

Data sharing and biobanking - Developing Global Norms for Public Health Emergencies

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Mandate and motivation of WHO

- to provide "leadership in matters critical to health", and to shape "the research agenda and stimulate the generation, translation and dissemination of valuable knowledge" in the interest of global public health
- Both of these areas fundamental to success in wider efforts to accelerate R&D and access to interventions for public health emergencies and severe epidemics

Knowledge gaps at the beginning of the EVD epidemic

- Natural history of the illness in humans
- Immunopathology in humans, including aspects of the immune response
- Routes of transmission/acquisition
- Transmission dynamics
- Environmental survival of the pathogen
- Essential interventions for disease control

Background to the data and results sharing consultation

- Positive: clinical trials registries; emergence of data-sharing platforms and repositories; examples of genomic and other data-sharing during this event
- Issues: reluctance of scientists - fear of impediments to publication; concern about recognition or stealing of data; inconclusive studies and "negative" results; proprietary issues
- History and ethics

What kind of data and results?

- Epidemiological/surveillance data
- Genomic data
- Research data – raw and analysed
- Research results – unpublished – with potential to alter practice
- Research results – pre-publication
- Research results – post-completion, not published
- ‘Negative’ and inconclusive results

Special features of a public health emergency

- During an outbreak, rapid sharing of raw and analyzed data and other pertinent findings is essential to designing the appropriate response
- impact of failure to share
- Ethical concerns about early sharing vs not sharing data - protection of privacy and autonomy vs risk to the individual and to public health from not sharing

Roles of sectors

- Publishers and editors of scientific journals
- science funders - private foundations; govt funders
- national policies
- industry

Conclusions – data and results sharing

- Data sharing must be the global norm in public health emergencies
- It is not enough to encourage data sharing. Systems have to be put in place to make the free flow of information as seamless and easy as possible for field staff and researchers
- The right incentives and protections must be identified for each group
- Multiple legitimate interests, but there must be attention to the needs of LMICs
- Immediate impact of knowledge gained and time pressures present different considerations for policies and practices during PHEs

Expectations of key actors/stakeholders

- Field workers
- Investigators
- Governments
- Funders
- Publishers
- Ethical and Regulatory Bodies

Biobanking for EVD– initial thoughts

- For epidemics of severe emerging diseases, biological samples represent a precious and non-renewable resource
- Opportunity to advance knowledge of the disease
- Opportunity to improve disease control tools and interventions
- Opportunity to increase national capacity for research on national disease priorities
- Opportunity to foster international collaborations
- There is a moral imperative to use them prudently to illuminate priority research questions
- Safety and biosecurity must be ensured

Considerations for EVD samples

- Samples already distributed in many countries
 - Own outbreaks/imported samples
 - Restrictions on movement from BSL4 labs
 - Availability of necessary technologies/skills/containment
- Other issues
 - Ownership, access to benefits and outcomes of research
 - Control/involvement in research decisions/initially and subsequently
 - Ethical options when retrospectively obtaining informed consent not possible; models of consent;

Possible ‘realistic’ options

- International collaboration – a distributed “virtual” resource of national biobanks, a common IT system sharing inventories and information, system of governance and decision-making
- One or more regional labs to serve as the repository for W. African samples until more local capacity is developed
- Sub-regional lab capacity is the goal of intensely affected countries – will take time, planning, resources
- Urgent interim measure of secure storage in each affected country until long-term solution is found

Learning from existing models

- Most developed country biobanks collections around rare diseases/cancers
- A few major population biobanks have explored and developed acceptable solutions for key ethical issues
- Several international models already exist in Africa
 - encountered complex challenges:
 - infrastructure, sustainability, international agreements
 - took years to work through - time not available in an outbreak

System needs

- A crisis is the worst time to develop systems to deal with complex issues – systems must be prepared in advance
- Nationally: research management system with appropriate tools
- Internationally: templates for MTAs, MoUs
- Platform(s) for data and knowledge sharing
- Clear agreements for access to benefits
- Connection to national public health/biomedical capacity

Obstacles

- History
- Habit
- Governance
- Continuity of focus
- Funding