GLOPID-R ROADMAP FOR DATA SHARING IN PUBLIC HEALTH EMERGENCIES
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**1 EXECUTIVE SUMMARY**
EXECUTIVE SUMMARY

Enhanced public health and research data sharing during Public Health Emergencies (PHEs) can result in significant public health benefit. Data sharing during PHEs is not currently sufficiently effective, has many challenges and is dependent on the establishment of collaboration in advance of emergencies. This roadmap aims to accelerate effective data sharing by highlighting measures GloPID-R research funders can take to improve research data sharing by their grantees and to advocate for increased research and public health data sharing more widely. These measures are aligned with the GloPID-R Data Sharing Principles and wider global policy work on data sharing and have been produced through a series of reviews and consultations commissioned by GloPID-R over the last two years.

A strategic framework with embedded recommendations is presented to GloPID-R members with the expectation that different funders may be able to take on different recommendations and some will need collaborative action.

A review of GloPID-R members identified the opportunity to strengthen funder requirements for rapid data sharing in PHEs. High standards for expectations on data sharing for GloPID-R grantees can be set, whilst acknowledging that not all institutions and researchers will currently be able to meet these (Recommendation 1). Associated tool improvement, capacity strengthening and building of trust (Recommendations 2 & 3) will be necessary to ensure that grantees can progress to meet these standards and that they do not disadvantage researchers, particularly in Low- and Middle-Income Countries (LMICs).

Much of the essential public health and research data that needs to be shared for research purposes in PHEs is not held by current GloPID-R funder grantees. Networks need to improve to bridge disciplines, especially between research and public health practice (Recommendation 3). GloPID-R funders need to work as a group to further align with external stakeholders, especially national and regional bodies in the affected areas, which need to take the lead on research prioritisation and data sharing in PHEs in their locations (Recommendation 4).

It is acknowledged that some funders can act with more agility than others can and therefore both short- (Recommendation 5a) and medium-term (Recommendation 5b) recommendations are given to foster a culture and support a trusted infrastructure where data sharing is an integral part of research.

Some of the recommended actions will require innovative funding mechanisms and commitment. Further development of each of these recommendations will be required by GloPID-R for implementation by those funders and wider stakeholders who decide to take them on.
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<td><strong>1</strong> IMPROVE FUNDER POLICIES</td>
<td>Many funders do not have rapid data sharing policies in place for PHEs and there is variability in those that do exist.</td>
<td>1a. Align on policies for data sharing in PHEs to require sharing of quality assured interim and final data in real time (wherever feasible).</td>
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<td></td>
<td>The threshold for activation of heightened requirements for data sharing (PHE or PHEIC) is too high.</td>
<td>1b. Where policies cannot be altered, align grant/contract conditions to require sharing of quality assured interim and final data in real time.</td>
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<td>Academic incentives for publishing restrict data sharing.</td>
<td>1c. Define appropriate thresholds for activation of rapid data sharing.</td>
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<td><strong>2</strong> ALIGN TOOLS AND STRENGTHEN CAPACITY</td>
<td>Need for effective Data Management Plans at study outset aligned with GloPID-R Data Sharing Principles.</td>
<td>2a. Align to improve guidance for Data Management Plans in grant applications.</td>
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<td>Need for improved data management capacity.</td>
<td>2b. Support the development and uptake of standardised tools and approaches to support international research collaborations &amp; data sharing, including MOUs, MTAs &amp; DTAs, data standards &amp; data collection templates.</td>
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<td></td>
<td>Need for improved use of tools to support data sharing.</td>
<td>2c. Fund capacity strengthening in data management and analysis (linked to 1a to enable equity).</td>
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<td><strong>3</strong> BUILD TRUST</td>
<td>Trust is key to data sharing and is hard to establish within a PHE.</td>
<td>3a. Fund improved equitable, multi-disciplinary, multinational, disease networks in advance of PHEs (linked to 2c and 4a) with real time external data sharing requirements (aligned with 1f).</td>
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<td>Many of the data holders in PHEs are not researchers funded by the GloPID-R funders. Many stakeholders are involved in effective data sharing.</td>
<td>3b. Facilitate coordination between established research networks.</td>
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<td><strong>4</strong> INFLUENCE</td>
<td>Need for systems for data sharing which researchers trust, without needing pre-established trust through known collaborators (linked to 3f).</td>
<td>4a. Collaborate within GloPID-R to align with and influence other stakeholders: national funders, Ministries of Health, Ministries of Science &amp; Technology, commercial companies, publishers, university hierarchy, policy makers (especially WHO) &amp; humanitarian sector.</td>
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<td>Communicate the PH benefits of data sharing. Continue to publish and advocate on the benefits.</td>
<td>4b. Communicate the PH benefits of data sharing. Continue to publish and advocate on the benefits.</td>
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<td><strong>5</strong> STRENGTHEN SYSTEMS</td>
<td>Many of the data holders in PHEs are not researchers funded by the GloPID-R funders. Many stakeholders are involved in effective data sharing.</td>
<td>5a. Support existing and expanded data sharing platforms for priority pathogens with agreed governance mechanisms and data security systems.</td>
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<td></td>
<td>Need for systems for data sharing which researchers trust, without needing pre-established trust through known collaborators (linked to 3f).</td>
<td>5b. Support an overarching unified governance structure for international data sharing within which existing platforms can be embedded and through which platforms for novel pathogens can be developed.</td>
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PurPOSe

The purpose of this roadmap is to accelerate effective data sharing in PHEs by highlighting measures GloPID-R research funders can take to improve research data sharing by their grantees and to advocate for further research and public health data sharing, in alignment with the GloPID-R data sharing principles\(^1\).

sCOPe

This roadmap focusses on implementable recommendations to the GloPID-R funders. These recommendations will also be of interest to other stakeholders including non-member funders, policy makers, researchers, PH practitioners, industry and publishers. The main type of data covered is research data, as that is what GloPID-R funders can directly influence through their grantees, but the potential for influencing wider public health data sharing is also in scope.

The roadmap has been produced through synthesising results of reviews and consultations commissioned by GloPID-R\(^2,4\) and alignment with other ‘non- GloPID-R’ work on Data Sharing in PHEs\(^5,6,7,8,9,10\).
Data sharing is an expectation within research, with most funders and journals requiring it following research publication in order to improve research impact. The importance of heightened and rapid sharing of research data in advance of publication has been highlighted for PHEs, given the time lag to publication. PHEs are defined by the WHO as “an occurrence or imminent threat of an illness or health condition, caused by bio terrorism, epidemic or pandemic disease, or a novel and highly fatal infectious agent or biological toxin, that poses a substantial risk of a significant number of human facilities or incidents or permanent or long-term disability”. Rapid data sharing in PHEs is predicted to accelerate health benefits through; facilitating research projects, reducing the duplication of work and ensuring a clearer picture of epidemiology and pathology through pooled results to improve intervention effectiveness in current or future PHEs.

Timeliness is of highest importance to enable both research and health systems data to guide responses during infectious disease outbreaks and preparedness for future outbreaks. This need for timely data sharing does however need to be balanced against a range of ethical, legal, political and social considerations. The quality of the data to be shared also needs to be appropriately assured to ensure correct decisions are made.

GloPID-R funders and other stakeholders have taken a range of policy steps in this area as outlined in the following sections but further high-level commitment and action is needed. GloPID-R’s recently commissioned case-studies show data sharing has certainly occurred during recent Public Health Emergencies, but that many opportunities were lost through barriers to data sharing. The GloPID-R funders’ review shows that many funders are looking for guidance in this area and are willing to act. The importance of collaboration is also highlighted and there is a need for further engagement of National Funders and other National and Regional bodies in the affected countries and with further stakeholders.

STATEMENTS, CODES OF CONDUCT & COMMITMENTS ON DATA SHARING IN PHEs

The global community has taken a range of steps to encourage timely data sharing during recent PHEs and made commitments for future PHEs.

The WHO has led on policy in this field with a range of guidance including ‘Developing Global Norms for Sharing Data and Results During Public Health Emergencies Statement’, the ‘Pandemic Influenza Preparedness Framework’ and its recent ‘Code of conduct for open and timely sharing of pathogen genetic sequence data during outbreaks of infectious disease’ (see Annex A for summaries).
In statements at the time of the recent Zika (2016) and Ebola (2018) epidemics, research funders committed to requiring researchers to share quality-assured interim and final data as rapidly as possible and journals committed to ensuring free access of data and pre-prints concerning the virus, which will not pre-empt their publication14,20.

There have also been commitments from funders to encourage sharing of early results through pre-prints defined as complete and public drafts of scientific documents, yet to be certified by peer review21.

The GloPID-R funders have contributed to this policy area with their Data Sharing Principles1 to underpin future implementation of timely data sharing. These principles are intended to support the development of systems for data sharing in PHEs that can be recognised by and adhered to by all stakeholders. The principles are also intended to align with other principles such as the FAIR Data Principles4, build on other work, such as the Chatham House Strengthening Data Sharing for Public Health project16, and to support critical work in this area, such as the WHO R & D Blueprint Process. In 2018, Case Studies2 and a GloPID-R funders’ review4 were commissioned on behalf of the GloPID-R data sharing working group.

GLOPID-R COMMISSIONED WORK: CASE STUDIES

Six case studies were undertaken on data sharing across a range of infectious disease outbreaks of different severity, geographical exposure and public health impact, where interventions were or were not available to develop a deeper understanding of the obstacles to and enablers of data sharing. In December 2018, a consultation meeting was held to discuss the outcomes of the case studies and synthesise the findings across them, summarised in a meeting report17. The identified obstacles and enablers are synthesised in this roadmap.

Overall, the case studies showed that data sharing (of both research and public health data) was not common or was often delayed in outbreaks where opportunities had already been lost for research to inform the public health response for that outbreak. Data sharing was most immediate through pre-established networks, where mechanisms and, most importantly, trust had already been built (this agreed with findings from a previous review15). Trusted informal contacts and networks were also used to share data when formal routes were not functioning.

The case studies highlight the complexity of factors influencing sharing and use of data in PHEs, not all of which can be addressed by the GloPID-R funders. They also show that what constitutes a PHE may not be clear-cut and that, for example, inadequate detection and control can contribute to an outbreak becoming a PHE. The epidemic potential of an emerging infection may also not be clear during the early stages of an outbreak.

GLOPID-R COMMISSIONED WORK: FUNDERS’ REVIEW

The GloPID-R funders’ review surveyed GloPID-R funders to determine and analyse their current policies and future plans in support of enhanced data sharing in PHEs (as well as data sharing in general and open-access policies). Funders policies on data sharing in PHEs can facilitate enhanced data sharing in line with agreed principles. The review showed that 12 out of the 15 funders* that responded had data sharing policies in place (ranging from encouraging data sharing for limited data to general policies requiring data sharing for all data types), however only 6 out of those 15 funders had policies or grant conditions in place referring to rapid data sharing in PHEs. An important difference was noted as to whether conditions were included in policies (which would apply to all grants) or grant conditions (where appropriate conditions might be missed for relevant grants funded in advance of an outbreak). Good practice was shown in grant conditions that provided a backup condition for all grants, which requires grantees to share data rapidly if it turns out to be relevant to a PHE.

All rapid data sharing funders’ policies or grant conditions referred to a PHE (with some funders verbally commenting on a link to the WHO definition of a PHE)6,8,9,10,11,12,13,14,15,16,17,18,19,20,21 as the trigger for their ‘rapid’ data sharing conditions. The definition of this PHE trigger was not well articulated in any of the policies but is assumed to relate to the WHO definition6. The funders’ review identified further definition of these triggers as necessary and important in considering when policies will be activated.

Existing policies and grant conditions vary in their definition of ‘rapid’ data sharing. Most funders convey that it was important for data to be shared as close to ‘immediately’ as possible, however highlighting the considerations limiting this ambition. Limitations cited included: quality assurance processes; safeguards to protect research participants and patients’ confidentiality; ethical, legal and commercial obligations; equity in research and not jeopardising publication. Best practice was shown by funders that set a time limit (the EC states ‘one month’) on ‘rapid’ data sharing to make their expectations clear (despite acknowledging the potential limitations). Advanced data planning and restricted access arrangements were cited as an appropriate way to address some of these limitations.

Indeed, Data Management Plans (DMPs) with feasible mechanisms for rapid data sharing (accounting for anticipated barriers) could be a key tool to accelerate the speed of ‘rapid’ data sharing in PHEs. DMPs are required by most of the funders surveyed, either at the grant application or award stage (including funders with no data policies or grant conditions).

There was a clear interest in considering revisions to these policies, with 9 of the 15 funders expressing plans to update their policies or grant conditions in these areas and many looking for further guidance. Some funders, especially national funders, are however limited in making changes to their policies (which were often institution-wide and sometimes affected multiple institutions). Recommendations for funders’ policies were made, based on the funders’ review, which are synthesised into this roadmap. This roadmap provides guidance for all GloPID-R funders, in improvements, which could fit within their range of institutional limitations.

* There are 28 funder members of GloPID-R.
This roadmap has been produced through synthesising the challenges and potential solutions identified by existing results of reviews commissioned by GloPID-R, alignment with other (non-GloPID-R work) on data sharing in PHEs and consultation with GloPID-R members (and other key stakeholders including researchers). Challenges and potential solutions are mapped against the GloPID-R Data Sharing Principles and a strategic framework for GloPID-R funders with embedded recommendations is then provided.
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 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 harmonised study protocols and the development of clear outlines for how, with whom, and to what extent data will be shared.

Challenges to data sharing are mapped against the GloPID-R Data Sharing Principles with associated potential solutions. In PHEs the most important principle is timeliness (this is underpinned by the other principles) and many of the barriers highlighted here fall within the timeliness principle. Several of the solutions are crosscutting.

**TIMELY: CHALLENGES & POTENTIAL SOLUTIONS**

**THRESHOLDS FOR RAPID DATA SHARING**

A potential bottleneck has been identified in the GloPID-R funders’ policies through linking the trigger for their rapid data sharing policies to the WHO definitions of a PHE or even PHEIC. What constitutes a PHE may not be clear. There are also many outbreaks or epidemics and even inter-epidemic periods (for epidemic prone pathogens that are of public health interest) where rapid data sharing of early research conducted may enable a response which ultimately prevents a PHE or PHEIC.

Discrete thresholds for enhanced data sharing need to be developed for research on certain epidemic prone pathogens. Rapid data sharing requirements for all research on outbreaks of novel/ emerging pathogens and pathogens with high epidemic potential could be considered (potentially linked to the WHO R&D blueprint priority pathogen list\(^{(2)}\)) whether or not there is currently a PHE. The WHO has already provided guidance on the importance of sharing Pathogen Genetic Sequence Data and associated metadata for all outbreaks (prior to PHE).

**COMPLEXITY OF DATA SHARING**

The useful data during a PHE can be highly complex. There is heterogeneity in the nature of the data being collected (e.g. epidemiological, clinical, and genetic) and varying format and content across these. There are also varying purposes of data collection (public health and research) and distinct data needs from different users. Harmonising data across these domains, formats and contents requires significant investment, which delays the utility of shared data.

Standardised data collection tools will further support consensus on which data should be prioritised for collection and ensure that key outcomes are measured to enable cross-analysis. Further development of and use of generic meta-data standards (such as those developed through the Clinical Data Interchange...
Standards Consortium (CDISC) will also help to enable cross analysis. The development of a comprehensive platform for data sharing could provide standardisation and facilitate coordination across all these issues, which would help address complexity.

**TRUST AND FURTHER CULTURAL AND BEHAVIOURAL FACTORS**

Trust has been identified as being key to timely data sharing. Issues with trust have been identified between research, public health, NGO and other response communities. Building trust within a PHE is difficult and therefore developing collaborations within inter-epidemic periods is needed.

Networks, established collaborators, training and capacity building have all be shown to enable rapid data sharing as a result of pre-existing protocols, relationships and trust. Building further multi-expertise and country networks in advance of PHEs to allow data sharing through a standardised system with transparent terms and protocols for data collection and access and sharing of research data would facilitate data sharing in future PHEs. It is important that these international networks build cross-sectoral relationships (both academic, public health and One Health) in advance of PHEs.

**ACADEMIC PUBLISHING MODELS & LINKED ACADEMIC INCENTIVES**

Established academic publishing models and culture are a clear barrier to timely data sharing. Authorship of academic papers is linked to academic advancement through grant applications and institutional hierarchies. This incentivises a culture of competition between researchers, even within the same institution, and a lack of willingness to share data.

Publishers have already aimed to address this through the introduction of pre-publication sharing for data of public health significance and fast track mechanisms for publication of results. Some funders align with the San Francisco Declaration on Research Assessment to base grant giving on an enhanced definition of ‘quality’ which encompasses published data sets and pre-publications.

The case studies and funders’ survey indicate that for many researchers (especially those in Low and Middle Income Countries - LMICs) there is remaining concern about data release jeopardising future publication.

**REGULATORY FRAMEWORKS**

Ethical approvals, especially within the complex situations of PHEs can slow research and therefore data sharing. The potential lengthy approval processes due to additional national regulatory and legal frameworks can inhibit international collaboration and data sharing.

Regional and international bodies could encourage further harmonisation and streamlining of practices including for data sharing. Nationally tailored, approved legal, ethical and regulatory frameworks for data sharing in advance of an outbreak would improve timeliness in those countries.

**ENSURING ETHICAL STANDARDS**

Clear ethics and governance frameworks for sharing of data that can be approved by ethics committees and governments in advance of outbreaks are needed. Funders should ensure these measures are in place prior to study initiation and ethics committees need to be briefed on the importance of broad consent and anonymisation for PHE situations.

Engaging communities and knowledge keepers in meaningful co-development of research, research data management and stewardship is needed. The potential health benefits to the communities whose data is being shared need to be recognised.

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**ETHICAL DATA SHARING PRINCIPLE**

Sharing of data must be done in accordance with applicable ethical and legal standards, ensuring respect for the privacy of individuals and the dignity of communities. This is essential for building the trust of the public. Additional attention should be given to respect for, and alignment with, cultural norms. This may include consultations with knowledge keepers, community members, local leaders/elders, 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.
TRANSPARENT: CHALLENGES & POTENTIAL SOLUTIONS

CULTURAL & BEHAVIOURAL
The case studies highlighted concerns by data providers that data would not be analysed appropriately by others (which might in turn impact on the data providers’ academic credibility). This resulted in data being shared only through informal networks of trusted associates. Such informal networks lack transparency and accountability and can exclude important potential users.

More work needs to be done to communicate the benefits and use of formalised research partnerships with Memorandums of Understanding (MOUs), Material Transfer Arrangements (MTAs) and Data Transfer Arrangements (DTAs). These are increasing in their transparency (about role distribution) and fairness (in authorship) thereby improving the scientific recognition for all counterparts. A cross-cutting data sharing platform would enable transparent processes and conditions to be put in place in advance of the next outbreak.

ACCESSIBLE: CHALLENGES & POTENTIAL SOLUTIONS

COMMERCIAL INTERESTS
A major barrier to accessible research data sharing highlighted by the case studies related to the involvement of commercial interests. Non-disclosure agreements may restrict researchers’ ability to make data available. Companies may also be reluctant to share negative findings because of commercial implications. Funders can align for further direct dialogue with industry partners to enable greater transparency through data-sharing agreements developed for Product Development Partnerships (PDPs) and other public-private partnerships. Where no public-private partnership exists discussion with industry associations may be productive.

LEGAL
Data transfer from one country to another must be compliant with national and international regulations. Pre-approved systems for data sharing are needed including federated data systems. Anonymisation of data is of high importance and appropriate protocols need to be put in place and assured.

TECHNICAL
A review of data from published research on pathogens of epidemic and pandemic concern (excluding case-reports which by nature provide individual patient data) showed that only 31% of the data were accessible (provided access to all the data underlying the paper, without having to request it from authors) and that 57% of these were as datasets in PDF format (which do not allow for easy data scraping or indexing) within supplementary material. Further use of data sharing platforms would improve open data sharing.

ACCESSIBLE DATA SHARING PRINCIPLE

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.

TRANSPARENT DATA SHARING PRINCIPLE

The process for sharing data and facilitating access should be clearly explained, outlining how and when the data can 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.

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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. 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 publicly available in an open and timely manner.

**EQUITABLE DATA SHARING PRINCIPLE**

We acknowledge that all interested parties will have different levels of resources available to them. Data that is shared should therefore 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. As such, whenever possible, sharing should be done free of charge. In cases where it is necessary to apply charges associated with data sharing, these charges should be kept to a minimum. 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 the health emergency.

**NEED FOR AGREED GUIDELINES**

The case studies did not highlight any instances of barriers to equitable data sharing (although they could not fully explore the many actors who may have wanted to but failed to gain access to the data). Equitable data sharing was identified through pre-established networks where the agreed protocols required there to be no cost implications. There is a need for more open data sharing practices to increase equity.

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**ALIGNMENT WITH NATIONAL NEEDS**

Closer alignment of funders’ research and capacity building priorities with that of national priorities in PHEs has been recommended to ensure research is more closely aligned with country needs. Funders could also develop clearer expectations for such alignment for their grantees.

**CAPACITY IMBALANCES**

Fears of ‘data exploitation’ can result from power and capacity imbalances. Partnerships need to be equitable with clear expectations.

Arrangements need to be formalised through collaborative agreements or specific MTAs or DTAs to appropriately acknowledge all parties involved. Capacity imbalances need to be addressed through support to develop the skills of those contributing to data collection to support data management and data analysis. The involvement of national/local sources of surveillance and research in further analysis generated by their data should be clearly stated in MTAs or DTAs. Feedback from the data that has been shared and ongoing partnership would also improve fairness. The Research Fairness Initiative provides useful guidance on fairness including data: [www.rfi.cohred.org](http://www.rfi.cohred.org)

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QUALITY: CHALLENGES & POTENTIAL SOLUTIONS

COMPLEXITY

Issues with data completeness, quality and accessibility are all highlighted through the case studies. Compatibility between different datasets has also provided a barrier to effective data sharing.

There is a clear highlighted need for capacity strengthening in data management (including all aspects from collection to analysis) in endemic countries to improve data quality. The use of standardised data collection protocols along with data handling and data collection manuals would improve standardisation. The use of existing pathogen specific platforms or development of a comprehensive global platform for data sharing could provide standardisation and facilitate coordination, which would help address complexity.

QUALITY DATA SHARING PRINCIPLE

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 meta-data, 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.

4

STRATEGIC FRAMEWORK FOR FUNDERS & RECOMMENDATIONS FOR ACTION
**PRIORITY CHALLENGES OUTLINE RECOMMENDATIONS**

**1. IMPROVE FUNDER POLICIES**

- **Many funders do not have rapid data sharing policies in place for PHEs and there is variability in those that do exist.**
  - 1a. Align policies for data sharing in PHEs to require sharing of quality assured interim and final data in real time (wherever feasible).
  - 1b. Where policies cannot be altered, align grant/contract conditions to require sharing of quality assured interim and final data in real time.
- **The threshold for activation of heightened requirements for data sharing (PHE or PHEIC) is too high.**
  - 1c. Define appropriate thresholds for activation of rapid data sharing.
- **Academic incentives for publishing restrict data sharing.**
  - 1d. Align funding policies to ensure that data sets and pre-publications are all included within assessment of researcher outputs (in accordance with the San Francisco Declaration on Research Data).

**2. ALIGN TOOLS AND STRENGTHEN CAPACITY**

- **Need for effective Data Management Plans at study outset aligned with GloPID-R Data Sharing Principles.**
  - 2a. Align to improve guidance for Data Management Plans in grant applications.
- **Need for improved data management capacity.**
  - 2b. Support the development and uptake of standardised tools and approaches to support international research collaborations & data sharing, including MOUs, MTAs & DTAs, data standards & data collection templates.
- **Need for improved use of tools to support data sharing.**
  - 2c. Fund capacity strengthening in data management and analysis (linked to 3a to enable equity).

**3. BUILD TRUST**

- **Trust is key to data sharing and is hard to establish within a PHE.**
  - 3a. Fund improved equitable, multi-disciplinary, multinational, disease networks in advance of PHEs (linked to 2c and 4a) with real time external data sharing requirements (aligned with 1).
  - 3b. Facilitate coordination between established research networks.

**4. INFLUENCE**

- **Many of the data holders in PHEs are not researchers funded by the GloPID-R funders. Many stakeholders are involved in effective data sharing.**
  - 4a. Collaborate within GloPID-R to align with and influence other stakeholders: national funders, Ministries of Health, Ministries of Science & Technology, commercial companies, publishers, university hierarchy, policy makers (especially WHO) & humanitarian sector.
  - 4b. Communicate the PH benefits of data sharing. Continue to publish and advocate on the benefits.

**5. STRENGTHEN SYSTEMS**

- **Need for systems for data sharing which researchers trust, without needing pre-established trust through known collaborators (linked to 3).**
  - 5a. Support existing and expanded data sharing platforms for priority pathogens with agreed governance mechanisms and data security systems.
  - 5b. Support an overarching unified governance structure for international data sharing within which existing platforms can be embedded and through which platforms for novel pathogens can be developed.
Recommendation 1: Improve Funder Policies

Rapid data sharing policies for PHEs have been identified as the most direct way in which funders can influence data sharing to accelerate public health benefits. Timeliness is of the greatest importance in PHEs, however this does need to be balanced against both quality and feasibility where researchers may have limited capacity due to the outbreak situation.

1a. Align on policies for data sharing in PHEs to require sharing of quality assured interim and final data in real time (wherever feasible).

To require sharing of quality assured interim and final data in PHEs in real time (within one month) and ensure that the grantees to which this applies uphold this requirement in Data Management Plans (wherever feasible considering capacity, ethical, legal and commercial obligations).

Providing a time limit for data sharing in PHEs will help give both clarity and parity for researchers working in this field. ‘Within one month’ is the highest standard currently used by GloPID-R funders. Any exceptions and access restrictions due to capacity, ethical, legal and commercial obligations can be detailed in grantees’ DMPs approved by the funders. It is recognised that some institutions/researchers in LMICs with limited capacity and outbreak response responsibilities will need to agree realistic timelines with their funders. If GloPID-R funders can align their policies, they will have strong influence over other funders and stakeholders.
Recommendation 1: Improve Funder Policies

to the WHO R&D blueprint priority pathogens of public health interest (linked
outbreaks of novel/ emerging pathogens and
sharing requirements for all research on
PHEICs). Consider implementing rapid data
restricted to the trigger of declared PHEs or
rapid data sharing with a low threshold (not
To include improved definition of triggers for
The aim of GloPID-R’s data-sharing work is to ensure
rapid data sharing where it may result in significant
public health benefit. Rapid data sharing may be benefici-
cial in certain outbreaks or epidemics which don’t meet
the criteria for PHEs or PHEICs or even in inter-epidem-
ic periods. In these cases, rapid data sharing may even
enable a response which prevents a PHE or PHEIC. This
needs further development by GloPID-R.

d. Align funding policies to ensure that
data sets and pre-publications are all includ-
ed within assessment of researcher out-
puts (in accordance with the San Francisco
Declaration2).

Funders need to ensure that data sharing
activities, data sets and pre-publications
are all included within their assessment of
researcher outputs when considering grant
applications, in line with the San Francisco
Declaration on research assessment2 (see
Annex B).

Ensuring alignment with the San Francisco Declaration
on research assessment is the most direct action
funders can take to address the perceived academic
disincentives to data sharing.

Recommendation 2: Align Tools and Strengthen Capacity

2a. Align to improve guidance for Data
Management Plans in grant applications.

To require a DMP for each project and to in-
clude coordinated expectation and guidance
from GloPID-R funders for the development
and enforcement of DMPs. Guidance should
cover all aspects of GloPID-R data sharing
principles (and FAIR principles3), covering
Material and Data Transfer Agreements
(aligning with WHO guidance).

Clear and robust DMPs can support implementing rapid
data sharing policies, grant conditions /contracts or
guidance and facilitating data sharing. Some funders
provide support in developing these data sharing
plans, but this could be a key area for further capacity
building. The quality of funder review of these data
management plans will also be important in ensuring
effective data sharing.

2b. Align on the use of standardised tools and
approaches to support international research
collaborations & data sharing, including MTAs
& DTAs.

The various templates and standardised
tools developed and endorsed by organisa-
tions such as WHO, Chatham House4 and
CDISC5 need to be promoted and embedded in
GloPID-R funded researchers’ work through
their DMPs. Further work should be supported
on the creation of common protocols, consent
forms, data capture forms, outcome meas-
ures and data standards to facilitate data
analysis across countries and studies within
the inter-pandemic period and fostering cross
inter-disciplinary network collaboration (link to
recommendation 2c).

Standardised trusted tools would speed up data
sharing and prevent the delays caused by translation in
 certain cases, where documents can only be signed in
the national language. The GloPID-R website could be
used to highlight these.

2c. Fund capacity strengthening in data man-
agement and analysis (linked to 3a to enable
equity).

Capacity development needs to be funded
across a broad range of data management
(including collection) and analysis skills in advance of PHEs to ensure that researchers and research managers can meet the requirements for data sharing. Capacity development should address equipment needs, such as the necessary IT infrastructure including servers and networks. This has also been identified as important in improving equity and fairness. This could be facilitated through national/regional/international collaboration across equitable partnerships (see recommendation 3a).

Capacity development in data management and analysis has been highlighted as a key need in advance of outbreaks. Alignment between GloPID-R funders in investment into training platforms would likely accelerate and enhance their development and use. This needs to be based on mapping of data management needs.

RECOMMENDATION 3
BUILD TRUST

Trust has been identified as vital to data sharing in PHEs. It is hard to build trust during a PHE. Personal connections and effective governance systems have been shown to produce trust.

3a. Fund improved equitable, multi-disciplinary, multinational, disease networks in advance of PHEs (linked to 2c. and 4a.) with real time external data sharing requirements (aligned with 1).

Funding improved equitable, multi-disciplinary, multinational, networks in advance of PHEs can enable immediate data sharing. It is important that these international networks build cross-sectoral relationships (both academic-public health (including e.g. endemic country MoHs, NGOs and specialty laboratories) and One Health (medical and veterinary) in advance of PHEs. Limited money could be given to establish the network (through meetings) and to develop pre-approved and dormant protocols (including governance, advanced ethics approvals for pre-approved protocols to be activated in the case of an outbreak of public health interest) and potentially capacity strengthening activities (linked to recommendation 2c). Once established, networks can provide platforms for further funding and expanded partnership in the event of an outbreak to implement research plans. Networks should be required to share data rapidly beyond the network in real time, as stated in Recommendation 1).

RECOMMENDATION 4
INFLUENCE

Pre-established networks have been shown to enable immediate data sharing in outbreaks and PHEs. Improving these to ensure they include the relevant cross-sectoral relationships (both academic and public health) and establishing them to develop protocols and undertake capacity strengthening prior to outbreaks could be the most efficient way to develop the trust required to enable rapid data sharing. Such networks also need to be held to the requirements in Recommendation 1 of ‘real-time’ data sharing to ensure that the greatest health benefits are gained. National funders and some of the less agile funders may find long term funding of such networks an effective way of having established funding relationships in place in advance of an outbreak.

3b. Facilitate coordination between established research networks.

Funding to support research networks to collaborate to enable cross-fertilisation within countries and across countries.

GloPID-R funders already support a range of established research networks. Providing funding to support their coordination and collaboration could expand networks of ‘trusted collaborators’ and facilitate the development of common tools.

4a. Collaborate within GloPID-R to align with and influence other stakeholders: national funders, Ministries of Health, Ministries of Science & Technology, commercial companies, publishers, university hierarchy, policy makers (especially WHO) & humanitarian sector.

Beyond their own individual and collaborative direct actions, the GloPID-R funders need to work as a group to further align with external stakeholders especially national and regional bodies in the affected areas which need to take the lead on research prioritisation and data sharing in PHEs in their locations. GloPID-R needs to align with its partner WHO and encourage further global consensus in this field. WHO should be expected to take leadership in promoting openness and data sharing during outbreaks amongst responders and national authorities. GloPID-R also needs to influence commercial companies, publishers, policy makers and the humanitarian sector.
4b. Communicate the Public Health benefits of data sharing. Continue to publish and advocate on the benefits.

GloPID-R should continue to communicate the public health benefits of data sharing through continued profiling and publishing on this to influence a range of stakeholders, including researchers, political leaders and Public Health officials. This roadmap can provide a framework for communicating on GloPID-R’s impact.

**RECOMMENDATION 5**

**STRENGTHEN SYSTEMS**

5a. Support existing and expanded data sharing platforms for priority pathogens with agreed governance mechanisms and data security systems.

Data platforms already exist for certain priority pathogens. GloPID-R funders should promote their use and expansion for further priority pathogens with robust data-governance and equitable data ownership principles that recognise the interests of all stakeholders. Databases for such platforms could be centralised or federated (to ensure equity).

Data platforms can certainly facilitate effective data sharing and greatly improve transparency, however the case studies showed that these were not currently the main routes for data sharing. These platforms are most likely to be successful if developed bottom up by researchers in collaboration with the countries affected by outbreaks, with funding support. Alignment between GloPID-R funders in investment into data sharing platforms would likely accelerate and enhance their development and use as well as certification.

5b. Support an overarching unified governance structure for international data sharing within which existing platforms can be embedded and through which platforms for novel pathogens can be developed.

An overarching unified governance structure with multilateral endorsement should be based on all the GloPID-R principles for data sharing. This could build legitimacy and ultimately build trust. Disease specific platforms (see 5a.) could be nested within it and the overarching structure would facilitate data sharing for new, emerging and re-emerging pathogens of PH interest.

An overarching structure for embedded disease specific platforms would have great benefits but will take time and resource to develop.

This roadmap provides a strategic framework, which can be used for reviewing progress.

GloPID-R funders can measure their collective progress against the priorities and recommendations outlined in this roadmap (different funders contribute to different parts). Individual funders may also choose to use it as a tool for reviewing progress and monitoring their grantees’ activities.

The results from these reviews would provide useful evidence to influence the many further stakeholders highlighted.
The WHO has led on policy in this field with a range of guidance including:

— The Developing Global Norms for Sharing Data and Results During Public Health Emergencies Statement arising from a WHO consultation in 2015 highlights the importance of timely data sharing on clinical, epidemiological and genetic features of emerging diseases as well as information on experimental diagnostics, therapeutics and vaccines. It recognises that epidemiological data belong to the countries where they were generated, but that the default is that this data should be shared. It also recognises that pathogen genetic sequence and associated clinical and epidemiological data are of the greatest value if made as openly available, in as close to real time as possible during a PHE. It also highlighted the role for funders in requiring that expedited timelines for sharing data & interim results in PHEs are a pre-condition for study initiation and continuation. The meeting finally recognised the imperative for capacity strengthening to enable locally led research & structures for data sharing in low- and middle-income countries.

— The Pandemic Influenza Preparedness framework (PIP framework) provides guidance for the sharing of potentially pandemic influenza viruses and associated data.

— WHO’s recent ‘Code of conduct for open and timely sharing of pathogen genetic sequence data during outbreaks of infectious disease’ recognises pathogen sequencing as a priority during outbreaks and seeks to enable rapid sharing of pathogen genetic sequence data in accordance with IHR 2005 through addressing the needs of data providers around the world to enable trust. It sets a timeline for data generation and release not exceeding 21 days and provides a Material Transfer Agreement (MTA) capacity building tool and draft disclaimer text for sharing of data.
There is a pressing need to improve the ways in which the output of scientific research is evaluated by funding agencies, academic institutions, and other parties. To address this issue, a group of editors and publishers of scholarly journals met during the Annual Meeting of The American Society for Cell Biology (ASCB) in San Francisco, CA, on December 16, 2012. The group developed a set of recommendations, referred to as the San Francisco Declaration on Research Assessment. We invite interested parties across all scientific disciplines to indicate their support by adding their names to this Declaration.

The outputs from scientific research are many and varied, including: research articles reporting new knowledge, data, reagents, and software; intellectual property; and highly trained young scientists. Funding agencies, institutions that employ scientists, and scientists themselves, all have a desire, and need, to assess the quality and impact of scientific outputs. It is thus imperative that scientific output is measured accurately and evaluated wisely.

The Journal Impact Factor is frequently used as the primary parameter with which to compare the scientific output of individuals and institutions. The Journal Impact Factor, as calculated by Thomson Reuters*, was originally created as a tool to help librarians identify journals to purchase, not as a measure of the scientific quality of research in an article. With that in mind, it is critical to understand that the Journal Impact Factor has a number of well-documented deficiencies as a tool for research assessment. These limitations include: A) citation distributions within journals are highly skewed [1–3]; B) the properties of the Journal Impact Factor are field-specific: it is a composite of multiple, highly diverse article types, including primary research papers and reviews [1, 4]; C) Journal Impact Factors can be manipulated (or “gamed”) by editorial policy [5]; and D) data used to calculate the Journal Impact Factors are neither transparent nor openly available to the public [4, 6, 7]. Below we make a number of recommendations for improving the way in which the quality of research output is evaluated. Outputs other than research articles will grow in importance in assessing research effectiveness in the future, but the peer-reviewed research paper will remain a central research output that informs research assessment. Our recommendations therefore focus primarily on practices relating to research articles published in peer-reviewed journals but can and should be extended by recognizing additional products, such as datasets, as important research outputs. These recommendations are aimed at funding agencies, academic institutions, journals, organizations that supply metrics, and individual researchers.

A number of themes run through these recommendations:

- the need to eliminate the use of journal-based metrics, such as Journal Impact Factors, in funding, appointment, and promotion considerations;
- the need to assess research on its own merits rather than on the basis of the journal in which the research is published; and
- the need to capitalize on the opportunities provided by online publication (such as relaxing unnecessary limits on the number of words, figures, and references in articles, and exploring new indicators of significance and impact).

We recognize that many funding agencies, institutions, publishers, and researchers are already encouraging improved practices in research assessment. Such steps are beginning to increase the momentum toward more sophisticated and meaningful approaches to research evaluation that can now be built upon and adopted by all of the key constituencies involved.

The signatories of the San Francisco Declaration on Research Assessment support the adoption of the following practices in research assessment.

General Recommendation

1. Do not use journal-based metrics, such as Journal Impact Factors, as a surrogate measure of the quality of individual research articles, to assess an individual scientist’s contributions, or in hiring, promotion, or funding decisions.

For Funding Agencies

2. Be explicit about the criteria used in evaluating the scientific productivity of grant applicants and clearly highlight, especially for early-stage investigators, that the scientific content of a paper is much more important than publication metrics or the identity of the journal in which it was published.

3. For the purposes of research assessment, consider the value and impact of all research outputs (including datasets and software) in addition to research publications, and consider a broad range of impact measures including qualitative indicators of research impact, such as influence on policy and practice.

For Institutions

4. Be explicit about the criteria used to reach hiring, tenure, and promotion decisions, clearly highlighting, especially for early-stage investigators, that the scientific content of a paper is much more important than publication metrics or the identity of the journal in which it was published.

5. For the purposes of research assessment, consider the value and impact of all research outputs (including datasets and software) in addition to research publications, and consider a broad range of impact measures including qualitative indicators of research impact, such as influence on policy and practice.

For Publishers

6. Greatly reduce emphasis on the journal impact factor as a promotional tool, ideally by ceasing to promote the impact factor or by presenting the metric in the context of a variety of journal-based metrics (e.g., 5-year impact factor, EigenFactor [8], Scimago [9], h-index, editorial and publication times, etc.) that provide a richer view of journal performance.
7. Make available a range of article-level metrics to encourage a shift toward assessment based on the scientific content of an article rather than publication metrics of the journal in which it was published.

8. Encourage responsible authorship practices and the provision of information about the specific contributions of each author.

9. Whether a journal is open-access or subscription-based, remove all reuse limitations on reference lists in research articles and make them available under the Creative Commons Public Domain Dedication [10].

10. Remove or reduce the constraints on the number of references in research articles, and, where appropriate, mandate the citation of primary literature in favour of reviews in order to give credit to the group(s) who first reported a finding.

For Organizations that Supply Metrics

11. Be open and transparent by providing data and methods used to calculate all metrics.

12. Provide the data under a licence that allows unrestricted reuse, and provide computational access to data, where possible.

13. Be clear that inappropriate manipulation of metrics will not be tolerated; be explicit about what constitutes inappropriate manipulation and what measures will be taken to combat this.

14. Account for the variation in article types (e.g., reviews versus research articles), and in different subject areas when metrics are used, aggregated, or compared.

For Researchers

15. When involved in committees making decisions about funding, hiring, tenure, or promotion, make assessments based on scientific content rather than publication metrics.

16. Wherever appropriate, cite primary literature in which observations are first reported rather than reviews in order to give credit where credit is due.

17. Use a range of article metrics and indicators on personal/supporting statements, as evidence of the impact of individual published articles and other research outputs [11].

18. Challenge research assessment practices that rely inappropriately on Journal Impact Factors and promote and teach best practice that focuses on the value and influence of specific research outputs.
REFERENCES


2. Case Studies on Data Sharing in Public Health Emergencies (to be published shortly on GloPID-R website)

3. Data sharing in public health emergencies: Learning lessons from past outbreaks. Workshop report (to be published shortly on GloPID-R website)

4. Data sharing in Public Health Emergencies to maximise health benefits- the role for the GloPID-R funders (to be published shortly on GloPID-R website)


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The authors would like to acknowledge all the individuals who contributed through the consultation process for this roadmap.

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The roadmap was developed through the GloPID-R Technical Secretariat. The Secretariat is funded through the European Union’s Horizon 2020 research and innovation programme under grant agreement number 643434.

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