SAGE TRACKING RECORD OF RECOMMENDATIONS AND ACTION POINTS

Topic	Recommendations/Action item	Category	Meeting Date	Status	Comments and Follow up
General	SAGE requested that cold chain and vaccine management, thiomersal and the non-specific effects of vaccines also be discussed by SAGE in the future.	Agenda item	Nov 2011	Pending/Ongoing	A specific session on 'Thiomersal: alternative preservatives and presentations' has been sloted in the April 2012 SAGE meeting. Other agenda items have been added on the master list of items to be discussed by SAGE and will be ready for discussion in the next 2 years.
General	SAGE recommended that new approaches, such as periodic intensification of routine immunization, be carefully evaluated prospectively to determine their effectiveness and cost-effectiveness.	Action	Apr 2009	Ongoing	Work with Immunization Basics to document country experiences is wrapping up. Mission to observe Zimbabwe Child Health Days which included routine catch up doses was undertaken in June 2009. Final report available (17 June 2010). Mission to Macedonia was undertaken in April/May 2010 to document the European Immunization Week (EIW) (draft report has been reviewed by WHO and will be finalized shortly). This topic has been referred to the WHO Immunization Practices Advisory Committee (IPAC) which has discussed it intensively at its meetings June and November 2010, particularly the issue of no longer being able to use the delivery strategy to reliably disinguish whether a dose is routine and supplementary. Jointly WHO & UNICEF prepared a Guidance Note outlining four criteria to determine if a given vaccination is a routine or supplemental dose. IPAC endorsed the Guidance Note at its meeting September 27-28, 2011. WHO/UNICEF are now proceeding to disseminate the criteria and consult with stakeholders regarding the consequences.
General	WHO to organize a special teleconference for SAGE to discuss action given by WHO in follow-up of SAGE recommendations.	Action	Nov 2011	Ongoing	Rather than organizing a specific teleconference, it was finally agreed with SAGE members that this would be featured in the second preparatory teleconference for the April 2012 SAGE meeting.
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 trainnig and curricula changes is ongoing in 9 countries in AFRO. Results may be available by end of 2011. An evaluation was conducted in late 2011, draft report has been prepared but it is not available for wider circulation yet. Evaluation report is expected in April 2012.
General	SAGE urged WHO to focus on vaccine norms and standards setting, policy recommendation development, progress monitoring, impact evaluation, surveillance and technical cooperation with countries.	Action	Nov 2011	Ongoing	Following the WHO-IVB functional review, a process and resources, both human and financial, are now established in the IVB Director's office to strengthen areas such as progress monitoring, impact evaluation, surveillance and technical cooperation with countries as well as to continue supporting norms and standards setting and policy recommendation development.

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General	SAGE encouraged AMRO to formally document the factors contributing to countries' ownership of the programmes and the successful delivery of immunizations and to share these with other regions.	Action	Nov 2010	Ongoing	Most of the lessons learned have been documented in our Immunization Newsletter, available at: http://new.paho.org/hq/index.php?option=com_content&task=view&id=3130&Itemid=3504&lang=en PAHO will soon have an e-book of this Newsletter with a thematic index to facilitate article searches. 1. The Expanded Program on Immunization (EPI) has been in place for over 30 years 2. Vaccines are considered a public good in the Americas 3. Immunization topics have been presented in most of PAHO's Directing Council meetings: (3a)Strengthening immunization programs (3b)Disease elimination goals (3c)Sustainability of immunization programs (3d)Vaccination Week in the Americas (VWA) 4. Several countries/territories have legislation regarding immunization; two other countries are in the process of passing such laws. These laws go from making vaccination mandatory to securing budget lines for vaccine purchase or ensuring the functioning of the immunization program. 5. PAHO's Revolving Fund for vaccine purchase belongs to the countries of the Americas and it is the preferred mechanism to procure vaccines and immunization supplies of assured quality and at the lowest price in the market 6. Several presidents, first ladies and other political figures have participated in vaccination activities and endorsed vaccination campaigns. They often participate in VWA launching events 7. There is a culture of vaccination among health care workers, parents, and communities 8. The immunization program makes an effort to engage professional societies, such as medical and nurse associations 9. Vaccination Week in the Americas has served to keep vaccines in the public agenda.
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	Pending	An analysis of health systems impact of new vaccine introduction will be presented to SAGE in April 2012. A framework for planning new vaccine introduction with a view to use the opportunity is also prepared. It is proposed that WHO documents the impact of the use of this framework wherever possible.
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. During the past few months: EMRO provided extensive support to Libya for procuring vaccines for routine immunization to avoid stock out and drop in routine immunization coverage as well as to respond to the measles outbreak; EMRO has conducted 2 training workshops on vaccine management in Egypt, attended by officers from all governments (provinces) Effective vaccine management assessment in Egypt will be conducted in September 2011 with EMRO support; EMRO continues to provide extensive technical and financial support to Yemen for conducting outreach and mobile activities to maintain and improve the routine immunization coverage; EMRO is working closely with Syria and is currently providing the necessary technical support for evidence-based decision on new vaccines introduction, including supporting surveillance of new vaccines and provision of information on vaccine availability and vaccine prices.

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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	The WHO European Region inaugurated its Immunization Communication Working Group in December 2010. At this meeting, the toolkit to profile and tailor responses was presented and feedback from members was provided. The toolkit will be piloted in Bulgaria and one other country in 2011 - work to begin in May 2011. At the European Union Hungary Presidency, the Regional Office presented the toolkit and best practices compendium with the EU countries. It was well received and many countries are interested in implementing. The WHO European Region Immunization Communication Working Group held its second meeting on 13-14 October in Istanbul. An algorithm for the toolkit titled “TIPPS” (Tailoring Immunization Programmes to Profile Susceptibles) has been developed and objectives and timelines finalized. There is still a plan to share with SAGE by the end of 2011. TIPPS will be piloted in Armenia the week of 17 October and in Bulgaria before the end of 2011. Funds have been secured for 2011 and 2012 to conduct these activities. There has been interest from Netherlands to work with WHO/Europe using TIPPS in defined populations refusing immunization and the Regional Office is interested in pursuing further discussions with France to assess the potential to implement it there as well.
Accessibility of affordable vaccines: gaps and WHO’s role in supporting emerging manufacturers	SAGE recommended that WHO monitor gaps and opportunities and develop a systematic process to respond to these needs in collaboration with key partners.	Pending	Nov 2010	Pending	This is in part being addressed through the general discussions on the process of technology transfers that are taking place under the leadership of the Innovation, Evidence, Information and Research Cluster and through the bilateral meetings with members from the Developing Countries Vaccine Manufacturer's Network (DCVMN). This will also be discussed in the context of WHO's contribution to the DoV work stream on global access. Regular 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. 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 needs.
Accessibility of affordable vaccines: gaps and WHO’s role in supporting emerging manufacturers	SAGE suggested that a more developed perspective be presented at a future SAGE meeting on accessibility of affordable vaccines.	Action	Nov 2010	Ongoing	Activities to lead to better vaccine price information and vaccine pricing transparency are being considered and under discussion for funding. Contribution of WHO to the DoV work stream on global access. Proposed to organize regular meetings with vaccine industry representatives on this topic and in particular with members of the Developing Countries Vaccine Manufacturer's Network (DCVMN). A general discussion is being proposed for the annual meeting of the DCVMN. 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. The purpose of the project is to support GAVI graduating and lower 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.

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Childhood mortality	SAGE noted the recommendation by QUIVER 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 QUIVER 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 QUIVER 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. QUIVER recommends that polio related data should be made available for multiple modeling groups to encourage comparison of results using different approaches.
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	Ongoing	A meeting on use of oral cholera vaccines in complex emergencies was held in early May 2011, and the WHA passed a resolution on mechanism for cholera control and prevention was passed in the May 2011 assembly. In addition, a meeting on cholera vaccine stockpile was held in Geneva from 6 to 7 September 2011.
Decade of Vaccines	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.
Decade of Vaccines	SAGE proposed stronger emphasis on consequences for non-delivery of programmes, and sustained funding for quality monitoring and surveillance. SAGE stressed the opportunity provided to use immunization programmes as the focus for health system strengthening and as a key pillar of primary health care. Specifically noted was the need to integrate vertical vaccination programmes and horizontal health care programmes to maximize the impact on improving health. SAGE supported the draft Global Vaccine Action Plan (GVAP) but sugguested that it needed to be more exciting and innovative, extending the benefits of immunization to populations beyond the traditional EPI childhood age group. SAGE felt that the DoVC should strongly address the emerging global challenge of vaccine hesitancy, which posed a major threat to immunization programmes worldwide. Innovative communication strategies and grassroots advocacy are required if community demand for immunization as a health right is to be mobilized. SAGE requested the planning teams to identify a few major “game-changers” which, if implemented, would have a significant impact.	Action	Nov 2011	Ongoing	All comments were taken into consideration in the revised version of the GVAP that was then used for the broad consultation process. Draft 3 was discussed during a SAGE extraordinary meeting in February 2012.

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Evidence and recommendations on use of hepatitis A vaccine	SAGE recommended that a revised hepatitis A position paper should be drafted to guide countries on decisions on hepatitis A vaccine introduction, including reference to vaccine response of high-risk groups (e.g. HIV-positive individuals). SAGE requested the working group to carefully consider all data on the use of a 1-dose schedule, and whether this could be recommended in the revised hepatitis A position paper.	Action	Nov 2011	Ongoing	A specific session with focus on long term protection achieved by a single dose administration of hepatitis A vaccines is scheduled for the April 2012 SAGE meeting. The plan is to then update the hepatitis A vaccine position paper, building on the SAGE recommendations from both the November 2011 and April 2012 discussions.
Feasibility of measles eradication	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	Ongoing	The new working group on measles and rubella has been formed. Peter Figueroa is the chair of the working group and as of 17 February the group has held 3 conference calls. The first face-to-face meeting is scheduled for 22 March immediately following the annual Global Measles Management Meeting (20-21 March). The working group is preparing for a session on measles and rubella at the November 2012 SAGE meeting. The session will include a report on progress, challenges, proposed new strategies as well as priorities for the research agenda aimed at achieving existing global and regional goals as milestones to the eventual eradication of measles and rubella.
Feasibility of measles eradication	SAGE requested that progress towards meeting the 2015 global targets and regional elimination goals be monitored.	Action	Nov 2010	Ongoing	See updated provided with respect to the measles rubella working group.
Feedback from IPAC	IPAC update.	Information	Nov 2011	Ongoing	The last IPAC meeting was held in September 2011, and feedback was provided to the SAGE meeting in November 2011. No additional meeting has been held since, and the next IPAC meeting will occur after the April 2012 SAGE meeting. Key topics on our upcoming agenda are the controlled-temperature-chain work, the revision of the mutli-dose vial policy, and the guidance for the delivery of the Hep. B birth dose.

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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. Actionable activities will be then adopted and discuss with partners for implementation. Work is now underway to consider ways of addressing the potential obstacles and issues faced by the 16 graduating countries from GAVI support. 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 draft GVAP has partly addressed some the issues but more clarity and consistency is needed. A brainstorming meeting was organized on the lower-middle-income countries activity information and coordination on 12-13 March 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. We are planning to present the results of this consultation and others to follow at the November 2012 SAGE.
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. Some key areas of the study: What are the barriers/challenges that limit the rate of new vaccine adoption by LMICs? What are the potential options to address these rate limiting constraints? And what are the likely costs, benefits and implications of various options for supporting countries to address identified rate limiting constraints? Based upon these analyses the study will develop prioritized strategies and suggest practical measures at the global, regional, and national level to support non GAVI and LMICs in their decisions to adopt new vaccines. An Advisory Group for the study team was set up with representatives from WHO, BMGF, GAVI, UNICEF, NVI (Netherland Vaccine Institute) and vaccine manufacturers (IFPMA&DCVMN). The study began in November 2009 and was completed in March 2011. Finding and preliminary conclusions and recommendations were presented to the SAGE in November 2010. An operational plan to implement is under discussion with various agencies and donors - At regional level: EMRO is working with LMICs in the region to set up a pooled procurement system with the support of UNICEF and other partners. AFRO is conducting a feasibility study on regional pooled procurement. 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 et develop transition plans. 2 regional assessment were already conducted on GAVI graduating countries (EURO and PAHO), 2 others will be undertaken by the end of 2011. A full set of activities has been approved for 2012 to support countries transitioning from GAVI support. 6 countries are on the top of the list: Angola, Congo Rep, Bhutan, Sri Lanka, Moldova and Georgia. The establishment of a pooled procurement in EMRO is still on the agenda and technical development despite the unstable political situation in most of the concerned countries. New efforts are necessary in mid 2012.

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GRADing and review of evidence	SAGE emphasised that SAGE working groups should identify the specific questions for grading early for endorsement by SAGE. SAGE also noted the need for training of working group members on the review of evidence process.	Action	Apr 2011	Ongoing	This information has been communicated to the SAGE working groups. As an illustration special effort was made by the hepatitis A WG to validate the PICO questions for GRADing with SAGE members way ahead of the SAGE session to discuss the recommendations that took place in November 2011. Due to limited resources, and need to limit time investment for working group members, it is proposed that support be provided by the secretariat by the working groups. Training organized by WHO will be advertised and offered to staff and WG members. In addition, brief video training sessions (2-4 hours)developed by CDC and the Cochrane Collaboration are being reviewed for their suitability and usefulness.
GRADing and review of evidence	SAGE endorsed the preparation of a shorter version of guidelines for peer-reviewed publication after incorporation of their guidance and using a few specific examples such as meningitis C conjugate vaccine.	Action	Apr 2011	Completed	Following the pilot testing of the guidance document (with conjugate meningococcal vaccines, measles, TBE and pertussis) and incorporation of resulting final adjustments, the guidance document has been circulated and posted on the website. A draft of a shorter version of this guidance intended for publication in the peer-reviewed journal Vaccine was prepared with the GRADE discussion working group. The paper is about to be published.
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	A Planning Group for the Global Vaccine Safety Initiative has been assembled and is currently developing a short-term work plan.
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 - PWIDs) 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 (ATD). 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 is being developed targeting the national regulatory authorities in countries where this type of trials are being planned in the coming years.

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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 is drafting a new global viral hepatitis strategy that will likely call for establishing a global time-limited control goal for hepatitis B virus. Following regional consultations, it is expected that this will be released by April, 2012. EMRO is working with Member States to ensure achievement of the Regional Committee goal for HBsAg reduction in vaccinated children. WPRO continues to monitor progress towards achieving 2012 goal--the 2011 WPR TAG recommended actions to ensure achievement of this goal. SEARO has a draft regional strategy and will convene two meetings in 2012 to finalize. AFRO has convened a regional hepatitis TAG and will bring their input to the Regional Committee in 2012. EURO will consider a regional hepatitis B control goal. PAHO has resolved to eliminate hepatitis B virus transmission and is formulating a regional strategy. EPI developed best practices for conducting serosurveys to support country impact work. IPAC has made inputs and these will be revised and reviewed in 2012.
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 that is in review. IPAC reviewed this work in early 2011 and has recommended a number of job aids be developed as well as further review take place. The JRF (Joint Reporting Form) and associated materials have been revised to improve reporting of birth dose and now steps are being taken to make HepB_BD a WHO/UNICEF "best estimate" in line with previous SAGE recommendations. Analysis of timely birth dose data for 2008 shows no significant changes from 2006 analysis and major issue is lack of data quality. A consultant is finalizing a study of the cost of scaling up the birth dose by country using previously published methodology used to look at cost of implementing GIVS goals.
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	- 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. - 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 final administrative arrangements should be finalized in the coming weeks. - A study on the safety to use needle remover has been completed in Bangladesh. Based on the findings of this study, a platform needs to be set up to define what should be the WHO position regarding the use of such device bearing in mind that it has an impact on safety but also on the management of waste from injection activities.

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Immunization schedules	Development of additional documents. 1. Guidance to countries on consideration for improving a national schedule, 2. Document on implementing vaccination programmes in older age groups; 3. Tool to help health workers avoid missed opportunities.	Action	Apr 2008	Ongoing	1. A "Users' Guide" to accompany the Summary Tables of WHO Recommendations for Immunization, has been finalized and is available on the WHO web site (http://www.who.int/immunization/policy/immunization_tables/en/index.html). This document outlines how countries can use the WHO recommendations to review their national immunization schedules. 2. As a first step existing WHO recommendations on delayed vaccination are being compiled from the position papers and summarized in a Table. 3. Discussions with IVR are on-going to explore revising the missed opportunities protocol and collaborating on a study of missed opportunities in 1-2 countries as part of the IVR EPI Schedules Optimization Project. A summary table of WHO Recommendations for Interrupted or Delayed Immunization has been posted on WHO's web site.
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	Ongoing	Work in progress. Presentation of the PCV evidence was done at the SAGE November 2011 meeting resulting in the updating of the rotavirus vaccines position paper. Evidence on rotavirus vaccines will be presented at the April 2012 meeting and on Hib at the November 2012 meeting.
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 continues to include a broad range of partner agencies (WHO, UNICEF, WB, CDC, PATH, JSI, LSHTM, JHU) and will seek endorsement of this work at senior levels of partner agencies.
Impact of the introduction of new vaccines on immunization and health systems	SAGE requested that WHO assesses how the introduction of new vaccines has helped strengthen immunization and health systems.	Action	Apr 2010	Ongoing	An ad-hoc working group has produced a framework on new vaccines introduction impact on the health and immunization systems, which contains hypotheses on major effects, backed by published and grey literature, which is to be reviewed by SAGE in April 2012.
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 3 countries was conducted by LSHTM in 2011-12 to gather further information. The ad-hoc group has updated the framework based on the data obtained and is presently drafting a guideline 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' which have been developed by the working group were shared with all partners and no objections have been received. A SAGE presentation and discussion is on the agenda for SAGE April 2012.
Influenza	SAGE expressed a need for more information about the shelf-life and other characteristics of pandemic influenza vaccines before making additional recommendations about options for the constitution of the stockpile.	Action	Nov 2010	Ongoing	This project is under consideration by SAGE influenza Working Group. Discussions on the pandemic stockpile by the Working group and SAGE is pending on outcomes of discussions for the Pandemic Influenza Preparedness (PIP) Framework.

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Influenza	SAGE requested that WHO report on the utilization of deployed vaccine, including by risk group, once data collection has been completed.	Action	Nov 2010	Ongoing	The results on the 2010 survey of countries on the utilization of deployed H1N1 pandemic vaccine was presented to the SAGE Working Group on Influenza Vaccines and Immunization (SAGE WGIVI) in their February 2011 meeting and to SAGE in the April meeting. The average vaccine utilization rate between WHO regions ranges from 15% to 73%. Vaccine coverage between WHO regions for targeted at risk populations ranged from 6% to 94% (results not available for EUR) representing 0.6% to 24% of general population of those regions. A report reflecting the results of the survey is being reviewed and will be made available.
Influenza	SAGE recommends WHO continue urgent development of H5N1 stockpile.	Action	Nov 2007	Ongoing	This project being taken forward by SAGE influenza working group. Discussions are ongoing, though after the H1N1 pandemic there is less perceived urgency. H5N1 stockpile has been reflected in the Pandemic Influenza Preparedness PIP)framework.
Influenza	SAGE approved the proposal from the Secretariat to update the WHO position paper on seasonal influenza vaccination as well as the establishment of a new working group on influenza vaccines and immunization.	Action	Apr 2010	Ongoing	During the last three face to face meeting of the SAGE WGIVI, the group had reviewed its workplan as outlined in the conceptual matrix and information on burden of disease, vaccine performance (vaccine effectiveness, safety), vaccine cost effectiveness and a number of operational issues. The group felt that there are sufficient information for updating the position paper on influenza vaccine. A background paper outlining evidence to support recommendations to update the position paper for influenza vaccine is included in the Yellow Book for the April 2012 SAGE meeting. Focus of the position paper is largely for low and middle income countries with consideration also be given to high income countries.
Influenza	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 Research	Apr 2007	Ongoing	Discussion on the H5N1 stockpile continued for the SAGE WGIVI during the last 3 face to face meetings. During the 2nd meeting in February, 2011, the WG concluded that the virtual stockpile option with a small physical stockpile of filled doses of H5N1 vaccine for outbreak control would provide maximum flexibility, minimize costs especially those involved with replenishment, obviate the risk of expending the pledged doses on the wrong vaccine and simplify the logistics of storage. WHO should ensure that it has procedures in place to facilitate the earliest possible receipt and deployment of pandemic strain vaccine to the low and middle income countries who would be dependent on the WHO stockpile in the event of another pandemic, and that procedures are in place for rapid delivery and utilization of the physical H5N1 stockpile released for outbreak control. 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 workplans are finalized pending internal approval and will be made available shortly.
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.

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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. Report in preparation.
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 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 is pending publication). WHO review might be needed once results are available. No new results have become available until today.
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 contracted to assemble a serum and CSF assessment panel to evaluate in-house and commercial JE ELISA assays. The preliminary assessment panel has been distributed to key JE reference Labs, first quarter 2010 and has been evaluated by the Lab working group. JE Lab workshops were held WPRO and SEARO 4th quarter 2010 with proficiency testing panels distributed to all participants. The 5th Biregional JE meeting was held in Lao, June 2011 and included a meeting for WPR labs. A paper summarizing the development of the JE LabNet is in the final editing stage and will be submitted 2nd quarter of 2012.
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 by end of 2011.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. 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 in supporting activities but they are still in the process to identify the best approaches. 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. 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. 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. The draft GVAP has partly addressed some the issues but more clarity and consistency is needed. A brainstorming meeting was organized on the lower-middle-income countries activity information and coordination on 12-13 March 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. We are planning to present the results of this consultation and others to follow at the November 2012 SAGE.

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Lower-middle-income countries: sustainable adoption and financing for new vaccines	SAGE encouraged WHO to assist countries to use data from neighbouring countries and their region for decision-making. SAGE recognized that this required strengthening of the WHO country offices in lower-middle-income countries.	Action	Nov 2010	Ongoing	WHO is working at regional level and in particular with EURO and EMRO to promote intercountry exchanges and cross fertilization on burden of disease, immunization system strengthening, vaccine management and vaccine safety, prioritization and immunization planning, vaccine procurement and immunization financing. All opportunities are used to assist countries to know and potentially use data from neighboring countries. We are also working with PROVAC and SIVAC to develop their scope of work and consider more lower and middle income countries in their work plan and activities. Funding to support such activities is a big constraint. Those issues and questions are also being raised at the Decade of Vaccine working groups discussions. Recommendations are made to prioritize country ownership and intercountry mutual support. 16 countries are now graduating from GAVI support and requesting specific support to transition from external financial support to using their national resources and budget to pay for new vaccines and related supplies. This creating a strong push to consider support for lower middle income countries to sustain the introduction of new vaccines. Coherent and fair policies should be designed and implemented including vaccine supply and prices.
Malaria	SAGE indicated that further discussion on the optimal schedule for a malaria vaccine will need to occur during the evaluation.	Action	Oct 2009	Ongoing	In March 2010, SAGE was provided with a summary of the unpublished results of a Phase 2 comparison of 0,1,2 month vs. 0,1,7 month schedule for RTS,S, conducted in Gabon, Ghana and Tanzania. The safety and immunogenicity results from this trial are now published in Journal of Infectious Disease (see ww.ncbi.nlm.nih.gov/pubmed/20735271). 511 infants were randomized to receive RTS,S/AS01(E) at 0, 1, and 2 months (in 3 doses with diphtheria, tetanus, and whole-cell pertussis conjugate [DTPw]; hepatitis B [HepB]; Haemophilus influenza type b [Hib]; and oral polio vaccine [OPV]), RTS,S/AS01(E) at 0, 1, and 7 months (2 doses with DTPwHepB/Hib+OPV and 1 dose with measles and yellow fever), or EPI vaccines only. The additional exploratory efficacy analyses from this trial were indicative that 3 doses of RTS,S are necessary for efficacy, and that 2 doses are insufficient. An additional schedule study is underway in Malawi, including explorations of several different 3 dose schedules, some of which include a birth dose of RTS,S, or a dose at 6 months of age. In 2014 data will emerge from the Phase 3 trial which will provide efficacy on a fourth dose given 18 months after the 3 dose primary immunization series.

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Malaria	SAGE requested that it be kept informed of developments in the ongoing multi-country Phase 3 trial.	Action	Oct 2009	Ongoing	The Phase 3 trial of RTS,S/AS01E completed enrolment Jan 2011 with 15,460 infants enrolled in 11 sites in 7 African countries. The first of 3 analyses is of 12 months follow up data for safety and clinical malaria efficacy on the 5-17 month olds(non-target population) without co-administration. This data was published in an NEJM article during October 2011 coinciding with a malaria forum held by the Gates Foundation in Seattle. A case-driven severe malaria analysis also became available at this time. The first data in the target population (6-14 week old infants in co-administration with pentavalent DTwP/HIb/Hep B and OPV) will become available to WHO in Q4 2012. This will include 12 month follow-up for pooled clinical malaria efficacy in the target population. The full trial results will be available in Q4 2014 and will include information on 30 month follow-up, the efficacy of a 18 month booster dose and site-specific clinical malaria efficacy. The Joint Technical Expert Group on malaria vaccines (JTEG) estimated that this 2014 data may support policy recommendation in 2015. At least 24 months follow-up data will probably be needed prior to a policy decision, and GSK/MVI state this will be available in 2014. JTEG meets 23-24 February 2012 with a SAGE liaison member attending. A JTEG teleconference on 10 Oct 2011 discussed the first analysis and guided WHO's media statements. The first regulatory submission will be to the European Medicines Agency under the article 58 procedure. A new Malaria Policy Advisory Committee (HPAC) has been convened for the first time by the WHO Global Malaria Programme in Q1 2012. An efficient process for JTEG presentation of candidate policy recommendations to both SAGE and MPAC will be determined. This is likely to occur in early 2015, if the data to become available to WHO in late 2014 supports this.
National regulatory authorities	SAGE agreed on the need to strengthen the capacity of national regulatory authorities and AEFI committees, since they have the primary responsibility for dealing with these events. SAGE encouraged further discussion of these issues with the Global Advisory Committee on Vaccine Safety (GACVS) and encouraged countries in the region to engage with organizations of health-care professionals at the country level.	Action	Apr 2010	Ongoing	The Global Vaccine Safety Blueprint project (GVSB) has been launched to develop the basis of a global consortium aiming at strengthening countries capacity for vaccine safety work. In November 2011 SAGE endorsed the GVSB's vision and strategic objectives.
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	Ongoing	April 2012 (see above) Nov 2011 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.
Optimizing immunization schedules	SAGE requested that the models reflect operational realities – for example, delays in vaccine administration.	Action	Nov 2010	Postponed	Feb 2012 Models to examine these factors have been developed. Their application to PCV was presented in Nov 2011. In the rotavirus session (2012), the implication of coverage and timeliness by age on rotavirus vaccine impact will be presented. Nov 2011 A new contract was issued with the modeller developers to introduce SAGE and QUIVER recommendations. In addition to West Africa data, modellers analyzed the Eastern Africa data. However, resource constraints have had a negative impact on the completion of some planned activities. Not all recommendations were introduced as funding was not available. The project is on hold pending financing.

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Optimizing 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	Feb 2012 PCV: evidence was reviewed by SAGE on November 2011. New recommendation on schedules issued and data was used to update teh position paper Rotavirus: evidence was reviewd by an ad-hoc group of experts in February 2012 and will be presented for SAGE consideration in April 2012. Hib: evidence review is being completed; an ad hoc consultation will be held in September 2012 and outcomes are proposed for SAGE consideration in November 2012. Nov 2011 PCV: Vaccine review completed; epidemiology review ongoing (availble by Nov 2011); model plus Incremental Cost-Effectiveness Analysis (ICEA) ongoing). However, limited financial resources have hampered the introduction of all SAGE recommendations; Hib: vaccine review ongoing (available by March 2012); epidemiology review ongoing (available by December 2011); no resources for model and/or ICEA. Rota: vaccine review ongoing (available by Dec 2011); epidemiology review finalized; no resources for model and/or ICEA (trying to "piggy back" on other efforts). 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).
Optimizing pneumococcal conjugate vaccine (PCV) schedules	SAGE requested that available evidence and guidelines to facilitate decision-making at country and regional level be posted on the WHO website.	Action	Apr 2012	Ongoing	A BETA version of the proposed approach to summarize the evidence and of the website will be presented to SAGE during the April 2012 meeting. Inputs from SAGE members and participants will be documented using a survey tool.
Optimizing pneumococcal conjugate vaccine (PCV) schedules	SAGE also suggested that schedules might need to be adjusted to ensure protection of special risk groups including HIV-positive infants and pre-term neonates, and suggested that specific guidance was needed for such groups.	Action	Apr 2012	Ongoing	Available evidence on special groups immunization was included in the revised PCV PP being circulated
Pertussis	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	Pending	The initial offer of the pertussis strains made by Dr Nicole Guiso from the Institut Pasteur (IP) was not presented to the ECBS in 2010 due to the lack of information regarding the use of the strains and the related data. The proposal is currently subject to the official decision regarding the future of these strains that the Institut Pasteur needs to make. A possibility for maintaining the strains in the IP repository is one of the options under consideration but we are still expecting feedback on this from IP.
Pneumococcal Position Paper	Consolidate the two existing pneumococcal related position papers, i.e. that on PCV7 and that on PPV23 into one and only updated penumococcal vaccines position paper.	Action	Apr 2012	Ongoing	It was initially envisioned that we could combine all recommendations and background information into one and only position paper on the use of conjugate and/or polysaccharide pneumococcal vaccines. The position paper on the use of PCV7 will indeed be phased out as soon as the updated position paper will be published. We have, however, decided to keep the position paper on the use of polysaccharide vaccine for reference on the web as it contains valuable background information that could not be sufficiently fitted in the new position paper on the use of pneumococcal vaccines. The key related recommendations are included in the new paper. When we further update the paper in 2-3 years we will then completely phase out the position paper on the use of polysaccharide pneumococcal vaccines and keep one and only accessible position paper on the use of pneumococcal vaccines.

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Polio	SAGE recommends that the mathematical model(s) of post-eradication risks be evaluated by the Quantitative Immunization and Vaccine Related Research Advisory Committee (QUIVER).	Action	Nov 2008	Ongoing	During the October 4-6, 2011 QUIVER meeting the EMOD polio eradication model by Intellectual Ventures was reviewed. QUIVER believes that the model is a potentially promising approach to guiding policy and identifying evidence gaps. Comparisons with epidemic data and publication of the model are essential steps. Given the complexity of the model it is important to educate and caution users on the capabilities and limitations of the software. QUIVER encourages ensuring potential users understand how to use the model and interpret its results.
Polio	SAGE agrees with the proposal for recommendations on the use of IPV in low-income settings in the post-eradication era to be issued in April 2012.	Action	Nov 2010	Ongoing	Following the publication of the WHO position paper on routine pre-eradication polio vaccination in June 2010, the SAGE Working Group on IPV continued to review evidence towards finalizing its main remit of advising SAGE on eventual post-eradication polio vaccination policy recommendations. It had initially been anticipated that the WG's second remit, recommendations on post-eradication IPV policies, would be presented to SAGE in April 2011. However, SAGE decided to extend this timeline following the adoption of an additional third main remit for the WG, to provide guidance on all workstreams related to the 'new polio endgame', including to assess the utility and feasibility of type 2 OPV cessation in the pre-eradication era (i.e. prepare for a switch from tOPV to bOPV for routine immunization). The WG initiated work on this third TOR during their 3rd meeting in March 2011, and continued the review of relevant evidence during the fourth meeting in Feburary of 2012. Awaiting additional evidence on vaccine-derived polioviruses following the June 2012 'state of the art'meeting on VDPVs, and on further progress towards affordable IPV, it is now expected that the WG will provide policy guidance on routine IPV use in low income settings in the post-eradication era with a target date of either November 2012 or April 2013.
Polio eradication	SAGE noted that more detailed work was needed on cost, vaccine availability, community information and communication needs. SAGE expected a progress report from the SAGE Polio working group at the next SAGE meeting, including the potential role of IPV in accelerating wild poliovirus eradication, based on key studies (e.g. ongoing in India and planned for Pakistan).	Action	Nov 2011	Ongoing	Following its fourth meeting in early February and a conference call, and in continuation of the presentation to SAGE at its mid-February extraordinary meeting, the SAGE Polio Working Group will give a detailed presentation on the proposed policy for a switch from 'tOPV to bOPV' globally; in addition, a detailed background paper on the available evidence for such a switch will be shared with SAGE.
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	The Executive Board in January 2012 adopted Resolution declaring the completion of polio eradication to be a programmatic emergency for global public health, requiring the application of appropriate vaccination recommendations for all travellers to and from areas infected with poliovirus. In response to the Independent Monitoring Board's report from February 2012, in its report to the World Health Assembly May 2012, the GPEI secretariat highlights that all approaches should be considered, including 'the possibility of using the International Health Regulations to limit the potential spread from affected countries.' Additionally, as in part years, the World Health Organization will in 2012 update 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 noted that the Inactivated Polio Vaccine (IPV) working group had revisited the issue of post-eradication IPV policy in low-income settings in the light of the new information on affordable IPV options and agreed that the group should now focus on further clarifying the criteria for IPV use (e.g. coverage and cVDPV risk) and the modalities of use (e.g. schedules and vaccine formulations) in the post-eradication era.	Action	Apr 2011	Ongoing	The Working Group has convened by teleconference in September 2011 to discuss the potential expansion of the remit of the Working Group to inform the development of a comprehensive new pre- and post-eradication 'polio endgame strategy'. Key strategic issues the Working Group will be asked to work on are a) a synchronized switch from tOPV to bOPV for routine immunization globally, and b) the early introduction of low-cost IPV, in advance of, or coinciding with, the tOPV-bOPV switch, and c) the synchronized cessation of all bOPVs for routine immunization globally. Since then, SAGE has renamed the group as 'SAGE Polio Working Group', and approved of the expanded remit to provide guidance on the 'new polio endgame', including the tOPV to bOPV switch.
Polio eradication	In connection with the IMB report SAGE added 2 major recommendations. Firstly, although accountability of all role-players is stressed in the IMB report, SAGE strongly recommended that there must be consequences at all levels for individuals, institutions and governments who fail to deliver on their mandates. Secondly, SAGE recommended that the IMB produce country reports which identify in detail the root causes of the failure by some infected countries to interrupt transmission, and hold appropriate individuals, agencies and authorities responsible.	Action	Nov 2011	Ongoing	The IMB regularly, in its reports, assesses individual countries' eradication efforts. In its most recent report from February 2012, it concluded that Nigeria and Pakistan now 'the gravest risk to global eradication'. These reports are shared directly with the heads of the spearheading partner agencies and the Bill & Melinda Gates Foundation, as well as with Regional Directors, and – most importantly – Ministers of Health. Conclusions and recommendations from the IMB have each time been met with appreciation and resulted in a clear response by partner agencies and governments across all levels. In response to SAGE's recommendation and IMB recommendations on the need for more accountability, the Executive Board in its Resolution from January 2012, declared the completion of polio eradication to be a programmatic emergency for global public health, requiring the institution of national oversight and accountability mechanisms for all areas infected with poliovirus. The Resolution further requested the Director-General to strengthen accountability and monitoring mechanisms to ensure optimal implementation of eradiation strategies at all levels. In response, national polio emergency action plans have been developed in all three remaining endemic countries, a primary focus of which is the strengthened accountability at district-level. Drawing on the lessons from the successful India eradication programme, active involvement of political leaders at district and sub-district level is now being actively tracked and monitored, and reported against to the highest provincial and national offices. Within WHO, a new accountability framework for global, regional and country level has been developed and is being rolled out. A new data and monitoring team is being established in Geneva, to more accurately track and monitor evolving epidemiology, surveillance and SIA quality in a near real-time basis.
Polio eradication	SAGE agreed that over the next 12 months the programme should further assess the prerequisites, risks and benefits, feasibility and programmatic implications of the switching from oral poliovirus vaccines containing a type-2 component (i.e. trivalent OPV, tOPV) to vaccines containing only types 1 and 3 (bivalent OPV, bOPV) for routine immunization.	Action	Apr 2011	Ongoing	Work is ongoing to conduct the assessment of risks and feasibility of the proposed discontinuation of OPV2, as specified by SAGE. This will be done in the context of a new 'polio endgame strategy', for which the guiding principles will be a) the phased removal of Sabin viruses from immunization programmes, beginning with the highest risk, type 2 Sabin virus, and b) the elimination of VDPV2s in parallel with the eradication of residual WPV1 and WPV3, when global surveillance and response capacity is anticipated to be highest.
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.

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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	Apr 2012	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.
Reports from other advisory committees on immunization	WHO and NIBSC should develop with other stakeholders, a business plan to assure long-term security of global public health resource and additional efforts 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	Ongoing	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.
Rubella and Measles Working Group	Secretariat to proceed with establishment of a combined working group on rubella and measles.	Action	Apr 2011	Completed	The Working Group was established and held its first face-to-face meeting on 22 March 2012.
Surveillance	SAGE supported the European Technical Advisory group of Experts (ETAGE) recommendation that the European Centre for Disease Control (ECDC) and the WHO European Regional Office work towards developing a common surveillance platform for measles and rubella data collection from Member States to avoid redundancy.	Action	Oct 2009	Ongoing	WHO European Regional Office and ECDC have met on two separate occasions to move this recommendation forward. In October 2010, data collection for the European Union resides with EUVAC.NET. There is an ongoing handover to ECDC planned to be completed by late 2011. WHO EURO and ECDC are discussing methods for data sharing and ensuring all data elements are captured to allow for accurate and reliable monitoring towards the measles and rubella elimination goal in the Region. In September 2011, ECDC will collect measles and rubella case data directly from EU Member States. The agreement and platform for sharing data and ensuring data integrity have been established between WHO/Europe and ECDC.
Surveillance	SAGE requested to receive a report on how surveillance networks are being reinforced in countries and regions.	Agenda item	Apr 2008	Completed	This was on the agenda of the November 2011 SAGE meeting.
The epidemiology of unimmunized children and gender-related issues	SAGE requested that WHO quickly roll out tools so that other countries can address low coverage of vaccination.	Action	Nov 2010	Ongoing	A framework to increase coverage has been drafted and was presented to a small group comprising of representatives from EURO (2), AFRO (1), HQ and Dr David Durrheim, member of SAGE. In addition to this body of work the EURO and AFRO regional offices of WHO are working on operational guidelines and demand generation side documents respectively.
Thiomersal	SAGE endorses the proposal for a scientific meeting on alternatives to thiomersal prior to the fourth session of the Intergovernmental Negotiating Committee to prepare a global legally binding instrument on Mercury (INC4), as this would support the aims of the INC and avert concerns that developing countries are using products no longer used in industrialized countries. SAGE asked GACVS to present a review of the safety of alternative preservatives. SAGE will also consider the broader implications of alternative preservatives for global immunization policy.	Action	Nov 2011	Ongoing	A scientific meeting is planned for 3-4 April to develop further guidance on vaccines for the UNEP-convened Intergovernmental Negotiating Committee meeting 4, and the conclusions of this meeting will be reported to SAGE on April 2012.

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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	Pending	This will be reviewed at the November 2012 SAGE meeting.
Typhoid	Need for feedback from WHO's regional offices and countries to determine how countries could implement SAGE recommendations.	Action	Nov 2007	Ongoing	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 all stakeholders interested in typhoid and to develop a global agenda for the control and prevention of typhoid fever. WHO will work closely with Sabin in this process.
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	The Coalition against Typhoid (CaT) grant from the Bill and Melinda Gates was approved and Sabin Vaccine Institute has received a three year grant to do this work. In collaboration with partners, CaT has now developed a detailed work plan for typhoid and partners need to mobilise resources to implement them. WHO prequalified the sanofi pasteur Vi polysaccharide vaccine which has been major step as it is the first typhoid vaccine to be WHO prequalified. [Update 27 Jan 2012]: Through a collaborative effort, revised technical document on advancing the use of existing typhoid vaccines was prepared and submitted to the GAVI Policy and Planning Committee in October 2011 for discussion by GAVI Board in November. The Board met and decided that GAVI will only open a typhoid vaccine support window when a WHO prequalified conjugate typhoid vaccine is available. This effectively dampens interest to use ViPS vaccine. And a conjugate typhoid vaccine is unlikely to be availabe in the next five years or so.
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 have been incorporated in the framework to reduce unvaccinated children. In addition a case study from India has also been included.
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	Ongoing	The work has been prioritized. A framework to increase coverage has been drafted and was presented to a small group comprising of representatives from EURO (2), AFRO (1), HQ and Dr David Durrheim, member of SAGE. The draft from HQ as well as parallel work going on in EURO and AFRO was presented. It was decided to develop the 3 documents in parallel. The HQ document will need an additional section on diagnostics and inputs from a professional social mobilization expert to develop the demand side further. Since this work cannot be completed quickly, it was decided to wait until these have been completed before presenting the document to SAGE.
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 (details available from: www.gatesfoundation.org/vaccines/Pages/rfp-immunity-assessment-tool.aspx). Question to SAGE should WHO in parallel also support new research or should upon the development of this tools review the feasibility of incorporating this tools in existing survey methods.

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Vaccine coverage	WHO to identify appropriate methods and develop guidelines for collecting, analysing, and interpreting biomarkers for validating coverage.	Action	Nov 2011	Ongoing	A consultant was identified to review currently available biomarkers and draft a guideline document. The guidance document will review, 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. For each selected disease study populations, sampling methods, data/specimen collection, laboratory/statistical analysis, and implications of results will be discussed.
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. Because methods leading to improved precision or usefulness may lead to increased cost and improved usefulness may be achieved despite methods that entail a loss of precision an explicit description of various trade-offs between alternative methods will constitute part of the exploration

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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	Since the November 2011 SAGE session on VPD surveillance, WHO has conducted the following activities as aligned with SAGE recommendations: 1) clear objectives of the sentinel site surveillance network should be established. WHO has drafted a mission statement and objectives, which are currently being internally reviewed 2) WHO leadership in establishing minimal criteria for national surveillance management commitment; use of modern data collection and sharing processes. In December 2011, WHO began the dissemination five (5) agreed minimal criteria, as follows: • The country establishes a surveillance management team , consisting of: o Ministry of Health focal point; Sentinel hospital focal point; Sentinel hospital laboratory focal point, and Data manager focal point. • Countries that are conducting only Tier 1 meningitis surveillance enrol at least 100 suspect meningitis cases per year into the surveillance system and investigate cases according to the established surveillance protocols; • The country reports data regularly to WHO according to the schedule agreed with the WHO Regional Office; • The sentinel sites (if applicable) and/or national laboratories in the country participate in the WHO laboratory IB-VPD external quality assessment programme; and • Countries conducting only Tier 1 meningitis surveillance will meet the established quality indicators for Tier 1 before WHO provides funding for the country to establish Tier 2 (meningitis-pneumonia-sepsis) surveillance. 3) Developing methods to estimate the catchment population. WHO has drafted a methodology for determining a catchment population for IB-VPD Tier 1 sentinel surveillance which is currently being discussed with partners and will be piloted in March in Nepal. 4) Adequate funding and human resources for surveillance. Currently, WHO has no firm commitment from donors for 2013 funding for sentinel site surveillance. WHO has been discussing continued funding with GAVI. 5) Sustaining the global and regional reference laboratories for training, quality assurance, and PCR testing of culture negative specimens. WHO is in the process of contracting with global and regional reference laboratories and is working to ensure that regional reference laboratories conduct PCR testing of CSF specimens from sentinel sites. 6) Developing global standard operating procedures for clinical, laboratory and data management; and enhancing site capacity. A new laboratory manual for IB-VPD meningitis laboratory diagnostics was finalized in November 2011 and is available on the WHO website. (http://whqlibdoc.who.int/hq/2011/WHO_IVB_11.09_eng.pdf) An accompanying laboratory poster and clinical poster (on the process of obtaining CSF) is currently being printed and will also be provided to all sentinel sites.

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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	Ongoing	A SAGE Working Group on vaccination in humanitarian emergencies was established in June 2011 http://www.who.int/immunization/sage/sage_wg_hum_emergencies_jun11/en/index.html Two face-to-face meeting of the working group took place on 20-21 September 2011 and on 16-17 February 2012. The group is holding regular teleconferences. Although it was initially envisoned that the working group would complete its work on time for a SAGE review of the conmplete framework for decision making on the use of vaccinations in humanitarian emergencies, the work is not yet complete and the working group requested some broad consulation with partners prior to submitting the framework to SAGE's review and approval. In April 2012 SAGE will then be provide with the outcome of the literature review and completed ethical perspective in support of the use of vaccination in humanitarian emergencies. It will be asked to discuss the proposed "Vaccination in acute humanitarian emergencies: a framework for decision-making" and advise on activities necessary to facilitate the further buy in and use of the framework. A review and definitive endorsement of the complete framework will then be sollicited in November 2012.
Varicella and Herpes Zoster vaccine Working Group	Establishment of a SAGE working group on the use of varicella and herpes zoster vaccine.	Action	Nov 2011	Ongoing	The establishment of a SAGE working group on the use of varicella and herpes zoster vaccine was slightly delayed to follow the establishment of the working group on dealing with vaccine hesitancy. Terms of reference and required expertise for the varicella working group have been drafted and a call for nomination of potential members was initated on 14 March. It is to be noted also that in terms of secretariat support to the working group and ability to orchestrate face-to-face meetings, with 7 working groups we are reaching our limit.