SAGE TRACKING RECORD OF RECOMMENDATIONS AND ACTION POINTS

Topic	Recommendations/Action item	Category	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.	Action	Apr 2012	Pending	Advice being sought through the 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 SAGE November 2012 meeting, SAGE further requested ECBS to 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.
General	SAGE noted the important potential of immunization programmes for strengthening the overall health system, suggesting that good examples be documented and shared.	Action	Nov 2011	Ongoing	An analysis of health systems impact of new vaccine introduction was presented to SAGE in April 2012. SAGE endorsed revised principles for adding a vaccine to a national immunization system while strengthening the immunization and health systems and endorsed the proposal that the 2005 WHO Vaccine Introduction Guidelines be updated to assist decision-makers and managers with identifying and taking opportunities to strengthen the health system through new vaccines introduction. The Vaccine introduction guidelines are now updated and in print
General	SAGE recommended that ways to improve curricula for medical personnel should be explored.	Action	Nov 2008	Ongoing	The African region started to work with academia to develop a pre-service curricula for nursing and medical staff. Annual courses for medical and nursing staff take place in collaboration with Network for education and support in immunization (NESI). An evaluation of the impact of pre/service training and curricula changes is ongoing in 9 countries in AFRO. An evaluation was conducted in late 2011 and a draft report has been prepared but it is not available for wider circulation yet. It first needs approval from countries involved. A report was expected for early 2013 yet this report was not recieved by October 2013.
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.	Action	Nov 2010	Ongoing	EURO is working to give countries tools to address vaccine hesitancy at the individual level. These include: 1. Development of the Tailoring Immunization Programs “TIP” toolkit, which allows a country or sub-national level authority 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. TIP was implemented in Bulgaria and on three projects in Sweden (Somali immigrants, migrants and anthroposophic communities) and Bulgaria. In 2013, TIP is to be implemented in France and use in Romania and in Israel and Tajikistan is planned for2014. A tool assessment is planned in 2014 and expansion to other regions that have expressed interest. 2. Strengthening the ability of member states to handle crises in vaccine confidence and trust through a guidelines document on vaccine safety communication was published in 2013. 3. Advocacy for immunization and strengthening the use of new media led to involvement of well-ranked bloggers who write in Russian and English to better engage around vaccine confidence. 4. A vaccines social media strategy and a smart-phone immunization tracker/reminder ‘app’ for parents has been launched and is currently being modified by national immunization programs in 10 countries to be adapted to local schedules. 5. An online vaccines resource centre was launched in 2012 and has been strengthened and improved through 2012-2013, with a number of MS using or translating the caregiver and health-care worker tools presented.

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General	SAGE requested to add strategies to reach older age groups and the issue of immune senescence on their list of agenda items for a future meeting.	Action	Apr 2013	Done	These two agenda items have now been added on the list of topics on the horizon for SAGE.
General	SAGE recommended strengthening national vaccination programs, integrating health services and strengthening health systems to promote universal health coverage.	Action	Apr 2013	Ongoing	Teleconference held May 13 2013 with J. Abramson, P. Figueroa, and N. Arora and EPI (M. Zaffran and T. Goodman) to discuss issue and provide briefing on the integration activities that historically and presently 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 IVB Director's next presentation to SAGE. Discussions are ongoing.
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.	Action	Apr 2011	Ongoing	There are no GAVI graduating countries in the 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 April 2013: • investigation of measles outbreak in Jordan, that affected Syrian refugees • Investigation of measles outbreak in Lebanon that affected the Syrian refugees • implementation of multi antigen vaccination campaign in the 2 provinces hosting the refugees camps in Jordan • resource mobilization and planning for the national MR/Polio synchronized campaigns in Syria and the surrounding countries (Syria, Jordan and Iraq) • provided support to Tunisia for recruiting technical staff to support EPI • Conducting comprehensive EPI review in Yemen, including DQS and PIE • Conducting EVM in Yemen
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 keys partners. A perspective is to be presented at a future SAGE meeting on accessibility of affordable vaccines.	Pending	Nov 2010	Ongoing	Activities to lead to better vaccine price information and vaccine pricing transparency have being considered and under discussion for sufficient funding. Contribution of WHO to the DoV work stream on global access and vaccine price indicator and report. IVB staff are actively participating 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. Discussions have taken place with DCVMN as such and individual DCVMN members to consult on potential and actual role of emerging manufactuers in supplying affordable vaccines. This could be followed by offering the possibility for bilateral meetings with manufacturers to discuss this issue as well as exchange on strategic orientations as this is already being done with some members of The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). General discussions on the process of technology transfers are taking place under the leadership of the Evidence Information and Research Cluster. IVB has launched a new project on vaccine product, price and procurement V3P). The purpose of the project is to support GAVI graduating and middle income countries to accelerate the introduction of new vaccines through the provision of improved vaccine product and price information for decision-making. It is a 3-year project funded by the BMGF. Country needs assessments and review of experiences on price information sharing mechanisms have been conducted in 2012, a V3P database and capacity building activities are under development in close collaboration with partners to support countries and facilitate dialogue on price transparency and pricing policies. V3P is only one piece of work. Many other initiatives and activities are under way and others should be developed, in a coordinated manner, to make vaccines available and affordable to countries and to support emerging manufacturers to be competitive and innovative.

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Childhood mortality	SAGE noted the recommendation by QUIVER (now 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.	Action	Nov 2010	Ongoing	All models reviewed by IVIR-AC are hampered by the lack of primary data, and more efforts should be made to make such data readily available. Specically, 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.
Cholera vaccines	Oral Cholera Vaccines(OCVs) - SAGE will further consider their use in endemic countries and whether a stockpile should be developed, particularly as current manufacturing capacity is limited.	Action	Apr 2011	Completed	OCV stockpile: A meeting on use of oral cholera vaccines (OCVs) in complex emergencies was held in early May 2011, and also in May 2011 the WHA passed a resolution(64.15) calling for an integrated, comprehensive strategy of cholera prevention and control. In April 2012, a meeting of the WHO Technical Working Group on creation of an oral cholera vaccine stockpile was convened by the Pandemic and Epidemic Diseases Dept (WHO HQ) to develop SOPs for implementation of the OCV stockpile for outbreak response, including definition of specific criteria for deployment of vaccine from the stockpile. An agreement for procurement of 2 million OCV doses for the stockpile was issued in June 2013 (with financial support from EU-ECHO, USAID, USFDA and three private entities) and efforts are ongoing to make Regions and countries aware of the stockpile availability. A GAVI proposal is under consideration (subject to PPC and Board approval) to contribute to the global cholera stockpile for use in epidemic and endemic settings. OCV use in endemic countries: A meeting was held in Feb 2012 to review the experiences of the Zanzibar study on pre-emptive use of OCV (2006-2012) and the Zanzibar Government developed a proposal for island-wide use of OCV in risk groups with the aim to eliminate cholera and to scale up WASH interventions. OCV campaigns for outbreak control were implemented in 2012 in Haiti and Guinea Conakry with positive results in both.
Decade of vaccines/GVAP	IVR was encouraged to contribute actively to the research component of the DoV.	Action	Apr 2011	Ongoing	IVR participates in the Research and Development subgroup, and tracks research issues emerging from delivery group. R&D working group meeting was held on 29 September 2011. Tentative list of research priorities short, mid and long-term was developed. IVR leads on coordinating R&D agenda with partners agencies. A formal memorandum was signed. Progress on establishing a vaccine research forum and implementation strategies in support of GVAP R&D related activities. The Global Vaccines and Immunization Research Forum (GVIRF)to be held on 4-6 March 2014 in Bethesda, MD, will review and discuss progress in the field.
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.	Action	Nov 2012	Ongoing	As part of GVAP resources invested in immunization will be tracked and monitored on a yearly basis throughout the decade, using the System of Health Accounts (SHA 2011) framework, the global standard to report spending in the health sector. The process to monitor resources invested in immunization will put emphasis on strengthening country capacity and creating a single platform for collecting, analyzing and reporting annually on all health expenditures, including those on priority diseases or programmes like immunization. This is intended to unify under a single platform other existing resource-tracking efforts, such as those being undertaken on national health accounts, and those for the Commission on Information and Accountability for Women's and Children's Health, and for the Global Fund to Fight AIDS, Tuberculosis and Malaria. This exercise will not only ensure regular and efficient reporting of good-quality data as part of the monitoring process, but also promote accountability and sustainability for immunization financing.

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Decade of vaccines/GVAP	SAGE requested consideration of the establishment of a SAGE standing working group to monitor GVAP implementation.	Action	Apr 2012	Completed	A SAGE DoV-GVAP standing working group has been established. The group holds monthly teleconferences and met for their first face-to-face meeting from 9-11 September 2013 in Geneva. During this meeting the working group reviewed the indicators related to the GVAP strategic objectives. The group will present the first review of progress on the GVAP implementation at the November 2013 SAGE meeting.
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.	Action	Nov 2012	Ongoing	The DoV SAGE Working Group reviewed the process to collection and reporting of data, the data quality and the formulation of the indicators and have made recommendations that will be presented in their report to SAGE in November 2013. The WG proposes to meet again in February 2014 where they may specifically address the formulation of indicators that they have found problematic in their review of progress and propose reformulation.
Dengue Vaccine	SAGE requested that future recommendations on dengue vaccine safety be linked to the dengue vaccine development strategy.	Action	Apr 2012	Ongoing	
Financing	SAGE identified the need to support countries that become ineligible and lower middle income countries through pooled procurement.	Action	Oct 2009	Ongoing	Various activities are conducted at global and regional level to support non GAVI and Lower Middle Income Countries (LMICs) - At global level: a study to enhance global knowledge and understanding of the challenges that Lower Middle Income Countries face as they explore potential adoption of new vaccines. The study was completed in March 2011. Finding and preliminary conclusions and recommendations were presented to the SAGE in November 2010. At regional level: EMRO is working with MICs in the region to set up a pooled procurement system with the support of UNICEF SD, CDC and PAHO and other partners . Identification of graduating countries and their potential constraints and issues is ongoing with GAVI and UNICEF to define measures and activities to overcome the obstacles and develop transition plans. 2 regional and 6 country assessment were conducted in 2012 on GAVI graduating countries. 4 country assessments and transition plans were conducted in 2013. Despite some progress, the challenges are enormous not only on the financial aspects but also on ownership, decision making, capacity, pricing, regulation and procurement aspects. The establishment of a pooled procurement in EMRO has been decided by the Regional Committee in 2012 and is under development despite the unstable political situation in the region. In November 2012, SAGE reviewed the situation faced by middle income countries including countries graduating from GAVI support and made strong recommendation calling for a global and coordinated effort to support MIC and for the establishment of a task force on Middle Income countries to advocate and support the implementation of the platform discussed at the November 2012 session on MIC. Terms of Reference drafted, potential composition identified and contact with key partners done to set up the SAGE recommended task force and working group. First teleconference to be held by 31 October 2013.

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Financing	SAGE requests that WHO conduct further situation analysis of financial challenges for low or middle-income countries and consultation with countries concerned & partners to distil issues to more actionable activities.	Action	Apr 2008	Ongoing	A Request for Proposal (RFP) has been drafted and submitted to the BMGF for funding. This was accepted, the RFP was issued in March 2009 and selection was made in June 2009. R4D was selected to conduct the study on LMIC to be launched early November 2009. Preliminary results were presented at the GIM and NUVI meeting in 2008 and 2010, findings and initial conclusions and recommendations will be presented to the SAGE in November 2010. Work is now underway to consider ways of addressing the potential obstacles and issues faced by the 20 graduating countries from GAVI support (as of Jan 2014). A Sharepoint on Middle-Income Countries and new vaccine introduction was created by IVB-WHO to facilitate data collection and exchange between the Middle-Income Country working group members. A Middle-Income Country presentation by EMRO during the 2009 WHA took place and was well received - the May 2008 WHA resolution on immunization referred explicitly to Middle-Income Countries. Sessions on Middle-Income Country was held during the NUVI meeting in June 2008 and 2010, an updated background document was discussed and an action plan for 2009-12 was approved with all concerned parties (vaccine industry, country and region representatives, WHO and UNICEF, Gates Foundation, ...). Ongoing discussions are taking place with UNICEF, BMGF and other entities to implement the R4D study recommendations. The GVAP has addressed some of the issues. A brainstorming meeting was organized on the lower-middle-income countries activity information and coordination on 12-13 March 2012 at HQ. On this occasion we discussed concepts, general approaches and specific plans for MIC with the ultimate objective of developing a platform and way forward for engagement and co-ordination with partners. The results of this and other consultations was presented at the November 2012 SAGE. A session was held on Middle-Income countries. The information provided in the paper was complemented by presentations from WHO, the former Yugoslav Republic of Macedonia, and UNICEF. Given the importance of the topic, SAGE requested that this issue and achievements be revisited in a subsequent meeting. A paper entitled "Global Support for New Vaccine Implementation in Middle-Income Countries" was published by Vaccine and shared with SAGE as a WHO contribution to define a common understanding and platform for action to be translated into actions by partners and donors.
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.	Action	Nov 2011	Ongoing	The Global Vaccine Safety Initiative has been launched and will host its second annual meeting in November 2013. The portfolio of activities is now publicly available covering all 8 strategic objectives with priorities endorsed by the Planning Group.

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HIV	SAGE requested regular updates on the progress of HIV-vaccine research.	Action	Apr 2010	Ongoing	In 2010/2011, with an objective of addressing ethical and regulatory challenges for follow up activities after the announcement of the Thai RV144 trial, which demonstrated for the first time moderate 31.2% level of efficacy in preventing HIV infection and following SAGE recommendation on these aspects: WHO/IVR/HVI and UNAIDS implemented the following 2 activities: 1. Development of a new ethics guidance point on ethical involvement of populations with high risk for HIV infection (i.e. people who injecting drugs) through extensive regional consultations held in June 2010 in Istanbul for the Eastern Europe region and Kuala Lumpur for the Asian region. This consultation allowed for the development of recommendations and drafting a new guidance point to be included in the new edition of the WHO/UNAIDS Ethics Guidelines. 2. In support of regulatory frameworks, WHO/IVR/HVI and UNAIDS have initiated a project on the development of policy/discussion paper to facilitate national decision making with regard to the novel strategies for testing HIV vaccines, namely, the recently proposed Adaptive Trail Design). A background working paper was developed and discussed at an expert group meeting co-organized in collaboration with WHO, UNAIDS, IAVI, NIH and the Global HIV Vaccine Enterprise. The expert group meeting took place on 10-11 February 2011 in New York. As an outcome of this meeting a technical discussion paper has been developed targeting the national regulatory authorities in countries where this type of trials are being planned in the coming years. This paper has been submitted to the journal Vaccine for review. In October 2013 a written update was provided to SAGE on the progress of HIV-vaccine research.
Hepatitis A	Long-term protection from single or 2-dose schedules should be regularly monitored by countries and reviewed by SAGE.	Action	Apr 2012	Ongoing	Post-market surveillance continues in Argentina and a detailed report on the 2012 epidemiological situation was provided to WHO. There is still no identified breakthrough case among vaccinated children since the introduction of hepatitis A in the national immunization program in 2005. A slight increase in the number of reported cases in 2012 mostly in those 45 years of age and over may in part be due to a surveillance artifact as surveillance keeps improving and the result of natural (or due to the impact of vaccination) evolution of the risk in those too old to have been vaccinated. These occurring cases indicate that 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. Both health system and societal costs prevented totaled ~US$ 137 million with health systems cost ~US$ 44 million. Based on the Argentinian's experience, in 2012 both Colombia and Paraguay introduced a single dose national immunization schedule for 1 year old children.Yearly review of the Argentina surveillance data will continue.

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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.	Action	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. IPAC reviewed this work in early 2011 and again in April 2012, and endorsed 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 WPRO and now steps are being taken to make HepB birth dose a WHO/UNICEF "best estimate" in line with previous SAGE recommendations. These WHO/UNICEF estimate process was piloted in 2012 in WPRO and will 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 GIVS goals.
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.	Action	Nov 2008	Ongoing	WHO HQ has completed and disseminated a new global viral hepatitis strategy. EMRO is working with Member States to ensure achievement of the Regional Committee goal for HBsAg reduction in vaccinated children. In 2012, WPR TAG endorsed the region's Hepatitis B Expert Resource Panel (ERP) proposal to set 2017 as the target year to achieve the goal of reducing childhood hepatitis B prevalence to <1%, this is being considered as a resolution during the Oct 2013 RCM. SEARO has a draft regional strategy and AFRO has convened a regional hepatitis TAG. EURO will consider a regional hepatitis B control goal. 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) has been published by the department of Immunization, Vaccines and Biologicals.
Hepatitis E	SAGE approved draft ToRs for a Working Group on Hepatitis E and requested that WHO establishes this group in the summer 2013.	Action	Apr 2013	Ongoing	The SAGE Hepatitis E working group has been established. A first teleconference of the working group should take place prior to the SAGE Nov 2013 meeting.
HiB	Update SAGE HiB Vaccine position paper, including recommendations from the April 2013 SAGE meeting.	Action	Apr 2013	Completed	The updated WHO Hib vaccines position paper was published in the 27 September 2013 issue of the WER.
Hib	SAGE recommended that a revised summary of the evidence, including a critical appraisal of the evidence with GRADE tables and justification for proposed recommendations, should be presented to SAGE in April 2013.	Action	Nov 2012	Completed	A revised summary of evidence including all the aspects suggested by SAGE along with the GRADE tables were presented to SAGE in April 2013. SAGE recommended to include Hib vaccination into national immunization programmes using a 2p+1, 3p+0 or 3p+1 dose schedule. These recommendations were reflected in the WHO SAGE position paper which was published on 27 September 2013.

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Immunization safety	SAGE encourages development of simple technological solutions with improved environmental characteristics, and encourages donors to support such work as a priority.	Action	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 to explore vaccine packaging that minimizes the impact on environment. VPPAG has 2 related streams of work 1) Working on recommendations to minimize primary, secondary, and tertiary container packaging. 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 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 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 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 (not recommends) the use of needle cutters but their introduction should come with training of HCWs on their use. An RCT on hub cutters has subsequently been completed in Ghana with WHO collaboration.
Immunization schedules	SAGE endorsed continuing work in the related research areas, with refinement of the research agenda undertaken by the research component of IVB, under the oversight of the research advisory bodies of WHO. SAGE asked to be kept informed of progress and results.	Information	Apr 2007	Completed	Work in progress. Presentation of the PCV evidence was done at the SAGE November2011 meeting resulting in the updating of the pneumococcal conjugate vaccines position paper in April 2012. Evidence on rotavirus vaccines was presented at the April 2012 meeting and the updated rotavirus position paper will be published in January 2013. Evidence on Hib was presented at the November 2012 meeting. During the discussion, SAGE members noted that the evidence on the number of primary doses and the need for booster doses requires further evaluation before recommendations can be made on optimizing the current schedule. Hib was revised during the SAGE April 2013 meeting. Revision was completed for the vaccines listed above. Revised position papers were developed using this information.

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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.	Action	Nov 2010	Ongoing	PCV: evidence was reviewed by SAGE on November 2011. New recommendation on schedules 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 will be published in February 2013. Hib: No resources for model and/or ICEA. Evidence review is being completed; an ad hoc consultation will be held in September 2012 and outcomes were proposed for SAGE consideration at the November 2012 meeting. During the discussion, SAGE members noted that the evidence on the number of primary doses and the need for booster doses requires further evaluation before recommendations can be made on optimizing the current schedule. The issue will be 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 DTP, TT and Hep B will likely be presented to SAGE in April 2014
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 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.	Action	Apr 2010	Ongoing	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 LSHTM in 2011-12 to gather further information. Final results will be 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 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 2013.
Impact of the introduction of new vaccines on immunization and health systems	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.	Action	Apr 2010	Ongoing	The ad hoc working group included a broad range of partner agencies (WHO, UNICEF, WB, CDC, PATH, JSI, LSHTM, JHU) and has sought endorsement of this work at senior levels of partner agencies. The revised Vaccine Introduction Guidelines to be published in 2013 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.
Influenza	SAGE recommends WHO continue urgent development of H5N1 stockpile. Further SAGE noted that WHO needs, concurrently with the acquisition of a stockpile, to develop the operational guidelines that would govern the management and release of the stockpiled H5N1 influenza vaccine, and to define appropriate methods for monitoring its use and evaluating outcomes. SAGE further recommended a feasibility study on the management and use of the stockpile.	Action	Nov 2010	Ongoing	This project is being taken forward by the SAGE influenza working group for influenza vaccines and immunization. Discussions are ongoing and continued during the last 3 face to face meetings. During the 2nd meeting in February, 2011, the WG favored the option of keeping the stockpile mainly as a virtual stockpile with a small physical stockpile of filled and finished doses of H5N1 vaccine for rapid response and outbreak control in case of need. WHO should ensure that it has procedures in place to facilitate the deployment of pandemic vaccine to countries in need of support. Lessons learned from the deployment of the H1N1 pandemic vaccine in 2009 and 2010 are used to develop guidance and procedures for future vaccine deployment activities. Guidance document and associated work plans are available in all UN languages from: http://www.who.int/influenza_vaccines_plan/resources/deployment/en/index.html. WHO H5N1 stockpile is also being discussed in the Pandemic Influenza Preparedness (PIP) framework. Further discussion by the SAGE working group for influenza vaccine on the stock and the the PIP framework took place. The working group will report to SAGE at the November 2013 meeting.

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Influenza	SAGE recommended that the Influenza Vaccines and Immunization Working Group develop a research agenda.	Action	Nov 2010	Ongoing	The Global Influenza Programme (GIP) presented their development of a WHO Public Health Research Agenda for Influenza (PHRAI) in the August 2011 SAGE WGIVI meeting. The WG acknowledged the extensive coverage of influenza research topics in the PHRAI and activities of the SAGE WGIVI can serve as one avenue to inform the RA. One area that may need further development is on vaccine communication and risk communication issues. It is recognized that communication is population-specific and how generalizable are the research work in this area would be an important topic to address. SAGE WGIVI also suggested that experiences from industry on the information gathered from countries on impact and lessons learned in view of research activities to inform the PHRAI. The importance of evidence-based recommendations was stressed and the PHRAI would be an important tool. There is also a need to identify more detailed research needs for influenza vaccines and the SAGE WGIVI encourages close collaboration with the PHRAI in addressing this need. In January 2013 WHO held a consultation on influenza vaccines in clinical trials, and on the development of broad-spectrum influenza vaccines. A closed session was held to discuss a research agenda. The conclusions are currently under review and should be published in due course.
Influenza	SAGE requested that WHO report on epidemiology and surveillance of H7N9 as well as on the development of a potential vaccine candidate.	Action	Apr 2013	Ongoing	1/10/2013-There is no sustained human to human transmission of H7N9 so far. It is still considered as a zoonotic disease. The situation might change in Autumn whith colder weather conditions and more virus circulation in poultry and human populations. The selection of the vaccine virus has been updated in September 2013. An update will be provided to SAGE at the November 2013 meeting as part of the pandemic influenza session.
Japanese encephalitis	Commercial kits for detection of JE-specific IgM should be compared and validated. Valuable experience had been gained from linking surveillance of encephalitis to detection of acute flaccid paralysis.	Action	Apr 2006	Ongoing	Assessment using serum carried out by PATH, published Am J Trop Med Hyg July 07. Field validation of serum and CSF in India and Bangladesh assessed in a joint WHO/CDC meeting, SEARO, February 2008. Nepal and Cambodia field evaluation of JE assays is complete and paper submitted to JID. Assessment of kits using CSFs accepted for publication in Am J Trop Med Hyg. CDC Fort Collins will distribute the 3rd serum and CSF proficiency test panel to evaluate in-house and commercial JE ELISA assays to WPRO JE labs 4ht quarter 2012. The three WPR JE regional reference labs (Japan, China and Republic of Korea) held their annual coordination meeting, Chengdu, China, 2nd quarter 2012. China CDC JE regional reference Lab was fully accredited by WPR and HQ Lab Coordinators, August 2012. A WPR JE labnet meeting too place on 15 March 2013 and a Regional JE workshop for WPR is planned 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 Western Pacific Region at the Victorian Infectious Diseases Reference Laboratory, Melbourne, has been fully accredited in Oct 2013. The Global Specialized Reference Laboratory for JE at the National Institute of Infectious Diseases, Tokyo, has also been fully accredited in Oct 2013. The currently used diagnostic assay produced by PanBio will cease production by 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.

Topic	Recommendations/Action item	Category	Meeting Date	Status	Comments and Follow up
Japanese encephalitis	Interference with the immune response to other vaccinations, number of doses required and the duration of protection need to be assessed.	Action	Apr 2006	Ongoing	Some studies are being initiated by PATH, and planned by Governments considering introduction of the vaccine. Issue of interference with measles vaccination discussed at the December 2007 GACVS meeting. Measles co-administration (S Gatchalian, Vaccine 2008) had to be redone due to assay inconsistencies - results still pending. Number of doses required (one or two doses for primary immunization with live JE vaccine) has been assessed through case control studies in Nepal and India (the Nepal study is published and India study published as a note to the editor, 2 April 2009 in NEJM). A comprehensive review of the vaccine performance is planned in conjunction with an update of the JE position paper from 2006.
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.	Action	Nov 2008	Ongoing	Planning and fundraising efforts are ongoing in the Regions. Control goals have currently not been formulated. A literature review on the JE burden of disease has been conducted, estimating the burden of JE to some 67,000 clinical cases and a CFR of above 20%. This was Published in the Bulletin of WHO, Bull World Health Organ 2011;89:766–774. Identification of target populations are being discussed in the context of country control strategies, and a review has been conducted at the 2011 biregional JE meeting. An update of the JE position paper (from 2006) is being initiated that will comprise a review of immunization strategies; a SAGE working group is being established. WHO also works with GAVI secretariat in preparing the opening of JE window, as a suitable JE vaccine has been WHO-prequalified.

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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.	Action	Nov 2010	Ongoing	Establishing a partnership among all relevant stakeholders to support middle income countries is our aim and has been clearly recommended by SAGE in 2011 and 2012. WHO has already started consulting with agencies, projects and initiative to explore what are the possibilities to collaborate and support middle income countries with procuring and financing vaccines and immunizations. This is the case with UNICEF, PAHO, SIVAC, OPTIMIZE, PROVAC and others. We have also consulted with the Bill and Melinda Gates Foundation (BMGF) on their concerns and plans. They showed a great interest and are trying. to identify the best approaches to support this objective. We have organized in January 2011 a successful brainstorming meeting on vaccine price and vaccine pricing focusing on issues faced by GAVI graduating and middle income countries. A proposal was submitted and is now funded by the BMGF on vaccine product, price and procurement (V3P project). This is a 3-year project aiming to identify, develop and establish the most appropriate and comprehensive method(s), mechanism(s) and/or tools to provide countries with accurate, reliable and useful data on vaccine product, price and procurement. This project has achieved its phase one (assessment if country needs and lessons learnt from other health sector) and is now starting its phase two (V3P tool development and roll out, testing with countries and capacity building activities). In parallel we have raised the LMIC issue within the Decade of Vaccines collaboration, it has been considered as one the priority of the decade of vaccines and is now reflected in the Global Vaccine Action Plan.(GVAP). Multiple consultations took place on GAVI graduating and middle-income countries activities and issues. The results of this consultative process were presented at the November 2012 SAGE. SAGE appreciated the efforts made by WHO, UNICEF and GAVI and other partners to extend discussions about vaccine supply and pricing to MICs where appropriate, and the adaptation of some activities to suit MIC-specific needs. However, 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 technical assistance and capacity building could be significantly strengthened. SAGE requested that this issue and achievements be revisited in a subsequent meeting and that a Task force is establish by WHO to coordinate policies and efforts of partners. At regional level, EMRO is working to launch by the end of 2013 the EMR Initiative on pooled procurement and to contribute to the UNICEF SD initiative on MIC and new vaccines. The political and general situation in Middle-East might delay concrete actions in that domain. This question will be discussed during the 2013 EMRO regional Committee meeting.
Lower middle-income countries: sustainable adoption and financing for new vaccines	SAGE noted that the lack of access to life-saving vaccines in MICs has not significantly improved since this was first raised in 2008 and that rapid action is now required. SAGE requested that this issue and achievements be revisited in a subsequent meeting.	Action	Nov 2012	Ongoing	Various initiatives are underway to facilitate access to new vaccines in middle income countries: UNICEF SD is consulting with Vaccine Industry and with countries to supply PCV, RV and HPV to middle income countries and to set up a ceiling price. The regional Committee of EMR has decided to establish a pooled vaccine procurement to support introduction of priority vaccines in middle income countries and to collaborate with UNICEF SD on its MIC initiative. GAVI PPC requested in October 2013 the Secretariat “to conduct analyses and consultations to develop and propose instruments to support access to affordable prices for all Lower Middle Income Countries (LMICs), including graduated countries and non-GAVI LMICs. Options would be brought to the Board for consideration in 2014” Concrete options, actions and results are still to be seen. Coordinated effort, consistent policy and financial support are needed to translate those initiatives into reality for middle income countries.

Topic	Recommendations/Action item	Category	Meeting Date	Status	Comments and Follow up
Lower middle-income countries: sustainable adoption and financing for new vaccines	SAGE recommended, as a priority, the creation of a task force convened by WHO as a mechanism for inclusive stakeholder engagement and forum for harmonization and implementation of projects and activities.	Action	Nov 2012	Ongoing	Terms of Reference drafted, potential composition identified and contact with key partners done to set up the SAGE recommended task force and working group. First teleconference to be held by 31 October.
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.	Action	Apr 2013	Ongoing	Development of malaria vaccine PPCs is underway and scheduled for finalization by end 2014.
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.	Action	Oct 2009	Ongoing	The timing for the "Decision" session depends on the outcome of the regulatory process. EMA is expected to make a regulatory decision in May 2015. If those timelines remain unchanged, a SAGE/MPAC (Malaria Policy Advisory Committee) joint session is expected in Oct 2015. The third set of results from the Phase 3 trial of RTS,S/AS01 is to be made publicly available on 8 Oct 2013. These results include site-specific efficacy and 18 month follow-up in both the 5-17 month age group and 6-14 week age group. SAGE members are to receive a 2 page briefing on 8 Oct 2013. JTEG met to review the new results on 19-20 Sep. Their assessment is that the booster dose results, expected in 2014, are critical. Depending on these booster results, JTEG may propose recommendations for use in the 5-17 month age range. It is considered unlikely that JTEG will propose recommendations for use in the 6-14 week age range given the new results, unless booster dose results in this age group give higher efficacy than after the primary immunization series. Any recommendation for use in the 5-17 month age range would require at least 2 new immunization visits. One possible schedule is 6 months (with vitamin A), 7-8 months (new visit) and 9 months (with measles first dose). JTEG considered that the data on co-administration with measles first dose is acceptable. Further exploration of possible schedules is underway. The first regulatory submission will be to the European Medicines Agency under the article 58 procedure. The first wave of 5 national regulatory submissions will be to Kenya, Tanzania, Ghana, Senegal and Burkina Faso, where Phase 4 studies of safety and effectiveness are planned.
Measles and rubella	SAGE requested that the measles and rubella working groups should merge and monitor progress, oversee the research agenda required for eradication and report back to SAGE regularly. The working group should liaise with QUIVER and IPAC to address relevant quantitative issues as well as those related to immunization practices. This activity has been included in the draft terms of reference for the combined measles and rubella working group.	Action	Nov 2010	Completed	The working group on measles and rubella was formed in late 2011. The terms of reference of the working group include overseeing the research agenda and liaising with other advisory groups. Peter Figueroa is the chair of the working group and as of 15 October 2013, the group has held conference calls approximately once a month as well as four face-to-face meetings. The working group will be providing an update to SAGE at its upcoming November 2013 meeting.

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Non-specific effects of vaccines	SAGE supported the two proposed literature reviews that include documentation of the current and proposed studies in the field. SAGE insisted that the reviewers should make efforted to include all available evidence and access all relevant data sets.	Action	Apr 2013	Ongoing	Working group constituted and functional. The two reviews are ongoing. The results will likely be presented to SAGE in April 2014.
Optimizing immunization schedules	SAGE recommended that WHO provide support to country-level policy-makers on the rational use of analyses generated by the tool.	Action	Nov 2010	Completed	We have approached SIVAC to collaborate in one African country as a case study (initially Cote d'Ivoire now considering Mozambique). After consulation with AFRO colleagues and, bearing in mind that the NITAGs have been only recently constituted, this activity has been postponed and no new date has been set yet. DRAFT of website tool was presented to NUVI meeting participants in June 2013. It was well received and appreciated.
Pertussis control	SAGE endorsed the establishment of a pertussis-vaccine strain repository and a database on the genealogy and characteristics of different vaccine strains. A proposal should be presented to the Expert Committee on Biological Standardization.	Action	Apr 2010	Ongoing	The initial offer of the pertussis strains made by Dr Nicole Guiso from the Institut Pasteur was not presented to the ECBS in 2010 due to the lack of information regarding the use of the strains and the related data. Discussions took place within the Institut Pasteur and their legal department advised that as strains had been received under specific contract from the vaccine manufacturers they could not be shared. They will however provide a list of strains received so that WHO can request permission directly from the vaccine manufacturers themselves for the strains to be used for research purpose in case of need and for the genetic filiation of the strains to be publicly released.
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.	Action	Apr 2013	Ongoing	The 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 is finalizing its workplan. One of the major activities within the workplan will be 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 will begin in early 2014 and continue through the rest of the year. The consultation will include plans for soliciting contributions from communities and front-line health workers' on their experiences of polio eradication.
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 OPV2 withdrawal and introduction of IPV.	Action	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 withdrawal and IPV introduction. The multi partner group has been operating wince mid-April in five areas of work : Regulatory, vaccine implementation, communication, financing and routine immunization strengthening. An update to SAGE will be provided at the next meeting. WHO/EPI is recruiting an additional 4 professional staff positions at HQ to contribute to this effort. Similar positions will also be supported at Regional levels, and at key partner organizations such as UNICEF and US-CDC.
Polio	SAGE recommended working closely with countries on activities towards OPV2 withdrawal.	Action	Apr 2013	Ongoing	Regional offices are working with countries to develop timelines. Timelines vary by region, with WPR requesting all plans by end of 2013, and others to follow. In addition, now that regional consultation committees have given their approval, are in the process of developing a TA strategy for OPV2 cessation and IPV introduction. This work will be supported and coordinated through the IMG and directed by Regional Offices .
Polio	SAGE encouraged a technical briefing on key OPV2 withdrawal issues at the WHA 2014, in advance of a potential WHA resolution in 2015 on a target date for the withdrawal of OPV2 from all routine immunization programmes globally.	Action	Apr 2013	Ongoing	After the careful review of the a comprehensive plan for the implementation of IPV introduction, developed by the collaboration between WHO, GAVI, and partners, the WG now encourages a WHA resolution in 2014 on accelerated IPV introduction due to the tight timelines for global IPV introduction

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Polio	SAGE will review suggested IPV schedules, a draft type 2 virus response protocol for the period after OPV2 cessation, and a draft IPV supply and financing strategy, at the next meeting in November 2013. SAGE requested to develop more detailed workplans for each of the main workstreams on critical OPV2 withdrawal pre-requisites, and the preparation of contingency plans for responding to possible delays or other problems.	Action	Apr 2013	Ongoing	The WG has been closely following the progress made on the planning for IPV introduction into the routine immunization schedule and OPV2 cessation in detail, including two face to face meetings (June and October). The WG will provide its key findings and recommendations at the next meeting in November 2013.
Polio eradication	SAGE requested that WHO/GPEI undertake further consultation with countries and regions to document the policy and programmatic implications of introducing an IPV dose (whether IM or ID) as part of the strategy to switch from tOPV to bOPV and to facilitate individual country decision-making.	Action	Apr 2012	Completed	A review of operational differences between using IPV as a full dose (IM) vs. application as fractional dose (ID), comparing differences relating to service delivery, cold chain and logistics, management, training, supervision, and cost. The assessment included detailed interviews with EPI managers from Asia (India), and Africa (one West and one East African country). Results of this investigation were reported to the SAGE Polio Working Group, and at the October 2 meeting of the Immunization Practices Advisory Committee (IPAC). Special sessions on the 'polio endgame', focusing in particular on the plans for OPV2 cessation (i.e. the switch from tOPV to bOPV for routine immunization) have been conducted at the EMRO EPI manager's meeting (September 2012) and are planned for the 4th quarter of 2012 at the regional EPI meetings in the South-East Asian and African Regions. During the November 2012 meeting, SAGE recommended that all countries should introduce at least 1 dose of IPV in their routine immunization programme to mitigate the risks associated with the withdrawal of OPV2.Over the next two years, the focus will be on introducing one IM IPV dose in addition to OPV. Many counties, and the African region as a whole, have indicated they will not consider an ID dose of IPV at this time. In addition, work will continue at the individual country level to support planning for IPV introduction and the switch to bOPV.
Polio eradication	SAGE recommended that WHO/GPEI work with vaccine manufacturers to develop both options and with regulatory authorities to initiate fast track review of ID IPV immediately, to ensure that a low-cost IPV option is available within a year.	Action	Apr 2012	Ongoing	On 26 July 2013, WHO convened a meeting with representatives from National Regulatory Authorities from countries that are experienced in the regulation of polio vaccine products. The overall objective of the meeting was to seek guidance and input from these representatives regarding different products, including intradermally administrated IPV. At the end of the consultation, the representatives from a few NRAs agreed on the design of the trial, which would meet the regulatory needs for a label change.The protocol was developed, and cleared by relevant NRAs and IPV suppliers. The study is expected to start early 2014.
Polio eradication	SAGE encouraged WHO to specifically assess how existing international mechanisms could be used to strengthen and implement vaccination recommendations for travellers entering and leaving polio-infected countries and areas and, for areas of uncontrolled transmission, to consider travel advisories.	Action	Nov 2011	Ongoing	WHO continues to assess the feasibility of using international mechanisms to implement such vaccination requirements and travel advisories. It is currently envisioned, that such measures (e.g. an IHR standing recommendation on vaccination of travelers) would be considered for any area with continuing poliovirus transmission at end-2014. Additionally, as in previous years, WHO has updated its International Travel and Health publication, providing vaccination recommendations to travellers based on the most up-to-date global polio epidemiology.

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Polio eradication	SAGE recommended that an IPV supply and funding strategy be established for timely introduction of IPV using existing whole dose products for a transition period if needed. For its next meeting SAGE requested additional details on the scientific evidence for, and programmatic implications of, targetng expanded age groups during polio campaigns in endemic areas.	Action	Nov 2012	Ongoing	Work focusing on the establishment of the required IPV supply and funding strategy with stakeholders and with GAVI has continued to allow the introduction of whole-dose IPV in time before the planned cessation of OPV2. The polio session during the November 2013 SAGE meeting will also include an update on the global IPV supply, financing and introduction strategy by the GPEI Immunization Systems Management Group.
Polio eradication	SAGE strongly encouraged the Global polio Eradication Initiative (GPEI) to proceed with its full IPV research agenda, in particular to clarify the duration and quality of the priming immune response to inform the work of the SAGE IPV working group.	Action	Apr 2011	Ongoing	The WHO polio eradication research team is coordinating additional research in this area, including further analysis of Cuba study data (e.g., titre of neutralizing Ab after one and two doses of IPV), and potential collaboration with the International Vaccine Institute (IVI), Korea, to measure mucosal and systemic antibody-secreting cell (ASC) responses against polio vaccines in young infants after one and two doses of IPV. The data have been shared on multiple occasions both with the SAGE WG, and the full SAGE. In addition, a manuscript has been published that summarizes these data from Cuba. (Resik S et al. Priming after a fractional dose of inactivated poliovirus vaccine. NEJM.2013;368:416-24).
Polio eradication	SAGE recommended that tight deadlines should be set for the completion of each step required to implement the switch from tOPV to bOPV. Similarly, urgent plans must be in place for the development of a low-cost IPV, and for its introduction by countries which choose to adopt this strategy. For countries planning to introduce IPV, including the low-cost IPV option, similar planning must take place.	Action	Apr 2012	Completed	Discussions among the GPEI partners, and activities of the SAGE Polio Working Group have continued since the November 2012 SAGE meeting to further refine the definition and timeline for the programme of work on the six main pre-requisites that need to be in place before the withdrawal of OPV2 (i.e. replacement of tOPV by bOPV for routine immunization) can be considered. As requested by SAGE, the considerably expanded work-streams on the OPV2 withdrawal pre-requisites - including lab containment of polioviruses, introduction and uptake of affordable IPV, IPV and bOPV product development and licensing, and MOPV2 stockpile and outbreak response, and anticipated time-lines within the polio endgame - will be presented at the April 2013 SAGE meeting.
Polio eradication	SAGE requested that WHO/GPEI draft a ‘GPEI Strategic Plan/Budget for 2013-2018’ by November 2012 that incorporates OPV2 cessation and eventual bOPV cessation, with different scenarios for the timing of IPV introduction for the period of the tOPV/bOPV switch and longer term IPV uptake following complete OPV cessation.	Action	Apr 2012	Completed	Following this request from SAGE and a similar recommendation from the GPEIs Independent Monitoring Board (IMB), a Strategic Plan for the Polio Endgame and Legacy Options 2014 to 2018 has been drafted. This document was developed in close consultation with GPEI spearheading partners and other initiatives (i.e. GAVI), as well as with WHO Regional Offices; the SAGE Polio Working Group also reviewed the draft and provided comments. The document has three main sections: a) the endgame strategic plan, including the eradication of polio and management of associated risk, b) the financial requirements 2014 to 2018 (i.e. a 2014 to 2018 indicative budget), and c)the legacy, i.e. to define the broader global health benefits of the global polio programme. In November 2012, SAGE welcomed the long-term vision of the draft GPEI Polio Eradication and Endgame Plan, 2013-2018 and endorsed the 4 major components.

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Polio eradication	SAGE recommended that WHO/GPEI continue to work with GAVI to ensure financing is available within 18 months for any GAVI-eligible countries wanting to introduce a low-cost IPV option as part of the switch strategy.	Action	Apr 2012	Ongoing	Since mid-April 2013, GAVI and GPEI have been working together through the Immunization Systems Management Group (IMG), utilizing their complementary strengths to ensure that the IPV introduction as well as existing vaccine introduction plans for other vaccines-- including those supported by GAVI-- can be achieved. The IMG's work has also focused on the broader objective 2 of the Endgame strategy and includes opportunities to strengthen routine immunisation services, through the use of polio human resources and through greater coordination between polio, GAVI and routine immunisation programmes. The IMG has created a financing sub-group to facilitate discussions on IPV financing across partners. The group has developed a joint budget for IPV introduction for 2014-2018; both GAVI and GPEI core partners are members of the group. In addition to developing the budget, the group has aligned costing and funding flow allocation mechansims to ensure the most efficient systems are used, and support is available to both GAVI and non-GAVI countries. GAVI has further been working on developing policies and processes around IPV introduction, with input from the IMG, to streamline and fast track the application and approval process for IPV funding in order to align with the endgame targets.
Reports from other advisory committees	SAGE recommended appointment of appropriate programmatic and implementation expertise to QUIVER's membership including representation of experts from low and middle-income countries.	Action	Nov 2011	Ongoing	The new QUIVER AC called Immunization and Vaccines related Implementation Research (IVIR) advisory committee has been expanded to 15 members with programmatic and implementation research expertise. It remains a challenge to include representatives from low and middle-income countries. Four of the five new members nominated are from LMICs with expertise in vaccine implementation issues and vaccine trials. Recruitment of new IVIR 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.	Action	Nov 2006	Pending	A comprehensive review of the work of the 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.
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.	Action	Apr 2012	Ongoing	Discussions with donors has advanced well and planning for meeting on new vaccine technologies being initiated. Further work on the report is still pending. Internal QSS-EPI discussions are in progress.
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.	Action	Nov 2011	Ongoing	Written update to SAGE was provided ahead of the November 2013 SAGE meeting.

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Typhoid	Need for advocacy and prioritization at international level. To include prioritizing WHO's prequalification for new-generation typhoid vaccines and the need for international financing mechanisms.	Action	Nov 2007	Ongoing	A 3-year grant from the Bill and Melinda Gates to the Coalition against Typhoid (CaT) and Sabin Vaccine Institute ends in 2013 and an application has been initiated to seek a supplementary grant to 2016. CaT, WHO and other partners continue to implement and support typhoid control and prevention activities, including immunization as well as water, sanitation and hygiene (WASH) strategies. The International Conference on Typhoid Fever and Other Invasive Salmonelloses held 1-2 March 2013 in Dhaka served as testament to increased advocacy and prioritization efforts. As previously reported to SAGE, WHO pre-qualified the sanofi pasteur Vi polysaccharide vaccine in June 2011, the first typhoid vaccine to be WHO prequalified. However Vi polysaccharide vaccine uptake has remained low for multiple reasons including lack of funding. In November 2011 the GAVI Board re stated its 2008 commitment to typhoid conjugate vaccines in the GAVI Vaccine Investment Strategy; it is expected that a typhoid vaccine support window will be opened when a WHO prequalified conjugate typhoid vaccine is available. Currently it is not expected that the first WHO pre-qualification of a typhoid conjugate vaccine will be before 2015. WHO guidelines on the quality, safety and efficacy of typhoid conjugate vaccines are scheduled to be presented to the ECBS in Oct 2013 for approval.
Typhoid	Need for feedback from WHO's regional offices and countries to determine how countries could implement SAGE recommendations.	Action	Nov 2007	Completed	A full report was presented to the November 2010 meeting of SAGE. SAGE reiterated that countries should consider introduction of existing typhoid vaccines and not necessarily wait for surveillance systems to be in place. Further, to take the typhoid agenda forward, the Bill and Melinda Gates Foundation awarded a three year grant to the Sabin Vaccine Institute, Washington DC,to coordinate the relevant stakeholders and to develop a global agenda for the control and prevention of typhoid fever. WHO is working closely with Sabin in this process. Typhoid vaccine is one of the 7 vaccines listed by GAVI as priority vaccines for support and a case for typhoid vaccine support was presented to the GAVI Board at its November 2011 meeting. The Board issued a clear statement that GAVI will not support the Vi-polysaccharide vaccine and will wait for a conjugate vaccine to be available. Given this decision, there was no donor funding to support ViPS typhoid vaccine use. Since 2012, typhoid activities by WHO and key partners have focused on activities to support the development, licensure and introduction of conjugate vaccines and strengthening surveillance in countries to generate better data on typhoid burden. Preparations are under way to define the appropriate pathway for a future SAGE session to consider recommendations for the use of typhoid conjugate vaccines.
Un/under-immunized children	SAGE requested that WHO quickly roll out tools so that other countries can address low coverage of vaccination.	Action	Nov 2010	Ongoing	A set of one diagnostic tool and 6 in-depth tools had been envisaged. The basic tool (diagnostic tool) has been developed at HQ. The EURO, AMRO/PAHO and AFRO regional offices and HQ of WHO; UNICEF; and MCHIP are working on developing the 6 in-depth tools to address different facets of the problem. The in-depth tool "A Guide to Tailoring Immunization Programmes (TIP) has already been developed by WHO-EURO and is available at http://www.euro.who.int/__data/assets/pdf_file/0003/187347/The-Guide-to-Tailoring-Immunization-Programmes-TIP.pdf
Un/under-immunized children	SAGE recommended that WHO prioritize the ongoing work on the development of the framework to guide countries in identifying determinants of low immunization coverage and institute corresponding local solutions.	Action	Apr 2011	Completed	A basic tool to identify the broad determinants of low immunization coverage has been developed. This tool then points to the use of one or more of 6 in-depth tools which will go into the depths of a particular issue flagged by the basic tool. The work has been prioritized. Parallel streams of work in EURO, AMRO, AFRO, UNICEF and other partners are going on to develop the in-depth tools to address different facets of the problem. The work on the TIP (tailoring immunization programmes) tool done by EURO is complete and the tool is available on the web at http://www.euro.who.int/__data/assets/pdf_file/0003/187347/The-Guide-to-Tailoring-Immunization-Programmes-TIP.pdf

Topic	Recommendations/Action item	Category	Meeting Date	Status	Comments and Follow up
Un/under-immunized children	SAGE recommended that the targeted approaches undertaken by Tanzania and Ethiopia to reduce to number of un/under-immunized children should be appropriately adapted for use in other countries.	Action	Apr 2011	Ongoing	The targeted approaches undertaken by Tanzania and Ethiopia to reduce to number of un/under-immunized children were presented to SAGE in October 2009. The lessons that could be drawn from these two country examples were used to draft the basic tool to identify which of 6 problem areas applied to an area. The 6 problem areas will be tackled through 6 in-depth tools, each focusing on one problem area. The work on the TIP (tailoring immunization programmes) tool done by EURO is complete and the tool is available on the web at http://www.euro.who.int/__data/assets/pdf_file/0003/187347/The-Guide-to-Tailoring-Immunization-Programmes-TIP.pdf
Vaccination in humanitarian emergencies	SAGE emphasized the value of piloting the framework in the setting of new emergencies if an opportunity is presented in the next 6 months, and retrospectively against recent emergencies including those described in the case studies. Ongoing collaboration with key stakeholders including regional offices and operational agencies should be arranged through the WHO Department of Emergency Risk Management and Humanitarian Response and the global health cluster.	Action	Apr 2012	Completed	Pilot testing ongoing in the Horn of Africa (completed); Pakistan; and South Sudan
Vaccination in humanitarian emergencies	SAGE also suggested that the framework approach to vaccine decision-making could be considered for other health interventions in emergencies.	Action	Apr 2012	Ongoing	The Emergency Risk Management and Humanitarian Response (ERM) Department will be reviewing the framework approach for other health interventions in emergencies with Global Health Cluster partners and other WHO technical departments after relevant staff return after the summer break and a new Technical Officer joins the team in September.
Vaccine Hesitancy	SAGE suggested that the definition include “when uptake of a vaccine or immunization programme in a community is lower than would be expected in the context of information given and services available”.	Action	Apr 2013	Ongoing	The Working Group reworded the definition of vaccine hesitancy taking into account the proposed wording by SAGE: "Vaccine hesitancy is an emerging term in the discourse on determinants of vaccine acceptance where uptake of a vaccine or immunization program in a community is lower than would be expected in the context of information given and services available. Vaccine hesitancy recognizes that issues of complacency, convenience and/ or confidence in vaccine(s) or immunization programs may all contribute to the delay or refusal of one, some or almost all vaccines. These factors which influence vaccine acceptance vary by setting and responses need to be locally assessed."
Vaccine Hesitancy	SAGE recommended close linkages and interaction with key WHO and UNICEF initiatives to address the unvaccinated or under-vaccinated groups and relevant interventions.	Action	Apr 2013	Ongoing	Close collaboration with partners, initiatives and key stakeholders in the field of vaccine hesitancy is sought. During the Working Groups monthly teleconferences partners are invited to present their work (eg UNICEF on their polio-related work) and link with the Working Group directly.
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.	Action	Nov 2012	Ongoing	Discussions have been initiated with UNICEF Supplies Division, and UNICEF Programme Division to work on global vaccine supply issues. A meeting was held in Copenhagen on 20 Feb to solidify the workplan, and work started in 2012 to combine WHO and UNICEF databases on vaccine forecasting, supply and distribution in countries is ongoing. It was agreed to have a joint discussion on DTP, HepB mono and TT/Td supply in Q2 2013. Several monthly updating teleconferences have been held subsequently. WHO also took part in the global forecasting discussions on 28 September 2013.

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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.	Action	Nov 2011	Ongoing	To improve the precision and usefulness of survey results and to reduce the cost of surveys, 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 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 will provide 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. A second meeting is scheduled for November 2013.
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 agenda.	Action	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 coverage	WHO to identify appropriate methods and develop guidelines for collecting, analysing, and interpreting biomarkers for validating coverage.	Action	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 was 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.

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Vaccine preventable disease 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 also noted that country ownership should be enhanced and that Ministries of Health should be encouraged to increase their own funding for surveillance. SAGE appealed for sustained financial support to ensure quality for sentinel site surveillance. SAGE underscored the importance of ensuring the representativeness of sentinel sites.	Action	Nov 2011	Ongoing	During 2013, a strategic review of the invasive bacterial vaccine preventable diseases (IB-VPD) and rotavirus surveillance networks was undertaken by WHO and its informal Technical Advisory Group for new vaccines surveillance. SAGE's advice on the findings, results and conclusions from the strategic review will be sought during the November SAGE meeting.
Vaccine safety	SAGE highlighted the urgent need for a safety review of other important vaccines that could be used during pregnancy.	Action	Nov 2012	Ongoing	A sub-group of GACVS has been launched to address vaccine safety during pregnancy. A finalized version of the GACVS report on safety of immunization during pregnacy was published and will be made available to SAGE ahead of the November 2013 meeting. A more systematic review has been piloted for Rubella and is expected to become available in summer 2014.
Vaccines during humanitarian emergencies will be discussed at a forthcoming SAGE meeting.	The use of vaccines during humanitarian emergencies will be discussed at a forthcoming SAGE meeting.	Action	Nov 2010	Completed	A SAGE Working Group on vaccination in humanitarian emergencies was established in June 2011. Multiple teleconferences were held and two face-to-face meeting of the working group took place on 20-21 September 2011 and on 16-17 February 2012. The group reported to SAGE in April and November 2012. In November 2012, SAGE endorsed the complete framework for decision making on the use of vaccinations in humanitarian emergencies as a major step forward and considers that it fills an existing gap but acknowledged that the framework focuses on vaccination, which is only one priority consideration in humanitarian emergencies. SAGE strongly affirmed the potential utility of this framework and recommended pilot testing in the field. The working group was asked to adapt the document to take into consideration SAGE's comments and proceeds with its finalization, hopefully prior to the April 2013 SAGE meeting.Consideration was given to the potential inclusion of case studies in the documents but this was debated, as disasters are very diverse. It was left to the working group to decide whether these should be included. The working group has since then finalized the framework which following final editing has been published.
Yellow Fever	Update of the Yellow Fever Vaccine position paper, including recommendations from the April 2013 SAGE meeting.	Action	Apr 2013	Completed	The updated Yellow Fever Vaccine position paper reflecting the new SAGE recommendations was published in the WER on 5 July 2013
Yellow Fever	SAGE requested WHO to revisit the IHR provisions relating to the period of validity for international certificates for vaccination against YF.	Action	Apr 2013	Ongoing	Guidance for States Parties on incorporating the SAGE conclusion into their practices regarding certificates for vaccination against YF is in preparation, as are different options for addressing related IHR processes.