GloPID-R Data Sharing WG: addressing the challenges of data sharing in a public health emergency

Katherine Littler, Wellcome
GloPID-R Zika Virus Research Workshop, 30 November 2016
Data Sharing: Mandating for change

Developing global norms for sharing data and results during public health emergencies

Statement arising from a WHO Consultation held on 1-2 September 2015

Leading international stakeholders from multiple sectors convened at a WHO consultation in September 2015, where they affirmed that timely and transparent pre-publication sharing of data and results during public health emergencies must become the global norm.

The following summary points represent WHO’s position with regard to data and results sharing in public health emergencies, having taken into account the perspectives of those who attended the meeting.

Summary Points
1. Research is essential in the context of public health emergencies. The primary purpose of such research is to advance public health, prevent illness and save lives. Researchers should always weigh the public health consequences of their actions in withholding and sharing results.

Data sharing in public health emergencies

On 10 February 2016, a group of leading global health bodies including academic journals, NGOs, research funders and institutes published a joint statement committing to share data and results relevant to the current Zika crisis and future public health emergencies.

We are committed to build on the momentum generated by this statement and to put these pledges into action. We would like other organisations and groups to join us in this effort.

If your organisation would like to become a signatory to the statement, please email Katherine Lister.

Statement on data sharing in public health emergencies

The arguments for sharing data, and the consequences of not doing so, have been thrown into stark relief by the Ebola and Zika outbreaks.

In the context of a public health emergency of international concern, there is an imperative on all parties to make any information available that might have value in combating the crisis.

We are committed to working in partnership to ensure that the global response to public health emergencies is informed by the best available research evidence and data, as such.

Journal signatories will make all content concerning the Zika virus free to access. Any data or preprint deposited for unrestricted dissemination ahead of submission of any paper will not preempt its publication in these journals.

Funder signatories will require researchers undertaking work relevant to public health emergencies to set in place mechanisms to share quality-assured interim and final data as rapidly and widely as possible, including with public health and research communities and the World Health Organisation.

We urge other organisations to make the same commitments.

This commitment is in line with the consensus statement agreed at a WHO expert consultation on data sharing last year whereby researchers are expected to share data at the earliest opportunity, once they are adequately controlled for release and subject to any safeguards required to protect research participants and patients.

Signatories to the statement
- Academy of Finland
- Academy of Medical Sciences, UK
The GLoPID-R Action Plan

**Aim:** Design a system for data sharing in public health emergencies (PHE) to support the research response

**Key Areas:**
- Define the data we are talking about & ‘public health emergency’
- Map the environment
- Develop policy and a framework for data sharing for PHE
- Focus on implementation of data sharing policy and practice
- Roadmap for collaboration – wider than the community we fund
Examples of key projects

1. Mapping Exercise
2. Decision Tree - ascertaining the data you will need to share, when & with whom
   - Creating an interactive tool to manage real time sharing
   - What key questions need to be addressed at what stage
3. Developing Principles for Data Sharing
4. Case Studies
   - Retrospective – learn from past PHEs
   - Current – learn in real time
   - Prospective – test on potential future PHEs
Mapping the environment: Headlines – data types

**Specific data**
- Surveillance data
- Clinical trials data
- Pathogen genome data
- Case reports
- Summary results

**Metadata**
- Opt-in data sharing agreement
- Informed consent
- Publications
- Post publication peer review
- Conference posters and presentations
- National coordination efforts

**Themes**
- Description
- Risks of sharing
- Benefits of sharing
- Standards
- Stakeholders/Stakeholders’ concerns
- Existing repositories/repository access
Navigation (boxes) –
colour coding to be carried throughout to facilitate linkage

- Surveillance data
- Pathogen genome data
- Summary results

- Clinical trials data
- Case reports
- Metadata data (etc.)
The Decision Tree

**Background**: the need to develop tools to assist with rapid data sharing during a public health emergency. The Decision Tree is to be one of those tools. This tool will be available online so that different users can click on it and benefit from the interaction with regard to highlighting *what data has to be shared between which key groups to ensure rapid data sharing during a PHE*.

- The **aim is**: to develop an online tool to encourage rapid data sharing during a PHE.
- The **objectives are**: to provide an easy to use tool that has in-built flexibility to inform the response to PHE and the changing requirements for data sharing.
- For **unknown and known diseases**
Decision Tree: an ontology

- A way of expressing human knowledge in a machine readable format
- A structured and logical approach to developing a hierarchy of research questions and identifying their accompanying data needs
- Idea is to have public-facing language which is without jargon
- Exploring mechanisms to interface with the decision tree – come in via a question, or an expertise, stage of outbreak etc
Decision tree: what are the key questions per stakeholder?

Process in which we gather these questions
  – Identify stakeholders
  – Common set of questions e.g. what 2 questions had they been answered would help or would have helped your discipline limit the spread and impact of – SARS, MERS, Ebola, H5N1, H1N1

The research questions can be prioritised by the user on the website if they can choose

The ontology of the questions, sub questions and linkages then has to be written

If new to the field can be a guide to utilise your skillset
Decision tree: Do we have all the stakeholders?

- Clinical researchers inc those new to the field e.g. MIT/EBOV
- Sociologists
- Public health responders
- Modellers
- Policy makers
- Industry inc vaccine manufacturers
- Military
- NGOs
- Funders
Decision tree: the future

• Development (12 month timeframe)
• User testing with different stakeholders
• Live management during an epidemic
• Possibly become the research questions around which the data collection tools are made and the database designed to all be part of a data sharing platform
  • Could assist with discoverability
• Other ideas – discussion in breakout group
Developing a framework for responsible data sharing

Key Principles for Data Sharing in a Public Health Emergency

- Timely
- Ethical
- Equitable
- Unencumbered
- Transparent
- Reciprocal
- Quality
Why principles and best practice important in PHE

- Principles have a practical and implementation focus
- Build standards that flow through the data sharing system and be recognised by and adhered to by all stakeholders
- Relationships of trust often key to research, public health response and data sharing, given the nature of a PHE, these might not always be possible to build – as a minimum, we need to aim for ‘confidence’ in our data sharing system
- Issues that we might not reach agreement on (i.e. ownership) but this need not be a barrier to sharing if all parties have confidence in the system, consider it ‘fair’ and support the underpinning principles
Case studies – past

A non-systematic review of outbreaks since 2000, to understand and analyse past data-sharing practice in a range of scenarios and contexts, in order to directly inform our work:

1. Unknown/ emerging pathogen
   – e.g. SARS, MERS-CoV, Nipah Virus

2. Known pathogen
   – e.g Chikungunya, West Nile

3. Known pathogen with licensed intervention
   – e.g. Cholera, Yellow Fever

Other factors for consideration:
within or cross-border, knowledge of pathogen and disease, transmission, availability of interventions, income status of country, type of health system, social/ economic impacts
Case studies – present

Aim: to document and analyse current data-sharing practice around Zika

1. to document challenges, advances and identify good/bad practices
2. to maintain visibility of data sharing in public health emergencies and sustain momentum for reform and innovation
Implementation: Challenges to overcome

1. Incentives & Recognition
   – Develop mechanisms to promote data sharing but not at expense of competitive benefits of science
   – ‘accountability’ - Censure those who misuse data

2. Infrastructure & Tools Development
   – Ascertain repository and discoverability needs
   – Develop norms for repositories & promoting best practice
   – Develop tools to enable pre-publication data sharing

3. Ethical, legal & Governance Issues
   – Regulatory and governance hurdles to sharing
   – Addressing issues of benefit sharing & reciprocity – MTAs & DTAs
   – Safeguarding participants, communities
   – Building trustworthiness, building confidence
Meetings and outreach

1. **International Data Week**, September, Denver, Colorado
2. **Zika Virus Workshop**, September, Wellcome Trust
3. **Zika workshop**, September, NIH
4. **Strengthening Data Sharing for Public Health: Final Strategic Roundtable**, September, Chatham House
5. **Mosquito-borne Viruses: can we build on commonalities to pre-empt the future**, October, WHO (at Wellcome)
6. **Fostering Open Science in Global Health: The Case of Public Health Emergencies**, October, World Health Summit
7. **GOARN Network Meeting**, October, WHO/ Institut Pasteur
8. **Grand Challenges Meeting**, October, Gates/ EC/ WT
9. **IMED**, November, ISID, Vienna
10. **GloPID-R Zika meeting**, November, GloPID-R Sao Paulo
Stakeholders

- WHO
- National governments
- NGOs
- Funders
- Researchers
- Journal publishers
- Pharma/ product developers
- Data scientists
- Regulators
- Ethicists
Further issues to consider

Preparedness is key – data sharing in PHE theoretically should be an extension of regular data sharing – systems, standards, principles need to be in place in advance of a PHE

Acceptable risk may be different in a PHE – are individuals/communities willing to take on greater risk given what is at stake and what impact will this have on sharing (timeliness) practices?

How to make allowance for the blurred line between the public health and research response in our data sharing practices?
What next? We need you!

Breakout groups

1. Decision Tree
2. Implementation Issues
3. Preparedness
4. Principles