12 – 13 October 2016 // Copenhagen, Denmark

16th meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE)

World Health Organization
REGIONAL OFFICE FOR Europe

ABSTRACT

The sixteenth full meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE) took place on 12 to 13 October 2016 to review and discuss immunization activities and developments in the WHO European Region and provide advice to the WHO Regional Office on appropriate activities. Main topics for discussion included the vaccine procurement and delivery challenges facing middle income countries (MICS), monitoring progress in implementation of the European Vaccine Action Plan (EVAP), the issues and challenges presented by false contraindications to vaccination and inappropriate vaccine safety concerns, proposed modifications the measles and rubella verification process, and challenges facing the Region in responding to re-emerging vaccine-preventable diseases, particularly diphtheria and pertussis.

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Contents

Abbreviations

ADC	Accelerated Disease Control
AEFI	adverse events following immunization
AFP	acute flaccid paralysis
aP	acellular pertussis vaccine component
bOPV	bivalent oral polio vaccine
CDC	Unites States Centers for Disease Control and Prevention
cVDVP	circulating vaccine-derived poliovirus
DAT	diphtheria anti-toxin
DTP	diphtheria, tetanus and pertussis combination vaccine
DTP3	third dose of DTP
ECDC	European Centres for Disease Control
ETAGE	European Technical Advisory Group of Experts on Immunization
EVAP	European Vaccine Action Plan 2015-2020
GACVS	Global Advisory Committee on Vaccine Safety
GAVI	Global Vaccine Alliance
GVAP	Global Vaccine Action Plan
HPV	human papillomavirus
HCWs	healthcare workers
IBD	invasive bacterial disease
IHR EC	International Health Regulations Emergency Committee
IPV	inactivated poliovirus vaccine
ISS	Immunization System Strengthening
MIC	middle-income country
MOV	missed opportunities for vaccination
NITAG	National Immunization Technical Advisory Group
NVC	National Measles and Rubella Verification Committee
OBRA	Outbreak Response Assessment
PCV	pneumococcal conjugate vaccine
POSE	Polio Outbreak Simulation Exercise
RC	Regional Committee for the WHO European Region
RCC	European Regional Commission for the Certification of Poliomyelitis Eradication
RSV	respiratory syncytial virus
RV	rotavirus
RVC	European Regional Verification Commission for Measles and Rubella Elimination
SAGE	Strategic Advisory Group of Experts on Immunization
TIP	Tailoring Immunization Programmes
tOPV	trivalent oral polio vaccine
VPI	Vaccine-preventable Diseases and Immunization programme of the WHO Regional Office for Europe
WHO	World Health Organization
wP	whole-cell pertussis vaccine component

Executive summary

The sixteenth meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE) was held on 12 to 13 October 2016 in Copenhagen, Denmark to review and discuss immunization activities and developments in the WHO European Region and provide advice to the WHO Regional Office for Europe (Regional Office) on appropriate actions.

Main topics for discussion included the vaccine procurement and delivery challenges facing middle income countries (MICs), monitoring progress in implementation of the European Vaccine Action Plan (EVAP), the issues and challenges presented by false contraindications to vaccination and inappropriate vaccine safety concerns, proposed modifications the measles and rubella verification process, and challenges facing the Region in responding to re-emerging vaccine-preventable diseases, such as diphtheria and pertussis. Information sessions were provided on the 6- and 12-month report outcomes following the Ukraine circulating vaccine-derived poliovirus (cVDPV) outbreak; the WHO Vaccine-preventable Disease Programme new organizational structure, roles and responsibilities; support for reviving routine immunization and conducting campaigns in northern Syria from the WHO Office in Gaziantep, Turkey; the vaccine pricing project, Tailoring Immunization Programmes (TIP) project, and the invasive bacterial disease (IBD) and rotavirus surveillance networks.

In comparison with higher- and lower-income (GAVI-eligible) countries in the European Region, middle-income countries (MICs) face significant additional challenges to effective vaccine delivery. It is also evident, however, that unique circumstances (including history, culture and political commitment) exist in each country which also influence the functioning of their immunisation programmes. Further work is required in this area to provide strategic guidance to MICs in strengthening immunization programmes, including a systematic assessment of needs. WHO has been requested to develop a concept note on a proposed technical package in support of strengthening immunization services in MICs, outlining the challenges and strategic approaches to addressing them, together with an outline plan of action and timeline. The processes of seeking and providing such information by Member States may itself promote awareness and improvement in immunization services over time.

ETAGE remains committed to supporting the implementation EVAP and endorses the establishment of an EVAP working group to develop and support preparation of annual and interim reports over the coming five years. ETAGE members would be pleased to actively support the working group, as

appropriate, and engage with the team in the monitoring and evaluation phase through the coming year.

With regard to measles and rubella surveillance and verification, further consideration should be given to refinement of the annual cycle of reporting to improve the timeliness and programmatic impact of the measles and rubella elimination status reports. Progress towards Regional elimination is being made using the country-based approach, but there are very real challenges posed by large unimmunised age cohorts. Greater programmatic focus is required on addressing challenges associated with remaining measles- and rubella-endemic foci. WHO has been requested to provide an outline plan of action for focussing Regional resources specifically on strengthening elimination activities in remaining endemic countries and epidemiological areas.

Resurgence of diphtheria and pertussis present a serious risk to the Region, and there is a consequent need for strengthening and maintenance of surveillance and re-evaluation of immunization schedules optimal to local epidemiology and available vaccine supplies. WHO has been requested to develop a current status report on diphtheria and pertussis epidemiology and challenges in the Region. Recognising concerns over the global shortage of diphtheria antitoxin, WHO has also been requested to conduct a thorough review of the status and availability of stocks of therapeutic doses of diphtheria antitoxin available to Member States in the Region.

There is relief that progress has been made in halting poliovirus transmission associated with the cVDPV outbreak in Ukraine but the outbreak response evaluation exercise has revealed causes for ongoing concern with regard to immunisation services in Ukraine and in some other parts of the Region.

Extraordinary efforts have been made by the Turkish government and government agencies, the WHO Country Office in Turkey and the VPI team in supporting efforts to the immunize Syrian children in both Syria and in Turkey under extremely difficult conditions. The establishment of a highly effective inter-Regional collaboration with the WHO Eastern Mediterranean Regional Office has been instrumental in delivering an immunization programme in this troubled area.

Significant progress has been made towards providing vaccine pricing transparency information and this work should be continued. Careful consideration should be given, however, to how market forces may respond to this initiative, particularly with regard to the impact on future prices offered to reporting countries.

Continuing ground-breaking work and achievements are being made in the field of immunization communications and education. The development of both pro-active and reactive trainer and healthcare worker (HCW) education, together with the effective distribution of information on reporting vaccine adverse events and contraindications, are significant contributions to addressing the challenge of lack of confidence in vaccination.

Introduction

The European Technical Advisory Group of Experts on Immunization (ETAGE) meets annually to review the progress of the Vaccine-preventable Diseases and Immunization Programme (VPI) towards the European Regional disease prevention goals. The 16th meeting of ETAGE was conducted from 12 to 13 October 2016 at the WHO Regional Office for Europe, Copenhagen, Denmark.

Chairman for the meeting was Professor Adam Finn, chair of ETAGE and 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:

- middle-income country (MIC) challenges: current WHO work package and support, and the development of a EURO MIC Strategy;
- EVAP:
  - monitoring progress – establishing a baseline, the monitoring and evaluation framework and ETAGE's role
  - EVAP implementation in countries – advocating for the adoption and uptake of EVAP priority activities towards Regional goals;
- false contraindications and vaccine safety concerns: the issues and challenges, WHO's current work package and support to Member States, and future considerations
  - spotlight on the human papillomavirus (HPV) vaccine safety concerns and response by Member States and WHO – consulting with ETAGE on the way forward;
- measles and rubella verification: consultation on modifying and streamlining the process of verification;
- diphtheria and pertussis: underfunded support and response – the challenge facing WHO/Europe and partners in responding to re-emerging diseases;

and to update ETAGE on:

- the Ukraine cVDPV outbreak, response and 6- and 12-month report outcomes;
- VPI's new organizational structure, roles and responsibilities;
- support for reviving routine immunization and conducting campaigns in northern Syria from the WHO Office in Gaziantep, Turkey;
- vaccine pricing, TIP project and IBD and rotavirus surveillance.

Opening remarks

The meeting was opened on behalf of the WHO Regional Office by Mr Robb Butler, Programme Manager, VPI, who introduced three new members of ETAGE, Dr F. Nur Baran Aksakal, Professor Alenka Kraigher and Professor Roman Prymula. Two future members of ETAGE, Dr Antonietta Filia and Dr Ole Wichmann were introduced as observers to the current meeting. Also welcomed to the meeting were the NITAG chairs and secretaries from Albania, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Republic of Moldova, Tajikistan and Uzbekistan.

Two retiring members of ETAGE, Professor Pierre Van Damme and Professor Christian Perronne, were warmly thanked for their many years of outstanding service to ETAGE and for the contributions they have made to strengthening immunization in the Region. Dr John Edmunds, who retired from ETAGE in 2015 and was not able to be present at the meeting, was also warmly thanked for his many years of service to ETAGE.

A warm welcome was extended to Professor Jon Abramson, chair of the Strategic Advisory Group of Experts (SAGE) on immunization. This represents the first occasion on which the chair of SAGE has participated in a formal ETAGE meeting. Welcome was also extended to Dr Günter Pfaff, chair of the European Regional Verification Commission for measles and rubella elimination (RVC), and to representatives from the United States Centers for Disease Control and Prevention (CDC), the European Centre for Disease Prevention and Control (EDCD) and the SIVAC Initiative.

Update on Strategic Advisory Group of Experts on Immunization (SAGE) discussions and recommendations from the April 2016 meeting, and agenda items for October 2016 meeting

SAGE considered the Global Report for 2015, noting the achievements made since 1990, particularly the global decline in deaths and increased life expectancy, but recognized the considerable scope for

further improvement. SAGE also noted that of the 5 main goals of the Global Vaccine Action Plan (GVAP) only one is currently on target.

On receipt of the report from the Global Advisory Committee on Vaccine Safety (GACVS) SAGE noted the continuing attention to safety concerns related to HPV vaccines, particularly within Europe. Given the substantial amount of accumulated experience and ongoing pharmacovigilance efforts, the main challenge remains one of communicating the excellent safety profile of HPV. SAGE was concerned to be informed of the anxiety-related clusters linked to receipt of HPV, given the potential severe impact on related immunization programs. GACVS has established a working group to further develop evidence-based prevention and intervention strategies and systematic reviews are in progress to examine anxiety clusters and their handling.

The status of development of vaccines against respiratory syncytial virus (RSV) was considered with more than 60 candidate vaccines currently in development, mostly in the pre-clinical stage and 16 currently in clinical trials. SAGE recommended the current critical 4–5 year interval should be used to systematically identify and fill gaps in evidence required from regulatory, prequalification and policy recommendation perspectives for RSV preventive interventions, including maternal immunization. In addition, SAGE advised WHO to endorse the importance and ethical imperative of clinical trials in pregnant women for potentially life-saving interventions such as RSV vaccine and future vaccines against other targets now in development (e.g., group B streptococcal disease).

In a review of missed opportunities for vaccination (MOV) SAGE concluded that data from two regions (Africa and the Americas) provided compelling evidence that children attending health facilities for vaccination, clinical care or other reasons were not offered all recommended vaccines. The reasons for MOV were mostly attributed to HCWs (>60%), caregivers (27%) and health services (11%). WHO has recently updated the protocol and tools for conducting MOV assessments, as well as the guidance for follow-up interventions. The MOV strategy was seen as a substantial advance with great potential impact and SAGE strongly endorsed the components of the updated MOV strategy as a simple and concrete way to improve coverage, equity and timeliness of vaccination.

Recognizing the benefits to establishing a strong platform for immunization in the second year of life (2YL), SAGE endorsed the development of the 2YL guidance as it supports a comprehensive public health approach with continuum of care where the immunization service requirements are firmly embedded into a broader delivery of health services appropriate for this age group.

Topics for discussion and review during the October 2016 SAGE meeting will include the maternal and neonatal tetanus elimination strategy and broader tetanus control, a mid-term review of the measles and rubella elimination strategy, hepatitis B vaccine birth dose requirements, and dealing with the current global shortage of yellow fever vaccine. Potential topics for SAGE meetings in 2017-2018 include review of the GVAP monitoring process, vaccination strategies for older age groups, maternal vaccination, and implementation of HPV immunization.

Discussion

The current SAGE recommendation on maternal vaccination with influenza vaccine is to continue with vaccination where it is now in use, but this recommendation is under review. Available evidence is in favour of maternal vaccination, but the evidence is not as strong as previously anticipated. More information from developing countries, and more specific analysis of data, is required before a revision to the recommendation can be considered. There appears to be little enthusiasm for maternal vaccination in MICs in Europe, but the WHO Regional Office will continue to offer technical support to Member States conducting assessments and developing action plans.

There is, as yet, no evidence that public concern over reported adverse effects following receipt of HPV vaccine has had a negative impact on broader childhood immunization programmes.

Regional update, VPI progress report

Recommendations made at the 15th meeting of ETAGE in October 2015 have largely driven the work of VPI over the past year, and to a large extent shaped the agenda of the current meeting. Specific recommendations and responses were the following.

- Identify specific circumstances in which serosurveys could materially contribute to policy making, or galvanization into action, to avoid vulnerability and prevent outbreaks.
  - The regional measles/rubella elimination strategy has been reviewed and plans are in hand to tailor resources more effectively towards remaining measles and rubella endemic countries in the Region.
- Recognizing the possibility of insufficient supplies of IPV and legislative issues on bOPV introduction in some settings in the next few months, a contingency plan should be formulated by WHO by 15 November 2015 to address potential problems.

  - The WHO Secretariat provided technical support to Member States in development of contingency plans in the event of a shortage of IPV, but vaccine supply issues continue to burden many Member States.
- Develop plans to evaluate and demonstrate the impact of the WHO educational, training and communication schemes.
  - There is an on-going evaluation of the tailoring immunization programmes (TIP) project and a monitoring and assessment component is being introduced into the TIP package.
- Establishment of an ETAGE Working Group on EVAP monitoring and evaluation and to determine the expected roles and responsibilities of ETAGE members in the functioning of this Working Group.
  - During the course of the current meeting a call will be made to ETAGE to nominate a member as the ETAGE focal point for EVAP monitoring and assessment.
- Every effort should be made to promote progress in establishing effective outbreak response immunization campaigns in Ukraine.
  - A presentation on progress made in Ukraine is provided later in the meeting.
- Consideration should be given to separation of the two Regional targets: measles and rubella elimination.
  - This is now under discussion within WHO and with the European Regional Verification Commission for Measles and Rubella Elimination (RVC).
- Rotavirus and invasive bacterial diseases (IBD) surveillance networks focus on engagement and collaboration with all sites, networks and agencies already functioning in this area within the Region.
  - Progress has been made in this area and will be discussed later in the meeting.
- Efforts to achieve higher primary schedule vaccination coverage are complemented by identifying and providing immunization coverage of susceptibles in older age groups.
  - A multi-agency meeting was conducted in Sienna, Italy in May 2016 to develop strategies to address this challenge.
- The Regional report on vaccine pricing should be made widely available, particularly to national purchasing authorities, in order to encourage greater equity and improved function of the vaccine market.
  - This will be discussed further during the meeting.

- Continuing efforts should be made to strengthen capacity for vaccine supply planning and procurement in the Region, and all countries should be encouraged to review their vaccine supply interruption contingency plans.
  - This will be discussed further, particularly in relation to the challenges faced by MICs.
- The ETAGE Terms of Reference should be updated and a renewed membership rotation programme should be initiated.
  - This process is now well underway, with the active participation of ETAGE.

In response to the challenges faced, the VPI team in the Regional Office has been reorganized to include two team leads in support of the programme manager. The two technical teams, under the team leads are Immunization System Strengthening (ISS) and Accelerated Disease Control (ADC).

Within ADC, major technical contributions over the past year include provision of support to the RVC (4th meeting in 2015) for determination of measles/rubella elimination status of the Member States, successful completion of the tOPV-bOPV "switch" activities along with introduction of bOPV to 17 Member States and IPV-only into two. Regional contributions were made to the Mid-term Review of the Global Measles and Rubella Strategic Plan, 2012-2020, and support was provided to the WHO Eastern Mediterranean Regional Office conducting immunization response and disease surveillance activities following the Syria crisis.

The team has participated in joint missions to Poland, Romania and Serbia together with missions focussed on measles and rubella elimination to Italy, Germany and Switzerland. Other missions were established to provide assistance to Member States during the tOPV-bOPV switch and subsequent monitoring of implementation effects. Missions for three POSE activities were conducted in central Europe, central Asia, and an interregional collaboration with the WHO Western Pacific Region. Onsite laboratory training for measles and rubella have been conducted at regional reference laboratories and training has been provided to all network laboratories on specific accreditation and elimination verification issues. Bio-risk management training, appropriate to laboratory containment requirements for poliovirus stocks, was provided to all polio laboratory network members.

The team has also undertaken activities to increase information sharing and documentation support to improve the quality of data available to the Regional Office, support advocacy for immunization and increase collaboration with partner organizations. The Regional Viral Hepatitis Action Plan was endorsed at the 66th session of Regional Committee for Europe in September 2016.

The ISS team has been active in the field of sustainable immunization financing and overall government funding for vaccines in the Region has continued to increase. All countries receiving GAVI support fulfilled their co-financing requirements in 2015, and all five graduating countries received support to assess the challenges related to graduation from donor support and have developed plans for a smooth transition. The team continue to provide technical support to GAVI-eligible and graduating countries in developing multi-year planning on immunization to identify funding gap and develop strategies for increased domestic funding and conducting joint appraisal updates that define technical assistance needs for further improvement in programme performance. Development of Health System Strengthening plans has also been supported in three Member States to address system-wide barriers.

The team has been active in vaccine management, immunization logistics and vaccine safety through provision of in-country support and subregional workshops. NITAGs have been strengthened through increased participation of NITAG members in international meetings and study tours. An evaluation survey of NITAGs has been conducted to explore common achievements and challenges.

Support is being provided for introduction of HPV vaccine into MICs and GAVI-graduating countries in the Region through technical support to NITAGs, high-level political advocacy and increased engagement of medical societies and immunization stakeholders. The rotavirus and IBV vaccine-preventable disease sentinel surveillance networks have continued to receive technical support and contact has been made with other surveillance networks in the Region to determine potential areas of collaboration. Work has begun on designing a sustainability strategy for the surveillance networks.

The VPI team has also been active on several cross-cutting activities including immunization acceptance, communications advocacy, resource mobilization and data management through the development of tools and training materials. Since March 2016, VPI has had a new data manager in the team and work has focussed on streamlining regular (weekly, monthly and annual) data collection and outputs. Improvements are also being made to data quality, the validation process and documentation (SOPs). Improvements have also been made to the coordination of the measles and polio laboratory data management systems.

Discussion

ETAGE greatly appreciates the technical expertise and commitment being provided by the VPI team and is gratified to know that previous recommendations have been, or are being adequately

addressed. There is a need for more active engagement of ETAGE in high-level advocacy, but also to draw more heavily on the technical expertise available through the ETAGE members. Activities to strengthen NITAGs also need to continue, and new terms of reference for NITAG members are being developed, together with improved guidelines on roles and responsibilities. Opportunities for NITAGS to share information between themselves, and gain greater access to high-quality information for evidence-based decision-making are also being increased.

Middle-income country (MIC) challenges

Concerns were raised globally more than a decade ago that a high proportion of vaccine-preventable deaths occurred in MICs while donors focused mainly on lowest income nations and that MICs were lagging behind in new vaccine introduction compared to the GAVI-supported countries. In response SAGE recommended establishment of a MIC Task Force in 2012 to define a shared strategy, action plan, and monitoring and evaluation framework to enhance sustainable access to vaccines in MICs.

Four common challenges to immunization were identified in MICs: inadequate mechanisms for timely and evidence-based immunization policy decision-making; insufficient political commitment and financial sustainability of immunization programmes; poor demand for and underperforming immunization services, and; unaffordable vaccine prices and unreliable vaccine supply. The MIC Strategy 2015-2020 proposed to address each of these challenges, however, most major donors have chosen to channel funding through GAVI, for which many MICs are ineligible. There are 13 MICs without GAVI support in the European Region, and evidence exists they lag behind high-income countries and those countries with GAVI support in terms of the number of antigens accommodated by national immunization programmes, the number of new vaccines introduced, coverage for the third dose of diptherial/tetanuse/pertussis (DTP)-containing vaccines, and coverage for the first dose of measles-containing vaccine.

There is perceived to be a need to build a strong case for investment in immunization in non-supported MICs that requires technical support for developing systems and addressing the challenges faced. This investment is urgently needed if the EVAP 2020 goals are to be achieved. The total estimated cost of developing a technical support package for the Region is USD 250 000 per year extending over a 3 to 4 year period. The WHO Regional Office is proposing to conduct more detailed analysis to define size and scope of the potential problem, defining differences within the MICs to provide guidance to development of a priority list of countries and problems and move to

development of a strategy to support the MICs within the Region. The strategy would be an adaptation of the global strategy in line with the EVAP objectives strategies.

Discussion

ETAGE recognizes the case being made for development of a Regional MIC strategy and endorses the broad scope of work proposed by the Secretariat and encourages further work in this area to provide strategic guidance to MICs in strengthening immunization programmes, including a systematic assessment of needs. ETAGE recognizes that the processes of seeking and providing such information by Member States may itself promote awareness and improvement in immunization services over time.

Challenges are clearly different in different countries, and the focus should be on developing national action plans to address the specific problems in each country, including problems encountered at sub-national level. Mobilizing resources for immunization has been a long-term challenge in the Region, and the breakdown of funding required, either for procurement of vaccines or system strengthening for vaccine delivery is not currently clear for several Member States.

False contraindications and vaccine safety concerns

There are concerns that false contraindications to vaccination and doubts over vaccine safety among HCWs and parents are resulting in decreased vaccine coverage. This is often based on outdated, non-evidence-based knowledge over potential contraindications and fear of causing harm to infants with chronic diseases and conditions, often strengthened though the belief that vaccines are only safe for “healthy” infants. There is also concern among HCWs that the vaccine provider will be blamed or prosecuted in cases of serious adverse events following immunization (AEFI), and a general scepticism over the public health value of vaccines against diseases that are not routinely diagnosed in the country or seen to be a major problem.

WHO has been providing training for health care professionals on vaccine safety and contraindications with the aim of preparing confident key trainers and provide training materials to educate frontline medical workers. The training covers key areas including monitoring vaccines safety during the pre-licensing and post-licensing periods, WHO recommendations on contraindications and the supporting evidence base, the essentials of AEFI classification and causality assessment, and the public health impact of routine and new vaccines. National training of trainers has now been conducted in Armenia, Azerbaijan and Republic of Moldova, and subsequent

training for frontline HCWs has taken place in Republic of Moldova. Regional training of trainers has taken place for representatives from Albania, Bosnia and Herzegovina, Croatia, Estonia, Georgia, Latvia, and the former Yugoslav Republic of Macedonia. Additional national training is planned for Georgia in December 2016 and sub-regional training for Armenia and Republic of Moldova in the 4th quarter of 2016. WHO intends to publish the training materials and incorporate the training materials into pre-service medical training.

Together with the European Society of Paediatric Infectious Diseases (ESPID), WHO has developed an online course for HCWs called Wiser Immunisers that provides an interactive, clinical approach focused on vaccine-preventable diseases, the vaccines in use and on strategies for communicating with patients and parents. The course is intended for all HCWs involved in programme activities at any level and includes videos, tutoring and links to downloadable resources. The course, which is hosted on the ESPID website, was pilot tested on 41 students from the 2015 Summer School on Vaccinology held in Antwerp, and the first cohort of students included 89 participants starting in March 2016. Registration of the second cohort is ongoing and the course is due to begin on 17 October 2016. WHO is now considering the best ways to move forward with the training course, including provision of materials in languages other than English.

WHO is also planning to hold an AEFI training workshop with the aim of increasing the capacity of national immunization programmes to detect, assess and respond to AEFIs. The participants will include three representatives each from 18 middle-to low-income countries who will each be given a pre-course self-assessment. Key areas covered include pharmacovigilance and AEFI surveillance, quality management approaches, incident and crisis management, and communications. The course will include group-based development of action plans.

Discussion

ETAGE endorses the work being carried out by WHO in this field and encourages further development and extension. There is a need for both proactive and reactive training provision for HCWs in vaccine safety, together with training on how and when to anticipate problems. It is also clear that more current information on the reasons for vaccine hesitancy and refusal, as well as reasons for failure of HCWs to provide vaccines, is required and further actions should be undertaken to gather this data. The effective distribution of information on reporting vaccine adverse events and contraindications being carried out by WHO is a significant contribution to addressing the challenge of lack of confidence in vaccination.

Measles and rubella verification

The European Regional Verification Commission for Measles and Rubella Elimination (RVC) concluded that at the of end 2014, there were 32 Member States in which endemic measles transmission had been interrupted and 32 Member States in which endemic rubella transmission had been interrupted. Surveillance sensitivity in many countries remained a major concern, however, and there were specific concerns regarding countries which had not submitted annual reports, which submitted incomplete data, or which did not have a National Verification Committee (NVC).

The WHO VPI team has proposed strengthening support provided to the elimination effort through focusing resources on remaining endemic countries. In order to more effectively target resources in the Regional Office on the remaining endemic countries, members of the VPI ADC team will be nominated as focal points to act as technical coordinators on measles and rubella elimination and verification activities for specific countries. The ADC team has also raised the potential for exploring a modified approach for verification of measles and rubella elimination in the smaller countries Monaco and San Marino, in the absence of an NVC. To increase collaboration and coordination between NVCs there will be a meeting of representatives from the German-speaking countries in January 2017. To make the outcome of the RVC meetings more timely and relevant to the meetings of other WHO advisory and oversight bodies, including ETAGE, the RCC, Immunization Programme Managers' meeting and the WHO European Regional Committee meeting, the Secretariat proposed that the date of the RVC meeting for 2017 be advanced from October to June.

The ADC team also proposed streamlining the annual reporting process for countries that have already demonstrated interruption of endemic measles and rubella transmission for at least 3 consecutive years and have been judged to have attained elimination status.

The Measles & Rubella Initiative (MRI) midterm review recognized the progress that has been made between 2012 and 2015, but noted the continuing challenge of lack of ownership of the elimination effort by many Member States and the apparent frailty of global political will to meet the elimination targets. The review recommended a focussing of efforts on achieving high-quality case-based, laboratory-supported surveillance for measles and rubella, and implementing effective CRS surveillance in all countries. The review underscored the need to strengthen immunization systems and implement a 2-dose vaccination strategy in all countries to increase population immunity. Findings of the midterm review will be used to define and develop the way forward for the MRI.

Discussion

ETAGE endorses the approaches being proposed to strengthen measles and rubella surveillance and streamline the verification process. ETAGE encourages further consideration be given to refinement of the annual cycle of reporting to improve the timeliness and programmatic impact of the measles and rubella elimination status reports. ETAGE acknowledges the progress made using the country-based approach to elimination, recognizes the very real challenges in the Region with large unimmunized age cohorts, and urges greater programmatic focus on addressing challenges associated with remaining measles- and rubella-endemic foci.

Diphtheria and pertussis

While there are no earmarked funds for specific activities on diphtheria and pertussis the WHO Regional Office conducts activities on these two diseases as part of the general programme of work on immunization. Available evidence suggests that Regional coverage with the third dose of DTP dropped in 2014 and 2015 from above 95% in 2013 to approximately 93% in 2015. Of particular concern are declines reported for Bosnia and Herzegovina, Republic of Moldova, Romania, San Marino and the former Yugoslav Republic of Macedonia.

Diphtheria remains a rare disease in the Region with 58 cases reported in 2015 (an increase on the 35 cases reported in 2014). Fifteen Member States reported cases in 2015 with very few fatal toxigenic cases being reported. There are, however, Regional challenges to maintaining diphtheria control. These include the challenge of waning immunity: in countries with high immunization coverage and where natural boosting is low, with a large proportion of the adult population gradually becoming susceptible to diphtheria as a result of waning immunity. The extent of routine re-vaccination of adults against diphtheria (and tetanus) every 10 years that may be necessary to sustain immunity is not known. In addition, laboratory diagnostic capabilities for diphtheria testing have diminished in many countries and need to be strengthened, and there is a need for a rapid test for the detection of diphtheria toxoid. It has also become apparent that in recent years diphtheria anti-toxin (DAT) availability has become limited and sourcing and maintaining adequate stockpiles of DAT for emergency use continues to be a problem in many countries.

In contrast to diphtheria, thousands of cases of pertussis continue to be reported in the Region each year, and resurgences of pertussis continue to be reported, even in countries with high vaccination coverage. In some instances resurgences have been associated with an increase in reported infant deaths. As global demand for acellular pertussis-containing (aP) vaccines has increased, with more

and more countries switching from whole-cell pertussis (wP) products to aP products, a global shortage of aP vaccines has developed. There are currently shortages of pentavalent, hexavalent and diphtheria, tetanus, and acellular pertussis (DTaP) vaccines. As with diphtheria, an important factor in disease transmission is waning immunity among adults. The shorter duration of protection and probably lower impact on infection and transmission conferred by acellular pertussis-containing vaccine compared with the wP-containing vaccines are also likely to play a role. The extent of re-vaccination of adults against pertussis that may be necessary to sustain immunity is not known.

In addition to broad activities of data collection and advocating for improved vaccine coverage and closure of immunity gaps, the WHO Regional Office has been active in dissemination of information on diphtheria and pertussis through publication of articles and reports. The VPI team has also established collaboration with the WHO Collaborating Centre for Diphtheria and Streptococcal Infections to extend a survey on the laboratory diagnostic capacity of diphtheria to countries in the Region beyond the EU/EEA countries. The survey initially exclusively involved EU/EEA countries. In 2014, VPI communicated with six countries (Denmark, Finland, Israel, Norway, Portugal and Sweden) that had high vaccination coverage and high-quality data on pertussis. Detailed information on the epidemiology of pertussis, laboratory diagnosis of cases and pertussis immunization programme including type of vaccine used, was compiled for each country and presented to the SAGE working group.

Discussion

Although diphtheria and pertussis control are core components of the work programme of VPI, ETAGE is concerned that specific activities within the programme remain under-resourced and under-funded. ETAGE recognizes the serious risks presented by diphtheria and pertussis in the Region and the consequent need for development and maintenance of appropriate disease surveillance, including strengthened laboratory capacity. More information on the current status of diphtheria and pertussis epidemiology and challenges faced in the Region would be helpful to ETAGE for considering future actions. A strategic plan of action to address recognized challenges should be developed. The action plan should outline future roles of WHO and partner agencies in supporting Member States to prevent morbidity and mortality from diphtheria and pertussis.

ETAGE is concerned over the global shortage of DAT and requests the Secretariat to provide more information on the status and availability of stocks of therapeutic doses of diphtheria antitoxin available to Member States in the Region.

Information sessions

- **EVAP**

EVAP was endorsed by the RC in September 2014 and launched in 2015. An implementation monitoring and evaluation framework has been established, with indicators in the process of being finalized, and work is underway establishing a baseline through collection and validation of data. In 2017 the Secretariat will provide feedback to Member States on progress made, and a mid-term report on implementation will be prepared for 2018. This will require a significant amount of work on the part of the Secretariat, starting with an initial annual progress report for 2015 and 2016. It would be helpful to the Secretariat if ETAGE could designate a current member to act as focal point for EVAP and participate in EVAP-associated work during 2017.

Discussion

ETAGE recognizes this as an important area for ETAGE participation, and further discussion is required within the Group to determine specific roles and responsibilities. The focal point should probably be the chair of ETAGE, with other members taking responsibility for specific components of the plan.

- **The Ukraine cVDPV outbreak, response and 6- and 12-month report outcomes**

In August 2015, highly divergent vaccine-derived polioviruses type 1 (VDPV1) were isolated from two acute flaccid paralysis (AFP) cases in Ukraine and the Regional Office confirmed that these cases represented an outbreak. Outbreak response activities were initiated within 48 hours and included 3 rounds of supplementary immunization, with the third round being extended to children aged up to 10 years to improve population immunity. Reported administrative coverage achieved, however, was not high.

In December 2015, the 3-month Outbreak Response Assessment (OBRA) concluded that "the polio outbreak response in Ukraine has been insufficient to meet internationally agreed requirements for a polio outbreak." In March 2016 a post-polio outbreak response survey was conducted to assess the national coverage with 3 doses of polio vaccine and concluded that coverage achieved was 48.4%. In April 2016 the 6-month OBRA considered the transmission of cVDPV-1 in Ukraine had most likely stopped but the assessment team remained concerned that significant programmatic gaps in immunization and surveillance put Ukraine at high risk for the possible emergence and circulation of another VDPV. In June 2016 the Regional Commission for Certification of Polio Eradication (RCC)

assessed Ukraine as high risk for polio transmission and requested a progress report and review at 12 months after the last reported case. In August 2016 the International Health Regulations Emergency Committee (IHR EC) removed Ukraine from the list of infected countries and added it to the list of at-risk countries.

The RCC will hold an ad-hoc meeting in October 2016 to review available surveillance data and immunization coverage in Ukraine since the 6-month OBRA. In November 2016 a serosurvey for polio, measles, rubella, hepatitis B, diphtheria and pertussis will be conducted to assess population immunity and identify gaps in the programme. In August 2017 the IHR EC 24-month report will be due to consider removing Ukraine from the "at-risk country" list.

Discussion

ETAGE appreciates the clear account given of the outbreak and following events. Ukraine remains of great concern as there are clearly challenges to the immunization programme as a whole. The situation in Ukraine presents a risk of outbreak, not only with polio but also with measles and rubella and diphtheria. There is also a broader risk to other countries in the Region with weak immunization systems, particularly Romania and Bosnia and Herzegovina. There may be benefit to be gained from individual ETAGE members gaining first-hand experience of the challenges faced in these countries.

- **Support for reviving routine immunization and conducting campaigns in northern Syria from the WHO Office in Gaziantep, Turkey**

Technical support for immunization activities in northern Syria has been provided by the WHO Office in Gaziantep, Turkey following the polio outbreak in Syria in 2013. This has been achieved through collaboration between the WHO regional offices for Europe and the Eastern Mediterranean. The European Polio Laboratory Network has also been supporting AFP surveillance in northern Syria with samples being tested in the National Polio Laboratory in Ankara, Turkey and the Regional Reference Laboratory in the Netherlands.

With the support of Turkey, a programme of accelerated implementation of routine immunization (AIRI) has been conducted, targeting approximately 1.4 million children less than 5 years of age in northern Syria, approximately 770 000 of whom with variable accessibility at any one time. Due to limited accessibility, activities have taken place over several months. Independent monitoring of immunization activities has been provided through the Qatar Red Crescent Society (QRCS).

Discussion

ETAGE strongly endorses the inter-regional work being conducted under very challenging circumstances and is encouraged by the level of success being achieved. ETAGE recognizes that the Turkish government has also established a strong programme for immunization of refugees fleeing Syria into Turkey, particularly children under 5 years of age.

- **Tailoring Immunization Programmes (TIP)**

The TIP package was developed in 2013 as a diagnostic toolkit to measure barriers to immunization in specific communities. The package has been modified to monitor attitudes to antimicrobial resistance, and extended for use in other WHO Regions. The project has been further extended to deliver materials for countries to use unaided. An evaluation of the entire project is now underway, and an evaluation report will be provided to ETAGE at its next meeting.

Discussion

ETAGE remains fully supportive of the TIP approach and looks forward to receiving the evaluation report.

- **Vaccine price transparency WHO support to Member States**

In 2015, 30 Member States in the Region shared vaccine price information through the WHO Vaccine Price Transparency project. Data collected over the three years the project has been running suggests that the price paid for measles/mumps/rubella (MMR) and hepatitis B vaccines has tended to decline slightly since 2012. Similar data for HPV and pneumococcal vaccine (PCV) suggest that highly divergent prices in 2012 have tended to consolidate towards more comparable prices in 2015. There is little evidence that the price paid for multi-antigen vaccines has increased over the three years. A challenge the project has faced is reluctance of Member States to share pricing information over concerns that sharing reduces the capacity of individual countries to negotiate a more advantageous price. It has become apparent that there is also limited expertise in some Member States within the Region to analyse pricing data and produce appropriate reports.

Discussion

This area is subject to powerful influences, primarily of a commercial nature, and there are concerns that pricing information should not be made available to all but restricted to those Member States that provide information on prices they are paying.

- **Intersectoral project - developing, testing and evaluating an education package on vaccines and immunization**

Vaccine hesitancy and the reasons behind decisions to delay or refuse vaccination are highly variable and context specific. The school setting offers a unique opportunity to reach important target groups directly with nuanced and comprehensible information about immunization. Health promotion messages can be reinforced throughout the most influential stages of children's lives, enabling them to develop lifelong healthy patterns. The intersectoral project aims to promote positive attitudes towards vaccination and help children and school staff, families and communities develop informed decision-making skills. Exploratory research has already been conducted, including desk research and expert consultation. The next steps will include selection of a project developer, development of the detailed concept and products and pilot testing in selected Member States.

Discussion

This project is at an early stage but shows great potential. There is, however, great heterogeneity in the educational systems present within the Region and the project will need to accommodate this heterogeneity while providing a focused approach. It is possible that the project could be placed within the progressive curricula for 'healthy living' approach to education. It may also be possible to link this package with records of receipt of vaccines.

- **IBD and rotavirus surveillance networks**

Seven Member States in the Region participate in the rotavirus sentinel surveillance network and there are plans to expand the surveillance platform to detect additional enteric pathogens using a multiplex real-time PCR methodology. Six Member States in the Region participate in the IDB sentinel surveillance network and a major achievement of this project has been the strengthening of laboratory capacity at hospital and national laboratory levels. In addition, for several countries the capacity for diagnostic testing using PCR has been developed or strengthened. Analysis of available data is underway to determine if there is a case for stopping use of rapid assays for IBD detection in favour of PCR.

Activities are underway to establish and develop collaborative links between the IDB and rotavirus surveillance networks with other infectious disease surveillance networks in the Region, particularly those coordinated through ECDC. The IDB and rotavirus surveillance networks are currently funded entirely through GAVI, but as several network members are graduating from GAVI support there are concerns over the sustainability of surveillance activities. A sustainability strategy for regional infectious diseases surveillance networks is being developed.

Discussion

A considerable body of evidence now exists on rotavirus vaccine effectiveness in vaccine recipients, but there remains great uncertainty on how high a level of vaccine coverage is required to produce indirect effects of immunization. It is possible that the rotavirus surveillance network can provide additional information to clarify the population coverage requirements to achieve community protection.

In terms of developing sustainability of these networks it may be possible to link one or both with the polio legacy activities and establish closer ties with the polio laboratory network.

Conclusions and recommendations

Conclusions

ETAGE greatly appreciates the continued personal attention and support for immunization given by the WHO Regional Director, is encouraged by the continuing high levels of achievement attained by VPI in the face of considerable challenges and appreciates the technical expertise and commitment being provided to address these challenges.

ETAGE greatly appreciates the participation of the chair of SAGE in the meeting and encourages SAGE members to actively participate in meetings of other Regional Technical Advisory Groups of Experts on immunization.

There is a broad programmatic requirement to engage ETAGE more fully in high-level advocacy for immunization and for the Secretariat to draw more extensively on the wealth of technical expertise provided by the current ETAGE. VPI is strongly encouraged to engage ETAGE members, dependent on availability and areas of expertise, more fully in delivering aspects of its programme of work.

ETAGE accepts the clear evidence presented that in comparison with higher- and lower-income (GAVI-eligible) countries in the European Region middle-income countries (MICs) face significant additional challenges to effective vaccine delivery. It is also evident, however, that unique circumstances (including history, culture and political commitment) exist in each country which also influence the functioning of their immunization programmes. ETAGE encourages further work in this area to provide strategic guidance to MICs in strengthening immunization programmes, including a systematic assessment of needs. ETAGE recognizes that the process of seeking and providing such information by Member States may itself promote awareness and improvement in immunization services over time.

ETAGE applauds the continuing ground-breaking work and achievements being made in the field of immunization communications and education. The development of both pro-active and reactive trainer and HCW education, together with the effective distribution of information on reporting vaccine adverse events and contraindications, are significant contributions to addressing the challenge of lack of confidence in vaccination. ETAGE encourages further development of these activities and continued evaluation of their impact and effectiveness.

ETAGE is reassured to be informed of the progress made in halting poliovirus transmission associated with the cVDPV outbreak in Ukraine but notes that the outbreak response evaluation exercise has revealed causes for ongoing concern with regard to immunization services in Ukraine and in some other parts of the Region. ETAGE encourages continued engagement with authorities responsible for immunization services in Ukraine, which ETAGE members would be pleased to support as appropriate.

ETAGE notes with concern the continuing global supply problems with both IPV and aP vaccines and the apparent lack of a clear supply mechanism for diphtheria antitoxin. In this context Member States should be advised and supported in formulating strategies to address these challenges.

ETAGE notes the progress made towards providing vaccine pricing transparency information. ETAGE supports continuation of this work but urges careful consideration of how market forces may respond to this initiative, particularly with regard to the impact on future prices offered to reporting countries.

With regard to measles and rubella surveillance and verification, ETAGE encourages further consideration be given to refinement of the annual cycle of reporting to improve the timeliness and programmatic impact of the measles and rubella elimination status reports. ETAGE acknowledges

the progress made using the country-based approach to elimination, recognizes the very real challenges in the Region with large unimmunized age cohorts, and urges greater programmatic focus on addressing challenges associated with remaining measles- and rubella-endemic foci.

ETAGE recognizes and applauds the extraordinary efforts made by the Turkish government and government agencies, the WHO Country Office in Turkey, the WHO Office in Gaziantep and the VPI team in supporting efforts to immunize Syrian children in both Syria and in Turkey under extremely difficult conditions. ETAGE also applauds the establishment of highly effective inter-regional collaboration with the WHO Eastern Mediterranean Regional Office.

ETAGE remains committed to supporting EVAP implementation and endorses the establishment of an EVAP working group to develop and support preparation of annual and interim reports over the coming 5 years. ETAGE members would be pleased to actively support the working group, as appropriate, and engage with the team in the monitoring and evaluation phase through the coming year.

ETAGE recognizes the serious risks presented by diphtheria and pertussis in the Region, the consequent need for development and maintenance of surveillance and re-evaluation of immunization schedules optimal to local epidemiology and available vaccine supplies.

Recommendations

1. The Secretariat is urged to develop a concept note on the proposed technical package in support of strengthening immunization services in MICs, outlining the challenges and strategic approaches to addressing them, together with an outline plan of action and timeline. This concept note should be available for review and discussion by ETAGE in January 2017.
2. Recognizing the regional achievements in measles and rubella elimination and the challenges presented in remaining endemic countries, the Secretariat is requested to provide an outline plan of action for focussing regional resources specifically on strengthening elimination activities in remaining endemic countries and epidemiological areas. The outline plan of action should be made available to ETAGE for review and discussion by the end of the first quarter 2017.
3. Recognizing concerns over the global shortage of diphtheria antitoxin, the Secretariat is requested to conduct a thorough review of the status and availability of stocks of

therapeutic doses of diphtheria antitoxin available to Member States in the Region. The results of the review should be made available to ETAGE by the end of the first quarter 2017.

4. Given the programmatic importance of EVAP, the Secretariat should ensure that all documents including assessments, progress reviews and reports on EVAP implementation, evaluation and monitoring are provided to ETAGE for review, comment and endorsement prior to distribution.

5. Recognizing that diphtheria and pertussis control are core components of the work programme of VPI, but that specific activities within the programme remain under-resourced, the Secretariat is requested to develop a current status report on diphtheria and pertussis epidemiology and challenges in the Region. A strategic plan of action to address recognized challenges should be developed and presented to ETAGE for review during the 2017 meeting. The action plan should outline future roles of WHO and partner agencies in supporting Member States to prevent morbidity and mortality from diphtheria and pertussis.

Participants

ETAGE
Prof Adam Finn (Chair)
Professor of Paediatrics
University of Bristol and Honorary Consultant Paediatrician, Bristol Royal Hospital for Children
United Kingdom of Great Britain and Northern Ireland

Prof F. Nur Baran Aksakal
Head
Department of Public Health
Faculty of Medicine
Gazi University
Turkey

Dr Cornelia Betsch
Scientific Manager
CEREB - Center of Empirical Research
in Economics and Behavioral Sciences
University of Erfurt
Germany

Dr Vladimir Chulanov
Head
Clinical Diagnostics and Research Center
Reference Center for Viral Hepatitis
Central Research Institute of Epidemiology
Russian Federation

Professor Alenka Kraigher
Head of Communicable Diseases Center
National Institute of Public Health Slovenia
Slovenia

Prof Christian Perronne
President
Haut Conseil de la Santé Publique
Hopital Raymond Poincaré
France

Professor Roman Prymula
University Hospital
Czech Republic

Professor Pierre Van Damme
University of Antwerp
WHO Collaborating Centre
Belgium

National Immunization Technical Advisory Group (NITAG)
Albania
Dr Silvia Bino
Dr Klodian Rjepaj

Armenia
Dr Anna Chobanyan
Dr Gayane Sahakyan

Azerbaijan
Professor Nasib Guliyev
Dr Sheyda Shikhaliyeva

Belarus
Dr Veranika Shymanovich
Professor Vladimir Zhernosek

Georgia
Dr Lia Jabidze
Dr Teona Kashibadze

Kazakhstan
Mrs Karlygash Abdizhabbarova
Mrs Lyazzat Yeraliyeva

Kyrgyzstan
Mr Tilek Buteshov
Mrs Damirakhan Chynyeva

Republic of Moldova
Dr Anatol Melnic
Mr Tiberiu Holban

Tajikistan
Dr Zafarjon Azizov
Dr Solohidin Miraliev

Uzbekistan
Dr Bahrom Almatov
Dr Bekturdi Normetov

Temporary advisers
Dr Antonietta Filia
Infectious Diseases Epidemiology Unit
Istituto Superiore di Sanità
Italy

Dr Ole Wichmann
Head

Immunization Unit
Germany

Strategic Advisory Group of Experts (SAGE) on immunization
Prof Jon Abramson
Chair

European Regional Verification Commission for measles and rubella elimination (RVC)
Dr Günter M. Pfaff
Chair

Partners
Centers for Disease Control and Prevention (CDC)
Dr Robert Linkins, Chief, Accelerated Disease Control and Vaccine Preventable Disease Surveillance Branch

European Centre for Disease Prevention and Control (ECDC)
Dr Lucia Pastore Celentano, Senior Expert

SIVAC Initiative
Dr Antoine Durupt, Program Officer

Vaccine-preventable Diseases and Immunization Programme, WHO Regional Office for Europe
Mr Robb Butler, Programme Manager
Dr Niyazi Cakmak, Team Lead
Dr Patrick O'Connor, Team Lead
Dr Vusala Allahverdiyeva
Ms Natasha Allen Grue
Dr Myriam Ben Mamou
Dr Oleg Benes
Ms Danni Daniels
Dr Siddartha Datta
Ms Susana Fernadez Tordrup
Ms Catharina de Kat
Dr Eugene Gavrilin
Dr Shahin Huseynov
Dr Dragan Jankovic
Dr Liudmila Mosina
Dr Mark Muscat
Ms Siff Malue Nielsen
Ms Dorina Pirgari
Dr Dovile Videbaek

Rapporteur
Dr Raymond Sanders

Interpreters
Ms Olga Aleksinskaya
Mr Georgy Pignasty

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: contact@euro.who.int // Website: www.euro.who.int