

## Annex A: Implications

### Financial implications

- A strategy to strengthen YF diagnostic capacity including diagnostic market shaping, technical assistance (TA), quality assurance/quality control (QA/QC) assessments, sample transportation, and coordination would require an estimated US\$ 13.5 million during 2019-2021.
- This estimate includes approximately US\$ 8.2 million for the procurement and distribution of laboratory reagents, supplies, and equipment, of which US\$ 4.6 million would be for 2019-2020. In addition, approximately US\$ 5.3 million would be needed for TA, QA/QC testing, sample transportation, and WHO global and regional YF laboratory coordination during 2019-2021, of which approximately US\$ 3.5 million would be for 2019-2020. The Gavi Secretariat will seek to absorb the 2019 estimated costs of approximately US\$ 1.7 million for TA, QA/QC testing, sample transportation, and WHO global and regional YF laboratory coordination within the existing approved PEF budget.

### Risk implications and mitigation

- If the problems with YF diagnostic capacity in Africa are not addressed, there is a risk that YF outbreaks will be detected late, leading to larger outbreaks that require more resources, including vaccines, to contain; result in more morbidity and mortality; disrupt routine immunisation more; and have greater potential to spread to additional countries, as occurred with the 2015-2016 Angola outbreak, in which international travellers imported yellow fever into China, the Democratic Republic of Congo, Kenya, and Mauritania.
- YF serologic tests are unable to distinguish between antibodies formed in response to YF infection and antibodies formed in response to YF vaccination, and the latter can persist for relatively long periods of time. An individual's vaccination history is necessary for interpreting serologic results, but that information is often not available or is uncertain. As a result, as vaccination coverage improves there will be an increased risk for false positive test results that could prompt unnecessary reactive mass vaccination campaigns that unnecessarily disrupt routine immunisation. Improving YF laboratory capacity in Africa so that molecular testing for YF RNA is readily available for appropriately timed specimens would help to offset this risk.
- There is a risk that at least some of the governments of countries at high risk for YF in Africa, may not provide funding for at least some portion of the costs of the supplies, equipment, and services supported through this initiative. Similarly, there is a risk that countries may not sustain their YF laboratory capacity after the end of Gavi support.
  - Initial discussions with laboratory directors from Nigeria, Cameroon, Chad, Benin, Togo, Cote d'Ivoire, Mali, and Uganda have been

encouraging regarding the eventual willingness of governments of countries at high risk for YF in Africa to provide the necessary support following an end of Gavi support.

- Advocacy from Gavi Alliance members through Gavi processes such as Joint Appraisals and sustainability planning as well as non-Gavi processes could encourage the needed domestic support.
- Alignment with the List of Essential In Vitro Diagnostics currently being developed by WHO could help encourage countries' commitment in this area.
- There is a risk that the impact of improved YF diagnostic capacity will be reduced in some countries by insufficient capacity to identify, report, investigate, and collect blood samples from suspect cases. This risk can be mitigated by support for such capacity through Gavi HSS and TCA funding. In addition, Gavi-eligible countries currently receiving significant amounts of support from the Global Polio Eradication Initiative (GPEI) could experience declines in their capacity to identify, report, investigate, and collect blood samples from suspect YF cases when GPEI reduces and ceases its support absent new support from domestic or international sources.
- There is a risk that Gavi involvement with improving the availability of yellow fever diagnostic tests could unduly raise expectations among countries and technical partners that similar support would be forthcoming to improve the availability of diagnostic tests for other vaccine preventable diseases. However, careful and consistent communications about Gavi's intentions and limitations in this area, particularly aimed to setting initial expectations among countries and partners, should help to offset this risk.
- There is a risk that large YF outbreaks could impair laboratory capacity strengthening efforts. For example, the RRLs and GSLs will have key roles in providing TA to improve regional and national laboratory capacity, and their efforts could be diverted to testing samples during large outbreaks. Similarly, there is a risk that large YF outbreaks could disrupt efforts to control other diseases by diverting laboratory staff and capacity into testing for YF during such outbreaks. A capacity for surging laboratory materials to affected countries during an outbreak can help mitigate these risks. Over time, an increase in the number of YF RRLs will also improve the region's capacity to cope with the volume of testing associated with outbreaks.
- The Gavi Secretariat is aware of initiatives to improve laboratory testing capacity for other diseases, including the World Bank's Regional Disease Surveillance System Enhancement (REDISSE) program in West Africa. There is a risk that a Gavi investment in YF laboratory strengthening could work at cross-purposes with other initiatives, but careful communication and alignment should allow Gavi investments to complement them instead.

### *Impact on countries*

- Countries would need to fund basic laboratory infrastructure, including laboratory buildings, staff, utilities, etc., to benefit from a potential Gavi investment in this area because such an investment would be limited to funding YF specific laboratory diagnostic capacity. Since almost all Gavi-eligible countries in Africa at high risk for YF already have laboratories that participate in the GYFLN, some infrastructure is already present in most countries. Gavi-funded laboratory assessment site visits to Angola, Benin, Cameroon, Central African Republic, Chad, Cote d'Ivoire, Democratic Republic of Congo, Ethiopia, The Gambia, Guinea, Mali, Senegal, Sudan, Togo, and Uganda confirmed that such basic infrastructure, including buildings and trained staff, are in place in those countries. For countries that do not have such infrastructure, particularly those with relatively small populations that would generate small testing volumes, support for international transportation of samples provided through this investment should facilitate sending samples to a neighbouring country's laboratory or RRL for testing.
- Countries seeking to receive support through a yellow fever diagnostic procurement mechanism will be required to submit applications. However, those applications should be relatively short and less taxing for countries compared to the applications for Gavi support for vaccine or cold chain equipment procurement, particularly given the much smaller scale of the support provided through a yellow fever diagnostic procurement mechanism.

### *Impact on Alliance*

- Addressing the limitations in yellow fever diagnostic laboratory capacity will improve the availability and quality of YF surveillance data for EYE strategy decision making, allowing more judicious use and allocation of vaccine and smoother functioning of Gavi Alliance efforts to support implementation the EYE strategy.
- Although Gavi support for YF diagnostic capacity strengthening would build on lessons learned from previous Gavi support for vaccine preventable disease surveillance, particularly pneumococcal, meningococcal, and rotavirus disease surveillance, there would also be important differences. For example, this proposal on YF diagnostic capacity strengthening would focus more on addressing laboratory procurement problems and seeks to improve nationwide outbreak detection capacity instead of supporting sentinel sites to measure vaccine impact. This investment also involves a broader range of technical partners and greater engagement with national governments.
- Implementation of a YF diagnostic procurement mechanism and complementary QA/QC and TA will require cooperation from a range of Gavi Alliance partners. For example, the WHO-organized EYE Laboratory Technical Working Group, which has members from public health agencies, academic institutions, and non-governmental organizations, will play a key

role in setting technical standards and protocols. YF reference laboratories will be critical in providing TA to national laboratories and conducting QA/QC activities. The development and functioning of a YF diagnostic procurement mechanism will require building on the experience of Gavi Alliance members with the procurement of vaccine and cold chain equipment. Consultations with Gavi Alliance partners to date indicate they would welcome and support this work.

- Independent review of proposed expenditures through a yellow fever diagnostic procurement mechanism will be required. However, this review process should be less elaborate and less taxing for Gavi Alliance partners than those used for Gavi support for vaccine or cold chain equipment procurement, particularly given the much smaller scale of the support provided through a yellow fever diagnostic procurement mechanism.