

**19TH MEETING OF THE
EUROPEAN TECHNICAL ADVISORY GROUP
OF EXPERTS ON IMMUNIZATION
(ETAGE)**

**29-30 October 2019
Copenhagen, Denmark**



Abstract

The European Technical Advisory Group of Experts on Immunization (ETAGE) met in Copenhagen, Denmark, on 29–30 October 2019 to be informed of global and regional immunization-related developments and activities of the Vaccine-preventable Diseases and Immunization programme (VPI) of the WHO Regional Office for Europe. VPI also sought advice and guidance from ETAGE related to specific activities including the 2030 European regional immunization agenda and strategy under development. ETAGE was further updated on the Strategic Response Plan for the measles emergency in the WHO European Region, VPI's middle-income country strategy and roadmap, progress in hepatitis B control, guidance on effective communication of immunization data, experience gained by national immunization technical advisory groups (NITAGs) in the past year, and proposals for withdrawal of oral polio vaccines from the European Region.

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Abbreviations

CDC	United States Centers for Disease Control and Prevention
cVDPV2	circulating vaccine-derived poliovirus type 2
DTP3	third dose of diphtheria-tetanus-pertussis vaccine
ECDC	European Centre for Disease Prevention and Control
ETAGE	European Technical Advisory Group of Experts on Immunization
EVAP	European Vaccine Action Plan 2015-2020
GVAP	Global Vaccine Action Plan
HPV	human papilloma virus
IA2030	Immunization Agenda 2030 strategic framework
IPV	inactivated polio vaccine
JRF	WHO/UNICEF Joint Reporting Form
MCV1	first dose of measles-containing vaccine
MCV2	second dose of measles-containing vaccine
MIC	middle-income country
mOPV2	type 2 monovalent oral polio vaccine
NITAG	National Immunization Technical Advisory Group
OPV	oral polio vaccine
PCV	pneumococcal conjugate vaccine
SAGE	Strategic Advisory Group of Experts on Immunization
SEEHN	South-eastern Europe Health Network
TIP	Tailoring Immunization Practices
UNICEF	United Nations Children's Fund
VPI	Vaccine-preventable Diseases and Immunization programme, WHO Regional Office for Europe
WHA	World Health Assembly
WPV1	wild poliovirus type 1

Executive summary

The 19th meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE) was organized by the WHO Regional Office for Europe (WHO Secretariat) on 29–30 October 2019 in Copenhagen, Denmark to inform ETAGE of global and regional immunization-related developments and activities of the Vaccine-preventable Diseases and Immunization programme (VPI) of the WHO Regional Office, and to seek ETAGE advice and guidance on specific ongoing and planned activities.

Among its conclusions and recommendations, ETAGE:

- noted the significant and important work that will be involved in the development of the 2030 European regional immunization agenda and strategy;
- acknowledged the Strategic Response Plan for the measles emergency in the WHO European Region (the Region) and supported the need for renewed efforts to eliminate measles and rubella across the Region;
- advised countries currently formulating human papillomavirus (HPV) vaccination policies that targeting females before sexual debut will have the maximum impact on reducing cervical cancer deaths and that, in light of continuing constraints on available vaccine supplies, policy makers should be aware that extending vaccination to other age groups and to males may restrict the availability of vaccine for the primary target group during this period;
- recommended that all countries collect, analyse and use subnational coverage data at the lowest available level, to identify geographic areas with suboptimal coverage, and to collect and use other appropriate data, as needed, that could provide information to identify inequalities;
- encouraged countries to report subnational coverage data annually via the WHO/UNICEF Joint Reporting Form (JRF);
- greatly valued the presence and active involvement of NITAG representatives, including their presentations and contributions to discussion and the valuable exchange of information and experience that resulted from this;
- noted with thanks the information provided from Kyrgyzstan, Tajikistan and the Russian Federation and interventions from other represented Member States on the development of their NITAGs and their work towards evidence-based evaluation of HPV vaccines;
- recommended further consultation with NITAGs regarding optimal delivery of training activities, collaboration, use and sharing of materials going forward;
- recommended that all countries prioritize strengthening the use of inactivated polio vaccine (IPV) in their national immunization schedule as part of primary polio prevention programmes to maximize coverage, as this will protect the Region from emergence of circulating vaccine-derived polioviruses (cVDPV) as we move towards eradication and subsequent discontinuation of oral polio vaccine (OPV) and universal IPV usage globally in future years.

Introduction

ETAGE meets annually to advise VPI on specific issues and to be informed of regional progress towards vaccine-preventable disease prevention goals. The 19th meeting of ETAGE was conducted on 29–30 October in Copenhagen, Denmark. Representatives of selected NITAGs were invited to attend the meeting alongside immunization partner agencies and organizations. The meeting was led by Professor Adam Finn, chair of ETAGE; Dr Ray Sanders was rapporteur.

VPI requested advice and guidance from ETAGE members on the following key topics:

- subnational immunization data to address immunization inequity;
- the 2030 European regional immunization agenda and strategy under development.

The following topics were also discussed:

- the decision-making processes of selected NITAGs in using existing guidance to develop recommendations towards introduction of vaccines;
- measles and rubella elimination in the Region and plans for 2020 and beyond;
- potential withdrawal of all OPV in the Region.

VPI further briefed ETAGE on:

- development of guidance on effective communication of immunization data;
- implementation of the middle-income country strategy and roadmap;
- development of a global cervical cancer elimination strategy;
- progress towards hepatitis B control in the Region.

Opening remarks

The meeting was opened on behalf of the WHO Regional Office by Dr Nedret Emiroglu, Director of the Division of Health Emergencies and Communicable Diseases. Dr Emiroglu emphasized the importance of this meeting in bringing together representatives from all three levels of immunization oversight and advisory bodies: the Strategic Advisory Group of Experts on Immunization (SAGE), ETAGE and select NITAGs. 2020 will be a crucial year, with finalization and publication of new immunization vision and strategy documents at global and regional levels. Concerns have been raised by the WHO Regional Office that vaccine coverage levels in several Member States are in decline; and efforts are being made to raise these concerns at the highest political level. Work is continuing on identifying the reasons for vaccine hesitancy in the Region, and this work is supporting Member States in their efforts to reach or maintain high coverage. Of particular concern is the upsurge in measles cases and outbreaks in the Region over the past two years, together with the reestablishment of measles transmission in four Member States previously declared free of endemic transmission of measles. In May of this year measles was designated a Grade 2 emergency in the Region and a Strategic Response Plan to scale up efforts by WHO, partners and Member States was subsequently launched.

On behalf of the WHO Regional Office, Dr Siddhartha Datta, Programme Manager, VPI expressed gratitude to Dr Roman Prymula for his technical advice and contributions as he ended his tenure as an ETAGE member. Dr Datta also welcomed Dr Ève Dubé, present at the meeting as a temporary advisor, who will serve as ETAGE member starting in 2020.

Session 1: SAGE Preliminary conclusions and recommendations

Dr Alejandro Cravioto, Chair of SAGE provided an account of the preliminary conclusions and recommendations from the SAGE meeting on immunization held in October 2019. Among other topics SAGE considered the recent review and evaluation of the Global Vaccine Action Plan (GVAP) and the value of lessons learned through its implementation. A key recommendation was the need to establish a new governance structure to better turn strategy into action, link to an operational model based on closer partner collaboration, respond to emerging issues with increased flexibility, and establish a stronger communications and advocacy strategy. SAGE also promoted the more effective use of data to stimulate and drive action. The meeting reviewed and endorsed the proposed Immunization Agenda 2030 (IA2030) Strategic Framework which outlines a global vision and strategy for the next decade.

SAGE reviewed the feasibility of measles and rubella eradication and concluded that given the gaps in coverage and population immunity and major outbreaks continuing to occur in all six WHO regions, achieving measles eradication is not realistic without significant further effort. SAGE confirmed that no changes were needed to the current WHO recommendations related to rubella vaccine performance. For the prevention of cervical cancer, SAGE reaffirmed the WHO recommendation to vaccinate girls aged 9-14 years old with HPV vaccine using a two-dose schedule. Concern was expressed that the current HPV vaccine shortage could result in failure to introduce or sustain HPV vaccine programmes in some countries, particularly those with high burdens of cervical cancer, and that there is an urgent need for a more equitable and transparent global allocation of limited HPV vaccine supply. SAGE called upon WHO and its partners to urgently convene a dialogue on global access to HPV vaccine and recommended that all countries should *temporarily* put on hold any decision related to introduction and implementation of HPV vaccination strategies that are gender-neutral, for older age group (>15 years), or for multi-age cohorts until the vaccine production situation improves and all countries have equitable access to HPV vaccine.

SAGE expressed serious concerns over the state of polio eradication efforts, particularly the increase in wild poliovirus type 1 (WPV1) cases in Afghanistan and Pakistan, and the outbreaks of cVDPVs in several countries in Africa and Asia. Having sufficient type 2 monovalent OPV (mOPV2) remains essential for cVDPV2 outbreak response and there is a high risk of supply shortages of mOPV2 in the next 6 months. SAGE recommended that the Public Health Emergency of International Concern (PHEIC) status of polio be maintained and that urgent high-level advocacy be conducted to ensure government and community commitment in Afghanistan and Pakistan to stop the current upsurge in WPV1 cases. An uninterrupted supply of mOPV2 is required through identification of 'fill and finish' capacity and new bulk production; accelerated clinical development of a genetically more stable mOPV2 (the novel OPV2 or nOPV2) is also needed to reduce the risk of seeding outbreaks of cVDPV2s. If mOPV2 supply reaches critically low levels and is not sufficient to respond to cVDPV2 outbreaks, SAGE suggested that countries consider a one-drop mOPV2 strategy instead of the standard two-drop strategy.

Discussion

Concerns were expressed that the SAGE recommendation to temporarily put on hold implementation of HPV vaccination strategies that are gender-neutral, for older age groups and for multi-age cohorts may be misunderstood by several of the Member States in the European Region, especially those that are already implementing such a programme or have made the decision to introduce such a strategy. It was stressed that the SAGE recommendation is aimed only at Member States that have not yet decided and have not yet started implementation of gender-neutral and expanded HPV vaccination programmes and that all countries, particularly those with high rates of cervical cancer, should, as a priority, include HPV vaccination of girls aged 9-14 years old in their national immunization programmes.

Constraints on the global supply of IPV are not yet fully resolved and further limitations in supply should be expected. Evidence for the ability of IPV alone to provide adequate mucosal and thereby population immunity against polio in light of perceived low levels of immunity in the intestine was discussed together with the requirement to conduct a more detailed evaluation of available information. This is of importance as the Region is currently considering the requirements for cessation of all OPV use by all Member States.

Session 2: Immunization Agenda 2030

Dr Ann Lindstrand, Coordinator, Expanded Programme on Immunization, WHO headquarters, provided an overview of the proposed Immunization Agenda 2030 (IA2030) and the process that has led to its development. IA2030 sets the new global immunization vision and strategy for the next decade, aiming to respond flexibly to the changing immunization context, address emerging challenges and embed immunization within the broader health and development agenda.

In 2010, the Global Vaccine Action Plan (GVAP) was developed as a rallying cry to accelerate efforts to achieve immunization goals and targets by 2020, and each WHO region developed regional vaccine action plans describing the regional priorities and implementation frameworks to achieve both regional and global immunization goals. While GVAP and the regional plans have met many of their targets and had significant successes, important gaps remain in vaccination coverage and in ensuring equity. With its new vision and strategy, IA2030 will build on the successes of recent strategies and respond to the changing global context.

The proposed document was developed through a consultative process involving over 100 countries and 60 organizations engaged in all aspects of immunization. A co-creation forum was formed in March 2019, and development of a succession of drafts resulted in the document submitted to SAGE for endorsement in October 2019. This document will now be shared with Member States for comment before being submitted to the WHO Executive Board in January 2020, with a view to being discussed by the World Health Assembly in May 2020.

IA2030 has seven strategic priorities, each with well-defined objectives, key areas of focus and achievable goals. The underlying core principles, based on lessons learned from GVAP implementation, are that the strategy should be people driven, country owned, partnership based and data driven. The strategy is intended to be operationalized at three levels: at national level, with translation of IA2030 into national immunization planning; at regional level, with development of new regional vaccine strategies and action plans providing tailored support to countries; and at global level, with a focus on strategic vision, principles and priorities and alignment and strengthening of global partnerships.

Discussion

ETAGE commented that the current draft IA2030 document provides an overall description of general guiding principles but does not provide any specific details of the strategy or a detailed monitoring and evaluation framework for the regional offices and the national immunization managers. It was emphasized that Member States will need to operationalize the strategy tailored to their own specific circumstances. To support them in this, the strategy will include annexes describing steps in the development of specific national strategies. Member States will require support, both technical and operational, in developing and implementing national strategies and plans, and this will necessitate that additional resources, both in terms of staffing and financial support, be made available to WHO at regional level.

Session 3: 2030 European regional immunization agenda and strategy

Dr Siddhartha Datta, Programme Manager, VPI, presented a review of the achievements of the European Vaccine Action Plan 2015–2020 (EVAP) and an account of plans to develop the 2030 European regional immunization agenda and strategy. Of the six EVAP goals, the Region is on track to achieve three, progress is being validated for one (control of hepatitis B), achievement is considered at risk for one (meeting vaccination coverage targets), and one goal (elimination of measles and rubella) will not be achieved. Building on the lessons learned from the implementation of EVAP, the

2030 European regional immunization agenda and strategy will adopt a more ‘bottom up’ approach, with specific focus areas in the Region developed by Member States and regional partners and agencies and thereafter national actions plans to be developed by Member States outlining how they will accomplish identified national priorities.

Core components of the regional strategy will include an advocacy framework aimed at the engagement of the highest possible political levels, a monitoring and evaluation framework, and an investment case demonstrating the full public health value of immunization to national health systems. Guiding principles of the strategy will include equitable provision and access to vaccination services across age groups in every community; leveraging of existing services and goals to enhance the immunization agenda; strengthening of national health systems ownership; expansion of the “value proposition” of immunization; adoption of programmatic and technological innovations, and; strengthening and amplification of partnerships at all levels.

The regional strategic focus areas will be determined through consultation with the Member States, based on their national priorities. Given the diversity of the Region, it is expected that there will be a broad diversity in national priorities for immunization. Accordingly, each country will be requested to provide a limited number of their highest priorities, and these will be discussed at the next immunization Programme Managers Meeting to develop the specific focus areas for the regional strategy. A core group, consisting of representatives of selected Member States, chairs of ETAGE, the European Regional Commission for Certification of Poliomyelitis Eradication (RCC), the European Regional Verification Commission for Measles and Rubella Elimination (RVC), hepatitis B control group and partners, supported by working groups for specific areas, will be established to develop the regional focus and strategy. The process to develop the 2030 European regional immunization strategy began in May 2019 with discussions on the proposed framework within the Regional Office and with the regional partners and agencies to agree on the guiding principles. The process is continuing in the 3rd quarter of 2019 with the formation of the core group and preparation of an online survey on national immunization priorities to be sent to immunization programme managers of the Region. Following a series of consultations and technical contributions from working groups it is expected that a draft strategy will be presented to ETAGE for comment in October 2020. The final strategy will be presented for endorsement by the WHO Regional Committee in 2021.

Discussion

ETAGE appreciated and applauded the systematic approach being taken to develop a regional strategy very much in the spirit of the proposed global vision and strategy. ETAGE requested that the process for establishing national priorities and the role of the national stakeholders in this process be clearly outlined. ETAGE encourages that as broad a consultative process as possible, to include all national stakeholders, be developed to determine the national priorities and develop the regional strategy. The strategy does not yet include goals and targets as these will be a component of global discussions that will be required to address the complex issues of equity at national and subnational levels. It is critically important that Member States recognize that developing the national priorities will set the stage for a two-way information exchange process between WHO, partners and Member States in developing the regional strategy. ETAGE encourages further development of the processes and the products related to the regional immunization agenda and strategy.

Session 4: Update on measles and rubella elimination in the WHO European Region

Dr Patrick O'Connor, Team Lead, Accelerated Diseases Control, VPI, provided an update on the current status of measles and rubella elimination in the Region and an overview of the conclusions of the RVC meeting held in June 2019.

While regional coverage with a first dose of measles-containing vaccine (MCV1) has remained stable around 93-95%, and coverage with a second dose of measles-containing vaccine (MCV2) has increased from 88% to 91% over the past six years, 2018 and 2019 have seen dramatic increases in the number of confirmed measles cases; and outbreaks have been reported in most of the countries in the Region. Of the cases confirmed in 2018, approximately 25% were <5 years of age, 54% were aged 5 to 29 years, and 20% were 30 and above. The majority of cases in the past year have been reported from Ukraine and Kazakhstan, but the entire Region has been affected with cases and/or outbreaks reported by most countries. In May 2019 measles was designated a grade 2 regional emergency, thereby facilitating a scale up of action under the WHO Emergency Response Framework (ERF). Situation reports were published in July and August 2019 and the graded emergency status was extended for a further 90 days in August 2019. The Region launched its Strategic Response Plan (SRP) in September 2019.

The number of reported rubella cases in the Region has remained relatively static since 2017 but a significant number of reported cases are not laboratory confirmed. In 2018 only 12% of reported cases were laboratory confirmed; this has risen to 20% of reported cases in 2019. Considerable effort is required to increase the level of laboratory confirmation to confirm the occurrence or absence of rubella in the Region and exclude the possibility of over-reporting. Of the 680 rubella cases reported between September 2018 and August 2019, 614 (90%) were reported by Poland, Ukraine, Germany, Turkey and the Russian Federation. Almost 50% of reported cases were from Poland, where only 1% of cases have laboratory confirmation.

At the RVC meeting in June 2019, the Commission reviewed the status of measles and rubella elimination in each of the Member States and concluded that 33 Member States had provided evidence for the elimination of both measles and rubella in 2018 and that 9 Member States remained endemic for both. The Commission also concluded that by the end of 2018, measles transmission had been re-established in 4 Member States (Albania, Czech Republic, Greece, the United Kingdom) that had previously attained eliminated status. Since 2012, the Region has made steady progress toward rubella elimination and the RVC requested the WHO secretariat to focus additional efforts on the remaining 11 rubella endemic countries. One of the requirements for a Member State to qualify for rubella elimination status is inclusion of rubella among its mandatory notifiable diseases, but this is still not in place in two Member States in the Region. Review of available evidence suggests that although this criterion has not been met by these two countries, they have provided sufficient surrogate evidence for the RVC to conclude that endemic transmission of rubella has been interrupted. A review of the current criteria for determination of rubella elimination status may be required.

All Member States in the Region have repeatedly committed to achieving measles and rubella elimination. Health authorities in all Member States are requested to use every opportunity to reach all children with routine immunization, as well as to identify and close immunity gaps in adolescent and adult populations. Measles cases and outbreaks should be regarded as an indication of challenges in making immunization services readily available to all sections of the community and of deficiencies in utilization of the available immunization services by the population.

Discussion

ETAGE noted the high incidence of measles in older age groups and the need to address existing population immunity gaps. It recognized, however, that closing immunity gaps in adolescent and adult age groups presents significant challenges, compounded by the varied disease patterns seen in different countries. There is an urgent need to provide support to Member States to identify immunity gaps in their own populations and to develop strategies to close these gaps, particularly at subnational level. Ongoing research is being conducted to accurately identify the role of susceptible adults in ongoing measles transmission.

Although there is a clear WHO case definition for rubella, definitions used in Member States appear to differ significantly, particularly for suspected rubella. Further work is needed to review case definitions in use by Member States in order to fully determine the status of rubella incidence and transmission, particularly if the majority of suspected cases lack laboratory investigation.

Session 5: Cervical cancer elimination strategy

Dr Liudmila Mosina, Technical Officer, Immunization Systems Strengthening, VPI, provided an update on the development of a global strategy for elimination of cervical cancer as a public health problem and the 2030 control targets. The draft global strategy covers the period 2020-2030 and calls for a comprehensive, population-based approach to put all countries on the path to the elimination of cervical cancer within the century. The proposed targets for 2030 are: 90% of girls are fully vaccinated with the HPV vaccine by 15 years of age; 70% of women are screened with a high-precision test; and 90% of women identified with cervical disease receive treatment and care. Models demonstrate that vaccination alone is insufficient. To achieve maximum impact and elimination in the shortest period of time, intensive vaccination, screening and treatment must be pursued in combination. Monitoring and surveillance will allow the world to track and improve processes and WHO will provide a framework to monitor implementation and to validate elimination. Innovations and research are required to reach elimination faster and more efficiently and WHO will work with partners to expedite research outcomes and to facilitate access to the resulting innovations. The draft strategy has been discussed in open consultations and regional consultations (April to August 2019) and the final document is intended to be presented to the World Health Assembly in May 2020 for adoption.

Discussion

There are currently constraints on the global supply of HPV vaccine, although limitations are expected to be resolved by 2024–2026. In the interim it would seem prudent to recommend that available vaccine supplies be targeted at the populations where they will have the greatest benefit, i.e. (pre-)teenage girls in high-incidence countries. Extending existing HPV vaccination programmes to include other age groups and boys would not appear to be the most beneficial use of the limited supplies of vaccine at this time. ETAGE urges that gender-neutral vaccination programmes already in existence should continue as they are, but Member States currently considering extending their programmes to include males and other age groups should consider delaying such a decision until global supply issues are resolved.

Session 6: Use of subnational immunization data to identify inequalities in immunization in the WHO European Region

Ms Danni Daniels, Technical Officer, Immunization and Surveillance Data Team, VPI, described the use of subnational coverage data to identify inequalities in immunization in WHO European Region and a first step to addressing immunization inequities. Countries in the Region are requested

annually to provide subnational coverage for key vaccines through the JRF, but administrative level varies greatly by country, and four Member States in the Region have only one administrative level. There has been an increasing trend in the number of countries reporting subnational data through this mechanism, and in 2018 over 80% of countries provided subnational data. From the information provided it is apparent that coverage inequalities within a country may be masked by national level coverage, as a quarter of countries with high national coverage with the third dose of diphtheria-tetanus-pertussis vaccine (DTP3) ($\geq 95\%$), 90% with moderate DTP3 national coverage (90-94%) and all countries with low national DTP3 coverage ($< 90\%$) had subnational areas with $< 90\%$ coverage in 2018. It is clear that summarizing and using only national level coverage data is insufficient to identify and quantify inequities. WHO receives data only at the administrative level provided by the country. All countries are encouraged to examine immunization data for their lowest administrative level, which will allow them to identify areas with potential inequalities.

Identifying geographic areas with suboptimal coverage is an important first step in identifying and quantifying immunization inequality in a country. Member States should collect, analyse and use subnational coverage data, and report subnational coverage data annually via the WHO/UNICEF Joint Reporting Form (JRF). Inequities in immunization are not limited to geographic inequalities and Member States should look at all available country data (e.g., surveillance data and surveys) and collect additional data, as needed, to make data-driven decisions to address identified inequalities. WHO will develop an operational guidance document laying out a systematic approach to measure and reduce inequities in immunization. Interventions and services should be tailored closely to the local context and requirements.

Discussion

In a Region as heterogenous as the European Region there is considerable variation in what constitutes 'subnational' data and the lowest administrative level from which information can be effectively collected. To be of value in tackling immunization inequities, data needs to be of good quality and Member States need to ensure transparency so that information can be analysed and interpreted for local action. Subnational coverage data should also be collected in a format that permits linkage to other data sources, national census data for example, to broaden the scope for analysis and identification of inequalities. While the analysis of subnational data may be useful in identifying poor performance and addressing any programme failure, it can also be used to highlight, document and demonstrate good performance and achievement; a message that should be made clear in any guidance produced.

Session 7: Middle-income country strategy and road-map

Dr Niyazi Cakmak, Team Lead, Immunization Systems Strengthening, VPI, provided a brief outline of the development of the European Regional Strategy for middle-income countries (MICs) and an update on progress achieved under each workstream. The WHO Regional Office conducted a regional analysis of country performance to determine the situation with regard to immunization inequities in the Region and to refine focus areas to address challenges faced by MICs lacking external donor support. In response to the findings, VPI further prioritized countries in greatest need of support and obtained commitment from priority countries to respond to identified challenges through collaborative work with WHO and regional partners. Working with the South-eastern Europe Health Network (SEEHN) a five-year immunization framework (roadmap) has been developed to provide support to national immunization programmes in accessing affordable vaccines, strengthening decision-making, improving financial sustainability, addressing concerns over vaccine hesitancy and ensuring equitable access to immunization services.

Under the Strategy, progress has been made in the past year in promoting access to affordable vaccines, achieving sustainable financing, developing evidence-based policies, increasing vaccine acceptance and demand, and developing equitable service delivery among the Member States that participated in developing the roadmap. Of these five workstreams, the development of equitable service delivery now requires the greatest attention and draft operational guidance on addressing inequalities in immunization is in preparation.

Discussion

ETAGE noted the work being conducted by VPI in this important field.

Session 8: Hepatitis B control progress in the WHO European Region

Dr Liudmila Mosina, Technical Officer, Immunization Systems Strengthening, VPI, provided an update on progress achieved in control of hepatitis B in the Region. One of the EVAP goals is control of hepatitis B through vaccination, with targets of 95% coverage with three doses of vaccine, 90% coverage with interventions to prevent mother to child transmission, and $\leq 0.5\%$ prevalence of the surface antigen of hepatitis B virus (HBsAg) in vaccinated cohorts. In 2018, 72% of Member States achieved the 95% hepatitis B coverage target, 83% of the 24 countries that implement universal newborn vaccination achieved a 90% hepatitis B birth dose coverage rate, and of the 30 countries that implement vaccination of newborns at risk 37% reached 90% coverage with antenatal screening for HBsAg. Four Member States (Netherlands, Portugal, Tajikistan and Ukraine) have demonstrated reaching the control target of $\leq 0.5\%$ HBsAg prevalence; and hepatitis B serosurveys are ongoing in a further 7 Member States. Evidence on hepatitis B control status is now being validated at regional level, with one Member State (Netherlands) already validated, 5 Member States ready for validation, 36 pending assessment or serosurvey, and a final 11 that require more work before being considered for validation.

While significant progress has been achieved in the implementation of hepatitis B vaccination and prevention of perinatal transmission of hepatitis B virus, additional efforts are needed to reach hepatitis B control targets in all Member States. In particular, hepatitis B vaccine coverage needs to be improved in low-performing countries and assessments of coverage, together with interventions to prevent perinatal transmission of hepatitis B virus, need to be made. Additionally, hepatitis B serosurveys are required to evaluate vaccination impact and validate reaching hepatitis B control targets in countries with high and intermediate endemicity of hepatitis B.

Discussion

ETAGE noted and applauded the progress being made in control of hepatitis B in the Region.

Session 9: Guidance on effective communication of immunization data

Ms Catharina de Kat, Communications and Web Officer, VPI, outlined the new area of work being undertaken by VPI in developing guidelines on effective communication of immunization data. Immunization programmes handle many types of data, using it not only to administer and monitor their own activities, but also to advocate for resources, report to national authorities, inform the public and build or regain trust in immunization. Communicating the data in the most appropriate and effective way for the specific target audiences is a challenge that has perhaps not received sufficient attention. Communicating data in the form of tables with words and numbers may not be the most effective way to cater to all objectives and audiences. For data to be used effectively, to inspire, change, educate, and influence, it is necessary to communicate it in a way that audiences will actively absorb. The new guidance developed by VPI provides insights from behavioural science and advice on shaping messages and numbers, choosing suitable formats, creating appropriate

visuals and disseminating communication products. A consultative process to develop the guideline document began in 2018 and the final version will be published in December 2019.

Discussion

ETAGE strongly supports this initiative and urges that appropriate training materials and resource libraries be developed in support of the guideline documentation. It would also be helpful to provide translations of the document in other WHO official languages.

[Session 10: Kyrgyzstan NITAG's experience in developing recommendations on introduction of HPV vaccine, with interventions from chairs of the Tajikistan and Russian Federation NITAGs](#)

Dr Gulnara Zhumagulova, Chair of the Kyrgyzstan NITAG, described the experience gained in developing a recommendation on introduction of HPV vaccine in Kyrgyzstan. Following receipt of training for NITAG members in evidence-based decision-making held in Copenhagen in 2016, the NITAG formed a Working Group on HPV vaccine with the objective of strengthening the capacity of the NITAG to collect and evaluate evidence on HPV vaccine introduction. The Working Group defined the criteria and sources of evidence to be used related to disease burden, implementation of the cervical cancer screening programme and the characteristics of available vaccines, including immunogenicity, efficacy and duration of protection. The Working Group considered the HPV vaccine's cost-effectiveness and the WHO recommendations on HPV vaccine introduction, together with a review of published literature on the experiences gained in other countries. The immunization system capacity to introduce HPV vaccine was assessed together with survey results on acceptance of HPV vaccine by the public and medical workers. Background documents on the Working Group findings and recommendations are in production and will be discussed by the NITAG in November 2019. NITAG recommendations will be discussed at the Inter-agency Coordination Committee before a preparation of a policy brief for the Ministry of Health. Establishment of a NITAG Working Group has been found to be critical for this process as has the adoption of a systematic approach to data collection and analysis. This approach, however, places a significantly increased workload on the NITAG secretariat and there is a need to increase the level of internal resource allocation to cope with this.

Dr Azamdzhon Mirzoev, Chair of the Tajikistan NITAG noted that members from Tajikistan also benefitted from attending the evidence-based decision-making training workshop provided by WHO in Copenhagen. The Tajikistan NITAG is now in the initial stages of preparation for the potential introduction of HPV vaccine and pneumococcal conjugate vaccine (PCV). A scientific article has been published on HPV vaccines, aimed primarily at the academic sector.

Dr Irina Mikheeva, Chair of the Russian Federation NITAG, provided an account of the Russian experience in the introduction of HPV vaccine. Approximately 10 years ago, two HPV vaccine-containing products were licensed for use in the Russian Federation. These were initially provided on a fee-for-service basis targeting teenage and pre-teen girls in selected regions, funded through regional budgets. The Moscow region provided immunization for 12-14-year-old girls, but vaccination coverage was low. The NITAG proposed adding HPV vaccine to the national immunization schedule and invited national discussion on the advantages and disadvantages of this proposal. A series of meetings in 2019 concluded there was a need to introduce HPV vaccine into the national immunization schedule, but the global shortage of vaccine was a constraint. In response it has been proposed that local production of HPV vaccine be developed in collaboration with a global producer.

Discussion

The training and guidance material developed by WHO have clearly been appreciated by the NITAGs but further training workshops are required to strengthen national capacity. Several of the NITAG representatives were of the opinion that in-country training workshops could be effective as all members of the NITAG could receive appropriate training at the same time and activities could be targeted on country-specific issues. There has also been a call for more opportunities for information exchange between NITAGs through peer-to-peer learning, increased participation in international meetings and workshops.

Session 11: Kazakhstan NITAG's recommendations on PCV product choice

Dr Dinagul Baesheva, Chair of the Kazakhstan NITAG, provided a presentation on experience gained in developing recommendations on pneumococcal conjugate vaccine product choice. Although not in existence when PCV was initially introduced, the Advisory Committee on Immunization (ACI) has been involved in PCV product choice since 2015. The potential switch from PCV-13 to PCV-10 to reduce the cost of vaccination has been discussed several times. In 2010, when PCV was first introduced, the country did not have surveillance for invasive pneumococcal; the decision was made to introduce PCV-13 which provides protection against more serotypes of *Str. pneumoniae*. Discussions on PCV product choice were held at 5 ACI meetings between 2015 and 2018. Some of these meetings were attended by representatives of PCV manufacturing companies, representatives of NITAGs from other countries and representatives of the National Centre of Expertise for Medicines.

Following these meetings, the ACI has recommended that the country continue using PCV-13, as there is still a lack of complete and reliable data on the roles of different serotypes of *Str. pneumoniae* in causing disease, although a pneumococcal carriage study conducted 2013-2016 confirmed the circulation of all serotypes represented in PCV-13. Although pneumonia and bacterial meningitis surveillance data have demonstrated the impact of PCV-13 on invasive bacterial disease in Kazakhstan, there is little available evidence on the potential difference in the net impact PVC-10 would have on overall disease burden. The ACI has not recommended conducting a comparative cost-effectiveness analysis of the two vaccines due to lack of data on disease burden and serotype prevalence, however the recommendation to continue using PCV-13 has led to significant cost implications for the immunization programme due to the high cost of the vaccine. The NITAG has questioned the capacity of NITAGs in countries lacking local disease burden and epidemiological data to make recommendations on vaccine product choice, and whether this should be left to national health authorities who also take financial affordability and sustainability into consideration.

Discussion

ETAGE recognizes the challenges faced by NITAGs over product choice. Lack of disease burden, epidemiological and surveillance data remains a significant challenge for many countries in the Region attempting to make evidence-based decisions on vaccine choice. Decisions will become even more difficult as more products come to market, further emphasising the need for local disease burden and epidemiological data. It should be stressed that all PCV-containing products have been demonstrated to be safe and effective, and in countries that lack local evidence on pneumococcal serotypes distribution, the questions over product choice should be based on considerations of affordability and financial sustainability. While there are different interpretations on the best

methods to collect information for making decisions on product choice, it is essential that the decision-making process used in countries is transparent.

Session 12: Review of withdrawal of OPV in the European Region

Dr Shahin Huseynov, Technical Officer, Accelerated Diseases Control, VPI, reviewed the potential for all Member States in the polio-free Region to use IPV only instead of in combination with OPV, in advance to a global cessation as a component of the polio post-certification process. In the Region at present, 35 Member States have already have an IPV-only schedule. Eighteen Member States have retained at least 1 dose of OPV in a mixed schedule, seven of which currently use OPV for primary protection. Several Member States use OPV (1 to 4 doses) for booster immunization.

SAGE currently recommends that, following global OPV withdrawal, countries implement a 2-dose IPV (fractional-dose) schedule administered at approximately 14 weeks and 9 months of age. SAGE also recommends that countries considering an IPV-only schedule in advance of global certification of polio eradication first ensure they have sustained high vaccination coverage and low risk of both poliovirus importation and transmission. Questions have been raised, however, on how to define and monitor the risk of importation and transmission. The SAGE Polio Working Group has provided some guidance to countries considering changing their schedules to IPV only, but questions remain over what constitutes the best and most effective IPV schedule, and discussions on appropriate schedules, possibly with fewer doses, are needed.

In the European Region, Member States have had a positive experience in moving to IPV-only schedules and they have opted to increase the number of IPV doses in their national routine immunization schedules. Several Member States have also proceeded with reduction of OPV doses or full OPV discontinuation, and the question arises as to whether this gradual approach to OPV cessation should be encouraged.

Discussion

The considerations in making a global recommendation on IPV use have been reviewed, but there is not enough evidence yet to make conclusive recommendations on which IPV schedule to use. This is obviously a changing immunization environment so the logic for using a particular schedule may change over time. The approach taken by countries will need to be flexible to accommodate changes in vaccine requirements with time and also national circumstances. It currently appears unlikely that there will be a synchronized global switch from bivalent OPV (bOPV) to monovalent OPV (mOPV) use as there was for trivalent OPV (tOPV) to bOPV use in 2016. If the next global switch happens it will probably be from bOPV use to IPV-only use. It is more likely that there will be a global recommendation to polio-free regions and sub-regions to change from bOPV use to IPV-only use as countries update their routine immunization schedules.

Conclusions and recommendations

Immunization Agenda 2030 the 2030 European regional immunization agenda and strategy, HPV vaccination, polio vaccination

Conclusions

- ETAGE notes the Immunization Agenda 2030 recently endorsed by SAGE, which includes 7 strategic priorities and 4 core principles, and the plan to develop a new governance model.
- ETAGE endorses the need to renew efforts to eliminate measles and rubella across the WHO European Region.

- ETAGE notes the need to support broad strategic use of available HPV vaccines during the immediate period of restricted supply over the next five years.
- Noting the significant problems being experienced in other WHO regions with continuing cases of WPV1 and outbreaks of cVDPV2 and consequent mOPV2 shortages, ETAGE considers reinforcement of IPV coverage to be vital across the WHO European Region.
- ETAGE notes the need to consult Member States in the Region on their plans and priorities prior to formulating a new regional immunization agenda and strategy for the next decade and agrees that this consultative process needs to be taken forward quickly, in cooperation with regional partners.

Recommendations

- ETAGE notes the significant and important work that will be involved in the development of the 2030 European regional immunization agenda and strategy and recommends that appropriate additional resources be allocated to the VPI team to permit timely completion of this task.
- ETAGE advises countries currently formulating HPV vaccination policies that targeting females before sexual debut will have the maximum impact on cervical cancer deaths. In the context of available vaccine supplies, which are projected to be limited globally during the period until 2024, policy-makers should be aware that extending vaccination to other age groups and to males may restrict the availability of vaccine globally for the primary target group during this period.

Measles and rubella elimination in the WHO European Region

Conclusions

- ETAGE notes the increasing numbers of cases and outbreaks of measles in the Region over the period 2017–2019 and the recent loss of elimination status in four Member States. Noting the importance of achieving and maintaining high routine MCV1 and MCV2 coverage, ETAGE also acknowledges the role played by historical low coverage rates in some areas and the significant challenges to closing population immunity gaps. The usefulness of monitoring measles epidemiology as an index of the effective functioning of immunization systems was also noted.
- ETAGE notes the progress being made towards rubella elimination in the Region and recognizes the existing procedural challenges that exist regarding certification of elimination of transmission in several countries. The continuation of this work is an important priority.
- ETAGE acknowledges the Strategic Response Plan for the measles emergency in the WHO European Region, published in September 2019, and strongly supports the continued efforts towards measles outbreak response.
- ETAGE acknowledges the need to allow other lines of evidence to demonstrate the absence of rubella virus transmission if a Member State does not have a case-based surveillance system in place. This ensures that the timely, evidence-based process can move forward appropriately.

Use of subnational immunization data to identify inequalities in immunization in the WHO European Region

Conclusion

- ETAGE notes the valuable data that are now available from many Member States on the significant variations in immunization coverage at subnational level.

Recommendations

- In the context of identifying immunization inequalities, ETAGE recommends that all countries collect, analyse and use subnational coverage data at the lowest available level, to identify geographic areas with suboptimal coverage, and to collect other appropriate data, as needed, that could provide information on inequalities. Availability of this data will provide the possibility to make data-driven decisions when addressing this topic.
- Countries are encouraged to report subnational coverage data annually via the JRF. ETAGE encourages the WHO Regional Office to develop guidance on a systematic approach to measure and reduce inequities in immunization. Guidance should include identifying root causes of inequality in immunization and tailoring interventions and services to the local context. Use of strategies for increasing vaccination uptake outlined in the WHO "Guide to Tailoring Immunization Programmes" (TIP) should also be promoted, when appropriate.

The middle-income country strategy and roadmap, progress in hepatitis B control and guidance on effective communication of immunization data in the WHO European Region

Conclusion

- ETAGE thanked members of the VPI team for important updates on their work in the areas of strengthening immunization programmes in middle-income countries, progress towards hepatitis B control in the Region and development of guidance on effective communication of immunization data.

NITAG experience in developing recommendations on introduction of HPV vaccine and PCV product choice

Conclusions

- ETAGE greatly valued the presence and active involvement of NITAG representatives in the ETAGE meeting, including their presentations and contributions to discussion and the valuable exchange of information and experience that resulted from this.
- ETAGE noted with thanks the information provided from Kyrgyzstan, Tajikistan and the Russian Federation and interventions from other represented Member States on the development of their NITAGs and their work towards evidence-based evaluation of HPV vaccines.
- ETAGE appreciated the presentation from Kazakhstan concerning evaluation of pneumococcal conjugate vaccines for their national immunization schedules and the fruitful discussion that followed. ETAGE acknowledged the challenges that exist in formulating balanced and actionable recommendations concerning alternative and competing licensed vaccine candidates for this and other infectious diseases which will maximize benefits in terms of public health and cost.

Recommendation

- ETAGE recommends further consultation with NITAGs as to how to optimize delivery of training activities, collaboration, and use and sharing of materials going forward.

Withdrawal of oral polio vaccines in the European Region

Conclusion

- ETAGE noted recent developments in the global polio eradication programme and agreed that there were important implications for polio control activities in the WHO European Region in the coming years.

Recommendation

- ETAGE recommends that all Member States in the Region prioritize strengthening the use of IPV in their primary polio prevention programmes to maximize coverage, as this will protect the Region from outbreaks of cVDPV2 as we move towards eradication and subsequent discontinuation of OPV and universal IPV usage in future years. 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. Further discussion on this topic will be necessary as new evidence and information emerges.

Annex 1: List of participants

ETAGE Members

Adam Finn, Chair
Fatma Nur Baran Aksakal
Antonietta Filia
Federico Martín-Torres
Roman Prymula
Ole Wichmann

National Immunization Technical Advisory Group

Armenia

Anna Chobanyan
Gayane Sahakyan

Azerbaijan

Nigar Mutalibova
Natalya Salimova

Belarus

Inna Karaban
Valiantsina Valchok

Georgia

Lia Jabidze
Teona Kashibadze

Kazakhstan

Nurshay Azimbayeva
Dinagul Bayesheva
Aizhan Yesmagambetova

Kyrgyzstan

Venera Shukurova
Gulnara Zhumagulova

Republic of Moldova

Ludmila Birca
Anatolie Melnic

Russian Federation

Irina Mikheeva

Tajikistan

Zafarjon Azizov
Azamdzhon Mirzoev

Ukraine

Fedir Lapii
Oleksandr Zaika

Uzbekistan

Umidjan Eraliev

Temporary Advisors

Thomas Cherian
Alejandro Cravioto
Ève Dubé
Günter Pfaff
David Salsbury

Rapporteur

Ray Sanders

Representatives of other organizations

CDC - Center for Disease Control and Prevention

Robert Linkins
Eric Mast
Umid Sharapov

ECDC - European Centre for Disease Prevention and Control

Edoardo Colzani

European Commission

Rita Figueira

GAVI, The Vaccine Alliance

Nilgun Aydogan

UNICEF

Svetlana Stefanet

World Health Organization

Regional Office for Europe

Malika Abdusalyamova

Vusala Allahverdiyeva

Zhanara Bekenova

Oleg Benes

Myriam Ben Mamou

Florencia Biviano

Niyazi Cakmak

Danni Daniels

Siddhartha Datta

Catharina de Kat

Sergei Deshevoi

Katharina-Sophia Dolezal

Nedret Emiroglu

Belete Gebrie

Katrine Habersaat

Shahin Huseynov

Maria Iakovenko

Dragan Jankovic

Robert Jensen

Theodoros Kaloumenos

Yana Kirillova

Nargis Maqsudova

Theodoros Michalas

Kubanychbek Monolbaev

Liudmila Mosina

Mark Muscat

Gabriella Nappi

Natalia Nemirova

Tinne Marie Neubert

Patrick O'Connor
Umeda Sadykova
Kamola Safaeva
Eugene Saxentoff
Simarjit Singh
Liudmyla Slobodianyuk
Dovile Videbaek

Headquarters

Ann Lindstrand
Nathalie Vande Maele
Susan Wang

Interpreters

Vladimir Ilyukin
Tatiana Gavrilenco

The WHO Regional Office for Europe

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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Uzbekistan

World Health Organization Regional Office for Europe

UN City, Marmorvej 51, DK-2100 Copenhagen Ø, Denmark

Tel.: +45 45 33 70 00 Fax: +45 45 33 70 01

Email: eurocontact@who.int

Website: www.euro.who.int