CONFERENCE REPORT

Closure conference of the Meningitis Vaccine Project

Ending and new beginnings

22 to 25 February 2016, Addis Ababa, Ethiopia

The conference was jointly hosted by the World Health Organization and PATH, partners in the Meningitis Vaccine Project. Special thanks to the Bill & Melinda Gates Foundation and the National Philanthropic Trust for their generous financial support.
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## Abbreviations and acronyms

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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>EPI</td>
<td>Expanded Programme on Immunization</td>
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<tr>
<td>Gavi</td>
<td>Gavi, The Vaccine Alliance</td>
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<tr>
<td>IST/CA</td>
<td>Inter-country Support Team for Central Africa</td>
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<td>IST/ESA</td>
<td>Inter-country Support Team for Eastern and Southern Africa</td>
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<td>IST/WA</td>
<td>Inter-country Support Team for West Africa</td>
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<td>MVP</td>
<td>Meningitis Vaccine Project</td>
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<tr>
<td>PsA</td>
<td>polysaccharide</td>
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<td>SIIPL</td>
<td>Serum Institute of India Pvt Ltd</td>
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<td>TT</td>
<td>tetanus toxoid</td>
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<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Executive summary

The Meningitis Vaccine Project (MVP) closure conference was organized to celebrate the success of the Project, to recognize all partners for their contributions, to share results and experiences and to plan the next steps to ensure continued support for the remaining vaccination campaigns and a smooth transition into routine immunization programmes. The project, a partnership between WHO and PATH, functioned from 21 June 2001 to 31 December 2014, with a single goal: the development, licensure and introduction of a group A meningococcal conjugate vaccine for use in sub-Saharan Africa.

The focus of the first day of the meeting was recognition of the contributions of the many individuals and institutions throughout the project, which culminated in the successful introduction of a safe, effective, affordable group A meningococcal conjugate vaccine and the near-elimination of outbreaks of group A meningococcal disease in sub-Saharan Africa. The participants also discussed timely formulation of recommendations for long-term control of the disease. The results and experiences shared ranged from the scientific development of the conjugate vaccine; intellectual property; scale-up and manufacture; clinical research strategies and implementation, including assessment of end-points; quality assurance and control; oversight, ethics and regulatory pathways; advocacy, community engagement and communication; surveillance; manufacture of vaccine on a public health scale and country experience; group A meningococcal carriage; the impact of the vaccine on carriage and disease, including economic aspects; modelling of long-term control strategies and the innovative project management strategies devised to overcome the challenges of developing an affordable conjugate vaccine for sub-Saharan Africa. One pillar of the project was planning the early stages of research and development specifically for a clearly defined public health goal. Another pillar was the quality of partnership characterized by trust, respect, transparent communication and good relations between WHO and PATH, the manufacturer, Serum Institute of India Pvt Ltd (SIIPL), the donor, the Bill & Melinda Gates Foundation, and all other partners, including countries and communities.

The project resulted in the licensure and WHO prequalification of two products, a 10-µg polysaccharide A (PsA)–tetanus toxoid (TT) vaccine for people aged 1–29 years (MenAfriVac®) and a 5-µg vaccine for children under 2 years of age (MenAfriVac 5 micrograms®). Since 2010, the 10-µg vaccine has been used to vaccinate millions of 1–29-year-olds in large vaccination campaigns in 16 of the 26 countries in the African “meningitis belt”. The remaining 10 countries are scheduled to conduct such campaigns in the next two years. The participants stressed the importance of completing mass vaccination campaigns in all countries in the meningitis belt and emphasized that these campaigns should be accompanied by high-quality surveillance and evaluation. From 2016, the 5-µg vaccine will be introduced into routine immunization programmes as a single dose at 9–18 months of age, concomitantly with other routinely administered vaccines. A one-time catch-up campaign targeting cohorts born since the mass vaccination campaigns will be conducted at the start of introduction of the vaccine into routine programmes. Modelling indicates that failure to put in place such a strategy could result in the recurrence of deadly epidemics after 15 years.

The focus of the second day of the meeting was building on the success of the project. Research is being conducted to establish the duration of protection after initial vaccination and on developing an affordable multivalent conjugate vaccine that would also offer protection against other meningitis serogroups. The need for such a vaccine is evident, given recent outbreaks of meningitis due to groups C, W and X. Work is also under way to expand and strengthen the surveillance systems in all the meningitis belt countries and to evaluate the long-term public health and economic impacts. Countries, agencies and institutions, such as Gavi, The Vaccine Alliance (Gavi), the United Nations Children’s Fund (UNICEF) and WHO, will work together to ensure financing, planning, monitoring and evaluation for the remaining vaccination campaigns and for the transition to routine immunization programmes.
Integration of the vaccine into these programmes poses challenges, but it is also an opportunity to strengthen routine health interventions, not just for infants but also older age groups. Countries and agencies will also maintain careful planning for the next meningitis epidemic season to ensure preparedness, in particular the availability of vaccines, for outbreak response. Other meningococcal serogroups with outbreak potential, such as C, W and X, will remain major threats for countries of the meningitis belt until an affordable multivalent conjugate vaccine becomes available.

In light of the recent WHO announcement that the complications associated with Zika virus disease are a public health emergency of international concern, a special session was added to present and discuss preparedness and response to Zika virus in the African Region. The WHO strategy for controlling the virus includes surveillance to identify clusters of the disease, its complications and mosquito and virus populations. The response plan will be effective, however, only if African countries reach core capacity for implementing the International Health Regulations (2005); none has yet done so.

The conference was unique in convening a wide range of experts, from bench scientists to ministers of health and programme managers, reflecting the unique features of the project itself, whereby integration, inclusiveness and collaboration were the keys to its success.
Background

The MVP, a partnership between PATH and WHO, was launched in June 2001 and formally ended in December 2014. The goal of MVP was to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa by developing, testing, licensing and introducing meningococcal conjugate vaccines. The Project was successful, resulting in widespread vaccination with MenAfriVac®, an affordable vaccine manufactured by SIIPL. To ensure sustainability, vaccination must now be introduced into existing routine immunization programmes. Mass vaccination campaigns will continue in the countries of the “meningitis belt” until December 2016, and the vaccine will be introduced into routine programmes, starting in 2016.

The closure conference convened representatives from all 26 countries in the meningitis belt and all MVP partners to share and celebrate their accomplishments and to plan the next steps. The conference took place on 22–23 February 2016 in Addis Ababa, Ethiopia, as a pre-satellite meeting to the Pan African Ministerial Conference on Immunization on 24–25 February at the headquarters of the Commission of the African Union. All the participants were also invited to the Ministerial Conference and to the MVP awards ceremony held in the evening of 23 February as part of the gala celebration dinner.

This report gives the highlights of the presentations, all of which can be found in full on the WHO website (http://www.who.int/immunization/research/meetings_workshops/en/). The report should therefore be read in conjunction with the presentations. The report also summarizes the discussions after the presentations.

Inaugural ceremony

(Chair, Dr Paul Mainuka, WHO Representative, Ethiopia)

Dr Mainuka recalled that sub-Saharan and Saharan Africa have experienced large, periodic, unpredictable epidemics of bacterial meningitis for more than 100 years. MVP represents a great achievement in public health and was made possible only through strong partnerships.

Dr M. Moeti, Regional Director for the WHO Regional Office for Africa, welcomed the participants, who had contributed to the achievement being celebrated: 5 years after the introduction of an affordable meningococcal A conjugate vaccine, vaccination has led to the control and near elimination of deadly epidemics in the African meningitis belt. The fight against group A meningococcus was led by a partnership between WHO and PATH, funded by the Bill & Melinda Gates Foundation, with South–South cooperation with SIIPL and active involvement of African clinical research sites and ministries of health in the Gambia, Ghana, Mali and Senegal. That cooperation should inspire work on other diseases that predominately affect low-income countries.

She thanked the governments of African countries, Gavi, UNICEF and other partners for their sustained support for mass immunization campaigns. Although meningococcal A epidemics are nearly eliminated from Africa, the job is not complete. The dramatic gains will be jeopardized unless countries maintain a high level of protection and sustained epidemiological surveillance. Catch-up vaccination campaigns and integration of the vaccine into routine childhood immunization schedules is essential to prevent a resurgence of the deadly epidemics of the past.

Other strains of meningococcal meningitis should now be addressed, based on the spectacular success of MenAfriVac®. In 2015, both Niger and Nigeria had outbreaks of meningococcal C, and meningococcal
W is responsible for current outbreaks in Ghana and Togo; meningococcal X also remains a threat. Therefore, a high-quality, affordable, multivalent meningococcal conjugate vaccine is needed that protects people against all the strains of meningococcus with outbreak potential, offers long-lasting protection to individuals and confers herd protection. The Regional Office is committed to supporting countries in reacting to outbreaks of meningococcal disease due to other strains. Moreover, we should not lose sight of the threat of meningitis due to Streptococcus pneumonia, with a current outbreak in Ghana coinciding with the group W meningococcal outbreak.

She congratulated all those involved, who, with foresight and determination, had actively contributed to MVP. In particular, she thanked Dr Marc LaForce for his devotion from the beginning in the mid-1990s until the end of the dream that is now virtually a reality.

Mr Steve Davis, President and Chief Executive Officer, PATH, said that the meeting recognized one of PATH’s proudest moments. The achievement has taught PATH a number of lessons about partnerships and about the introduction of new vaccines. The first lesson is to listen to and engage with country leaders. The model for the project was based on the specifications of African leaders. The second lesson is to find the right partners, in this case WHO and also SIIPL, the Centers for Disease Control and Prevention in the USA, Public Health England and Médecins sans Frontières, among many others. PATH learnt how to work with partners in a way that allowed all the ideas, solutions, results and collaboration to come together to achieve this singular success. The third lesson is to seize opportunities to innovate, not only in the development, approval and delivery of a vaccine but also in its thermostability.

His Excellency Dr Amir Aman Hagos, State Minister, Ministry of Health of Ethiopia, also welcomed the vaccine, which meets the highest international standards. More than 60 million people aged 1–29 years have been vaccinated in Ethiopia, and the programme can be qualified as a success. Now, the challenge will be to ensure that the achievements are sustained. It is therefore essential to remain vigilant and to start planning and implementing the next phase in meningitis control. He welcomed all participants and declared the conference open.

Dr Marie-Pierre Preziosi, former Director of MVP, presented the agenda of the conference. She said that the three main objectives were to:

- celebrate the success of MVP and recognize partners for their contributions;
- share results, experience and lessons learnt; and
- plan the next steps, to ensure continued support for the remaining vaccination campaigns and a smooth transition into routine immunization programmes.
Session 1. The Meningitis Vaccine Project: results and experience

The session addressed the creation and evolution of the MVP partnership and aspects of vaccine development, including technology, manufacture and scale-up, technology transfer, quality control and clinical development. These were all necessary steps to reach the point at which the new group A meningococcal conjugate vaccine, MenAfriVac®, could be ready for licensure and used in meningitis control.

Project lifeline and highlights
(Co-chairs: Dr Sylvain Zeba, Ministry of Health, Burkina Faso, and Dr Abraham Aseffa, Ministry of Health, Ethiopia)

Key events in the development of PsA-TT, a new meningococcal conjugate vaccine
Dr F.M. LaForce, SIIPL (former Director of the MVP)

Dr LaForce described the events that led up to commercial production of MenAfriVac®. He said that there had been no plans to develop a meningococcal A conjugate vaccine for Africa until the terrible meningitis epidemic in 1996, when African public health officials asked WHO for help. MVP was created in 2001 as a 14-year partnership between WHO and PATH, with support from the Bill & Melinda Gates Foundation. Discussions with African public health officials and with the WHO Regional Office for Africa showed consistently that cost was the most important limiting factor to the introduction of new vaccines in Africa; the vaccine had to cost less than $US 0.50 per dose. MVP could not reach an agreement with major vaccine manufacturers, and therefore decided to become a virtual vaccine company. A business plan indicated that the cost of making 25–50 million doses of a group A meningococcal conjugate vaccine could allow a price per dose as low as US$ 0.18.

Vaccine manufacturers in five emerging economies were approached, and MVP set about finding a method of preparing a PsA-TT conjugate vaccine. After a number of setbacks, a method was found, and the technology was transferred to the SIIPL. Once a formal agreement had been signed between PATH and SIIPL in 2004, production based on good manufacturing practice was gradually scaled up, analytical techniques were developed, and a dedicated facility was built in Pune. Doses were tested at the National Institute for Biological Standards and Control in the United Kingdom in 2004, and clinical trials began in 2005. MenAfriVac® was licensed by the Drugs Controller General of India in December 2009.

Some of the factors that led to the success of the project were respect for cultural realities, a willingness to travel for face-to-face consultations as needed and transparent communication.

Vaccine development
Technical development of a group A meningococcal conjugate vaccine
Dr C.E. Frasch (now retired) and Dr C.H. Lee, Center for Biologics Evaluation and Research, US Food and Drug Administration

Dr Frasch outlined a project on the chemistry of conjugation that had been conducted to improve the efficiency of vaccine conjugation by activating both the polysaccharide and the carrier protein. At the request of MVP, they had focused on the group A meningococcal polysaccharide and found that a conjugate made with hydrazide-activated TT raised a strong antibody response in mice. This is the technology that was transferred to SIIPL.
Overcoming the challenges in scale-up and manufacture of MenAfriVac®
Dr S. Jadhav, SIIPL

Dr Jadhav said that partnership, transparency and trust were the elements that had permitted MVP to succeed. The senior management of his company are strongly committed to public health, ensuring the availability of high-quality, affordable vaccines for public health. They use sophisticated equipment with a high level of automation and the latest technologies for conjugation and purification. The rapidity of scale-up of production was unprecedented, between transfer of the technology in 2004 to current production of more than 70 million doses every year. By 2011, 25 million doses had been used to vaccinate children in Burkina Faso, Mali and Niger. The company is committed to supplying the global community with as many doses as required, at an affordable price (by agreement with PATH). In 2014, WHO asked for studies on use of the vaccine outside the cold chain in the Expanded Programme on Immunization (EPI), and SIIPL showed that MenAfriVac® is stable for 2 weeks at 25 °C or 4 days at 40 °C. Despite the success of the vaccine, Africa remains at high risk for meningitis due to other strains (C, Y, W and X), and the company is prepared to continue its vaccine development programme.

Technology transfer with the human element
Mr P. Soukas, National Institute of Allergy and Infectious Diseases, Technology Transfer and Intellectual Property Office, USA

Mr Soukas described the procedure used for licensing MenAfriVac®, which was different from that used normally, in which large companies retained the intellectual property rights for their own profit. Several countries held patent rights for MenAfriVac®, and the patents cover three methods of conjugation. The final licensing method could be used as a model for other, similar agreements for vaccines to be used in low-income countries.

MenAfriVac clinical development
Dr M.-P. Preziosi, WHO headquarters

Dr Preziosi presented two slides on behalf of Dr I. Feavers and Dr B. Bolgiano of the National Institute for Biological Standards and Control in the United Kingdom, which showed the quality control procedure that had been used before licensure of the vaccine. She then described the steps in clinical development of MenAfriVac®, from posing the scientific and public health questions to be answered to the regulatory perspective and strategy for licensure, WHO prequalification and wide-scale use. The process was conducted according to international standards with a high level of oversight and had required commitment, collaboration, mutual learning and persistence. She praised and thanked all the partners present.

Discussion
In the discussion that followed the presentations, participants asked whether the lessons learnt could be extended to produce vaccines against other diseases, such as malaria and Zika virus disease. The speakers replied that the model could indeed be used for producing vaccines against other diseases of public health priority; its success might encourage donor agencies to look at such projects. Participants commented that the success of the project was largely due to the quality of the partnerships and the
importance of personal relations among people in different institutions. It is important now to strengthen the capacity of all research communities for clinical research, regulatory aspects and operations in the field. The lesson for African leaders is that vaccination is essential, and Mr Soukas said that the US Government is ready to help countries to obtain vaccines.

**Regulatory pathways**
*Dr S. Jadhav, SIIPL; and Dr N. Dellepiane, WHO headquarters (now retired)*

Dr Jadhav spoke about the unprecedented situation of a vaccine for sub-Saharan Africa being made by a manufacturer in a developing country. A number of challenges arose, which were overcome one by one with assistance from the National Institute for Biological Standards and Control in the United Kingdom, the Drug Controller General of India, Health Canada and WHO. A unique feature was training by WHO for African governments to strengthen their national regulatory authorities, as the vaccine had to be registered in each country in which it was used.

**Ethics and community perspectives during the MenAfriVac® clinical trials**
*Professor S. Sow, Centre pour les Vaccins en Développement-Mali; and Mr L. Martellet, PATH*

The presenters described how MVP clinical studies were conducted in the field. They emphasized the importance for the research team of engaging with the community, including elders, religious leaders, women’s associations and community liaison officers. Before the start of the study, public meetings were organized to present the objectives and obtain the permission of the community to conduct the research, and questions and concerns were addressed. During the study, frequent visits to the field by the research team maintained awareness and support for the study. Several examples of ethical approaches were highlighted, including an interactive process for obtaining informed consent, a confidential procedure for pregnancy testing, provision of health care during the trial, response to health issues in the study area and community meetings to present the findings of the study. The experience was extremely positive, with sharing of information among ethics committees, refining best practices, guidelines to protect research participants, bridging universal principles and respecting local specificities.

**Meningitis A campaigns: lessons learnt in advocacy and social mobilization**
*Mr J. Shadid, UNICEF Regional Office for West and Central Africa; and Mr R. Barry, WHO Inter-country Support Team West Africa (WHO IST/WA)*

Mr Shadid explained how the scientific achievement of MenAfriVac® was accepted by the target population. The successes of the campaign included the involvement of the Ministry of Education and teachers, as most children were vaccinated in the classroom. Another success, although also a challenge, was the strategies chosen to engage young people aged 15–29 years, such as the use of celebrities they admired, engaging peer groups and strategic use of community radio stations. One of the most innovative initiatives reported was strengthening the capacity of high-level spokespersons to respond to negative rumours sparked by coincidental deaths and to counter vaccine refusal for social, political, medical or religious reasons. After training, these spokespersons were able to calm the situation and restore confidence on several occasions during the campaigns. One of the challenges was explaining that the vaccine protects against only one form of meningitis – that due to group A meningococcus – when in everyday language no distinction is made between different causes of the disease, which are all referred to as “meningitis”. Other challenges were poor interpersonal communication by the vaccinators
and integrating the vaccine into relatively weak EPI systems. The presentation highlighted the opportunities for using mobile phone technologies for evaluating, monitoring, messaging and strengthening community-based approaches and sustaining high-level advocacy.

Mr Rodrigue Barry stressed that good communication channels are vital and maintaining them is not a one-off activity but must be continuous. This was demonstrated in Burkina Faso, where a child died during the vaccination campaign of a cause that was unrelated to the vaccination. With that knowledge, rumours that would have undermined the campaign were dispelled within a few days. That was possible only because a crisis communication strategy was in place, including relationships with all the relevant stakeholders and agencies.

Vaccine introduction
MenAfriVac® vaccine roll-out
Dr A. Fall, Dr A. Bita and Mr C. Lingani, WHO IST/WA; Dr M. Djingarey, WHO Country Office Guinea (formerly at IST/WA); and Dr W. Perea, WHO headquarters

Dr Fall described the extent of the meningococcal A problem in Africa and the strategies that have been used to contain it. MVP resulted in vaccination of over 235 million children within 5 years in districts at high risk, which had been prioritized with a reliable tool developed by WHO. The campaigns should be finalized in 2016–2017 in the 10 remaining countries. Follow-up campaigns should be conducted to vaccinate children who were too young or not yet born at the time of the first vaccination campaigns. At the same time, MenAfriVac® should be introduced into routine EPI. SIIPL should be supported in developing an affordable pentavalent conjugate vaccine to prevent outbreaks due to the five most prevalent meningococcal strains.

Introduction of the new conjugate vaccine against meningococcal A disease, MenAfriVac®, in Mali
Dr F. Siby, Dr A. Guindo and Dr B. Tounkara, Ministry of Health, Mali

Dr Siby described the situation with regard to meningitis in her country, with 16 of the 64 health districts in an insecure region in the north-east. The other challenges are case-based surveillance, maintaining the cold chain and preparing the response to meningitis outbreaks due to other serogroups. The financial engagement of the Government and its partners is important, especially for training and to strengthen the laboratory network.

Introduction of the vaccine in Sudan
Dr Omayma Abdalla, Ministry of Health, Sudan

Dr Abdalla recounted the way in which the Ministry of Health had conducted the campaign in her country, with vaccine coverage of more than 95% in all states. The challenges of conducting vaccination campaigns in the country are the high cost, limited access to hard-to-reach and insecure areas and delay in implementing phase 2 of the campaign because of rumours spread by the media. A challenge for the future will be maintaining a high level of immunity in new cohorts of children that have not yet been vaccinated. The success of the campaign was due in part to good coordination with all partners, including nongovernmental organizations. Quality performance indicators should be strengthened, and partnerships and greater engagement of the community should be sought.
**Chad’s experience in introducing MenAfriVac®**
*Dr M. Tamadji, Ministry of Health, Chad*

Dr Tamadji said that the epidemic in 2011 had been the worst for many years, and meningococcus A had been the cause in 93% of cases. The country was therefore a priority for the introduction of MenAfriVac®. The four-phase approach required micro-planning to overcome local difficulties, but the launch of the campaign by the President and good financing had made it possible. The Inter-agency Coordination Committee had played a decisive role. Preparation of communication messages to dispel rumours is essential.

**Discussion**

Dr Hacen, retired WHO Country Representative in Burkina Faso, recalled that Dr LaForce had approached him in 2001, at the beginning of an epidemic, and presented a dream, with risks. Dreams and risks are needed to support Africa in managing public health problems, including epidemics, with communication, research and development, regulation, large vaccination campaigns and strengthening disease control and health systems. Dr Aissatou Touré Balde, a member of the MVP Project Advisory Group, commented on questions raised about the ethical aspects of conducting trials and especially of selecting certain study sites over others; however, the Project Advisory Group had provided advice on these aspects, and she considered that the trials that had been described had adequately respected human rights and had been well managed.

Another discussion focussed on the phased roll-out in Chad. Before countrywide roll-out was completed, an outbreak due to group A meningococcus had occurred. Therefore, some districts were protected by vaccination while others were still unprotected, effectively serving as a control group. It was stressed that this was not intentional but just how events unfolded.

**Project lifeline and highlights (continued)**
*(co-Chairs: Dr Saada Daoud, Ministry of Health, Chad, and Dr Omayma Abdalla, Ministry of Health, Sudan)*

**Meningitis surveillance in the African meningitis belt**
*Dr A. Bita and Mr C. Lingani, WHO IST/WA and Dr O. Ronveaux, WHO headquarters*

Dr Bita recalled that the three-pillar strategy for eliminating meningitis in Africa involves surveillance, case management and vaccination. In order to improve the detection of cases and to assess the impact of MenAfriVac®, enhanced surveillance and case-based surveillance were introduced, which have different uses. WHO analyses the performance of surveillance and issues weekly reports during epidemics, with monthly reports between epidemics. It encourages inter-country coordination of meningitis surveillance, especially in view of the high mobility of trained personnel. In 2016, case-based surveillance will be extended to another four countries in the meningitis belt: the Democratic Republic of the Congo, Guinea, Mauritania and Togo. In countries where case-based surveillance cannot be implemented, enhanced surveillance will be maintained until resources become available for case-based surveillance. Management tools, databases and applications should be standardized, with updated standard operating procedures. All countries need more financial and material resources and personnel trained in conducting lumbar puncture. He recommended that the annual meningitis workshops be continued.
Public health impact of MenAfriVac®: the first four years
Dr M. Djingarey, WHO Country Office Guinea (formerly at WHO IST/WA); Dr R. Novak, US Centers for Disease Control and Prevention; and Professor J. Stuart, London School of Hygiene and Tropical Medicine

Dr Novak and Dr Djingarey said that case-based surveillance had been strengthened in Burkina Faso between 2007 and 2012, and national laboratory and epidemiological capacity had been built to support the country in evaluating the performance of MenAfriVac®. Thus, the various clinical, epidemiological and laboratory data collected were linked in a central database; real-time PCR was introduced in national laboratories, and a pilot study was conducted. It was found that large epidemics occur every 3–5 years but that there were fewer cases due to group A meningococcus.

Dr Stuart reported on the effects of the vaccination programme in Chad, which the health authorities conducted over two successive years for logistical reasons. As the programme was implemented during an epidemic of group A meningococcal disease, districts in which vaccination had been conducted in the first year of the campaign could be compared with those without vaccination. The programme demonstrated an overwhelmingly positive impact of vaccination, with a dramatic reduction in the number of cases of meningitis in the vaccinated districts.

Impact of MenAfriVac® on meningococcal carriage in Burkina Faso
Professor D. Caugant and Dr P. Kristiansen, Norwegian Institute of Public Health

Dr Kristiansen described the three sites at which the study had been carried out, with one central laboratory. Seropositive samples were sent to Oslo for confirmation, and negative samples underwent quality control. The overall prevalence of carriage predictably showed higher rates in the dry than in the rainy season. Significant differences in carriage were found between districts; however, after vaccination, group A meningococcal disease disappeared completely from all three sites. MenAfriVac® thus acts not only against the disease but also against carriage of the bacterium. In tests in 200 vaccinated schoolchildren, high antibody titres were found in their saliva. Carriage of the other meningococcal serogroups after vaccination differed, but group X carriage appeared to be sustained over time. Whole-gene sequencing indicated that various subtypes change and adapt. Differences in carriage were also found by site, age group, sex and the size of the household.

The African Meningococcal Carriage Consortium
Professor B. Greenwood, London School of Hygiene and Tropical Medicine

Professor Greenwood said that the purposes of the Consortium, which is a “cousin” of the MVP, are to find the best way of measuring meningococcal carriage, the prevalence of carriage, the pattern of spread of infection within households, the pattern of immunity to meningococcus A and the effect of MenAfriVac® on carriage. Training was conducted in laboratories on swabbing techniques and handling samples. Cross-sectional surveys showed wide heterogeneity in carriage by place and time, although the prevalence is lower and of shorter duration than in industrialized countries. Transmission within households was demonstrated. The project will end in April 2016.

Discussion
One participant asked why no information was available on carriage of meningococcus A in Nigeria, where severe epidemics have been occurring since 1900. Others agreed that risk should be documented...
in countries other than the seven included in the Consortium study and that surveillance should be strengthened, including for risk factors, such as weather. As the guidelines for meningococcal meningitis are being updated, other serogroups should be added.

A participant commented that there is still no pathophysiological explanation for the occurrence of meningococcal A disease in the dry season; research will proceed more quickly once that is understood. Collaboration with weather specialists could result in a model of risk factors for each country. Professor Greenwood said that the nasopharyngeal mucosal flora appear to change with each season, and that is being studied. One participant commented that the apparent shift in serogroup is due to an overall increase in the proportions of the remaining serogroups once meningococcus A has been suppressed. However, there is as yet no evidence that the absolute numbers of cases due to other serogroups is increasing.

**Safety of MenAfrivac: monitoring, challenges and lessons**

*Dr G. Enwere, WHO headquarters*

Dr Enwere showed in detail how the safety of vaccines is assured; furthermore, WHO has reviewed post-licensure surveillance. The only two vaccine-related serious adverse events seen during the MenAfriVac® clinical trials were one case of facial oedema and one of simple febrile convulsion. All 29 deaths reported during vaccine development were determined not to be related to the vaccine but due instead to malaria, gastroenteritis or sepsis. Data on adverse events must be collected in a timely, uniform manner, even in remote places, although ethical committees and health systems have different requirements. Furthermore, surveillance for adverse events must continue when the vaccine is given as part of the routine immunization programme.

**MVP persistence studies (The Gambia, Mali, Senegal)**

*Dr O. Idoko, Medical Research Council Unit, The Gambia; and Dr A. Diallo, Institut de Recherche pour le Développement, Senegal*

Dr Idoko described a cross-sectional observational study to assess meningococcal group A antibody persistence, up to 5 years after vaccination for children initially vaccinated at 12–23 months of age and up to 4 years after vaccination for people initially vaccinated at 2–29 years of age. Dr Idoko focussed on the follow-up of participants in the PsA-TT 002 clinical trial, which took place in The Gambia and Mali. Dr Diallo highlighted the results from the PsA-TT 003 clinical trial at the same sites, but also including a site in Senegal. The study demonstrated that a single dose of MenAfriVac® induces a sustained level of meningococcal A antibody for up to 5 years. Further work is being done to determine whether immunity could persist for up to 10 years.

**Influence of age on antibody response and persistence following immunization with MenAfriVac**

*Dr P. Kulkarni, SIIPL and Dr Y. Tang, PATH*

Dr Tang reported the results of an investigation to determine whether the age at which a person is vaccinated with MenAfriVac® affects the immune response and persistence, in order to decide on the optimal schedule of vaccination. The results from three clinical trials conducted in Africa showed that young children tended to have higher immune responses than infants, and the pattern persists at least one year after vaccination. Although the results two years after vaccination are not complete, the immune response appears to be similar to that at one year.
Measuring immune responses to PsA-TT using human complement serum bactericidal antibody assays
Dr M.C. Bash, Center for Biologics Evaluation and Research, US Food and Drug Administration

Dr Bash said that she used human complement serum bactericidal antibody assays to measure immune responses to the vaccine because *Neisseria meningitidis* is strictly a human pathogen and is adapted to resist killing by human complement. She was investigating ways to overcome the difficulties of finding suitable human complement sources for testing samples from clinical studies. The findings were compared with those obtained with the most commonly used rabbit complement serum bactericidal antibody assay. The PsA-TT induced a strong human serum bacterial antibody response. The titres decreased over 52 weeks, especially in children under 10 years of age, but remained higher than in children given only PsA at the same age. The dramatic response after the second dose indicates that priming is important. Full interpretation of the differences between immunoassays would require data on vaccine failures; however, none have been reported to date.

Discussion
In answer to a query, Dr Bash said that results beyond one year post-vaccination were not yet available; samples from children with persisting immunity would have to be examined.

An anti-tetanus vaccine
Professor R. Borrow, Public Health England, Manchester Medical Microbiology Partnership

Professor Borrow recalled that maternal and neonatal tetanus are still substantial but preventable causes of mortality in many developing countries, and treatment is limited by scarcity of resources and effective drugs. MenAfriVac® contains 10–33 μg of TT per dose as the carrier protein, because it has been used in other conjugate vaccines and because tetanus remains a public health problem in sub-Saharan Africa. Furthermore, meningococcal conjugate vaccines with TT enhance the immune response to other TT-conjugated vaccines, such as that against *Haemophilus influenzae* b. His collaborators obtained data on neonatal tetanus cases in meningitis belt countries from the WHO website and compared them with data on maternal tetanus vaccine coverage in countries in which countrywide PsA-TT vaccination campaigns in 1–29-year-olds were complete, countries with partial coverage and countries that had not yet begun vaccination. They found a 25% reduction in the number of cases of neonatal tetanus in five of the countries with full coverage and also immunity to tetanus among adolescent girls.

Discussion
In response to questions, Professor Borrow said that MenAfriVac® would not be used to replace TT vaccine. Dr LaForce added that the regulatory complications of using MenAfriVac® to replace TT vaccine would be huge and expensive, even though the conjugate is functionally a bivalent vaccine. It would de facto replace TT vaccine in women who have not been vaccinated against tetanus and would boost tetanus immunity in people who had already been vaccinated. The additional anti-tetanus effect of MenAfriVac® makes it even more cost–effective than has been calculated so far.
Transition to routine vaccination

Results from clinical trials in infants and young children

Dr A. Hodgson, Ghana Health Service, Ghana

Dr Hodgson reported on two MenAfriVac® clinical studies in infants in Ghana and Mali that were conducted to determine the optimal vaccine dosage and schedule in infancy. They concluded that, after a sustained functional immune response, a 5-µg dose of the vaccine would be sufficient to maintain immunity. They also looked at concomitant administration of EPI vaccines such as pentavalent diphtheria–tetanus–pertussis–hepatitis B virus–H. influenzae b vaccine, oral polio vaccine, measles vaccine, yellow fever vaccine and measles and rubella vaccine and found no adverse reactions or immunological interactions. The vaccine could be administered as one or two doses, depending on a country’s epidemiological specificities.

Modelling strategies for the long-term use of MenAfriVac®

Dr C. Trotter, University of Cambridge

Dr Trotter described results obtained from mathematical models of \textit{N. meningitidis} group A transmission and disease, which were designed to determine the optimal use of MenAfriVac® in the long term. She illustrated the use of models in general and described an age-structured transmission dynamic model that captures the stochastic epidemiological features of meningococcal A in the African meningitis belt. Four vaccination strategies were tested in the model: only the initial mass campaign; periodic vaccination of children aged 1–4 years; routine EPI; and routine EPI plus catch-up vaccination of children aged 1–4. The initial campaigns are predicted to result in low meningitis incidence for about 15 years if 10 years’ duration of protection is assumed, but a serious resurgence would then be highly likely. All the long-term strategies are effective, although the mean incidence and time to peak are lowest for the combination strategy.

Economic Impact of vaccination strategies against group A Neisseria meningitidis in Burkina Faso

Ms A. Colombini, WHO consultant

On the basis of the epidemiological model presented by Dr Trotter, Ms Colombini calculated the direct medical and non-medical costs and the indirect costs to households and health systems of the introduction of MenAfriVac®, in terms of both monetary cost and the number of cases avoided. A combination of catch-up and routine vaccination would save most costs for both households and health systems and avoid the most cases, despite the expense of a second campaign, with higher savings for households because of the decreased disease burden.

MenAfriVac®. Transition to routine vaccination: recommendations

Dr M.-P. Preziosi, WHO headquarters

Dr Preziosi presented the updated WHO guidance on use of meningococcal A conjugate vaccine. Countries that have completed mass vaccination campaigns should introduce the vaccine into the routine childhood EPI within 1–5 years of the campaign, and a one-off catch-up campaign should be conducted for cohorts born after mass vaccination and outside the age range targeted by routine EPI. WHO recommends a one-dose schedule at 9–18 months of age, and any children who missed vaccination at the recommended age should be vaccinated as soon as possible thereafter.
However, the dose schedule should be based on the age distribution of cases and programmatic and economic considerations; if there are compelling reasons, a two-priming dose schedule should be started at 3 months of age, with doses at least 8 weeks apart. MenAfriVac® at 5 µg is indicated for routine vaccination of infants and young children aged 3–24 months, whereas MenAfriVac® at 10 µg remains indicated for catch-up and periodic campaigns from 12 months of age onwards.
Session 2: The future: routine immunization, surveillance and impact, next-generation vaccines

(Co-chairs: Dr Fanta Siby Diallo, Ministry of Health, Mali, and Dr Ado J.G. Muhammed, Ministry of Health, Nigeria)

The Bill & Melinda Gates Foundation’s perspective on building partnership that begin and end with countries
Dr O. Levine, Bill & Melinda Gates Foundation, USA

Dr Levine congratulated all those present who had made MVP a success. He said that bacterial meningitis, the “dry wind disease”, cannot be controlled by changing the environment: the harmattan cannot be stopped. The sustainability of the achievement will depend on further work, in which the Foundation will also be involved. The defining features of MVP were that so many disparate bodies had worked together, the goal was reached after only 15 years, communities were deeply involved, and additional innovative solutions had been found, for instance to the problem of the cold chain and the cost of dose delivery. The next step was to move to routine vaccination and maintain case-based surveillance, with adjustments to the programme as necessary.

Discussion
In answer to a question about how the Foundation would help African leaders and their people to sustain immunity, Dr Levine said that it would be important to ensure that, over the next 2 days, at the Ministerial Conference on Immunization in Africa, the ministers of health of countries in the African and the Eastern Mediterranean regions committed themselves to sustainable protection. Africans must own their immunization programmes, with the capacity to procure vaccine and implement campaigns.

Forward plans
Meningitis vaccine sustainability project
Dr C. Keech, PATH

Dr Keech introduced the PATH programme, funded by the Bill & Melinda Gates Foundation, for sustaining the achievements of MVP. The availability of vaccine will depend on the vaccine manufacturer, SIIPL, and successful applications to Gavi. Samples will be made available for further research and analysis, as described by Mr Martellet later during the conference. Two studies are under way, and she welcomed feedback on their design.

Evaluation of Men A-specific antibody persistence in Ghanaian children more than five years after immunization with PsA-TT (2.5 μg, 5 μg or 10 μg PsA concentration)
Dr P. Ansah, Navrongo Health Research Centre, Ghana Health Service, Ghana

Dr Ansah described the design of a study of circulating bactericidal antibodies and immunoglobulin G concentrations in infants and young children who took part in early trials of MenAfriVac®, to determine long-term immune persistence five to six years after vaccination. He invited comment on whether one or two blood draws should be performed.
MVP Access Program: access to data and sera collected during the MenAfriVac® clinical trials
Mr L. Martellet, PATH

Mr Martellet said that samples from all the studies carried out during the MVP will be available to qualified researchers, working in collaboration with the study investigators, for research of public health interest, except for genetic research. The samples are being held in a secure system at the University of Siena, Italy, until 2017. Memoranda of understanding have been signed between PATH, SIIPL and each participating study site, and clear steps are established for accessing samples and data, including requirements for research protocols and ethical clearance. Overall access and process are governed by the terms of the initial informed consent obtained from study participants at the time of sample collection. At the end of each study, all samples must be destroyed.

Discussion
Several questions were raised about the ethical aspects of the access programme with regard to informed consent and the exclusion of genetic studies. Mr Martellet replied that informed consent is available for all the samples that are in long-term storage, and each proposed new study will undergo ethical review at the study centre at which the samples were taken. Samples from studies in Ghana are available for only 10 years and will therefore have to be destroyed in December 2017. Genetic research was excluded in the informed consent forms. Dr Keech added that PATH will provide biostatistics support and training in transfer of datasets for investigators. Professor Sow described the protocol for obtaining informed consent in detail, including ethical oversight.

MenAfriNet, a regional catalyst
Dr R. Novak, Centers for Disease Control and Prevention, USA; and Dr J. Mwenda, WHO Regional Office for Africa

Dr Novak said that MenAfriNet is based on three surveillance systems, which build on each other. The system will require extensive technical support and international partners to reinforce case-based surveillance. Strategically, the network will initially cover mainly high-risk countries. It will be used to measure the impact of the vaccine, for research and for decision-making, such as when to introduce routine immunization. The network will also serve to fill gaps in WHO advice, from assessment to technology transfer, training and mentorship, and the MenAfriNet Quarterly CBS Bulletin complements the WHO Enhanced Meningitis Surveillance Bulletin. The successful model used in Burkina Faso will be replicated in other countries, with a work plan adapted to each country. Some tools are being revised, such as case report forms for standardized data. The network was used during an epidemic due to meningococcus C in Niger in 2015, where staff were deployed from Burkina Faso to provide technical assistance, and data in the network were used for decision-making.

Case-based surveillance of meningitis: the experience of Burkina Faso
Dr I. Medah, Ministry of Health, Burkina Faso

Dr Medah described the organization of case-based surveillance at three levels throughout the country. Surveillance has shown that pneumococci are the most common infective agents, followed by meningococcus W. In 2014–2015, five cases of meningitis suspected to be due to group A were notified, one of which was in a nine-year-old girl who had been vaccinated with MenAfriVac® (the causal agent is yet to be fully confirmed). In general, the performance indicators of surveillance were good, except for
those associated with transport of samples of cerebrospinal fluid, indicating that training is needed. Burkina Faso intends to maintain coverage of the entire country with case-based surveillance, for which it will require financial support.

**Discussion**

Participants raised a number of questions about the case of meningitis due to meningococcus A in a vaccinated child. Others emphasized the importance of case-based surveillance for providing evidence of the effectiveness of MVP and for detecting vaccine failures. Greater investment is needed in training and research at university level to form a national core of human resources to sustain high-quality surveillance. The experience gained in case-based surveillance in MVP should be extended to other diseases, with pooling of resources. The quarterly bulletins issued by both WHO and MenAfriNet could perhaps be merged to ensure sharing of information, and the format of the database should be similar to those for other diseases.

Dr Medah replied that the case in the vaccinated child had been confirmed at the national reference laboratory, and samples were being investigated in reference laboratories in other countries. The girl had been vaccinated in 2010 when she was four years old, and a photocopy of her vaccination card had been obtained. The five cases appear to be concentrated in the north of the country, where epidemics usually begin, and are being investigated with the US Centers for Disease Control and Prevention. He said that sustainability is the responsibility of countries; their partners provide support, but the countries must invest in their own programmes.

Dr Novak said that the sustainability of immunity was part of the original grant application to the Bill & Melinda Gates Foundation. Countries must decide what their priorities are and estimate the cost. In Burkina Faso, the priority is equipment for collecting specimens, and MenAfriNet is providing a 5-year grant for case-based surveillance. Other organizations have agreed to implement the WHO guidelines in the most critical areas. With regard to data management, the goal is eventually to transfer all data to the existing WHO platform. The *MenAfriNet Quarterly CBS Bulletin* will soon be distributed as a complementary tool to communicate information on meningitis for the long-established *Meningitis Weekly Bulletin* compiled by the WHO Inter country Support Team in West Africa. Merging the two bulletins would currently not be sensible, and colleagues were encouraged to sign up for the *MenAfriNet Quarterly CBS Bulletin* by contacting Dr Novak.

**Development update on a new African pentavalent ACYWX conjugate vaccine**

*Dr M. LaForce and Dr P. Kulkarni, SIIPL*

Studies are under way at SIIPL and PATH on development of an effective, affordable pentavalent meningococcal conjugate vaccine against the A, C, Y, W and X serogroups, specifically for Africa. Preclinical studies of the new vaccine have been completed at SIIPL, which showed that the new vaccine is highly immunogenic in rabbits. The first human phase-1 study will begin at the Center for Vaccine Development, University of Maryland, USA, in May 2016; all other clinical studies are to be done in Africa and India. Licensure is expected in 2019–2020.
**MenA vaccine introduction: country experience, Ethiopia experience**

*Dr L. Woldegiorgis, Ministry of Health, Ethiopia*

Dr Woldegiorgis described the background of the EPI in Ethiopia and the vaccination campaigns that have been conducted in response to massive epidemics due to meningococcus A. Risk mapping was completed in 2012, and national priorities were set to vaccinate 61.7 million people aged 1–29 years (about 70% of the entire population) between 2013 and 2015. Additional targets were to establish a pharmacovigilance system and strengthen case- and laboratory-based surveillance. A “health development army” and social networks were used to mobilize and inform communities, with messages in the media. The campaign involved assessments of cold chain requirements, training and a waste management plan. The operational cost, vaccines, and supplies were provided by Gavi.

The opportunities were local nongovernmental and private partners, which provided vehicles and human resources; understanding the consequences of meningitis and therefore willingness to receive MenAfriVac®; committed teams who vaccinated beyond the daily requirement in gathering places such as churches and market-places; and the availability of health extension workers (community health workers), who were the main source of information for the campaign, especially in rural areas. The strengths include high Government commitment at all levels, the strong commitment of the peripheral teams, local initiatives to produce information material, timely distribution of vaccines and logistics and a post-campaign coverage survey. The challenges were heavy rains in some areas, which disturbed campaign activities, delays in starting the campaign in hard-to-reach areas, packaging of vaccination cards and a gap in target distribution.

High coverage (98.4%) was achieved in all three rounds, and the vaccine was well accepted. The country has a well-structured public health emergency management system, from national to community levels, and meningococcal meningitis is one of the weekly reportable diseases of public health priority. Six sentinel surveillance sites have been established as part of enhanced meningococcal surveillance, and sentinel sites are also available for other new vaccines, such as rotavirus, which are also used to isolate meningococcal bacteria. The country has rich experience in introducing new vaccines, and, in order to maintain herd protection through vaccination of new birth cohorts to sustain meningitis elimination, the country plans to introduce vaccination against meningococcus A into the routine immunization programme.

**Discussion**

In response to a question about the cost of the pentavalent vaccine, Dr LaForce said that it would be impossible to produce it at less than US$ 2.00 per dose. One participant commented that, when the pentavalent vaccine is introduced, case-based surveillance will be simpler, as there will be fewer cases. Dr LaForce said that surveillance was important to determine when all children were protected and to plan booster doses.
Transitioning the MenA conjugate vaccine into routine immunization programmes
(Co-chairs: Dr Marie Mbolo epse Kobela, Ministry of Health, Cameroon, and Dr Badu Sarkodie, Ministry of Health, Ghana)

Gavi’s role in strengthening immunization systems and reducing burden of meningitis in Africa
Dr S. Berkley, Gavi the Vaccine Alliance

Dr Berkley described Gavi’s involvement in MVP from its inception. The impact of the Project is clear, including an economic impact, with early savings between 2010 and 2016 of US$ 90 million, as compared with reactive campaigns. The issue now is introduction of the vaccine into routine immunization programmes. Gavi is working with five countries in the meningitis belt to identify areas for coverage and equity. Gavi is also investing more than US$ 700 million to strengthen health systems and increase coverage in the meningitis belt. Group A and ACWY vaccine stockpiles are funded until the end of 2015, with a no-cost extension granted until the end of 2016, and longer-term support for meningitis stockpiles is being considered. Gavi will support a controlled-temperature-chain campaign in South Sudan in 2016. The challenges include the evolving epidemiology, with circulation and outbreaks of serogroups other than A, highlighting the need for affordable conjugate multivalent vaccines, and the security of the supply, as vaccines for both routine and campaign vaccination depend on one manufacturer.

Discussion
Participants asked Dr Berkley whether he was optimistic about the financial sustainability of meningitis vaccination and whether Gavi would continue to make the vaccine available. One participant pointed out that disease prevention is associated with Sustainable Development Goal 3. Dr Jadhav, responding to the disquiet expressed by Dr Berkley about there being a single manufacturer, said that SIIPL had hitherto not defaulted on supply. The problem has been one of aligning manufacture of the vaccine to the implementation of campaigns that are subject to delays due to the lengthy process of applying to Gavi for support and for procurement from UNICEF. Dr Preziosi said that WHO would work with countries during the fragile 2–4-year period while they were organizing inclusion of the vaccine into routine immunization programmes to ensure that they received enough vaccine through Gavi and UNICEF and that all partners exercise good will to minimize delays.

Dr Berkley replied that all countries had committed themselves to the Global Vaccine Action Plan and universal health coverage. Vaccination, the most widely distributed health intervention, is the base of that pyramid, and countries must ensure that they can buy all the EPI vaccines. They should advocate with their finance ministries and political leaders to make sure that they understand the value of immunization and prioritize it. Gavi will continue to make the vaccine available, but plans should be submitted in a timely manner to avoid creating susceptible populations. He agreed with SIIPL that better demand forecasts are needed to ensure the required supply of vaccine on time. He noted that 8 of the 16 countries that have implemented campaigns are now planning to integrate MenAfriVac® into routine immunization programmes; the remaining 8 countries should follow their lead.
Transition to routine vaccination: overview of plans in the meningitis belt
Dr C. Tevi-Benissan, WHO Regional Office for Africa; Dr N. Teleb, WHO Regional Office for the Eastern Mediterranean (WHO Regional Office for the Eastern Mediterranean); and Dr I. Ogbuanu, WHO headquarters

Dr Tevi-Benissan pointed out that, in addition to the preventive campaigns, the overall meningitis control strategy must also include routine immunization, enhanced surveillance, and adequate treatment and care of patients with meningitis. Modelling has shown that, if no further routine vaccination activities are undertaken, there will be a massive surge in the number of cases of meningitis again in 2025; the WHO recommendations have therefore been updated to ensure that meningococcal A vaccine is included in routine childhood immunization programmes, at a dose of 5 µg for children 9–18 months of age. She showed photographs of the vials containing the 5-µg (copper-gold cap and pink label) and the 10-µg doses of MenAfriVac® (silver caps and sienna brown label) and commented that training would be required to ensure correct use. A phased plan has been drawn up for introduction of routine immunization in the meningitis belt over 2016–2018, which is of course open for discussion and has been communicated to Gavi. The plan also indicates the five countries in which risk assessments have not yet been conducted. The challenges, opportunities and next steps will be discussed with each country.

Meningococcal A conjugate vaccine: supply planning for meningitis belt
Ms A. Ottosen, UNICEF Supply Division

Ms Ottosen illustrated the divergences between the planned amounts of vaccine required and those actually used. The manufacturer has succeeded in adapting the supply, but the situation will become more complex when two forecasts will have to be made for use of the two different dosages. Countries should attempt to make realistic plans and adhere to them, as it takes about six months to produce a vaccine batch, and procurement is possible only about four months after Gavi has approved a request.

Discussion
In answer to a question about whether countries should first complete mass vaccination before changing to inclusion of the vaccine in routine immunization, Dr Tevi-Benissan said that it would be best to conduct mass vaccination campaigns in zones at high-risk before routine use. One participant commented that, although Senegal has not had any cases of meningitis for 10 years, the model described by Dr Trotter shows that periodic campaigns would be less effective than routine vaccination. Concern was raised regarding the way forward for countries that have not conducted nationwide mass campaigns but introduced MenA vaccines in only part of the country. It was recommended that the question should be discussed with each country.

His Excellency Dr Felix Kabange Numbi Mukwampa, Minister of Public Health, Democratic Republic of the Congo, said that the question of perceived inequity in vaccination is illustrated by the case of his country, where only 6 of the 20 provinces are in the meningitis belt. Dr Tevi-Benissan said that a theoretical solution would be to cover the entire country; however, the rationale would have to be strong and be discussed with partners. It might be more appropriate to enhance communication and advocacy of the concept of “high-risk areas”.

Several participants raised the problem of giving multiple injections at nine months of age. Injections could be spaced out between 9 and 18 months, taking every opportunity of a contact with health services to give the necessary vaccines. One-off catch-up vaccination for children born after mass campaigns will mean that fewer children are missed and full coverage is maintained.
Brief overview of selected Gavi processes
Ms P. Musanhu, Gavi

Ms Musanhu described the immunization-related activities supported by Gavi, their policies and processes and how the application process could be simplified. If a “mainstreamed” application is submitted now, introduction could start in 2017, as in Burundi, Eritrea, Kenya, Rwanda and the United Republic of Tanzania. The applications for those five countries could include aspects of both routine and mass preventive campaigns and be cost-efficient, as there would be no catch-up population. A separate budget request must be made for each component. The application, review and approval process can be accelerated to meet dates that countries have set for introduction of e.g. a mini-campaign. The Gavi website should be consulted for the dates for submission of applications and the calendar for decisions. Successful applications lead to issuance of decision letters that are transmitted both to the UNICEF Supply Division, which can then commit by placing a purchase order to the manufacturer, and to the countries concerned, at which point Gavi decentralizes funds to the country. Training in the use of indicators for monitoring and reporting outcomes is being given in some countries.

Financial sustainability in MenA belt countries
Mr S. Cornejo, Gavi

Mr Cornejo described Gavi’s model for ensuring the financial sustainability of vaccination activities. In co-financing, it is up to countries to decide how they will procure vaccines. Gavi’s goal is to ensure that countries have ownership of their immunization programmes.

Discussion
Participants commented that, in the Gavi application procedure, applicants were given a very limited time to provide clarifications. Representatives of Gavi replied that a high-level panel was attempting to reconcile the timing of stages in the application process, and a regional working group has been set up to provide technical assistance to countries, especially for a long-term vision of the introduction of routine vaccination.

Sustaining the MenAfriVac® gains in Africa
Dr I. Mirza and Dr R. Kezaala, UNICEF Programme Division; and Dr M.T. Guigui, UNICEF Regional Office for West and Central Africa, Senegal

Dr Mirza pointed out that the average total health expenditure per capita in meningitis belt countries is below $50 per annum, while the average cost of care for a patient with meningitis is more than US$ 100, which is equivalent to two months’ wages in countries such as Ghana. Thus, preventing group A meningitis will reduce the economic burden on households and save thousands from catastrophic expenditure and pauperization. It is also likely to increase population well-being and development capacity, especially by improving child health. Therefore, to sustain the current success and to protect future generations, MenAfriVac® should be introduced into routine immunization schedules. The vaccine is to be introduced into an increasingly crowded schedule of vaccinations, with implications for programme cost and sustainability, the number of injections, cold chain capacity and programme management. The introduction of MenAfriVac® into routine programmes will strengthen all health programmes more broadly if properly planned. The success of MVP has attracted high-level political and popular interest, and forward-looking ministries of health could channel that interest towards
strengthening routine programmes to achieve maximum vaccination coverage. Disease burdens tend to be disproportionately concentrated in more marginalized populations. As illustrated by vaccination with a first dose against measles, the distribution in the population is inequitable, even in countries with high coverage; therefore, reaching more people will not only achieve greater equity but will also have a greater health impact and contribute to economic development. Introduction of MenAfriVac® provides an opportunity to reduce coverage inequity and to achieve regional measles elimination targets, through joint planning and training of health workers.

**Discussion**

Dr LaForce emphasized that introduction of the conjugate vaccine into the EPI will benefit everyone by maintaining herd protection. MenAfriVac could be given at the time of the first dose of measles vaccine at 9–12 months or with the second dose of measles vaccine at 15–18 months and would therefore require yet another injection; however, this would have the huge advantage of covering more children. Dr Mirza said that countries would plan their vaccination schedules accordingly to ensure that the programmes reach the most children. In answer to a question, Dr Mirza said that current grants from Gavi for introducing new vaccines do not cover all costs, such as collateral costs, but joint strategic planning, health systems strengthening and other grants could help to cover those elements and costs.

**Special session on Zika virus as a public health emergency of international concern**

Note: In light of the recent WHO announcement that Zika virus disease is a public health emergency of international concern (currently graded 2), a special session was added to the agenda to present and discuss preparedness and response activities to Zika virus in the African Region, in line with the WHO guidelines recently distributed to Member States.

**Zika outbreak: a public health emergency of international concern and Zika virus preparedness and response activities in the African Region**

*Dr Z. Yoti, WHO Regional Office for Africa; and Dr A. Stewart, WHO headquarters*

Dr Yoti reported that the WHO Regional Office for Africa and WHO headquarters had established a combined programme on Zika virus. Dr Stewart presented the WHO strategy for controlling the virus, which is also available on the WHO website. He noted the parallel with the distribution of dengue, due to the common vector that transmits the two pathogens. He specified that the “public health emergency of international concern” appellation concerns the complications associated with Zika virus infection and that grade 2 indicates that the emergency is subject to an international management system. The emergency calls for US$ 55 million to implement the strategy and for surveillance over 6–9 months to identify any other clusters of the disease. The strategic response plan includes surveillance of mosquito and virus populations.

Dr Yoti added that the same mosquito vector also transmits yellow fever, dengue and chikungunya. Although Zika virus has been identified at various sites over the past few years, the disease is under-reported, as it is only one of many febrile diseases. The Zika virus outbreak in Cape Verde was preceded by dengue outbreaks in 2009 and 2010. WHO is taking advantage of all meetings in Africa to communicate information about Zika virus and to foster partnerships for research. The priorities include integrated vector management, instituting systematic reporting of circulation of the virus, monitoring cases of Guillaun-Barré syndrome and microcephaly and strengthening research to determine why the virus appears in such widely spaced areas.
Discussion
In answer to questions, Dr Yoti confirmed that only mild, self-limiting febrile illness has so far been observed in Cape Verde, but surveillance is continuing to identify any complications. Areas considered to be at risk for epidemics of Zika virus disease are those in which the mosquito vector is prevalent and in which transmission of the virus has been seen previously; however, the criteria are being refined. The response plan will be effective only if African countries reach core capacity for implementing the International Health Regulations (2005); none has yet done so, and more resources are needed to support them in achieving that capacity.

Dr Stewart added that US$ 6.4 million of the fund for the emergency has been allocated for research, as detailed in the strategy. A causal relation between Zika virus infection and microcephaly has not yet been unequivocally demonstrated, although the spatio-temporal relation is strong, and the virus has been recovered from infants post mortem. Of the 4783 cases in Brazil, more than 1000 appear to be associated with congenital infection. It is also not clear why cases of microcephaly have occurred in only two areas – Brazil and French Polynesia. He replied to one participant that the vector control agent used does not appear to be linked to microcephaly. With respect to possible sexual transmission of the virus, he said that one case has been reported of a health worker who infected his wife; the case is being investigated.

Planning for the next epidemic meningitis season
Revised standard operating procedures for meningitis control – risk of group C outbreaks and preparedness in the belt for 2016
Dr O. Ronveaux, WHO headquarters; Mr C. Lingani, WHO IST/WA; and Ms K. Fernandez, WHO headquarters

Dr Ronveaux introduced the revised guidelines for outbreak response. As early confirmation of cases is critical, a LabMobil will be sent as rapidly as possible to any site. Countries must make sure that all the vaccines that may be needed are already registered in the country, so that they can be obtained rapidly. An expert group is examining reports of the re-emergence of N. meningitidis C in south-western Niger, because of the high risk of extension from that area, which is a new focus. All neighbouring countries should therefore be on the alert for new cases. A side meeting was to be held the next day to work on the preparedness checklist with country representatives responsible for surveillance.

Preparedness for 2016 meningitis epidemics in Nigeria
Dr B. Okposen, Ministry of Health, Nigeria

Dr Okposen described the activities for ensuring preparedness in Nigeria, highlighting the success of MVP and the lessons learnt for sustainability. Nigeria completed its fifth and last mass vaccination campaign in 2013, and no case of group A meningitis has been recorded since. There have been sporadic outbreaks of group C meningitis, and the challenge ahead will be to control meningitis due to other groups as well as introducing the vaccine into routine immunization programmes.

Meningococcal vaccine International Coordinating Group stockpile 2016
Dr M. Henkens, Médecins sans Frontières and Mr A. Costa, WHO headquarters

Dr Henkens described the role of the International Coordinating Group for vaccine provision, its objectives and its supporting networks of experts. She illustrated the divergence between the ideal and actual timelines for provision and commented that the stockpile was smaller than expected.
Mr Costa added that the UNICEF Supply Division, the mandatory procurement agent for the International Coordinating Group is having difficulty in finding enough vaccine for 2016. Most vaccines are either not available or the stocks are already committed, mainly for European countries. Thus, meningitis vaccines cannot be ensured until April 2016. A meningococcus C conjugate vaccine may be available but is not licensed in African countries; they should therefore authorize its use as soon as possible. Although the vaccine has not yet received WHO prequalification, the dossier could be sent to national authorities, so that countries could evaluate it themselves. The vaccine will be stored in Dubai, which will add to the cost of transport. The most important issue is to ensure that vaccine is available for the peak season of meningitis.

Closure

The co-Chair, Dr B. Sarkodie, Director of Public Health, Ghana Health Service, thanked the participants for their contributions, both as presenters and discussants. The meeting had been a fitting tribute to the spectacular success of MVP. The meeting was not yet over, and he urged the participants to proactively persuade the ministers of health of African countries who would be meeting over the next 2 days to collaborate and to commit themselves to vaccination against all vaccine-preventable diseases.

Dr Preziosi thanked all the participants for their contributions to the success of the Project and for their presence at and insightful contributions to the conference. She invited them to join the Ministerial Conference and in particular the MVP Awards Ceremony to be held as part of the Conference gala celebration dinner.
Annex 1. Ministerial conference cocktail reception and MVP celebration, recognition awards

The MVP Awards Ceremony
The gala dinner was hosted by the Regional Director of the WHO Regional Office for Africa, Dr Matshidiso Moeti, and the Regional Director of the WHO Regional Office for the Eastern Mediterranean, Dr Ala Alwan. They also presided over the awards ceremony, which was to recognize the contributions of all those who made MVP a success. Introductory remarks were made by Dr Marie-Paule Kieny, WHO Assistant Director-General, and Mr Steve Davis, President and Chief Executive Officer, PATH. Awards were presented to Dr Chris Elias for the Bill & Melinda Gates Foundation, by Dr Moeti; to Dr Seth Berkley for Gavi, by Dr Alwan; to Dr Suresh Jadhav for SIIPL, by Dr Kieny; and to Dr Geeta Rao Gupta for UNICEF, by Mr Davis. The MVP celebration continued as Dr Preziosi and Dr LaForce warmly thanked the institutions listed below and presented representatives from these institutions that were present with a certificate of appreciation.

Aérial
Agence Africaine de Recherche en Santé Humaine
Agence de Médecine Préventive
Armauer Hansen Research Institute
Axio, Partners in Research
Bill & Melinda Gates Foundation
Burness Communications
Center for Biologics Evaluation and Research, Food and Drug Administration, USA
Centers for Disease Control and Prevention, USA
Centre pour le Développement des Vaccins – Mali
Center for Vaccine Development, University of Maryland, USA
DiagnoSearch Life Sciences
Fondation Mérieux
Gavi, the Vaccine Alliance
Institut de Recherche pour le Développement, Sénégal
Intox
KEM Hospital and Research Center, Pune
London School of Hygiene and Tropical Medicine
Medical Research Council Unit, The Gambia
Médecins sans Frontières
Michael & Susan Dell Foundation
National Philanthropic Trust
National Institute for Biological Standards and Control, United Kingdom
National Institutes of Health, USA
Navrongo Health Research Centre, Ghana
The Nizam’s Institute of Medical Sciences, Hyderabad
Norwegian Institute of Public Health
Public Health England
Robert Koch Institute
Rockhopper TV
Serum Institute of India Pvt. Ltd
Annex 2. Programme

The closure meeting was organized as follows:

Day 1  Describing the MVP experience and its public health results
Day 2  Ensuring an effective transition into routine immunization programmes
Day 3  Ministerial Conference on Immunization in Africa
Day 3 evening  Ministerial Conference cocktail reception and MVP celebration, recognition awards
Day 4  Ministerial Conference on Immunization in Africa

Monday 22 February 2016
08:00–8:30  Arrivals and registration
            Secretariat
08:30–9:20  Inaugural ceremony
            Chair Dr Paul Mainuka, WHO Representative
            Administrative announcements, security briefing
            Secretariat
            Welcome address
            Dr Matshidiso Moeti, Regional Director, WHO Regional Office for Africa
            Mr Steve Davis, PATH, President and Chief Executive Officer
            Opening
            H.E. Dr Amir Aman Hagos, State Minister, Ministry of Health, Ethiopia
            Objectives of the conference and agenda
            Dr Marie-Pierre Preziosi, MVP
            Group photo

Session 1: The Meningitis Vaccine Project: results and experiences
Part 1, Chairs: Representatives from ministries of health of Burkina Faso and Ethiopia
09:20–9:40  Project lifeline and highlights
            Keynote. Creation, evolution and key decisions,
            product development partnership
            Dr Marc LaForce
9:40-10:35  Vaccine development
            A new meningococcal A conjugate vaccine
            Dr Carl Frasch, Dr Suresh Jadhav, Mr Peter Soukas, Dr Marie-Pierre Preziosi
            Discussion and audience Q&A
10:35–11:05  Morning break
11:05–11:45  Vaccine development
            Regulatory pathways
            Dr Suresh Jadhav, Dr Nora Dellepiane
            Ethics and community perspectives
            Prof Samba Sow, Mr Lionel Martellet
The role of Communication
Mr Rodrigue Barry, Mr Jonathan Shadid
Discussion and audience Q&A

11:45–12:30 Vaccine introduction
Vaccine roll-out
Dr Amadou Fall, Dr Mamoudou Djingarey, Dr William Perea,
Dr André Bita, Mr Clément Lingani
Country introduction experience
Representatives of the ministries of health, Chad, Mali, and Sudan
Discussion and audience Q&A

12:30–13:30 Lunch break
Part 2, Chair: Representatives from ministries of health of Niger and Sudan
13:30–14:50 Meningitis surveillance in the African meningitis belt
Dr André Bita, Mr Clément Lingani, Dr Olivier Ronveaux
Public health impact of MenAfriVac: the first four years
Dr Mamoudou Djingarey, Dr Ryan Novak, Prof James Stuart
Impact of MenAfriVac on meningococcal carriage in Burkina Faso
Prof Dominique Caugant, Dr Paul Kristiansen
MenAfriCar
Prof Brian Greenwood
Discussion and audience Q&A

14:50–15:45 Pharmacovigilance and vaccine safety
Dr Godwin Enwere
Immune persistence and protection
Dr Olubukola Idoko, Dr Aldiouma Diallo, Dr Yuxiao Tang,
Dr Prasad Kulkarni, Dr Margaret Bash
Discussion and audience Q&A

15:45–16:00 Afternoon break
16:00–16:30 An anti-tetanus vaccine
Prof Ray Borrow
Discussion and audience Q&A

16:30–18:00 Transition to routine vaccination
Clinical research results
Dr Abraham Hodgson
Modelling of strategies
Dr Caroline Trotter
Economic impact
Ms Anais Colombini
Recommendations
Dr Marie-Pierre Preziosi
Discussion and Audience Q&A
18:00  End of Day 1
19:00–22:00  Reception

Tuesday 23 February 2016

Session 2: The Future: routine immunization, surveillance and impact, next generation vaccines

Part 1, Chair: Representatives from ministries of health of Chad and Nigeria
08:30–9:00  Keynote. The Bill & Melinda Gates Foundation’s perspective on building partnership that begin and end with countries
Dr Orin Levine
Discussion and audience Q&A
9:00–10:30  Forward plans
Sera and Data Access program
Dr Cheryl Keech, Mr Lionel Martellet
Antibody persistence studies
Dr Patrick Ansah, Dr Cheryl Keech
Discussion and audience Q&A
MenAfriNet, a regional catalyst
Dr Ryan Novak, Dr Jason Mwenda
A country experience for sustainable surveillance
Representative of the Ministry of Health, Burkina Faso
Multivalent conjugate vaccines for the African meningitis belt
Dr Marc LaForce, Dr Prasad Kulkarni
Discussion and audience Q&A

10:45–11:00  Morning break
11:00–12:00  Sharing the Ethiopia experience: plans for routine vaccine introduction and disease surveillance, building on lessons learned
Representative of the Ministry of Health, Ethiopia
Discussion and audience Q&A

12:00–13:00  Lunch break

Session 2: The Future: routine immunization, surveillance and impact, next generation vaccines

Part 2, Chair: Representatives of the ministries of health, Ghana and Mali
13:00–15:00  Transitioning the MenA conjugate vaccine into routine immunization programmes
Keynote. Gavi’s role in strengthening immunization systems and reducing meningitis burden in Africa
Dr Seth Berkley
Discussion and audience Q&A
Overview of plans in the meningitis belt
Dr Carol Tevi-Benissan, Dr Nadia Teleb, Dr Ike Ogbuanu, Ms Ann Ottosen
Discussion and audience Q&A
Gavi programme management, policies and processes
Ms Patience Musanhu
Immunization financing and sustainability
Mr Santiago Cornejo
Discussion and audience Q&A
Light at the end of the tunnel: sustaining the MenAfriVac gains in Africa
Dr Imran Mirza, Dr Marie-Thérèse Guigui
Discussion and audience Q&A

15:15–15:30 Afternoon break
15:30–16:30 Special session on Zika virus as a public health emergency of international concern
Zika virus preparedness and response activities to be instituted in the African Region
Dr Zabulon Yoti
Discussion and audience Q&A
16:30–18:30 Planning for the next epidemic meningitis season
Revised standard operating procedures for meningitis control. Risk of group C outbreaks and preparedness in the belt for 2016
Dr Olivier Ronveaux, Mr Clément Lingani, Ms Katya Fernandez
Meningococcal group C outbreak in Niger, 2015
Representatives of the Ministry of Health, Niger
Preparedness for 2016 meningitis epidemics in Nigeria
Representatives of the Ministry of Health, Nigeria
International Coordinating Group emergency meningitis vaccine stockpile for 2016
Mr Alejandro Costa, Dr Myriam Henkens
Discussion and audience Q&A

18:30 End of day 2

Wednesday 24 February 2016
Ministerial Conference on Immunization in Africa
Agenda available at http://immunizationinafrica2016.org/agenda/
19:00–22:00 Ministerial Conference cocktail reception and MVP celebration, recognition awards

Thursday 25 February 2016
Ministerial Conference on Immunization in Africa
Agenda available at http://immunizationinafrica2016.org/agenda/
Annex 3. List of participants

**Country representatives**

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His Excellency Dr Amir Aman Hagos, State Minister
Dr Taye Tolora Balcha, State Minister Adviser
Dr Ephrem T. Lemango, Director, Maternal and Child Health
Dr Liya Woldegiorgis, Coordinator, EPI
Dr Nafkot Abadura, EPI team member
Dr Mengistu Bogale, EPI team member
Dr Sagni Challi, EPI team member
Dr Tesfaye Dejene, EPI team member
Dr Seralem Genet, EPI team member
Dr Netsanet Negeri, EPI team member
Dr Mulat Nigus, EPI team member
Dr Belete Tafesse, EPI team member
Dr Gezahegn Tamir, EPI team member

**Benin, Ministry of Health**
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Dr Orou Bagou Yorou Chabi, National Director, Public Health
Dr Franck Bete, Public Health Adviser

**Burkina Faso, Ministry of Health**
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Dr Isaié Medah, Director, Disease Prevention and Control

**Burundi, Ministry of Health**
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**Cameroon, Ministry of Health**
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Dr Marie Mbolo epse Kobela, Manager, EPI

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Dr Mathurine Bertille Yolande Kel Kouguerre Ndoide, Manager, EPI

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