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	A workshop organized by WHO/AFRO was held in Grand Bassam (Cote d'Ivoire) from 13-17 May 2013, in collaboration with the MOH and other immunization partners (GAVI, UNICEF, USAID/MCHIP et NESI) to revise the 2006 EPI prototype curricula for medical & nursing/midwifery teaching schools in the AFR. During the workshop, 4 drafts of EPI prototype curricula were produced and were to be harmonized, finalized and edited. That is 2 curricula for medical schools in French and 2 curricula French & English for nursing/midwifery schools. The 4 curricula have been finalized and edited and will be ready for diffusion to countries by end 2014.
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 Germany is being discussed. TIP will be adapted for use on a global level and a second edition will be published later in 2014. In June 2014, TIP was pilot tested in South Africa 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 was discussed at the April 2014 SAGE meeting. SAGE concluded that addressing integration, by its very nature, requires a broader discussion beyond SAGE. In this regard, it was proposed that the SAGE working group on the DoV consider options for moving forward, as integration is reflected as both a guiding principle and a strategic objective of the GVAP.

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General	SAGE encouraged the Regional Office in EMRO to pay special attention to countries affected by political turmoil and requested specific monitoring for any adverse impacts on immunization programmes in GAVI graduating countries.	Action	Apr 2011	Ongoing	There are no GAVI graduating countries in the EMR. EMRO is working closely with and is paying special attention to the countries affected by political turmoil. The following support was provided since the last SAGE meeting in April 2014: • continuing implementation of routine vaccination in the provinces hosting the refugees camps in Jordan. • implementation of the national Measles campaign in Syria in June 2014. • provision of support to Tunisia for recruiting technical staff to support EPI. • provision of support to Tunisia for preparing for introduction of IPV vaccine. Provision of technical support to MOH and NITAG, Egypt for setting alternate vaccination schedule and procurement modalities to overcome the stock-out of different vaccines.
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	Ongoing	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 its October 2014 meeting. The paper clarifying the differences between regulatory decisions and public health recommendations has been commissioned and is under development. A draft paper intended for publication in a peer review journal should be available around the time of the October 2014 SAGE meeting.
General	SAGE called for the identification of novel communication strategies for the work of GACVS to have a greater impact and help maintain confidence in vaccines.	Action	Apr 2014	Ongoing	A document on GACVS future is currently under preparation and will address this issue in particular.
General	A recommendation was made for consideration of a platform for immunization coverage in the 2nd year of life, in view of potential necessary booster doses and opportunities to catch up with incomplete vaccination, and removing the artificial barrier often experienced after the 1st birthday.	Action	Apr 2014	Ongoing	A draft concept note on developing a 2nd year of life platform has been produced, and is being used as the basis to establish a discussion group of partners to move this area of work forward. Additionally, the 2nd year of life platform has been included in a WHO proposal for funding support which is currently being reviewed for consideration by the BMGF.

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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 key 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) A new committee known as the Product Development for Vaccines Advisory Committee was established and met for the first time 8-10 Sep 2014. The group reviewed 19 pathogen specific global pipeline analyses (all available from the meeting website) and advised WHO on strategic prioritization for WHO activities related to early stage vaccine R&D (pre-licensure to Phase 2). The group will oversee the development of Vaccine Preferred Product Characteristics. 7) the Vaccine Product, Price and Procurement project (V3P) to support GAVI graduating and middle income countries through the provision of improved vaccine product and price information for decision-making. More information on V3P is provided under the topic of financing in the tracking sheet.
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.
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	IVIR-AC concluded that the DOVE study presented on the approximate cost and impact may be adequate for high level use such as tracking of the GVAP and justifying its funding to donors on return of investment but had observations with the regard to the state of the art of the individual modeling components. Furthermore, IVIR-AC identified the need for increased transparency and clarity in all methods used including refined sensitivity and uncertainty analysis.

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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. The SAGE assessment report was further presented to the WHA. A record number of 54 interventions on the report were made. In general, the report was very positively received. Several issues were highligted, the most prominent being the issues of vaccine prices and access to affordable vaccines. The 2013 secretariat progress report was reviewed by the DoV WG. The WG assessment report will be presented to SAGE at its October 2014 meeting.
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. A risk management plan will be discussed at the December 2014 GACVS meeting.
Global vaccine safety Blueprint	The Blueprint implementation should be led by WHO and its partners. It should be aligned with other related WHO capacity-building efforts. This includes in particular immunization programme and national regulatory authorities strengthening together with the development of national expert advisory bodies. SAGE suggested that a mechanism be developed to enable prioritization of both activities and countries in the implementation of the Blueprint. SAGE invited the GAVI Alliance and other partners to support this implementation.	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. The GVSI has been operating with 2 annual Planning Group meetings. The third GVSI meeting will take place in October 2014 in China, jointly with national pharmacovigilance centres meeting.
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 a further update will be provided ahead of the October 2014 SAGE meeting.

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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.
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	EMR has a Regional Committee goal of reducing childhood hepatitis B prevalence to <1% among children <5 years by 2015. EMRO is working with Member States to ensure achievement of this goal. WPR established a Regional Committee goal to reduce hepatitis B infection to <1% among children at least 5 years of age by 2017. 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) was published in 2011 by the department of Immunization, Vaccines and Biologicals. In 2012, WHO HQ has published a framework for global action to control viral hepatitis (http://www.who.int/csr/disease/hepatitis/Framework/en/index.html).
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 the 2013 publication of 'Practices to Improve Coverage of the Hepatitis B birth dose vaccine'. From this, work is ongoing to develop field guidelines for scaling up Hepatitis B birth dose. The JRF (Joint Reporting Form) and associated materials have been revised to improve reporting of birth dose with a particular focus in WPRO. The WHO/UNICEF estimate process was piloted in 2012 in WPRO and was applied globally for the first time to the 2013 JRF birth dose data. Analysis of timely birth dose data for 2008 shows no significant changes from 2006 analysis and major issue is lack of data quality. A study of the cost of scaling up the birth dose by country has been completed, based upon previously published methodology estimating the cost of implementing the 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 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 was established in 2013. The group met face-to-face in June 2014 and held multiple teleconferences. It will report to SAGE at the October 2014 meeting.

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Immunization Supply Chains	SAGE commended the IPAC “Call-to-Action” as a strong advocacy document and suggested the recommendations be distilled into key messages that could be used in the GVAP report to the WHA and in the context of the 40-year anniversary of EPI. SAGE endorsed the IPAC ‘Call-to-Action” and affirmed the importance of the WHO-UNICEF Joint Statement on EVM as tools for global policy advocacy. Both need to be packaged in an effective and complementary manner.	Action	Apr 2014	Closed	The IPAC "Call to Action" has been finalized in English and published as an official WHO document. It is currently being translated into French. The document was shared as part of the materials provided for the Ceremony around the WHA commemorating the 40 years of EPI. Both the IPAC "Call to Action" and the WHO/UNICEF Joint Statement have been finalized and have been packaged in a way that highlights their differences and complementarity.
Immunization Supply Chains	SAGE recommended that the EVM assessment include the measurement of human resource capacity and encouraged WHO to use EVM assessments in alignment with new vaccine introduction impact assessments, to strengthen the links between supply chain issues and programme outcomes. To further improve the EVM assessment, it was suggested that the tool be used for supervisory purposes and that a composite score be developed to complement the across-the-board benchmark of 80%.	Action	Apr 2014	Ongoing	This will be undertaken in 2015 as part of expanding the EVM assessment with additional modules covering Human Resources; LMIS; and System Design (among possible others). The EVM assessment has already been designed for supervisory purposes.

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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: 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 and Hep B will be presented to SAGE in April 2015.

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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. 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	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. 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 were published in 2014 (Principles and Considerations for Adding a Vaccine to a National Immunization Programme) 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 outlined some considerations for IVIR-AC to include in their deliberations – assessment of the use of high quality randomized controlled trials where feasible (noting the substantial ethical and methodological challenges involved), with sufficient power to explore sex differences, and a priori defined and standardized immunological endpoints designed to answer the specific question of non-specific effects– and emphasized that future research should draw on a broad investigator pool and from a wide range of geographic locations using a standardized protocol.	Action	Apr 2014	Ongoing	During IVIR-AC September 2014 meeting it was suggested to develop standardized protocols and start implementing high quality RCTs where feasible. At least studies should mimic RCT situations with sufficient power to explore sex differences, and a priori defined and standardized immunological endpoints. With BMGF support a multi-disciplinary team with IVIR-AC participation will start reviewing the evidence and identify research questions.
Implementation Research	SAGE identified the conditions necessary for pertussis resurgence and the effective strategies for prevention of resurgence as important topics for modelling research.	Action	Apr 2014	Ongoing	The September 2014 IVIR-AC meeting concluded that the models presented by modeling groups from Australia, UK and US were appropriate in terms of structure to better understand both schedule optimization in various countries and different transmission settings. However, availability and quality of data in LMICs remains the key problem, thus IVIR-AC calls for better surveillance systems in LMICs. An IVIR-AC subgroup under the "WHO VPD burden and impact framework" will identify specific data needs for parameterization of various models by conjoining need with epidemiological expertise.
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. During the September 2014 meeting IVIR-AC identified the need for standardization of research tools and protocols to examine the integration of immunization with other health interventions and non-vaccination to be applied locally, by antigen including on how to translate the evidence to community messaging. IVIR-AC recommended to establish a sub-group to propose elements of the menu of solutions on the integration of care with immunization programs and another sub-group on non-vaccination. A two year time line selective approach on integration was proposed at two levels i.e. service delivery and management. IVIR-AC recommended to use the project proposal on "Evaluation of GAPPD interventions: example for Mazabuka District in Zambia" as a case study.

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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	There has been no sustained human to human transmission of H7N9. As of 28 August 2014, 453 cases have been confirmed with 154 deaths in two waves ((1) Feb-May 2013, (2) Oct. 2013 – present). These cases were from China (Mainland, HK and Taiwan) including a Chinese case detected in Malaysia. WHO, through its global network GISRS, has been monitoring the evolution of the H7N9 and conducting continuous risk assessment. So far, although internal genes of the H7N9 virus are constantly reassorting with avian influenza A(H9N2) endemic in poultry locally, the HA and NA are less divergent. Antigenically the H7N9 virus remains closely related to the WHO recommended vaccine virus A/Anhui/1/2013-like virus. Clinical and epidemiological features of H7N9 remain unchanged: CFR: 34.6%; Mean age of cases in 2nd wave: 53yo; M:F=2.3:1. So far 8 reverse genetics engineered candidate vaccine viruses developed and available from the WHO GISRS. However classical reassortment has not yet succeeded.
Integration of vaccine services	SAGE requested a session during the April 2014 meeting on integrated approaches in immunization and other healthcare programs.	Action	Apr 2014	Completed	A session on integrated approaches in immunization and other healthcare programs took place at the SAGE meeting in April 2014. During the session in April 2014 it was noted that addressing integration, by its very nature, requires a broader discussion beyond SAGE. In this regard, it was proposed that the SAGE working group on the DoV consider options for moving forward, as integration is reflected as both a guiding principle and a strategic objective of the GVAP. Monitoring progress with integration of immunization with other primary health care programmes, as part of the GVAP monitoring, was discussed with the Chairs of SAGE and the SAGE DoV WG. It was agreed that the secretariat would put together data for a couple of indicators for review by the WG, on the basis of which they could choose one. While the quality of the data may not currently be sufficient to effectively monitor integration, it was felt that the report would serve to highlight the importance of integration and the fact that this was an important component of GVAP.
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. This will be presented in the context of the JE session at SAGE Oct 2014.

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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 was held the week of 17 June in Seoul. Submission for publication of a paper summarizing the development of the JE LabNet is pending. The Regional Reference Laboratory for JE in the 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. A biregional laboratory training workshop and laboratory network meeting is being planned for March 2015.
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	A comprehensive evidence review has been conducted by SAGE WG and findings will be presented at SAGE Oct 2014 meeting.

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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	Access to vaccines for Middle Income Countries (MICs) is important from a public health impact perspective and from an equity viewpoint. Also, MICs could provide a large demand volume for vaccine supply, promoting competition and a healthy vaccine market to the benefit of both recipient countries and suppliers. Various efforts are ongoing to support MICs including: GAVI Alliance support for about 40% of MICs, capacity building for market intelligence and procurement (UNICEF SD and WHO), efforts to promote price transparency (GVAP price report and Vaccine Product, Price Procurement initiative V3P), initiatives to explore access to afforable prices (Harvard Glonal Health Institute, GAVI Alliance preliminary studies), support to countries graduating out of GAVI support (graduation assessments and funded graduation plans), pool procurement efforts (UNICEF SD; PAHO; and regional efforts - EMRO, Baltic States), technical assistance efforts for setting up of CMYPs, strengthening of NRAs, NITAGs, initiatives to improvie sustinable financing (SIVAC, SIF) and informed decision making (ProVac). Exceptional, catalytic support is also provided to non GAVI countries for introduction of IPV in accordance with the Polio Endgame timelines. However, in 2012 SAGE noted with concern that these efforts are fragmented and are failing to optimize synergies in the work being undertaken by each agency. SAGE noted that with a modest investment in technical assistance and capacity building 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. WHO has set up a MICs Task Force in June 2014. The Task Force includes main immunization stakeholders (WHO, UNICEF, World Bank, GAVI Secretariat, BMGF, AMP, Sabin, Task Force for Global Health) and is working to establish a shared strategy for sustainable access to vaccines in MICs in consultation with countries, CSOs and industry. The aim is to finalise a strategy and plan of action by April 2015. This will allow coordination of efforts for effective and efficient results and idenfitication of gaps for further action. Strengthening of country procurement regulation and capacity has already been identified as a clear need in past consultations/analytical work. Different efforts are ongoing in this area: UNICEF SD MICs tender, PAHO revolving fund, EMRO and Baltic States pool procurement initiatives, different discussions on procurement planned or initiated by WHO regions (e.g. WPRO). The Vaccine Product, Price, Procurement initiative (V3P) provides a platform for countries to share and receive information on available procurement method and to convene countries for procurement discussions. The work of the MICs task force will allow to take stock of ongoing effort and shape future direction in this as well as related areas.

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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	Malaria Vaccine Preferred Product Characteristics were shared by email with SAGE committee members for their individual comment during July 2014. The document has passed external review with positive comments, and is now in the process for publication as a WHO document during 2014. A new committee known as the Product Development for Vaccines Advisory Committee met for the first time 8-10 Sep 2014. The group reviewed 19 pathogen specific global pipeline analyses (all available from the meeting website) and advised WHO on strategic prioritization for WHO activities related to early stage vaccine R&D (pre-licensure to Phase 2). The meeting report will be shared with SAGE as soon as it is available. The criteria the committee used to prioritize WHO activities in early stage vaccine R&D were the unmet public health need, the chances of a product emerging in 5-10 years, and the added value of WHO engagement to advance product development to meet the need in low income countries. WHO plans to engage in further PPC development and clinical trial design consensus-building in the chosen priority pathogen areas as resources and staffing.
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 timing of the regulatory decision. The European Medicines Agency is expected to make a regulatory decision between July and September 2015. The submission was made in July 2014. If the September 2015 timeline is met for EMA decision a SAGE/Malaria Policy Advisory Committee meeting joint session is expected in Oct 2015. The final results from the Phase 3 trial were reviewed by JTEG 25-26 September 2014, and SAGE will be sent the JTEG meeting report as soon as it is available. Any recommendation for use in the 5-17 month age range is likely to focus on the 5-9 month age period for the primary immunization series due to the age pattern of malaria. JTEG reviewed the data on a fourth booster dose given 18 months after the primary immunization series. The first wave of African national regulatory authorities will receive submissions for marketing authorization during early 2016. If EMA gives a positive opinion, WHO recommendations for use are issued, and PQ has occurred by 2016, the GAVI Board will meet to consider the updated impact estimates to make a decision on the possible opening of a window for the malaria vaccine.
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	A review was conducted by the Essential Medicines group in July 2014 (report in preparation). Secretariat is working with a public heath/regulatory consultant on an options paper that will be available in 2015. Recommendations from that work will also be considered in the implementation of the influenza maternal immunization project, that begun in 2014.

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Pertussis	A systematic review of the optimal primary immunization schedules (in association with diphtheria, tetanus toxoid containing vaccine) is ongoing and will be presented at the October 2014 SAGE meeting. The 2010 pertussis position paper will be updated after the results of this review are available. In the meantime a short update to the position paper will be published to clarify that the previous statement on the choice of vaccine contained in the 2010 vaccine position paper no longer holds true.	Action	Apr 2014	Ongoing	An update of the pertussis position paper was published in the WER on Friday July 25. The systematic review was completed and a face-to-face meeting of the pertussis Working group took place at the end of August 2014. In view of the conclusions of the group that there was no evidence to recommend significant changes to the immunization schedules and in the context of the Ebola outbreak pressure, the decision was made to postpone the reporting to SAGE and related discussions to the April 2015 meeting. The publication of the full update to the pertussis position paper will then be initiated after the April 2015 SAGE meeting.
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 has finalized and is implementing its workplan. One of the major activities within the workplan is to hold broad consultations with relevant stakeholders to document the lessons learnt and knowledge of the programme, to guide the direction of the legacy work, and to establish what benefit the lessons and resources of the GPEI could be to other initiatives. These consultations began in early 2014 and are continuing 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. In addition, the GPEI has contracted a consultant group that will conduct in-country interviews that will include learning lessons of polio eradication.
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. All regions have held, or will have held by the end of this year, at least one meeting that included a substantive focus on IPV introduction. In addition, many regions have held Gavi application development workshops; this has led to 66 out of 73 eligible countries applying for support already. Joint WHO/UNICEF regional coordination mechanisms are established to ensure countries are suitably supported in the decision making process and in the development and implementation of introduction plans. A large number of countries (113 of 126, or 90%) have confirmed decision or intent to introduce IPV by end of 2015 in preparation for the withdrawal of type 2 OPV. Work is now ongoing to i) ensure that declared intent materializes into commitement and ii) countries with no plan developed for IPV introduction have one ready before the end of the year.
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. SAGE reinforced the importance of conducting a technical briefing on IPV introduction for OPV-using countries during the WHA in May 2014.	Action	Apr 2013	Completed	A side-event on IPV introduction and OPV2 withdrawal was held during the WHA in May 2014.

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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 two additional HQ positions. Significant numbers of staff and consultants have also been deployed at Regional levels of both organizations, and funding has been sent to all regional offices. 66 out of 73 GAVI eligible countries have applied for IPV introduction support. For non GAVI countries, a financing mechanism has been rolled out to support 16 countries in Tier 2 and Tier 3 or LMIC which are not GAVI eligible. This mechanism will enable partners to support some countries that need it with vaccine introduction grants and/or time limited procurement of IPV. As of September 26 2014, a total of 113 countries (90%) have indicated their intent to introduce IPV by the end of 2015.
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	The WHA noted the progress of IPV introduction in 2014, based on the report from Immunization systems management group (IMG). The resolution on OPV2 withdrawal, including accelerated introduction of IPV, is scheduled to be proposed and discussed during the WHA 2015, if persistent cVDPV in Nigeria and Pakistan are eliminated and major criteria for judging country readiness for OPV2 withdrawal are met by then. These criteria include a) status of introduction of IPV in OPV-only using countries, b) registered bivalent OPV for routine immunization, c) establishment of stockpile and outbreak response protocol for type 2 virus, d) completion of phase 1 containment activities under the Global Action Plan (GAP) and e) affirmation of wild poliovirus type 2 eradication by the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC).
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	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	Completed	This topic was extensively discussed during the SAGE polio WG meeting in February 2014, and subsequently presented to SAGE in April 2014. The Emergency Committee under IHR met in late April and the DG made a temporary recommendation for travelers from polio-exporting and infected countries.
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. Since 2014 IVIR-AC includes a mathematical modeler/economist from SEAR and a medical anthropologist from AFR. Currently 3 seats are vacant for a mathematical modelers and two health economists with experience in vaccine implementation research.

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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. A paper on the process of the review will be discussed by ECBS during its October 2014 meeting. 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 "Lower middle-income countries: Sustainable adoption and financing for new vaccines", we have discussed internally and have decided that, for the time being the production of a report was not warranted. SAGE will be kept informed on an on-going basis of progress made and new developments. More information on the topic of financing can be found at under respective topic in the tracking sheet.
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. After a meeting of the working group of GHSI on 17-18 March, 2014, the framework was finalized, including the legal considerations, terms and conditions.WHO and Japan are also working on material transfer agreement. It will be presented at the GHSI Senior Official meeting on 29th September 2014 in Washington and hopefully approved at the GSHI Ministerial meeting in December 2014. The agreement with Japan for vaccine donation is still under negotiation since there are still some regulatory issues to be solved before accepting the vaccine. The agreement with France for vaccine donation is with LEG, however before accepting the vaccine we may have to wait for an approval from PQT. WHO is now submitting a proposal to HHS/BARDA to finance the smallpox vaccine prequalification for WHO stockpile.

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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 has developed a sentinel surveillance management framework to prioritize and guide actions to implement all SAGE recommendations from the 2013 meeting. Actions already implemented including: quarterly sharing of case-based data for both IB-VPD and RV networks; quarterly assessment of sentinel site performance based on agreed process and performance indicators, piloting of a web-based, case-based data management system in PAHO and SEARO (the system will include realtime data entry, verification and analysis; Regional Office support has been enhanced to selected sentinel sites including site visits and training. WHO's informal Technical Advisory Group for these sentinel surveillance networks is being briefed quarterly on progress and will meet in Geneva the week of 27 October 2014 to discuss the network status and ability to measure vaccine impact. Priority next steps for implementation in 2015 will also be identified.
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	Completed	The status on the specific recommendation from the 2007 SAGE meeting is now considered "completed" (with the last update for the April 2014 SAGE mtg in archive). A SAGE session on typhoid conjugate vaccines is expected to be scheduled after 2015. 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 WHO expert consultation in July 2014 reviewed the adequacy of the clinical data to inform the SAGE pathway and recommended further clinical data to be generated for a future SAGE review.
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. In June 2014 a meeting in South Africa took place to pilot test TIP in a low-income setting.

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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 Central Communications and the Vaccine Safety and Vigilance Team were attending the 3rd face-to-face meeting of the Working Group in December 2013.UNICEF staff is participating in the proceedings of the Working Group as part of the Secretariat.
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.

Topic	Recommendations/Action item	Category	Meeting Date	Status	Comments and Follow up
Vaccine coverage	WHO to identify appropriate methods and develop guidelines for collecting, analysing, and interpreting biomarkers for validating coverage.	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. Currently, WHO is developing global guidelines on conducting serosurvey studies on measles and rubella and primarily to be applicable in a pre- and post-SIA (supplementary immunisation activity) setting.An expert working group has been assembled and based on the expertise in the various fields of each of the members, needed to conduct such studies, including statisticians, epidemiologists, laboratory experts, and program experts, given subtasks in developing parts of these guidelines that pertain to their respective expertise. A working draft will be finished by the end of Q4/2014 and will be tested subsequently in pilot studies in two different settings, pre- and post-campaign, for its applicability. These pilot studies are expected to take start Q1 2015 and will run during the entire year of 2015. Based on the outcome, the working draft guidelines will be corrected where needed and finalised. The final document is planned to be ready by Q1 2016 and to be rolled out as a tool to evaluate the immune status of the target or targeted population.
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 provided written recommendation to these agencies. An informal working group has been created to review and revise WHO guidance on measuring immunization coverage through household and community surveys. The working group met in July 2013 to agree on the scope of work, to identify initial products, and establish a plan of document production, review, pilot testing, and clearance. Draft guideline was circulated to external reviews. Protocol for pilot testing was developed and pilot testing is currently undergoing in Bangladesh. The methods will be reviewed in September by Immunization and Vaccines Related Implementation Research (IVIR) Advisory Committee.

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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 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 has been made available to SAGE in November 2013. The report is currently in publication. A new work track was started with IVR in order to harmonize safety monitoring during pregnancy clinical trials.
Varicella	The recommendations by SAGE on the use of varicella and herpes zoster vaccines should be reflected in an update of the previous 1998 WHO position paper on varicella vaccines.	Action	Apr 2014	Completed	The updated varicella and herpes zoster position paper including the recommendations from the April 2014 SAGE meeting was published in the WER on the 20th of June 2014.(http://www.who.int/wer/2014/wer8925.pdf?ua=1)
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 International Health Regulations (2005) (IHR)to extend the validity of a certificate of vaccination against yellow fever from 10 years to the extent of the life of the vaccinated person was endorsed by the WHO Executive Board in January 2014, and recommended for adoption to the World Health Assembly (WHA); 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). In May 2014, the WHA adopted revised provisions on yellow fever vaccination under the IHR.