South-East Asia Regional Roadmap for Diagnostic Preparedness, Integrated Laboratory Networking and Genomic Surveillance (2023-2027)
South-East Asia Regional Roadmap for Diagnostic Preparedness, Integrated Laboratory Networking and Genomic Surveillance (2023–2027)

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World Health Organization
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Foreword

Within the WHO South-East Asia Region there has been accelerated progress towards strengthening laboratory systems and diagnostic capacity during the COVID-19 pandemic. Reliable laboratory services play a critical role in ensuring efficiency and effectiveness of surveillance and prevention of major emerging, re-emerging and endemic communicable and noncommunicable diseases, including diagnosis, prevention, treatment, research and health promotion.

The COVID-19 pandemic has been a wake-up call for countries in the Region and across the world to invest in diagnostic and surveillance systems as the backbone of resilient health-care systems. It has highlighted that diagnostic tests and laboratory capacity are as essential as medicines.

But diagnostics are not just about pandemic preparedness and emergency response. Ensuring the availability, accessibility, affordability and quality of diagnostics is a key element of facilitating universal health coverage (UHC), which since 2014 has been one of the eight Flagship Priorities for the Region. In fact, progress on all eight Flagship Priorities depends on access to quality diagnostic and laboratory services.

Given the recent COVID-19 pandemic and the need to prepare for future health emergencies, it is imperative that laboratory services in the Region are nationally coordinated, strengthened and enabled to make informed decisions. However, substantial challenges faced by the Member states remain. These include a) sustaining infrastructure, workforce and capabilities built over the years, in particular during the pandemic; b) integrating national laboratory networks for optimised efficiency; and c) strengthening national procurement, supply chain and regulatory processes.

The South-East Asia Regional Roadmap for diagnostic preparedness, integrated laboratory networking and genomic surveillance addresses policy and technical issues for strengthening health laboratory services. It builds on past and current strategies such as the Asia-Pacific Strategy for Emerging Diseases and Public Health Emergencies (APSEDIII) and the Asia-Pacific Strategy for Public Health Laboratories. The roadmap is interconnected with the Regional Strategic Action Plan for enhancing genomic surveillance for pathogens of pandemic and epidemic potential in the South-East Asia Region developed in April 2022 and aligns with the Regional Strategic Roadmap on health security and health system resilience for emergencies 2023-2027.

Besides it being an endeavour to raise awareness on the need to strengthen public health laboratory services, this document provides Member States a set of actions for building resilient and modernized national laboratory systems. This roadmap takes a comprehensive approach in strengthening diagnostic services and provides a guiding framework for Member States to align their policies and plans to enhance financial and technical support for health laboratory services.

The WHO Regional Office for South-East Asia encourages its Member States to use this document as a blueprint for providing comprehensive laboratory services, including the monitoring and evaluation of its performance at the national level and its associations with regional and global networks, to achieve better health outcomes for all.

Dr Poonam Khetrapal Singh
Regional Director
Acknowledgements

The South-East Asia Regional Roadmap for diagnostic preparedness, integrated laboratory networking and genomic surveillance was developed through a series of literature reviews, country interviews and regional consultations involving representatives from governments, global health organizations and donors.
## Abbreviations and acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>AMR</td>
<td>Antimicrobial Resistance</td>
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<tr>
<td>APSEDIII</td>
<td>Asia-Pacific Strategy for Emerging Diseases and Public Health Emergencies</td>
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<td>CBRN</td>
<td>Chemical, Biological, Radioactive and Nuclear</td>
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<td>COVID-19</td>
<td>Coronavirus disease 2019</td>
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<td>EDL</td>
<td>Essential Diagnostics List</td>
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<td>GLLP</td>
<td>Global Laboratory Leadership Programme</td>
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<td>JEE</td>
<td>Joint External Evaluation</td>
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<td>MERS-CoV</td>
<td>Middle East respiratory syndrome coronavirus</td>
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<td>PHSM</td>
<td>public health and social measures</td>
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<td>R&amp;D</td>
<td>Research and Development</td>
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<td>SARS</td>
<td>Severe acute respiratory syndrome</td>
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<td>SEARO</td>
<td>WHO South-East Asia Regional Office</td>
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<td>SEARN</td>
<td>South-East Asian Regulatory Network</td>
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<tr>
<td>SoPs</td>
<td>Standard Operating Procedures</td>
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<td>SPRP</td>
<td>WHO Strategic Preparedness and Response Plan</td>
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<td>WHO</td>
<td>World Health Organization</td>
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</table>
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Fig. 1. Voluntary joint external evaluation (JEE) of IHR (2005) data for national laboratories among eight countries (Bangladesh, Bhutan, Indonesia, Maldives, Myanmar, Sri Lanka, Thailand and Timor-Leste) in the WHO South-East Asia Region (2016–2018)

Fig. 2. The WHO South-East Asia Regional Roadmap for diagnostic preparedness, integrated laboratory networking and genomic surveillance 2023–2027

Fig. 3. Strategic Objectives to the WHO South-East Asia Regional Strategic Action Plan for genome surveillance for pathogens of epidemic and pandemic potential 2023–2027

Fig. 4. Conceptual design of the Regional Expert Laboratory Network

Fig. 5. Conceptual design of Regional Genome Consortium and key areas of prioritization at the national level
Executive summary

Access to diagnostics is the cornerstone for early warning, response and containment strategies and is essential for ensuring “health for all”. The COVID-19 pandemic has not only revealed and underscored the crucial need for timely and accurate diagnostics, but also highlighted that systemic problems remain in every aspect of the laboratory services and diagnostic ecosystem.

Within the WHO South-East Asia Region, despite progress towards strengthening laboratory capacity, substantial challenges remain. The requirements for laboratory core capacities under the International Health Regulations (IHR, 2005) have not yet been met in many Member States, and issues related to weak or non-existent regulatory frameworks for laboratory services, insufficient funding and inadequate access, quality of testing, equipment and supplies, and competence of the workforce, remain.

The WHO South-East Asia Regional Roadmap for Diagnostic Preparedness, Integrated Laboratory Networking and Genomic Surveillance was developed to provide Member States with collective guidance. The overarching goal of the Roadmap is to strengthen laboratory diagnostic preparedness for health security through enabling laboratories to rapidly, accurately and safely identify infectious and non-infectious hazards in a “One Health” approach, by improving multisectoral collaboration and partnerships.

The vision of the Roadmap calls for continuous efforts and investment towards advancing interconnected disease diagnosis and surveillance through resilient, quality assured, safe and timely laboratory services with efficient linkages to reporting, referrals and care. This vision will be achieved through six strategic objectives:

1. Strengthen national leadership, governance and multisectoral collaboration encompassing the broader “One Health” approach.
2. Ensure adequate investment to build and modernize clinical and public health laboratory networks.
3. Build agile and resilient laboratory policies and systems as an all-hazards approach.
4. Promote research, development of and access to new and innovative technologies.
5. Facilitate learning for continuous improvement and sustain readiness for public health emergencies.
6. Establish a trust architecture for rapid information and sample sharing, access to tools and resources to enable and strengthen pathogen surveillance and sequencing systems.

The Roadmap outlines a range of policy options that the Member States can use to develop sustainable strategies to improve their national laboratories and prepare the laboratory systems to improve surveillance and respond more effectively to emerging and re-emerging diseases, and other potential public health emergencies. Implementation of the Regional Roadmap will be imperative to increase investments in diagnostics and laboratory systems, support the development of new diagnostic tools, and ensure that national response systems are of adequate quality to prepare for and prevent or contain the next pandemic.
Introduction

In the first quarter of this century alone, the South-East Asia Region experienced several outbreaks of influenza A (H1N1), avian influenza A (H5N1), influenza A (H9N2), Nipah virus, Japanese encephalitis, Crimean–Congo haemorrhagic fever (CCHF), Middle East Respiratory Syndrome coronavirus (MERS-CoV), chikungunya, dengue, and severe acute respiratory syndrome (SARS), and prepared for a potential Ebola outbreak, before grappling with the latest SARS-CoV-2 outbreak that has caused the COVID-19 pandemic (1). But threats are not viral alone in nature, the pandemic has also accelerated the global crisis of antimicrobial resistance (2). Besides causing considerable morbidity, mortality and economic loss, these events have highlighted significant gaps in disease surveillance systems for early detection and response due to the limitations in clinical and public health laboratory capacities across the Member States.

Access to reliable, credible and sustainable diagnostics is the cornerstone for early warning, response and containment strategies and is essential for ensuring health for all (3). Given the growing emphasis on evidence-based health practices, it is imperative that diagnostics and laboratory services are strengthened to deliver early detection of pathogens, characterize epidemics, safely contain and prevent emerging and re-emerging diseases, and improve patient care.

Overview of regional capacities and lessons learnt during the COVID-19 pandemic response

The role of diagnostics has evolved throughout the COVID-19 pandemic from enhancing surveillance to guiding response strategies holistically. The inclusion of genomic sequencing as a key response tool highlighted its role as part of a continuum of laboratory-based services for surveillance, clinical management, primary research and other purposes.

Since January 2020, Member States have made concerted efforts to increase the regional molecular testing capacity from five laboratories providing confirmatory testing for SARS-CoV-2 to more than 5500 across the region as of June 2022. New diagnostic tools have rapidly been integrated into national testing strategies, with 10 Member States carrying out rapid antigen tests and all countries with confirmed cases of COVID-19 having access to genomic characterization facilities (in-country or external). Access to these diagnostics has led to early identification, prompt isolation and more effective treatment of COVID-19 cases. The testing strategies remained dynamic based on the local demands, changing landscape of transmission and ongoing relaxation of public health and social measures (PHSM), and were subject to high levels of pandemic fatigue.

A review of national policies and strategies and focused group discussions with the laboratory leadership in select Member States identified the major drivers for success of laboratory preparedness and response. Countries have benefited from preparedness activities through strengthening of laboratory capacities for pandemic influenza, vaccine preventable diseases and antimicrobial resistance (AMR). Leveraging of these existing resources was key to successful laboratory responses during the COVID-19 pandemic.

Global initiatives towards pandemic preparedness and disease surveillance programmes (such as with tuberculosis, HIV, malaria, measles–rubella and similar programmes) have collectively contributed to the overall strengthening of diagnostics systems in the Region. In particular, the Pandemic Influenza Preparedness Framework has made significant contributions to establish national laboratory systems for the identification of influenza viruses, which served as the first line of response for quickly setting up diagnostic capacity during the emergence of COVID-19 in the Region. It also prepared the platforms for national/international specimen transfers for testing and characterization, as well as related technical and technological exchange between countries.
Other significant drivers of success for laboratory preparedness and response were:

- Availability of national policies for governance, centralized coordination and multisectoral collaboration.
- Importance of scalability of testing and workforce ensuring surge capacities.
- Adaptability of testing strategies to changing transmission patterns.
- Rapid implementation of sequencing and analysis of capacity for rapid pathogen and variant identification.
- Impact of rapid sharing of information on public domains, including genomic data, for monitoring pathogen evolution to fast-track diagnostics, therapeutics and vaccine development.
- Need for differential diagnosis capacity across referral pathways from the community to tertiary levels of the health system.
- Role of testing outside the health-care system within schools, workplaces and during mass gatherings.
- Need for optimization of laboratory networks for efficient and effective delivery of services and response to health emergencies.

Despite massive scale-up of diagnostic capacity for SARS-CoV-2 by the Region, several challenges persist vis-a-vis the desired improvements to the pre-COVID-19 infrastructure before March 2020. The voluntary joint external evaluation (JEE) of IHR (2005) conducted in eight Member States (Bangladesh, Bhutan, Indonesia, Maldives, Myanmar, Sri Lanka, Thailand and Timor-Leste) between 2016 and 2018 revealed several gaps in the areas of national laboratory systems and networking, biosafety/biosecurity and quality assurance (see Fig. 1).

**Fig. 1.** Voluntary joint external evaluation (JEE) of IHR (2005) data for national laboratories among eight countries (Bangladesh, Bhutan, Indonesia, Maldives, Myanmar, Sri Lanka, Thailand and Timor-Leste) in the WHO South-East Asia Region (2016–2018)

<table>
<thead>
<tr>
<th>National laboratory system</th>
<th>D.1.1 Laboratory testing for detection of priority diseases</th>
<th>3 4 3 4 4 4 3</th>
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<tr>
<td>D.1.2 Specimen referral and transport system</td>
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<td>Biosafety and biosecurity</td>
<td>P.6.1 Whole-of-government system in place for all sectors</td>
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<td>P.6.2 Training and practices in all relevant sectors</td>
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During the virtual Regional Meeting on “Learning from the COVID-19 response to strengthen health security and health systems resilience in the South-East Asia Region”, held on 20–22 October 2021, the major systemic gaps and challenges that hinder sustainability of laboratory systems and diagnostic capacities were identified. These challenges have contributed to significant delays in every aspect of outbreak response from initial detection to final containment both during and prior to the COVID-19 pandemic which include;
- Limitations in trained human resources, equipment maintenance and supply management.
- Infrastructural deficiencies for real-time monitoring of laboratory information flow and management systems.
- Lack of regulatory mechanisms for laboratory equipment and supplies.
- Varied interests and priorities of different stakeholders/partners/donors that are not coherent with local context.
- Sustained financials and commitments for developmental exercises during preparedness/inter-pandemic phases.
- Limited R&D for new diagnostic tools for priority pathogens during non-outbreak periods.
- Inadequate diagnostic testing capacity at both national and community levels of health care.
- Fragmented and unreliable funding pathways.

**Rational for developing the Regional Roadmap**

For diagnostics to play an optimal role within a broader health system, overall capacity strengthening through integration of laboratory systems into existing preparedness activities, disease surveillance programmes and health-care systems is critical. Novel strategic approaches are required for capacity strengthening and efficient data management systems, paving the way for resilient laboratory systems that complement the overall improvement of clinical care pathways and rapid detection of future outbreaks, and aid timely implementation of containment measures with the potential of saving many lives and substantially reducing the health-care burden. Resilience is needed in every building block of the laboratory services ecosystem.

While the laboratory and diagnostics services within the WHO South-East Asia Region were enhanced during the COVID-19 pandemic, the lessons learnt highlight the need for focused strengthening of certain key aspects to achieve sustainability and resilience of national laboratory systems.

To provide Member States with collective guidance, the national health authorities, the WHO Regional Office and a diverse group of international partners collaborated to develop a strategic roadmap for strengthening the laboratory services and integrating the networks. The roadmap outlines a range of policy options that the Member States can use to develop sustainable strategies to improve their national laboratories and bolster laboratory systems, improve surveillance and respond more effectively to emerging and re-emerging diseases and other potential public health emergencies.

This [WHO South-East Asia Regional Roadmap for diagnostic preparedness, integrated laboratory networking and genomic surveillance 2023–2027](#) aims to address the existing gaps and challenges to efficiently and effectively strengthen diagnostic preparedness and laboratory systems at national and regional levels in collaboration with Member States and partners. It is the culmination of extensive literature review and consultations with representatives of Member State governments and development partners on identifying and agreeing on newer evidence, information and approaches that have emerged to build a future-ready diagnostics capability in the Region. The Roadmap is interconnected with the [Regional Strategic Action Plan for enhancing genomic surveillance for pathogens of pandemic and epidemic potential in the South-East Asia Region](#) developed in April 2022. It is also aligned with the [Regional Strategic Roadmap on health security and health system resilience for emergencies 2023–2027](#).

The Regional Roadmap will build on past and current strategies such as the Asia-Pacific Strategy for Emerging Diseases and Public Health Emergencies (APSEDIII) and the Asia Pacific Strategy for Public Health Laboratories jointly developed by the Regional Offices for South-East Asia and the Western Pacific(4,5).
WHO South-East Asia Regional Roadmap for diagnostic preparedness, integrated laboratory networking and genomic surveillance 2023–2027

Vision
Ensure that within the South-East Asia Region, continuous efforts and investments are made towards advancing interconnected disease diagnosis and surveillance through resilient, quality-assured, safe and timely laboratory services with efficient linkages to reporting, referrals and care.

Goal
Strengthen laboratory diagnostic preparedness for health security through enabling laboratories to rapidly, accurately and safely identify infectious and non-infectious hazards in a “One Health” approach, by improving multisectoral collaboration and partnerships, in the WHO South-East Asia Region.

Strategic Objectives
1. Strengthen national leadership, governance and multisectoral collaboration encompassing the broader “One Health” approach.
2. Ensure adequate investment to build and modernize clinical and public health laboratory networks.
3. Build agile and resilient laboratory policies and systems as an all-hazards approach.
4. Promote research, development of and access to new and innovative technologies.
5. Facilitate learning for continuous improvement and sustain the readiness posture for public health emergencies.
6. Establish a trust architecture for rapid information and sample sharing, access to tools and resources to enable and strengthen pathogen surveillance and sequencing systems.

Strategic approaches
At the Regional level
- Establish a diagnostic advisory group to prioritize diagnostic needs and develop pragmatic approaches to promote innovation to advance laboratory services for surveillance and clinical care.
- Support the strengthening of diagnostic availability across the health system through policies, governance and investment of sustainable laboratory systems.
- Establish a regional network to consolidate pathogen-specific expertise, diagnostic and surveillance capabilities and rapid information sharing mechanisms across disease networks and sectors.
- Establish regional mechanisms and best practices for rapid information and sample sharing for public health decision-making.
- Support the operationalization of the South-East Asia Regional Genomics Consortium to foster partnerships and collaboration across international borders to enable access to tools and resources, and information and biological samples.
- Foster collaborations with various stakeholders to promote a community of practice for peer-to-peer learning between Member States.
• Sustain technical and financial support for diagnostics, laboratory and surveillance systems strengthening.
• Establish partnerships to strengthen regional supply chain mechanisms for diagnostic tools, reagents and consumables.

At the country level
• Policymakers at the national level recognize the importance of strengthening diagnostics and laboratory systems for health security and universal health coverage as a cross-sectoral collaboration under the “One Health” approach.
• Advocate for and catalyze investment and resource mobilization towards multiyear strengthening of public health laboratories to improve emergency preparedness and response.
• Strengthen the links of public health laboratory systems with disease surveillance, risk assessment and effective public health decision-making under the “One Health” approach.
• Increase access to quality testing in clinical and public health laboratories across the health system.
• Strengthen sample referral and sample collection transport systems through the development of SoPs, capacity-building and leveraging the use of digital tools.
• Introduce diagnostic stewardship and strengthen linkages to clinical services for improved clinical management.
• Establish national quality assurance programmes and national biorepositories to catalogue samples for research and development and diagnostic test evaluations.
• Facilitate learning for continuous improvement of public health laboratories to enhance readiness for health emergencies.
Fig. 2. The WHO South-East Asia Regional Roadmap for diagnostic preparedness, integrated laboratory networking and genomic surveillance 2023–2027

- **Issues**
  - Under investment in diagnostics and laboratory systems
  - Low political commitment
  - Vertical surveillance and laboratory systems
  - Lack of data interoperability
  - Lack of regulatory harmonisation
  - Limited linkage to clinical care
  - Lack of standardisation of sample collection and storage
  - Limited coordinated research

- **Inputs**
  - Countries commit to –
    - Increasing funding and expenditure
    - Multi-sectorial network and establishing public-private partnership
  - Donors commit to funding laboratory systems, away from vertical structures
  - Partners commit to joint planning and implementation to strengthen interconnected disease surveillance and diagnosis

- **Outputs**
  - Strengthen national leadership, governance and multi-sectorial collaboration encompassing the broader “One Health” approach
  - Ensure adequate investment to build & modernise clinical and public health lab networks
  - Build agile and resilient laboratory systems and policies as an all-hazards approach
  - Promote research, development of and access to new and innovative technologies
  - Facilitate learning for continuous improvement and sustain readiness posture for public health emergencies
  - Trust architecture for rapid information and sample sharing

- **Outcomes**
  - Modernised and sustainable laboratory systems
  - Regional laboratory network
  - Diagnostic advisory group
  - Decentralisation of testing and increased access to testing
  - Improved tools for diagnosis and data capture
  - Quality assured and safe testing
  - Increased awareness and commitment to diagnostics
  - Improved sample and data sharing
  - Regional genomic consortium

- **Impact**
  - Rapid detection of outbreaks
  - Effective use of data for public health actions
  - Improved diagnostic stewardship
Priority activities to achieve Strategic Objectives

Strategic Objective 1: Strengthening national leadership, governance and multisectoral collaboration

• **Enhance political commitment to diagnostics and laboratory systems**
  National diagnostic roadmaps should be developed to build effective and sustainable diagnostics and laboratory systems in countries. The national roadmaps should be inclusive of existing plans such as the AMR national action plans, the national plans for Health Security, and the national laboratory policies. The strategies should be used to advocate with political leadership for continued support and investment to sustain national diagnostics and laboratory systems.

• **Enhance national leadership and coordination of laboratory services**
  Leveraging on the successes of the COVID-19 pandemic, countries should ensure that a dedicated national focal point or national technical working group is established to oversee and coordinate laboratory services across various sectors including but not limited to clinical services, public health services, private sector, the animal and environment sectors, and academia.

• **Develop an integrated national laboratory strategic plan including emergency planning to align resources from vertical and horizontal programmes**
  Based on the best practices and lessons learnt from the COVID-19 pandemic, countries should review and update the national laboratory strategic plans and relevant national policies to address and/or ensure: governance and coordination structures, multisectoral coordination, domestic and international partnerships, emergency preparedness and response planning, integration of new technologies, integration of surveillance and laboratory networks, quality assured and safe testing, harmonized regulatory processes, and resource mobilization to align resources for building effective laboratory systems.

• **Develop national policies for rapid information and sample sharing at national and international levels**
  Information and sample sharing is a critical element of an effective response to infectious disease outbreaks. National policies to facilitate rapid sharing at subnational, national and international levels should be developed adhering to international access and benefit sharing frameworks and legal instruments such as the International Health Regulations (2005). National mechanisms should also support and operationalize regional systems such as the WHO South-East Asia Genome Surveillance Consortium during public health emergencies.

• **Establish a package of laboratory services to be available across the health system**
  A package of clinical and public health laboratory services should be available to ensure that diagnostic testing is accessible at all levels of the health system. The development of national essential diagnostic lists (EDL), an evidence-based guide, can be used to plan for service delivery packages across the tiered laboratory networks and the health system. The EDL will help to improve resource allocation for diagnostics, laboratory systems and human resources leading to improved access and service delivery.
Strategic Objective 2: Ensuring adequate investment to build and modernize laboratory networks

- **Develop focused, multiyear budgets to finance diagnostic and laboratory services**
  To ensure sustainability and periodic improvement of laboratory infrastructure, data informatics, technical capacities and capabilities, an advanced workforce, and equitable access to laboratory services across the health system, a multiyear budget should be developed and be made available for allocation of domestic funds within the national health budgets. It should be used for resource mobilization efforts with international and national partners. Collective action and a diversified investment strategy can support the right mix of diagnostic technologies, enhance workforce and sustain functionality. Private–public partnerships should also be established to identify new sources of funding. A monitoring and evaluation framework should be developed to review and reset investment priorities.

- **Increased annual national spending on diagnostics and laboratory services**
  Countries should demonstrate increased annual spending to improve and modernize laboratory infrastructure, data informatics and equipment and to strengthen the workforce for effective and efficient laboratory services.

- **Improve diagnostic literacy, advocacy and communication strategies**
  The work of science communicators during the COVID-19 pandemic was critical to reduce the impact of misinformation, encourage adherence to public and social measures and build trust in the national laboratory systems. National communication strategies must be developed to educate policymakers, health workers and the public on diagnostics and their uses. Use of behavioural communication and human-centred design studies are encouraged to understand the enablers and barriers to diagnostics from the perspectives of both the provider and end-user.

Strategic Objective 3: Building agile and resilient laboratory systems with an all-hazards approach

- **Enhancing national laboratory networking for better preparedness to health emergencies as part of ‘One Health’ Approach**
  The COVID-19 pandemic has demonstrated that a coordinated national laboratory network is critical to sharing early alerts, to rapidly scale a laboratory response with advanced planning for surge capacities, broadly validate new assays, provide consolidated data on quality and performance, and scale up the workforce. Existing and new collaborative relationships should be established between public health, clinical, animal, environmental, chemical, toxicology, radiation and the private sectors as well as academia as a platform for cross-country collaboration using the “One Health” approach. A tiered structure should be maintained and enhanced to increase connectivity between clinical and public health laboratories and include a package of services to be available across the health system. Efforts should be made to incorporate laboratory testing and confirmation across the health system through networks and sample referral mechanisms. National laboratory networks should also facilitate a community of practice on networking, quality management, disease surveillance, training and capacity-building and outbreak investigations.

- **Establish regional reference laboratory network and enhance readiness for public health emergencies (Annex C)**
  A regional network of laboratories should be established and formalized. This should consolidate existing institutional and disease-specific expertise. The network shall provide guidance and set
standards for detection of emerging pathogens with epidemic and pandemic potential, facilitate innovations in product development and evaluations, serve as a platform for cross-country collaboration, provide technical expertise, referral services and advanced characterization during public health emergencies, and lead in the development of research agendas. The regional network shall work in collaboration with existing pathogen-specific networks and stakeholders to advance interconnected surveillance and laboratory systems. Efforts should continue to strengthen and enhance capacities and capabilities of existing pathogen-specific networks.

- **Strengthen laboratory linkages to clinical services for improved diagnostic stewardship**
  Increased efforts should be made to support the systematic utilization of laboratory testing through diagnostic stewardship. Tools, capacity-building and resources should be provided to introduce diagnostic stewardship that will ensure that the correct test is ordered on the right patient at the right time.

- **Foster a new cadre of laboratory workforce**
  Laboratory leadership and management are necessary skills required for effective and efficient operation of laboratories. A national strategy and workplan should be developed for comprehensive training and retention of laboratory workforce including appropriate planning for surge capacities. Leadership programmes such as the Global Laboratory Leadership Programme (GLLP) should be implemented in countries to ensure that efforts are on to train and retain critical laboratory workforce. Efforts should also be made to embed necessary training within national training and academic programmes for long-term sustainability. National and regional mentorship programmes should also be established to improve core laboratory capacities in areas such as supply chain management, biosafety and biosecurity, and quality management. Continuous education and training should be provided to health-care workers and community health workers to recognise disease syndromes, standard notification procedures and information systems that will ultimately strengthen surveillance capacities.

- **Promote the generation, curation, analysis and use of laboratory data for evidence-based public health action**
  Laboratory data has been critical to inform the development of medical countermeasures and risk-based decision-making related to a public health emergency, and to support the effectiveness of clinical interventions and operational efficiency of laboratory networks and surveillance systems. Efforts should be made to develop integrated and interoperable data systems and linkages to national systems through harmonization of existing data systems, building data management infrastructure and developing data-sharing policies and promoting the use of digital tools to improve laboratory services.

- **Link public health laboratories with surveillance and risk assessment**
  Early warning systems are needed for the early recognition and identification of unusual disease syndromes. For this end, countries should support linkages of laboratories to surveillance and risk assessment functions. This includes strengthening roles of laboratories in event-based surveillance (immediate reporting of high-threat pathogens to public health systems), as well as indicator-based surveillance (to supplement case-based surveillance) through data-sharing related to vaccine-preventable diseases, AMR, zoonotic pathogens, food safety and unusual events.
• **Implement a comprehensive phased approach to quality management systems using evidence-based tools**

A comprehensive and phased approach promoting country ownership is required to assist countries to strengthen quality management systems. Efforts should be driven towards building national quality structures to improve monitoring, supervision, workforce development and licensing.

• **Further strengthen biosafety and biosecurity**

The recent publication of the evidence and risk based approach of the WHO Laboratory and Biosafety Manual (4th edition) allows countries to assess risks based on a case-by-case approach with regard to working with biological agents. Countries should rapidly implement the approach to develop sustainable laboratory biosafety and biosecurity policies and practices without compromising on safety.

• **Establish collaborations and linkages for laboratories and experts for chemical and radiation emergencies**

To facilitate the reduction of risks associated with chemical, biological, radioactive and nuclear (CBRN) public health emergencies and to ensure a coordinated response to them, countries should establish linkages to national networks and technical expertise for chemical and radionuclear hazards. Improved coordination with the public health sector can improve preparedness and response as an all-hazards approach.

**Strategic Objective 4: Promoting research and development of and access to new and innovative technologies**

• **Establish a regional diagnostic advisory group**

A dedicated group of regional experts with a broad range of expertise should be established to review and prioritize diagnostic needs for disease programmes, define the research needs for multisectoral disease surveillance, define diagnostic use case scenarios and target product profiles, and provide the SE Asia Region with technical advice on diagnostics and laboratory systems strategies. Periodic landscaping of diagnostic technologies and pathogen characterization technologies for use in laboratory and field settings should be undertaken to improve access, timeliness and efficiency of diagnostic and characterization activities. The group of experts will also be responsible for establishing partnerships to support funding, development, and validation and implementation of diagnostic tools and national laboratory systems strengthening.

• **Promote the development of national and regional biorepositories to facilitate sample sharing for research and development of medical countermeasures (Annex C)**

Access to specimen panels is a key challenge to rapidly developing quality diagnostics and medical countermeasures. Regional centres of excellence should be established to facilitate the sharing of clinical specimens for characterization and storage. Resources should be provided to countries to establish mechanisms for the standardized and ethical collection, characterization and archiving of specimens, and sharing these specimens for research development and evaluation for pathogens of epidemic and pandemic potential. Regional best practices for rapid sharing and characterization of clinical specimens during epidemic and non-epidemic periods should be developed based on global instruments and policies. Collaborations should be established through public–private partnerships with manufacturers for research and development and to facilitate technology transfer to scale up the manufacture of diagnostic tools.
• **Strengthen regulatory processes and frameworks**
  Stronger collaboration and coordination are needed between public health laboratories and national regulatory authorities to ensure quality assurance of diagnostic tools. Training, protocols and funding should be made available to enhance regulatory system strengthening and implementation of vigilance and post-market surveillance. Country participation should be facilitated for regional initiatives such as the South-East Asian Regulatory Network (SEARN) to promote strengthening of regulatory practices and processes for medical devices and in vitro diagnostic tests.

• **Operational research to identify gaps and challenges and provide solutions for laboratory systems efficiency and effectiveness**
  Multiple challenges continue to persist that prevent the establishment of sustainable and resilient laboratory systems broadly affecting the diagnostic ecosystem from policies, supply chain management, capacity-building, workforce development and the implementation of new tools. Evidence-based approaches such as operational research should be conducted to identify barriers to optimizing laboratory systems for efficiency and effectiveness.

**Strategic Objective 5: Maintaining and sustaining readiness for public health emergencies**

• **Exercises to improve laboratory preparedness and response**
  A package of tools, training materials and resources should be made available at national and regional levels to foster best practices and assess laboratory network readiness and ensure that the former are implemented to achieve the highest quality standards through active learning. Simulation exercises and after-action reviews should be conducted at national and subnational levels for ensuring readiness with demonstrated performance following a laboratory response, leading to context-specific plans to improve laboratory core capacities and indicators that will enforce and monitor rapid response.

• **Optimize laboratory network efficiency and performance**
  Advocacy, tools, training and resources should be provided to countries to effectively align testing strategies with demands during inter- and intra-pandemic periods to optimally utilize existing capacities in the most cost-effective way, exercise optimization for laboratory networks during the preparedness phase, and derive scalability to address surges.

• **Establish a monitoring and evaluation framework for health laboratory services**
  A standardized timeliness framework should be developed that measures functionality and performance metrics against global standards. The framework will measure the time taken to implement laboratory response activities allowing countries to identify challenges that can result in improvements in laboratory systems.
Strategic Objective 6: Establish a trust architecture for rapid information and sample sharing, access to tools and resources to enable and strengthen pathogen surveillance and sequencing systems

The Regional Roadmap has incorporated The WHO South-East Asia Regional Strategic Action Plan for genome surveillance for pathogens of epidemic and pandemic potential as its sixth strategic objective. The regional action plan addresses five strategic objectives (see Fig. 3) aligning to the WHO Global genomic surveillance strategy (6) to strengthen national surveillance and laboratory and information systems to integrate genomic surveillance into the wider public health architecture. The overarching goals of the Regional Action Plan are to:

1. develop a robust regional pathogen genomic surveillance system to detect and monitor SARS-CoV-2 and other pathogens of pandemic and epidemic potential; and
2. establish a trust architecture for rapid information and sample-sharing, and access to tools and resources to enable and strengthen pathogen surveillance and sequencing systems for pandemic preparedness and response.

To operationalize the Regional Action Plan, a Regional Genomic Surveillance Consortium for the WHO South-East Asia Region will be established to foster multidisciplinary collaboration to deliver an epidemic intelligence system that couples genomic data with data from multiple sources for risk assessment, preparedness planning and response decisions to manage pandemic and epidemic threats for health security. Ultimately the consortium will facilitate a broader scope of expanding the utility of genomic sequencing as a critical tool for preparedness and response to future health emergencies (see Annex C).

The inclusion of genomic sequencing as part of a continuum of laboratory-based services for surveillance and risk assessment has been critical throughout the COVID-19 pandemic and for other infectious diseases with epidemic and pandemic potential. Effective use of genomic information requires not only strengthening of genomic sequencing capacities, but also ensuring better linkages between laboratory and surveillance systems, including joint planning and other mechanisms for timely exchange of information. Countries should continue to participate in and contribute to initiatives such as the Regional Genomic Surveillance Consortium of the WHO South-East Asia Region to enhance regional collaboration and information-sharing for genomic surveillance and related risk assessment. The strategic objectives and actions of the WHO South-East Asia Regional Strategic Action Plan for genome surveillance for pathogens of epidemic and pandemic potential are summarized in Annex A.

Monitoring and evaluation framework

The Regional Roadmap will be implemented through complementary regional and country-level activities, and in cooperation between Member States, WHO, other United Nations Specialized Agencies, donors and development partners.

The monitoring and evaluation framework will be designed to enable a systematic and real-time understanding of implementation of this Regional Roadmap and its effectiveness to achieve the Strategic Objectives.
**Fig. 3.** Strategic Objectives to the WHO South-East Asia Regional Strategic Action Plan for genome surveillance for pathogens of epidemic and pandemic potential 2023–2027

### South East Asia Regional Action Plan for enhancing genomic surveillance for pathogens of pandemic and epidemic potential (2023-2027)

<table>
<thead>
<tr>
<th>Planning, coordination and monitoring</th>
<th>Tools and systems</th>
<th>Enhancing workforce</th>
<th>Information sharing and connectivity</th>
<th>Risk assessment and decision making</th>
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<tr>
<td>• Develop national action plans</td>
<td>• Enhance analytics systems</td>
<td>• Establish regional training hub/s</td>
<td>• Establish data and sample sharing and access principles</td>
<td>• Strengthen national capacities for risk assessment</td>
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<td>• Establish national coordinating body</td>
<td>• Optimized national genomic surveillance objectives and protocols</td>
<td>• Retention of workforce</td>
<td>• Establish regional standards for information and sample sharing</td>
<td>• Tools for risk assessment</td>
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<tr>
<td>• Sustainability of genomic surveillance</td>
<td>• Accurate and sensitive laboratory systems</td>
<td>• Communities of practice</td>
<td>• Targeted collaboration between academia, private sector and One Health partners</td>
<td>• Regional and country capacities to characterize pathogens and variants</td>
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<td>• Readiness and continuous improvement plans</td>
<td>• Map and monitor capability and capacity</td>
<td>• Genomics and risk assessment of variants in training programme of field epidemiologists</td>
<td>• Strengthen regional networking</td>
<td>• Regional mechanism for rapid sharing of information</td>
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<td>• Monitoring and evaluation</td>
<td>• Procurement and supply chain management</td>
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<td>• Establish mechanism for regional biorepositories</td>
<td>• Operational research</td>
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## Annex A: Strategic actions, activities and outcomes

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<tr>
<th>Objectives</th>
<th>Specific objectives</th>
<th>Activities</th>
<th>Outcomes</th>
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| **Strategic Objective 1:** Strengthen national leadership, governance and multisectorial coordination | * Enhance political commitment to diagnostics and laboratory systems | • Develop national strategies to improve clinical and public health diagnostics and laboratory services across the health system  
• Develop advocacy tools and initiatives to build political commitment  
• Develop position paper on the investment case for diagnostics | • Greater political commitment to increasing accessibility and affordability of laboratory services |
|   | * Enhance national leadership and coordination of laboratory services | • Establish unified technical working group or multisectoral coordinating mechanism | • Clear national governance, leadership and coordination mechanisms in place and operational |
|   | * Develop an integrated national laboratory strategic plan including emergency planning to align resources from vertical and horizontal programmes | • National strategic plans and contingency plans available for public health laboratory network  
• Improved linkage to national regulatory authority to harmonize processes  
• Contingency plans available for priority pathogens and other hazards including chemical, biological, radionuclear | • Improved laboratory preparedness and planning for health emergencies as an all-hazards approach |
|   | * Develop national policies and legal framework for rapid information and sample sharing at national and international levels | • Review and update national policies for rapid sharing of information and specimens  
• Develop national MTAs | • Operational mechanisms and enabling legal framework in place for rapid information and sample sharing |
|   | * Establish a package of laboratory services to be available across the health system | • Develop national essential diagnostic list and implementation framework  
• Map and strengthen domestic/indigenous production of diagnostic tools, reagents and consumables | • Improved allocation of tests and optimized use of laboratories  
• Decentralization of services through a coordinated national approach |
| **Strategic Objective 2** Ensuring adequate investment to build and modernize laboratory networks | * Develop focused, multiyear budgets to finance diagnostic and laboratory services | • Include budget for diagnostics and laboratory services within national health budget  
• Develop multiyear budgets for operationalizing and maintaining national public health laboratory and national networks and workforce  
• Develop resource mobilization plan with clear allocations and commitments for domestic and international funding | • Increase commitment and spending on diagnostic and laboratory services |
|   | * Increased annual national spending on diagnostics and laboratory services | • Document spending and impact of investments on laboratory services | • Improved infrastructure, equipment and capabilities to detect pathogens of endemic and pandemic potential |
|   | * Improve diagnostic literacy, advocacy and communication strategies | • National communication strategies in place  
• Capacity building workshops with media, clinicians, policy makers  
• Conduct research to understand enablers and barriers to diagnostics from both provider and end user perspective | • Improved awareness and trust in laboratory systems |
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<tr>
<th>Strategic Objective 3: Building agile and resilient laboratory systems with an all-hazards approach</th>
<th>• Enhancing national laboratory networking for better preparedness to health emergencies as part of 'One Health' approach</th>
<th>• Develop a tiered national network with clear TORs, agreements for data and sample sharing and multisectoral engagement</th>
<th>• Integrated national laboratory networks ready to test and report results in a safe, timely and reliable manner for the detection of and response to disease outbreaks and other health emergencies</th>
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<tr>
<td>• Establish regional reference laboratory network and enhance readiness for public health emergencies</td>
<td>• Develop criteria for the development of centres of excellence and WHO CCs to establish an integrated multi-pathogen expertise regional network</td>
<td>• Multifunctional regional network incorporating institutional and pathogen specific expertise for the detection of and response to disease outbreaks and other health emergencies</td>
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<td>• Strengthen laboratory linkages to clinical services for improved diagnostic stewardship</td>
<td>• Provide continuous training to healthcare works to improve awareness and understanding of AMR</td>
<td>• Optimized use of diagnostics for clinical management</td>
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<td>• Foster a new cadre of laboratory workforce</td>
<td>• Develop a national strategy for comprehensive laboratory workforce development</td>
<td>• Optimized use of antimicrobial medicines and reduced incidence of AMR</td>
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<td>• Promote the generation, curation, analysis and use of laboratory data for evidence-based public health action</td>
<td>• Conduct a review of laboratory data management systems</td>
<td>• Increased workforce and improved staff retention</td>
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<td>• Link public health laboratories with surveillance and risk assessment</td>
<td>• Provide training to strengthen the roles of laboratories in event-based surveillance</td>
<td>• Rapid detection and reporting of unusual events</td>
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<td>• Implement a comprehensive phased approach to quality management systems using evidence-based tools</td>
<td>• Provide training to strengthen national QMS</td>
<td>• Improved risk assessment</td>
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<td>• Develop plans strengthen quality management in private sector</td>
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<td>• Provide training to increase skilled workforce for quality management and supervision</td>
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<td>• Improved quality testing</td>
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<td>Strategic Objective 4: Promote research and development of and access to new and innovative technologies</td>
<td>Strategic Objective 5: Maintaining and sustaining readiness for public health emergencies</td>
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<td>• Further strengthen biosafety and biosecurity</td>
<td>• Exercises to improve laboratory preparedness and response</td>
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<td>• Provide training on LBM4</td>
<td>• Conduct intra action and after-action reviews of laboratory responses</td>
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<td>• Conduct periodic audits to ensure effective implementation of biosafety and biosecurity protocols</td>
<td>• Develop user-friendly tools to monitor and assess laboratory responses during health emergencies</td>
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<td>• Establish national policies to improve waste management across the national laboratory networks</td>
<td>• Demonstrated utilization of models for improved service delivery</td>
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<td>• Risk-based approach to facility based biosafety risk assessments and improved staff health and well being</td>
<td>• Institutionalized learning and incremental improvements to laboratory responses to health emergencies</td>
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<td>• Establish collaborations and linkages for laboratories and experts for chemical and radiation emergencies</td>
<td>• Optimize laboratory network efficiency and performance</td>
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<tr>
<td>• Establish coordination and communication mechanism between public health laboratory network and chemical and radionuclear networks and experts</td>
<td>• Provide tools and resources for diagnostic network optimization</td>
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<td>• Map existing laboratory assets and capacities at national level, including linkages between laboratories and structures of existing networks</td>
<td>• Optimized resources, improved supply chain management, effective utilization of equipment and improved planning</td>
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<td>• Improved all hazards preparedness and increased access to infrastructure, equipment and workforce during public health emergencies</td>
<td>• Strengthen regulatory processes and frameworks</td>
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<td>• Establish a regional diagnostic advisory group</td>
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<td>• Develop ToRs for the regional advisory group</td>
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<td>• Conduct periodic diagnostic landscapes to provide recommendations for updated testing strategies</td>
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<td>• Establish collaborations with private sector to improve market availability, support quality assured validations and uptake of new technologies</td>
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<td>• Rapid development of reference materials and diagnostic evaluations during health emergencies</td>
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<td>• Increased regional product development and stronger collaboration with academia, public health and industry</td>
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<td>• Timely and appropriate introduction of new diagnostic technology to maximize laboratory performance</td>
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<td>• Promote the development of national and regional biorepositories to facilitate sample sharing for research and development of medical countermeasures</td>
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<td>• Develop criteria for establishing regional biorepositories with linkages to global initiatives such as WHO Biohub system</td>
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<td>• Develop national protocols standardized collection, characterization, and archiving of specimens</td>
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<td>• Develop regional mechanism to facilitate sharing and storage for evaluations</td>
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<td></td>
<td>• Improved availability, quality of diagnostic tests and devices</td>
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<td>• Strengthen regulatory processes and frameworks</td>
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<td>• Establish coordination mechanism between NRAs and PHL</td>
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<td>• Establish protocols for rapid evaluations of IVDs during emergencies</td>
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<td>• Develop protocols for post market surveillance and reporting</td>
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<td>• Reduced systemic challenges, efficient and effective laboratory networks and service delivery</td>
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<td>• Implementation research to identify gaps and challenges and provide solutions for laboratory systems efficiency and effectiveness</td>
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<td>• Develop research agenda to address systemic challenges</td>
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<td>• Develop training on conducting operational research</td>
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<td>• Provide resources to increase regional publications</td>
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<td>• Design processes and tools for the monitoring outcomes and impact of research</td>
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<td>• Exercises to improve laboratory preparedness and response</td>
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</table>
| Strategic Objective 6: Establish a trust architecture for rapid information and sample sharing, access to tools and resources to enable and strengthen pathogen surveillance and sequencing systems | • Establishing a monitoring and evaluation framework for health laboratory services | • Reviewing existing laboratory assessment tools to develop a standardized tool for regional implementation  
  • Establishing regional laboratory performance benchmarks for network functionality and laboratory performance during health emergencies | • Improved benchmarks to monitor networking performance |
| --- | --- | --- | --- |
| | • Strengthening planning, coordination and monitoring | • Developing national action plan to strengthen genomic surveillance  
  • Establishing national coordinating body and technical working groups  
  • Developing Readiness and continuous improvement plans  
  • Developing M&E framework | • Strong national leadership and unified strategy to integrate genomics into public health system |
| | • Enhancing use of appropriate, effective and innovative technical tools and systems | • Enhancing analytics systems to interpret the data at national and regional levels  
  • Optimizing national genomic surveillance objectives and protocols - including sampling approaches  
  • Mapping and monitoring capability and capacity landscape | • Enhanced access to and use of optimized, simple, interoperable and affordable tools and infrastructure |
| | • Enhancing workforce for genomic sequencing and surveillance | • Establishing regional hub for wet lab and bioinformatics capacity-building  
  • Promoting communities of practice to disseminate & share knowledge and good practices  
  • Incorporating in genomics and risk assessment of variants in training programme of field epidemiologists | • Establishment of an enhanced technical workforce that meets country needs to detect, monitor and respond |
| | • Improving information sharing and connectivity | • Establishing data and sample sharing and access principles  
  • Establishing mechanism for regional biorepositories to facilitate rapid sharing of biological materials | • Enhanced information sharing of genomic and metadata and connectivity within and across the countries in the region and globally |
| | • Strengthening risk assessment and decision making for public health action | • Strengthening national capacities for risk assessment to inform decision making  
  • Strengthening tools for risk assessment of variants  
  • Regional mechanism for rapid sharing of information for risk assessments  
  • Catalyzing and supporting operational research in the region | • Enhanced synthesizing of available information for risk-based decision making |
Annex B: Regional Expert Laboratory Network

The Regional Expert Laboratory Network will also serve the function of the expert laboratories within the Regional Genomic Surveillance Consortium (Annex B). The Regional Expert Laboratory Network will consolidate existing technical and institutional expertise across disease networks.

The Diagnostic Advisory Group will work closely and collaborate with the regional network of expert laboratories to establish regional priorities, review the diagnostic technology landscape and engage closely with partners, donors and diagnostics developers.

Fig. 4. Conceptual design of the Regional Expert Laboratory Network
Annex C: WHO South-East Asia Regional Strategic Action Plan for genome surveillance for pathogens of epidemic and pandemic potential 2023–2027

Fig. 5. Conceptual design of Regional Genome Consortium and key areas of prioritization at the national level
References

1. Emergency Risk Profile of the South-East Asia Region [Internet]. New Delhi: World Health Organization. Regional Office for South-East Asia; 2017. Available from: https://apps.who.int/iris/handle/10665/258766


The WHO South-East Asia Regional Roadmap for diagnostic preparedness, integrated laboratory networking and genomic surveillance was developed to provide Member States with a range of policy options for enumerating sustainable strategies to improve their national laboratories and prepare laboratory systems to bolster surveillance and respond more effectively to emerging and re-emerging diseases and other potential public health emergencies.