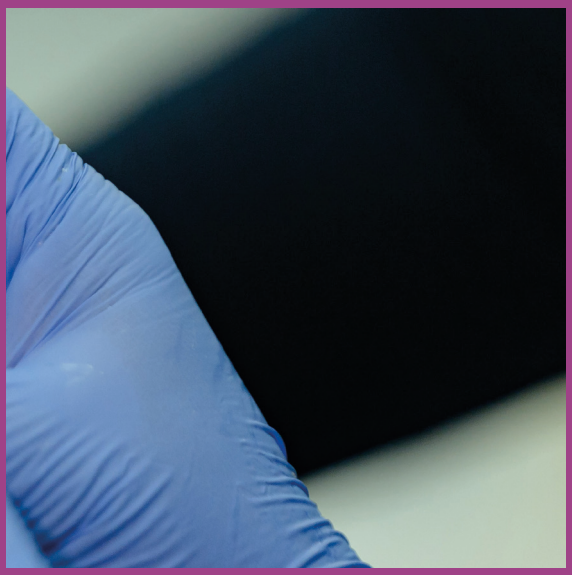
World Health Organization

European Region

Report of the Twenty-fourth Meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE)

5–6 November 2024
Copenhagen, Denmark



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Abstract

At its twenty-fourth meeting, held on 5–6 November 2024, the European Technical Advisory Group of Experts on Immunization (ETAGE) reviewed progress with immunization in the WHO European Region and provided policy advice to the WHO Regional Office for Europe and its Member States.

Keywords

IMMUNIZATION
VACCINES
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Abbreviations

AEFI	adverse event following immunization
AMR	antimicrobial resistance
bOPV	bivalent oral polio vaccine
CRS	congenital rubella syndrome
CI	confidence interval
COVID-19	Coronavirus disease
cVDPV	circulating vaccine-derived polioviruses
DTaP	diphtheria-tetanus-acellular pertussis (vaccine)
DTP	diphtheria-pertussis-tetanus (vaccine)
DTP3	three-dose course of DTP vaccine
DTwP	diphtheria-tetanus-whole cell pertussis (vaccine)
ECDC	European Centre for Disease Prevention and Control
EIA2030	European Immunization Agenda 2030
EPI	Expanded Programme on Immunization
ETAGE	European Technical Advisory Group of Experts on Immunization
GCC	Global Certification Commission for Polio Eradication
HPV	human papillomavirus
IA2030	Immunization Agenda 2030
IPV	inactivated poliovirus vaccines
JRF	WHO-UNICEF Joint Reporting Form
LMIC	low- and middle-income country
LRTI	lower respiratory tract infection
MCV	measles-containing vaccine
MCV1	first dose of MCV
MCV2	second dose of MCV
MIC	middle-income country
NITAG	National Immunization Technical Advisory Group
nOPV	novel oral polio vaccine
OCV	oral cholera vaccine
OPV	oral poliovirus vaccines
PHC	primary health care
RSV	respiratory syncytial virus
RSVpreF	bivalent RSV prefusion-F protein (vaccine)
SAGE	Strategic Advisory Group of Experts on Immunization
SIA	supplementary immunization activity
UNICEF	United Nations Children's Fund
VE	vaccine effectiveness
VPD	vaccine-preventable disease
WPV1	wild poliovirus type 1

Executive summary

The Twenty-fourth Meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE) was held in Copenhagen, Denmark on 5–6 November 2024, to review progress with immunization in the WHO European Region and provide policy advice to the WHO Regional Office for Europe and its Member States.

ETAGE received reports on the status of global and regional immunization programmes, and progress against the European Immunization Agenda 2030 (EIA2030) monitoring indicators. ETAGE was briefed on the conclusions and recommendations of the Strategic Advisory Group of Experts on Immunization (SAGE) and considered the implications of SAGE recommendations on the cessation of bivalent oral poliovirus vaccines (bOPV) and the use of newly available products to prevent respiratory syncytial virus (RSV) disease in infants in the Region. In addition, ETAGE reviewed evidence on recent outbreaks of pertussis in the Region and the progress made in enabling access to affordable new vaccines in middle-income countries in the Region.

ETAGE commended countries for filling historical data gaps for EIA2030 implementation, although significant gaps in timely data reporting to monitor trends remain. ETAGE noted that while there was success in maintaining the Region's polio-free status, progress in achieving measles and rubella elimination and hepatitis B control, and advances in evidence-based decisions on vaccine introduction, overall progress towards EIA2030 targets is not on track. ETAGE reiterated the recommendations issued in December 2023 to accelerate progress towards EIA2030 and requested the Regional Office to continue monitoring progress, consider reviewing the usefulness of the monitoring indicators and explore options for disseminating the technical progress report.

ETAGE welcomed the WHO/SAGE recommendations on the use of immunization products for the prevention of severe RSV disease in young infants. ETAGE recognized the significant burden of RSV disease, particularly in young infants, and acknowledged the potential of new immunization products, including maternal RSV vaccination and long-acting monoclonal antibodies, to reduce this burden and encouraged countries in the Region to consider these recommendations based on their national contexts.

ETAGE noted that the Region is well advanced in bOPV cessation; 41 countries are already using only inactivated poliovirus vaccines (IPV) in their polio immunization schedules, and the remaining 12 are moving towards this goal at a varying pace. ETAGE strongly encouraged Member States to minimize the use of oral polio vaccine and move to an IPV-only schedule, in advance of the global bOPV cessation. ETAGE also aligns with the SAGE recommendation that countries not using bOPV for routine immunization should only use IPV for the initial outbreak response.

ETAGE expressed concern about the changing epidemiology of pertussis in the Region, with a resurgence of cases and an increase in infant deaths, with continued transmission in 2024. ETAGE encouraged countries to ensure timely high coverage with the primary series of pertussis vaccinations. In countries with an increase in infant pertussis cases, ETAGE recommended the introduction or strengthening of maternal tetanus-diphtheria-acellular pertussis vaccination, where feasible.

ETAGE noted that middle-income countries (MICs) are lagging with the introduction of new vaccines and acknowledged that improving the affordability, availability, accessibility and acceptability of assured quality vaccines is required for supporting equitable access to vaccines and life-course immunization. ETAGE supports WHO initiatives to improve access to affordable vaccines in MICs by building capacity to enhance the use of vaccine market information to inform national decisions regarding the introduction or use of vaccine products.

Introduction

Opening remarks

The meeting was opened by Dr Ole Wichmann, Chair of the European Technical Advisory Group of Experts on Immunization (ETAGE), who welcomed participants and noted that having all ETAGE members attend in person would enable more direct interaction and facilitate the discussions. He also welcomed Dr José Hagan who has replaced Dr Siddhartha Datta as the acting Regional Advisor for Vaccine-preventable diseases and Immunization of the WHO Regional Office for Europe.

Dr Hagan stated that it was an honour for him to represent the Vaccine-Preventable Diseases and Immunization team at the Regional Office, and thanked ETAGE for its valuable support and guidance.

Remarks from the Director of the Division of Communicable Diseases, Environment and Health, Regional Office

Mr Robb Butler, Director of Communicable Diseases, Environment and Health welcomed ETAGE members and briefed them on recent developments in the Region.

Dr Hans Henri P. Kluge was re-elected for a second term as the WHO Regional Director for Europe and has indicated that his first task will be to consult all Member States and health partners to develop the next five-year plan, the European Programme of Work. The Regional Director has identified the key themes going forward as: (i) national health security; (ii) noncommunicable diseases and mental health; (iii) tackling the climate crisis; and (iv) ageing in good health *(1)*.

Mr Butler noted that a very low proportion of national plans in the Region to address antimicrobial resistance (AMR) were being funded. The Regional Office plans to develop an accountability index to foster mutual accountability for actions to address AMR in the Region. He also noted that the Regional Office is considering adding new disease elimination goals, such as a tuberculosis-free central Asia. ETAGE was urged to consider and advise WHO on the metrics and process to certify the elimination of cervical cancer. To stimulate renewed efforts to address the health impact of climate change, the WHO European Centre for Environment and Health in Bonn, Germany, has been given the mandate to focus on this area.

The Vaccine-Preventable Diseases and Immunization Programme at the Regional Office has an important role to play in sharing experiences with other programmes to contribute to improving programme monitoring, addressing health inequities and jointly using measles as a tracer to identify and address health inequities.

Finally, he noted that it was important that ETAGE engages directly with the Regional Director and announced that a face-to-face meeting between the Chair of ETAGE and the Regional Director had been organized to immediately follow the meeting to brief him about the deliberations and recommendations from ETAGE.

Session 1. Global and regional overview of immunization, vaccine-preventable disease epidemiology and priority focus areas in 2025

1.1 Global update

The meeting marked 50 years since the establishment of the Expanded Programme on Immunization (EPI). The opportunity was used to reflect on the accomplishments of the programme during the past five decades and imagine its future. An envisioning exercise is planned to take place during the next 18 months.

Since the establishment of EPI, the global population has more than doubled, the infant mortality rate has declined from 92 to 26 per 1000 live births and life expectancy has increased from 59 to 73 years. During this period, the coverage with three doses of diphtheria-pertussis-tetanus (DTP) containing vaccines (DTP3) has increased from around 5% to almost 85%. The global immunization programme has driven progress towards equity in access to health care and served as a foundation for primary health care (PHC). The number of globally recommended vaccines has increased from seven in 1974 to 13 in 2024, with more than 20 additional vaccines available to prevent additional diseases in specific contexts.

A recently published modelling study estimated that 154 million deaths have been avoided from 14 vaccine-preventable diseases (VPDs) due to immunization efforts since the establishment of EPI 50 years ago, with measles accounting for 60% of lives saved; 40% of the reduction in infant mortality since 1974 can be attributed directly to vaccination *(2)*.

The Immunization Agenda 2030 (IA2030) provides the global vision and strategies for immunization for the current decade and is accompanied by several guidance documents for the implementation of the strategy. In 2024, the Member States of WHO reaffirmed their commitment to IA2030 during the World Health Assembly, with interventions from over 50 speakers that covered a range of issues.

However, progress with the implementation of IA2030 is not on track and has been affected by backsliding during the COVID-19 pandemic. While there is evidence of recovery, the number of unvaccinated children remains above the 2019 level. In 2023, while there was progress in reducing the number of unvaccinated children in the WHO African Region and the Region of the Americas, their numbers have increased in the other regions compared to 2022. Around 55% of unvaccinated children live in 31 countries with fragile, conflict-affected and vulnerable settings. The unprecedented number of conflicts in these countries have had a severe impact on health programmes.

Coverage with measles-containing vaccines (MCVs) did not increased in 2023 compared to 2022 and remains below the 2019 levels, resulting in large and disruptive measles outbreaks affecting all WHO regions. Despite these setbacks, there has been progress, with an increasing number of countries being verified as having eliminated measles and/or rubella; in 2022, 83 countries were verified as having eliminated measles and 99 as having eliminated rubella.

The past two years have seen an unprecedented number of VPD outbreaks, highlighting the importance of resilient routine immunization programmes for achieving global health security.

The "Big Catch-up" was launched by WHO and partners in 2023 and aims to vaccinate children who missed their vaccination doses during the pandemic, restore immunization programmes, strengthen immunization systems within PHC and improve their resilience.

New indicators to monitor the conduct of studies to assess the behavioural and social drivers of immunization have been included in the WHO-United Nations Children's Fund (UNICEF) Joint Reporting Form (JRF). A sizeable proportion of countries, including in the European Region, have reported conducting assessments to determine the reasons for under-vaccination.

There has been progress with some unfinished priority agendas, with an increasing number of countries introducing malaria and human papillomavirus (HPV) vaccines. As of 2023, 144 countries reported having introduced HPV vaccines and around 27% of adolescent girls globally have been vaccinated.

While DTP3 coverage has stagnated, coverage with pneumococcal and HPV vaccines and the second dose of MCV has increased, indicating progress with life-course vaccination.

WHO has published several guidance documents to support life-course vaccination, including for health workers. While over 80% of countries reported having recommendations for vaccination of pregnant women, newborns, children and adolescents, less than 50% reported recommendations for adult vaccination. The COVID-19 pandemic has changed the adult vaccination landscape, providing an opportunity to accelerate progress with life-course vaccination.

Looking forward, there is a robust pipeline of vaccines in development targeting a range of diseases. There is growing momentum to introduce and scale up the use of newer tuberculosis vaccines. A Tuberculosis Vaccine Accelerator Council has been established and tuberculosis vaccines for adults and adolescents are likely to be included in the Gavi portfolio in its next strategy period. With the availability of many new vaccines, countries will need to make informed choices to prioritize their introduction. WHO has recently published a list of priority pathogens, by region, for vaccine research and development, using multicriteria decision analysis *(3)*. WHO has also conducted a systematic review to estimate the impact of 44 vaccines that exist or are under development in reducing AMR *(4)*.

Accelerating progress in achieving the Sustainable Development Goals in an increasingly complex environment will pose a significant challenge and the expected innovations in developing new vaccines, delivery platforms and system improvements can make an important contribution.

1.2 Regional overview of 2024 and priority focus areas for 2025

There has been a slow recovery of immunization coverage since 2020, though major coverage gaps persist at the national level. In addition, national coverage data masks disparities between subnational levels.

Since 2000, the average national coverage with the first dose of MCV (MCV1) ranged from 63% in Montenegro to 99% in Hungary. While 34 countries maintained MCV1 coverage ≥ 90% from 2019 to 2023, in one country coverage has been consistently < 60%. In addition to the reported coverage levels, the uptake of MCV1 is not timely, leading to the accumulation of susceptible children in younger age cohorts. The delayed uptake is driven by an erroneous fear among both parents and healthcare providers that MCV could lead to developmental problems in infants. In addition, countries are unable to adequately estimate immunity gaps in the younger age cohorts using national immunization coverage data. Modelled estimates indicate that in many countries in the Region, the number unvaccinated in the under-5 age group exceeds the size of one birth cohort, increasing the risk of outbreaks. This was reflected in a resurgence of measles in the Region in 2023 and the first half of 2024; the decline in cases in the latter half of 2024 reflects the impact of outbreak response vaccination, catch-up vaccination and natural immunity.

Recurrent outbreaks of circulating vaccine-derived polioviruses (cVDPV) pose a challenge to sustaining the polio-free status of the Region. Many of these outbreaks occur in countries classified as low risk for the spread of cVDPV following importation. Inequitable immunization coverage is an important cause of such outbreaks, and the ongoing use of oral poliovirus vaccines (OPV) presents a constant risk of the emergence of cVDPV in the Region, highlighting the need to shift to the sole use of inactivated poliovirus vaccines (IPV).

The Regional Office's actives in 2024 were guided by the strategic priorities of the European Immunization Agenda 2030 (EIA2030) with a focus on strengthening systems, improving immunization coverage and equity, improving commitment to and demand for immunization, and managing outbreaks and emergencies. An operational framework for EIA2030 has been developed to guide country efforts.

The Regional Office is providing countries with targeted support to strengthen immunization systems. This includes support to make informed decisions on vaccine introduction and the choice of schedules, country assessments and targeted interventions to improve vaccination coverage, strengthening National Immunization Technical Advisory Group (NITAG) capacity by using the findings from structured evaluations to develop improvement plans, and strengthening pharmacovigilance systems.

The EIA2030 monitoring and evaluation process is being used to strengthen the capacity to analyse and use data for action. In-country training programmes have been held in several countries to enhance capacities to use data to inform actions to improve coverage and equity.

The Regional Office has recently published a practical guide to identify, address and track immunization inequities, including through data triangulation *(5)*. Technical support is being provided to countries to conduct situational analyses and formative research to understand barriers and develop tailored interventions to achieve measurable improvement.

A review of surveillance system performance and immunization data was undertaken in Ukraine to identify gaps and take steps to strengthen systems. Regional webinars and technical support are being provided to improve the quality of surveillance for measles, rubella, pertussis and diphtheria. The Regional Office is also supporting the regional measles, rubella and polio reference laboratory networks to conduct laboratory accreditation, external quality assurance and training of national laboratories.

Technical assistance was provided to 9 countries[1] experiencing measles or polio outbreaks to guide outbreak investigations, response planning and the evaluation of root causes leading to the outbreaks. In addition, support is being provided to monitor supplementary immunization activities (SIAs) in Kyrgyzstan, to develop a national action plan for measles and rubella elimination and a measles outbreak preparedness plan in Poland, to conduct outbreak preparedness simulation exercises in the Republic of Moldova and Ukraine, and to review polio and measles/rubella outbreak response planning in all countries of the Region.

Efforts to increase and sustain acceptance and demand for vaccination remain a priority for the Region. The Regional Office has supported behavioural insights and formative research, developed training packages to strengthen vaccine confidence and communication about vaccination, and developed innovative educational interventions in collaboration with education ministries.

Force of the Future is a youth action programme co-created with youth representatives from 31 countries, representing 44 youth organizations and supported by several partner organizations. The initiative aims to (i) foster and strengthen relationships between young professionals/young professional associations and the Regional Office focused on the topic of immunization; (ii) identify ways to engage and communicate with young people on immunization; (iii) build capacity of young people to understand and engage with others on the topic of immunization; and (iv) identify opportunities for co-creation and collaboration between youth representatives and technical experts, including community engagement activities at the regional and/or country level *(6)*.

European Immunization Week 2024 was used to conduct a range of activities across the Region to promote immunization.

The key focus areas for 2025 include: (i) verification of rubella elimination in the remaining three countries and the Region as a whole; (ii) strengthening surveillance and outbreak preparedness; (iii) supporting countries in developing national action plans for improving immunization equity; and (iv) strengthening pharmacovigilance. It was noted that the three countries that are not verified as having eliminated rubella are mainly reporting suspected cases. Surveillance capacity in these countries needs to be strengthened to conduct laboratory confirmation of all suspected cases as part of the verification process.

The Regional Office plans to develop guidance on best practices based on the findings from the review of national measles and rubella outbreak plans. A draft operational framework for measles and rubella elimination in the Region aims to operationalize the concept of using "measles as a tracer" to address health inequities and to drive and measure progress against broader health systems strengthening goals. The next step in developing this framework is to engage with other relevant programmes outside

1 Azerbaijan, Bosnia and Herzegovina, Israel, Kazakhstan, Kyrgyzstan, Republic of Moldova, Serbia, Tajikistan and Ukraine.

immunization to consider how this concept can be used to collectively address health inequities and maximize the potential contributions of multiple public health objectives.

In collaboration with WHO headquarters and the London School of Hygiene and Tropical Medicine, there is an ongoing effort to model the cost of inaction to address immunization gaps, with the aim of informing government decision-making and increasing commitment to and investments in immunization programmes.

Discussion

ETAGE enquired whether there had been any increase in congenital rubella syndrome (CRS) cases in Poland. It was noted that no such increase was recorded in the country, and that misclassification of cases due to lack of laboratory confirmation was therefore suspected.

ETAGE also enquired about plans to sustain and build on the Force of the Future youth action programmes. The Regional Office aims to continue the engagement with youth networks and create a working group to sustain and build on the early efforts.

Concerning the reporting of VPD outbreaks, the Regional Office informed ETAGE that since there is no mandate for countries to report to WHO and at times reporting data to WHO may conflict with their data protection policies, such reporting is weak in the Region.

Session 2. Regional technical progress report of EIA2030 and status of country implementation of ETAGE recommendations

The monitoring and evaluation process of EIA2030 is based on reporting by Member States to WHO through multiple reporting channels. Data quality is reviewed and then analysed to generate the annual technical progress report that describes the progress against each of the EIA2030 indicators. This progress against the indicators is supplemented with qualitative information, including on best practices and unmet and emerging challenges. Following the review by ETAGE, the report, along with ETAGE recommendations will be published and disseminated. The EIA2030 technical progress report for 2023, which evaluates progress as of 2022, is the first publication of this series *(7)*. The indicators themselves, along with their operational definitions, data sources and limitations are described in a compendium of indicators *(8)*. The year 2019 serves as the baseline for most indicators. Some baseline values were retrospectively updated based on improved data completeness for the most recent reporting period.

This section summarizes the key findings of the 2024 technical progress report, evaluating progress as of 2023, and ETAGE discussions.

2.1 Progress against the impact goal indicators

Impact goal indicator 1: sustain polio-free status

The Region has maintained its polio-free status. All four cVDPV outbreaks that occurred in 2021 and 2022 have been closed. Based on 2023 data, three countries have been assessed as being at high risk and 11 at intermediate risk for the sustained circulation of polioviruses following importation or the emergence of cVDPVs. Of the 32 poliovirus essential facilities, 29 have entered the certification process, though delays in certification have been noted in several countries. Coverage with three doses of poliovirus vaccines remains suboptimal and in 2023, 11 countries have coverage of < 90%.

Impact goal indicator 2: measles and rubella elimination

Measles has been eliminated in 33 (62%) countries and rubella in 49 (92%) in the Region as of 2022. While progress in rubella elimination is sustained, in 2023 there was a surge in measles, with 60 860 cases being reported in 41 countries; 25% of cases were reported in the 33 countries verified as having eliminated measles in 2022. About half of the cases were in children < 10 years and 64% were unvaccinated.

Impact goal indicator 3: hepatitis B control

Nine countries (17%) have been validated as having achieved the control target, which is four more than in 2022. Twenty-three (43%) countries provide universal hepatitis B vaccination at birth and 19 of them have achieved and sustained coverage ≥ 90% since 2019. The remaining 30 countries use universal screening of pregnant women and provide passive and/or active immunization to prevent transmission to their infants. Challenges with conducting representative serosurveys and obtaining data on non-vaccination perinatal interventions, which are required for validation, limit the validation process. The ETAGE Working Group on Hepatitis B has proposed that alternate approaches for validation be explored.

Impact goal indicator 4: cervical cancer elimination through HPV vaccination

The number of countries that have included the HPV vaccine in their national programmes has increased from 38 (72%) in 2019 to 45 (85%) in 2023. The regional average vaccination coverage increased from 27% in 2019 to 30% in 2023. However, only four (8%) countries have achieved ≥ 90% coverage with the last dose of HPV vaccines among girls aged 15 years; nine countries (17%) have achieved ≥ 90% coverage with a single dose of HPV vaccine.

Impact goal indicator 5: trend in VPD outbreaks

The baseline rate for this indicator, the three-year average of the number of VPD outbreaks (2018–2020) was 1276. In 2022, only 34 outbreaks were reported, representing a 93% reduction. However, the unavailability of 2023 data on measles outbreaks by the time of report writing poses a challenge in assessing trends considering the surge in measles cases. Cases of invasive meningococcal disease may be underestimated because of inadequate laboratory confirmation and unknown surveillance quality. Reduction in VPD transmission during the COVID-19 pandemic skews the trend assessment; excluding data from 2020–2021 could be considered.

Outbreaks of pertussis and diphtheria are not included in this indicator. Nevertheless, there were steep increases in cases for both diseases in 2022–2023.

Impact goal indicator 6: evidence of under-immunized children at the subnational levels

This indicator applies only to 48 of the 53 countries of the Region; the remaining countries have very small populations and no subnational administrative levels for which coverage is reported. The composite indicator includes DTP3 coverage of at least 95% in at least 90% of districts and the absence of evidence of outbreaks of polio or measles in children < 5 years of age.

In 2023, evidence of inequity as per this indicator was present for 69% of countries in the Region, which is better than the baseline of 79%, but the same as in 2022. Data availability to monitor this indicator has improved but is still suboptimal.

Impact goal indicator 7: PHC and immunization across the life-course

This indicator is defined as the number of countries that have achieved coverage of ≥ 90% with DTP3, the last dose of pneumococcal conjugate vaccine, the second dose of MCV (MCV2), and the last dose of HPV vaccine in the annual target population of girls.

Only 8% of countries have achieved this target as against the baseline of 6% and the goal of 60%.

Progress is limited because of the low coverage of the HPV vaccine, though there is also a concerning trend in MCV2 coverage. Progress is slower in the middle-income countries (MICs) compared to the high-income countries.

2.2 Progress against the strategic priority indicators

EIA2030 includes seven strategic priorities, each of which has one or more associated indicators. This section summarizes progress against selected indicators. Details on all the indicators are presented in the forthcoming EIA2030 dashboards and annual EIA2030 technical progress report *(7)*.

Strategic priority 1: PHC and universal health coverage

Although 92% of countries had a NITAG in 2023, only 36 (68%) met all six functionality criteria; the disclosure of conflicts of interest and representation of five or more areas of expertise were the criteria most often not met. Following the evaluation of 12 NITAGs in MICs, WHO and the Robert Koch Institute revised the evidence-to-recommendations process to enable its use based on resources available to NITAGs in MICs in the Region.

There has been an increase in the proportion of countries conducting periodic surveillance reviews; in 2023, 43% of countries (23) reported conducting an assessment compared to 36% at baseline (19). On average, VPD surveillance reviews included two VPDs (range 1–10) and most countries opted for disease-specific, rather than comprehensive reviews.

In 2023, 35 (66%) countries reported one or more serious adverse events following immunization (AEFIs) per 1 million population through VigiBase (9); 11 countries, three of which are not members of the WHO Programme for International Drug Monitoring, did not report on serious AEFIs, though two of them reported data in the JRF. It was noted that there has been a change in the definition of the indicator, and the estimated date of occurrence of the AEFI is now being considered rather than the date of reporting to VigiBase.

Strategic priority 2: commitment and demand

Twenty-eight (53%) countries assessed demand-related reasons for under-vaccination at least once during 2021–2023; 20 (38%) reported having conducted research and implemented interventions informed by the results of these assessments in 2023. A variety of interventions, mostly targeted at health worker capacity strengthening, were reported.

Strategic priority 3: coverage and equity

Eighteen (34%) countries reported having a targeted immunization plan to improve immunization in high-risk communities, of which 11 (21%) reported having allocated resources for its implementation. In 2023, 25% of countries did not report data and the accuracy of the responses may be inadequate.

It was noted that the concept of "high-risk communities" varies across countries.

Strategic priority 4: life course and integration

In 2019, 21 (40%) countries reached 95% MCV2 coverage, which decreased to 12 (23%) countries in 2020 and has not recovered since; four countries reported < 80% coverage. Seven countries achieved 90% coverage with the last dose of HPV vaccine in the annual target population of girls in 2023, which is three more than in 2022. Though all countries have introduced influenza vaccination since 2021, the coverage among older adults ranged from < 1% to > 95%; missing data due to weak monitoring systems, and lack of reporting of vaccination in the private sector affects the assessment of influenza coverage in several countries.

In 2023, 35 (66%) countries reported having formal collaboration to integrate vaccination with PHC services provided within or outside the health sector; such settings included antenatal care, schools, occupational health, family medicine and long-term care facilities. It was noted that the integration indicator did not provide insights into the level of engagement between different programmes or the quality of implementation.

Pneumococcal conjugate vaccines have been introduced in 47 (89%) countries of the Region and HPV vaccine in 45 (85%); rotavirus vaccine use is limited to 28 (53%) countries.

Strategic priority 5: outbreaks and emergencies

Data to assess a timely response to measles outbreaks were not available for 2023 since they are dependent on the annual assessment of the European Regional Verification Commission for Measles and Rubella Elimination, which was not yet published. Hence, progress could only be assessed for 2022 when 12 of 23 (52%) countries with outbreaks conducted a timely response. The timeliness of detection and response of measles outbreaks had improved in 2022 compared to the previous two years. The timeliness of detection of polioviruses (including through environmental surveillance) declined in 2023; however, since there were no new outbreaks in 2023, the monitoring of a timely response was not applicable.

Strategic priority 6: supply and sustainability

In 2023, four countries reported a national-level stockout lasting more than one month. However, only one was linked to a procurement delay. The remaining three were due to a shortage of the vaccine, distribution issues or an inaccurate forecast. This represents significant progress compared to the 13 stockouts reported in 2019 (baseline) and 11 in 2022.

The analyses of expenditure on PHC and vaccines are affected by the limited availability of data.

Strategic priority 7: research and innovation

As of 2023, 23 (43%) countries reported having conducted operational research over the previous three years; only 14 (26%) reported having applied the findings from the research. The reports of research conducted by countries were reviewed; a variety of studies using different methodologies (both qualitative and quantitative) targeting one or more of several vaccines in different target groups were reported.

2.3 Follow-up of 2023 ETAGE recommendations to accelerate EIA2030 progress

As per the EIA2030 monitoring, evaluation and accountability framework, the WHO Secretariat is expected to report annually on the implementation of ETAGE recommendations. For this first year of reporting, information on the implementation of recommendations was not systematically collected from countries. Information already available through existing sources was used. Some examples of implementation in specific countries were also presented.

Improve completeness and reporting of data

In response to the ETAGE recommendation, WHO contacted all 53 countries and provided them with a list of missing or inaccurate data for 2019–2022. Forty-five countries responded and provided the missing or corrected data or justified why they could not report the data.

Increase immunization coverage through catch-up vaccination and strengthening routine service delivery

Several countries conducted catch-up activities. A detailed description of activities conducted is available for Serbia. Data on catch-up doses administered in 2023 and SIAs in 2022–2023 were reported through the JRF. Less than half the countries had systems to collect and report catch-up doses.

The reported data on vaccine doses administered as part of catch-up vaccination or through SIAs are shown in tables 1 and 2, respectively.

Table 1. Catch-up vaccination doses administered in the Region, 2023

Antigen	Reporting countries	Total catch-up doses	Comparison with annual target population
DTP3	13	2 453 380	84% (range 5–179%)
MCV1	14	1 728 151	56% (1–208%)

Source: Reported by Member States through the JRF

Table 2. Vaccination doses administered during SIAs, 2023

Type of SIA	Antigen	Reporting countries	Targeted age groups	Total number of doses
OR & catch-up	MCV	8	< 5 years (4) < 15 years (1) > 10 year (1) NA (2)	12 586 575
Catch-up	POL	1	< 5 years (1)	961 758
Catch-up	HPV	1	13–14 years (1)	6 677

NA: OR=outbreak response; MCV= measles containing vaccine; POL= polio vaccine; HPV= human papillomavirus vaccine

Source: Reported by Member States through the JRF

Identify and address immunization inequities

The Regional Office has published a practical guide for countries to identify, address and track immunization inequities (5). A companion document on operational considerations is pending publication. Guidance on the use of data analyses and triangulation to identify under-vaccinated communities is under development.

Azerbaijan implemented evidence-based activities to address barriers to vaccination among low performing districts. Cyprus implemented a project to increase access to vaccination among newly arrived immigrants. Armenia, Denmark and Ireland reported conducting SIAs targeting unvaccinated and under-vaccinated refugees, those seeking protection and displaced populations.

Detect, respond to and investigate VPD outbreaks

In response to the ETAGE recommendation, a range of activities were implemented in countries, including outbreak response assessments; reviewing surveillance performance; training on surveillance standards, outbreak response for national and subnational workers, and the use of data for outbreak prevention and response; update of national regulations and guidelines for surveillance and outbreak response; simulation exercises to assess preparedness; and root cause analysis of VPD outbreaks.

The Regional Office conducted a webinar on pertussis surveillance and laboratory diagnosis; continued strengthening of measles, rubella and polio laboratory surveillance; published dashboards for measles, rubella and acute flaccid paralysis surveillance *(10)*; and published a guidance document on integrated surveillance, outbreak response and verification of elimination of measles and rubella *(11)*.

WHO has also designated a collaborating centre for diphtheria in the Centre for Diphtheria at the Bavarian Health and Food Safety Authority in Germany.

Integrate COVID-19 vaccination into routine immunization

Data reported in the first two-quarters of 2024 show that COVID-19 vaccination is ongoing in at least 37 (69%) countries, though 85% of administered doses are in high-income countries.

Action is yet to be taken on the remaining two recommendations: (i) for the Regional Office to develop technical guidance on life-course vaccination; and (ii) for countries to develop monitoring and evaluation frameworks for their respective national strategic or action plans for immunization.

Discussion

With the shift towards using a one-dose schedule for HPV vaccination, ETAGE asked if the indicator could be revised accordingly. It was noted that the Regional Office aligns with the definition and target used at the global level. The WHO coverage estimation with the last HPV dose is based on the number of doses in the national schedule, which was the reason not to change the definition of the indicator. HPV coverage and other indicators are standardized between the global and regional levels to facilitate comparison, and require consensus to change the indicator definition. ETAGE feedback on the usefulness of the indicators is welcome and could inform their revision. A mid-term revision of the EIA2030 monitoring and evaluation framework is planned.

ETAGE discussed the difficulties faced in obtaining data on the impact of catch-up vaccination. Annual reporting of coverage reflects timely vaccination only. It was noted that countries with electronic immunization registries with individual transactional data can generate accurate estimates on the implementation and impact of catch-up vaccination.

ETAGE questioned why only select VPDs were included in the indicator for outbreaks and noted that it was heavily influenced by the number of measles outbreaks. It was reported that this indicator is based on the global indicator and the selection of VPDs was based on those where there was a standard definition of an outbreak, and data were reported to WHO. There are differences in the quality of data between the different VPDs, with a lower quality of data on outbreaks of invasive meningococcal disease. The three-year average was used to account for year-to-year fluctuations. ETAGE suggested exploring the possibility of using the most recent data on measles outbreaks and excluding the COVID-19 pandemic years from the calculation of trends. A revision of the indicator is under discussion.

ETAGE members asked about the rationale for the equity indicator, including the exclusion of five countries. It was noted that the five excluded countries have very small populations and the indicator, which focuses on subnational-level differences in coverage and occurrence of outbreaks, does not apply.

ETAGE discussed the missing data on AEFIs for indicator Strategic Priority 1.4. It was reported that some countries have data on AEFIs but are not yet reporting the data to the WHO programme for international drug monitoring (VigiBase). In some countries, reporting of AEFIs is sensitive because they are considered to represent a failure of the immunization programme. The lack of adequate coordination and sharing of information between the immunization programme and the regulatory authority responsible for pharmacovigilance also impeded accurate reporting in some countries. The target set for the severe AEFI reporting rate is not applicable for countries with very small populations.

ETAGE observed that the integration indicator should look beyond the co-administration of interventions. However, it was acknowledged that an indicator that looks more broadly at integration may be complex and difficult to measure based on reporting through the JRF.

ETAGE congratulated the Regional Office for their efforts to collect and analyse a large amount of data to monitor progress with the implementation of EIA2030. However, ETAGE expressed concern that having too many indicators may divert attention from key issues that affect immunization programmes. ETAGE encouraged the Regional Office to use the technical progress report to motivate countries to report by highlighting the benefits of accurate reporting and the use of the outputs of the report to advocate for adequate resources and improvement of the immunization programme.

Session 3. SAGE September 2024 meeting: summary and considerations for regional adaptation

3.1 Summary of the proceedings of the SAGE 2024 meeting

In 2024, the Strategic Advisory Group of Experts on Immunization (SAGE) celebrated 25 years since its establishment in 1999. Since then, 78 vaccine position papers have been published or updated under the guidance and advice of SAGE.

At its September 2024 meeting, SAGE discussed eight topics: (i) global reports on vaccines and immunization; (ii) progress with implementation of IA2030, including regional progress; (iii) respiratory syncytial virus (RSV); (iv) cholera; (v) poliomyelitis; (vi) rubella and CRS; (vii) mpox and influenza H5N1; and (viii) COVID-19.

Report from the WHO Department of Immunization, Vaccines and Biologicals

The report acknowledged that while social and cultural life is resuming post-pandemic, there are strains on global systems that affect health and well-being. In 2023, immunization coverage remained below pre-pandemic levels, and the number of zero-dose children increased. Recovery is uneven between regions and countries.

An unprecedented number of outbreaks have been reported globally despite efforts to fill immunity gaps through campaigns, highlighting the importance of strengthening routine immunization delivery.

Despite setbacks, there are encouraging examples of success in some countries. Global coverage of HPV and malaria vaccines has increased.

Going forward, the tension between improving routine immunization coverage through systems strengthening and the imperative to act quickly to prevent or respond to outbreaks using vertical approaches needs to be comprehensively addressed.

Progress with the implementation of IA2030

Close to the halfway period of IA2030, dialogue and collaborations between the various stakeholders has increased. However, the monitoring scorecard shows that progress against most of the goals and targets is not on-track. The implementation of IA2030 faces vulnerability to multiple ongoing crises.

SAGE observed that accountability at all levels, including subnational levels, and the use of actionable metrics to assess progress and inform operational decisions are required to make progress.

The metrics to measure progress should be broader than the absolute number of unvaccinated children. Composite indicators that provide a more comprehensive view are needed. SAGE noted that strengthening data systems to enable the analysis and use of data to inform actions is essential to improve programme performance. SAGE also proposed flexible funding and technical support to countries for strengthening data systems and enhancing country capacity to use data to inform decisions on prioritization, programme implementation and evaluation.

SAGE acknowledged that the introduction of new vaccines needs to be balanced with strengthening systems if the full benefits of immunization are to be realized and encouraged country-led processes to make informed choices, invest in systems strengthening and establish accountability mechanisms to achieve the right balance between the two.

SAGE encouraged WHO to explore strategies for political engagement at global, regional and national levels to secure adequate investments in immunization within the national health plans.

Poliomyelitis

There has been an increase in paralytic poliomyelitis cases caused by wild poliovirus type 1 (WPV1) detected in the endemic zones of Afghanistan and Pakistan in 2024. Thirty-four cases were detected between January and September 2024 compared to seven in the same period of 2023.

SAGE expressed support for the ongoing development of the bivalent OPV (bOPV) cessation policy framework, which defines and delineates the guiding principles, triggers and enablers of success. The five triggers, defined as non-negotiable conditions that must be fulfilled before bOPV cessation are: (i) certification of the eradication of WPV1 by the Global Certification Commission (GCC); (ii) certification of elimination of cVDPV2 by the GCC; (iii) the absence of cVDPV1 or cVDPV3 outbreaks lasting ≥ 6 months over 24 months; (iv) adequate stockpiles of type-specific OPV (novel OPV (nOPV) or Sabin); and (v) establishment of IPV schedules with two or more doses for a minimum of two years in all countries. In places where IPV coverage is < 80%, a risk-tiered approach for pre-cessation SIAs with bOPV and/or IPV should be used to boost immunity.

Since many countries desire to switch to IPV-only schedules ahead of synchronized bOPV cessation, SAGE requested WHO to develop a risk-grading criteria framework to define eligibility for a safe transition ahead of bOPV cessation and present it to SAGE in 2025.

Based on a review of recent evidence and genetic data from a clinical trial of co-administration that indicated a low risk of the emergence of recombinant viruses, SAGE revised its earlier recommendation and recommended concomitant administration of nOPV2 and bOPV as an option in areas where multiple poliovirus types co-circulate.

SAGE acknowledged that OPV remains the primary tool for outbreak response but recommended that IPV may be added to concomitant nOPV and bOPV administration during an outbreak response if the timeliness of the response is not affected.

Rubella and CRS

SAGE reviewed existing recommendations on the introduction of rubella vaccines and new evidence and data from modelling.

There are 19 countries yet to introduce rubella vaccine and 10 of them do not meet the recommended 80% coverage with MCV1. These countries experience sustained transmission of rubella virus and account for most of the global burden of CRS.

SAGE was presented with modelled data on the risk of a paradoxical increase in CRS following rubella vaccine introduction. The data from the model indicate that if the introduction of the rubella vaccine is accompanied by high-quality catch-up campaigns and follow-up campaigns, there is no risk of a paradoxical increase in CRS.

Based on the new evidence and model, SAGE recommended introduction in the remaining 19 countries, accompanied by high-quality campaigns and periodic follow-up campaigns.

Mpox

SAGE was presented with the recent evidence of the epidemiology of mpox. The current "public health emergency of international concern" mainly affects the WHO African Region and is caused by mpox clade 1b, with most cases reported from north and south Kivu districts and Kinshasa in the Democratic Republic of the Congo and neighbouring countries in central Africa. There has been limited transmission outside Africa; on 30 October, the UK Health Security Agency confirmed that the first case of clade 1b mpox was diagnosed in an individual with recent travel to Africa.

Mpox cases due to clade 2b, which caused the previous outbreak, are still being reported mainly from the WHO Region of the Americas, the European and Western Pacific regions.

A global strategic preparedness and response plan has been developed, which includes a comprehensive approach addressing surveillance, case management, safe and scalable home care, communication and community protection.

The first mpox vaccine (MVA-BN) was prequalified in September 2024 for use in those aged 18 years and above, and discussions are ongoing to have the LC16 vaccine emergency use listed by WHO.

H5N1 influenza

Influenza A H5N1 Clade 2.3.4.4b viruses have affected many different species since 2020, including birds and terrestrial and marine mammals. High-priority avian influenza viruses have been reported in cattle in the United States in 2024. Human cases have been detected across all WHO regions. Continuous monitoring and response for animal influenza viruses with zoonotic potential is in place.

COVID-19

The Omicron variant and its sub-lineages continue to circulate without an increase in virulence and are associated with lower case rates, fewer hospitalizations, milder cases and a decline in post-COVID conditions.

Several COVID-19 vaccines have been updated to target the latest Omicron JN.1 and KP.2 subvariants. While viral-vectored vaccines are being phased out, at present, mRNA and protein-based vaccines are in highest demand.

Vaccine effectiveness (VE) against severe disease caused by the Omicron subvariants remains substantial and relatively stable over time; VE against mild disease and infection is lower compared to VE against pre-Omicron variants of concern and wanes more quickly after the last vaccination.

SAGE reaffirmed the validity of the interim recommendations in the existing WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines, including the priority-use groups *(12)*.

Cholera

SAGE was provided with an update on the current cholera outbreaks. From January to September 2024, 28 countries reported more than 365 000 suspected cases and over 2600 deaths, though significant underreporting is likely. Case fatality rates continue to be very high.

While the current supply situation remains insufficient to meet the needs for outbreak response, let alone preventive vaccination, efforts by various stakeholders have led to an increase in oral cholera vaccine (OCV) production from mid-2024 and further increases are expected in the coming years.

SAGE expressed concern about the ongoing outbreaks and OCV supply constraints and called on the global health community to continue working together to find timely solutions to improve the situation.

SAGE requested periodic updates on cholera epidemiology, OCV supply and the status and results of research efforts to inform planning for issuing strategic and policy guidance.

SAGE work plan and priorities

Currently, SAGE has 10 active working groups addressing policy issues for several different vaccines. A working group for chikungunya is being established. The HPV working group is currently dormant, whereas activities of other groups related to varicella-zoster virus and IA2030 are ongoing.

The proposed new activities for SAGE in 2025 will include the development of a position paper on chikungunya vaccines, an updated position paper on yellow fever vaccines, the consolidation of recommendations for COVID-19 vaccination into a single position paper, and updates to the Japanese encephalitis and pertussis vaccine position papers.

The SAGE Meningitis Working Group plans to update the relevant vaccine position paper in 2025, which will also include the meningococcal type B vaccine.

Other discussion topics are likely to include tuberculosis vaccines and combination vaccines.

Discussion

The discussion focused on SAGE processes and the timelines for the discussion of the topics under consideration. It was noted that SAGE had to strike a balance between needs and the capacity to respond to them and hence needed to prioritize topics and use processes other than working groups for some topics. For example, updating some SAGE recommendations will involve an internal process, rather than a working group. It was observed that for some topics, such as RSV, varicella-zoster virus and pneumococcal disease in older adults, there was very little data on the burden and epidemiology of these diseases from low- and middle-income countries (LMICs) to inform recommendations for the use of the vaccines. Since these countries were the main users of SAGE recommendations, these topics sometimes received lower priority when the SAGE agenda was full.

3.2 Immunization products to protect infants from RSV disease

RSV is a leading cause of lower respiratory tract infections (LRTIs), hospitalizations and mortality in children globally – causing an estimated 101 400 deaths, 3.6 million hospitalizations and 33 million RSV-LRTI episodes in children annually. About 97% of all RSV deaths occur in LMICs, where a large proportion of deaths occur before presentation to a health facility. Nearly half of the RSV deaths occur in infants aged < 6 months.

In temperate settings, RSV occurs in seasonal epidemics. It circulates year-round with seasonal peaks in semi-temperate settings and can cause year-round disease in equatorial regions. The timing of RSV circulation can vary year to year adding complexity to prevention efforts.

Two products, a long-acting recombinant monoclonal antibody (nirsevimab) and a bivalent RSV prefusion-F protein vaccine (RSVPreF), have recently been licensed for preventing severe RSV disease in young infants. Nirsevimab has been shown to be safe and efficacious in infants in clinical trials. VE against hospitalized RSV-LRTI was 81% (95% confidence interval (CI): 62–90) and was 79% (95% CI: 69–86) against RSV-positive, medically attended LRTI up to 150 days after administration *(13,14)*. The product has demonstrated high effectiveness in initial post-marketing studies in several high-income countries *(15,16)*.

RSVPreF is administered to pregnant women to protect their infants through the transplacental transfer of antibodies. In a phase 3 clinical trial among pregnant women at 24–36 weeks gestation, VE was high against RSV-positive severe medically attended LRTI (VE=70%; 95% CI: 51–83) and RSV-positive medically-attended LRTI (VE=49%; 95% CI: 31–63) in infants up to 180 days after birth. The VE was similar across countries of varying income levels. A statistically non-significant increase in preterm births (< 37 weeks gestational age) was observed in the vaccine group. The imbalance was mainly seen in two upper-middle-income countries, with a statistically significant increase in South Africa. Most preterm births occurred > 30 days after vaccination. There was no excess in preterm births < 33 weeks gestational age in vaccine recipients. Overall, more infant deaths, including neonatal deaths, occurred among placebo recipients *(17)*. A similar signal of excess preterm births was observed in a trial of another experimental maternal prefusion-F vaccine conducted during the same period *(18);* for both vaccines, the excess in pre-term births coincided approximately with waves of coronavirus disease (COVID-19) cases caused by the Delta and Omicron variants, although no causal relationship has been established.

A benefit–risk analysis modelled mortality risk in South Africa, comparing the benefit of averting RSV deaths through vaccination against the potential risk of deaths due to excess preterm births. When restricting the analysis to women vaccinated at 27–36 weeks in South Africa in the clinical trial, 98% of the simulations found the benefit of vaccination to be greater than the risk. However, SAGE acknowledged that the results of this analysis are based on limited data from a single country, whose preterm birth rates and neonatal mortality rates may differ from other LMICs.

Both nirsevimab and the RSVPreF vaccine have received market authorization in more than 40 countries. There are differences in the gestational age window for the administration of RSVPreF as authorized by the regulatory authorities or recommended for use by NITAGs in different countries.

Given the global burden of RSV disease, SAGE recommended that all countries introduce products for the prevention of severe RSV disease in infants. Decisions to use maternal RSVPreF vaccination and/or nirsevimab should consider cost, financing, supply, anticipated coverage and feasibility of implementation within the existing health system.

For countries deciding to use the maternal vaccine to prevent severe RSV disease in infants, SAGE recommended a single vaccine dose in the third trimester of pregnancy, as defined in the local context (≥ 28 weeks of gestation in most settings). No upper gestational limit for vaccine administration was prescribed, except for women in active labour. The recommendation to limit vaccination to the third trimester is a precautionary approach to minimize potential adverse impacts of preterm births before the third trimester, which are associated with the highest risk of mortality and serious sequelae, while preserving the benefits and enhancing programmatic feasibility in LMICs.

Maternal RSV vaccine could be administered at routine antenatal care contacts, at any health-care contact or during outreach activities. A year-round approach to RSV vaccination is preferable in most countries in tropical and subtropical regions, where RSV circulates for much of the calendar year, or where seasonality patterns are not well-described.

For countries deciding to use nirsevimab, SAGE recommended a single dose administered to all infants at birth, or at the earliest opportunity after birth, if a year-round approach is adopted. With a seasonal approach, administration of nirsevimab is recommended for all infants born during the RSV season or those aged ≤ 12 months entering the season. In settings with clearly defined RSV seasonality, a seasonal approach may be more cost-effective than a year-round approach, particularly for nirsevimab whose product costs are higher.

Both nirsevimab and RSVPreF can be co-administered with vaccines normally given at the same time. SAGE noted with concern the limited availability and high cost of nirsevimab, which will seriously limit global access and equity.

A post-licensure, multicentre, randomized controlled study of the safety and effectiveness of RSVPreF is planned in several African countries to assess its effectiveness, safety and full public health impact in LMICs.

Both RSV immunization products are included in Gavi's vaccine investment strategy and the Gavi Board will consider support for the introduction of this vaccine in eligible countries in June 2025. Currently, there is only a price commitment for the RSVPreF vaccine for Gavi purchase.

Discussion

ETAGE acknowledged the importance of the SAGE recommendations on the products for the prevention of RSV disease in infants. There was a query as to why there was no mention of the use of these products, especially nirsevimab in high-risk infants. ETAGE also enquired as to whether there is likely to be a reconsideration of the restriction of the gestational age window for the administration of RSVPreF. The SAGE Secretariat responded by saying that though recommendations for the use of nirsevimab in high-risk infants were not presented to ETAGE, they will be included in the WHO position paper. The gestational age window when the vaccine can be administered will be reviewed as additional safety data become available, including from the planned impact study in Africa.

Access to nirsevimab for selective use in high-risk infants whose mothers may not have received RSVPreF vaccine was discussed, in light of difficulties that a few countries encountered in accessing the product for selective use. The issue was acknowledged as an important one, though it was expected that this may no longer be an issue once additional manufacturers enter the market.

The need for affordable pricing for RSV prevention products for LMICs was highlighted with a call for consideration for UNICEF procurement to enable access for these countries at affordable prices.

There was a discussion on the bodies issuing recommendations for the use of nirsevimab in the Region, where the NITAGs may not be considered as the recommending bodies since the product was considered a medicine and not a vaccine. It was noted that this could also affect the collection and reporting of data to monitor the effectiveness of nirsevimab following its introduction. It was also noted that the European Centre for Disease Prevention and Control (ECDC) was planning to systematically collect and analyse the data to estimate the real-world effectiveness of the two products in their Member States.

3.3 bOPV cessation and the use of IPV in poliovirus outbreak response

This session considered the use of IPV in countries in the Region in light of the existing and recently introduced SAGE recommendations on IPV use for routine immunization and outbreak response.

Currently, WHO recommends that only countries at low risk of polio (as designated by each WHO region) that have attained high routine immunization coverage with at least two doses of IPV should consider transitioning to IPV-only schedules ahead of the planned synchronized bOPV cessation.

In the European Region, Bosnia and Herzegovina, Romania and Ukraine are assessed as high-risk countries by the Regional Committee for Certification of Poliomyelitis Eradication; Tajikistan and Ukraine are on a watch list based on GPEI risk assessment.

An IPV-only schedule is used by 41 countries in the Region, while the others use different mixed schedules of IPV and bOPV.

In its recommendations on bOPV cessation, SAGE did not specify the coverage threshold for defining "high coverage". The coverage with two doses of IPV is high in the Region with most countries achieving coverage of ≥ 90%; only three countries among those still using mixed schedules have coverage of 80–89%. Coverage with three doses of polio vaccine is also high in most countries, with coverage levels of > 80% in those countries with < 90% coverage with two doses of IPV. In terms of proximity to endemic countries, Tajikistan remains on the watch list and is likely to be the last country in the Region to move to an IPV-only schedule.

In the Region, three of the four outbreaks in recent years were successfully managed with catch-up SIAs using IPV alone. Initial IPV catch-up followed by two rounds of nOPV2 was used in Tajikistan because two cohorts of children were left without protection against type 2 poliovirus due to shortfalls in the switch from trivalent OPV to bOPV.

There has been an increase in the number of poliovirus detections in the Region due to the extensive environmental monitoring by the Member States. Most detections in 2024 were vaccine strains followed by VDPV2 and 3 from environmental sources, though there has been one aVDPV3 detection from an acute flaccid paralysis case in the Russian Federation and a wild poliovirus type 3 isolate from an accidental WPV3 exposure in a manufacturing plant in France *(19)*.

ETAGE issued a recommendation in 2019 that "individual Member States may wish to gradually augment IPV use and thus progressively reduce and/or replace OPV doses in their schedules depending upon vaccine availability, available resources and local circumstances" *(20)*. Since then, a number of countries have transitioned to using IPV-only schedules. Several of the remaining countries, including Israel, have requested WHO to provide clearer recommendations about whether to transition fully to IPV-only schedules.

In view of the recent SAGE recommendations, the Regional Office requested ETAGE to provide guidance for countries in the Region.

ETAGE reviewed the draft recommendations proposed by the Regional Office. The intent of the updated recommendations was to delink the switch to IPV-only schedules from bOPV cessation, recognizing that a few Gavi-eligible countries may not be immediately able to afford a complete switch.

It was also recognized that SAGE had requested the Global Polio Eradication Initiative to develop a risk-tiered approach to guide decisions to transition to an IPV-only schedule, and a recommendation for a switch by ETAGE may pre-empt the forthcoming risk assessment matrix.

ETAGE endorsed the proposed recommendations with some minor modifications in the language.

Session 4. Pertussis vaccination to prevent morbidity and mortality in young infants

There has been a resurgence in pertussis across the Region in 2023 with levels exceeding those in the pre-COVID-19 pandemic period, in some instances associated with an increase in infant deaths. A large proportion of the cases are occurring in infants.

In view of the recent resurgence of pertussis, the objectives of the session were to:

- review the changing recent epidemiology of pertussis in the Region;
- discuss strengthening pertussis vaccination in pregnancy in routine immunization programmes across the Region;
- reiterate the importance of timely vaccination of infants with the three-dose primary series of pertussis-containing vaccines; and
- advocate for initiating the three-dose primary series of pertussis-containing vaccine early in infancy, particularly during increased pertussis activity.

4.1 Pertussis in the European Region: epidemiology and vaccination strategies

As coverage with DTP vaccine has increased since 1980, there has been a sharp decline in reported cases of pertussis globally. Global coverage with DTP3 has been sustained at over 80% during the past decade. However, the European Region experienced a recent sharp increase in the number of reported pertussis cases. The 87 046 cases reported in 2023 *(21)* constitute 54% of the globally reported cases. This resurgence followed a sharp decline in reported cases during the COVID-19 pandemic. The number of reported cases in the Region in 2023 was higher than in the immediate pre-pandemic period and the highest in over two decades, despite regional DTP3 coverage remaining constant at around 95%.

The Russian Federation accounted for 52 783 (61%) cases in the Region, followed by Denmark (6059 cases) and Croatia (4806 cases); the top 10 countries reported over 1000 cases each in 2023. Of the total cases reported, 32% were laboratory confirmed, 1% were epidemiologically linked to a confirmed case and 3% were clinically compatible cases; about 64% of cases, mostly from the Russian Federation, were not classified. The incidence of cases in 2023 was highest in infants < 12 months, followed by children aged 5–9 years. The incidence in those ≥ 15 years was very low. Of the cases in infants aged < 12 months, approximately half occurred in those who were not eligible for vaccination as per the national schedule. Twenty pertussis-related deaths among infants were reported, of which 10 were from the Russian Federation. Vaccination status was unknown for 79% of cases, 5% were unvaccinated, 5% had received 1–3 doses of DTP and 11% had received more than three doses. The age distribution of cases varied between countries; for example, in the Netherlands and the Russian Federation, the highest incidence was in infants, whereas in Croatia and Denmark, it was in the 10–14-year age group.

The ECDC also reported a surge in pertussis cases in 2023 in European Union countries. From January 2023 to April 2024, 19 pertussis deaths were reported, 11 in infants and 8 in adults ≥ 60 years.

In its position paper published in 2015, WHO recommends that all children worldwide should be immunized against pertussis *(22)*. WHO urges all countries to seek to achieve early and timely vaccination, starting as early as 6 weeks and no later than 8 weeks of age

and maintain high coverage (≥ 90%) with at least three doses of the vaccine. Booster doses are recommended at 1–6 years of age, preferably in the second year of life and ≥ 6 months after the previous dose.

The timing of the first dose of DTP-containing vaccines in the Region ranges from 6 weeks to 3 months; in all but three countries it is between 8 weeks and 3 months.

WHO also recommends booster doses in adolescents and adults once high coverage has been achieved in infants, consideration of tetanus-diphtheria-acellular pertussis vaccination in pregnant women, and prioritization of vaccination of health workers.

In the Region, 23 countries provide pertussis vaccination during pregnancy. In countries where data are available, the coverage with maternal vaccination ranges from 64% to 88%.

4.2 Maternal pertussis immunization – the United Kingdom experience

Notifications of pertussis declined substantially in the United Kingdom from 1957 when the diphtheria-tetanus-whole-cell pertussis (DTwP) vaccine was introduced. Around 1976, the number of cases increased dramatically, coinciding with a sharp drop in vaccination coverage due to concerns about the side effects of the vaccine; cases declined once coverage improved. In 1990, an accelerated schedule of DTwP (three doses at 2, 3 and 4 months) was introduced, leading to a further decline in notifications. In 2004, DTwP was replaced with a five-component diphtheria-tetanus-acellular pertussis (DTaP) vaccine in the primary infant series. In 2011/2012, there was an increase in the reported incidence of pertussis in all age groups, with the highest increase in infants aged < 3 months and children aged 10–14 years. This increase was associated with a rise in whooping cough infant deaths. A model simulation indicated that the resurgence of pertussis in 2012 was likely the result of the change to DTaP in 2004 and predicted that a continued higher incidence would be sustained in infants and older age groups *(23)*.

In response to this increase in infant burden, the United Kingdom maternal vaccination programme was introduced in October 2012 as part of an emergency response. Several studies documented the effectiveness of the maternal vaccination programme as being around 90% in preventing infant disease. VE was high in mothers vaccinated more than one week before birth. The incidence of pertussis in infants < 3 months declined after the peak in 2012, although disease activity in older age groups persisted at heightened levels. Following an evaluation of the cost-effectiveness of the maternal vaccination programme in England, the Joint Committee on Vaccination and Immunisation recommended routine maternal pertussis vaccination in 2019.

From the second half of 2023, there has been an increase in cases across all age groups, including infants, especially those aged < 3 months.

In 2024, pertussis notifications were at their highest levels in more than a decade. Maternal pertussis vaccination has declined since 2016 with varying coverage in different ethnic groups, ranging from 30% in the Black or Black British Caribbean population to 67% in the White British population. A campaign has been launched to improve coverage with maternal pertussis vaccination.

Discussion

ETAGE acknowledged with concern the recent increase in the Region in the number of reported pertussis cases and pertussis-related deaths in infants. It also acknowledged the importance of maternal vaccination in protecting young infants from pertussis.

The ETAGE Secretariat was asked if the epidemiological data were analysed based on whether DTwP or DTaP was being used for routine immunization. The Secretariat explained that this analysis was not done because the focus was on the burden of pertussis in infants and the importance of maternal vaccination in protecting infants irrespective of the type of routine vaccine used in national vaccination schedules.

It was pointed out that increases in pertussis in school-age children, due to waning immunity following a primary series with DTaP without adequate coverage with booster doses, could result in an increase in cases in infants too young to be vaccinated. This aspect may need further exploration, especially if it is difficult to scale up maternal vaccination coverage.

Data are available in the WHO database on countries offering a booster dose in adolescence, but these data were not analysed because of the focus on young infant pertussis and the need for timely infant vaccination and improving coverage with maternal vaccination. It was noted, however, that data from the United Kingdom indicated that transmission from adolescent children to infants was low based on mixing patterns between the two groups, though this is likely to be country-specific and would depend on differing mixing patterns.

It was noted that studies in the United Kingdom showed that the inclusion of IPV reduced the immune response to the pertussis component of combination vaccines. Hence, it was decided to use a vaccine that does not contain IPV for maternal vaccination.

There was a question as to whether improvement in surveillance practices and particularly laboratory confirmation methods was contributing to the increase in cases and whether COVID-19 testing resulted in increased testing for other pathogens. The available data at the Regional Office did not permit such an analysis. It was highlighted that close to two-thirds of cases did not have a final diagnosis classification (laboratory confirmed, epidemiologically linked or clinically compatible), although some countries reported very high laboratory confirmation rates.

Session 5. Securing access to affordable new vaccines in MICs: decision-making and a product life-cycle approach

The session included an update from the Regional Office on the current context of vaccine access in the Region and a presentation on the experience in Estonia in using market intelligence in decision-making.

5.1 Update from the Regional Office

The objective of the session was to identify and mitigate the risks to access and affordability of new vaccines through the product life cycle and address inequities and life-course vaccination.

In the Region, six MICs (Armenia, Azerbaijan, Georgia, Republic of Moldova, Ukraine and Uzbekistan) and Kosovo [1] have transitioned out of Gavi support but are still dependent on donor support and access vaccines through the UNICEF pooled procurement mechanism. In addition nine MICs (Albania, Belarus, Bosnia and Herzegovina, Kazakhstan, Montenegro, North Macedonia, Serbia, Türkiye and Turkmenistan) are financially self-sustainable. These nine MICs in particular lag behind in terms of new vaccine introduction, impeding efforts to achieve the EIA2030 goals on equity and life-course vaccination.

Several factors affect the ability of MICs to access vaccines at an affordable price, including: (i) a limited supplier base; (ii) unique product characteristics and supply constraints; (iii) new products from emerging market suppliers; and (iv) limited self-procurement experience.

Country consultations through questionnaires and online meetings, and subregional workshops are being held to support these countries to understand the vaccine market and how to align efforts across product lifecycle domains to improve access to affordable vaccines.

The role of NITAGs in promoting access to vaccines is being explored by aligning the recommendation-making process with different dimensions of this life cycle. Several areas across the product life cycle have been identified that are within the remit of NITAGs and where they could play a role (such as supplier base and product availability, product formulations characteristics, financing and resources, demand and access) . At the same time there are areas that NITAGs do not usually interact with such as vaccine procurement, which could support recommendation-making process with important vaccine market intelligence insights.

Data are being collected to map the roles that NITAGs play in different areas using a set of indicators.

ETAGE was requested to provide guidance on enhancing the use of market information and intelligence in NITAG decision-making.

[1] All references to Kosovo in this document should be understood to be in the context of the United Nations Security Council resolution 1244 (1999)

5.2 The role of market intelligence in vaccine introduction decision-making in Estonia

The presentation provided an overview of how market intelligence is defined and used in the decision-making process for vaccine introduction in Estonia.

The sources of data needed for qualitative market research and risk analysis across four domains – demand forecasting, price trends, supplier mapping and market trends – to support NITAGs with decision-making were outlined.

Examples were provided of how strategic and operational issues related to procurement enable access to the right product in the right presentation at the right price. These issues are important for NITAGs to consider when making decisions.

To promote interactions the national procurement manager and the immunization manager are part of the NITAG. There is also an informal NITAG subgroup that meets more regularly and filters the data to ensure that the NITAG has the most important information for it to make more informed decisions.

Market intelligence plays a role in three steps of NITAG decision-making: initial NITAG discussions; the cost-effectiveness analyses, so that the procurement price level is accurately captured; and expert discussions.

An example was provided on the use of market intelligence for HPV vaccine introduction. Here, market intelligence provided early information on possible price ranges for the bivalent and nonavalent vaccines and informed the choice of procurement evaluation criteria (considered both the price and the quality/valency of the product). That led to a competitive procurement involving both product formulations and resulting in the introduction of the nonavalent HPV vaccine in a two-dose schedule in 2018 at affordable price (despite delays due to legal challenges to the procurement decisions). In 2023, there were renewed NITAG discussions about switching to a one-dose schedule, at which time market intelligence indicated potential access challenges if only the nonavalent product in use was considered. Flexibility of the NITAG recommendation regarding the use of either bivalent or nonavalent vaccine for 1-dose schedule allowed again for competitive procurement that resulted in signing a 3-year contract for the nonavalent product at an affordable price. Furthermore, the NITAG discussion and the new procurement procedure were conducted one year before the planned schedule switch in 2024. That was aiming to provide the time to plan for an eventual change to a bivalent vaccine and ensure that the public is informed should the product formulation change have happened.

Discussion

A question was raised about the independence of the NITAGs from industry influence and whether there was any information on the extent to which this was an issue. It was noted that the current questions in the JRF related to NITAG functions did not capture this information. Nevertheless, it is important to ensure the independence of the NITAG so that they make their decisions without undue industry influence.

ETAGE was informed that WHO is developing a global process to support country prioritization of new vaccines for introduction into national schedules and product optimization. This process would include the use of market intelligence. There is also ongoing discussion on whether these decisions should be taken by NITAGs, health ministries or some other bodies.

It was noted that while NITAGs may receive information about market intelligence, their decisions are primarily based on scientific considerations; decisions on other factors, such as pricing and procurement, are made by health ministries. NITAGs may provide scientific information on the pros and cons of the different products available, without specifically recommending a particular product.

ETAGE conclusions and recommendations

Based on the evidence presented and the discussions held, ETAGE made the following conclusions and recommendations.

2. Progress with the implementation of EIA2030

- ETAGE commends countries for filling historical data gaps for EIA2030 implementation, although significant gaps in the timely reporting of data to monitor trends remain.
- ETAGE notes the success in maintaining the Region's polio-free status, sustaining progress towards rubella elimination, achieving regional hepatitis B control targets, introducing WHO-recommended vaccines, and increasing the use of evidence-based and targeted approaches to address immunity gaps.
- ETAGE notes that overall progress towards EIA2030 targets was affected by the surge in VPD outbreaks, underlying existing inequity in immunization coverage, and the dual challenges of re-establishing high routine coverage following the COVID-19 pandemic and catching up those who were not vaccinated during its course.
- ETAGE commends countries on ongoing efforts to provide catch-up vaccination doses to those who missed them during the pandemic and refugees from countries affected by humanitarian crises, and acknowledges the challenges in estimating the impact of such activities in reducing immunity gaps.
- ETAGE acknowledges that despite the progress made against several targets, at the current pace, it is unlikely that all the EIA2030 milestones and targets will be reached. The occurrence of pertussis, diphtheria and measles outbreaks in the Region pose a challenge and highlight the inequities in immunization coverage within and between countries, and suboptimal VPD surveillance and response. These challenges, unless they are rapidly addressed, will hinder further progress and the realization of EIA2030's vision.

ETAGE reiterates the recommendations issued in December 2023 to accelerate progress towards EIA2030. Notably, ETAGE:

- encourages countries to review the completeness of reporting on their data and information to WHO and continue improving reporting on EIA2030 indicators;
- recommends that countries systematically identify un- or under-vaccinated populations and inequities in immunization for all or selected vaccines in the national schedule, guided by local data on coverage and surveillance, research-based evidence on the barriers and enablers for vaccination, and the quality of immunization services provision.
- recommends that countries devise tailored, evidence-based interventions to strengthen timely vaccination of newly eligible target groups and scale up targeted catch-up vaccination activities to close immunity gaps in all relevant age groups.
- recommends that WHO provide guidance on monitoring the impact of catch-up vaccination (delayed routine vaccination or SIAs) on reducing the immunity gap in targeted populations.

- recommends that countries strive to strengthen the capacity of VPD surveillance systems and immunization service delivery for the timely detection of and response to outbreaks; VPD outbreak investigations should be leveraged as an opportunity to identify immunity gaps and their root causes to devise locally tailored interventions to increase population coverage and prevent future outbreaks;
- requests the Regional Office to develop technical guidance and operational considerations for countries to establish or strengthen appropriate frameworks and platforms for vaccination across the life-course to leverage the full benefits of existing and new vaccines for all age groups; this includes guidance on strengthening the maternal vaccination platform and improving acceptance of vaccination during pregnancy.
- recommends that countries report to the Regional Office the actions taken to implement ETAGE's recommendations on advancing progress towards EIA2030 targets; countries are encouraged to develop and/or update a national immunization action plan or national immunization strategy and implement a corresponding national monitoring and evaluation framework; and
- requests the Regional Office to continue monitoring progress towards EIA2030 goals and targets, consider reviewing the usefulness of the monitoring indicators, and explore options for the dissemination of the technical progress report.

3. RSV

- ETAGE welcomes the WHO/SAGE recommendations on the use of immunization products for the prevention of severe RSV disease in young infants. ETAGE recognizes the significant burden of RSV disease, particularly in young infants, and acknowledges the potential of new immunization products, including maternal RSV vaccination and long-acting monoclonal antibodies, to reduce this burden.
- ETAGE encourages countries and areas in the Region to consider these recommendations and, based on their national contexts, develop recommendations for use in their national programmes. This includes defining clear criteria for the use of maternal vaccines and/or long-acting monoclonal antibodies. The key factors to consider include:
    - clinical and epidemiological data on RSV disease, including seasonality;
    - efficacy, safety and duration of protection of maternal vaccines and long-acting monoclonal antibodies;
    - perceptions and acceptability of the target population of RSV immunization products;
    - availability, cost and long-term supply of RSV immunization products;
    - programmatic feasibility for introducing and sustaining RSV prevention programmes; and
    - modelling the impact and cost-effectiveness of various immunization strategies where the capacity to do so exists.

- ETAGE encourages countries to ensure robust surveillance mechanisms to prepare for and monitor the implementation and impact of these products post-introduction. This includes monitoring uptake, AEFIs, birth outcomes (for maternal vaccine), and changes in RSV epidemiology (incidence, mortality, high-risk groups).

- ETAGE requests WHO to advocate to donors and support market shaping to reduce inequity in access to RSV immunization products for MICs that are presently ineligible for Gavi support.

4. Polio

- ETAGE notes that the Region is advanced in bOPV cessation – with 41 countries already using IPV-only schedules, and the remaining 12 moving towards this goal.
- ETAGE notes that the European Region has generated most of the evidence required to implement the recent SAGE recommendations on IPV use for outbreak response and bOPV cessation.
- ETAGE strongly encourages the Member States of the European Region to minimize the use of OPV and urges them to move to an IPV-only schedule, in advance of the global bOPV cessation. ETAGE aligns with the SAGE recommendation that in countries where bOPV is not used in routine immunization programmes, outbreak response should use IPV for the initial response.

5. Pertussis

- ETAGE notes with concern the changing epidemiology of pertussis in the Region, with a resurgence of cases and an increase in infant deaths in 2023 and continued transmission into 2024.
- ETAGE stresses the importance of strengthening pertussis surveillance, including data on infant deaths, and improving the collection of data on pertussis vaccination status of cases. ETAGE requests that WHO presents an analysis of pertussis epidemiology and severity, comparing countries using whole-cell and acellular pertussis-containing vaccines.
- ETAGE encourages countries to ensure high coverage and timely administration of the three-dose primary pertussis vaccination series in infants as recommended in the national schedule.
- In the context of increased pertussis disease burden and an increase in infant deaths, ETAGE recommends that countries which have a documented burden of pertussis in infants introduce, if feasible, and/or strengthen vaccination of pregnant women with one dose of DTaP vaccine as per WHO recommendations. Such countries should monitor and optimize the uptake of vaccination.

6. Access to new vaccines in MICs

- ETAGE notes that MICs are lagging with the introduction of new vaccines and acknowledges that improving the affordability, availability, accessibility and acceptability of assured quality vaccines is required for supporting equitable access to vaccines and life-course immunization.
- ETAGE notes that improving access to new vaccines is a multidimensional challenge involving numerous stakeholders and requires complex and interdependent processes.
- ETAGE supports the Regional Office initiatives to improve access to affordable vaccines in MICs by building capacity to enhance the use of vaccine market information throughout the product life cycle, and encourages the systematic use of such evidence to inform national decisions regarding introduction or use of vaccine products in a

manner that would prevent barriers and enable sustainable access. This is of particular importance for newly developed immunization products with unique characteristics and a limited supplier base.

- ETAGE acknowledges the challenges that exist in formulating balanced and actionable NITAG recommendations concerning alternative and competing licensed vaccines and optimizing their public health impact and cost-effectiveness. ETAGE reaffirms its advice to MICs regarding the selection of specific vaccine products: if different products have been demonstrated to be safe and effective, and if countries lack local evidence on serotypes distribution, the questions over product choice should be based on considerations of affordability and financial sustainability.

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