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The difficulties in obtaining reliable Zika virus diagnostics

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We read the Personal View by Marion Koopmans and colleagues[1] with great interest. The authors highlight two major obstacles delaying the international response to the catastrophic Zika virus outbreak that has struck Brazil and is ongoing in different parts of Latin America. First, the delays in obtaining dedicated funding. Second, the difficulties of ensuring adequate laboratory diagnostics in Latin America, which the authors illustrate with the inability to establish an external quality assurance for Zika virus detection within the EU-funded ZIKAlliance project[1].

As ZIKAlliance partners, we fully agree with these challenges. Notably, we can provide crucial insight into laboratory quality in affected regions. In 2017, we did a Zika virus external quality assurance in Brazil. 73% of Brazilian laboratories presented with reduced sensitivity and specificity in detection of Zika virus genetic material[2]. The overall risk of false-negative results was 16·7% (95% CI 5·4–28·0), and the overall risk of false-positive results was 26·7% (5·0–48·5). The high risk of incorrect test results is alarming, but not restricted to resource-limited areas, such as Brazil. Albeit to a lesser extent, similar problems were also observed in European laboratories, for which the overall risk of false-negative results was 14·5% (8·9–20·1) and the overall risk of false-positive results was 4·4% (2·1–6·8)[3] (**Figure 1**). The similarities between the studies from Brazil and Europe show that adequate laboratory diagnosis of Zika virus infection is universally challenging. Unreliable Zika virus diagnostics have a huge effect on individual and public health, potentially including illegal abortions based on false-positive test results[4], unwarranted delays of pregnancy, and biased estimates of the absolute risk of congenital disease upon maternal infection during pregnancy[2].

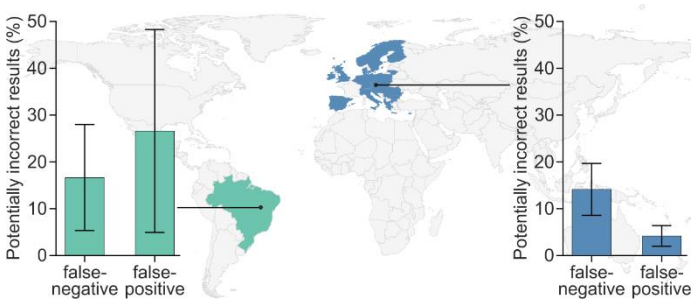

Figure 1 Limitations of molecular Zika virus diagnostics in Brazil and Europe. Risks for false results were calculated based on recently published data.[2,3] Mean risks are depicted by bars and 95% confidence intervals are shown by whiskers. Participating countries from the European study are coloured in blue, Brazil in green.

The article we published on our study[2] attracted broad attention. After our paper went to press in May, 2018, the largest Brazilian newspaper, Folha de São Paulo, reported on our results[5]. Subsequently, we were approached by Brazilian stakeholders to reveal the identity of our study participants. We were unable to comply with this request since confidentiality is crucial to ensure participation of laboratories in external quality-control studies, particularly in resource-limited settings such as Brazil. Access of laboratories in affected regions to state-of-the-art reagents and external quality control is an unresolved key component of outbreak response[2]. Thus, national and supranational stakeholders must support public laboratories in outbreak regions that commonly deal with a huge burden of testing in the absence of adequate reagent supply.

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