SAGE TRACKING RECORD OF RECOMMENDATIONS AND ACTION POINTS

Topic	Recommendations/Action item	Category	Meeting Date	Status	Comments and Follow up
General	SAGE recommended that ways to improve curricula for medical personnel should be explored.	Action	Nov 2008	Ongoing	The African region started to work with academia to develop a pre-service curricula for nursing and medical staff. Annual courses for medical and nursing staff take place in collaboration with Network for Education and Support in Immunization (NESI). An evaluation of the impact of pre-service training and curricula changes is ongoing in 9 countries in AFRO. An evaluation was conducted in late 2011 and a draft report has been prepared but it is not available for wider circulation yet. It first needs approval from countries involved. A report was expected for early 2013 but this report was not recieved by October 2013.
General	SAGE encouraged the European region to document and share its experiences in country profiling, tailoring responses and using novel communication strategies to effect behaviour change.	Action	Nov 2010	Ongoing	EURO is working to give countries tools to address vaccine hesitancy at the individual level. These include: 1. Development of the Tailoring Immunization Programs “TIP” toolkit, which allows a country or sub-national level authority to segment/profile a population based on behaviors rather than background characteristics. The resulting group profile can help inform programmatic responses that could be communication-oriented or inform improved service delivery. Best practices from other disease programs are included that can be adapted for country-specific issues. Pilot testing of the framework has been conducted in several European countries: TIP was implemented in Bulgaria and on three projects in Sweden (Somali immigrants, migrants, and anthroposophic communities) and Bulgaria. In 2013, TIP was implemented in France and the UK. Use of the tool in Switzerland is envisaged for 2014. A tool assessment is planned in 2014 and expansion to other regions that have expressed interest. TIP will be adapted for use on a global level and a second edition will be published later in 2014. 2. Strengthening the ability of member states to handle crises in vaccine confidence and trust through a guidelines document on vaccine safety communication was published in 2013. 3. Advocacy for immunization and strengthening the use of new media led to involvement of well-ranked bloggers who write in Russian and English to better engage around vaccine confidence. 4. A vaccines social media strategy and a smart-phone immunization tracker/reminder ‘app’ for parents has been launched and is currently being modified by national immunization programs in 10 countries to be adapted to local schedules. 5. An online vaccines resource centre was launched in 2012 and has been strengthened and improved through 2012-2013, with a number of MS using or translating the caregiver and health-care worker tools presented.
General	SAGE recommended strengthening national vaccination programs, integrating health services and strengthening health systems to promote universal health coverage.	Action	Apr 2013	Ongoing	A teleconference was held May 13 2013 with J. Abramson, P. Figueroa, and N. Arora and EPI (M. Zaffran and T. Goodman) to discuss issue and provide briefing on the integration activities that historically and presently EPI is working on. Subsequently, in early June a draft typology was produced and shared that summarizing this area of work. It was agreed that an effort would be made to highlight this area of work in a few slides of the IVB Director's next presentation to SAGE. Discussions are ongoing. The topic of integration is on the agenda of the April meeting.

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General	SAGE requested that a paper be developed, highlighting the circumstances under which off-label use of any vaccine can be recommended, while clarifying the differences between regulatory decisions and public health recommendations. Legal and programmatic implications of off-label recommendations and the need for clear communication should be considered.	Action	Apr 2012	Pending	Advice being sought through the ECBS - added to agenda of next meeting, 15-19 October 2012. SAGE had previously requested that a paper be developed, highlighting the circumstances in which off-label use of any vaccine could be recommended, while clarifying the differences between regulatory decisions and public health recommendations. During the November 2012 SAGE meeting, SAGE further requested that ECBS prepare guidance for national regulatory authorities on studies needed to support evidence-based, off-label use of vaccines which benefit public health. It was noted that for regulators, product specific data are paramount. SAGE requested that an additional document be prepared to advise the national immunization technical advisory committees about the type of data that might support a policy recommendation to use a vaccine outside its licensed schedule in order to achieve public health benefits such as operational simplicity or cost savings. The ECBS guidance document has been delayed and will be prepared after the 2014 meeting. The paper clarifying the differences between regulatory decisions and public health recommendations has been commissioned and is under development. The aim is to have it ready for submission to a peer review journal in the spring 2014.
General	SAGE encouraged the Regional Office in EMRO to pay special attention to countries affected by political turmoil and requested specific monitoring for any adverse impacts on immunization programmes in GAVI graduating countries.	Action	Apr 2011	Ongoing	There are no GAVI graduating countries in the EMR. EMRO is working closely with and is paying special attention to the countries affected by political turmoil. The following support was provided since the last SAGE meeting in November 2013: • implementation of routine vaccination in the 2 provinces hosting the refugees camps in Jordan • implementation of the national MR/Polio synchronized campaigns in Syria and the surrounding countries (Syria, Jordan and Iraq) • provision of support to Tunisia for recruiting technical staff to support EPI • Conduction of comprehensive EPI review in Sudan, including DQS and PIE • Conduction of EVM in Sudan. • Introduction of Hib (Pentavalent) vaccine in Egypt.
Accessibility of affordable vaccines: gaps and WHO's role in supporting emerging manufacturers	SAGE suggested to monitor gaps and opportunities and consecutively develop a systematic process to responds to these needs in collaboration with keys partners. A perspective is to be presented at a future SAGE meeting on accessibility of affordable vaccines.	Pending	Nov 2010	Ongoing	WHO is actively contributing to increasing global access to vaccines through the following activities: 1) close collaboration (participation in annual meetings and bilateral meetings) with IFPMA and DCVMN as federations of manufacturers form developing and industrialized countries to ensure that they all have clarity on the needs of developing countries both in terms of types of vaccines but also in terms of their programmatic suitability; 2) Active participation in the annual DCVMN meeting to update them on new developments, concerns, and issues related to vaccine presentations, prequalification, regulation financing and priority country need. 3) WHO has resurrected and chaired the VPPAG (Vaccines Presentations and Packaging Advisory Committee) a forum for discussion between the public and private sectors on the characteristics of vaccines required for developing countries. The full participation of industry enables them to have more visibility of the needs and constraints of countries; 4) The DoV work stream on global access and vaccine price indicator which gets reported every years to the SAGE working group on the DoV. 5) General discussions on the process of technology transfers are taking place under the leadership of the Evidence Information and Research Cluster. 6) the Vaccine Product, Price and Procurement project (V3P) to support GAVI graduating and middle income countries through the provision of improved vaccine product and price information for decision-making. This 3-year project funded by the BMGF has conducted a number of assessments. It has also reviewed experiences on price information sharing mechanisms for medicines. The V3P database development is almost completed and should be live by the time of the April 2014 SAGE meeting. Capacity building activities are under development in close collaboration with partners to support countries and facilitate dialogue on price transparency and pricing policies.

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Childhood mortality	SAGE noted the recommendation by IVIR-AC that WHO would encourage countries to collect local data at country level and not only estimated age specific mortality rates by epidemiological modeling or expert elicitation.	Action	Nov 2010	Ongoing	All models reviewed by IVIR-AC are hampered by the lack of primary data, and more efforts should be made to make such data readily available. Specically, for pertussis disease burden estimation IVIR-AC suggests validating the parameter estimates against data from Senegal and Europe as a first step, although primary data from developing countries that is currently not publicly available would provide a more compelling comparator for validation. For polio more primary data should be made available for all models. IVIR-AC recommends that polio related data should be made available for multiple modeling groups to encourage comparison of results using different approaches.Ongoing/standing issue for many other diseases.
Cholera vaccines	Oral Cholera Vaccines(OCVs) - SAGE will further consider their use in endemic countries and whether a stockpile should be developed, particularly as current manufacturing capacity is limited.	Action	Apr 2011	Completed	OCV stockpile: A meeting on use of oral cholera vaccines (OCVs) in complex emergencies was held in early May 2011. Also in May 2011, the WHA passed a resolution (64.15) calling for an integrated, comprehensive strategy of cholera prevention and control. In April 2012, a meeting of the WHO Technical Working Group on creation of an oral cholera vaccine stockpile was convened by the Pandemic and Epidemic Diseases Dept (WHO HQ) to develop SOPs for implementation of the OCV stockpile for outbreak response, including definition of specific criteria for deployment of vaccine from the stockpile. An agreement for procurement of 2 million OCV doses for the stockpile was issued in June 2013 (with financial support from EU-ECHO, USAID, USFDA and three private entities). In Nov 2013, the GAVI Board approved a contribution towards a global OCV stockpile for the period 2014-2018 to increase OCV access in outbreak situations and endemic settings. OCV use in endemic countries: A meeting was held in Feb 2012 to review the experiences of the Zanzibar study on pre-emptive use of OCV (2006-2012) and the Zanzibar Government developed a proposal for island-wide use of OCV in risk groups with the aim to eliminate cholera and to scale up WASH interventions. OCV campaigns for outbreak control were implemented in 2012 in Haiti and Guinea Conakry with positive results in both.
Decade of vaccines/GVAP	SAGE requested consideration of the establishment of a SAGE standing working group to monitor GVAP implementation.	Action	Apr 2012	Completed	A SAGE DoV-GVAP standing working group has been established. The group met for their first face-to-face meeting from 9-11 September 2013 in Geneva. During this meeting the working group reviewed the indicators related to the GVAP strategic objectives. The group presented the first review of progress on the GVAP implementation at the November 2013 SAGE meeting and SAGE prepared the first progress report for the 2014 World Health Assembly. The GVAP working group met in February 2014 and will meet again in September 2014 to prepare for the next yearly review of progress to be presented at SAGE at its October 2014 meeting.
Decade of vaccines/GVAP	SAGE also recognized the urgency for having approximate cost and impact estimates and recommended that the technical group provide preliminary estimates for SAGE review in November 2013.	Action	Nov 2012	Ongoing	As part of GVAP resources invested in immunization will be tracked and monitored on a yearly basis throughout the decade, using the System of Health Accounts (SHA 2011) framework, the global standard to report spending in the health sector. The process to monitor resources invested in immunization will put emphasis on strengthening country capacity and creating a single platform for collecting, analyzing and reporting annually on all health expenditures, including those on priority diseases or programmes like immunization. This is intended to unify under a single platform other existing resource-tracking efforts, such as those being undertaken on national health accounts, and those for the Commission on Information and Accountability for Women's and Children's Health, and for the Global Fund to Fight AIDS, Tuberculosis and Malaria. This exercise will not only ensure regular and efficient reporting of good-quality data as part of the monitoring process, but also promote accountability and sustainability for immunization financing.

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Decade of vaccines/GVAP	The SAGE working group should continuously review the need for reformulation of the indicators or mechanisms for collection and reporting of data.	Action	Nov 2012	Ongoing	The SAGE report of progress with GVAP was presented to the WHO Executive Board on January 20, 2014. The concerns expressed by SAGE on lack of progress in some areas was noted by the EB. The EB Members also acknowledged the importance of data quality for monitoring programs and taking corrective actions. The WG met again in February 2014 where it specifically addressed the formulation of indicators that they found problematic in their review of progress and proposed reformulation.
Decade of vaccines/GVAP	IVR was encouraged to contribute actively to the research component of the DoV.	Action	Apr 2011	Ongoing	The Global Vaccines and Immunization Research Forum (GVIRF), to be held on 4-6 March 2014 in Bethesda, MD, will review and discuss progress on R&D and implementation research related to the GVAP. R&D indicators will be reported in 2014 and are being discussed at SAGE working group.
Dengue Vaccine	SAGE requested that future recommendations on dengue vaccine safety be linked to the dengue vaccine development strategy.	Action	Apr 2012	Ongoing	The dengue vaccine safety profile will be updated once an application for licensure has been filed.
Financing	SAGE identified the need to support countries that become ineligible and lower middle income countries through pooled procurement.	Action	Oct 2009	Ongoing	Various activities are conducted at global and regional level to support non GAVI and Lower Middle Income Countries (LMICs) - At global level: a study to enhance global knowledge and understanding of the challenges that Lower Middle Income Countries face as they explore potential adoption of new vaccines. The study was completed in March 2011. Finding and preliminary conclusions and recommendations were presented to the SAGE in November 2010. At regional level: EMRO is working with MICs in the region to set up a pooled procurement system with the support of UNICEF SD, CDC and PAHO and other partners. Identification of graduating countries and their potential constraints and issues is ongoing with GAVI and UNICEF to define measures and activities to overcome the obstacles and develop transition plans. 2 regional and 6 country assessment were conducted in 2012 on GAVI graduating countries. 4 country assessments and transition plans were conducted in 2013. Despite some progress, the challenges are enormous not only on the financial aspects but also on ownership, decision making, capacity, pricing, regulation and procurement aspects. The establishment of a pooled procurement in EMRO has been decided by the Regional Committee in 2012 and is under development despite the unstable political situation in the region. In November 2012, SAGE reviewed the situation faced by middle income countries including countries graduating from GAVI support and made strong recommendation calling for a global and coordinated effort to support MIC and for the establishment of a task force on Middle Income countries to advocate and support the implementation of the platform discussed at the November 2012 session on MIC. Terms of Reference were drafted, potential composition was identified, and contact with key partners was done to set up the SAGE recommended task force and working group. First teleconference to be held by 31 October 2013. The group was not convened as scheduled. Change in staff at HQ has resulted in delays in this area of work. The new staff has now started and we will regroup and revisit this area of work in the context of similar effoirts also being undertaken by GAVI and the Task Force for Global Health. An update on progress will be provided by June 2014.

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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 hosted its second annual meeting in November 2013. The portfolio of activities is now publicly available covering all 8 strategic objectives with priorities endorsed by the Planning Group.
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 a moderate (31.2%) level of efficacy in preventing HIV infection. Following SAGE recommendation on these aspects WHO/IVR/HVI and UNAIDS implemented the following 2 activities: 1. Development of a new ethics guidance point on ethical involvement of populations with high risk for HIV infection (i.e. people who injecting drugs) through extensive regional consultations. In 2013-14, the focus of work in this area is on "standards of prevention", i.e. the development of a framework that provides guidance on the non-vaccine preventive interventions, e.g. pre-exposure prophylaxis, to be provided during HIV vaccine trials. 2. In support of regulatory frameworks, WHO/IVR/HVI and UNAIDS have initiated a project on the development of a policy/discussion paper to facilitate national decision making with regard to the novel strategies for testing HIV vaccines; namely, most recently HIV vaccine trials in adolscents, adaptive trial design, etc. Currently, i.e. in Q1 2014, guidance on the future use of adenoviral vectors in HIV vaccine research. In October 2013, a written update was provided to SAGE on the progress of HIV-vaccine research, and the next update will be provided for the October 2014 SAGE meeting.
Hepatitis A	Long-term protection from single or 2-dose schedules should be regularly monitored by countries and reviewed by SAGE.	Action	Apr 2012	Ongoing	Post-market surveillance continues in Argentina and a detailed report on the recent epidemiological situation was provided to WHO in February 2014. There is still no identified breakthrough case among vaccinated children since the introduction of hepatitis A in the national immunization program in 2005. Hepatitis A cases have reached an all time low in 2013. Still occurring cases indicate that the risk persists in the population. As also requested by SAGE, an economic analysis of the impact of the single dose immunization strategy against hepatitis A in Argentina has been done. Estimated total vaccination cost for the 2006-2010 post vaccination period was ~US$ 45 million. The total of medical and societal costs plus immunization cost decreased from ~US$ 105 million for 2000-2004(prevaccination) down to ~US$ 56 million for the 2006-2010 post vaccination period i.e. a reduction rate of 46.5%. Both Colombia and Paraguay also introduced a single dose national immunization schedule for 1 year old children. Yearly review of the Argentina surveillance data will continue.

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Hepatitis B	SAGE recommended that the timely delivery of a birth dose of hepatitis B vaccine (that is, within 24 hours of birth) should be used as a performance measure for all immunization programmes. Reporting and monitoring systems should be strengthened to improve the quality of data on the birth dose.	Action	Apr 2009	Ongoing	A consultation on implementation of new universal birth dose recommendation was conducted in December 2010 with special focus on countries with a high percentage of home births. Outputs include a monograph documenting the systematic review and best practices from the consultation. IPAC reviewed this work in early 2011 and again in April 2012, and endorsed publication of 'Practices to Improve Coverage of the Hepatitis B birth dose vaccine'. From this, work is ongoing to develop field guidelines for scaling up Hepatitis B birth dose. The JRF (Joint Reporting Form) and associated materials have been revised to improve reporting of birth dose with a particular focus in WPRO and now steps are being taken to make HepB birth dose a WHO/UNICEF "best estimate" in line with previous SAGE recommendations. The WHO/UNICEF estimate process was piloted in 2012 in WPRO and was applied globally for the first time to the 2013 JRF birth dose data. Analysis of timely birth dose data for 2008 shows no significant changes from 2006 analysis and major issue is lack of data quality. A study of the cost of scaling up the birth dose by country has been completed, based upon previously published methodology estimating the cost of implementing the GIVS goals. In 2012, WPRO convened EPI and MCH managers from the five priority counties to jointly propose actions towards improving birth dose uptake.
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	In 2012, WHO HQ has published a framework for global action to control viral hepatitis (http://www.who.int/csr/disease/hepatitis/Framework/en/index.html). EMRO is working with Member States to ensure achievement of the Regional Committee goal for HBsAg reduction in vaccinated children. During the 2013 WPR's Regional Committee Meeting, 2017 was set as the target year to achieve the goal of reducing childhood hepatitis B prevalence to <1%. SEARO has a drafted regional strategy. AFRO has convened a regional hepatitis TAG and plans to present a plan for comprehensive viral hepatitis control during the 2014 RC Meeting. EURO will consider a regional hepatitis B control goal. PAHO has resolved to eliminate hepatitis B virus transmission and is formulating a regional strategy. Documenting the Impact of Hepatitis B Immunization: best practices for conducting a serosurvey (WHO/IVB/11.08) has been published by the department of Immunization, Vaccines and Biologicals.
Hepatitis E	SAGE approved draft ToRs for a Working Group on Hepatitis E and requested that WHO establishes this group in the summer 2013.	Action	Apr 2013	Completed	The SAGE Hepatitis E working group has been established and started its proceedings by teleconference. The group will have a face to face meeting in the summer of 2014 and aim to report at SAGE in October 2014 or at the subsequent meeting.

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

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Immunization supply chains	SAGE requested the following additional information: evidence and root-cause analyses of the EVM data, quantified evidence on invest ments needed to address the challenges (particularly on the relative expenditures on vaccine and cold chain equipment), information on the challenges in middle income countries; promising and innovative approaches (controlled temperature chain; supply chain integration; public-private partnerships in immunization supply chains), information on the GAVI end-to-end supply chain strategy and the role of the WHO-UNICEF immunization supply chain hub.	Action	Nov 2013	ongoing	A deeper analyses of the EVM data is ongoing and more insights on the root-causes of the EVM scores in countries will be presented in April together with an econometric analysis trying to understand whether there is a relationship between supply chain performance (as measured by the EVM) and immunization performance (as measured by coverage). The Secretariat is working on preparing for the SAGE Session in April. The content of the presentation will include promising and innovative approaches (controlled temperature chain; supply chain integration; public-private partnerships in immunization supply chains) and information on the GAVI end-to-end supply chain strategy and the role of the WHO-UNICEF immunization supply chain hub. At the moment it is unlikely that we will be able to analyse the situation in middle income countries given the paucity of date from this group of countries. Question to SAGE: on the quantified evidence on investments needed to address the challenges, would it be sufficient to present the estimates generated for the GVAP related to immunization supply chains?
Impact of the introduction of new vaccines on immunization and health systems	SAGE recommended that the ad-hoc working group work towards producing guidelines and tools for WHO to assist decision-makers and EPI managers contemplating the introduction of new vaccines, in order to take account of collateral effects inherent in introduction. The guidelines should provide a set of indicators that would enhance the potential positive effects, and reduce any potential negative effects, both on the immunization system and the health system. The guidelines should accommodate vaccines with different characteristics.	Action	Apr 2010	Ongoing	Further information was collected through a search of the published, unpublished and grey literature (such as post-introduction evaluation reports), as well as through key informant interviews. An in-depth study in 7 countries was conducted by LSHTM in 2011-12 to gather further information. Final results were presented in a meeting in London in November 2013. The ad-hoc group has updated the framework based on the data obtained and has drafted a guideline (Vaccine Introduction Guidelines – Adding a vaccine to national immunization programme) to assist country decision makers and EPI managers to take account of the potential effects/impacts of new vaccine introduction on the immunization and health systems. The 'Principles for adding a vaccine to a national immunization programme while strengthening the immunization and health systems' were endorsed by SAGE in April 2012 and form part of this guideline document, to be published in 2014.
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, about to be published in 2014 as a result of the proceedings of the ad hoc working group, have been vetted by the partner agencies and endorsed by their senior personnel.
Implementation research	SAGE suggested that implementation research on vaccines should be linked with the WHO Implementation Research Platform.	Action	Nov 2013	ongoing	
Implementation research	The implementation research agenda should define equity beyond traditional economic money metrics such as social economic status gradients, to include other measures of inequity such as the multidimensional poverty index or impacts on marginalized populations. SAGE suggested that studies to examine the integration of immunization with other health interventions should be included in the implementation research agenda.	Action	Nov 2013	ongoing	This recommendation is now part of the new IVIR-AC agenda under research to minimize barriers and improve coverage of vaccines currently in use.

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Influenza	SAGE requested that WHO report on epidemiology and surveillance of H7N9 as well as on the development of a potential vaccine candidate.	Action	Apr 2013	Ongoing	1/03/2014-There is no sustained human to human transmission of H7N9. As of February 25, 368 cases have been confirmed with a minimum of 112 deaths occuring in two waves ((1) Feb-May 2013, (2) Oct. 2013 – present). WHO updated its recommendation for vaccine development in February 2014. The recommended strain, A/Anhui/1/2013-like, remains the same. An update was provided to SAGE during the 2nd preparatory teleconference in March 2014 and a discussion on H7N9 and the influenza WG will be added to the agenda for one of the breakfast meetings during the April 2014 SAGE meeting, depending on H7N9 progression.
Influenza	SAGE recommends WHO continue urgent development of H5N1 stockpile. Further SAGE noted that WHO needs, concurrently with the acquisition of a stockpile, to develop the operational guidelines that would govern the management and release of the stockpiled H5N1 influenza vaccine, and to define appropriate methods for monitoring its use and evaluating outcomes. SAGE further recommended a feasibility study on the management and use of the stockpile.	Action	Nov 2010	Ongoing	This project is being taken forward by the SAGE influenza working group for influenza vaccines and immunization. Discussions are ongoing and continued during the last 3 face to face meetings. During the 2nd meeting in February, 2011, the WG favored the option of keeping the stockpile mainly as a virtual stockpile with a small physical stockpile of filled and finished doses of H5N1 vaccine for rapid response and outbreak control in case of need. WHO should ensure that it has procedures in place to facilitate the deployment of pandemic vaccine to countries in need of support. Lessons learned from the deployment of the H1N1 pandemic vaccine in 2009 and 2010 are used to develop guidance and procedures for future vaccine deployment activities. Guidance document and associated work plans are available in all UN languages from: http://www.who.int/influenza_vaccines_plan/resources/deployment/en/index.html. WHO H5N1 stockpile is also being discussed in the Pandemic Influenza Preparedness (PIP) framework. The issue of the stockpile and the pre-pandemic use of H1N1 vaccine was reviewed by SAGE once more in Nov 2013. In view of the fact that (a) the PIP Framework secures access to pandemic vaccine production, (b) there is no significant change in A(H5N1) epidemiology, (c) there is a substantial risk of poor antigenic/strain match between the actual pandemic virus and stockpiled A(H5N1) vaccine and (d) the value of a stockpiled vaccine for containment of a nascent pandemic remains doubtful, SAGE recommended that WHO should not create a stockpile of A(H5N1) vaccine, but should ensure immediate access to pandemic vaccines under the PIP Framework. SAGE also highlighted the need for WHO (a) to ensure equitable access by low and middle-income countries and (b) to put in place a strategy for timely communication of any delays in vaccine availability in case of a pandemic. Regarding the question of inter-pandemic use of A(H5N1) vaccines (if and when available), SAGE agreed that (a) no clear change in the low level of risk to exposed populations has been observed, (b) no changes in populations at risk for highly pathogenic avian influenza (HPAI) H5N1 virus infection have been observed and (c) while risk remains low, even in exposed populations, certain high-risk groups may benefit from vaccination given the severity of the disease. Therefore, SAGE concluded that its previous recommendations on the use of A(H5N1) vaccine during inter-pandemic periods, mainly focusing vaccination of persons at high risk of A(H5N1) disease through occupational exposure, should remain unchanged.
Influenza	SAGE recommended that the Influenza Vaccines and Immunization Working Group develop a research agenda.	Action	Nov 2010	Ongoing	Elements of an influenza research agenda were identified by the SAGE working group on influenza and a consultation on clinical trials of new influenza vaccines was done in 2013. Together with a consultation planned to be held in May 2014, a more formal influenza research agenda will be developed jointly with the global influenza programme of WHO.
Integration of vaccine services	SAGE requested a session during the April 2014 meeting on integrated approaches in immunization and other healthcare programs.	Action	Nov 2013	ongoing	A session on integrated approaches in immunization and other healthcare programs was added to the agenda of the upcoming SAGE meeting in April 2014.
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	WHO secretariat is currently reviewing existing evidence (one new publication on the subject) in context of the SAGE JE working group.

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Japanese encephalitis	Commercial kits for detection of JE-specific IgM should be compared and validated.	Action	Apr 2006	Ongoing	Assessment using serum was carried out by PATH and published Am J Trop Med Hyg July 07. Field validation of serum and CSF in India and Bangladesh was assessed in a joint WHO/CDC meeting, SEARO, February 2008. Nepal and Cambodia field evaluation of JE assays is complete and paper has been submitted to JID. Assessment of kits using CSFs accepted for publication in Am J Trop Med Hyg. CDC Fort Collins will distribute the 3rd serum and CSF proficiency test panel to evaluate in-house and commercial JE ELISA assays to WPRO JE labs 4ht quarter 2012. The three WPR JE regional reference labs (Japan, China and Republic of Korea) held their annual coordination meeting in Chengdu, China in the 2nd quarter 2012. China CDC JE regional reference Lab was fully accredited by WPR and HQ Lab Coordinators, August 2012. A WPR JE labnet meeting took place on 15 March 2013 and a Regional JE workshop for WPR is planned the week of 17 June in Seoul. Submission for publication of a paper summarizing the development of the JE LabNet is pending. The Regional Reference Laboratory for JE in the Western Pacific Region at the Victorian Infectious Diseases Reference Laboratory, Melbourne, has been fully accredited in Oct 2013. The Global Specialized Reference Laboratory for JE at the National Institute of Infectious Diseases, Tokyo, has also been fully accredited in Oct 2013. The diagnostic assay produced by PanBio ceased production at the end of 2013. An alternative assay produced by InBios with similar performance will be used in the WHO laboratory network. The training workshop at the Korean CDC in June was intended to introduce the network to this kit.
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	WHO is reviewing evidences in context of the SAGE working group on JE.

Topic	Recommendations/Action item	Category	Meeting Date	Status	Comments and Follow up
Lower middle-income countries: sustainable adoption and financing for new vaccines	SAGE requested that WHO facilitate the establishment of a partnership among all relevant stakeholders to consider: pooled procurement; tiered pricing; greater transparency of pricing; and exploring the role that UNICEF, the Pan American Health Organization and foundations can have in assisting these countries with procuring and financing vaccines.	Action	Nov 2010	Ongoing	Establishing a partnership among all relevant stakeholders to support middle income countries is our aim and has been clearly recommended by SAGE in 2011 and 2012. WHO has already started consulting with agencies towards projects and initiatives to explore possibilities to collaborate and support middle income countries with procuring and financing vaccines and immunizations. This is the case with UNICEF, PAHO, SIVAC, OPTIMIZE, PROVAC and others. We have also consulted with the Bill and Melinda Gates Foundation (BMGF) on their concerns and plans. They showed a great interest and are trying to identify the best approaches to support this objective. We have organized in January 2011 a successful brainstorming meeting on vaccine price and vaccine pricing focusing on issues faced by GAVI-graduating and middle income countries. A proposal was submitted and is now funded by the BMGF on vaccine product, price, and procurement (V3P project). This is a 3-year project aiming to identify, develop, and establish the most appropriate and comprehensive method(s), mechanism(s) and/or tools to provide countries with accurate, reliable, and useful data on vaccine product, price and procurement. This project has completed phase one (assessment of country needs and lessons learnt from other health sector) and is now starting phase two (V3P tool development and roll out, testing with countries and capacity building activities). In parallel, we have raised the LMIC issue within the Decade of Vaccines collaboration, it has been considered as one the priority of the decade of vaccines and is now reflected in the Global Vaccine Action Plan.(GVAP). Multiple consultations took place on GAVI graduating and middle-income countries activities and issues. The results of this consultative process were presented at the November 2012 SAGE meeting. SAGE appreciated the efforts made by WHO, UNICEF and GAVI and other partners to extend discussions about vaccine supply and pricing to MICs where appropriate, and the adaptation of some activities to suit MIC-specific needs. However, SAGE noted with concern that these efforts are fragmented and are failing to optimize synergies in the work being undertaken by each agency. SAGE noted that with a modest investment in technical assistance and capacity building could be significantly strengthened. SAGE requested that this issue and achievements be revisited in a subsequent meeting and that a task force is establish by WHO to coordinate policies and efforts of partners. At regional level, EMRO is working to launch, by the end of 2013, the EMR Initiative on pooled procurement, and to contribute to the UNICEF SD initiative on MIC and new vaccines. The political and general situation in Middle-East might delay concrete actions in that domain. This question was discussed during the 2013 EMRO regional Committee meeting.
Malaria	SAGE noted the utility of PPCs to developers and funders, and proposed that the opportunity for input into future PPCs at an early stage for any vaccine of public health importance could be included as part of SAGE's global public health mandate.	Action	Apr 2013	Ongoing	Development of malaria vaccine Preferred Product Characteristics is underway and scheduled for finalization by end 2014. A pre-final version will be sent to SAGE for comments in July 2014. A workshop was being held on the concept of WHO Preferred Product Characteristics at the Global Vaccine & Immunization Research Forum in March 2014.

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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	The timing for the "Decision" session depends on the outcome of the regulatory process. The European Medicines Agency is expected to make a regulatory decision in June 2015. If those timelines remain unchanged, a SAGE/MPAC (Malaria Policy Advisory Committee) joint session is expected in Oct 2015. The third set of results from the Phase 3 trial of RTS,S/AS01 was made publicly available on 8 Oct 2013. These results include site-specific efficacy and 18 month follow-up in both the 5-17 month age group and 6-14 week age group. In Jan 2014, SAGE members received the JTEG meeting report summarising these most recent results. Depending on the booster dose results, expected by Sep 2014, JTEG may propose recommendations for use in the 5-17 month age range. It is considered unlikely that JTEG will propose recommendations for use in the 6-14 week age range given the results to date, unless booster dose results in this age group give higher efficacy than after the primary immunization series. Any recommendation for use in the 5-17 month age range would require at least 2 new immunization visits. One possible schedule is 6 months (with vitamin A), 7-8 months (new visit) and 9 months (with measles first dose). JTEG considered that the data on co-administration with measles first dose is acceptable. Further exploration of possible schedules is underway. The first wave of 5 African national regulatory submissions will be to Kenya, Tanzania, Ghana, Senegal and Burkina Faso, where Phase 4 studies of safety and effectiveness are planned.
Maternal Immunization	SAGE concluded that the recommending bodies, including WHO, need to engage in a dialogue with regulators and manufacturers to review current regulatory practices against the evidence on risks and benefits and biological plausibility on product safety. SAGE requested WHO to develop a process and a plan to move this agenda forward in support of an increased alignment of data safety evidence, public health needs and regulatory processes.	Action	Nov 2013	ongoing	Secretariat is working with a public heath/regulatory consultant on an options paper that will be available at the time of the April SAGE meeting. Recommendations from that work will also be considered in the implementation of the influenza maternal immunization project, that begun Januray 2014.
Non-specific effects of vaccines	SAGE supported the two proposed literature reviews that include documentation of the current and proposed studies in the field. SAGE insisted that the reviewers should make efforted to include all available evidence and access all relevant data sets.	Action	Apr 2013	Ongoing	Working group constituted and functional. The results of the two systematic reviews were presented to the working group during their face-to-face meeting in January and will be presented to SAGE in April 2014.
Optimizing immunization schedules	SAGE recommended that WHO provide support to country-level policy-makers on the rational use of analyses generated by the tool.	Action	Nov 2010	Completed	We have approached SIVAC to collaborate in one African country as a case study (initially Cote d'Ivoire now considering Mozambique). After consulation with AFRO colleagues and, bearing in mind that the NITAGs have been only recently constituted, this activity has been postponed and no new date has been set yet. A draft of the website tool was presented to NUVI meeting participants in June 2013. It was well received and appreciated. The tool will be finalized once the systematic review of evidence on the remaining vaccines is completed and presented to SAGE.

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Pertussis control	SAGE endorsed the establishment of a pertussis-vaccine strain repository and a database on the genealogy and characteristics of different vaccine strains. A proposal should be presented to the Expert Committee on Biological Standardization.	Action	Apr 2010	Closed	The initial offer of the pertussis strains made by Dr. Nicole Guiso from the Institut Pasteur was not presented to the ECBS in 2010 due to the lack of information regarding the use of the strains and the related data. Discussions took place within the Institut Pasteur and their legal department advised that as strains had been received under specific contract from the vaccine manufacturers they could not be shared. However, they provided a list of strains received so that WHO can request permission directly from the vaccine manufacturers themselves for the strains to be used as needed for research purposes and for the genetic filiation of the strains to be publicly released.
Polio	The documentation for 'legacy planning' should include contributions from communities and front-line health workers on their experiences with the polio programme, what it has meant for them and how lessons learnt could further improve the routine vaccine and health programme.	Action	Apr 2013	Ongoing	The GPEI has constituted a Legacy Working Group (LWG), currently comprised of representatives from the spearheading partners (Rotary, WHO, CDC and UNICEF) and the Bill and Melinda Gates Foundation to take forward the legacy planning work. The LWG is finalizing its workplan. One of the major activities within the workplan will be to hold broad consultations with relevant stakeholders to document the lessons learnt and knowledge of the programme, to guide the direction of the legacy work, and to establish what benefit the lessons and resources of the GPEI could be to other initiatives. These consultations will begin in early 2014 and continue through the rest of the year. The consultation will include plans for soliciting contributions from communities and front-line health workers' on their experiences of polio eradication.
Polio	Sufficient capacity should be established at the global level to provide technical and programmatic support to countries to plan and implement all activities associated with OPV2 withdrawal and introduction of IPV.	Action	Apr 2013	Ongoing	The Immunization Systems management group, co-chaired by WHO and UNICEF, has been established to coordinate efforts towards the activities relating of OPV2 withdrawal and IPV introduction. The multi partner group has been operating since mid-April 2013 in five areas of work : Regulatory, vaccine implementation, communication, financing and routine immunization strengthening. The time investment dedicated by the staff of the six agencies engaged in the IMG (CDC, WHO, UNICEF, BMGF, Rotary and GAVI) since April 2013 has been impressive. WHO/EPI has filled an additional 3 professional staff positions at HQ to contribute to this effort. UNICEF HQ has filled one additional position. Similar positions will also be supported at Regional levels. These have yet to be filled.
Polio	SAGE encouraged a technical briefing on key OPV2 withdrawal issues at the WHA 2014, in advance of a potential WHA resolution in 2015 on a target date for the withdrawal of OPV2 from all routine immunization programmes globally.	Action	Apr 2013	Ongoing	A side-event on the IPV introduction and OPV2 withdrawal is being planned during the WHA in 2014.
Polio	SAGE recommended working closely with countries on activities towards OPV2 withdrawal.	Action	Apr 2013	Ongoing	A joint letter to all OPV only using countries was sent by the WHO DG and UNICEF ED, and the GAVI CEO where applicable, highlighting the importance of IPV introduction and outlining the SAGE recommendation on IPV introduction schedules and planning timelines. At the same time all WHO and UNICEF regional Offices have advanced in this area, with IPV being discussed at key meetings in all regions in Q4/2013 and Q1/2014. Further briefings to countries are planned at EPI manager meetings and regional working group meetings in February and March. Joint WHO/UNICEF regional coordination mechanisms are being established to ensure countries are suitably supported in the decision making process and in the development and implementation of introduction plans.

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Polio eradication	SAGE recommended that tight deadlines should be set for the completion of each step required to implement the switch from tOPV to bOPV. Similarly, urgent plans must be in place for the development of a low-cost IPV, and for its introduction by countries which choose to adopt this strategy. For countries planning to introduce IPV, including the low-cost IPV option, similar planning must take place.	Action	Apr 2012	Completed	Discussions among the GPEI partners, and activities of the SAGE Polio Working Group have continued since the November 2012 SAGE meeting to further refine the definition and timeline for the programme of work on the six main pre-requisites that need to be in place before the withdrawal of OPV2 (i.e. replacement of tOPV by bOPV for routine immunization) can be considered. As requested by SAGE, the considerably expanded work-streams on the OPV2 withdrawal pre-requisites - including lab containment of polioviruses, introduction and uptake of affordable IPV, IPV and bOPV product development and licensing, and MOPV2 stockpile and outbreak response, and anticipated time-lines within the polio endgame - were presented at the April 2013 SAGE meeting.
Polio eradication	SAGE requested that the Polio working group draft the necessary protocols for the 5 major components of the proposed strategy for type 2 virus detection and response after OPV2 cessation, in the areas of virus notification, surveillance, vaccine stockpiles, response and management of travellers for presentation to the SAGE in 2014.	Action	Nov 2013	ongoing	It is ongoing in collaboration with HSE cluster. It is planned to be submitted for SAGE October 2014 for review.
Polio eradication	"To facilitate prioritization, planning and implementation of IPV introduction at country level, SAGE recommended that consideration be given to developing a resolution on accelerated IPV introduction for submission to the World Health Assembly (WHA) in 2014."	Action	Nov 2013	ongoing	It is planned to be proposed and discussed during the WHA 2014.
Polio eradication	SAGE encouraged WHO to specifically assess how existing international mechanisms could be used to strengthen and implement vaccination recommendations for travellers entering and leaving polio-infected countries and areas and, for areas of uncontrolled transmission, to consider travel advisories.	Action	Nov 2011	Ongoing	This topic was extensively discussed during the SAGE polio WG meeting in February 2014, and will be subsequently presented to SAGE in April 2014.
Polio eradication	Update SAGE Polio Vaccine position paper, including recommendations from the November 2013 SAGE meeting on the introduction of at least one dose of IPV in national schedules.	Action	Nov 2013	ongoing	The updated polio position paper including the recommendations from the November 2013 SAGE meeting was published in the WER on the 28th of February 2014 (http://www.who.int/wer/2014/wer8909.pdf).
Polio eradication	SAGE requested that WHO/GPEI draft a 'GPEI Strategic Plan/Budget for 2013-2018' by November 2012 that incorporates OPV2 cessation and eventual bOPV cessation, with different scenarios for the timing of IPV introduction for the period of the tOPV/bOPV switch and longer term IPV uptake following complete OPV cessation.	Action	Apr 2012	Completed	Following this request from SAGE and a similar recommendation from the GPEIs Independent Monitoring Board (IMB), a Strategic Plan for the Polio Endgame and Legacy Options 2014 to 2018 has been drafted. This document was developed in close consultation with GPEI spearheading partners and other initiatives (i.e. GAVI), as well as with WHO Regional Offices; the SAGE Polio Working Group also reviewed the draft and provided comments. The document has three main sections: a) the endgame strategic plan, including the eradication of polio and management of associated risk, b) the financial requirements 2014 to 2018 (i.e. a 2014 to 2018 indicative budget), and c)the legacy, i.e. to define the broader global health benefits of the global polio programme. In November 2012, SAGE welcomed the long-term vision of the draft GPEI Polio Eradication and Endgame Plan, 2014-2018 and endorsed the 4 major components.

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Reports from other advisory committees	SAGE recommended appointment of appropriate programmatic and implementation expertise to IVIR-AC membership including representation of experts from low and middle-income countries.	Action	Nov 2011	Ongoing	Since 2013 IVIR-AC includes two programmatic and implementation research members from AFR and SEAR. Recruitment of new IVIR members is ongoing in 2014 to replace members who will rotate off and to fill existing vacant positions. Call for nomination will be posted soon for economists, mathematical modelers, social scientists, epidemiologists and an EPI manager (rotating membership).
Reports from other advisory committees on immunization	WHO and NIBSC should develop with other stakeholders, a business plan to assure long-term security of the development of WHO reference preparations as a global public health resource and additional efforts should be undertaken to disseminate outcomes of the committees deliberations and to explain the relevance of its work to the broader immunization community.	Action	Nov 2006	Pending	A comprehensive review of the work of the ECBS is still pending. The review will include (but not be restricted to) consideration of communication of ECBS outcomes. This will be linked with an overriding review of Expert Committees by the department of Essential Medicines and Health Products. SAGE will be invited to participate as soon as the review is terminated.
Security of vaccine supply	SAGE requested WHO to produce a report on the security of the supply of affordable vaccines and encouraged donors to invest in the development of new vaccine technologies that facilitate the delivery of effective, affordable vaccines to populations most at risk.	Action	Apr 2012	Ongoing	Discussion with donors has advanced well and planning for meeting on new vaccine technologies being initiated. Internal WHO discussions are in progress. Meeting on new vaccine technologies held in February 2014. The work on the supply of affordable vaccine is an on-going effort in which all immunization partners are engaged. Affordability of vaccine remains an on going challenge for a number of countries however recent accomplishments in the area of IPV supply and financing are a good indication that the trend is evolving positively through strong partnership between the public and the private sectors. Given the amount of work going on in this area under several other initiatives includign those reflected under item "Financing", we have discussed internally and have decided that, for the time being the production of a report was not warranted. SAGE will be kept informed on an on-going basis of propgress made and new developments .
Smallpox vaccines	SAGE recommended that WHO initiate discussions with countries in possession of smallpox vaccine to establish mechanisms for replenishment of the WHO stockpile in case of need.	Action	Nov 2013	ongoing	Negotiations have already started. An operational framework for vaccine donation has been developed with USA and Germany. A working group of GHSI is going to meet 17-18 March, 2014 to finalize the legal aspects of the framework. WHO and Japan are also working on material transfer agreement. WHO and France have sent an official letter to donate vaccine.

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Surveillance	SAGE endorsed the recommendations of the ad hoc TAG for improving the quality of the IB-VPD surveillance network and urged that the objectives of this network be more clearly defined, that collaboration with other surveillance systems and laboratory networks (i.e. the polio/measles laboratory networks) be continued, and that, where feasible, activities be linked with other programmes enhancing country capacity, including implementation of the International Health Regulations. SAGE urged greater attention to integration of data systems, which would facilitate real-time analysis and performance monitoring. SAGE also noted the opportunities for integration by building upon the enhanced capacity developed by these networks to conduct surveillance for other diseases using a similar case-definition and personnel trained in applying and adhering to rigorous surveillance protocols. Both networks should continue to share experiences with the polio surveillance network. Integration efforts must be strategically designed in ways that are logical and synergistic.	Action	Nov 2013	ongoing	During 2013, a strategic review of the invasive bacterial vaccine preventable diseases (IB-VPD) and rotavirus surveillance networks was undertaken by WHO and its informal Technical Advisory Group for new vaccines surveillance and presented to SAGE in November 2013. WHO is now developing a sentinel surveillance management framework to prioritize and guide actions to implement all SAGE recommendations from the 2013 meeting. Actions already implemented related to data include: development of an agreed IB-VPD variable list for sentinel sites and Regional Reference Laboratories; development of a draft rotavirus list for sites and an agreed list for rotavirus Regional Reference Laboratories; agreement to share case-based sentinel site data throughout the network and to increase data reporting frequency to a quarterly basis for sentinel sites and to twice yearly for IB-VPD RRL data; discussion with AMRO & SEARO countries regarding web-based data reporting with realtime data entry, verification and analysis; initial steps taken to pilot such a web-based data system in one to two AMRO countries, with additional discussions in SEARO and with WPRO regarding lessons learned from their new web system that will be launched in 2014. To better integrate with other VPD surveillance networks, the sentinel site surveillance laboratory coordinator will continue to have monthly meetings with the polio and measles laboratory coordinators.
Tuberculosis vaccines	SAGE endorsed the establishment of a WHO TB vaccine technical expert group with representation from SAGE. An annual written report on TB vaccine developments should be provided to SAGE.SAGE would be provided with two-page summaries of progress every year. TB would only be included on the agenda of SAGE when there is a meaningful development of decision from SAGE required.	Action	Nov 2011	Ongoing	Written update to SAGE was provided ahead of the November 2013 SAGE meeting. In December 2012, the first consultation of the TB TEG was held to review clinical trial plans for two advanced new TB vaccine candidates, VPM1002 (VPM, Germany) and M72 (GSK Biom, Belgium). Another meeting is planned for Q3 with the remianing (advanced) developers of new TB vaccines, and a report will be provided to SAGE together with the 2014 annual update on TB vaccines, in Oct. 2014.
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	As previously reported to SAGE, the first (and to date the only) typhoid polysaccharide vaccine was prequalified in June 2011. However Vi polysaccharide vaccine uptake has remained low for multiple reasons, including lack of funding. In November 2011, the GAVI Board re stated its 2008 commitment to fund typhoid conjugate vaccines in the GAVI Vaccine Investment Strategy; it is expected that a typhoid vaccine support window will be opened when a WHO prequalified vaccine is available. Currently, 2 typhoid conjugate vaccines have been licensed by NRAs, one vaccine is undergoing review for national licensure, and several others are in clinical trials. A first application to WHO for pre-qualification is expected in late 2014. WHO guidelines on the quality, safety and efficacy of typhoid conjugate vaccines were approved by the ECBS in Oct 2013 and published. WHO/IVB is planning an expert meeting in 2014 to review the availability of clinical data to inform the future SAGE policy process. An initial 3-year grant (2011-2013) from the Bill and Melinda Gates to the Coalition against Typhoid (CaT) and Sabin Vaccine Institute was renewed for an additional two years to support typhoid control and prevention activities, including immunization. The International Conference on Typhoid Fever and Other Invasive Salmonelloses held 1-2 March 2013 in Dhaka served as testament to increased advocacy and prioritization efforts.

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Un/under-immunized children	SAGE requested that WHO quickly roll out tools so that other countries can address low coverage of vaccination.	Action	Nov 2010	Ongoing	A set of one diagnostic tool and 6 in-depth tools had been envisaged. The basic tool (diagnostic tool) has been developed at HQ. The EURO, AMRO/PAHO and AFRO regional offices and HQ of WHO; UNICEF; and MCHIP are working on developing the 6 in-depth tools to address different facets of the problem. The in-depth tool "A Guide to Tailoring Immunization Programmes (TIP) has already been developed by WHO-EURO and is available at http://www.euro.who.int/__data/assets/pdf_file/0003/187347/The-Guide-to-Tailoring-Immunization-Programmes-TIP.pdf
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	Due to lack of staff and three Level 3 emergencies in 3 months, The Emergency Risk Management and Humanitarian Response (ERM) Department lacked the capacities to complete this task. The relevance and applicability of this recommendation will be reviewed in the coming months, once the demands on ERM staff for field deployments to assist in emergencies have settled down.
Vaccine Hesitancy	SAGE suggested that the definition include “when uptake of a vaccine or immunization programme in a community is lower than would be expected in the context of information given and services available”.	Action	Apr 2013	Completed	The Working Group reworded the definition of vaccine hesitancy taking into account the proposed wording by SAGE: "Vaccine hesitancy is an emerging term in the discourse on determinants of vaccine acceptance where uptake of a vaccine or immunization program in a community is lower than would be expected in the context of information given and services available. Vaccine hesitancy recognizes that issues of complacency, convenience and/ or confidence in vaccine(s) or immunization programs may all contribute to the delay or refusal of one, some or almost all vaccines. These factors which influence vaccine acceptance vary by setting and responses need to be locally assessed." During the face to face meeting in December 2013, the working group revisited the definition to shorten and make it more comprehensive. The wording of new definition is: "Vaccine hesitancy refers to delay in acceptance or refusal of vaccines despite availability of vaccine services. Vaccine hesitancy is complex and context specific varying across time, place, and vaccines. It includes factors such as complacency, convenience, and confidence."
Vaccine Hesitancy	SAGE recommended close linkages and interaction with key WHO and UNICEF initiatives to address the unvaccinated or under-vaccinated groups and relevant interventions.	Action	Apr 2013	Ongoing	Close collaboration with partners, initiatives, and key stakeholders in the field of vaccine hesitancy is sought. During the Working Group's monthly teleconferences, partners are invited to present their work (e.g. UNICEF on their polio-related work) and link with the Working Group directly. In addition, WHO colleagues from other departments such as Communications and the Vaccine Safety and Vigilance Team, as well as UNICEF staff, were attending the 3rd face-to-face meeting of the Working Group in December 2013.
Vaccine Supply	It was noted that SAGE needs to address the constraint experienced across Regions of repetitive shortfalls in vaccine supply, both for existing vaccination programmes (in particular for DTP-containing vaccines) as well as for new/emerging vaccines, and the impact on vaccine coverage in several countries.	Action	Nov 2012	Ongoing	Discussions have been initiated with UNICEF Supplies Division, and UNICEF Programme Division to work on global vaccine supply issues. A meeting was held in Copenhagen on 28 September 2013 to review the supply of traditional vaccines. Both DTP vaccine and to a lesser extent mono-HepB vaccine are increasingly of limited supply. Further intelligence is needed on countries plans to start DTP booster doses and Hep B birth doses, both of which require the vaccines without further combination.

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Vaccine coverage	SAGE recommended that WHO support new research for biological specimen collection including rapid on-site diagnostics that could improve coverage and susceptibility estimates. Improved serological surveillance techniques could be integrated with existing population-based surveys such as DHS or MICS. These research topics should be included on the QUIVER (now IVIR-AC) agenda.	Action	Nov 2011	Ongoing	As the Bill & Melinda Gates Foundation is now accepting Letters of Inquiry for the development of an easy-to-use tool that rapidly assesses the immune status of children against select vaccine-preventable diseases. Inquiries will be welcome that focus on prototype development and detail plans for future commercialization possibilities.
Vaccine coverage	SAGE recommended that WHO explore alternative survey methods to improve the precision, reduce the cost and improve the usefulness of survey results to national and local immunization programmes.	Action	Nov 2011	Ongoing	To improve the precision and usefulness of survey results and to reduce the cost of surveys, SIG proposes to explore 1) recent advances in sampling methodology, 2) new technologies for constructing sampling frames, supervision of field work, data collection, and analysis and 3) alternative content, collection, analysis, presentation and linkages with other data sources. An explicit description of precision, usefulness and cost of various trade-offs between alternative methods will constitute part of the exploration. An initial meeting was convened of the IVB Informal Advisor Group on Monitoring Immunization Programme Performance through Household and Community Surveys. First meeting addressed the need to modify Demographic and Health Surveys (DHS) - implemented by ICF International; the UNICEF Multiple Indicator Cluster Surveys and the WHO Immunization Cluster Survey to accommodate changes in immunization system strategies. On 17-18 September 2012 a meeting was held with representatives of ICF and UNICEF to discuss modifications to their standard recommendations on data collection, analysis and presentation of immunization coverage data. WHO and UNICEF will provide written recommendation to these agencies. An informal working group has been created to review and revise WHO guidance on measuring immunization coverage through household and community surveys. The working group met in July 2013 to agree on the scope of work, to identify initial products, and establish a plan of document production, review, pilot testing, and clearance. Guideline drafting has been begun and a working group meeting to finalize a draft for external review is scheduled for March 2014. Regional offices have been contacted for suggestions regarding potential countries for pilot testing. A protocol for pilot test is being developed and a consultant has been identified to coordinate test.
Vaccine coverage	WHO to identify appropriate methods and develop guidelines for collecting, analysing, and interpreting biomarkers for validating coverage.	Action	Nov 2011	Ongoing	WHO to identify appropriate methods and develop guidelines for collecting, analysing, and interpreting biomarkers for validating coverage. A draft document which reviews, for a selected list of vaccine-preventable diseases, laboratory test available and associated requirements for specimen collection/transport, personal experience and training, and laboratory supplies and equipment has been prepared. The draft will be reviewed internally and following recommended changes will be submitted for review by external experts. For each selected disease study populations, sampling methods, data/specimen collection, laboratory/statistical analysis, and implications of results were summarized in an accompanying document. Work in progress was presented to WHO and UNICEF Regional Focal Points for immunization during the Meeting on Monitoring National Immunization Systems, 9-11 October 2012 for their comments. Internal and external review of the document will continue and after incorporating the comments draft guidelines will be developed for use of sero-surveillance as an evaluation tool for immunization programmes.
Vaccine safety	SAGE highlighted the urgent need for a safety review of other important vaccines that could be used during pregnancy.	Action	Nov 2012	Ongoing	A sub-group of GACVS has been launched to address vaccine safety during pregnancy. A finalized version of the GACVS report on safety of immunization during pregnacy was published and has been made available to SAGE in November 2013. Publication of the report is to be expected in the first half of 2014. A more systematic review has been piloted for Rubella and is expected to become available in summer 2014.

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	Completed	A SAGE Working Group on vaccination in humanitarian emergencies was established in June 2011. Multiple teleconferences were held and two face-to-face meeting of the working group took place on 20-21 September 2011 and on 16-17 February 2012. The group reported to SAGE in April and November 2012. In November 2012, SAGE endorsed the complete framework for decision making on the use of vaccinations in humanitarian emergencies as a major step forward and considers that it fills an existing gap but acknowledged that the framework focuses on vaccination, which is only one priority consideration in humanitarian emergencies. SAGE strongly affirmed the potential utility of this framework and recommended pilot testing in the field. The working group was asked to adapt the document to take into consideration SAGE's comments and proceeds with its finalization. The working group has since then finalized the framework which following final editing has been published and is available on the web at http://www.who.int/iris/bitstream/10665/92462/1/WHO_IVB_13.07_eng.pdf. More efforts need to be made to disseminate the framework to partners and to evaluate its usefulness and update as necessary down the road.
Yellow Fever	SAGE requested WHO to revisit the IHR provisions relating to the period of validity for international certificates for vaccination against YF.	Action	Apr 2013	Ongoing	A proposed revision to the relevant provisions in the International Health Regulations (2005) (IHR) was endorsed by the WHO Executive Board in January 2014, and recommended for adoption to the World Health Assembly (WHA) which meets in May; any revision to the IHR must be adopted by the WHA, followed by an extended period prior to which the revised provisions enter into force for the 196 States Parties to the IHR (including all WHO Member States).