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 The “Meeting Date” column displays the date of the SAGE meeting during which the recommendation was originally made.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 recommended strengthening national vaccination programs, integrating health services and strengthening health systems to promote universal health coverage.	Apr 2013	Ongoing	A teleconference was held on 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. At the April 2016 SAGE meeting, session on 'Implementation in the context of health system strengthening (HSS) and universal health coverage' was held. It was proposed that improvement of immunization services within the broader health services should be a third dimension of vaccine programmes alongside safety and effectiveness.
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	Completed	A review paper on the Global Advisory Committe on Vaccine Safety (GACVS) future is published: Asturias EJ, et al. Contributions and challenges for worldwide vaccine safety: The Global Advisory Committee on Vaccine Safety at 15 years. Vaccine. 2016 Jun 17;34(29):3342-9.
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 second country case study of Senegal (after Zambia, which was presented to SAGE in April 2016) is under way and will feed into the development by JSI of the generic guidance of establishing a 2YL platform for delivery of vaccinations and other health interventions.
General	SAGE recommended that ways to improve curricula for medical personnel should be explored.	Nov 2008	Ongoing	This area of work has been stalled as the main person steering this work retired 2 years ago. 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, also due to limited staff capacity.
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, it is done on annual basis. In October 2016, at the Global monitoring meeting, discussion will take place about collecting this information annually from all regions and regular consolidation and dissemination.

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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 was sought from the Expert Committee on Biological Standardization (ECBS), and added to the agenda of meeting on 15-19 October 2012. SAGE had previously requested a paper that highlights 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 ECBS to 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 to 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 to public consultation until 19 February 2016 and it is hoped that the document will be finalized during the October 2016 ECBS meeting which is taking place in parallel with the SAGE meeting. A paper clarifying the differences between regulatory decisions and public health recommendations was commissioned. Unfortunately, there were protracted delays in finalization of the publication. The paper was finally submitted for publication in April 2016 and acceptance of publication is still pending.
AEFI reporting	SAGE urged that efforts be pursued to enhance Adverse Events Following Immunization (AEFI) reporting worldwide.	Apr 2016	Ongoing	With GAVI support, 30 AFR countries have established work plans. A first analysis of the new GVAP indicator for AEFI monitoring has identified 84 member states that meet the recommended level of at least 10 AEFI cases reported per 100,000 surviving infants per year.
AEFI reporting	SAGE commented on the passive surveillance data from the Uppsala Monitoring Centre (UMC) and raised concerns that the safety signal detection was not undergoing appropriate peer review. SAGE concurred with GACVS on the need to increase collaboration and to implement a strong review process.	Apr 2016	Ongoing	The GACVS concluded that signals documented by the UMC provide useful information in monitoring the safety of vaccines from worldwide sources. It was proposed that a strengthened process of collaboration with UMC would allow use of the expertise on vaccine safety available within the GACVS and partner agencies for the review of this information before it is communicated to the network of pharmacovigilance centres and to vaccine manufacturers. This review should take into account the limitations of signal detection methods along with the reviews performed routinely by the FDA and EMA, given their extensive experience and access to more complete information with the ICSRs they receive and that may not all be shared with UMC. The GACVS Secretariat will liaise with UMC to identify mechanisms for such collaboration. UMC revised its signal assessment guideline in April 2015. In March 2016, UMC was recommended to establish a review group for the vaccine signals.
Agenda item	SAGE requested a discussion on the global shortage of vaccines at the next meeting.	Apr 2015	Completed	After some delay, a session on preempting and responding to vaccine shortages was held at the April 2016 SAGE meeting.
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 be included to the Davos 2016 agenda. Therefore, it has been agreed upon 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). This topic has been discussed with the B&MGF in June during which a principle agreement has been reached. A concept note detailing the objectives, message and format of a possible Davos session has been developed by WHO to engage the discussion. Next step is to agree with partners on the basis of this note so a formal process can be initiated.

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Decade of vaccines/GVAP	The SAGE working group should continuously review the need for reformulation of the indicators or mechanisms for collection and reporting of data.	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 at the WHA in May 2016. Twenty five speakers, including 20 delegates from Member States, one observer (Chinese Taipei), three civil society organizations and Gavi, the Vaccine Alliance took the floor during the discussion on the Global Vaccine Action Plan. The SAGE GVAP working group meeting took place on August 31 - September 1 2016. Following this meeting, the SAGE DoV finalized its draft GVAP assessment report 2016, which has been included in the SAGE Yellow Book. SAGE members will have to review, discuss, possibly amend the report and then endorse its final version during a dedicated SAGE session on 19th October 2016.
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	Closed	The SAGE Working Group on Dengue Vaccines was constituted and held monthly teleconferences. Two face-to-face meetings of the group were held 23-25 September 2015 and 10-11 February 2016. The SAGE session for decision took place on 14 April 2016. A revised WHO position paper on the use of Dengue vaccine was published in July 2016.
Dengue Vaccine	SAGE requested that future recommendations on dengue vaccine safety be linked to the dengue vaccine development strategy.	Apr 2012	Closed	SAGE and GACVS reviewed the evidence on the safety of the licensed dengue vaccine. SAGE recommendations were incorporated into the dengue vaccine position paper published in July 2016, which highlighted critical post-licensure safety studies to be undertaken to further inform the risk/benefit profile of the vaccine.
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 titled, "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. No new data from the clinical trials in West Africa is available. There is information regarding a Russian developed vaccine that was licensed in Russia, but despite WHO requests no data is available. The final Ring trial data will be available in the Fall of 2017.
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 vaccine before revising the topic and issuing draft recommendations. The Secretariat has had interactions with the two WG co-Chairs. A teleconference of the WG is planned for 3 October, 2016 to discuss the new data and subsequently a decision will be made regarding a face to face meeting in the fall of 2017.

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Hepatitis A	Long-term protection from single or 2-dose schedules should be regularly monitored by countries and reviewed by SAGE.	Apr 2012	Ongoing	Post-market surveillance continues in Argentina and a detailed report on the recent epidemiological situation was provided to WHO in 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. However, there is currently 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 Argentinian 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 ongoing 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) still protected. A proactive further follow-up will be done ahead of the April 2017 SAGE meeting.

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Hepatitis B	SAGE recommended that the timely delivery of a birth dose of hepatitis B vaccine (that is, within 24 hours of birth) should be used as a performance measure for all immunization programmes. Reporting and monitoring systems should be strengthened to improve the quality of data on the birth dose.	Apr 2009	Ongoing	A consultation on implementation of a 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 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 the 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 Hepatitis B birth dose consultations to improve birth dose coverage. In Feb 2015, An AFRO workshop on birth dose introduction was conducted in Brazzaville; this workshop included guidance on birth dose monitoring. An assessment of birth dose 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 Hepatitis B birth dose training workshop in Dec and introduced birth dose in January 2016. Guidance for Hep B birth dose introduction was published on June 2016 ('Preventing Perinatal Hepatitis B Virus Transmission: A Guide for Introducing Hepatitis B Birth Dose Vaccination', available from: http://www.who.int/immunization/documents/general/ISBN9789241509831/en/). In May 2016, guidelines for introducing birth dose vaccination have been publish and include a chapter on reporting and monitoring birth dose vaccination: http://apps.who.int/iris/bitstream/10665/208278/1/9789241509831_eng.pdf. In July 2016, a proposal to revise WHO/UNICEF Joint Reporting Form (JRF) report on birth dose was submitted (suggesting to report late and timely birth dose globally).

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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	In June 2016, the South East Asian Regional Office (SEARO)'s ITAG recommended to establish a Regional control goal of less than or equal to 1% HBsAg sero prevalence by 2020 among children aged 5 years. In August 2015, an HQ mission took place to discuss HepB control targets. In August 2016, the The African Regional Office (AFRO) Regional Committee discussed adopting a viral hepatitis strategy in line with the Global Health Sector Strategy (GHHS) for viral hepatitis which includes a hepatitis B control target in-line (although more ambitious) with the target endorsed as part of the immunization strategy at the 2014 RC meeting. In 2014, the AFRO RC meeting adopted resolution to reduce Hep B infection to <2% among children under 5 years of age by 2020 and adopted hepatitis B activities as part of the RVAP that was also endorsed at the same RC meeting. 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 RC goal to reduce hepatitis B infection to <1% among children at least 5 years of age by 2017. 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.
HIV	SAGE requested regular updates on the progress of HIV-vaccine research.	Apr 2010	Ongoing	The anticipated start of a phase 2 efficacy trial in South Africa constitutes an important progress in the HIV vaccine research and development area, building on the promising results from the RV144 Phase 3 trial in Thailand (which showed 31 % protection against new HIV infection during the 3.5 years after vaccination, 60 % during the first year), and an ongoing preparatory study in South Africa. The vaccination regimen in the upcoming HVTN 702 trial in South Africa will, like RV144, be based on a canarypox-based vaccine called ALVAC-HIV and a bivalent gp120 protein subunit vaccine, but will also include a new adjuvant, target HIV subtype C and include the addition of booster doses. Other live-attenuated candidate vaccine constructs are under evaluation in early clinical development. 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 time frame, but raise the prospect of cross-clade protection.
Immunization in Humanitarian Emergencies	SAGE stressed the need for continuous efforts in strengthening vaccination in humanitarian crises including further updating of field vaccination guides.	Apr 2016	Ongoing	A stakeholder meeting was convened on 20 June 2016 on identifying challenges and resolving barriers to timely supply of affordable vaccines in humanitarian crisis situations with participation from WHO, UNICEF, MSF, Save the Children, UNHCR and others. On 10/11 October 2016, a follow-up meeting will be held to ensure finalization of documents in the making and follow up on the June meeting. Current work on specific documents in progress includes 1. updating of the framework for decision making; 2. facilitating the use of the framework by developing an operational manual plus related online-based tools; 3. developing an implementation guideline for use of vaccination in humanitarian emergency situations; and 4. developing appropriate communication and dissemination plan to ensure wide distribution of the package of tools.
Immunization schedules	SAGE requested that IVIR-AC assess 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.

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Immunization schedules	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 in 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. New PP was issued. Pertussis vaccine was reviewed in 2015. New position paper was issued. Hep B vaccine will be reviewed in Oct 2016. HPV vaccine will be reviewed in Oct 2016. TT vaccine will be reviewed in Oct 2016. A systematic review of Diphtheria vaccines was conducted. 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). Delays due to impact of Ebola outbreak on staff responsibilities. A consultation to develop an analytic tool to support countries with the selection and/or adjustment of vaccine schedules in different epidemiological and operational scenarios will take place in Dec 2016.
Immunization Supply Chains	SAGE requested future update on approaches to prioritization within supply chain improvement plans.	Oct 2014	Completed	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 SAGE. The approach builds on 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.
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 and 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	Completed	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, Gavi, and the 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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Implementation	SAGE recommended the formation of an implementation group that had a broad array of expertise in this area.	Apr 2015	Ongoing	In April 2015, SAGE stressed the importance of applying the rigour and science in implementation programme design and evaluation of delivery of vaccines, in order to maximize the impact of current and future vaccines and delivery technologies. SAGE had further elaborated the above in a two page concept note. This document was then discussed within WHO. It was proposed and agreed upon by SAGE that instead of forming a SAGE working group, the Department of Immunization, Vaccines and Biologicals would first work with the Department of Health Systems Governance and Financing, which is involved with health systems strengthening (HSS), and the Department of Service Delivery and Safety group to organize a session on Implementation in the context of health system strengthening and universal health coverage at the April 2016 SAGE meeting. This session was successfully held. SAGE noted the advancements in knowledge in the field of HSS, which should support the attainment of immunization goals in a sustainable manner. The need to embed health systems thinking in every initiative and action, without losing goals so far attained, was appreciated by SAGE as a way forward. SAGE emphasized the importance of ensuring the visibility of immunization goals in planning HSS efforts. A system to generate data for evidence-based decision-making, with a focus on implementation research, is a route to achieving this. It was proposed that implementation research take up specific challenges that lead to strengthening of health systems. Improvement of immunization services within the broader health services should be a third dimension of vaccine programmes alongside safety and effectiveness, and this will need appropriate long term funding. SAGE recommended that WHO more actively promote further progress in this arena and that a preparatory team continue the dialogue and develop a more targeted agenda. For the time being it was concluded that no SAGE working group would be established, but that SAGE would be kept informed of meaningful developments.
Implementation	SAGE recommended that WHO promote further progress in the arena of implementation more actively, and that a preparatory team continue the dialogue and develop a more targeted agenda.	Apr 2016	Ongoing	WHO is currently implementing multiple WHA resolutions that mandate integration of disease-specific programs, using a HSS framework. This aims to seek universal immunization coverage as part of UHC. Within the Gavi sphere, the Alliance has committed to having HSS be the framework for each country, under which all Gavi grants will be managed as a single investment. This is captured in the new Country Engagement Framework, which WHO HIS/HGS has assisted the Gavi Alliance Partners and Gavi Secretariat in developing.
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 part of the agenda of IVIR-AC.
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) June 2015 meeting, IVIR-AC endorsed the designing of one or more protocols to assess the prospective non-specific effects of immunization on mortality. The work of the WHO Secretariat needs to be completed in preparing the protocols for the questions identified and trials outlined during the ad-hoc expert consultation of February 2016. These generic protocols would enable harmonized implementation of the trials across multiple settings. While further development of all the proposed trial designs is important, IVIR-AC recognizes that full evaluation necessitates a complete protocol. IVIR-AC will help inform decisions on feasibility and the selection of designs, and formulate questions.

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Implementation Research	SAGE identified the conditions necessary for pertussis resurgence and the effective strategies for prevention of resurgence as important topics for modelling research.	Apr 2014	Ongoing	The June 2015 meeting of the Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) meeting agreed on the plan for phase 1 of the comparison of pertussis models from Australia, England & Wales and the United States of America, which is meant to be a rapid assessment on the relative contributions of vaccine formulations, waning immunity, vaccine coverage and schedule to the 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 LMICs (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. The work under Phase 1 has recently been completed by the modelers and will be shared with SAGE Chair soon for further follow up. Meanwhile the WHO burden of pertussis disease estimates have been updated by the WHO secretariat in collaboration with Hong Kong University.
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	During the April 2016 SAGE meeting, SAGE members were successfully updated on the ongoing work in AFRO, PAHO and SEARO on using the missed opportunities for vaccination (MOV) strategy to facilitate the integration of immunization with other health services. Following the SAGE session, WHO has received multiple requests from countries for technical assistance to implement the MOV strategy in additional countries. Based on the two MOV assessments conducted in Chad and Malawi in 2015 (draft manuscripts prepared for peer reviewed journal submission), the package of methodology materials will be finalized by Q4-2016. These include: a planning guide, the assessment methodology (including the MOV protocol, sample questionnaires and generic field guides) and an intervention guidebook. Having strengthened the capacity of AFRO to implement MOV assessments (discussions with DRC, Nigeria, Mauritania and Kenya are ongoing), collaboration is now ongoing with SEARO where MOV assessments have been completed in Timor Leste (interventions are ongoing) and are being planned and supported in Indonesia and Cambodia. To establish a network of partners engaged in MOV, an informal coordination meeting was conducted in March 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. The second partner coordination call took place on June 30, 2016, to provide an update partners on the successful April SAGE session and to coordinate ongoing and future MOV activities.

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IVIR-AC	IVIR-AC should seek linkages with the WHO Alliance for Health Policy and Health Systems Research as they might be useful in priority setting and discussions.	Oct 2014	Ongoing	The Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) secretariat have had initial discussions with WHO staff of the Alliance for Health Policy and Health Systems Research (HPSHR) to update on the IVIR-AC deliberations in September 2014. Discussions for concrete steps for their involvement in vaccine implementation research are ongoing. The WHO Alliance for HPHSR will have a seat in the WHO Secretariat of the IVIR-AC. In addition, Initiative for Vaccine Research (IVR) was involved in a call for proposals issued by the WHO Alliance with financial support from 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. New projects have been granted and a workshop on implementation research protocol development took place in August 2016.
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 were prepared for review and discussion at June 2016's IVIR-AC meeting.
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	The guidance document is now available on WHO website: 'WHO guide to measuring effectiveness and impact of Japanese encephalitis vaccination' (available at http://www.who.int/immunization/diseases/japanese_encephalitis/JE_effectiveness.pdf).
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 set up a Middle Income Countries (MIC) Task Force in June 2014 with main immunization stakeholders (WHO, UNICEF, World Bank, Gavi Secretariat, BMGF, AMP, Sabin, Task Force for Global Health), which led to the creation of the "MIC strategy", presented at SAGE in April 2015. The strategy aims at improving sustainability of immunization programmes and access to vaccines in non-Gavi MICs. The MIC strategy is based on four pillars : 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. 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's investments in fully self-financing countries. Following SAGE's endorsement of the strategy, the WHO Secretariat has led implementation efforts in collaboration with immunization partners. Missions have been conducted in Swaziland, Romania and Jordan by WHO and partners 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 (V3P has now grown to include data from 50 countries). 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.

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Malaria	SAGE noted the utility of PPCs to developers and funders, and proposed that the opportunity for input into future PPCs at an early stage for any vaccine of public health importance could be included as part of SAGE's global public health mandate.	Apr 2013	Ongoing	Malaria Vaccine Preferred Product Characteristics are finalized and available on WHO website: (http://apps.who.int/iris/bitstream/10665/149822/1/WHO_IVB_14.09_eng.pdf). RSV Preferred Product Characteristics are now under development. In addition, two Ebola vaccine Target Product Profiles (TPPs) have been developed for reactive and prophylactic use, and these are available from WHO website: (http://www.who.int/immunization/research/target-product-profile/ebolavaccine/en/). A Zika vaccine TPP went through public consultation, and is now available on WHO website: (http://www.who.int/immunization/research/meetings_workshops/WHO_Zika_vaccine_TPP.pdf).
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 secure funding for the SAGE/MPAC recommended malaria vaccine pilot implementation programme. For resource reasons, WHO is seeking to proceed in 3 countries. SAGE/MPAC recommended 3 to 5. In June 2016, the Gavi board approved funding for the pilots of up to 50% (up to $27.5 million for the first 4 years out of a total needed of $55 million). Gavi indicated they could provide 1 to 1 matching funds meaning that alternative sources must be found for the other 50% if the pilots are to continue. On 5th September, the UNITAID board committed $9.6 million for the first 4 years leaving a critical gap (as a further $27.5 million was requested by WHO). WHO is now refining the budget to the minimum possible for 2 countries and is in discussions with potential funders to try to find a way forward. Unfortunately, given the current funding positions by major donor organizations, the future of the malaria vaccine pilots is in doubt.
Maternal immunization	SAGE recommended that WHO endorse the importance and ethical imperative of clinical trials in pregnant women for potentially life-saving interventions such as RSV vaccine (and future vaccines against other targets currently in development, such as group B streptococcal disease).	Apr 2016	Ongoing	WHO is promoting vaccine trials be conducted in pregnant women. Updated TRS guidance for vaccines includes a section on trials in pregnant women. WHO Draft Preferred Product Characteristics for Next Generation Influenza Vaccines includes advocacy for clinical trials in pregnant women. Also, IVR has supported two efforts evaluating the ethics of maternal immunization: 1) Beeler JA, Lambach P, Fulton TR, Narayanan D, Ortiz JR, Omer SB. A systematic review of ethical issues in vaccine studies involving pregnant women. Hum Vaccin Immunother. 2016 May 31:1-8. [Epub ahead of print] PubMed PMID: 7246403, and 2) Verweij M, Lambach P, Ortiz JR, Reis A. Maternal Immunisation: Ethical Issues. In press at Lancet Infectious Diseases. Both publications advocate for the ethical imperative of clinical trials in pregnant women.
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 the process of producing many implementation research tools and guidance regarding: 1) assessment of vaccine confidence/hesitancy in pregnant women; 2) maternal influenza immunization program costing tool; 3) guidance document to estimate the influenza economic burden of a country; 4) guidance document to estimate the cost effectiveness of influenza vaccines in a country; 5) field guide for the evaluation of influenza vaccine effectiveness; 6) maternal immunization AEFI surveillance guidance; and 7) implementation guidance document. IVR is collaborating with the US CDC to pilot some of these tools in LMICs.
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.

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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	Ongoing	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. - During 2015 PAHO conducted, 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 enabled 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.
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 of 2016. Modeling work is being done 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 by end 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 was 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.
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 received approval from Gavi, the Vaccine Alliance 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. Among them, one country (Sudan) has launched their introduction at the age of 9 months in July 2016, another 2 countries (Ghana and Mali) will do so in November 2016 and the remaining 5 countries (Burkina Faso, Central African Republic, Chad, Niger and Nigeria) intend to do so in 2017. Other meningitis belt countries intend to apply for the introduction of the vaccine into their routine programme at the next Gavi application windows in September 2016 or in 2017.
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.

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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 being 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, relevant regulatory pathways and country health worker and caregiver acceptability. A BMGF RFP to support preclinical development of Measles-Rubella microarray patches is about to be published.
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 ensured 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 at odds with SAGE's guidance 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. Steps have been taken and discussions started to also reflect the measurement of pain at time of injection in the updated Guidelines on clinical evaluation of vaccines to be discussed and endorsed by ECBS in October 2016. More specific activities still need to be implemented with respect to points 3 and 4.

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Polio	SAGE recommended working closely with countries on activities towards type 2 oral polio vaccine (OPV2) withdrawal.	Apr 2013	Completed	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 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 the same on the tOPV to bOPV switch in 2015. Joint WHO/UNICEF regional coordination mechanisms were 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 was conducted in 2015 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 was conducted in an accelerated manner with substantial technical assistance provided to countries through Partners and Regional offices. Financing was also be provided to high risk countries. A full update was be provided to SAGE in April 2016 as the Switch took place at about that time. A special tracking effort has been undertaken to ensure that no country falls between the cracks. As of the start of May 2016, all 155 countries and territories were no longer using the trivalent oral polio vaccine (tOPV).
Polio	SAGE emphasised that UNICEF Supply Division, PAHO Revolving Fund and WHO should secure the global supply of prequalified bOPV.	Oct 2015	Closed	OPV supply through the switch was considered sufficient for both tOPV as well as bOPV to ensure timely switch of the vaccines in routine vaccination programmes 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 were on track for procurement of bOPV to introduce the vaccine in routine programmes after the switch, and are expected to continue to have sufficient bOPV supply after the switch. Demand forecasts were under review with the Vaccine Supply Task Team to ensure OPV supply was available in sufficient quantities. It was concluded that bOPV supply is available for 2017 and beyond.
Polio	SAGE requested the Polio Working Group to evaluate options for catch-up vaccination for cohorts born after 1 May 2016 in countries where IPV introduction will be delayed or regular supply disrupted.	Apr 2016	Ongoing	The topic was discussed at the SAGE Polio WG in August 2016. Given uncertainties surrounding the future supply of IPV, recommendation for catch-up vaccination will be discussed in future WG meetings.
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	A Legacy Working Group has been established by the AFRO Regional Director. Planning guidance is now available for countries and the GPEI Transition Management Group (previously '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 planning purposes. There is a joint WHO-UNICEF workplan for supporting the countries of Africa, and a separate workplan for the countries of Asia.
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 being closely monitored. SAGE WG and SAGE issued a statement in March and made recommendations in April SAGE meeting regarding IPV supply. This issue was further reviewed in the SAGE Polio WG meeting in August 2016. Update from the meeting, including discussion with vaccine producers, will be provided in Oct SAGE meeting.

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Polio	The documentation for ‘legacy planning’ should include contributions from communities and front-line health workers on their experiences with the polio programme, what it has meant for them and how lessons learnt could further improve the routine vaccine and health programme.	Apr 2013	Ongoing	Capturing this information is integrated into the country-level transition planning guidelines, and the work of Transition Management Group of the Global Polio Eradication Initiative is emphasising the importance of this.
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 3 August 2016, 204 countries and territories have completed the first part of Phase I, with 1 Member State having yet to respond and 14 Member States yet to complete their reports on the destruction or planned retention of WPV2 or VDPV2 materials. Reports on the destruction or planned retention of all Sabin type 2 poliovirus materials are beginning to be collected in all Regions, as the deadline for completion of the second part of Phase I was set at 31 July 2016, 3 months after the switch. However, guidance on 'Assignment of samples to high, moderate or negligible risk categories of being potentially contaminated with PV2 and recommended conditions for their handling and storage' is still being developed. It is only based on this guidance that countries will be able to complete Phase I, so it is tacitly understood that completion of Phase I will be delayed.
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 on completion of phase I of GAPIII is posted every week. The map also identifies countries that have designated poliovirus-essential facilities and have nominated national authorities for containment that will certify facilities against GAPIII. In addition, the much awaited new guidance 'GAPIII Containment Certification Scheme' is undergoing internal clearance for publication and will be made available shortly for NACs and PEFs to start containment certification activities under the global oversight of the Global Commission for the Certification of Poliomyelitis Eradication.

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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	1. Guinea: Seven cVDPV2 cases have been reported in Guinea from September through December 2015, all under the age of 5 years. These are genetically linked to a case from August 2014 for which response was hampered due to the Ebola outbreak. Seven SIAs were carried out using tOPV between September 2015 through April 2016. The country completed the switch to bOPV on 30 April 2016. The first outbreak response assessment took place on 29 February 2016, and another is currently underway (starting August 2016). Main recommendations are: improving commitment of national authorities; strengthening immunity in the population through routine immunization and SIAs, including reinforcing communication and social mobilization; improving sensitivity of surveillance and optimizing management of international consultants. Main risk and challenges are: inability to ensure interruption in transmission due to surveillance gaps; undetected low level circulation possible (consultants now focused on two regions, thus surveillance efforts in the rest remains understaffed. Medium to high risk of exporting polio virus to neighbouring countries, especially Liberia and Sierra Leone through migrant workers, population movement. Insufficient ownership of the PFA database by the EPI coordination); low involvement of national actors at the provincial and district level; repeated mistakes in investigation sheets, irregular follow-up meetings, large number of AFP samples (n=229) pending in Dakar lab database (overflow from increased sampling will be sent to other approved labs to accelerate pace of testing). Although there is an improvement in SIAs, micro-plans for SIAs should be updated to address shortfalls and lessons learned. Need to work on the reasons for missed children. National public health emergency not yet declared. Funding shortfall: half of international consultant contracts will end by the end of September and insufficient funds for contracts; Insufficient funds for active case search in June - July in Kankan and Faranah). 2. South Sudan: South Sudan reported 2 cases in Rubkona County, Unity State with the latest onset on 12 September 2014. In 2015 one aVDPV2 case was identified in Mayom County, Unity State (adjacent to Rubkona County) with an onset of 19 April 2015. It was 14 nucleotides different from Sabin 2 but not related to the 2014 outbreak nor any other strains. Switch was confirmed by the country on 1 May 2016. The country was supported with 25 international STOP team members as well as 8 international and 38 national consultants from WHO, UNICEF and BMGF, deployed to support outbreak response. In response to the outbreak, a total of 10 vaccination campaigns (4 NIDs, 2 sNIDs, 3 SIADs) were carried out in the counties of three conflict affected states (Jonglei, Unity, and Upper Nile). The assessment team recognized that there has been significant improvement in the quality of surveillance, the quality of SIAs, and application of communication strategies, particularly in conflict affected states. The team concluded that given the improvements in surveillance (NPAFP rates greater than 3.8 nationally and in conflict affected states), and the non-detection of poliovirus for more than 13 months, that it was unlikely that the surveillance system had failed to pick up persistent transmission. Nonetheless, sub-optimal specimen adequacy and silent counties, as well as pockets of under-immunized children especially in conflict affected ones. Outbreak Response Assessment recommendations included strengthening of coordination between MoH and partner agencies, conducting bottom-up micro planning before the next SIA, improving IPV coverage, active case search and specimen transport, and accelerating rollout of community based surveillance in conflict affected states.

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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	Completed	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. Since April 2013, significant time was dedicated to the Immunization Systems Management Group by the staff of the six agencies: Center for Disease Control and Prevention (CDC), WHO, UNICEF, Bill and Melinda Gates Foundation (BMGF), Rotary and Gavi. WHO/EPI (Expanded Programme on Immunization) has filled additional 3 professional staff positions at HQ to support 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 non-Gavi eligible. This mechanism will enable partners to support some countries that need 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 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 switch was successfully carried out in April 2016, sufficient capacity was established at the global level to provide technical and programmatic support to countries to plan and implement all activities associated with OPV2 withdrawal.
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. The OPV2 withdrawal was implemented in late April to early May 2016.
Regulatory	SAGE recommended that the further development of the Emergency Use Assessment and Listing procedure being developed by WHO, which would allow use of a vaccine in the context of a Public Health Emergency of International Concern, be done in close consultation with relevant regulatory authorities, including those of the affected countries.	Apr 2015	Ongoing	A document entitled, “Vaccine evaluation in public health emergencies – review of regulatory pathways in selected countries” was prepared and 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 National Regulatory Authorities (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 to review the document's 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 Q3-Q4/2016.

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Reports from other advisory committees on immunization	WHO and NIBSC should develop with other stakeholders, a business plan to assure long-term security of the development of WHO reference preparations as a global public health resource and additional efforts should be undertaken to disseminate outcomes of the committees deliberations and to explain the relevance of its work to the broader immunization community.	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.
RSV	SAGE asked for preparations to be made to support global policy-making for respiratory syncytial virus (RSV) maternal immunization as well as passive immunization with long-acting mAb. SAGE emphasized the need to link maternal immunization platform strengthening with influenza, tetanus and pertussis vaccines along with preparations for potential country introductions of RSV vaccine.	Apr 2016	Ongoing	Further discussions have been held with the PQ team with regard to prequalification processes for both RSV vaccines and mAbs. The ECBS Guidelines for RSV vaccines are planned for development and possible adoption at ECBS 2018, as these are a prequisite for consideration for PQ. The Essential Medicines department is considering an approach to PQ of mAbs. Intensive discussions continue about the most appropriate way to prepare for policy-making in LMICs, without any results yet available for efficacy trials in these settings. A Phase 3 trial of the Novavax RSV F Vaccine in 11,856 older adults (60 years of age and older, enrolled in the USA), did not meet the pre-specified primary or the secondary efficacy objectives, and did not demonstrate vaccine efficacy. This information is from a press release dated 15 September 2016, and a full review of the data will be necessary to understand what may underlie them. Clearly efficacy may differ between elderly and healthy pregnant women target groups. The Novavax Phase 3 trial in late 2nd/early 3rd trimester pregnant women continues with endpoints accruing in neonates and young infants. The RSV vaccine pipeline remains very robust and can be accessed at the IVR Vaccine Pipeline Tracker: http://who.int/immunization/research/clinicaltrials_newvaccinepipeline/en/ (open the page then navigate to the RSV tab of the spreadsheet)
Second year of life (2YL)	SAGE requested that the final guidance for national programmes to establish routine healthy child visits during the second year of life (2YL) be reviewed by the Immunization Practices Advisory Group and then sent to SAGE for endorsement.	Apr 2016	Ongoing	The 2YL guidance is being prepared by a consultant and will then be used to implement in 4 countries in 2017. Following this, the guidance will be presented to IPAC and SAGE for endorsement (probably by early 2018).
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 is envisaged to be published in Q4 2016.
Strengthening of NITAGs	SAGE requested a regular update on the number of established National Immunization Technical Advisory Groups (NITAGs).	Apr 2016	Ongoing	This information is collected via the WHO/UNICEF joint reporting form and analyzed every year. The figures are included in the GVAP secretariat report, which is made available to the SAGE DoV working group and then to SAGE. Although some data verification is still pending, in 2015 127 countries reported the existence of a NITAG and 77 countries the existence of a NITAG that meets all 6 basic process indicators included in the JRF and used as part of the GVAP indicator. These figures can also be included in the global report on a yearly basis. A specific NITAG session is planned for the April 2017 SAGE meeting.
Supply shortages	SAGE proposed as immediate action to communicate effectively to countries on causes of shortages and current mitigation and long term activities.	Apr 2016	Ongoing	Shortage discussion was integrated into the GVAP secretariat report and regular quarterly calls with regions. More actions have been conducted regarding specific vaccines, such as YF or IPV, for which clear impacts of the current shortages have been identified and are being addressed with both short and long term strategies. For other vaccines, actions have been limited by the lack of resources, concentrating instead on assessing the feasibility of creating a supply exchange forum.

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Supply shortages	SAGE recommended that WHO could play a key role in setting up an “Exchange Forum”, helping to collect demand information from all Member States and to enhance dialogue between countries’ demand (including anticipation of schedule evolution and new introductions) and manufacturers’ supply availability and risks.	Apr 2016	Ongoing	Concerns about ongoing shortages of vaccines persist. Internal WHO discussions and discussions with partners are in progress, in light of the SAGE session on vaccine shortages held in April 2016 and of resolution 69.25 on "Addressing the global shortage of medicines and vaccines." WHO IVB Department, in collaboration with EMP and with support from Linksbridge consulting, is leading a project to set up an “Exchange Forum” to enhance dialogue between countries and manufacturers on demand predictability, supply availability and potential threats to vaccine supply, particularly for vaccines and countries not supported by UNICEF Supply Division or Gavi. In order to make sure that the Exchange Forum is built on existing data, knowledge and processes, WHO secretariat (IVB, in coordination with EMP) is following a two-phase approach. Phase 1 will focus on mapping existing information and highlighting gaps. Based on results from Phase 1, a Phase 2 may be launched to develop a platform or exchange forum to make sure that all available and appropriate information identified in Phase 1 is shared with countries, manufacturers and partners.
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. By 2016, we have made significant progress toward strengthening the Networks and meeting those goals. In 2015, the Global Rotavirus Surveillance Network comprised 114 sentinel surveillance sites in 53 countries and the Global IB-VPD Surveillance Network comprised 114 sentinel sites in 52 countries. 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. 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 being rolled out in one Region (PAHO) and has great potential to improve data quality and sharing across the Network. Some new activities involve testing for other pathogens and integrating with other VPD surveillance platforms. Specifically, a pilot to include typhoid surveillance as part of IB-VPD surveillance has started 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 conducted a survey of existing capacity to explore how to use the rotavirus surveillance network to monitor norovirus, and a network study will be launched in late 2016 using the TAC technology to test for other enteric pathogens including ETEC and Shigella in specimens collected as part of the network. We are planning a meeting to evaluate the cost of surveillance to help countries and funders develop sustainable surveillance plans, including other VPDs such as measles. We also continue to support sites where PCV and/or RV vaccine impact evaluations may be feasible due to sufficient pre- and post-vaccine introduction data, including using secondary data sources such as hospital administrative data. We have an ongoing evaluation of what sites to include in the Network, how to incorporate countries conducting surveillance outside of the Network, and how to make surveillance sustainable in the long term.

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Sustainable Development Goals	Approval of a vaccination coverage indicator under the child mortality target of the Sustainable Development Goals (SDGs) has not yet been obtained. SAGE urged WHO and countries to request an aspirational immunization indicator under the SDGs.	Apr 2016	Ongoing	Several immunization partners (Gavi, Unicef, BMGF, US-CDC, WHO, Center for Vaccine Ethics and Policy NYU) have worked together to explore possible indicators to be added to the SDGs monitoring framework in addition to currently included ones (Target 3.8.1 UHC coverage composite indicator, and the Hepatitis B control strategy, three doses of Hep B vaccine). It was agreed to propose GVAP G2 Indicator Coverage for all vaccines in national schedule to be included for SDGs sustainability and access to health and essential medicines & vaccines goal (3.b).1. The choice of this indicator has been validated by the SAGE DoV WG. The proposed indicator has been submitted to IAEG-SDGs secretariat the 24th June 2016. We are waiting now to hear back from them.
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 June 2016. Since the adolescent/adult population carry the heaviest disease burden, there is consensus within the TB vaccine community that prioritizing this target population will have the highest and most immediate public health impact from reduction in transmission. In addition, key data will emerge from separate clinical studies with 2 TB vaccine candidates (VPM1002 and M.Vaccae) during in 2016. M.vaccae is a heat killed homogenized lysate developed by Anhui Zhifei Longcom, China. It is undergoing Phase III testing for prevention of pulmonary TB among adults with latent infection in China. VPM 1002 is a recombinant BCG, originally developed by the Max Planck Institute; now licensed to the Serum Institute of India (SII) and being developed with Vakzine Projekt Management (VPM), Hannover, Germany. It is currently in Phase II trial vs. BCG in HIV+ and HIV- infants <12 days old in South Africa. Interim data assessment is anticipated in 2016, and may also be assessed in a Phase III prevention of recurrence study in adults in India. 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 2017. GSK also have a candidate undergoing Phase IIb evaluation in TB exposed, HIV negative adults in South Africa, with results expected in 2018. Considering the time frame to phase III studies and licensure, PDVAC recommended that WHO derive guidance on preferred product characteristics for TB vaccines targeted to adults and adolescents. IVB is actively seeking funding for the resources to undertake this over the next 2 years.
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 and has initiated the evidence review process. 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.

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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 guidance document on implementation issues has been initially produced by EMRO. This document is being adjusted some as a result of limited preliminary peer-review and will soon be distributed for a much broader peer review. 'Vaccination in acute humanitarian emergencies: a framework for decision making' has also been adjusted/updated based on the feedback received during the Cairo meeting and a draft operational manual is being developed. Work is ongoing for the development of 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. Finally, although there was no separate specific session during the April 2016 SAGE meeting an update was featured in the IVB Director's global report at this meeting. A meeting was jointly organized with MSF on June 20 to tackle the issue of supply and procurement obstacles in humanitarian emergencies: a. Discuss/map the obstacles to necessary access to affordable vaccines in a timely manner in emergency and humanitarian crisis situations. b. Discuss proposed solutions for addressing the key barriers to timely provision of affordable vaccines in humanitarian crisis situations. c. Agree upon a set of priority issues to be addressed by partners with a proposed plan of action/timeframe for follow up. A follow-up meeting will take place on 10-11 October to develop consensus on the various guidance and priorities mentioned above and discuss how to best communicate and advocate for their implementation.
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 sub-tasks in developing parts of these guidelines that pertain to their respective expertise. A working draft has been circulated for comments and was finished by the end of 2015. It was tested subsequently in pilot studies in two different settings, pre- and post-campaign, for its applicability. A pilot study is taking place in Mongolia in 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.

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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	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 focusing on prototype development and detailed plans for future commercialization possibilities are welcomed.
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; and 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 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 website: (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.
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 reviewed methods, and encourages studies on vaccine delivery costing and financing (HPV, influenza and OCV) and vaccine uptake/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, how to secure funding from donors in support of the listed activities and advance validation of the questions in LMIC settings is being explored. The survey questions have been translated in Arab and French and are available on the WHO hesitancy website: http://www.who.int/immunization/programmes_systems/vaccine_hesitancy/en/

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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 as well as 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. Sessions and discussions on vaccine hesitancy are held in the context of immunization managers meetings.
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 safety	SAGE highlighted the urgent need for a safety review of other important vaccines that could be used during pregnancy.	Nov 2012	Completed	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	Also see item 331. Concerns about ongoing shortages of vaccines persist. Internal WHO discussions and discussions with partners are in progress, in light of the SAGE session on vaccine shortages held in April 2016 and of resolution 69.25 on "Addressing the global shortage of medicines and vaccines". WHO secretariat (EPI) is now working to develop an approach to improve the availability of information regarding supply and demand as requested by member states, the industry, and identified as a contributing factor to shortages. This may lead to the development of an exchange platform to facilitate communication between supply and demand.
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	Closed	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 entered into force and became legally binding upon all IHR States Parties on 11 July 2016. There were no legal rejections or reservations expressed by countries. For countries with risk of yellow fever transmission and countries requiring yellow fever vaccination (see http://www.who.int/ith/2016-ith-annex1.pdf?ua=1).