

Thirteenth Meeting of the WHO South-East Asia Regional Immunization Technical Advisory Group (SEAR ITAG)

New Delhi, India, 17–19 August 2022

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Acronyms and abbreviations

AEFI	adverse event following immunization
AES	acute encephalitis syndrome
AFP	acute flaccid paralysis
BeSD	behavioural and social determinant
cMYP	comprehensive multiyear plan
COVAX Facility	COVID-19 Global Vaccine Access Facility
CoWin	winning over COVID-19; a digital vaccination registration platform
CRS	congenital rubella syndrome
cVDPV	circulating vaccine-derived poliovirus
DPR Korea	Democratic People's Republic of Korea
DQA	data quality assessment
DTP	diphtheria-tetanus-pertussis vaccine
EPI	Expanded Programme on Immunization
ES	environmental surveillance
EUA	emergency use authorization
GAP	Global Action Plan
GAT	gender assessment tool
Gavi	Gavi, the Vaccine Alliance
HepB	hepatitis B vaccine
HepB-BD	hepatitis B vaccine-birth dose
Hib	Haemophilus influenzae type b
HPV	human papilloma virus
IBD	invasive bacterial disease
IPC	infection prevention and control

IPV	inactivated poliovirus vaccine
ITAG	Immunization Technical Advisory Group
JE	Japanese encephalitis
JEV	Japanese encephalitis vaccine
JRF	Joint Reporting Form
MCV	measles-containing vaccine
ME&A	monitoring evaluation and action cycle
MNCH	maternal newborn and child health
MNTE	maternal and neonatal tetanus elimination
MoH	ministry of health
MR	measles–rubella
MRCV	measles–rubella-containing vaccine
NIP	national immunization programme
NITAG	national immunization technical advisory group
NPSN	national public health support programme
NRA	national regulatory authority
OPV	oral poliovirus vaccine
PCV	pneumococcal conjugate vaccine
PEF	poliovirus-essential facilities
PHC	primary health care
PIE	post-introduction evaluation
PVA	post-validation assessment
Q	Quarter
QMS	quality management system
RC	Regional Committee
RCCPE	Regional Certification Commission for Polio Eradication
RCV	rubella-containing vaccine
RI	routine immunization
RVAP	Regional Vaccine Action Plan

RVIP	Regional Vaccine Implementation Plan
RVV	rotavirus vaccine
SAGE	Strategic Advisory Group of Experts on Immunization
SBA	skilled birth attendant
SEAR-ITAG	South-East Asia Regional Immunization Technical Advisory Group
RVC	Regional Verification Commission for Measles and Rubella Elimination
SIAs	supplementary immunization activities
SIV	seasonal influenza vaccine
SP	strategic priority
TCV	Typhoid conjugate vaccine
Td	Tetanus and diphtheria toxoids vaccine
TT	tetanus toxoid
TT2+	more than two doses of vaccine containing tetanus toxoid
UHC	universal health care
UNICEF	United Nations Children's Fund
US CDC	United States Centers for Disease Control and Prevention
VDPV	vaccine-derived poliovirus
VPD	vaccine-preventable disease
WHO	World Health Organization
WPV	wild polio virus

Introduction

The 13th meeting of the World Health Organization's (WHO's) South-East Asia Regional Immunization Technical Advisory Group (SEAR-ITAG) was held in 17–19 August 2022 in New Delhi, India. The ITAG is a regional technical expert group established by the WHO Regional Director for South-East Asia to provide advice on all aspects of immunization, vaccines, and the prevention, control, elimination, and eradication of vaccine-preventable diseases (VPDs). It comprises experts from such disciplines as programme management, communicable disease and VPD control, virology, epidemiology, immunization and behavioural sciences. The managers of the national Expanded Programme on Immunization (EPI), national surveillance focal points, representatives of national immunization technical advisory groups (NITAGs) and partner agencies participate in the ITAG's annual meeting.

The SEAR-ITAG meets at least once a year as well as on an ad hoc basis to provide guidance to the immunization programme, with a particular focus on:

- ◉ setting regional priorities for immunization and vaccines;
- ◉ reviewing Regional and Member States' policies, strategies and plans for the control, elimination and/or eradication of VPDs, in particular, the eradication of polio, elimination of measles and rubella, elimination of maternal and neonatal tetanus, and acceleration of the control of hepatitis B;
- ◉ making recommendations on the framework for the development of national immunization policies, and on the operational aspects of the implementation of these policies;
- ◉ recommending a framework for and approaches to the periodic evaluation and strengthening of routine immunization (RI) services and systems;

- ⦿ advising Member States on the choice of new vaccines and optimal strategies, and providing technical guidance on the introduction of these vaccines and on monitoring and evaluating their impact after their introduction into national immunization programmes (NIPs);
- ⦿ promoting and providing technical guidance on the implementation of high-quality VPD surveillance, and on setting up high-quality laboratory networks to support VPD surveillance;
- ⦿ advising Member States on the regulatory requirements for ensuring the quality and safety of the vaccines used in NIPs;
- ⦿ providing guidance on public–private partnerships in immunization and vaccines; and
- ⦿ identifying research topics in the area of immunization and vaccines and reviewing the conduct and results of such research projects.

Objectives of the meeting

The objectives of the meeting were to:

- ⦿ review the status/progress of the NIPS, especially in the context of the impact of the COVID-19 pandemic, and the actions taken to revive the immunization programme and surveillance for VPDs;
- ⦿ review the progress/challenges in the deployment of COVID-19 vaccines in the countries of the Region;
- ⦿ review the status of implementation of the recommendations of the 12th meeting of the SEAR-ITAG conducted in August 2021; and
- ⦿ finalize the Regional Vaccine Implementation Plan (RVIP) 2022–2026 under the Strategic Framework for the Regional Vaccine Action Plan (RVAP) 2022–2030.

Organization of the meeting

The deliberations were focused on the thematic areas under the three impact goals of the Strategic Framework for the RVAP 2022–2030, mentioned below.

- ◉ Reducing overall mortality and morbidity from VPDs across the life course
 - by strengthening routine immunization systems.
- ◉ Pursuing VPD elimination/control goals of
 - elimination of measles and rubella;
 - polio eradication and polio transition;
 - other VPDs with elimination/control targets.
- ◉ Leaving no one behind by increasing equitable access to and use of new and existing vaccines:
 - introducing new and underutilized vaccines; and
 - deploying COVID-19 vaccines.

The ITAG also reviewed the draft RVIP 2022–2026 and the related monitoring and evaluation framework.

Informational sessions were organized on some new vaccines, such as respiratory syncytial virus vaccine, meningitis vaccine, malaria vaccine and monkeypox vaccine.

The meeting began with the opening remarks of Dr Poonam Khetrpal Singh, Regional Director for South-East Asia that were delivered by Dr Pem Namgyal, Director Programme Management, Regional Office (Annex 1).

This was followed by remarks by Shri Rajesh Bhushan, Secretary, Health and Family Welfare, Government of India. Shri Bhushan emphasized the need for greater enthusiasm, innovation, efficiency, timely action and cutting-edge technologies to achieve better results in the area of immunization. Dr Alejandro Craviato, Chair, Strategic Advisory Group of Experts on Immunization (SAGE) commended the work done in the Region and stressed on evidence-based planning and programming to mitigate the impact of the COVID-19 pandemic on immunization activities. He also spoke about the importance of implementing the SAGE recommendations.

The technical session of the meeting was chaired by Professor Gagandeep Kang and attended by the ITAG members. The other participants of the meeting included:

- ◉ chairs of the NITAGs
- ◉ national focal persons for immunization and VPD surveillance of the ministries of health (MoH), WHO and UNICEF from the countries in the Region
- ◉ chair of SAGE and its members from countries of the Region
- ◉ chairs of regional certification/verification bodies for polio eradication and measles elimination
- ◉ representatives from the headquarters and regional offices of WHO and UNICEF
- ◉ representatives of partners and donors, including Gavi, US-CDC, USAID and Rotary International
- ◉ vaccine manufacturers and regulators.

(Please see Annex 4 for the list of participants.)

The reports submitted by the NITAGs on the performance of the programme in the countries were discussed in closed-door sessions. These were incorporated in the conclusions and recommendations of the advisory group.

The code of conduct (to prevent harassment, including sexual harassment) to be followed at WHO events was shared with all the participants prior to the meeting.

Methodology for the review of NITAG reports

- ⦿ A template tailored to the countries was prepared for reporting on the impact of COVID-19 on immunization and VPD surveillance, as well as the actions taken by countries to improve/maintain immunization coverage and VPD surveillance. The template included reporting on the progress and challenges related to the roll-out of vaccines and the scaling up of vaccination in the countries.
- ⦿ The template was pre-populated with the data available with the Regional Office and shared with all NITAGs in the Region eight weeks prior to the ITAG meeting.
- ⦿ Nine NITAGS submitted reports, based on the template mentioned above, to the ITAG (through the Regional Office) prior to the meeting. The Democratic People's Republic (DPR) of Korea and Myanmar did not submit reports.
- ⦿ Two ITAG members were assigned the task of reviewing one country's NITAG report (please see Annex 3 for the list of reviewers). They were provided with a checklist for guidance.

Progress towards the achievement of impact goals

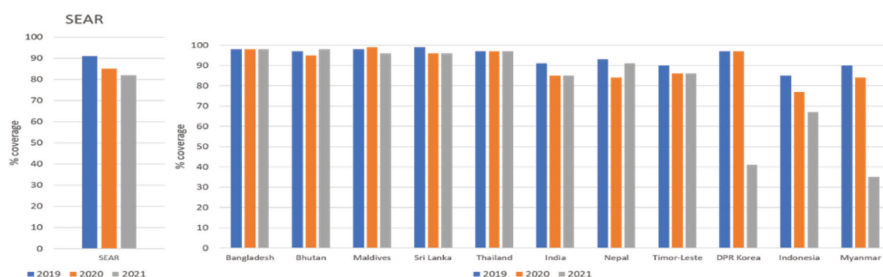
A. Reducing overall mortality and morbidity from VPDs across the life course

Strengthening routine immunization systems

Strengthening immunization systems and services with the objective of improving RI coverage has been the overarching priority for the elimination, eradication, and control of VPDs in the WHO South-East Asia Region. Concerted efforts have been made by all countries and plans for improving RI have been incorporated in comprehensive multi-year plans for immunization.

The overall coverage with three doses of diphtheria–tetanus–pertussis vaccines (DTP3) increased from 83% in 2010 to 91% in 2019. Ten countries achieved $\geq 90\%$ coverage, with India reaching 91% coverage with three doses of the pentavalent vaccine (DTP, hepatitis B and Haemophilus influenzae type b or DTP-HepB-Hib). Indonesia had 85% of DTP3 coverage. The coverage with the first and second doses of the measles- and rubella-containing vaccine (MRCV1 and MRCV2) also increased rapidly.

Despite the efforts made by the countries to sustain RI coverage during the COVID-19 pandemic, the pandemic-associated disruptions and the COVID-19 vaccination efforts strained the health and immunization delivery systems in 2020 and 2021. Thus, the regional DTP3 coverage decreased from 91% in 2019 to 85% in 2020 and 82% in 2021. The number of children who did not receive the first dose of DTP vaccine (“zero-dose children”) increased from 2 million in 2019 to 4.6 million in 2021.

Fig. 1. DTP3 coverage in the South-East Asia Region, 2019–2021

Source: WHO/UNICEF Estimates of National Immunization Coverage, July 2022

More than 2 billion doses of COVID-19 vaccine injections were administered in 2021, amounting to an additional 313% doses of injectable vaccines provided in 2021 in comparison to 2019. Excluding DPR Korea, where COVID-19 vaccine has not been introduced, the increase in injectable vaccine injections administered in 2021 in comparison to 2019, varied from 143% in Timor-Leste to 1499% in Thailand.

On the basis of the DTP3 coverage, the number of zero-dose children, and district-level variability in coverage in 2020 and 2021, the countries in the Region can be divided into the following three groups.

a. Countries that maintained high DTP3 coverage (Bangladesh, Bhutan, Maldives Sri Lanka, and Thailand)

There was a decline in immunization achievements in these countries in the first half of 2020. However, the catch-up immunization activities conducted during the second half of the year and the first half of 2021, brought the overall number of children vaccinated to the 2019 level. Variability in coverage at sub national level has been less marked in these countries.

b. Countries that faced a decline in DTP3 coverage in 2020 but stabilized/ showed recovery trends in 2021 (India, Nepal and Timor-Leste)

Following a reduction in the number of children vaccinated in the second quarter of 2020, immunization activities were revitalized in these countries from the third quarter onwards. India conducted catch -up immunization activities after each COVID-19 wave. Three to four rounds of catch-up immunization activities were conducted each year (Mission Indradhanush). District-level

coverage declined in 2020 but started to recover in 2021. Monthly coverage at subnational levels was monitored and action was taken to improve the coverage. Consequently, more children received DTP3 vaccine in the first six months of 2022, compared to the same period in 2019, 2020 or 2021. DTP3 coverage declined in Nepal in 2020, however the monthly district coverage showed improving trends in 2021, following a slight dip during the second quarter of 2021. There was variability in coverage at the subnational level in all the three countries.

c. Countries with continued decline in DTP3 coverage: (DPR Korea, Indonesia, and Myanmar)

These countries showed a continued decline in coverage until 2021. The number of zero-dose children continued to increase from 2019 to 2022. District-level coverage also decreased from 2019. In DPR Korea, immunization was halted since July 2021 because vaccines were not available due to a complete closure of the border. Indonesia conducted the first phase of the National Childhood Immunization Month (referred to as BIAN in Indonesia) from June to July 2022. The aim of the drive was to provide children with measles–rubella (MR) vaccines, and to provide catch-up pentavalent vaccine, inactivated poliovirus vaccine (IPV) and oral poliovirus vaccine (OPV) to children who had missed their doses, in 23 out of 31 provinces. However, these catch-up activities have not shown the expected results and there were issues related to vaccine supply. The second phase of BIAN started in August 2022 in the remaining eight provinces. In Myanmar, there was good recovery in the second half of 2020, but a decline set in since the beginning of 2021.

Bangladesh: Bangladesh shared the lessons learnt on maintaining RI during the pandemic. The country assessed the impact of the pandemic on RI systematically and drew up revised microplans to conduct catch-up activities at all levels on the basis of the assessment. It used the World Immunization Week (WIW) in 2021 to vaccinate 88 000 zero-dose children and almost a million partially vaccinated children. The next year, it identified and vaccinated more than 490 000 zero-dose children and around 35 000 partially vaccinated children during WIW. It framed guidelines to conduct RI sessions during the pandemic, conducted data-driven monitoring and supervision of immunization activities, imparted IPC training to all vaccinators, maintained an uninterrupted supply chain and developed social and behaviour change communication. These initiatives were made possible by the commitment shown at the highest level of the government.

Indonesia: Indonesia presented the challenges it faced in conducting RI activities and the efforts it made to close the immunity gap. Of the annual birth cohort of 4.4 million, approximately one million missed RI during the pandemic. The coverage of DTP3 ranged from 42% to 100% across the districts. Several actions were taken to close the immunity gap created during pandemic as well as the gaps that existed before the pandemic. A multiantigen catch-up campaign called “National Childhood Immunization Month (BIAN)” was launched in May 2022 and conducted in two phases. The second phase was ongoing at the time this report was written. More than 16 million children have received the measles- and rubella-containing vaccine during the campaign. However, the coverage of the other antigens has not been optimal, and efforts are being made to improve the situation. The other efforts made to revitalize the RI programme were:

- ⦿ revitalizing posyandu (outreach clinics) through the training of cadre on demand generation and target mobilization and strengthened collaboration with sectors related to the Ministry of villages, development of disadvantaged regions, and transmigration; as well as the Ministry of home affairs;
- ⦿ improving the capacity of health workers on focused microplanning, local area monitoring, multiple injections, and defaulter tracking by training mid-level managers in all districts and holding regular workshops at health centres;
- ⦿ digitalizing home-based records and reporting through a new electronic immunization registry called ASIK;
- ⦿ enhancing monitoring and evaluation activities, including biweekly desk reviews and providing feedback
- ⦿ strengthening school-based immunization and initiated checking of immunization status at school entry; and
- ⦿ Strengthening the commitment of the local government through advocacy and implementation of minimum service standard with immunization as a key indicator.

VPD surveillance

All countries in the Region conduct VPD surveillance. However, the systems suffer from fragmentation across various platforms such as notifiable disease surveillance and early warning reporting systems supported by the respective

departments in the ministries of health, national case-based surveillance (extensively supported by WHO in several countries), and sentinel site surveillance (mostly supported by academia and research institutes). The current situation of priority VPD surveillance is shown in Fig. 2.

Fig. 2. Situation of VPD surveillance in the Region, 2022

Country	Polio	MR	CRS	NNT	Diphtheria	Pertussis	JE/AES	Rota	IBD	Typhoid
Bangladesh	Nationwide case-based	Nationwide case-based	Nationwide case-based	Nationwide aggregated	Sentinel, case-based with laboratory confirmation of every case	Nationwide aggregated	Nationwide case-based	Nationwide case-based	Nationwide case-based	
Bhutan	Nationwide case-based	Nationwide case-based	Nationwide case-based	Nationwide aggregated	Nationwide aggregated	Nationwide aggregated	Nationwide case-based	Nationwide case-based		
DPR Korea	Nationwide case-based	Nationwide case-based	Nationwide case-based	Nationwide aggregated	Nationwide aggregated	Nationwide aggregated		Nationwide case-based		
India	Nationwide case-based	Nationwide case-based	Nationwide case-based	Nationwide aggregated	Nationwide aggregated	Nationwide aggregated	Nationwide case-based	Nationwide case-based	Nationwide case-based	Nationwide case-based
Indonesia	Nationwide case-based	Nationwide case-based	Nationwide case-based	Nationwide aggregated	Nationwide aggregated	Nationwide aggregated	Nationwide case-based	Nationwide case-based		
Maldives	Nationwide case-based	Nationwide case-based	Nationwide case-based	Nationwide aggregated	Nationwide aggregated	Nationwide aggregated				
Myanmar	Nationwide case-based	Nationwide case-based	Nationwide case-based	Nationwide aggregated	Nationwide aggregated	Sentinel, case-based with laboratory confirmation of every case	Nationwide case-based	Nationwide case-based		
Nepal	Nationwide case-based	Nationwide case-based	Nationwide case-based	Nationwide aggregated	Sentinel, case-based with laboratory confirmation of every case	Nationwide aggregated	Nationwide case-based	Nationwide case-based	Nationwide case-based	
Sri Lanka	Nationwide case-based	Nationwide case-based	Nationwide case-based	Nationwide aggregated	Nationwide aggregated	Nationwide aggregated	Nationwide case-based	Nationwide case-based	Nationwide case-based	Nationwide aggregated
Thailand	Nationwide case-based	Nationwide case-based	Nationwide case-based	Nationwide aggregated	Nationwide aggregated	Nationwide aggregated	Nationwide case-based	Nationwide case-based	Nationwide case-based	
Timor-Leste	Nationwide case-based	Nationwide case-based	Nationwide case-based	Sentinel, case-based with laboratory confirmation of every case	Sentinel, case-based with laboratory confirmation of every case	Sentinel, case-based with laboratory confirmation of every case	Nationwide case-based	Nationwide case-based	Nationwide case-based	

Nationwide lab supported case-based ■ Nationwide case-based ■ Nationwide aggregated ■ Sentinel, case-based with laboratory confirmation of every case ■

WHO-SEARO had developed regional VPD surveillance guidelines in 2016 to support countries in establishing and/or expanding VPD surveillance. The 2016 version of the regional VPD surveillance guidelines has been updated in 2022. The fourth regional workshop to review progress in measles–rubella and other priority VPD surveillance and outbreak preparedness and response was conducted in Dhaka, Bangladesh, on 13–16 June 2022. It identified a number of issues and recommended some critical actions to be taken to strengthen VPD surveillance in the countries and the Region.

Initiatives to improve data quality

Monthly reporting of the number of children vaccinated in the EPI was initiated from the onset of the COVID-19 pandemic. The Regional Office provided regular feedback to the countries. All countries now report immunization data from the subnational to the national level and from the national to the regional level on a monthly/quarterly basis. However, the timeliness and completeness of data vary. A systematic review of the submission of the first electronic Joint Reporting Form (e-JRF) from 2021 was conducted, and the Regional Office and headquarters provided feedback to improve the data quality. Data quality trainings were conducted and data quality improvement plans made in some countries.

Immunization Supply chain and logistics

Close to 1.24 billion doses of vaccines were procured for RI in 2021, according to the e-JRF reports of 2022. There was a manifold increase in national and subnational cold chain capacities in the countries, including the installation of ultracold chain equipment to accommodate COVID-19 vaccines. The digitalization of immunization supply chain information, including the rapid introduction of the electronic logistic management information system (eLMIS) in India and Indonesia has been helpful. Seven of the 11 countries are using electronic vaccine stock management systems. Effective vaccine management (EVM) initiative continues to be implemented as the backbone of vaccine management, monitoring and continuous improvement planning. Six EVM assessments were conducted during the COVID-19 crisis, and another six are planned for 2022–2023.

Demand generation

Certain priorities have been identified to help the countries recover from the disruptions related to the COVID-19 pandemic, accelerate equitable immunization coverage, and support the delivery of COVID-19 vaccines (outlined in UNICEF's Immunization Roadmap 2018–2030). These priorities are:

- ⦿ building resilience by facilitating catch-up vaccination through RI;
- ⦿ reimagining immunization programmes to strengthen their equity focus and rebuilding trust in the health system;
- ⦿ using zero-dose agenda to drive wider integration and alignment for primary health care;
- ⦿ Using a multisectoral approach to reach zero-dose communities with an integrated package of services; and
- ⦿ engaging with health and non-health programmes and stakeholders.

Activities related to generating demand must focus on imparting knowledge, raising awareness, preventing gender biases and cultural norms. They must garner support from the community, and dispel rumours/misinformation regarding the side-effects, safety and efficacy of vaccines. Efforts need to be made beyond the commonly implemented demand-side activities to work on the supply-side of immunization, including improving access and quality of service. Using a health system strengthening approach, increased focus is needed on; vaccine supply and its availability, distances and available transport,

waiting time and service hours, cost and poverty, occupation and related seasonal and daily low outreach, any possible mistrust, and other needs and priorities.

Technical support has been provided to Member States to integrate behavioural and social drivers of immunization (BeSD) quantitative surveys and qualitative interview guides to generate evidence to gain a better understanding of the barriers to and enablers of immunization. Data collection has been completed in a UNICEF/APRO-led research study in Indonesia focussing on perceptions of COVID-19 vaccination and impact of the pandemic on routine immunization and other maternal and child health services.

Countries have undertaken a wide range of demand generation activities for routine immunization and COVID 19 vaccination in the past year. These include risk Communication and Community Engagement (RCCE) strategies, and capacity building activities. Capacity building includes the launch and implementation of a regional workshop on the newly released WHO/UNICEF guidance on Human Centred Design for Tailoring Immunization Programmes (HCD-TIP). Further support had been provided on systems strengthening for community engagement and social listening, proactive resource mobilization for RCCE/Social & Behaviour Change interventions that reduced funding gaps. Countries have acknowledged the sub national differences and planned to focus on local evidence generation using community participatory methods for demand management.

Surveillance for adverse events following immunization

Before the COVID-19 pandemic, all the countries in the Region had made substantial progress towards building capacity for the surveillance of the safety of vaccines under the EPI. All of them had established national monitoring systems and set up review committees for adverse events following immunization (AEFI). They had expanded their national AEFI committees to include relevant specialists, such as physicians, cardiologists, respiratory physicians, obstetricians, and endocrinologists. Since the roll-out of COVID-19 vaccination in January 2021, nine Member States (except DPR Korea and Myanmar) have reported 11, 186 serious AEFIs and 278, 412 non serious AEFIs leading to a cumulative total of 289 598 serious and non-serious AEFIs. This represents a total AEFI reporting rate of 9.64 per 100 000 COVID-19 vaccine doses and a serious AEFI reporting rate of 0.37 per 100 000 doses of COVID-19 vaccine doses administered as of 08 August 2022.

Strengthening capacity for vaccines regulation

There are great differences between the countries as regards the production of vaccines and the functioning of the national regulatory authorities (NRAs). Four of the countries have large vaccine manufacturing capacities, while two have global suppliers with multiple products that are prequalified by WHO. Three of the NRAs are at maturity level-3 as per the WHO global benchmarking tool (GBT) that takes into account nine mandatory NRA functions. The COVID-19 pandemic brought additional challenges by way of expediting marketing authorization, reliance and regulatory agility. Several regulatory preparedness exercises and capacity-building activities were conducted between 2020–2022 for NRAs across the Region. These included workshops/webinars for vaccine regulators and manufacturers on vaccine introduction and deployment, safety surveillance, expediting the regulatory pathway for the approval of imported vaccines and converting Emergency Use Authorizations (EUAs) into full license through the WHO's Emergency Use Listing (EUL) system. Some other related activities included:

- ⦿ the signing of confidentiality agreements between NRAs and WHO for access to technical documents for vaccines with EUL;
- ⦿ expediting harmonized marketing authorization procedures with harmonized quality management systems (QMS) and enhanced standard operating procedures (SOPs);
- ⦿ redrafting the Institutional Development Plan (IDP) for Member States in the light of the experience gained during the pandemic,
- ⦿ strengthening the South-East Asia Regulatory Network (SEARN) through annual meetings of the heads of NRAs,
- ⦿ drafting novel tools and a framework for the monitoring and evaluation of activities aimed at strengthening the regulatory system in the Region; and
- ⦿ advocacy and sensitization workshops on WHO's collaborative registration procedure for fast-track marketing authorization of prequalified vaccines, medicines and diagnostics.

The key challenges are shortage and over-occupancy of NRA staff due to the pandemic, limited public–private partnership opportunities for the development of new vaccines and for establishing agile and efficient manufacturing units, and shortage of trained human resources for vaccine regulation and vaccine manufacturing.

B. Pursuing VPD elimination/control goals

Measles and rubella elimination

The Seventy-second session of the WHO Regional Committee for South-East Asia endorsed resolution SEA/RC72/R3 in September 2019, in which Member States of the Region adopted the revised goal of measles and rubella elimination by 2023. The previous goal set in 2013 was “measles elimination and rubella/CRS control by 2020”.

Measles and rubella elimination by 2023 is one of the Flagship Priority Programmes of the Region. To ensure adequate technical guidance to accelerate progress towards the goal, a “Strategic Plan for Measles and Rubella Elimination” in the WHO South-East Asia Region 2020–2024 was developed. Significant progress has been made in the Region towards measles and rubella elimination since 2014. Five countries – Bhutan, DPR Korea, Maldives, Sri Lanka and Timor-Leste – have been verified to have achieved measles elimination while rubella elimination has been verified in two countries – Maldives and Sri Lanka. Three countries have remained free of endemic rubella transmission for more than 12 months (Bhutan, DPR Korea, Timor-Leste) but are yet to be verified.

The Region has around 1925 implementation units (IU) of which 319 IUs (17%) have reported zero incidence of measles in 2021 in the presence of well-performing surveillance systems (defined as non-measles non-rubella discard rate of 2 or more per 100 000 population). Similarly, 477 IUs (25%) with high surveillance performance have reported zero incidence of rubella.

The annual reported incidence of measles decreased by 79% between 2014 and 2020 (from 23.4 to 4.8 cases per million population). The reported incidence of rubella declined from 5.1 cases per million population in 2014 to 0.8 cases per million in 2020. Coverage of MRCV1 in the Region increased from 66% in 2003, to 87% in 2014, and 94% in 2019. It then declined to 88% in 2020 and 86% in 2021 due to the COVID-19 pandemic. A similar trend was observed in the case of MRCV2 coverage in the Region. It declined from 83% in 2019 to 80% in 2020 and 78% in 2021. More than 619 million persons received MR-containing vaccines through supplementary immunization activities (SIAs) between 2014 and 2021.

The non-measles non-rubella discard rate, which is a proxy to the sensitivity of surveillance for measles and rubella, has never reached the target of 2 or more per 100 000 population in the Region. In fact, there has been a decline in the rate from 1.68 in 2019 to 1.52 in 2021, despite the initiation of a more sensitive

syndromic definition of “acute fever and maculopapular rash” in all countries of the Region. Out of the 1925 IUs in the Region, 1071 (56%) have reported a non-measles non-rubella discard rate of more than 2 per 100 000 population. An outbreak readiness assessment, using the WHO outbreak preparedness checklist, was conducted in 5 countries of the Region. It showed that there was a need for such assessment to be conducted regularly and ensure more than 95% readiness, something that has not been observed in any of the countries yet.

All countries have at least one proficient measles–rubella laboratory to support the surveillance programme. The measles–rubella laboratory network has expanded from 23 laboratories in 2013 to 58 in 2021. This includes a major expansion in India. Of the 58 laboratories, two subnational laboratories in Indonesia and one in Myanmar are currently non-functional, and 54 out of the remaining 55 laboratories are accredited as “proficient” for measles and rubella testing.

Gender assessment was conducted in five countries using the WHO GAT tool. It showed that the measles and rubella elimination programme was gender sensitive. An independent external review of progress towards measles and rubella elimination in the Region conducted in Q4 of 2021 observed that while great progress had been made, greater political commitment and excellence in technical and operational deployment were critical to achieve the target by 2023. The reviewers were of the view that the immunization coverage and surveillance sensitivity required for elimination were not likely to be reached by all the countries of the Region by 2023.

Sri Lanka: Sri Lanka is one of the countries that has eliminated both measles and rubella. It has identified the following challenges to maintaining the elimination status.

- ◉ It would be a challenge to ensure a high level of political commitment to sustaining the elimination status because of other competing health priorities. Policymakers would need to be convinced with effective advocacy programmes to ensure the financial support needed to maintain and strengthen surveillance and laboratory services.
- ◉ Sustaining a high level of age-appropriate community-level vaccination coverage may pose a challenge due to the emergence of other public health priorities, e.g. COVID-19, and increasing cost of vaccines for the self-procuring countries. An efficient monitoring and evaluation mechanism would be required to detect pockets of suboptimal or poor

coverage and additional efforts would have to be made to motivate the people to get vaccinated.

- ◉ To continue to maintain high sensitivity of surveillance when the disease is no longer perceived as a threat may be a problem. Regular reinforcement activities may help to maintain a high alertness among medical staff for the early detection of diseases that are not visible in the community.

Polio eradication and polio transition

Globally, wild poliovirus type 1 (WPV1) remains endemic in two countries — Afghanistan and Pakistan. Importation from endemic regions was detected in two countries of the African Region – Malawi (2021) and Mozambique (2022). Several actions are being taken by the national governments of these countries and Global Polio Eradication Initiative (GPEI) partners to end WPV1 transmission. Outbreaks due to circulating vaccine-derived polioviruses (cVDPV), in particular type 2 (cVDPV2), continue to affect countries of the African, Eastern Mediterranean, and European regions. Most of the past cVDPV2 emergences were stopped by using mOPV2 (monovalent OPV)—a powerful tool. However, all the currently active emergences, except in Somalia, could potentially be attributed to seeding following the use of Sabin OPV2. To stop the cVDPV2 more effectively and sustainably, novel oral polio vaccine type 2 (nOPV2) continues to be rolled out through the EUL system. As of July 2022, over 450 million doses of nOPV2 have been administered; 21 countries have used it and 17 others have met the readiness requirements and are ready to use it if needed.

The South-East Asia Region was certified polio-free in 2014 and has maintained this status since then. However, the international spread of poliovirus remains a public health emergency of international concern as WPV is still endemic in two countries and there have been outbreaks of cVDPVs in several countries of the African, European and Eastern Mediterranean regions.

No poliovirus outbreaks – due to wild or vaccine-derived polioviruses – have been reported in the South-East Asia Region in 2021–2022. A VDPV type 1 (VDPV1) was isolated in April 2022 from an environmental sample in Kolkata, West Bengal, India. Genetic analysis of the virus suggested a high likelihood that the origin of the isolated virus was a person with primary immunodeficiency. The national programme in India, with the support of WHO, swiftly responded to the event as per the global SOP. No further VDPV1 has been detected.

The coverage of three doses of OPV (OPV3) in the Region decreased to 82% in 2021 from 85% in 2020. Member States have been taking actions related to the resumption and strengthening of RI while vaccinating their populations with COVID-19 vaccines. Several countries have been able to either improve coverage or stabilize it. DPR Korea, Indonesia and Myanmar have shown significant decline in OPV3 coverage. The overall coverage of IPV increased to 79% in 2021 from 77% in 2020, however it remained below the pre-pandemic level of 83% achieved in 2019. In 2021, the overall surveillance indicators in the Region were maintained above the global certification standards (non-polio AFP rate: 4.57 and stool adequacy: 86%). However, there are variations at the national and subnational levels that are being addressed. The polio laboratory network in the Region continues to perform adequately with quality assurance mechanisms in place. Environmental surveillance is currently conducted in 93 sites in 34 provinces of six countries (Bangladesh, India, Indonesia, Myanmar, Nepal, and Thailand).

The 14th meeting of the Regional Certification Commission for Polio Eradication (RCCPE) recommended the introduction of the second dose of IPV in national immunization programmes in accordance with the recommendation of the SAGE. It also recommended that India and Indonesia should complete the prerequisites to prepare for the deployment of nOPV2. The India Expert Advisory Group on polio has recommended that India should prepare to meet the pre-defined readiness requirements for the deployment of nOPV2.

Containment activities as per the WHO Global Action Plan (GAP III) are steadily progressing. Four poliovirus-essential facilities (PEF) have been identified in the Region (3 in India and 1 Indonesia). National authorities for containment have been established in both countries. All four designated PEFs received the certificate of participation. The Region continues to be at risk of importation of WPV from endemic countries and of cVDPV emergence and/or importation from other WHO regions with ongoing outbreaks.

The five polio priority countries in the Region (Bangladesh, India, Indonesia, Myanmar, and Nepal) have developed national transition plans, adopting a country-centric approach. The pace of implementation of these plans is guided by country readiness (technical, financial, and managerial capacity), financing available and operational modalities. The Region has a single integrated network for surveillance and immunization that provides support not only for polio eradication, but also for measles and rubella elimination, surveillance of other VPDs, strengthening immunization and responding to emergencies. Independent evaluations conducted by the Transition Independent Monitoring

Board (TIMB) and through the WHO Evaluation Office have highlighted that the integrated network makes the Region the most advanced for polio transition among all the WHO regions.

India: The progress made by India in polio transition was presented. Its National Polio Surveillance Project (NPSP) Transition Planning Framework 2018–2026 envisages that by 2026 the Government of India will have full ownership and primary responsibility for implementing core public health functions at all levels through a well-developed plan. As a key process in polio transition, WHO in consultation with the Ministry of Health and Family Welfare (MoHFW) re-purposed the NPSP to the National Public-Health Support Network (NPSN). The NPSN will utilize the learning and experience gained during polio eradication efforts to provide support for capacity-building, implementation and monitoring & evaluation to strengthen immunization efforts, and provide need-based support for response to any public health emergency, such as the COVID-19 pandemic. The polio infrastructure in India has been realigned with the emerging priorities of accelerating RI, introducing new vaccines, eliminating MR, expanding VPD surveillance and responding to public health emergencies. It extended support during the COVID-19 emergency to help in capacity-building, planning and monitoring, assessment of hospitals, contact tracing, planning containment zones and vaccine roll-out. The NPSN is expected to play a significant role in the upcoming GAVI 5.0 health system strengthening support for reaching zero-dose children and in strengthening immunization and VPD surveillance activities in the country.

Other VPDs with elimination/control targets

Maternal and neonatal tetanus

The WHO South-East Asia Region achieved maternal and neonatal tetanus (MNT) elimination in May 2016, following validation in Indonesia. The elimination status has been sustained through 2021, with no district reporting neonatal tetanus cases above the threshold (1 case per 1000 live births).

A simplified risk analysis was conducted based on coverage with two or more doses of tetanus toxoid-containing vaccines (TTCV2+), booster doses of TTCV, skilled birth attendance (SBA) and inequities; to identify and guide the need for district-level analysis of core and surrogate indicators make a specific post-validation assessment (PVA) in countries with a higher risk score, as shown in Table 1. To date three countries have conducted a PVA (Bhutan, Indonesia, and Timor-Leste).

Table 1. Simplified risk analysis for MNTE in countries of the Region, 2021

Risk points	TTCV2+				Booster doses	SBA	Inequity	Total risk points	PVA
	≥90% = 1; 70–89% = 2; 50–69% = 3 and <50% = 3								
	2019	2020	2021						
Bangladesh	0	0	0	0.00	2	2	1	5.00	
Bhutan	1	0	0	0.33	0	0	0	0.33	2014
DPR Korea	0	0	1	0.33	2	0	0	2.33	
India	0	1	1	0.67	0	1	1	2.67	
Indonesia	2	2	3	2.33	0	0	1	3.33	2020
Maldives	0	0	1	0.33	1	0	0	1.33	
Myanmar	1	1	3	1.67	2	1	1	5.67	
Nepal	1	1	1	1.00	2	1	1	5.00	
Sri Lanka	0	0	0	0.00	0	0	0	0.00	
Thailand	0	1	1	0.67	0	0	1	1.67	
Timor-Leste	1	2	3	2.00	0	2	1	5.00	2018

Hepatitis B control

Hepatitis control continues to be an important public health issue in the Region. An estimated 60 million people live with chronic hepatitis B and 218 000 die every year of hepatitis B and C. Of the persons eligible for antiviral treatment, only 10.5% know their status and only 4.5% of them are on treatment. Given this background, it is critical to immunize infants against hepatitis B to protect them from chronic infection due to mother-to-child transmission. All 11 countries of the Region have been providing hepatitis B vaccination in the national immunization schedule for at least the past 10 years. Eight of them (except Bangladesh, Nepal, and Sri Lanka) also provide a birth dose. Four countries (Bangladesh, Bhutan, Nepal, and Thailand) have been verified as having achieved the 2020 control goal of hepatitis B surface antigen (HBsAg) <1% in children at least 5 years old; as assessed through nationally representative surveys.

A key barrier to the high coverage of hepatitis B birth dose is unattended home deliveries. While realizing that facility delivery/skilled birth attendance data that

are available from periodic surveys have shown significant improvements in all but one country (Myanmar) during the past 10 years, the birth dose coverage has not yet reached the level of facility delivery/skilled birth attendance rates in some countries.

Maldives: The Health Protection Agency of Maldives is planning to conduct a national cross-sectional school-based cluster serosurvey to measure the prevalence of HBsAg among Grade 1 children, in coordination with the Maldives National University and with technical support from WHO. The survey protocol was presented during the meeting. The survey also aims to collect data on immunization and timeliness of vaccination and to evaluate the effectiveness of the hepatitis B vaccine in preventing chronic infection. The result will serve as primary evidence to assess whether the hepatitis B control target has been achieved in the country.

C. Leaving no one behind by increasing equitable access to and use of new and existing vaccines

Introduction of new and underutilized vaccines

To achieve the goal of promoting equity, it is necessary to improve access to and use of new and existing vaccines. The priority vaccines targeted by the Immunization Agenda (IA) 2030 and the RVIP 2022–2026 include: HepB birth dose, Hib, human papilloma virus (HPV), IPV2, MCV2, Pneumococcal conjugate Vaccine (PCV), rotavirus (RVV), rubella, DTP booster, COVID-19, Japanese encephalitis (JEV), yellow fever (YF), meningitis A (MenA), multivalent meningitis, typhoid (TCV), cholera, dengue, rabies, hepatitis A (HepA), influenza (SIV), varicella, and mumps. The status of the use of some of the listed vaccines that are relevant to the Region is shown in Table 2.

In 2021, the Region completed the development of surveillance databases for rotavirus, invasive bacterial diseases (IBD) and Japanese encephalitis/acute encephalitis syndrome (JE/AES), with the aim of incorporating field and laboratory surveillance data for use at the regional and country levels. Currently, all countries in the Region are conducting one or more types of surveillance for new vaccines, as shown in Table 3. The table shows the number of national laboratories and sentinel sites for IBD, rotavirus and JE/AES surveillance. The regional laboratories continue to provide support for training, quality assurance and external quality assessment (EQA).

Table 2. Introduction of new or underutilized vaccines in the Region

	Hep B BD	Hib	IPV2	MCV2	Mumps	DTP booster	JEV	HPV	PCV	RCV1	RWV	TCV	SIV	Rabies	COVID-19	Total
Bangladesh																7
Bhutan																12
DPR Korea																5
India																11
Indonesia																10
Maldives																10
Myanmar																11
Nepal																10
Sri Lanka																10
Thailand																13
Timor-Leste																8
Total	8	11	5	11	4	7	6	6	7	11	5	1	4	11	10	

Table 3. New vaccine surveillance in the Region

Country	JE/AES surveillance (under 15 or whole population)		IBD surveillance (under 5)		Rotavirus surveillance (under 5)			GPDS surveillance (under 5)	
	NL	SS	NL	SS	NL	SS	Genotyping (Yes/No)	NL	SS
Bangladesh	1	103	1	4	1	7	Yes	0	0
Bhutan	1	4	1	4	1	11	No	0	0
DPR Korea	1	Nationwide	1	1	1	1		10	0
India	5	223	1	NA	1	4	Yes	1	3
Indonesia	1	58			0	0	Yes	0*	0
Maldives					1	1	No	0	0
Myanmar	2	Nationwide			1	4	No	1*	1
Nepal	2	Nationwide	1	1	1	3	Yes	0	0
Sri Lanka	1	Nationwide	1	1	0	0		0	0
Thailand	1	Nationwide			1	4		0	0
Timor-Leste	1	Nationwide			1	6	No	0	0

NL: national laboratories; SS: sentinel Sites; NA: not available; * Country reports to Global Rotavirus Surveillance Network)

Nepal: Nepal presented a report on the success of its typhoid conjugate vaccine (TCV) campaign to introduce the (TCV. The school-based TCV campaign was conducted to provide population immunity/protection through one dose of TCV to all children in the age group of 15 months–15 years. The campaign was also used to promote RI and identify children who had missed full immunization, including MR 2. In addition, it aimed to promote good hygienic habits and introduce TCV in RI, to be given at the age of 15 months. Approximately 7.7 million children were targeted across the country and an astounding administrative coverage of 99.7% was achieved. The coverage was confirmed by a rapid monitoring exercise in which approximately 46 000 children were reached and 92% of them were found to be vaccinated with TCV.

SAGE recommendations on HPV vaccine schedule optimization

The global strategy to accelerate the elimination of cervical cancer and the SDG goals target of reducing mortality from cervical cancer by 30% have prompted the SAGE recommendations on the HPV vaccination schedule. According to the

recommendations, all countries must introduce HPV vaccination and vaccinate 90% of girls by the age of 15 years by 2030.

Table 4. SAGE recommendations on optimization of HPV vaccine schedule, 2022

		2017 WHO position	SAGE Recommendations April 2022 (research question)
Primary target group		Girls aged 9–14 years	Girls aged 9–14 years
Vaccination schedule	9–14 years	2-dose schedule	Either 1-dose or 2-dose schedule (Further research required on duration of protection with single dose)
	15–20 years	3-dose schedule	Either 1-dose or 2-dose* schedule
	≥21 years	3-dose schedule	2-dose schedule
	Immuno-compromised (Any age)	3-dose schedule	Should be prioritized and should receive at least 2 doses, if programmatically feasible. (Further research on immunocompromised persons should be prioritized.)
Vaccination prioritization	Multi-age cohort (MAC)	Temporarily postpone	Catching up with missed girls through MAC vaccination must be prioritized where feasible and affordable.
	Boys	Temporarily postpone	Introducing the vaccination of boys and older females should be managed carefully until the global supply situation is fully unconstrained.
	Older age cohorts	Temporarily postpone	(Further research is needed on schedule optimization in boys and older cohorts.)

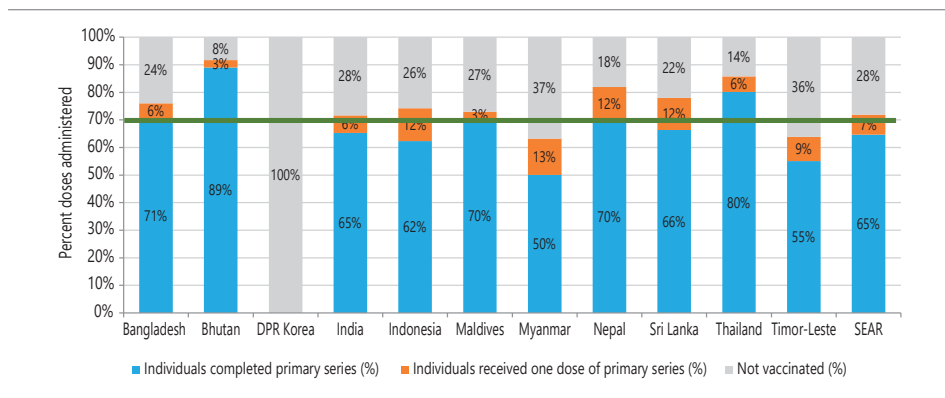
COVID-19 vaccine deployment

The first COVID-19 case in the Region was reported on 13 January 2020. As of 16 August 2022, approximately 59 million cases of COVID-19 and 792 000 deaths had been reported in the Region. In response to the spread of this disease, countries implemented various public health and social measures (PHSM), along with COVID-19 vaccination. Vaccines were introduced in the Region on 13 January 2021, and so far, 10 of the 11 Member States, except DRR Korea, have rolled them out. Vaccination data is documented and shared through a Regional dashboard.

All countries have prioritized the vaccination of certain groups. The highest priority has been accorded to health workers and the elderly. Adults with comorbidities, pregnant women, frontline workers and disadvantaged populations at a higher risk of disease have been given greater priority than the general population. All countries are vaccinating individuals above the age of 12 years and providing boosters to certain priority groups, while three are also vaccinating children in the age group of 5–11 years.

As of 16 August 2022, more than 3 billion doses of COVID-19 vaccines had been administered in the Region, with at least 1.48 billion (72%) individuals having received at least one dose and 1.33 billion (65%) having completed the primary series. Fig. 3 shows the percentage of people vaccinated with the primary series in the Region. Five countries (Bangladesh, Bhutan, Maldives, Nepal, and Thailand) have reached the global target of vaccinating at least 70% of their population with a complete series of two doses.

Fig. 3. Percentage of vaccinated and unvaccinated people in countries of the Region



As of 16 August 2022, approximately 100% of health workers had completed the primary series in four countries (Bhutan, Indonesia, Sri Lanka, and Timor-Leste,) while the coverage was 95% or more in another four (India, Myanmar, Nepal, and Thailand). Booster doses had been provided to 100% of health workers in two countries (Bhutan and Indonesia). Sri Lanka and Thailand had provided boosters to 86% and 79% of their health workers, respectively. The coverage of the primary series in the elderly was 100% in Bhutan and Nepal, and $\geq 95\%$ in Maldives and Sri Lanka. In Bhutan and Maldives, 100% and 73% of the elderly, respectively had received booster doses.

The countries of the Region have made significant efforts to enhance the coverage of COVID-19 vaccines.

Myanmar: It developed the COVID-19 National Vaccine Deployment Plan (NVDP) to guide the smooth implementation of COVID-19 vaccination. A central committee was constituted on the prevention, control, and treatment of COVID-19 and an intersectoral coordination mechanism was established in consultation with all the relevant ministries for emergency response. The MOH established a technical working group with eight subgroups to provide technical guidance on various aspects of vaccine roll-out. The key factor responsible for the successful roll-out was the government's efforts to secure the required doses of vaccines through bilateral deals, donations, and in-country manufacturing. The cold chain capacity was strengthened, all midwives, Basic Health Staff (BHS), and EPI focal persons from all states and regions were trained rapidly and vaccination sessions were held with the support of the General Local Administration Department and volunteers were recruited through a massive communication campaign on TV, radio, the print media and social media platforms. Some private facilities and ethnic health organizations (EHOs) were identified for the vaccination effort. The private sector was permitted to import and provide booster doses of vaccines to help increase the reach. Surveillance for AEFI and safety was enhanced, and adverse events tracked. The Ministry of Defence and Home Affairs developed a vaccine management information system to track vaccination by target groups. The country is taking steps toward stakeholder collaboration and the integration of COVID-19 vaccination with RI.

Several countries have initiated efforts towards the integration of COVID-19 vaccination and RI.

Timor-Leste: The country has a single plan and budget for RI and COVID-19 vaccination. All fixed sites and outreach services provide COVID-19 vaccines and RI antigens; there are no separate sites for COVID-19 vaccination. However, COVID-19 vaccines and RI vaccines are stored and transported in separate vaccine carriers. Integrated health promotion, social mobilization, and default tracking at the household level for both COVID-19 vaccines and RI are conducted with the full support of community leaders, community volunteers and NGOs. There is a strong partnership with CSOs and other key stakeholders, including line ministries for these integrated activities. Timor-Leste is planning to conduct a campaign on MR, OPV, PCV, Vit A and albendazole, targeting children who are less than 5 years of age and integrating this with COVID-19 vaccination for parents.

The main enablers of COVID-19 vaccine deployment in the Region were as follows:

- ⦿ high-level political commitment and an unprecedented high level of coordination during 2021;
- ⦿ country ownership to introduce vaccines through deployment plans and allocating resources;
- ⦿ rapid provision of guidance for readiness assessment and vaccine deployment and use;
- ⦿ leveraging of existing EPI systems and experience, including from the Polio Eradication Initiative and influenza vaccine delivery to adult target groups;
- ⦿ availability of local and donor financial resources including support for cold-chain and logistics management;
- ⦿ donation of vaccines, cooperation among countries for the procurement of vaccines and COVAX allocations;
- ⦿ rapid regulatory approval for the deployment of vaccines;
- ⦿ commitment and capacity-building of health professionals;
- ⦿ support for drafting and reviewing national deployment and vaccination plans and regional partner coordination; and
- ⦿ high public demand in the early phases of vaccine deployment.
- ⦿ Implementation of COVID-19 vaccine safety surveillance monitoring and vaccine efficacy studies which are ongoing or planned studies in six countries (Bangladesh, India, Indonesia, Maldives, Sri Lanka, and Thailand). Moreover, post-introduction evaluations have been conducted in 7 countries.

Challenges related to the deployment of COVID-19 vaccines have evolved with the changing epidemiology and vaccine availability. The current challenges include:

- ⦿ The coverage of boosters among health workers and the elderly is low in several countries. The coverage of the primary series among the elderly is also low in several countries.

- ◉ There are considerable variations in subnational coverage, including in countries that have attained 70% coverage for the primary series.
- ◉ The increased workload and focus on COVID-19 vaccination has had a negative impact on the implementation of RI activities, including VPD surveillance.
- ◉ The demand for COVID-19 vaccines has decreased in most countries because of the reduction in the number of cases, negative perception of vaccine efficacy due to the circulation of variants of concern, and misinformation about vaccine safety due to rare events detected during post-deployment monitoring.
- ◉ Most countries are facing a marked reduction in vaccine utilization rates partly due to the hesitancy mentioned above and also due to the fatigue of the health workforce. Vaccination rates have slowed markedly in Sri Lanka and in Indonesia. This creates a risk of increased wastage of vaccine stocks due to expiry.
- ◉ Only four countries report vaccine safety events to the global surveillance network at present.
- ◉ The political situation in Myanmar and Sri Lanka is posing a challenge to scaling up the vaccination programmes in these countries.
- ◉ Despite the efforts made by WHO and partners, DPR Korea has not started vaccination.

Vaccine effectiveness of COVID-19 vaccines-primary series and booster

Several vaccines are now available against COVID-19 and vaccine effectiveness (VE) studies are being conducted globally. Studies are available for VE against BA.1/BA.2 variants for AstraZeneca's Vaxzervia, Moderna's Spikevax and Pfizer BioNTech's Comirnaty. Limited studies are available for Janssen's Ad26.COV2 and Sinovac's Coronavac. One study is available for Sinopharm's CNBG-BBIBP-CorV. Almost all vaccines show less than 50% VE against infection and symptomatic disease that wanes over time. However, VE against severe disease is higher, with minimal waning. Most of the first booster vaccination studies are for mRNA vaccines and show improved VE against all outcomes. While waning has been seen against infection, the waning is minimal against severe disease. A meta-regression has found a decline of 47.6 (36.6-60.2) percentage points

within 1–6 months of the primary series and 24.3 (19.9–29.1) percentage points within 1–4 months of the booster dose against symptomatic disease. A 28.5 (18.3–40.5) percentage point decline is projected for 1–6 months. However, no change has been seen against severe disease over time after the primary series and a decline of around 5 percentage points has been seen within 1–4 months of a booster dose. There are limited studies for the second booster, and these are mostly from Israel. These studies show that VE increases against all outcomes compared to the first booster dose. However, in some cases the gains are small, and the cost–benefit ratio for this incremental improvement is unclear especially against severe disease. There is minimal data on VE against BA.4/BA.5. More data are needed and may take time due to change in testing patterns.

Post-introduction evaluations of COVID 19 vaccines

Seven countries in the Region conducted post-introduction evaluation (PIE) of COVID-19 vaccines under the ten thematic areas of regulatory preparedness; planning and coordination; service delivery; costing and funding; supply chain and waste management; human resources, training and supervision; vaccine demand, advocacy, and communication; vaccine safety and AEFI reporting; monitoring and evaluation; and surveillance.

Bhutan and Thailand presented their learnings.

Bhutan: Bhutan’s presentation was related to the implementation of the recommendations of the PIE, which was conducted in the first week of May 2021 . Of the 43 recommendations, 30 have been implemented, five are in the process of being implemented, and three will be implemented. The remaining five recommendations are not planned to be implemented. The key challenges faced were that policy decisions take time; sustaining multisector coordination and support requires a huge effort and continuous advocacy, virtual training may not always be as effective as desired, and the success of using electronic systems depends on regular updates and support provided to users.

Thailand presented the preliminary findings of the PIE conducted in April 2022. The PIE identified some key achievements related to service delivery, registration system, and community engagement and awareness activities. The fixed and mobile sites for vaccination and the system of registration and appointment were found to be well organized. Village health volunteers and community leaders had been motivating the people to get vaccinated through advocacy and awareness generation, and by helping to solve the problems faced by

the people. The PIE pointed out the need to review cold chain requirements and practices for all vaccines and recommended that the data monitoring system be standardized and expanded. The key actions recommended by the PIE were to develop a programme improvement plan to support continuous improvement, increase vaccine coverage, especially among the elderly through outreach/ mobile units, improve public awareness of booster vaccines and engage a data management expert to assess problems and develop solutions for data flows.

Regional Vaccine Implementation Plan 2022–2026

The Strategic Framework for the Regional Vaccine Action Plan 2022–2030 is the regional adaptation of the Immunization Agenda 2030, which was endorsed by the Regional Committee in September 2021. The Regional Vaccine implementation Plan (RVIP) 2022–2026 has been developed to operationalize the Strategic Framework. A draft of the RVIP was presented to the ITAG, NIPs and partners in August 2021. The ITAG recommended that “Countries and partners work together to review the current version of the Plan and identify national and regional key performance indicators, baseline values for them, targets for 2026, and important activities for country-level and regional-level implementation.” ITAG members, countries and partners provided feedback/inputs to the draft version and these have been included in the current version.

Member States and partners would need to pay renewed attention to achieve the following impact goals:

- ◉ leaving no one behind, in the South-East Asia Region by increasing equitable access to and use of new and existing vaccines;
- ◉ pursuing VPD elimination and control goals: achieving measles and rubella elimination, sustaining polio elimination, sustaining MNT elimination, achieving hepatitis B control; and
- ◉ reducing overall mortality and morbidity from VPDs all across the life course

The strategic priorities and key areas of focus of the RVAP are shown in Fig. 4.

The key priority interventions in the RVIP 2022–2026 are: 1. coordinated operational planning; 2. planning and implementation of COVID-19 vaccination; 3. addressing the impact of COVID-19 on routine immunization and VPD surveillance; 4. sustain the gains of VPD elimination and control; 5. ownership and accountability; 6. monitoring and evaluation; 7. communications and advocacy; 8. regional implementation; and 9. country-level implementation.

Fig. 4. Strategic priorities of the Regional Vaccine Action Plan 2022–2030

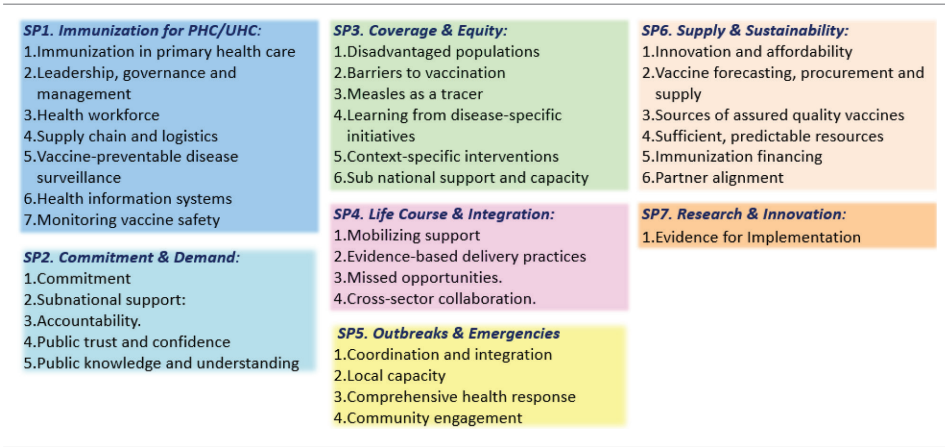


Fig. 5. Continuous quality improvement cycle



A number of implementation accelerators were identified. These include national quality improvement cycles; regional expertise; peer support and partnership; leveraging the disease control infrastructure and an accountability mechanism and capacity-building at the subnational level.

To meet the targets of the RVIP, continuous quality improvement is necessary. National EPI programmes will lead coordinated planning with the guidance of NITAGs and the support of partners. The annual work plan developed in the process will be implemented by national EPI programmes with the support of partners and communities. Another component of the quality improvement cycle shown in Fig. 4 is embedded monitoring by the national EPI programme

with the support of the NITAG and all partners. Annual reviews are to be conducted in each country by the EPI programme with the support of the NITAG and ITAG. The gaps identified by the review will need to be addressed in the annual work plan of the following year.

A regional monitoring framework was developed to assess the achievement of the targets of the RVIP. The indicators to measure the intended outcomes were selected to align with regional priorities, global mandates, and relevance to the country in terms of applicability and feasibility. The key components of the monitoring framework are shown in Table 5.

Table 5. Monitoring framework for the Regional Vaccine Implementation Plan 2022–2026

What to monitor?	How?	Where?	Current status of data source
3 impact goals	7 impact goal indicators	Global and regional	3: from countries 2: global estimates based on country immunization coverage data 2: global estimates based on multiple sources
7 strategic priorities and 21 strategic priority objectives	15 strategic priority objective indicators + two regional indicators	Global and regional	13: from countries 2: global estimates based on country immunization coverage data 2: global estimates based on multiple sources
33 key areas of focus	Key performance indicators from available options	Regional	From countries
33 key areas of focus	Key performance indicators from available options	Country	From countries

The current status of the data related to the seven impact indicators, 15 strategic priority indicators and two regional indicators was presented. It was observed that the Region has data for all the impact indicators and around 70% of the information for the strategic priority indicators for 2021.

Informational sessions

Respiratory syncytial virus vaccine

Respiratory syncytial virus (RSV) is a leading cause of severe acute respiratory illness and death globally. It causes severe pneumonia with a greater burden of severe disease and death in children who are less than 6 months of age due to the higher risk of obstruction of smaller airways. The illness is characterized mainly by cough, dyspnoea, wheezing, apnoea in neonates. RSV infection is also a leading cause of serious bacterial infection in children. Vaccines against RSV are in an advanced stage of clinical development and RSV maternal vaccines and long-acting monoclonal antibodies will likely be available in the next few years. Regions and countries need to raise awareness and knowledge of RSV infection among clinical leaders and policymakers to be able to make decisions about future RSV products

Defeating meningitis by 2030

Meningitis is a threat in all countries of the world. In 2019, there were an estimated 2.5 million new cases and 250 000 deaths globally from meningitis in all ages. The South-East Asia Region accounts for 27% of the global bacterial meningitis cases and 19% of the global bacterial meningitis deaths. The first ever resolution on the prevention and control of meningitis was passed by the Seventy-third session of the World Health Assembly in November 2020, and a road map on controlling meningitis was launched in September 2021. The road map focuses on the four organisms responsible for the majority of acute bacterial meningitis: *Neisseria meningitidis*, *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Streptococcus agalactiae* (Group B streptococcus). It proposes five interconnected pillars: prevention and epidemic control, diagnosis and treatment, disease surveillance, support and care for people affected by meningitis, and advocacy and engagement. The prevention of meningitis by

vaccination is a cost-effective way to reduce cases, deaths and disabilities. All countries in the Region have introduced Hib vaccine since 2020, four Member States have introduced PCV nationwide and two in specific areas, as of 2022, while the meningococcal vaccine is offered to specific groups (travellers/pilgrims). The South-East Asia Region plans to conduct a landscape analysis and adapt the global road map to frame a regional implementation plan to defeat meningitis. The Region has requested Member States to integrate meningitis vaccines in their national immunization strategies or comprehensive multi-year plan (cMYP).

Malaria vaccine

In October 2021, WHO recommended that the RTS,S/AS01 malaria vaccine be used for the prevention of malaria caused by *P. falciparum* in children living in regions with moderate to high transmission as defined by WHO. The vaccine is provided in a schedule of 4 doses to children from the age of 5 months. The introduction of the vaccine should be considered in the context of comprehensive national malaria control plans. Given the limited supply of the vaccine and the high demand for it, WHO has supported the development of a Framework for Allocation, available on the WHO website (<https://www.who.int/publications/m/item/framework-for-allocation-of-limited-malaria-vaccine-supply>).

The Framework prioritizes allocation to children living in areas where the burden of malaria and the risk of death from the disease are the greatest. No country is excluded by the Framework, but the limited supply means that not all countries will be able to introduce the vaccine immediately. To help manage expectations and support decision-making and planning, countries are informed through a dialogue about the allocation principles and potential initial allocation quantities. All countries will need to use a phased approach to vaccine roll-out, starting in areas with the highest need, and expanding after the supply increases in the coming years.

Monkeypox vaccine

Since 1 Jan 2022, monkeypox cases have been reported to WHO by 91 Member States/territories across all 6 WHO regions. As of 10 August 2022, a total of 31 665 laboratory-confirmed cases (and 150 probable), including 12 deaths, have been reported to WHO. The WHO interim guidance (<https://www.who.int/news/item/14-06-2022-vaccines-and-immunization-for-monkeypox--interim->

guidance--14-june-2022) on the use of vaccines for monkeypox addresses, in particular, the issue of human-to-human transmission. It should be noted that there is significant uncertainty about the efficacy and effectiveness of vaccination, both pre- and post- exposure, in the context of the current monkeypox outbreak. Some considerations that countries implementing vaccination should keep in mind are:

- ⦿ involvement of NITAGs, NRAs, and other relevant agencies in the decision-making process;
- ⦿ involvement of the civil society and community-based organizations;
- ⦿ prioritization of vaccination in the context of limited supply;
- ⦿ timely contact tracing for the effectiveness of post-exposure preventive vaccination;
- ⦿ If difficult, targeted primary preventive vaccination (PPV) may be the most effective strategy, while avoiding stigmatization
- ⦿ ensuring informed joint clinical decision-making by the individual and health-care provider;
- ⦿ making use of existing services such as sexual health clinics or HIV centres;
- ⦿ acquainting the health workforce with vaccination techniques (bifurcated needle, intradermal delivery, as appropriate); and
- ⦿ providing information on and communicating the risks and benefits of vaccination.

Member States using vaccines against monkeypox are strongly encouraged to do so within a framework of collaborative clinical studies in order to facilitate evidence generation, especially on vaccine efficacy/effectiveness and safety.

Conclusions

The ITAG appreciated the timely submission of annual reports by the NITAGs of 9 of the 11 countries of the Region despite the COVID-19 pandemic. It appreciated and generally agreed with the conclusions and recommendations made by the NITAGs.

It recognized the efforts made by the countries to recover/stabilize immunization services and VPD surveillance, following an initial decline during the COVID-19 pandemic, and noted with appreciation the efforts made by countries to implement the recommendations made during its previous meeting in August 2021.

The ITAG noted that four country offices had conducted a self-assessment of the gender responsiveness of their immunization programmes and that the programmes appeared gender responsive in these countries.

It also noted the numerous demands placed on the health workforce recently (with more to come due to the introduction/expansion of new vaccines) and expressed concern about the availability of adequate support to handle the workload.

The ITAG recognized that digital real-time data collection could improve transparency, efficiency, monitoring/surveillance and reliability of a programme and that the COVID-19 pandemic has offered newer platforms to strengthen immunization systems.

A. Reducing overall mortality and morbidity from VPDs across the life course

Strengthening RI systems and VPD surveillance

The ITAG commended the NIPs and partners for the extensive efforts made to ensure the continuity of RI services and to revitalize immunization and VPD surveillance amidst the COVID-19 pandemic. It noted, however, that immunization and VPD surveillance activities continued to be affected by pandemic response activities in several countries of the Region, causing increased vulnerability to VPD outbreaks. It expressed concern about the 4.6 million zero-dose children in 2021, which was 2.3 times greater than the number in 2019. It also expressed concern about the recent outbreaks of diphtheria and measles in several countries of the Region.

The ITAG noted the reasonably high RI coverage during the pandemic in five countries, recovery trends in three countries and declining trends in the remaining three countries. It also noted that the RI coverage was low in several migratory and displaced populations and that there was significant variation in national and subnational coverage across countries.

It noted that the investments made for the COVID-19 vaccination roll-out had strengthened immunization systems. National and subnational cold chain capacities, including additional ultra-cold chain equipment, had been enhanced, for example.

The ITAG noted that effective vaccine management (EVM) initiative continued to be implemented as the backbone of vaccine management, monitoring and continuous improvement planning. Six EVM assessments were conducted amidst the COVID-19 crisis and another six are planned in 2022–2023.

The ITAG emphasized the need for high-quality data, while appreciating the data quality assessments conducted in Indonesia, Myanmar and Timor-Leste during recent years.

Adverse events following immunization

The ITAG noted that all countries had functional AEFI committees with expanded membership to include broader specialities and that all countries had adapted the AEFI surveillance systems established for EPI vaccines to COVID-19 vaccines.

It appreciated the recent efforts by WHO to strengthen the capacity of the countries on AEFI and causality assessments through various meetings and workshops, as well as the country-focused support extended by it. It also noted the plan to conduct a regional workshop on strengthening vaccine safety surveillance in September 2022.

The ITAG noted with concern that the reporting of AEFIs related to EPI antigens had declined in 2021 compared to 2019. It also noted that there were delays in the completion of causality assessment for serious adverse events, as well as limited sharing of data on serious events between vaccine manufacturers, national regulatory authorities, and EPI authorities.

Strengthening regulatory capacity

The ITAG recognized that the Region is the largest manufacturer and supplier of vaccines globally.

It appreciated the regulatory preparedness assessment and simulation exercises conducted for NRAs across the Region to expedite EUA processes for COVID-19 vaccines. It commended WHO for conducting activities to strengthen regulatory capacity, including capacity building on expedited harmonized marketing authorization procedures, harmonized quality management system and implementation of the revised institutional development plan in nine countries.

The ITAG noted that the three key vaccine manufacturing countries in the Region had functional NRAs and were compliant with maturity level-3 in accordance with the WHO global benchmarking. It pointed out the need for strengthening NRAs in the remaining countries to expedite marketing authorization and regulatory agility.

B. Pursuing VPD elimination/control goals

Measles and rubella elimination

The ITAG commended five countries for sustaining measles elimination and two countries for sustaining rubella elimination. It noted the progress made across the Region in reducing the incidence of and mortality due to the two diseases and the fact that several subnational units had reported no measles transmission for more than 12 months.

The ITAG concurred with the conclusions of the 7th meeting of the Regional Verification Commission for measles and rubella elimination.

It appreciated the fact that an independent external review of progress towards measles and rubella elimination had been conducted in Q4 of 2021 and concurred with the findings of the review. It expressed concern over the findings of the review that the immunization coverage and surveillance sensitivity required for elimination were not likely to be reached by all countries of the Region by 2023.

It also expressed concern over the high likelihood of large and disruptive measles outbreaks in the Region over the next few years and over the fact that none of the countries had demonstrated the required level of preparedness. It appreciated the efforts made by six countries to conduct measles outbreak preparedness assessment.

The ITAG noted the benefit of a switch from a 10-dose MR vial to a 5-dose vial to increase coverage and reduce wastage.

Polio eradication and polio transition

The ITAG commended the Region for maintaining its polio-free status and for no outbreaks of cVDPVs in recent years. It appreciated the recovery of immunization and surveillance performance in 2021 compared to 2020 in most countries, noting that pre-pandemic levels were yet to be achieved in several countries.

It noted that the Region continued to be at risk of importation of polio viruses (wild and vaccine-derived) from endemic and outbreak countries, as well as the emergence of cVDPVs in areas with low immunization coverage. It also noted the importance of environmental surveillance as a complement to AFP surveillance for the early detection of any poliovirus importation and transmission in the Region.

The ITAG noted the recent SAGE recommendation on the introduction of IPV2 in national programmes. It also noted the progress in polio transition made by the Region and the continued risk related to the long-term sustainability of the immunization networks in the five polio priority countries.

Other VPDs with elimination/control targets

The ITAG commended the Region for maintaining the status of having eliminated maternal and neonatal tetanus and appreciated that the control of hepatitis B through immunization achieved in four countries in 2019 had been sustained.

It welcomed plans for national serosurveys for hepatitis B in Maldives and Sri Lanka and noted with concern that several countries faced challenges regarding the elimination of MNT and control of hepatitis B due to the existence of areas of low immunization coverage, challenges with sensitive NT surveillance and a significant number of births without skilled attendants.

C. Leaving no one behind by increasing equitable access to and use of new and existing vaccines

New and underutilized vaccines

The ITAG appreciated that some priority vaccines had been introduced or their use had been expanded in 2021 despite the competing priorities related to COVID-19 vaccine roll-out and appreciated the fact that all countries in the Region were conducting one or more types of surveillance for diseases for which new vaccines were available/being used.

It noted that the introduction and surveillance of new and underutilized vaccines were impacted by the COVID-19 pandemic, resulting in delays in the development of applications, vaccine introduction and post-introduction evaluation, and reduced accessibility (e.g. school delivery platforms for the HPV vaccine).

The ITAG noted that the off-label 1-dose schedule of HPV vaccine recommended by SAGE could potentially increase vaccine coverage by facilitating new introductions and expansions.

Roll-out of COVID-19 vaccines

The ITAG appreciated the fact that more than 3 billion doses of COVID-19 vaccines had been administered in 10 countries across the region, with 72% coverage for the 1st dose, 65% coverage for the complete primary series and 12% for at least one booster dose. It also noted that five countries had achieved

>70% coverage for the primary series and that the SAGE prioritization road map had been followed by countries to vaccinate target population groups.

The ITAG commended the proactive role played by governments to ensure the availability of vaccine supplies for their populations and appreciated that more than 15 types of vaccines had received EUA and were available in the Region.

However, it noted with concern the inequity in subnational coverage of the primary series in a number of countries, the low coverage of boosters among health workers and the elderly in several countries, the low coverage of the primary series among the elderly in some countries, and the lack of disaggregated data on the booster dose vaccination for all priority groups in some countries. It also noted with concern that vaccine hesitancy had increased in some population subgroups.

The ITAG noted that the workload of vaccinators had increased manifold due to the COVID-19 vaccines roll-out and that this and the focus on COVID-19 vaccination had negatively impacted the implementation of RI activities, including VPD surveillance.

While the ITAG appreciated that seven countries had conducted post-introduction evaluations of COVID-19 vaccines, it noted with concern the paucity of data on vaccine effectiveness from the Region.

Country-specific conclusions

Bangladesh

- ◉ The ITAG noted, with appreciation, the recovery of RI coverage to pre-pandemic levels through catch-up immunization and constant monitoring of logistical requirements and immunization coverage.
- ◉ It noted that a large proportion of positions involved in the delivery of routine EPI vaccination continued to be vacant and concurred for the fast-track development and institutionalization of the National Immunization Policy and Vaccination Act to strengthen the governance and management capacity of the EPI.
- ◉ The ITAG noted the development of the Urban Immunization Strategy and the plan to vaccinate children who had missed doses at school entry.

- ⦿ It expressed concern over the low immunization coverage among migrant populations in Cox's Bazaar (68% fully immunized) and the ongoing diphtheria transmission among them.
- ⦿ It commended the progress made towards measles and rubella elimination and the highly sensitive surveillance system that had made this possible.
- ⦿ The ITAG noted and appreciated the fact that the roll-out of the primary series of the COVID-19 vaccine was conducted successfully.

Bhutan

- ⦿ The ITAG noted the recovery of RI coverage in 2021 for most antigens, with a hepatitis B coverage of around 80%. It also noted that children who had missed vaccination during the lockdown had been followed up and vaccinated and that there had been a reduction in zero-dose children.
- ⦿ The ITAG appreciated the high coverage of the primary series and booster dose of COVID-19 vaccine among all priority population groups and the effective strategy to sustain programme acceptance, quality and access.
- ⦿ It commended the programme for monitoring, reporting and managing AEFIs and completing the causality assessments for all serious COVID-19 AEFIs.
- ⦿ The ITAG expressed concern at the decline in MCV2 coverage in some districts and the lack of data on the demand for and acceptance of vaccines.

India

- ⦿ The ITAG noted the marked impact of the COVID-19 pandemic on routine vaccination coverage in 2020 and 2021 and appreciated the efforts made to increase the coverage of RI. It noted that RI coverage had started to show visible recovery in the first half of 2022.
- ⦿ It appreciated the development of state plans to revitalize RI by making a risk assessment and identifying areas (districts, subdistricts) with the highest number of zero-dose children.

- ◉ It noted the recommendations of the India Expert Advisory Group for Polio regarding a revision in the existing IPV schedule as per the guidance of SAGE, and the preparation for any probable future use of the novel OPV type 2 (nOPV2).
- ◉ The ITAG noted the progress made towards polio transition, including the commitment of domestic resources for the National Public-Health Support Network.
- ◉ It appreciated the successful roll-out of COVID-19 vaccination, with more than 2 billion doses being administered and commended the development and use of the CoWin application for recording, reporting and monitoring the vaccination roll-out. However, it expressed concern at the inequitable coverage of the primary series of vaccines across some large states and the low coverage of the booster/precaution dose among high-risk groups.

Indonesia

- ◉ The ITAG appreciated the involvement of the NITAG in the joint programme review.
- ◉ It noted that both the immunization and VPD surveillance activities were severely impacted in 2020 and 2021 by the COVID-19 pandemic and expressed concern over the marked decline in the coverage of all routine antigens in 2020 and 2021, resulting in a sharp increase in zero-dose children.
- ◉ The ITAG emphasized that there was a high risk of outbreak of VPDs, including polio outbreaks, in the country.
- ◉ It noted the multiple strategies being used to address the decline in the coverage of routine antigens, including the multi-antigen National Childhood Immunization Activity (BIAN) along with MR SIA in 2022.
- ◉ The ITAG noted that there were no stock-outs of vaccines at the national level during 2020 and 2021, but expressed concern over the stock-out of several vaccines at the subnational level.
- ◉ It noted the challenges related to human resources, as reported by the NITAG, and the challenges of manual data recording and reporting that lead to data discrepancies at all administrative levels.

Maldives

- ⦿ The ITAG appreciated the fact that despite the challenges of the pandemic, RI services were maintained well, with a high coverage across antigens and the immunization system continued to function well.
- ⦿ It noted that there were no mechanisms to track children for RI in the greater Male' area.
- ⦿ It also noted that regular/periodic reviews of VPD surveillance had not been conducted since the start of the COVID-19 pandemic.
- ⦿ The ITAG expressed concern over inadequate human resource capacity for immunization and VPD surveillance (and no long-term plan).
- ⦿ It noted some areas of concern in the performance of the VPD surveillance system.

Myanmar

- ⦿ The ITAG, based on the review of the information provided in the e-JRF, expressed concern over the very low coverage of all routine antigens across the country in 2021 that makes the country vulnerable to large outbreaks of VPDs.

Nepal

- ⦿ The ITAG commended the interventions to improve coverage of routine antigens in 2021 after a decline in 2020 and recognized that the elimination of the age barrier for routine vaccination was a significant step to close the immunity gap in missed children.
- ⦿ It appreciated the successful implementation of the TCV campaign and the subsequent introduction of TCV in RI. It also appreciated the fact that the TCV and MR SIAs were used to identify and vaccinate zero-dose children.
- ⦿ The ITAG noted the high coverage of the primary series of COVID-19 vaccines, including in all priority groups.

Sri Lanka

- ◉ The ITAG appreciated the maintenance of high coverage of routine antigens in 2020 and 2021.
- ◉ While appreciating the high coverage of the first dose of the primary series of COVID-19 vaccines, it noted the slow progress with the coverage of the second dose, as well as the booster dose, in recent months.
- ◉ The ITAG commended Sri Lanka for the steps taken to integrate COVID-19 vaccination with the RI programme.
- ◉ It expressed concern over the negative impact of school closure on HPV and other school-based vaccination programmes.
- ◉ The ITAG noted the emerging challenges arising from the existing political and economic situation that may have a negative impact on the immunization programme in the country.

Thailand

- ◉ The ITAG appreciated the high coverage of the primary series of COVID-19 vaccines among all priority groups. However, it noted that the coverage of the booster dose among the elderly population and the population with comorbidities required to be enhanced.
- ◉ It acknowledged the efforts made to strengthen services to promote the high uptake of vaccinations for RI and COVID-19 and appreciated the availability of vaccines and ancillaries, as well as teams to respond to VPD outbreaks.
- ◉ The ITAG noted that the immunization programme planned to vaccinate additional populations, including private sector health providers and migrants, with MRCV to accelerate progress towards the elimination of measles and rubella.
- ◉ It noted the challenges encountered in the causality assessment of AEFI and the need to strengthen surveillance and response, and a plan for doing so in late 2022.

Timor-Leste

- ⦿ The ITAG noted that routine vaccination was hampered due to the COVID-19 pandemic and has yet to recover, but disease surveillance, particularly for measles and rubella, had bounced back. It also noted that a catch-up activity for MR and OPV had been planned in the last quarter of 2022, and that there was a plan to introduce PCV at around the same time.
- ⦿ It noted the integration of COVID-19 vaccination and RI in some areas of the country with the help of NGOs and local leaders and the plan to extend this all over the country.
- ⦿ The ITAG expressed concern over the inequitable administration of COVID-19 vaccines among people in remote areas.
- ⦿ While acknowledging the use of a digital platform to monitor the daily vaccine situation, it noted that the same was not used for the monthly monitoring of RI.
- ⦿ The ITAG expressed concern over the stock-out of OPV at the national and subnational levels in certain months of 2021.
- ⦿ It noted with significant concern that a large proportion of AEFIs had been reported due to programme error.

Recommendations

- ◉ The ITAG endorsed the Regional Vaccine Implementation Plan (RVIP) 2022–2026 and encouraged countries to adapt/adopt the RVIP in the national immunization strategy or equivalent.

Overarching recommendations for all countries

- ◉ The NIPs should optimally implement the recommendations of the NITAGs and the Regional ITAG and report to the NITAG at least twice a year on the status of implementation.
- ◉ The gains made and lessons learnt from the COVID-19 vaccination roll-out must be used to strengthen RI and fast-track reaching zero-dose children.
- ◉ All countries should consider conducting gender responsiveness assessments for their immunization programmes and ensure the gender responsiveness of the programmes.
- ◉ All countries should consider the systematic collection and analysis of data on behavioural and social drivers to understand the barriers and facilitators and adjust programmatic interventions.
- ◉ The Region must prioritize research to guide the immunization programme.

A. Reducing overall mortality and morbidity from VPDs across the life course

Strengthening RI systems and VPD surveillance

- ◉ Initiate urgent actions to improve the recovery process of immunization services from the impact of the COVID-19 pandemic, by applying the principles outlined in the Strategic Framework for the Regional Vaccine

Action Plan 2022–2030 and the Regional Vaccine implementation Plan 2022–2026.

- ⦿ Identify and focus on subnational high-risk areas with a large number of zero-dose children as well as on special populations (migrants / displaced /vulnerable populations) and ensure revised microplans to improve access to and utilization of RI in these areas/population groups.
- ⦿ Review the implementation of catch-up immunization activities, including catch-up campaigns, and where necessary, increase the age limit of the target populations to include those who have crossed the maximum age of eligibility for RI.
- ⦿ Identify opportunities to strengthen screening for vaccination status (for example, at school entry) to close immunity gaps.
- ⦿ Immunization partners must support critical needs, including the mobilization of human resources in areas with missed children, until full recovery from the impact of the COVID-19 pandemic.
- ⦿ Ensure that the country action plans developed to strengthen VPD surveillance during the “Fourth Regional workshop to review progress towards priority VPD surveillance and outbreak preparedness and response” in June 2022 are included as an integral part of national plans and monitor implementation of the plans.
- ⦿ NIPs must undertake periodic programme reviews, including VPD surveillance and environmental surveillance reviews, with NITAG engagement and partner support for timely course correction.
- ⦿ Assess the BeSD of immunization uptake and use these to guide a combination of strategies to increase the uptake of vaccines at national and subnational levels.
- ⦿ Review strategies for risk communication and community engagement, as well as outbreak communication and take the necessary actions at national and subnational levels.
- ⦿ Undertake periodic mapping of the population, health-care facilities and immunization and surveillance workforce and develop plans to address gaps.
- ⦿ Use the experience of digitalization of immunization coverage data and supply chain management data from the COVID-19 vaccine deployment for RI.

- ⦿ Use opportunities to triangulate various data sources to better identify immunity gaps and inform actions; and explore ways to improve real-time data in all countries.
- ⦿ Conduct a detailed data quality assessment at the subnational level periodically and ensure optimal implementation of the improvement plans.

Adverse events following immunization

- ⦿ The countries must develop work plans for 2022–2023 to strengthen AEFI reporting, investigation, and causality assessments with support from WHO.
- ⦿ Those countries which do not meet the AEFI surveillance sensitivity indicator of one serious AEFI per million population for EPI antigens need to improve AEFI reporting.
- ⦿ National AEFI committees must conduct timely causality assessments for serious AEFIs for COVID-19 and EPI antigens and regularly share data with the NITAGs, WHO and the Upsala Monitoring Centre through ViGiBase.
- ⦿ Data on case investigation and causality assessment of serious events must be shared at least every six months between vaccine manufactures, NRAs and immunization programmes.
- ⦿ Evaluate the experience of Adverse Events of Special Interest (AESI) surveillance in Indonesia to assess the benefits so that it may be initiated in other countries.
- ⦿ Integrate risk communication and community engagement in AEFI response activities and consider the inclusion of a communication expert in the national AEFI committee.

Strengthening regulatory capacity

- ⦿ Continue NRA capacity-building for the introduction, deployment and safety surveillance of vaccines, as well as the expedited grant of EUA and conversion of EUAs into full license.
- ⦿ The three vaccine-manufacturing countries with functional NRAs must take the necessary action to get certified as WHO Listed Authorities.

- ⦿ NRAs should consider adopting and implementing reliance mechanisms amongst themselves and other relevant institutions and take initiatives to legalize such reliance systems.
- ⦿ Considering that vaccine regulation in the Region is seriously impacted by the shortage of trained staff, additional staff should be recruited by the NRAs, after resource mapping, to carry out mandatory NRA functions.
- ⦿ NRAs must continue to support passive AEFI systems (reporting, investigation, causality assessment) and regularly engage with the AEFI committees to share information and make decisions.
- ⦿ WHO will coordinate the development of a digital platform for the sharing of regulatory information between various governmental/regulatory agencies within each country and between countries in the Region.
- ⦿ WHO will advocate for the establishment of dedicated regional training centres for regulatory sciences and related areas.

B. Pursuing VPD elimination/control goals

Measles and rubella elimination

- ⦿ All countries must expedite the implementation of the recommendations of the 7th meeting of the Regional Verification Commission (RVC) for Measles and Rubella Elimination and the independent external review conducted in q3 2021.
- ⦿ The Regional Office will conduct high-level consultations with experts and Member States by early 2023 on the urgency to achieve the goal of MR elimination, as well as the need for revisiting the strategies and mechanisms.
- ⦿ All countries will conduct assessments of outbreak preparedness and response at the national and subnational levels. This will include simulation exercises.
- ⦿ The countries that are yet to switch from the 10-dose to the 5-dose vials will review the local context and plan for a switch to enhance coverage and reduce wastage. Health workers will need to be sensitized prior to the switch.

- ◉ WHO will continue to explore innovative approaches to enhance the sensitivity of MR surveillance, including the use of innovative sample collection approaches.

Polio eradication and polio transition

- ◉ Implement the recommendations of the meeting of the RCCPE held in October 2021. This includes preparing for a potential use for nOPV2 as per the preparatory framework developed by GPEI.
- ◉ The countries will update their national polio outbreak response plans in accordance with the global guidance issued in March 2022 and maintain adequate capacity for outbreak detection and response.
- ◉ The countries are encouraged to conduct polio outbreak simulation exercises.
- ◉ All countries will introduce the second dose of IPV and adopt one of the two options recommended by SAGE.
- ◉ Considering the risk of importation of WPV and transmission of cVDPVs, the countries should, with the support of WHO, conduct an assessment for the establishment/expansion of environmental surveillance, especially in high-risk areas with a high number of zero-dose children or a vulnerable population of significant size.
- ◉ The continued commitment of Member States and partners is required to ensure the timely implementation of national transition plans. This includes resource allocation, maintaining essential polio functions and contributing to the strengthening of the immunization system, as well as to the achievement of coverage and equity goals.

Other VPDs with elimination/control targets

MNTE

- ◉ All countries must work towards the restoration of immunization services, which were impacted by the COVID-19 pandemic. This includes the vaccination of pregnant women, booster doses for children and adolescents and revitalization of school-based health services.
- ◉ There should be regular district level monitoring of the maintenance of MNT elimination, especially in countries that are at a higher level

of risk. Post-validation assessments of the MNTE programme must be made and course correction must be carried out if necessary.

- ⦿ WHO will explore the possibility of conducting post-validation assessments in one or two countries every year.
- ⦿ Countries must develop systems to track the coverage of TTCV booster doses and report regionally and globally.
- ⦿ Countries are encouraged to implement/strengthen NNT surveillance as per WHO guidelines.
- ⦿ They are also encouraged to implement as appropriate the actions proposed in the 2017 WHO position paper on tetanus vaccines. These include a high coverage of the 3-dose primary series plus the 3-dose booster series prior to adolescence. All pregnant women should have their tetanus vaccination history reviewed at their first antenatal care visit and be provided with adequate doses if needed.

Controlling hepatitis B through immunization

- ⦿ All NIPs must take action to improve the coverage of hepatitis B birth dose (BD) through strong coordination between EPI and MNCH, including:
 - Joint assessments and data analysis as well as identifying incentives and mutual benefits of Hepatitis B BD delivery systems
 - Reducing the gap between facility/SBA deliveries and Hepatitis B BD coverage
 - ensuring adequate vaccine products and logistics including forecasting, vial presentation and cold chain capacities and management
 - effective communication strategies tailored for different target audiences
- ⦿ Include the Hepatitis B BD assessment component in upcoming EPI reviews, as appropriate

C. Leaving no one behind by increasing equitable access to and use of new and existing vaccines

Introduction of new and underutilized vaccines

- ⦿ Countries are encouraged to assess the disease burden and introduce new and underutilized vaccines in accordance with the situation. NITAGs should play an important role in evidence-based decision-making related to the introduction of vaccines.
- ⦿ Countries with a high burden of typhoid and cholera could take the Gavi funding opportunity to introduce vaccines against these diseases.
- ⦿ Assess the progress on the implementation of the VPD surveillance guidelines for all targeted priority diseases.
- ⦿ Countries must strengthen surveillance of new vaccines to ensure the completeness, compilation and analysis of data, as well as sharing of data with clinicians and decision-makers for public health action.
- ⦿ Countries must ensure the completeness of reporting of Japanese encephalitis, typhoid, invasive bacterial/meningococcal disease in the JRF.
- ⦿ They must ensure the quality of laboratory surveillance through quality control and external quality assessment activities.
- ⦿ Countries are encouraged to consider the implementation of the recent SAGE recommendations on the HPV vaccine introduction and schedule, and on activities to improve coverage.
- ⦿ Countries are encouraged to assess the impact of the introduction of new vaccines on disease burden.
- ⦿ Countries must conduct post-introduction evaluations of newly introduced vaccines, including those that were delayed due to the COVID-19 response, and use the findings for corrective action.
- ⦿ WHO will support countries to finalize the drafting of applications for Gavi support for new vaccines, to accelerate planned introductions or expansions, and disseminate new guidelines and data management solutions for surveillance (JE/AES, Rota/GPDS, IBD).

COVID-19 vaccine roll-out

- ⦿ Countries must ensure high coverage of the primary series and booster doses of COVID-19 vaccines among the highest priority and high priority groups before expanding vaccination to other groups. They must:
 - set realistic targets and timelines to reach the remaining population groups;
 - develop strategies to reach unvaccinated individuals in the priority groups (for example, house-to-house campaign and tailored communication); and
 - monitor subnational coverage to ensure the equitable administration of vaccines.
- ⦿ Countries must develop strategies for the integration/combination of services and resources for COVID-19 vaccination with those for RI to reach population groups that have missed COVID-19 and routine vaccines, including zero-dose children.
- ⦿ WHO will develop a learning/sharing platform to document and share experiences across countries on integrating COVID-19 vaccination into primary health care (PHC) services.
- ⦿ Countries must continue to enhance risk communication and community engagement in relation to adverse events and misinformation related to vaccination.
- ⦿ Countries must conduct waste management assessments at the PHC level, and plan for improvement, including guidance on managing/handling wasted doses of vaccines.
- ⦿ Countries must leverage the investment in cold chain and digital technology for COVID vaccination to benefit RI and the health system.
- ⦿ Countries must use the findings of the post-introduction evaluations of COVID-19 vaccines to improve vaccine roll-out and strengthen RI.
- ⦿ Countries must use results of local/regional vaccine effectiveness studies to inform decision-making.

Additional country-specific recommendations

Bangladesh

- ⦿ Measure the impact of the Urban Immunization Strategy and report the findings during the next meeting of the ITAG.
- ⦿ Monitor the epidemiology of VPDs in the Cox's Bazaar population and plan urgent interventions to improve coverage of EPI and COVID-19 vaccines.

Bhutan

- ⦿ Assess the need for MCV catch-up among children who reached the milestone age in 2020. Consider the need for catch-up in districts where the MCV2 coverage is low.

DPR Korea

- ⦿ The ITAG strongly recommends the immediate resumption of RI services, including catch-up for children who have missed vaccination.

India

- ⦿ Implement the state-level plans for strengthening and recovery of RI optimally, with emphasis on reducing zero-dose children.
- ⦿ Implement, in a timely manner, the recommendations of the India Expert Advisory Group for Measles-Rubella (IEAG-MR) and IEAG-polio, including the road map developed by the IEAG-MR on immunization, surveillance and laboratory.
- ⦿ Ensure continued support for the polio workforce that has transitioned/transformed to NPSN.

Indonesia

- ⦿ Develop province/district-level plans (involving the local government and other stakeholders) to identify barriers to RI coverage and develop tailored strategies to overcome these barriers and reduce zero-dose children. The following steps are recommended:

- better coordination between national, provincial and district governments; and
- strengthened mechanisms for greater accountability at subnational level for the strengthening of immunization systems.
- ⊙ Monitor the availability of all vaccines at the national and subnational levels, and ensure timely vaccine procurement and distribution.
- ⊙ Implement the improvement plan developed following the most recent data quality assessment.
- ⊙ Urgently undertake facility survey in accordance with the GAP III requirements to identify poliovirus infectious materials.

Maldives

- ⊙ Develop a long-term plan for human resource management for immunization and surveillance.
- ⊙ Take the following steps to assess strategies to identify high-risk groups and areas:
 - perform coverage evaluation survey of RI to understand coverage levels as well as monitoring, evaluation and action of the immunization programme for PHC/UHC; and
 - develop a mechanism to track children in the greater Male' area for immunization.
- ⊙ Assess the feasibility of initiating rotavirus surveillance.
- ⊙ Develop inter-ministerial coordination to improve the coverage of TTCV and introduce the second booster (Td) dose for adolescents.
- ⊙ Consider implementing the existing policy for Hep B vaccination for all health workers.

Nepal

- ⊙ The NIP should be proactive and engaged in getting the maximum out of the new federal structure so that achievements in the field of immunization are maintained and improved further.
- ⊙ Focus on strengthening and institutionalizing the concept of "fully immunized village" and extending it to palikas and municipalities.

Sri Lanka

- ⦿ In consideration of the present economic situation, keep in constant touch with WHO and RITAG regarding the availability of vaccines and impending faltering of vaccination.
- ⦿ Continue to monitor closely the coverage data at the subnational level and ensure the timely ordering and distribution of vaccines and logistics at all levels through innovative approaches.
- ⦿ Ensure transition from TT to Td vaccine use.

Thailand

- ⦿ Identify areas with low immunization coverage and its reasons and develop area-specific strategies to reach target benchmark.
- ⦿ Conduct an in-depth independent external review of the national EPI programme with a focus on factors affecting vaccine uptake (demand, supply, access and utilization issues).

Timor-Leste

- ⦿ Conduct an in-depth review of VPD surveillance with a focus on AFP and measles and rubella and take corrective measures accordingly.
- ⦿ Conduct a high-quality readiness assessment for the successful implementation of the planned MR SIA in the fourth quarter of 2022.
- ⦿ Assess AEFI surveillance and implement corrective measures for the large number of AEFI reported due to programme errors.

Annex 1

Opening address of Regional Director

Shri Rajesh Bhushan, Secretary, Ministry of Health & Family Welfare, Government of India; Members of the South-East Asia Region Immunization Technical Advisory Group, Chairpersons and Representatives of National Immunization Technical Advisory Groups from Member States, technical experts, programme managers, representatives of partner agencies, ladies, and gentlemen.

Good morning and welcome to this Thirteenth Meeting of the WHO South-East Asia Regional Immunization Technical Advisory Group (ITAG).

I first want to congratulate all immunization stakeholders on the COVID-19 vaccine roll-out.

At this time last year, just over 7% of people in the Region had received the primary vaccination series.

Today, almost 65% have completed the primary series and around 12% have received at least one booster dose.

Over the last 19 months, more than 3 billion doses of COVID-19 vaccines have been administered in the Region, with five countries having achieved the 70% coverage target for the primary series.

The commitment you have shown is truly remarkable, and I urge you to continue to dig deep, fully mindful that the pandemic is not over, and that we must continue to urgently vaccinate or boost high-priority groups.

And I also extend to you my sincere gratitude for your efforts to maintain the Region's many immunization achievements.

The Region continues to be polio-free – eight years since certification, coming up on a decade.

Since 2016 we have maintained elimination of maternal and neonatal tetanus.

Five countries of the Region have eliminated measles and two have eliminated rubella.

Four countries have controlled hepatitis B through immunization.

By 2026, we aim to have averted approximately 6 million deaths in the Region through immunization, and 10 million by 2030, in line with the Immunization Agenda 2030.

All Member States continue to implement strategies to fully revive immunization and surveillance activities, which in many countries were disrupted by the pandemic, despite our best efforts.

In 2021, DTP3 coverage in the Region was reduced to 82%, down from 91% in 2019.

Between 2019 and 2021, coverage of the first dose of measles-containing vaccine declined from 94% to 86%, and coverage for the second dose declined from 83% to 78%. Coverage of rubella-containing vaccine declined from 93% to 86%.

Globally, as a result of the COVID-19 pandemic, the world has witnessed the largest sustained decline in childhood vaccinations in approximately 30 years.

In 2021, an estimated 25 million children missed out on one or more doses of DTP through routine immunization services.

This is 2 million more than those who missed out in 2020 and 6 million more than in 2019, highlighting the growing number of children at risk from devastating but preventable diseases.

Over the course of this four-day meeting, I urge this ITAG:

First, to help countries refine the strategic, operational and policy guidelines by which they can maximize surveillance and immunization coverage while responding to and recovering from the COVID-19 pandemic.

Second, to share key lessons to fast-track progress on the Strategic Framework for the Regional Vaccine Action Plan 2022–2030.

Third, to recommend technical and programmatic guidance to optimally implement immunization and surveillance activities.

Fourth, to help countries develop context-specific plans to achieve the milestones and targets identified in the Strategic Framework and its Implementation Plan.

Fifth, to consider how best countries can harness and apply new innovations at both national and subnational levels to improve efficiency and impact.

And sixth, to deliberate on how each country can better integrate immunization programmes with other PHC services, in line with the Region's new Strategy for Primary Health Care.

My message to all participants is to make the most of this opportunity to define how best we in the Region can build back better, more equitable and resilient immunization systems, together.

Over the course of this meeting, your actionable feedback will be critical to countries as they close remaining gaps and achieve routine immunization coverage and surveillance performance equal to or greater than pre-pandemic levels.

It will help countries accelerate coverage of the COVID-19 primary vaccination series, and also increase booster doses among priority population groups, in line with the SAGE prioritization roadmap.

It will help ensure all countries can decide on how best to synergize routine immunization and COVID-19 vaccination, integrating COVID-19 vaccination into existing infrastructure and immunization services.

It will help increase Region-wide accountability, facilitating full implementation of the Regional Vaccine Implementation Plan, and accelerating progress towards our targets and goals.

Now more than ever, we must pull together to achieve our vision of a Region in which no child suffers or dies from vaccine-preventable diseases, and in which everyone, everywhere, at every age, fully benefits from vaccines.

Thank you.

Annex 2

Agenda

Day 1

- ⦿ Opening remarks by Regional Director
- ⦿ Remarks by Secretary, Ministry of Health and Family Welfare, Government of India
- ⦿ Objectives of the meeting and introduction of the ITAG members
- ⦿ Progress in and challenges to immunization and VPD surveillance in the South-East Asia Region
- ⦿ Global report on immunization
- ⦿ Updates from Gavi, the Vaccine Alliance
- ⦿ Efforts to strengthen RI systems in the Region
 - Progress in and challenges to strengthening of immunization systems and VPD surveillance, including data quality, vaccine supply and cold chain
 - Demand generation for RI – status, challenges and way forward
 - Efforts towards strengthening capacity for regulation of vaccines in the Region
- ⦿ Measles and rubella elimination in the Region
 - Progress in and challenges to measles and rubella elimination
 - Independent assessment of progress against the strategic plan for measles and rubella elimination in the Region – key findings and recommendations
 - Challenges to maintaining measles and rubella elimination in Sri Lanka
- ⦿ ITAG closed-door session

Day 2

- ⊙ Polio eradication and polio transition
 - Efforts to maintain polio-free status of the Region
 - Global update, including guidance on use of IPV and nOPV2
 - Polio transition in South-East Asia
 - Progress in polio transition in India
- ⊙ Other VPDs with elimination/control targets
 - Hepatitis B control through immunization in the Region
 - Planning a national Hepatitis B seroprevalence survey in Maldives
 - Sustaining maternal and neonatal tetanus elimination in the Region
- ⊙ Introduction of new and underutilized vaccines in the Region
 - Overview of introduction of new vaccines
 - Introduction of typhoid conjugate vaccine and developing linkages with RI – experience/lessons learnt from Nepal
 - SAGE guidance on HPV immunization schedule
- ⊙ COVID-19 vaccine deployment
 - Overview of COVID-19 vaccine deployment in the Region
 - Global progress/challenges/way forward, including efforts towards integrating with life course vaccination
 - Vaccine effectiveness of COVID-19 vaccines, including boosters
 - Progress in AEFI surveillance for COVID-19 vaccination and utilizing opportunities to strengthen AEFI surveillance for routine vaccines
 - Utilizing learnings from post-introduction evaluation of COVID-19 vaccines for coverage improvement in Bhutan
 - Post-introduction evaluation of COVID-19 vaccines – key conclusions, recommendations, and way forward in Thailand
 - Enhancing coverage of COVID-19 vaccines in Myanmar
 - Efforts towards integration of COVID-19 vaccination and RI – lessons learnt from Timor-Leste
 - Closed-door session

Day 3

- ⊙ Regional Vaccine Implementation Plan – way forward
- ⊙ ITAG closed-door session and parallel informational sessions
 - Respiratory syncytial virus vaccine
 - Defeating meningitis by 2030 – role of vaccination
 - Malaria vaccine
 - Monkeypox vaccine
- ⊙ Conclusions and recommendations of the ITAG and discussion
- ⊙ Closing

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The Thirteenth Meeting of the World Health Organization's South-East Asia Regional Immunization Technical Advisory Group (SEAR-ITAG) was held on 17-19 August 2022 in New Delhi, India.

SEAR-ITAG is a technical group comprising experts from disciplines such as programme management, communicable diseases and vaccine preventable disease control, virology, epidemiology, and immunization. SEAR-ITAG provides guidance on setting regional priorities for immunization and offers technical support for strengthening routine immunization services to Member States. It meets annually with national Expanded Programme on Immunization managers and surveillance focal points, and partner agencies, to review progress on immunization coverage, surveillance, programme issues, and matters related to vaccine quality assurance.

This report provides an overview of proceedings, conclusions, and recommendations from the thirteenth annual meeting of the SEAR-ITAG in 2022.

