SAGE TRACKING RECORD OF RECOMMENDATIONS AND ACTION POINTS

SAGE recommendations are reflected in the SAGE tracking sheet. The “Recommendations/Action item” column reflects the specific recommendation made by SAGE. The “Meeting Date” column displays the date of the SAGE meeting during which the recommendation was originally made. The “Status” column indicates whether the work is currently ongoing, pending or completed.

Each recommendation has an appointed WHO focal point (not displayed in SAGE Yellow Book). The focal points are requested to update their recommendation in advance of each SAGE meeting and report on progress towards the recommendation in the “Comments and Follow Up” column.

When the recommendation is finalized, it is displayed as “Completed” in the SAGE yellow book. This item is then included in the SAGE Yellow Book for one additional SAGE meeting. After, the completed item is archived. Archived recommendations are no longer displayed in the SAGE Yellow Book but may still be accessed upon request to the SAGE secretariat. Therefore, the online tracking sheet provides a historical record of all SAGE recommendations and the Yellow Book displays the current recommendations.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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.	Apr 2014	Ongoing	The proposal to the Bill and Melinda Gates Foundation (BMGF) was successful, and the Working Group (WG) is being put together at this time. Two pilot countries are being identified to review their experience with the establishment of a vaccination visit in the second year of life, and to propose strategies to improve on these visits. This will be used in the next two years to develop generic guidance to countries wishing to establish such a visit.
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.	Apr 2014	Ongoing	A review paper on the Global Advisory Committe on Vaccine Safety (GACVS) future is currently under preparation and will address this issue in particular. The final draft should be submitted by end 2015 to a peer-reviewed journal.

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General	SAGE encouraged the European region to document and share its experiences in country profiling, tailoring responses and using novel communication strategies to effect behaviour change.	Nov 2010	Ongoing	WHO European Regional Office (EURO) is working to support countries in addressing vaccine hesitancy at the individual and community levels, in building risk and crisis communication capacity, in strengthening resource mobilization and advocacy capacity, and in using behavioural insights methodologies to tailor programme delivery and to drive demand for vaccines. This includes activities in the following areas: 1. Application of the Tailoring Immunization Programs “TIP” toolkit, which allows a country or sub-national level authorities 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) in 2014, and in the UK, Kazakhstan and Germany in 2015. In partnership with Wits University in South Africa, TIP is being adapted for use on a global level and a second edition (LIC, low income country, field guide) to be published in 2016. 2. Strengthening the ability of Member States to handle crises in vaccine confidence and trust through a guidelines document on vaccine safety communication, which was published in 2013. In 2014, 13 countries received exercise/simulation-based training on managing the communications response to vaccine safety events with an additional 11 countries having received training in 2015 (as of August 2015). 3. A resource mobilization and immunization advocacy workbook has been developed and was launched during European Immunization Week 2015. A subregional training has already been delivered with a further group of countries due to receive training later in 2015. 4. A vaccine communications review methodology has been developed by EURO and has been applied in 2 Member States in 2014 and in Montenegro, Georgia, and Moldova in 2015. An additional review is planned to take place in the Russian Federation later in 2015. 5. A vaccines social media strategy has been launched. A vaccination reminder ‘app’ for smart phones has been developed and country versions have been launched in 4 Member States launching the app during European Immunization Week 2015. 6. An online vaccines resource centre was launched in 2012 and has been strengthened and improved through 2014, with a number of member states using or translating the caregiver and health-care worker tools presented. 7. In 2015 work continues on developing the school-based learning module on vaccines and immunization – drawing on a ‘flipped learning’ methodology – with children aged 8-10 learning with parents at home and reinforcing understanding in the classroom setting.
General	SAGE recommended that ways to improve curricula for medical personnel should be explored.	Nov 2008	Ongoing	A workshop organized by WHO/AFRO (African Regional Office) was held in Grand Bassam (Cote d’Ivoire) from 13-17 May 2013, in collaboration with the Ministry of Health MOH and other immunization partners (GAVI, UNICEF, United States Agency for International Development USAID/Maternal and Child Health Integrated Program MCHIP and Network for Education and Support in Immunisation NESI) to revise the 2006 EPI (Expanded Program on Immunization) prototype curricula for medical & nursing/midwifery schools in the African Region of WHO (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. AFR staff steering this work has retired, there are no immediate plans communicated by AFRO to HQ to replace this position or to continue with the project.

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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.	Apr 2011	Ongoing	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 2015: •Egypt: Provision of technical support to Ministry of Health (MOH), Egypt, for controlling measles outbreak and planning outbreak response supplemental immunization activities (SIAs). The SIAs are planned for November 2015. Conducting desk review for routine immunization system to identify the factors behind the lower coverage. •Iraq: conducting national workshop for provincial EPI managers to discuss the strengthening routine immunization services, measles outbreak and outbreak response, introduction of IPV and PCV •Syria: conducting national training workshops on effective vaccine management, on development of cMYP as well as development of cMYP for the period 2015-2017 •Northern Syria: provision of all technical support for planning of MR SIAs, and resuming routine immunization. WHO EMRO is providing back-up to 2 dedicated consultants recruited to provide the day to day technical support •Yemen: conducting outreach strategy and periodic intensification of routine immunization (PIRI) in the low coverage governorates. Provision of financial and technical support for procurement of cold chain equipment to replace the destruction. Mobilizing financial resources for procurement of fuel for the cold chain. Supporting reprogramming of GAVI HSS funds to be utilized to support the crises. WHO remained functional under the difficult war situation and EPI WHO medical officer was one of the 3 priority staff allowed to remain in country
General	SAGE recommended strengthening national vaccination programs, integrating health services and strengthening health systems to promote universal health coverage.	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 the issue and provide briefing on the integration activities that historically and presently Expanded Program on Immunization (EPI) is working on. Subsequently, in early June a draft typology was produced and shared that summarizes this area of work. 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 Decade of Vaccines (DoV) consider options for moving forward, as integration is reflected as both a guiding principle and a strategic objective of the Global Vaccine Action Plan (GVAP). The Department secured funding at the end of 2014 to establish a position dedicated to the issue of integration. Recruitment has been completed and the recruited staff will start in October 2015.
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.	Apr 2012	Ongoing	Advice being sought through the Expert Committee on Biological Standardization (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 would 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 preparation only started to be prepared after the October 2014 meeting. A paper clarifying the differences between regulatory decisions and public health recommendations has been commissioned. Unfortunately there have been sustained protracted delays in finalization of the publication. It is now hoped that submission will occur prior to end of year 2015.
General	SAGE stressed that additional disaggregation was needed in the analysis of the progress achieved on the ground, and in identifying bottlenecks for progress, and recommended that reports display disparities observed at sub-national levels.	Apr 2015	Pending	WHO HQ is working closely with regional offices to obtain subnational level data. Surveillance data for measles and rubella as well as for new vaccines is collected on district level on regular basic and there are efforts to collect sub-national level coverage data. Currently it has been done in AFR on monthly as well as annual basis and in SEAR and EUR on annual basis.

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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.	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 International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and Developing Country Vaccine Manufacturer Network (DCVMN) as federations of manufacturers from 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 Group) 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 Decade of Vaccines (DoV) work stream on global access and vaccine price indicator which gets reported every year 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. 8) A Task Force on Middle Income Countries (MIC) has been established. More information on this is also provided elsewhere in the tracking sheet.
Administrative matter	Members asked that a clarification of what members were asked to report (i.e. what directly concerns their department or the departments under their line of authority) be included in the web posting of the Declarations of Interests summary in the future.	Apr 2015	Pending	This was followed up with WHO Ethics and Compliance Department. It was specified that SAGE members would need to report only interests directly linked with their respective research unit as sub-unit of the department, not the entire institution. A brief on the process for declaring and assessing interests of SAGE members was posted on the WHO SAGE website.
Agenda item	SAGE requested a global shortage of vaccines discussion at the next meeting .	Apr 2015	Pending	The topic is tentatively scheduled for the April 2016 SAGE meeting.
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.	Nov 2010	Ongoing	All models reviewed by the Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) are hampered by the lack of primary data, and more efforts should be made to make such data readily available. Specifically, 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.

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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.	Nov 2012	Completed	IVIR-AC (Immunization and Vaccines related Implementation Research Advisory Committee) concluded that the Decades of Vaccine (DoV) study presented on the approximate cost and impact may be adequate for high level use such as tracking of the Global Vaccine Action Plan (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. In June 2015 IVIR-AC reviewed the DOVE project. More information can be found in the IVIR-AC recommendations 2015.
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.	Nov 2012	Ongoing	The SAGE report of progress with the Global Vaccine Action Plan (GVAP) was presented to the WHO 68th World Health Assembly in May 2015. Fifty-two speakers, including 46 representatives from Member States, one observer (Chinese Taipei), four civil society organizations and GAVI, the Vaccine Alliance took the floor during the discussion on the Global Vaccine Action Plan. Delegates welcomed the GVAP assessment report and commended the Strategic Advisory Group of Experts (SAGE) and WHO on the report. The recommendations in the report were welcomed by most of the delegations who took the floor. Countries took note and expressed concern that the progress with the implementation of GVAP was patchy and slow and “far off-track” for achieving five out of six targets for 2014 and 2015. While Member States acknowledged WHO’s fundamental role in facilitating the implementation of the GVAP, they also stressed the important and leading role that WHO could play to: - Improve vaccine price transparency and build mechanisms that promote healthy and competent vaccine markets, tackle the problems faced by middle income countries to secure sustainable supplies of vaccines at affordable prices, particularly for the newer vaccines. - Work to enhance awareness of the value of vaccines to increase acceptance of immunization and to mitigate the risks posed by misinformation leading to vaccine hesitancy and refusal. - Analyse the causes of vaccine stock out and develop tools to respond immediately to any supply shortfalls. - Regularly convene countries that remain off-track to assist with diagnosing the problems and finding solutions. - Support countries to improve the quality of data and to use data for informing decisions and for improving programme performance. - Expand the existing guidance for vaccination in humanitarian emergencies to also include guidance on sustaining routine immunization during periods of conflict and crisis, including outbreaks of disease, such as the current Ebola epidemic in west Africa. Delegates acknowledged that countries and particularly national governments play a leading role in making the needed investments in immunization. Governments are accountable for the progress as well as the monitoring of their own programme performance. The Health Assembly adopted a resolution tabled by Libya that specifically addressed the issue of access to sustainable supplies of affordable vaccines for low and middle income countries, including the promotion of vaccine price transparency, support for pooled procurement mechanisms and for increased capacity for the manufacture of vaccines of assured quality to foster competition for a healthy vaccine market. http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R6-en.pdf

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Decade of vaccines/GVAP	The Director-General of WHO should convene a special session at the 2015 World Health Assembly for countries with routine vaccination (DTP3) coverage of less than 80%, to which each Minister of Health will be asked to report on their challenges, plans and timelines to improve coverage to meet the GVAP goals. In addition the SAGE's GVAP assessment reports should remain as standing items at the WHA until 2020.	Oct 2014	Ongoing	As recommended by SAGE, the Director-General of WHO convened a side session at the 2015 World Health Assembly for countries with routine vaccination (DTP3) coverage of less than 80%. The aim was to have a discussion with the Member States to understand the reasons for low coverage and find ways to collectively work together to overcome obstacles. Ministers of Health and high-level senior officials from several targeted countries attended and participated. The meeting was chaired by Dr Flavia Bustreo, Assistant Director General, Family, Women's and Children's Health (FWC), WHO. Dr Margaret Chan, Director General of WHO was in attendance. The sponsors of the meeting were the National Governments of Thailand, the Democratic Republic of Congo (DRC), and the United States of America (USA), respectively. Representatives of agencies comprising the Global Vaccine Action Plan (GVAP) secretariat, namely Gavi, the Vaccine Alliance (Seth Berkley), UNICEF (Nina Schwalbe), and the Bill & Melinda Gates Foundation (Chris Elias), were in attendance. The Civil Society Organizations were represented by the International Federation of the Red Cross and Red Crescent Societies (Amy Dietterich). Countries (e.g. Iraq, Haiti, Pakistan, Uganda, Benin, Niger...) presented their own issues and challenges and shared solutions and activities in place or to be implemented. Partners expressed their views and reiterated their willingness to support countries to address low coverage. WHA confirmed GVAP assessment report to stay a standing item for future meeting until 2020.
Dengue	A SAGE dengue working group should be convened to revise the data and prepare recommendations to SAGE as clinical trial data is expected to be submitted to the regulatory authorities in early 2015.	Oct 2014	Ongoing	The SAGE Working Group on Dengue Vaccines has been constituted and is holding monthly teleconferences. A face-to-face meeting of the Working Group was held 23-25 September 2015. The SAGE session for decision is still planned for April 2016.
Dengue Vaccine	SAGE requested that future recommendations on dengue vaccine safety be linked to the dengue vaccine development strategy.	Apr 2012	Ongoing	The dengue vaccine safety profile will be updated once an application for licensure has been filed. The Global Advisory Committee for Vaccine Safety (GACVS) has reviewed the company's risk management plan at its June 2015 meeting.
Ebola vaccines	SAGE was asked to immediately establish a SAGE working group on Ebola vaccines and vaccination.	Oct 2014	Ongoing	The working group (WG) was established and has met three times via teleconference. A face-to-face meeting of the WG took place on March 9 and 10, 2015. The WG reviewed the current epemiological data on Ebola Virus Disease (EVD), the preliminary results of the phase 1 trials, the status of the phase 2 and 3 trials, and the preparations for the large scale deployment of vaccines. They also identified the scope of the recommendations and the key questions and data for formulating recommendations. The framework was presented to SAGE at the April 2015 meeting. The SAGE working group met on August 19-20 in Geneva to review the available information and begin to start framing recommendations, based on the framework approved by SAGE in April 2015. The working group input will be presented to SAGE at the October 2015 meeting.
Ebola vaccines	Noting WHO's unique position to coordinate the development of Ebola vaccines, SAGE stressed the importance of transparent and prompt sharing of information on the trial protocols and data from the phase 3 clinical trials, and the need for a greater role for WHO in facilitating the sharing of information so that results between studies will generate the greatest benefit for policy decision-making.	Apr 2015	Ongoing	The paper published in the Lancet " Efficacy and effectiveness of an rVSV-vectored vaccine expressing Ebola surface glycoprotein: interim results from the Guinea ring vaccination cluster-randomized trial." was shared with SAGE members. The positive results of the trial prompted SAGE to schedule an extraordinary teleconference mid- August after the SAGE Ebola Working Group meeting to discuss the further steps and the possible need for a preliminary statement/recommendation from SAGE.

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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.	Apr 2012	Ongoing	Post-market surveillance continues in Argentina and a detailed report on the recent epidemiological situation was provided to WHO in January 2015. In 2014 in the context of a localized outbreak in a border area, 8 potential breakthrough cases were identified. For 5 of them there is uncertainty about the vaccination status and/or conditions (cold chain) in which vaccination was administered. Seven of these cases are in the 5-9 age group (distributed throughout the period) and one in the 1-4 age group. This has resulted in an enhanced vigilance in the country. Currently, however, there is still no evidence of waning immunity and the situation is still compatible with very high vaccine effectiveness. The situation continues to be investigated. Hepatitis A cases have reached an all time low in 2013 and have remained low in 2014. As exemplified by the outbreak in San Martin 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 was 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.	Nov 2008	Ongoing	The Eastern Mediterranean Region (EMR) has a Regional Committee (RC) goal of reducing childhood hepatitis B prevalence to <1% among children <5 years by 2015. Its regional office, EMRO is working with Member States to ensure achievement of this goal. The Western Pacific Region (WPR) established a Regional Committee goal to reduce hepatitis B infection to <1% among children at least 5 years of age by 2017. The South East Asian Regional Office (SEARO) has a drafted regional strategy. An HQ mission to discuss HepB control targets is scheduled for Aug 2015. The African Regional Office (AFRO) has convened a regional hepatitis Technical Advisory Group (TAG) and presented a plan for comprehensive viral hepatitis control during the 2014 RC Meeting. In 2014, the AFRO Regional Committee meeting adopted resolution to reduce Hep B infection to <2% among children under 5 years of age by 2020. The European Regional Office (EURO) will consider a regional hepatitis B control goal. The Pan American Health Organization (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).

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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.	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. Immunization Practices Advisory Committee (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 Western Pacific Regional Office (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 Global Immunization Vision and Strategy (GIVS) goals. In 2012, WPRO convened Expanded Program on Immunization (EPI) and Maternal and Child Health (MCH) managers from the five priority countries to jointly propose actions towards improving birth dose uptake. In Jan 2015 the African Regional Office AFRO, and in March 2015 the WPRO, held Hep B birth dose consultations to improve birth dose coverage. An assessment of Sao Tome Principe's birth dose vaccination strategy took place in July 2015 and an assessment took place in Nigeria in September 2015.
HIV	SAGE requested regular updates on the progress of HIV-vaccine research.	Apr 2010	Ongoing	There are now 3 major streams of HIV vaccine related research and development. Firstly follow-on to the RV144 Phase 3 trial in Thailand reported in 2009. Two follow-on Phase 3 trials of similar protein-poxvirus prime-boost approaches are planned in Thailand and South Africa. It was initially stated that the South African trial would start in 2015, although the start dates may now be in 2016. Secondly there are several ongoing Phase 1-2 clinical trials of recombinant viral vectored approaches focusing on non Ad5 adenoviruses such as Ad26, Ad3, Ad35 and recombinant poxviruses such as MVA (Modified Vaccinia virus Ankara). Replicating vectored approaches (eg sendai virus) are also witnessing a renaissance in the global portfolio. Finally there are major, and promising, vaccine science initiatives underway to attempt to induce broadly neutralising antibodies through re-engineered antigens. These have a longer timeframe, but raise the prospect of cross-clade protection.
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.	Nov 2010	Ongoing	Pneumococcal Conjugate Vaccine (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. Haemophilus influenzae type b (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 diphtheria-tetanus-pertussis (DTP) was presented to SAGE in April 2015, with a focus on Pertussis leading to the update of the Pertussis Position Paper, published in August 2015. Evidence on Hep B vaccines will be presented at the April 2016 meeting - delays due to impact of Ebola outbreak.

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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%.	Apr 2014	Ongoing	Under the umbrella of the WHO-UNICEF Immunization Supply Chain and Logistics Hub, a process has started to develop a revised version of the Effective Vaccine Management (EVM) assessment tool for it to become an assessment that covers broader immunization supply chain and logistics aspects beyond vaccine management policies and practise. Since this is a significant undertaking and a time consuming one, the approach in 2015 is to include additional data collection and/or assessment modules for Human Resources alongside the existing approach to EVM assessments. This Human Resource module is being developed by UNICEF Supply Division under the auspices of the People that Deliver (PtD) initiative and the Global Alliance for Vaccines and Immunizations (GAVI)People and Practise working group of the immunization supply chain taskforce. In addition, the revisions of the EVM assessment tool will include more supply chain performance measures and indicators that are more outcome oriented but aligned with the global key performance indicators being developed to track performance in countries with regards to the GAVI Supply Chain strategy.
Implementation	SAGE recommended the formation of an implementation group that had a broad array of expertise in this area.	Apr 2015	Pending	A document on applying rigour and science in implementation programme design and evaluation of delivery of vaccines was drafted by SAGE members. This document was then discussed by WHO/IVB. It was agree that as a first step, instead of forming a SAGE working group, the Director of the Department of Immunization, Vaccines and Biologicals will work with the WHO health systems strengthening (HSS) group and have them come to the feedback presented at the April 2016 SAGE meeting in order to look at what is being done in the context of universal health care. Then, it will be decided if a SAGE or extended working group is needed.
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.	Nov 2013	Ongoing	This recommendation is now part of the new Immunization and Vaccines related Implementation Research Advisory Committee (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 the Integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD) interventions: example for Mazabuka District in Zambia” as a case study. As part of the Broader Social and Economic Value of Vaccines work portfolio in WHO several research proposals on this topic were suggested by a network of international researchers from academia, NGOs and decision makers during a ad-hoc WHO consultation in November 2014. Proposals were submitted for funding at Centres for Disease Control and Prevention (CDC)/Global Immunization Division (GID), the Global Alliance for Vaccines and Immunizations (GAVI), and Bill and Melinda Gates Foundation (BMGF). In March 2015, the "Impact of reaching hard to reach populations through routine immunization" proposal was awarded funding and has been started. Currently the work is still ongoing as there have been some delays with the implementation of the projects.

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Implementation Research	SAGE identified the conditions necessary for pertussis resurgence and the effective strategies for prevention of resurgence as important topics for modelling research.	Apr 2014	Ongoing	The June 2015 meeting of the Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) meeting agreed on the plan for phase 1 of the comparison of pertussis models from Australia, England & Wales and the United States of America, which is meant to be a rapid assessment on the relative contributions of vaccine formulations, waning immunity, vaccine coverage and schedule to observed pertussis resurgence in these countries. If successful, phase 2 offers further opportunities to test whether existing models are sufficiently robust to changes in factors such as demographics, spatial heterogeneity, immunity and contact matrices across multiple settings. In many countries using aP vaccine in the national immunization programme, aP vaccine is used in the private sector which represents a variable proportion of infant immunizations, so these complexities will need to be reflected when the models are extended to low and middle income settings. Pertussis surveillance and laboratory capacity are still extremely poor in LIMCs particularly in Africa), and beyond the scope of the model comparison exercise to address. The committee noted that data are expected to be forthcoming through ongoing studies and follow-on analysis of maternal influenza trials, and strongly endorses the identification or further opportunities to add pertussis markers (primarily PCR on respiratory specimens) to studies such as GAVI– or the BMGF– supported vaccine impact studies. There were concerns that the opportunistic process by which the 3 models were identified may not have included all relevant parameters or modelling approaches. The feasibility of taking into account other models and parameters identified through a literature review and/or open call should be assessed, focusing on the main results of the different models for phase 1, and if they are interested to include them in phase 2.
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.	Apr 2014	Ongoing	During the Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) September 2014 meeting, it was suggested to develop standardized protocols and start implementing high quality Randomized Controlled Trials (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 Bill and Melinda Gates Foundation (BMGF) support a multi-disciplinary team with IVIR-AC participation will start reviewing the evidence and identify research questions.
Integration	WHO should discuss and develop guidelines on how to fully integrate vaccination (GVAP) into the operation of all aspects of the health-care system and to reduce missed opportunities to vaccinate.	Oct 2014	Ongoing	Guide on Missed Opportunities for Vaccination (MOV) Assessment Methodology has been finalized and is being used to conduct MOV assessments in Chad (July 2015) and Malawi (August 2015) in collaboration with AFRO. The plan to include an MOV Assessment module as part of larger revision on the Expanded Program on Immunization (EPI) Coverage Survey methodology is progressing.
IVIR-AC	SAGE noted that a sub-group of IVIR-AC members and external subject experts should make recommendations on the types of prospective studies to assess the non-specific effects of vaccines.	Oct 2014	Ongoing	Subject experts on non-specific immunological effects of vaccination came together 1-2 February 2015 in Oxford to discuss and review the available evidence, identify key questions regarding non-specific effects (NSE), discuss pilot studies and its designs. A meeting on NSE epidemiological effects is expected end of 2015.

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IVIR-AC	IVIR-AC should seek linkages with the WHO Alliance for Health Policy and Health Systems Research as they might be useful in priority setting and discussions.	Oct 2014	Ongoing	The Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) secretariat have had initial discussions with WHO staff of the Alliance for Health Policy and Health Systems Research (HPSHR) to update on the IVIR-AC deliberations in September 2014. Discussions for concrete steps for their involvement in vaccine implementation research are ongoing. The WHO Alliance for HPHSR will have a seat in the WHO Secretariat of the IVIR-AC. In addition, Initiative for Vaccine Research (IVR) was involved in a call for proposals issued by the WHO Alliance with financial support from the Global Alliance for Vaccines and Immunizations (GAVI) and UNICEF on implementation research studies in low and middle income countries (LMICs) in 2015. Seven proposals have been selected for funding and being implemented with a one year timeline until 2016
Japanese encephalitis	Commercial kits for detection of JE-specific IgM should be compared and validated.	Apr 2006	Ongoing	Assessment using serum was carried out by PATH and published in the American Journal of Tropical Medicine and Hygiene (Am J Trop Med Hyg) July 2007. Field validation of serum and cerebrospinal fluid (CSF) in India and Bangladesh was assessed in a joint WHO/CDC (Centre for Disease Control and Prevention) meeting, at the South East Asian Regional Office (SEARO), February 2008. Nepal and Cambodia field evaluations of Japanese encephalitis (JE) assays were completed and a paper was submitted to the Journal of Infectious Diseases (JID). Assessment of kits using CSF were accepted for publication in Am J Trop Med Hyg. CDC Fort Collins distributed the 3rd serum and CSF proficiency test panel to evaluate in-house and commercial JE ELISA assays, to Western Pacific Regional Office (WPRO) JE labs in the 4th quarter of 2012. The three Western Pacific region 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 Centre for Disease Control CDC JE regional reference Lab was fully accredited by WPR and HQ Lab Coordinators, in 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 WPR at the Victorian Infectious Diseases Reference Laboratory, Melbourne, was fully accredited in Oct 2013. The Global Specialized Reference Laboratory for JE at the National Institute of Infectious Diseases, Tokyo, was also 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 bi-regional laboratory training workshop and laboratory network meeting was conducted 17-21 August 2015, at the National Institute of Health in Bangkok, bringing together JE lab staff from both WPR and SEAR South East Asian Region. The two-day meeting provided a forum of laboratory experts to update on progress and challenges for the program, the JE laboratory network, the renewal of the roles and responsibilities of the JE network laboratories in the WPR and SEAR, update on new technologies for the diagnosis of JE, and panel discussions on surveillance of JE and possible integration wirh other non JE causes of Acute Encephalitis Syndrome. The following 3-day laboratory workshop provided hands-on training using the newly introduced InBios diagnostic kits, and compare its performance with other kits used in the two WHO Regions. All laboratories represented used the opportunity to provide updates on the current JE situation with particular focus on laboratory-based surveillance.
Japanese encephalitis	Guidance is needed on how to approach Japanese encephalitis (JE) vaccine impact assessments. This guidance should address surveillance data sources and analysis to measure JE vaccine impact, design of surveillance and special studies for impact measurement, JE laboratory diagnostics, and data collection and analysis for observational studies to measure vaccine effectiveness	Apr 2015	Ongoing	WHO held a meeting May 26-27, 2015, on methods for JE vaccine effectiveness and impact studies. We are now working on the meeting report and guidance document (analogous to the one prepared for Haemophilus influenzae type b (Hib)/pneumococcus titled "Measuring impact of Streptococcus pneumoniae and Haemophilus influenzae type b conjugate vaccination" published in 2012).

Topic	Recommendations/Action item	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.	Nov 2010	Ongoing	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 Task Force has first focused its work on redefining the problem statement. Following these analyses it was decided that the Task Force would concentrate its efforts on non-GAVI MICs only; that the Task Force would move away from the perceived issue of a lag between MICs and GAVI-supported countries, and would focus instead on the fact that MICs are far from reaching their Decade of Vaccines (DoV) targets. The strategy was finalised in April 2015 and presented at SAGE. It was approved to move into implementation phase. Four main areas of action have been identified as the pillars of the MIC strategy: i) Strengthening evidence-based decision-making; ii) Enhancing political commitment and ensuring financial sustainability of immunization programmes; iii) Enhancing demand for and equitable delivery of immunization services; and iv) Improving access to timely and affordable supply. Improving access to timely and affordable supply is seen as the main area where further efforts are needed, especially related to vaccine procurement. This area includes the following activities: increasing procurement skills and knowledge ; increasing access to revolving funds ; harmonizing product choice & registration processes ; increasing availability of price and contract information ; strengthening pooled procurement options and influencing market dynamics (supply). The timeline for the strategy is up to 2020 to align with the GVAP timeframe and up to 2025 for a longer term horizon. In the longer term, the MIC strategy could provide a platform to ensure sustainability of GAVI investments in graduated countries. In the implementation phase, the Task Force, with WHO as Secretariat, would continue its role of coordination and information sharing.
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.	Apr 2013	Ongoing	Malaria Vaccine Preferred Product Characteristics are finalized and available on WHO's website. RSV Preferred Product Characteristics are now under development. In addition, two Ebola vaccine Target Product Profiles are under development for reactive and prophylactic use.
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.	Oct 2009	Ongoing	The European Medicines Agency (EMA) announced a positive article 58 scientific opinion on RTS,S/AS01 in July 2015. This is the first ever positive regulatory assessment of a submission of a malaria vaccine. It is not licensure, but may be helpful to African regulatory authorities that will consider licensing the vaccine during 2016-2017. For the first time a SAGE/Malaria Policy Advisory Committee (MPAC) joint decision session on malaria vaccines will occur in Oct 2015. The Joint Technical Expert Group (JTEG) is both the SAGE WG on malaria vaccines, and the MPAC's expert group on malaria vacines (reporting to two departments). JTEG met on June 29-30, and agreed by consensus candidate policy recommendations for decision by SAGE and MPAC. These will be submitted to SAGE/MPAC as part of the background paper on malaria vaccines in mid September. A separate process has coordinated harmonization and comparison of the malaria models available for RTS,S/AS01 impact and cost-effectiveness predictions. The report from this process will also be submitted to SAGE and MPAC in mid September.
Maternal Immunization	SAGE encouraged the Regional Office for the Americas to document the successful regional experience of delivering influenza vaccine to pregnant women.	Apr 2015	Pending	

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Maternal Immunization	SAGE encouraged WHO to promote more implementation research to generate generalizable data on the best ways to integrate maternal immunization into routine antenatal care in low resource settings	Apr 2015	Ongoing	IVR is in conversations with partners to develop a proposal to conduct maternal immunization implementation research in low-resource settings. IVR is in the process of producing many implementation research tools and guidance regarding: 1) assessment of vaccine confidence/hesitancy in pregnant women; 2) maternal influenza immunization program costing tool; 3) guidance document to estimate the influenza economic burden of a country; 4) guidance document to estimate the cost effectiveness of influenza vaccines in a country; 5) field guide for the evaluation of influenza vaccine effectiveness; 6) maternal immunization AEFI surveillance guidance; and 7) implementation guidance document. IVR is planning to develop 1) maternal influenza immunization implementation evaluation research tool and post-introduction evaluation guidance; 2) guidance for the estimation of vaccine coverage among pregnant women; and 3) principles document for influenza vaccine program implementation.
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.	Nov 2013	Ongoing	WHO has reviewed various regulatory approaches to labelling of the pregnancy and lactation sections of product inserts, and it has convened two meetings on the subject: a consultation at WHO in July 2014 and a session at a meeting of the Developing Country Vaccine Regulators' Network (DCVRN) in China in November 2014. No regulatory consensus was achieved in these meetings regarding data requirements for product labelling, and further consultations are planned to discuss this issue further in 2015. The meetings did identify potential alternative methods by which WHO could promote more permissive language in package inserts regarding vaccine use in pregnancy, including use of WHO Prequalification (PQ) Model Package Inserts for influenza vaccines. WHO is currently planning to convene a working group of regulators to draft guidance for the completion of pregnancy/lactation sections of influenza vaccine package inserts, and it is exploring other mechanisms that would promote evidence-based, permissive language in package inserts and that would improve understanding of precautionary language in package inserts.
Meeting preparation	SAGE members asked that in the executive summaries inserted in the Yellow Book for each section, an orientation be included describing the entire package of documents inserted.	Apr 2015	Ongoing	This has been specifically flagged and requested from each WHO session focal point in preparation for the October 2015 SAGE meeting.
Meningococcal A conjugate vaccine	SAGE recommended that countries completing mass vaccination campaigns introduce meningococcal A conjugate vaccine into the routine childhood immunization programme within 1–5 years following campaign completion, along with a one-time catch-up campaign for birth cohorts born since the initial mass vaccination and which would not be within the age range targeted by the routine immunization programme. SAGE recommended a 1-dose schedule, with vaccine administration by deep intramuscular injection, preferably in the anterolateral aspect of the thigh, at 9–18 months of age based on local programmatic and epidemiologic considerations. This recommendation for routine immunization programmes is based on the high level of herd immunity following mass campaigns, epidemiologic evidence on the age distribution of disease, and programmatic and economic considerations. Any children who miss vaccination at the recommended age should be vaccinated as soon as possible thereafter.	Oct 2014	Ongoing	The recommendations from SAGE are reflected in an update to the WHO meningococcal vaccine position paper. The updated guidance has been published in the Weekly Epidemiological Record WER on 20 February 2015: http://www.who.int/wer/2015/wer9008/en/. One of the meningitis belt countries (Ghana) has already submitted an application to Gavi, the Vaccine Alliance in January 2015 for introduction of the meningococcal A conjugate vaccine into their routine immunization programme, with a single dose at 18 months of age concomitantly with the administration of the second dose of Measles/Rubella vaccine. Another 6 meningitis belt countries intend to apply for the introduction of the vaccine into their routine programme at the next Gavi application window closing on 8 September 2015 (Burkina Faso, Chad, Mali, Niger, Nigeria and Sudan).
Middle Income Countries Strategy	SAGE called upon WHO Secretariat to report back on progress in implementation of the Middle Income Strategy.	Apr 2015	Pending	WHO will work on the implementation of the MIC strategy and will report back to SAGE in 2016.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Middle Income Countries Strategy	SAGE recommended that the MICs strategy be aligned with the Global Investment Framework for Women's and Children's Health and the Global health 2035 analysis, and noted that some of the approaches proposed may be useful in addressing challenges that MICs face in accessing other health commodities.	Apr 2015	Completed	This has been done, the MIC Task Force looked into these initiatives and aligned analyses as relevant.
Multiple injections	SAGE noted the need for further research on multiple injections during the same visit and recommended the following research topics and activities: (i) impact of multiple injections in the same visit on vaccine coverage, disease reduction, vaccine programme success and caregiver and provider experience; (ii) development of a standardized monitoring protocol for acceptance and acceptability by caregivers and providers and for prevalence of adverse events; (iii) development of optimal provider and infant caregiver communication approaches; (iv) optimal multiple injection administration techniques, and (v) development of new technologies, such as intradermal patches and new combination vaccines, which would decrease the number of vaccine injections in a single visit.	Apr 2015	Ongoing	A multiple injection study is soon to be conducted in Nepal in collaboration with US CDC (delayed due to the recent earthquake). A protocol was submitted for WHO ERC clearance to evaluate healthcare provider and infant caregiver attitudes and practices regarding administration of multiple injectable vaccines in the same visit following introduction of IPV and PCV. A separate work stream in WHO IVB - in conjunction with WHO EMP - is investigating the development of intradermal patch technologies with IPV and MR including the relevant regulatory pathways.
Pain mitigation	SAGE recommends that WHO: 1) includes pain mitigation recommendations with WHO immunization practice guidance materials; 2) disseminates pain/distress mitigation recommendations through the usual dissemination channels, immunization managers, National Immunization Technical Advisory Group (NITAG) and partner organizations; 3) monitors and evaluates the implementation success of pain mitigation measures; 4) works with industry, ECBS and regulatory agencies to advocate that grading of pain experienced during the vaccine injection be included in data for licensing and in the product monograph.	Apr 2015	Ongoing	Internal discussions have taken place on how to move forward across relevant WHO departments. A brief position paper was drafted based on the SAGE recommendations and published in the Weekly Epidemiological Record on 25 September 2015. This will form the basis for more proactive communication activities. Work is also ongoing to ensure appropriate incorporation of pain mitigation in WHO guidance documents when they get updated and to ensure that any recommendation posted on the web that would be at odd with SAGE's guidance would be adjusted/removed.
PDVAC	SAGE requested to be updated by Product Development for Vaccines Advisory Committee (PDVAC) on the criteria used for prioritizing vaccines for IVR's work.	Oct 2014	Ongoing	SAGE was updated at the April 2015, and updates will be provided each year at the October meeting. A major area of activity in pipeline vaccines relates to RSV vaccines, where a pivotal Phase 3 trial is due to start soon. There will be a For Information session on RSV vaccines at the April 2016 SAGE meeting.
Pertussis control	The SAGE recommendations will be used in the preparation of a revised WHO pertussis vaccine position paper, with publication planned for the third quarter of 2015.	Apr 2015	Completed	An updated position paper has been finalized and was published in the Weekly Epidemiological Record on 28 August 2015.

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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.	Apr 2013	Ongoing	The Global Polio Eradication Initiative (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 were continuing through the rest of the year. The consultation included 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. As well as having produced a paper for the Journal of Infectious Diseases (JID) on the lessons of polio eradication (Cochi, Freeman, Guirguis, Jafari, Aylward, Global Polio Eradication Initiative: Lessons Learned and Legacy), the GPEI Legacy Management Group is seeking input on lessons at the country level. This work will be led by Regional and Country-based colleagues and will involve the input of front-line workers. In addition, a team from the Boston Consulting Group supporting the legacy planning work in 2014 and early 2015 have sought input from 10 countries on contributions of polio-funded staff to other health priorities including immunization. The first segment of this work was reported to the Polio Partners Group and the Polio Oversight Board in December 2014. The Legacy Planning guidelines were revised in June 2015, including key steps in its planning and development (including engagement of donor and civil society, coordination and oversight, communication strategy). As part of the 2015-16 transition plan 10 priority countries for GPEI transition planning were identified. A survey of the focus countries (Afghanistan, Pakistan, Nigeria, South Sudan, India, Nigeria, DRC, Chad, Ethiopia, Angola), indicated that polio country personnel currently devote 46% of their working schedule to RI and EPI related activities, of which 22% is dedicated to RI. The guidelines outline how assets and capabilities of the GPEI (staff, infrastructure and know-how) can be transferred and used to benefit other global health and development programs, as exemplified by the recent Nigerian response to the Ebola outbreak.
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 type 2 oral polio vaccine (OPV2) withdrawal and introduction of inactivated polio vaccine (IPV).	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 (type 2 component of oral polio vaccine) withdrawal and IPV (inactivated polio vaccine)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 Immunization Systems Management Group, IMG (Centre for Disease Control and Prevention CDC, WHO, UNICEF, Bill and Melinda Gates Foundation BMGF, Rotary and Global Alliance for Vaccines and Immunization GAVI) since April 2013 has been impressive. WHO/EPI (Expanded Programme on Immunization) 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. All of the expected GAVI eligible countries (71) have applied and been approved 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 (low and middle income countries) 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. In December 2014 the above financing mechanism was extended to another 9 countries from the American (AM) and Western Pacific (WP) regions to help them, in a catalytic manner, initiate the procurement of IPV.Of the 25 countries offered this opportunity, 18 have requested and been approved for funding. As of June 30, 2015, all 126 OPV-only using countries have committed to IPV introduction, and 22 countries have introduced to date. The effort is now focusing on managing the IPV supply and providing countries with the necessary information and technical assistance to develop a plan to carry out a switch from trivalent OPV (tOPV) to bivalent OPV (bOPV) in April 2016.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Polio	SAGE recommended working closely with countries on activities towards type 2 oral polio vaccine (OPV2) withdrawal.	Apr 2013	Ongoing	In January 2014 a joint letter to all oral polio vaccine (OPV)-only using countries was sent by the WHO Director General and UNICEF Executive Director, and the Global Alliance for Vaccines and Immunizations (GAVI) CEO where applicable, highlighting the importance of inactivated polio vaccine(IPV) introduction and outlining the SAGE recommendation on IPV introduction schedules and planning timelines. This was followed up in May 2015 with a joint letter from the DG and UNICEF ED to all tOPV using countries on the importance of planning for the switch. All regions have held, at least one meeting that included a substantive focus on IPV introduction in 2014/5 and have held or will hold the same on the tOPV to bOPV switch in 2015. 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 for IPV and the switch. Work is now ongoing to i) ensure that declared intent materializes into commitment and ii) countries with no plan developed for the switch have one ready before the end of the year. In alignment with the SAGE April meeting discussions and the WHO resolution on the Switch, technical materials and standard operating procedures (SOPs) have been developed to accelerate switch planning at country level and have been shared with countries through regional consultations.
Polio eradication	SAGE requested the polio Working Group to continue monitoring progress towards cVDPV2 elimination and ensuring that remaining challenges are addressed including contingencies for vaccine supplies (IPV, bOPV and tOPV), registration of bOPV for routine use, surveillance sensitivity, and reaching inaccessible children. The Working Group will make a full report to SAGE in October 2015, when SAGE may reconfirm April 2016 as the definite date for OPV2 withdrawal.	Apr 2015	Ongoing	This is being closely monitored by the Polio WG. In June, there was a conference call of WG where WG reviewed the progress towards eliminating persistent cVDPVs. This was again reviewed by the WG during its September meeting and the WG will report back to SAGE in October 2015.
Polio eradication	SAGE noted the importance of the work on the polio legacy and asked for a full report on this at its October 2015 meeting.	Apr 2015	Pending	It will be discussed during the September WG meeting and presented to SAGE during the October 2015 meeting.
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."	Nov 2013	Ongoing	The World Health Assembly (WHA) noted the progress of inactivated polio vaccine (IPV) introductions in 2014, based on the report from Immunization systems Management Group (IMG). During the WHA 2014, the 5 criteria for withdrawal were discussed. These criteria include a) status of introduction of IPV in oral polio vaccine 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). In 2015, WHA adapted the resolution that calls on member states to prepare for the OPV2 withdrawal in April 2016.
Regulatory	SAGE recommended that the further development of the Emergency Use Assessment and Listing procedure being developed by WHO, which would allow use of a vaccine in the context of a Public Health Emergency of International Concern, be done in close consultation with relevant regulatory authorities, including those of the affected countries.	Apr 2015	Ongoing	A document entitled “Vaccine evaluation in public health emergencies – review of regulatory pathways in selected countries” is curently being drafted. This document will be submitted to the Expert Committee on Biological Standardization (ECBS)for review and advice and will be discussed with the Committee in October 2015. A brief report on the progress was presented to SAGE WG on Ebola vaccines in August 2015.

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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.	Nov 2011	Ongoing	Since 2013 Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) includes two programmatic and implementation research members from the African Region (AFR) and the South East Asian Region (SEAR). Since 2014 IVIR-AC includes a mathematical modeler/economist from SEAR and a medical anthropologist from AFR. Currently 2 seats are vacant for health economists with experience in vaccine implementation research. Recruitment of new members is ongoing. There was a call for new members in 2015. Three potential candidates were selected to attend the June 2015 meeting. The mathematical modeler was selected to become a member but the two health economists were not selected as they did not meet the expectations. A new call for Committee Members will go out later in 2015.
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.	Nov 2006	Pending	A comprehensive review of the work of the Expert Committee on Biological Standardization (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. Discussion on a paper on the process of the review was initiated by ECBS during its October 2014 meeting; however biotherapeutic biological drugs were identified as first priority.
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.	Nov 2013	Ongoing	An operational framework for vaccine donation was developed and agreed by the Global Health Security Initiative (GHSI) Medical countermeasures (MCM) task force. Discussion with the French Government for the donation of 5 million doses of vaccine are still ongoing. WHO is working on smallpox vaccine prequalification for emergency stockpile. A WHO meeting took place in Geneva 7-8 September 2015 to discuss with the National Regulatory Authorities and vaccine manufacturers what would be the minimum criteria to pre-qualify smallpox vaccines in case of re-emergence of variola virus.
Supply Chain	SAGE requested future update on approaches to prioritization within supply chain improvement plans.	Oct 2014	Ongoing	Under the umbrella of the WHO-UNICEF Immunization Supply Chain and Logistics Hub, a process has started to implement the more holistic approach to immunization supply chain improvement planning as part of the WHO-UNICEF Joint Statement that was endorsed by the SAGE. The approach builds in a methodology to prioritize strategies and activities that will have the largest impact on immunization supply chain improvements. In addition, evidence around cost-effective solutions is being compiled by the Hub which will be transformed into an Solutions Toolbox to help countries tailor and prioritize the right solutions. 5 countries have developed a supply chain improvement plan - Pakistan, Democratic Republic of Congo, Lao People's Democratic Republic, Bangladesh, and Nepal.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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.	Nov 2013	Ongoing	During 2013, a global strategic review was conducted of the invasive bacterial vaccine preventable diseases (IB-VPD) and rotavirus sentinel hospital surveillance networks. During that meeting, 50 recommendations were made to advance the status of both networks. During 2014, significant progress was made to further improve the IB-VPD and rotavirus sentinel hospital surveillance networks. Network management was strengthened with the use of a Performance Management Framework to track implementation status of annual global recommendations. A major achievement was the transition to standardized, case-based reporting with quarterly data sharing plus feedback of standard process and performance indicators to sites. Data management processes continue to be improved toward having a more systematic approach in reporting, cleaning, analysing and interpreting data. The reference laboratories are appropriately supporting sites and network laboratory performance has been successfully monitored by the global external quality assessment (EQA) program as well as quality control (QC) programmes. Sentinel site and laboratory assessments have been prioritized but have not been able to include all priority sites. The most recent 2013 data available for the meeting may underestimate data quality because none of the actions taken after the 2013 strategic review are yet reflected. IB-VPD data analysis focused on assessing laboratory testing performance of culture and PCR, and found <30% of PCR results were linked into the clinical database as well as a 3-fold improved detection of pathogen by PCR over culture alone. Beginning in 2014, Regional Reference Laboratories (RRLs) will only process specimens with a unique identification number and it is thus anticipated that a larger percentage of cases will have clinical data that can be linked with RRL data. Network data has contributed to vaccine introduction decisions and the surveillance networks have been used as platforms for vaccine impact evaluations. Moving forward, the rapid introduction of Pneumococcal Conjugate Vaccine (PCV) and Rotavirus Vaccines (RV) by Member States now requires the surveillance networks to focus on improving baseline data for sites in non-vaccine using Member States and to ensure consistent surveillance practices for sites that meet inclusion criteria in vaccine-using Member States. The web-based data management tool has great potential to improve data quality and may be expanded to other vaccine preventable diseases in due course. WHO, the iTAG (informal Technical Advisory Group) and partners will work to implement recommendations to further improve the network during 2015 including to strengthen programme management: • Strengthen involvement of Ministry of Health and national EPI (Expanded Programme on Immunization) programmes; • By end-April 2015, IB-VPD specimen sharing agreements should be established between all 71 IB-VPD target hospitals and RRLs to further increase access to PCR's improved diagnostic yield; • All IB-VPD cerebrospinal fluid specimens should be tested by PCR at an RRL; • Further focus efforts and define a subset of sites where PCV and/or RV vaccine impact evaluations may be feasible due to sufficient pre- and post-vaccine introduction data; And to Improve data management and analysis: • Link clinical and laboratory data by use of unique identification numbers. Prospective data linking established by 31 Dec 2014, and sites prioritized for retrospective linking; Validation of these activities pending until June 2015. • Zero reporting to be implemented at all sites by 31 Dec 2014; In March 2015, regional activities are in progress, but zero reporting not yet been implemented. • Identify a subset of core data variables for vaccine impact assessments; • Draft guidelines for rotavirus data analysis/interpretation and assess probable bacterial meningitis data; • Finalize the web-based data management tool; • Revise site inclusion criteria: for rotavirus, reduce the number of annual stool specimens tested in vaccine using countries; for IB-VPD, include consistently performing sites that enrol fewer meningitis cases.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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.	Nov 2011	Ongoing	An update on the development status of TB vaccine candidates has been received in preparation for the upcoming PD-VAC meeting. Consensus is emerging that targeting the adolescent/adult population, who carry the heaviest disease burden, will have the highest and most immediate public health impact due to reduction in transmission. A Phase IIb study with GSK's M72/ASO1E candidate is underway in 3600 HIV-uninfected, latently infected adults and may inform correlates of protection and risk, as well as efficacy to prevent activation of disease. Several other candidates are in Phase IIa, including assessment of H4/IC31 compared to BCG re-vaccination to prevent infection by Mtb (as opposed to disease) in adolescents.
Typhoid	Establish a SAGE working group on typhoid conjugate vaccines in 2016 to prepare for a SAGE review of the evidence in 2017.	Oct 2014	Pending	Following the accumulation of sufficient data, the Working Group will be established early 2016 to prepare for a SAGE review in 2017.
Un/under-immunized children	SAGE requested that WHO quickly roll out tools so that other countries can address low coverage of vaccination.	Nov 2010	Ongoing	The in-depth tool "A Guide to Tailoring Immunization Programmes (TIP) has already been developed and used by WHO-EURO (European Regional office). Currently the Univ. of Witwatersrand in South Africa has been contracted to adapt the methodology to developing countries, and less intensive consultant-based inputs. The Health Worker KAP tool has been completed and will be piloted with the assistance of JSI in Kenya. Work is ongoing on the tool to assess "Missed Opportunities". On a broader level, a companion document to the GVAP focusing on Routine Immunization, entitled "Global Routine Immunization Strategies and Practices" (GRISP) is in the final stage of drafting, and has been presented to the SAGE WG on DoV twice. In addition to a comprehensive framework of RI strategies, it highlights nine "transformative investments" to guide global partners and countries in RI strengthening.
Vaccination in humanitarian emergencies	SAGE also suggested that the framework approach to vaccine decision-making could be considered for other health interventions in emergencies.	Apr 2012	Ongoing	The Emergency Risk Management and Humanitarian Response (ERM) Department was slow in the uptake of this recommendation due to lack of staff and the high number of Level 3 emergencies. A discussion was held at the MICs Task Force meeting held in February 2015 on the possibilities of having an emergency fund for vaccines in disaster situations. The discussion resulted in a mapping of emergency funds available and gaps, which was presented in the April SAGE meeting in 2015.

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Vaccine coverage	SAGE recommended that WHO explore alternative survey methods to improve the precision, reduce the cost and improve the usefulness of survey results to national and local immunization programmes.	Nov 2011	Ongoing	To improve the precision and usefulness of survey results and to reduce the cost of surveys, the Strategic Information Group (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 Department of Immunization Vaccines and Biologicals' (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. The proposed methods were reviewed in September by Immunization and Vaccines Related Implementation Research (IVIR) Advisory Committee. The methodology is currently tested in Burkina Faso and in Lao PDR. The working draft of the manual has been distributed and posted on the departmental web site(http://www.who.int/entity/immunization/monitoring_surveillance/Vaccination_coverage_cluster_survey.pdf?ua=1). A briefing workshop on the methodology for regional focal points and consultants is planned for early December.
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.	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 detailed plans for future commercialization possibilities.
Vaccine coverage	WHO to identify appropriate methods and develop guidelines for collecting, analysing, and interpreting biomarkers for validating coverage.	Nov 2011	Ongoing	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 has been circulated for comments and will be finished by the end of 2015 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 2016 and will run during the entire year of 2016. Based on the outcome, the working draft guidelines will be corrected where needed and finalised. The final document is planned to be ready by end of 2016 and to be rolled out as a tool to evaluate the immune status of the target or targeted population.
Vaccine Hesitancy	SAGE encourages validation of the developed compendium of survey questions on vaccine hesitancy, which have been assessed and validated only in some high-income countries or not at all.	Oct 2014	Ongoing	Discussions with various stakeholders are ongoing (Centre for Disease Control CDC, WHO EURO, Middle Income Countries MIC task force) on the ways forward to identify partners to take on the validation of the survey quesions. The MIC task force framework was presented to SAGE during the April 2014 meeting, which highlighted the importance to advance this initiative. Currently it is being explored how to secure funding from donors in support of the listed activities and advance validation of the questions in LMIC settings.

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Vaccine Hesitancy	SAGE underlined the importance of distributing the matrix of determinants, the definition of hesitancy and the other deliverables to countries and partners.	Oct 2014	Ongoing	Discussions and presentations were held in the context of the immunization managers' meeting in the Eastern Mediterranean Region (EMR) and the African Region (AFR) Task force on immunization(TFI) meetings. A Special Issue on Vaccine Hesitancy has been published on August 18 2015 in the journal Vaccine with a series of 10 full papers plus one editorial. In conjunction, a WHO press briefing was held on 18 August to emphasize WHO initiatives addressing vaccine hesitancy. This generated much positive media coverage.
Vaccine Hesitancy	SAGE acknowledged the necessity to develop core capacities at headquarters and regional level for gaining behavioural insights that can be applied in an integrated fashion for prevention of many communicable and non-communicable diseases, as well as vaccine hesitancy. This will require the involvement of sociologists, psychologists, anthropologists, experts in social marketing, communication experts, and specific disease and vaccine experts.	Oct 2014	Ongoing	Discussions are ongoing within WHO and UNICEF and with partners on how to collectively establish core capacities in order to support and provide technical assistance to countries. For this, discussions were initiated on how to advance the establishment of a network of expertise/excellence and collaborating centres by capitalizing on currently ongoing initiatives and activities which have been established and are conducted by WHO (HQ and Regions), partners and stakeholders in the field of vaccine hesitancy. A package listing resources from a number of excellence centers which could support countries and regions has been prepared for circulation to regions and countries.
Vaccine safety	SAGE highlighted the urgent need for a safety review of other important vaccines that could be used during pregnancy.	Nov 2012	Ongoing	A sub-group of the Global Advisory Committee on Vaccine Safety (GACVS) has been launched to address vaccine safety during pregnancy. A finalized version of the GACVS report on safety of immunization during pregnancy has been made available to SAGE in November 2013 and is now available on the Global Vaccine Safety (GVS) website. A new work track was started with WHO Initiative for Vaccine Research (IVR) in order to harmonize safety monitoring during pregnancy clinical trials. WHO is a contributor to the Gates funded Global alignment of immunization safety assessment in pregnancy project that should run until the end of 2016.
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. 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.	Nov 2012	Ongoing	Concerns about the ongoing shortages of traditional vaccines persist. Recent discussions with UNICEF SD (Supply Division) have indicated that a vaccine such as BCG may face supply shortages in 2015 to the extent of being unable to deliver vaccines to all countries needs, potentially prompting stock-outs. For other vaccines, including measles containing vaccines, supply is currently adequate, but largely dependent on a single manufacturer. Discussion with donors has advanced well and planning for meeting on new vaccine technologies being initiated. Internal WHO discussions are in progress. A meeting on new vaccine technologies was held in February 2014. The work on the supply of affordable vaccine is an on-going effort in which all immunization partners are engaged. WHO secretariat (EPI) is now working to develop an approach to expand timely access to supply for both traditional and new vaccines through improved demand and supply management/forecasting. A report on this area of work will be provided to SAGE in 2016.
Yellow Fever	SAGE requested WHO to revisit the IHR provisions relating to the period of validity for international certificates for vaccination against yellow fever (YF).	Apr 2013	Ongoing	The WHO World Health Assembly in May 2014 adopted an amendment to Annex 7 of the International Health Regulations (2005) (IHR), which stipulates that the period of protection afforded by yellow fever vaccination, and the term of validity of the certificate will change from 10 years to the duration of the life of the person vaccinated. This change will enter into force legally in June 2016. Until then the current IHR text on yellow fever vaccination and certificates continues to apply, and some countries may continue to request proof of vaccination or a booster within the last 10 years from travellers. As of the end April 2015, 34 countries have notifed WHO that already accepted the validity yellow fever (YF) vaccination certificate for life. The online WHO 2015 International Travel and Health (ITH) edition report on the status of YF vaccination requirements per countries.