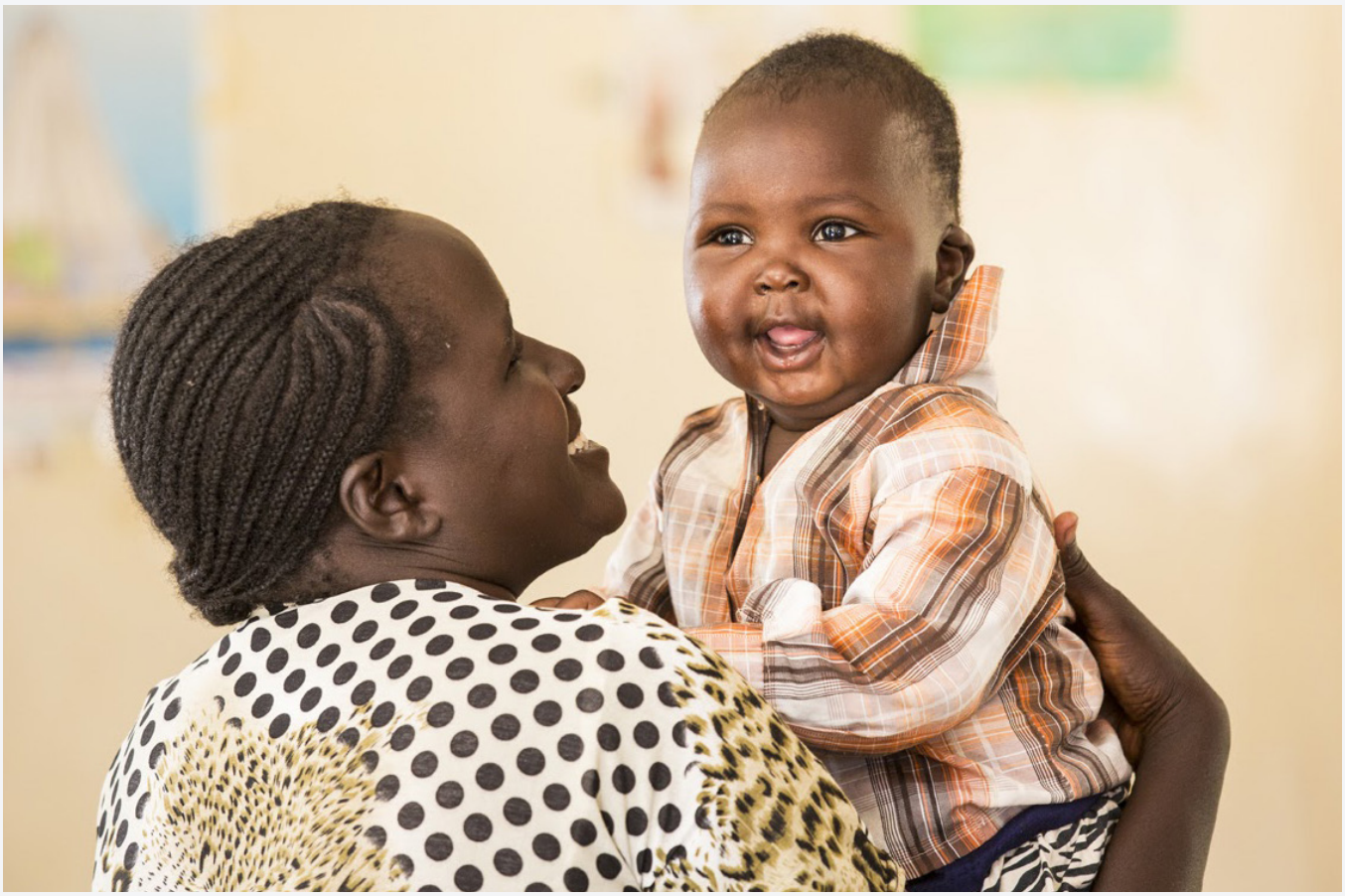
FIND
Diagnosis for all

Policy brief



Diagnostics & vaccines

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Vaccine development

Participants in vaccine clinical trials are routinely tested to establish whether they are or have previously been infected with the pathogen targeted by the vaccine. This is required to calculate vaccine efficacy, which compares the number of vaccinated versus unvaccinated participants who were subsequently infected. Regulatory bodies require vaccines to meet a pre-specified target efficacy value for licensing, and efficacy data can inform estimates of the proportion of a population that must be vaccinated to prevent disease or achieve population-level immunity. Diagnostic tests that can detect the pathogen targeted by the vaccine, and confirm whether a trial participant is infected, are therefore an essential component of vaccine clinical development programmes.

Vaccine effectiveness

Clinical trials have stringent eligibility criteria and conduct evaluations under strictly controlled conditions. Post-licensure studies are therefore important to assess whether the effectiveness of a vaccine in larger and more diverse real-world populations matches the efficacy observed in clinical trials.

Vaccine effectiveness data comes from ongoing public health surveillance programmes that monitor the incidence of disease in a particular population.

These programmes rely on diagnostics to determine the causative pathogen in people with suspected infections.

Targeted vaccination campaigns

Early distribution of vaccines during a disease outbreak can prevent the outbreak from spreading, thus saving more lives. Early detection of outbreaks requires disease surveillance systems that monitor infection and spread of disease. Diagnostics are the cornerstone of disease surveillance systems, not only for detection of human infection, but also for monitoring infection in animal reservoirs, vectors and environmental sources that have potential to spill over into human populations.

Timely diagnostic confirmation of an outbreak has been proven to be crucial to outbreak response campaigns.[1] Diagnostic testing can also determine when an outbreak is not caused by a vaccine-preventable pathogen, thus avoiding unnecessary response efforts and preserving valuable resources.

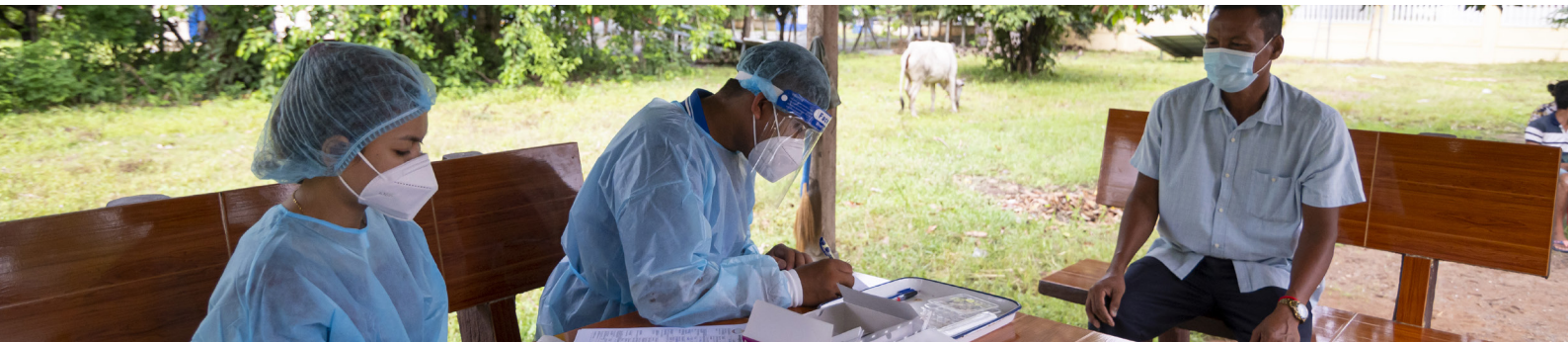
Disease surveillance allows identification of areas or populations at the highest risk of disease, enabling targeted vaccination campaigns that ensure the most effective use of limited vaccine supplies and minimize costs.[2] This even applies to vaccines that are used for routine immunization, as outbreaks may still occur, requiring surge vaccination.

Unmet diagnostic needs

A high burden of vaccine-preventable disease falls on low- and middle-income countries. However, existing diagnostic tests are often unsuitable for use in these countries due to cost restraints and lack of laboratory resources and infrastructure, especially at the primary and community healthcare levels. Many vaccines used in routine immunization or outbreak management in low- and middle-income countries, such as yellow fever, typhoid, meningococcal disease, rubella, measles and cholera, lack fit-for-purpose diagnostic tests that are suitable for use in such settings. There is also a lack of evidence for the clinical accuracy of many tests for vaccine-preventable diseases.[3]

Improved access to reliable, affordable, high-quality diagnostics for these diseases, that can be used at or near to the point of care, is urgently needed to enable effective and efficient use of current vaccines.

In addition, there is currently no diagnostic test for 60% of the World Health Organization “Blueprint” pathogens, which have been identified as having the greatest outbreak potential.[4] Many of these pathogens also lack effective vaccines. Diagnostic tests will be needed to support vaccine development programmes for these diseases, as well as to improve disease surveillance.



Improving access to diagnostics to support vaccine development and deployment

Strategies to accelerate development of new diagnostics include the production of target product profiles to provide guidance for diagnostic developers on the desired characteristics of a particular test suitable for use in low-resource settings. Independent performance evaluations of existing tests or tests in development are needed to ensure that the highest quality diagnostics are used to support immunization programmes.

Guidance on the use of diagnostics to make immunization programmes more effective and efficient is needed to support decision making.

SUMMARY

Diagnostics are an essential enabler of vaccine development and effective and efficient vaccination campaigns. Developing diagnostics for critical diseases would support the development of new vaccines, and increasing the availability of diagnostic tests suitable for use in low-resource settings would improve disease surveillance data for immunization programme decision making, which in turn should lead to better value for money in efforts to prevent disease through vaccination.

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References

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2. Hampton LM, Johnson HL, Berkley SF. Diagnostics to make immunisation programmes more efficient, equitable, and effective. *Lancet Microbe* 2022; 3: e242–243.
3. World Health Organization. The selection and use of essential in vitro diagnostics. https://www.who.int/publications/i/item/9789240019102 [Accessed 20 July 2022].
4. Kelly-Cirino CD, Nkengasong J, Kettler H, *et al*. Importance of diagnostics in epidemic and pandemic preparedness. *BMJ Global Health* 2019; 4(Suppl 2): e001179.

ABOUT THIS POLICY BRIEF

FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis across the world. We connect patients, communities, health care providers, governments, global health agencies, decision makers, product developers, and the diagnostics industry to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems. We are working to save 1 million lives through accessible, quality diagnosis, and to save US$1 billion in healthcare costs to patients and health systems.

From time to time, FIND publishes technical briefs and policy briefs on issues relevant to the diagnostics equity agenda. All briefs, including this one, are prepared by FIND staff and reflect FIND's view at the time of publication. Further information on this and other technical briefs and policy briefs can be found on our website at **www.finddx.org**. We also welcome feedback on this and other briefs at **info@finddx.org**.

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