

The Global Immunization Meeting: Protect, Innovate, Accelerate was organized jointly by WHO and UNICEF and served as forum to update the global immunization community on implementing the new vaccines, strengthening routine immunization and accelerated disease control pillars of the Global Vaccine Action Plan. The meeting also provided a basis for discussions with immunization partners to identify areas where each partner will best contribute to advancing the common agenda.

Objectives of the Meeting

The objectives of the Global Immunization Meeting were to review and discuss among global, regional and country immunization partners, key issues related to strengthening routine immunization, to the implementation of new and under-utilized vaccines and to accelerated disease control efforts – notably for measles, rubella and maternal and neonatal tetanus – including alignment with polio eradication efforts.

This year, particular consideration and review were given to the following issues:

- Technical updates on new strategies for reaching unreached populations with routine vaccination, and discussions on major opportunities and challenges with new approaches.
- Review of activities and lessons learned from countries and regions in the implementation of new vaccines.
- Discussion of innovative approaches for achieving measles, rubella and tetanus elimination, and new vaccine delivery technologies.
- Exchange of information between WHO, UNICEF and other immunization partners - at all levels - on respective roles and responsibilities in the provision of support to countries.

Meeting Participants

Meeting participants included representatives of:

- Ministries of Health from 26 countries;
- WHO and UNICEF Headquarters and Regional and Country Offices;
- Partner agencies: Agence de Médecine Préventive, American Red Cross, The Bill and Melinda Gates Foundation, US Centers for Disease Control and Prevention, Clinton Health Access Initiative, Gavi the Vaccine Alliance, Maternal and Child Survival Programme of John Snow, Inc., the Lions Club, Médecins sans Frontières, PATH, Sabin Vaccine Institute, Save the Children and USAID;
- Academia: Johns Hopkins School of Public Health, London School of Hygiene and Tropical Medicine, Manhiça Health Research Centre, Network for Education and Support in Immunization, University of Antwerp, and the Swiss Tropical and Public Health Institute;
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA);
- Developing Country Vaccine Manufacturers Network (DCVMN);
- Civil Society Organizations (CSOs).

Venue

With the WHO European Region as host, the meeting was organized in Sitges, Spain. Hotel Melià

Sitges provided excellent conference facilities as well as room for smaller groups and informal meetings.

The meeting was opened by the Subdirector of Health Promotion and Epidemiology of the Spanish Ministry of Health, Social Services and Equity, Dr Elena Andradas.

Executive Summary

The Global immunization Meeting took place from 23 to 25 June 2015 and set out to explore key issues related to strengthening routine immunization, encompassing all aspects of new vaccine implementation and accelerated disease control efforts, involving global, regional and country-based immunization partners.

Particular emphasis was given to technical updates on new strategies and approaches in areas with major opportunities and challenges. Participants reviewed lessons learned from the introduction of new vaccines and technologies, innovative approaches to disease elimination, and exchanged perspectives on establishing more original methods for the provision of technical assistance.

The agenda mixed formal plenary sessions and interactive workshops, each day focusing on one of the overriding meeting themes; protect, innovate, and accelerate.

From the outset of day one, lively discussions and sharp presentation content set the tone for the overall meeting. An update on GVAP targets pushed participants to help drive a step change on priority problems that will contribute to closing the gaps, highlighting the need for new accountabilities. Assumptions were challenged through an examination of inequity within countries, shifting attention to systems strengthening and appealing for catalytic change in four major areas; community engagement, capacity building, management and financing, and using data for action.

Day two delved into game-changing innovations on topics such as supply chain and logistics, integrated approaches, a life-course approach, information systems and vaccine delivery technologies. Drawing on recent advances and promising initiatives, sessions reviewed the latest data, implementation issues, lessons learned and barriers. Specific recommendations were generated to inform future directions, aiming to catalyze a substantial boost in programme performance.

Achieving and sustaining disease elimination was the core theme of day three. The plenary assessed progress, country examples, and strategic directions going forward for maternal and neonatal tetanus and measles and rubella, as well as a range of experiences in new vaccine implementation. Together with new tools and strategies, a renewed global commitment and strong country ownership will be critical to impacting the burden of these diseases.

On the final afternoon, a summary of the main outcomes was presented and next steps identified to help advance the global immunization agenda. There is reason to applaud the important progress made in a number of fields, however much remains to be done to make sure that both new and traditional vaccines reach every woman and child.

Key Outcomes of the Meeting

These are provided as individual reports of the various sessions of the meeting and arranged following the meeting agenda.

Day One: PROTECT

Day One - Plenary Session 1:

Global Vaccine Action Plan Goals (Decade of Vaccines 2011-20)

Dr. Rebecca Martin presented the progress against the goals for the Decade of Vaccines as assessed by the WHO Strategic Advisory Group of Experts for Immunization(SAGE). The report, that was presented to the WHO governing bodies in 2015 noted that the world was not on track to meet 5 of the 6 targets established for 2014 or 2015, namely the goals related to: polio eradication; measles, rubella and maternal and neonatal tetanus elimination; and immunization coverage. The only target on track was the one related to the addition of new or underutilized vaccines.

SAGE identified five broad areas that were responsible for the stagnant coverage and the failure of progress against the disease eradication and elimination goals. These are:

- weak implementation of the GVAP;
- poor data quality and use;
- vaccine affordability and supply;
- failures of basic integration and missed opportunities for vaccination; and
- situations disrupting service delivery.

SAGE issued eighteen recommendations for corrective action. The assessment report and recommendations were well received and the failure to make progress was noted by Member States during WHO governing body meetings. A resolution primarily relating to access to sustainable supply of affordable vaccines was adopted at the World Health Assembly (WHA). A side meeting was held during the WHA with countries with low immunization coverage to discuss the challenges faced by the countries and to collectively find ways to address them.

In the discussion that followed, participants commented on or sought clarification on issues related to community demand, immunization data quality, and financial gaps for implementing strategies for measles, rubella and maternal and neonatal tetanus elimination.

Key Messages:

- The world is not on track to meet 5 of the 6 GVAP targets established for 2015: polio eradication; measles, rubella and maternal and neonatal tetanus elimination; and immunization coverage.
- Multiple issues and challenges have to be overcome in countries; they can be categorized into 5 main areas: weak implementation of the GVAP; poor data quality and use of data; vaccine affordability and supply; failures of basic integration and missed opportunities for vaccination; and situations disrupting service delivery.
- Immunization partners and countries need to increase their efforts and investments in the immunization services to get back on track.

Innovating for High, Equitable Vaccine Coverage

Dr Orin Levine from the Bill and Melinda Gates Foundation challenged the participants in a presentation on innovating for high, equitable vaccine coverage. There were certainly areas for applause, including the introduction of new vaccines in ninety low- and middle-income countries, the near-completion of polio-eradication and the historic low of measles cases and deaths. However, we are still off track in meeting the GVAP goals for coverage and equity, and preventable deaths still disproportionately affect the poorest and most vulnerable.

Through the Gavi Alliance, huge strides in equity have been made in terms of new vaccine introduction, and since 2000, the Alliance has helped ensure better vaccine coverage and increased equity in accessing new vaccines. Partners in the Gavi Alliance, including national governments, have made significant gains: Gavi support has contributed to the immunization of an additional 500 million children and the Gavi Alliance has helped prevent more than seven million future deaths from vaccine-preventable diseases. However, country adoption does not mean equitable access for individuals between or within countries – as for example both Costa Rica and DR Congo have pneumococcal vaccine in the national immunization programme, but 94% of children in Costa Rica are reached, while only 26% of children in DRC are. Inequity within countries is also a challenge, including inequities between rich and poor, urban and rural and maternal education.

Innovation, not business as usual, is needed to strengthen routine immunization systems in country-owned programmes. Areas for innovations included broadening the focus to support countries in strengthening community engagement, new approaches to training and capacity building, financial management and using innovative data collection and analysis tools for improving coverage.

In respect of training and capacity building, the Global Routine Immunization Strategies and Practices document (GRISP) calls for immunization partners including governments to “invest in vaccinators and district managers by regularly and systematically building their capacity, strengthening their performance and supervising them.” The assumptions on which direct technical assistance and national training workshops are based are sometimes flawed.

Capacity building should change to new concepts such as:

- in-service training to people in their work environment, with minimal disruption of service delivery;
- using a variety of learning methodologies including mentoring and peer-to-peer learning, as well as e-learning and online learning approaches;
- build on adult learning principles and methodologies.

GRISP also calls to “invest in an information system that identifies and tracks the vaccination status of everyone targeted” and to “invest in modernizing vaccine management and supply chains to make sure that each vaccination session has sufficient amounts of the right and potent vaccines available.” Ensuring that accurate, actionable information is accessible to health workers at the district levels is critical to enable programme functioning. Most health centres use paper-based systems to collect and report data and hand-drawn maps to identify communities. Health workers vary in ability to record, analyse and interpret data, and recording data is time-consuming and comes at expense of other priorities. The use of more efficient data tools including electronic means of recording, reporting and analysing (e.g. GIS mapping) are needed.

In closing, Dr Levine pointed out that if the global community continues to facilitate the introduction of new vaccines without addressing equity in coverage between countries and within countries, then with each new vaccine introduction we will just be widening the “equity gap.” Those who have access already will have access to more life-saving technologies; those without access, who need the prevention technologies the most, will have relatively less access.

Key Message:

- To reach the full potential of GVAP and GRISP, we will no longer be able to do more of the same to reach our goal. In addition to maintaining the activities that have brought us to this level of programme coverage, we will have to do things *differently* to reach the last unreached children.

Day One - Plenary Session 3:

Going Beyond RED

Alan Brooks from the Gavi Secretariat opened the session with the question: what works? While this has been intensively studied, across multiple interventions we need a shared understanding of what it will take to go beyond “Reaching Every District “(RED) for routine immunization. There are two aspects to increasing routine immunization coverage, i.e. activities to increase coverage and doing so in a way that is sustained over time.

Both the Global Routine Immunization Strategies and Practices (GRISP) and the new Gavi Strategy for 2016 – 2020 describe the investments needed to attain the GVAP goals, although further alignments are necessary. Investment should go beyond just funding, but include time, engagement, and especially creativity. Investments also imply taking risks and venturing to strategies and activities that are new and have not been tried before. A good place to start is to invest in the nine transformative areas for routine immunization strengthening in GRISP. As we move forward, we should support well-aligned, potentially transformative interventions based on national bottlenecks and plans, and should seek to be informed by what’s worked in other, well-performing countries and build on that work. While continuing to implement proven approaches including RED, where appropriate, innovative approaches and development support of increased effectiveness have to be initiated.

Richard Duncan from UNICEF Programme Division pointed out that we know a lot about those children that are reached with immunization, but very little about those that remain unreached. We really don’t know their demographic data or even the number of kids who miss out, and are limited to generalized knowledge such as lowest coverage is linked to poverty or a low education level of the mother (in both low and middle income countries).

UNICEF has summarized its experience with this issue in formulating five strategies that address the GVAP call to recast “Reaching Every District” to “Reaching Every Community” in order to deal with inequities within districts.¹

Learning the lessons from RED implementation and the accelerated services brought by polio eradication, five points are described to achieving equity in immunization²:

¹ Global Vaccine Action Plan – Strategic objective 3

² UNICEF publication: What does it take to immunize every child? Achieving equity in immunization; June 2015

1. Understand which high risk communities are associated with lowest coverage, using available data such as from DHS/MICS. Give these high risk communities labels so that health workers can identify them, and understand their specific barriers.
2. Prioritize these communities. Use detailed maps to identify them and to include these communities in microplans. Prioritize resources to health facilities that serve them, and ensure that they are reached at least four times per year, through outreaches.
3. Adjust programmes to accommodate them. These groups may have been missed for years, and may not value or be aware of immunization or feel excluded. Build trust of parents and their social leaders with the health workers and facilities.
4. Make sure the plans are implemented through monitoring and supervision of activities. This cannot be done just from the health facility, but requires getting out to the high risk communities.
5. Prioritize activities and required funding for high risk communities. To enable services to reach these communities requires more travel, more health workers, and more vaccines. Also, these children need to be a national priority in terms of policy, strategies, and planning.

Robert Steinglass from JSI described how a community-driven approach is needed but under-recognized to close the equity gap and achieve community ownership. Health workers may feel that caregivers are irresponsible; caregivers feel the converse. Ideally, we should strive for a vision where immunization services are viewed as a *joint responsibility* where communities and health services work together with a shared sense of responsibility and accountability. We must do things differently, even as it goes beyond our typical comfort zone. We need to go beyond messaging and share responsibilities for immunization services continuously, not once-off.

Sharmin Zahan from BRAC Bangladesh supplemented this presentation with an outline of the civil society organization (CSO) role in engaging communities for immunization. It was recognized that CSOs are a very diverse group including global and local NGOs, professional associations and academic institutions. Community ownership was defined as: People working together voluntarily to achieve their own initiatives using available resources for their health and socio-economic development. One key role that is played by CSOs is to listen to communities and elevate their voices to stimulate action on their behalf. The activities that CSOs support include building capacity of community leaders, demanding accountability from stakeholders, and advocating to vaccine producers to lower vaccine prices. PATH and Johns Hopkins University's International Vaccine Access Center have developed a toolkit for CSOs and others to use for advocacy for immunization.

The Hon. Dr. Benjamin Andriamitantsoa, Member of the Madagascar Parliament and Vice President of its Public Health Committee presented Madagascar's experience in prioritizing community engagement to strengthen routine immunization. In Madagascar, three pillars of EPI were established: strengthen community health worker competencies, improve health systems, and promote family attitudes and community practices. A large cadre of community health workers was critical in enabling well-functioning immunization services. In late 1990s/early 2000s, RED was used by EPI and several partners to reinforce the relationship between health staff and the community. This was augmented by inter-district sharing and support for learning, as well as the integration of MCH services. Several paper-based tools were established and used to help with finding and tracking children. IEC materials were developed, including diplomas for completing vaccination schedules, mobilizers guides, and a bulletin. Due to a lack of finances since 2009 these tools have sometimes been limited, and partners are trying to address these shortfalls. Another concept to improve coverage was the "champion community" approach used since 2009, where those communities that improve coverage are recognized and celebrated.

Key Messages:

- Getting a community's children vaccinated and protected is a joint responsibility of health services and the community. They need to work together in planning, providing, monitoring, and continuously improving vaccination services and their utilization. Approaching the community as a resource and partner, not a target of programmes or passive recipient of services, can be effective in improving routine immunization.
- Community engagement is not only about creating demand and improving coverage but also about building resilient communities that can deal with (and counter) rumors.
- Achieving coverage that is both high and equitable requires placing a deliberate priority on high-risk communities: identifying them clearly, planning and budgeting to reach them, and actively monitoring progress in reaching them.
- Stakeholders outside the formal health system, including politicians and CSOs, have important roles to play in supporting both the supply of and demand for immunization services.

Day One - Workgroup 1:

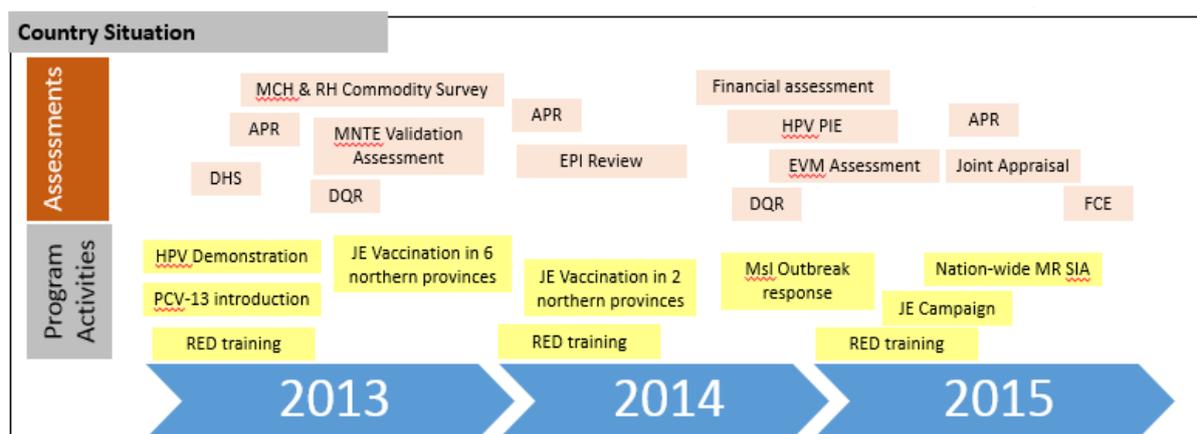
Towards Aligning Country Assessments

Session Overview:

Over the past decade, the number of country assessments of immunization programmes has increased considerably; it is estimated that a national immunization programme would be engaged in assessments 40% - 70% of the year if all recommended assessments took place (Figure 1).

The objectives of this working group were to identify ways to increase efficiency and decrease burden of assessments in three categories: Immunization programme reviews, vaccine management assessments and data quality assessments.

Figure 1: Example of multiple independent assessments occurring at a country-level



Key Discussion Points:

The working group had strong opinions that EPI reviews should be the core assessment activity with which other assessments would be linked. The group discussed the value of continuing to require certain assessments, e.g. post-introduction evaluations (PIEs) and opportunities to integrate assessments by either conducting them at the same time or using results from one to inform the other.

Next Steps/Recommendations:

- EPI Reviews should be a country programme's core assessment activity. Other assessments should be aligned with the EPI review to the extent possible and facilitating a moratorium on conducting assessments of at least 2-3 years. EPI Reviews should be synchronized with the country planning cycle allowing the results to guide programme activities and priorities.
- Additional essential assessments include the Effective Vaccine Management assessment and data quality reviews to be conducted every 5 years; these should inform or supplant aspects of the EPI Review.
- The recommendation to conduct PIEs after every new vaccine introduction should be revisited and PIEs made optional or phased out altogether unless the vaccine product or strategy is drastically different than current practice (e.g. HPV or measles second dose).
- Linkages between the Gavi Joint Appraisal mechanism and the EPI Review need to be improved, as well as with annual national planning processes and other country monitoring mechanisms.
- Additional feedback from EPI managers and other global partners should be gathered concerning opportunities to align assessments and improve efficiency.

Key Messages:

- There is a growing number of immunization-related country assessments which are likely to overburden national immunization programmes.
- Immunization assessments should ideally be combined into one comprehensive EPI Review and performed only every 3 to 5 years, with a moratorium on additional assessments in the interim.
- All assessments should be firmly aligned with country planning processes.

Day One - Workgroup 2:

Promising Practices in Driving and Sustaining Demand

Session Overview:

The second strategic objective (SO2) of the Global Vaccine Action Plan (GVAP) calls for 'individuals and communities to understand the value of vaccines and demand immunization as both a right and a responsibility.' As demand for vaccines and vaccination has received limited attention in the past, the issues of defining and measuring demand have been the subject of much work over the past two years, building in part on work related to 'vaccine hesitancy'. This session described the progress of a working group formed at the request of the GVAP Secretariat to develop options for indicators related to GVAP Strategic Objective 2 (SO2) followed by presentations from a variety of national contexts illustrating the breadth of approaches available to create and sustain demand for immunization.

Session objectives were to:

- understand the rationale and review what is meant by 'vaccination demand' and its measurement;
- share promising practices by countries and civil society organizations (CSOs) in driving community demand for immunization to close immunity gaps
- identify how communities voice their agenda and what tools and mechanisms are most effective at establishing accountability to communities.

Key Discussion Points:

The discussion of the definition of demand highlighted that the mere absence of vaccine hesitancy (i.e. 'acceptance') does not constitute demand. For immunization programmes to be successful, demand for both vaccines and vaccination services must be high. The proposed definition recognizes that immunization programme success requires service-side responsiveness to individual and community perspectives and that community participation is needed in key service delivery decisions. The definition proposed by the GVAP SO2 working group, which meeting participants seemed to support, is: *'Demand is the actions of individuals and communities to seek, support, and/or advocate for vaccines and vaccination services'*. The literature review and analysis that underpin this definition is currently being written up for publication.

One option for an indicator currently under consideration by the GVAP SO2 working group was presented at the breakout session for feedback. The proposed indicator is not meant to be a direct measure of 'demand' per se, but is instead intended to capture National Immunization Program investments (inputs) related to driving and sustaining demand. The indicator, which will be piloted in the JRF in at least two regions, is currently formulated as: 'Number of countries that include in their annual immunization plans budgeted activities to stimulate and/or sustain public demand for vaccines and vaccination services'. The wording of the associated question is being revised in light of feedback from the recent SEAR Immunization Technical Advisory Group and the GIM PIA meeting. Depending on the results of the regional JRF pilots and future consultations with EPI managers, this indicator may be taken up by the GVAP working group for presentation as an option to SAGE in Q4 2015.

The challenges of using a single, global-level indicator to capture work on such a context-specific topic as actions to address demand were pointed out by meeting participants and facilitators. Participants also noted that it would be desirable for the indicator to provide useful information to the countries themselves. Facilitators invited input on proposed versions of the SO2 indicator so that one can be finalized as an option to present to the GVAP Secretariat within the next few months.

Experiences from Ethiopia, Sierra Leone, Pakistan, and global level highlighted the role of CSOs in acting on, and nurturing, community demand for immunization and health services. A gallery walk of poster presentations from Cameroon, northern Nigeria, Belgium, Sweden, and South Sudan highlighted that very different approaches, all based on a common thread of understanding community perspectives and priorities, could bring about improvements to immunization.

As the demand dimension of immunization is a topic of relatively recent attention, much has yet to be learned about what works in what context, and how to measure it.

Next Steps/Recommendations:

Next steps include capturing additional input on the proposed JRF indicator; discussing other options for indicators related to GVAP SO2; sharing experience around demand-generation activities; and arranging for a full plenary session and breakout working group focusing on the dimensions of demand for immunization and health services at the next Global Immunization Meeting.

Key Messages:

- Demand is an action requiring more than 'acceptance' and is not directly measurable as coverage.
- Demand includes three primary actions: 'seeking' (individual behavior), 'supporting' (expressing a social norm) and 'advocating' (organized action to influence decision-makers).

- Responsibility for immunization programme success includes service-side responsiveness to individual and community perspectives; this entails establishing mechanisms for community participation in key decisions and immunization service delivery.
- Governments and supply-side actors are responsible for fostering demand in primarily two ways: 'stimulating' and 'sustaining'.
- Demand is dynamic and varies by context, vaccine, vaccination services provided, time, and place. Demand is fostered by governments, immunization programme managers, public and private sector providers, local leadership, and CSOs hearing and acting on the voices of individuals and communities.
- All immunization programme stakeholders have a role in sustaining what works, cultivating resilience so that setbacks that might compromise public trust in vaccines can be quickly remediated, and ultimately enhancing our ability to achieve key immunization outcomes related to coverage with equity.
- Demand for immunization and other health services includes a component of trust; communities may be more likely to express demand to actors whom they trust to respond.

Day One - Workgroup 3:

Sustainable Access to Vaccines in Middle Income Countries

Session Overview:

The objective of the presentations provided by WHO, Gavi, UNICEF, and the experience in WHO EURO and in Indonesia was to stimulate discussion of experience in the areas of procurement, price transparency, financing and Gavi graduation that allowed participants to brainstorm around possible creative solutions moving forward.

The central concerns that were identified by participants included:

- A large number of middle income countries (MICs) do not benefit from coordinated donor support or a unified global strategy;
- There is a lack of political commitment to prioritize immunization and its financing (not just the procurement) in MICs;
- Though various initiatives, tools and technical assistance are available - mechanisms for MICs to access these need to be facilitated;
- More advocacy and more coordinated efforts are required to enhance the availability and access to technical assistance by non-Gavi MICs.

Key Discussion Points:

Key themes that were raised in the discussion included **leveraging the experience of Gavi transition** for graduating countries that was beyond financial support for immunization programmes/new vaccine introduction. What are the opportunities from Gavi graduation work that could be translated to the MIC strategy?

The work of the MIC Task Force included a mapping of the needs expressed by MIC, which included:

- Strengthening national decision making bodies and the performance for immunization services;
- Harmonization/strengthening regulatory authorities;
- Ensuring the financial sustainability of immunization programmes; and
- Access to affordable prices and reliable supply .

The Task Force's work highlighted that 40 MICs currently supported by Gavi receive support to address these issues and meet GVAP targets, but that the remaining 63 MICs do not benefit from donor support nor a coordinated strategy to meet their needs in these areas. It was recognized in the MICs Strategy that there is not one answer or solution that will be suitable for all MICs. Different tools and mechanisms need to be available to respond to country specific challenges as MICs are diverse. The Task Force therefore designed the strategy as a menu of options, from which countries would be able to choose the kinds of assistance they identify as priority. In providing this assistance, the strategy would emphasize collaboration among MICs and peer-to-peer learning. This and other aspects of strategy implementation will require innovation in the way participating organizations work to enable greater collaboration and flexibility. In transitioning the strategy to its implementation stage, it will also be important to think about the incentives for stakeholders in this space.

Another theme raised in the discussion was **resource mobilization**, or how can we translate capacity building efforts and innovations to MICs that may not require large investment of funding or resources (e.g. e-learning; peer to peer exchanges). The needs of MICs, as far as financial investments required to support their needs, is substantially less than Gavi allocates to eligible countries. It was observed by participants that technical assistance is required more so than financial resources to strengthen immunization programmes. One possible way forward would be to develop a mechanisms for countries to submit proposals to understand the demands of MICs and how global partners, including CSOs and other NGOs, may provide support and guidance. This might however raise expectations that will have to be managed

Next Steps/Recommendations:

- Given the needs expressed by MICs through the World Health Assembly GVAP resolution, continued efforts to reduce inequities between countries eligible or ineligible for financial and technical support from global partners are required.
- In order to achieve this, access to coordinated TA in MICs should be facilitated, and market shaping activities as well as the ongoing work conducted in the area of price transparency through the WHO Vaccine Product, Price, Procurement (V3P) Project should be enhanced.
- Further thinking is required around incentives for sustaining new vaccines in routine immunization schedules in MICs in the absence of Gavi support, as well as means of leveraging political commitment and resources towards immunization in both non-Gavi MICs and MICs transitioning from Gavi support.
- Mechanisms to facilitate the sharing of best practices and experiences, or peer learning between non-Gavi MICs and MICs transitioning from Gavi support should be identified and implemented.

Key Messages:

- The majority of poor people and vaccine-preventable deaths are now occurring in MICs, and although MICs are generally recognized as having stronger systems and the potential to make rapid gains if key barriers are removed, they are far from attaining the GVAP targets.
- While approximately 40% of countries classified as MICs by the World Bank are supported by Gavi in their immunization efforts, many of these countries are transitioning out of Gavi support.
- The remaining 60% of MICs do not benefit from a unified strategy for action although these countries also face challenges in the area of immunization.
- A shared MIC strategy was developed by partners in immunization to support this latter group of countries, and was endorsed by the WHO Strategic Advisory Group of Experts (SAGE, April 2015).
- The MIC strategy will in the medium to long term also benefit countries who transition out of Gavi support.

Day Two: INNOVATE

Day Two - Plenary Session 4:

Polio Eradication

This session covered the second objective of the Polio eradication and endgame strategic plan which aims at the withdrawal of oral polio vaccine (OPV) from all routine and supplementary immunization activities. The path to the achievement of this objective includes the introduction by all OPV-only using countries of at least one dose of the inactivated polio virus vaccine (IPV) in their routine immunization programme, the withdrawal of type 2 OPV through a globally synchronised switch from trivalent OPV (tOPV) to bivalent OPV (bOPV) and an on-going effort to strengthen routine immunization services.

The first presentation described how the multi-partner polio eradication collaboration (WHO, UNICEF, Rotary International, BMGF, and CDC to which GAVI is now associated) has been able to secure the commitment of and support 126 countries in their efforts to introduce IPV. At the time of the meeting 21 countries had already introduced IPV and 105 had committed to do so by the end of 2015 or, because of supply constraints, very early in 2016. Progress so far was made possible through very high level advocacy, a strong collaboration with the vaccine industry leading to a substantial reduction in the price of IPV, the use of the Gavi experience and systems for introducing vaccines, financial support provided by the GPEI to all Gavi countries as well as to another 25 lower middle income countries, a strong communication effort and enhanced technical collaboration with countries.

The risks associated with the use of type 2 OPV now outweigh its benefits since wild polio virus type 2 has not been seen since 1999 and the vaccine virus can cause cases of paralytic polio or revert to neuro-virulence causing outbreaks of circulating vaccine derived polio virus. In May 2015, the World Health Assembly confirmed that the world is on track for the withdrawal of type 2 OPV. This will occur over a two week period in April 2016 through a globally synchronized switch from tOPV to bOPV by the 156 countries and territories that currently use tOPV. This unprecedented undertaking requires extensive planning on the part of countries to successfully recall tOPV, minimize quantities of tOPV that must be destroyed after the switch while ensuring that all children continue to be vaccinated and validating that tOPV is not available at any storage and service delivery points.

The example of Nigeria shows that the eradication of polio (11 months without a case caused by wild polio virus) was made possible through a strong commitment on the part of the Government, which scaled up funding for the programme thus ensuring timely availability of vaccines and support for operations and established a Presidential Taskforce and state taskforces to ensure oversight of the implementation of emergency plans. The assets put in place for the polio eradication effort were deployed to contribute to the strengthening of the routine immunization programme, for the identification of priority areas with low routine coverage, for the monitoring of immunization sessions (fixed and outreach), for tracking defaulters and supporting social mobilization and for supportive supervision.

The brief discussion touched upon the limited supply of IPV caused by a combination of challenges faced by industry to scale up production and the need to secure large quantities of vaccine for SIAs and outbreak response and the extraordinary accomplishment of the Nigeria programme in the context of unrest and the success brought about by strong government ownership.

Key Messages:

Extraordinary progress has been made thanks to a strong collaboration across all immunization partners :

- A remarkable momentum has been created for the introduction of IPV, building on the lessons learned from the Gavi experience,
- An extraordinary amount of planning is underway by 156 countries to prepare for the globally coordinated switch from tOPV to bOPV;
- In-country “dry runs” have shown that, when broken down into the various necessary steps, the tOPV-bOPV switch is totally feasible;
- The Nigeria immunization programme achievements in the interruption of the circulation of WPV and with the strengthening routine coverage using polio assets and experience are remarkable

Day Two - Plenary Session 5:

Immunization Supply Chain and Logistics

Effective and efficient immunization supply chain and logistics (ISCL) are the backbone to the Expanded Programme on Immunization (EPI). It refers to the network of people, cold chain equipment and management systems in place to deliver safe, potent vaccines from the point of entry in-country to the point of its administration - to the child, adolescent or adult. It also refers to the reporting systems in place to provide information on programme performance like vaccine utilization and stock levels that gives evidence for management decisions, corrective action and future forecasting. Well-functioning ISCL facilitate achieving the ‘6 Rights’ - getting the *Right products in the Right quantities and in the Right condition, to the Right place, at the Right time and at the Right cost.*

However, today’s approach to ISCL was established in 1974 with the launch of EPI, over 40 years ago. Inadequate investments have been made in ISCL, and as a consequence they are struggling to absorb the increasing demands on EPI in the changing environment. As compared to the 1980s, the number of doses given per child has grown over three-fold and the vaccine volume this requires in the cold chain has multiplied over ten-fold. Global analysis of 70 WHO-UNICEF Effective Vaccine Management (EVM) assessments conducted over the period of 2010-2013 provide evidence that national systems are under-performing on a range of supply chain indicators from primary store to service delivery level. Without further attention, ISCL will continue to be a bottleneck to new vaccine introduction and strategies to ‘reaching more’, putting at-risk our global aspirations for morbidity and mortality reduction as articulated in the Global Vaccine Action Plan.

Global partners such as WHO and UNICEF are working on an array of upstream and downstream activities to address the recognised challenges and improve overall performance of the immunization supply chain in countries. On the upstream side, this includes partnering with manufacturers to design more suitable vaccine products, equipment and new technologies that better serve the developing world. On the downstream side, WHO sets norms and standards for best practice, develops guidelines and policies and generates training materials for use by Member States to facilitate and improve access to vaccines at the last mile, to serve those who are most hard-to-reach. This includes focusing greater attention on the comprehensive EVM process, where countries are accompanied to develop EVM improvement plans and provided technical assistance to

make these plans actionable. It also includes promising innovations such as the strategy for delivering vaccines in a controlled temperature chain.

In addition, the GAVI supply chain strategy, approved by the Board in June 2014, provides an unprecedented opportunity to redress the shortcomings in ISCL. The strategy, developed through an 18 month consultation across dozens of partners and hundreds of individuals, lays out an implementation plan through 2020 to catalyse essential improvements in five fundamentals areas: Data for management, people and practices, continuous improvement processes, cold chain equipment, and system design. In June 2015, the Gavi Board additionally established a Cold Chain Equipment Optimisation Platform to amplify implementation of the strategy. Countries will be able to apply as part a health systems application, and receive a co-investment from Gavi of 80% towards the cost of some equipment for low-income countries, 50% for wealthier Gavi countries, and graduating/graduated countries will be able to access Gavi's prices. More information will be available as part of the 2016 Gavi Application Guidelines once released on the Gavi website.

A critical step to national implementation of supply chain plans and improvements requires the building of political will. Suggestions for advocacy efforts include: understanding the motivations, agendas and barriers of decision-makers; finding influential voices and champions to take up the cause; ensuring that ICCs, policy-makers and others understand the importance of the EVM and move to implement its recommendations in immunization plans such as the comprehensive Multi-Year Plans (cMYP). There is a new tool which can help with learning more about how to do advocacy for immunization at <http://advocacy.vaccineswork.org>. Because we are all advocates for strengthened immunization, we are each the voice of the fifth child.

Key Messages:

- Without additional investments by Member States and the global community - both in terms of human resource capacity and in necessary cold chain equipment – to strengthen the performance of immunization supply chain and logistic systems (ISCL), ISCL will put at-risk the achievement of our global aspirations for morbidity and mortality reduction as articulated in the Global Vaccine Action Plan.
- Delivering safe, potent vaccines where needed at the point of administration will not be able to be achieved without this cornerstone of EPI firmly in place.
- Realising these important investments in ISCL improvements will require on-going advocacy and political engagement.

Day Two - Plenary Session 6:

Integrated Approaches to Pneumonia and Diarrhoea Control in the Context of Maternal and Child Health

Currently, pneumonia and diarrhoea are leading killers of children under the age of five, together accounting for 24% of all child deaths globally, while effective interventions are not provided equitably across all communities. Children living in poor or remote communities are most at risk, and the burden pneumonia and diarrhoea places on their families and health systems aggravates existing inequalities. Only 36% of infants less than 6 months of age are exclusively breastfed; only about 58% of caregivers seek appropriate care for suspected pneumonia, and proper antibiotic treatment is given in about 47% of cases. Less than half of children (49%) with diarrhoea receive oral rehydration

therapy. Beyond adoption, the uptake of elemental zinc in the treatment of diarrhoea remains very low.

The majority of diarrhoea and pneumonia deaths could be eliminated through ambitious scale-up of key interventions. In responding to this challenge, WHO, UNICEF and partners launched the integrated Global Action Plan for Pneumonia and Diarrhoea Control (GAPPD), which proposes a comprehensive approach to end preventable child deaths from these diseases by 2025, potentially saving the lives of more than two million children each year. However, the set goal can only be achieved through an intensified and sustained coordinated effort from child health related programmes such as immunization, nutrition, WASH and environmental health.

Phanuel Habimana, Acting Director, WHO AFRO Family and Reproductive Health, reviewed progress of integrated approaches to pneumonia and diarrhoea control and maternal and child health. There was an almost 50% reduction in child mortality from 1990 to 2013, but progress in Africa is still insufficient, with only 15 of 47 countries on track to meeting the MDG4 goal. Pneumonia and diarrhoea still account for almost 16% and 10% of deaths, respectively, in children under the age of 5 years in the WHO African Region. The GAPPD combines key strategies to protect children (e.g. exclusive breastfeeding, adequate nutrition, zinc and Vit A supplementation, hand washing, safe water and sanitation), to prevent disease (e.g. vaccination against pertussis, measles, Hib, pneumococcus and rotavirus) and to treat sick children (e.g. improved care seeking and case management, low osmolarity ORS, zinc, and antibiotics). There are still substantial gaps in coverage of these key interventions in the WHO African Region, with less than half of the children with diarrhoea, for instance, receiving ORS.

GAPPD needs to be firmly embedded in national child survival strategies and coordination among programmes and partners is of utmost importance, with vaccine introductions and local champions used to advocate for specific strategies. Capacity building at all levels and securing the availability of necessary commodities at the health facility level is key to success. An AFRO EPI/IMCI interactive resource and training tool assists with these tasks. Other opportunities for integrated child health interventions exist, such as integrated community case management and integrated adolescent health interventions. The African vaccination week in 2014 delivered a multitude of life-saving interventions in conjunction with vaccines, such as Vitamin A, deworming tablets, malnutrition screening, iron distribution, malaria treatment and distribution of long-lasting insecticide-treated bed nets.

Elika Kamiji, Chief EPI Officer from Zambia, provided a country experience of GAPPD implementation. The country had developed an integrated GAPPD framework in the context of Zambia's roadmap for 'A Promised Renewed'. Mazabuka district in the Southern Province was selected for the first implementation of GAPPD and the Minister of MCDMCH launched the programme in this district in October 2014 as initiation to expanding to all districts after the nationwide launch of the rotavirus vaccine in the same district in 2013. Key GAPPD activities include training of health providers in integrated management of childhood illnesses (IMCI) and integrated community case management (iCCM), integrated disease surveillance and response (IDSR) and programme management. PATH has since expressed interest to include Mazabuka district in the 'Better Immunization Data' programme and supports the training of iCCM supervisors.

Ongoing advocacy activities attempt to include GAPPD in the technical guidelines for 2015 district plans, and into existing partner-supported programmes and projects, such as the EU supported MDGI programme, Health for the Poorest People, the Programme for Awareness and Elimination of Diarrhoea and the World Bank supported Reproductive, Maternal, Neonatal, Child Health and Nutrition project.

Key Messages:

- GAPPD has become a catalyst to bring together key stakeholders to jointly plan and agree on roles and responsibilities.
- District pilot plans offer lessons learned about the alignment of activities and pooling of resources and acknowledging the importance of multi-sectoral coordination.
- The implementation of GAPPD needs to be accompanied by a strong monitoring and documentation process to share lessons learned with other districts and countries.
- Priority actions to accelerate progress need to be identified for further priority countries.

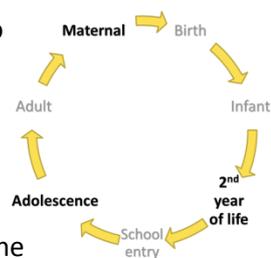
Day Two - Workgroup 4:

Life Course Approach to Vaccination

Session Overview:

The life course session focused on three aspects of the life course approach, as outlined in the figure below. The objectives included the following:

- To promote awareness of the opportunities of a life-course approach to immunization.
- To examine the life course approach to immunization implementation in three areas: Second year of life (2YL), adolescent and maternal immunization and their impact,
- To share examples of successful life course immunization strategies that reached previously unreached populations with routine immunization.
- To identify implementation opportunities and bottlenecks, and explore research gaps.



Key Discussion Points:

Second Year of Life Platform

In addition to outlining the scope of the 2YL activities, the Zambia experience was presented. The country had introduced measles 2nd dose (MSD) at the same time as PCV, leading to less emphasis on measles and resulting in a very low 2nd dose coverage, despite high first dose coverage. The missed opportunity of using the MSD to promote communication and messaging to health workers and caregivers on the value of the second year of life visit was highlighted. It was agreed that re-branding of routine immunization as extending beyond the first months of life will be critical for success in improving coverage as well as promoting integration. In addition, it was emphasized that 2YL should not just be for MSD but also for booster doses, catch-up on missed doses in the first year, new vaccines (e.g. malaria and Men A conjugate vaccine in routine immunization services), integration (e.g. well-baby visit, nutritional assessments, Vitamin A supplementation). The discussions underlined the importance of social mobilization and logistics, as well as the need to generate more data on best practices and global guidance.

Adolescent Immunization Platform

The advantages and challenges in promoting an adolescent vaccination platform were presented, highlighting the relative lack of experience of most EPI programmes in reaching adolescents, challenges with communication, differences in the consent procedures for infants versus adolescents and the value and challenges of working with non-traditional EPI partners. Several

comments and questions focused on strategies to utilize the opportunity of adolescent vaccination to promote an integrated approach to health services in this age group; on the definition of adolescence; and on other vaccines that should be promoted in this age group (especially TT/Td for boys and girls). The EPI managers from Lao PDR and Zambia were on a panel to share country-specific experiences on Td and HPV vaccination. Major issues highlighted included the challenge and need to work with multiple stakeholders in implementation; the need for more emphasis on social mobilization; new challenges of obtaining consent from unaccompanied minors in school settings; enumeration of out-of-school girls and other (invisible) vulnerable populations; and the relative lack of data on best practices, including for integration with other reproductive and health/social services.

Maternal Immunization

Global policies and experiences available from WHO were discussed to support immunization of pregnant women. A panel discussion of the experiences on maternal influenza immunization in Lao PDR and Malawi served to identify key success factors and bottlenecks to implementation, including demand and acceptance, economic and disease burden data needs, logistics issues (e.g. cold chain), and opportunities arising from the bundling of interventions. More implementation research should be conducted to answer critical questions around the capacity of the antenatal care system; the burden of the disease to be prevented; and cost effectiveness analyses. The acceptance of health care workers was regarded as particularly critical, especially their perception of risk to themselves and their patients.

Next Steps/Recommendations:

- Develop innovations in social mobilization strategies to promote behavioral change and increase demand (including communities and CSOs).
- Consider new terminology, tools, and trainings for a more inclusive 'routine' programme, so that EPI no longer just means babies and so that home-based records span across the life course.
- Expand adverse events following immunization (AEFI) systems to allow detection of such events among all age groups.
- Reframe health system strengthening towards life course vaccination using the '9 transformative investments' of the Global Routine Immunization Strategies and Practices (GRISP).
- Develop guidance on the best way to bundle services into integrated 'packages' – logistically, financially, and politically.
- Support quality studies and projects to assess life course approaches in different countries and contexts, in order to inform best practices (e.g. KAP, impact, and cost-effectiveness).
- Develop global road maps and guidance documents that span across vaccines and platforms.
- Form steering committees for new platforms (2YL, adolescence, maternal, or all life course approaches)

Key Messages:

- The life course approach should not be limited to 2YL, adolescent and maternal health, but should also emphasize school-entry requirements and other platforms.
- The adolescent vaccination platform should not be limited to issues related to HPV introduction but should include TT/Td vaccine and other vaccines, as well as the vaccination of boys.
- Although there are several unanswered questions about the life course approach, the inherent opportunities are apparent and future efforts should focus on more research and demonstration projects to develop best practices and global guidelines to maximize these opportunities.

A Vision for Information Systems in Immunization Programmes

Session Overview:

Participants discussed a common framework for immunization data monitoring, and data for management, that would help to align investments and efforts towards joint objectives in this area. Such a framework is being developed in the WHO IVB department. The current state of thinking around the Gavi Alliance 'Data' Strategic Focus Area (SFA) was presented including a discussion on continuity of efforts regarding data quality and surveillance at different levels.

Participants were asked to think about specific implementation issues, barriers and best practices in the fields of data and information systems. Two smaller groups focussed on:

- What data is currently being collected and why?
- How to move from data assessments to improvements?

Key Discussion Points:

Data is a major priority for countries and immunization stakeholders, but the immunization world lacks a clear shared vision, pathway, and funding mechanisms.

Some of the major challenges include:

- Limitations in workforce capacity, in countries as well as with technical partners;
- Lack of sustainability and institutionalization of information systems;
- Healthcare workers overburdened by administrative tasks across programmes;
- Unreliable denominators, mostly not under responsibility of immunization programmes.

There are many opportunities to improve and put the country users in the driver seat:

- The current momentum for better immunization data, including potential funding through Gavi engagement;
- Innovation, including e-health (e.g. e-registration), new processes (e.g. use of dashboards), workforce development (e.g. online learning and mentoring);
- Synergies that can be found with HMIS systems and workforce development.

Next Steps/Recommendations

- Re-assess what data is being collected and why. Not everything that can be measured should be measured. Partners need to rationalize data requirements and align them with country processes and timelines. Countries are encouraged to push back when appropriate. WHO should work on robust guidance in this area and prioritize data that is needed for decision making.
- Better integration of health information systems: Partners investing in information systems should align with national policies, and at least ensure interoperability between systems such as DVDMT, DHIS2, LMIS, and others.
- Assessments should result in improvement plans and then in "small doable actions" (short term – long term). WHO should develop methodologies that facilitate this kind of improvement planning. Activities may include looking for synergies, innovations, and activities to empower people at all levels through data use and feedback. In-country capacity (e.g. institutions, field epidemiology training programs) should be harnessed wherever possible.

Key Messages:

- It is time to take a critical look at what is being monitored and why.
- Data and info system assessments need to result in small doable actions.

Game-Changers in Immunization Technologies

Session Overview:

The WHO estimates that approximately 21.8 million infants are still not fully immunized with the basic vaccines, and approximately 1.5 million children under five die each year from vaccine preventable diseases. The Global Vaccine Action Plan realises the vision to extend the full benefits of immunization to all people, regardless of their circumstances. This could be accelerated through initiatives to develop innovative vaccine delivery technologies that have the potential to become 'game changers' and the ability to expand coverage of existing vaccines or facilitate the rapid uptake and reach of new vaccines that are on the horizon.

The objectives of this working group were to review progress, and discuss pros and cons of various vaccine delivery technologies in development; perform a 'deep-dive' into the feasibility and status of Measles Rubella (MR) vaccine delivery using intradermal patches ; and to review the progress of vaccines that are qualified for Controlled Temperature Chain (CTC) use, and consider prospects for the application to new vaccines.

Key Discussion Points:

Vaccine Delivery Technologies

Technology updates were provided on integrated reconstitution technologies, methods to bundle multi-component products (e.g., lyophilized vaccine and diluent), disposable-syringe jet injectors, intradermal microneedle patches, needle-based intradermal delivery technologies, inhalation technologies (aerosol and dry powder), biodegradable implants, and alternative primary containers for oral and parenteral vaccines.

PATH, WHO and other stakeholders are working to prioritize potential new delivery technologies and their application to priority vaccines to inform strategies and investment decisions. In addition, a delivery device working group is being created under the Vaccine Presentation and Packaging Advisory Group which is expected to serve as a venue for delivery technology developers to obtain feedback from the public sector and/or the vaccine industry and to serve as an expert review group for the prioritization work.

Preliminary analyses highlight the potential of intradermal patches for MR vaccine. Preclinical data suggests that the humoral immunogenicity of MR vaccine is equivalent or improved following microneedle patch delivery, as compared to conventional sub-cutaneous administration (same antigen dose level). Currently 53% of infants do not receive their second MR dose because of delivery issues and challenges of handling the vaccine once reconstituted, while there are approximately 150,000 deaths annually due to measles disease.

Intradermal patches could be a significant game changer for MR coverage for the following reasons:

- Ease of use (no vaccine reconstitution and simpler administration);
- Less complex and less constrained cold chain requirements;
- Improved safety (no reconstitution needed, reduced risk from sharps);
- Single dose presentation avoids missed opportunities and reduces vaccine wastage;
- Could be used by trained volunteers enabling house to house vaccination.

However, there remain some significant technology performance and programmatic gaps with respect to intradermal patch delivery that need to be investigated, such as the time requirement for

the patch to be in contact with human skin for delivery, possible constraints of wear time for childhood vaccination, coverage impact of house-to-house campaigns as compared to static clinics, and total system cost effectiveness. Most importantly, we await clinical proof-of-concept, and acknowledge that, currently, a clear global regulatory or prequalification pathway for vaccine and device combination products is lacking.

Vaccines in Controlled Temperature Chain

CTC use of vaccines is an example of a game-changer that is specifically targeted to improve delivery of campaign and special strategy vaccines that struggle to reach the last mile due to cold chain constraints. To date, just over 1.5 million people have been successfully vaccinated using the CTC approach. Experience with Meningitis A vaccine in a CTC has demonstrated no increased risk for severe adverse events following immunization. In addition, the amount of vaccine wastage has decreased as fewer vials experience a temperature deviation.

The WHO has published guidance on when and how to use CTC for MenAfriVac™ (up to 4 days at 40°C) to inform immunization programme decision-makers and managers and to support training for its use in immunization sessions. There has been high acceptance of the CTC protocol by health workers as a result of easier vaccine handling and transportation since ice packs no longer need to be carried.

PCV13 has recently been WHO prequalified for use in a CTC, and other vaccines are in the pipeline, namely oral cholera, HPV and rotavirus vaccines. Currently, the WHO requires demonstration of stability at 40°C for a minimum of 3 days. However, it is known that some vaccines (e.g., measles) will not be feasible for CTC due to stability issues.

Next Steps and Recommendations:

Vaccine Delivery Technologies

Following this meeting, the WHO will initiate an effort to evaluate what is required to establish a regulatory framework for various vaccine-device combinations:

- Specifically, WHO, in partnership with other stakeholders, will undertake a landscape analyses of existing processes for regulation, global licensure and prequalification of the various delivery platforms, with the aim of identifying gaps and assessing what is needed.
- In support of the encouraging intradermal patch delivery data for MR vaccine (as well as other vaccines for which preclinical and clinical exist), WHO plans to define the Preferred Product Characteristics (PPC) for MR vaccine delivery. This will be critical for global public health stakeholders to provide clear direction to MR patch developers in terms of required technology features and performance early in the development process.

Vaccines in Controlled Temperature Chain

- Building on the success of Meningitis A and PCV13, the focus now is on development and licensure of more CTC-compatible vaccines. This involves promoting awareness and interest in CTC, and regular dialogue with manufacturers and regulators to encourage thermostability testing of existing vaccines as well as CTC consideration in new product development.
- In addition, WHO is undertaking operational activities in the field to support further implementation and assess the impact of CTC, such as impact on coverage, knowledge, attitudes and practices (KAP) surveys, monitoring AEFIs and vaccine wastage and improving training, supervision, and monitoring tools.

Key Messages:

- Development, and implementation, of innovative strategies to deliver new and existing vaccines is urgently needed if we are to achieve the coverage targets defined within GVAP.
- There are several promising technologies on the development path, however in addition to supporting the advancement of these novel products in the clinic, the route to regulatory approval in low and middle income countries, and prequalification, must be clearly defined so as not to impede their use in the field.
- More CTC-compatible vaccines will improve delivery of campaign and special strategy vaccines that struggle to reach the last mile.

Day Three: ACCELERATE

Day Three - Plenary Session 7:

Progress and Challenges for Maternal and Neonatal Tetanus Elimination

Professor Narendra K Arora presented the progress and challenges to maternal and neonatal tetanus elimination (MNTE). Maternal and neonatal tetanus (MNT) is a marker of inequities in health as cases mostly occur among the most disadvantaged populations with limited access to health care and information about safe delivery practices, resulting in increased risk for life-threatening infections including tetanus.

The implementation of various initiatives under the MNTE programme led to a significant 94% reduction in cases of neonatal tetanus (NT) from an estimated 780,000 in 1988 to 49,000 in 2013, according to WHO estimates. These initiatives included promotion of maternal tetanus immunization along with safe delivery, and avoidance of unsafe abortion and umbilical cord care practices. A cheap and effective vaccine for tetanus is in existence since the 1930s and reaching a high-risk woman in a remote village with 3 doses costs only 3 USD. MNT should have been history decades ago. However, the goals for global MNT elimination have been repeatedly missed in 1995 and 2005, and will not be met in 2015. During the intervening years a number of lessons have been learned. China and India have provided cash incentives for institutional births, Sierra Leone and Liberia have conducted immunization campaigns for TT under the leadership of the civil administration with support from a coalition of partners and other countries have used innovations such as TT Uniject leading to high coverage and MNT elimination.

However, as of May 2015, globally, 22 countries are yet to be validated for maternal and neonatal tetanus elimination mainly due to a 129 million USD funding gap with numerous missed opportunities to protect communities from their childhood to adult life. Global MNT elimination can be rapidly achieved through renewing global commitment by the partnership to bridge the funding gap, providing 50 million doses of TT Uniject, developing a road map with clear milestones and monitoring the progress by SAGE and partners.

India's Achievement of MNTE

Dr Pradeep Halder, Deputy Commissioner for Immunization, EPI Manager, India, presented on how MNTE was achieved in India including the plans to sustain elimination. India recognized the high NT disease burden in the country, based on studies estimating 150,000 to 200,000 cases annually in the late 1970s and early 1980s and committed to achieving MNTE through strengthening of routine

immunization activities, including TT vaccine coverage, improving clean delivery practices through institutional births and training of birth attendants.

The immunization programme in India began offering tetanus toxoid (TT) to pregnant women in 1983. The nationally reported coverage for two or more doses is nearly 80% in 2014. In addition to the three doses of DTP in infancy, TT booster doses are given at 16-24 months and five to six years with additional booster doses at 10 and 16 years by extending outreach services through village health and nutrition days.

The launch of the National Rural Health Mission (NRHM) in 2005 helped strengthen these initiatives for MNT elimination. Strategies to improve clean delivery included the innovative *Janani Suraksha Yojana (JSY)*, a conditional cash transfer scheme, to encourage women to give birth in a health facility. The *Janani Shishu Suraksha Karyakram (JSSK)* was launched in 2011. Under this scheme, women delivering in health facilities receive additional benefits such as free drugs, consumables, diagnostics, blood transfusions if needed, free transport, and food during their stay. Other interventions to improve TT vaccine coverage and reduce maternal and neonatal tetanus mortality include operationalization of sub-centers and community health centers to provide obstetric and neonatal care services 24/7; engagement of more than 900,000 accredited social health activists (ASHA) to generate demand and facilitate use of health care services by communities and poor women; and the introduction of a “Dial 108” ambulance system to address the need for emergency transport. As a result, safe deliveries increased from 34% (as per district-level household and facility survey 1998-99) to 75% (as per Sample Registration System, 2013).

The country is also focusing its efforts in improving the maternal and child health services under the Reproductive, Maternal, Neonatal and Child Health Strategy wherein 184 districts have been identified for additional efforts. Such efforts at the community level have been targeted to reduce harmful cord practices and adopt clean birth practices through trained frontline health workers. The surveys conducted for MNT validation in 2013-14 have demonstrated that application of cow dung and other harmful substances has virtually disappeared.

In recent years, India has used lessons learned from polio eradication to ensure that more than 400,000 high-risk areas identified by the polio programme were reached through catch-up immunization drives such as *Mission Indradhanush* with vaccines available under the Universal Immunization Programme. The first such drive was rolled out on 7 April 2015. More than 2 million children and nearly 0.6 million pregnant women were vaccinated during this drive.

MNT validation has marked the start of a new phase to sustain elimination. The Government of India is committed to further improving TT coverage and institutional births in identified weak pockets.

Shift from TT to Td Vaccine

Countries should prioritize the switch from TT to Td vaccine based on WHO SAGE recommendation of 1998 aimed at increasing protection against diphtheria following huge outbreaks in the mid-1990s in Europe, and affecting especially pregnant women with high case fatality rates. There are on-going outbreaks in South Africa and Indonesia in 2015. Forecasting should henceforth seriously consider Td in place of TT.

Key Messages:

- The strategies to attain MNT are known, and have been shown to work.
- 37 of 59 priority countries targeted since 1999 have been validated for the attainment of elimination by June 2015.

- The attainment of MNTTE by the remaining 22 countries is being hampered by a funding gap of USD 129 million, including funds for delivering TT using the appropriate technology, Uniject, that can significantly help in reaching the most difficult to reach high risk communities and groups.
- Some donors have sustained their support to the initiative, but there is need to widen the donor base in view declining partnerships so that the funding gap is filled.

Day Three - Plenary Session 8:

Achieving and Sustaining Measles and Rubella Elimination

Dr Peter Figueroa gave the keynote presentation entitled: *What will it take to achieve measles and rubella elimination? Lessons to learn and costs to consider.*

While coverage with MCV1 has reached over 80%, measles mortality has been reduced by 75% since 2000, and rubella elimination has been achieved and verified in the Americas, progress towards the GVAP measles and rubella elimination targets has stalled. Lessons learned from polio eradication are that the primary challenge was poor quality of the programme, failure to reach underserved populations, and chronic funding gaps. Lessons learned from measles and rubella elimination include the importance of very high coverage ($\geq 95\%$) and the need to improve EPI programme infrastructure to support routine immunization. In addition, there is large inequity in access to a routine second dose of measles vaccine and for rubella vaccine, and regions and countries not using rubella vaccine bear the greatest burden of CRS today.

Economics studies consistently demonstrate that a strategy of 'high-level control' is not optimal if eradication is feasible. Recent estimates show the annual high costs of maintaining the current high-level control of measles and rubella; the current annual costs include 2.3 billion USD for sustaining the vaccination programme, and 6.6 billion USD for treatment of measles, rubella, and CRS. Additionally, for each outbreak, there are substantial costs for response activities and loss of productivity. Because both measles and rubella are eradicable diseases there is the potential to save billions of dollars and prevent human suffering from measles, rubella, and CRS; but, there is an ongoing need for upfront commitments of the resources required to achieve existing elimination goals.

The recommendation was made to conduct a mid-term review to rethink the strategies, targets, and/or expectations for elimination of measles and rubella. The strategy for 2016-2020 should include agreement among all partners and countries as to the programme targets and strategies, stronger emphasis on building health infrastructure to sustain high routine immunization, a coordinated strategic approach to support those countries most in need, and multi-year country planning, financing and vaccine forecasting.

Dr Abdur Rahim presented the experience in Bangladesh with implementing strategies to eliminate measles and control rubella and congenital rubella syndrome (CRS) during the years 2003 to 2015. Bangladesh introduced measles immunization in 1979 and by 2000 had achieved MCV1 coverage of 74%. In 2003, enhanced measles surveillance was begun and in 2006 the first measles catch-up campaign was conducted. In 2008, case-based surveillance for measles was initiated and in 2010 a measles follow-up campaign was conducted for children ages 9 months to <5 years. In 2012, Bangladesh introduced rubella vaccine into the routine schedule with a dose of MR vaccine given at age 9 months and in the same year added MCV2 at 15-18 months. In 2014, the MR catch-up

campaign was conducted for children ages 9 months to <15 years. Currently Bangladesh has a 2 dose MR schedule (doses at 9 months and 15 -18 months) and MCV1 coverage has steadily increased to 89%.

There has been a marked reduction in the incidence rate of measles and rubella since the MR catch-up campaign in 2014. In 2015, case-based surveillance has detected 101 confirmed measles cases, 92 rubella cases and 0 CRS cases. Based on risk assessment, 26 of 64 districts have been prioritized for further strengthening of routine immunization and a follow-up MR campaign is planned by 2018.

Critical success factors in Bangladesh have been strong country ownership and high political commitment, use of Gavi health system strengthening funds for immunization, and transfer of experience and resources from polio eradication towards strengthening the national immunization programme. Bangladesh is on track to achieve measles elimination and rubella/CRS control by 2018.

Key Messages:

- Despite paying high costs associated with maintaining “high control” globally, significant burden of disease from measles and rubella continues.
- A shared vision and sustained funding is needed among global partners to achieve equity in MR vaccination coverage and to reach global targets for measles and rubella elimination.

Day Three - Workgroup 7:

New Tools and Strategies for Maternal and Neonatal Tetanus and Measles/Rubella Elimination

Session Overview:

The objectives of this session were to highlight tools and strategies for getting back on track for GVAP tetanus and measles/rubella elimination goals.

The following tools and guidelines were highlighted:

- MNTE pre-validation “high-risk” assessment guidelines;
- Programme risk assessment tool;
- Global guidelines for conducting SIAs with injectable vaccines (including SIA readiness assessment).

Key Discussion Points:

The high-risk MNTE approach involves conducting risk assessments at district level prior to national elimination validation. All women of reproductive age in areas identified as medium or high risk should be vaccinated with either 2 or 3 doses of TT/Td, respectively. After validation, strategies to sustain MNTE are based on risk categorization of strategies necessary to reach elimination.

The measles programme risk assessment tool can serve as a means of assessing the programmatic risk at the district level, to help identify at-risk sub-national areas for prioritization of programmatic activities. It is not for predicting outbreaks, but rather for preventing them. Population immunity and surveillance quality over the preceding three years, programme delivery performance, and threats are weighted in the risk assessment. Various members of the audience pointed out that an alternate method was simply to calculate the accumulation of susceptibles, based on coverage data.

The impetus for the *SIA Field Guide*, soon to be published by WHO HQ, was declining SIA quality. The guide covers all injectable vaccine SIAs, including measles, with a focus on reaching the hard-to-reach, on monitoring and evaluation, and on integration with other interventions. Complementing the guide is the *SIA Preparedness Assessment Tool*, as well as a revised version of the *Rapid Convenience Monitoring Tool*.

Next Steps/Recommendations:

The high-risk strategy has been in use for many years, with a great deal of success. Its targeted use can contribute to eliminating MNT in more countries.

The programme *Measles Risk Assessment Tool* should be used for annual updates to monitor progress, supplemental immunization activity planning, outbreak response planning, measles case-based surveillance and EPI reviews, supervisory visits, for advocacy and resource mobilization, and by regional verification committees. It will soon be packaged for widespread use in a robust IT package. In addition, an updated version 2.0 may be rolled out incorporating additional factors such as routine immunization indicators and updated international borders.

The *SIA Field Guide* is a welcome addition and should be adopted for injectable campaigns. Feedback from piloted use of the *Preparedness Assessment Tool* included the importance of adapting to local context, early inclusion in the planning process with appropriate lead time, supervisory visits, and staff training.

Key Messages:

- Ongoing implementation of established best practices, as well as innovation in developing and implementing new control strategies, should be continued as a means of attaining accelerated disease control goals.
- The programme risk assessment tool could be used as a broader diagnostic check on the EPI programme.

Day Three - Workgroup 8:

After the Crisis: Immunization and Post-Emergency Response

Session Overview:

There is a growing number of complex emergencies across the world including many that are disrupting health services and negatively impacting traditional approaches to vaccination of children. WHO has published guidelines: '*Vaccination in Acute Humanitarian Emergencies: A Framework for Decision-Making*' that outline strategies for prioritization and vaccination in a crisis situation. Use and adaptation of this material in the field is encouraged, and Médecins sans Frontières reported on experiences in Syria, South Sudan, Uganda, Chad, and Ethiopia.

Key Discussion Points:

Ebola was a Public Health Emergency of International Concern (PHEIC) that had a major impact on health workers and immunization services in West Africa. It was a complex outbreak requiring rapid scale-up of financial, technical and human resource support to health system. It revealed health system weaknesses, particularly related to infection control practices. The outbreak negatively impacted EPI including a decrease in coverage in all three countries and delays in implementation of priority activities including new vaccine introductions and programme evaluations. Coordination of

partners was critical to stopping the outbreak and building country capacity to respond to the outbreak.

Strong communication efforts are central to regaining the populations trust in immunization, as rumors related to Ebola vaccine and new infection control procedures for immunization services have reduced demand for vaccination. A key learning is that these negative effects can be anticipated and addressed proactively in advance for future public health emergencies. Often times it is the health workers themselves who need information, education and communication (IEC) in order to limit disruption to services.

Despite considerable challenges posed by conflict and insecurity, programmes in Northern Nigeria and Afghanistan have been able to achieve remarkable progress in reaching children with vaccination services. The workshop revealed there is an ongoing global exchange on innovative strategies to vaccinate children in complex emergencies (for example Nigeria visited Afghanistan on a study tour). A strong capacity to assess the risk of vaccine preventable disease outbreaks and to focus the response is critical.

Early intervention is needed to prevent or stop vaccine preventable disease outbreaks (e.g. cholera, measles). Success depends on strong political leadership, partner coordination, preparedness (financial, human and supplies) for rapid response when opportunities open up, and community engagement. Addressing community needs beyond vaccination (primary health care more generally, or medical treatment) can help gain access. In emergencies where infrastructure may be nonexistent, new strategies that allow certain vaccines to be transported at ambient temperature (in a controlled temperature chain) can be of special benefit.

Next Steps/Recommendations:

- WHO guidelines for 'Vaccination in Acute Humanitarian Emergencies: A Framework for Decision-Making' http://apps.who.int/iris/bitstream/10665/92462/1/WHO_IVB_13.07_eng.pdf should be widely disseminated and it would be useful if experiences using and/or adapting these guidelines were documented.

Key Messages:

- EPI programmes are remarkably resilient and valued by communities, and after an emergency they can be an important foundation for restoration of functioning health services.
- The process of restoration is an opportunity to revisit and rebuild immunization programmes that are flexible and stronger.

Day Three - Workgroup 9:

Vaccine Implementation Lessons Learned (Rotavirus and Pneumococcal Vaccines)

Session Overview:

The session objectives were to share experiences on the process of introduction of rotavirus and pneumococcal conjugate vaccines; to share information on methods and findings from surveillance and special studies to document vaccine impact and to share experiences with the Gavi graduation process.

Key Discussion Points:

The programmatic impact of vaccine introduction in Mozambique and Moldova was discussed as well as disease impact studies and surveillance in Mozambique, Moldova, and globally. Sustainability issues around GAVI graduation in Moldova and overall in the EURO region were highlighted.

Vaccine introduction was overall very smooth and well accepted. Country experiences emphasized the importance of preparedness including availability of funds well in advance of the launch. Social mobilization must include information on disease as well as the vaccination strategy so that the community is clear about eligibility for vaccination and that the immunization workers are not overwhelmed by demand for vaccination. Overall, health worker and caretaker knowledge was focused on the vaccine, with relatively low level knowledge of other prevention and treatment measures, despite IEC materials that included broader diarrhea and pneumonia prevention and control measures. Vaccine safety concerns, and vaccine hesitant and migrant populations contribute to decreasing immunization coverage in some countries, particularly in the European Region.

Preliminary results show direct and indirect impact of Pneumococcal conjugate vaccine (PCV) on cases of invasive pneumococcal disease, pneumonia hospitalizations and radiologically confirmed pneumonia cases. There is growing evidence globally of the impact (direct and indirect) on rotavirus gastroenteritis. Technical coordination projects for pneumococcal and rotavirus diseases were formed to fill strategic information gaps, provide technical assistance to countries, and conduct systematic reviews to inform policies and strategies.

Careful planning for GAVI graduation for programme and financial sustainability is critical and must start well in advance (2-3 years). This will include advocacy for increased funding for immunization nationally and strategies to improve evidence-based decision making, and address programme performance to ensure accessibility and demand for vaccines.

Next Steps/Recommendations:

Vaccine Introduction: Trainings, communication, and social mobilization should be tailored to the community and best local practice (videos, billboards) and must include information on disease as well as the eligibility for vaccination. Training and practice should be reinforced through supportive supervision. Immunization coverage is a joint responsibility of the primary health center, the community and partners (schools) in immunization.

Sustainability: More studies (impact, economic, product analysis) will be necessary to meet country requirements for sustainable financing and continued implementation of the vaccine. Advance planning and technical assistance is important to develop a Gavi graduation plan (including focus on national and local budgets, advocacy, procurement planning, evidence-based decision making). The planning process should identify, advocate and plan for specific challenges that the country will face.

Key Messages:

- Available data suggest that PCV and rotavirus vaccines can have a significant impact on the burden of pneumonia and diarrhea in children.
- Both vaccines are well accepted by communities, though careful planning is required to optimize the process and manage community expectations
- Careful advance planning is essential for a smooth and efficient transition in countries graduating out of Gavi support.

Market Place

Several displays were showcased during all three days of the meeting on a variety of topics:

Home-Based Vaccination Records

This exhibit provided a snapshot of the home-based records used in 122 different countries. Home-based vaccination records play an important role in tracking and documenting immunization services and, in some cases, additional health interventions received by individuals.

See <http://www.immunizationcards.org> for examples of records used across the world.

New Delivery Devices

An opportunity for a 'hands-on' experience of some novel vaccine delivery technologies and discussion of their pros and cons with PATH and WHO.

Immunization e-Learning Initiative

A preview of the new Immunization e-learning initiative being developed by WHO and UNICEF to provide training to immunization staff in subject areas considered vital to the advancement of the Global Vaccine Action Plan.

Promising Practices in Driving and Sustaining Demand

Showcasing examples from Belgium, Cameroon, Nigeria, South Sudan and Sweden, a series of posters presented initiatives in driving and sustaining demand, to help contribute to improved knowledge and awareness of best practices, new approaches, and shared language on demand generation.

Measles/Rubella China Country Poster

China has demonstrated exemplary progress towards measles elimination and the use of new tools for high quality SIAs. The country poster and hand-outs demonstrated the practical use of a number of tools, in particular: The Readiness Assessment Tool, the Supplementary Immunization Field Guide, the Measles Programmatic Risk Assessment Tool, and the Rubella Vaccine Introduction Guide.

Tools from the International Vaccine Access Centre (Johns Hopkins University)

Some of JHU IVAC's most widely-used tools were on display, including VIEW-Hub, a publicly accessible interactive platform designed for stakeholders at all levels and domains to visualize real-time information relevant to accelerating and optimizing vaccine implementation. Also shown was a video on the introduction of IPV in early adopter countries.

Gavi's Grant Application, Monitoring and Review (GAMR) Redesign

Gavi's poster presented the overall picture of the grant cycle from 2016 onwards and together with handouts, explained how these changes fit together. A particular focus was placed on sharing new information and tools on the Joint Appraisal process and the Performance Frameworks.

Controlled Temperature Chain - Video Screening

The Controlled Temperature Chain (CTC) is an innovative approach to vaccine management and distribution. It allows certain vaccines to be kept at temperatures outside of the traditional cold chain of +2°C to +8°C for a limited period of time under monitored and controlled conditions, at the last mile of service delivery. A film on CTC explained what CTC is, why it is useful and how it is feasible. It also featured a case study of CTC implementation during a vaccination campaign in Côte d'Ivoire, providing insight on the health workers' perspective, and provided an outlook on the options for countries and what manufacturers can do to support countries.