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Report on the

# Twenty-seventh meeting of national managers of the Expanded Programme on Immunization

Sharm El-Sheikh, Egypt  
16–19 September 2012



World Health  
Organization

Regional Office for the Eastern Mediterranean

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## 1. INTRODUCTION

The Twenty-seventh intercountry meeting of national managers of the Expanded Programme on Immunization (EPI) was organized by the World Health Organization (WHO) Regional Office for the Eastern Mediterranean in Sharm El-Sheikh, Egypt, from 16 to 19 September 2012. The meeting was attended by national EPI managers from countries of the Eastern Mediterranean Region, chairpersons of National Immunization Technical Advisory Groups (NITAGs) and the Regional Technical Advisory Group (RTAG), representatives from the United Nations Children's Fund (UNICEF) headquarters, regional offices and country offices, the Centers for Disease Control and Prevention (CDC, Atlanta), Sabin Vaccine Institute, Network for Education and Support in Immunization (NESI), Agence de Médecine Préventive (AMP), and WHO staff from headquarters, the Regional Office and country offices.

The objectives of the meeting were to:

- review national and regional progress in EPI: achievements, constraints and the way forward;
- discuss recent advances in new vaccines and technologies: progress, constraints and the challenges facing their use;
- update the NITAG chairpersons and RTAG members on progress and constraints facing EPI and the expected role of NITAGs for supporting EPI.

Dr Ala Alwan, WHO Regional Director for the Eastern Mediterranean, inaugurated the meeting. In his opening address, Dr Alwan noted that countries of the Region had adopted several important targets for control, elimination and eradication of vaccine-preventable diseases. At the top were polio eradication, measles elimination, maternal and neonatal tetanus elimination and hepatitis B control. As vaccine-preventable diseases accounted for more than 20% of child deaths, immunization was certainly a key tool for achieving the targets of Millennium Development Goal (MDG) 4. Reaching high routine immunization coverage in all districts, introducing new life-saving vaccines and technologies, and implementing accelerated disease control strategies were the key pillars for achieving these targets. In the past few years, therefore, the Regional Office for the Eastern Mediterranean had been focusing on supporting countries to strengthen routine immunization services to reach the unreached, build national managerial and decision-making capacity to support new vaccines introduction and build partnership, and mobilize additional resources for effective implementation of specific disease control, elimination and eradication strategies.

Dr Alwan noted that there had been impressive progress in the programme maintaining the polio-free status of the 21 countries. Nonetheless, significant challenges and risks remained in some countries, including Pakistan and Afghanistan, which were still polio-endemic. Polio eradication had been declared a programmatic emergency for global public health by the Sixty-fifth World Health Assembly in May 2012. He underlined that achievement of MDG 4, especially in the priority countries, would continue to be at risk unless we tackled the major causes of under-five mortality, at the top of which were pneumonia and diarrhoea, with introduction of new vaccines as a main tool.

Dr Alwan further noted that, despite the commendable achievements in different areas of EPI, much remained to be done in order to achieve the targets set. Seven countries still had not reached the target for third dose of diphtheria-tetanus-pertussis vaccine (DTP3) coverage of 90% at national level. Around 2 million infants missed their third dose of DTP vaccine in 2011. He also committed that from now onwards, EPI would be a regular agenda item of the Regional Committee meeting each year.

Dr Alwan's address was followed by election of the chairperson and adoption of the agenda. The programme and list of participants are included as Annexes 1 and 2, respectively.

## **2. GLOBAL AND REGIONAL UPDATES**

### **2.1 Update on global situation of EPI**

*Dr J.M.Okwo-Bele, WHO headquarters*

Impressive achievements have been observed globally, including the greater number of vaccines and technologies available, and more deaths prevented in every region of the world. Globally, the coverage of DTP3, measles and hepatitis B vaccines is increasing, and polio is on the verge of eradication.

To take immunization to the next level, there is a need to innovate, to learn from our successes and failures, and to work more closely and in a more coordinated fashion than ever before. The delayed achievement of polio eradication is linked to the failure of today's health systems to ensure basic preventive and curative services. To scale up the delivery of life-saving vaccines and reach our goals during the next decade, systematic action and innovation against each of the six cross-cutting strategic areas proposed in the Global Vaccine Action Plan (GVAP) is required, including: improved national policy decision-making, governance and accountability; tailored strategies to stimulate public demand for vaccines and health services; going beyond reaching every district to ensure every community is reached; addressing immunization needs of the population beyond childhood; better integration and sustainable funding; and improved quality of vaccines. As well as implementation research to identify problems and solutions, support for development of new vaccines and tools of regional relevance is required. Immunization will contribute to exceeding the MDG 4 target for reduction in child mortality and millions of dollars of productivity will be gained.

### **2.2 Regional overview**

*Dr N. Teleb, WHO Regional Office for the Eastern Mediterranean*

The Region has witnessed substantial progress towards achieving regional immunization targets during the past few years. Despite recent events and increasing security concerns in several countries, the regional coverage of DTP3-containing vaccine reached 88% in 2011. Sixteen countries continued to report coverage of DTP3 above the 90% target, and a remarkable improvement in routine vaccination coverage was observed in South Sudan (63% in 2011).

Some drop in vaccination coverage was observed in countries passing through internal changes. The DTP3-containing vaccine coverage in the Syrian Arab Republic dropped from 99% in 2010 to 91% in 2011. Similarly, the DTP3-containing vaccine coverage in Yemen dropped between 2010 and 2011, whereas coverage was maintained in Egypt and Tunisia. Reported vaccination coverage in Afghanistan and Pakistan continued to fluctuate, which reflects the inadequate strength of the programme and inadequate reliability of the reported data.

The target date of measles elimination was revised to 2015 (EM/RC58/R.5). Currently, 14 countries have achieved the target of 95% coverage with the first routine dose of measles-containing vaccine, and 11 countries have achieved 95% coverage with two routine doses. Three countries (Bahrain, Jordan and Palestine) continued to be free from any indigenous transmission for the third consecutive year; a further six countries have reported very low incidence and are moving towards measles elimination. However, large outbreaks continued to be reported from Afghanistan, Pakistan and Sudan despite supplementary immunization activities. In addition, high incidence is reported from Kuwait, Qatar, Saudi Arabia and the United Arab Emirates, despite supplementary immunization activities and the reported high routine coverage data.

New vaccines introduction witnessed more success, with the introduction of *Haemophilus influenzae* type B (Hib) and rotavirus vaccines in Iraq in 2012, pneumococcal conjugate vaccine (PCV) in Yemen in 2011, rotavirus vaccine in Sudan in 2011 and Yemen in 2012, as well as implementation of the first phase of the meningococcal A conjugate vaccine campaign in Sudan in 2012. PCV introduction is also expected in Djibouti and Pakistan in 2012. Currently, Hib vaccine is in use in 19 countries, PCV in 9 countries and rotavirus vaccine in 6 countries. All GAVI-eligible countries have successfully fulfilled their co-financing commitment so far. However, middle-income countries continue to experience a relative delay in uptake of new vaccines compared to high-income countries that can afford the high vaccine price, and low-income countries that are supported by GAVI. Increased domestic financial allocations, improved procurement procedures and joining the regional pooled vaccine procurement (PVP) system are necessary to enhance new vaccines introduction in middle-income countries.

The main challenges facing the Region include: inadequate technical and managerial capacity of national EPI in some countries, and consequent inability to respond to the multiple priorities; the perception of decision-makers in some countries that EPI is a well-performing programme that has achieved all targets, and, hence, inadequate financial allocation to meet the current requirements; and, financial constraints to achieving the targets, especially lack of funds needed to implement measles follow-up campaigns and new vaccines introduction. The security situation in an increased number of countries has added to the challenges facing the Region in the past two years.

### **2.3 Briefing on SAGE sessions 2010–2012, conclusion and recommendations**

*Dr P. Duclos, WHO headquarters*

Since the last regional EPI managers' meeting in July 2010, five meetings of the Strategic Advisory Group of Experts (SAGE) on immunization have been held and a total of seven new or updated WHO position papers have been published on: rabies and pertussis vaccines in 2010, tick-borne encephalitis, rubella, and meningococcal vaccines in 2011, and pneumococcal and hepatitis A vaccines in 2012. In addition, updated position papers on the use of influenza and rotavirus vaccines will be published in November 2012 and January 2013, respectively. All conclusions and recommendations from SAGE meetings, as well as position papers, are available on the WHO website at <http://www.who.int/immunization/sage/meetings/en/> and at <http://www.who.int/immunization/documents/positionpapers/en/> (also available in French and in Arabic). Summary tables of WHO recommendations are regularly updated, and an additional summary table concerning interrupted or delayed schedules is posted.

Cross-cutting topics covered by SAGE during this period have included: low-middle-income countries: sustainable adoption and financing of new vaccines; accessibility to affordable vaccines: gaps and WHO's role in supporting emerging vaccine manufacturers; epidemiology of the unimmunized and gender-related issues; the Decade of Vaccines – Global Vaccine Action Plan; the Global Vaccine Safety Blueprint; monitoring national immunization coverage: WHO and UNICEF estimates; reinforcing surveillance; the impact of introduction of new vaccines on immunization and health systems, and how to ensure a positive impact of new vaccines introduction; information on vaccines for an intergovernmental negotiating committee on mercury; and, the use of vaccination in humanitarian emergencies.

Salient points from the revised position papers on rubella, pneumococcal and hepatitis A vaccines were presented together with the latest SAGE recommendations concerning measles and polio eradication. In April 2012, SAGE recommended five priority groups for countries using or considering introduction of seasonal influenza vaccination. Pregnant women are the highest priority group, based on compelling evidence of substantial risk of severe disease in this group, and evidence that seasonal influenza vaccine is safe and effective in preventing the disease in pregnant women as well as their young infants, in whom disease burden is also high. The four other priority groups (in no particular order) are: health-care workers; children aged under 5 years (particularly 6–23 months); the elderly; and those with underlying health conditions. Countries should individually decide how they prioritize the groups based on burden of disease, cost-effectiveness, feasibility and other appropriate considerations. The prioritization of specific target groups, local implementation timelines and target coverage goals should be determined at regional and country levels, as influenza immunization programmes are dependent on country-specific epidemiology, capacity and resources.



## **2.4 National Immunization Technical Advisory Groups (NITAGs): Progress and role in strengthening EPI and immunization programmes**

*Dr P. Duclos, WHO headquarters*

The establishment and strengthening of National Immunization Technical Advisory Groups (NITAGs) is a global recommendation. In May 2012, the World Health Assembly adopted the Decade of Vaccines Global Vaccine Action Plan (GVAP). In its first strategic objective that all countries commit to immunization as a priority, the GVAP states that “Independent bodies such as regional or national immunization technical advisory groups (NITAGs) that can guide country policies and strategies based on local epidemiology and cost effectiveness should be established or strengthened, thus reducing dependency on external bodies for policy guidance. It is important that NITAGs or their regional equivalents, engage with academia, professional societies, and other national agencies and committees to ensure a cohesive and coordinated approach to achieving national health priorities.”

The purpose of a NITAG is to be a deliberative body to guide policy-makers and programme managers in making evidence-based immunization-related policy decisions concerning all age groups and all vaccine-preventable diseases. A NITAG strengthens immunization programmes by allowing independent technical input with broad expertise, and evidence-based review and decision-making for an increasingly complex area. It allows for a more comprehensive and cohesive country immunization programme perspective, and makes off-license indications of a vaccine possible. It allows for adaptation of global policy recommendations in consideration of local epidemiology and social contexts. It brings credibility, and organizations’ buy-in and acceptance of the programme. It is also a way to demonstrate country ownership and is an important element of other Decade of Vaccines GVAP guiding principles such as sustainability, shared responsibility and partnership, equity, integration, sustainability and even innovation. The NITAG should play a role in the monitoring of the GVAP implementation.

Six basic process indicators have been included on the WHO/UNICEF Joint Reporting Form. According to analysis of the 2012 Joint Reporting Form, much progress was achieved in 2011 and 54% of countries reported the existence of a NITAG with a formal legislative or administrative basis (with a high of 90% in the Eastern Mediterranean Region). Although only 39% of countries reported the existence of a NITAG with declaration of interests by members (a 5% increase from 2010), there were 59 countries (32%) with a NITAG that met the six process indicators (an 8% increase from 2010), including 11 countries in the Eastern Mediterranean Region and a total of 38 developing countries.

## **2.5 Overview of the Decade of Vaccines, Global Vaccine Action Plan**

*Dr T. Cherian, WHO headquarters*

The Decade of Vaccines Global Vaccine Action Plan (GVAP) was developed in response to a call for such an effort, recognizing progress with immunization over the past few decades, the potential of immunization if some of the existing challenges could be overcome, and the opportunity to make a difference.

The GVAP was developed through a broad consultative process involving more than 1100 individuals from close to 140 countries. Six guiding principles form the basis of the GVAP, namely: country ownership, shared responsibility and partnership, equitable access, strong systems that are an integral part of the broader health system, sustainable access to quality vaccines and supply, and innovation. The GVAP has five overarching goals related to disease eradication and elimination, achievement of high and equitable immunization coverage, development and use of new vaccines and technologies, and contribution to achieving and exceeding MDG 4.

The GVAP was discussed and endorsed by the Sixty-fifth World Health Assembly in May 2012 in resolution WHA65.17. In the resolution, the Health Assembly urged Member States to apply the GVAP framework to their national immunization programmes and report progress annually to the respective regional committees. It also requested the WHO Director-General to monitor progress and report annually through the Executive Board. At the same time, the Health Assembly also adopted a resolution (WHA65.18) establishing World Immunization Week during the last week of April each year.

The priority now is to establish processes that lead to adaptation and implementation of the GVAP at regional and national levels and to establish a strong monitoring and accountability framework. Several regions have already had preliminary meetings to update the regional strategies and plans using the GVAP framework. Updated guidance for developing national comprehensive multi-year plans (cMYPs) for immunization that are based on the GVAP framework is currently under development.

The monitoring and accountability framework is considered to be the “game changer” in GVAP. This framework will aim to track progress against the monitoring indicators for each of the GVAP goals and strategic objectives, document and monitor commitments made and resources invested in GVAP, and establish a process for independent review and reporting of progress to the WHO governing bodies at regional and global levels. Countries are encouraged to develop a similar process at the country level. The proposed monitoring and accountability framework will be presented to SAGE in November 2012 and, with the endorsement of this body, to the WHO Executive Board and the World Health Assembly in 2013. The GVAP and its accompanying resolutions have implications for WHO regional offices and Member States, who need to initiate actions in response to the resolutions.

### **3. REACHING AND SUSTAINING HIGH ACCESS TO ROUTINE IMMUNIZATION IN DIFFICULT SITUATIONS**

#### **3.1 Strengthening EPI in complex emergency situations**

##### *3.1.1 Re-establishing EPI in Somalia*

*Dr Assegid Kebede*

In 1978, EPI in Somalia was launched as a mobile strategy and saw modest achievements before the civil war broke out, which totally collapsed the service in 1991.

After three years of discontinuation of the service, the international community re-started immunization activities through around 100 maternal and child health (immunization) centres. In 1997, the cold chain was further strengthened with the start of the Polio Eradication Initiative. Although service delivery was thus re-established, coverage has continued to be historically low.

The EPI system was assessed by partners and a number of obstacles were identified, among which the establishment of an EPI unit was given priority. Accordingly, EPI units were established within the existing health ministries of northeast and northwest Somalia. After the establishment of EPI units, the programme became Ministry of Health-driven, unity of purpose started to build among partners, and coordination improved. EPI management and service delivery have contributed to an improvement in immunization coverage from a historic low of 20–40% to more than 60% in 2011. The same model of improving management and service delivery has been applied in southern Somalia, since Al-Shabaab left Mogadishu in 2011. Somalia needs more technical and financial support to maintain the gains made so far, and to implement the remaining activities of the cMYP that ends in 2015. Somalia is also determined to improve immunization data quality.

### *3.1.2 Improving vaccination coverage in South Sudan*

*Dr Anthony Laku*

The Republic of South Sudan is still facing many constraints and challenges in infrastructure, which play a large role in the difficulty of delivering health services to communities. As such, routine vaccination coverage remains low in respect to the target.

With financial and other forms of support from partners including WHO, UNICEF, GAVI, United States Agency for International Development (USAID), Management Sciences for Health (MSH) and nongovernmental organizations, EPI was able to improve DPT3 coverage from 18% in 2007 to 63% in 2011. One state (out of 10) achieved 90% DPT3 coverage and a DPT1 to DPT3 drop-out rate of less than 10%.

The main activities that have led to improvement in routine coverage are microplanning in the states and counties on the “reaching every county/child” approach; implementation of planned sessions and acceleration campaigns; Eastern Mediterranean Region vaccination weeks 2010–2012; training; social mobilization; and, the availability of vaccines throughout the year.

Other activities that have contributed to improvement in immunization are external EPI review in 2011; cold chain inventory assessment in 2011; Effective Vaccine Management Assessment in 2011; EPI coverage survey, conducted between September 2011 and April 2012; dry season campaigns, including vaccination activities in Jonglei and Upper Nile in 2012; social mapping from 2010 to 2011; and, vaccination of returnees and refugees.

The challenges include insufficient trained human resources; ageing cold chain; lack of adequate transport; unreliable population denominator; poor reporting; insecurity in some locations; and, difficult terrain. Current activities include:

- conduction of outreach activities and defaulter tracing;
- conduction of tetanus toxoid (TT) campaigns in Western Equatoria and Eastern Equatoria;
- preparation for conduction of two national immunization days in November and December 2012;
- development of the second generation cMYP 2012–2016, and submission of the application for introduction of pentavalent vaccines to GAVI on 31 August 2012.

For improvement in immunization programme coverage, advocacy to the Government is of the utmost importance as it can help create ownership and organization of partners for immunization financing and activities. Organization and establishment of EPI committees at central and state levels is crucial to advise the country in issues pertaining to immunization. At the central level, the NITAG and national certification committee for polio eradication are in the final stages of formation, while at state level EPI coordination committees are yet to be established.

As the country still relies heavily on partner support and GAVI funds in particular to implement routine vaccination outreach services, soliciting of funding for continuation of the activities is very important. Lack of financial support will lead to difficulties in sustaining the achievements attained and possible deterioration of the coverage gained. The programme is looking forward to approval of the application to introduce pentavalent vaccines as, besides providing protection from Hib disease, this is likely to increase demand for vaccination services.

## **3.2 Situation of EPI in countries undergoing internal changes**

### *3.2.1 Situation and challenges facing EPI in Egypt*

*Dr Mohammed Sibak Hussein*

Egypt has maintained high routine immunization coverage at above 95%, which has been independently validated by Demographic and Health Survey and data quality assessment. An EPI review conducted in 2010 to 2011 found the immunization programme to be reasonably strong. Egypt has been polio-free since 2006, neonatal tetanus elimination was validated in 2007, and measles and rubella are currently in the pre-elimination phase.

Since the Egyptian Revolution on 25 January 2011, there have been some incidences of incorrect media coverage regarding EPI, mainly due to the conflict of interests between uprising political forces and the previous regime. Due to security instability in some areas, EPI was obliged to change supplementary immunization strategies and reduce the number of campaign rounds. EPI in Egypt also faces, albeit to a small extent, the issue of refugees and

illegal immigration from Libya at the western border and from Sudan at the southern border, as well as illegal immigration from some other neighbouring countries.

Demand for vaccines is high, and immunization sessions are held as planned. All health workers promote EPI, helping to create demand and consequently achieving high immunization coverage. However, in some governorates (4 out of 29), the mid-2012 DPT3 coverage was less than 95%, with the minimum being 83% in North Sinai.

Two rounds of measles supplementary immunization activities were held in 2010, one round was held in 2011, and one round has been held by mid-2012. Fixed team strategy is used in urban areas and vaccination timing is prolonged during supplementary immunization activities. Intensive social mobilization activities are undertaken, which are supported by some political parties. Despite unrest and the transitional state of the country, a subnational polio vaccination campaign was successfully conducted in Aswan and in areas on the Red Sea coast (Halayeb and Shalateen) bordering Sudan. This was in response to the detection of wild poliovirus imported from Sudan in an environmental sample. A central team helped in preparation, implementation and evaluation of the campaign. There was some delay in administrative procedures for vaccine procurement (for the fiscal year 2011 to 2012), vaccine safety stock levels were reduced, and there was a shortage of DPT and DPT-hepatitis B vaccines for a short while in early 2012.

Acute flaccid paralysis (AFP) performance indicators also decreased slightly in 2011. The AFP rate dropped to 3.3% in 2011 compared to 3.7% in 2010. Some delay in specimen delivery to the laboratory was also noted. Reporting rates for fever and rash and of confirmed measles cases increased to 825 and 24 in 2011 compared to 461 and 16 in 2010, respectively. Surveillance of adverse events following immunization is well sustained and progressing. A number of trainings were conducted as planned, despite the unrest; however, dates and venues were often changed.

### *3.2.2 Situation and challenges facing EPI in Libya*

*Dr Mohamed Najeb Smeo*

The National Programme on Immunization (NPI) in Libya is run on three levels: central level (through the National Centre for Disease Control), city level (through 36 NPI district managers), and through vaccination centres. There is a functional NITAG. Programmes related to the NPI are polio eradication, and measles and rubella elimination. In addition, the programme has introduced auto-disable syringes and safety boxes to ensure injection safety.

During 2011, the district managers had to act independently as there were breaks in communication. The key reason for the success of NPI during these difficult times is that the population trusts in immunization as the best protective measure, and are keen to vaccinate their children. By the end of 2011, the priorities were to ensure the availability of vaccines, through resuming vaccine delivery by producers and procurement through the Regional Office; and resuming NPI-related and seasonal immunization activities.

During 2012, the following EPI functions were resumed and enhanced:

- efforts to ensure vaccine procurement;
- school immunization days held (for 2011 and 2012);
- polio abridged annual report submitted to the Regional Certification Committee;
- measles regular reporting to the Regional Office;
- polio subnational immunization days, in response to the Chad outbreak;
- two meetings of NPI district managers;
- three NITAG meetings, mainly on new vaccination schedule;
- participation in the third regional (the first international) Vaccination Week;
- preparation for the *Hajj* season, including seasonal influenza vaccine;
- school immunization days planned for 2012 and 2013;
- preparation for introduction of new vaccines and review of the vaccination calendar.

The main challenges facing the programme are: resuming capacity-building, data collection and data quality; introducing new vaccines in due time; and, maintaining the programme and its stability.

### *3.2.3 Situation and challenges facing EPI in Yemen*

*Dr Ghada Showqi Al Haboub*

During 2011, DPT3 coverage in Yemen dropped to 81% compared to 87% in 2010. There was an increase in the percentage of districts reporting coverage less than 80%, from 43% in 2011 compared to 25% in 2010. Twenty-five per cent of DPT3 coverage was through outreach activities.

The main challenge for EPI services delivery was the deteriorating security situation in the country during 2011. Other challenges included: suspension of vaccinations in a number of health facilities due to lack of gas to run gas-powered refrigerators; difficulties in movement of supplies; lack of access to health facilities in some governorates for maintenance of cold-chain equipment, supervision and training; vaccine refusal for some vaccines in Sa'adah district; and, the overburdening of health systems by supplementary immunization activities weakening outbreak response.

## **4. ACHIEVING THE REGIONAL ERADICATION AND ELIMINATION TARGETS**

### **4.1 Poliomyelitis eradication**

#### *4.1.1 Global and regional overview of polio eradication status: Progress and challenges*

*Dr T. Mir, WHO Regional Office for the Eastern Mediterranean*

The global polio eradication situation is in its strongest position ever, at any point in time, both in terms of numbers as well as geographical distribution of polio cases. In 2010, there were 1298 polio cases reported from 21 countries globally, and in 2011 this decreased to

651 cases. In 2012, there have been 140 polio cases reported to date, as compared to 397 cases during the same period of the previous year. No polio case has been reported in India since January 2011, and the most recent case from Chad was in June 2012. Three WHO regions have already been certified polio-free, and the South-East Asia Region will be the fourth. In 2012, a significant development was the declaration of polio eradication as a programmatic emergency for global public health, first by the WHO Executive Board (EB130/R.10) and later by World Health Assembly resolution WHA65.5. At the same time, the programme has had serious financial constraints. Due to this, the programme was compelled to curtail and scale back supplementary immunization activities in 24 countries.

In response to the Executive Board resolution, emergency standard operating procedures were activated in the Region. Additional human resources support to Afghanistan and Pakistan has been provided, and the management and accountability framework has been introduced in the high-risk districts of both countries. Advocacy visits to Afghanistan and Pakistan were made by the Regional Director, resulting in sustained political commitment at the highest levels. The Regional Office is holding a weekly teleconference with the Polio Eradication Initiative Team in both countries. There is a separate technical advisory group for Afghanistan and Pakistan, allowing more in-depth and focused discussions. Monitoring mechanisms for supplementary immunization activities are being strengthened through the expansion of lot quality assurance sampling and improved independent monitoring. Fast-track consultations with partners and WHO headquarters are ongoing.

The polio-free status of 21 countries is very well maintained. However, circulating vaccine-derived poliovirus (cVDPV) is the emerging challenge in the Region, particularly in Somalia and Yemen mainly due to low EPI coverage. The vaccination status of non-polio AFP cases (6–59 months) in countries of the Region reveals a high proportion of susceptible (unvaccinated) children in Somalia and Yemen. Somalia has revised its strategy, and aggressive immunization campaigns will be conducted in the newly-freed areas accordingly. It is important to note that there are some areas where there are no security concerns, but still there is an alarming proportion of zero-dose oral polio vaccine (OPV) children both in Somalia and Yemen.

There is a need to develop synergies between polio eradication and routine immunization. Important areas where the Polio Eradication Initiative can support EPI are: harmonization of polio and routine immunization microplans; awareness-raising and creation of demand for EPI through polio communication channels; and, intensification of monitoring (routine immunization sessions, community surveys and role of polio field workers). In Bihar state in India, while conducting 9–11 supplementary immunization activities each year from 2006 to 2011 and with this additional support, the state was able to improve routine immunization coverage from 38% to 68%.

In Pakistan, 35 polio cases have been reported in 2012 to date, while 94 polio cases were reported during the same period in 2011. There are three poliovirus sanctuaries: Gadap Town, Karachi; the Federally Administered Tribal Areas/Khyber Pakhtunkhwa; and, Quetta block. In Gadap Town, a new strategy with permanent vaccination teams was piloted in

Union Council-4 to replace the conventional campaign; however, recent serious security incidents have put the operation on hold. Despite best efforts, the Federally Administered Tribal Areas (and Khyber Agency) remain a concern and going beyond this will require efforts from all. The ban on vaccination in North and South Waziristan, linked with drone attacks and the Osama bin Laden operation, has been a further issue. In Quetta block, the Pishin district does not seem to be moving in the right direction, although recent developments may bring positive changes. Country-level expansion of Lot Quality Assurance Sampling and the rising trend in the proportion of lots accepted at 95%, 90%, and 80% is positive evidence of improvement in the quality of the immunization campaign. However, at the same time, isolation of wild poliovirus from sewage samples indicates that much still needs to be done in areas where the virus is not being detected through AFP surveillance.

In Afghanistan, 17 polio cases have been reported in 2012 to date (all type one) as compared to 34 cases reported during the same period in 2011. Priority areas in the national emergency action plan include: addressing management and accountability gaps; reaching the inaccessible children in the south; creation of demand and public awareness; and, emphasising the importance of routine immunization. The new interventions introduced through the national emergency action plan are: establishment of a district EPI management team in the 13 high-risk districts; establishment of permanent polio vaccination teams in the 13 high-risk districts; regular performance reviews and assessment, linked with an accountability framework; engagement of the provincial and district governors; and, continuous oversight by the President's Office and the Inter-Ministerial Task Force on Polio Eradication.

An independent review of the Afghanistan polio eradication programme was conducted on the advice of the Independent Monitoring Board. Key findings focused on: reducing the number of missed children in the delivery of OPV; directing programme investment at the district level (and capacity-building at this level); and mounting all action proportional to the Sixty-fifth World Health Assembly's declaration of polio eradication as a global public health emergency.

In conclusion, polio-free countries of the Region should have sustained routine immunization, continuous monitoring at the subnational level using the risk assessment model, adequate preparedness (guidelines/plans) to respond to an outbreak, and OPV of choice available in case of any importation. Countries facing the challenge of cVDPV should strictly follow the guidelines for immediate investigation and vaccination response, ensure the availability of OPV, and put more focus on improving routine immunization. These countries can benefit by using a risk assessment model for corrective measures, advocacy and fundraising. To support the two endemic countries of the Region, there will be a session on "Polio-free Eastern Mediterranean Region: A joint responsibility" during the Fifty-ninth Regional Committee in 2012, to discuss how other governments can assist. The persistent presence of the wild poliovirus in these countries is not only holding back global eradication, but is a threat to countries that have already completed the task. All the investment, efforts and gains made so far are at risk until eradication is achieved in the polio-endemic countries.



#### *4.1.2 Risk assessment for polio outbreaks in polio-free areas: Methodology, interpretation and response*

*Dr H. Safwat, WHO Regional Office for the Eastern Mediterranean*

Following the large outbreaks in 2010 in Member States that had been polio-free for more than 10 years, countries and regions conducted risk assessments to assess the risk of outbreaks after importation, prioritize activities and mitigate risks.

Different approaches have been used by countries and WHO regions, including the Eastern Mediterranean Region. A global risk analysis group was developed in June 2011 comprising members from the six WHO regional offices, WHO headquarters and CDC, Atlanta. The global risk analysis group harmonized different regional models and developed a national standardized risk assessment model built on three categories of risk factors (surveillance, immunization, and additional/environmental indicators). The categories were scored and given different weights (surveillance 30%, immunity 50%, environment 20%). Full standardization using the exact same factors and criteria in each Region was not considered feasible or desirable by the group.

In 2011, the Independent Monitoring Board of the Global Polio Eradication Initiative emphasized the importance of standardizing, validating and strengthening risk assessments and requested reports on risk assessments and mitigation activities. The global risk assessment group responded to the Independent Monitoring Board by further developing the model, following up on risk mitigation activities, and highlighting the need to develop a subnational risk assessment tool.

The Regional Office for the Eastern Mediterranean reviewed and modified the national risk assessment model according to the above recommendations, and validated the modified national model by doing a retrospective analysis to cover the period 2004 to 2012 to show trends of risk in countries and relate risk scores to major importation events in the Region. The Regional Office also initiated the development of a subnational risk assessment tool.

The presentation demonstrated the national risk assessment model, the scores used, and the outcome of prioritizing countries according to their risk of outbreak after importation. The presentation also demonstrated the validation of the tool, showing score trends of risk over the years and dividing countries into three groups (high, medium and low risk). Finally, the presentation demonstrated the preliminary subnational risk analysis model.

#### *4.1.3 Vaccine-derived polioviruses: What are they, how do they emerge and what is the response?*

*Dr H. Asghar, WHO Regional Office for the Eastern Mediterranean*

Vaccine-derived polioviruses (VDPVs) are rare, but have serious implications for the Polio Eradication Initiative. With the decrease in wild poliovirus circulation there is greater focus on VDPVs, which are in fact adverse events associated with the use of OPV. Historically, Sabin virus type 1 and type 3 with  $\geq 1\%$  nucleotide divergence ( $\geq 10$  nucleotides)

in VP1 sequence were classified as VDPV of the same serotype. Since 2010, Sabin virus type 2 with  $\geq 0.66\%$  nucleotide divergence ( $\geq 6$  nucleotides) in VP1 sequence is classified as VDPV. Types of VDPVs include:

- iVDPV: immunodeficiency-related vaccine-derived poliovirus, detected among immunodeficient cases and usually associated with long-term excretion of the virus from the patient;
- cVDPV: circulating vaccine-derived poliovirus, more than 1 paralytic case (evidence of circulation) with isolation of related but non-identical viruses;
- “other” VDPV (aVDPV, or ambiguous VDPV): single isolate with no immunodeficiency in patient; environmental source without cases.

The iVDPVs (2005–2012) detected in the Region have been isolated from immunodeficient children in Egypt, Islamic Republic of Iran, Iraq, Kuwait, Morocco, Saudi Arabia, Tunisia and Yemen. Most iVDPVs are type 2, only Egypt and Tunisia have reported one case of type 1 and type 3 each. Three iVDPVs (one each for the three serotypes) have been detected through a “VDPV surveillance” pilot project in Egypt (2011–2012).

cVDPV (2008–2012) outbreaks have been reported in Afghanistan (2009–2011), Somalia (2008–2012) and Yemen (2011). In Afghanistan, data suggest that there was circulation in 2009, but no obvious epidemiological evidence was found at that time. In 2010, there was clear evidence of circulation in Helmand province. The last case of cVDPV2 was reported from Nad Ali district in January 2011, which was related to circulation in 2010.

In Somalia, a total of 22 cases of cVDPV2 have been reported from 2008 to 2012 in the Central and South zones. These zones have had no national immunization days or child health days since 2010, due to local authorities’ refusal to allow vaccination campaigns. This has led to low population immunity, which in turn has resulted in continued circulation of cVDPVs in these areas. The last cVDPV2 was isolated in July 2012. Two cVDPV2 were isolated from Kenya, which are related to Somalian cVDPV2.

In Yemen, since April 2011, nine cVDPV2 have been isolated from cases/contacts from Sa’dah, Ibb, Sana’a and Amran governorates. They represent three independent emergences of cVDPV2: Sa’dah group is one emergence and clearly represents circulation; Amran group consists of two contacts and is from a separate emergence. One aVDPV2 each has been detected in Al-Jawf (2011) and Dhamar (2012) governorates, without evidence of circulation. One type 3 VDPV has been isolated from Al-Hudaydah governorate (2012). Potential turmoil, inaccessibility and discontinuation of immunization activities have led to low population immunity in Yemen.

The aVDPVs isolated in the Region (2005–2012) were detected in sewage (wastewater) samples in Egypt (aVDPV1 and aVDPV2), and from one AFP case each in Syrian Arab Republic (aVDPV2), South Sudan (aVDPV2) and Sudan (aVDPV2).

The most important risk factor associated with emergence of cVDPVs is low levels of immunity against polioviruses, which may result from low routine immunization or halting polio supplementary immunization activities but the continued use of OPV. Emergence of VDPVs will cease only after OPV use is discontinued once all wild polioviruses are eradicated.

Upon discovery of a VDPV, an exhaustive epidemiological and clinical investigation should be carried out to determine the cause and type of VDPV. This should include clinical and immunologic assessment of the case; immunization coverage in the area and review of surveillance quality including retrospective record review; active case finding for missed cases and contacts; and, follow-up sampling to assess circulation. Laboratory investigation should be carried out to determine genetic characteristics in order to track the possible source or relatedness of viruses. The results of these investigations will guide further interventions. In the case of cVDPV, mop-up campaigns are needed; but in the case of iVDPV or aVDPV, action will depend on immunization coverage data. Immunization response to cVDPV should be initiated immediately, and all national and international partners informed. Immunization response depends on the extent of the outbreak, but in principal it should be on a large scale.

#### *4.1.4 OPV-IPV use in polio pre-eradication phase and proposed policy for a switch from tOPV to bOPV*

*Dr E. Mohsni, WHO Regional Office for the Eastern Mediterranean*

Taking in consideration some of the key new developments in the area of polio eradication – such as the high and increasing type 2 cVDPV burden, interruption of wild poliovirus type 2 transmission since 2004, availability of a new bivalent OPV (bOPV) proved to outperform trivalent OPV (tOPV) for types 1 and 3, as well as affordable inactivated polio vaccine (IPV) options in the near-term – WHO, in collaboration with the Global Polio Eradication Initiative, has developed a new endgame strategy and submitted it for SAGE review, comment and recommendations.

The proposed strategy is based on a parallel approach that recommends: (1) a phased removal of Sabin/OPV viruses, beginning with highest-risk (type 2); (2) elimination of type 2 in parallel by switching from tOPV to bOPV for routine EPI and campaigns; and (3) promotion of one IPV dose to boost immunity prior to a tOPV-bOPV switch and provide type 2 “priming”. The main advantages of this strategy include accelerating type 1 and 3 eradication (with bOPV), addressing more than 90% of VDPV risk while surveillance and response capacity is optimized, substantially shortening the post-eradication phase, and boosting routine coverage (i.e. IPV at DPT3).

In its April 2012 meeting, SAGE recommended that countries “consider” at least one dose of IPV in routine immunization schedules prior to a tOPV-bOPV, but recognized and accepted a high probability of low uptake in low-coverage countries; requested “low-cost intramuscular and intradermal IPV options” within one year; and, decided 2014 was too early for a tOPV-bOPV switch (it is an urgent issue, but not an emergency).

In May 2012, the World Health Assembly endorsed a tOPV-bOPV switch, but expressed alarm over current IPV prices, lack of medium- and long-term price(s), limited IPV supply options, and lack of clear cost-benefit assessments; requested WHO to work with partners and manufacturers to enhance IPV affordability and availability; and requested a 2014–2018 polio endgame strategy and budget.

From a practical point of view, the new proposed strategy in terms of tOPV-bOPV switch will essentially impact countries that have not yet introduced IPV. While those countries of the Region that have already introduced at least one dose of IPV into their routine EPI have mostly to work on preparing for bOPV registration, the remaining countries have to start thinking and planning for the tOPV-bOPV switch and the introduction of at least one IPV dose in this context. Expected financial and programmatic implications need to be identified by each country and reported back to regional and global levels in order to be considered by SAGE, as well as the Global Polio Eradication Initiative, in making final recommendations and decisions.

In summary, the “polio endgame” is evolving rapidly, with substantial implications expected for polio immunization policy as well as the country routine immunization programmes. So far, 10 countries in the Region have introduced at least one dose of IPV into their national routine immunization schedule, and one country is in the process of doing so. The remaining 12 countries include the seven GAVI-eligible countries from the Region (Afghanistan, Djibouti, Pakistan, Somalia, South Sudan, Sudan and Yemen) and five low-middle income countries (Egypt, Islamic Republic of Iran, Iraq, Morocco and Tunisia).

The tOPV-bOPV switch session was conducted first in plenary, with all countries, and several issues were raised, mainly concerns about the IPV price. Different prices were raised for the full intramuscular IPV: (1) currently prices paid by some countries in the Region (self-procuring middle- and high-income countries) are around US\$ 3.2 to US\$ 3.5; (2) UNICEF price is currently around US\$ 2.5; and (3) participants were informed about the Serum Institute of India’s (SII) new offer to UNICEF of US\$ 1.5. The SII initiative was well received from the country representatives and they consider it a positive sign towards lower prices in the future (competition between producers), but still this is considered by middle-income countries as beyond their current financial capacities as most of them are still struggling to introduce new vaccines such as pneumococcal conjugate vaccine (and even Hib) despite practitioners’ and public pressure and the availability of strong evidence of high disease burden related to these new vaccines.

Participants also raised concerns about bOPV and IPV global production capacity, the best timing for the IPV dose (with DPT1 to provide better protection against vaccine-associated paralytic poliomyelitis, or with DPT3), IPV and maternal antibodies, OPV birth dose and the new proposed strategy, OPV/IPV sequential versus simultaneous administration, IPV as additional dose or replacing one of the OPV doses, the lack of trained human resources in countries with poor health systems, and the need to reach high coverage with the required additional injectable vaccine (IPV), and the expected impact on the cold chain of the additional IPV dose, etc. Participants from some Gulf Cooperation Council (GCC) countries

reported that their countries are currently considering adding a second IPV dose to their routine immunization schedule, and that this issue is one of the agenda items of the second GCC States Symposium on new trends in vaccination, which will be held in Dubai, United Arab Emirates from 9 to 10 October 2012.

Following the plenary session participants agreed on the importance for each country to start preparing for registering the bOPV, as well as mOPV1 and mOPV2, as soon as possible. They raised several concerns, in particular regarding the cost of IPV. The countries requested SAGE to be more explicit about whether the IPV dose should be an additional dose or replace one OPV dose, as well as the best recommended administration time.

Noting that countries which have already introduced at least one IPV dose into their routine immunization schedule do not have great concerns about the proposed tOPV-bOPV switch (except for bOPV, mOPV1 and mOPV3 registration), the meeting organizers decided to conduct group work with the remaining countries that have not yet introduced IPV into their routine EPI, to discuss future plans as well as financial and programmatic capacities and expected constraints in relation to the proposed switch strategy.

#### *4.1.5 Group work on IPV introduction*

The meeting had a group work session to discuss risk analysis and applying the tool at subnational level. Countries were divided into two groups: countries that have already introduced IPV, and countries that have not yet introduced IPV. The groups discussed the policy, technical and programmatic implications of introduction of IPV.

The main outcomes from the group work included the following points.

- Morocco and Tunisia are already planning to introduce at least one dose of IPV by 2014 and 2015, respectively. Egypt and the Islamic Republic of Iran raised their national vaccine production as a major constraint for both bOPV and IPV use. The remaining countries stated that introducing one dose of IPV in the context of a global tOPV-bOPV switch might be possible, pending partners financial support (GAVI ++). Pakistan alone believed that this most probably would not be possible mainly because of the expected financial impact, even if supported by GAVI, as well as the expected programmatic implications.
- All countries, except Tunisia, and in particular the GAVI-eligible countries, are more in favour of an intramuscular IPV option, mainly because of concerns about the capacity of field staff to deliver intradermal injections. Tunisian representatives stated that their country would choose the intradermal IPV option for financial reasons. All participants were concerned about the possible impact of a non-correct intradermal injection of IPV on the expected immunologic response and requested clarification from SAGE.
- The main challenges expected by the participants related to financial constraints both in terms of IPV vaccine price and introduction costs (training, cold chain, etc.), programmatic constraints (another injectable vaccine for already overloaded and poor delivery systems, increased number of injections during one session, capacity of field

staff to deliver intradermal injections, capacity of the programme to reach as high coverage figures with an injectable vaccine as with OPV particularly in remote and difficult areas,) and logistical constraints (cold-chain issues). Participants highlighted their wish to see a low-cost hexavalent vaccine option among WHO and partners' priorities.

## **4.2 Measles/rubella elimination**

### *4.2.1 Measles elimination in the Eastern Mediterranean Region: Current situation*

*Dr H. Ahmed, WHO Regional Office for the Eastern Mediterranean*

The Fifty-eighth Session of the Regional Committee for the Eastern Mediterranean resolved to revise the target date of measles elimination to 2015 (EM/RC58/R.5). To achieve elimination of measles in the Region, the regional strategy aims at reaching at least 95% of the population in every district with two doses of measles-containing vaccine through routine and/or supplementary vaccination.

Despite the challenges faced by many countries in the Region due to political changes, conflicts, floods and famine as well as shortages of funds from partners, substantial progress has been made on moving towards measles elimination. Many countries are likely to achieve the measles elimination goal by 2015, and routine measles vaccination coverage has also improved in priority countries. From 2011 to 2012, over 33 million people in the Region were vaccinated through measles supplementary immunization activities. The total number of confirmed measles cases reported was 11 886 in 2011 and 10 531 (from January to June) in 2012; of these, 82% and 90%, respectively, were reported from Afghanistan, Pakistan, Sudan and Yemen, mainly due to delayed implementation of follow-up campaigns and poor quality of supplementary immunization activities.

The measles and rubella laboratory network has developed strong capacity and is capable of increased surveillance activities. Meeting of measles elimination surveillance indicators is much improved and specimens are collected from the chain of transmission for measles virus detection and genotyping, although gaps exist in few countries. However, more efforts are needed to sustain these gains in light of the current political and security situation in some countries.

### *4.2.2 New GAVI window on rubella vaccine introduction*

*Dr E. Eltayeb, WHO Regional Office for the Eastern Mediterranean*

Rubella is a very mild disease for which 20–50% of infections are asymptomatic. Complications of encephalitis and arthritis are rare in children. Rubella infection in early pregnancy can result in miscarriage, fetal death, congenital birth defects or congenital rubella syndrome (CRS). CRS is a major public health issue with an estimated 112 000–120 000 annual cases occurring globally, of which 80% are in GAVI-eligible countries. Only 42% of the global birth cohort is covered by vaccination; as of 2010, 131 countries had introduced rubella-containing vaccine (RCV). In the Eastern Mediterranean Region, 15 countries have

included the vaccine in their national immunization schedules. Rubella vaccine is not used in GAVI-eligible countries in the Region. The Region is moving towards measles and rubella elimination, and targets for both have been set for most countries. The 2011 WHO position paper on rubella vaccines stated clearly that, “In light of the remaining global burden of CRS and proven efficacy and safety of RCVs, WHO recommends that countries take the opportunity offered by accelerated measles control and elimination activities to introduce RCVs.”

In November 2011, the GAVI Alliance Board approved a new funding window for rubella vaccines. All GAVI countries are eligible for rubella vaccine campaign support and it was anticipated that 30 countries could introduce rubella vaccine by 2015, and 51 in total before 2020. GAVI will pay for bundled measles-rubella vaccines and injection safety materials for catch-up campaigns for the target age group of 9 months–14 years, and contribute US\$ 0.65 per child for the campaign operational costs. In addition, GAVI will provide a vaccine introduction grant to the amount of US\$ 0.80 per child or US\$ 100 000 (whichever is higher) for introduction of the vaccine in the routine schedule. Countries are responsible for the remainder of the operational costs for the catch-up campaign, sustainable financing of the measles-rubella vaccine for routine dose, subsequent follow-up campaigns, and implementing a strategy for vaccinating women of childbearing age. Application guidelines were developed and approved by the end of March 2012, and country applications are expected between April and September 2012. In order to be recommended for approval, countries must provide evidence that they can achieve high immunization coverage and can finance the introduction of RCV in their routine programme. In addition, countries must demonstrate the epidemiology and burden of disease of rubella, and provide a new vaccine introduction plan either as a stand-alone plan or part of their cMYP. If all goes according to the plan, the rubella virus might not survive the twenty-first century.

#### *4.2.3 Yemen’s decision on introduction of rubella vaccine: Mobilization of national resources Dr Ghada Showqi Al Haboub, EPI Manager, Yemen*

Yemen recognizes rubella as a public health problem. According to available estimates, around 700–3600 cases of CRS occur during any epidemic year in Yemen. With the GAVI window of opportunity becoming available to support measles-rubella catch-up campaigns, the Ministry of Health led strong advocacy to ensure that the Ministry of Finance approved the extra funds required for introduction of rubella vaccine in the routine immunization schedule and for contributing to the measles-rubella campaign. The NITAG has supported the plan to introduce rubella vaccine into the national immunization programme and the Health Systems Strengthening Coordination Committee has also approved the application. The Ministry of Health convened a series of meetings with partners (WHO, UNICEF, World Bank, Government of Saudi Arabia) to secure the required funds. The Ministry and its partners are committed to closing the funding gap of the operational cost of the campaign. Furthermore, humanitarian agencies (including UN agencies and nongovernmental organizations) will contribute to the cost of the campaign in conflict-affected areas.

The vaccine introduction plan includes:

- establishing CRS surveillance in the second half of 2013;
- introducing measles-rubella vaccine into the national immunization programme in July 2013;
- conducting a phased measles-rubella campaign, targeting children aged under 15 years, during November to December 2013.

#### 4.2.4 Briefing on regional consultation on rubella/CRS

*Dr N. Teleb, WHO Regional Office for the Eastern Mediterranean*

A regional consultation on rubella and CRS was held in January 2012. Objectives of the consultation were:

- to review the current epidemiological situation of rubella/CRS in countries of the Eastern Mediterranean Region;
- to review vaccine use and immunity against rubella in countries of the Eastern Mediterranean Region;
- to discuss the feasibility of developing a rubella/CRS elimination target for the Eastern Mediterranean Region.

The consultation was attended by experts in rubella/CRS from CDC, Atlanta and WHO Regional Office for the Americas, responsible staff in WHO headquarters and the Regional Office for the Eastern Mediterranean, and national participants from Egypt, Islamic Republic of Iran, Jordan, Oman and Sudan.

The review and the discussion during the consultation covered the following areas for each country of the Region:

- population immunity against rubella, as indicated by history of use of RCV in routine and supplementary immunization, information from serosurveys, and age- and sex-specific incidence of rubella;
- rubella and CRS surveillance systems;
- incidence of rubella and CRS during the past few years.

Findings showed that 15 countries in the Region are currently using rubella vaccine, while Morocco discontinued its use in 2008. All countries that are currently using rubella vaccine have developed a rubella and/or CRS elimination objective with/without a target date. The table below shows the targets for the different countries.

<b>Country</b>	<b>Target</b>
Oman	Rubella/CRS elimination by 2010
Bahrain, Egypt, Iraq, Jordan, Qatar, Saudi Arabia, Syrian Arab Republic	Rubella/CRS elimination by 2015
Kuwait	Rubella 2020/CRS elimination by 2015
Islamic Republic of Iran, United Arab Emirates	Rubella/CRS elimination, no definite target date
Libya	Rubella elimination, no definite target date



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Lebanon, Palestine, Tunisia	CRS, no defined target date
Afghanistan, Djibouti, Morocco, Pakistan, Somalia, South Sudan, Sudan, Yemen	Rubella vaccine not in EPI schedule and no target date

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According to the findings, the countries can be divided into three groups based on population protection through use of rubella vaccine, population protection identified by serosurvey, and incidence of rubella.

- 1) Countries close to rubella elimination: Bahrain, Egypt, Islamic Republic of Iran, Jordan, Libya, Oman, Palestine and Syrian Arab Republic
- 2) Intermediate progress toward elimination: Iraq, Kuwait, Lebanon, Qatar, Saudi Arabia, Tunisia and United Arab Emirates
- 3) No rubella vaccination or programme halted: Afghanistan, Djibouti, Morocco, Pakistan, Somalia, South Sudan, Sudan and Yemen

Participants of the consultation discussed the possibility of establishing a regional rubella/CRS elimination target, taking into consideration the following issues:

- eight countries are very close to elimination and seven more are progressing towards elimination;
- availability of a new GAVI window for supporting measles-rubella catch-up campaigns;
- epidemiology of rubella in countries that have not introduced the vaccine, where the vast majority of cases are among children aged under 15 years and GAVI-supported measles–rubella campaigns will be undertaken;
- rubella is less infectious than measles and relatively lower coverage is needed to achieve elimination.

Based on the review and the discussion, the consultation concluded that:

- developing and achieving a regional elimination target is possible;
- rubella/CRS elimination by 2020 is feasible for at least 16 countries (including Morocco, who will resume rubella vaccination in 2012);
- rubella/CRS elimination is feasible in the other countries, if they introduce rubella vaccine by 2015 in the routine schedule, and using catch-up campaigns and regular follow-up campaigns in countries with low routine coverage;
- efforts are needed for establishing/strengthening CRS surveillance.

### **4.3 Maternal and neonatal tetanus elimination**

#### *4.3.1 Global and regional situation and way forward to achieve elimination*

*Dr A. Raza, UNICEF headquarters*

An overview of global and regional progress towards maternal and neonatal tetanus elimination (MNTE) was provided, including salient features of the strategies for maintaining

elimination, and the current status of SAGE recommendations on the tetanus toxoid/tetanus-diphtheria (TT/Td) vaccine switch, globally.

Since the re-launch of the programme, 27 out of 59 countries have eliminated maternal and neonatal tetanus; however, 32 countries are still conducting supplementary immunization activities to achieve the global target of MNTE by 2015. More than 113 million women of reproductive age have received two or more doses of TT (TT2+) in 52 countries, reducing neonatal tetanus deaths by 90%. Globally, 7 countries (China, Eritrea, Malawi, Namibia, Rwanda, South Africa and Zimbabwe) have achieved elimination status by strengthening routine immunization and reproductive health programmes without any supplementary immunization activities. Three countries in the Eastern Mediterranean Region have a neonatal tetanus mortality rate of more than 4% (Afghanistan, Somalia and Yemen), while overall skilled birth attendance coverage in the Region is less than 50%. Out of eight high-risk countries (Afghanistan, Egypt, Iraq, Pakistan, Somalia, South Sudan, Sudan and Yemen), Egypt is the only country that has validated MNTE so far, while Iraq is in process of undertaking a validation survey. So far, more than 18 million women of reproductive age (62% of the target) have been reached with TT2+ during supplementary immunization activities in the Region. Therefore, to achieve the elimination target by 2015, besides strengthening routine immunization and reproductive health services delivery, the countries are urged to complete pending TT supplementary immunization activities as a priority along with periodic maternal and neonatal tetanus risk analysis. To maintain validation status, the countries need to maintain high skilled birth attendance and DTP3 coverage, complemented by TT/Td boosters through school vaccination campaigns and/or Child Health Days. It is time to move forward with the SAGE recommendation of a TT/Td switch in next few years, in order to gain double benefits with marginal additional cost and no programmatic overload. UNICEF Supply Division is working closely with the manufacturers for this programmatic shift, and 40 million doses of Td will be available in 2013.

The presentation generated intense discussions on low financing and lack of programmatic priority for MNTE efforts, TT2+ versus protection at birth for MNTE risk assessment and monitoring, and the necessity of completing supplementary immunization activities but not at the cost of routine immunization. The discussion concluded with the joint request to the donors to prioritize financial support for MNTE in line with polio, measles and rubella.

#### *4.3.2 Validating MNTE in Iraq*

*Dr N. Ibrahim Abbas, Assistant EPI Manager, Iraq*

In Iraq, epidemiological data show that reported neonatal tetanus cases have numbered less than 1 per 1000 live births since 1996; thus, according to the WHO definition, Iraq has achieved MNTE.

Iraq submitted an official request to WHO to carry out a validation survey to confirm MNTE. A team from WHO and UNICEF was trained on MNTE validation in Ghana. A task force was established with members from the Ministry of Health, Ministry of Higher

Education, Ministry of Planning, WHO and UNICEF. The task force established a workplan to carry out the validation survey in February 2013. The worst performing district was identified, sample size was determined and clusters were selected by task force members. The validation survey will be carried out by nursing school students as interviewers and monitored by the Iraqi field epidemiology training programme resident medical doctors. The survey will be monitored by WHO and UNICEF.

#### **4.4 Hepatitis B control**

##### *4.4.1 Introduction of hepatitis B birth dose in Djibouti*

*Dr S. Banoita Tourab, Ministry of Health, Djibouti*

In 2007, EPI in Djibouti included pentavalent vaccine in the national immunization programme following discussion with partners and the endorsement of the NITAG and Inter-Agency Coordination Committee. In order to include the hepatitis B birth dose in the national immunization programme, advocacy was directed to partners and particularly to UNICEF to access the vaccine. In early 2011, UNICEF accepted to make available the necessary quantity of vaccine in order to start hepatitis B immunization at birth.

There were three main reasons behind the introduction of a first dose of hepatitis B vaccine at birth: the efficacy of the vaccine if provided to the child early in life immediately after birth, the high prevalence of hepatitis B virus in Djibouti, and compliance with the recommendations of the Twenty-sixth intercountry meeting of the national EPI managers in 2012 (WHO/UNICEF).

During 2011, a preparatory activity was undertaken to sensitize the health service beneficiaries. Information, education and communication materials were produced. In addition, training, reporting and monitoring tools were prepared. Since introduction, from January 2012 until August 2012, 15 740 children have received the hepatitis B zero dose. The vaccine is well accepted by mothers, and no constraints have been notified.

##### *4.4.2 Monitoring progress: Hepatitis B serosurvey in Sudan*

*Dr A. Abdel Moniem, EPI Manager, Sudan*

Sudan is among the high-endemic countries in the Eastern Mediterranean Region for hepatitis B prevalence. Studies prior to 2006 showed that chronic hepatitis B prevalence ranged between 6.8% and 26%, which led the country to decide to introduce monovalent hepatitis B vaccine into the national immunization programme. In 2008, hepatitis B pentavalent vaccine was introduced into the programme and the coverage rate increased from less than 70% in 2006 to 93% in 2011. In 2012, the programme decided to study the seroprevalence of hepatitis B and the risk factors related to its occurrence, in order to document progress towards achievement of the control target of less than 1% hepatitis B prevalence among children aged under 5 years. The objectives of the study were:

- to measure the prevalence of hepatitis B surface antigen (HBsAg) among children aged under 5 years;
- to determine the risk factors associated with hepatitis B among children under 5 years;
- to measure the prevalence of HBsAg and hepatitis B “e” antigen (HBeAg) among mothers of positive children.

The study sample included 3600 children aged under 5 years from throughout the country (insecure areas were excluded from the sampling frame). The result of the study showed that HBsAg among children aged under 5 was 0.4% and the third dose coverage of hepatitis B vaccine was 86.5%. The significant risk factors were gender (0.7% among males compared to 0.2% among females), hepatitis B vaccination status (0.1% among children with three doses compared to 7.3% among non-vaccinated children), history of invasive practices (2% among children exposed to invasive procedures compared to 0.4% among those who were not), chewing of food before giving to the child (2.9% among children who received food after mother’s chewing compared to 0.3% who did not) and history of family members affected by jaundice (1.3% among children living with a family member with jaundice compared to 0.3% among children who had no contact). Mothers of 75% of positive children were found positive. The study suggested that maintaining high hepatitis B vaccination coverage is essential to control hepatitis B disease and further studies are necessary to assess vertical transmission. The final results of the study will be available soon.

#### 4.4.3 Hepatitis B: Regional situation

*Dr N. Teleb, WHO Regional Office for the Eastern Mediterranean*

The regional target for hepatitis B control is a reduction in prevalence of chronic hepatitis B virus infection to less than 1% among children aged under 5 years by 2015 (EM/RC56/R.5). The regional hepatitis B control strategies include:

- high coverage of routine infant hepatitis B immunization within the first 6 months of life;
- catch-up vaccination of children aged under 5 at beginning of vaccine introduction, if needed;
- ensuring vaccine effectiveness;
- advocacy and social mobilization;
- monitoring and evaluation of progress towards the regional target.

Countries of the Eastern Mediterranean Region were divided into categories according to hepatitis B prevalence: countries with intermediate prevalence of 2–8% (16 countries), and countries with high prevalence of more than 8% (7 countries).

Since 1990, 15 countries have introduced the hepatitis B birth dose in their immunization schedule, 6 countries have not introduced the birth dose, and 2 countries have

not yet introduced the vaccine in their immunization schedule (Somalia and South Sudan).<sup>1</sup> Challenges for the hepatitis B birth dose are that in many countries it is given at first contact rather than in the first 24 hours of life; it is not implemented in high-burden countries; and, there is a funding problem for the birth dose in GAVI-supported countries.

Progress on hepatitis B control since resolution EM/RC56/R.5:

- regional strategy developed and shared with all countries;
- review of Joint Reporting Form to include reporting on the birth dose;
- implementation of hepatitis B serosurvey supported in Sudan and Yemen, to monitor progress and establish baseline data to support advocacy on the need for the birth dose;
- Djibouti introduced the birth dose in October 2011;
- Bahrain: Ministry of Health generalized implementation of the birth dose;
- Egypt: reported implementation of the birth dose in maternity services;
- Iraq, Libya and Syrian Arab Republic (countries implementing the birth dose): reviewed definition of the birth dose in the national immunization policy to ensure vaccination during first 24 hours of life.

Group work was undertaken to review the situation of hepatitis B control in countries and plans for reaching the target. The countries were divided into three groups, according to their situation in implementation of the regional strategy, and the outcomes included: re-emphasizing the importance of implementing the different components of the regional strategy for achieving the control target; reviewing progress towards achieving the target; and discussion of country plans for achieving the target with regards to introduction of hepatitis B birth dose, improving coverage of birth dose and the required support.

## **5. INTRODUCTION OF NEW VACCINES**

### **5.1 Global update on new vaccines introduction**

*Dr C. Mantel, WHO headquarters*

The WHO GVAP comprises five work areas. Since the last regional EPI managers' meeting in 2010, progress in these areas has been substantial.

In line with WHO norms and standards, there were 11 vaccines were prequalified and an expedited procedure for licensing MenAfriVac™ was implemented in countries in the meningitis belt. Routine vaccine schedules tables are being regularly updated.

Countries were assisted in the decision-making process for new vaccines introduction and with GAVI applications: 44 countries were approved for 68 introductions in 2011 and

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<sup>1</sup> Somalia will be introducing pentavalent vaccine (DPT-HepB-Hib) into the immunization schedule in early 2013 with GAVI support. South Sudan has applied to GAVI for pentavalent vaccine support.

2012 (pentavalent, pneumococcal and rotavirus vaccines); at least 25 countries submitted applications in 2012 (pentavalent, pneumococcal, rotavirus, human papillomavirus, measles second dose, rubella, meningitis A conjugate and yellow fever vaccines), and seven new WHO position papers have been launched since the last meeting (on rabies, pertussis, hepatitis A, meningococcal vaccines, pneumococcus, rubella, and tick-borne encephalitis vaccines). As of 2011, 59 NITAGS meet all six quality criteria, 11 of which are in GAVI-eligible countries. Burden of disease estimates for rotavirus mortality were updated for 2008; regional and global estimates for pneumococcal (*Streptococcus pneumoniae*) and Hib deaths were updated for 2008; and cervical cancer incidence, mortality, and prevalence was published for 2008. The WHO Immunization, Vaccines and Biologicals (IVB) website has been updated with revised information and slide sets.

In terms of planning, financing and procurement, prices contracted by UNICEF with suppliers are now published on UNICEF and WHO websites, assessment tools and benchmarks for planning of human resources for immunization are being developed and strategic demand forecasting processes are regularly updated for 14 vaccines. The cMYP guideline is in revision to better align the planning process with health-sector planning and the Global Vaccine Action Plan. Pooled procurement initiatives are ongoing specifically in the Eastern Mediterranean Region with assistance of UNICEF Supply Division, while other WHO regions are interested to expand such initiatives, for example, the European Region (in the Baltic States) and the South-East Asia Region.

With regards to vaccine delivery, major successes have been achieved. Since 2011, there have been 51 vaccine introductions (8 Hib, 23 pneumococcal, 11 rotavirus, 6 human papillomavirus, 3 meningitis A conjugate vaccines), the GAVI introduction grant was revised upwards to US\$ 0.80 per child and guidelines for pneumococcal and rotavirus vaccine introductions and training materials were developed and updated. A GAVI Alliance Task Team is working with the Democratic Republic of the Congo, India and Nigeria, and is to provide more flexible support to fragile countries. A WHO data repository on country immunization indicators is being established and will be made available to countries, regions and partners on the WHO website to be used for information exchange and coordination of technical assistance. A school immunization readiness assessment tool is available and a checklist approach has been initiated to improve immunization sessions.

In the field of vaccine supply and logistics there is ongoing use and revision of the Effective Vaccine Management Assessment, with 34 assessments and implementation of improvement plans done since 2011, and 21 priority assessments planned for 2012. An analysis is ongoing to better define unopened and opened vial wastage. Project Optimize works on development of new cold-chain technologies, controlled temperature chain strategies and a vision for immunization supply systems for the year 2020. Strategies to reach new target populations are being evaluated and new vaccine introduction guidelines are being updated to include the impact of new and underutilized vaccines implementation on immunization and health systems, with a set of principles on adding a new vaccine to a national immunization programme recently endorsed by WHO SAGE.

In terms of monitoring and surveillance, rotavirus and pneumococcal conjugate vaccination coverage for 2011 was published in July 2012. The global rotavirus and invasive bacterial vaccine-preventable disease surveillance networks are showing robust data for rotavirus gastroenteritis surveillance while invasive bacterial disease surveillance data quality is being strengthened through standardized site evaluations, use of rapid diagnostic tests and polymerase chain reaction, external quality assurance processes, and improved data management. The Global Reference Laboratory and regional reference laboratories support sentinel sites and surveillance bulletins are regularly published. Since 2011, post-introduction evaluations have been conducted in 14 countries for pentavalent, rotavirus, pneumococcal conjugate and human papillomavirus vaccines introduction, and immunization programme evaluations have been done in 11 countries.

The new vaccines supply and demand situation is dynamic, and requires close monitoring and management. The unprecedented scale-up of demand through GAVI applications has led to supply constraints for pneumococcal conjugate, rotavirus and yellow fever vaccines.

**Hib vaccine** is now in use in national schedules in 179 of 193 Member States (93%), with eight additional GAVI applications since 2011. It was introduced in two states in India in 2011, with plans to expand to six additional states; in Russia it was partially introduced in 2011; in Nigeria it was introduced in 12 states in May 2012; and Indonesia is to introduce the vaccine in May 2013. However, about one quarter of the world's children still do not have access to Hib vaccine, as it has not yet been nationally introduced in the People's Republic of China and some other countries.

**Pneumococcal conjugate vaccine (PCV10)** prequalification was upheld with recommendations for provision of benefit-risk information, additional training and materials, and close monitoring. PCV10 and PCV13 have now been introduced in 78 countries (of which 26 are low- or lower-middle-income countries) and GAVI-graduating countries can now apply for access to the vaccine at an advance market commitment tail price of US\$ 3.50 per dose. Supply constraints for 2012–2013 caused delays in introduction. Regarding pneumococcal serotype replacement (after PCV7), an overall reduction of invasive pneumococcal disease in children aged under 5 years was seen despite increases in incidence of non-vaccine serotypes, which are likely to be mitigated by use of PCV10/13.

**Rotavirus vaccines** are now in use in 40 countries, with 11 countries having introduced since January 2011. A first UNICEF procurement round was finalized with the price for a two-dose course now at around US\$ 5 (€1.88) per dose, and the price for a three-dose course at US\$ 7–15 (US\$ 2.5–5 per dose). Rotavirus vaccine age restrictions were recently relaxed by WHO SAGE with a focus on timeliness of vaccination starting at 6 weeks of age. Intussusception surveillance is to be intensified in all countries, with a generic protocol being developed by WHO and US CDC.

**Human papillomavirus vaccine** is now being used in 41 countries in the national immunization programme, with a new GAVI application window opened for human

papillomavirus vaccine support. Human papillomavirus vaccine demonstration project applications are being accepted with a deadline of 15 October 2012. The present price of US\$ 5 per dose for UN purchase is expected to further reduce during tendering. GAVI support to operational costs was increased to US\$ 2.40 per girl. A new WHO cervical cancer prevention and control costing tool is available and a human papillomavirus vaccine coverage monitoring tool has been piloted. Increased collaboration is needed on cervical cancer prevention, screening, treatment and adjunct interventions.

Regarding **typhoid vaccine**, GAVI will open a window for vaccine support only after availability of a conjugate vaccine. There was recent demonstration of high disease burden in Africa through an International Vaccine Institute surveillance project. Evaluation of the programmatic feasibility of school-based typhoid programmes is ongoing, and regulatory standards for typhoid conjugate vaccines are being developed. Six pipeline typhoid conjugate vaccines are in different phases of clinical development.

Results of a new **dengue vaccine** (YF17D/DEN) phase IIb efficacy trial in children aged 4–11 years were recently published. While the safety profile was satisfactory, efficacy data are not yet conclusive: there was no overall reduction in dengue cases and while efficacy was seen against DEN-1, DEN-3 and DEN-4 this was not the case against DEN-2, although there was good immune response against the latter virus. Follow-up of study participants is ongoing, as well as further phase III efficacy trials in around 31 000 children and adolescents in 10 countries in Asia and Latin America. Pivotal efficacy data are anticipated in 2014 to 2015.

For **malaria vaccine** (RTS,S/AS01), first phase III interim data on 5–17 month olds without co-administration were made publicly available in October 2011. These data are not from the population that the initial policy recommendation will be targeting, and a WHO recommendation on use will not be formulated before 2015. Full phase III data are to become available in late 2014, including 30-month follow-up data in infants aged 6–14 weeks with co-administration, site-specific clinical malaria efficacy data, and data on an 18-month booster dose. RTS,S will need to be considered for policy recommendation in addition to existing malaria preventive measures. Malaria control measures have saved an estimated 1.1 million lives since 2000 through the use of long-lasting insecticidal bednets, indoor residual spraying and prompt diagnostic testing and effective treatment. The addition of RTS,S will not remove the need for these interventions and some vaccinated children will still get malaria, but less often. Mothers and health-care workers will need to understand that it is vital to be able to diagnose and treat malaria – even for those who have received the vaccine.

## **5.2 Strengthening the decision-making process for new vaccines introduction**

### *5.2.1 Burden of diseases assessment through regional surveillance networks*

*Dr E. Eltayeb, WHO Regional Office for the Eastern Mediterranean*

Surveillance of vaccine-preventable diseases is a global demand. The World Health Assembly in 2008 (WHA61.15) urged all Member States “to accelerate the implementation



of the global framework for vaccine-preventable disease surveillance and immunization programme monitoring, through the gathering of the comprehensive epidemiological data required to guide immunization programmes, and to strengthen national capacity for making evidence-based policy decisions to adopt new vaccines.” Surveillance and other burden of disease studies are very powerful tools for informed and evidence-based decision-making on new vaccines introduction. Surveillance networks that exist in the Region include the invasive bacterial vaccine-preventable diseases network (for bacterial meningitis, pneumonia and sepsis surveillance) in addition to the rotavirus surveillance network.

The main objective of the regional surveillance networks is to determine the burden of diseases and serotype/genotype distribution, in order to allow evidence-based decision-making on introduction of new vaccines and to study the impact of new vaccines on disease occurrence after introduction.

Regarding bacterial meningitis surveillance, most countries in the Region are moving to nationwide sentinel surveillance as compared to 2004 when most were conducting syndromic surveillance with outbreak confirmation. Data on causative organisms of bacterial meningitis identified in countries in the network (namely Afghanistan, Libya, Morocco, Iraq, Islamic Republic of Iran, Pakistan, Sudan and Syrian Arab Republic) revealed that *Neisseria meningitidis* (Nm) was the most predominant serotype in the Region and it was mainly prevalent in Morocco and Sudan during 2007 to 2011. As far as pneumonia and sepsis are concerned, *Streptococcus pneumoniae* (Spn) was the most predominant serotype isolated from blood and cerebrospinal fluid culture results. Pakistan provides a good example of the NITAG using evidence to decide on vaccine introduction. The new PCV10 vaccine to be introduced in the country by October 2012 will cover more than 40% of serotypes isolated by the invasive bacterial vaccine-preventable diseases surveillance network.

Fourteen countries are participating in the regional rotavirus surveillance network. Data presented for these countries have clearly shown that the rotavirus-positivity rate among acute gastroenteritis cases admitted to hospitals is around 38%, ranging between 65% in the Islamic Republic of Iran and 11.2% in Tunisia. Age distribution of rotavirus-positive cases during the same period shows that the burden of disease is concentrated among infants aged 0–11 months. It was noted that rotavirus gastroenteritis peaked in November during the last 5 years, and G2P4 is the most common genotype found in the Region by the rotavirus network.

In 2008, analysis of the estimated burden of Hib, pneumococcal and rotavirus diseases in children under 5 years of age showed that 17.1% of under-5 deaths in the Region were attributed to these diseases. With the exception of GCC countries, these estimates were prior to vaccine introduction and thus provide baseline data to assess disease impact post vaccine introduction in the countries.

In conclusion, regional surveillance networks for vaccine-preventable diseases contribute to evidence-based decisions by NITAGs on new vaccines introduction, as well as strengthening national surveillance systems and providing a model for future collaboration and partnership. The main challenges are issues of sustainability and ownership, financial

constraints in supporting middle-income countries, building laboratory capacity, and the transfer of specimen samples across countries. In addition, high turnover of trained qualified staff is a huge challenge faced by many countries in the Region. Planned future activities include: establishing one to two surveillance sites in each of Djibouti, Somalia and South Sudan; organizing a regional training workshop on surveillance, monitoring and evaluation; conducting field visits and surveillance reviews; and, encouraging use and dissemination of information and publications.

*5.2.2 Cost-effectiveness studies for decision-making on introduction of new vaccines: ProVac  
Dr K. Senouci, AMP*

The ProVac Initiative is a programme of the Pan American Health Organization, created after a 2006 Directing Council Resolution (CD47.R10). Its main objective is to strengthen the technical capacity in countries of the Americas for evidence-based decisions, mainly through the use of cost-effectiveness analysis tools for new vaccine introduction. The models used focus on four vaccines, namely: rotavirus, pneumococcal conjugate, human papillomavirus and influenza.

In 2012, the ProVac International Working Group, a partnership of international technical agencies, was established to generalize the use of the tools and methodology developed by ProVac to other WHO regions.

AMP in collaboration with the WHO Regional Office for the Eastern Mediterranean is in the process of developing support to countries in the Eastern Mediterranean Region. For the pilot phase in 2012–2013, this will be through direct support to two countries and the organization of a regional training workshop. Egypt and the Islamic Republic of Iran have been identified as the pilot countries, as these are the last two countries in the Region yet to include the Hib vaccine in the routine schedule. Tunisia will also benefit from activities provided through the Supporting Independent Immunization and Vaccine Advisory Committees (SIVAC) Initiative. Other countries will benefit from training during the regional workshop and then will be able to request direct support based on needs assessment.

*5.2.3 Role of NITAG in supporting NVI: Experience of Pakistan  
Dr T. Bhutta, Chairperson, NITAG Pakistan*

The National EPI Advisory Group (NEAG) in Pakistan was formed in 2003 under an executive order of the Federal Secretary (Health), Ministry of Health. The objectives of the NEAG were to provide policy direction regarding EPI to the Government of Pakistan on advocacy, immunization schedules, innovations in EPI, vaccine-handling and storage, and other technical issues as required. Since then, the achievements of the NEAG include endorsement of the national EPI policy and strategic guidelines, recommendation for introduction of hepatitis B vaccine in the EPI schedule, adoption of injection safety measures into the routine EPI schedule, the switch to tetravalent combination vaccine, recommendation for introduction of Hib vaccine (pentavalent), and recommendation for introduction of a second dose of measles vaccine in the routine EPI schedule.

In July 2008, NEAG reformed as a NITAG, with updated terms of reference in line with WHO criteria regarding nomination of members, revised guidelines and terms of reference.

In April 2009, NITAG endorsed the country proposal for introduction of pneumococcal conjugate vaccine with GAVI support. On 22 August 2009, NITAG endorsed the decision to resubmit the application as per the recommendation of the GAVI Independent Review Committee, along with an updated cMYP. The pneumococcal conjugate vaccine introduction plan and its progress were discussed in subsequent NITAG meetings; however, it was known that the desired PCV13 was not available in adequate quantity for Pakistan.

In 2010, therefore, NITAG recommended for immediate introduction of PCV10 with the aim of switching to PCV13 when available. In 2011, NITAG was updated on PCV10 introduction and endorsed the country decision for introduction of rotavirus vaccine in 2013. In March 2012, NITAG reviewed country preparations for introduction of PCV10 and recommended to launch introduction on 1 July 2012. In August 2012, NITAG and the national committee for PCV10 introduction reviewed the level of preparation and recommended phased introduction of PCV10 starting from 1 October 2012.

### **5.3 Lessons learned from introduction of new vaccines in countries of the Region**

#### *5.3.1 Introduction of rotavirus and Hib vaccines: Experience from Iraq*

*Dr N. Ibrahim Abbas, Assistant EPI Manager, Iraq*

In 2007, EPI and WHO proposed to introduce rotavirus and Hib vaccines in the routine EPI schedule in Iraq. The proposal was based on epidemiological data on morbidity, mortality and hospitalization of children under 5 years of age. Sentinel surveillance for rotavirus and bacterial meningitis in children under 5 was established, in addition to surveillance of intestinal intussusception in children under 1 year of age.

According to the results of sentinel surveillance, and experiences of other countries in the Region, NITAG recommended introduction of rotavirus and Hib vaccines in the national EPI schedule. A task force was established to develop a workplan for the introduction of new vaccines. All necessary preparations were completed, and new vaccines implementation began on 1 January 2012.

#### *5.3.2 Rotavirus vaccine introduction and intussusception surveillance: Lessons learned from Sudan*

*Dr A. Abdel Moniem, EPI Manager, Sudan*

The under-five mortality rate in Sudan is 78 deaths per 1000 live births (Sudan Household Health Survey, 2010). Diarrhoeal diseases are the fourth leading cause of admissions to hospitals and the fifth leading cause of death in children aged under 5 (Annual Health Statistical Report, Sudan, 2010). In April 2007, the Federal Ministry of Health in collaboration with WHO joined the surveillance networks for rotavirus and invasive bacterial

vaccine-preventable diseases. Initially, eight sentinel sites were selected; this was later reduced to five sites, in 2011. Rotavirus surveillance data from 2007 to 2010 reflected a high burden of rotavirus disease in Sudan. Based on morbidity data, the NITAG recommended the introduction of rotavirus vaccine. Sudan applied to GAVI for introduction of rotavirus vaccine in 2009, was approved in 2010, and introduced the vaccine in July 2011. Preparation activities such as cold chain expansion, rehabilitation, training, updating of the information system and social mobilization activities were implemented in a timely manner and implementation practices were closely monitored.

The lessons learned from rotavirus vaccination with regard to the different programme components are:

- planning and budget – microplanning should consider the frequency of outreach and mobile sessions, and vaccine transport costs should be considered in the budget plan;
- cold chain and vaccine management – cold-chain capacity should be considered at the facility level as well as upper levels;
- training – practical implementation and role play are essential for good training;
- social mobilization – it is essential to start early and maintain momentum after introduction;
- monitoring and evaluation – continuous monitoring and supervision, with a modified checklist, is essential.

To monitor vaccine safety, following the Global Advisory Committee on Vaccine Safety recommendation to develop a system of post-marketing surveillance for new vaccines, intussusception surveillance was established in Sudan under the support and guidance of the Regional Office and CDC. The main objective of surveillance is to monitor any potential change in intussusception incidence following the introduction of rotavirus vaccine and to assess rare adverse events after vaccination through robust, feasible and specialized epidemiologic methods. The surveillance methodology is designed as a self-controlled case series method, with an estimated 242 case patients (vaccinated and unvaccinated) necessary to determine whether a greater than 2.5 fold risk (~1 in 100 000 infants) exists within 7 days of receiving any of the 2 doses of rotavirus vaccine. Surveillance will be continued until doubling of the sample size as recommended, with periodic monitoring and analysis in consultation with experts. The main finding of the surveillance system showed that 65% of intussusception cases were among children under 1 year old, and 65% were males. Out of 112 cases reported, only 50 cases were eligible for vaccination and 67% of them were vaccinated. The main finding about the time interval between rotavirus vaccine administration and date of onset of intussusception was that none of the cases occurred within 7 days of vaccination, one case occurred 10 days after vaccination by second dose, and the rest of the cases (97%) had an onset more than one month after vaccination.

The lessons learned from intussusception surveillance include the need to involve related parties (national regulatory authority, paediatric surgeons and paediatricians); need for frequent supervision and follow-up for timely correction; greater effort needed for collection of vaccination status; and, the importance of feedback and information sharing.

Future plans are to increase the coverage of the second dose of rotavirus vaccine by strengthening the “reaching every district” approach and implementing plans for special groups and security compromised areas; to use rotavirus surveillance data to evaluate the impact of the introduction of rotavirus vaccine; to analyse the post-marketing intussusception data; to conduct a post-introduction evaluation (PIE); to implement cost-effectiveness studies as needed; and, to secure Government co-financing.

#### **5.4 Establishing pooled vaccine procurement in the Region**

*Mr. M.Ozturk, WHO Regional Office for the Eastern Mediterranean*

Higher-income and GAVI-supported lower-income countries in the Eastern Mediterranean Region have been successful in the uptake of new vaccines. However, middle-income countries have been experiencing financial and operational difficulties in the introduction of new vaccines. Lack of sufficient funds and the prevailing high prices of the new vaccines on the supply side constitute two major obstacles. Given the successful examples of pooled systems such as the Pan American Health Organization’s Revolving Fund and UNICEF Supply Division, the establishment of a pooled vaccine procurement (PVP) mechanism in the Eastern Mediterranean Region has emerged as a crucial need.

Member States expressed their strong interest in establishing a regional vaccine procurement system and requested the WHO Regional Office for the Eastern Mediterranean to initiate, lead and coordinate the efforts. One of the main goals of the PVP initiative is to improve access to high-quality vaccines, particularly to new and underutilized vaccines, at competitive prices with predictable and appropriate timing to maximize efficiency and minimize the risk of disruption to immunization programmes due to access and supply issues. The envisioned PVP system in the Region will be based on the principles of country ownership, sustainability, solidarity, collaboration and mutual learning.

## **6. STRENGTHENING EPI TO MEET THE TARGETS**

### **6.1 Improving programme management**

*Dr N. Teleb, WHO Regional Office for the Eastern Mediterranean*

Inadequate technical and managerial capacity of national EPIs in the wake of expanding scope and multiple priorities of the programme is a major challenge hindering proper implementation of the recommended strategies and, hence, achievement of the targets. Aware of this challenge, the Regional Committee for the Eastern Mediterranean in its fifty-eighth session in October 2011, urged Member States to “Review and strengthen the structure and managerial capacity of the national immunization programme at all levels” (EM/RC58/R.5).

The national immunization programme structure includes (under the overall supervision of a national EPI manager) focal persons and teams to handle immunization operations, strengthening routine immunization, disease eradication and elimination, training, vaccine procurement and logistics, advocacy and communications, and operations research as well as

support staff. Staff might be shared between different functions. The total number of staff performing these functions will depend on the country situation, availability of human resources, workload and staff performance.

Inadequate skills of health-care providers affect quality of performance and ability to deliver services, especially to poor and disadvantaged populations. A large number of unqualified staff might result in low performance of the programme. Appropriate staff selection, training and motivation are essential for ensuring high performance and might allow dependency on a smaller number of staff.

Adequate human resource capacity of EPI depends on the adequacy of recruitment and placement, proper in-service management and establishment of a system for ensuring staff retention. Recruitment of the appropriate staff should start with proper staff planning, based on needs assessment, and inclusion of staff and staff recruitment in the cMYP. A clear job description, fair competitive selection, and proper pre-service training are essential. Periodic in-service training, a continuing education programme and regular supportive supervision keep staff updated and motivated. Complementary inputs including supplies, equipment, transportation and operational costing of the planned activities will ensure timely implementation of activities.

Rapid turnover of staff is one of the major challenges facing EPI in many countries of the Region, especially low-resourced countries. Suitable remuneration and timely payment of salaries are basic requirements for improving staff retention. It is important to set a “health workers’ retention scheme” as part of the overall human resource plan, including clear and transparent performance-based rewards, staff recognition and staff promotion systems, promotion of leadership and autonomy, as well as career development.

## **6.2 Improving EPI monitoring and evaluation of EPI**

### *6.2.1 Improving data quality*

*Dr E. Eltayeb, WHO Regional Office for the Eastern Mediterranean*

Reliable immunization coverage data are crucial for monitoring programme performance and design, adapting strategies, and prioritizing areas and populations with low coverage rates that are, hence, more susceptible to vaccine-preventable diseases. Coverage is important not only as an epidemiological indicator, but also as a proxy indicator for equity in service delivery and as a development indicator used to monitor progress towards the MDGs. The presentation highlighted problems encountered in monitoring and reporting routine immunization coverage data, and the use of different monitoring and evaluation tools.

Coverage data are subject to many numerator and denominator issues that can affect their quality, credibility and reliability. Numerator issues include unjustified year-to-year differences of more than 5% when compared to WHO/UNICEF estimates, negative drop-outs, and variations in survey results. Denominator issues that have been observed in many countries of the Region include the existence of different denominator sources, reported

immunization coverage that exceeds 100% or number of Bacille Calmette–Guérin (BCG) and DPT1 doses administered that exceed the denominator.

Regarding tools for reporting and monitoring, problems and issues encountered when reviewing data reported through the Joint Reporting Form were highlighted. A few observations from the forms are: mixing the use of number of live births and number of surviving infants as a denominator, missing data, inconsistency and discrepancies observed in different responses, unusual immunization schedules, inconsistency in reporting incidence of vaccine-preventable diseases, and unreliable data on sources of vaccine and supplies.

Another important tool is the district reporting regional database. This database helps to identify high-risk areas and pockets of susceptible population, and facilitates timely response. Countries are to consider using this database, and resolve any issues that hinder data-sharing with the Regional Office and other development partners in a timely manner. It is worth noting that countries need to assess the quality of their coverage data on a more regular basis. Data quality self-assessment is a systematic and periodic assessment of coverage data accuracy, consistency, completeness and timeliness; it also promotes supportive supervision and instant feedback. Coverage surveys, which aim to estimate immunization coverage at either national or subnational levels, are used to establish baseline information or provide comparison with administrative estimates and/or satisfy the demand of a partner agency. Other tools which are commonly in use for coverage estimation include EPI cluster survey, lot quality assurance sampling survey, demographic and health survey, and multiple indicator cluster survey. Survey estimates differ from routine administrative data sources, and EPI managers need to be aware of the different survey methodologies.

In conclusion, it is important to systematically monitor numerators and denominators of coverage data at all levels. The Joint Reporting Form deserves considerable attention as an important source of data at the global, regional and national level. Data reported in the Joint Reporting Form have to be timely, accurate, and complete. Countries need to continuously update their guidelines on data quality and immunization coverage monitoring, and be familiar with the existing tools used for the purpose.

#### *6.2.2 Monitoring results for equity*

*Dr M. Sheth, UNICEF Regional Office for North Africa and the Middle East*

Globally, under-five mortality rates have declined from 12 million in 1990 to 6.9 million in 2011, and the annual rate of under-five mortality reduction has increased from 1.8% to 3.2%. Despite this, some 19 000 children die every day from preventable causes and there are great divides and disparities among regions and within countries: the economically poorest regions, least-developed countries, most fragile nations, and most disadvantaged and marginalized populations continue to bear the heaviest burden of child deaths.

In the Middle East and North Africa (MENA) Region, under-five mortality declined from 192 per 1000 live births in 1990, to 41 per 1000 live births in 2010. There has been good progress in EPI, polio eradication, measles elimination, and addressing key child

survival issues. However, 415 000 children die every year before the age of five and 320 000 children die every year before their first birthday in the MENA Region.

Committing to Child Survival: A Promise Renewed, a global consultation hosted by Ethiopia, India and United States of America, took place in Washington DC in June 2012. The meeting was attended by around 700 senior officials and proposed to scale up action on three fronts:

- revitalizing the global movement for maternal, newborn and child survival;
- sharpening and resourcing evidence-based country plans;
- enhancing transparency and accountability for maternal, newborn and child survival.

National leaders pledged to achieve an ambitious but attainable target of reducing child mortality to 20 deaths per 1000 live births by 2035. To date, 100 Member States globally and 11 Member States in the MENA Region have signed the pledge. One of the key aims is to sharpen evidence-based country plans and equity focus. The “monitoring results for equity system” is one such tool. It is a conceptual framework for effective planning, programming, implementation, monitoring and managing for results, in order to achieve the desired outcomes for the most disadvantaged children. The framework is based on three key principles: equity refocus; management for results; and, bottleneck and barrier analysis

The presentation highlighted the inequities among the richest and poorest populations in accessing basic health services, and presented a framework for monitoring equity systems in terms of enabling environments, supply, demand and quality barriers, and frequency of monitoring the barriers and bottlenecks.

In conclusion, committing to the pledge offers an opportunity to revitalize efforts towards child survival, and the pledge needs to be signed by all countries. Donors are looking for results and progress. Identifying and addressing barriers and bottlenecks contributes to sustainability, and links up well with the accountability framework for maternal and child health. It is recommended that national plans of action include a bottleneck analysis and its monitoring on a regular basis.

### *6.2.3 Comprehensive review of EPI*

*Dr I. Chaudhri, WHO Regional Office for the Eastern Mediterranean*

The objective of the comprehensive EPI review is to systematically review different components of the programme, and identify strengths and weaknesses for further improvement. Usually, assessment of different programme components is undertaken including injection safety, data quality, cold chain and vaccine management, post-introduction evaluation and measles elimination review. However, the need was felt for an overall integrated assessment of all programme components at various levels. The findings of such a comprehensive EPI review might suggest the need for a more focused assessment of certain areas. The comprehensive EPI review also provides a major opportunity for advocacy.



The WHO Regional Office for the Eastern Mediterranean developed a first draft of regional EPI review tools and guidelines in January 2010, in collaboration with CDC Atlanta, learning from available experiences/instruments such as the WHO common assessment tool for immunization services, the PAHO review tool and the Viet Nam review tool, as well as specific assessment tools such as PIE, data quality self-assessment, the injection safety assessment tool, and the Effective Vaccine Management Assessment tool. Drafts are updated periodically; the latest draft was updated in June 2012, in consultation with WHO temporary advisers from various countries in the Eastern Mediterranean Region.

The review is primarily qualitative and is undertaken by relevant partners, along with the ministries of health including EPI. The process is managed by a core group. In particular, the review assesses political commitment and legal basis, advocacy and communication, planning and management, policy, budget and financing, human resources, training, operation research/evaluation, vaccine and supplies/logistics, procurement, vaccine management, injection supplies, cold chain, waste disposal, distribution logistics, service delivery, monitoring and supervision, reporting system, and vaccine-preventable diseases surveillance. The data collection tools covering the above areas are for use at national, provincial, district and service-delivery level. The tools are modified according to the country context.

The review is usually conducted in three phases: planning phase, fieldwork/data collection phase, and data analysis and report writing phase. The phases are spread over a period of 4 to 5 weeks. Since May 2010, WHO has conducted comprehensive EPI reviews in Afghanistan, Egypt, Pakistan (Punjab), Qatar and Saudi Arabia. In the Syrian Arab Republic, the EPI review was conducted by nationals.

It is important to develop a plan of action based on the review findings. The plan of action should be monitored regularly as regards to its implementation status.

#### *6.2.4 Pre- and post-introduction evaluation*

*Dr D. Aden, WHO Regional Office for the Eastern Mediterranean*

Many countries in the WHO Eastern Mediterranean Region have added new vaccines in their national immunization programme, with the financial support of GAVI or with funding from their own national budget. The absence of documented experience and the rapidity with which countries introduced the new vaccines have raised concerns about the effect of introduction on national immunization programmes.

The introduction of new vaccines carries certain risks, both for the success of the introduced vaccine and for the maintenance of the national immunization programme. Questions include whether the introduction of these vaccines is harming the delivery of traditional EPI vaccines; and, whether these vaccines are reaching children in a potent and safe state. To address these questions, WHO in collaboration with other partners recommended undertaking a PIE in order to assess the programmatic impact of new vaccines introduction.

The main objectives of the PIE are to evaluate the process and its impact, document and learn from the country experience, implement any corrective measures before the next introduction and, finally, to share experiences with other countries in the Region. However, the PIE is not assessing the impact of a new vaccine on disease burden.

The PIE lasts 10 days, conducted within 6 to 12 months of vaccine introduction, and is performed at all levels of the health system. An evaluation team is composed of three evaluators: one external and two internal. They use a PIE tool that has to be adapted to the country's health administration context. There is no random selection of sites; selection is based on geographical representation and performance (good, moderate or worst), taking into account the type of facilities, equity issues and feasibility.

The instruments of the PIE are standardized questionnaires for each level and a standardized checklist. Questionnaires should be adapted during the training workshop. There are no major difficulties in using the tool, but the main challenge is to isolate the PIE of new vaccines from routine evaluation.

The 10 key areas to be evaluated are: planning and introduction of the new vaccine, coverage and reporting, cold-chain management, vaccine management and storage, monitoring and supervision, training and knowledge of health-care workers, waste management and injection safety, adverse events following immunization, advocacy, communication and acceptance of the new vaccine.

At the end of the PIE, a debriefing session should be organized with the ministry of health, inter-agency coordination committee and partners. Preliminary findings and recommendations should be presented and discussed with participants. A final report of the PIE is submitted to the country.

In the Eastern Mediterranean Region, three countries (Afghanistan, Djibouti and Sudan) have undertaken PIE for pentavalent vaccine.

### **6.3 Improving vaccine management and logistics**

#### *6.3.1 Controlled temperature chain*

*Dr N. Musa, WHO Regional Office for the Eastern Mediterranean*

Through project Optimize, there have been great technological and innovative efforts regarding using vaccines in a controlled temperature chain. A controlled temperature chain is defined as storing and transporting vaccines under controlled temperatures, possibly outside the traditional range of +20°C to +80°C, and suitable to the vaccine's stability profile. The expected benefits will allow easier transportation and handling of vaccines to:

- reach more children, including those in hard-to-reach areas, with more options for immunization strategies;

- deliver vaccines to the right groups at the right time (e.g. hepatitis B birth dose to newborns, tetanus toxoid vaccine to women, human papillomavirus vaccine to adolescent girls);
- reduce programmatic costs and constraints such as the burden of ice pack freezing, and lower costs for investment in cold-chain and transport expansion, especially in preparation for introduction of new vaccines;
- reduce the risk of freeze damage to vaccines.

There are three strategic streams of work to adopt:

- country-level evidence: documenting lessons learned and practices from the field (e.g. Mali feasibility study conducted during polio national immunization day campaigns);
- regulatory pathway: working to license vaccines in accordance with their true stability;
- programmatic work: developing the necessary programmatic guidelines to support implementation of approved policy.

Although some countries have already been taking advantage of the stability of today's vaccines (using certain antigens outside the cold chain for limited periods of time, or relying on the vaccine vial monitor (VVM)), this use is considered "off-license" and is not supported by manufacturers and regulators. The timing for this work is therefore longer than anticipated, and re-licensed hepatitis B vaccine will not be available before 2014.

Collaborative effort is still needed to:

- reflect true vaccine stability in manufacturers' prescribing information;
- encourage industry to carry out stability tests at higher temperature ranges and submit data to regulatory bodies;
- finalize and endorse guidelines for countries, putting vaccine quality and safety as the first priority.

Collaboration among the vaccine manufacturer, PATH, WHO, and the Canadian and Indian regulatory bodies is under way in order to obtain a license variation for this vaccine.

### 6.3.2 *New temperature monitoring devices*

*Mr B. Al Rawahi, EPI, Oman*

Knowledge of new vaccine temperature monitoring devices is important for EPI to prevent vaccine damage during distribution, ensure proper storage and handling, and make the most of the benefits of VVMs. At some stage, vaccines must be distributed to intermediate, district and service levels; however, optimal storage conditions may not be available during movement of the vaccine. Vaccines are exposed during transport and it is essential to minimize any damage. Knowledge must be in place regarding temperature stability, effective vaccine management requirements, types of vaccine monitoring device (VVMs, freeze tags, TransTracker, Q-tag, fridge tags and wireless data loggers), and benefits of VVMs.

In conclusion, VVMs are the basis for vaccine management. However, VVMs are not put on all vaccines, so the heat exposure of individual vials is not known. Only comprehensive temperature monitoring can record the temperature history of vaccines passing through the supply chain.

### *6.3.3 Project Optimize in Tunisia*

*Dr R. Ouhichi, WHO Tunisia*

The presentation shared experiences gained in Tunisia through Project Optimize and showcased innovations that countries in the Region can share. Since 2010, the Tunisian Ministry of Public Health has collaborated to explore new logistic and supply chain solutions to optimize the vaccine supply chain for the future. The three-year collaboration aimed to demonstrate the benefits of a supply chain that is more streamlined and integrated with those of other temperature-sensitive health products. This means bypassing the Ministry of Public Health's national medical store. Instead, the Central Medical Store of Tunisia takes responsibility for the procurement, storage and distribution of all temperature-sensitive health products to regional level. Further down the supply chain, regional and district stores have been consolidated so that all delivery of health products (including vaccines) are grouped in convenient transportation circuits by efficient route planning.

The project relies on solar energy to achieve zero net energy consumption. Solar panels were installed on subnational stores, and the energy consumption for the storage and transport of vaccines and other health commodities is offset by the electricity produced. This "green" supply chain system – which uses electric vehicles to transport health commodities and workers for service delivery – relies on renewable energy. The energy balance is zero – what is produced on-site will be consumed on-site by cold-chain storage and vaccine transportation. It also removes any reliance on fuel for transport.

The management information system can track and trace vaccines in real-time throughout the supply chain, mitigating the risk of overstocking, expiry, and vaccine wastage. The existing paper-based system will be replaced by a computerized system that links national, regional and district levels. This will enable the exchange of real-time data on key vaccine forecasting, stock management, and order status information, ensuring the timely delivery of vaccines. The three supply chain innovations are being piloted in two areas of Tunisia (Kasserine and Sousse) to improve efficiencies in procurement, supply, storage, distribution, stock management and quality of services.

It is necessary to ensure the responsiveness of the supply chain to routine and emergency requests, and prepare it for the introduction of new, larger volume and higher cost health products. The reliability of this environmentally friendly system is a good example of sustainable development in the health sector.

#### **6.4. Sustainable immunization financing**

*Dr M. McQuestion, Sabin Vaccine Institute*

In 2011, the Decade of Vaccines and GVAP launched to provide a strong policy basis for countries to achieve sustainable immunization financing. The countries are currently highly dependent on external financing for their routine EPI. This dependency implies a series of missed opportunities such as capacity-building spillovers, greater public engagement, and improving development outcomes in other sectors. The cMYP and Joint Reporting Form platforms have generated useful valid data for analysing immunization finance. Countries are paying more for routine immunization, however, they need to raise the rate of budget increases if they are to achieve country ownership (defined here as fully financing routine immunization). Studies of reported cMYP and Joint Reporting Form data show that most GAVI-eligible countries could increase their spending from US\$ 18 to the needed US\$ 40–60 by 2016 without taking resources from existing programmes, i.e. by capturing 20–30% of future revenue growth. The immunization budgets lack rigour: this is true for budget formulation, execution and reporting. Hence, countries must take control of their EPI budget allocation procedures. cMYP projected budgets are the recommended starting point. Governments can assert ownership by using national funds to finance routine programme costs. External funds should be shifted to meet “upstream” needs. Managers must begin monitoring EPI expenditures: just as they now monitor vaccine coverage and surveillance data, they must also analyse and report their expenditures (“adding the third leg to the EPI stool”).

The transition to country ownership can be seen as a series of organizational and institutional innovations (i.e. the development of new best practices). These innovations are taking place within the public institutions that are key for sustainable immunization financing: ministries of health, ministries of finance, parliaments and local governments. Innovations are undertaken by individuals (champions) in these institutions. They happen through four distinct pathways. When and where they will materialize is unpredictable. The examples of innovations for immunization financing are evident in some of the sustainable immunization financing pilot countries. Parliaments are engaging actively in new ways in the budget process. Ministries are responding to their requests with organizational restructuring and stronger investment cases for immunization. Health and finance ministry counterparts are beginning to share and analyse financial and budget information. Domestic private-sector donors are stepping forward, and governments are finding ways for them to co-finance routine immunization (such as tax credits, or trust funds). Government ministries and parliaments are jointly updating or drafting new immunization legislation. At Organizational level, immunization managers are beginning to analyse their expenditures and to more widely report programme efficiency and effectiveness. External partners are also innovating through joint training and other activities. They need to further innovate by shifting their financial support away from recurrent immunization programme costs to upstream needs. Innovations within the key public institutions need to be promoted and supported from the outside. Sabin’s Sustainable Immunization Financing programme does this using a collective action framework. Collective action is supported through peer exchanges, periodic inter-institutional

briefings, and regular monitoring and feedback on best practices and progress toward the sustainable immunization financing objective.

## **7. CONCLUSIONS**

Participants noted the slight drop in reported DTP3 coverage in the Region in 2011 – despite substantial constraints and challenges that several countries have experienced – and expressed appreciation to EPI in Egypt, Tunisia, Libya and Yemen for the extra efforts devoted to maintaining the high performance of the programme.

Participants noted with concern the likely effect of the recent administrative change in Pakistan on EPI, including timely availability of the vaccines for routine use.

Participants of the meeting would like to thank the Regional Director for the Eastern Mediterranean, for declaring that EPI will be a fixed agenda item in the Regional Committee every year and requested the VPI Regional Office for the Eastern Mediterranean to utilize this opportunity for further advocacy to strengthen EPI.

## **8. ACTION POINTS**

### *Strengthening of routine immunization*

1. Countries that have not yet achieved routine immunization coverage targets (at least 90% DTP3-containing vaccine coverage at national level and 80% in all districts) to place greater emphasis on analysing district-level data, identifying the unreached population, identifying the barriers to immunization, using all opportunities, adapting recommended global strategies and tools to the country specificities, and strengthening collaboration with other ministries and sectors in order to reach the unreached and achieve the target.
2. Countries that are passing through internal difficulties to take all necessary measures, including ensuring timely availability of vaccines, to maintain the momentum and sustain the performance of the programme.
3. WHO to advocate with GAVI Secretariat the need to clearly communicate to countries the change in GAVI policy regarding the scope of health systems strengthening funds, with the focus on utilization of this fund for immunization services strengthening.
4. EPI managers to utilize all available guidelines and materials for human resource capacity-building, improving overall knowledge and reviewing performance. EPI managers should provide the available technical documents and information to NITAGs to facilitate informed decision-making.
5. NITAGs to analyse the human resource capacity of EPI and capitalize on the commitment expressed in resolution EM/RC58/R.5 for recommending, advocating and mobilizing resources to improve structure and management capacity of EPI.
6. Countries to develop/update and share national policy and strategies for vaccination of older age groups and high-risk populations.

7. EMRO to continue advocating for strengthening capacity of national EPI at all levels in order to ensure that all required functions are addressed and EPI is empowered to respond to evolving needs.
8. EMRO to organize a workshop to discuss pertussis surveillance in the Region.
9. EMRO to develop a regional plan of action for implementation of the GVAP and provide the necessary technical support to the countries for development and implementation of national plans of action.
10. Countries are to update their multi-year plan in line with the GVAP.

#### *Improving data quality*

11. All countries to ensure high quality of administrative coverage data and use the data for improving programme performance.
  - 11.1 Countries are to ensure timely collection and analysis of district-level vaccination data and use the data to identify high-risk areas and pockets of susceptible population. EPI managers and their teams are to analyse EPI-related data and triangulate available data from different sources (coverage, disease burden, vaccine supply, etc.) to examine data quality and implement corrective measures.
  - 11.2 Countries are to periodically undertake data quality self-assessment to identify problems in the reporting system and undertake corrective measures.
  - 11.3 Countries are to periodically undertake vaccination coverage surveys, when and where necessary, at national or subnational level, to validate administrative coverage data and apply corrective action.
  - 11.4 In order to follow up on the global target of DTP3 coverage of 90%/80%, countries are to report monthly district-level coverage data to the Regional Office using the standard data transfer sheet.
  - 11.5 WHO to provide the necessary technical support for building national capacity for improving the quality of the EPI reporting system and improving quality of coverage calculations/estimates methodology, helping the country to generate the most accurate coverage figures.

#### *Strengthening EPI logistics system*

12. Countries are encouraged to use the new and available prequalified cold-chain monitoring devices to ensure cold-chain function.
13. All countries to ensure procurement of all vaccines with VVM.
14. WHO and partners to provide necessary technical support for building national capacity in the area of vaccine management and logistics.

#### *Measles/rubella control and elimination*

15. Countries that have not introduced rubella vaccine to undertake epidemiological analysis of the situation, utilizing data generated by laboratory case-based surveillance

- and serosurvey, if available, for informed decision-making on vaccination strategy and on age limits for implementation of the catch-up measles-rubella campaign.
16. Before rubella vaccine introduction, countries to secure necessary resources for routine vaccination and follow-up supplementary immunization activities with rubella-containing vaccine.
  17. All countries to establish a suitable CRS surveillance system and generate data necessary for advocacy on introduction of rubella vaccine (for countries yet to introduce the vaccine) as well as monitoring progress towards achieving the national elimination target (for countries that have developed an elimination target).
  18. WHO and partners to provide necessary technical support for establishing CRS surveillance, analysing data for decision-making and mobilizing necessary resources for introduction of rubella vaccine.

#### *Hepatitis B disease reduction target*

19. Countries to establish a national programme for hepatitis B control. EPI is to advocate for this, with full collaboration between all concerned sectors.
20. Countries that have introduced hepatitis B birth dose to seek all possible actions to achieve high coverage (at least 90%) for the hepatitis B birth dose during the first 24 hours after birth.
21. The Regional Office to prepare guidance for introducing/enhancing the uptake of hepatitis B birth dose.
22. All countries are encouraged to undertake hepatitis B serosurveys to document the impact of the hepatitis B vaccination programme and document progress towards achieving the target (EM/RC56/R.5.) and to use the data for further advocacy for introducing/improving coverage of the birth dose.
23. WHO and partners to provide necessary technical support for undertaking hepatitis B serosurveys, if required by the countries.
24. Sudan to publish the results of the recent hepatitis B serosurvey in a peer reviewed journal with the support of WHO.

#### *Maternal and neonatal tetanus elimination*

25. Countries that have not yet achieved maternal and neonatal tetanus elimination to review their current situation, identify high-risk districts and update national plans for achieving the elimination target and to mobilize necessary resources for its implementation.
26. WHO, UNICEF and partners to provide necessary technical support and help to mobilize resources for implementation of planned activities, including supplementary immunization activities.



*New vaccine introduction*

27. Countries to continue to generate surveillance data for vaccine-preventable diseases and to use it effectively in making evidence-based decisions on new vaccines introduction and monitoring impact of a vaccine on disease reduction.
28. Countries that are not implementing vaccine-preventable disease surveillance are encouraged to join the regional surveillance network and benefit from the available technical support and quality-control system.
29. Countries are encouraged to undertake cost-effectiveness studies on new vaccines introduction. Egypt, Islamic Republic of Iran and Tunisia are encouraged to utilize available technical and financial support from ProVac and WHO to implement cost-effectiveness studies.
30. EMRO, in collaboration with AMP, to organize a training workshop on cost-effectiveness of new vaccines introduction and to provide technical support to the countries where needed.
31. In view of the advantage of lifting the age restriction on rotavirus vaccination on coverage of the vaccine, countries that introduced rotavirus vaccine with application of age restriction are to review the situation and consider implementation of the new SAGE recommendations on lifting the age restriction. Countries that are introducing the vaccine soon should consider lifting the age restriction from the outset.
32. WHO and partners to provide support to ensure successful introduction of pentavalent vaccine in Somalia and help mobilize necessary resources for conducting hepatitis B catch-up campaign.
33. In view of the expected advantage of the pooled vaccine procurement (PVP) mechanism, countries are encouraged to join phase one of the initiative and send a letter of intent to join.
34. EPI managers, NITAG members and other representatives to take immediate action to communicate the possible benefits of the PVP initiative to their countries' decision-makers (health ministers, finance ministers and other stakeholders).
35. WHO to advocate with GAVI for re-examining the situation and need of middle-income countries and consider reviewing the eligibility criteria, and provide support or partial support initiating PVP in support of new vaccines introduction in middle-income countries.

**Annex 1****PROGRAMME****Sunday, 16 September 2012**

08:00–09:00	Registration	
09:00–09:45	Opening session	
	Opening address	Dr Ala Alwan, Regional Director, WHO/EMRO
	Introduction of participants and election of officers	Dr J. Mahjour, DCD/EMRO
	Video on third regional vaccination week, 2012	
	Objectives of the meeting and introduction to the agenda	Dr N. Teleb, WHO/EMRO
	Adoption of the agenda	Chairperson
	Session I: Global and regional briefings	
09:45–10:05	Update on global situation of EPI	Dr J.M. Okwo-Bele, WHO/HQ
10:05–10:35	Regional overview	Dr N. Teleb, WHO/EMRO
10:35–11:00	Discussion	
11:30–11:50	Briefing on SAGE sessions 2010–2012	Dr P. Duclos, WHO/HQ
	Conclusion and main recommendations	
	Salient points of the revised WHO position papers	
11:50–12:00	NITAG: Progress and role in strengthening EPI	Dr P. Duclos, WHO/HQ
12:00–12:30	Briefing on Global Vaccine Action Plan (GVAP)	Dr T. Cherian, WHO/HQ
12:30–13:00	Discussion	
	Session II: Reaching and sustaining high access to routine immunization in difficult situations	
14:00–14:15	Re-establishing EPI in Somalia	EPI manager, Somalia
14:15–14:30	Improving vaccination coverage in South Sudan	EPI manager, South Sudan
14:30–14:45	Post-devolution strengthening of routine immunization at provincial level in Pakistan: Implementation of provincial plans of action	EPI manager, Pakistan
14:45–15:00	Reaching “hard-to-reach population” in Sudan	EPI manager, Sudan
15:00–15:30	Discussion	
15:45–16:00	Situation and challenges facing EPI in Egypt	EPI manager, Egypt
16:00–16:15	Situation and challenges facing EPI in Libya	EPI manager, Libya
16:15–16:30	Situation and challenges facing EPI in Yemen	EPI manager, Yemen
16:30–17:00	Discussion	

**Monday, 17 September 2012**

## Session III: Achieving the regional targets

	1. Poliomyelitis eradication	
08:30–08:50	Global and regional overview of polio eradication status: Progress and challenges	Dr T. Mir, WHO/EMRO
08:50–09:15	Discussion	
09:15–09:40	Risk assessment for polio outbreaks in polio-free areas: Methodology, interpretation and response	Dr H. Safwat, WHO/EMRO
09:40–10:15	Discussion and demonstration	
10:15–10:30	Vaccine-derived poliovirus (VDPV): What are VDPVs, how they emerge, what is response	Dr H. Asghar, WHO/EMRO
10:30–10:45	Discussion	
11:15–11:40	OPV-IPV use in polio pre-eradication phase and proposed policy for a switch from tOPV to bOPV	Dr E. Mohsni, WHO/EMRO
11:40–12:00	Discussion	
12:00–13:00	Group work: Group 1 (Countries already using or planning to introduce IPV by end of 2013): Risk analysis: Applying the tool at subnational level Group 2 (Remaining countries) Switch from tOPV to bOPV: Policy, technical, financial and programmatic implications	
	2. Measles/rubella elimination	
14:00–14:15	Measles elimination: Current situation	Dr H. Ahmed, WHO/EMRO
14:15–14:30	Discussion	
14:30–14:40	New GAVI window on rubella vaccine introduction	Dr E. Eltayeb, WHO/EMRO
14:40–14:50	Yemen decision on introduction of rubella vaccine: Mobilization of national resources	EPI manager, Yemen
14:50–15:10	Discussion	
15:10–15:30	Briefing on regional consultation on rubella/CRS	Dr N. Teleb, WHO/EMRO
15:30–15:50	Discussion	
	3. Maternal and neonatal tetanus elimination	
16:00–16:20	MNT elimination: Global and regional situation and way forward to achieve elimination	Dr A. Raza, UNICEF HQ
16:20–16:35	Validating MNT elimination in Iraq	EPI manager, Iraq
16:35–17:00	Discussion	

**Tuesday, 18 September 2012**

## Session III: Achieving the regional targets (cont'd)

	4. Hepatitis B control	
08:30–09:00	Implementation of the regional strategy on hepatitis B control and progress so far: Introduction of hepatitis B birth dose: Decision-making and implementation Monitoring progress: Hepatitis B serosurvey in Sudan	EPI manager, Djibouti EPI manager, Sudan
09:00–09:10	Introduction to the group work: Reviewing national situation of hepatitis B control	Dr N. Teleb, WHO/EMRO
09:10–11:00	Group work: Reviewing country situation of hepatitis B control Group 1: Afghanistan, Egypt, Jordan, Pakistan, Somalia, South Sudan, Sudan, Yemen Group 2: Djibouti, Iraq, Islamic Republic of Iran, Lebanon, Libya, Morocco, Syrian Arab Republic, Tunisia Group 3: Bahrain, Oman, Palestine, Qatar, Kuwait, Saudi Arabia, United Arab Emirates	
Session IV: Introduction of new vaccines		
11:30–12:00	Global situation: Global situation of new vaccine introduction Global availability of new vaccines and vaccines in the pipeline Principles and considerations for adding a new vaccine to EPI and ensuring readiness for new vaccines introduction	Dr C. Mantel, WHO/HQ
12:00–12:20	Discussion	
12:20–12:40	Burden of diseases assessment through regional surveillance networks: Strengths and challenges	Dr E. Eltayeb, WHO/EMRO
12:40–13:10	Briefing on conducting cost-effectiveness studies for decision-making on introduction of new vaccines: ProVac	Dr K. Senouci, AMP
13:10–13:30	Discussion	
14:30–14:45	Role of NITAG in supporting NVI Role of NITAG/Pakistan in PCV introduction	NITAG Chairperson, Pakistan
14:45–15:00	Discussion	
15:00–15:15	Hib and rotavirus vaccines introduction in Iraq	EPI manager, Iraq EPI manager, Sudan
15:15–15:30	Rotavirus vaccines introduction and intussusception surveillance in Sudan	

15:30–15:45	Discussion	
16:00–17:00	Establishing pooled vaccine procurement (PVP) in the Eastern Mediterranean Region Discussion	Mr M. Ozturk, WHO/EMRO

**Wednesday, 19 September 2012**

## Session V: Strengthening EPI to meet the targets

08:30–09:00	Ensuring optimum structure and function of EPI	Dr N. Teleb, WHO/EMRO
09:00–10:00	Coverage problems: Problems with denominator/numerator errors in Joint Reporting Form Regional reporting of district data Data quality assessment Vaccination coverage survey Discussion	Dr E. Eltayeb, WHO/EMRO
10:00–10:15	Monitoring results for equity	Dr M. Sheth UNICEF/MENARO
10:15 –10:45	Briefing on EMRO guidelines on comprehensive review of EPI Pre- and post-introduction evaluation	Dr I. Chaudhri, WHO/EMRO Dr D. Aden, WHO/EMRO
10:45 –11:00	Discussion Improving vaccine management and logistics	
11:30–12:20	Effective Vaccine Management Assessment and cold chain upgrading Controlled temperature chain New temperature monitoring devices VVM Project Optimize in Tunisia Movie on Optimize Tunisia	Dr N. Musa, WHO/EMRO Mr B. Al Rawahi, Oman Dr R. Ouhichi, Tunisia
12:20–12:40	Discussion	
12:40–13:40	Sustainable immunization financing	Dr M. McQuestion, Sabin Vaccine Institute
14:30–15:00	Conclusion and recommendations	
15:00	Closing session	

**Annex 2**

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