Zika Virus: Research Priorities for Preparedness and Response 4

Specimen and data sharing to advance research and development on Zika virus

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For diseases with epidemic potential, specimen and data sharing is crucial for sustained research and development of medical countermeasures such as diagnostics, therapeutics, and vaccines. In the case of Zika virus, although a global framework for specimen and data sharing to advance research and development is highly desirable, challenges related to legal, ethical, and intellectual property issues persist. Since the 2015–16 Zika virus outbreak, regional laboratory networks and research partnerships have made some progress in specimen and data sharing among some Zika virus-endemic countries. Pragmatic steps such as securing funds for augmenting laboratory capacity, building biobanks within public health laboratory infrastructures in low-income and middle-income countries, clearly defining the specimens and data that need to be collected, developing standardised protocols, harmonising data system interoperability to facilitate sharing, and defining mechanisms for benefit sharing will pave the way for timely development and deployment of medical countermeasures in public health emergencies.

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For more on the **Nagoya Protocol**, see https://www.cbd.int/abs/default.shtml

Introduction

Preparedness and response to outbreaks and epidemics of novel or re-emerging pathogens often involve developing new diagnostics, therapeutics, and vaccines. Access to quality specimens and data has long been recognised as crucial for research and development of health products. Developed in 2021, the WHO Zika Virus Research and Development (R&D) Roadmap contains several milestones relevant to overcoming barriers to specimen and data access for developing medical countermeasures, including the need to build a virtual biorepository network.[1] To develop a priority research agenda for Zika virus diagnostics, therapeutics, and vaccines, the Wellcome Trust (London, UK) and Center for Infectious Disease Research and Policy at the University of Minnesota (Minneapolis, MN, USA), together with the University of Texas Medical Branch (Galveston, TX, USA), held a meeting of 130 global leaders in research and development on Zika virus in London, UK, in December, 2023. This Series paper summarises instances of past and current initiatives in specimen and data sharing, reports on discussions at the stakeholders meeting, and proposes concrete steps to advance research and development on Zika virus diagnostics, therapeutics, and vaccines in the future.

Challenges of specimen and data sharing for research and development of health products

Although low-income and middle-income countries (LMICs) have been affected by Zika virus outbreaks more than high-income countries, LMICs have inadequate laboratory capacity for detection, characterisation, and biobanking of specimens.[2] Biobanking facilities require substantial and sustained investment, which is seldom available in LMICs.[3] Clinical and surveillance specimens, specimens collected for research, specimens collected to provide insights into host–pathogen interactions and correlates of protection, and the data associated with these specimens are all useful for research and development of products to counter the virus (table). Although the US Food and Drug Administration has issued a statement allowing the use of residual clinical samples collected as part of routine care that would otherwise be discarded, many valuable, well characterised samples continue to be discarded due to inadequate funding or infrastructure for biobanking.[4]

Specimens collected as part of research studies are often unavailable for sharing due to the stipulations of institutional research boards or research ethics committees, due to volume restrictions, or because the research funding does not cover retention of stored specimens. Even when specimens are available for sharing, material-transfer agreements are often difficult and time consuming to negotiate. Moreover, regulations for specimen import–export are complex and some countries prohibit the export of specimens, whereas others have made exceptions during public health emergencies.

The reluctance of countries to share resources such as pathogen strains, specimens, and their associated data for research and development of health products has its origins in their inability to access the benefits from products that were developed and commercialised with the resources they had contributed and their contribution not being recognised. For instance, during the COVID-19 pandemic, despite global efforts such as the Access to COVID-19 Tools Accelerator, access to vaccines and other countermeasures remained inequitable.[5] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization is seen by many as a barrier to specimen sharing.[6]

During the Zika virus outbreaks of 2015–16, the difficulty in accessing specimens and associated data led to substantial delays in the development of diagnostic tests. Establishment

	Type of specimens	Volume	Accompanying data	Ethical considerations
Routine clinical care (would be otherwise discarded)	Blood or urine	Small	Laboratory test data, ideally accompanied by relevant epidemiological data (including severe or non-severe disease, fatal or non-fatal outcome)	Informed consent usually not required as specimens are collected as part of routine care; specimens can be used for diagnostic evaluation or research if they are de-identified*
Routine surveillance	Dried blood spots, serum, or plasma	Small	Basic epidemiological data (including severe or non-severe disease, fatal or non-fatal outcome)	Specimens usually stored without personal identifiers; specimens can be used for diagnostic research and development
Blood banks	Blood	Large	Screened for blood-borne pathogens	Informed consent required
Research studies†	Blood, urine, oral fluid, amniotic fluid, or cerebral spinal fluid	Can be large and stored as aliquots; serial samples from same individual	As required for the study	Informed consent required from study participants with specification that samples can be used for further research by the study team or other researchers
Purposefully collected specimens for research and development‡	Blood, urine, oral fluid, or exudate	Can be large and stored as aliquots; serial samples from same individual	As required for a specific purpose§	Informed consent required, and consent required for storage over a specific time period

*Statement from the US Food and Drug Administration on the use of leftover specimens.[4] †Eg, biomarker studies or drug and vaccine trials. ‡Including pharmacovigilance or vigilance for vaccines. §Eg, to understand the immunological response to infection or correlates of protection.

Table: **Types of specimen collections and the corresponding ethical considerations**

of efficient access to specimens and data before the outbreak would have most likely ensured better clinical management and public health response.

Examples of initiatives for sharing of specimens and related data

Despite the challenges, various global and regional initiatives have led to successful implementation of mechanisms for specimen and data sharing to accelerate research and development. Although only some of these initiatives include arboviruses, studying these initiatives, identifying the drivers of their success, and highlighting the lessons learnt is nevertheless important as the global community seeks to be better prepared for the next Zika virus epidemic.

For more on the **PIP Framework**, see https://www.who.int/initiatives/pandemic-influenza-preparedness-framework

Global initiatives

Global Influenza Surveillance and Response System (GISRS)

The first example is a global initiative, GISRS, which was established in 1952 as a global alert mechanism for influenza viruses with pandemic potential through a network of 21 collaborating laboratories in 25 countries.[7] As of 2024, 149 laboratories in 127 countries, areas, and territories detect, report, and share data on influenza and other respiratory viruses in circulation. Through this network, countries also share clinical specimens and virus samples for genetic analysis, which allows GISRS to not only track the circulation patterns of extant influenza and other respiratory viruses and identify new and emerging ones, but also offer advice on seasonal influenza virus vaccine compositions. GISRS proved to be a crucial global resource during the outbreaks of severe acute respiratory syndrome and Middle East respiratory syndrome (MERS) and the COVID-19 pandemic, as many GISRS laboratories had the technical competency and resources to undertake testing for respiratory viruses other than influenza viruses. WHO regards sharing of specimens and data on influenza virus as "an essential cornerstone of preparing the world against pandemics".[7]

The governance for GISRS-mediated specimen and data sharing has evolved over time. At the 2011 World Health Assembly, WHO member states adopted a resolution on the Pandemic Influenza Preparedness (PIP) Framework as a global and unified approach for pandemic preparedness and response.[8] Under the PIP Framework, sharing of biological materials within the GISRS network of laboratories is governed by a standard material-transfer agreement that establishes the rights and obligations of GISRS laboratories with respect to transferring and handling of biological materials, intellectual property rights, and dispute resolution.

Through the PIP Framework, WHO brings together industry and other stakeholders and member states to contribute resources for shipping and sharing of influenza viruses with potential to cause a human pandemic through the GISRS network. As a recognition for sharing, LMICs benefit from having their laboratory capacity strengthened and are assured of access to antivirals, vaccines, and other pandemic-related supplies.

For more on **CEPI**, see https://cepi.net/

Coalition for Epidemic Preparedness Innovations (CEPI)

Another global initiative, CEPI, was established in 2017 with a focus on accelerating the development of vaccines and biologics against high-priority viral pathogens. Since its inception, CEPI has supported vaccine

development and testing against Ebola, Lassa, Nipah, MERS, chikungunya, Rift Valley fever, SARS-CoV-2, and monkeypox viruses. CEPI also funds crucial research, clinical trials, and regulatory activities that enable accelerated vaccine development. One of these enablers is the development of antibody standards and reference assays to study the vaccine-induced immune response against vaccine candidates. For most of the priority pathogens, CEPI has developed WHO international standards that are available to any developer through the National Institute for Biological Standards and Control, now part of the UK Medicines and Healthcare products Regulatory Agency.

International standards are preferably developed from specimens obtained from convalescent individuals with a target disease or pathogen, as opposed to animal-modelled sources.[9] CEPI's approach to sample sourcing is not just to bank them for global access but also to have the samples processed and well characterised for use as control reagents in both immunoassay and vaccine-manufacturing pipelines. Sourcing of biospecimens and their characterisation for vaccine and assay development can take 1–4 years.

To further accelerate vaccine development and prepare for a new pathogen (disease X), CEPI aspires, in its 100 Days Mission, to have a vaccine available within 100 days of emergence of disease X.[10] CEPI has been working with partners globally to establish biospecimen-sourcing mechanisms and a pipeline to streamline these activities before a new outbreak. CEPI's non-negotiable policy of equitable access for global use with partners has generally been well received.

European Virus Archive-GLOBAL (EVAg)

The European Virus Archive (EVA) was established in 2008, with funding under the FP7–EU Infrastructure programme, in direct response to the need for a collection of viruses that could be readily accessed by academia, public health organisations, and industry within Europe.[6,11] EVA is now global (EVAg), with a network of 43 laboratories, including 17 non-EU partners. During the COVID-19 pandemic, EVAg provided 73% of its materials to non-EU countries, 53% of which were to LMICs.[12]

EVAg materials now include cell lines for virus isolation from clinical samples, molecular detection assays, antibodies, proteins, external quality assessment panels, RNA, and other standards for deployment in epidemics. Materials, available through a web catalogue, are free to academic institutions for research. For commercial use of EVAg materials, a separate licensing agreement has been established with access and benefit sharing for countries providing materials.

EVAg has established a repository of diagnostic, therapeutic, and research tools for arboviruses, but the recipients need to have appropriate expertise and containment facilities to process the viruses or to use reagents. EVAg has cooperative agreements with the European Centre for Disease Prevention and Control, WHO, and World Organisation for Animal Health. EVAg is currently working on three core areas. First, it is developing networks for biological specimens, collaborations on harmonised protocols such as the International Severe Acute Respiratory and emerging Infection Consortium (ISARIC) Zika Virus Case Report Forms, communication strategies, and data-sharing tools and methodologies. Second, EVAg is coordinating past and current clinical studies, such as the Partnerships for Rural Europe network and ZIKAlliance, to unify resources for a multidisciplinary network of networks for arbovirus research, and the European Clinical Research Alliance on Infectious Diseases, to build a pan-European, multidisciplinary, centralised base sharing resources, data, and expertise. Finally, EVAg aims to coordinate clinical studies on infectious diseases, strategy development, stakeholder management, and service and network development.

For **ISARIC**, see https://isaric.org/

For more on **ISARIC Zika Virus Case Report Forms**, see https://zikainfection.tghn.org/research-tools-and-resources/crfs/

For the **Partnerships for Rural Europe network**, see https://prepare-network.eu/

For more on **ZIKAlliance**, see https://zikalliance.tghn.org

For more on **European Clinical Research Alliance on Infectious Diseases**, see https://www.ecraid.eu/

Regional initiatives

The Arbovirus Diagnosis Laboratory Network of the Americas (RELDA)

RELDA was originally established in 2008 as the Dengue Laboratory Network of the Americas, but expanded in 2016 to become the Arbovirus Diagnostic Laboratory Network, including 40 laboratories in 35 countries and territories.[13] RELDA, with the Pan American Health Organization (PAHO) as its Technical Secretariat, has supported the strengthening of national and local laboratory networks and capabilities for timely detection of dengue virus and other arboviruses using molecular technologies; evaluation of commercial assays for molecular, serological, and antigen diagnosis; development of diagnostic protocols and algorithms; exchange of reagents among laboratories; and training in genomic sequencing, biosafety, and quality management systems. RELDA is working intensively to strengthen genomic surveillance in the region for dengue virus, Zika virus, and chikungunya virus, and participates in the establishment and expansion of entomovirological surveillance.

Although data sharing within RELDA is well established, specimen sharing has been a challenge because exporting specimens out of some countries is difficult. As a result, PAHO has repositories of the willing, whereby, in exchange for sample sharing, countries receive resources such as kits for validation. At its 2023 meeting, RELDA updated diagnostic algorithms for arboviruses and developed agreements between collaborating centres and national reference laboratories for producing and distributing in-house reagents.

European Commission initiatives

The three European Commission-funded projects, ZIKAlliance, ZikaPLAN, and ZikAction, shared a common overarching work package on data sharing and harmonisation. The lessons learnt from the collaborative work led to the European Commission-funded Reconciliation of Cohort Data for Infectious Diseases (ReCoDID) project. With support from ReCoDID and its successor project, the Cohort Network To Be Activated In Outbreaks (CONTAGIO), a virtual biorepository system was built as

For more on **ZikaPLAN**, see https://zikaplan.tghn.org

For more on **ZikAction**, see https://zikaction.org

For more on **RecoDID**, see https://recodid.eu/

For more on **CONTAGIO**, see www.contagio.network

a trusted, globally representative source of specimens and associated data needed for calibration of serological diagnostics, research, and surveillance.[14] The virtual biorepository system aims to establish a sustainable, equitable system for specimen sharing for infectious diseases of epidemic potential, starting with ten sites and expanding. The virtual biorepository system will allow for ownership of specimens to remain with the institution where they were collected, while ensuring common standards of quality and accessibility.

Africa Centres for Disease Control And Prevention (CDC) biobanking network

Africa CDC established a biobanking network as a sustainable mechanism to accelerate the development and evaluation of diagnostic tests in Africa.[15] The biobanking network consists of 12 centres of excellence covering all five regions of Africa.[16] To operationalise the biobanking network and harmonise operations, working documents are under development, covering: ethics and governance; biosecurity and biosafety; biospecimen collection, processing, storage, and sharing; quality assurance; and data management. Africa CDC will provide technical support to harmonise the process of collection, processing, and archiving of specimens for its priority diseases with epidemic potential.[17] The Africa biobanking network will also leverage ongoing efforts of the Africa CDC Genomics Programme to strengthen cross-border collaboration and specimen sharing, which were successfully implemented during the COVID-19 pandemic.

The Biobanking Information Management of the network will be integrated into the wider Laboratory Network Information Management System of Africa CDC to enable specimen selection for diagnostic evaluations through a dashboard.

Specimen sharing in Asia

Institutions such as the Mahidol University (Bangkok, Thailand), Institut Pasteur du Laos (Vientiane, Laos), and Institut Pasteur du Cambodge (Phnom Penh, Cambodia) have archived samples from arbovirus surveillance or research studies. In Singapore, arboviruses isolates, residual arbovirus diagnostic surveillance samples, and well characterised serial samples of dengue virus are archived at the Environmental Health Institute, whereas those of Zika virus are archived at the National Centre for Infectious Disease. These samples have been used to evaluate commercial diagnostics kits, with the results widely disseminated and virus isolates shared.[18–21]

For the **World Reference Center for Emerging Viruses and Arboviruses**, see https://www.utmb.edu/wrceva

For more on **TDR**, see https://tdr.who.int/about-us

Special initiatives for specimen sharing for diagnostic evaluation

The UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) has set up a series of biobank networks to accelerate development and evaluation of diagnostics for neglected tropical diseases, recognising that access to well characterised specimens is a major barrier to these processes.[15,22] Mechanisms for sharing of specimens and their associated data were based on the guiding principles of transparency, equitable access, ethics, and respect for national laws that support country ownership and sustainability, with standardised methods for collection, characterisation, and archiving of specimens.[15] Adapting the Nagoya Protocol, sharing of specimens from national biobanks can be rewarded through mechanisms such as equitable access to diagnostics at negotiated prices.

When the Zika virus outbreaks began in 2015, the London School of Hygiene & Tropical Medicine (London, UK) was funded by the European Commission to develop a network of sites for specimen collection and evaluation under ZikaPLAN.[23] The ZikaPLAN diagnostic work package members adopted the TDR biobanking guiding principles, governance, and quality criteria for selection of biobanking sites and included some sites from the TDR dengue network.[24] To ensure the sustainability of the specimen and data-sharing network, companies that submitted tests for evaluation were asked to reimburse the sites for the cost of the evaluation and for replacement of the specimens used for the evaluation. In return, the companies were given an opportunity to review the data before publication and to use the data for obtaining regulatory approval. To overcome the challenges of specimen export and shipping, tests under evaluation were sent to the biobanking sites where they were evaluated using a common protocol. This mechanism was successfully used for evaluating Zika virus rapid tests to inform UNICEF procurement and became the sustainable model that Africa CDC adopted to set up their biobanking network.[15,25]

National initiatives for Zika virus specimen and panel sharing

During the 2015–16 Zika virus outbreaks, agencies of the US Department of Health and Human Services formed a partnership to create the Health and Human Services Zika specimen repository. The Biomedical Advanced Research and Development Authority and the US CDC collected convalescent serum samples and plasma aliquots from donors, confirmed Zika virus test results, and assembled molecular and serological panels for distribution to test developers from both the public and private sectors.[26–28] Informal specimen sharing also facilitated test evaluations and approval of tests for emergency use authorisations; for example, samples from the Zika cohort in Nicaragua were shared with over ten collaborators, which led to more than 20 publications and facilitated at least two emergency use authorisation approvals.[29–37] The US National Institutes of Health connected interested parties with Zika cohort study sites. National Institutes of Health funded the World Reference Center for Emerging Viruses and Arboviruses at the University of Texas Medical Branch, which sent antibodies and viruses all over the world and provided reagents for development of Zika virus diagnostics in 2015–16.

National blood banks can also be a source of Zika virus specimens. Blood banks that are engaged in arboviral

research have access to larger volumes of blood collected from viraemic donors. Some of the blood banks are set up for follow-up of donors, to define viral and immune dynamics or kinetics.[38]

Lessons learnt from specimen-sharing initiatives

Two important lessons can be learnt from these initiatives. First, specimen sharing is currently occurring only through repositories of the willing. Developing more advocacy and incentives for Zika virus specimen sharing, such as those for the influenza network, is an urgent need. Second, trust is at the basis of willingness to share and these relationships cannot be built during public health emergencies. Hence, the development of partnerships, standardised procedures, and agreements on the sharing of resources need to be negotiated ahead of outbreaks, to optimise each partner's contribution and build synergies for a coordinated response.

Examples of data-sharing initiatives

Global Initiative on Sharing All Influenza Data (GISAID)

The GISAID platform was launched at the 2008 World Health Assembly as a publicly accessible database designed by scientists for scientists, initially for sharing of data on influenza among WHO collaborating centres and national influenza centres for the biannual influenza virus vaccine recommendations by GISRS. During the COVID-19 pandemic, approximately 15 million SARS-CoV-2 genome sequences were shared through this platform.[39] GISAID launched the GISAID EpiArbo for sharing arbovirus genome sequences in 2023.

GenBank

GenBank is a public database of genome and protein sequences with supporting bibliographic and biological annotation that was developed by the National Center for Biotechnology Information, a division of the US National Library of Medicine. In 1986, the genome sequence from a yellow fever virus became the first arboviral sequence shared in GenBank,[40] which now hosts more than 20 000 arboviral genome sequences. Knowledge of genome sequences is crucial not only for the development of diagnostics, therapeutics, and vaccines, but also for tracking the epidemiology and evolution of pathogens. The open-access policy of GenBank and a requirement by most scientific journals that genome and protein sequences cited in scientific papers be submitted to a public sequence repository such as GenBank before publication have greatly contributed to the sharing of genomic sequencing data globally.

European Commission-funded initiatives

As previously mentioned, the ReCoDID project was established from the European Commission-funded Zika research consortia during the 2015–16 Zika virus epidemic. The overarching aim of ReCoDID was to create a data-sharing infrastructure comprising both clinical and epidemiological data from infectious disease cohorts, in addition to high-dimensional data from sequencing and other advanced laboratory analysis of biological material.[41] The COVID-19 data portal, established with funding from ReCoDID and other sources, has now been expanded into a pathogens portal, which includes Zika virus and dengue virus. The ReCoDID project has developed and published a large body of methodological literature for pooled cohort analysis, data sharing and harmonisation, and governance of data.[42,43] The legacy is now continued in the European Commission-funded consortium CONTAGIO project.

For the **pathogens portal**, see https://www.pathogensportal.org

Parallel to this process, the WHO Zika virus Individual Participant Data Meta-Analysis Initiative was set up in 2016 to facilitate data sharing among Zika virus projects globally, including cohorts.[44,45]

The Africa CDC genomics programme

Africa CDC, in collaboration with partners, launched the Africa Pathogen Genomics Initiative during the COVID-19 pandemic.[46] With the Africa Pathogen Genomics Initiative, the capacity for genomic sequencing has expanded more than five-fold to include 40 countries in the continent.[47] This momentum, which was built during the COVID-19 pandemic, needs to be maintained and expanded to cover other epidemic-prone diseases of priority in Africa, through strengthening of national public health institutions in the continent. Despite the successes, notable barriers to generation of genomic sequencing data exist in Africa, which are related to data governance, data infrastructure, workforce development, bioinformatic solutions, internet bandwidth, and data quality, standardisation, and sharing.[48] To overcome these barriers, Africa CDC is leading the implementation of key initiatives such as the African Pathogen Data Sharing and Archive Platform, increasing access to cloud-based solutions and promoting data standardisation, sharing, and publication.

For more on **GISAID**, see https://gisaid.org/

For more on **GenBank**, see https://www.ncbi.nlm.nih.gov/genbank/

Data-sharing initiatives in Asia

UNited In Tackling Epidemic Dengue (UNITEDengue) was formed by some members of the Association of Southeast Asian Nations in 2012, with focus on surveillance and cross-border sharing of epidemiological and genomic data on dengue virus, to assist dengue programmes in risk assessment and capacity building on diagnostics, phylogeny analysis, and surveillance.[49–51] Supported by various entities such as the Asia-Pacific Economic Cooperation, Singapore Cooperation Programme, and respective state governments, the network shared data through a website, conducted training programmes, and came together in 2016 (when the Zika virus threat was imminent) to exchange laboratory protocols and experiences. Efforts to strengthen the network is ongoing, including extension to wastewater surveillance for Zika virus.

For more on **UNITEDengue**, see https://unitedengue.org

Data sharing during outbreaks

During the Ebola virus, yellow fever virus, and Zika virus outbreaks, genomic data and sequencing protocols were

shared in real time.[52–54] The Zika in Brazil Real Time Analysis project—which involved the Brazilian Ministry of Health, PAHO, and other research institutions—led to the generation of 750 Zika virus genomes from Brazil, with the hope that this effort will serve as a beacon for open science during a public health emergency.[55]

Throughout the COVID-19 pandemic, sharing research data was facilitated by an important decision of scientific journal editors to make COVID-19 papers and preprints open access. Dashboards were created to display real-time global data on the number of cases and deaths.[56] Such dashboards and transparency build public trust, which is important in encouraging the public to contribute to the prevention and control of epidemics.

Lessons learnt from data-sharing initiatives

Genomic data has been shared for four decades, initially to gain a deeper understanding of the genomic diversity of microorganisms and their epidemiology, but increasingly, as a crucial step to counter the rapid evolution of pathogens observed during epidemics due to selective pressure imposed by population immunity, therapeutics, or vaccines.[57] However, the sharing of data pertaining to the omicron variant of SARS-CoV-2 by South Africa led to border closures with serious effects on its economy. These negative repercussions can threaten future willingness of countries to share data.[58]

Building on past success to advance research and development on Zika virus

For more on the **Global Arbovirus Initiative**, see https://www.who.int/initiatives/global-arbovirus-initiative

In March, 2022, WHO launched the Global Arbovirus Initiative with six pillars of work: monitor risk and anticipate; reduce local epidemic risk; strengthen vector control; prevent and prepare for pandemics; enhance innovation and new approaches; and build a coalition of partners. Specimen and data sharing underlie the first five pillars. For Zika virus, regional networks can provide the foundation for the Global Arbovirus Initiative's coalition of partners. Although a global framework for fair and equitable access to specimen, data, and benefit sharing for Zika virus is complex and will take time to be negotiated, as long as nations have the political will for sharing, concrete steps can be taken to move forward and leverage the success of global and regional initiatives to advance research and development on Zika virus.

Public health laboratory networks coordinated by a regional organisation such as RELDA, the Association of Southeast Asian Nations, or Africa CDC, show great promise as biobanking networks in terms of willingness to share specimens and data, adopt standardised protocols and quality standards, and achieve consistent funding, which is crucial for sustainability.

Compared with global networks, regional agreements are easier to establish for setting priorities and for standardising protocols for specimen and data collection, which enable comparisons or aggregation of results to assess trends. Regional networks have similar emerging infectious disease threats and research needs, and their alliances are already well established.

For sharing of research specimens and relevant clinical data, long-standing north–south and south–south research partnerships established between academic institutions, such as the Mahidol Oxford Tropical Medicine Research Unit (Bangkok, Thailand) in Thailand, the Oxford University Clinical Research Unit in Viet Nam, and the Duke–National University of Singapore, have been highly successful in their work on dengue pathogenesis, diagnostic evaluations, and vaccine trials. The US CDC also has long-standing country partnerships with the Kenya Medical Research Institute (Nairobi, Kenya) and the Uganda Virus Research Institute (Kampala, Uganda) on arbovirus research. An integrated arbovirus approach, wherever possible, would make research on Zika virus more sustainable.

Long-standing partnerships within countries also offer great promise, examples of which include the partnership of Institut Pasteur Dakar (Dakar, Senegal) with the Senegalese Ministry of Health to conduct surveillance and research on pathogens with epidemic potential, including dengue virus, chikungunya virus, and Zika virus. Institut Pasteur du Laos and Institut Pasteur du Cambodge have been collaborating with the respective Ministries of Health on arbovirus surveillance and research.

These regional networks and partnerships form a solid foundation for accelerating research and development of Zika virus diagnostics, vaccines, and therapeutics. At the moment, collaborations are restricted to countries that are willing and have the resources to participate, leaving blind spots in which Zika virus epidemiology and genetic diversity remain unknown, preventing researchers from gaining a more comprehensive understanding of Zika virus pathogenesis, epidemiology, and outcomes.

Long-term sustainability through stable funding, strong governance in terms of ethics and regulatory oversight, trust in the quality of the specimens and data, and equitable access to benefit sharing are the key drivers of successful specimen-sharing and data-sharing initiatives.[59–63] To advance research and development on Zika virus, substantial progress needs to be made on the priorities listed in the following paragraphs.

First, sustainable funding to support laboratory networks and biobanks is crucial to the advancement of research and development on Zika virus. Learning from the example of specimen and data sharing to advance the research and development of influenza virus diagnostics and vaccines, a strategy is needed to create a pool of research and development funding from public and private sectors that can be used to build laboratory capacity for the diagnosis and surveillance of Zika virus and other arboviruses, embed biobanks in public health laboratories in LMICs, and generate standardised protocols for accessing specimens and data from existing biobanks.[64] The goal is to have a win-win scenario in which more countries benefit from improved capacity for Zika virus diagnosis, and in addition, surveillance for Zika virus becomes more comprehensive globally. The

Search strategy and selection criteria

We searched three online databases (PubMed, Cochrane Library, and Google Scholar) to identify peer-reviewed articles published in English between Jan 1, 2003, and June 30, 2024, using the terms "Zika specimen and data sharing", "specimen and data sharing", "specimen sharing", and "Zika virus research and development". We also searched the WHO, European Virus Archive, and Pan American Health Organization websites for global and regional frameworks and programmes for specimen and data sharing. Although a large body of literature exists on legal, ethical, and other issues related to biobanking, the selection of articles was restricted to concrete examples of specimen and data sharing for Zika virus or other infectious disease pathogens with epidemic potential, to facilitate and accelerate research and development of countermeasures such as diagnostics, therapeutics, and vaccines that have been implemented since 2003.

pool of funding can be organised through existing entities, such as the Global Dengue & *Aedes*-Transmitted Diseases Consortium.

Second, defining the types of specimens and relevant data needed for each purpose is important to ensure that biobanks provide their best support for research and development on Zika virus. This list of crucial samples can be made available on a dashboard with quality indicators and volumes. In addition, a registry of research studies with available specimens and data should be initiated. Funding agencies should require researchers to plan for specimen storage and sharing.

Third, if specimens and data are to be trusted as a resource for research and development on Zika virus, quality standards in the collection, characterisation, and storage of specimens need to be assured. In addition, software for data collection and management needs to be harmonised or made interoperable. Use of open-access software, such as REDcap, is preferred to enable participation of as many countries as possible.

Finally, fair and equitable access to benefits is at the heart of a country's willingness to participate in specimen and data sharing. Bilateral agreements for benefit sharing could lead to unfair practices and comparisons that endanger the attainment of a broader framework for sharing. The evolution of the PIP Framework under which 20 000 specimens are shared annually within the GISRS is an example of what is possible. Both EVAg and GISRS have templates for benefit sharing governing private sector access to specimens and data.

Conclusions

A solid foundation of specimen and data sharing to advance research and development on Zika virus has been laid since 2004, mostly involving regional laboratory networks, academic research, and country partnerships. To move forward, continual engagement of all Zika virus-endemic countries in specimen and data sharing is important to ensure early alerts of outbreaks and to improve the understanding of Zika virus pathogenesis so that effective medical countermeasures can be developed and deployed. Priorities for moving forward include securing sustainable funding to strengthen laboratory capacity for the diagnosis and surveillance of Zika virus and other arboviruses and country partnerships. After the COVID-19 pandemic, as countries rebuild their health-care systems with enhanced diagnostic and surveillance capacity, now is a good time to advocate for investments to build biobanks in public health laboratories, especially in LMICs. Defining the type of specimens and data that should be collected and ensuring specimen and data quality by developing standardised protocols for collection, characterisation, and archiving is also important. Harmonisation of data acquisition and management across sites will ensure interoperability and facilitate data sharing. Finally, negotiations on fair and equitable benefit sharing such as negotiated pricing for diagnostic kits and access to therapeutics and vaccines need to continue with the participation of industry and all Zika virus-endemic countries. Increased public and private investment in biobanking will accelerate discoveries essential for enhanced outbreak preparedness and response.

For the **Global Dengue & *Aedes*-Transmitted Diseases Consortium** see https://gdac-dengue.org/

Zika Expert Workgroup
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RWP was the lead author for all aspects of this manuscript, including the conceptualisation of the scope of the work, development of the outline, literature reviews, writing of the initial manuscript draft, and editing and updating of all subsequent drafts. EML contributed to the conceptualisation, project coordination, discussion of content, and reviewing of manuscript drafts. NTF, MSA, MGG, JAM-R, and TJ contributed sections relevant to their organisations, participated in discussions of content, and critically reviewed the manuscript drafts. Members of the Zika Expert Workgroup critically reviewed the content and edited drafts of the manuscript.

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