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.
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 Information on vaccines for an Intergovernmental Negotiating Committee to prepare a global legally binding instrument on the use of mercury took place at the April 2012 SAGE meeting. It discussed thiomersal and alternative preservatives and presentations. A session on the non-specific effects of vaccines is under preparation and tentatively slotted for April 2013. 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	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. EURO is working to give countries tools to address vaccine hesitancy at the individual level. These include: 1. Development of the Tailoring Immunization Programs to Profile Susceptibles “TIPPS” 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 on the service/demand side. Best practices from other disease programs are included that can be adapted for country-specific issues. TIPPS was piloted in Sweden and Bulgaria The Toolkit is being further pilot tested and will hopefully be rolled out in more countries next year. 2. Strengthening the ability of member states to handle crises in vaccine confidence and trust through a guidelines document on vaccine safety communication. It is currently under peer-review. This was done at the request of EPI managers. 3. Advocating through Immunization Week, which began in 2006. Activities are independent for each country. 4. Strengthening the use of new media. Well-ranked bloggers who write in Russian and English will be brought in to dialogue about how to better engage around vaccine confidence.

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General	WHO to organize a special teleconference for SAGE to discuss action given by WHO in follow-up of SAGE recommendations.	Action	Nov 2011	Completed	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. During the conference as time was limited, it was proposed that the Chair and Vice-Chair of SAGE would review in detail the SAGE tracking sheet of action items and recommendations and would review if recommendations were given adequate follow-up and if not if these were high or low priorities in the context of the necessary prioritization of WHO activities in a context of limited resources. The Chair of SAGE will reported on this during the second preparatory teleconference for the November 2012 SAGE meeting and the very few areas for necessary additional attention were flagged.
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. Expected early 2013.
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.
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.
General - GVAP	SAGE requested consideration of the establishment of a SAGE standing working group to monitor GVAP implementation.	Action	Apr 2012	Ongoing	Draft Terms of Reference for a SAGE DoV-GVAP standing working group have been drafted. They will be discussed at the November 2012 SAGE meeting. Following finalization of the group's ToRs we will proceed with a call for nominations and selection of working group members.

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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	Pending	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. 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. 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.
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. A meeting on the experience of Zanzibar to use cholera vaccine as a preventive tool was held in February and the Zanzibar Government is keen to use the vaccine island-wide if support is forthcoming. Further, in May meeting on the finalization of cholera stockpile was held and the building of a cholera vaccine stockpile is now a reality. In the meantime, cholera vaccine has been introduced as a pilot in Haiti as well as in Guinea. The preliminary reports from both appear highly encouraging on the utility of vaccine to prevent cholera.

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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	Completed	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.
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. IVR leads on coordinating R&D agenda with partners agencies. Progress on establishing a vaccine research forum; progress on establishing R&D related indicators for the GVAP.
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 update provided with respect to the measles rubella working group.
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 working group on measles and rubella was formed in late 2011. Peter Figueroa is the chair of the working group and as of 27 September 2012, the group has held monthly conference calls and 2 face-to-face meetings (22 March and 20-21 September 2012). 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, lessons learnt, and opportunities for achieving measles and rubella targets. In addition, there will a presentation on aeorsol measles vaccination and a brief update on the planned outputs from the working group in 2013.
Feedback from IPAC	IPAC update.	Information	Nov 2011	Ongoing	The last IPAC meeting was held in October 2012, and feedback will be provided on this meeting as well as the April 2012 meeting, to SAGE in November 2012. The next IPAC meeting will occur April 2013, one week prior to the SAGE meeting. Key topics on IPAC upcoming agenda include solar refrigeration guidance to countries, development of unvaccinated framework, health worker checklist piloting and controlled temperature chain (CTC) application with Meningococcal A vaccine MenAfriVac.

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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. EMRO Regional Committee will discuss in the October 2012 session the official estalishment of a pooled procurement mechanism with the support of UNICEF. WHO and GAVI partners are conducting situation analysis in GAVI graduating countries and developing transition plan (6 countries are on the 2012 agenda). The challenges are financial but also link to pricing, procurement, reliable data and decision making processes.

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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. A session is now planned on Middle income countries at the November SAGE meeting.
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. Brief video training sessions (2-4 hours)developed by WHO, the CDC and the Cochrane Collaboration were reviewed for their suitability and usefulness. As a result of further discussions with SAGE members and considering that these videos were not adequately targeted for our intended audience and sill long, SAGE requested the development of a brief video that could also be useful for other immunization related advisory groups. A 15 minutes and 20 seconds duration video was developed in the summer 2012 and the video has been circulated and posted on the SAGE website.
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 shorter version of this guidance was prepared with the GRADE discussion working group and published in Vaccine in early 2012. The general guidance document was also revised and version 2 posted on the SAGE website in March 2012.

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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 hosts its first annual meeting in November 2012.
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 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. A written update will be provided on the progress of HIV-vaccine research for the April 2013 SAGE meeting.
Hepatitis A	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	Completed	A specific session with focus on long term protection achieved by a single dose administration of hepatitis A vaccines took place at the April 2012 SAGE meeting. The updated vaccine position paper was published in July 2012 building on the SAGE recommendations from both the November 2011 and April 2012 discussions.
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	

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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 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%. 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. 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 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_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 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.

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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	- 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 final administrative arrangements should be finalized in the coming weeks. - 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. Following this study a project proposal from GEF was submitted to the Gates Foundation Grant Challenge and granted (100,000 USD). This project will start with a pilot in one district. Used syringes will be collected and decontaminated by autoclave and supplied to a manufacture for recycling. As of today the project is waiting for the purchase of an autoclave.
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 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 will be presented at the November 2012 meeting.
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	Completed	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.

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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 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, which is to be published after external review in early 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 which are to be published in early 2013 as a result of the proceedings of the ad hoc working group are being vetted by the partner agencies and will be endorsed by their senior personnel.
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 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. The report for the survey on the deployment of H1N1 pandemic vaccines is available at: http://whqlibdoc.who.int/publications/2012/9789241564427_eng.pdf.
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. 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 doses of H5N1 vaccine for 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 workplans are available 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 work by the SAGE Influenza working group will have to wait for the output from discussion in the PIP framework.

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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.
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 RO 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. WPR JE Lab workshop planned 2nd quarter 2013 in RO Korea. A paper summarizing the development of the JE LabNet has been delayed but planned for submission 4th quarter 2012.
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 planned that will comprise a review of immunization strategies.

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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 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.EMRO is wotking with UNICEF SD to launch in 2013 the EMR Initiative on pooled procurement and contribute to the UNICEF pooled procurement for MIC focusing on new vaccines.
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.

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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	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. The Phase 3 trial of RTS,S/AS01E completed enrollment 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 efficacy on the 5-17 month old without co-administration. This data was published in an NEJM article in October 2011. It reported 55% efficacy (95% CI 50-59) against all episodes of out-patient malaria, and 47% (95%CI 22-64) efficacy against severe, life-threatening malaria. There were no safety signals, although febrile seizure and meningitis will be further explored. The first data in the initial 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 both out-patient clinical malaria and in-patient severe malaria efficacy. The full trial results will be available in Q4 2014 and will include information on 30 month follow-up, the efficacy of an 18 month booster dose and site-specific clinical malaria efficacy. The Joint Technical Expert Group on malaria vaccines (JTEG) met in Feb 2012 and has advised that this 2014 data may support policy recommendation in 2015. 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. The dates for regulatory submissions remain unconfirmed, with a recent indication that GSK may defer their previously stated submission date of June 2013 until more data is available. 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. A new Malaria Policy Advisory Committee (MPAC) 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. The policy recommendations are likely to occur during a planned joint SAGE/MPAC session in April 2015, if the data to become available to WHO in late 2014 supports this. The vaccine development partnership has been encouraged to fully explore optimal schedules and age groups for possible administration of this vaccine and additional schedule and co-administration studies are ongoing. A major issue for communication will be the clear need to consider RTS,S/AS01 as an addition to, not a replacement for, existing preventive measures, particularly long-lasting insecticidal nets and the need for ongoing availability of rapid diagnostic tests, and high quality safe and effective antimalarial drugs after any possible use of this vaccine in the future. Furthermore there will be a need to communicate what 50% efficacy means in this context (i.e. a reduced rate of malaria episodes). 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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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	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.
Optimizing immunization schedules	SAGE requested that the models reflect operational realities – for example, delays in vaccine administration.	Action	Nov 2010	Postponed	Models to examine these factors have been developed. Their application to PCV was presented in Nov 2011. The implication of coverage and timeliness by age on rotavirus vaccine impact was presented at the April 2012 SAGE meeting.
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	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 vaccinesNov 2011 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 are proposed for SAGE consideration at the November 2012 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).
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	Nov 2011	Ongoing	Available evidence on special groups immunization was included in the revised PCV PP that was published in April 2012
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	Nov 2011	Completed	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.
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	Nov 2011	Done	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. The updated paper was published on 6 April 2012.

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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. Following the fifth SAGE Polio WG meeting in September 2012, it is anticipated that SAGE will review, by April 2012, the potential timeframe towards synchronouse OPV2 cessation, which is now targeted for 2015 or 2016, pending progress towards affordable IPV options and establishing other key pre-requisites for OPV2 cessation, including policies for longterm biocontainment policy and post-OPV outbreak response. The WG, recognizing the continued risks associated with eventual cessation of all OPV use (i.e. cessation of bOPV), recommended at their 5th meeting that countries should plan to continue IPV vaccination for at least 5 years after bOPV cessation. This issue will be reviewed as additional information becomes availabel, particularly the experience with OPV2 cessation.
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	Ongoing	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.
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 WHO PE research team continued to provide updates on ongoing studies conducted to inform the programme of work on the new polio endgame at the 4th and 5th SAGE Polio WG meetings in 2012.

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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 tOPVÕbOPV switch and longer term IPV uptake following complete OPV cessation.	Action	Apr 2012	Ongoing	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. Further consultations towards finalization of the document will be held with the IMB in October and a during the polio session at the November 2012 SAGE meeting.
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	The financial requirements for the 'Endgame' are projected to be US$ 5.5 billion for the period 2013-2018; this reflects substantial work under various scenarios and is the consensus position of the core GPEI partners, in consultation with the relevant global, regional and country stakeholders. The proportion across key budget categories, which include the introduction of IPV, surveillance and laboratory costs, outbreak response capacity & vaccine stockpiles, as well as containment certification costs, will be adjusted as progress against key polio eradication milestones is evaluated. Adjusting the estimated year of interruption will increase/decrease costs accordingly. The financial needs of this plan will be met by implementing a resource mobilization, communications and advocacy strategy jointly developed by GPEI partners with the guidance of the relevant executive groups in the GPEI architecture, particularly the Polio Partners' Group and the Polio Emergency Steering Committee. Discussions with GAVI are ongoing to ensure financing for the introduction of a low-cost IPV option as part of OPV2 cessation for GAVI-eligible countries.
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	The SAGE Polio WG will, during the November 2012 SAGE meeting, report in detail on the outcome of discussions about the ongoing work towards achieving options for affordable IPV, including on the WGs direct interaction with four IPV manufacturers; discussions with regulatory authorities have started but will need to continue and be intensified as progress is made on this important issue with manufacturers.
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.

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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 a 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 previous 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.
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	Ongoing	As a fundamental step in the polio endgame, the SAGE Polio Working Group recommends that synchronous OPV2 cessation should be targeted for the near-term (i.e. 2015 or 2016). The SAGE Polio WG, at their 5th meeting in September 2012, continued to review in detail progress towards preparing for the eventual cessation of OPV2 (i.e. the 'tOPV-bOPV switch'); this included direct interaction with four IPV manufacturers to elucidate options and timeframe for the availability of affordable IPV, as well as a detailed review of key pre-requisites for OPV2 cessation such as long-term policies for laboratory biocontainment of polioviruses and post-OPV outbreak response, as well as the status and sensitivity of surveillance for polioviruses. It is expected that by April 2013, SAGE will be presented with a more detailed time-frame on the evolution of the polio endgame, including the time-frame to prepare for OPV2 cessation by 2015 or 2016.
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.
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.
Rotavirus immunization schedules	SAGE requests WHO to develop tools to support country decision-making and where possible National Immunization Technical Advisory Groups (NITAGs)and Regional Technical Advisory Groups(RTAGs)should assist this process.	Action	Apr 2012	Completed	Communication strategy, country summaries, global summaries and web site have been completed.
Rotavirus immunization schedules	SAGE recognized that a comprehensive communication strategy that explains the reasons for this change of schedules should be developed and made available to all stakeholders including policymakers, programme managers, communities and parents, and requested WHO to develop appropriate tools.	Action	Apr 2012	Completed	Communication strategy, country summaries, global summaries and web site have been completed.

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Thiomersal	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
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	Completed	A scientific meeting was held on 3-4 April 2012 to develop further guidance on vaccines for the UNEP-convened Intergovernmental Negotiating Committee meeting 4, and the conclusions of this meeting were reported to SAGE on April 2012 for a specific session Information on vaccines for an Intergovernmental Negotiating Committee to prepare a global legally binding instrument on the use of mercury took place at the April 2012 SAGE meeting. It discussed thiomersal and alternative preservatives and presentations.
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	Written update will be provided for 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. Since typhoid vaccine is one of the 7 vaccines that GAVI listed as their priority vaccines for support, for the November 2011 meeting of the GAVI Board, a case was made for typhoid vaccine support. The GAVI Board finally 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 stand there is clearly no appepite for any donors to support ViPS typhoid vaccine. Thus all activities related to encouraging countries to consider ViPS are stopped. Focus is now on supporting the development of conjugate vaccine and strengthening surveillance in countries to generate better data on typhoid.

Topic	Recommendations/Action item	Category	Meeting Date	Status	Comments and Follow up
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. The finalization of the framework is on-going. A follow-up meeting with the WHO regions and partners was scheduled on the 4th October 2012 to review the different approaches in progress.
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. A follow-up meeting with the WHO regions and partners was scheduled on the 4th October 2012 to review the different approaches in progress.
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 has been conceptualized. In addition to the work on the framework at HQ, the EURO, AMRO/PAHO and AFRO regional offices of WHO are working on operational guidelines and demand generation side documents respectively. 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. A follow-up meeting with the WHO regions and partners has been scheduled on the 4th October 2012 to review the different approaches in progress.
Vaccination in humanitarian emergencies	SAGE asked the working group to consider how a broader awareness among agencies of the Siracusa principles,4 particularly the balance between individual and community rights, could be communicated.	Action	Apr 2012	Ongoing	The draft has been circulated to all major agencies for review and comments are already being received. Further awareness raising efforts regarding Syracusa principles among agencies should occur through fora such as health cluster mechanisms, etc
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	ERM staff do consider that the framework approach for other health interventions in emergencies is a good recommendation from SAGE. There is currently a lack of staff to follow-up on this recommendation but ERM hopes to revisit this issue in the coming months.

Topic	Recommendations/Action item	Category	Meeting Date	Status	Comments and Follow up
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	Ongoing	Pilot testing ongoing in the Horn of Africa (completed); Pakistan; and South Sudan
Vaccination in humanitarian emergencies	SAGE requested that the finalized framework be presented to the November 2012 SAGE meeting for consideration.	Action	Apr 2012	Ongoing	Finalization of the draft is ongoing and the draft will be presented at the November 2012 SAGE meeting.
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.
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. As of September 2012: A consultant has been recruited to review currently available biomarkers and draft a guideline 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. For each selected disease study populations, sampling methods, data/specimen collection, laboratory/statistical analysis, and implications of results will be discussed. Work in progress will 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.
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. As of September 2012: • Convened initial meeting 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, the UNICEF Multiple Indicator Cluster Surveys and the WHO Immunization Cluster Survey to accommodate changes in immunization system strategies.

Topic	Recommendations/Action item	Category	Meeting Date	Status	Comments and Follow up
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.

Topic	Recommendations/Action item	Category	Meeting Date	Status	Comments and Follow up
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	Completed	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. Following a call for nominations, the working group was finally established in May 2012 and has since then held monthly teleconferences.