SAGE TRACKING RECORD OF RECOMMENDATIONS AND ACTION POINTS

SAGE recommendations are reflected in the SAGE tracking sheet. The “Recommendations/Action item” column reflects the specific recommendation made by SAGE. The “Meeting Date” column displays the date of the SAGE meeting during which the recommendation was originally made. The “Status” column indicates whether the work is currently ongoing, pending or completed.

Each recommendation has an appointed WHO focal point (not displayed in SAGE Yellow Book). The focal points are requested to update their recommendation in advance of each SAGE meeting and report on progress towards the recommendation in the “Comments and Follow Up” column.

When the recommendation is finalized, it is displayed as “Completed” in the SAGE yellow book. This item is then included in the SAGE Yellow Book for one additional SAGE meeting. After, the completed item is archived. Archived recommendations are no longer displayed in the SAGE Yellow Book but may still be accessed upon request to the SAGE secretariat. Therefore, the online tracking sheet provides a historical record of all SAGE recommendations and the Yellow Book displays the current recommendations.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
General	A recommendation was made for consideration of a platform for immunization coverage in the 2nd year of life, in view of potential necessary booster doses and opportunities to catch up with incomplete vaccination, and removing the artificial barrier often experienced after the 1st birthday.	Apr 2014	Ongoing	The proposal to the Bill and Melinda Gates Foundation (BMGF) was successful, and the Working Group (WG) is being put together at this time. Two pilot countries are being identified to review their experience with the establishment of a vaccination visit in the second year of life, and to propose strategies to improve on these visits. This will be used in the next two years to develop generic guidance to countries wishing to establish such a visit.
General	SAGE encouraged the Regional Office in EMRO to pay special attention to countries affected by political turmoil and requested specific monitoring for any adverse impacts on immunization programmes in GAVI graduating countries.	Apr 2011	Ongoing	There are no GAVI graduating countries in the Eastern Mediterranean Region (EMR). EMRO is working closely with and is paying special attention to the countries affected by political turmoil. The following support was provided since the last SAGE meeting in October 2014: • Egypt: Provision of technical support to Ministry of Health (MOH), Egypt, for controlling measles outbreak and planning outbreak response supplemental immunization activities (SIAs). Preparing proposal for inactivated polio vaccine (IPV) introduction utilizing Polio support to non GAVI countries • Jordan: continuing implementation of routine vaccination in the provinces hosting the refugees camps in Jordan. • Iraq: implementation of the national Measles campaign, reviewing EPI schedule and improving vaccine procurement in Iraq • Syria: Conducting comprehensive Expanded Program on Immunization (EPI) review, including data quality assessment and effective vaccine management assessment • Libya: Planning for priority areas for supporting EPI in Libya in 2015 • Yemen: Supporting implementation of measles/rubella MR campaign and 2 rounds periodic intensification of routine immunization (PIRI) in the low coverage governorates
General	SAGE recommended that ways to improve curricula for medical personnel should be explored.	Nov 2008	Ongoing	A workshop organized by WHO/AFRO (African Regional Office) was held in Grand Bassam (Cote d’Ivoire) from 13-17 May 2013, in collaboration with the Ministry of Health MOH and other immunization partners (GAVI, UNICEF, United States Agency for International Development USAID/Maternal and Child Health Integrated Program MCHIP and Network for Education and Support in Immunisation NESI) to revise the 2006 EPI (Expanded Program on Immunization) prototype curricula for medical & nursing/midwifery teaching schools in the African Region of WHO (AFR). During the workshop, 4 drafts of EPI prototype curricula were produced and were to be harmonized, finalized and edited. That is 2 curricula for medical schools in French and 2 curricula French & English for nursing/midwifery schools. The 4 curricula will be finalized during a meeting in AFR to review the pre service curriculum and AFRO mid level manager (MLM) modules (April 6-16, 2015).
General	SAGE called for the identification of novel communication strategies for the work of GACVS to have a greater impact and help maintain confidence in vaccines.	Apr 2014	Ongoing	A document on the Global Advisory Committe on Vaccine Safety (GACVS) future is currently under preparation and will address this issue in particular. The final draft should be submitted by mid-April 2015 to a peer-reviewed journal.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
General	SAGE encouraged the European region to document and share its experiences in country profiling, tailoring responses and using novel communication strategies to effect behaviour change.	Nov 2010	Ongoing	WHO European Regional Office (EURO) is working to support countries in addressing vaccine hesitancy at the individual and community levels, in building risk and crisis communication capacity, in strengthening resource mobilization and advocacy capacity, and in using behavioural insights methodologies to tailor programme delivery and to drive demand for vaccines. This includes activities in the following areas: 1. Application of the Tailoring Immunization Programs “TIP” toolkit, which allows a country or sub-national level authorities to segment/profile a population based on behaviors rather than background characteristics. The resulting group profile can help inform programmatic responses that could be communication-oriented or inform improved service delivery. Best practices from other disease programs are included that can be adapted for country-specific issues. Pilot testing of the framework has been conducted in several European countries: TIP was implemented in Bulgaria and on three projects in Sweden (Somali immigrants, migrants, and anthroposophic communities) and Bulgaria in 2013, and in the UK, Kazakhstan and Germany in 2014. In partnership with Wits University in South Africa, TIP is being adapted for use on a global level and a second edition (LIC, low income country, field guide) to be published towards the end of 2015. 2. Strengthening the ability of Member States to handle crises in vaccine confidence and trust through a guidelines document on vaccine safety communication, which was published in 2013. In 2014, 13 countries received exercise/simulation-based training on managing the communications response to vaccine safety events. 3. A resource mobilization and immunization advocacy workbook has been developed and will be launched region-wide in English and Russian languages during European Immunization Week (April 20-24). Subsequent sub-regional training sessions are planned in June and October 2015. 4. A vaccine communications review methodology has been developed by EURO and has been applied in 2 Member States in 2014 and in Montenegro and Moldova in 2015. An additional review is planned to take place in the Russian Federation later in 2015. 5. A vaccines social media strategy has been launched. A vaccination reminder ‘app’ for smart phones has been developed and country versions have been launched in 4 Member States with others due to launch in European Immunization Week 2015. 6. An online vaccines resource centre was launched in 2012 and has been strengthened and improved through 2013-14, with a number of member states using or translating the caregiver and health-care worker tools presented. 7. In early 2015 work continues on developing the school-based learning module on vaccines and immunization – drawing on a ‘flipped learning’ methodology – with children aged 8-10 learning with parents at home and reinforcing understanding in the classroom setting.
General	SAGE recommended strengthening national vaccination programs, integrating health services and strengthening health systems to promote universal health coverage.	Apr 2013	Ongoing	A teleconference was held May 13 2013 with J. Abramson, P. Figueroa, and N. Arora and EPI (M. Zaffran and T. Goodman) to discuss the issue and provide briefing on the integration activities that historically and presently Expanded Program on Immunization (EPI) is working on. Subsequently, in early June a draft typology was produced and shared that summarizing this area of work. It was agreed that an effort would be made to highlight this area of work in a few slides of the WHO Department of Immunization, Vaccines and Biologicals (IVB) Director's next presentation to SAGE. Discussions are ongoing. The topic was discussed at the April 2014 SAGE meeting. SAGE concluded that addressing integration, by its very nature, requires a broader discussion beyond SAGE. In this regard, it was proposed that the SAGE working group on the Decade of Vaccines (DoV) consider options for moving forward, as integration is reflected as both a guiding principle and a strategic objective of the Global Vaccine Action Plan (GVAP). The Department secured funding at the end of 2014 to establish a position dedicated to the issue of integration. The recruitment is underway and should be completed during April 2015 and the position filled by the summer. We will report at the October 2015 SAGE on progress made with activities in this area.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
General	SAGE requested that a paper be developed, highlighting the circumstances under which off-label use of any vaccine can be recommended, while clarifying the differences between regulatory decisions and public health recommendations. Legal and programmatic implications of off-label recommendations and the need for clear communication should be considered.	Apr 2012	Ongoing	Advice being sought through the Expert Committee on Biological Standardization (ECBS) - added to agenda of next meeting, 15-19 October 2012. SAGE had previously requested that a paper be developed, highlighting the circumstances in which off-label use of any vaccine could be recommended, while clarifying the differences between regulatory decisions and public health recommendations. During the November 2012 SAGE meeting, SAGE further requested that ECBS prepare guidance for national regulatory authorities on studies needed to support evidence-based, off-label use of vaccines which benefit public health. It was noted that for regulators, product specific data are paramount. SAGE requested that an additional document be prepared to advise the national immunization technical advisory committees about the type of data that might support a policy recommendation to use a vaccine outside its licensed schedule in order to achieve public health benefits such as operational simplicity or cost savings. The ECBS guidance document has been delayed and will be prepared after its October 2014 meeting. A paper clarifying the differences between regulatory decisions and public health recommendations has been commissioned. Following much delay, this paper intended for publication in a peer reviewed journal should be available for submission prior to the April 2015 SAGE meeting.
Accessibility of affordable vaccines: gaps and WHO's role in supporting emerging manufacturers	SAGE suggested to monitor gaps and opportunities and consecutively develop a systematic process to responds to these needs in collaboration with key partners. A perspective is to be presented at a future SAGE meeting on accessibility of affordable vaccines.	Nov 2010	Ongoing	WHO is actively contributing to increasing global access to vaccines through the following activities: 1) close collaboration (participation in annual meetings and bilateral meetings) with International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and Developing Country Vaccine Manufacturer Network (DCVMN) as federations of manufacturers form developing and industrialized countries to ensure that they all have clarity on the needs of developing countries both in terms of types of vaccines but also in terms of their programmatic suitability; 2) Active participation in the annual DCVMN meeting to update them on new developments, concerns, and issues related to vaccine presentations, prequalification, regulation financing and priority country need. 3) WHO has resurrected and chaired the VPPAG (Vaccines Presentations and Packaging Advisory Group) a forum for discussion between the public and private sectors on the characteristics of vaccines required for developing countries. The full participation of industry enables them to have more visibility of the needs and constraints of countries; 4) The Decade of Vaccines (DoV) work stream on global access and vaccine price indicator which gets reported every years to the SAGE working group on the DoV. 5) General discussions on the process of technology transfers are taking place under the leadership of the Evidence Information and Research Cluster. 6) A new committee known as the Product Development for Vaccines Advisory Committee was established and met for the first time 8-10 Sep 2014. The group reviewed 19 pathogen specific global pipeline analyses (all available from the meeting website) and advised WHO on strategic prioritization for WHO activities related to early stage vaccine R&D (pre-licensure to Phase 2). The group will oversee the development of Vaccine Preferred Product Characteristics. 7) the Vaccine Product, Price and Procurement project (V3P) to support GAVI graduating and middle income countries through the provision of improved vaccine product and price information for decision-making. More information on V3P is provided under the topic of financing in the tracking sheet. 8) A Task Force on Middle Income Countries (MIC) has been established. More information on this is also provided elsewhere in the tracking sheet.
Childhood mortality	SAGE noted the recommendation by IVIR-AC that WHO would encourage countries to collect local data at country level and not only estimated age specific mortality rates by epidemiological modeling or expert elicitation.	Nov 2010	Ongoing	All models reviewed by the Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) are hampered by the lack of primary data, and more efforts should be made to make such data readily available. Specifically, for pertussis disease burden estimation, IVIR-AC suggests validating the parameter estimates against data from Senegal and Europe as a first step, although primary data from developing countries that is currently not publicly available would provide a more compelling comparator for validation. For polio more primary data should be made available for all models. IVIR-AC recommends that polio related data should be made available for multiple modeling groups to encourage comparison of results using different approaches.Ongoing/standing issue for many other diseases.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Decade of vaccines/GVAP	The SAGE working group should continuously review the need for reformulation of the indicators or mechanisms for collection and reporting of data.	Nov 2012	Ongoing	The SAGE report of progress with the Global Vaccine Action Plan (GVAP) was presented to the WHO Executive Board (EB) on January 26, 2015. Twenty seven speakers made interventions. The report was very well received and the recommendations were uniformly welcomed. EB members highlighted several areas that required special attention. A meeting of the Working Group (WG) was held on March 11-13, 2015 to start preparations for the 2015 report.
Decade of vaccines/GVAP	SAGE also recognized the urgency for having approximate cost and impact estimates and recommended that the technical group provide preliminary estimates for SAGE review in November 2013.	Nov 2012	Completed	IVIR-AC (Immunization and Vaccines related Implementation Research Advisory Committee) concluded that the Decades of Vaccine (DoV) study presented on the approximate cost and impact may be adequate for high level use such as tracking of the Global Vaccine Action Plan (GVAP) and justifying its funding to donors on return of investment but had observations with the regard to the state of the art of the individual modeling components. Furthermore, IVIR-AC identified the need for increased transparency and clarity in all methods used including refined sensitivity and uncertainty analysis.
Dengue	A SAGE dengue working group should be convened to revise the data and prepare recommendations to SAGE as clical trial data is expected to be submitted to the regulatory authorities in early 2015.	Oct 2014	Ongoing	The SAGE Working Group on Dengue Vaccines has been constituted and will hold its first teleconference on March 31, 2015. The SAGE session for decision is still planned for April 2016.
Dengue Vaccine	SAGE requested that future recommendations on dengue vaccine safety be linked to the dengue vaccine development strategy.	Apr 2012	Ongoing	The dengue vaccine safety profile will be updated once an application for licensure has been filed. The Global Advisory Committee for Vaccine Safety (GACVS) will review the company's risk management plan at its June 2015 meeting.
Ebola	SAGE was asked to immediately establish a SAGE working group on Ebola vaccines and vaccination.	Oct 2014	Ongoing	The working group (WG) was established and has met three times via teleconference. A face-to-face meeting of the WG took place on March 9 and 10, 2015. The WG reviewed the current epemiological data on Ebola Virus Disease (EVD), the preliminary results of the phase 1 trials, the status of the phase 2 and 3 trials, and the preparations for the large scale deployment of vaccines. They also identified the scope of the recommendations and the key questions and data for formulating recommendations. The framework will be presented to SAGE at the April 2015 meeting.
Global vaccine safety Blueprint	The Blueprint implementation should be led by WHO and its partners. It should be aligned with other related WHO capacity-building efforts. This includes in particular immunization programme and national regulatory authorities strengthening together with the development of national expert advisory bodies. SAGE suggested that a mechanism be developed to enable prioritization of both activities and countries in the implementation of the Blueprint. SAGE invited the GAVI Alliance and other partners to support this implementation.	Nov 2011	Ongoing	The Global Vaccine Safety Initiative (GVSI) has been launched. Its portfolio of activities is now publicly available covering all 8 strategic objectives with priorities endorsed by the Planning Group. The GVSI has been operating with 2 annual Planning Group meetings. It hosted its second annual meeting in November 2013. The third GVSI meeting took place in October 2014 in China, jointly with the national pharmacovigilance centres meeting.
GVAP	The Director-General of WHO should convene a special session at the 2015 World Health Assembly for countries with routine vaccination (DTP3) coverage of less than 80%, to which each Minister of Health will be asked to report on their challenges, plans and timelines to improve coverage to meet the GVAP goals. In addition the SAGE's GVAP assessment reports should remain as standing items at the WHA until 2020.	Oct 2014	Ongoing	The Director has called for a meeting of the heads of the technical units at the partner agencies to discuss a coordinated and cohesive response to the recommendations in the SAGE GVAP (Global Vaccine Action Plan) Assessment Report, including the selection of countries and the objectives, expected outcomes, and format for the meeting to be held during the World Health Assembly (WHA) 2015. Sponsorship has been submitted from 2 member states for a side meeting during the WHA 2015; final decision from governing bodies secretariat at WHO expected soon.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Hepatitis A	Long-term protection from single or 2-dose schedules should be regularly monitored by countries and reviewed by SAGE.	Apr 2012	Ongoing	Post-market surveillance continues in Argentina and a detailed report on the recent epidemiological situation was provided to WHO in January 2015. In 2014 in the context of a localized outbreak in a border area, 8 potential breakthrough cases were identified. For 5 of them there is uncertainty about the vaccination status and/or conditions (cold chain) in which vaccination was administered. Seven of these cases are in the 5-9 age group (distributed throughout the period) and one in the 1-4 age group. This has resulted in an enhanced vigilance in the country. Currently, however, there is still no evidence of waning immunity and the situation is still compatible with very high vaccine effectiveness. The situation continues to be investigated. Hepatitis A cases have reached an all time low in 2013 and have remained low in 2014. As exemplified by the outbreak in San Martin there are the risk persists in the population. As also requested by SAGE, an economic analysis of the impact of the single dose immunization strategy against hepatitis A in Argentina has been done. Estimated total vaccination cost for the 2006-2010 post vaccination period was ~US$ 45 million. The total of medical and societal costs plus immunization cost decreased from ~US$ 105 million for 2000-2004(prevaccination) down to ~US$ 56 million for the 2006-2010 post vaccination period i.e. a reduction rate of 46.5%. Both Colombia and Paraguay also introduced a single dose national immunization schedule for 1 year old children. Yearly review of the Argentina surveillance data will continue.
Hepatitis B	All regions and associated countries should develop goals for hepatitis B control appropriate to their epidemiologic situations. Serologic surveys of hepatitis B surface antigen (HBsAg) prevalence, representative of the target population, will serve as the primary tool to measure the impact of immunization and achievement of the control goals.	Nov 2008	Ongoing	EMRO: The Eastern Mediterranean Region (EMR) has a Regional Committee (RC) goal of reducing childhood hepatitis B prevalence to <1% among children <5 years by 2015. Its regional office, EMRO is working with Member States to ensure achievement of this goal. WPRO: The Western Pacific Region (WPR) established a Regional Committee goal to reduce hepatitis B infection to <1% among children at least 5 years of age by 2017. SEARO: The South East Asian Regional Office (SEARO) has a drafted regional strategy. AFRO: The African Regional Office (AFRO) has convened a regional hepatitis Technical Advisory Group (TAG) and plans to present a plan for comprehensive viral hepatitis control during the 2014 RC Meeting. In 2014, the AFRO Regional Committee meeting adopted resolution to reduce Hep B infection to <2% among children under 5 years of age by 2020. EURO: The European Regional Office (EURO) will consider a regional hepatitis B control goal. PAHO: The Pan American Health Organization (PAHO) has resolved to eliminate hepatitis B virus transmission and is formulating a regional strategy. Documenting the Impact of Hepatitis B Immunization: best practices for conducting a serosurvey (WHO/IVB/11.08) was published in 2011 by the department of Immunization, Vaccines and Biologicals. In 2012, WHO HQ has published a framework for global action to control viral hepatitis (http://www.who.int/csr/disease/hepatitis/Framework/en/index.html).

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Hepatitis B	SAGE recommended that the timely delivery of a birth dose of hepatitis B vaccine (that is, within 24 hours of birth) should be used as a performance measure for all immunization programmes. Reporting and monitoring systems should be strengthened to improve the quality of data on the birth dose.	Apr 2009	Ongoing	A consultation on implementation of new universal birth dose recommendation was conducted in December 2010 with special focus on countries with a high percentage of home births. Outputs include a monograph documenting the systematic review and best practices from the consultation. Immunization Practices Advisory Committee (IPAC) reviewed this work in early 2011 and again in April 2012, and endorsed the 2013 publication of 'Practices to Improve Coverage of the Hepatitis B birth dose vaccine'. From this, work is ongoing to develop field guidelines for scaling up Hepatitis B birth dose. The JRF (Joint Reporting Form) and associated materials have been revised to improve reporting of birth dose with a particular focus in Western Pacific Regional Office (WPRO). The WHO/UNICEF estimate process was piloted in 2012 in WPRO and was applied globally for the first time to the 2013 JRF birth dose data. Analysis of timely birth dose data for 2008 shows no significant changes from 2006 analysis and major issue is lack of data quality. A study of the cost of scaling up the birth dose by country has been completed, based upon previously published methodology estimating the cost of implementing the Global Immunization Vision and Strategy (GIVS) goals. In 2012, WPRO convened Expanded Program on Immunization (EPI) and Maternal and Child Health (MCH) managers from the five priority counties to jointly propose actions towards improving birth dose uptake. In Jan 2015 the African Regional Office AFRO, and in March 2015 the WPRO, held Hep B birth dose consultations to improve birth dose coverages.
Hepatitis E	SAGE approved draft ToRs for a Working Group on Hepatitis E and requested that WHO establishes this group in the summer 2013.	Apr 2013	Completed	The SAGE Hepatitis E working group was established in 2013. The group met face-to-face in June 2014 and held multiple teleconferences. The group reported to SAGE at the October 2014 meeting and as a result of SAGE recommendations a WHO position paper on the use of hepatitis E vaccine has been finalized and will be published on May 1.
HIV	SAGE requested regular updates on the progress of HIV-vaccine research.	Apr 2010	Ongoing	There are now 3 major streams of HIV vaccine related research and development. Firstly follow-on to the RV144 Phase 3 trial in Thailand reported in 2009. Two follow-on Phase 3 trials of similar protein-poxvirus prime-boost approaches are planned in Thailand and South Africa. It was initially stated that the South African trial would start in 2015, although this has not been confirmed, and the start date may be deferred. Secondly there are several ongoing Phase 1-2 clinical trials of recombinant viral vectored approaches focusing on non Ad5 adenoviruses such as Ad26, Ad3, Ad35 and recombinant poxviruses such as MVA (Modified Vaccinia virus Ankara). Replicating vectored approaches (eg sendai virus) are also witnessing a renaissance in the global portfolio. Finally there are major, and promising, vaccine science initiatives underway to attempt to induce broadly neutralising antibodies through re-engineered antigens. These have a longer timeframe, but raise the prospect of cross-clade protection.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Immunization safety	SAGE encourages development of simple technological solutions with improved environmental characteristics, and encourages donors to support such work as a priority.	Nov 2007	Ongoing	- The WHO manual: Safe Management of Wastes from Health Care Activities second edition was published in 2013. http://apps.who.int/iris/bitstream/10665/85349/1/9789241548564_eng.pdf A series of 25 training modules for use in implementation of the manual and training health workers including waste handlers in the safe handling, treatment and disposal of health care waste has been completed. -Work is on-going through Project Optimize in collaboration with the Vaccine Packaging and Presentation Advisory Group (VPPAG) to explore vaccine packaging that minimizes the impact on environment. VPPAG has 2 related streams of work: 1) Developing recommendations to minimize primary, secondary, and tertiary container packaging, and 2) Drafting a consensus statement with industry about use of materials for vaccine packaging that will minimize environmental impact. - A document on Environmental due diligence procedures has been developed and shared with the Global Alliance for Vaccines and Immunizations (GAVI). It expresses steps to be taken to minimize and manage waste from immunization activities in an environmentally friendly manner. The WHO reference document is: WHO policy paper on Health Care Waste Management(see http://www.who.int/water_sanitation_health/medicalwaste/hcwmpolicy/en/index.html) - The health care waste component of Global Environment Facility (GEF) project is developing a small autoclave in Tanzania to treat waste produced in low income countries. The technology is ready and was launched at the final GEF meeting in December 2012 in Tanzania and is planned for use in a new GEF-funded project together with UNDP beginning in 2014 in four African countries: Ghana, Madagascar, Tanzania and Zambia. Replication of the design for scale-up in southeast Asia is in planning stages. - The issue of needle-cutters and WHO recommendation about their use have been in debate for at least 6 years now during every Safe Injection Global Network (SIGN) meeting. At the 2010 SIGN meeting, there was a special session on needle cutters. A Bangladesh study on the safety of using needle removers was reviewed. The results showed that hub cutters do not lead to increased needle-stick injuries among health care workers (HCWs). Based on the findings of this study, although there was no unanimity among the group, it was decided to state that WHO doesn't object (nor recommends) to the use of needle cutters, but their introduction should be associated with training HCWs on their use. A randomized controlled trial (RCT) on hub cutters has subsequently been completed in Ghana with WHO collaboration.
Immunization schedules	SAGE encouraged WHO to complete the project promptly. SAGE requested a critical appraisal of alternative schedules for pneumococcal conjugate vaccine, rotavirus vaccine and Hib vaccine in 2011.	Nov 2010	Ongoing	Pneumococcal Conjugate Vaccine (PCV): evidence was reviewed by SAGE on November 2011. New recommendation on schedules was issued and data was used to update the position paper. Rotavirus: evidence was reviewed by an ad-hoc group of experts in February 2012 and presented to SAGE in April 2012. An updated vaccine position paper on the use of rotavirus vaccines was published in February 2013. Haemophilus influenzae type b (Hib): The issue was revised during the April SAGE 2013 meeting. For all: review of number of contacts during first years of life (ongoing); cost of contacts (planned); update on actual age at vaccination data (completed and used in conjunction with rotavirus epidemiology). Completed for PCV, Rotavirus and Hib vaccines. Evidence on diphtheria-tetanus-pertussis (DTP) will be presented to SAGE in April 2015, with a focus on Pertussis. Evidence on Hep B vaccines will be presented in the October 2015 meeting - delays due to impact of Ebola outbreak.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Immunization Supply Chains	SAGE recommended that the EVM assessment include the measurement of human resource capacity and encouraged WHO to use EVM assessments in alignment with new vaccine introduction impact assessments, to strengthen the links between supply chain issues and programme outcomes. To further improve the EVM assessment, it was suggested that the tool be used for supervisory purposes and that a composite score be developed to complement the across-the-board benchmark of 80%.	Apr 2014	Ongoing	Under the umbrella of the WHO-UNICEF Immunization Supply Chain and Logistics Hub, a process has started to developed a revised version of the Effective Vaccine Management (EVM) assessment tool for it to become an assessment that covers broader immunization supply chain and logistics aspects beyond vaccine management policies and practise. Since this is a significant undertaking and a time consuming one, the approach in 2015 will be to include additional data collection and/or assessment modules for Human Resources alongside the existing approach to EVM assessments. This Human Resource module is being developed by UNICEF Supply Division under the auspices of the People that Deliver (PtD) initiative and the Global Alliance for Vaccines and Immunizations (GAVI)People and Practise working group of the immunization supply chain taskforce. In addition, the revisions of the EVM assessment tool will include more supply chain performance measures and indicators that are more outcome oriented but aligned with the global key performance indicators being developed to track performance in countries with regards to the GAVI Supply Chain strategy.
Impact of the introduction of new vaccines on immunization and health systems	SAGE recommended that the ad-hoc working group work towards producing guidelines and tools for WHO to assist decision-makers and Expanded Program on Immunization (EPI) managers contemplating the introduction of new vaccines, in order to take account of collateral effects inherent in introduction. The guidelines should provide a set of indicators that would enhance the potential positive effects, and reduce any potential negative effects, both on the immunization system and the health system. The guidelines should accommodate vaccines with different characteristics. SAGE noted the importance of the ad hoc working group continuing to include a broad range of partner agencies, and encouraged to seek endorsement of this work at senior levels of partner agencies.	Apr 2010	Completed	Further information was collected through a search of the published, unpublished and grey literature (such as post-introduction evaluation reports), as well as through key informant interviews. An in-depth study in 7 countries was conducted by the London School of Hygiene and Tropical Medicine (LSHTM) in 2011-12 to gather further information. Final results were presented in a meeting in London in November 2013. The ad-hoc group has updated the framework based on the data obtained and has drafted a guideline (Vaccine Introduction Guidelines – Adding a vaccine to national immunization programme) to assist country decision makers and Expanded Program on Immunization (EPI) managers to take account of the potential effects/impacts of new vaccine introduction on the immunization and health systems. The 'Principles for adding a vaccine to a national immunization programme while strengthening the immunization and health systems' were endorsed by SAGE in April 2012 and form part of this guideline document, to be published in 2014. The ad hoc working group included a broad range of partner agencies (WHO, UNICEF, World Bank, Centre for Disease Control and Prevention CDC, PATH, John Snow Inc JSI, LSHTM, Johns Hopkins University JHU) and has sought endorsement of this work at senior levels of partner agencies. The revised Vaccine Introduction Guidelines (Principles and Considerations for Adding a Vaccine to a National Immunization Programme) which were published in 2014 as a result of the proceedings of the ad hoc working group, have been vetted by the partner agencies and endorsed by their senior personnel.
Implementation research	The implementation research agenda should define equity beyond traditional economic money metrics such as social economic status gradients, to include other measures of inequity such as the multidimensional poverty index or impacts on marginalized populations. SAGE suggested that studies to examine the integration of immunization with other health interventions should be included in the implementation research agenda.	Nov 2013	Ongoing	This recommendation is now part of the new Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) agenda under research to minimize barriers and improve coverage of vaccines currently in use. During the September 2014 meeting IVIR-AC identified the need for standardization of research tools and protocols to examine the integration of immunization with other health interventions and non-vaccination to be applied locally, by antigen including on how to translate the evidence to community messaging. IVIR-AC recommended to establish a sub-group to propose elements of the menu of solutions on the integration of care with immunization programs and another sub-group on non-vaccination. A two year time line selective approach on integration was proposed at two levels i.e. service delivery and management. IVIR-AC recommended to use the project proposal on "Evaluation of the Integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD) interventions: example for Mazabuka District in Zambia" as a case study. As part of the Broader Social and Economic Value of Vaccines work portfolio in WHO several research proposals on this topic were suggested by a network of international researchers from academia, NGOs and decision makers during a ad-hoc WHO consultation in November 2014. Proposals were submitted for funding at Centres for Disease Control and Prevention (CDC)/Global Immunization Division (GID), the Global Alliance for Vaccines and Immunizations (GAVI), and Bill and Melinda Gates Foundation (BMGF). In March 2015, the "Impact of reaching hard to reach populations through routine immunization" proposal was awarded funding and has been started.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Implementation Research	SAGE outlined some considerations for IVIR-AC to include in their deliberations – assessment of the use of high quality randomized controlled trials where feasible (noting the substantial ethical and methodological challenges involved), with sufficient power to explore sex differences, and a priori defined and standardized immunological endpoints designed to answer the specific question of non-specific effects– and emphasized that future research should draw on a broad investigator pool and from a wide range of geographic locations using a standardized protocol.	Apr 2014	Ongoing	During the Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) September 2014 meeting, it was suggested to develop standardized protocols and start implementing high quality Randomized Controlled Trials (RCTs) where feasible. At least studies should mimic RCT situations with sufficient power to explore sex differences, and a priori defined and standardized immunological endpoints. With Bill and Melinda Gates Foundation (BMGF) support a multi-disciplinary team with IVIR-AC participation will start reviewing the evidence and identify research questions.
Implementation Research	SAGE identified the conditions necessary for pertussis resurgence and the effective strategies for prevention of resurgence as important topics for modelling research.	Apr 2014	Ongoing	The September 2014 Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) meeting concluded that the models presented by modeling groups from Australia, UK and US were appropriate in terms of structure to better understand both schedule optimization in various countries and different transmission settings. However, availability and quality of data in low and middle income countries (LMICs) remains the key problem, thus IVIR-AC calls for better surveillance systems in LMICs. An IVIR-AC subgroup under the "WHO vaccine preventable diseases (VPD) burden and impact framework" will identify specific data needs for parameterization of various models by conjoining need with epidemiological expertise. Discussions are ongoing with modeling groups to discuss:) 1) Extending the models to high-mortality (i.e. low/middle-income) settings (including identifying data needs/gaps 2) Understanding the impact of differences in scheduling 3) Testing models with data from Colin Sanderson (London School of Hygiene and Tropical Medicine LSHTM) and the countries reviewed by the SAGE working group (WG). Preliminary results are expected to be presented at the upcoming IVIR-AC meeting in June 2015.
Influenza	SAGE requested that WHO report on epidemiology and surveillance of H7N9 as well as on the development of a potential vaccine candidate.	Apr 2013	Ongoing	Assessment of risk associated with avian influenza A(H7N9) remains unchanged. As of 1 Feb 2015, 486 cases have been confirmed with 185 deaths from China (Mainland, HK and Taiwan) including a Chinese case detected in Malaysia, and 2 cases with travel history to China reported from Canada. The majority of human cases are associated with exposure to infected live poultry or contaminated environments, including markets where live poultry are sold. A(H7N9) viruses seem circulating in poultry and their environments in the areas where human cases are occurring. Clinical and epidemiological features of H7N9 remain unchanged. So far the A(H7N9) virus antigenically are closely related to the WHO recommended vaccine virus A/Anhui/1/2013-like virus, although internal genes of the viruses are under constant reassortment with avian influenza A(H9N2) viruses endemic in poultry in parts of Asia. Several reverse-engineered high-growth reassortant candidate viruses are available for A(H7N9) vaccine development, though classical reassortment has not yet succeeded. WHO, through its global network, the Global Influenza Surveillance and Response System (GISRS), has been monitoring the evolution of the A(H7N9) and conducting continuous risk assessment.
Integration	WHO should discuss and develop guidelines on how to fully integrate vaccination (GVAP) into the operation of all aspects of the health-care system and to reduce missed opportunities to vaccinate.	Oct 2014	Ongoing	Guide on Missed Opportunities for Vaccination (MOV) Assessment Methodology to be finalized by end of April 2015. Implementation of assessments are planned with AFRO (African Regional Office) in 3 countries (Kenya (May) Chad, and Mauritania). Also planning to including MOV Assessment module as part of larger revision on the Expanded Program on Immunization (EPI) Coverage Survey methodology.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
IVIR-AC	IVIR-AC should seek linkages with the WHO Alliance for Health Policy and Health Systems Research as they might be useful in priority setting and discussions.	Oct 2014	Ongoing	The Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) secretariat have had initial discussions with WHO staff of the Alliance for Health Policy and Health Systems Research (HPSHR) to update on the IVIR-AC deliberations in September 2014. Discussions for concrete steps for their involvement in vaccine implementation research are ongoing. The WHO Alliance for HPHSR will have a seat in the WHO Secretariat of the IVIR-AC. In addition, Initiative for Vaccine Research (IVR) will be involved in a call for proposals issued by the WHO Alliance with financial support from the Global Alliance for Vaccines and Immunizations (GAVI) and UNICEF on implementation research studies in low and middle income countries (LMICs) in 2015.
IVIR-AC	SAGE noted that a sub-group of IVIR-AC members and external subject experts should make recommendations on the types of prospective studies to assess the non-specific effects of vaccines.	Oct 2014	Ongoing	Subject experts on non-specific immunological effects of vaccination came together 1-2 February 2015 in Oxford to discuss and review the available evidence, identify key questions regarding non-specific effects (NSE), discuss pilot studies and its designs.
Japanese encephalitis	Interference with the immune response to other vaccinations, number of doses required and the duration of protection need to be assessed.	Apr 2006	Completed	Based on the work of the SAGE working group on Japanese encephalitis (JE), these matters were discussed at the SAGE meeting October 2014, and have been reflected in the updated JE position paper, published in February 2015
Japanese encephalitis	SAGE looked forward to better assessment of the disease burden and identification of target populations for immunization and to reviewing the regional JE control goal currently under development and the activities to achieve this goal.	Nov 2008	Completed	WHO reviewed the evidence in context of the SAGE working group on Japanese encephalitis (JE). This issue was presented in the context of the JE session at SAGE October 2014 meeting. The evidence and SAGE recommendations were included in the WHO position paper on JE published on 27 Feb 2015.
Japanese encephalitis	Guidance is needed on how to approach Japanese encephalitis (JE) vaccine impact assessments. This guidance should address surveillance data sources and analysis to measure JE vaccine impact, design of surveillance and special studies for impact measurement, JE laboratory diagnostics, and data collection and analysis for observational studies to measure vaccine effectiveness	Apr 2015	Ongoing	WHO is holding a meeting May 26-27, 2015 to be followed shortly by development of a document (analogous to the one prepared for Haemophilus influenzae type b (Hib)/pneumococcus titled "Measuring impact of Streptococcus pneumoniae and Haemophilus influenzae type b conjugate vaccination" published in 2012).

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Japanese encephalitis	Commercial kits for detection of JE-specific IgM should be compared and validated.	Apr 2006	Ongoing	Assessment using serum was carried out by PATH and published in the American Journal of Tropical Medicine and Hygiene (Am J Trop Med Hyg) July 2007. Field validation of serum and cerebrospinal fluid (CSF) in India and Bangladesh was assessed in a joint WHO/CDC (Centre for Disease Control and Prevention) meeting, at the South East Asian Regional Office (SEARO), February 2008. Nepal and Cambodia field evaluations of Japanese encephalitis (JE) assays were completed and a paper was submitted to the Journal of Infectious Diseases (JID). Assessment of kits using CSF were accepted for publication in Am J Trop Med Hyg. CDC Fort Collins distributed the 3rd serum and CSF proficiency test panel to evaluate in-house and commercial JE ELISA assays, to Western Pacific Regional Office (WPRO) JE labs in the 4th quarter of 2012. The three Western Pacific region WPR JE regional reference labs (Japan, China and Republic of Korea) held their annual coordination meeting in Chengdu, China in the 2nd quarter 2012. China Centre for Disease Control CDC JE regional reference Lab was fully accredited by WPR and HQ Lab Coordinators, in August 2012. A WPR JE LabNet meeting took place on 15 March 2013 and a Regional JE workshop for WPR was held the week of 17 June in Seoul. Submission for publication of a paper summarizing the development of the JE LabNet is pending. The Regional Reference Laboratory for JE in the WPR at the Victorian Infectious Diseases Reference Laboratory, Melbourne, was fully accredited in Oct 2013. The Global Specialized Reference Laboratory for JE at the National Institute of Infectious Diseases, Tokyo, was also fully accredited in Oct 2013. The diagnostic assay produced by PanBio ceased production at the end of 2013. An alternative assay produced by InBios with similar performance will be used in the WHO laboratory network. The training workshop at the Korean CDC in June was intended to introduce the network to this kit. A biregional laboratory training workshop and laboratory network meeting is scheduled for 17-21 August 2015, to be held at the National Institute of Health in Bangkok, bringing together JE lab staff from both WPR and SEAR South East Asian Region.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Lower middle-income countries: sustainable adoption and financing for new vaccines	SAGE requested that WHO facilitate the establishment of a partnership among all relevant stakeholders to consider: pooled procurement; tiered pricing; greater transparency of pricing; and exploring the role that UNICEF, the Pan American Health Organization and foundations can have in assisting these countries with procuring and financing vaccines.	Nov 2010	Ongoing	Access to vaccines for Middle Income Countries (MICs) is important from a public health impact perspective as well as from an equity perspective. Also, MICs could provide a large demand volume for vaccine supply, thereby promoting competition and a healthy vaccine market to the benefit of both recipient countries and suppliers. The issue of access to vaccines for MICs is often discussed in relation to access to affordable pricing. Yet, previous work has shown that the needs of MICs span from evidence and capacity building to policy and advocacy, domestic financing, and procurement and supply. Various efforts are ongoing to support MICs, but a clear strategy and action plan in this area does not exist, nor a framework to coordinate across partners and to monitor progress. In 2012 SAGE noted with concern that these efforts are fragmented and are failing to optimize synergies in the work being undertaken by each agency. SAGE noted that with a modest investment in technical assistance and capacity building, programmes in MICs could be significantly strengthened. SAGE requested that this issue and related achievements be revisited in a subsequent meeting, and that a task force be established by WHO to coordinate the policies and efforts of partners. WHO set up a MICs Task Force in June 2014. The Task Force includes main immunization stakeholders (WHO, UNICEF, World Bank, the Global Alliance for Vaccines and Immunizations (GAVI) Secretariat, Bill and Melinda Gates Foundation (BMGF), Agence de Médecine Préventive (AMP), Sabin, Task Force for Global Health) and is working to establish a shared strategy and action plan for sustainable access to vaccines in MICs in consultation with countries, civil society organizations (CSOs), and industry. The Task Force has first focused its work on redefining the problem statement. Following these analyses it was decided that the Task Force would concentrate its efforts on non-GAVI MICs only; that the Task Force would move away from the perceived issue of a “lag” between MICs and GAVI-supported countries, and would focus instead on the fact that MICs are far from reaching their Decade of Vaccines (DoV) targets. Following the initial literature review and analytical work, the Task Force conducted country consultations to develop a need assessment that highlighted the most important needs in MICs. The Task Force also contacted 20 partners and WHO regional offices to take stock of ongoing activities to address these needs, revealing a lack of funding and focused activities outside of GAVI-countries. Following these consultations, a gap analysis was conducted, on which the Task Force built the MIC strategy. The MIC strategy is a shared and comprehensive approach with the goal to “enhance sustainable access to vaccines for populations in middle-income countries to meet Global Vaccine Action Plan (GVAP) targets”. The strategy promotes the development of a mix of new activities and existing activities that need to be expanded or modified to focus on MICs’ specific needs. In order to respect the heterogeneity of MICs and align with their national priorities, the MIC strategy was developed to be tailored to the specific needs of each MIC, around four main areas: - Strengthened decision making for timely and evidence-based immunization policy and programmatic choices; - Increased political commitment and financial sustainability of immunization programmes; - Enhanced demand for and equitable delivery of immunization services; - Improved access to affordable and timely supply. The timeline for the strategy is up to 2020 to align with the GVAP timeframe and up to 2025 for a longer term horizon. In the longer term, the MIC strategy could provide a platform to ensure sustainability of GAVI investments in graduated countries. In the implementation phase, the Task Force, with WHO as Secretariat, would continue its role of coordination and information sharing.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Malaria	SAGE requested that it be kept informed of developments in the ongoing multi-country Phase 3 trial and indicated that further discussion on the optimal schedule for a malaria vaccine will need to occur.	Oct 2009	Ongoing	The timing for the Decision session depends on the timing of the regulatory decision. The European Medicines Agency (EMA) is expected to make a regulatory decision between July and September 2015. The submission was made in July 2014. If the September 2015 timeline is met for EMA decision a SAGE/Malaria Policy Advisory Committee (MPAC) meeting joint session is expected in Oct 2015. The final results from the Phase 3 trial were reviewed by Joint Technical Expert Group (JTEG) 25-26 September 2014, and SAGE has received the JTEG meeting report. A final JTEG meeting is planned for June 29-30, at which candidate policy recommendations will be drafted for decision by SAGE and MPAC. A separate process has coordinated harmonization and comparison of the malaria models available for RTS,S/AS01 impact and cost-effectiveness predictions. The independent assessment from this process will also be presented to SAGE and MPAC. Any recommendation for use in the 5-17 month age range is likely to focus on the 5-9 month age period for the primary immunization series due to the age pattern of malaria. JTEG reviewed the data on a fourth booster dose given 18 months after the primary immunization series. If EMA gives a positive opinion, WHO recommendations for use are issued, the Global Alliance for Vaccines and Immunizations (GAVI) Board will meet to consider the updated impact estimates to make a decision on the possible opening of a window for the malaria vaccine.
Malaria	SAGE noted the utility of PPCs to developers and funders, and proposed that the opportunity for input into future PPCs at an early stage for any vaccine of public health importance could be included as part of SAGE's global public health mandate.	Apr 2013	Ongoing	Malaria Vaccine Preferred Product Characteristics were shared by email with SAGE committee members for their individual comment during July 2014. The document was published as a WHO document during January 2015 - the first of the new class of WHO Preferred Product Characteristics documents. These will provide information about WHO's preferences and processes for priority public health needs to be met by new vaccine development.
Maternal Immunization	SAGE concluded that the recommending bodies, including WHO, need to engage in a dialogue with regulators and manufacturers to review current regulatory practices against the evidence on risks and benefits and biological plausibility on product safety. SAGE requested WHO to develop a process and a plan to move this agenda forward in support of an increased alignment of data safety evidence, public health needs and regulatory processes.	Nov 2013	Ongoing	WHO has reviewed various regulatory approaches to labelling of the pregnancy and lactation sections of product inserts, and it has convened two meetings on the subject: a consultation at WHO in July 2014 and a session at a meeting of the Developing Country Vaccine Regulators' Network (DCVRN) in China in November 2014. No regulatory consensus was achieved in these meetings regarding data requirements for product labelling, and further consultations are planned to discuss this issue further in 2015. The meetings did identify potential alternative methods by which WHO could promote more permissive language in package inserts regarding vaccine use in pregnancy, including use of WHO Prequalification (PQ) Model Package Inserts for influenza vaccines. WHO is also exploring other mechanisms that would promote evidence-based, permissive language in package inserts and that would improve understanding of precautionary language in package inserts.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Meningococcal A conjugate vaccine	SAGE recommended that countries completing mass vaccination campaigns introduce meningococcal A conjugate vaccine into the routine childhood immunization programme within 1–5 years following campaign completion, along with a one-time catch-up campaign for birth cohorts born since the initial mass vaccination and which would not be within the age range targeted by the routine immunization programme. SAGE recommended a 1-dose schedule, with vaccine administration by deep intramuscular injection, preferably in the anterolateral aspect of the thigh, at 9–18 months of age based on local programmatic and epidemiologic considerations. This recommendation for routine immunization programmes is based on the high level of herd immunity following mass campaigns, epidemiologic evidence on the age distribution of disease, and programmatic and economic considerations. Any children who miss vaccination at the recommended age should be vaccinated as soon as possible thereafter.	Oct 2014	Ongoing	The recommendations from SAGE are reflected in an update to the WHO meningococcal vaccine position paper. The updated guidance has been published in the Weekly Epidemiological Record WER on 20 February 2015: http://www.who.int/wer/2015/wer9008/en/. One of the meningitis belt countries (Ghana) has already submitted an application to the Global Alliance for Vaccines and Immunizations (GAVI) in January 2015 for introduction of the meningococcal A conjugate vaccine into their routine immunization programme, with a single dose at 18 months of age concomitantly with the administration of the second dose of Measles/Rubella vaccine. Other meningits belt countries intend to apply for the introducton of the vaccine into their routine programme at the next GAVI application window in September 2015.
PDVAC	SAGE requested to be updated by Product Development for Vaccines Advisory Committee (PDVAC) on the criteria used for prioritizing vaccines for IVR's work.	Oct 2014	Ongoing	SAGE will be provided with an update during the April 2015 SAGE meeting.
Pertussis	A systematic review of the optimal primary immunization schedules (in association with diphtheria, tetanus toxoid containing vaccine) is ongoing and will be presented at the October 2014 SAGE meeting. The 2010 pertussis position paper will be updated after the results of this review are available. In the meantime a short update to the position paper will be published to clarify that the previous statement on the choice of vaccine contained in the 2010 vaccine position paper no longer holds true.	Apr 2014	Ongoing	An update of the pertussis position paper was published in the Weekly Epidemiological Record (WER) on Friday July 25 2014. The systematic review was completed and a face-to-face meeting of the pertussis Working group took place at the end of August 2014. In view of the conclusions of the group that there was no evidence to recommend significant changes to the immunization schedules and in the context of the Ebola outbreak pressure, the decision was made to postpone the reporting to SAGE and related discussions to the April 2015 meeting. The publication of the full update to the pertussis position paper will then be initiated after the April 2015 SAGE meeting, and is currently planned for Q3 2015.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Polio	The documentation for 'legacy planning' should include contributions from communities and front-line health workers on their experiences with the polio programme, what it has meant for them and how lessons learnt could further improve the routine vaccine and health programme.	Apr 2013	Ongoing	The Global Polio Eradication Initiative (GPEI) has constituted a Legacy Working Group (LWG), currently comprised of representatives from the spearheading partners (Rotary, WHO, CDC and UNICEF) and the Bill and Melinda Gates Foundation to take forward the legacy planning work. The LWG has finalized and is implementing its workplan. One of the major activities within the workplan is to hold broad consultations with relevant stakeholders to document the lessons learnt and knowledge of the programme, to guide the direction of the legacy work, and to establish what benefit the lessons and resources of the GPEI could be to other initiatives. These consultations began in early 2014 and were continuing through the rest of the year. The consultation included plans for soliciting contributions from communities and front-line health workers' on their experiences of polio eradication. In addition, the GPEI has contracted a consultant group that will conduct in-country interviews that will include learning lessons of polio eradication. As well as having produced a paper for the Journal of Infectious Diseases (JID) on the lessons of polio eradication (Cochi, Freeman, Guirguis, Jafari, Aylward, Global Polio Eradication Initiative: Lessons Learned and Legacy), the GPEI Legacy Management Group is seeking input on lessons at the country level. This work will be led by Regional and Country-based colleagues and will involve the input of front-line workers. In addition, a team from the Boston Consulting Group supporting the legacy planning work in 2014 and early 2015 have sought input from 10 countries on contributions of polio-funded staff to other health priorities including immunization. The first segment of this work was reported to the Polio Partners Group and the Polio Oversight Board in December 2014
Polio	Sufficient capacity should be established at the global level to provide technical and programmatic support to countries to plan and implement all activities associated with type 2 oral polio vaccine (OPV2) withdrawal and introduction of inactivated polio vaccine (IPV).	Apr 2013	Ongoing	The Immunization Systems management group, co-chaired by WHO and UNICEF, has been established to coordinate efforts towards the activities relating of OPV2 (type 2 component of oral polio vaccine) withdrawal and IPV (inactivated polio vaccine)introduction. The multi partner group has been operating since mid-April 2013 in five areas of work : Regulatory, vaccine implementation, communication, financing and routine immunization strengthening. The time investment dedicated by the staff of the six agencies engaged in the Immunization Systems Management Group, IMG (Centre for Disease Control and Prevention CDC, WHO, UNICEF, Bill and Melinda Gates Foundation BMGF, Rotary and Global Alliance for Vaccines and Immunization GAVI) since April 2013 has been impressive. WHO/EPI (Expanded Programme on Immunization) has filled an additional 3 professional staff positions at HQ to contribute to this effort. UNICEF HQ has filled two additional HQ positions. Significant numbers of staff and consultants have also been deployed at Regional levels of both organizations, and funding has been sent to all regional offices. 66 out of 73 GAVI eligible countries have applied for IPV introduction support. For non GAVI countries, a financing mechanism has been rolled out to support 16 countries in Tier 2 and Tier 3 or LMIC (low and middle income countries) which are not GAVI eligible. This mechanism will enable partners to support some countries that need it with vaccine introduction grants and/or time limited procurement of IPV. As of September 26 2014, a total of 113 countries (90%) have indicated their intent to introduce IPV by the end of 2015. In December 2014 the above financing mechanism was extended to another 9 countries from the American (AM) and Western Pacific (WP) regions to help them, in a catalytic manner, initiate the procurement of IPV. The effort is now focusing on providing countries with the necessary information and technical assistance to develop a plan to carry out a switch from trivalent OPV (tOPV) to bivalent OPV (bOPV) in April 2016.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Polio	SAGE recommended working closely with countries on activities towards type 2 oral polio vaccine (OPV2) withdrawal.	Apr 2013	Ongoing	A joint letter to all oral polio vaccine (OPV)-only using countries was sent by the WHO Director General and UNICEF Executive Director, and the Global Alliance for Vaccines and Immunizations (GAVI) CEO where applicable, highlighting the importance of inactivated polio vaccine(IPV) introduction and outlining the SAGE recommendation on IPV introduction schedules and planning timelines. All regions have held, or will have held by the end of this year, at least one meeting that included a substantive focus on IPV introduction. In addition, many regions have held GAVI application development workshops; this has led to all 72 eligible countries applying for support already. Joint WHO/UNICEF regional coordination mechanisms are established to ensure countries are suitably supported in the decision making process and in the development and implementation of introduction plans. A large number of countries (120 of 126) have confirmed decision or intent to introduce IPV by end of 2015 in preparation for the withdrawal of type 2 OPV. Work is now ongoing to i) ensure that declared intent materializes into commitement and ii) countries with no plan developed for IPV introduction have one ready before the end of the year. The matter of OPV withdrawal was discussed by the WHO Executive Board at it January 2015 session. The Board endorsed a secretariat recommendation that a WHA resolution be drafted and put forward in May 2015 on this subject. In the interim high level communication will be initiated with all 156 OPV using countries to encourage them to develop a plan of action for the withdrawal of OPV and replacement with bOPV which should be ready by september 2015. Technical materials and standard operating procedures (SOPs) have started to be shared with countries through regional consultations.
Polio eradication	SAGE requested that the Polio working group draft the necessary protocols for the 5 major components of the proposed strategy for type 2 virus detection and response after OPV2 cessation, in the areas of virus notification, surveillance, vaccine stockpiles, response and management of travellers for presentation to the SAGE in 2014.	Nov 2013	Completed	SAGE reviewed the presented protocols for the 5 major components of the proposed strategy in October 2014, and endorsed them.
Polio eradication	"To facilitate prioritization, planning and implementation of IPV introduction at country level, SAGE recommended that consideration be given to developing a resolution on accelerated IPV introduction for submission to the World Health Assembly (WHA) in 2014."	Nov 2013	Ongoing	The World Health Assembly (WHA) noted the progress of inactivated polio vaccine (IPV) introductions in 2014, based on the report from Immunization systems Management Group (IMG). During the WHA 2014, the 5 criteria for withdrawel were discussed. These criteria include a) status of introduction of IPV in oral polio vaccine OPV-only using countries, b) registered bivalent OPV for routine immunization, c) establishment of stockpile and outbreak response protocol for type 2 virus, d) completion of phase 1 containment activities under the Global Action Plan (GAP) and e) affirmation of wild poliovirus type 2 eradication by the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC). In 2015 a session at the WHA is held to endorse the envisioned timing of the switch (currently scheduled in April 2016).
Reports from other advisory committees	SAGE recommended appointment of appropriate programmatic and implementation expertise to IVIR-AC membership including representation of experts from low and middle-income countries.	Nov 2011	Ongoing	Since 2013 Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) includes two programmatic and implementation research members from the African Region (AFR) and the South East Asian Region (SEAR). Since 2014 IVIR-AC includes a mathematical modeler/economist from SEAR and a medical anthropologist from AFR. Currently 2 seats are vacant for a mathematical modelers and one health economists with experience in vaccine implementation research. Recruitment of new members is ongoing.
Reports from other advisory committees on immunization	WHO and NIBSC should develop with other stakeholders, a business plan to assure long-term security of the development of WHO reference preparations as a global public health resource and additional efforts should be undertaken to disseminate outcomes of the committees deliberations and to explain the relevance of its work to the broader immunization community.	Nov 2006	Pending	A comprehensive review of the work of the Expert Committee on Biological Standardization (ECBS) is still pending. The review will include (but not be restricted to) consideration of communication of ECBS outcomes.This will be linked with an overriding review of Expert Committees by the department of Essential Medicines and Health Products. Discussion on a paper on the process of the review was initiated by ECBS during its October 2014 meeting; however biotherapeutic biological drugs were identified as first priority.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Security of vaccine supply	SAGE requested WHO to produce a report on the security of the supply of affordable vaccines and encouraged donors to invest in the development of new vaccine technologies that facilitate the delivery of effective, affordable vaccines to populations most at risk.	Apr 2012	Ongoing	Discussion with donors has advanced well and planning for meeting on new vaccine technologies being initiated. Internal WHO discussions are in progress. A meeting on new vaccine technologies was held in February 2014. The work on the supply of affordable vaccine is an on-going effort in which all immunization partners are engaged. Affordability of vaccine remains an ongoing challenge for a number of countries however recent accomplishments in the area of inactivated polio vaccine (IPV) supply and financing are a good indication that the trend is evolving positively through strong partnership between the public and the private sectors. Given the amount of work going on in this area under several other initiatives including those reflected under item "Lower middle-income countries: Sustainable adoption and financing for new vaccines", we have discussed internally and have decided that, for the time being the production of a report was not warranted. SAGE will be kept informed on an ongoing basis of progress made and new developments. More information on the topic of financing can be found at under the respective topic in the tracking sheet. No further development to report at this stage
Smallpox vaccines	SAGE recommended that WHO initiate discussions with countries in possession of smallpox vaccine to establish mechanisms for replenishment of the WHO stockpile in case of need.	Nov 2013	Ongoing	An operational framework for vaccine donation has been developed adn agreed by the Global Health Security Intitiative (GHSI) Medical countermeasures (MCM) task force.WHO and Japan agreed on the donation of 10.000 doses of LC16m8 vaccine from Kaketsuken.WHO is working with the manufacturer to ship the vaccine to Geneva. The agreement with France for the donation of 5 million doses of vaccine still ongoing, depending on the prequalification (PQ). WHO is working on smallpox vaccine prequalification for WHO stockpile.
Supply Chain	SAGE requested future update on approaches to prioritization within supply chain improvement plans.	Oct 2014	Ongoing	Under the umbrella of the WHO-UNICEF Immunization Supply Chain and Logistics Hub, a process has started to implement the more holistic approach to immunization supply chain improvement planning as part of the WHO-UNICEF Joint Statement that was endorsed by the SAGE. The approach builds in a methodology to prioritize strategies and activities that will have the largest impact on immunization supply chain improvements. In addition, evidence around cost-effective solutions is being compiled by the Hub which will be transformed into an Solutions Toolbox to help countries tailor and prioritize the right solutions. 5 countries have developed a supply chain improvement plan - Pakistan, Democratic Republic of Congo, Lao People's Democratic Republic, Bangladesh, and Nepal.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Surveillance	SAGE endorsed the recommendations of the ad hoc TAG for improving the quality of the IB-VPD surveillance network and urged that the objectives of this network be more clearly defined, that collaboration with other surveillance systems and laboratory networks (i.e. the polio/measles laboratory networks) be continued, and that, where feasible, activities be linked with other programmes enhancing country capacity, including implementation of the International Health Regulations. SAGE urged greater attention to integration of data systems, which would facilitate real-time analysis and performance monitoring. SAGE also noted the opportunities for integration by building upon the enhanced capacity developed by these networks to conduct surveillance for other diseases using a similar case-definition and personnel trained in applying and adhering to rigorous surveillance protocols. Both networks should continue to share experiences with the polio surveillance network. Integration efforts must be strategically designed in ways that are logical and synergistic.	Nov 2013	Ongoing	During 2013, a global strategic review was conducted of the invasive bacterial vaccine preventable diseases (IB-VPD) and rotavirus sentinel hospital surveillance networks. During that meeting, 50 recommendations were made to advance the status of both networks. During 2014, significant progress was made to further improve the IB-VPD and rotavirus sentinel hospital surveillance networks. Network management was strengthened with the use of a Performance Management Framework to track implementation status of annual global recommendations. A major achievement was the transition to standardized, case-based reporting with quarterly data sharing plus feedback of standard process and performance indicators to sites. Data management processes continue to be improved toward having a more systematic approach in reporting, cleaning, analysing and interpreting data. The reference laboratories are appropriately supporting sites and network laboratory performance has been successfully monitored by the global external quality assessment (EQA) program as well as quality control (QC) programmes. Sentinel site and laboratory assessments have been prioritized but have not been able to include all priority sites. The most recent 2013 data available for the meeting may underestimate data quality because none of the actions taken after the 2013 strategic review are yet reflected. IB-VPD data analysis focused on assessing laboratory testing performance of culture and PCR, and found <30% of PCR results were linked into the clinical database as well as a 3-fold improved detection of pathogen by PCR over culture alone. Beginning in 2014, Regional Reference Laboratories (RRLs) will only process specimens with a unique identification number and it is thus anticipated that a larger percentage of cases will have clinical data that can be linked with RRL data. Network data has contributed to vaccine introduction decisions and the surveillance networks have been used as platforms for vaccine impact evaluations. Moving forward, the rapid introduction of Pneumococcal Conjugate Vaccine (PCV) and Rotavirus Vaccines (RV) by Member States now requires the surveillance networks to focus on improving baseline data for sites in non-vaccine using Member States and to ensure consistent surveillance practices for sites that meet inclusion criteria in vaccine-using Member States. The web-based data management tool has great potential to improve data quality and may be expanded to other vaccine preventable diseases in due course. WHO, the iTAG (informal Technical Advisory Group) and partners will work to implement recommendations to further improve the network during 2015 including to strengthen programme management: • Strengthen involvement of Ministry of Health and national EPI (Expanded Programme on Immunization) programmes; • By end-April 2015, IB-VPD specimen sharing agreements should be established between all 71 IB-VPD target hospitals and RRLs to further increase access to PCR's improved diagnostic yield; • All IB-VPD cerebrospinal fluid specimens should be tested by PCR at an RRL; • Further focus efforts and define a subset of sites where PCV and/or RV vaccine impact evaluations may be feasible due to sufficient pre- and post-vaccine introduction data; And to Improve data management and analysis: • Link clinical and laboratory data by use of unique identification numbers. Prospective data linking established by 31 Dec 2014, and sites prioritized for retrospective linking; Validation of thesea activities pending until June 2015. • Zero reporting to be implemented at all sites by 31 Dec 2014; In March 2015, regional activities are in progress, but zero reporting not yet been implemented. • Identify a subset of core data variables for vaccine impact assessments; • Draft guidelines for rotavirus data analysis/interpretation and assess probable bacterial meningitis data; • Finalize the web-based data management tool; • Revise site inclusion criteria: for rotavirus, reduce the number of annual stool specimens tested in vaccine using countries; for IB-VPD, include consistently performing sites that enrol fewer meningitis cases.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Tuberculosis vaccines	SAGE endorsed the establishment of a WHO TB vaccine technical expert group with representation from SAGE. An annual written report on TB vaccine developments should be provided to SAGE. SAGE would be provided with two-page summaries of progress every year. TB would only be included on the agenda of SAGE when there is a meaningful development of decision from SAGE required.	Nov 2011	Ongoing	In December 2012, the first consultation of the TB Technical Expert Group (TEG) was held to review clinical trial plans for two advanced new TB vaccine candidates, VPM1002 (VPM, Germany) and M72 (GSK Biom, Belgium). Written update to SAGE was provided ahead of the November 2013 SAGE meeting. The 2014 annual update on TB vaccines was provided in Oct. 2014.
Typhoid	Establish a SAGE working group on typhoid conjugate vaccines in 2016 to prepare for a SAGE review of the evidence in 2017.	Oct 2014	Pending	The plan is to establish the Working Group in 2016 to prepare for a SAGE review in 2017.
Un/under-immunized children	SAGE requested that WHO quickly roll out tools so that other countries can address low coverage of vaccination.	Nov 2010	Ongoing	The in-depth tool "A Guide to Tailoring Immunization Programmes (TIP) has already been developed and used by WHO-EURO (European Regional office). Currently the Univ. of Witwatersrand in South Africa has been contracted to adapt the methodology to developing countries, and less intensive consultant-based inputs.
Vaccination in humanitarian emergencies	SAGE also suggested that the framework approach to vaccine decision-making could be considered for other health interventions in emergencies.	Apr 2012	Ongoing	The Emergency Risk Management and Humanitarian Response (ERM) Department was slow in the uptake of this recommendation due to lack of staff and the high number of Level 3 emergencies.
Vaccine coverage	SAGE recommended that WHO explore alternative survey methods to improve the precision, reduce the cost and improve the usefulness of survey results to national and local immunization programmes.	Nov 2011	Ongoing	To improve the precision and usefulness of survey results and to reduce the cost of surveys, the Strategic Information Group (SIG) proposes to explore 1) recent advances in sampling methodology, 2) new technologies for constructing sampling frames, supervision of field work, data collection, and analysis and 3) alternative content, collection, analysis, presentation and linkages with other data sources. An explicit description of precision, usefulness and cost of various trade-offs between alternative methods will constitute part of the exploration. An initial meeting was convened of the Department of Immunization Vaccines and Biologicals' (IVB) Informal Advisor Group on Monitoring Immunization Programme Performance through Household and Community Surveys. First meeting addressed the need to modify Demographic and Health Surveys (DHS) - implemented by ICF International; the UNICEF Multiple Indicator Cluster Surveys and the WHO Immunization Cluster Survey to accommodate changes in immunization system strategies. On 17-18 September 2012 a meeting was held with representatives of ICF and UNICEF to discuss modifications to their standard recommendations on data collection, analysis and presentation of immunization coverage data. WHO and UNICEF provided written recommendation to these agencies. An informal working group has been created to review and revise WHO guidance on measuring immunization coverage through household and community surveys. The working group met in July 2013 to agree on the scope of work, to identify initial products, and establish a plan of document production, review, pilot testing, and clearance. Draft guideline was circulated to external reviews. Protocol for pilot testing was developed and pilot testing is currently undergoing in Bangladesh. The methods will be reviewed in September by Immunization and Vaccines Related Implementation Research (IVIR) Advisory Committee. The proposed methods were reviewed in September by Immunization and Vaccines Related Implementation Research (IVIR) Advisory Committee. The methodology is currently tested in Burkina Faso and in Lao PDR and manual will be updated based on the inputs.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Vaccine coverage	WHO to identify appropriate methods and develop guidelines for collecting, analysing, and interpreting biomarkers for validating coverage.	Nov 2011	Ongoing	WHO to identify appropriate methods and develop guidelines for collecting, analysing, and interpreting biomarkers for validating coverage. A draft document which reviews, for a selected list of vaccine-preventable diseases, laboratory test available and associated requirements for specimen collection/transport, personal experience and training, and laboratory supplies and equipment has been prepared. The draft will be reviewed internally and following recommended changes will be submitted for review by external experts. For each selected disease study populations, sampling methods, data/specimen collection, laboratory/statistical analysis, and implications of results were summarized in an accompanying document. Work in progress was presented to WHO and UNICEF Regional Focal Points for immunization during the Meeting on Monitoring National Immunization Systems, 9-11 October 2012 for their comments. Internal and external review of the document will continue and after incorporating the comments draft guidelines will be developed for use of sero-surveillance as an evaluation tool for immunization programmes. Currently, WHO is developing global guidelines on conducting serosurvey studies on measles and rubella and primarily to be applicable in a pre- and post-SIA (supplementary immunisation activity) setting.An expert working group has been assembled and based on the expertise in the various fields of each of the members, needed to conduct such studies, including statisticians, epidemiologists, laboratory experts, and program experts, given subtasks in developing parts of these guidelines that pertain to their respective expertise. A working draft will be finished by the end of Q4/2014 and will be tested subsequently in pilot studies in two different settings, pre- and post-campaign, for its applicability. These pilot studies are expected to take start Q1 2015 and will run during the entire year of 2015. Based on the outcome, the working draft guidelines will be corrected where needed and finalised. The final document is planned to be ready by Q1 2016 and to be rolled out as a tool to evaluate the immune status of the target or targeted population.A draft has been circulated for comments and will be tested subsequently in pilot studies in two different settings, pre- and post-campaign, for its applicability. These pilot studies are expected to take start Q1 2015 and will run during the entire year of 2015. Based on the outcome, the working draft guidelines will be corrected where needed and finalised. The final document is planned to be ready by Q2 2016 and to be rolled out as a tool to evaluate the immune status of the target or targeted population.
Vaccine coverage	SAGE recommended that WHO support new research for biological specimen collection including rapid on-site diagnostics that could improve coverage and susceptibility estimates. Improved serological surveillance techniques could be integrated with existing population-based surveys such as DHS or MICS. These research topics should be included on the QUIVER (now IVIR-AC) agenda.	Nov 2011	Ongoing	As the Bill & Melinda Gates Foundation is now accepting Letters of Inquiry for the development of an easy-to-use tool that rapidly assesses the immune status of children against select vaccine-preventable diseases. Inquiries will be welcome that focus on prototype development and detail plans for future commercialization possibilities.
Vaccine Hesitancy	SAGE acknowledged the necessity to develop core capacities at headquarters and regional level for gaining behavioural insights that can be applied in an integrated fashion for prevention of many communicable and non-communicable diseases, as well as vaccine hesitancy. This will require the involvement of sociologists, psychologists, anthropologists, experts in social marketing, communication experts, and specific disease and vaccine experts.	Oct 2014	Ongoing	Discussions are ongoing within WHO and UNICEF and with partners on how to collectively establish core capacities in order to support and provide technical assistance to countries. For this, discussions were intiated on how to advance the establishment of a network of expertise/excellence and collaborating centres by capitalizing on currently ongoing initatives and activities which have been established and are conducted by WHO (HQ and Regions), partners and stakeholders in the field of vaccine hesitancy.
Vaccine Hesitancy	SAGE encourages validation of the developed compendium of survey questions on vaccine hesitancy, which have been assessed and validated only in some high-income countries or not at all.	Oct 2014	Ongoing	Discussions with various stakeholders are ongoing (Centre for Disease Control CDC, WHO, European Regional Office EURO, Middle Income Countries MIC task force) on the ways forward to identify partners to take on the validation of the survey quesions.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Vaccine Hesitancy	SAGE underlined the importance of distributing the matrix of determinants, the definition of hesitancy and the other deliverables to countries and partners.	Oct 2014	Ongoing	Discussions and presentations were held in teh context of the immunization managers' meeting in the Eastern Mediterranean Region (EMR) and the African Region (AFR) Task force on immunization(TFI) meetings. A series of 9 full paper plus one editorial has been submitted to the journal Vaccine and will be published as a supplement. The online version should be accessible early April at the latest.
Vaccine safety	SAGE highlighted the urgent need for a safety review of other important vaccines that could be used during pregnancy.	Nov 2012	Ongoing	A sub-group of the Global Advisory Committee on Vaccine Safety (GACVS) has been launched to address vaccine safety during pregnancy. A finalized version of the GACVS report on safety of immunization during pregnacy has been made available to SAGE in November 2013 and is now available on the Global Vaccine Safety (GVS) website. A new work track was started with WHO Initiative for Vaccine Research (IVR) in order to harmonize safety monitoring during pregnancy clinical trials. WHO is a contributor to the Gates funded Global alignment of immunization safety assessment in pregnancy project that should run until the end of 2016.
Vaccine Supply	It was noted that SAGE needs to address the constraint experienced across Regions of repetitive shortfalls in vaccine supply, both for existing vaccination programmes (in particular for DTP-containing vaccines) as well as for new/emerging vaccines, and the impact on vaccine coverage in several countries.	Nov 2012	Ongoing	Concerns about the ongoing shortages of traditional vaccines persist. Recent discussions with UNICEF SD (Supply Division) have indicated that a vaccine such as BCG may face supply shortages in 2015 to the extent of being unable to deliver vaccines to all countries needs, potentially prompting stock-outs. For other vaccines, including measles containing vaccines, supply is currently adequate, but largely dependent on a single manufacturer.
Yellow Fever	SAGE requested WHO to revisit the IHR provisions relating to the period of validity for international certificates for vaccination against yellow fever (YF).	Apr 2013	Ongoing	The WHO World Health Assembly in May 2014 adopted an amendment to Annex 7 of the International Health Regulations (2005) (IHR), which stipulates that the period of protection afforded by yellow fever vaccination, and the term of validity of the certificate will change from 10 years to the duration of the life of the person vaccinated. This change will enter into force legally in June 2016. Until then the current IHR text on yellow fever vaccination and certificates continues to apply, and some countries may continue to request proof of vaccination or a booster within the last 10 years from travellers. As of the end February 2015, 22 countries have notifed WHO that already accept the validity yellow fever (YF) vaccination certificate for life. Starting with the online 2015 International Travel and Health (ITH) edition, WHO will report on the status of YF vaccination requirements for countries.