



As you know, our relatively poor knowledge of the Zika virus presents a series of challenges for R&D. However, I am pleased to say that, based on our experience with R&D during the West Africa Ebola epidemic, WHO's R&D response is proceeding very quickly for Zika.

After Ebola, WHO began to draw up a master plan for R&D to both prepare for health emergencies and to be able to mount a fast R&D response in case of need. The R&D Blueprint – as the initiative is called – aims to accelerate the availability of medical countermeasures during epidemics and limit damage as much as possible. We now have established critical paths for coordinated action, and industry interest in providing platform technologies for the development of medical products.

We have already identified a large number of manufacturers and research institutions either involved in the development of medical tools for Zika, or interested in embarking on such research.

Apart from what has already appeared in the press, numerous other groups are looking at the feasibility of initiating animal or human testing, particularly for vaccines and diagnostics.

For vaccines:

- The landscape is evolving very rapidly and numbers change daily. About 15 companies/groups have been identified so far, most have only just started work.
- Two vaccine candidates seem to be more advanced: a DNA vaccine from the US National Institutes for Health, and an inactivated product from Bharat Biotech, in India.
- The current absence of standardized animal models and reagents is slowing down development.

In spite of this encouraging landscape, vaccines are at least 18 months away from large-scale trials.

For Diagnostics:

- 10 biotech companies have been identified so far that can provide nucleic acid or serological tests. Nucleic acid tests are based on a molecular technique used to detect a virus in the blood; serological tests measure the levels of antibodies as a result of exposure to a particular virus
- 10 other companies are at various stages of development.
- It is important to point out, however, that none of these tests have been independently validated and none have regulatory approval.
- The biggest task in the area of diagnostics will probably be to ensure an adequate

reference method is used by manufacturers when generating their data, so that the performance of the various Zika diagnostics can be tested through an independent assessment. This will help prevent the distribution of poor quality or fake Zika tests that are sure to come up rapidly – as was the case with Ebola.

Laboratory based Zika diagnostics (mostly non-commercial) are already playing an important role to better understand this outbreak, however, new validated and broadly available diagnostics are urgently needed to step up research, clinical management and surveillance. Although it is difficult to predict the time for the first commercial and independently validated tests to be available, we are talking weeks and not years.

WHO will continue working on landscape analyses for diagnostics and vaccines, as well as therapeutics, and innovative vector control measures. These analyses will be published on our web site in the next two weeks.

Immediately after, we will convene independent experts to gauge which of these products seem the most promising as they move to the testing phase.

At the same time, WHO is developing what is called “target product profiles” for these medical tools – for example, what may be the best characteristics for a vaccine to immunize women of child-bearing age?

In terms of diagnostics, we need to understand which type of product – nucleic acid, serologic, rapid test, etc. – will best serve our purposes. We should have target product profiles ready in the next weeks.

In the area of therapeutics, studies are being carried out on medicines and other therapies that could prevent infection in vulnerable groups, especially pregnant women, as is done for malaria. This seems for the moment a more viable and faster option than a curative treatment.

For vector control, innovative methods seem promising options – biological approaches for example, such as the controlled release of bacteria to prevent viral replication in mosquitoes; or genetic approaches, such as the release of genetically modified mosquitoes to reduce the mosquito population.

In terms of what happens afterwards, when potential products reach an advanced stage of testing and show promising data: we have in place the WHO Emergency Assessment and Listing procedure for the use of experimental products during an epidemic. This accelerated assessment process was established during the Ebola epidemic and aims to ensure that products meet acceptable levels of quality, safety and efficacy – even if evaluation is fast-tracked - before they are rolled out in countries.

Dr Kieny was speaking at a press conference in Geneva today 12 February 2016

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We will also provide support to countries wishing to register proven products to compress the time it takes to carry out ethical and regulatory reviews, so that these tools become available rapidly.