

17TH MEETING OF THE EUROPEAN TECHNICAL ADVISORY GROUP OF EXPERTS ON IMMUNIZATION (ETAGE)

26–27 October 2017
Budva, Montenegro



ABSTRACT

The 17th full meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE) took place on 26 to 27 October 2017 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. This meeting was held in conjunction with the WHO European Regional Meeting of National Immunization Programme Managers, held from 24-26 October, and attended by ETAGE members and chairs and representatives from 45 national technical advisory groups (NITAGs). Topics for discussion included review and feedback from the recent global NITAG meeting and opportunities for further coordination and strengthening of NITAGs in the Region, the proposed mid-term evaluation of the European Vaccine Action Plan (EVAP), development of a life-course immunization approach and improving vaccination equity, and potential actions to address ongoing vaccine supply and procurement challenges.

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Abbreviations

BCG	Bacille Calmette-Guérin (tuberculosis vaccine)
CDC	US Centers for Disease Control and Prevention
ECDC	European Centres for Disease Control
ETAGE	European Technical Advisory Group of Experts on Immunization
EVAP	European Vaccine Action Plan 2015-2020
GNN	Global NITAG Network
GVAP	Global Vaccine Action Plan
MIC	Middle-income country
NITAG	National Immunization Technical Advisory Group
NRC	NITAG Resource Centre
PCV	pneumococcal conjugate vaccine
PEP	Rabies post-exposure prophylaxis
PrEP	Rabies pre-exposure prophylaxis
RIG	rabies immunoglobulin
RNN	Regional NITAG Network
RTAG	Regional Technical Advisory Group on Immunization
RVC	Regional measles and rubella Verification Commission
SAGE	Strategic Advisory Group of Experts on Immunization
SEEHN	South-eastern Europe Health Network
TB	tuberculosis
TCV	typhoid conjugate vaccine
V3P	Vaccine Product, Price and Procurement
VPI	Vaccine-preventable Diseases and Immunization Programme of the WHO Regional Office for Europe
WHO	World Health Organization

Executive summary

The 17th meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE) was held on 26 to 27 October 2017 in Budva, Montenegro 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 actions.

The main topics for discussion included a review of vaccine pricing and procurement challenges, together with consultation between National Immunization Technical Advisory Group (NITAG) representatives and ETAGE on key issues and action points. The outcomes of the recent global NITAG meeting and a proposal to establish a regional NITAG network were also discussed. The proposed methodology, timelines and role of ETAGE in the European Vaccine Action Plan (EVAP) mid-term review were discussed, and feedback from the ETAGE working group on hepatitis B control received. Recent progress on defining life-course-immunization and vaccine equity was reviewed and the requirements to establish guidelines in this area discussed.

Staging the ETAGE meeting in conjunction with the regional Programme Managers Meeting, giving ETAGE members the opportunity to communicate directly with country representatives, was highly appreciated. The innovative interactive approach employed in conducting the meetings, including introduction of a meeting mobile app, was considered to have been very successful and ETAGE looks forward to further development and extension of this innovative approach to the management of future meetings.

While considerable progress has been made towards achieving the EVAP goals and sustainability objectives, significant challenges remain to be overcome to achieve several of these objectives within the planned timeframe. The EVAP mid-term review, to be conducted in early 2018, is expected to provide clear indications on where the resources of the programme need to be focused and what activities require prioritization. All Member States are urged to collect and report the data necessary for the mid-term review by the agreed deadline so the evaluation process can be completed in accordance with the strict timeline for submission to the Regional Committee and the World Health Assembly.

Evidence is accumulating that the range of prices paid by Member States for paediatric vaccines has substantially narrowed following the work carried out on vaccine price transparency and that several countries have been able to procure vaccines at lower prices than those previously paid. Middle-income countries (MICs) without donor support, however, still appear to be paying above average prices for their vaccines and further technical support is required to strengthen their capacities to

negotiate for and procure affordable vaccines. Efforts made to assist countries in strengthening strategic procurement of vaccines, broaden their range of potential products and accelerate the approval processes to enable them to respond to vaccine shortages more rapidly, remain of critical importance.

There remain significant challenges to the gathering and sharing of complex information necessary to improve the match between vaccine supply and demand, including the nature of any transparent exchange of information with vaccine manufacturers that does not breach confidentiality or conflict of interest. A mechanism to reliably predict impending vaccine shortages would be valuable at a regional level and possibilities for establishing such a mechanism should be investigated.

Establishment of a regional NITAG network was strongly supported, and every effort should be made to make best use of the existing NITAG Resource Centre and Global NITAG Network resources in developing a regional NITAG.

Proposed Terms of Reference for the ETAGE hepatitis B Working Group have been approved and the proposed validation targets, criteria, approaches and procedures agreed. The allocation of resources to this work programme should be maintained and strengthened as this will contribute significantly to achieving the EVAP goal of controlling hepatitis B infection.

Strong approval was given for the development of technical documents and guidelines in the areas of life-course immunization, financial sustainability, integration and equity and the initiative towards southeastern European countries and MICs.

Introduction

ETAGE meets annually to review the progress of the Vaccine-preventable Diseases and Immunization Programme (VPI) towards the European regional disease prevention goals. The 17th meeting of ETAGE was conducted from 26 to 27 October 2017 in Budva, Montenegro, and held in conjunction with the WHO European Regional Meeting of National Immunization Programme Managers, held on 24–26 October. ETAGE members and chairs and representatives of 43 NITAGs participated in both meetings. The ETAGE meeting was also attended by Dr Kari Johansen, representing the Strategic Group of Experts on Immunization (SAGE). Chairman for the meeting was ETAGE Chair Professor Adam Finn; Dr Ray Sanders was rapporteur.

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

- NITAGs: a review of the outcomes of the recent global NITAG meeting and receive feedback from NITAG representatives. Discussion of the regional NITAG network coordination/facilitation and the next steps to establish a NITAG knowledge hub, and key challenges facing NITAG functionality, operations, guidance and communication.
- Life-course immunization and equity: reviewing progress on defining these terms and the dimensions of extending the benefits of vaccination equitably and across the life-course in the European Region.
- EVAP mid-term evaluation: Proposed methodology, timelines, and role of ETAGE.
- Supply and procurement challenges: consultation with NITAGs and ETAGE on key issues and potential action points emerging from the southeastern European health ministerial roundtable and previous Member State consultations.

Opening remarks

The meeting was opened on behalf of the WHO Regional Office by Mr Robb Butler, Programme Manager, VPI. Due to rotation of appointment to ETAGE this meeting was the last for four retiring members: Dr Cornelia Betsch, Professor Paolo Bonanni, Dr Vladimir Chulanov and Dr Hans Houweling. Mr Butler expressed his gratitude, on behalf of the WHO Regional Office, to the retiring members for their hard work and significant contribution to guiding and improving immunization services in the Region. For the coming period, ETAGE comprises its chair, Professor Adam Finn, and 6 additional members: Professor F. Nur Baran Aksakal, Dr Antonietta Filia, Professor Alenka Kraigher, Dr Federico Martín-Torres, Professor Roman Prymula and Dr Ole Wichmann.

Chair of the meeting, Professor Adam Finn welcomed Dr Kari Johansen, representing SAGE, and the chairs and representatives from 43 NITAGs. Welcome was also extended to Dr Gunter Pfaff, chair of the European Regional Verification Commission for Measles and Rubella Elimination (RVC), and to representatives from the various international partner agencies, including the US Centers for Disease Control and Prevention (CDC), and the European Centre for Disease Prevention and Control (ECDC).

Update on Strategic Advisory Group of Experts on Immunization (SAGE) discussions and recommendations from the October 2017 meeting

Rabies vaccine: SAGE reviewed new evidence and programmatic experiences available on rabies immunization in humans and issued recommendations on pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP) and rabies immunoglobulin (RIG) administration. Shortened schedules

for both PEP and PrEP were recommended. PEP regimens administered intradermally are cost and dose-sparing, even in clinics with low patient throughput. Patients with documented immunodeficiency should be evaluated on a case-by-case basis. New evidence from Cambodia and Tanzania shows that when thorough wound washing and prompt administration of vaccine is provided to category III bite victims, 99% survive. Trials and programmatic experience indicate that infiltration of RIG in and around the wound neutralizes rabies virus within hours and RIG administered intramuscularly distant to the wound is of limited value. These recommendations will allow RIG dose sparing and guidance for aseptic use of remaining RIG will need to be developed. Equine RIG is clinically equivalent to human RIG and skin testing prior to its administration should be abandoned. SAGE recommended these updates that allow a more efficient, prudent and equitable use of human rabies biologics, particularly in endemic settings.

Pneumococcal conjugate vaccines (PCV): SAGE reviewed data on the optimal use of PCV with respect to dosing schedules, product differences, and use of catch up immunization. SAGE concluded that both 2p+1 and 3p+0 schedules have a substantial impact on overall vaccine type disease. SAGE also concluded that 2p+1 has a desirable impact on serotype 1 (ST1) disease; more limited data on 3p+0 suggest an impact on ST1 disease from this schedule. SAGE found that both 10-valent (PCV10) and 13-valent (PCV13) formulation vaccines have substantial impact against pneumonia, vaccine-type invasive disease and carriage. PCV13 may have additional benefit in settings where disease attributable to serotype 19A (ST19A) or serotype 6C (ST6C) is significant. Modelled data indicate that catch up immunization in those <5 years of age will accelerate PCV impact on disease burden regardless of transmission intensity, however the efficiency of catch-up varies by age strata, and that variation depends on the transmission intensity of the setting.

Typhoid vaccine: SAGE recommended the introduction of typhoid conjugate vaccine (TCV) for infants and children over 6 months of age as a single dose in typhoid endemic countries. Introduction of TCV should first be prioritized to countries with the highest burden of disease or a high burden of antimicrobial resistant *S. Typhi*. Introduction of TCV should include post-licensure monitoring of effectiveness and robust monitoring of vaccine safety, including any potential risks in special population groups. Priority should be given to further research to support TCV policy and introduction decisions.

Measles: SAGE reviewed modelling evidence on the importance of attaining high measles vaccine coverage in school-age children and the impact of measles transmission during the period of first school attendance.

Bacille Calmette-Guérin (BCG): SAGE reaffirmed the current recommendation of universal birth dose vaccination with BCG in high incidence tuberculosis (TB) settings and expanded this to include high burden leprosy settings regardless of the TB incidence. SAGE further stressed that BCG vaccination together with hepatitis B vaccination should be administered as soon as possible after birth, ideally within 24 hours and that it is safe to do so. SAGE identified several topics for further research needs and emphasized the need for new vaccines against TB and leprosy for all age groups.

Polio eradication: SAGE reviewed the progress of the Global Polio Eradication Initiative and expressed concern over the waning mucosal immunity against type 2 poliovirus, and reiterated the need to maintain high polio immunization coverage to sustain population immunity against types 1 and 3, especially in high risk countries and sub-national high-risk populations. SAGE agreed that low-risk bivalent OPV-using countries may adopt a 2-dose IPV schedule prior to global OPV cessation. In such cases, countries should continue bivalent OPV in their routine schedule. SAGE recommended that countries which have delayed the introduction of IPV, or had a vaccine stock-out, should provide 1 full dose or 2 fractional doses to all children who were missed, as soon as supply becomes available.

Regional update and VPI progress report

Implementation of ETAGE 2016 recommendations

In line with conclusions and recommendations from the 16th ETAGE meeting, the WHO Regional Office has continued to actively engage in high-level advocacy for immunization, and VPI has continued to work on developing strategic guidance to MICs. The planned southeastern European health ministerial meeting could be used to launch the MICs strategy. VPI has also continued development on immunization communications and education activities together with evaluation of their impact and effectiveness. The date of the annual RVC meeting has been advanced to June to permit more effective use of data provided in the annual status update reports. Work on providing vaccine pricing transparency information has continued and expanded. The Regional Office has provided ongoing support to the WHO Turkey Country Office in the immunizing of Syrian children in both Syria and in Turkey. An outline plan of action to strengthen measles and rubella elimination activities in remaining endemic countries and epidemiological areas has been developed. An EVAP working group to develop and support preparation of annual and interim reports has not yet been developed, and further work is required to ensure that all relevant documents on EVAP implementation, evaluation and monitoring are provided to ETAGE for review, comment and endorsement prior to distribution. Requests to conduct a review of the status and availability of

stocks of therapeutic doses of diphtheria antitoxin, develop a current status report on diphtheria and pertussis epidemiology in the Region and develop a strategic plan of action to address recognized challenges have not yet been completed.

VPI progress report. October 2016 - October 2017

The VPI team has been restructured to better address the four major focus areas of disease elimination and control, including surveillance: accelerated disease control; immunization systems strengthening; immunization and surveillance data, and; vaccine acceptance, demand, communications and advocacy. Each of these focus areas now has a dedicated team leader within VPI.

With regard to progress towards achieving the 6 EVAP goals; 4 are on track, 1 has stalled, and 1 is off track. The goal of sustaining polio-free status is on track, with the RCC concluding that no wild poliovirus circulated in the Region in 2016, although high risk areas remain. The RCC has continued to develop its adoption of a risk assessment approach to certification of polio eradication, an approach that is now being adopted and adapted in other WHO regions. Laboratory containment of poliovirus materials is progressing and Member States are complying with requirements to minimize polio facility-associated risk.

The EVAP goal to control hepatitis B infection is on track, with WHO European Regional Committee endorsement of the action plan for the health sector response to viral hepatitis and establishment of an ETAGE working group to review and validate data on control activities. The EVAP goal to make evidence-based decisions on introduction of new vaccines is on track, with most Member States now introducing vaccines based on recommendations from their NITAGs. The EVAP goal to achieve financial sustainability for immunization services is on track, with 47 Member States having achieved financial sustainability in procuring routine vaccines and the development of 'transition plans' for Member States moving away from donor support.

The EVAP goal to meet regional vaccination coverage targets has stalled, with a slight decline in regional coverage of the third dose of diphtheria, tetanus and pertussis combination vaccine in the past 3 years, and a substantial decline in Ukraine since 2012. Coverage with all antigens has shown some decline in many of the MICs. The EVAP goal on regional elimination of measles and rubella is off track, although slow, steady progress continues to be made, with 79% of countries having eliminated measles and 70% of countries having eliminated rubella by the end of 2016.

Unfortunately, 2017 has seen a significant rise in the number of reported measles cases and outbreaks, with Italy and Romania contributing the majority of cases. It is of particular concern that there have been at least 18 measles-associated deaths so far in 2017.

Despite advances made, a major challenge faced within the Region continues to be complacency in conversion of statements of political commitment into practical action. Another is the continued existence of low vaccination coverage at subnational level, due mainly to lack of access, loss to follow-up or lack of demand. Vaccine hesitancy and lack of public trust in immunization services and/or health authorities, together with continuing knowledge and communication gaps also threaten achieving the EVAP goals. Targeted action will be required to maintain and achieve universally high vaccination coverage, close immunity gaps through innovative and locally tailored approaches, ensure high-quality vaccine-preventable diseases surveillance and provide better understanding of barriers to vaccination in underserved populations.

Discussion

ETAGE appreciates the good work being done by VPI and recognizes the challenges to accomplishing set goals, particularly with regard to the situation in Ukraine. There is a need for ETAGE to have a better grasp of the situation in Ukraine before any recommendations can be made.

The high number of measles-associated deaths is of great concern, and more information on the cases, diagnosis and cause of death may be helpful to understanding of these measles outbreaks. It is possible that the number of vaccine preventable diseases-associated deaths is underestimated, and a broader investigation into cause of death may help understand the true burden of VPDs.

Vaccine pricing and procurement challenges

Vaccine pricing and procurement has been of high interest to Member States and at global management level in recent years. World Health Assembly resolutions on developing strategies for establishing effective vaccine production, supply, procurement, delivery and forecasting mechanisms were passed in 2015 and 2016. A key element of any strategic supply management mechanism is to find a balance between vaccine supplies and predictable demand through effective communication between the two components. There have been new developments at global level towards strengthening this mechanism, with the provision of information on market research and market knowledge, and an increasing number of Member States sharing information on vaccine pricing. For the Global Vaccine Action Plan (GVAP) Vaccine Price and Procurement Report 2017, 144 countries shared vaccine price data covering 3.2 million doses of vaccine from 73 manufacturers. The Vaccine Product, Price and Procurement (V3P) Web Platform produces country fact sheets that provide an analysis of reported vaccines, lists of manufacturers, list of available vaccine presentations and lists of prices paid by country.

While the number of reported vaccine shortages in the Region has declined in the decade, they still occur, and usually result from an imbalance between complex supply-side and demand-side

components. There remains no effective reporting process for vaccine shortage at global level, and alerts depend on gathering fragmented sources of information with little or no advance notification. This has resulted in a range of *ad-hoc* responses to vaccine shortages. At regional level there have been some new developments towards strengthening vaccine supply management, a study of paediatric vaccine prices conducted in 20 European Union/European Economic Area countries that revealed large price variations between countries. A joint procurement mechanism for the 3 Baltic States of Estonia, Latvia and Lithuania was established for procurement of BCG and rotavirus vaccine. Joint procurement has also been investigated for the SEEHN countries.

Further discussion is required on how to improve predictability of vaccine demand, for example by extending the use of data provided through the WHO/UNICEF Joint Reporting Form. Learning of impending or predicted shortages faced by Member States remains a significant challenge at WHO Regional level, and mechanisms are required to identify both supply-side and demand-side issues in a timely manner. There are also questions over the value and impact of the V3P work and whether this is worth further support given the limited resources available, and the potential for establishing more extensive vaccine joint procurement mechanisms in the Region.

Discussion

It should be recognized that reported widespread shortages of vaccine may not be the result of lack of vaccines, but problems in delivering vaccines to the places they are needed, associated with lack of accurate information on vaccine demand and available supply. WHO attempts to provide broad oversight of the situation, but Member States facing potential shortages need to request support before the problem escalates.

There is evidence that the V3P work has resulted in a general lowering of prices paid for vaccines, and has certainly decreased the price differential between those countries paying the most and those paying the least. Work on V3P should be continued and more Member States encouraged to share vaccine pricing information. It is important to recognize, however, that the different procurement mechanisms in use in the Region can have significant influences on the price paid for vaccines. There is evidence that longer-term planning of vaccine demand results in increased price stability. Several countries have incorporated cost-effectiveness studies into their procurement systems, providing manufacturers with advanced notice of the acceptable prices for vaccines. Increased dialogue with vaccine manufacturers, determining supply-side projections and intentions, is required, but WHO, because of its nature, finds it a challenge to establish and maintain direct contact with commercial manufacturers. Despite the challenges it is essential that Member States

are encouraged and supported to establish mechanisms that permit them to respond effectively to potential vaccine shortage situations.

EVAP mid-term evaluation

EVAP was endorsed in 2014, and the end of 2017 represents the mid-term point. Progress made in the 3 years of operation will be measured at the beginning of 2018. A monitoring and evaluation framework has been developed to assess progress and determine the strengths and weaknesses of the programme. The formal evaluation will take place from November 2017 to May 2018, and the results will be presented in draft format to the Standing Committee of the Regional Committee in May 2018 for consideration by the Regional Committee at its meeting in September 2018. Member States will be encouraged to increase data collection activities in the first quarter of 2018 in order to develop a draft evaluation report by mid-April 2018. Data from the EVAP mid-term evaluation will be incorporated into the GVAP evaluation that will be presented to the World Health Assembly in May 2019.

ETAGE will establish a working group to oversee the EVAP evaluation process. The next Programme Managers Meeting is planned for the first quarter of 2019, where the results of the mid-term review will be discussed and components of the post-2020 plan will be developed.

Update on NITAGs

Forty-Five Member States in the Region have now established statutory advisory bodies that fulfil the role of a NITAG, providing advice to the national health authorities on immunization policy and implementation. WHO has established a list of 6 requirements that need to be met before an advisory body can be considered to be a NITAG, and a performance analysis of reported NITAGs in the Region has shown that 60% of them meet all 6 WHO requirements. Of greatest concern is that only 80% of reported NITAGs have formal mechanisms to exclude conflicts of interest for NITAG members, with evidence that some lack independency from national health authorities of other agencies engaged in provision of immunization services. It is also of concern that some lack full recognition by national health authorities, and are being excluded from the national decision-making processes, and some recently established NITAGs have limited capacities to provide evidence-based recommendations.

There is increasing collaboration at global and regional levels between NITAGs, with increased sharing of resources and experience on a peer-to-peer basis, and increased networking, both between NITAGs and with other advisory bodies including ETAGE and SAGE. What is lacking is a

mechanism to establish conflict-of-interest-free dialogue between NITAGs and vaccine manufacturers.

The 2nd Global NITAG Network (GNN) meeting was held in Berlin from 28 to 29 June, with attendance from 26 Member States representing all 6 WHO Regions. The aims of this meeting were to finalize and formalize the establishment of the GNN and, in line with SAGE recommendations, to enlarge and enhance NITAG function, quality and integration. The role of Regional Technical Advisory Groups on Immunization (RTAGs) and regional networks in the establishment and strengthening of existing NITAGs was discussed, and NITAGs were encouraged to share experiences on communication and dissemination. Views on NITAG independence and access to resources were exchanged, and priority activities for the GNN and its global partners were identified. The Strategic document of the Global NITAG Network¹ was endorsed by the meeting, and the vision, objectives, values, structure and governance of the Network adopted. Meeting participants emphasized the importance of collaboration beyond the regions, through sharing materials and information via the NITAG Resource Centre (NRC) as well as through direct country to country collaborations. By having NITAGs share their work plans through the NRC, a NITAG would know whom to turn to if necessary when starting work on a new topic. The 3rd GNN meeting has been tentatively scheduled for 26-27 June 2018.

Preliminary draft objectives and terms of reference for a Regional NITAG Network in the European Region are being developed by VPI, with the aims of supporting NITAGs in the decision-making process and providing opportunities for recently established NITAGs to learn from the experiences and best practices of well-functioning NITAGs. The proposed regional NITAG Network (RNN) will actively facilitate sharing of information between NITAGs, including arranging for translation of key documents into relevant languages, and moderating discussions, including peer-to-peer technical support. The RNN could potentially conduct surveys and provide summaries of challenges and threats within the Region. The proposed RNN would not duplicate the work of the GNN, but would be a collaborating partner. The initial step is for VPI to identify appropriate funding sources to establish the network and allow it to function. The proposed role of ETAGE would be to monitor implementation of the RNN through regular updates from the Secretariat, provide guidance to the Regional Office and its partners on providing support to address NITAG challenges, and advocate for prioritizing the establishment and strengthening of NITAGs.

¹ **Strategic document of the Global NITAG Network.** Available online: http://www.nitag-resource.org/media-center/document/3864-strategic-document-of-the-global-nitag-network?page=1&disease=0&document_type=54&topic=37&geographical_area=&country=0&sort=recent&keyword=0&author=0&source=0&document_language=0

Discussion

There was general support within ETAGE for the concept of a European RNN, particularly if it is instrumental in establishing core values for the decision-making process that can be used by Member States to meet their specific requirements according to national needs. The RNN could also be useful for distribution of essential updated information on a multitude of vaccine-related subjects, and be used to recommend standardized approaches to particular challenges and develop systematic evidence-based reviews of interventions and practices. ETAGE endorsed the concept of establishing a European RNN.

Potential funding for a European RNN has been investigated, with a good response shown by potential donors at the recent SAGE meeting, and there is ongoing liaison between Member States, WHO and ECDC over potential funding mechanisms. Great care must be taken, however, to ensure that the needs of NITAGs from all WHO Member States, not only those belonging to the European Union, are met and that their experience and achievements are shared. The initiative must be seen to be independent of WHO or ECDC control, but these agencies need to be active in establishment of the Network. Potential donors have been identified, but the arguments for establishment of an RNN need to be marshalled and presented convincingly. It will be critical that the RNN Secretariat is totally independent of a UN or European agency, and, as such, will require an appropriate funding source; preferably one that is sustainable. Concerns were expressed over how an RNN would communicate and interact with commercial vaccine producers in a totally transparent manner, but examples of how this issue is handled at a national level in a number of Member States are available, and may form the basis for developing standard procedures for an RNN.

ETAGE Working Group on hepatitis B

The ETAGE Working Group on hepatitis B provides independent review and expert technical input to ETAGE, increasing the effectiveness of ETAGE deliberations on achieving progress towards the regional hepatitis B control targets. The first meeting of the Working Group was conducted from 18 to 19 September 2017 and the Group agreed on the terms of reference. The meeting also discussed proposed guidelines on validation of country data in respect to having achieved hepatitis B control. The validation process is to be initiated by request from Member States, and the Working Group will review documents submitted by the country; draw conclusions on reaching control targets and provide recommendations to the country on strengthening sustainable hepatitis B control. Conclusions and recommendations from the Working Group will be submitted to the full ETAGE. Indicators used for validation include hepatitis B vaccination coverage over the previous 3 years;

evidence of effective measures to prevent perinatal transmission, and; representative data on seroprevalence of hepatitis B surface antigen among immunized cohorts. Many Member States currently lack data on prevention of perinatal transmission and seroprevalence among immunized cohorts, and are urged to begin the process of planning to collect this data.

Discussion

ETAGE strongly endorses the terms of reference of the Working Group and the proposed validation methodology. Although global guidelines exist on methodologies for conducting hepatitis B serosurveys, it would be helpful to have guidelines tailored to the requirements of the European Region, particularly for the smaller countries.

‘Statement of Intent’ and roadmap for southeastern European and MICs in the European Region

More than 70% of the under-vaccinated children in the European Region reside in 13 MICs that are not eligible for external support and are challenged by securing domestic financing for their immunization programmes. Resource mobilization and procurement negotiation capacity is often sub-optimal, and several of these countries are paying above-average prices for their vaccines. Some of these countries have also experienced increasing vaccine hesitancy and anti-vaccination lobbying, and deteriorating public confidence in vaccination and in government health services. Many of these countries have also been challenged by the recent influx of migrants and refugees into the Region.

It has become apparent that greater effort is required in providing support to these MICs, particularly those in southeastern Europe. Several ministers of health agreed to meet to commit to a road-map for immunization. This meeting was scheduled for February 2018, to refine a Statement of Intent to secure political commitment of Member States around a limited number of key areas, including programme sustainability, pricing and procurement, vaccine acceptance and demand, and equity and migrant health policy. The next step is to develop a 3- to 5-year roadmap, including costing for the initial years so that potential donors can be sought. The current concept is that each of the streams of work will be assigned to a specific Member State, and support will be provided to that Member State to serve as a technical hub and driver for that particular work-stream.

WHO work to define the dimensions and measures of equity, life-course, integration, efficiency and sustainability in the European context

Conducting the EVAP mid-term review over the coming months provides an opportunity to call for increased political commitment to achieving the EVAP goals and promote policies for life-course immunization, improved efficiency, integration of immunization services, and vaccine equity. It is intended that implementation guidance materials for each policy area will be developed by May 2018 that will provide further guidance to immunization programme managers and also build a foundation for developing the post-2020 regional vaccine action plan. It is expected that draft documents for comment will be available by the end of March 2018, and support will be required from Member States to review and comment on these documents prior to finalization.

Conclusions and recommendations

Conclusions

ETAGE commends VPI on the continuing high levels of achievement attained in the face of considerable challenges and appreciates the technical expertise and commitment being provided to address these challenges.

ETAGE greatly appreciates the opportunity to participate in the Programme Managers Meeting and strongly approves the innovative interactive approach employed in conducting the meeting. Introduction of the meeting mobile app, in particular, is especially appreciated. ETAGE looks forward to further development and extension of this innovative approach to management of future meetings.

ETAGE acknowledges the progress made towards achieving the EVAP goals and sustainability objectives and notes the challenges that remain in achieving several of these objectives on time. Acknowledgement is also made of the work conducted to implement recommendations from the 16th ETAGE. It is noted, however, that an EVAP working group is still to be established and that ETAGE review and comment on EVAP documents should be implemented.

ETAGE acknowledges the programmatic importance of the EVAP mid-term review, to be conducted in early 2018, and is fully aware of the requirement to collect all necessary data from Member States and conduct the evaluation process in accordance with the strict timeline for submission to the Regional Committee and the World Health Assembly.

ETAGE notes evidence provided that the range of prices paid by Member States for paediatric vaccines has substantially narrowed following the work carried out on vaccine price transparency and that several countries have been able to procure vaccines at lower prices than those previously paid.

ETAGE endorses the critical importance of efforts made to assist countries in strengthening strategic procurement of vaccines and thus broaden their range of potential products and accelerate the approval processes to enable them to respond to vaccine shortages more rapidly.

ETAGE acknowledges the challenges and complexities of gathering and sharing information necessary for improving the match between vaccine supply and demand. ETAGE considers that a mechanism to ascertain vaccine shortages would be valuable at a regional level and possibilities for establishing such a mechanism should be investigated.

ETAGE strongly endorses the move to support the establishment of a regional NITAG network. The value of the existing NITAG Resource Centre and Global NITAG Network resources is noted and their potential usefulness to regional NITAGs is emphasized. ETAGE notes, with thanks, the extraordinary efforts made by the UK Joint Committee on Vaccination and Immunisation secretariat and members in liaison NITAG work in the Region.

ETAGE approves the proposed Terms of Reference of the ETAGE hepatitis B working group and supports the validation targets, criteria, approaches and procedures proposed. ETAGE also supports the allocation of resources to this work programme and anticipate this will contribute positively to achieving the EVAP goal of controlling hepatitis B infection.

ETAGE notes and approves the development of technical documents and guidelines in the areas of life-course immunization, financial sustainability, integration and equity and the initiative towards southeastern European and MICs and looks forward to having the opportunity to review these in due course.

Recommendations

1. ETAGE urges that mechanisms be explored to engage further with the vaccine production industry at regional level to establish two-way flow of non-confidential information on anticipated levels of vaccine supply and demand. ETAGE further recommends that closer liaison and collaboration be established with those working on the global vaccine market at WHO headquarters.

2. ETAGE recommends that urgent consideration be given to the potential advantages and challenges of establishing an ETAGE working group on vaccine acceptance and demand. The Secretariat should respond to ETAGE with conclusions and, if accepted, any mechanisms for the establishment of such a working group by the end of February 2018.
3. ETAGE urges consideration be given to identifying and securing funding to support an independent secretariat for a regional NITAG network, towards the establishment of regular face-to-face meetings, resource and experience sharing and peer-to-peer support activities.
4. To ensure that the strict timeline for submission of results from the EVAP mid-term review be met, ETAGE strongly urges all Member States to collect and report the required data by April 2018 in order for the evaluation process to be completed and be presented to the Standing Committee of the Regional Committee.

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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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: eucontact@who.int

Website: www.euro.who.int