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 The “Meeting Date” column displays the date of the SAGE meeting during which the recommendation was originally made.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	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 paper has been submitted to a peer-reviewed journal end of 2015, though there has not been any reply so far.
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 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 started in October 2015. A session on implementation/integration will be held at the April 2016 SAGE meeting.
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 first country assessment planned in this project, Zambia, has been completed by the consultant, Rebecca Fields from JSI. It was incorporated into the existing country strategies to improve the routine immunization delivery in the second year of life, and will be used in the development of the WHO guidance on this matter. UNICEF is completed a landscape analysis of this area of work and presented their findings at the Global Vaccine and Implementation Research Forum (GVIRF) in March in Johannesburg, South Africa. A Second year of life platform session is on the agenda of the April 2016 SAGE meeting.
General	SAGE recommended that ways to improve curricula for medical personnel should be explored.	Nov 2008	Ongoing	This area of worked has been stalling as the main person steering this work, retired 2 years back. AFRO has not been able to find a replacement for capacity building work. Only limited work has been happening in other regions in this area.
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	Ongoing	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 this is happening in AFR on monthly as well as annual basis and in SEAR and EUR on an annual basis.

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General	SAGE requested that a paper be developed, highlighting the circumstances under which off-label use of any vaccine can be recommended, while clarifying the differences between regulatory decisions and public health recommendations. Legal and programmatic implications of off-label recommendations and the need for clear communication should be considered.	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. Guidelines on procedures and data requirements for changes to approved vaccines were adopted by ECBS in October 2014 (TRS 993, annex 4). Preliminary consultations took place around the 2015 ECBS meeting for specific guidance on Labelling information of inactivated flu vaccines for use in pregnant women. This document is subject of public consultation until 19 February 2016 and it is hoped that the document will be finalized during the 2016 ECBS 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. This submission process for this paper has been initiated at the beginning of March 2016.
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	Completed	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 a department and not the entire department or 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 discussion on the global shortage of vaccines at the next meeting.	Apr 2015	Ongoing	After some delay, a session on preempting and responding to vaccine shortages is scheduled for the April 2016 SAGE meeting.
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) for 2015 was published online and is available at:http://www.who.int/immunization/global_vaccine_action_plan/en/ This report was tabled at the Executive Board in January 2016 and will be tables with the comments received from the EB tabled at the WHA in May 2016. Preparations have begun for preparing the 2016 progress report.
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	SAGE recommended that the 2016 GVAP assessment report be presented at the World Economic Forum in Davos where the Decade of Vaccines was launched.	Oct 2015	Ongoing	The recommendation made at the October 2015 SAGE meeting arrived too late to include to the Davos 2016 agenda. Therefore, it has been agreed with DoV partner agencies to include at World Economic Forum in Davos in January 2017. It will allow us to share the 2016 mid-term SAGE assessment report and also to be able to include some inputs from both SAGE recommendations on MNTE and Measles-Rubella Elimination revised strategies (to be presented to SAGE in October 2016).

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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 was constituted and held monthly teleconferences. Two face-to-face meetings of thewere held 23-25 September 2015 and 10-11 February 2016. The SAGE session for decision will take place on 14 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. This material will inform the SAGE WG in preparation for the April 2016 SAGE 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. The Working Group presented to SAGE in October 2015. Regulatory evaluation of the vaccine is currently ongoing. At this stage, there are no new peer-reviewed data and the trials are still ongoing.
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 regularly 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 again 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 was presented to SAGE at the October 2015 meeting. Currently the Working Group is awaiting new evidence from the clinical trials and regulatory approval of the vaccie before revising the topic and issuing draft recommendations.
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 February 2016. 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 compatible with very high vaccine effectiveness. The situation continues to be investigated. Hepatitis A cases have remained low in 2014 and 2015. Although a reduction in hepatitis A rates was experienced in all age groups, there is an increasing proportion of the remaining cases occurring in persons > 14 years of age in the post vaccination period. Most of these represent non-vaccinated adolescents or adults that escaped HAV-infection in previous outbreaks. Regarding children with a confirmed HAV-acute infection, many are unvaccinated children arriving from Bolivia where HAV vaccine is not included in the regular calendar. As exemplified by the outbreak in San Martin the risk persists in the population. 73% of of HAV acute infection cases reported occurred in individuals over >10 years. All cases reported occurred in unvaccinated individuals. 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 as Argentina was the front runner country to introduce a 1 dose schedule with the inactivated vaccine. A third phase immunogenicity study is undergoing in Argentina, to assess long term protective antibodies in children more than 9 years following single dose vaccination. So far the results of the phase two study conducted in 2013 and with a median post-vaccination interval of 7.7 years have been quite reassuring with 97.4% (95% CI: 96.3-98.3).

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Hepatitis B	All regions and associated countries should develop goals for hepatitis B control appropriate to their epidemiologic situations. Serologic surveys of hepatitis B surface antigen (HBsAg) prevalence, representative of the target population, will serve as the primary tool to measure the impact of immunization and achievement of the control goals.	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 took place in Aug 2015. The African Regional Office (AFRO) 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 and adopted hep B activities as part of the RVAP that was also endorsed at the same RC meeting. The European Regional Office (EURO) will consider a regional hepatitis B control goal as proposed by ETAGE. 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). The 2016 WHO Executive Board approved a global health sector strategy on viral hepatitis 2016-2021 that proposes an impact target of less than 1% HBsAg prevalence among children by 2020 and 0.1% by 2030.
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 WPRO, held Hep B birth dose consultations to improve birth dose coverage. An assessment of BD implementation has taken place in Sao Tome Principe in July 2015 and Nigeria in September 2015 and in the Gambia in December 2015. Senegal held a Hep B birth dose training workshop in Dec and introduced birth dose in January 2016. Guidance for Hep B birth dose introduction have been cleared for publication and should be available in Q1 2016.

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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. We now understand that the South African trial will be a Phase 2b trial rather than a Phase 3 trial, and is scheduled to start in late 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 requested that IVIR-ACassess optimal immunization schedules based on both direct and indirect effects and not only direct effects.	Oct 2015	Ongoing	As part of any vaccine impact evaluation IVIR-AC reviews and encourages studies of optimal schedules on both direct and indirect effects. Study projects and meetings have been held and are planned on HPV, Hep B vaccines, rotavirus vaccines among others.
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 October 2016 meeting - delays due to impact of Ebola outbreak. Further current ongoing work is a review of emerging evidence on HPV vaccination including the 9-valent vaccine and vaccination of boys as well as a review of the impact of vaccination schedules.
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.

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Immunization Supply Chains	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.
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. A session on implementation is scheduled for the April 2016 SAGE meeting and the main WHO focal point for the session is from HSS.
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. Since 2014 research topics on the non-specific effects of vaccines, missed opportunities and community vaccine acceptance have been been part of the agenda of IVIR-AC.
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. Phase 1 has been implemented and preparations are under development for Phase 2 and implementation will depend on funds being made available. 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.

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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) of June 2015 meetings, the need to develop standardized protocols for randomized controlled trials on non-specific effects of vaccines (NSE) was highlighted. Two IVIR-AC members volunteered to follow up this work. On 16–17 February 2016, IVR convened an ad-hoc expert consultation on NSE clinical trials. Eighteen experts (including 3 IVIR-AC members) contributed to this consultation, whose main objectives were to reach a consensus on priority trial questions and to propose trial designs for each of the priority questions. Protocol synopses for the six different trials that the experts proposed are being prepared for review and discussion at June 2016's IVIR-AC meeting.
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	A session to update SAGE on this area of work is planned for the April 2016 SAGE Meeting. Based on the two Missed Opportunity Assessments (MOV) conducted in Chad and Malawi in 2015 (draft manuscripts prepared for peer reviewed journal submission), the package of methodology materials will be finalized by June. These include: main assessment guide, health facility intervention guide, the MOV protocol, sample questionnaires and generic field guides. Having strengthened the capacity of AFRO to implement MOV assessments (discussions with Kenya are ongoing), collaboration is now beginning in 2016 with SEARO where MOV assessments are being planned and supported in Indonesia and Timor Leste. To establish a network of partners engaged in MOV, an informal coordination meeting is being planned for April 2016 to provide briefing on the process and outcomes of the recent country MOV assessments, share future plans and framework for implementation, and achieve consensus on a coordination mechanism for all MOV work among all partners.
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	An ad-hoc consultation on clinical trials for non-specific effects of vaccines (NSE) was held on 16–17 February 2016. Eighteen experts (including 3 IVIR-AC members) contributed to this consultation, whose main objectives were to reach a consensus on priority trial questions and to propose trial designs for each of the priority questions. Protocol synopses for the six different trials that the experts proposed are being prepared for review and discussion at June 2016's IVIR-AC meeting.
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 A new funding proposal is being prepared for 2016-2017 with support from Gavi and UNICEF.
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 best practices for JE vaccine effectiveness and impact studies. A draft guidance document will soon be circulated for peer review, followed by publication.

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Japanese encephalitis	Commercial kits for detection of JE-specific IgM should be compared and validated.	Apr 2006	Completed	Assessment using serum was carried out by PATH and published (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 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. 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 3 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 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. 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. 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 with 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. A bi-regional JE meeting for SEAR and WPR is being planned for 10-14 October 2016.

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Lower middle-income countries: sustainable adoption and financing for new vaccines	SAGE requested that WHO facilitate the establishment of a partnership among all relevant stakeholders to consider: pooled procurement; tiered pricing; greater transparency of pricing; and exploring the role that UNICEF, the Pan American Health Organization and foundations can have in assisting these countries with procuring and financing vaccines.	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. Following SAGE's endorsement of the strategy, the WHO Secretariat has led Strategy implementation efforts in collaboration with immunization partners. A first mission was conducted in Swaziland as part of the country engagement process encouraged by SAGE. Also, different small efforts to support countries to strengthen their procurement capacity have taken place. some effort is being undertaken also in the area of decision making and hesitancy. Work on price transparency continues. Despite these efforts, progress in implementation of the strategy is very slow due to lack of funding. As discussed at the April 2015 SAGE meeting, the partners would require US$20M per year to fully implement the strategy.
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 have been developed for reactive and prophylactic use, and these are available from WHO's website. A Zika vaccine TPP is now under development and will undergo public consultation in the first half of 2016.

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Malaria Vaccine	SAGE requested continued review of the planning of the pilot implementations and to receive regular updates on the results.	Oct 2015	Ongoing	The WHO position paper was published in January 2016. WHO is working to identify potential funding for the malaria pilots, including discussions with GAVI and UNITAID. No funding commitments have been made. This is a joint two department activity with Global Malaria Programme. A WHO/PATH partnership will oversee the pilots. A public call for expressions of interest (EoI) from Ministries of Health was issued by WHO in December 2015. 10 countries submitted EoI, and WHO is in the process of country selection with the intention to proceed with pilots in 3 countries. The pilots will be cluster randomised with feasibility of implementation, impact and safety as primary considerations. A meeting was held on January 19 with external advisors with the relevant expertise including SAGE, MPAC and GACVS representation. WHO and PATH are preparing a technical proposal, for submission to appropriate financing bodies. The earliest pilots could start in late 2017, with 2018 as a realistic start date if funding can be found. Separate to the pilots there are a set of smaller Phase 4 studies to be sponsored by GSK, with before and after design, and with the primary objective of providing further safety information to meet post-marketing obligations with EMA. WHO and GSK are in discussions to ensure good linkages and complementarity between the GSK sponsored Phase 4 studies and the pilots.
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 is supporting evaluations of product monograph language regarding safety and use during pregnancy, as well as a survey of health care provider's perceptions of the specific product monograph language regarding use in pregnancy. WHO has reviewed various regulatory approaches to labelling of the pregnancy and lactation sections of product inserts, and it has convened several 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. In collaboration with multiple NRAs globally, WHO has produced a draft guidance document titled 'labelling information of inactivated influenza vaccines for use in pregnant women'. The document is currently available for public comment. It will be revised to reflect the public consultation and reviewed by ECBS in late 2016.
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	Regarding PAHO/WHO's documentation of the successful regional experience of delivering influenza vaccines to pregnant women, PAHO has progressed significantly: - we have submitted a manuscript describing influenza uptake in the LAC region since the pandemic, highlighting the improvements in targeting pregnant women for vaccination in 29 countries. -PAHO conducted during 2015, a survey among 14 LAC countries that aimed at describing the process from vaccine introduction decision, to implementation among pregnant women. It also tackled obstacles and enablers in vaccine promotion and uptake. - In order to complement this survey, we are planning another in-depth survey to develop case-studies with key countries that have acquired a lot of experience in maternal immunization. As part of these case-studies countries will share lessons learned. - PAHO convened a multi-disciplinary, inter-institutional working group to develop a field guide for maternal immunization which is in its finalization phase. This field guide targets EPI managers, EPI staff, and other healthcare workers involved in maternal and child health care. it should be published during 2016.
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.

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Measles	SAGE recommended further clinical, immunological, epidemiological and modelling studies regarding the impact of different measles vaccination schedules.	Oct 2015	Ongoing	The RIVM in the Netherlands (the same group that did the systematic review of use of measles vaccine under 9 months of age) will have results from their clinical studies of the immune response to an early dose of MMR vaccine by end 2016. Modeling work is ongoing at US CDC to explore the effect of different vaccination schedules on the epidemiology of measles. An update on this work will be provided to the SAGE MR Working Group during the course of 2016.
Measles	SAGE requested evidence on the need for measles revaccination of HIV-infected adolescents and adults. Further research is needed to monitor the long-term immune responses to measles vaccine in HIV-infected children revaccinated after starting HAART and in HIV-infected children starting HAART prior to receiving their first dose of MCV.	Oct 2015	Ongoing	Compiling the evidence on the need for measles revaccination of HIV-infected adolescents and adults is on the 2016 work plan of the SAGE Measles and Rubella Working Group (SAGE MR WG). Professor William Moss at Johns Hopkins University is taking the lead on this work. Research on the long-term immune responses to measles vaccine in HIV-infected children revaccinated after starting HAART needs to be taken up by clinical research groups and is not the focus of the SAGE MR WG.
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. The same applies to the upcoming SAGE meeting in April 2016 where focal points will be asked to provide an executive summary as necessary.
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.	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/. Eight of the 26 meningitis belt countries have already submitted an application to Gavi, the Vaccine Alliance in January 2015 (Ghana), in September 2015 (Burkina Faso, Central African Republic, Chad, Mali, Sudan) and in January 2016 (Niger, Nigeria) for introduction of the meningococcal A conjugate vaccine into their routine immunization programme, with a single dose at 9, 15 or 18 months of age concomitantly with the administration of the first or second dose of Measles/Rubella vaccine. Another 7 to 8 meningitis belt countries intend to apply for the introduction of the vaccine into their routine programme at the next couple of Gavi application windows in May and in September 2016. The first introductions of the vaccine into routine programmes are expected to occur in 2016.
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 October 2016.
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 about to be conducted in Nepal in collaboration with US CDC 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 and external partners (PATH, AMP)- is investigating the development of microarray patch technologies with IPV and MR with special emphasis on Preferred Product Characteristics and relevant regulatory pathways.

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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 formed the basis for additional proactive communication activities. As example of actions in response to points 1 and 2 WHO endured that information in WHO guidance on multiple injections and IPV was consistent with the SAGE recommendations on reducing pain, specifically in two documents: Practical considerations for the successful introduction of IPV, and Multiple Injections: Acceptability and Safety, both available on this web page. The PP on reducing pain was also added on the same web page. In relation to the training aspects for IPV introduction, we updated training modules for health workers, also to reflect the recommendations from the latest PP. The Immunization in Practice recently published has in module 5 'Managing immunization sessions', recommendations on vaccine sequence (increasing pain- oral before injection, rota before OPV), positioning the recipient, no aspiration etc. IIP will be widely distributed to countries and the last edition was also translated into several local languages. 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. The pain mitigation guidance has been included in the NITAG resource center. PDVAC will consider pain mitigation within their preferred product characteristics to guide target product profiles and include the topic in their envisage Vaccine special issue on the PDVAC pipeline analyses for 25 pathogens. More specific activities still need to be implemented with respect to points 3 and 4.
Polio	SAGE advised GPEI to develop a targeted advocacy and communication plan to engage key countries and stakeholders to ensure completion of phase I and implementation of phase II, including establishment of national containment authority and national regulation for containment of poliovirus in designated essential poliovirus facilities.	Oct 2015	Ongoing	A communications plan and a new web page for poliovirus containment have been developed. A map showing global progress with completion of phase I of GAPIII is posted every week. The map also identifies countries that have desgnated poliovirus-essential facilities and have nominated national authorities for containment that will certify facilities against GAPIII.
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. Planning for the Switch has continued in an accelerated manner with substantial technical assistance provided to countries through Partners and Regional offices. Financing is also be provided to high risk countries. A full update will be provided to SAGE in April as the Switch will be taking place at about that time. A special tracking effort has been undertaken to ensure that no country falls between the cracks and is entirely ready for the Switch. As of January 2016 only a handful of countries are of concern and the topic of specific attention by WHO and UNICEF.

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Polio	SAGE emphasised that UNICEF Supply Division, PAHO Revolving Fund and WHO should secure the global supply of prequalified bOPV.	Oct 2015	Ongoing	OPV supply is considered sufficient to meet requirements at the moment both for tOPV through to the switch as well as for bOPV to ensure timely introductions in routine programmes of this vaccine after the switch for countries procuring through UNICEF. The additional award made for 70 mds tOPV has allowed Pakistan to adjust its plans and to add more tOPV to the calendar and ensured sufficient supply to meet VDPV2 outbreaks in Myanmar and Lao. Countries procuring through UNICEF are on track for procurement of bOPV to introduce in routine programmes after the Switch, and expect to have continued sufficient bOPV supply beyond the switch. Demand forecasts are under review with the Vaccine Supply Task Team to ensure sufficient OPV supply will be available for 2017 and beyond.
Polio	SAGE advised the GPEI to ensure a full outbreak response to interrupt the cVDPV2 outbreak in Guinea and in South Sudan within 120 days of outbreak confirmation.	Oct 2015	Ongoing	South Sudan: the country reported 2 cVDPV2 cases in 2014 and one aVDPV2 on 16th of April 2015. Three mop up rounds were completed in Unity State after 2014 cases (age 0-15 years); 4 NIDs were completed in 2015 in the seven secure states and two were conducted in Unity, Jonglei and Upper Nile States. Due to persisting insecurity in these three states many areas remain unvaccinated. Four additional WHO international consultants are being deployed to South Sudan in addition to nine international WHO consultants who are in the country to support polio operations. CDC is in the process of deploying 25 international STOP team members. Guinea: An outbreak response was launched in the eastern part of the country during the week of 14 September covering 4 regions with 20 (52.6%) districts of the country. Two additional rounds (one regional and one national) were conducted in November and December. The quality of December SIA round was good in most of the locations, including the infected Kankan region, although the two preceding rounds had been assessed as falling short of the required quality standards to stop transmission. Three additional SIA rounds are planned in the country before the Switch. The surge is almost complete with 8 international and 38 national consultants deployed to support outbreak response and outbreak coordinator in place. AFP case reporting has improved in 5 of 8 Regions and active surveillance commenced recently. The initial issues with shipment of samples for laboratory investigation were resolved; currently the samples are shipped to Institute Pasteur in Dakar.
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	Capturing this information is fully integrated into the country-level transition planning guidelines, and the work of Legacy Management Group of the Global Polio Eradication Initiative is emphasising the importance of this.

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Polio	Sufficient capacity should be established at the global level to provide technical and programmatic support to countries to plan and implement all activities associated with 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. To date, 92 countries introduced IPV since January 2013, including all 17 tier 1 countries and 14/19 tier 2 countries. Due to the IPV supply shortage, 20 low-risk countries and one self-procuring country (Indonesia) will introduce IPV after the switch. 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.
Polio	SAGE encouraged further engagement of WHO regional offices in regard to the polio legacy planningto ensure adequate technical support to countries.	Oct 2015	Ongoing	Work has been ongoing on this front. A Legacy discussion took place at the regional Committee meeting of AFRO in October and a Legacy Working Group has been established by the AFRO Regional Director. Planning guidance is now available for countries and the GPEI Legacy Management group, which includes representations from EPI and Gavi, among others, is actively engaged in supporting the planning process. Funding has been made available by the GPEI to secure Technical Assistance to 14 countries for Legacy planning purposes.
Polio	SAGE requested its Polio Working Group to provide urgent guidance on optimal management of IPV supply and mitigation of other risks in case the IPV supply is further reduced.	Oct 2015	Ongoing	IPV supply situation is closely monitored. In February and March 2016, the two main IPV suppliers (i.e. Bilthoven Biologicals and Sanofi Pasteur) informed WHO/UNICEF that they will substantially reduce or delay the quantities of IPV supplied in 2016 and 2017, due to technical challenges in scaling up IPV bulk production and the associated quality control testing and releases. This has created significant delays in IPV introduction and shortages of supply in many countries. SAGE WG and SAGE reviewed the IPV supply situation closely, and issued a statement (please see separate document).
Polio	SAGE advised GPEI to accelerate implementation of the WHO Global Action Plan for containment (GAPIII) including: a) all countries completing phase I; b) regional focal points closely monitoring country activities and ensuring each country completes its inventories of facilities that hold or handle polioviruses, and destroys or commits to destroying WPV2 by end 2015 and any other type 2 containing materials including Sabin poliovirus by July 2016.	Oct 2015	Ongoing	As of 8 March 2016, 134 countries have completed the first part of Phase I, with 38 Member States having yet to respond and 22 Member States yet to complete their reports on the destruction or planned retention of WPV2 or VDPV2 materials. By end July 2016, 3 months after the switch, countries are expected to complete the second and last part of Phase I, and report on the destruction or planned retention of all Sabin type 2 poliovirus materials.

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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.	Apr 2015	Ongoing	The Polio Working Group reported to SAGE in October 2015 and SAGE reconfirmed April 2016 as the definite date for OPV2 withdrawal.
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	Completed	This was discussed during the September 2015 Working Group meeting and presented to SAGE during the October 2015 meeting.
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” was prepared and briefly presented to SAGE WG on Ebola vaccines in August 2015. In October 2015, the document was submitted to the Expert Committee on Biological Standardization (ECBS) for review and advice. The Committee considered that a guidance document might be of value to NRAs and other public health organizations, however it also recognized the complexity of emergency situations each of which is essentially unique, and that decisions ultimately rest on a benefit/risk assessment. The ECBS agreed that the report could provide useful information to NRAs, and looked forward to reviewing progress in 2016
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 be issued in Q1-Q2/2016.
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 ongoing. The review will include (but not be restricted to) consideration of communication of ECBS outcomes. 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	Discussion with the French Government for the donation of 5 million doses and Japanese Gov for 10.000 doses are still ongoing. WHO is working on smallpox vaccine prequalification for the 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. The report will be pusblished in April 2016

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Surveillance	SAGE endorsed the recommendations of the ad hoc TAG for improving the quality of the IB-VPD surveillance network and urged that the objectives of this network be more clearly defined, that collaboration with other surveillance systems and laboratory networks (i.e. the polio/measles laboratory networks) be continued, and that, where feasible, activities be linked with other programmes enhancing country capacity, including implementation of the International Health Regulations. SAGE urged greater attention to integration of data systems, which would facilitate real-time analysis and performance monitoring. SAGE also noted the opportunities for integration by building upon the enhanced capacity developed by these networks to conduct surveillance for other diseases using a similar case-definition and personnel trained in applying and adhering to rigorous surveillance protocols. Both networks should continue to share experiences with the polio surveillance network. Integration efforts must be strategically designed in ways that are logical and synergistic.	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 and 2015, significant progress was made to further improve the IB-VPD and rotavirus sentinel hospital surveillance networks and additional recommendations made. 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; by 2015, all six WHO regions were reporting case-based data linked to laboratory testing. Data management processes continue to be improved toward 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 program as well as quality control programmes. Sentinel site and laboratory assessments are ongoing at priority sites. The most recent data available is from 2015, and it reflects the strength of the data and the network. One recent global analysis of IB-VPD data found that PCR identified 5-7 fold more bacterial meningitis than culture depending on region and CSF characterization and that in resource-limited settings, targeted PCR testing of probable bacterial meningitis cases only may maximize efficiency. Based in part of this analysis, the recommendation that all IB-VPD cerebrospinal fluid specimens should be tested by PCR at an RRL has been implemented. Network data has contributed to vaccine introduction decisions, such as choice of Pneumococcal Conjugate Vaccine (PCV) formulation, and the surveillance networks have been used as platforms for vaccine impact evaluations, particularly for Rotavirus Vaccines (RV). Moving forward, the rapid introduction of PCV and 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. A web-based data management tool is still under development and has great potential to improve data quality and sharing. Some new activities revolve around testing for other pathogens and integrating with other VPD surveillance platforms. Specifically, a pilot to include typhoid surveillance as part of IB-VPD surveillance is being implemented in 2016 in 2 sites in Asia and 2 in Africa. We are discussing how to better integrate IB-VPD meningitis surveillance with existing meningococcal meningitis surveillance systems. We are exploring how to use the rotavirus surveillance network to monitor norovirus, and a network study is using the TAC technology to test for other enteric pathogens in specimens collected as part of the network. WHO, the informal Technical Advisory Group and partners will work to implement recommendations to further improve the network during 2016 including to strengthen programme management. Other activities planned include:an evaluation of the cost of surveillance to help countries and funders develop sustainable surveillance plans; strengthening involvement of Ministry of Health and national EPI programmes; defining a subset of sites where PCV and/or RV vaccine impact evaluations may be feasible due to sufficient pre- and post-vaccine introduction data; draft guidelines for rotavirus data analysis/interpretation and standard operating procedures; re-evaluate site inclusion criteria: for rotavirus, reduce the number of annual stool specimens needed in vaccine using countries; for IB-VPD, include consistently performing sites that enroll fewer meningitis cases.

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Tuberculosis vaccines	SAGE endorsed the establishment of a WHO TB vaccine technical expert group with representation from SAGE. An annual written report on TB vaccine developments should be provided to SAGE. SAGE would be provided with two-page summaries of progress every year. TB would only be included on the agenda of SAGE when there is a meaningful development of decision from SAGE required.	Nov 2011	Ongoing	Progress in TB vaccine development was reviewed by PDVAC in September 2015. Modelling studies suggest, and 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. Key data points will emerge from separate clinical studies with 3 candidates (H4, VPM1002 and M.Vaccae) during in 2016. M.vaccae is a heat killed homogenized lysate being developed by Anhui Zhifei Longcom, China, undergoing Phase III testing for prevention of pulmonary TB in latently infected adults in China. VPM 1002 is a recombinant BCG, originally developed by the Max Planck Institute; now licensed to the Serum Institute of India (SII), Pune, India and being developed with Vakzine Projekt Management (VPM), Hannover, Germany, currently in Phase II trial vs. BCG in HIV+ and HIV- infants <12 days old (South Africa), interim data assessment anticipated in mid 2016. H4/IC31 is an adjuvanted recombinant protein under development by sanofi Pasteur, SSI and Aeras, currently in a Phase II prevention of infection study in adolescents (Phase II) with data expected in Q3 2016. WHO is planning to meet with GSK and VPM/SII to discuss their programs in May 2016.
Typhoid	Establish a SAGE working group on typhoid conjugate vaccines in 2016 to prepare for a SAGE review of the evidence in 2017.	Oct 2015	Ongoing	The SAGE Working Group on Typhoid Vaccines was established in March 2016. The Working Group will review updated evidence to support the use of typhoid vaccines overall with a focus on typhoid conjugate vaccines. A SAGE review is tentatively scheduled for Oct 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 during humanitarian emergencies	SAGE emphasized the need to advance work on refining guidance in delivering continuous immunization services during humanitarian conflicts. A session on human emergencies will tentatively be slotted at the April 2016 SAGE meeting.	Oct 2015	Ongoing	A WHO meeting on implementation of vaccination during humanitarian emergency situations was convened in Cairo from 12-14 January 2016.The objectives were to: -reflect on the experience of EMR countries in implementing vaccination in humanitarian emergencies and the issues, challenges, best approaches and existing country guidance documents to ensure satisfactory vaccination of the target populations. -reflect on countries experience using Vaccination in acute humanitarian emergencies: a framework for decision making -build on countries experience to initiate development of a draft guidance document on the implementation of vaccination in humanitarian emergency situations. A draft version of the guidance document on implementation issues has been produced by EMRO that will undergo broader consultation before finalization. Further there will be adjusting/updating of the framework based on the feedback received during the meeting as well as further development of an operational manual of the framework based and web based interactive tools to support its use and facilitate further updating. Attempts will be made to have a proactive dissemination and communication plan to ensure adequate distribution. Although there will not be a separet SAGE session in April 2016 this will be featured in the IVB Director's global report at this meeting.

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Vaccination during 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	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. No further updates have resulted from this discussion. The Emergency Risk Management and Humanitarian Response (ERM) Department is currently undergoing a reform process. Once the process is finalized we will have a clearer indication of our engagement in and collaboration with this area of work.
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 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 has been conducted in December 2015.

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Vaccine coverage	SAGE recommended that WHO support new research for biological specimen collection including rapid on-site diagnostics that could improve coverage and susceptibility estimates. Improved serological surveillance techniques could be integrated with existing population-based surveys such as DHS or MICS. These research topics should be included on the QUIVER (now IVIR-AC) agenda.	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 delivery research	SAGE requested that IVIR-AC explore research studies and methods including behavioural science studies for ranking reasons behind lack of vaccine delivery and other 'barriers to access'.	Oct 2015	Ongoing	IVIR-AC reviews methods and encourages studies on vaccine delivery costing and financing (HPV, influenza and OCV) and vaccine uptake/hesitancy.
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. Resources to support related activities are currently being established at HQ and in EURO. A package listing resources from a number of support centers which could assist countries and regions has been prepared and was circulated to regions in December 2015.
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 in 2014 and 2015. A Special Issue on Vaccine Hesitancy has been published in August 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 2015 to emphasize WHO initiatives addressing vaccine hesitancy. This generated much positive media coverage. A compilation of centers to assist countries in addressing vaccine hesitancy has been finalized and sent to WHO regions to disseminate to countries. A manuscript has been submitted which outlines the results of the 2015 JRF indicators on vaccine hesitancy. The manuscript contains the matrix of determinants and the definition of vaccine hesitancy.
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 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. WHO is also advising another Gates funded project with Seattle Children's hospital on maternal immunization pharmacovigilance in low- and middle-income countries.
Vaccine Supply	SAGE requested WHO to produce a report on the security of the supply of affordable vaccines and encouraged donors to invest in the development of new vaccine technologies that facilitate the delivery of effective, affordable vaccines to populations most at risk.	Nov 2012	Ongoing	Concerns about the ongoing shortages of traditional vaccines persist. Internal WHO discussions are in progress, in particular in context of WHA resolution 68.6, as well as discussions with partners. 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 October 2016. A session on preempting vaccine shortages will be organized for SAGE April 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.The amendment will enter into force and be legally binding upon all IHR States Parties on 11 July 2016. There were no legal rejections or reservations expressed by countries. 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 travelers. As of 2 February 2016, 49 countries or territories have notified WHO that already accepted the validity yellow fever (YF) vaccination certificate for life (see http://www.who.int/ith/2016-ith-annex1.pdf?ua=1.)