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

Hybrid meeting, hosted in Copenhagen, Denmark
6–7 December 2022
Abstract

The twenty-second meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE) was held as a hybrid meeting in Copenhagen, Denmark on 6–7 December 2022 to review and discuss immunization activities and developments in the WHO European Region and provide advice to the WHO Regional Office for Europe on appropriate activities. Advice and guidance from ETAGE were sought on COVID-19 vaccination in the WHO European Region and regional adaptation of recommendations of the Strategic Advisory Group of Experts on Immunization (SAGE). Advice was also sought on paediatric diarrhoeal disease surveillance in the Region and the pathway moving forward, National Immunization Advisory Group (NITAG) strengthening activities in the Region, and the role of NITAGs in guiding the agenda of future ETAGE meetings.
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<tr>
<td>AEFI</td>
<td>adverse events following immunization</td>
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<td>CG</td>
<td>collaboration group</td>
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<td>cVDPV</td>
<td>circulating vaccine-derived poliovirus</td>
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<td>DG SANTE</td>
<td>Directorate-General for Health and Food Safety</td>
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<td>ECDC</td>
<td>European Centre for Disease Prevention and Control</td>
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<td>ETAGE</td>
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<td>EtR</td>
<td>evidence to recommendations</td>
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<td>GNN</td>
<td>Global NITAG Network</td>
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<td>Global Paediatric Diarrhea Surveillance</td>
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<td>Global Rotavirus Surveillance Network</td>
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<td>Immunization Agenda 2030</td>
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<td>IPV</td>
<td>Inactivated polio vaccine</td>
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<td>IVB</td>
<td>Immunization, Vaccines and Biologicals</td>
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<td>JCVI</td>
<td>Joint Committee on Vaccination and Immunization</td>
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<td>LIC</td>
<td>low-income country</td>
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<td>LMIC</td>
<td>low-middle-income country</td>
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<td>M&amp;E</td>
<td>monitoring and evaluation</td>
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<td>NITAG</td>
<td>National Immunization Technical Advisory Group</td>
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<td>NITAG Resource Center</td>
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<td>OPV</td>
<td>oral polio vaccine</td>
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<td>PHC</td>
<td>primary health care</td>
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<td>Regional Immunization Programme Managers Meeting</td>
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<td>RKI</td>
<td>Robert Koch Institute</td>
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<td>Acronym</td>
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<td>RRL</td>
<td>regional reference laboratory</td>
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<td>RSV</td>
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<td>Strategic Advisory Group of Experts on Immunization</td>
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<td>SYSVAC</td>
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<td>ToR</td>
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<td>UMIC</td>
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<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<td>US CDC</td>
<td>United States Centers for Disease Control and Prevention</td>
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<td>VDPV</td>
<td>vaccine-derived poliovirus</td>
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<td>VE</td>
<td>vaccine effectiveness</td>
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<td>VLP</td>
<td>vaccine-like particle</td>
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<td>VPD</td>
<td>vaccine-preventable disease</td>
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<td>VPI</td>
<td>Vaccine-preventable Diseases and Immunization Programme of the WHO Regional Office for Europe</td>
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<td>WPV</td>
<td>wild poliovirus</td>
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Executive summary

The twenty-second meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE) was held as a hybrid meeting in Copenhagen, Denmark on 6–7 December 2022 to review and discuss immunization activities and developments in the WHO European Region (Region) and provide advice to the WHO Regional Office for Europe (Regional Office) and its Member States.

ETAGE received a report on conclusions of the global Strategic Advisory Group of Experts on Immunization (SAGE) from its October 2022 meeting, as well as, for the WHO European Region, updates on implementation of the European Immunization Agenda 2030 (EIA2030), COVID-19 vaccination, paediatric diarrhoeal disease surveillance, WHO Regional Office for Europe activities to strengthen national immunization technical advisory groups (NITAGs) and the role of NITAGs in the WHO European Region in guiding the agenda of ETAGE meetings.

ETAGE reiterates its recommendations that achieving high vaccine coverage of the primary series and booster doses in high-risk populations remains the highest priority. Countries should undertake additional efforts to ensure that all eligible people are up to date on COVID-19 vaccinations according to national recommendations. ETAGE concurs with the SAGE recommendation that countries may use ancestral virus vaccines or new variant-containing COVID-19 vaccines for booster doses according to availability. Countries should plan for the integration of COVID-19 vaccination into routine healthcare strategies using lessons learned from the COVID-19 vaccine rollout. Countries should sustain systems to monitor COVID-19 vaccination and adapt them as vaccination policies and reporting requirements evolve. If applicable, they should consider leveraging reporting mechanisms and digital platforms that were developed for COVID-19 vaccination to monitor routine immunization uptake through the life course.

ETAGE recommends that the Regional Office support global paediatric diarrhoea Surveillance (GPDS), building upon efforts already made to develop capacity for the Global Rotavirus Surveillance Network (GRSN). The valuable data on rotavirus epidemiology and vaccine effectiveness generated by GRSN should be further used to develop investment plans to support policy decisions on rotavirus vaccine implementation. Countries are encouraged to continue conducting rotavirus surveillance using their own resources. WHO should consider supporting more countries in conducting paediatric diarrhoea surveillance based on common standards, regardless of income level, funding eligibility or participation in the GPDS network. WHO should consider conducting a landscape analysis to better understand the surveillance gaps in paediatric diarrhea surveillance at the regional level and liaise with existing regional networks to coordinate the use of data to estimate disease burden due to enteropathogens.

ETAGE recommends the Regional Office continue advocating for the establishment of NITAGs in the three remaining countries in the Region. Ministries of Health should prioritize support for and recognize the important role of NITAGs and their secretariats in making independent, informed recommendations on immunization in their countries. ETAGE encourages NITAGs to use the Regional Office “Guidance on an adapted evidence to recommendation process for National Immunization Technical Advisory Groups” to improve their recommendation-making processes, and NITAG partners to use it as part of the capacity building of NITAGs in the Region. Building upon the efforts to strengthen the work of NITAGs in the WHO European Region, the Regional Office and partners should further strengthen ongoing collaboration towards capacity building of NITAGs to increase efficiency and create synergies. NITAG partners should further enhance their collaboration by ensuring that documents, tools and training materials are shared and made available to all NITAGs in the Region and globally and conducting joint meetings for NITAGs, whenever possible, to facilitate the exchange of experiences between all NITAGs in the Region.

The enhanced exchange between ETAGE and NITAGs in developing COVID-19 recommendations should continue in the future when ETAGE develops recommendations on other immunizations and vaccine-preventable diseases. The Regional Office should develop a process to collect NITAG requests for regional guidance and consider them when defining future ETAGE meeting agendas.
**Introduction**

ETAGE meets regularly to provide independent review and expert technical recommendations to national immunization programmes and WHO Regional Office for Europe’s Vaccine-preventable diseases and immunization programme. The twenty-second meeting of the ETAGE was held as a hybrid meeting in Copenhagen, Denmark on 6–7 December 2022. In line with ETAGE terms of reference, Professor Adam Finn retired from his role as Chair of the meeting and turned the role of Chair over to Dr Ole Wichmann.

The objectives of the meeting were to request advice and guidance from ETAGE members on the following key topics and issues:

- COVID-19 vaccination in the WHO European Region and regional adaptation of SAGE recommendations.
- Paediatric diarrhoeal disease surveillance in the WHO European Region and its relevance/pathway moving forward.
- NITAG strengthening activities in the WHO European Region and the role of NITAGs in guiding the agenda of ETAGE meetings.

**Opening remarks**

The meeting was opened by Professor Adam Finn who welcomed participants and reminisced on his time as Chair of ETAGE. Dr. Alejandro Cravioto, Chair of the Strategic Advisory Group of Experts on Immunization (SAGE), was in attendance. Meeting participants were welcomed on behalf of the Regional Office by Dr Siddhartha Datta, VPI, Regional Office. Dr Datta thanked Professor Finn for his incredible leadership over the years and passed on the regards of Dr Hans Kluge, WHO Regional Director for Europe, and Dr Nino Berdzuli, Director of Country Health Programmes, who also thanked him for his leadership and service. Dr Datta thanked the ETAGE members for their engagement and support of the Regional Office in supporting Member States and thanked members who had attended the recent Regional Immunization Programme Manager Meetings (PMMs).

The Regional Office has new partnerships with the European Commission on COVID-19 projects and the Directorate-General for Health and Food Safety (DG Sante) which has a new initiative to fund projects in the Member States. The Regional Office continues to work with traditional partners such as the United States Centers for Disease Control and Prevention (US CDC), United Nations Children’s Fund (UNICEF), and Gavi as well as the Bill and Melinda Gates Foundation. Dr Datta presented Professor Finn and Professor Nur Baran Aksakal with commemorative plaques to honor them for their service to ETAGE and also thanked Dr Alenka Kraigher (not present) for her service. The Chair of ETAGE was passed from Professor Finn to Dr Wichmann and Dr Antoinetta Filla was named Deputy Chair.

Dr Wichmann thanked Professor Finn for his dedicated leadership, as well as fellow outgoing members Professor Alenka Kraigher and Professor F. Nur Baran Aksakal, for their important contributions to ETAGE in recent years. Dr Wichmann also welcomed three new members, Dr Arman Badalyan, Dr Fedir Lapii, and Dr Marianne A. Riise Bergsaker.

The past two years of the pandemic have been challenging but the Chair looks forward to working with the group to meet the future challenges in routine immunization. Dr Fillia expressed her honour to accept the
role as Deputy Chair and looks forward to continuing the important work in the Region. Dr Baran Aksakal thanked the group for the opportunity to be a member of ETAGE.
Session 1: Global update: SAGE October 2022 meeting recommendations and Immunization Agenda 2030

Dr Joachim Hombach, Executive Secretary to SAGE, and Dr Cravioto provided an update from the October 2022 SAGE meeting. With regard to polio outbreaks, SAGE noted its concern about renewed wild poliovirus type 1 (WPV1) circulation in Pakistan; continuing detections of WPV1 in South-eastern Africa; and ongoing transmission of vaccine-derived poliovirus (VDPV) type 2, particularly in the African region and Yemen, and in Jerusalem, London and New York City. SAGE stressed the need for increased efforts to improve polio vaccination coverage. SAGE endorsed the option for timely initial use of the inactivated poliovirus vaccine (IPV) to respond to outbreaks in countries that use only IPV for routine childhood immunization. This option is only recommended if poliovirus transmission is confined to a well-defined population or geographic area with high levels of sanitation. Preparation for response with oral polio vaccines (OPVs) should begin in parallel if transmission continues following the IPV response.

SAGE reiterated that the primary target age group in outbreak polio response campaigns should be children less than 5 years of age. A wider age range response may be considered if there is evidence of immunity gaps in older age groups or low historical vaccination coverage rates. SAGE also recommended that all countries have outbreak response plans to be prepared for a timely response against VDPV or WPV1 outbreaks. SAGE expressed the importance of improving routine immunization coverage and taking action to ensure that zero-dose children are included in routine immunization micro plans for all recommended vaccines. SAGE expressed the importance of accelerated efforts to develop and authorize novel OPVs against type 1 and type 3 poliovirus, VLP (virus-like particle) vaccines, polio antivirals, and monoclonal antibodies.

For mpox, SAGE recommended (1) primary preventive vaccination for groups at high risk for Mpox including gay, bisexual or other men who have sex with men with multiple partners. Others at risk may include individuals with multiple casual sexual partners; sex workers; health workers (HWs) at risk of repeated exposure; laboratory personnel working with orthopoxviruses; clinical laboratory and health care personnel performing diagnostic testing for mpox; and outbreak response team members. The level of risk may vary between groups and could be used for prioritization in case of limited vaccine supply. Post-exposure preventive vaccination is recommended for close contacts of cases, ideally within four days of first exposure and up to 14 days in the absence of symptoms.

Recommendations on the choice of mpox vaccine for healthy adults are non-replicating vaccines (MVA-BN), minimally replicating vaccines (LC16m8), or replicating vaccinia-based vaccines (ACAM2000). Persons with immune suppression, who are at high risk of infection, or who are exposed to a mpox case should be prioritized for MVA-BN vaccination. For pregnant and breastfeeding women, for primary or post-exposure preventive vaccination, MVA-BN vaccine should be used and ACAM2000 should not be used; no data are available to assess the risk of LC16m8 vaccines in pregnant or lactating women. For children, for post-exposure preventive vaccination, MVA-BN or LC16m8 vaccines should be used.

With regard to COVID-19 vaccine booster doses, any WHO emergency use listed (EUL) COVID-19 vaccines or authorized mRNA bivalent variant-containing vaccines can be used for booster vaccination. According to the SAGE Roadmap for prioritizing uses of COVID-19 vaccines (2), WHO recommends a first booster dose to all persons aged 12 years and above, particularly to the highest priority groups, with an interval of 4-6 months after completion of the primary series. Any of the WHO EUL vaccines or authorized bivalent variant-containing vaccines can be used for the first booster dose. WHO recommends second boosters and, as the...
pandemic evolves, potentially additional boosters for all older persons, persons with moderately and severely immunocompromising conditions, adults with comorbidities that put them at higher risk of severe disease, pregnant women, and HWs. Such booster doses are recommended 4-6 months after the previous dose and any of the WHO EUL vaccines or authorized bivalent variant-containing vaccines can be used.

Corbevax (BECOV-2) COVID-19 vaccine does not yet have EUL, so no SAGE recommendations have been published as of yet. This vaccine was endorsed for use in individuals ≥5 years of age once EUL has been granted. SAGE noted that data in those aged <12 years lacked precision and approved the vaccine for use as a booster and a heterologous booster. SAGE emphasized the need for further data regarding the effectiveness of the vaccine in all age groups and in special sub-populations and continued safety surveillance post-administration for adverse events of special interest after introduction.

A report from the WHO Immunization, Vaccines and Biologicals (IVB) Director highlighted the unprecedented backsliding of routine immunizations in 2021 with 25 million children unvaccinated or under-vaccinated. Ten countries account for 62% of all zero-dose children and disruption of immunization services persists. HW capacity and health-seeking behaviour have been negatively affected and disease outbreaks are on the rise. Malnutrition, conflict and economic crises have acted as amplifiers of these issues. Positive learnings from the COVID-19 vaccination efforts should be adopted for routine immunizations. Supply chain management, logistics and electronic data management should be improved. There was an emphasis on vaccination across the life-course and the use of novel vaccination technologies.

The Immunization Agenda 2030 (IA2030) progress report describes factors impeding the achievement of IA2030 goals including an inadequate and overstretched health workforce; insecurity and population displacement; competing priorities and diversion of resources from routine service delivery; and inadequate financing. Regions are taking urgent actions to mitigate the risk of further vaccine-preventable disease (VPD) outbreaks. The Measles and Rubella initiative will join the IA2030 partnership structure.

RSV disease burden is high with more than 100 000 deaths attributed to RSV in children under 5 years of age and 97% occurring in low- and middle-income countries (LMICs). The market authorization of a long-acting monoclonal antibody is imminent (by Q4 2022) and there is a maternal vaccine in Phase 3 trials. A review of the existing and emerging data is needed, particularly data on low-income countries (LICs) and middle-income countries (MICs), to understand the full public health potential.

There is currently an outbreak of the Sudan strain of ebolavirus in Uganda with 44 confirmed cases, 20 suspected cases and 10 deaths as of 6 October 2022. Vaccines against the Zaire ebolavirus do not offer cross-protection against the Sudan ebolavirus. There are six candidate vaccines under development against the Sudan ebolavirus. Ring vaccination approaches are being used to evaluate the efficacy of candidate vaccines and protocols are under review.

SAGE endorsed the following IA2030 recommendations:

1. Urgent actions are needed to address the backsliding during the COVID-19 pandemic and promote catch-up vaccination.
2. Medium- and long-term actions to strengthen immunization programmes as a core component of resilient and equitable primary health care (PHC) and pandemic preparedness and response.
3. Actions needed to address new vaccine introduction.
4. Actions needed to accelerate vaccine development.
5. Actions needed to enhance coordination and promote global monitoring, evaluation, and accountability cycles for continuous quality improvement.

The full report from the meeting will be available on the SAGE section of the WHO website (3).
Session 2: Regional update: European Immunization Agenda 2030

Dr Siddhartha Datta provided an update on the EIA2030 (4). The efforts made to recover routine immunization coverage in 2022 should continue and coherent actions from partners and donors are needed. In 2022, HWs had to provide infant vaccine doses; vaccines for the second year of life, adolescents and the elderly; influenza vaccine for vulnerable populations; respond to outbreaks of polio, measles, diphtheria, and mpox; respond to the Ukrainian crisis in neighbouring countries; and provide vaccine to migrants. ETAGE needs to help prioritize the actions that should be taken moving forward and define the recovery efforts needed in 2023 in the Region.

Thus far, 1.7 billion COVID-19 vaccine doses have been administered in the Region, but inequitable uptake points to health system vulnerability. Upper-middle-income countries (UMIC) and LMICs are falling behind the rates of high-income countries, including coverage of vulnerable groups like adults >60 years of age. Countries’ health system characteristics will play a big role in the implementation of life course vaccinations.

The main focus of EIA2030 is programme implementation with the key pillars of equity in immunization, immunization across the life course, and local solutions to local challenges. The strategic pivots are increased local ownership; data-enabled, tailored subnational policies; life-course vaccination and platforms; and a monitoring, evaluation and accountability framework. EIA2030 has been developed using a bottom-up process which was reviewed during the regional PMMs; the final PMM will be held in Türkiye in May 2023.

The framework of coordinated actions to operationalize the EIA2030 was reviewed. The EIA2030 monitoring and evaluation (M&E) framework will be key to measuring the overall impact and will be built upon the existing European Vaccine Action Plan M&E and adapted to the regional context. Twenty-four indicators were defined through a consultative process and a “compendium of indicators” has been developed. ETAGE’s role in this process will be to review progress and monitor the implementation of recommendations starting in 2024. A bi-annual progress report will be provided to the Regional Committee.

Recovery of immunization rates is needed through catch-up, particularly for unvaccinated and under-vaccinated children from 2020 and 2021. The Regional Office has developed Operational considerations for planning and implementing catch-up vaccination in the WHO European Region (5). There is inequity in COVID-19 vaccination uptake in MICs in the Region and there are children who missed routine immunizations from 2019–2022 in countries of all income levels. The recovery for routine immunizations in 2021 has been variable and LMICs have had better performance. The Regional Office has identified two groups of priority countries for focused partner support based on underperformance for coverage with the third dose of diphtheria/pertussis/tetanus vaccine and/or first dose of measles-containing vaccine.

VPD outbreaks continue to occur in the Region, including polio. There have been outbreaks of Sabin type 2, circulating vaccine-derived poliovirus (cVDPV) type 2, VDPV type 1, VDPV type 2, and wild poliovirus (WPV) spills. Measles outbreaks have also been occurring, including a large outbreak in Tajikistan and increasing cases in Türkiye. In 2022, 236 cases and one death from diphtheria were reported in eight countries with 78% of cases among asylum seekers. Regional activities on diphtheria in late 2022 included an information note and VPD update on reported cases, a training workshop on laboratory diagnosis of diphtheria, webinars for countries reporting diphtheria cases, and assistance procuring diphtheria antitoxins.
Several countries have been validated for the achievement of hepatitis B control targets including Georgia, Italy, the Netherlands, the Republic of Moldova, and the United Kingdom. The Regional Office is developing a communication package to share with Member States on this topic.

Strategic focus areas will support Member States in responding to ongoing VPD outbreaks. A diagonal approach using measles as a tracer will be used to develop a European strategic plan of action in 2023. There will be a review and optimization of supplementary surveillance for polio, including environmental surveillance, and guidance tailored to the Region. Laboratories will be added to conduct measles and rubella real-time PCR testing. The measles and polio national action plans for outbreak preparedness and national poliovirus containment inventories (including certification of poliovirus essential facilities) should be reviewed and updated.

A resilient immunization system and strengthening of subnational immunization performance are needed. There will be a strategic focus on the “quality of immunization performance” and the maturity of systems. The Regional Office is moving to assess the maturity of national immunization technical advisory groups (NITAGs) including the use of a systematic approach in developing recommendations. Committees should be established to assess for causality of serious adverse events following immunizations (AEFIs) using a systemic approach. Effective vaccine management assessments should move toward strengthening the immunization system using an improvement plan and facilitating systematic cold-chain inventory. Data systems for immunization should be digitalized and local-level governance should be established to move toward a sustainable, comprehensive digital system; a Roadmap to digitalization of immunization information systems will be developed.

Qualitative insights research should be used to understand the barriers and drivers to vaccination in order to address inequities and should be expanded from COVID-19 vaccination to routine immunizations. Regional resources include TIP: Tailoring Immunization Programmes (6) and Rapid qualitative research to increase COVID-19 vaccination uptake (7). The Regional Office is supporting national immunization programmes in achieving and sustaining high and equitable vaccination uptake. A guidance document and operational framework have been developed for Member States.

Support is needed to prevent and stop VPD outbreaks in and around Ukraine. There was a cVDPV2 outbreak in Ukraine in 2021 and IPV catch-up was conducted in 2022 during the conflict. Support has been provided to Ukraine on COVID-19 and routine vaccination and support has also been provided to neighbouring countries to address the influx of refugees.

As the Region recovers from the COVID-19 pandemic, an equity lens should be used to respond to outbreaks and sustain routine immunization coverage. EIA2030 needs to be operationalized at the service delivery level and an investment case for immunization is needed. Processes and immunization service delivery platforms should be coordinated with non-immunization health strategies and traditional and non-traditional stakeholders should be engaged to plan local-level actions.
**Discussion on sessions 1 and 2**

ETAGE thanked SAGE for the review of the polio outbreak response recommendations.

ETAGE suggested that SAGE provide guidance to Member States on how to prioritize COVID-19 vaccinations in the context of routine immunizations.

ETAGE discussed moving toward life course vaccinations and leveraging the experiences learned during the COVID-19 vaccination roll-out. There is some complacency in elderly populations to receive COVID-19 vaccine booster doses and it may be helpful to pair the COVID-19 vaccine with the influenza vaccine and the use of adult pneumococcal vaccine should also be considered (8).

Surveillance of COVID-19 should continue to monitor changing variants. The WHO has an advisory group on virus evolution which reviews surveillance data and genetic information and there is a second advisory group on vaccine composition (TAG-CO-VAC) that reviews COVID-19 vaccine performance and provides advice on whether the COVID-19 vaccine needs to be adapted.

Countries should consider documenting lessons learned from the pandemic with special focus towards integration of COVID-19 vaccination roll-out into routine immunization service delivery. A compendium of lessons learned across countries on different aspects of COVID-19 vaccination is being developed and these lessons should be integrated into routine immunizations.

ETAGE’s role is to ensure that recommendations are evidence-based and to serve as an interface between technical advisors and politicians. There is a need to provide countries with data showing that vaccines are cost-effective. The Regional Office would appreciate ETAGE’s assistance in developing an investment case for immunizations.

ETAGE discussed and appreciated the work of the WHO Regional Office and country offices in Ukraine and neighbouring countries to prevent VPD outbreaks.
Session 3: COVID-19 vaccination in the WHO European Region and Regional adaptation of SAGE recommendations

Dr Liudmila Mosina, VPI, Regional Office, provided an update on COVID-19 vaccination in the Region and the regional adaptation of SAGE recommendations. COVID-19 cases and deaths were reviewed. By 29 November 2022, over 1.6 billion doses of COVID-19 vaccine have been administered in the Region with an overall vaccine uptake of 65% with a complete series, 31% with a first booster dose, and 6.5% with a second booster dose. Vaccine uptake was highest among those ≥60 years of age (81% with complete series, 69% with first booster dose, and 29% with second booster dose). There is wide variation in COVID-19 vaccine uptake between different countries in the Region.

Data on vaccine effectiveness against symptomatic disease, severe disease due to the Omicron variant, and vaccine effectiveness of the second booster dose against Omicron were reviewed. Currently, COVID-19 vaccine supply is not an issue in the Region. The ETAGE recommendations on prioritization of COVID-19 vaccination from March 2022 were to prioritize the most vulnerable populations, close contacts of immunocompromised people, and essential service workers. ETAGE recommendations on the COVID-19 vaccine strategy for autumn 2022 included the following:

- Reach high coverage with the primary vaccination series and a first booster dose among all eligible people.
- Countries should ensure that all eligible people are up to date with COVID-19 vaccinations for the primary series and first booster dose.
- In addition, countries should:
  - administer a second booster dose to moderately and severely immunocompromised individuals aged 5 years of age and above and their close contacts;
  - consider offering a second booster dose to specific at-risk groups, including older adults, HWs and pregnant women;
  - consider co-administration of COVID-19 vaccines and seasonal influenza vaccines, whenever feasible.

In August 2022, SAGE published a Good practice statement on the use of second booster doses for COVID-19 vaccines (9) which recommended countries prioritize achieving high vaccine coverage of the primary and first booster doses and consider a second booster dose for certain priority groups. Updated COVID-19 vaccines have been licensed including Moderna and Pfizer-BioNTech bivalent COVID-19 vaccines. In October 2022, SAGE released a Good practice statement on the use of variant-containing COVID-19 vaccines (10) which recommended the following:

- Achieving high and equitable coverage with the primary series remains the highest priority, particularly for risk groups.
- First booster should be offered to all persons aged 12 and above, particularly to the highest priority-use groups.
- Second booster should be administered to people at high risk of severe COVID-19 and health care workers.
• Countries should use:
  o Only ancestral virus WHO EUL COVID-19 vaccine for primary series
  o Ancestral virus vaccines or new variant-containing vaccines for either booster doses (choice depends on access to vaccines and costs).

• Use of heterologous boosting, which provides superior immunogenicity:
  o primary series with inactivated vaccines- mRNA vaccine booster
  o primary series with vectored vaccines- mRNA vaccine booster
  o primary series with mRNA vaccines- vectored vaccine booster.

• Co-administration of COVID-19 vaccines with seasonal influenza vaccine.

An International Health Regulations (2005) Emergency Committee statement (1) released in October 2022 stated:

• The pandemic continues to adversely and strongly affect the health of the world’s population.
• The risk of new variants exacerbating the ongoing health impact remains.

Temporary recommendations include to:
  o strengthen integrated surveillance and achieve vaccination targets for at risk groups;
  o continue to develop strategies to increase access to affordable therapeutics;
  o strengthen pandemic preparedness planning, while continuing to protect the most at-risk populations.

During the regional PMMs, participants were informed about updated WHO recommendations on COVID-19 vaccination, countries shared progress and challenges in implementing COVID-19 vaccination, and future WHO support to countries in reaching high COVID-19 vaccination coverage was defined. The WHO Collaborating Centre for Vaccine Safety has developed a website with information and resources on COVID-19 vaccines (2).

Discussion
ETAGE discussed COVID-19 vaccination coverage in Ukraine. It is difficult to estimate the population of Ukraine during the conflict and current COVID-19 vaccination coverage data are likely inaccurate.

ETAGE discussed the current recommendations for COVID-19 vaccination. The secretariat noted that the main reasons people are not receiving the primary series of COVID-19 vaccine in the Region include systematic barriers and refusals due to HW advice or vaccine safety concerns. The SAGE Chair stressed that the booster dose should be prioritized for the most vulnerable people. The current recommendations should be reiterated and countries should be encouraged to administer both booster doses and the primary vaccination series, focusing their efforts on the most vulnerable populations.

During the regional PMMs, countries requested SAGE recommendations for COVID-19 vaccination for autumn 2023 as soon as possible to help them with planning. The SAGE Chair acknowledged that planning for next year will be a challenge and noted that SAGE will be reviewing the Roadmap for COVID-19 vaccine. ETAGE could request SAGE provide COVID-19 vaccine recommendations for the 2023-2024 season by mid-year 2023 to give countries time to plan.
ETAGE noted the ongoing discussion in some countries about the need to adapt the COVID-19 vaccination monitoring to new vaccine recommendations.
Session 4: Paediatric diarrhoeal disease surveillance in the WHO European Region and its relevance/pathway moving forward

Dr Roberta Pastore, VPI, Regional Office, reviewed rotavirus and paediatric diarrhoea surveillance, which has been in place for more than ten years. In 2010, the WHO-coordinated Global Rotavirus Surveillance Network (GRSN) was established with aggregate, unlinked data and was transitioned to case-based, laboratory-linked data in 2013. The Global Paediatric Diarrhoea Surveillance (GPDS) project was piloted in 2015 and expanded to all six WHO regions in 2017; GPDS is building on the GRSN by expanding the criteria for case enrollment and laboratory testing of selected enrolled cases from rotavirus to 16 enteric pathogens using Taqman array cards (TACs).

The Global Rotavirus Surveillance Laboratory Network had 33 countries participating in 2021. From 2017–2018, there were 33 GPDS surveillance sites from 28 countries but some sites were removed and added in 2019 and 2020. The differences between the GRSN and GPDS were reviewed, and surveillance objectives, WHO case definitions for rotavirus and paediatric diarrhoea, laboratory testing approach were compared. The main objective for GRSN is to support decision making for rotavirus vaccine introduction and evaluate effectiveness and impact of vaccination. The main objective of GPDS is to provide evidence on burden of enteric pathogens for which vaccines are in the pipeline (e.g., norovirus, Shigella, ETEC, Campylobacter, non-typhoidal Salmonella), support vaccine introduction and provide platform for future vaccine evaluation.

WHO has developed rotavirus surveillance standards (3) and the Global strategy for comprehensive VPD surveillance (4), which states that not all countries are required to have rotavirus surveillance. Minimal rotavirus surveillance is active, case-based, in ≥1 sentinel hospital, and with laboratory confirmation. Enhanced surveillance includes:

- laboratory-based surveillance – in countries where samples from acute gastroenteritis cases are already routinely tested for rotavirus;
- population-based surveillance – expands sentinel surveillance to multiple facilities in an area with a known population (incidence monitoring);
- household-based surveillance/community clinics – expands to outpatient and non-hospital settings to describe a complete picture of the clinical rotavirus disease spectrum.

Sites should undertake surveillance for ≥2 years prior to rotavirus vaccine introduction and 2–5 years after introduction. The concept of GPDS is described in the rotavirus surveillance standards.

In the WHO European Region, the GRSN was established in 2006 in seven Gavi-eligible countries, with 1–2 sentinel sites per country, with a regional reference laboratory (RRL) based in Minsk, Belarus. In 2017 five countries continued GRSN and established GPDS in the same participating sites. The GRSN and GPDS are financially supported by WHO in all sites and countries. In 2020–2022, due to the COVID-19 pandemic and the conflict in Ukraine, there was an interruption or reduction of site activities in several countries (Armenia, Republic of Moldova, Tajikistan, Ukraine and Uzbekistan) and of technical assistance provided by the Regional Office.
Many countries in the Region (37 of 53; 70%) reported that their NITAG had issued recommendations on the introduction of rotavirus vaccine, including all seven of the countries participating in GRSN. There have been vaccine effectiveness (VE) or vaccine impact studies conducted in Armenia (2016), Republic of Moldova (2016), Tajikistan (2020) and Uzbekistan (2019). A study on the direct costs of hospitalization for rotavirus gastroenteritis was conducted in 2016 in Republic of Moldova.

Since 2010, a large number of countries in the Region have introduced the rotavirus vaccine for a total of 30 countries by 2021. The overall rotavirus vaccination coverage in the Region was 34% in 2021 with a range of 20% –98% coverage by country.

The GPDS data are used to estimate pathogen-specific attributable burdens of diarrheal hospitalizations and deaths, at the site, country, regional, and global levels. Thus far, GPDS data indicate that the aetiology of hospitalized diarrhoea has been fairly stable from 2017–2019, with rotavirus, shigella, and norovirus being the top three pathogens, although there is variability across countries.

There are additional rotavirus and enteric pathogen surveillance systems in the Region including the European Rotavirus network (EuroRotaNet), the European Center for Disease Control and Prevention (ECDC) coordinated surveillance for European Union (EU) and European Economic Area (EEA) countries, and national-based systems.

**Discussion**

It was noted that the capacity of these networks is important for future work and there are plans to continue with this surveillance. In the Region, surveillance data from the GNRS have been made available to countries to help them make a decision on rotavirus vaccine introduction. For countries that have participated in the network and have not introduced the rotavirus vaccine, this is not due to a lack of information but for programmatic reasons. Surveillance conducted after rotavirus vaccine introduction do show a reduction in incidence and cost savings. Wealthier countries are introducing the rotavirus vaccine. For lower-income countries, there are high numbers of diarrhoeal cases and deaths, and financing for the vaccine is often the only barrier. If countries can calculate the cost of the disease burden, the case can be made for introducing the rotavirus vaccine because it is cost-saving. There should be a discussion with countries to see if they can take over GNRS surveillance by investing national resources if they would like to continue surveillance beyond the timeframe indicated in the surveillance standards.

Within GDPS, rotavirus is one of the pathogens that is tested from the TACs to monitor the burden of disease. The use of TACs is important because they allow WHO to measure the attributable burdens of diarrheal hospitalizations and deaths of infections that may have vaccines in the future, such as norovirus.

WHO headquarters clarified that the rotavirus surveillance network is the platform for the paediatric diarrhoeal surveillance network. In the sites conducting surveillance, all paediatric diarrhoea cases are tested for rotavirus, whereas only a subset of 100 randomly selected samples are tested by TACs for the other enteropathogens. If rotavirus surveillance were discontinued, WHO would have to find an alternate method to enroll and sample cases for representative TAC testing. From a global perspective, rotavirus and paediatric diarrhoeal surveillance will continue for another 5–6 years to answer some key questions. In most WHO regions, the current number of surveillance sites will be maintained and, in some regions, the number of sites will increase.
Session 5: NITAG strengthening activities and the role of NITAGs in the WHO European Region in guiding the agenda of the ETAGE meeting

Dr Mosina and Dr Wiebe Külper-Schiek provided an overview of NITAG strengthening activities conducted in the Region. Overall, 50 of 53 countries in the Region have NITAGs and the 2021 NITAGs’ performance on the six WHO performance criteria were reviewed. The Regional Office provided support to NITAGs in developing recommendations on COVID-19 vaccination policies in collaboration with Robert Koch Institute (RKI) through regular webinars during the COVID-19 pandemic. NITAG members were also encouraged to participate in ETAGE and SAGE meetings and there was direct communication between the ETAGE and SAGE Chairs and secretariats and NITAGs through their participation in these webinars.

The Regional Office has a joint project with RKI through 2025 to strengthen NITAGs in the Region and enhance NITAGs’ capacity to use a systematic approach in developing evidence-based recommendations. NITAGs are being evaluated to identify strengths and challenges, develop improvement plans, and define future targeted support by WHO and RKI, as well as other NITAG partners. An evaluation methodology was developed including a standardized evaluation questionnaire and a review of NITAG documents; the evaluations have been both external or self-evaluations. Evaluations have been conducted in Belarus and Uzbekistan (external evaluations) and Albania, Armenia, Bosnia and Herzegovina, Kazakhstan, Republic of Moldova and Turkmenistan (self-evaluations).

A Regional Guidance on an Adapted Evidence to Recommendation Process for National Immunization Technical Advisory Groups has been developed (5). NITAG recommendations should be based on the best available evidence and developed using a systematic approach. The evidence-to-recommendation (EtR) process has been used by long-functioning NITAGs, but this process is extensive and resource-intensive. An adapted EtR process was established by the Regional Office and may be used by recently established NITAGs with limited financial and human resources. This process uses pre-defined criteria (generic criteria tables), a systematic collection of the evidence, and a consistent format to synthesize (summary of evidence and expert judgments) the evidence (EtR framework). Through this method, recommendations become consistent, transparent, and comparable. This approach has been used by the NITAG working groups of Armenia, the Republic of Moldova and Uzbekistan with the WHO Regional Office and RKI providing training on the process. The Regional Office and RKI offer hands-on support to countries on the implementation of the adapted EtR process and work with them through each step of the process.

Dr Tarik Derrough, ECDC, provided background on the EU/EEA NITAG collaboration. The EU/EEA NITAG Collaboration Group (CG) was established in 2018 to create opportunities for sharing experiences and increasing effectiveness by sharing evidence. The aim of the network is to bring together experts in the field of public health and immunization from the various EU/EEA national committees, exchange existing and new scientific evidence, and generate new scientific evidence.

Each EU/EEA country nominates two representatives to be part of the CG, the ECDC serves as secretariat and there is a five-member steering committee. This was a pilot project from 2019–2022 to assess the feasibility, acceptability and added value of the new collaboration. The collaboration was expected to support the advisory role of NITAGs but not interfere with decision-making and vaccine recommendations at a national level.
The main activities of the CG included group meetings, webinars, technical meetings, and working groups. The four pillars of collaboration included sharing of information and methods, evidence reviews, education/capacity building, and modelling/health economics. There is a European Health and Digital Executive Agency contract for “Systematic Reviews of Scientific Evidence on Vaccines and Capacity Building Activities” to support EU Member States in their decision-making on national vaccination programmes, including COVID-19 vaccines and any adaptation of those vaccines. The CG project is now moving towards a more proactive and interactive system (e.g., a dynamic communication platform, system for conducting systematic reviews, and capacity-building).

Discussion
ETAGE acknowledged the progress that has been made in recent years to strengthen NITAGs in the Region and the development of supportive documents. ETAGE congratulated all of the colleagues involved in this important work.

It was noted that communication with NITAGs could still be improved. Continued education of NITAG members is also very important. All 53 Member States receive the documents and resources that are prepared for NITAGs by the Regional Office. NITAG documents and experiences will also be shared with countries at the final PMM in 2023. The Global NITAG Network (GNN) was developed to support NITAG activities and the NITAG Resource Center (NRC) is also an important resource for NITAGs. One barrier is that materials are not always translated into other languages and the GNN meetings do not always provide language interpretation. The Regional Office will continue to encourage the remaining three countries in the Region to establish a NITAG.

ETAGE asked ECDC to consider sharing the topics of ECDC’s planned systematic reviews with NITAGs so that efforts will not be duplicated. ECDC plans to publish the main activities that will be conducted for its CG project. ECDC confirmed that the 16 new systematic reviews that are being conducted will be included in SYSVAC. ETAGE asked ECDC to share with other countries in the Region and globally the resources and training materials on systematic literature review, which will be developed by the CG project.

ETAGE discussed the future priorities of work and meeting topics, which are normally defined by the Chair and secretariat. The secretariat should develop a mechanism to collect requests from the Member States on ETAGE meeting topics or bring them to the attention of SAGE.
Conclusions and recommendations

COVID-19 vaccination in the WHO European Region and Regional adaptation of SAGE recommendations

Conclusions

• In the WHO European Region, 1.7 billion COVID-19 vaccine doses have been administered so far, but inequitable uptake has left many high-risk individuals vulnerable to serious outcomes of the disease.
• The rate of immunization coverage with the primary series and at least one booster dose among adults aged 60 years and older is much higher in high-income countries than in lower-middle-income countries in the Region.

Recommendations

• ETAGE reiterates its recommendations that achieving high vaccine coverage of the primary series and booster doses in high-risk populations remains the highest priority. Countries should undertake additional efforts to ensure that all eligible people are up-to-date on COVID-19 vaccinations according to national recommendations.
• ETAGE concurs with the SAGE recommendation that countries may use ancestral virus vaccines or new variant-containing COVID-19 vaccines for booster doses according to product availability.
• Member States should plan for the integration of COVID-19 vaccination into routine healthcare provision strategies using lessons learned from the COVID-19 vaccine roll-out.
• Member States should sustain systems to monitor COVID-19 vaccination and adapt them as vaccination policies and reporting requirements evolve. Member States should consider leveraging reporting mechanisms and digital platforms that were developed for COVID-19, if applicable, to monitor all routine immunization uptake through the life course.
Paediatric diarrhoeal disease surveillance in the WHO European Region and its relevance/pathway moving forward

Conclusions

- The WHO-coordinated Global Rotavirus Surveillance Network (GRSN) coordinates hospital-based sentinel surveillance, using hospital sites in multiple countries to conduct rotavirus surveillance in a standardized and quality-assured manner. Data from GRSN have been instrumental in supporting decision-making for the introduction of rotavirus vaccination in countries of the WHO European Region. Any further goals related to rotavirus surveillance can be addressed through GDPS.

- The Global Paediatric Diarrhoea Surveillance (GPDS) network analyses diarrhoeal specimens collected through GRSN sites, thereby leveraging the existing GRSN to conduct broader testing for enteropathogens, including rotavirus. GPDS data are used to estimate pathogen-specific attributable burdens of diarrhoeal hospitalizations and deaths, at site, country, regional, and global levels. GPDS is used to guide the development of new enteric vaccines and will support decision-making on their introduction.

- Due to the small and decreasing number of countries and sites in the European Region with continued and consistent participation in GPDS, as well as GRSN, pooled data are unlikely to describe the disease burden and genotype circulation for rotavirus and other enteropathogens in the Region.

Recommendations

- Considering availability of data, status of rotavirus vaccine introduction and challenges in sustaining sentinel surveillance in the European Region, WHO support in this area should focus on GPDS surveillance, building upon efforts already made to develop capacity for GRSN.

- The valuable data on rotavirus epidemiology and vaccine effectiveness generated by GRSN should be further used to develop investment plans to support policy decisions on rotavirus vaccine implementation.

- Countries are encouraged to continue conducting rotavirus surveillance using their own resources. Countries should consider increasing ownership and domestic funding for GPDS surveillance within overall investments in immunization and vaccine-preventable disease surveillance.

- WHO should consider supporting more countries in conducting paediatric diarrhoea surveillance based on common standards, regardless of income level, eligibility for specific donor funding or participation in the GPDS network, by:
  - providing guidance on a minimum set of pathogens to be included in paediatric diarrhoea surveillance, a case definition for enrolment of cases in the surveillance, handling of specimens, laboratory testing, data management and analysis; and
  - enabling access to laboratory testing through TAC or similar testing platforms and standards, and building needed technical laboratory capacity.

- WHO should consider conducting a landscape analysis to better understand the surveillance gaps in paediatric diarrhoea surveillance at regional level and liaise with existing regional networks to coordinate use of the data to estimate disease burden due to enteropathogens.
NITAG-strengthening activities in the WHO European Region

**Conclusions**

- Notable progress has been made in establishing NITAGs; 50 out of 53 countries of the WHO European Region reported having a NITAG established. However, when considering the six performance indicators identified by WHO, the performance of NITAGs varies considerably.

- The WHO Regional Office for Europe in collaboration with the Robert Koch Institute, has been providing guidance and support to NITAGs in defining their maturity level; developing and implementing improvement plans; and building their capacities to develop evidence-based recommendations following a systematic approach.

- The newly developed WHO Regional Office for Europe “Guidance on an adapted evidence to recommendation process for National Immunization Technical Advisory Groups” has been pilot tested in a few countries with positive results.

- A EU/EEA NITAG Collaboration Network has been established recently with activities to enhance the exchange between EU/EEA NITAGs and strengthen NITAG capacities.

**Recommendations**

- The WHO Regional Office for Europe should continue advocating for the establishment of NITAGs in the three remaining countries in the Region. Ministries of health should prioritize support for and recognize the important role of NITAGs and their secretariats in making independent, informed recommendations on immunization in their countries.

- ETAGE encourages NITAGs to use the WHO Regional Office for Europe “Guidance on an adapted evidence to recommendation process for National Immunization Technical Advisory Groups” to improve their recommendation-making processes, and NITAG partners to use it as part of the capacity building of NITAGs in the Region.

- Building upon the efforts to strengthen the work of NITAGs in the WHO European Region, the WHO Regional Office for Europe and partners should further strengthen ongoing collaboration towards capacity building of NITAGs. Such enhanced coordination between partners will increase efficiency and create synergies.

- ETAGE encourages NITAG partners to further enhance their collaboration by:
  - ensuring that documents, tools and training materials are shared and made available to all NITAGs in the Region and globally, including tools developed by WHO and RKI and reviews of scientific evidence conducted by/for the EU/EEA NITAG Collaboration Network; and
  - conducting joint meetings for NITAGs, whenever possible, to facilitate peer-to-peer learning and the exchange of experiences between all NITAGs in the Region.
NITAGs’ participation in defining topics to be discussed at ETAGE meetings

Conclusions

• The regular contact between ETAGE, NITAGs and the Regional Office during the COVID-19 pandemic provided the opportunity to learn about NITAGs’ challenges and needs in developing COVID-19 vaccination strategies and allowed the Regional Office to tailor its support to NITAGs.

Recommendations

• The enhanced exchange between ETAGE and NITAGs in developing COVID-19 recommendations should continue in the future when ETAGE develops recommendations on other immunizations and vaccine-preventable diseases. The WHO Regional Office for Europe should develop a process to collect NITAG requests for regional guidance and consider them when defining future ETAGE meeting agendas or bring them to the attention of SAGE.
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- Ève Dubé
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The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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