



**World Health
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WHO regional
meeting on new
vaccines introduction:
experience and issues
in the WHO European
Region

Izmir, Turkey, 25–27 June 2014



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ABSTRACT

The WHO regional meeting on new vaccines introduction held in Izmir, Turkey, on 25–27 June 2014 involved participation from representatives of 24 countries of the WHO European Region, including national immunization programme managers, chairs and secretaries of national immunization technical advisory groups (NITAGs) and personnel responsible for implementing surveillance for diseases that can be prevented by new vaccines. Participants discussed how decision-making on the introduction of new vaccines can be strengthened through establishing NITAGs and defining their future priorities, accumulating evidence about burden of disease and cost-effectiveness, and sharing experiences and impacts of new vaccine introduction. Comprehensive approaches to reducing pneumonia and diarrhoea were also discussed. This report summarizes key points from presentations, discussions and a panel session at the meeting.

Keywords

IMMUNIZATION
IMMUNIZATION PROGRAMS
PUBLIC HEALTH
SURVEILLANCE
VACCINES

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Acronyms and abbreviations

C4P	Cervical Cancer Prevention and Control Costing (tool)
CDC	Centers for Disease Control and Prevention, United States
CVAC	Childhood Vaccine Advisory Council (United States)
DALY	disability-adjusted life-year
EPI	expanded programme on immunization
ETAGE	European Technical Advisory Group of Experts on Immunization
GAPPD	global action plan for pneumonia and diarrhoea
GDP	gross domestic product
Hib	<i>Haemophilus influenzae</i> type b
HPV	human papillomavirus
IBD	invasive bacterial disease
IMCI	integrated management of childhood illness
MDG	(United Nations) Millennium Development Goal
MIC	middle-income country
NIP	national immunization programme
NITAG	national immunization technical advisory group
PCV	pneumococcal vaccine
PRIME	Papilloma Virus Rapid Interface for Modelling and Economics (tool)
SAGE	Strategic Advisory Group of Experts (on immunization)
SIVAC	Supporting Independent Immunization and Vaccines Advisory Committees (initiative)
TriVac	triple-vaccine model (focusing on Hib, PCV and rotavirus vaccines)
UNICEF	United Nations Children's Fund

1. Meeting scope and purpose

The WHO regional meeting on new vaccines introduction held in Izmir, Turkey, on 25–27 June 2014 involved participation from representatives of 24 countries of the WHO European Region, including national immunization programme managers, chairs and secretaries of national immunization technical advisory groups (NITAGs) and personnel responsible for implementing surveillance for diseases that can be prevented by new vaccines.

The objectives were to:

- discuss progress achieved in establishing and strengthening NITAGs and define future priorities;
- share experiences and best practice in making informed decisions on introduction of new vaccines between countries;
- discuss implementation of new vaccines surveillance and improvement of data quality;
- present and discuss utilization of new vaccines surveillance data to make informed decisions on introduction of new vaccines and evaluate impact; and
- discuss collaboration between partners to support countries and create synergies.

Expected outcomes were to:

- achieve common understanding and commitment in establishing and strengthening NITAGs to support evidence-based decision-making on immunization;
- define needs for further capacity-building for recently established NITAGs and identify required support from WHO and partners;
- learn about positive experiences and best practice in implementation of new vaccines and evaluation of impacts;
- define the role of surveillance in providing evidence for decision-making and evaluation of new-vaccine impact; and
- define regional priorities and achieve commitment in further strengthening surveillance of new vaccines.

2. Plenary sessions

Session 1. Strengthening decision-making in immunization

Liudmila Mosina from the WHO Regional Office for Europe opened the session by providing a regional overview of decision-making and implementation of new vaccines. She stressed the value of NITAGs in decision-making, which includes empowering authorities and policy-makers to make evidence-based decisions and enabling resistance to pressure from interest and lobby groups. She noted, however, that 11 countries in the WHO European Region do not have a NITAG in place and that the composition and functioning of 40% are not in line with WHO recommendations on issues such as disclosure of conflict of interest and independence from ministries of health. Opportunities to strengthen decision-making include the experience

available from the European Technical Advisory Group of Experts on Immunization (ETAGE) and support from WHO and partners.

She then reviewed the introduction of new *Haemophilus influenzae* type b (Hib), pneumococcal, rotavirus and human papillomavirus (HPV) vaccines in the Region, emphasizing that the WHO vaccine action plan for 2014–2020 presents a vision of a Region free of vaccine-preventable diseases in which all countries can provide equitable access to vaccines to their populations throughout the life course. A new WHO publication sets out principles and considerations for adding a vaccine to a national immunization programme (NIP).

Future steps in the Region include building capacity in middle-income countries (MICs) to enable them to make informed decisions on vaccine introduction and providing ongoing support to those countries scheduled to lose funding from the GAVI Alliance over the next few years.

Philippe Duclos from WHO headquarters provided an overview of NITAGs' roles in implementing the global vaccine action plan. He stressed that NITAGs have a technical advisory role for policy-makers and programme managers and should not serve as implementing, coordinating or regulatory bodies, although they do have a role in facilitating coordination, particularly through the participation of liaison members. Their contribution to implementing the global vaccine action plan should therefore fall within that remit. He identified six basic process indicators of a well-functioning NITAG as defined by WHO, which include inter alia having formal terms of reference, ensuring at least five expertise areas among the membership and securing a declaration of interest from members. These critical indicators are used to monitor progress but they are not sufficient to ensure that a NITAG that is working well, and a further series of indicators to assess process, outputs and outcomes and an assessment tool have now been developed.

Alex Adjagba, Director of the Supporting Independent Immunization and Vaccines Advisory Committees (SIVAC) initiative, offered guidance on developing evidence-based recommendations on immunization policy and practice. The process includes elements before, during and after NITAG meetings and is based on the best available data identified by using a transparent, rigorous and standardized approach. The steps in the process are to:

- frame the question to inform the recommendation
- assess and summarize the evidence
- present the proposed recommendations and supporting evidence to the NITAG
- discuss the recommendations and evidence in the NITAG and come to a decision
- submit the agreed recommendations to competent authorities at national level.

The quality of evidence, as assessed by the grading system of the Strategic Advisory Group of Experts (SAGE) on Immunization, is crucial, but recommendations can be issued with low scientific evidence. NITAG executive secretariats have a crucial role in drafting policy briefs that explain the rationale behind the recommendations.

A country presentation from **Ukraine** followed, delivered by **Ganna Moiseieva**. The NITAG was established by the Ministry of Health in November 2012 to provide evidence-based opinions on immunization to the ministry. The NITAG charter was changed in January 2014, affecting the composition of core and ex-officio members and ensuring that they submit a declaration of

interest prior to taking up their three-year positions and sign a confidentiality agreement on joining. Short-life working groups are now being established to consider challenging and special topics.

Christian Perronne described ETAGE's role in strengthening evidence-based decision-making in the Region. ETAGE has eight independent experts from seven countries and aims to provide high-quality technical advice and recommendations to develop and improve public health policies in the Region. It works closely with NITAGs, inviting NITAG members to participate in ETAGE meetings and participating in WHO workshops since 2010 that bring members of newly created NITAGs together with people from those that are long-established. The issue of progressing efficient and sustainable collaboration among NITAGs will be discussed at ETAGE's Third International Technical Meeting planned for Paris, France in December 2014, the objective of which is to establish a functional structure for collaboration.

Session 2. Informed decisions on introduction of a new vaccine: evidence on disease burden

Annemarie Wasley of the Regional Office described WHO regional surveillance networks for rotavirus and invasive bacterial disease (IBD), noting that WHO recommends surveillance before and after vaccine introduction.

IBD sentinel surveillance is challenging to implement, she suggested. While it provides information on the relative frequency of etiologies among hospitalized cases of IBD, it does not measure the total burden of disease, as it does not capture nonhospitalized and noninvasive cases. Meningitis, on which the surveillance focuses, accounts for only a small proportion of pneumococcal disease, and the small number of cases makes it impossible to detect changes over time.

The WHO Regional Rotavirus Surveillance Network is well established and produces reliable data. Its results indicate that a high proportion of severe diarrhoea in children is due to rotavirus, averaging 39% in six network countries prior to vaccine introduction. This proportion is similar to other countries in the network and comparable to other parts of Europe. Three of the six countries have now introduced the vaccine and early indications suggest that an impact on surveillance trend data will be seen.

The WHO Regional IBD Surveillance Network, which focuses on bacterial meningitis, is a newer network, with three of the six participating countries only enrolling cases since 2011. Significant progress has nevertheless been made in relation to laboratory strengthening, etiology identification and serotype information-gathering. Many factors affect the ability to identify meningitis cases and accurately determine etiology, however, and the low number of cases identified in the Region limits the ability to track trends over time. Other methods and types of data will need to be incorporated in future to complement sentinel surveillance.

Mary Agócs from WHO headquarters expanded on the role and limitations of sentinel hospital surveillance in defining disease burden. The costs of sentinel hospital surveillance in a well-run institution is relatively small and builds capacity and infrastructure to conduct surveillance. It can detect outbreaks and can be used to strengthen the expanded programme on immunization (EPI) by allowing full investigation of the vaccine status of cases. However, policy-makers need to be made aware that sentinel surveillance underestimates the national burden of disease: it can only provide an estimate of disease in the hospital catchment population.

Session 3. Informed decisions on introduction of a new vaccine: economic evidence

Liudmila Mosina opened the session by focusing on self-evaluation of cost–effectiveness of new vaccines in MICs. She emphasized the challenges in making decisions on introducing new vaccines faced by countries that currently receive financial support from the GAVI Alliance but will cease to do so in the next few years, for whom long-term financial sustainability of vaccine programmes is clearly a vital issue. MICs that receive no support from the GAVI Alliance also face challenges in relation to identifying the burden of vaccine-preventable disease and bearing the full cost of vaccine introduction.

She then described a self-evaluation project of the cost–effectiveness of new-vaccines introduction taken forward by WHO and partners in four MICs, using the TriVac model (which focuses on PCV and rotavirus vaccines). The project demonstrated the importance of using a standardized approach, method and tools in assessing cost–effectiveness, deploying expert teams and international consultants at national level and ensuring strong collaboration among partners. Such approaches are, however, resource-intensive, particularly in relation to personnel workloads. In addition, while evidence of cost–effectiveness is important, it is not the only kind of evidence that needs to be considered.

Specific country examples then followed. **Iria Preza** of the Institute of Public Health reported on a cost–effectiveness evaluation of introducing rotavirus vaccine into the NIP carried out to strengthen the evidence base for its introduction in **Albania**. Diarrhoeal disease causes high morbidity in Albania, with rotavirus infections common among infants and children. Using the TriVac model, the evaluation found the vaccine prevented around 5000 outpatient visits, 1500 hospital admissions and three deaths per year, with 66% of the costs of the vaccine being outweighed by health care costs saved. The risk–benefit of the vaccine was calculated as one death caused against 60 deaths prevented over 20 years. Introduction of the vaccine was therefore found to be cost–effective or highly cost–effective for nearly all scenarios.

Vusala Jalal Allahverdiyeva of the WHO country office in **Azerbaijan** reported on a similar study of the introduction of PCV. Using the TriVac model, the study looked at the disease burden of all-cause otitis media, all-cause pneumonia, pneumococcal meningitis and non-pneumonia/non-meningitis pneumococcal disease of 10 cohorts of children aged 1–59 months. It found that overall, 30 562 DALYs had been averted. The incremental cost-effectiveness ratio was US\$ 66 per DALY averted. The GDP per capita for Azerbaijan is US\$ 7490.50, so in accordance with the WHO definition, the intervention can be classed as highly cost–effective; the social advantages accrued mean the actual cost–effectiveness of the vaccine is likely to be much higher. The country is now looking at the potential of using a similar approach to assessing the cost–effectiveness of other vaccines, such as HPV.

Mark Jit of the London School of Hygiene and Tropical Medicine, United Kingdom, focused on costing and cost–effectiveness of HPV vaccination. Having briefly described how health technology agencies assess a new technology (which includes economic considerations), he proposed a range of issues that should be considered when introducing a new vaccine: affordability, sustainability, impact on disease, value for money and price negotiation. Economic tools for HPV vaccination and screening include the Cervical Cancer Prevention and Control Costing (C4P) tool, which estimates the incremental costs of vaccination and screening. C4P provides users with five-year cost estimates. A case study of tool use in Uzbekistan found the largest cost estimate was vaccines and supplies, with service-delivery costs next highest.

WHO recommends that cost-effectiveness be considered before HPV vaccination is introduced to a NIP. The Papillomavirus Rapid Interface for Modelling and Economics (PRIME) tool supports countries to conduct cost-effectiveness evaluations of HPV vaccination. PRIME has an easy-to-use interface and provides valid, reliable estimates of the impact and cost-effectiveness of HPV vaccination prior to sexual debut, although it is not suitable for more complex scenarios such as assessing herd immunity. Plans are now in place to pilot the tool in low- and middle-income countries; WHO and the developers are keen to support countries in how to use the tool and are taking discussions forward with countries on how this may be accomplished.

Khatuna Zakhshvili of the National Centre for Disease Control and Public Health described the burden of pneumococcal disease in **Georgia**, in which pneumonia accounted for 11% of under-5 mortality in 2010. She described a cost-effectiveness study of 10-valent pneumococcal vaccine (PCV 10) introduction which showed that by using the WHO threshold (the cost of disability-adjusted life-years (DALYs) averted = 1 x gross domestic product (GDP) per capita), PCV introduction could be categorized as being highly cost-effective. Forty-one deaths and 1438 DALYs from all diseases were averted: the total cost of PCV 10 over the 10 cohorts studied was US\$ 4.44 million but US\$ 2.14 million was saved in treatment costs, resulting in net costs of US\$ 2.26 million. While the study had some limitations, PCV 10 introduction was identified as a low-cost, high-effectiveness intervention.

Session 4. Countries' experience of introduction of new vaccines

Session 4 consisted of a panel discussion with country presentations on experiences of vaccine introduction.

Estonia and Georgia presented on rotavirus vaccines. Rotavirus is very common in **Estonia**, with most cases occurring in infants. There is a high hospitalization rate and, consequently, high health care costs. The Advisory Committee on Immunization does not meet all the criteria of a NITAG, but has wide representation. It is funded by, and provides advice to, the Ministry of Social Affairs, but is not involved in implementation of decisions. A cost-effectiveness analysis of rotavirus in 2011 found that by the age of 5 years, vaccine could prevent around 2700 mild, 1850 moderate and 960 severe cases of rotavirus gastroenteritis among an annual birth cohort of 16 000. All cases of death would probably be averted. Rotavirus vaccine is now part of the NIP, and the aim is to achieve greater than 95% coverage. Steps taken to ensure this include exploring experiences of introduction of the vaccine in Finland and developing regional seminars and information materials for the public and professionals. Preparatory work for introducing the new vaccine took a year, with six months for procurement, and new resources were required for development of information materials.

In **Georgia**, rotavirus vaccine was introduced to the NIP in March/April 2013, cofinanced by the GAVI Alliance. Surveillance data had shown that rotavirus was responsible for up to 40% of diarrhoea cases in children under 5 and economic evaluations demonstrated the vaccine's high cost-effectiveness. Pre-implementation planning was thorough, involving training for key professionals and a communication plan for the public. An evaluation of population perceptions of vaccination was conducted with support from the United Nations Children's Fund (UNICEF) prior to introduction of rotavirus vaccine. This involved representatives of many groups in society and pre-introduction communication activities were based on its results. A post-introduction evaluation found evidence of good advanced planning but a need to increase vaccine coverage through, for example, sharing good practice among professionals, providing refresher training and arranging outreach vaccination sessions in remote areas.

Bulgaria and Turkey reported on pneumococcal conjugate vaccines. In **Bulgaria**, the Expert Committee for Communicable Disease Surveillance, Immunoprophylaxis and Control, chaired by the Deputy Minister of Health, advises the Minister of Health and proposes new vaccines, with the Ministry of Health taking the final decision. Members are appointed following nominations from medical specialty professional associations. These experts (11 members) have a vote on committee decisions. The annual average incidence of *Streptococcus pneumoniae* meningitis between 2001 and 2010 was 0.48 cases per 100 000; after vaccine introduction in 2010, incidence was 0.34 in 2012. Deaths reduced from 16 in 2010 to 6 in 2012. Immunization coverage (mandatory immunizations only) in 2013 were 96.3% for first dose, 95.2% for second, 93.7 for third and 93.3% for booster.

Turkey was the first MIC in the Region to introduce PCV in 2008, following a NITAG recommendation to introduce seven-valent (PCV 7) to the NIP for all children aged under 1 year. Catch-up has now been carried out on children born after May 2008. A national invasive pneumococcal disease surveillance exercise was carried out between June 2009 and February 2010, which suggested that 13-valent vaccine (PCV 13) would meet the country's needs better (due to serotype coverage). PCV 13 commenced in April 2011.

Latvia and Uzbekistan presented on introduction of HPV vaccine. The public health strategy in **Latvia** in 2011 identified a reduction in cervical cancer rates as a public health priority. The State Immunization Council supported inclusion of HPV vaccine in the NIP from 2010, which was accepted following amendments by the Ministry of Health. A strong advocacy and communication programme was launched, including education for professionals and information for the public via the mass media and materials for parents and schoolchildren. Target coverage of 97% has not yet been achieved, with coverage in 2013 of 57.7%; the anti-vaccine lobby in the country is strong and refusals average 12.5% per year. Actions now reflect a WHO evaluation in 2013 which called for intensified advocacy and communication, better information for general practitioners and studies of the reasons behind refusals to accept vaccination.

Uzbekistan was the first country eligible for GAVI Alliance support to introduce the HPV vaccine, building on the country's strong history of school vaccinations and reflecting cervical cancer's status as the second most common cause of deaths in women of childbearing age. The vaccine is part of a national prevention strategy that also includes screening and testing for pre-cancerous conditions. Preparatory work included an assessment of school immunization and the economic feasibility of introducing HPV vaccine, after which the strategy was devised. Uzbekistan plans to introduce HPV vaccine across the whole country and vaccinate around 253 000 12-year-old girls. Key elements in moving forward are maintaining the comprehensive strategic approach and ensuring long-term financial sustainability.

Session 5. Evaluations of the impact of new vaccines

Ben Lopman of the Centers for Disease Control and Prevention (CDC), United States, discussed the impact of rotavirus vaccination in the United States. Prior to introduction of the vaccine in 2006 (RV 5 vaccine in 2006 and RV 1 in 2008), a study of one birth cohort followed to age 5 years estimated 2.7 million episodes of rotavirus gastroenteritis, 50 000–70 000 hospitalizations and 20–60 deaths per year. Following introduction, data from three hospitals in the New Vaccines Surveillance Network showed major reductions (in the order of 80–90%) in rotavirus positivity in hospitalized gastroenteritis cases by 2012. Pre-vaccine (2006), 51% of gastroenteritis cases were rotavirus-positive: by 2008, this had reduced to 6%. An 85% reduction was seen in children aged between 2 and 3 years, who had not received the vaccine; it is believed

that this is a result of herd immunity. This effect was also observed in hospital admissions of older children and even adults. An apparent bounce-back in alternate years after vaccine introduction can be attributed to the natural dynamics resulting from accumulation of susceptibles in the population with incomplete vaccine coverage.

Evidence of major reductions in diarrhoea mortality following rotavirus vaccination introduction has been collected in Mexico. Data suggest that even the monovalent vaccine is effective against nonvaccine strains (70% and above) and is safe, with studies in the United States, Mexico, Brazil and Australia identifying a low-level risk of intussusception after the first dose. Surveillance for intussusception is ongoing in countries that have introduced the vaccine.

Stela Gheorghita of the National Centre for Public Health in the Republic of Moldova reported that rotavirus vaccine was introduced to the country's NIP in July 2012, making it the first lower-middle-income country in the Region to do so. The impact of the vaccine has been evaluated using population-based passive surveillance data on communicable diseases and trends in the incidence of diarrhoeal disease. A decrease in cases of gastroenteritis in children under 1 year has been observed. Sentinel hospital surveillance data show a ~50% decrease in rotavirus-positive diarrhoea after vaccine introduction among hospitalized children under 1 year.

With support from WHO and CDC, a case control study is being conducted to determine the effectiveness of rotavirus vaccination. Using data from sentinel hospital surveillance, the study is comparing children who were under 1 year when the vaccine was introduced and had severe diarrhoea caused by rotavirus against those whose diarrhoea was rotavirus-negative. Preliminary results demonstrate that vaccine coverage among age-eligible controls rose from 30% to 70% between 2012 and 2014. Overall vaccine effectiveness was 57% (61% in those under 1 year). Children aged 2–5 years who had not received the vaccine nevertheless showed a 40% reduction in rotavirus positivity, suggesting substantial indirect benefits.

Svetlana Grigoryan discussed rotavirus vaccine safety assessment in Armenia. Sentinel intussusception surveillance was introduced in September 2011 to monitor the safety of rotavirus vaccine, with retrospective data from 2007 being collected to provide baseline information on intussusception. Following preparatory activity, sentinel surveillance was carried out in three hospitals and also in three regions. Children under 1 year with intussusception and who were hospitalized were involved. Retrospective and sentinel data covering 2007–2013 showed no changes in the incidence of intussusception following introduction of rotavirus vaccine to the NIP in November 2012. Trend data were also presented on the impact of rotavirus vaccine on rotavirus and all-cause gastroenteritis hospital admissions.

Marianne Bergsaker provided an overview of the impact of pneumococcal conjugate vaccines in Norway. PCV 7 was introduced in January 2006 following a meningitis death causing media attention, with the vaccine being offered (all vaccinations in Norway are voluntary, with very high uptake) to children born in 2006 and onwards. The vaccine was given to infants at 3, 5 and 12 months of age. PCV 13 was adopted in 2011. An action plan for monitoring PCV implementation was developed, involving vaccine coverage, enhanced surveillance of adverse effects following immunization and incidence of invasive pneumococcal disease, identification of vaccine failures and studies of vaccine impact and effectiveness. A range of tools was used in the monitoring plan, including the national immunization registry and national reference laboratory.

Vaccine coverage at age 2 years was 93% in 2013. In the first year following vaccine introduction, 60% of adverse effects reported were PCV-related, with fever, rash and injection-site reactions most common. Serious reactions (such as febrile seizures) were very rare, and no adverse reactions caused significant concern. Cases of invasive pneumococcal disease in children under 2 years reduced from just under 80 per 100 000 in 2005 (pre-introduction) to 15 in 2013. The respective figures for adults aged 65 and over were 78 and 39. The vaccine therefore appeared to have not only a direct impact on vaccinated groups, but also an indirect effect on those who were not vaccinated. With high uptake, few adverse effects, reductions in cases of invasive pneumococcal disease and two vaccine failures only, the PCV immunization programme was deemed highly effective.

Session 6. Moderated discussions

6.1 Strengthening decision-making in immunization

Discussions focused on NITAGs.

NITAG structure

- All countries seemed to have a structure in place, but not all meet the WHO criteria for a NITAG.
- One country (Bulgaria) claimed it was not possible to have a fully independent NITAG as the country was too small and lacked sufficient high-level expert capacity.

NITAG chair

- One of the countries believed that the chair should be a child rights ombudsman appointed by the Prime Minister and should not report to the Minister of Health to ensure independence. Immunization is more than a health issue and the Prime Minister has a greater understanding of wider social issues, it was argued. Other countries disagreed, however, feeling the chair needs to have a medical background to ensure that sessions are chaired by a knowledgeable expert.
- The chair requires credibility and neutrality, must be committed to securing the best evidence-based review, must possess moderation skills and should not advocate for any particular vaccine.
- One country (Estonia), whose committee is chaired by the Deputy Minister of Health, mentioned the advantages this brings in ensuring recommendations are accepted at ministerial level.

NITAG membership

- NITAGs need more than just high-level experts – a mix of experience is required beyond the vaccine specialty, including specialists such as gynaecologists and general practitioners, the media and civil society. In small countries (such as Montenegro), members' enthusiasm and commitment count for as much as their expertise. The crucial element is an interest in improving immunization and an understanding of what constitutes good evidence.
- Involving people who are not specialists in vaccination, either as full members or on an ad hoc basis, widens the foundation of the NITAG's expertise.

- Forming working groups on specific issues offers an opportunity to use specialists' expertise in particular areas.
- A participant from Georgia expressed concern that having experts from too many fields could complicate and delay the NITAG process.
- Members appointed by ministries of health are not necessarily compromised in terms of independence – they can still express an independent view.
- There is an expectation among some people that membership of a NITAG should entitle them to payment; people in other countries view NITAG membership as an honour and do not expect payment.

NITAG role

- Countries have different expectations of NITAGs' role. Some see it as being primarily about advocacy, but others cautioned about the risks of this approach – the role is primarily about identifying the best evidence and making competent decisions, they argued.
- It was suggested that rather than sending recommendations to ministries of health, recently established NITAGs should present their findings in person to ministers and argue for prioritization of immunization.

NITAG independence and members' declaration of interest

- The independence of the NITAG is about members' independence from the institutions in which they work – they represent only themselves.
- Ministry of Health and NIP officials should be ex-officio members only and not be involved in the decision-making process.
- All NITAGs and similar groups should require members to declare possible conflict of interests. The principle is about transparency and credibility, not about exclusion.
- An absence of conflict of interest does not mean the member should have no contact with the industry. A doctor being funded by a company to attend a conference is minor, but having a seat on the company's executive or advisory board would be more significant.
- WHO has guidance on conflicts of interest, and the Childhood Vaccine Advisory Council (CVAC) in the United States has a repository of information on how it can be managed.

WHO support

WHO was requested to:

- facilitate the sharing of knowledge and experience of how NITAGs work in different countries; countries with well-established NITAGs are willing to share their expertise, and while language is an issue, smaller countries would welcome the opportunity to attend established NITAG sessions in matched countries;
- host a Regional forum to facilitate exchange of experience and expertise; and
- provide training and support on: developing evidence-based recommendations; ensuring sound composition of NITAGs; increasing NITAG capacity; and promoting self-evaluation of NITAG activity (using evaluation tools).

6.2 Introduction of new vaccines

- Participants from the former Yugoslav Republic of Macedonia set out a process for introducing a new vaccine that appeared common among countries. First, the NITAG suggests the need for the new vaccine, based on evidence review and expert opinion. The recommendation is passed to the Ministry of Health and the Government for a final decision (which includes financial considerations). If approved, the Ministry of Health assumes responsibility for implementation via the state budget (the country does not have GAVI Alliance or other external support). An open international tendering procedure is launched: while this is underway, preparations for implementation are made, including changing the immunization calendar, amending legislation, training health care workers and informing the public and media.
- Countries described problems in implementing HPV programmes, which include the high price of the vaccine (€75 per dose for a yearly cohort of 12 000 in the former Yugoslav Republic of Macedonia), negative media coverage (which seemed to be having a particular impact on coverage in urban areas) and lack of a communication crisis action plan (the former Yugoslav Republic of Macedonia), health care workers' unwillingness to vaccinate (Romania) and reduced political commitment with a change of government (Romania).
- Norway mounted a strong public involvement campaign prior to HPV introduction, which included public forums and a dedicated telephone helpline.

WHO support

WHO was requested to provide support on:

- advocacy and prioritization
- how to achieve best price from manufacturers
- how to develop communication crisis plans and vaccine-introduction plans.

6.3 Collecting evidence and evaluating the impact of new vaccines

- Some countries have used global WHO data on the burden of diseases to support their cost-effectiveness evaluations. Georgia, for example, had limited local data on burden of pneumococcal diseases so used the WHO Global Disease Burden Estimate data for its cost-effectiveness evaluation. Global estimates appear to carry some weight with ministers. Countries can also benefit from reviewing data from other countries on their disease burdens.
- Surveillance needs to be strengthened in countries to evaluate the national burden of diseases.
- Cost-effectiveness data can be helpful in facing challenges on vaccine prices. In Estonia, for instance, the national cost-effectiveness study for rotavirus vaccine calculated the country's upper-limit cost (€24 per child). This figure has been used in national procurement procedures and the actual cost of vaccines has now reduced to a figure very close to this.
- Among the positive outcomes of economic evaluation tools is their capacity to determine optimum prices for vaccines and give countries greater bargaining power.

WHO support

WHO was requested to:

- provide workshops on conducting cost-effectiveness evaluations and collecting surveillance data on national burden of diseases; and
- share tools on processes for estimating cost-effectiveness and securing best price from manufacturers.

Session 7. Comprehensive approach to preventing pneumonia and diarrhoea

Liudmila Mosina looked at implementation of the integrated global action plan for pneumonia and diarrhoea (GAPPD) in the Region. Good progress had been seen in relation to achieving United Nations Millennium Development Goal (MDG) 4 targets on reducing infant and under-5 mortality: the former has reduced from 28 per 1000 live births in 1990 to 11 in 2011, and the latter from 34 to 13. Inequities nevertheless persist between and within countries, and it is anticipated that some Member States will not meet the MDG targets by 2015 unless prevention measures are accelerated. Pneumonia and diarrhoea accounted for 12% and 4% respectively of under-5 deaths in the Region in 2011 – they are preventable and steps to reduce their incidence will support efforts to achieve MDG 4. Introduction of PCV and rotavirus vaccine will reduce mortality, but they will not be sufficient to achieve MDG targets – other pathogens also cause pneumonia and diarrhoea. Interventions of proven efficacy that can prevent all pneumonia and diarrhoea are underutilized; establishing better coordination between existing programmes can lead to synergies and efficiencies that will maximize the benefits of individual interventions.

The GAPPD has a vision of ending preventable pneumonia and diarrhoea deaths in the Region by 2025. Specific targets for reductions in incidence and mortality have been set, along with coverage targets for each vaccine and other preventive measures, such as breastfeeding. Additional coverage targets have been set for 2030, focusing on hygiene and potable water issues. GAPPD recognizes that preventive measures for pneumonia and diarrhoea are similar and therefore lend themselves to a comprehensive approach focusing on protection, prevention and treatment. WHO has built on a positive and enabling political environment to encourage and support comprehensive approaches in countries and has set out five steps to developing and scaling-up a coordinated approach.

Sonia Arushanyan then shared experiences of using a comprehensive approach to preventing pneumonia in Armenia. Protection of maternal and child health is a national priority, as reflected in the state programme on maternal and child health, and progress towards achievement of MDG 4 has been good. Under-5 mortality has reduced by more than 50% since 1990: it stood at 11.1% in 2013, against the MDG target of under 10%. One of the main factors in this is the NIP: the MDG target of immunization coverage of 95% has been achieved, with coverage in 2013 of 97%. Child deaths from pneumonia and diarrhoea have seen large reductions since 1990. Interventions that have proved effective include exclusive breastfeeding during the first six months and continued breastfeeding with introduction of appropriate formula thereafter, and use of Hib, measles and pertussis vaccines. *S. pneumoniae* vaccine is scheduled for introduction into the NIP from September 2014.

Also significant, however, is the implementation of an integrated management of childhood illness (IMCI) strategy,¹ which uses using simple, standard manuals on identification and treatment of pneumonia to enable significant decreases in child mortality. The IMCI strategy offers health protection for children under 5 years by ensuring adequate treatment, effective monitoring and full rehabilitation, increasing the efficiency of primary health care worker performance indicators and increasing the role of mothers and families in supporting optimal development of children. This has resulted in improvements in children's general condition and nutrition status, decreases in disease incidence, a significant decrease in infant and child mortality indicators from diseases included in the IMCI and improved access to better-quality medical care.

Challenges to progress remain, including insufficient systems for supporting supervision, monitoring and assessment, low health care budgets (1.4% of GDP), insufficient health worker motivation in primary health care and uneven distribution of personnel across regions. The Ministry of Health nevertheless recognizes the importance of collaboration and supports the adoption of comprehensive approaches to challenging childhood illnesses.

Closing

Liudmila Mosina closed the meeting, emphasizing:

- the importance of NITAGs in making evidence-based decisions on new vaccines and promoting confidence in their recommendations from ministries and the public;
- the importance of economic evidence in securing adequate financing from ministries and supporting negotiations on vaccine prices; it is hoped that countries will be able to access support on how to use tools such as TriVac and PRIME;
- the support WHO and other partners can provide to help countries overcome their challenges; and
- that fewer children are falling sick and dying because of immunization; the work of convincing ministries and others of the need to prioritize vaccination must go on, with countries working closely with WHO, other partners and each other to ensure the benefits vaccines present are realized.

¹ IMCI provides opportunities to adopt a holistic approach to child health and development, focus on major causes of mortality and morbidity, and address child health problems at all levels of care. It provides a technical programme that coordinates and unites relevant initiatives and instils flexibility and regular adaptation. From a health system perspective, IMCI minimizes lost opportunities for integration, promotes investment in the health system and harmonizes health sector responses.

Annex 1

MEETING AGENDA

Objectives of the meeting	Liudmila Mosina WHO Regional Office for Europe
Welcome by the Ministry of Health of Turkey	M. Bahadır Sucaklı, Ministry of Health, Turkey

Session 1. Strengthening decision-making in immunization

Chair: Annemarie Wasley

Regional overview of decision-making and implementation of new vaccines	Liudmila Mosina, WHO Regional Office for Europe
Global overview of NITAGs; role of NITAGs in implementation of global vaccine action plan	Philippe Duclos, WHO headquarters
Countries' experiences in establishment of NITAGs: Ukraine	Ganna Moiseieva Ministry of Health, Ukraine
Guidelines on development of evidence-based recommendations on immunization policy and practice	Alex Adjagba, SIVAC
Role of European Technical Advisory Group of Experts on Immunization (ETAGE) in strengthening evidence-based decision-making in the Region	Christian Perronne, ETAGE

Session 2. Informed decisions on introduction of a new vaccine: evidence on disease burden

Chair: Christian Perronne

Regional surveillance network for rotavirus and invasive bacterial diseases	Annemarie Wasley, WHO Regional Office for Europe
Role and limitations of surveillance in defining burden of diseases preventable by new vaccines	Mary Agocs, WHO headquarters
Defining national burden of pneumococcal diseases in Georgia	Khatuna Zakhshvili, Georgia

Session 3: Informed decisions on introduction of a new vaccine: economic evidence

Chair: Philippe Duclos

Self-evaluation of cost-effectiveness of new vaccines in middle-income countries	Liudmila Mosina WHO Regional Office for Europe
Evaluation of cost-effectiveness of rotavirus and pneumococcal vaccines: experiences from Albania and Azerbaijan	Iria Preza, Albania

Vusala Allahverdiyeva,
WHO Azerbaijan

Costing and cost-effectiveness of HPV vaccine introduction to strengthen cervical cancer prevention and control programmes: WHO-supported tools and experiences in the field

Mark Jit,
London School of
Hygiene and Tropical
Medicine

Session 4. Countries' experiences of introduction of new vaccines

Chair: Liudmila Mosina

Panel discussion

Rotavirus vaccines: Estonia, Georgia

Pneumococcal conjugate vaccines: Bulgaria, Turkey

Human papilloma virus vaccines: Latvia, Uzbekistan

Session 5. Evaluation of the impact of new vaccines

Chair: Mary Agocs

Impact of rotavirus vaccination in United States

Ben Lopman,
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Prevention and Control,
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Utilization of diarrhoeal diseases and rotavirus surveillance data to measure an impact of rotavirus vaccine in the Republic of Moldova

Stela Gheorghita,
Republic of Moldova

Monitoring of rotavirus vaccine safety in Armenia

Svetlana Grigoryan,
Armenia

Impact of pneumococcal conjugate vaccines in Norway

Marianne Bergsaker,
Norway

Session 6. Moderated discussions

Strengthening decision-making in immunization and introduction of new vaccines

Facilitator:
Shahin Huseynov

Collecting evidence and evaluating the impact of new vaccines

Facilitator:
Vusala Allahverdiyeva

Session 7. Comprehensive approach to preventing pneumonia and diarrhoea

Chair: Marianne Bergsaker

Implementation of Global Action Plan for Pneumonia and Diarrhoea in WHO European Region

Liudmila Mosina
WHO Regional Office for
Europe

Experience in introduction of comprehensive approach in prevention of pneumonia in Armenia

Sonia Arushanyan
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Conclusions and meeting closure

Annex 2

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