GLOPID-R

Global Research Collaboration for Infectious Disease Preparedness

Principles of data sharing in public health emergencies

June 2018

ABOUT THIS DOCUMENT

This document has been drafted by the members of the GloPID-R data sharing working group, which aims to develop a system for data sharing in public health emergencies which can support the scientific research response, including a common framework, common tools, processes and principles which can be embedded in research practice. The working group includes individuals from funding organisations working in infectious disease preparedness with an interest in issues (regulatory, ethical and technical) relating to data sharing in public health emergencies. Further information on the working group can be found here.

These principles are intended to inform the development of a framework and system to support data sharing[1] in public health emergencies as part of the research response, from preparedness and public health response through to the development of vaccines, diagnostics and therapeutics. These are being shared with the express intention of seeking buy-in and, where possible, endorsement from the broader community including researchers, responders and other agencies.

These principles were initially drafted by members of the GloPID-R data sharing working group, taking into consideration existing guidance and recommendations (please refer to References). Following a series of discussions within the group over a number of months, the principles were then shared publicly for a public consultation period between April 1 and May 26, 2017. In addition to an online consultation, meetings and discussions were held with stakeholders (experts and key groups, such as NGOs and researchers involved in public health emergency).

Comments received during this period were summarised and are in the attached table. Many of the proposed changes have been incorporated in this document; comments falling outside of the scope of the Principles (for example, issues relating to implementation) will be addressed through other activities. Following this initial consultation, these principles will continue to be reviewed and revised periodically in parallel with other work to develop practical guidance and approaches to support implementation.

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[1] Excluding biological samples

1. INTRODUCTION

GloPID-R is a network of research funding organizations in the area of infectious disease preparedness research.[2] Together, these funders intend to develop a system for data sharing in public health emergencies which can support the scientific research response.[3] To this end GloPID-R formed a working group on data sharing, one of whose tasks is the elaboration of core principles to guide the setting up of such a data sharing system.

These principles have been developed to underpin the timely sharing of data, which an effective and efficient response to a public health emergency (PHE) demands. They are intended to support the development of systems for data sharing in PHEs that can be recognised by and adhered to by all stakeholders.[4] This framework derives from a perspective which views the research needed to respond to PHEs as a global public good.

The principles are also intended to align with other principles such as the FAIR Data Principles, build on other work, such as the Chatham House Strengthening Data Sharing for Public Health project, and to support critical work in this area, such as the WHO R & D Blueprint Process.[5][6]

As an initial framework these principles are intended to promote discussion about approaches to data sharing in a PHE for all stakeholders, including those individuals and communities from which the data is derived. Ultimately, these principles should be responsive to the needs of communities affected by a PHE and support the requirements for quality in research even when speed is essential. Further, the principles should inform and help drive forward the eventual implementation of the systems, governance and infrastructure required to coordinate emergency response as quickly as possible, including data sharing in PHEs.

Trust is often the key for data sharing, but difficult to develop rapidly in the context of a PHE. Therefore, as a minimum, there is a need to ensure ‘confidence’ in the data sharing system for PHEs. While recognising that there may not be firm consensus on specific issues (such as ownership vs. custodianship of data), this should not prevent sharing if all parties have confidence in the system, consider it fair and support the underpinning principles. We also recognise that at times these principles may represent competing demands and there is a need to consider how they interact.

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[2] www.glopid-r.org

[3] Wilkinson, M. D. et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci. Data 3:160018 doi:10.1038/sdata.2016.18

[4] ‘Stakeholders’: those involved with the research and public health response to outbreaks, including clinical and public health researchers (including virologists, epidemiologists, geneticists, and epidemiologists among others), social science scholars, clinicians, funders, modellers, non-governmental organisations and humanitarian organisations, and public health bodies

[5] https://www.chathamhouse.org/about/structure/global-health-security/strengthening-data-sharing-public-health-project

[6] http://www.who.int/ihr/procedures/SPG_data_sharing.pdf

2. DATA SHARING PRINCIPLES

There is a growing consensus that health and medical research data should be shared to improve disease prevention, diagnosis, treatment, management and ongoing clinical care.[7] To facilitate effective sharing, it is vital to cultivate relationships built on trust, full engagement, mutual understanding and shared respect for high standards of quality in research.

In the context of an outbreak or public health emergency, the rapid sharing of data and results is critical to the ability of global communities to respond to, coordinate, adapt and manage effective response strategies.[8] The ability to mobilize effective data sharing networks in a timely and highly collaborative manner enables researchers to develop and test hypotheses with greater speed, ultimately accelerating the public health response and the pace at which lives can be saved.

Sharing data with involved stakeholders will not only extend the value of limited resources but will also reduce duplication of work and the delay between identification of a PHE and the mounting of an effective coordinated response strategy. This overall approach to data sharing will better prepare the world for future disease outbreaks and public health emergencies. It will also facilitate the rapid adaptation of response strategies during an event through identification and adoption of better interventions.

Data made available according to the following key principles:

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[7] Sharing Research Data to Improve Public Health (2011)

[8] Modjarrad K, Moorthy VS, Millett P, Gsell P-S, Roth C, Kieny M-P (2016) Developing Global Norms for Sharing Data and Results during Public Health Emergencies. PLoS Med 13(1): e1001935. doi: 10.1371/journal.pmed.1001935

Timely

The first and most immediate concern when responding to PHEs is to mobilise resources and knowledge in a logical, efficient and rapid manner. In order to ensure a successful response to PHEs, it is vital that data be shared and made available as quickly as possible, with as few access limitations as possible. Timely data sharing through quality-assured mechanisms or platforms should be the expected global norm during PHEs in order to extract the maximum available benefit out of the data in an efficient, collegial and non-competitive manner. Speed of response for data sharing requires preparation and coordination in advance of a PHE. This may include the use of tools such as standardised reporting forms and harmonised study protocols, and the development of clear outlines for each data type which determine how, by what mechanisms, with whom, under what conditions and to what extent data will be shared, and which also begin to define considerations such as quality and timeliness for different data types.

Ethical

Sharing of data must be done in accordance with applicable ethical and legal standards, ensuring beneficence and respect for confidentiality, the privacy of individuals and the dignity of communities. This is essential for building the trust of the public and all stakeholders. Additional attention should be given to respect for, and alignment with, cultural norms. This may include consultations with knowledge keepers, community members, local leaders, and following appropriate protocols. Recognising the ethical importance of consent, informed consent models that allow for secondary use of data with conditions, known as broad consent should be used to the maximum extent possible.

Accessible

Data pertaining to PHEs should be shared with as few restrictions, either technical or legal, as possible. Providers of data should clearly indicate what, if any, conditions are in place, and for how long they apply.

Transparent

The process for sharing data and facilitating access should be clearly explained, outlining how and when the data can and cannot be shared and defining the associated descriptors of the data. Information outlining the process by which data can be requested and requests considered should be provided, including timelines and conditions governing use and access.

Equitable

We acknowledge that interested parties have different levels of resources available. However, data should be made available to all interested parties during a PHE at no cost, or at a cost-recovery level only. It is not acceptable to seek monetary profit from data sharing in this context. This approach will help to ensure that all parties, including data providers and data users, have equal access to the data needed to collaborate and collectively deliver benefits to communities affected by a health emergency.

Fairness

The provision and use of data must be done in such a way that ensures fair treatment of all parties involved and recognition of their contributions. Further, any use of data should respect and acknowledge the provider and/or origin of the data and terms under which that data can be accessed and should reflect international commitments to benefits sharing. This helps to ensure that benefits resulting from data sharing flow back to the communities from which they were derived. Any analyses or new data generated through reuse should be made publically available in an open and timely manner.

Quality

The minimum quality standard of data must be ensured by the provider while data users must also ensure that data processing, analysis and interpretation are conducted with an equal or greater application of quality standards. Appropriate and recognised data standards should be adhered to, while all relevant metadata, methodology, assumptions and experimental details should be provided with the data. This will ensure that any work conducted from the data takes into account the context in which the data was originally produced. The treatment and transfer of data must also be conducted with appropriate security measures, including protection of individual privacy.

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4. KEY REFERENCES

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