):



Dr Colin Pillai, Working Group Chair | South Africa

(replaced by Dr Joel Tarning, Working Group Member, Thailand)

Working Group Members

- Eleni Aklillu
- Elizabeth Allen
- Karen Barnes
- Philippe Guérin
- Mohammed Lamorde
- Andréia Melo
- Colin Pillai (Chair)
- Joel Tarning
- Nick White
- Getnet Yimer

Year One

Clinical Pharmacology during pandemic research

Cross-cutting field underpinning prevention, therapeutics, pre- & post-approval activities

Working Group

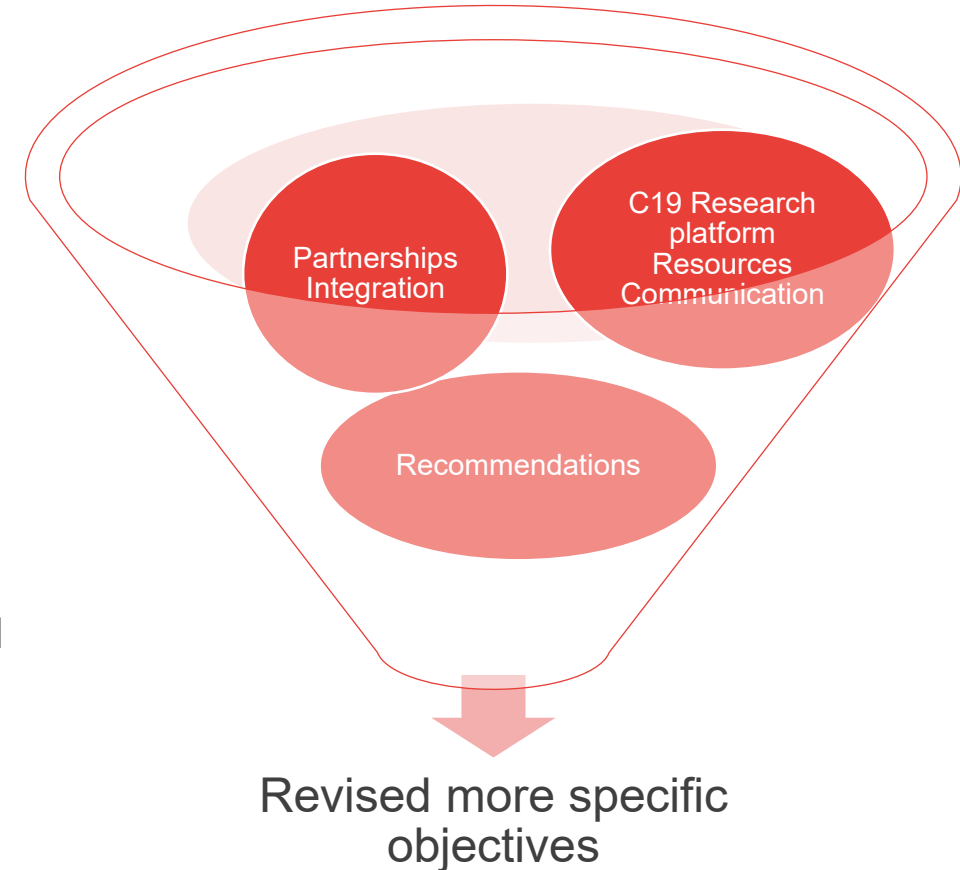
Aim : Use members' research activities and capabilities to **educate, review and support** therapeutic interventions. **Advocate** for multicentre clinical trials of the safety, efficacy, and effectiveness of interventions in resource-limited settings

Reality : Clinical development arena **devoid of new small molecules**; Conflicting **evidence** to support treatment guidelines; **Repurposed** medications dominate

Approach: Advocate for data sharing and use of **basic to advanced methodologies** (e.g. individual case reports through to mathematical (PKPD) modelling); Inform W.G. members about **collaboration** opportunities.

Activities : **Webinars** (Controlled Human Infection Challenge Studies, Model-informed Drug Repurposing for COVID, Steroids for COVID), **Opinion pieces** (Traditional medicines and COVID research), **Guidance** (practical ECG & blood PK for COVID trials)

Broad Objectives



The Next Year – Stand Up for Good Science

Guideline Review

- **Guideline review** (global, national) to ensure robust evidence base, avoid inconsistencies, and provide strong opinions that can be used to inform strategies for the COVID 19 pandemic in low resource settings
- **Assessment of drugs** included in country-specific COVID 19 treatment algorithms
- **Provide comment** on WHO guidance

Interdisciplinary approach to research

- **Complement** other Coalition WG efforts
- Identify researchers internally and externally whose **work can be strengthened** by Pharmacology expertise

Education

- **Gather available resources** / tools on Clinical Pharmacology, make them **accessible** through the Coalition website and advocate for their use
- **Discussions** with health care professional teams dealing with COVID patients in resource limited setting to provide **advisory role / query resolution**
- Contribute to the **scientific literature**

Regulatory Authorities

- Actively reach out to and offer **Technical support** (Clinical Pharmacology expertise) to Health Authorities and regulatory bodies from resource limited settings





**8 SUBSTANDARD & FALSIFIED COVID-19
VACCINES (SUPPLY & MARKET DYNAMICS WG)**

DURATION: 10 minutes

PRESENTER(S):



Prof. Paul Newton, Working Group Member | UK



Mr Paul Lotay
WG Co-Chair | Kenya



Prof. Andrew Farlow
WG Co-Chair | Brazil, Germany & UK

Working Group Update – Looking for partners & resources

Digital and AI tools

- New expert group on digital and AI applied to health launched April 2021
- July 2021: Second meeting to focus on COVID-19
- Sep/Oct 2021 (set-up) and Jan/Feb 2022 (run), digital tools and AI for health hackathon

WHO-Germany Global Hub for Pandemic & Epidemic Intelligence:

- July 2021: joint meeting *‘Pandemic Lessons and Future Preparedness’* Global Health Strategy Group; Supply and Market Dynamics and Medicine Quality Working Group; WHO; others
- WHO seeking joint projects
- Link to UK’s new advanced international pathogen

Human resources arriving over summer:

- 1 RA, July onwards
- Masters in Public Policy summer projects, July-August (some can attach to groups in Coalition...please ask)
- 4 interns/young researchers on new Global Health Future Leaders Programme (Nigeria, Zimbabwe, Sierra Leone, Egypt), August

Working Group members (as of May 2021) and objectives

The Working Group is looking forward to :

- Reconfiguring with some new members for specific focus areas
- A possible joint webinar with the Social Science Working Group
- Resources (recent efforts mostly created human resources)

- Pascale Boulet
- Céline Caillet
- Michelle Childs
- Chioma Ejekam
- **Andrew Farlow** (co-chair)
- Gamal Khalafalla
- **Paul Lotay** (co-chair)
- Patrick Lukulay
- Jorge Magalhães
- Paul Newton
- Eureka Ranjit
- Raffaella Ravinetto
- Sean Regan
- Kerlijn Van Assche
- Ed Vreeke

Prevention, detection and response to SF COVID-19 vaccines – what are the risks?

Paul Newton

paul@tropmedres.ac

Medicine Quality Research Group, MORU Tropical Health Network & Infectious Diseases Data Observatory, Centre for Tropical Medicine & Global Health, University of Oxford, UK



Medical Product Quality Report – COVID-19 vaccine issues

18 March 2021

Data included up to 5 March 2021

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- 6. Miscellaneous 27
- Annex: MQM Globe general discussions and alerts on COVID-19 vaccines 30

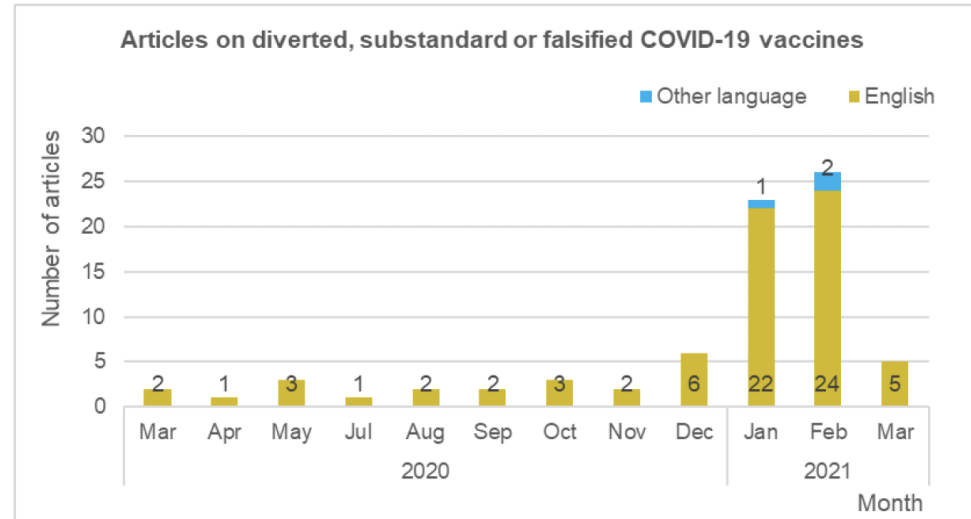
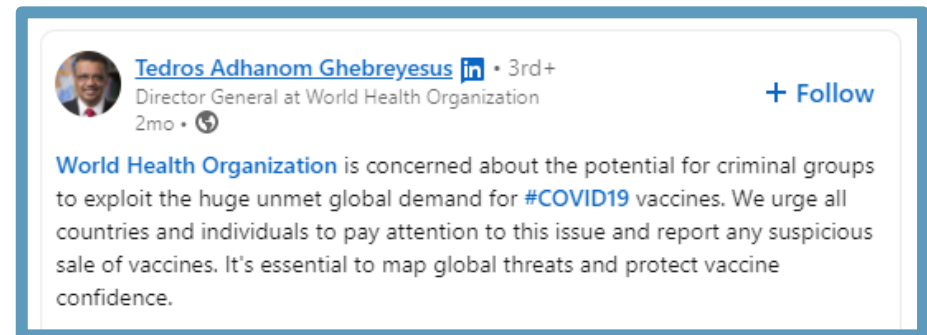


Figure 2. Articles on diverted, substandard or falsified COVID-19 vaccines on the Medicine Quality Monitoring Globe. Reports date from 12 March 2020 until 5 March 2021. We have tried to identify primary reports – there are many other reports describing these issues.

<https://www.iddo.org/mq/research/medical-product-quality-report-covid-19-vaccines>

Plus warnings by WHO, Interpol, UNODC.....



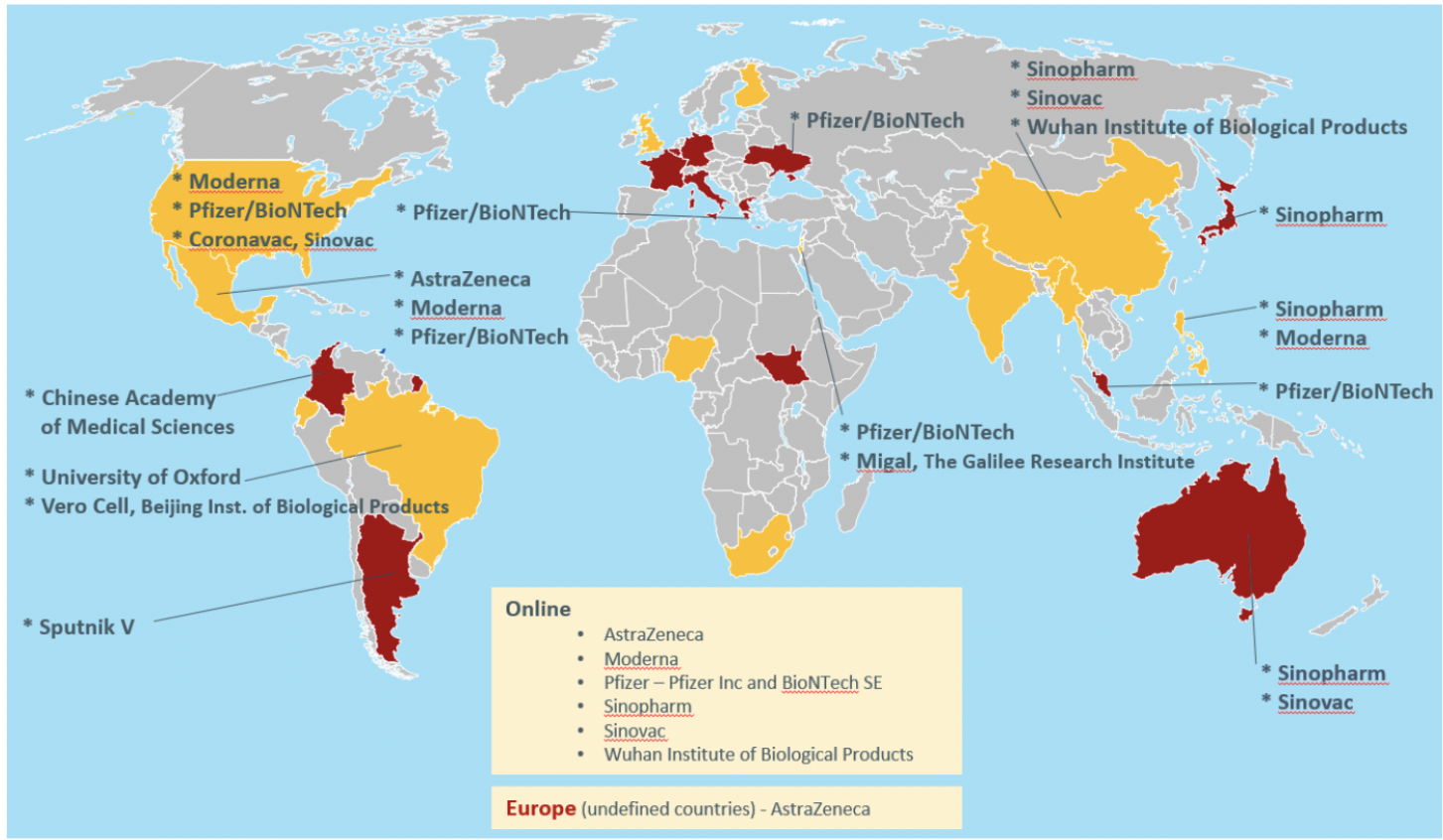


Figure 1. Countries with public reports on diverted, substandard or falsified COVID-19 vaccines. Countries with reports are indicated in orange or red. Orange shaded countries were reported as affected in the previous issue of this report. The red shaded countries are those for which there were no incidents reported in the previous issue. If a public report mentions a product name or a company, this detail is indicated on the map. Source of the information - see table 1 and 2.

Risk assessments for their occurrence and impact

- Inequitable distribution, difficulties with access and private sector vaccine sales will fuel profit-motive for falsified vaccines
- Errors in cold chain risk degradation risk reduced vaccine potency
- Diverted vaccine risks degradation
- Theft and reuse of vaccine vials
- Multiple manufacture sites may risk substandard production
- Adulteration of falsified vaccines with harmful components, intentional or unintentional, risks adverse events, health harm and vaccine hesitancy
- Risk of leaving vulnerable communities unprotected, hampering ending of the pandemic, increasing mortality & morbidity, engendering new variants, harming faith in vaccines
- Risk of fueling vaccine hesitancy, needs urgent discussion for community-specific engagement for this neglected driver of impaired trust

JOHANNESBURG (Reuters) - South African police have seized hundreds of fake COVID-19 vaccines and arrested four suspects in connection with the haul, the Interpol global police co-ordination agency said.

What interventions could reduce the risks?

- Joined up stakeholder data sharing, across manufacturers, regulatory authorities, health ministries, enforcement, customs, donors, international organisations
- Risk analysis – global and for countries to identify and rank risks to inform risk-based post-market surveillance – prevent, detect & respond strategies
- Authentication, e.g. as bar code systems – but is the infrastructure there, especially in countries that have not implemented such systems pre-pandemic?
- Where are reference labs for different vaccines? Which and how samples are submitted, which assays, who and when are data shared with and what actions are taken?
- No devices available for screening vaccines in supply chains – flying blind
- Public engagement on SF risks in different communities. How will community engagement be conducted to reduce risk of vaccine hesitancy in SF ‘outbreaks’?



PART 4

16:35 – 16:55 (CEST)

MODERATED BY:



Dr Brenda Okware
Coalition Secretariat | Uganda

AGENDA

9 CRISIS OXYGEN MANAGEMENT (CLINICAL MANAGEMENT IN RESOURCE-LIM. SETTINGS WG)

Prof. Marcus Schultz, Working Group Member | Netherlands

Including Q&A

10 EXCESS MORTALITY PROJECT PRESENTATION

Prof. Philippe Guérin, Steering Committee Member | UK

Including Q&A

**9 CRISIS OXYGEN MANAGEMENT (CLINICAL
MANAGEMENT IN RESOURCE-LIM. SETTINGS WG)**

DURATION: 10 minutes



PRESENTER(S):



Prof. Marcus Schultz, Working Group Member | Netherlands

Working Group Members

- Diptesh Aryal (Co-Chair)
- Tim Baker
- Abi Beane
- Arjen Dondorp
- Khiem Dong Phu
- Thuy Duong Bich
- Madiha Hashmi
- Bharath Kumar (Co-Chair)
- Yen Lam Minh
- Ben Morton
- Abel Mussa
- Emmanuel Nsutebu
- Tamara Phiri
- Jamie Rylance
- Hendry Sawe
- Marcus Schultz
- Chaisith Sivakorn

Oxygen shortages threaten 'total collapse' of dozens of health systems

Data reveals Nepal, Iran and South Africa among 19 countries most at risk of running out as surging Covid c

'A hopeless situation': oxygen shortage fuels Nepal's Covid crisis

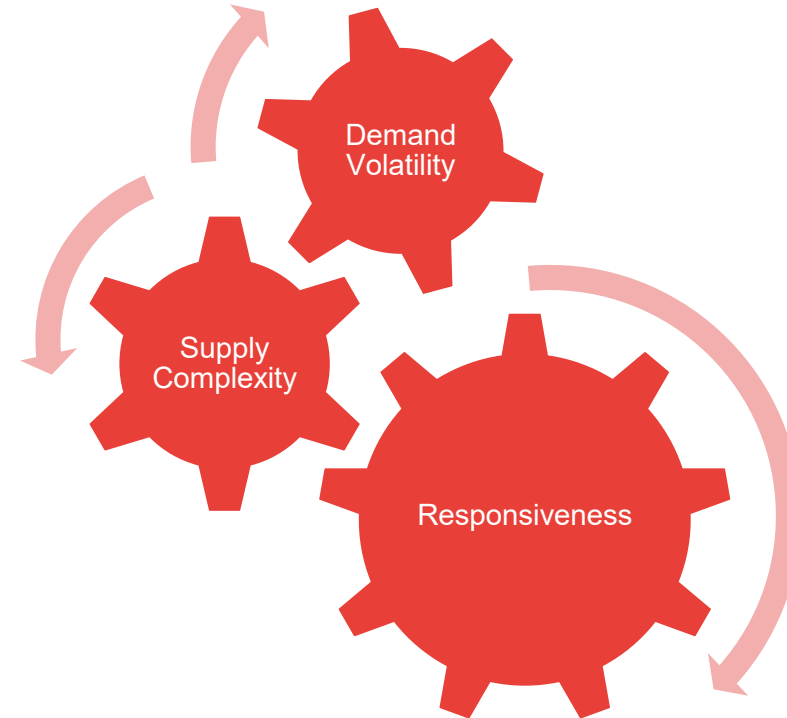
India Covid: Delhi hospitals plead for oxygen as more patients die

Kenyans suffer as hospitals face acute oxygen shortage

Rising COVID-19 cases cause shortage in East African country

Oxygen availability in LMICS

- Many RLS currently grappling with surges in COVID 19 cases
- Oxygen **shortages** already **preceded** COVID 19 **pandemic** in many RLS .
- Main delivery in LMICs - **Cylinders** - most costly option but they are not O2 source
- Need to assess current **oxygen capacity** ; true need / oxygen epidemiology unknown -> projections for need required
- Demand **MUST** be met by Supply **BUT** need to balance Demand Volatility with Supply Complexity .



Need to find balance between the complexity and responsiveness

Oxygen Sources



What can be achieved in the :

- Immediate-
- Mid-
- Long-term ?

Slide Image courtesy of Dr Rebecca Inglis

Emergency Consultation Meeting Convened by the Coalition

- Responding to **urgent** need to provide **immediate guidance** to clinicians / policy makers in areas facing oxygen crisis.
- **Objective** of consultation was to evaluate where and how Coalition could determine:
 - Current oxygen availability in low-resource settings
 - Immediate measures to be instituted now, including determining priorities
 - Simple, practical clinical guidance to be given to clinicians in contexts of limited oxygen supply?
- **Participants** : Emergency Medicine Physicians , Clinical Management Working Group
- **Oxygen conservation strategies** in setting of limited supply are key and include:
 - Increasing effectiveness of existing systems:
 - Increase effectiveness of clinical use
 - Use Oxygen conservation devices

Practical Solutions

Sources



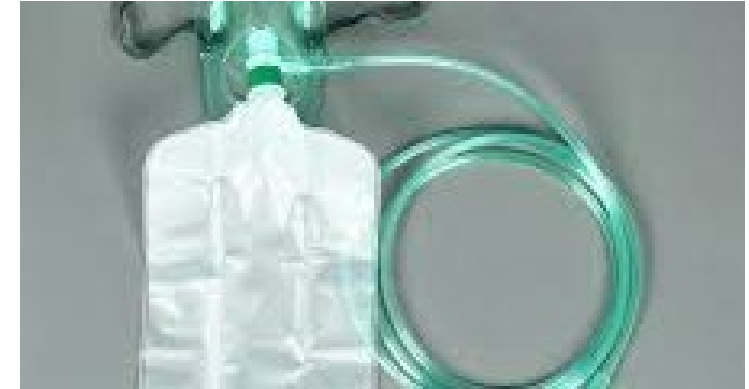
- **Low-flow devices** likely to save more lives than high-flow devices or invasive mechanical ventilation and **should be prioritized** in low-resource settings.
- Oxygen **concentrators** with sufficient capacity (>10L/min) are an important alternative
- Do not forget **back-up power** generator or large batteries).

Delivery



- Accurate **pulse-oximetry** is an essential monitoring tool.
- Low oxygen saturation is never an indication for endotracheal intubation **on its own**.
- Oxygen saturations of 90% are **often well tolerated** and can be accepted in patients with severe COVID-19.

Conservation



- **Close fitting non-rebreather masks** with 10 to 15 L/min increase FiO₂ efficiently. HFNO always uses large amounts of oxygen.
- Awake prone **positioning**, physiotherapy
- **Biomedical engineering support** to manage supply, ensure optimal performance, deal with leaks, and reduce fire hazards is invaluable.

Conclusion : What can be done ?

- **Simple measures can save lives:**
 - Prioritize low-flow devices above high-flow devices.
 - Use the correct oxygen interface, i.e., the one that best fits a patient's individual need.
 - Monitor oxygen saturation and assess the patient regularly, and set lower targets for starting and finishing supplemental oxygen.
 - Reduce leaks and wastage to save a lot of oxygen.

Acknowledgement

Clinical Management Working Group Members
(Co-chaired by Dr Bharath Kumar and Dr Diptesh Aryal)

Dr Cliff Robertson, MSF France

Dr Rebecca Inglis, Nuffield Dept. of Medicine





10 EXCESS MORTALITY PROJECT PRESENTATION

DURATION: 10 minutes



PRESENTER(S):



Prof. Philippe Guérin, Steering Committee Member | UK

WHAT?

Assemble & expand an all-cause mortality surveillance monitoring system

Measure the direct and indirect impact of the pandemic

Focus on regions with less resilient health systems

Where the outbreak's indirect impacts might be significantly underestimated

Using an innovative approach

Bottom-up approached using the research community

Complementary to WHO regional hub / IHME

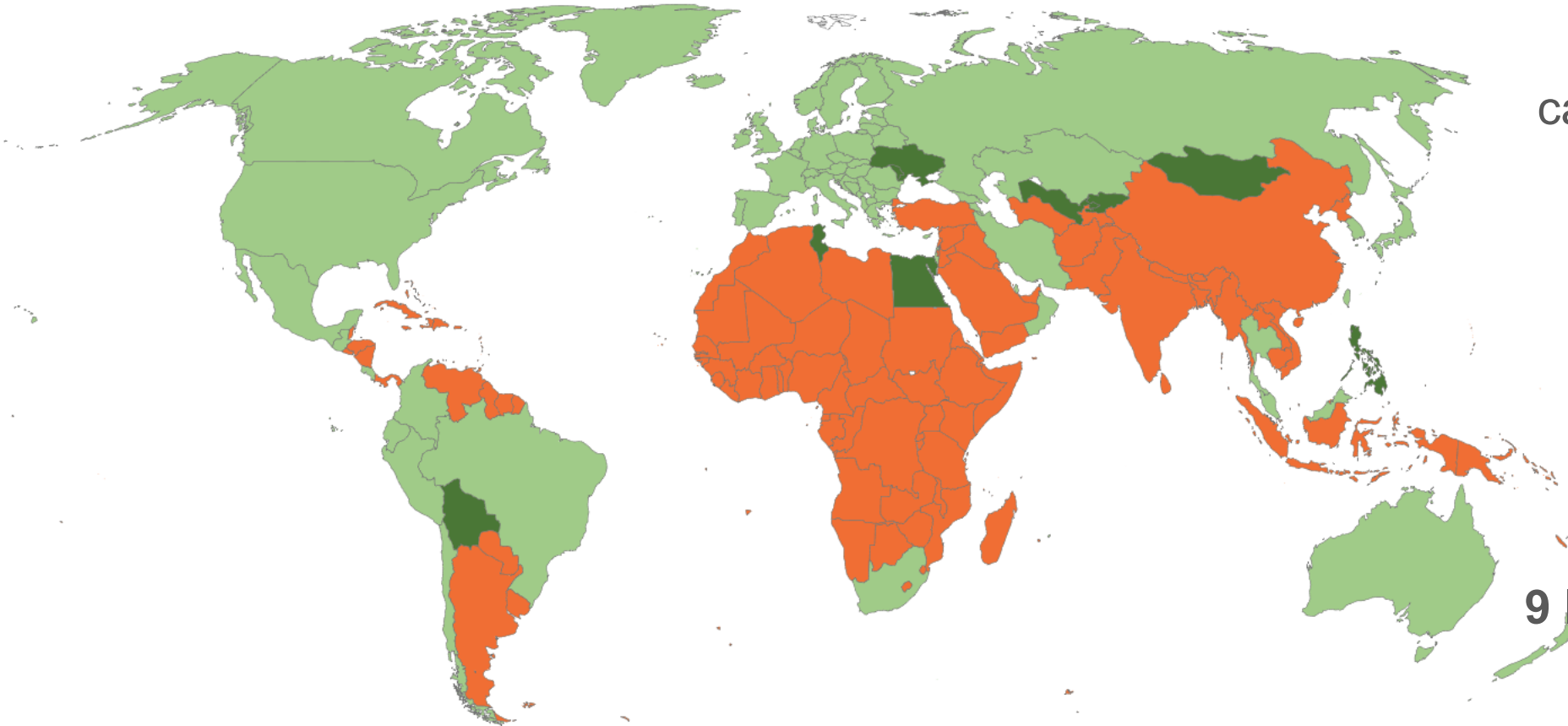
Multiple data sources and tailored methodologies

Offering a framework to share, analyse, and compare data

Creating an added value for countries & researchers

Open access & equitable recognition

WHY?



81 national datasets identified for which all-causes mortality numbers are reported by week, month or quarterly and updated in 2020

None were from low-income countries

9 lower-middle income had available information

Datasets available from HIC & Upper-MIC ■ Lower-MIC ■ No dataset publicly available ■

HOW?

During the 18-months of the project:

1. Map and valorise existing regional and local demographic registries and other data sources in absence of reliable and available national registry data
2. Present first estimates of mortality derived from those regional data sources
3. Develop 10 regional hubs each responsible to scope information for 10 countries in its geographical area through partnership with the coalition network members

Estimated funding: 1.5 million USD

- 10 Regional hubs + coordination

WHO?

- Multi-sites, multi-country project
- Institut de Santé et Développement, University Cheick Anta Diop, Dakar, Senegal
- Universities of Oxford, Geneva, IMT, IRD
- Involve the members of the coalition to establish and supervise regional hubs
- Involve the members of the coalition to develop partnership with countries outside the coalition
- Require manpower from countries within the regional hubs and a granted access to scope existing data registries, demographic health surveys
- Exploratory meeting with African CDC



PART 5

16:55 – 17:30 (CEST)

AGENDA

WHAT NEXT FOR THE COALITION?

Prof. Sir Nick White, Steering Committee Chair | Thailand & UK

A moderated discussion with all attendees

CLOSING REMARKS & NEXT STEPS

Ms Akhona Tshangela, Steering Committee Member | Ethiopia

Meeting wrap-up by Prof. Sir Nick White



WHAT NEXT FOR THE COALITION?

DURATION: 15 minutes

PRESENTER(S):



Prof. Sir Nick White, Steering Committee Chair | Thailand & UK

Questions to guide the discussion – please share your reflections!

1. Given the strengths & achievements of the coalition shared today, what do you think we should be trying to do **MORE OF**? (*Slido: one word*)
2. Is there anything we should be doing **LESS OF**? (*Slido: one word*)
3. What should we as a coalition be aiming to achieve? (*use “raise hand” function*)



Given the strengths & achievements of the coalition shared today, what do you think we should be trying to do MORE OF?



Join at
slido.com

#CRC





Is there anything we should be doing LESS OF?

Join at
slido.com
#CRC



Question to guide the discussion – please share your reflections!

3. What should we as a coalition be aiming to achieve?
(use “raise hand” function)



SAVE THE DATE: Funders Meeting



When: Thursday, **17 June** 2021 | 14:30 CEST for 2 hours (*same start time as today's Assembly*)



What: Meeting including a small number of the coalition's working groups to present projects developed in response to a shortlist of identified priority research questions, with the theme "**Addressing neglected COVID-19 research priorities in low-resource settings**".



Attendees: Key funders, presenting working groups, interested coalition members



Objectives:

1. Give coalition members an **opportunity to share with funders** the projects being developed, based on working group-identified COVID-19 research priorities in low-resource settings.
2. Provide funders with a "**no-strings-attached**" **opportunity to learn more** and ask questions about proposed projects in priority areas.
3. Create a forum for open discussion on how we can collectively facilitate priority research in resource-limited settings, including suggestions for additional partners and areas for project group consideration.



Speakers: Prof. Dr **Veronika von Messling** | Director-General for Life Sciences at the Fed. Ministry of Education and Research | Germany & Prof. **Charles Shey Wiysonge** | GloPID-R Vice Chair | South Africa (*more speakers will be announced soon*)



Invitations: Coming soon!

CLOSING REMARKS AND NEXT STEPS

DURATION: 10 minutes



PRESENTER(S):



Ms Akhona Tshangela, Steering Committee Member | Ethiopia



Thank you

for your

participation!

C  **VID-19**
Clinical Research Coalition