## COVID-19 Research Synergies Meetings

A Series of Virtual Meetings

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<th>Summaries and Discussion Panel (Session 5)</th>
<th>Thursday, July 23, 2020 at 12:00 – 3:00 PM UTC</th>
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The **Global Research Collaboration for Infectious Disease Preparedness** is an international network of research funding organizations launched in 2013 by the Heads of International Research Organisations (HIROs).

**Aim:** To facilitate, accelerate and deepen collaboration among research funders on emerging diseases by:

- **Investing to strengthen global research preparedness** between crises.
- **Mobilizing resources to respond rapidly and effectively** to significant infectious disease outbreaks.

G20 Health Ministers recognized GloPID-R
G7 leaders welcomed its action
EC finances the GloPID-R Secretariat from Fondation Merieux & University of Oxford
29 Members and 2 Observers From Around the World
The Response of GLoPID-R to the COVID-19 Pandemic

1. Members, observers and stakeholders mobilized in the response

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<td>GLoPID-R Members TC _ Outbreak</td>
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<td>07/02/2020</td>
<td>GLoPID-R _ Data Sharing WG</td>
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<td>07/02/2020</td>
<td>GLoPID-R _ WHO-SEC</td>
<td>response to 2019-nCoV</td>
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<td>11/02/2020</td>
<td>GLoPID-R _ WHO _ COVID Research priorities</td>
<td>COVID-19 _ Roadmap of R&amp;D priorities</td>
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<td>28/02/2020</td>
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<td>04/03/2020</td>
<td>GLoPID-R _ WHO _ COVID-19 Research priorities</td>
<td>R&amp;D Blueprint _ SAG &amp; GCM _ COVID-19</td>
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2. Collecting information from Members on existing research activities

3. Close collaboration with WHO Blueprint (Priorities/Road map)

4. Launching emergency calls (European Commission, UK medical research primary government funders, CEPI, BMGF, Government of Canada, Wellcome/DfID)

5. Coordinating Funders to optimize resources, avoid duplication and cover priorities listed in the R&D BP research roadmap
COVID-19 Research Synergies Meetings

Ending COVID-19 Vaccine Session:
Summary from Co-Chairs

Co-Chairs:

Dr. Anita Zaidi,
Director of Vaccine Development,
Surveillance, and Enteric and Diarrheal Diseases, BMGF

Dr. Melanie Saville,
Director of Vaccine Development, CEPI

Dr. Debra Yeskey,
Head of Regulatory Affairs, North America, CEPI
1. Vaccine Safety & Correlates of Protection

- **>250 vaccine candidates** in development globally; >60 entering clinical development by the end of 2020
  - Paradigm shift: Parallel progression through pipeline to compress timelines, while balancing **speed, scale and access**
  - **Various platforms** being tested (DNA, RNA, mRNA, protein, viral vector)
  - Some have shown **good immunogenicity** including antigen presentation, strong T cell immunity and potent antibody responses

- **Animal models** used to study vaccine safety & efficacy
  - Combination of multiple models is best
    - **Hamster**: More severe pathology (pneumonia, weight loss), can study age-related differences in susceptibility, better model for challenges
    - **Ferret**: Less severe disease
    - **Non-human primate**: Safety & efficacy

- **Need for standardized assays and controls**
  - Required to **compare between tests, operators, lab facilities and countries**, especially in preparation for multisite studies
  - **Easy-to-measure readouts** to assess correlates of protection that can be conducted outside of Level 3 facilities

- **Correlates of protection**
  - Importance of T cell immunity vs. humoral immunity (neutralizing antibodies) unclear
  - Different vaccine platforms will have different correlates of protection
2. Clinical Trials & Regulatory Considerations

- **Standardization of clinical endpoints**
  - Current diversity in endpoints prevents pooling of data to assess vaccine efficacy
  - Difficult task due to variables associated with the disease; needs careful consideration to ensure potential efficacy data is not lost

- **Harmonization of regulatory processes**
  - Increased collaboration, consultations and transparency between regulatory agencies would help develop multinational large-scale trials
    - Multisite studies required to ensure sufficient statistical power to draw accurate conclusions
  - Will help ease concerns of conducting “first-in-human” trials

- **Commitment to trial sites**
  - Help address challenges regarding logistics, health systems and regulatory processes (especially in LMICs)
  - Provide vaccine doses (if efficacious) to populations located at the trial site
  - Inclusion of different sub-groups that are relevant to the context of the population at the trial site
3. Manufacturing, Implementation & Access

- **Portfolio approach required**
  - Will allow for the **rapid configuration of manufacturing capability** as new data becomes available
  - **Building capacity from existing platforms** may be a more rapid solution than starting from scratch
  - Funders should ensure they **fund multiple candidates** and not only a single one

- Manufacturing capacity exists in aggregate within countries, but **sharing is required to ensure global access**
  - Avoid vaccine nationalism
  - **Greater governmental transparency** regarding IP & negotiation of procurement of vaccine doses

- **Parallel progression through development pipeline**
  - High-risk manufacturing needed with accelerated speed, with potentially manufacturing / purchasing vaccines that are not efficacious
  - Advanced purchase commitment will help reduce investment fragmentation, and better demand forecasting required

- **Greater government commitment for supporting equitable access**
  - Clear strategies on how they will “**walk the talk**”
  - **De-linkage of incentives**
  - Vaccine-related **tech transfer** should be undertaken early
4. General Takeaway Messages

- **Vaccines are the best exit strategy**
  - Vaccine needs to establish long-lasting immunity

- **Global standardization** and **harmonization**
  - This includes standardization of assays assessing correlates of protection, clinical trial endpoints & regulatory procedures
  - Harmonization of regulatory processes to facilitate large scale multisite studies

- **Global access**
  - COVAX will tackle issue in a product agnostic manner
  - Aim to procure 100 million doses by the end of 2020, 2 billion doses by end of 2021 ($20 billion USD)
  - Dependent on transparency & commitments from manufacturers and governments
Thank you
COVID-19 Research Synergies Meetings

Ending COVID-19 Therapeutics Session: Summary from Co-Chairs

Co-Chairs:

Dr. Glenda Grey,
President and CEO of the South African Research Medical Council (SARMC)

Dr. Valdílea G. Veloso,
Director of the National Institutes of Infection at INI-Fiocruz, Brazil
1. Therapeutic Compounds Research

- Importance of innovative methods, example of computer-aided drug design
  - Could be used when no other promising strategies out of wet lab
  - Can run simulations before *in vitro* and *in vivo* analysis

- Added value of re-purposing of drugs
  - Efficient use of time and resources
  - Facilitates moving into Phase 1
  - Use partnerships with industry

- Need evidence on efficacy/added value of combination treatment

- Need research on interactions
  - Treatment – treatment (pharmaco-kinetics, pharmaco-dynamics)
  - Treatment – stage of illness
  - Treatment – setting (co-morbidities, co-infections)

- Need good connection pre-clinical evidence and clinical trials
  - Risk to take compounds with weak pre-clinical evidence-base into clinical trials
2. Clinical Trials

- Coordination for large-scale trials
  - Multitude of small-scale studies, that are underpowered, inaccurately controlled, and not powered to look at small yet important differences
  - Need globalisation over nationalisation; collaboration over competition

- Added value of adaptive methodology
  - To allow to study multiple questions and compounds
  - To allow stratification on various levels
  - To reach endpoints more efficiently

- Standardisation and sharing of data
  - Need more standardization of trials (endpoints) to allow for comparison and pooling of data between studies & regions
  - Need institutional support regarding patents, IP, data sharing, biobanking, etc.
  - Have in place strong translation pipeline and PPP culture
  - Trust is key, environment of reciprocity between data providers and data analysts to maintain lines of communication and engagement

- Community engagement
  - Public must be empowered to get involved in the decision-making structures,
  - Requires communication and transparency
3. Importance of Context

- Make use of existing clinical trial capacity in LMICs, also consider geographic differences in the COVID-19 pandemic
  - Consider experience in LMICs, to run trials, regulatory capacity, lab capacity, etc.
  - High interest to participate in COVID-19 research efforts

- But also take into account differences
  - Standard of care
  - Feasibility of endpoints
  - Health care infrastructure conditions
  - Staff training
  - Co-morbidities, co-infections, e.g. TB and HIV in high-burden countries

- Data sharing policies should be inclusive to researchers from LMICs to provide ownership & autonomy
  - To increase opportunities for LMIC researchers to be published, get recognized, get funding
  - Use of data obtained from studies conducted in LMICs could be linked to commitment of collaboration with / capacity building of researchers
4. Global Coordination

- Prospective collaboration across national borders
  - Standards for clinical research: ethics, standardisation of trials, data sharing – role of funders!
  - Use existing networks and infrastructures to get things moving rapidly
  - Strengthen lab capacities, overcome bureaucratic hurdles for trial implementation
  - Establish sustainable data sharing platforms

- Need to anticipate new viral epi/pandemic
  - Research for development of pan-antivirals (pan-genus, pan-family or multi-family) into Phase I clinical trials
  - Drug screening on continuous basis, to identify drugs and drug targets for known viruses
Thank you
COVID-19 Research Synergies Meetings

Preparing for a Second Wave - Understanding Transmission and How to Stop COVID-19 Session: Summary from Co-Chairs

Co-Chairs:

Dr. Marion Koopmans,
Professor & Head Department of Viroscience, Erasmus MC

Dr. David Fisman,
Professor in the Division of Epidemiology, University of Toronto
What we know (virus-host)

- SARS-CoV-2 replicates in the upper respiratory tract and spreads efficiently in animal models
- Shedding peaks at late incubation period
- Infection is asymptomatic or (apparently) mild in the majority of persons
- **Infectious** virus has been detected up to 3 weeks in nasal swabs, RNA (much) longer. Virus is shed in stool, culture rare
- SARS-CoV-2 is stable for prolonged periods of time in droplets, aerosols, and on surfaces
What we know (epidemiology, ecology)

- SARS-CoV-2 is spread through droplets

- Household transmission and superspreading events are important drivers of spread

- The role of children seems to differ from other respiratory infections (reasons not yet fully clear)

- Human to pet and farm animal transmission is possible (documented for cat, dog, mink)
Unresolved / partially resolved issues

- What happened at the start of the pandemic?
- Is forward transmission of SARS-CoV-2 to animals a problem? Can SARS-CoV-2 be foodborne?
- What is the relative contribution of droplet, aerosol, contact transmission in different settings?
- What is the contribution of asymptomatic transmission?
- (How) can we recognize if viruses arise with important phenotypic changes? *(D614G spike, furin cleavage site mutations, RBV mutations)*
• Critical need: multidisciplinary outbreak research to address key knowledge gaps re: transmission

1 Infection biology and Immunity in relation to susceptibility, severity, transmission

2 Contribution of different modes of transmission in high risk settings

3 Role of animals in transmission, virus evolution and sustenance

4 Virus properties, virus evolution in relation to 1, 2 and 3

Galbadage et al, 2020
Critical need: multidisciplinary intervention studies

5 PPE, physical distancing
Behavioral intervention
Treatment

6 SARS-CoV-2 Infected Host
Fomites (?) Environmental Stability
Droplet >5 \mu m diameter <6 feet distance
Aerosols (?) <5 \mu m diameter >6 feet distance
Susceptible Host

7 Environmental engineering, aerobiology, architectural science

8 Biosecurity, ecosystems resilience
Hotspot surveillance

Galbadage et al, 2020
A new twenty-first century science for effective epidemic response

Juliet Bedford¹, Jeremy Farrar²*, Chikwe Ihekweazu³, Gagandeep Kang⁴, Marion Koopmans⁵ & John Nkengasong⁶

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<tr>
<th>Area</th>
<th>Key areas and/or disciplines</th>
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<td>Governance and infrastructure</td>
<td>Local, national and international organizations; integrate accountability and transparency across multiple stakeholders; improve data sharing, improve logistics and crisis management</td>
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<td>Engagement and communication</td>
<td>Encourage a community-led response, community engagement and health diplomacy</td>
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<td>Social sciences</td>
<td>Anthropology, political science, human geography, linguistics</td>
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<td>Ethics</td>
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<td>Pathogen genomics, metagenomics, systems serology and analytics, data science and artificial intelligence</td>
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<td>One Health</td>
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• Understanding public communication networks and communities, their evolution and impact

Tweets of COVID-related keywords (Jan-May 2020: 270M tweets)
Directed weighted network: user (node 22.5M) retweet (link 176M)
Hierarchy: 0.1% top users have >77% retweets

Remondini, Salathe et al, 2020
One size may not fit all!

Public health interventions attempting to slow transmission of COVID-19 will have to be “personalized” or “situationalized” to different countries and potentially even different areas within larger countries. The measures will require customization based on current pandemic developments as well as cultural differences.
Standing on each others shoulders: the critical need for data harmonization, governance and sharing

- Seemingly competing data sharing initiatives
- Need for data, terminology, technology standards across the board
- Particular need to arrange this for cross border studies
Standing on each others shoulders: the critical need for continued investing in basic science

- Virology, biology, immunology
- Ecology, animal sciences
- Social science
- Health sciences, health system sciences
- Detection technology
- ..........
Thank you
COVID-19 Research Synergies Meetings

Social Sciences Research in COVID-19 Session: Summary from Co-Chairs

Co-Chairs:

Kristy Crooks
APPRISE, Charles Darwin University, Australia

Dr. Kenneth Camargo
Rio de Janeiro State University
1. Population experiences

- Vulnerable populations have been more strongly affected.
- Social distancing policies (lockdown, quarantines) created social and economic problems and disrupted research itself:
  - On one hand, socioeconomic inequalities meant that compliance with such measures was unevenly distributed (informal jobs, housing problems, sanitation problems make some or all of those measures impossible to implement; financial government support has not been widely available as necessary).
  - On the other hand, the pandemic is serving as an excuse for abusing control and surveillance of the population.
- The pandemic exposed and aggravated pre-existing problems.
- There is a need to further understand the health impact of the pandemic on other social issues, such as, for instance, possible increase in mortality due to other causes as a result for health care system overload.
2. Communications and engagement

- Spread of disinformation about several aspects of the epidemic is a serious problem and hampers necessary responses.

- Contextual and semantic adequation of communication with diverse population segments is extremely important and will not be achieved without deep and meaningful, and respectful engagement with target communities.

- Co-producing knowledge with communities is essential to direct communications strategies that makes sense and valuable to target population groups.
3. Governance

- Governance is about rules and processes through which societies get organised, it is about the relationships between public leaders, technocrats and the wider community; it is about the decisions; it is about who is at the table and who is left out; about good and bad responses and not just COVID-19 crisis, but also a governance emergency.

- Problems with policy making, both from not having adequate community participation and not taking seriously expert advice.

- Need to re-think the silos and establish good working relationships, and how we produce knowledge and engage communities.
4. Methodologies

- Mixed methods approaches to research is needed; drawing the strengths of both qualitative and quantitative to explore and uncover perspectives and relationships, not just describing the problem.
- Importance of inter/transdisciplinary approaches.
- Need to integrate multiple sources and types of data; challenges for analysis.
- Difficulties in integrating different timeframes; some research projects need more time and will not provide responses in the short term.
- Difficulties in conducting fieldwork with the pandemic restrictions; need to renegotiate schedules and even whole projects with funders.
4. Overall Key Points (1)

- Population vulnerabilities are socially produced and thus require social sciences methods to be understood and to devise adequate responses.
- Consider difficulties in accessing certain populations with higher vulnerabilities (refugees, homeless, Indigenous) and importance of addressing demands from overlooked groups (e.g. caregivers in the community).
- Working with and engaging communities in making decisions to co-design, guide, and implement public health strategies that make sense, are achievable and build, support and empower communities.
- Perceived hierarchies between different methods and types of data (esp. quantitative/qualitative) must be dispelled.
- Need to provide adequate funding for sustainable projects.
4. Overall Key Points (2)

- Better articulation among different parties in order to avoid duplication and waste of resources.

- Need to have more collaboration and interactions with other researchers, funders and health authorities and a platform to share resources: find ways to build infrastructure for easier interaction between those actors.

- The whole cycle of research (identifying priorities; proposing funding opportunities; selecting projects to be funded; executing the research; analysing the data; disseminating results) has to be interdisciplinary, with participation of social scientists, and include inputs from affected communities.

- Importance of critical approaches that discuss ethical issues and power relationships, not only in the field but among researchers/funders/authorities as well; imperative to make room for voices from the "Global South".
Thank you
Thursday, July 23, 2020

Audience Questions & Summary Discussion

Dr. Debra Yeskey  
CEPI

Dr. Valdílea G. Veloso  
National Institutes of Infection at Fiocruz

Dr. Marion Koopmans  
Department of Viroscience, Erasmus MC

Dr. David Fisman  
University of Toronto

Kristy Crooks  
Charles Darwin University

Dr. Kenneth Camargo  
Rio de Janeiro State University
Thursday, July 23, 2020

Panel Discussion

Dr. Marco Cavaleri  
EMA

Dr. Jeremy Farrar  
Wellcome Trust

Dr. Nina Gobat  
University of Oxford

Dr. Richard Hatchett  
CEPI

Dr. Marion Koopmans  
Erasmus MC & GloPID-R Scientific Advisor

Dr. Michael Makanga  
EDCTP

Dr. Soumya Swaminathan  
WHO

Dr. Barbara Kernstein  
EC & GloPID-R Co-Chair

Dr. Jeffrey Mphahlele  
SA MRC & GloPID-R Co-Chair
Thank you!