

**FGAI4H-O-045**

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**Source:** University of Oxford

**Title:** Workshop: WG-CO - Data sharing and managed access

**Purpose:** Discussion

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**Abstract:** This PPT contains a presentation from the WG-CO workshop on “Equitable data infrastructures to support equitable and effective pandemic intelligence”.

# Data sharing and managed access

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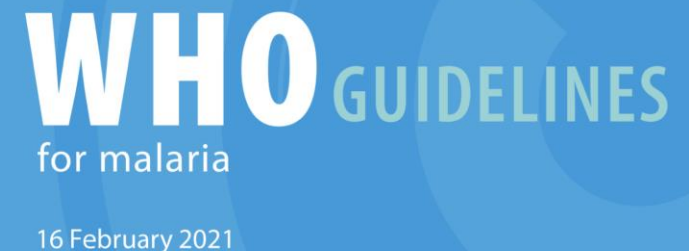
Professor of Global Health, University of Oxford

Coordinator, Data Access Committee, Mahidol  
Oxford Tropical Medicine Research Unit (MORU)

Chair, Data Sharing Working Group, Covid-19 Clinical  
Research Coalition



- Part of University of Oxford, collaborate with Mahidol University
- Bangkok hub, but conducting clinical research internationally
- > 40 years old
- Tropical medicine and infectious diseases: Malaria, antimicrobial resistance, COVID-19 – large datasets
- MORU Data Access Committee – Jan 2016
- Talk is largely about data from research (but principles apply)



# Ethical imperative

- Maximise use of data (utility)
- Secondary analyses (different research questions) or combined with other datasets
- Improve science
- Improve health – reducing suffering, improving QOL
- Transparency and trust
- Honoring altruism of participants

# Some ethical issues

- Tension between utility (rapid, real-time sharing) and equity (equitable access)
- Exacerbates existing inequality
- Confidentiality and anonymisation
- Group harms e.g. stigma
- Misinterpretation of data
- Ownership
- Broad Consent



DATA AND DEVELOPMENT

## *Open data sharing and the Global South—Who benefits?*

Limited capacity, deep mistrust pose challenges to sharing

# Consent Issues

...either

- **specific informed consent** for a particular use or
- **broad informed consent** for unspecified future use must be obtained from the person from whom the data were originally obtained
- The ethical acceptability of broad informed consent relies on proper **governance**

## International Ethical Guidelines for Health-related Research Involving Humans

Prepared by the Council for International  
Organizations of Medical Sciences (CIOMS)  
in collaboration with the  
World Health Organization (WHO)



# Challenges in broad consent

RESEARCH ARTICLE

Open Access



## Challenges arising when seeking broad consent for health research data sharing: a qualitative study of perspectives in Thailand

Phaik Yeong Cheah<sup>1,2,3\*</sup>, Nattapat Jatupornpimol<sup>1</sup>, Borimas Hanboonkunupakarn<sup>4</sup>, Napat Khirikoekong<sup>1,5</sup>, Podjanee Jittamala<sup>6</sup>, Sasithon Pukrittayakamee<sup>4</sup>, Nicholas P. J. Day<sup>1,2</sup>, Michael Parker<sup>3,7</sup> and Susan Bull<sup>3,7</sup>

- Consent for the primary study is challenging enough
- Is **broad consent** considered “informed” or valid consent?
- Many don’t understand broad consent

# The solution?

- If broad consent is imperfect (relies on governance)
- And there are there are potential problems with data sharing
- Instead of making data completely open
- We need good governance, managed access
- E.g. Data Access Committees (or equivalent)



Instead of open access, have a review process e.g. data access committee (or equivalent)

- Are collaborations necessary e.g. to better understand the context, capacity building?
- Are primary researchers (or collaborators) working/intend to work on the same research question



POLICY FORUM

DATA AND DEVELOPMENT

## *Open data sharing and the Global South—Who benefits?*

Limited capacity, deep mistrust pose challenges to sharing

- What will the data be used for? In line with broad consent?
- Any potential for group harms?
- Any potential for breach of confidentiality – if so do we need to further anonymise?
- What are the cost implications?
- What other documents/information is required?

# Role of Data Access Committees


- As the data custodian/steward (not owner)
- Promote data sharing
- Promote the interest of primary researchers
- Protect of data subjects, their communities, data producers, their institutions and the scientific enterprise
- Prioritise research questions (if necessary)
- Prioritise researchers in LMIC/where data was collected from

- Data access should be granted by DACs as long as the data reuse has potential social value and provided there is low risk of foreseeable harms. (default)
- The approach to review of applications should be proportionate to the potential risks involved.
- DACs should be established within institutional and legal frameworks with clear lines of accountability, terms of reference and membership
- Should not operate like an ethics committee

Cheah and Piasecki *BMC Medical Ethics* (2020) 21:12  
<https://doi.org/10.1186/s12910-020-0453-z>

## DEBATE

# Data Access Committees

Phaik Yeong Cheah<sup>1,2,3\*</sup>  and Jan Piasecki<sup>4</sup>

# Data access agreements

Between provider and recipient institutions

- Protects both parties
- Data used for specific objectives only
- Data cannot be shared with third parties
- Any collaborations
- Acknowledgements
- Further sharing

# Thank you

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