Regional Roundtable meeting on 'Access to COVID-19 Tools-Accelerator (ACT-A) diagnostics pillar' in the WHO South-East Asia Region

New Delhi, India, 24 August 2021

World Health Organization
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Contents

The ongoing pandemic has disrupted livelihoods, economies and health systems globally. During the first six months of 2021, the WHO South-East (SE) Asia Region has experienced widespread transmission of SARS-CoV-2 virus due to the emerging SARS-CoV-2 variants, especially the Delta variant. The new wave of cases emerging from SARS-CoV-2 variants such as Delta has also led to conspicuous setbacks on the road to achieving success with COVID-19 control measures in several Member States of the Region.

Since January 2020, when the SARS-CoV-2 (COVID-19) virus first emerged, the global diagnostic community has adapted itself despite the existing shortcomings and gaps. Dynamic testing strategies continue to be implemented based on the changing landscape of transmission, ongoing relaxation of public health and social measures (PHSM) and high pandemic fatigue.

Prior to the emergence of the COVID-19 pandemic the South-East Asia Region had limited molecular testing capacity and genomic sequencing capacity. However, since January 2020 the regional molecular testing capacity has increased from five laboratories capable of testing for SARS-CoV-2 to more than 4600 as of August 2021. New diagnostic tools have rapidly been integrated into national testing strategies with 10 Member States implementing rapid antigen tests and seven countries having in-country capacity to carry out genomic sequencing, while an additional three countries have external access to regional referral laboratories. Access to these diagnostics has led to early identification, prompt isolation and more effective treatment of COVID-19 cases. This has likely led to the improved outcomes for COVID-19 patients and reduced the spread of COVID-19 during the first and second waves.

The regional roundtable meeting was held on 24 August 2021, in collaboration with the ACT-Accelerator partners and WHO, to better understand the challenges countries continued to face to scale up testing required to rapidly interrupt transmission of the Delta and other variants. The ACT-Accelerator is a ground-breaking global collaboration to accelerate the development, production and equitable access to COVID-19 tests, treatments and vaccines.[1] Since April 2020, the Diagnostics pillar of the Access to COVID-19 Tools (ACT) Accelerator has enabled WHO and its ACT-Accelerator partners to identify and deliver more than 92.9 million affordable, high-quality diagnostic tests to low- and low-middle-income countries globally, including in the South-East Asia Region.

The objectives of the roundtable were to identify diagnostic barriers and challenges faced in scaling up and sustaining the COVID-19 diagnostics and laboratory capacity. The information gathered during the roundtable will be used to: (i) raise awareness among ACT-Accelerator stakeholders about the gaps and needs, (ii) support resource mobilization efforts, and (iii) maximize opportunities for WHO and partners to rapidly respond to country needs in an agile manner.

[1] *https://www.who.int/initiatives/act-accelerator*

The meeting with ministerial participants from the national public health laboratories and regulatory agencies as well as international partners discussed the challenges, and shared key innovations and lessons learned to strengthen their national laboratory responses. The meeting was facilitated by Professor Stuart Blacksell of the Mahidol Oxford Tropical Medicine Research Unit.

1. Opening address

The WHO Regional Director for South-East Asia, Dr Poonam Khetrapal Singh, reiterated the need for strengthening laboratory capacity as a "core priority" within the overall COVID-19 response in the midst of ongoing waves of transmission and the emergence and spread of new variants of concern. She also stated that in all countries of the Region, dynamic testing strategies continue to be implemented based on the changing landscape of transmission, and in alignment with the 10 pillars of WHO's Strategic Preparedness and Response Plan 2021.

Dr Emma Hannay, Chief Access Officer, Foundation of New and Innovative Diagnostics (FIND), highlighted the growing gap in vaccine rollout, and the need to use the existing toolkits to stop the pandemic, of which laboratory testing is a part. She also highlighted the 90-fold difference in testing between high and low- and middle-income countries, and the need for the ACT-Accelerator diagnostics pillar to refine its strategy based on regular engagement with countries and discussions on their needs.

2. Regional survey

Preparatory events for the regional roundtable included an online survey to gather information on current challenges in scaling up testing, and the expectations of Member States from the international community that could benefit the national responses. The questionnaire *(see Annexure 1)* included areas pertaining to national testing strategies, strategies and challenges in diagnostic response including scaling up of human resources, utilization of other sectors (private, academia, universities etc.), laboratory communication plans, local manufacturing capacity and expectations from the international community to augment the scaling up of testing capacity.

Nominees for the meeting from the relevant ministries of Member States of the Region were invited to complete the survey through the Microsoft Office online survey tool. Having received 18 responses, limitations existed in attributing the outcomes to any country in the Region as the participants were anonymized. Thus, the overall outcomes collectively reflect the responses from the Region.

3. Country experiences and requests

3.1 Nepal

Dr Runa Jah, Director of the National Public Health Laboratory, Kathmandu, described the efforts by Nepal to expand testing laboratories from one national testing laboratory in 2020 to 105 laboratories (96 PCR and 9 GeneXpert) in 2021. The network of laboratories includes both public, veterinary and private sector laboratories. While the acceptance of antigen rapid diagnostic tests (Ag RDTs) was slow by both the government and community health workers, it is being rolled out at the community level. However, PCR remains the main diagnostic platform. The laboratory network design incorporates different use of technologies at various levels; PCR tests are conducted at the national and peripheral laboratories while antigen rapid diagnostic tests (AgRDTs) are used at the community level for contact tracing.

The challenges faced during the stepwise scale-up activity included lack of a skilled workforce, limited biosafety and biosecurity capacities, limited sample transportation logistics due to the travel restrictions, and limited infrastructure. Some of the interventions used to address the challenges included using the Nepalese Army to courier samples across the country, providing training to an increased workforce and developing a national policy that ensured all laboratories were coordinated under a single structure – the national public health laboratory. The national guidance also covered the establishment of new testing facilities including criteria for infrastructure requirements, workflow processes, biosafety and biosecurity. Assessments were conducted before approving facilities to commence molecular testing. A national quality assurance programme was also developed to monitor testing quality across the network.

To increase the availability of human resources (HR) capacity, a week-long training programme was designed to build capacities for molecular testing for 400 persons with varying levels of qualification and experience. These participants were included in a roster to deploy to new laboratories due to the shortage of HR. Training modules included sample collection and sample processing, Personal Protective Equipment (PPE) donning and doffing, waste management, biosafety, and sample testing. The training was adapted to the level of knowledge of participants with students with a Masters level of education receiving training in all modules.

Developing a Trainer-of-Trainer's programme also helped scale up training when the National Public Health Laboratory (NPHL) was overwhelmed with testing. Training modalities included face-to-face and virtual sessions. Weekly meetings were held within the network to address technical issues arising due to testing.

Within the umbrella network of public and private laboratories, all data reporting was also coordinated through the NPHL under a single reporting structure which allowed the NPHL to have information on HR, availability of equipment and reagents, and perform oversight on quality control. Frequent supervisory visits including onsite mentoring were conducted throughout the network.

The challenges currently facing Nepal include support to implement genomic sequencing including establishing bioinformatics capacity. Guidance for the use of various

diagnostic tools such as LAMP and CRISPR was also needed from WHO. It was highlighted that low- and middle-income countries (LMICs) with limited capacities for molecular testing require new diagnostic tools with ease of training and that allows for the monitoring of quality control.

3.2 India

Dr Ravikant Sharma from the Ministry of Health and Family Welfare (MoHFW) of India provided information on how India supported the expansion of the local manufacturing capacities for diagnostic products. The national regulatory authority worked in collaboration with the Indian Council of Medical Research, which provides standardized protocols for test validations.

Through the regulatory body, manufacturers were provided information required for target product profiles. To date, India has 60 manufacturers producing molecular diagnostic kits, more than 34 manufacturers producing Ag RDTs, more than 50 manufacturers producing antibody test kits, and three manufacturers of home-based testing equipment. In addition, there are over 147 registered importers for diagnostic products. All kits and reagents in India are regulated through the Indian Council of Medical Research (ICMR).

Test manufacturers are provided with a licence after an assessment of facilities and processes to ensure good quality practices and ISO standards are adhered to. Post-marketing surveillance is also implemented and products removed and licensing revoked when products fail to perform at the field level. Apart from the regulatory processes and quality monitoring, a procurement system was put in place under the coordination of ICMR to ensure that kits were procured and distributed to the thousands of testing sites in hospitals and laboratories.

The challenges faced by India included monitoring the performance of the kits in wide use throughout the country. Another limitation included allowing new technologies into the country for faster testing and reporting of results. The Indian Government has allowed kits approved by the United States Food and Drug Administration (FDA) and other developed nations to be marketed. A key felt need is for training to monitor effective quality assurance of tests by laboratories.

3.3 Maldives

Dr Ibrahim Afzal, Epidemiologist with the Health Protection Agency of Maldives, made the presentation for the country. The biggest need for Maldives was training to increase the availability of skilled workforce for PCR testing, genomic sequencing and bioinformatics. The lack of laboratory networking in the country to connect national and private laboratories was also described as a challenge. Funding was highlighted as a concern to maintain the capacities built during the pandemic, as well as the lack of a BSL3 laboratory and virus isolation capacities. Lack of experienced human resource capacity was also noted.

3.4 Timor-Leste

At the start of the pandemic, Timor-Leste had no capacity for PCR testing but this has been rapidly expanded and today the country can perform between 1200 and 1500 tests per day using the GeneXpert platforms. Ms Endang, Executive Director of the National Health Laboratory (NHL), described the ToT programme established to train staff and expand PCR testing to eight municipalities. The training included sample collection, packing and transportation, waste management, and pre- and post-analytical testing. The online Gx alert system is also in use and allows the NHL to monitor testing and data quality across the testing laboratories.

The use of Ag RDTs has recently been approved and will be used to test symptomatic persons and health-care workers. Due to the high health-care worker infection rate HR capacity is limited within community health centres, and through prioritized and frequent testing it is expected to maintain service delivery.

3.5 Indonesia

Dr Vivi Setiawaty, Director for Research and Development for Biomedical and Basic Health Technology, highlighted the efforts by Indonesia to expand testing to 830 laboratories in 34 provinces across the archipelago. Testing is done through RT-PCR and GeneXpert platforms. An integrated reporting system was implemented where all data is reported to the national level on a single data reporting platform. Reagents and consumables are provided by the government for public health testing only and not for commercial use.

A genomic sequencing network has also been established. A monitoring and supply distribution system was also put in place as it takes up to 2–3 days to ship supplies to remote regions of the country. The major challenge faced by the country was Internet connectivity for reporting of daily results.

3.6 Thailand

Dr Wanna Hanshaoworakul, Department of Disease Control, Royal Government of Thailand, explained that the National Institute of Health in Thailand provides genomic sequencing for the public health response nationally as well as supporting countries in the Region. The network of laboratories has the capacity for next generation sequencing and molecular testing targeted for the detection of Delta and other variants of concern.

The network of laboratories for sequencing included medical schools with advanced capacities. The sampling strategy includes samples from large clusters, deaths and vaccine breakthrough cases. The challenges experienced include data management and delayed reporting. A request was made for a framework for data management, training and tools.

3.7 Bhutan

An example of leveraging the influenza surveillance data system for COVID-19 was provided by Dr Sonam Wangchuk, Head of the Royal Centre for Disease Control in Bhutan. A

centralized web-based data system was used across all the testing laboratories and has also been adapted to generate QR codes for travel certificates. The centralized database integrated the civil registration data and citizen identification number, which allowed for easy importation of data and reporting of results. Bhutan also leveraged the national early warning system with the community when mass testing was in progress.

4. Concluding remarks

Dr Sebastien Cognat, Unit Head of Public Health Laboratory Strengthening in WHO headquarters, summarized the following key discussion points:

- Frequent adaptation is required of global guidance and recommendations to the local contexts.
- Greater capacity is needed to validate and regulate new diagnostic assays coming to the market.
- Greater effort is needed to support workforce development, data management, genomic sequencing and bioinformatics capacity.
- Advocacy and communication materials are needed to address testing hesitancy for Ag RDTs.

He also added that the roundtable discussion outcomes will be used to adjust and improve budgeting and workplans for WHO and ACT Accelerator partners to support the Region.

5. Recommendations for support

The discussions highlighted several key areas where additional support was required from the international community including:

- improving training methodology to rapidly scale up the workforce;
- supporting local production and validation of diagnostic tools;
- strengthening supply chain systems within the national settings;
- improving data management systems;
- providing support to implement genomic sequencing for SARS-CoV-2 variants;
- sustaining the expanded diagnostic capacities as well as the need to address the dynamics of the current wave and potential future pandemics.

The outcomes of the meeting have reiterated the need for ACT Accelerator partners to mobilize additional resources to ensure equitable access to COVID-19 diagnostic testing across the Region.

Annex 1

Results of the survey; (n = number of responses)

National testing strategies

About 94% of the responses (n = 17) indicated that the national testing strategies are available and adapted according to changes in the epidemiological situation, resources and tools, and towards country-specific contexts. One response (6%) mentioned that the strategy is currently under revision.

Antigen RDTs are currently used in the following settings (listed in descending order based on the number of responses):

- for symptomatic suspect cases including contact tracing (n = 15);
- community screening (n = 9);
- routine health worker screening (n = 9);
- hospital settings (n = 8);
- to confirm localized outbreaks (n = 7);
- schools and workplaces (n = 5);
- ports of entry (airports, seaports, land borders) (n=5); and
- prisons (5).

Scaling up laboratory response (including workforce)

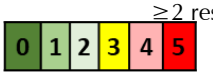
The participants were asked to quantify the challenges on a scale of 0 ("No challenge") to 5 ("Significantly highly challenged") across different areas of laboratory response as indicated in Table 1. Human resource and data management including HR has been flagged as significantly highly challenged (with over 15 responses indicating ≥3 on the requested quantification scale).

Table 1. ***Challenges to scale the national laboratory response***

Area/gaps in scale/number of responses	**0**	**1**	**2**	**3**	**4**	**5**
Human resource	0	1	2	6	5	**4**
Equipment	1	1	5	7	3	1
Data management including HR	0	1	1	4	6	**6**
Reagents and consumables	1	1	4	5	6	1
PPE	1	6	5	5	1	0
Funding	2	2	3	3	3	**5**
Validation and certification of diagnostic kits	2	1	5	4	6	0
Monitoring quality management	1	2	3	7	2	**3**
Biosafety measures	2	3	3	5	5	0
Leveraging national laboratory Networks	0	4	4	5	5	0
Sample transportation systems	1	5	2	8	1	0

0 = "No challenge" & 5 = "Significantly highly challenged"

Colour codes - - ≥2 responses have been indicated in respective colour codes



Scaling up the workforce: Specific challenges highlighted to rapid scaling up of the workforce as mentioned were the limited availability of trainers of trainers (n = 8), funding (n = 5), limited training materials (n = 1), policy-related challenges (n = 1), lack of in-country capacity (n = 1) fear and hesitancy among the workforce over laboratory-acquired infection of SARS-CoV-2 (n = 1) and mobilization of paramedical staff from other laboratories (n = 1). More virtual trainings (n = 9), hands-on training (n = 5), webinars (n = 4) and supportive supervision (n = 3) were identified to be the modalities of training that have contributed towards rapid development of a skilled workforce (across sample collection, transportation, testing and data management areas).

Leveraging other sectors (e.g. academia, animal health, etc.): This was considered to be a significant intervention to increase diagnostic testing capacity (72% positive responses), with 83% of respondents indicating the inclusion of private sector testing laboratories in the national response. However, implementing quality control and monitoring (n = 8), result reporting and data sharing (n = 5) and funding requirements to support testing (n = 1) were flagged as the critical challenges experienced while working with private sector laboratories.

Strategic Interventions: The following areas were observed to be optimized across national laboratory/disease networks to effectively address changing diagnostic demands; appropriate testing locations were identified (n = 13), Integrated data reporting systems were put in place (n = 12), leveraging of the workforce across disease networks and sectors was carried out (n = 11), as well as integrated specimen referral (n = 10), optimized network linkage referrals (n = 10), optimal mix of instruments (n = 9) and leveraged quality management systems (n = 9).

Diagnostic communication plan: About 35% of responses indicated the availability of a diagnostic communication plan to reduce misinformation and testing hesitancy, particularly in interpreting discordant results, and to improve knowledge and capacity for contact tracing. However, a large number of responses (53%) revealed that the respondents were not sure of the availability of the diagnostic communication plan and 12% indicated that it was not available.

Genomic surveillance: The following were the current gaps that challenge the implementation of genomic surveillance for variants:

- reagents and consumables (n = 13)
- human resources (n = 14)
- funding (n = 11)
- bioinformatics support (n = 11)
- equipment (n = 11)
- training (n = 6)
- SOPS and protocols (n = 4).

Post-pandemic planning: Most of the participants (44%; n = 8) were not sure about the development of a post-pandemic plan for the utilization of laboratory capacities built during the pandemic (e.g. post-pandemic contingency planning, national laboratory policy, etc.). However, 39% (n = 7) indicated the availability or development of such plans.

Local manufacturing: Promoting or supporting local manufacturing of diagnostics has been observed to be significantly accommodated (indicated by 55% of the responses) in the national policy agenda, while 28% (n = 5) did not have relevant knowledge in this area. Not surprisingly, 72% expressed interest in learning more about promoting or supporting local manufacturing of diagnostics.

Expectations from the international community: The following were the key support mechanisms expected from the international community that could benefit the country's diagnostic capacity for SARS-CoV-2:

- funding, human resources and training;
- strengthening of sustainable genomic/gene sequencing and bioinformatic capacity;
- funding/technical support for establishing more laboratories;
- strengthening laboratory networking: quick and easy technology transfer, exchange visits;
- newer point-of-care testing platforms, multiplex kits;
- minimum essential standards for COVID-19 Invitro diagnostics;
- sharing of regulatory approval data by NRAs (approved/not approved);

- supporting local manufacturing of diagnostic reagents and consumables;
- quality assurance and sharing of the standardized testing panels and samples;
- information sharing, data analysis and disease modelling;
- use of artificial intelligence in health care; and
- integrated data management systems.

Annex 2

Agenda

- Welcome remarks by Dr Jos Vandelaer, Regional Emergency Director, SEARO
- Inaugural address by Dr Poonam Khetrapal Singh, Regional Director, WHO South-East Asia Region
- Remarks by ACT-A diagnostics Co-leads (FIND)

Session 1:

- Meeting Objectives
- Presentation of the survey results (Mr Francis Inbanathan, SEARO)

Session 2:

- Facilitated discussions based on survey outcomes (HQ and Regional Office)

Session 3:

- Summarizing key outcomes (HQ and Regional Office)

Closing remarks by Dr Jos Vandelaer

Annex 3

List of participants

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The Access to COVID-19 Tools (ACT) Accelerator is a ground-breaking global collaboration to accelerate development, production and equitable access to COVID-19 tests, treatments and vaccines. Launched in April 2020, the ACT Accelerator brings together governments, scientists, businesses, civil society, philanthropists and global health organizations.

To better understand the challenges faced in scaling up testing required for rapidly interrupting transmission of the emerging variants of the SARS CoV-2 coronavirus, the WHO Regional Office for South-East Asia in collaboration with the ACT-Accelerator partners organized a regional roundtable with policy-makers, experts from national public health laboratories and the ministries of health, as well as international partners. This report describes the proceedings, outcomes and recommendations of the roundtable.

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