

# ZIKA VIRUS RESEARCH AGENDA

OCTOBER 2016

WHO/ZIKV/PHR/16.1

© World Health Organization 2016

All rights reserved. Publications of the World Health Organization are available on the WHO website ([www.who.int](http://www.who.int)) or can be purchased from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: [bookorders@who.int](mailto:bookorders@who.int)).

Requests for permission to reproduce or translate WHO publications –whether for sale or for non-commercial distribution– should be addressed to WHO Press through the WHO website ([www.who.int/about/licensing/copyright\\_form/en/index.html](http://www.who.int/about/licensing/copyright_form/en/index.html)). The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

# CONTENTS

<b>THE WHO ZIKA VIRUS RESEARCH AGENDA .....</b>	<b>1</b>
Background.....	1
Goals.....	1
<b>NEEDS ANALYSIS .....</b>	<b>2</b>
Research gaps.....	2
Coordination and management.....	3
Implementation Framework .....	4
<b>RESEARCH AGENDA.....</b>	<b>6</b>
1. Characterization .....	6
2. Prevention and control.....	7
3. Women, communities and Health Systems .....	8
4. Coordination and management .....	8
5. Research support activities.....	9
<b>IMPLEMENTATION .....</b>	<b>10</b>
Budget.....	10
Timeframe.....	10
Next steps – Translating knowledge into action.....	10
Contacts.....	10
<b>ANNEXES</b>	
Annex 1: Development of regional research priorities.....	11
Annex 2: Global consultative meetings .....	15

# THE WHO ZIKA VIRUS RESEARCH AGENDA

## BACKGROUND

Zika virus is a growing concern – it is endemic in parts of Africa, has been reported in South East Asia and is becoming established in the Americas and Caribbean. Since its detection in Brazil in 2015, it has emerged as a major public health challenge in the Americas. As of 16 June 2016<sup>1</sup>, 60 countries and territories report continuing mosquito-borne transmission of which:

- 46 countries are experiencing a first outbreak of Zika virus since 2015, with no previous evidence of circulation, and with ongoing transmission by mosquitos.
- 14 countries have reported evidence of Zika virus transmission between 2007 and 2014, with ongoing transmission.

While the virus is known to cause mild illness (characterized by conjunctivitis, fever, rash and joint pain) many of the countries affected by Zika virus are also reporting potential neurological and auto-immune complications related to Zika virus infection with increased reports of Guillain-Barré syndrome, and birth defects including microcephaly.

In December 2015 the WHO's *R&D Blueprint for Action to Prevent Epidemics*<sup>2</sup> classified Zika virus-related neurological diseases as "serious" on its list of disease priorities needing urgent R&D attention.

The wide geographical range of the mosquito vector of the virus and the emerging complications of infection call for a global response. Based on the advice of the Emergency Committee of the World Health Organization (WHO), the WHO Director-General declared the clusters of microcephaly cases and the other neurological disorders in endemic areas as constituting a public health emergency of international concern on 1 February 2016.

Further to this declaration, WHO activated an emergency Incident Management System to coordinate the international response. This has included the development of a global *Zika Strategic Response Plan*<sup>3</sup> encompassing surveillance, response activities and emphasising the urgent need for research to better characterize Zika virus infection to respond to this public health emergency.

## GOALS

The goal of the WHO *Zika Virus Research Agenda* is to support the generation of evidence needed to strengthen essential public health guidance and actions to prevent and limit the impact of Zika virus and its complications.

The Research Agenda identifies critical areas of research where WHO is uniquely placed to implement or coordinate global activities. Research and evidence are the foundation for sound health policies. WHO is recognized for its access to decision-makers, public health experts, scientists and data, and for its ability to coordinate actors at national, regional and global levels. As the United Nations' specialized agency for health, WHO plays a pivotal role in leveraging its ability to convene experts and partners at the highest level to collaboratively address global health challenges. The WHO *R&D Blueprint* is an action plan to accelerate research and development for emerging pathogens likely to cause severe outbreaks in the near future, and for which few or no medical countermeasures exist.

The *Zika Virus Research Agenda* also acknowledges that management and support are needed to enable scientific research. The Research Agenda

<sup>1</sup> Situation Report: Zika virus Microcephaly Guillain-Barré Syndrome. Geneva: World Health Organization; 16 June 2016. Available at <http://apps.who.int/iris/bitstream/10665/242439/1/zikasitrep-16Jun2016-eng.pdf>.

<sup>2</sup> About R&D Blueprint (webpage). Geneva: World Health Organization. Available at <http://www.who.int/csr/research-and-development/blueprint/en/>

<sup>3</sup> Zika Strategic Response Plan: revised for July 2016 - December 2017. Geneva: World Health Organization; 2016. Available at <http://apps.who.int/iris/bitstream/10665/246091/1/WHO-ZIKV-SRF-16.3-eng.pdf>.

---

outlines support activities and functions that will be required to ensure research coordination, management, capacity building and quality assurance. The Research Agenda is also intended to serve as a catalyst to align and mobilize partners to address core scientific questions about Zika virus. In doing so, it will strengthen relationships between healthcare professionals, researchers, response partners, donors and other stakeholders to advance our understanding of Zika virus and our response to the threats that it poses.

---

## NEEDS ANALYSIS

---

### RESEARCH GAPS

Gaps in research related to Zika virus were identified by a process initiated from the WHO Region of the Americas – the region at the centre of the current crisis. At regional level, this process identified priority research and development needs in:

- characterizing Zika virus infection including investigating public health and clinical implications;
- describing the dynamics of arbovirus epidemics in the Americas region and characterizing arbovirus vectors; and
- developing and enhancing laboratory platforms to support surveillance
- piloting new vector control tools

This process was complemented by consultative meetings convened by WHO at global level to expand on the identified areas. Meetings were convened to discuss research and product development (as part of the WHO *R&D Blueprint* process), vector control and the management of complications associated with Zika virus infection. These highlighted additional global research needs including:

- developing diagnostic products and increasing access to common standards, methods and reference materials to facilitate development;
- developing a vaccine, with a focus on protecting women of child-bearing age, pregnant women and their babies;
- developing effective therapeutics for both Zika virus and complications;
- holding cohort studies of pregnant women (infected and not infected with Zika virus) to better understand the outcomes of Zika virus infection on pregnancy;
- developing a causality framework to evaluate the association between Zika virus and neurological disorders; and
- understanding the natural history of Zika virus infection and identifying risk factors for severe complications.

Most importantly, the research needs to address Zika virus have been focused by the unfolding human cost of the epidemic. At the fore are the stories of families of infants born with microcephaly and other congenital syndromes, whose conditions are now being linked to maternal infection with Zika virus during pregnancy. Many of these infants will develop learning and motor disabilities as they grow older, and will require life-long care and social support. As of June 2016, the overwhelming majority of these infants have been born in Brazil where a Zika virus outbreak began in late 2015. However more cases are projected from other countries that have experienced outbreaks of Zika virus in 2016 as women who were infected in these areas during their pregnancies come to full term.

*See Annex 1 for further details of the WHO Region for the Americas Zika virus research prioritisation process.*

---

---

*See Annex 2 for further details of the WHO global consultative meetings.*

---

In addition to identifying priority research gaps, a need was also identified to align the activities of partners at all levels in order to implement effective and coordinated international research, and to provide supportive functions to enable robust research to take place.

Coordination and management support will be critical to address the research priorities identified and to harmonise the efforts of partners across countries, regions and institutions. Key actors will need to collaborate on scientific research projects and will also need to work with responders to translate research findings into improved public health responses.

The following key research coordination and management functions have been identified to support the *Zika Virus Research Agenda*.

### **Research and partner coordination**

Close partner coordination and collaboration is required to ensure that research and response activities are aligned to agreed global priorities within the Research Agenda. This will require strengthening mechanisms to implement collaborative international research, share and access data, and disseminate preliminary research findings.

Towards this goal, WHO is working with Chatham House and Wellcome Trust as part of the *WHO R&D Blueprint* effort to develop a global coordination mechanism to improve global capacity for coordination and consensus about key actors supporting research and development before and during emergencies.

### **Common platform for standardised processes, protocols and tools, and for sharing specimens, data and information**

Global, regional and national actors will require clear and standardized protocols to effectively detect, track and monitor Zika virus infection and associated complications. Standardization is required to assure the accuracy of data collection, to increase the power of research and to improve both quality assurance and quality control. Standardized protocols will be required for biological sampling, sample storage, shipment and transport, testing, record taking and data entry. Shared platforms will include common repositories for data, research outcomes and findings, and dissemination strategies will be put in place to enable the sharing of preliminary research findings and data.

### **Training and capacity building for research and public health response**

The execution of new and harmonized tools, standards, processes and protocols requires enhanced training of users including laboratory technicians, public health workers, clinicians and others. Training is also required at local level for public health responders working on clinical management of Zika virus and its complications, vector control and risk communications.

### **Financing, implementation monitoring and management**

Financing will be sought to initiate and maintain work in the Research Agenda over an anticipated timeframe of June 2016 to December 2018. Support will be sought from key funding partners and donors, and robust mechanisms established to ensure transparent monitoring, management, reporting, and accountability of funds and activities.

### **Ethics, regulatory support and quality assurance**

The potential impact of Zika virus infection on pregnant women and their

---

babies raises additional ethical and regulatory complexities for research in this field. Public health decisions may have to be made on an urgent basis and in the context of scientific uncertainty. Establishing a sound basis of ethics, regulatory support and quality assurance for the Research Agenda will be key to enabling researchers and decision-makers to lead an evidence-based and robust response to the challenges posed by Zika virus.

WHO has recently published Ethics guidance<sup>4</sup> for infectious disease outbreaks to focus on the cross cutting ethical issues that apply to infectious disease outbreaks generally, and examines how these principles can be adapted to different epidemiological and social circumstances.

---

## IMPLEMENTATION FRAMEWORK

---

The coordination and management elements described above form the key support structure for the overall implementation of the WHO *Zika Virus Research Agenda*. The proposed research areas and the coordination and management functions that enable them are shown in the Implementation Framework below (Figure 1).

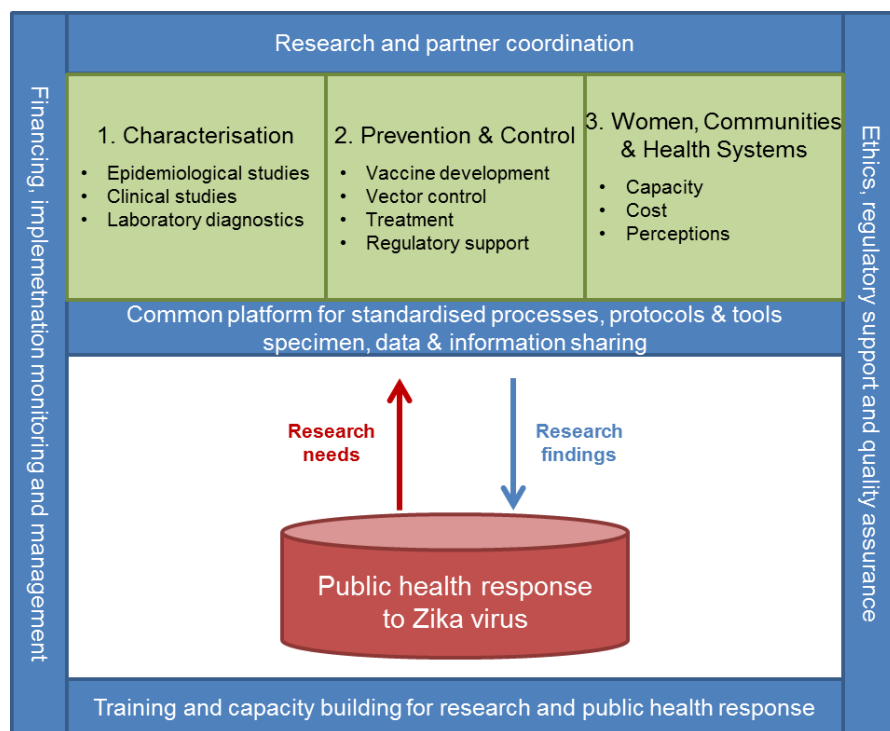
The Implementation Framework identifies three prioritised research areas: 1) Characterisation, 2) Prevention and Control, and 3) Women, Communities and Health Systems. These are coordinated by an overall research and partner coordination function. The research areas are supported by common platforms for standardised processes, protocol and tools, and specimen, data and information sharing. These platforms allow needs from the public health response to flow up to and inform research activities, and will also enable research findings to guide and improve the international response.

Training and capacity building for research and public health response forms the foundation of the Implementation Framework. Developing these skills in the key workforce involved in implementing the Research Agenda – laboratory technicians, clinicians, responders and others – is fundamental to making the Research Agenda operational and achieving its goals.

The management and administration of the Research Agenda is supported by two cross-cutting functions encompassing financing, implementation monitoring and management as well as ethics and quality assurance. These functions will provide the necessary organizational support required to run this major international project, as mechanisms to ensure that the highest levels of quality and accountability are maintained.

---

<sup>4</sup> [http://www.who.int/csr/research-and-development/guidance\\_for\\_managing\\_ethical\\_issues.pdf?ua=1](http://www.who.int/csr/research-and-development/guidance_for_managing_ethical_issues.pdf?ua=1)



**Figure 1. WHO Zika Virus Research Agenda Implementation Framework**

预览已结束，完整报告链接和二维码如下：

[https://www.yunbaogao.cn/report/index/report?reportId=5\\_26804](https://www.yunbaogao.cn/report/index/report?reportId=5_26804)

