

Meeting Report

24th Meeting of the Technical Advisory Group on Immunization and Vaccine-Preventable Diseases



9–12 June 2015
Manila, Philippines



WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC

MEETING REPORT

24th MEETING OF THE TECHNICAL ADVISORY GROUP ON IMMUNIZATION AND
VACCINE-PREVENTABLE DISEASES

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NOTE

The views expressed in this report are those of the participants of the 24th Meeting of the Technical Advisory Group on Immunization and Vaccine-Preventable Diseases in the Western Pacific Region and do not necessarily reflect the policies of the conveners.

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This report has been prepared by the World Health Organization Regional Office for the Western Pacific for Member States in the Region and for those who participated in the 24th Meeting of the Technical Advisory Group in Immunization and Vaccine-Preventable Diseases in the Western Pacific Region in Manila, Philippines from 9 to 12 June 2015.

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SUMMARY

The Technical Advisory Group (TAG) on Immunization and Vaccine-preventable Diseases in the Western Pacific Region was established in 1991 with the following terms of reference:

- 1) to recommend, in coordination with the Regional Certification Commission, technical issues regarding sustaining the poliomyelitis-free status of the Western Pacific Region and global certification of poliomyelitis eradication;
- 2) to review the epidemiological situation in the Western Pacific Region and recommend appropriate goals, targets, strategies and surveillance indicators, and monitor progress towards the reduction of vaccine-preventable diseases, including the control and elimination of measles and maternal and neonatal tetanus;
- 3) to recommend suitable strategies and processes for the introduction and integration of new vaccines into the Expanded Programme on Immunization (EPI), including methods of monitoring progress for the diseases concerned;
- 4) to recommend suitable strategies for sustaining high-quality national immunization programmes in the Western Pacific Region, including management, vaccine supply, cold chain and the safety of injections;
- 5) to strengthen, in coordination with the Inter-agency Coordinating Committee, the active involvement of all institutions, national and international organizations, and political leaders concerned with immunization and vaccine-preventable disease control efforts in sustainable programme activities, including participation at the meetings of the Technical Advisory Group on EPI and Poliomyelitis Eradication and Inter-agency Coordination Committee meeting; and
- 6) to advise the WHO Regional Director for the Western Pacific Region on the above points.

Since 1991, TAG has met annually to review the progress of the immunization programme in the Western Pacific Region and provide guidance on establishing and achieving immunization goals. The 24th TAG meeting was held in Manila, Philippines, from 8 to 12 June 2015. The meeting was attended by five TAG members, five temporary advisers, 23 participants from 15 countries and areas, 27 representatives from partner organizations, and WHO staff from headquarters, the Regional Office for the Western Pacific and country offices.

After the *Global Vaccine Action Plan 2011–2020* was approved by the World Health Assembly (WHA) in 2012, the Western Pacific Region developed a Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific. In 2014, the sixty-fifth session of the Regional Committee for the Western Pacific endorsed the Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific in resolution WPR/RC65.R5. The 24th TAG focused on reviewing progress towards the implementation of the regional framework. Topics included achieving targets and programme indicators for the polio endgame; measles, rubella, and maternal and neonatal tetanus elimination; and hepatitis B control. Discussions were also held on the acceleration of Japanese encephalitis (JE) control in the Western Pacific Region, introduction of affordable new vaccines, immunization supply chain systems, and the use of quality vaccines. The meeting also covered work towards the new regional immunization coverage goals that aim to ensure equity in immunization services to reach unreached target populations and improve data quality.

1. INTRODUCTION

1.1 Meeting organization

The meeting was attended by five Technical Advisory Group (TAG) members, five temporary advisers, 23 participants from 13 countries and areas, 40 representatives from partner organizations, and WHO staff from headquarters, the Regional Office for the Western Pacific and country offices. The timetable of the meeting is provided in Annex 1. The list of participants is included in Annex 2.

1.2 Meeting objectives

The objectives of the meeting were:

- 1) to review progress, identify critical issues and discuss key actions to achieve regional immunization goals and strategic objectives as specified in the *Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific*; and
- 2) to identify opportunities to enhance collaboration and coordination among immunization partners to support countries in implementing the *Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific*.

2. PROCEEDINGS

2.1 Opening session

Dr Shin Young-soo, WHO Regional Director for the Western Pacific, welcomed TAG members and participants to the 24th TAG meeting in the Western Pacific Region. He expressed immense pride with the accomplishments Member States have made since the last meeting.

He acknowledged that Member States have adopted the *Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific* and summarized recent immunization achievements in the Western Pacific Region. He also noted the substantial progress towards implementing the *Polio Eradication and Endgame Strategic Plan 2013–2018* and expressed confidence with the target to introduce inactivated polio vaccine (IPV) by the end of 2015 and to switch to bivalent oral polio vaccine by April 2016. He further noted the progress made towards measles elimination with three more countries having achieved the interruption of endemic measles virus transmission for at least 36 months, and also noted the progress made towards the target of less than 1% hepatitis B chronic infection prevalence among 5-year-old children by 2017, as well as the progress in maternal and neonatal tetanus elimination in countries such as Cambodia and the Philippines, and the successful support of continuously expanding high-quality laboratory networks.

The Regional Director also noted progress towards evidence-based vaccine introduction with Japanese Encephalitis (JE) vaccine, pneumococcal conjugate vaccine (PCV) and rotavirus vaccine, as well as the human papillomavirus (HPV) vaccination demonstration project in the Western Pacific Region. He also acknowledged the Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific for providing assistance to vaccine procuring countries to build sustainable regulatory systems.

The Regional Director concluded by thanking participants for making the Expanded Programme on Immunization a vibrant and innovative force in the Western Pacific Region. He emphasized working collaboratively to bring the benefits of strong national immunization programmes to the people in the Western Pacific Region – no matter where they live or how limited their resources.

2.2 Global update on Global Vaccine Action Plan

Dr Thomas Cherian discussed progress on implementation of the *Global Vaccine Action Plan 2011–2020* (GVAP), which is monitored annually by the WHO Strategic Advisory Group of Experts (SAGE) for immunization. The assessment of progress is reported annually to the WHO governing bodies. The 2014 SAGE report, which was presented to the WHO governing bodies in 2015, noted that progress against five of the six targets for 2014 and 2015 was not on track. WHO Member States highlighted a number of issues related to GVAP, including: (1) the affordability of new vaccines; (2) vaccine supply shortages and stock-outs; (3) the need to create greater awareness of the value of vaccines in order to mitigate hesitancy and refusals; (4) improvement in the quality and use of data; and (5) guidance for sustaining immunization services during periods of conflicts and crisis. Following this discussion, a resolution tabled by Libya calling for better access to sustained supply of vaccines at affordable prices was adopted by the World Health Assembly.

National immunization programmes in most countries have evolved and become increasingly complex, but the health and immunization systems in many countries remain fragile. Raising the immunization coverage beyond 80% requires new strategies to identify and vaccinate children who are being repeatedly missed by the programme. Those strategies also must include an assessment of missed opportunities and next steps to address the problems. Solutions are available to address many of the challenges. WHO and the United Nations Children's Fund (UNICEF) have developed guidance to address the challenges. The new Gavi strategic plan provides opportunities to eligible countries to address the challenges they face.

2.3 Overview on Expanded Programme on Immunization in the Western Pacific Region

Dr Sergey Diorditsa presented an overview of the Region's progress towards achieving regional EPI objectives. One accomplishment was the development of the *Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific*. The framework was endorsed by the sixty-fifth session of the Regional Committee for the Western Pacific in October 2014.

The framework consolidates eight regional and global goals: 1) sustaining polio-free status; 2) maternal and neonatal tetanus elimination; 3) measles elimination; 4) rubella elimination; 5) accelerated control of hepatitis B; 6) accelerated control of JE; 7) meeting regional vaccination targets (> 95%); and 8) introduction of new vaccines.

It was noted that progress of GVAP is slow. Only targets in the area of introduction of new vaccines were met globally. The Western Pacific Region also progressed well in this area. All low- and middle-income countries in the Region are likely to meet the target of introducing at least one new vaccine by 2020, with a baseline year of 2010.

Introduction of IPV is the next challenge for 17 countries in the Region. It should be completed by the end of this year and should then be followed by the switch from trivalent oral polio vaccine to bivalent oral polio vaccine (tOPV to bOPV) vaccine in April 2016.

Seven countries and areas in the Region have been already verified as having achieved the interruption for more than 36 months of endemic measles transmission. Several Member States are approaching rubella elimination or setting the goal to achieve it by 2020.

As of February 2015, 12 countries and areas have been verified as having reached the goal of less than 1% HBsAg prevalence among 5-year-old children. However, the persistent low birth-dose vaccination coverage in six countries makes it unlikely that the goal will be achieved in all countries and areas by 2017.

The Region also progressed towards the reaching the regional vaccination targets. However, the equity issue remains a concern. The WHO Regional Office for the Western Pacific has paid continuing and heightened attention to building country capacity to ensure the use of vaccines of assured quality in national immunization programmes.

2.4 Update from Strategic Advisory Group of Experts

Associate Professor Nicola Turner reported that SAGE recognized that GVAP has been adopted by all WHO regions. However, there is an urgent need for adequate investments and a focus to improve routine immunization coverage, which has been almost static globally since 2009.

In order to prepare for polio eradication, all countries should plan for April 2016 as the designated date for OPV2 withdrawal. SAGE reviewed JE vaccines and concluded that vaccination should be extended to all areas where JE is a public health priority. SAGE encouraged all countries to incorporate plans that fit their settings to measure and address vaccine hesitancy concerns.

Administration of multiple injections during the same visit are safe, well tolerated and are to be encouraged. Pain or distress from vaccinations is common and not addressing this issue can lead to vaccine hesitancy. SAGE published mitigation strategies relevant to all countries and encourages these to be included as part of best practices. The majority of poor people in the world are now in middle-income countries and many do not benefit from Gavi support. SAGE calls on partners to support implementation of a new coordinated strategy and on countries to take advantage of the proposed solutions from a menu of options.

SAGE also has encouraged WHO to promote more research to generate data for maternal immunization as a part of routine antenatal care in low-resource settings. SAGE reviewed the evidence both supporting and opposing different primary schedules for diphtheria, tetanus, and pertussis (DTP) vaccines in terms of pertussis control. There is no compelling evidence to shift from many current schedules, and any country's proposed change should consider its current epidemiological context and the impact on pertussis. SAGE meetings and conclusions are published in *The Weekly Epidemiological Record* (WER), a WHO publication.

2.5 Measles and rubella elimination

2.5.1 Global update

Dr Cherian reported that all the WHO regions have established measles elimination goals, and three regions have established rubella elimination goals. In addition, there are interim global targets for 2015, which are: (1) to achieve coverage with the first dose of measles-containing vaccines (MCV1) $\geq 90\%$ at the national level and $\geq 80\%$ in all districts; and (2) to reduce measles incidence to less than 5 cases per one million population and to reduce measles mortality by 95% compared with 2000.

Other than the Region of the Americas, none of the other regions are on track to achieve the global 2015 targets or the regional elimination goals. Coverage with MCV1 has remained stagnant for the past five years and the coverage with MCV2 is inadequate. Several countries have conducted supplementary immunization activities and taking steps to verify the coverage have been achieved.

While most countries are reporting measles data, the quality of surveillance is heterogeneous and lacks sensitivity in many countries. Nevertheless, the available data show declining trends in the incidence of disease. Large outbreaks have been reported from a number of countries in 2014. Analysis of the data showing varying age distribution patterns with a bimodal pattern of disease, mainly affecting infants, adolescents and young adults in communities that have achieved high routine measles vaccination rates. It has been estimated measles deaths have been reduced by 75% compared to 2000. Rubella vaccine was introduced in 137 countries by 2013, with introduction planned in 11 additional countries in 2014 and 2015. Most countries are now reporting rubella cases, though the quality of surveillance remains suboptimal in many countries. The challenges faced in different

regions vary, depending on the level of control and the coverage with routine measles vaccination. In light of the evolving epidemiology of measles in some regions, a number of policy considerations are under review, including administration of measles vaccine to infants younger than 8 months, vaccination of adolescents and adults, and the MCV 1 coverage threshold of 80% as the precondition to introducing a routine second dose of MCV.

2.5.2 Regional overview

Dr Yoshihiro Takashima summarized progress and achievements in implementation of the strategies for elimination of measles, emerging issues to be addressed for further progress, and actions to be taken for accelerating progress towards measles elimination in the Western Pacific Region.

In the Region, the recommended immunization strategies, i.e. achieving and maintaining >95% vaccination coverage with MCV-1 and MCV-2 and through supplementary immunization activities, have been successfully carried out.¹ The surveillance activities required for measles elimination have continued to improve across the Region. Outbreak response immunizations were carried out in 2013–2015 in countries affected by measles outbreaks.² As a result, seven countries³ were verified by the Regional Verification Commission in 2014–2015 to have interrupted endemic measles virus transmission for more than 36 months. To accelerate or initiate activities for rubella elimination, many countries in the Region have been utilizing the measles elimination platform and strategies. Since 2008, many countries with large populations in the Region started introducing rubella-containing vaccine (RCV) and measles and rubella (MR) or measles, mumps and rubella (MMR) vaccines into routine immunization programmes⁴ and conducted a wide-age-range, nation-wide MCV-SIA with MR vaccine, which enabled these countries to vaccinate almost 15 birth cohorts born after around the year of 2000.⁵

Despite the successful implementation of the strategies for measles elimination, the Region experienced a region-wide measles resurgence in 2013–2014.⁶ The increased incidence of measles virus transmission can be attributed to three factors: the resurgence of endemic transmission in endemic countries; large-scale outbreaks following importation in countries with a low number or no recent documented cases of measles transmission; and multiple importations in countries that have achieved or are approaching interruption of endemic measles virus transmission.

Issues becoming more apparent during the recent measles resurgence and outbreaks in the Region include: increased infections and transmission of measles virus among people outside the target of current immunization strategies (i.e. infants aged less than 8 months, adolescents and adults); importation-induced large-scale outbreaks of measles in countries with residual or quickly accumulating susceptible populations; and repeated resurgence or large-scale outbreaks of measles in endemic countries.

To address these emerging issues, the following eight interventions and activities should be urgently and more actively implemented: (i) perform a detailed analysis of measles outbreaks and resurgence in 2013–2014; (ii) update national measles elimination plans and strategies; (iii) prepare subnational plans and strategies; (iv) update outbreak response plans and procedures; (v) employ appropriate

¹ China, Hong Kong SAR (China), Mongolia and the Republic of Korea have maintained >95% vaccination coverage with both MCV-1 and MCV-2 since 2010. Viet Nam has maintained >95% vaccination coverage with MCV-1 since 2010 and improved MCV-2 coverage from 83.2% in 2012 to 94% in 2014. Since 2010, Cambodia, China, the Lao People's Democratic Republic and Viet Nam conducted at least one nationwide SIA and marked >95% MCV coverage and Mongolia and Philippines marked >90% MCV coverage

² The Lao People's Democratic Republic, the Federated States of Micronesia, Papua New Guinea, Philippines, Solomon Islands and Viet Nam.

³ Australia, Macao SAR (China), Mongolia and the Republic of Korea in March 2014, and Cambodia, Brunei Darussalam and Japan in March 2015.

⁴ Countries which recently introduced RCV into the routine immunization programme include China (2008), Mongolia (2009), the Philippines (2010), the Lao People's Democratic Republic (2013), Solomon Islands (2013) and Cambodia (2014). Viet Nam and Papua New Guinea plan to introduce RCV in 2015 and 2016, respectively.

⁵ Countries which recently conducted nationwide MCV-SIAs with MR include the Lao People's Democratic Republic (2011 and 2014), the Philippines (2011 and 2014), Mongolia (2012), Cambodia (2013), Solomon Islands (2014) and Viet Nam (2014–2015).

⁶ The regional measles incidence per one million population significantly increased from 5.9 in 2012 to 17.7 in 2013 and 44.0 in 2014.

infection-control measures to prevent nosocomial transmission of measles; (vi) ensure surveillance activities with aggressive case detection and thorough outbreak investigations; (vii) annually review and identify immunity gaps by geographic area and by birth cohort; and (viii) perform proactive and corrective actions for filling immunity gaps.⁷

2.5.3 Virologic surveillance

Dr Zhang Yan introduced the Western Pacific Region measles and rubella laboratory network, or MR LabNet, and then briefly discussed the focus on Virologic Surveillance for Measles viruses in the Western Pacific Region.

There are different levels of measles and rubella laboratories in the Region. A total 389 laboratories are in MR LabNet, ranging from global to the prefectural level. The MR LabNet is composed of one global specialized laboratory, three regional reference laboratories (RRL), 17 national laboratories, five subnational laboratories, 31 provincial laboratories and 331 prefectural laboratories, which is more than 50% of the global MR LabNet total. The MR LabNet performs laboratory diagnoses for suspected measles cases, virologic surveillance to genotype the virus, and quality assurance to ensure the quality of detection.

Virologic surveillance shows widespread circulation of B3 genotypes in the Western Pacific Region in 2013–2014. An endemic H1 genotype virus circulation pattern still exists in China, but other genotypes have been detected in recent years. For Member States that have verified measles elimination, genotype evidence could help support the interruption of endemic measles virus transmission. In endemic countries, the replacement of genotypes or mixed genotype patterns were found. The proportion of genotyped cases increased, but this could be improved. The importance of the integration of virologic data and epidemiologic information is emphasized. Virologic data should be interpreted with supporting epidemiological information to track transmission pathways and identify sources of infection.

2.5.4 Country reports on measles elimination

China

Dr Hao Lixin reported that the resurgence of measles following the nadir in 2012 continues, with the number of cases in 2014 greater than in 2013 cases. But 2015 cases are slightly lower compared to the same time last year. The age distribution shows cases concentrated among three groups: children too young to vaccinate; young preschool children not completely vaccinated; and adults over 20 years of age. However, the age distribution varies by province, especially in the proportion of adult cases. In all provinces, schoolchildren have the lowest number of cases. China conducted a risk assessment that uses – but expands upon – the WHO risk assessment tool. Some provinces are at greater risk than other provinces.

Planning is ongoing for mitigation of the resurgence. The basis of measles elimination is and will be the routine vaccination programme. A catch-up supplementary immunization activity (SIA) is being considered that may vary by area, with some areas using a selective catch-up campaign while others use a non-selective campaign. The school entry immunization record check and vaccination programme is being strengthened with national implementation guidelines. Health-care workers will be recommended for MR vaccination, as will new college students who are not completely vaccinated. A serological survey for measles and rubella susceptibility from 1 to 30 years of age will be completed this year.

⁷ e.g. selective immunization activities, smaller-scale (region- or province-wide) SIAs or more frequent follow-up SIAs targeting birth cohorts born after the last SIA in specific regions or provinces

Viet Nam

Professor Dang Duc Anh reported that during a large measles outbreak in 2013–2014, a total of 15 033 confirmed cases were reported nationally, including nearly 150 deaths in 2014. The outbreak started in a low MCV coverage area in the northern mountainous district bordering China in April 2013. The other districts in the other provinces also bordering China suffered a measles outbreak in June and September in 2013. Despite outbreak response immunizations (ORI) in those areas, a large outbreak occurred with a peak of more than 3500 cases in April 2014. At the same time, a measles outbreak was also reported in other regions. The most-affected age group was less than 5 years of age, especially babies less than 1 year. There was a small peak in young adults 15–30 years old. From field investigations, it was suggested that delayed vaccination – not vaccinated on time – could be a primary reason for this outbreak.

Different genotypes (H1, B3, and D8) were detected from different regions. However, more detailed information of sample collection would be needed to understand the route of transmission. Measles mop-up activities in high-risk age groups and areas were conducted in early 2014, followed by a nationwide MR-SIA from September 2014 to April 2015, which targeted nearly 20 million children with 97.2% coverage. After a nationwide SIA, only sporadic cases have been reported in 2015. Viet Nam proposes strengthening routine immunization, selected MR-SIAs for young adults in high-risk areas, cross-border collaboration and high-quality surveillance for measles elimination.

Lao People's Democratic Republic

Mr Sisouveth Norasingh highlighted the measles elimination efforts in the Lao People's Democratic Republic. He reported that the country has a single dose MR vaccine at nine months in the national immunization schedule using routine immunization service delivery. The country has used outbreak response activities, either province-wide or localized based on the extent and geographical location of the positive cases, in the event of an outbreak. He said that the routine MCV1 coverage has improved from 40% in 2007 to 87% in 2014, while the measles/MR SIA coverage has been above 95% in last three SIAs. He provided an overview of measles cases in last three years. He highlighted that the 2015 measles cases are geographically related to the 2014 cases. In 2014, 83 laboratory-confirmed measles cases were detected in four provinces, while in 2015, six provinces reported 14 laboratory-confirmed cases.

The genotype of the 2014 cases was confirmed to be of H1. The most of the cases in 2014 and 2015 were among children less than 10 years who were primarily from Hmong ethnic community. Most of the measles cases were found to be unvaccinated in both the years. The country conducted immediate outbreak response in all the affected provinces with wide-age, non-selective vaccination in affected villages and districts. The Lao People's Democratic Republic conducted a nationwide MR-SIA conducted in November 2014 targeting children 9 months to under 10 years of age. The country plans to improve and strengthen the routine immunization programme including fever and rash surveillance. The country plans to strengthen border-area vaccination activities.

Philippines

Ms Dulce Elfa reported that since 1998, there have been five SIAs for measles elimination. The routine measles series consists of MCV1 at 9 months of age and MCV2 at 12 months of age.

From fourth quarter of 2013 to the first quarter of 2014, large-scale measles outbreaks occurred in all regions, especially the National Capital Region and surrounding provinces. Subsequently, guidelines were established to give on conducting ORIs. A MR-OPV SIA was conducted in September 2014. More than 10 million children were reportedly vaccinated during the SIA; overall coverage was 91%.

Since the SIA of September 2014, a significant decrease of measles was observed. In 2015, there have been continuing measles clusters and chains of transmission, especially in the southern part of

Philippines. In April of 2015, the Department of Health issued an advisory on measles catch-up immunization.

Although routine immunization (RI) is being strengthened, outbreak response will still be important, but it will only be considered if initial strategies are proven ineffective. For now, the "Reaching Every *Purok*" (small district) strategy will be used to strengthen RIs.

The Department of Health is now emphasizing three main strategies for RIs: 1) two doses of MCV for children under 2 years through the Reaching Every *Purok* strategy; 2) school-based MCV doses for Grade 1 (6–7 years); and 3) school-based MR and tetanus diphtheria vaccines for Grade 7 (13 years). School-based immunization will be in partnership with the Department of Education.

National surveillance target indicators have not been optimal and show the surveillance system must be strengthened. Sustainability of these approaches will be ensured through resources obtained at the national and regional levels.

Pacific island countries and areas

Dr Jayaprakash Valiakollerli presented the measles elimination status in the Pacific. Pacific island countries and areas have a combined population of slightly more than three million people. From 2006 to 2013, the Pacific island countries and areas did not report any measles outbreaks. Measles immunization coverage is low in some countries (Kiribati, the Marshall Islands, the Federated States of Micronesia, Solomon Islands and Vanuatu).

In 2014, measles outbreaks were reported in the Federated States of Micronesia, Solomon Islands and Vanuatu. In May 2014 an outbreak occurred in Kosrae in the Federated States of Micronesia (166 cases). The outbreak spread to Pohnpei (249 cases and one death) and Chuuk (two cases). SIAs were subsequently conducted in all four states (6 months to 49 years in Pohnpei and Chuuk, and 6 months to 57 years in Kosrae and Yap). Over 50% of the cases had received at least one documented dose of MCV. In Solomon Islands more than 4400 cases were reported during the outbreak with nine deaths. An SIA was conducted (6 months to 30 years). In Vanuatu 10 cases were reported. Efforts were carried out to increase the coverage of measles vaccine among children 12–23 months including conducting immunization mop-up activities in the highest populated areas. Lessons learnt included surveillance failure to detect initial cases on time (Kosrae), significant number of cases with documented evidence of having received vaccine, and changes in the age distribution of measles cases in several countries with cases among infants, adolescents and adults.

Mongolia

Dr Dorj Narangerel reported that although Mongolia has been verified as having eliminated measles by the Regional Verification Committee in March 2014 thanks to sustainable high MCV coverage and good measles surveillance, the country has been facing a measles outbreak since mid-March 2015. The country presentation, therefore, includes the most recent outbreak-related information, such as measles characteristics, responses, issues to be addressed, and proposed actions in near future.

The very first suspected measles case was reported on 18 March 2015 in the capital city and confirmed by a laboratory as measles the next day. As of 5 June 2015, there were 11 779 suspected cases from all administrative units (21 provinces, as well as the capital city). Samples were taken from 1623 cases in total. Of that total, 517 cases were positive, 895 cases were negative and 164 cases were equivocal. National measles laboratory (NML) has identified the measles virus type as H1 which is currently actively circulating in China. NML sent samples to RRL in Hong Kong SAR (China) for confirmatory purpose and got 100% concordance for both of serology and polymerase chain reaction (PCR) testing. The most affected age groups are children aged below 1 year, especially below 9 months of age (for MCV first dose) and people aged above 18 years old. The last nationwide MR-SIA campaign was conducted in 2012 targeting children aged 3–14 years old. Thus, the outbreak rate

among children aged 6–17 years old were the lowest, indicating the good protection of those children by the high-quality campaign in 2012.

In response to the most recent measles outbreak, the Government of Mongolia has been taking response measures such as enhancement of the surveillance, public awareness activities, vaccination with measles, mumps and rubella (MMR) of close contacts and non-selective SIAs with MCV-mono vaccine targeting children aged 6 months to 5 years old during the May round of the National Immunization Days. The reported SIAs vaccination coverage was 92% as of 5 June 2015.

MCV2 vaccination coverage was below 90% during the so-called the economic transition period (1991–1998) when all sectors of the country, including health sector, faced crises.

Case detection and case management were increased following the surveillance enhancement and the Government has operationalized MV-SIAs on a very short notice (a decision made within two weeks, and the campaign conducted within two months of first report) in close collaboration with WHO and UNICEF.

It is too early to talk about impact of SIAs, however virus transmission among children under 5 years is expected to be reduced, although it has shifted to older age groups (above 18 years old).

In order to interrupt residual transmission and prevent future resurgence, the country needs to: (i) close the immunity gap in the population by carefully considering the characteristics of the most affected age group (aged between 18 and 39 years) which is relatively mobile as well as more crowded; (ii) maintain the population immunity level against measles and rubella at 95% through high vaccination coverage for MR-CV as well as periodic SIAs; and (iii) revise the current national measles elimination strategy to include rubella elimination and outbreak response components.

2.5.5 Country reports on rubella elimination

Malaysia

Dr Jamiatul Aida Md. Sani provided an overview of vaccination programme against rubella, surveillance for rubella, and epidemiology of rubella and congenital rubella syndrome (CRS) in Malaysia.

Malaysia started a rubella vaccination programme with primary goal to prevent congenital rubella infection and reduce CRS by immunizing adolescent girls and women of childbearing age. Rubella monovalent vaccine (RV) was introduced into the national immunization programme in 1987 targeting females aged 16 years, the country conducted supplemental immunization activities with RV in 1987–1989 targeting females aged 15–44 years. The target age for RV vaccination was dropped from 16 to 15 years in 1990, and then from 15 to 12 years, with a catch-up vaccination for females aged 13 to 15 years and incorporation of the RV vaccination programme into the school health programme in 1993. MMR started to be given as MCV1 for children aged 12 months and MCV2 for children aged 7 years from 2002 and 2004, respectively, in the national immunization programme targeting both boys and girls. RV vaccination targeting females aged 12 years continued until 2009. As a result, female birth cohorts born in 1943 and onwards and male births cohort born in 1997 were targeted for rubella-containing vaccine (RCV) campaigns. RCV1 coverage reached >95% in 2009 to 2013.

In 2010, an administrative order was issued to ensure all fever and rash cases suspected as measles or rubella to be notified and investigated. Since then, rubella has been included into the extended case-based measles surveillance, which was established in 2007, under the Measles Elimination Programme (MEP) in Malaysia that started in 2004. Rubella incidence (per one million population) in Malaysia increased from 3.3 in 2010 to 32.6 in 2012 and 31.6 in 2013 with the peak of distribution of rubella cases by age group at 16–20 years of age. The proportion of male cases was significantly higher than the proportion of females every year (83% in 2009, and 77% to 91% in 2011 to 2013).

CRS has been reported only from inpatient discharges of Government hospitals over the country to Health Management Information System based on ICD-10 code. Since 2000, CRS was reported every year in Malaysia with the number of cases from 1 in 2007 to 43 in 2011 (18 in 2009, 32 in 2010, 10 in 2012, and nine in 2013).

Mongolia

Rubella is a notifiable disease in Mongolia, and rubella surveillance is currently accomplished by testing suspected measles cases. RCV was introduced in 2009 by replacing MCV-mono vaccine. Currently doses of MMR are given at 9 months and 2 years of age, and MMR2 coverage was 96% in 2014.

There are a few rubella-related policy documents existing, such as rubella case management and surveillance standards, and there are generic surveillance guidelines that include rubella.

Three outbreaks due to rubella were reported in 2000–2001, 2006–2008, and 2012. During the 2006–2012 rubella outbreaks, the incidence rate had reached 2038 cases per 100 000 population in the capital and 135 cases in provinces, while during the non-outbreak period the incidence was below 1 case per 100 000 population. Following the 2006–2008 outbreak, the Government in 2009 introduced MMR into the routine vaccination schedule. After RCV introduction, rubella was reported among children aged above vaccination age (above 5 years old). Furthermore, Mongolia conducted preventive SIAs with MR vaccines targeting children aged 3–14 years old in 2012 with vaccination coverage of 92%.

Currently, there is no systematic monitoring for CRS. For example, 2000 live births were evaluated in 2000 and out of them 42 cases has congenital defects. Only three out of 42 were rubella IgM positive. With WHO support, a one-year sentinel surveillance activity for CRS was conducted in 2009 during which 9510 cases were evaluated, and out of them only 16 met the clinical case definition, but none were found to be positive by the laboratory.

Currently, Mongolia has national surveillance for birth defects, and according to a 2014 report there were 634 birth defects and out of them 17 cases had CRS-related defects. Unfortunately, none were tested in a laboratory due to the absence of systematic surveillance for CRS.

Mongolia has a national strategy on measles elimination that aims to maintain measles elimination status, and a revision of the strategy is under way to include rubella elimination and outbreak response components. The proposed revision has three strategic objectives: (i) population immunity; (ii) surveillance; and (iii) outbreak response. Under each objective the expected results were identified.

Newly added key activities under Strategic Objective 1 were to conduct an EPI performance assessment annually and develop accurate definition of denominators. Those under Strategic Objective 2 are establishment of CRS surveillance and every measles and rubella case to be verified by expert panel. For Strategic Objective 3 the activities are development of national outbreak guidelines and genotyping for initial cases from new areas during outbreak setting.

2.6 Hepatitis B accelerated control

2.6.1 Regional overview

Mr Eric Wiesen reported that hepatitis B burden is very high in the Western Pacific Region. As a result, there is strong demonstrated political commitment to controlling hepatitis B through immunization in the Region. While at the regional level coverage with three doses of hepatitis B is above 90% and birth-dose vaccination coverage is almost 80%, in several countries birth-dose coverage is still below 50%. The Western Pacific Region Hepatitis B Expert Resource Panel met in January 2015 and recommended, among other things, to engage with media to increase confidence in the hepatitis B vaccine in Viet Nam, to catalogue hepatitis B rapid tests in use in the Region, and to

recommend to TAG that all countries adopt a policy to vaccinate health workers against hepatitis B. A target for establishing hepatitis B health worker vaccination policies is included in the draft Regional Action Plan for Viral Hepatitis.

Projects to improve birth-dose coverage have been planned or implemented in four priority countries. In addition, six priority countries developed birth-dose improvement plans during a recent birth-dose workshop. Several countries are taking steps to strengthen or introduce hepatitis B vaccination outside the cold chain as a method to improve birth-dose vaccination coverage in health facilities without a functioning refrigerator. Twelve countries have been verified as having reached the 2017 hepatitis B control goal of less than 1% HBsAg prevalence among 5-year-old children. While the impact of the hepatitis B vaccination programme has been tremendous, further efforts are needed in order to reach the goal in all countries.

2.6.2 Controlled temperature chain overview

Regulatory approval that allows for use of vaccines in a controlled temperature chain (CTC) is important to ensure that vaccines remain potent and safe throughout their life cycle. WHO's CTC programme focuses on some of existing vaccines that are either delivered in campaigns or through special strategies. These vaccine delivery strategies show the greatest potential to benefit from the CTC approach due to large volumes, short time frames, remote sites, non-routine schedules or extensive outreach requirements, lack or impaired electricity, and lack or non-functional cold chain equipment – all of which make it challenging to deliver vaccines in the traditional cold chain. The first vaccine that went through this process was meningitis A vaccine through the Meningitis Vaccine Project, a WHO/PATH collaboration. WHO drafted guidelines on scientific and regulatory considerations and initiated a formal process for an adoption decision in October 2015. Further steps to be taken include: a) to consult regulators and industry experts if existing stability data on 2–8° C, 25° C and 37° C are sufficient for a CTC label (e.g. 37° C for one month); and b) if additional data are needed, consult international experts on minimum data requirements for a CTC label that can allow single-planned excursion up to 37° C for one month.

2.6.3 Country reports

Philippines

Ms Elfa shared that this year the Philippine Department of Health developed a *National Plan of Action for the Accelerated Control of Hepatitis B* that dovetailed with the *Maternal and Neonatal Tetanus Maintenance Plan*. The objectives of the plan include increasing the birth dose coverage to >65% by December 2017 and to increase availability and access to the hepatitis B birth dose and tetanus-containing vaccine (TCV) and other maternal and newborn care services to vulnerable populations, such as those living in hard-to-reach areas and geographically isolated and depressed areas.

Since its nationwide introduction and despite of having national policies and a law that promotes the birth dose, coverage for the hepatitis B birth dose remains under 60%. Barriers to high birth dose include high proportion of home deliveries assisted by non-skilled birth attendants, health workers not complying with the open-vial policy or hesitant to provide birth dose to low birth weight or premature babies, the non-compliance of the private practitioners/health facilities to reporting requirements and the repeated stock-out of hepatitis B vaccine over the past five years.

One of the major strategies to improve access to hepatitis B vaccine and increase birth-dose coverage is to change the procurement from multi-dose vial monovalent hepatitis B vaccine to a single-dose vial to reduce wastage and allow birth attendants to bring a vial even when assisting home deliveries. The plan also promotes strong partnership and collaboration with the maternal and child health programme and the private health sector, including updating the existing policy to include them in the reporting of birth dose coverages. Lastly, there is a plan to conduct a hepatitis B sero-prevalence survey in 2016 to determine progress in achieving the hepatitis B control goal.

Viet Nam

Dr Duong Thi Hong reported how Viet Nam introduced hepatitis B vaccine into EPI in high-risk areas in 1997, and covered whole country in 2003. Birth dose <72 hours was initiated in 2003, then changed to <24 hours in 2005. An HBsAg sero-survey conducted in 51 provinces in 2011 revealed sero-prevalence fell to 1.63% in children born in 2007–2008, followed by 2.13% in 2004–2006 and 3.62% in 2000–2003. This indicated that hepatitis B vaccination in Viet Nam is an effective preventive measure of hepatitis B control. However, its coverage dropped after serious adverse effects following immunization (AEFI) cases in 2007. The Ministry of Health communicated with the public and health staff against vaccination hesitancy, and coverage of the birth dose has gradually increased to 70% through 2012. In 2013, it decreased again up to 50% mark due to serious AEFI following pentavalent vaccine. The Ministry of Health continues various kinds of activities to improve hepatitis B coverage for achieving the hepatitis B control goal, such as communication through media and developing communications materials. In addition, health staff training, supplying the cold chain and strengthening vaccine management has been ongoing for secure vaccine safety.

2.7 Polio eradication and Polio Endgame Strategy

2.7.1 Global update

Wild poliovirus eradication

Dr Graham Tallis reported that in the last six months, wild poliovirus WPV1 has occurred in only two countries, Pakistan (36 cases) and Afghanistan (three cases). Compared to the same period in 2014, there has been a notable fall in both these countries. This is a marked improvement, and there were no cases anywhere in Africa in 2015. In Nigeria, there was a demonstrable improvement in the quality of SIAs contributing to the lack of cases. However risks include insecurity and conflict in the north-east, possible loss of political commitment with a new government, and programme complacency. In Pakistan, there has been improved accessibility in Karachi and Waziristan, but there are still quality gaps. There needs to be a focus on missed children. In Afghanistan, the programme needs to accelerate engagement with new leadership, maintain dialogue with non-state actors, and ensure programme neutrality and reduce the number of missed children.

The Public Health Emergency of International Concern (PHEIC) declared by the WHO Director-General on 5 May 2014 has been extended four times. The current “temporary recommendations” emphasize regional cooperation and cross-border coordination according to three categories of countries – exporting, infected and vulnerable countries.

Elimination of persistent cVDPV2

Only two countries, Nigeria and Pakistan, have persistent circulation of type two vaccine-derived poliovirus (VDPV2) since start of 2014. No cases have occurred thus far in 2015, although isolated environmental detection occurred in both countries. Both countries have conducted tOPV +/-IPV campaigns in 2014 and first half of 2015, with further campaigns scheduled later in 2015 prior to the tOPV-bOPV switch in vaccines.

Legacy transition planning

Countries should commit to finalizing a transition plan with Global Polio Eradication Initiative (GPEI) partner agency (UNICEF, WHO) legacy focal points in their country to begin transition planning, solicit stakeholder input and identify the opportunities and risks.

2.7.2 Objective 1: Poliovirus detection and interruption

Acute flaccid paralysis (AFP) surveillance, routine and supplementary polio immunization

Dr William Schluter reported that in January 2013 the Executive Board of WHO approved the Polio Eradication and Endgame Strategic Plan 2013–2018. The plan has four objectives: poliovirus

detection and interruption; immunization systems strengthening and OPV withdrawal; containment and certification; and legacy planning.

Overall progress in the WHO Western Pacific Region towards fulfilling the first two objectives of the plan has been remarkable. The Region has retained its polio-free status since 2000 with last indigenous wild polio case identified in 1997, last imported wild poliovirus registered in 2011 and last circulating vaccine-derived poliovirus detected in 2012. Overall, the countries of the Region maintain high-performing AFP surveillance. However, surveillance gaps at national and subnational levels still exist in some countries. Overall the countries of the Region maintain high (>95%) coverage with the third dose of polio vaccine. Immunity gaps that exist in some countries are being filled with implementation of mass vaccination campaigns.

However, there are still some national and subnational areas in the Region with a high risk of wild poliovirus circulation in case of importation. During 2014–2015 several activities were conducted in the Region to reduce this risk in reply to Regional Commission for the Certification of Poliomyelitis Eradication 2013 recommendations. In addition in 2015 second Biregional Cross Border Meeting on Polio, Measles and Other Vaccine Preventable Diseases for the WHO South-East Asia and Western Pacific regions was conducted with the following objectives:

- to identify high-risk border areas and populations and define activities to mitigate the risk
- to update the coordination mechanism for data sharing
- to make recommendations for further strengthening of cross-border disease-control efforts.

All countries and areas in the Region using only OPV committed to introduce IPV by end of 2015.

Laboratory network including intratypic differentiation expansion and environmental surveillance

Ms Varja Grabovac reported that polio laboratory network in the Western Pacific Region is comprised of 43 fully accredited laboratories and continues to monitor the polio-free status of the Region with performance indicators, timeliness of reporting and proficiency of testing. Thirty-three laboratories have capacity to perform intratypic differentiation (ITD) of polioviruses, and by end of 2015 it is expected six more laboratories be accredited to have ITD capacity. Quality assurance and quality control have been successfully established throughout the network through annual proficiency testing for virus isolation, ITD/VDPV screening and sequencing of polioviruses. The confirmatory testing mechanism also is well established in the Region. Currently, four countries are conducting environmental surveillance in the Region; no specific plans for expansion in the Western Pacific Region have been introduced.

2.7.3 Objective 2: Immunization systems strengthening and oral polio vaccine (OPV) withdrawal

IPV introduction update and switching from trivalent OPV to bivalent OPV Mr Michel Zaffran said a critical part of the strategy for achieving global polio eradication, as outlined in the *Polio Endgame Strategy*, is the withdrawal of the oral polio vaccine (OPV).

As agreed at the 2015 World Health Assembly, the phased withdrawal of OPV will start in April 2016 through the switch from trivalent OPV (tOPV) to bivalent OPV (bOPV), which will remove the Type 2 component of OPV from immunization programmes in a globally synchronized manner. This is a key step to eliminate the rare risks of vaccine-associated paralytic polio (VAPP) and circulating vaccine-derived poliovirus (cVDPV). In recent years, OPV Type 2 has been responsible for 97% of all paralyses from cVDPVs. At its April 2015 meeting, SAGE concluded that progress towards elimination of persistent cVDPV Type 2 is on track and recommended that all countries and GPEI should plan firmly for an April 2016 switch.

In advance of the switch, as a risk mitigation measure, all countries should introduce at least one dose of IPV to their routine immunization programmes. To date, 20 countries of the 126 using only OPV have introduced IPV. The remaining 106 countries have committed to do so before the switch. Two Western Pacific Region countries have introduced IPV, and the remaining countries have committed to do so within the *Polio Endgame Strategy* timelines. Constrained global supply remains a challenge to achieving this and some countries may have to delay introduction until early 2016.

The 17 Western Pacific Region countries still using tOPV in 2016 should develop their national switch action plans by September 2015, involving national regulatory authorities to ensure bOPV licensure and so that they can develop strategies to minimize stocks of tOPV while avoiding stock-outs prior to the switch date. It is important to remember that in addition to the execution of the switch, validation of its completeness will be critical, especially for higher risk countries.

2.7.3.2 Technical guidance for the switch from trivalent (tOPV) to bivalent oral polio vaccine (bOPV)

Ms Diana Chang-Blanc reported on the technical guidance for the globally coordinated replacement of (tOPV) with bivalent oral polio vaccine (bOPV), targeted for April 2016, which is the switch date. Once polio eradication is certified, the withdrawal of all oral polio vaccines is targeted for 2019–2020.

There are 149 Member States and seven areas that currently use tOPV and will participate in the globally synchronized switch. The withdrawal of tOPV in April 2016 is an unprecedented task in polio eradication efforts that will require global leadership and country commitment. Implementation guidelines and support tools are readily available, highlighting the main steps in planning, preparing, implementing and monitoring the switch. Countries will need to establish management and operational oversight structures, which include a National Switch Management Committee and an independent National Switch Validation Committee. It is recommended that these bodies be developed from existing expert group mechanisms.

The global switch window will span a two-week time frame during which countries will select a National Switch Day. On this day, each country will: a) recall tOPV from the cold chain and initiate its disposal; and b) begin administration of bOPV. The two vaccines cannot be administered simultaneously. Countries will subsequently have a two-week period following the National Switch Day to dispose of and conduct monitoring of the withdrawal of tOPV stocks.

To ensure a successful switch, it is recommended that countries develop a costed national switch plan by the end of September 2015, which will describe activities for training, supply and distribution management, disposal, and monitoring. To ensure the proper balance between tOPV and bOPV stocks at the time of the switch, countries should conduct stock inventories in October 2015 to identify the necessary strategies to adequately consume tOPV prior April 2016, without risking stock-outs.

Resource materials are available at

http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/en/

Country report: China

Dr An Zhijie reported that the tOPV is provided free in EPI in China in order to sustain a polio-free China. IPV has been used in the private market in recent years. IPV phased introduction started in one prefecture Guangdong and in the entire province Beijing in 2014, and will expand to other five provinces in July 2015. Children obtain protection immunity against poliomyelitis through routine vaccination with one dose IPV followed by three doses OPV given at two months, three months, four months and four years. Even though China still faces challenges on wild poliovirus importation, as well as VAPP, VDPV and IPV supply issues, to achieve the global synchronization of the tOPV to bOPV switch in April 2016, national authorities are making great efforts in nationwide IPV use, bOPV licensure and preparation for Type 2 poliovirus containment.

As the first province that has smoothly switched from full OPV to IPV/OPV use, the EPI programme Beijing vaccinated with over 100 000 doses of IPV, detected no serious AEFI and no negative public feelings. The successful experience included an evaluation of cold chain capacity before IPV introduction; assessed social acceptance with participation by stakeholders; the development of a communication plan, key messages and frequently asked questions; and the conduct of cascade trainings and media monitoring after IPV introduction.

2.7.4 Objective 3: Containment and certification

Global Action Plan III and laboratory containment

Ms Grabovac reported that the third edition of the *Global Action Plan* (GAP III) establishes a long-term goal to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of OPV use by reducing the number of facilities holding polioviruses to a minimum, as endorsed by Sixty-eighth World Health Assembly in May 2015. Implementation of GAP III will be done in three phases: 1) identification, destruction or preparation for containment of all WPV, OPV/Sabin; 2) containment of WPV2, OPV2/Sabin2 poliovirus; and 3) final containment of WPV and all Sabin polioviruses. Countries have been requested by the end of June to update their inventories to reflect type-specific/virus-specific number of polioviruses, to nominate national polio containment coordinator responsible for organizing and monitoring containment in a country, and to identify the national regulatory agency for containment responsible for certification of essential facilities handling and storing PV2.

WHO is recommending that all countries in the Western Pacific Region by end of 2015 to destroy unneeded poliovirus material (WPV infectious and potentially infectious materials, and any OPV/Sabin materials) and transfer all needed poliovirus Type 2 material to essential poliovirus facilities.

Certification of regional polio-free status and global eradication of Type 2 wild poliovirus

Professor Anthony Adams said that according to Strategic Objective 3 of the *Polio Eradication and Endgame Strategic Plan 2013–2018* global containment of polioviruses and polio-free certification are to be completed by 2019. The first step towards fulfilment of this objective will be withdrawal of poliovirus Type 2 from the oral polio vaccine (OPV) following interruption of circulation of persistent cVDPV 2. However, withdrawal of OPV2 will lead to a rapid increase of susceptibility of the global birth cohort to the Type 2 wild poliovirus. Therefore, ensuring absence/eradication and effective containment of Type 2 polioviruses will be critical in mitigating risk associated with OPV2 withdrawal.

Certification of eradication of polio virus is declared by the Global Commission for the Certification of Polio Eradication (GCC) based on the reports submitted by the respective regional commissions and national certification committees for polio eradication (RCCs and NCCs). Currently the following WHO regions are certified by the GCC as polio-free: Region of Americas in 1994; the Western Pacific Region in 2000; the European Region in 2002; and South-East Asia Region in 2014.

In March 2015, Member States received communications from their respective WHO regional directors with a request to present existing data on the last WPV2 detection in their country and to provide additional information if relevant. It is expected that based on evidence submitted by the Member States at its next meeting in September 2015, GCC will formally declare/reaffirm eradication of WPV2 for more than 15 years.

2.7.5 Objective 4: Legacy planning

Recognition of the 25th anniversary of global polio laboratory network and legacy planning

Ms Grabovac reported that the Global Polio Laboratory Network (GPLN) was established in 1989 and currently is comprised of 146 laboratories in 92 countries. An assessment of the network's strengths, weaknesses, threats and opportunities (SWOT) was conducted in 2014. Strengths of the network

include a strong network structure with high technical capacity built over the years, with efficient collaboration at different levels within the network and good integration with EPI programmes. Weaknesses were found in lack of financial and human resources and national support, inadequate communication among laboratories, and with the public.

Opportunities are identified in areas of global integration with EPI and other programmes, adoption of new technologies and the diversification of activities. Threats exist in maintaining sustainability of the network, competing priorities, managing available resources, post-eradication of poliovirus and political security in some regions. Priority actions were identified in areas of staff development, establishing a clear budget plan, and promoting the GPLN contribution to the success of the GPEI through better visibility, education and communication across all stakeholders. As part of legacy planning, we must ensure that polio assets, lessons learnt and knowledge acquired are applied to support the broad immunization agenda and other health priorities and that the potential legacy of polio eradication is fully realized. A comprehensive polio legacy plan should be developed with clear objectives to maintain polio functions through continued polio immunization (with IPV); surveillance, response and containment; leveraging the knowledge and lessons learnt; and transitioning the assets and infrastructure.

2.8 Maternal and neonatal tetanus elimination

2.8.1 Regional progress towards and maintenance of maternal and neonatal tetanus (MNT) elimination

Dr Schluter reported that in 1999, 57 countries were identified as priority countries for neonatal tetanus elimination. This list was later expanded to include two more when Timor-Leste was added in 2002 and South Sudan in 2011. Globally, 37 countries have been validated as having eliminated maternal and neonatal tetanus. Six countries were identified as priority countries in the Western Pacific Region. Of these, Viet Nam was validated in 2005, China in 2012, and the Lao People's Democratic Republic in 2013. The Philippines conducted a validation survey in 2015 in which 16 of 17 regions were validated as having achieved MNT elimination. Cambodia is planning a validation survey immediately following the TAG meeting. In 2015, WHO and UNICEF have drafted guidelines on maintaining MNT elimination. Annually countries should review district performance. If risks are identified, immediate responses may include implementation of strategies to provide additional doses of tetanus toxoid-containing vaccine (TTCV) to women of reproductive age. Medium- or long-term strategies include modification of routine immunization schedules or changing the availability of skilled birth attendants and/or facility-based deliveries. In accordance with the 2006 WHO tetanus position paper, six doses of TTCV including a three-dose primary series followed by boosters at 4–7 years of age, 12–15 years of age and an adult booster. Only five doses are needed if vaccination starts in adolescence or as an adult.

2.8.2 Country reports

Philippines

Ms Elfa reported on improvements in key maternal and neonatal tetanus elimination (MNTE) indicators that were observed in the Philippines in the recent years, indicating the country is ready for formal validation. A series of subnational data reviews followed by pre-validation field visits in potentially at risk provinces were jointly conducted by the Department of Health, UNICEF and WHO between 2013 and 2014, it was concluded that 16 of 17 regions were ready for the formal validation. The Autonomous Region of Muslim Mindanao (ARMM) was not included in the validation survey because of security and safety risks to external validators.

In February 2015, a lot quality assurance survey (LQA-CS) was successfully conducted to quantitatively confirm MNTE in Occidental Mindoro, which has the lowest performance on MNTE indicators. Twelve eligible live births (ELB) born in 2014 were surveyed in each of the 146 randomly selected clusters to assess their survival status. Additional information on key MNTE indicators was also collected from three ELB mothers per cluster. Of the 20 neonatal deaths found, none of them died

of neonatal tetanus and this implies that all provinces in the 16 regions have eliminated neonatal tetanus.

To fully validate MNTE in the whole country, a three-round tetanus toxoid (TT) SIA targeting women aged 15–40 years will be conducted in four high-risk districts in ARMM, while strategies to achieve high TCV coverage among children and women, improve neonatal tetanus surveillance and strengthen maternal and child health services, especially among indigenous people and those living in hard-to-reach areas, were recommended to the low-risk districts. In addition, the Department of Health prepared a national plan to sustain MNTE in the Philippines in the succeeding years.

Malaysia

Dr Sani reported that in Malaysia tetanus is one of 28 mandatory notifiable diseases. The incidence of neonatal tetanus has been relatively higher in Sabah than in the rest of Malaysia, but has been <1.0/1000 live births since 1988. Malaysia's current immunization schedule includes a primary series with DTaP-IPV-Hib at two, three, five and 18 months, with boosters for school-aged children using diphtheria-tetanus (DT) at seven years and TT at 15 years of age that are administered through the school health programme. Coverage in the school health programme has been above 95% since 2008. A five-dose schedule for pregnant women is still included in the national programme in order to provide tetanus protection for pregnant mothers who were missed in the childhood and adolescent vaccination programme.

2.9 Evidence-based introduction of new vaccines

2.9.1 Global and regional update on new vaccines

Dr Kimberley Fox presented an update on new vaccine introduction in the Western Pacific Region. In October 2014, the Regional Committee for the Western Pacific adopted the global goal that all low- and middle-income countries in the Region introduce a new vaccine by 2020, and endorsed an evidence-based approach for countries to prioritize vaccines for introduction. Countries have made rapid progress in the last five years in the introduction of *Haemophilus influenzae* type b (Hib), pneumococcal conjugate (PCV), rotavirus and human papillomavirus (HPV) vaccines. However, progress in low- and middle-income countries has been limited primarily to Hib and PCV introductions.

Several new WHO vaccine position papers and WHO disease-burden estimates are available to support decision-making processes in countries. To date, only a few countries with the highest estimated rotavirus and cervical cancer mortality rates have introduced the relevant vaccines. Cost studies are used to determine affordability and for financial planning, and cost-effectiveness studies can support requests for immunization funding and help set priorities for new vaccines. Vaccine impact and effectiveness studies can provide evidence useful to sustain vaccine introduction policies. Studies of these types are now being undertaken by numerous countries in the Region. When planning vaccine introductions, complementary disease prevention and control measures for diarrhoea, pneumonia and cervical cancer should be considered.

2.9.2 Regional update: IBVPD and rotavirus laboratory network

Ms Grabovac reported that EPI at the WHO Regional Office for the Western Pacific coordinates over 500 public health laboratories in 18 Member States in support of regional EPI goals. All laboratories follow standardized, validated procedures and share accurate and timely data on EPI related vaccine-preventable disease (VPD) surveillance to their national programmes and to WHO. These networks generate surveillance data that are vital for country decision-making pertaining to the introduction of vaccines, monitoring circulating strains and subsequent monitoring of vaccine impact.

The Rotavirus Laboratory Network was established in the Western Pacific Region in 2008 to identify cases of rotavirus in children with diarrhoea. The invasive bacterial vaccine-preventable disease (IBVPD) network was established to support the surveillance system for bacterial meningitis, pneumonia

and sepsis caused by *Streptococcus pneumoniae*, *Haemophilus influenza* and *Neisseria meningitidis* pathogens. For quality assurance of the VPD laboratory network, annual proficiency tests were successfully conducted every year, and a confirmatory testing mechanism also is well established in the Region. The Western Pacific Region rotavirus and IBVPD laboratory networks are sustaining high standards and are constantly being assessed for performance.

2.9.3 Country report: Human papillomavirus pilot introduction in the Philippines

Ms Elfa reported that cervical cancer caused by human papillomavirus (HPV) is one of the major public health concerns in the Philippines. Both women and adolescents are at risk of acquiring HPV. It was estimated that 12 Filipino women die of cervical cancer each day. HPV vaccination is an effective strategy to prevent cervical cancer. While HPV is not yet included in the country's routine immunization, there are efforts to increase access to free HPV vaccine among adolescents.

From September 2013 through March 2014, the Philippines Department of Health embarked on an HPV vaccination demonstration project in partnership with measles second dose (MSD) and the Department of Education to assess the feasibility and acceptability of implementing a school-based HPV vaccination targeting adolescents. The study was conducted in selected public schools and a Catholic school in two districts targeting Grade 5 female students aged 10–14 years. A total of 8862 female students were targeted and of this number, 88% completed three doses of HPV vaccine. Keys to the success of the demonstration project are the strong inter-agency partnership and a good advocacy and communication strategy, which lead to better acceptance and cooperation among teachers, parents and students.

Following the success of the demonstration project, the Philippine Department of Health will scale up HPV vaccination in all public schools in 20 selected provinces in August 2015. The school-based vaccination targets 323 115 girls aged between 9–13 years in Grade 4 for this year and the following year. Sustainability of this immunization activity depends on the success of the scale up.

2.9.4 Global and regional updates on influenza vaccines and vaccination

Update on influenza vaccination strategies

Dr Fox presented a global and regional update on season influenza vaccination. WHO issued an updated position paper on influenza vaccines in 2012, recommending that pregnant women be the highest priority for countries considering initiation or expansion of programmes for seasonal influenza vaccination. Implementation of this recommendation requires addressing operational feasibility issues and creates an opportunity to strengthen maternal immunization programmes. WHO is developing programme implementation guidance, AEFI monitoring guidance, and programme monitoring and evaluation guidance for maternal influenza immunization. WHO is also developing guidance and tools for economic burden-of-disease assessment and an economic evaluation of influenza vaccination.

According to a recent survey and data from the WHO–UNICEF Joint Reporting Form, 25 countries and areas in the Western Pacific Region include seasonal influenza vaccine in a national schedule or programme, and 19 include pregnant women as a target group. In tropical countries, appropriate selection of vaccine formulation depends on the timing of peak influenza activity relative to the timing of availability of the northern and southern hemisphere vaccine formulations. In a recent survey in the Western Pacific Region, mismatches of disease activity and vaccine formulation led to months of influenza activity with no vaccine available. Some countries with year-round influenza virus circulation have both formulations available. WHO is developing specific guidance for influenza vaccination in tropical countries.

Influenza surveillance in the Western Pacific Region and vaccine strain selection

Dr Erica Dueger discussed the epidemiologic surveillance necessary for influenza vaccine formulation, including timing challenges due to frequent viral evolution and the lengthy manufacturing process. Global acute respiratory infection surveillance focuses on outpatients (influenza-like illness) and inpatients (severe acute respiratory infection, or SARI) with fever and cough of <10 days. Patient naso/oropharyngeal swabs are sent to National Influenza Centres (NICs) for preliminary testing for viral type and subtype; there are 142 NICs in 115 countries. A sample subset is then sent to one of five WHO Collaborating Centres to test for immune response, genetic components and anti-viral sensitivities. This system, the Global Influenza Surveillance and Response System (GISRS), was established in the 1950s and has been reporting influenza activity on WHO's FluNet since 1997.

Twice each year, WHO proposes the next season's vaccine composition, allowing for identification of frequent viral changes and the 8–9 month lead time required for vaccine production. Southern hemisphere vaccine recommendations are made in September for May distribution; northern hemisphere recommendations are made in February for October distribution. The 2014–2015 northern hemisphere vaccine was used as an example of the challenges faced in matching circulating strains and vaccine. Asian vaccine selection presents the additional challenges of varied influenza peaks with year-round tropical and June–September monsoon circulation.

Influenza vaccine selection continues to be highly dependent on effective surveillance and laboratory work. Although the selection process has improved through WHO's twice yearly strain recommendations, proposed schedules considering Asia's tropical and monsoon season circulation may improve vaccine effectiveness.

Influenza vaccine regulatory issues

There are many different inactivated influenza vaccines (IIVs) marketed, and each IIV is manufactured by different companies with slightly different technologies. The national regulatory authority (NRA) of a country considers safety and efficacy product by product. Pregnant women were not included in clinical trials in general, therefore, no randomized, controlled trial-based evidence for the vaccine safety and efficacy exists for this group. Evidence from post-marketing use of IIV in pregnant women is less convincing of support for a label indication and – in the case of government databases – data sharing and ownership issues for manufacturers. Recently a few controlled clinical trials in pregnant women have been conducted and complete information is not yet available.

The package insert (prescribing information) does not indicate the use of vaccines in pregnant women. Pregnant women, vaccinators and programme managers are reluctant to use flu vaccines without a stated recommendation in prescribing information. WHO's Strategic Advisory Group of Experts (SAGE) on immunization in 2013 recommended that an inactivated influenza vaccine class-specific approach could allow integration of biological similarities into the risk evaluation process. The current regulatory view is IIVs cannot be considered biosimilar, but all have a very similar formulation including hemagglutinin (HA) and excipients, with or without adjuvants, a similar purity profile, and similar safety and immunogenicity. Further work is warranted to better define a class approach and collect evidence globally.

Country report: Lao People's Democratic Republic

Dr Anonh Xeuatvongsa presented an overview of influenza vaccination activities in the Lao People's Democratic Republic. He shared the evolution of the influenza surveillance and decision-making process in the introduction of the vaccine in the country. He provided an overview of the identification of seasonality and circulating subtypes of the influenza in the Lao People's Democratic Republic. He said the Lao People's Democratic Republic was the only low-middle-income country in the Region to have introduced influenza vaccine in the Region with the donor support from the Walgreen Company, the largest retail pharmacy in the United States of America, in 2012 and bioCSL (Australia) in 2013 and 2014, which was arranged by United States

Centers for Disease Control and Prevention's Influenza Division. In these three campaigns, the country has been able to vaccinate more than 95% of the target population.

No severe AEFIs have been found in any of the campaigns. In the Lao People's Democratic Republic, TT vaccination coverage among the pregnant women has improved. The influenza vaccine also was available for older people for the first time, providing benefits to this population who are usually not targeted. The Lao Government plans to procure doses of influenza vaccine using its own funds. The country will explore avenues such as private–public partnerships and regional purchasing agreements for pooled procurement. The Lao Government plans to assess the impact of the vaccine in pregnant women and on birth outcomes, including modelling vaccine and deployment costs associated with SARI and influenza-SARI.

2.10 Japanese encephalitis (JE) accelerated control

2.10.1 Global and regional update

Dr Fox reported on Japanese encephalitis (JE). The global annual JE burden is estimated at 68 000 cases, and 40 000 of those cases occur in the Western Pacific Region. In October 2014, the Regional Committee for the Western Pacific endorsed a regional goal for accelerated control of JE. In February 2015, WHO issued a new position paper on JE vaccines, the culmination of a working group process that included members from several countries in the Region. In May 2015, WHO held an expert consultation on methods to measure the impact and effectiveness of JE vaccines. The position paper and consultation report will provide key inputs to developing the strategies, targets and timelines for achieving the regional goal. A third JE vaccine received WHO prequalification this year, expanding the options for countries that procure vaccine through United Nations agencies. Several countries expanded JE vaccination or made plans to do so this year: Viet Nam reached national coverage with JE vaccinations; the Lao People's Democratic Republic completed a catch-up campaign and is now introducing the vaccine into routine immunizations; Cambodia is planning a catch-up campaign followed by introduction into routine immunization in January 2016; and the Philippines will introduce JE vaccine in 2018 as stated in its recent strategic plan for immunization. Surveillance quality is variable and may not be sufficient to use surveillance to measure the impact of JE vaccine introduction in some countries. Surveillance quality should be improved so that trends in disease detection can be interpreted.

2.10.2 Japanese encephalitis laboratory network update

Ms Grabovac reported that the JE laboratory network in the Western Pacific Region was established in 2008–2009 following the recommendation of the 17th Technical Advisory Group (TAG) in 2008. Where possible, the capacity of already established networks was used, and many of the JE laboratories have been established as designated WHO measles/rubella laboratories. The goal was to improve and standardize the capability of JE diagnosis in countries where the disease is endemic and for determining disease burden with a view to vaccine introduction. Samples from cerebrospinal fluid and paired serum samples from acute encephalitis syndrome (AES) cases at sentinel surveillance sites and from hospital referrals are collected and tested for IgM detection of JE/dengue. For quality assurance of the JE laboratory network, annual proficiency tests for JE were successfully conducted every year, and a confirmatory testing mechanism also is well established in the Region with high concordance rate of testing.

2.10.3 Country reports

Lao People's Democratic Republic

Dr Xeuatvongsa presented an overview of the JE vaccine in the Lao People's Democratic Republic. He said most of the identified JE cases were predominantly among children less than 15 years. Case fatality seen has been around 8–18% with significant neurological sequelae in the survivors. Disease surveillance, sero-epidemiologic studies and swine surveillance in the Lao People's Democratic Republic has confirmed circulation of JE virus across all geographic areas. He provided an overview

of the vaccine introduction, wherein the Ministry of Health in 2013 obtained donation of some 700 000 doses from Chengdu Institute of Biological Products, with support from PATH.

Six northern provinces were targeted in 2013, with two additional northern provinces targeted in 2014. The other 10 provinces in central and southern regions were targeted in 2015 using Gavi JE vaccination campaign support. The surveillance data from the northern region of the country showed a significant reduction in the number of cases in 2014 from the 2009 level. In 2015, the southern and central regions were targeted for 1.5 million children from 9 months to <15 years. The vaccination coverage had been above 90% in all the provinces, except for the northern provinces of Phongsaly and Xiengkhouang. The Lao Government plans to introduce JE vaccine in the National Immunization Schedule at 9–11 months along with MR vaccine. The plan is to start with the Northern Region followed by all other provinces. Operational guidelines have been developed, and the country plans to strengthen the surveillance to monitor vaccination performance.

Viet Nam

JE vaccine was introduced into EPI in 1997 in high-risk areas. It has been expanded step by step to other districts, with almost 100% coverage in 2014 by domestic vaccine only. However, it is still not provided on a routine basis. During decades, the incidence of acute viral encephalitis has been decreasing. Because of better reporting, a greater number of JE cases have been investigated by case-based surveillance in sentinel hospitals in five provinces and three children hospitals. Combined with WHO laboratory network in two national JE laboratories, 421 JE cases were captured in 2014. Some 45% of cases did not receive JE vaccine despite the fact that most of the cases were children; 48% cases had an unknown vaccination history. This indicated that a large number of children remained as susceptible. The Ministry of Health decided to introduce JE vaccine into routine immunizations since 2015. A JE vaccination campaign is also planned in 2016 to reduce immunization gaps. It would be expected that the JE vaccine impact would be known through well-maintained surveillance in Viet Nam.

2.11 Strengthening immunization system

2.11.1 Regional update

Routine immunization in the Western Pacific Region: what are the main challenges?

The Western Pacific Region in the last six years has maintained high coverage for most of the traditional vaccines. While most countries show high-level coverage at the national level, disparities, gaps and inequities are evident at subnational levels, and resurgence of diseases such as pertussis is becoming more frequent in some of them. Stagnant vaccination coverage is also seen at the national level in a number of countries in the Region (the Lao People's Democratic Republic, the Marshall Islands, the Federated States of Micronesia, Papua New Guinea, the Philippines, Solomon Islands and Vanuatu). Targeted interventions are being conducted in some countries in an effort to improve coverage, although progress is variable.

At the 24th TAG meeting in June 2015, Dr Jorge Mendoza-Aldana's presentation provided an updated analysis of routine immunization performance in countries of the Region, highlighting marked heterogeneous performance at subnational levels in priority countries and differences in immunization coverage between groups of countries in terms of economic development, as classified by the World Bank. Vaccine stock-outs at national and for some countries at subnational levels were also a serious problem in a number of countries.

During the presentation strong and resilient routine immunization was emphasized as the basis for achieving and sustaining elimination and control of VPDs and to effectively introduce new vaccines and decrease mortality and morbidity across the life cycle. Greater investment is needed for a programme able to efficiently manage and monitor a complex and evolving EPI landscape, and can help mobilize people to increase active demand for vaccination, thereby maximizing reach to reduce inequities in vaccination coverage.

Health system perspectives for sustainable immunization programmes

GVAP and the *Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific* are the current guiding frameworks for strengthening immunization systems and emphasizing country ownership, shared responsibility, equity, integration and financial sustainability in the pursuit of ambitions of the Decade of Vaccines goals.

Financial sustainability of immunization programmes has been raised as a concern not only in low-income countries but also in other income groups of countries. Research has found that health expenditures per capita are positively associated with DTP3 coverage and data from the Joint Reporting Form (JRF) show that in the Western Pacific Region the percentage of government funding for vaccines and routine immunizations has been declining. This is a concern given major increases in the cost of immunization programmes associated with the introduction of new vaccines and immunization-related technologies. In the Western Pacific, the ability of countries graduating from Gavi to financially sustain the introduction of new vaccines is of particular concern.

At the 24th TAG meeting in June 2015, Dr Ayesha de Lorenzo in her presentation provided a preview of the work her unit was doing in preparing financing-focused country profiles, including vaccine price and immunization cost monitoring, as well as graduation and post-graduation scenarios for Gavi-supported countries. This material can provide helpful financial evidence to countries to be used in decision-making regarding the introduction of new vaccines and other concerns.

Dr de Lorenzo also highlighted the relevance of sharing vaccine prices and provided a comparison between vaccine prices as found on the Vaccine Product, Price and Procurement (V3P) web platform, a WHO initiative to encourage transparency and sustainability.

Strategy and experience in improving immunization equity

The Division of Health Systems or MICS survey data show that significant disparities in immunization coverage exist between the richest and poorest quintiles in the Region, as large as 44% in one country. There is geographic or social distance to overcome the final stretch to reach the “last child” with immunization services. In response to the challenge, GVAP calls to recast “Reaching Every District” as “Reaching Every Community” (REC). Several countries in the Western Pacific Region have been exploring the REC strategy since as early as 2009. Commonly there are five components in REC, including identification of underserved communities, development of micro-plans securing services accessible by those communities, adapting innovations, building systems to monitor progress, and securing commitment and resources at all levels. However, the journey to implement REC is not easy in all countries due to various constraints including financing. Countries have made further efforts including issuing Ministry of Health decrees, development of national action plans or linking with HSS grants.

Challenges remain, such as the difficulty of strengthening routine immunization due to competing priority within National Immunization Programme and a lack of equity-sensitive policies and financing mechanisms. To overcome these challenges, a call to action is required to secure high-level support. There are both chronic and emerging challenges such as inadequate training and supervision, rapid urbanization and the generation of a new public health workforce, requiring different approaches and timely actions such as the development of an urban strategy and capacity-building.

2.11.2 Global update

Immunization financing in the Western Pacific: recent trends, challenges and opportunities

The Regional Committee for the Western Pacific during its sixty-fifth session in October 2014 endorsed the *Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific*, which provides countries in the Region with clear goals, objectives and main areas of work such as country ownership, shared responsibility, equity, integration and financial sustainability to achieve the goals of the Decade of Vaccine.

Ensuring that sufficient national financial resources are efficiently allocated over the long term for immunization programmes is a concern not only in low-income countries. The increased cost of immunization programmes associated with the introduction of new vaccines is a major concern also for middle-income countries (MICs), a number of which during the 2014 World Health Assembly voiced their concerns about vaccine affordability that cause many MICs to lag behind Gavi-supported countries in introducing new vaccines (e.g. PCV) into their national immunization programmes.

In her presentation, Ms Diana Chang Blanc from WHO headquarters reviewed decision-making processes and financial cycles and how they are affected by raising immunization costs, emphasizing countries graduating from Gavi support and the importance of sound comprehensive and costed multi-year planning, which all Gavi-supported countries in the Region have to update to ensure government commitment to cover those costs.

Using Western Pacific Region country data from the JRF, which Ms Chang Blanc emphasized as the main source of financial data for assessing GVAP progress, she provided examples of financial indicators. Noting an increasing trend in government financing for routine immunization since 2010, Ms Chang Blanc highlighted main challenges such as difficulty in monitor financial expenditures for routine immunization as 15 countries fail to report data through JRF.

Sustainable access to vaccines for middle-income countries – a shared strategy

Mr Michel Zaffran reported that over the past decade access to vaccines in MICs has been much debated, fuelled by the understanding that the majority of poor people and vaccine-preventable deaths are now in MICs and by a concern that this group of countries may be missing out on opportunities to introduce new vaccines, with donors focused on low-income countries.

In light of the above and at the request of SAGE, WHO in June 2014 convened the MIC Task Force to develop a coordinated strategy and action plan. The MIC Task Force, a group of nine immunization partners, presented to SAGE in April 2015 a proposed way forward for coordinated action to enhance sustainable access to vaccines in MICs, especially focusing on the 63 MICs not supported currently by Gavi. SAGE concurred with the general direction of the proposed MIC strategy.

Based on consultations and analyses, the MIC Task Force confirmed that the issue of access to affordable prices and timely supply is a major challenge for MICs, yet agreed that this issue should not be tackled in isolation and that activities to consolidate demand are key to success. Four main areas of action have been identified as the pillars of the MIC strategy:

- strengthening evidence-based decision-making;
- enhancing political commitment and ensuring financial sustainability of immunization programmes;
- enhancing demand for and equitable delivery of immunization services; and
- improving access to timely and affordable supply.

In the coming months, the MIC Task Force will focus on: coordinating, monitoring and providing visibility to ongoing efforts in MICs; advocating for limited but predictable financial resources to support implementation of the strategy; and implementing pilots of comprehensive and coordinated partner support in a few selected countries and pilots of creative tools and platforms.

Collecting and disseminating vaccine product, price and procurement information through the V3P mechanism

Mr Zaffran reported that following frequent calls from several countries for greater vaccine price transparency at World Health Assembly over the last decade, WHO has been actively working with partners and countries to promote vaccine price data sharing. The WHO Vaccine Product, Price and Procurement (V3P) web platform collects and publishes data and analytics on vaccine prices and

procurement practices, through an online platform accessible on the following link: www.who.int/immunization/V3P.

The V3P website allows countries to browse through vaccine price information shared by countries and procurement agencies, as well as graphs and analyses in a very accessible and user-friendly way.

The goal of V3P is to equip countries, particularly MICs not receiving support for the purchase of their vaccines, with the information and tools they need to make informed and sustainable immunization-related decisions. Price information sharing offers a transparency that can promote stronger understanding of the factors that influence prices, enabling meaningful comparisons and improved engagement in price-related discussions.

SAGE and the World Health Assembly recommend that every country should share vaccine price information. Indicators on vaccine pricing and on the number of countries reporting prices are now monitored and reported to SAGE and the Assembly every year through the GVAP monitoring report. Twenty-five countries reported their price information last year and about 38 countries have already shared price records in 2015, including five countries from the Western Pacific Region.

All countries are therefore encouraged to participate, especially graduating or non-Gavi eligible MICs that could benefit the most from the initiative.

Any country submitting information by June 2015 will be contributing to this year's GVAP vaccine price report.

For more information, please contact: V3P-project@who.int

2.12 Vaccine safety, quality and supply chain

2.12.1 Regional update

GVAP Strategic Objective 4 highlights the importance of ensuring capacity for vaccine safety activities, including the capacity to collect and interpret safety data, with enhanced capacity in countries that introduce newly developed vaccines. During 2014–2015 many vaccine safety capacity-building activities were conducted in the Western Pacific Region. The third edition of regional immunization safety surveillance guidelines and regional vaccine safety communication guidelines are about to be finalized. Vaccine safety surveillance system assessments as part of regulatory systems assessments were conducted in Cambodia, The Lao People's Democratic Republic, the Philippines and Viet Nam. The Regional Office for the Western Pacific is finalizing a concept paper to establish subregional AEFI causality assessment committee for Pacific islands countries and areas.

A workshop on vaccine safety signal detection was held in China in October 2014, and a vaccine safety training workshop was held in Cambodia in December 2014. Technical guidance and assistance were provided to Papua New Guinea regarding the management of vaccine safety issues in view of Special Integrated Routine EPI Strengthening Programme (SIREP) and the introduction of MR vaccine (SIREP Plus) in August 2015. The Regional Office for the Western Pacific has provided technical support and advice to China, Mongolia, Papua New Guinea and Viet Nam, where serious vaccine safety incidents were reported. The Regional Office for the Western Pacific has actively cooperated with global vaccine safety initiatives and supports Western Pacific Region countries in the introduction of performance indicators and software tools such as the Vaccine Adverse Event Information Management System (VAEIMS).

2.12.2 Country report

Japan

Dr Mugen Ujiie gave a presentation on adverse events following HPV vaccination in Japan. Dr Ujiie described the AEFI surveillance system in Japan and provided information on the HPV

vaccination programme. Both Cervarix and Gardasil vaccines were being used in Japan; nearly 9 million doses were distributed and 617 severe AEFI cases were reported from December 2009 to March 2014, a rate of 6.9 per 100 000 doses. No significant difference was observed between the two types of vaccines when compared to the reported incidence rates of severe AEFIs. Adverse events categorized as “pain other than injection site” or “movement disorder” reported following HPV vaccination caused huge public and media concern.

In light of an expert committee’s recommendation, the Government in June 2013 suspended the recommendation of HPV vaccination until adequate information was provided. Following extensive investigations, the expert committee on vaccine safety concluded in January 2014 that the symptoms were likely a psychosomatic reaction. However, some experts disagreed. Thus, in October 2014 a follow-up investigation of AEFIs following HPV vaccinations was initiated. Still HPV vaccines are licensed in Japan and available in the NIP. In addition to sound scientific assessments, an effective communications strategy may help to resolve this issue.

Viet Nam

Dr Nguyen Van Cuong reported that Viet Nam domestically produces 12 kinds of vaccines. All EPI vaccines are covered by domestic production, except pentavalent vaccine. Full immunization coverage has been sustained at over 80% the past 15 years. At the same time, an AEFI surveillance system has been established as a part of national regulatory authorization (NRA) system. Provincial preventive medicine centre staff members are responsible for the investigation of AEFI cases in coordination with regional staff. The causality committees at the provincial level make assessments based on investigations and report their findings to the national level within 24 hours.

The national level has responsibility for the conclusive assessment of cases, and provides quality control and feedback to the public. All health workers at each level have been trained for the AEFI surveillance system. Serious AEFI cases in 2007 and 2013 led to a significant drop immunization coverage of hepatitis B and pentavalent vaccine. This experience led the Ministry of Health to develop a risk communication strategy at all levels and emphasize strengthening timely AEFI assessments in the NRA. In conclusion, the functioning of the NRA in this regard has been improved, and the NRA was assessed by WHO in April 2015 as functional. Viet Nam will continue to strive to provide a strong immunization system.

2.12.3 Regional update on national regulatory authorities

Since the last TAG meeting, the assessments of regulatory systems have been conducted in one producing country (Viet Nam) and three importing countries (Cambodia, the Lao People's Democratic Republic and the Philippines). The assessment in Viet Nam in April 2015 concluded that it has reached the fully functional status as per WHO criteria, granting eligibility for manufacturers to apply their vaccines for WHO prequalification.

Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific convened its second steering committee meeting and the third NRA workshop in Manila in September 2014, where it updated its annual work plan and agreed on priority areas for working group activities. The Regional Office for the Western Pacific, in collaboration with Regional Office for South-East Asia, also supported initiating vaccine security collaboration with the Association of Southeast Asian Nations (ASEAN) by bringing various stakeholders from 10 ASEAN countries.

The Regional Office for the Western Pacific is working in the following areas:

- **Capacity-building** for critical regulatory functions, especially, the participation of countries procuring vaccines through the United Nations in collaborative registration procedures for vaccines, and for national and global information-sharing on vaccine pharmacovigilance.

- **Addressing regulatory issues** to meet the programmatic needs of NIPs in increasing immunization coverage, including regulatory evaluations of label variations that allow on-label controlled temperature chain (CTC) use for hepatitis B and regulatory evaluations of label variations that allow maternal immunization for inactivated influenza vaccines.
- Supporting NRA collaboration, including quality control (QC) laboratory collaboration to develop regional working reference standards that allow inter-laboratory comparison of vaccine QC assay results and the establishment of a vaccine security forum.

2.12.4 Regional update on immunization supply chain

Regional Office for the Western Pacific

The success of the immunization programme greatly depends on a functional end-to-end immunization supply chain and logistic system. GVAP Strategic Objective 4 highlights the importance of strengthening infrastructure and logistics and innovating to improve cold-chain capacity and logistics, as well as waste management, minimizing the environmental impact of energy, materials and processes used in immunization supply systems, both within countries and globally. Strategic Objective 4 also calls for staff supply systems with adequate numbers of competent, motivated and empowered personnel at all levels and the establishment of information systems that help staff to track the available supply accurately.

In 2014–2015 several capacity-building activities were conducted in the Western Pacific Region. An assessment of needs in 2014–2018 for effective vaccine management (EVM) was conducted for priority countries. Formal EVM assessments (EVMAs) were conducted in Kiribati, the Lao People's Democratic Republic and Vanuatu in 2014–2015. Arrangements are under way to conduct EVM assessment in Cambodia, Mongolia, Papua New Guinea and Viet Nam in 2015. With the IPV introduction fund and funds from Gavi, Cambodia, the Lao People's Democratic Republic, the Philippines and Solomon Islands were supported for the purchase of cold-chain equipment. Key challenges include: a) an increasing demand for cold-chain capacity with the introduction of new vaccines; b) timely maintenance and replacement of cold-chain facilities and equipment; and c) limited financial support for maintenance, upgrading and refurbishment, particularly in hard-to-reach areas.

United Nations Children's Fund (UNICEF)

Immunization supply chain (ISC) systems serve as backbone of the immunization programme. With the rapid introduction of bulky new vaccines in recent years, ISC systems are overstretched. EVMAs in several Western Pacific Region countries in 2010–2013 reveal that significant gaps existed in the systems. The assessments also observed gaps in developing, implementing and monitoring EVM improvement plans. A high number of EVMAs were conducted in the Region in 2015. Adequate attention should be given to a comprehensive EVM approach by emphasizing continuous improvement, including EVMAs, EVM IP development, and implementation and monitoring. Also, it is imperative to ensure a few essential elements are in place, such as a regularly updated cold-chain inventory, a well-functioning maintenance mechanism, effective stock management and establishment of continuous temperature monitoring systems.

The existing ISC systems were designed 30 years ago, and there is a need to review ISC systems and redesign them as required. Human resources remain a critical constrain, thus there is urgent need to address this bottleneck. New technologies can provide some potential solutions to address various challenges that countries face.

In summary, there are growing concerns about under-investment in ISC systems and tremendous work will be required to fix the basic systems and adopt innovations. Sufficient attention is required for comprehensive EVM approaches, and the close monitoring of EVM IP implementation is crucial.

Action to address human resource constraint also is needed, and looking into future, system reviews and redesigns should be high on the NIP agenda.

2.12.5 Country reports

Lao People's Democratic Republic

Dr Kongxay Phounphenghack discussed the components of the ISC, including human resources, cold-chain equipment, and vaccine stock management and logistics. He spoke about the changing immunization scenario of his country, which has a bearing on the supply chain. He presented the EVM score of 2010 and 2014, which showed a significant improvement in the scores. He reported the available human resources in the country for ISC, and said that around 82% of the health facilities have a functional cold chain. He outlined the challenges related to human resources, vaccine management and cold-chain vaccine management. He outlined the initiatives taken by the Government which included the cold chain information system, with cold-chain management system at all levels. He highlighted the way forward for the country, including finalization and implementation of EVM improvement plan, emphasizing routine programme monitoring and performance improvement and the establishment of an appropriate management information system.

Papua New Guinea

Dr William Lagani said the cold chain remains a big challenge for Papua New Guinea. Currently 70% of the health facilities have functional cold-chain equipment, but 82% of it is more than 10 years old. Cold-chain distribution is mainly controlled by National Vaccine Store in the capital city, with support from 22 provincial store and eight district stores to cover more than 800 health facilities and 10 000 field clinics (mobile and outreach clinics) in the country.

The country is currently using the Government procurement system for all non-Gavi vaccines and the UNICEF procurement system for the Gavi-supported vaccines. The Government procurement system is time consuming and often takes almost seven to eight months to procure any specific vaccine resulting in stock-outs. The Department of Health is planning to use the UNICEF procurement system to overcome the problem.

Additional challenges to the routine EPI in Papua New Guinea include a decentralized government administrative system that does not ensure adequate financial resources for EPI programme, lack of commitment from the managers, poor communication from the national to provincial level, and poor access to the community.

Despite all these challenges, the country is moving forward to improve routine EPI activities, vaccine management and the cold-chain system. The procurement of cold-chain equipment is one of the priorities for the Department of Health. The department, with support from other technical agencies, has already started rolling out an EPI management and micro-plan workshop for all the provinces. The country is also planning to implement the Special Integrated Routine EPI Strengthening Programme starting August 2015 to achieve the national target of at least 90% coverage of every antigen by 2020.

2.13 Interagency Coordinating Committee meeting

An Interagency Coordinating Committee meeting was attended by all TAG meeting participants, as well as representatives of 16 agencies. Areas of work requiring partner support and collaboration included routine immunizations, the *Polio Endgame Strategy*, measles and rubella elimination, hepatitis B control, laboratory activities, new vaccine introduction, surveillance, and immunization safety and regulation.

Five representatives from donor and partner organizations spoke during the session: from Gavi, the Vaccine Alliance, Dr Raj Kumar; from the National Institute of Infectious Diseases, Japan,

Dr Tomimasa Sunagawa; from Rotary International Polio Plus, Mr Oscar de Venecia; and from the UNICEF East Asia and Pacific Regional Office, Dr Wang Xiaojun.

The donors and partners described their immunization programmes, presented their activities, highlighted their continued commitment to immunization in the Western Pacific Region. They proposed new areas of work and collaboration. They also praised the results achieved in the Region. The TAG chairperson thanked the donors and partners for their support and acknowledged the importance of their work in collaboration with ministries of health, WHO and other partners.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Measles and rubella elimination

A. Measles Elimination

TAG congratulates the three countries – Brunei Darussalam, Cambodia and Japan – that were verified in March 2015 as having achieved the interruption of endemic measles virus transmission for a period of at least 36 months; these countries joined the four countries and areas that were verified in March 2014 –Australia, Macao SAR (China), Mongolia and the Republic of Korea.

TAG notes that the regional measles incidence (per one million population) significantly increased from 5.9 in 2012 to 17.7 in 2013 and 44.0 in 2014. This increased incidence of measles virus transmission can be attributed to: (i) resurgence of endemic transmission in endemic countries; (ii) large-scale outbreaks following importation in countries with low or no recent documented measles transmission; and (iii) multiple importations in countries that have achieved or are approaching interruption of endemic measles virus transmission.

TAG notes the changing epidemiology and age distribution of measles cases observed in recent outbreaks, with decreased incidence among children targeted for vaccination and increased incidence among infants too young to be vaccinated, as well as among adolescents and adults. This age pattern may be expected when vaccination has prevented measles cases among children in age groups targeted through routine and supplemental immunization activities and immunity gaps remain in older persons.

As of June 2015, all except four countries (the Lao People's Democratic Republic, Papua New Guinea, Solomon Islands and Vanuatu) in the Region have introduced a routine second dose of measles- containing vaccine (MCV2).

TAG acknowledges that a highly proficient laboratory network with strong quality assurance provides laboratory confirmation and genotyping evidence to the measles and rubella elimination programme in the Western Pacific Region, which can better inform immunization strategies.

TAG notes that for the countries that have verified measles elimination, genotype evidence supports the interruption of endemic measles virus transmission.

B. Rubella Elimination

TAG acknowledges that a regional rubella elimination goal was endorsed by the Regional Committee for the Western Pacific in October 2014 as one of eight regional immunization goals specified by the Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific. TAG notes that rubella-containing vaccine has now been introduced or will soon be introduced (Papua New Guinea, Vanuatu and Viet Nam) into the routine immunization programmes of all Member States.

TAG notes that many countries in the Region have been utilizing the measles elimination platform and strategies to accelerate or initiate activities for rubella elimination. Several countries in the Region have made significant progress toward rubella elimination recently and have set target years for achieving elimination (e.g. 2020 for Japan and Mongolia). The Global Vaccine Action Plan 2011–2020 has established the goal of achieving measles and rubella elimination in five of six WHO regions by 2020.

To support countries in the Region to develop a national policies, plans and strategies to eliminate rubella and prevent CRS as the TAG recommended in 2014, a regional plan of action for rubella elimination and CRS prevention in the Western Pacific should be prepared just as the Western Pacific Regional Plan of Action for Measles Elimination was developed in 2003. Since several countries in the Region are approaching the interruption of indigenous rubella virus transmission, guidelines for verification of rubella elimination should be also developed, similar to what was developed for measles elimination.

Recommendations

- 1) TAG recommends that countries achieve and maintain high coverage with the timely administration of two doses of measles- and-rubella-containing vaccine in accordance with the national immunization schedule. Countries in the Region that have not yet introduced the second routine dose of measles- and-rubella-containing vaccine (MRCV) should take steps to improve coverage of MRCV1 and introduce MRCV2. School enrolment for all ages (primary, secondary and post-secondary) should be used as an opportunity to check full vaccination status and administer missed doses.
- 2) Countries experiencing endemic measles virus transmission or measles outbreaks following importation(s) should recommit to implement actions recommended by TAG in its 23rd meeting in June 2014, specifically to:
 - a. conduct detailed analyses of the coverage data and the epidemiology of measles cases and outbreaks including genotyping data on chains of transmission;
 - b. update their national measles-rubella elimination plans and strategies;
 - c. develop or update subnational plans and strategies (endemic countries with large population);
 - d. update and actively implement their measles outbreak response plans including the early notification of nearby countries and areas about measles virus transmission;
 - e. enhance surveillance activities with aggressive case detection and thorough outbreak investigations as well as appropriate case management and vaccination of susceptible contacts;
 - f. identify immunity gaps by geographic area, birth cohort and risk group;
 - g. fill immunity gaps (e.g. selective immunization activities or smaller-scale, such as regional or province-wide, supplemental immunization activities [SIAs] targeting appropriate age groups; or more frequent follow-up SIAs targeting birth cohorts born after the last SIA in specific regions or provinces), based on country-level data; in outbreak settings, children 6 months of age and older should be vaccinated. Children who receive a dose of measles-rubella vaccine before the recommended age specified in the national immunization schedule should receive two doses according to the national schedule with at least 30 days between doses. Measles-rubella combination

vaccines should be used for all routine and supplementary immunizations activities rather than using single antigen measles or single antigen rubella vaccines;

- h. conduct high-quality SIAs with >95% coverage based on thorough analysis of and lessons learnt from the past SIAs; analysis should include identification of the susceptible population(s), the geographic areas to be covered and specific high-risk groups; post-campaign coverage surveys should be conducted;
 - i. implement infection control measures and health-care facility practices to prevent nosocomial transmission of measles and rubella including vaccination of health workers; and
 - j. encourage full vaccination prior to international travel for all travelers and especially for those who travel to and from measles-endemic or measles-infected countries and areas.
- 3) WHO should continue to work with other international partners in supporting countries to plan and conduct these actions.
 - 4) WHO should update the current *Western Pacific Regional Plan of Action for Measles Elimination* (2003) with inclusion of the following components:
 - a. guidance on conducting risk assessments and outbreak response immunization activities followed by implementation of targeted strategies for preventing and interrupting measles virus transmission among young infants, adolescents and adults by identifying risk factors/characteristics of affected people (e.g. health-care workers, university students, military personnel, migrants); and
 - b. strategies for rubella elimination.
 - 5) TAG endorses the report and recommendations of the Fourth Annual Meeting of the Regional Verification Commission (RVC) for Measles Elimination in the Western Pacific held in March 2015. TAG encourages expanding the terms of reference of the RVC to include rubella elimination. WHO should update the current *Guidelines on Verification of Measles Elimination* (2013) with inclusion of components for verification of rubella elimination.
 - 6) Now that all countries and areas have introduced (or will introduce during 2015–2016) rubella- containing vaccine into their routine immunization programmes and the Western Pacific Region has committed to eliminate rubella, TAG recommends:
 - a. establishment of a regional rubella elimination target date of 2020; and
 - b. that the sixty-seventh session of the Regional Committee for the Western Pacific in 2016 consider setting a target year for rubella elimination as an agenda item.
 - 7) WHO should continue to work with other international partners in supporting countries to strengthen rubella and CRS surveillance, including virological investigation.

3.2 Hepatitis B accelerated control

Conclusions

TAG is pleased with the tremendous progress towards the 2017 goal of <1% HBsAg prevalence among 5-year-old children. The progress is due to the commitment and actions of Member States and is a true public health success story. TAG recognizes, however, that in several countries additional efforts to increase hepatitis B birth-dose coverage are needed in order to achieve the goal. TAG notes

with concern the persistent low birth-dose coverage in high-population countries, including the Philippines and Viet Nam.

TAG notes the increased interest of countries in the Region in using hepatitis B vaccine outside the traditional 2–8° C range. TAG recognizes that this strategy is important for achieving the regional hepatitis B control goal. The main obstacle to widespread adoption of this strategy is the lack of a hepatitis B vaccine that is labelled for use outside the traditional 2–8° C range. Despite a large body of evidence documenting the safety and effectiveness of many hepatitis B vaccines when used for up to one month at ambient temperatures, without a product label for use in this manner, it is difficult for countries to adopt this strategy.

Recommendations

- 1) TAG endorses the proposed hepatitis B health worker vaccination target in the *Regional Action Plan for Viral Hepatitis in the Western Pacific*: adoption of a health worker hepatitis B vaccination policy in all Western Pacific Region countries and areas by 2020.
- 2) TAG recommends that a decision on including a new target on further reducing mother-to-child transmission of hepatitis B in the *Regional Action Plan for Viral Hepatitis in the Western Pacific* be deferred until global guidance on the strategies and a means for measuring progress in reducing mother-to-child hepatitis B transmission, such as the addition of antivirals in late pregnancy, is provided.
- 3) TAG reiterates its support for the time-limited (up to 30 days) use of hepatitis B vaccine outside of the traditional 2–8° C range for health facilities without a working refrigerator. TAG calls on hepatitis B vaccine manufacturers to initiate the necessary steps to seek a label variation of their hepatitis B vaccine for use at temperatures outside the traditional 2–8° C range in a controlled temperature chain.
- 4) TAG recommends that countries with hepatitis B vaccine hesitancy problems undertake activities to regain health worker and public confidence in hepatitis B birth-dose vaccination.
- 5) TAG endorses the 2015 Expert Resource Panel (ERP) recommendations.
- 6) TAG recommends that countries and areas strengthen collaboration between immunization and maternal and child health programmes to utilize opportunities to improve birth-dose vaccination.

3.3 Polio eradication and polio endgame strategy

Conclusions

- 1) TAG acknowledges the tremendous progress towards global polio eradication, noting that in 2015 wild poliovirus Type 1 (WPV1) has been identified in only two countries (Pakistan with 24 cases and Afghanistan with two cases), which is markedly lower than during the same period in 2014. No cases have been reported from Africa in 2015. Furthermore, no wild poliovirus Type 2 (WPV2) has been reported in the world since 1999 and no wild poliovirus Type 3 (WPV3) since 2012. The Western Pacific Region has retained its polio-free status since 2000.
- 2) TAG notes the presence of countries and subnational areas that have been identified as being at increased risk for poliovirus importation or ongoing transmission following an imported virus.
- 3) TAG acknowledges the plan for the Global Polio Laboratory Network to expand the number of laboratories in the Region with the capacity to perform intratypic differentiation and to introduce an enhanced intratypic differentiation method to increase the sensitivity for detecting and identifying polioviruses quickly.

- 4) TAG notes that four countries in the Region are performing environmental surveillance to complement acute flaccid paralysis (AFP) surveillance, and that the Region will need to start preparing for the expansion of environmental surveillance to monitor the effectiveness of Type 2 containment in essential facilities.
- 5) TAG acknowledges progress at the country and regional levels in implementation of the global *Polio Eradication and Endgame Strategic Plan 2013–2018* with all 17 countries and areas that use only OPV committing to introduce at least one dose of IPV by end 2015.
- 6) TAG notes that delays in IPV introduction may occur in some countries and areas due to lack of global supply.
- 7) TAG notes the recent WHA resolution calling on Member States to accelerate preparation and planning for the globally synchronized replacement of tOPV with bOPV in April 2016 (i.e. the switch) including the need for countries to register bOPV before April 2016 for use in routine immunization programmes and to develop costed national switch plans by September 2015.
- 8) TAG notes the need to support implementation of appropriate containment of WPV2 in essential facilities by the end of 2015 and of Type 2 Sabin poliovirus within three months of global withdrawal in April 2016 of the Type 2 component in OPV as articulated in the *WHO Global Action Plan to Minimize Poliovirus Facility-associated Risk (GAP III)*.

Recommendations

- 1) TAG recommends that countries and areas in the Region achieve and maintain international standards for AFP surveillance performance supported by WHO-accredited laboratories. High-risk areas should be identified by conducting annual subnational risk assessments. Special emphasis to strengthen immunization and surveillance programmes should be given to underperforming and high-risk areas.
- 2) Countries should finalize their national polio endgame plans addressing all four objectives included in the *Polio Eradication and Endgame Strategic Plan 2013–2018*.
- 3) TAG recommends that countries and areas adhere to timelines for the 2015 introduction of IPV, recognizing that vaccine supply may force some countries or areas to delay introduction to early 2016.
- 4) All countries that will continue using OPV in their routine immunization programmes after January 2016 should:
 - a. expedite the registration of bOPV for use in the routine immunization programmes and, if required in the interim, authorize its use on the basis of its prequalification granted by WHO;
 - b. complete other requirements, such as adding bOPV to the national drug formulary, that may be required for use of bOPV in the routine immunization programme;
 - c. in preparation for the April 2016 switch, develop a plan to switch from tOPV to bOPV by September 2015, with plans to include activity timelines, bOPV requirements, a tOPV disposal strategy and costing; and
 - d. to increase population immunity, to decrease the risk of vaccine-derived polioviruses (VDPVs) and to reduce vaccine wastage, countries should utilize excess stocks of tOPV in SIAs during the first quarter of 2016.
- 5) TAG recommends that countries and areas comply with the requirements of GAP III and also:
 - a. update national inventories of polio viruses (wild-type, vaccine-derived or OPV/Sabin-like) and prepare for destruction or containment of WPV2 by end of 2015 (Phase I);
 - b. nominate a national/subregional poliovirus containment coordinator;

- c. identify a national regulatory authority for containment that shall certify proposed essential facilities as compliant with GAP III in preparation for the commencement of Phase II; and
- d. implement appropriate containment of WPV2 in essential facilities by the end of 2015 and of Type 2 Sabin poliovirus within three months of global withdrawal of the Type 2 component in OPV in April 2016 (Phase II) in accordance with GAP III.

3.4 Maternal and neonatal tetanus elimination

Conclusion

TAG acknowledges progress in the Region towards maternal and neonatal tetanus elimination with the validation of Viet Nam (2005), China (2012) and the Lao People's Democratic Republic (2013).

The TAG congratulates the Philippines for conducting a lot quality assurance-cluster sampling (LQA-CS) survey in 2015 in which 16 of 17 subnational regions were validated as having achieved MNT elimination and notes that additional tetanus toxoid supplementary immunization activities (TT-SIAs) were recommended for the one remaining region, the Autonomous Region of Muslim Mindanao and looks forward to national validation of MNT elimination.

TAG notes that Cambodia is planning to conduct an LQA-CS survey immediately following the TAG meeting in June 2015.

Recommendations

- 1) TAG recommends that the three remaining countries implement required actions to achieve the validation of MNT elimination as soon as possible:
 - a. the Philippines should complete the recommended TT-SIAs in the Autonomous Region of Muslim Mindanao by the end of 2016 in order to achieve national validation of MNT elimination;
 - b. Cambodia should conduct the planned LQA-CS survey in 2015; and
 - c. Papua New Guinea should complete the planned data review and if supported by data review conduct a pre-validation assessment in 2016.
- 2) Countries and areas should maintain MNT elimination by implementing the following actions:
 - a. Review, and if necessary modify, the national immunization schedule to provide protection against tetanus from infancy through adulthood for both males and females;
 - b. annually review the WHO/UNICEF district data spreadsheet and take appropriate corrective actions;
 - c. achieve and maintain a sensitive neonatal tetanus surveillance system; and closely collaborate with maternal and child health programmes to promote administration of tetanus-toxoid-containing vaccine (TTCV) during antenatal care visits, as well as clean delivery and clean cord-care practices.³ In accordance with the 2006 Tetanus vaccine WHO position paper, TAG recommends, as a rule, that vaccine combinations containing diphtheria toxoid and tetanus toxoid, rather than tetanus toxoid alone, should be used when immunization against tetanus is indicated.^{3.5} Evidence-based introduction of new vaccines.

3.5 Evidence-based introduction of new vaccines

Conclusion

TAG notes that low- and middle-income countries in the Western Pacific Region have made significant progress in introducing new and underutilized vaccines, especially PCV, in the past year, yet an equity gap persists as they still lag far behind high-income countries in including new or underutilized vaccines in their national immunization programmes. Achievement of the *Global Vaccine Action Plan* goal for introduction of new and underutilized vaccines, as adopted in the *Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific*, requires that countries evaluate evidence on the epidemiology and burden of disease, cost and cost-effectiveness of vaccination, the role of other disease prevention and control measures, vaccine characteristics, vaccine supply, and immunization programme and health system requirements for introducing the vaccines. It is noted that the introduction of new vaccines increases immunization programme costs for both vaccines and related service delivery.

An increasing number of Member States are collecting and evaluating such evidence to develop and sustain vaccine introduction policies, and some Member States have used the evidence to formulate national plans. Disease-burden evidence from other countries in the Region and official disease-burden estimates are relevant and appropriate to use in assessing the need for a vaccine. WHO plays an important role in providing technical support and capacity strengthening for the generation of required evidence. Surveillance with laboratory confirmation is a key source of evidence, and the quality of surveillance requires consistent attention. Implementation of the recent WHO recommendations for seasonal influenza vaccination requires consideration of regulatory issues and vaccine selection for tropical countries.

Recommendations

- 1) TAG reiterates its advice that each Member State develops a national plan for evidence-based introduction of new vaccines in consultation with national immunization technical advisory groups (NITAGs) or similar groups. Countries are urged particularly to consider the new and underutilized vaccines recommended for inclusion in all national infant immunization programmes, namely *Haemophilus influenzae* Type b, hepatitis B, inactivated polio, pneumococcal conjugate, rotavirus and rubella vaccines. Japanese encephalitis (JE) vaccine should be considered in endemic areas and human papillomavirus (HPV) vaccine where cervical cancer is a public health priority. TAG suggests that the plan for new vaccine introduction be part of the comprehensive multi-year plan for immunization or other health plans. TAG reiterates its advice that each Member State develops a national plan for evidence-based introduction of new vaccines in consultation with national immunization technical advisory groups (NITAGs) or similar groups. Countries are urged particularly to consider the new and underutilized vaccines recommended for inclusion in all national infant immunization programmes, namely *Haemophilus influenzae* Type b, hepatitis B, inactivated polio, pneumococcal conjugate, rotavirus and rubella vaccines. Japanese encephalitis (JE) vaccine should be considered in endemic areas and human papillomavirus (HPV) vaccine where cervical cancer is a public health priority. TAG suggests that the plan for new vaccine introduction be part of the comprehensive multi-year plan for immunization or other health plans.
- 2) TAG again urges countries to strengthen surveillance, including laboratory confirmation, for diseases targeted by new vaccines to monitor and improve the quality of surveillance implementation.
- 3) TAG requests WHO to provide technical support and capacity strengthening for the development of national plans for the evidence-based introduction of new vaccines and to assess and improve the quality of surveillance.
- 4) TAG encourages countries introducing new vaccines to utilize the opportunities to establish synergistic approaches, as outlined in the *Global Action Plan for Pneumonia and Diarrhoea* and

the *Comprehensive Cervical Cancer Prevention and Control* guidance note, and to strengthen immunization systems.

3.6 Japanese encephalitis accelerated control

Conclusions

TAG notes several important advances in JE control during the past year. In October 2014, the Regional Committee for the Western Pacific endorsed a regional goal for accelerated control of JE. In addition, advances in the development, licensure and availability of vaccines, as well as global guidance and programmatic steps by Member States, are moving the Region towards achievement of this new regional goal. These advances include the prequalification by WHO of a third JE vaccine, improvement in the choice and availability of vaccines for introduction by countries that rely on Gavi support or UNICEF procurement; publication of a new WHO position paper on JE vaccines; the provision of guidance on vaccine selection and vaccination strategies; and the expansion of JE vaccination programme coverage by the Lao People's Democratic Republic and Viet Nam. In addition, Cambodia and the Philippines established target dates for national JE vaccine introduction, and the Philippines became the first country to use a new tool to assess the quality of JE surveillance.

Although some progress has been made, weaknesses in surveillance continues to limit efforts to define JE epidemiology and disease burden and to measure the impact of vaccination in some countries. Strengthening of surveillance in countries that have not yet achieved a high degree of JE control is critical for providing disease-burden data and evidence of vaccine impact. The quality of testing in the Western Pacific Region JE laboratory network has improved but needs continued strengthening.

Recommendations

- 1) TAG requests the WHO Regional Office for the Western Pacific develop operational definitions and targets, timelines and strategies to achieve a JE accelerated control goal through consultation with experts and Member States during the coming year.
- 2) The TAG reiterates the recommendation of the 22nd and 23rd TAGs that JE surveillance with laboratory confirmation should be further strengthened in endemic areas of the Western Pacific Region, and sentinel surveillance should be systematized to facilitate reporting at the regional level.
- 3) TAG suggests that the WHO Regional Office for the Western Pacific expand use of the JE surveillance structured tool to assess the quality of surveillance in countries that have not yet achieved a high degree of JE control.

3.7 Strengthening Immunization Systems – Routine Immunization

Conclusions

- 1) TAG acknowledges the sustained high immunization coverage at the regional level and commends countries' efforts to develop and implement strategies to improve coverage including the Reaching Every Community and Reaching Every Child strategies.
- 2) TAG notes, especially in priority countries, the uneven progress in vaccination coverage at subnational levels that may be related to inequitable access.
- 3) TAG notes the heterogeneous (variable and insufficient) progress in vaccination coverage in middle-income countries and welcomes the initiative by WHO and other partners to support middle-income countries without external support to improve vaccination coverage levels and the uptake of new vaccines.

- 4) Further improvements in immunization coverage will require tailored solutions based on country-specific analysis to access underserved and hard-to-reach children. Among these solutions are two approaches that offer opportunities to reach unvaccinated and under-vaccinated children beyond the first year of life with recommended vaccines to ensure they are fully vaccinated against vaccine-preventable diseases. The strategies are:
 - a. establishing an immunization visit platform in the second year of life to deliver scheduled vaccines such as DTP4 and MCV2, as well as providing catch-up vaccination for those vaccine doses missed during the first year of life; and
 - b. establishing routine school immunization record checks and follow-up vaccinations with missed doses of measles, rubella and other vaccines so all children can enter school fully protected from vaccine-preventable diseases.
- 5) TAG notes the need for continued efforts by Member States to improve the quality of immunization data, including financing-related data.
- 6) TAG acknowledges increased country ownership of immunization programmes as reflected by the overall trend of increasing domestic expenditures for routine immunization in the Region when compared to the 2010 baseline, but recognizes that countries will continue to be significantly challenged in securing financial sustainability given growing programme costs.

Recommendations

- 1) TAG recommends countries with insufficient levels of vaccination coverage or prolonged vaccine-preventable disease outbreaks consider conducting comprehensive programme reviews to identify characteristics of children who are unvaccinated or under-vaccinated and define approaches to address them.
- 2) TAG encourages countries to establish and maintain a platform to provide immunizations in the second year of life as an opportunity to reach all children, including hard-to-reach children, with scheduled vaccines and for catch-up immunizations as needed. The WHO Regional Office for the Western Pacific should inventory which countries and areas have programme policy restrictions that limit vaccinations offered after 12 months of age and should work with countries and areas to remove these barriers to vaccination.
- 3) TAG encourages all countries to implement school immunization record-checking programmes to maximize immunization coverage through catch-up immunization as needed. The recently published experience of China in the use of school immunization record checking should be distributed to all countries by the Regional Office for the Western Pacific as an example of what can be achieved.
- 4) TAG reiterates its recommendation from the 23rd TAG to countries to share subnational coverage data with the WHO Regional Office for the Western Pacific.
- 5) TAG urges Member States to develop costed multi-year immunization plans as a tool to advocate for and enable the development of financial sustainability strategies.
- 6) Member States are urged to sustain and improve the consistency of annual reporting of government immunization expenditures including vaccine price and procurement information in the WHO–UNICEF Joint reporting form or V3P platform to strengthen programme management and to facilitate monitoring of progress on the *Global Vaccine Action Plan* goal for Strategic Objective 1.

- 7) TAG continues to endorse the implementation of Immunization Week annually in April and encourages all Member States in the Region to participate in this important event as one mechanism to increase population demand for vaccination.
- 8) TAG reiterates its request to WHO to explore interest among Member States in the Region to establish a regional pooled procurement mechanism, such as the Vaccine Independence Initiative or VII, to increase vaccine security and to facilitate access to new vaccines.

3.8 Vaccine/Immunization safety, quality supply and immunization supply chain/logistics

Conclusions

- 1) TAG reiterates that ensuring immunization safety and effectively responding to AEFIs is critical for building public trust in national EPI programmes. This includes timely and effective communication with the public.
- 2) TAG appreciates Member States' timely and effective responses to immunization safety incidents.
- 3) TAG notes that Member States have made strenuous efforts to improve vaccine safety including analysing the capacity gap, developing regional and national guidelines on causality assessment and communications, and conducting national and subnational vaccine safety training.
- 4) TAG notes the fragility of the immunization supply chain, including the cold chain, logistics and effective supply chain management. TAG notes that Member States and international partners have made considerable efforts to improve cold-chain capacity and logistics through periodic effective vaccine management assessments and updating cold chain and logistics improvement plans.
- 5) TAG congratulates Viet Nam's Ministry of Health for establishing a fully functional national regulatory authority aligned to WHO's assessment criteria for vaccine-producing countries.
- 6) TAG notes that NRA systems and functions for vaccines require strengthening in many countries and areas, especially non-producing countries and areas of the Region.
- 7) TAG appreciates that the WHO Regional Office for the Western Pacific and Member States made progress in establishing a regional alliance to coordinate and support countries in vaccine safety.

Recommendations

TAG urges all Member States:

- 1) to further strengthen the immunization safety surveillance systems, including AEFI surveillance and NRA adverse drug reactions surveillance, considering the importance of immunization safety practices to maintain high-quality immunization services;
- 2) to make continuous efforts to analyse the capacity gap, develop and update national guidelines on vaccine safety surveillance, provide national and subnational training, and establish and ensure functionality of national immunization safety causality committees;
- 3) to provide timely and appropriate responses to immunization safety incidents including effective and timely communication with media and the public, and to share the information rapidly through regional and global vaccine safety surveillance networks;

- 4) to continue strengthening immunization supply chain performance through periodic effective vaccine management assessments and actively implement and monitor the improvement plans, and ensure that they are incorporated within the overall comprehensive multi-year plan;
- 5) to invest in human resources for the immunization supply chain, recognizing that they serve as the backbone of immunization programmes;
- 6) to regularly analyze immunization safety surveillance data and use it to guide capacity-building for immunization safety practices, particularly in areas where programme errors are often observed;
- 7) to implement appropriate waste-management policies, including recommended systems for disposing sharps;
- 8) to strengthen vaccine regulatory systems and implement World Health Assembly resolution WHA67.20 on regulatory system strengthening for vaccines as appropriate; and
- 9) to engage in and strengthen the regional alliance of national regulatory authorities, recognizing the importance of collaboration to pool regulatory capacities to promote greater access to quality, safe, efficacious and affordable vaccines.

The TAG advises WHO:

- 1) to continue to support Member States to improve vaccine/immunization surveillance systems in low- and middle-income countries in the Region;
- 2) to accelerate the process of formulating subregional AEFI causality assessment committees for Pacific Island countries and areas;
- 3) to provide capacity-gap assessment and capacity-building support to low- and middle-income countries for continued improvement of vaccine regulatory systems and implementation of institutional development plans;
- 4) to promote the greater participation of Member States in existing international and regional initiatives for collaboration and cooperation for regulatory harmonization of norms and standards and procedures in accordance with WHO principles and guidelines; and
- 5) to develop regional plans for NRA strengthening following global guidance and in consultation with the Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific.

ANNEXES

Annex 1. Timetable

Time	Tuesday, 9 June 2015	Time	Wednesday, 10 June 2015	Time	Thursday, 11 June 2015	Time	Friday, 12 June 2015
0800–0830 0830–0900	REGISTRATION 1. Opening <ul style="list-style-type: none"> Opening speech Self-introduction Election of officers: Chairperson, Vice-Chairperson and Rapporteur Administrative announcements 	0800-0815 0815-0830 0830-0845 0845-0915 0915-0945 0945-1000 1000-1030	5. Polio eradication and Polio Endgame Strategy 5.1 Global updates 5.2 Objective 1: Poliovirus detection and interruption <ul style="list-style-type: none"> Acute flaccid paralysis surveillance, routine and supplementary polio immunization Laboratory network including intratypic differentiation expansion and environmental surveillance 5.3 Objective 2: Immunization systems strengthening and oral polio vaccine (OPV) withdrawal <ul style="list-style-type: none"> IPV introduction update and switching from trivalent OPV to bivalent OPV Technical guidance for the switch from trivalent (tOPV) to bivalent oral polio vaccine (bOPV) Country report : China Discussion	0830-0850 0850-0855 0855-0905 0905-0915 0915-0925 0925-0945 0945-1000 1000-1015 1015-1035	8. Japanese encephalitis (JE) accelerated control 8.1 Global and regional update 8.2 JE laboratory network update 8.3 Country reports <ul style="list-style-type: none"> Lao People's Democratic Republic Viet Nam Discussion 9. Strengthening immunization system 9.1 Regional update <ul style="list-style-type: none"> Routine immunization in the Western Pacific: what are the main challenges? Health system perspectives for sustainable immunization programmes Strategy and experience in improving immunization equity Discussion	0800–1130	Preparation of the Technical Advisory Group's conclusions and recommendations <i>(TAG members only)</i>
0900–0930	GROUP PHOTO AND COFFEE BREAK	1030–1100	COFFEE BREAK	1035-1105	COFFEE BREAK		
0930-0950 0950-1010 1010-1030 1030-1045	2. Overview/Introduction 2.1 Global update on Global Vaccine Action Plan 2.2 Expanded Programme on Immunization in the Western Pacific Region 2.3 Update from Strategic Advisory Group of Experts Discussion 3. Measles and rubella elimination	1100-1120 1120-1130 1130-1140 1140-1200	5.4 Objective 3: Containment and certification <ul style="list-style-type: none"> Global Action Plan III and laboratory containment Certification of regional polio-free status and global eradication of type 2 wild poliovirus 5.5 Objective 4: Legacy planning <ul style="list-style-type: none"> Recognition of the 25th anniversary of global polio laboratory network and legacy planning Discussion	1105-1120 1120-1140 1140-1155 1155-1215	9.2 Global update <ul style="list-style-type: none"> Immunization Financing in the Western Pacific: recent trends, challenges and opportunities Sustainable access to vaccines for middle-income countries - a shared strategy Collecting and disseminating vaccine product, price and procurement information through V3P mechanism Discussion	1130–1230	11. Technical Advisory Group conclusions and recommendations

1045-1105 1105-1125 1125-1145 1145-1200	3.1 Global update 3.2 Regional overview 3.3 Virologic surveillance Discussion						
1200–1330	LUNCH BREAK	1200–1330	LUNCH BREAK	1215-1345	LUNCH BREAK	1230–1330	LUNCH BREAK
1330-1345 1345-1400 1400-1415 1415-1430 1430-1445 1445-1500 1500-1515	3.4 Country reports on measles elimination <ul style="list-style-type: none"> China Viet Nam Lao People's Democratic Republic Philippines Pacific island countries and areas Mongolia Discussion	1330-1345 1345-1400 1400-1415 1415-1430 1430-1450 1450-1500 1500-1510 1510-1520	6. Maternal and neonatal tetanus elimination 6.1 Regional progress towards and maintenance of maternal and neonatal tetanus elimination 6.2 Country reports <ul style="list-style-type: none"> Philippines Malaysia Discussion 7. Evidence-based introduction of new vaccines 7.1 Global and regional update on new vaccines 7.2 Regional update: IBVPD and rotavirus laboratory network 7.3 Country report: Human papillomavirus introduction in the Philippines Discussion	1345-1355 1355-1410 1410-1425 1425-1435 1435-1445 1445-1455	10. Vaccine safety, quality, and supply chain 10.1 Regional update on vaccine safety 10.2 Country reports <ul style="list-style-type: none"> Japan Viet Nam 10.3 Regional update on national regulatory authority 10.4 Regional update on immunization supply chain <ul style="list-style-type: none"> Western Pacific Regional Office United Nations Children's Fund 	1330–1500 1500–1520	Interagency Coordinating Committee meeting Closing
1515–1545	COFFEE BREAK	1520-1550	COFFEE BREAK	1455-1525	COFFEE BREAK		
1545-1555 1555-1605 1605-1615 1615-1630 1630-1645 1645-1655 1655-1705 1705-1715 1715-1730 1730	3.5 Country reports on rubella elimination <ul style="list-style-type: none"> Singapore Malaysia Mongolia Discussion 4. Hepatitis B accelerated control 4.1 Regional overview 4.2 Controlled temperature chain overview 4.3 Country reports <ul style="list-style-type: none"> Philippines Viet Nam Discussion Regional Director's reception	1550-1605 1605-1615 1615-1630 1630-1640 1640-1650	7.4 Global and regional updates on influenza vaccines and vaccination <ul style="list-style-type: none"> Update on influenza vaccination strategies Influenza surveillance in the Western Pacific Region and vaccine strain selection Influenza vaccine regulatory issues 7.5 Country Report: Lao People's Democratic Republic Discussion	1525-1535 1535-1545 1545-1555	10.5 Country perspective on ISC <ul style="list-style-type: none"> Lao People's Democratic Republic Papua New Guinea Discussion		

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