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 The “Meeting Date” column displays the date of the SAGE meeting during which the recommendation was originally made.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 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 headquarters (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 at the district level on regular basis and there are efforts to collect sub-national level coverage data. Currently this is happening in the African Region on monthly as well as annual basis; and in the South East Asian Region and the European Region it is done on annual basis. In October 2016, at the Global Monitoring Meeting all regions agreed to collect and submit to HQ district level coverage data (numerator, denominator and coverage from DTP1, DTP3 and MCV1) as part of annual data collection exercise. Out of 194 member states, 125 countries reported subnational coverage, 36 at the 1st subnational level and 89 at the 2nd subnational administrative level (often corresponding to districts). The 20,000 districts for which data were received are home to 88 million children, two-thirds of the surviving infants worldwide. An initial analysis shows large differences in the size of these districts and the coverage they report. A large proportion report coverage over 100%, revealing the challenges to accurately measure coverage at subnational level. Detailed analysis and reported data are availalbe from http://www.who.int/immunization/monitoring_surveillance/data/subnational/en/
General	SAGE recommended that ways to improve curricula for medical personnel should be explored.	Nov 2008	Ongoing	The Regional Office for Africa (AFRO) has published the pre-service curriculum and efforts are being made to disseminate the findings and ensure that medical and nursing schools change their outdated curriculum. This is a long process but few steps have started in that direction.
AEFI reporting	SAGE urged that efforts be pursued to enhance Adverse Events Following Immunization (AEFI) reporting worldwide.	Apr 2016	Ongoing	With Gavi support, 30 African countries have established work plans. A first analysis of the new Global Vaccine Action Plan (GVAP) indicator for adverse events following immunization (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. A manuscript is currently submitted that describes the AEFI reporting ratio through Joint Reporting Form (JRF). 2016 data are currently analyzed and indicate an increase in the number of member states that fulfill the indicator requirement. In addition, a paper is in press that describes the AEFI ratio indicator during 2000-2015.
Data quality	SAGE requested the establishment of a Working Group on Quality and Use of Global Immunization and Surveillance Data.	Apr 2017	Ongoing	The Working Group was established in August 2017. Thirteen members are part of this working group. The terms of reference were split into 6 and a member was assigned as a lead each. Several teleconferences have been held and nine members participated in the “Data Partners Meeting” organized by EPI/WHO in October 2017. Work is ongoing.
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 Decade of Vaccines (DoV) Working Group (WG) continues to review annually progress on the Global Vaccine Action Plan (GVAP) indicators. The SAGE report of progress with the Global Vaccine Action Plan (GVAP) for 2017 was published online and is available at: http://www.who.int/immunization/global_vaccine_action_plan/en/ This report was noted by the Executive Board in Jan 2018. The WG will start its calls in March for the yearly planning and proceed with its regular calls in July and August 2018 when draft secretariat report becomes available. The SAGE DoV WG will met in person from 28-30 August for the yearly revision of progress in the implementation of GVAP for the year 2017. GVAP will an item on the SAGE Oct 2018 agenda.

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Diphtheria	SAGE recommended that surveillance standards, guidelines for the investigation including diagnostics and reporting of diphtheria cases and outbreaks, be updated to improve the quality of data and to facilitate pooled analysis. The guidelines should include standard formats for reporting age with increased granularity and immunization status categorization.	Apr 2017	Ongoing	Work is ongoing to update the global vaccine-preventable disease (VPD) surveillance standards and will include a new and improved chapter on diphtheria surveillance. It will address the points recommended by SAGE and should be ready by early 2018.
Diphtheria	SAGE advised that WHO collaborate closely with partners to establish and manage a global procurement mechanism and a physical or virtual DAT stockpile that would be available to all countries. SAGE further urged that regulatory pathways be established to ensure the rapid deployment of DAT. In the long term, SAGE advised WHO to identify mechanisms to support the development of a monoclonal antibody as an alternative to DAT of equine origin.	Apr 2017	Ongoing	WHO has established a DAT international working group to coordinate and allocate extremely limited DAT supplies. In the short term the working group will coordinate the procurement of DAT to avoid competition among different procurement agencies and partners. The DAT-WG currently prioritizes the urgent requests from Yemen, Bangladesh, Indonesia, Venezuela and Haiti. Around 20,000 vials have been deployed between WHO, PAHO and MSF supply mechanism. In the mid-long term the DAT-WG is looking for more sustainable solutions to establish a stockpile and a decision making mechanism for allocation like the ICG for vaccines. WHO DAT-WG coordinates the group to look at the following areas of work: 1. Procurement strategy 2. Forecasting and Stockpiling 3. Decision making criteria and mechanism for DAT allocation 4. Quality, standardization and WHO prequalification 5. DAT production capacity and new products (mAbs) Members of the coordinating group: MSF, UNICEF, ECDC, CDC, PEI, MHRA, EC, FDA, EMA, PHE, NIBSC
Diphtheria	SAGE expressed concern with the shortage of Td vaccine (tetanus toxoid + reduced diphtheria toxoid content) for routine immunization of children and adolescents, catch-up vaccination of adults and tetanus prevention after injury, and recommended that the demand and supply scenarios for Td vaccines should be assessed.	Apr 2017	Ongoing	An assessment of global demand and supply for Diptheria and Tetanus containing vaccines has been finalized and is available for SAGE members and wider public. The main objective of the assessment was to understand possible supply implications of global implementation of WHO recommended schedule for D&T containing vaccines. The assessment can also be useful to guide current supply access issues. The assessment was conducted with support from Linksbridge and MMGH consulting group. A temporary Advisory Group of expert was convened to guide this work advising on methodology, assess current and future supply risks and advice on policy implications. A final meeting of the Advisory Group was held on September 13th concluding that: • WHO recommends for all countries: 1) a life course of 6 doses of Diphtheria and Tetanus containing vaccines and 2) use of Td in place of TT • 100 / 194 countries do not meet these recommendations, but due to conducive circumstances, they are now likely to implement WHO recommendations • Full implementation of the recommendations would increase global demand for all D&T containing vaccines by ~20% • Sufficient supply is available to cover both current and future demand for wP / non-aP containing vaccines • Supply of aP-containing vaccines is currently sufficient to support demand from countries where the product is in use; access in additional countries may be problematic • Countries with only one locally-registered product are at risk of supply shortages, irrespective of the global supply-demand balance

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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	SAGE established an Ebola working group (WG) in Nov 2014 which met regularly via teleconference as well as during a face-to-face meeting on the 9-10 Mar 2015. The WG reviewed the epidemiological 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 Apr 2015 meeting. The WG met again on 19-20 Aug 2015 to review the available information and to start framing recommendations, based on the framework approved by SAGE in Apr 2015. The WG input was presented to SAGE at the Oct 2015 meeting. Now, that the final results of the Ring trial have been published in the Lancet in Dec 2016, a WG meeting took place 14-15 Mar 2017 to discuss the results. Regulatory evaluation of the vaccine is currently ongoing. There is information regarding a Russian developed vaccine that was licensed in Russia, but despite WHO requests no detailed data are available. The emerging data and draft recommendations were discussed during the face to face meeting of the WG which took place Mar 2017. The evidence was presented during the April 2017 SAGE meeting.
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 March 2017. The next active follow-up report will be requested ahead of the April 2018 SAGE meeting. 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 resulted in an enhanced vigilance in the country. As exemplified by the outbreak in San Martin, the risk persists in the population. 73% of of hepatitis A virus (HAV) acute infection cases reported occurred in individuals over >10 years. All cases reported occurred in unvaccinated individuals. After now 11 years of follow-up, there is currently still no evidence of waning immunity and the outbreak experienced in 2014 was compatible with very high vaccine effectiveness. Hepatitis A cases have remained low in 2014, 2015, and 2016. 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. 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. The results of the phase 2 study conducted in 2013 with a median post-vaccination interval of 7.7 years were quite reassuring with a prevalence of protective antibodies of 97.4% (95% CI: 96.3-98.3) still protected. More recent analysis (phase 3) indicates that the prevalence of protective antibodies in children > 9 years following a single dose of hepatitis A vaccine was still 87.6% but a decrease was observed in all centers with decreased GMCs. It is still unclear if different samples or differences in methodology or recall bias in seronegative individuals could actually account for the difference, but this requires continued follow up. For the time being epidemiologic surveillance continues to show very low infection rates in all regions and age groups with sporadic cases occurring mainly in frontier regions and non-vaccinated adolescents.

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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 2017, it was approved to collect an additional variable on hepatitis B birth dose to distinguish birth dose vaccine adminstered within 24 hours (TIMELY) and any birth dose administered (TOTAL) as part of the WHO/UNICEF Joint Reporting Form (JRF). Previoulsy only timely birth dose was requested. As of August 2017, all regions have had the regional committees (RCs) on immunization endorse hepatitis B control goals, except for the South East Asian Regional Office (SEARO) which as noted below had a 2016 ITAG recommendation to establish a goal. Regional goals slightly differ in target dates, threshold prevalence and specific ages in which to measure prevalence - but are largely similar nonetheless. In Sept 2016, the European Regional Office (EURO) held a consultation to discuss establishing a regional verification mechanism. In June 2016, the 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 April 2016, WHA Endorsed the GHHS for viral hepatitis that includes immunization-related 'elimination targets'; specifically to reduce chronic HBV infection rates (HBsAg prevalence) in children to at least 1% by 2020 and to at least 0.1% by 2030. 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 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 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).

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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	WER on status of global introduction and implementation of hepatitis B birth dose has been drafted and cleared; scheduled for publication in Feb 2018. A new indicator for Hepatitis B birth dose has been added to the WHO /UNICEF Joint Reporting Form (JRF) 2017 - this new indicator will allow the distinction between timely (24 hours) and late birth dose administration. In Nov 2016, AFRO held consultation on hepatitis B control and included discussing barriers, actions and support needed towards hepatitis B birth dose introduction. This was part of joint meeting held with viral hepatitis counterparts. A consultation on implementation of a new universal birth dose recommendation was conducted in Dec 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 Apr 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 Mar 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 Dec 2015. Senegal held a Hepatitis B birth dose training workshop in Dec and introduced birth dose in Jan 2016. Guidance for hepatitis 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 English, French and Spanish. An Arabic version is under development). The guidance includes a chapter on reporting and monitoring birth dose vaccination.
Hepatitis B	SAGE strongly urges all the pre-qualified vaccine manufacturers of monovalent hepatitis B vaccine to pursue regulatory approval for Controlled Temperature Chain (CTC) as soon as possible, given the available evidence of compatibility with CTC requirements.	Oct 2016	Ongoing	As of March 2018, one Hepatitis B vaccine manufacturer is actively testing its birth-dose vaccine with a view to seeking a label variation for licensed and WHO Pre-qualified use in a Controlled Temperature Chain (CTC). In parallel, the CTC working group under the Immunization Practices Advisory Committee (IPAC) is finalizing a landscape analysis and strategy to further promote the use of hepatitis B birth-dose in a CTC.
Hexavalent IPV-based combination vaccines PQ and supply	tracking progress on Hexavalent IPV-based combination vaccines prequalification and supply	Oct 2017	ongoing	

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HIV	SAGE requested regular updates on the progress of HIV-vaccine research.	Apr 2010	Ongoing	Two HIV vaccine efficacy studies have started in Africa, late 2017. The HVTN702 phase 2b efficacy trial in Southern Africa, builds on analyses of correlates of protection in 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), is testing an immunization regime based on a canarypox-based vaccine called ALVAC-HIV and a bivalent gp120 protein subunit vaccine. As compared to the Rv144 trial this regimen includes a new adjuvant, targets the HIV Clade C and includes the addition of booster doses. The HVTN 705 Phase 2b trial in several African countries will test for a regimen based on 4 mosaic recombinant Ad26 and the gp140 protein trimer in alum. Another important development relates to the testing of several monoclonal antibodies having broadly neutralizing antiretroviral properties. Two multicenter, multi-country studies, one of which in women in South Africa, will test for prevention of HIV infection after several VRC01 monoclonal antibody injections. Building on progress in B cell biology and the structural characterization of the envelope protein, vaccine studies aiming to induce broadly neutralizing are starting . Several other approaches are being tested in translational research . WHO IVR will organize a consultation on HIV vaccine development late february to discuss the status of HIV vaccine research and the need for the global health community to prepare for the outcome of ongoing efficayc trials in highly endemic countries.
Immunization schedules	SAGE requested a critical appraisal of alternative schedules for pneumococcal conjugate vaccine, rotavirus vaccine and Hib vaccine in 2011.	Nov 2010	Ongoing	The funding grant from Bill & Melinda Gates Foundation (BMGF) for schedules-related work to inform SAGE discussions on immunization schedules is now over. All delays in regard to this work were due to the Ebola outbreak and the R&D Blueprint on staff responsibilities. - Pneumococcal Conjugate Vaccine (PCV): evidence was reviewed by SAGE in November 2011. A new position paper was published in 2012. - 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 was published in February 2013. A new review of evidence is ongoing. - Haemophilus influenzae type b (Hib): The issue was revised during the April SAGE 2013 meeting. A new position paper was issued. - Pertussis: evidence was reviewed by SAGE in 2015. A new position paper was was published in August 2015. - Hepatitis B: evidence was reviewed by SAGE in Oct 2016. A new position paper was published in July 2017. - HPV: evidence was reviewed by SAGE in in Oct 2016. A new position paper was published in May 2017. - TT vaccine: evidence was reviewed by SAGE in Oct 2016. A new position paper was published in February 2017. - Diphtheria: evidence was reviewed by SAGE in Apr 2017. A new position paper was published in August 2017. A consultation to develop analytic tools to support countries with the selection and/or adjustment of vaccine schedules in different epidemiological and operational scenarios took place in December 2016.The critical evidence elements needed at country level to inform the choice of schedules were outlined. The tools are being further developed with the inputs of policy makers. With support from the BMGF we are updating the review of the evidence (epidemiology, vaccine efficacy and effectiveness, safety, risk benefit, impact)of rotavirus vaccines. A consultation will took place in the October 2017. The data presented and discussed did not indicated that the 2013 SAGE policy recommendation needs to be changed. We are now reviewing the evidence on human papilloma virus vaccines (epidemiology, vaccine efficacy and effectiveness, safety) and assessing the impact of different HPV vaccination strategies as well as examining the conditions under which elimination could be possible.

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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.
Implementation	SAGE recommended that WHO promote further progress in the area of implementation more actively, and that a preparatory team continue the dialogue and develop a more targeted agenda.	Apr 2016	Ongoing	The WHO is currently implementing multiple World Health Assembly (WHA) resolutions that mandate integration of disease-specific programs, using a Health Systems Strengthening (HSS) framework to achieve Universal Immunization coverage as part of Universal health Coverage (UHC). This fits well with the Sage proposal to make integration a 'third pillar' of immunization service provision. Within the Gavi sphere, the Alliance has committed to having HSS underpin the Country Engagement Framework (CEF), under which all Gavi grants will be aligned and managed as a single package of results-focused investments. WHO Health Systems and Innovation (HIS)/Health Sys Governance, Policy & Aid Effectiveness (HGS) has assisted the Gavi Alliance Partners and Gavi Secretariat in developing CEF. The WHO's Regional and Country Office HGS/HSS Focal Points are the organizational drivers for CEF engagement, providing technical Assistance on strategic, financial and operational integration of core immunization functions and systems.
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	Closed	This recommendation is 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	Closed	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 (NSE) 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 Feb 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. At the February 2017 meeting, IVIR-AC reviewed the final proposals for 2 trial designs suggested by the ad-hoc Working Group on NSE. It was presented at the SAGE April 2017 meeting as part of the briefing of IVIR-AC by chair Rob Breiman.

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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. The global pertussis estimates for age under 5 have been published in Lancet Infect Dis. 2017 Jun 13. pii: S1473-3099(17)30390-0.
Influenza	SAGE issued the recommendation to establish a Working Group on influenza vaccines.	Apr 2017	Ongoing	A SAGE Working Group on Influenza Vaccines has been established in December 2017. http://www.who.int/immunization/policy/sage/sage_wg_influenza_dec2017/en/

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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 received multiple requests from countries for technical assistance to implement the MOV strategy in additional countries. Based on MOV assessments conducted in Chad and Malawi in 2015 (draft manuscripts prepared for peer reviewed journal submission) and Kenya in 2016, WHO has published a set of updated guidance documents and field tools in Q3-2017. These include: a planning guide, the assessment methodology (including the MOV protocol, sample questionnaires and generic field tools) and an intervention guidebook (in draft status). In the meantime, WHO has launched an MOV web page with links to all the available materials for easy access to countries. Having strengthened the capacity of AFRO to implement MOV assessments (Chad, Malawi, Burkina Faso (led by partner AMP), Kenya, DRC and Nigeria completed; Jordan, Mozambique and Zimbabwe completed in Q4-2017), collaboration is ongoing with SEARO (MOV assessment completed in Timor Leste; interventions are ongoing) and WPRO (MOV workshop in Q4-2017 in Cambodia, in collaboration with CDC). A network of partners engaged in MOV has been established since March 2016 to provide regular updates via teleconference on the process and outcomes of the recent country MOV assessments, share future plans and framework for implementation, exchange lessons learned, and achieve consensus on a coordination mechanism for all MOV work among all partners. The fourth partner coordination call took place on Oct. 31, 2017. In May 2017, WHO held a training workshop in AFRO for partners and consultants on the MOV strategy with the objectives of training a pool of consultants to support countries in planning and conducting MOV assessments, to further strengthen the regional, subregional and country capacity for MOV work and to serve as a platform to discuss opportunities to address MOV and improve routine immunization coverage. The workshop was attended by 8 partner organizations (CDC, UNICEF, VillageReach, AMP, MSF, JSI, SA-MRC, CHAI), WHO-CO, partner and MOH staff from 8 countries (Cameroon, Ethiopia, Liberia, Mozambique, Nigeria, Uganda, South Sudan, Zimbabwe) and WHO colleagues from HQ, AFRO and IST-Eastern and Southern. The focus for 2018 is to ensure that all countries that have completed the assessments move on to implement interventions. Through monitoring and evaluation, these country intervention action plans will be assessed and reported back to SAGE at a future date.
IPV Supply	THE IPV supply situation is expected to improve in 2018; all countries are expected to have access to IPV for routine immunization from the end of Q1 2018. SAGE acknowledged WHO´s work with Imperial College, London, to grade risks in Tier 3 and 4 countries based on susceptibility, transmission, exposure, and primary immunodeficiency-associated vaccine-derived poliovirus (iVDPV) prevalence.	Oct 2017	ongoing	

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Lower middle-income countries: sustainable adoption and financing for new vaccines	SAGE requested that WHO facilitate the establishment of a partnership among all relevant stakeholders to consider: pooled procurement; tiered pricing; greater transparency of pricing; and exploring the role that UNICEF, the Pan American Health Organization and foundations can have in assisting these countries with procuring and financing vaccines.	Nov 2010	Ongoing	WHO 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 endorsement of the MIC Strategy in Apr 2015, the WHO-led MIC Task Force initiated a country engagement process: in collaboration with key immunization partners WHO started multi-partner dialogues with four countries struggling with raising or maintaining high immunization coverage and/or introducing new vaccines. With each of these countries, the MIC Task Force has identified obstacles to achieving and sustaining the immunization system performance and potential solutions to reaching GVAP targets through plans of action. The MIC Task Force selected four countries for the MIC strategy implementation based on potential for impact (birth cohort, coverage of traditional vaccines, status of new vaccines introduction) and feasibility of engagement. Selected countries were Romania, Swaziland, Jordan and Philippines. Also, some efforts to support all MIC countries in the area of access to timely and affordable supply have been implemented. Notably, the creation of a mechanism for access to supply in humanitarian emergencies in MICs not supported by Gavi; set up of a peer platform and regional workshop to strengthen country procurement capacity; work on price transparency continues successfully with 85% of world (n. of countries) sharing vaccine product, price and procurement information since the beginning of WHO price transparency efforts and the recent launch of the Market Information for Access to Vaccine (MI4A) project. Despite these efforts, progress in implementation of the strategy accross its 4 pillars is very slow due to lack of funding. As discussed at the Apr 2015 SAGE meeting, the partners would require about US$20M per year to fully implement the strategy. In Oct 2016, a meeting of the MIC Task Force was held to review progress and discuss next steps. The TF determined having concluded its mandate through a review of the MIC issue and the development of a partner-shared MIC strategy. It was thus proposed that the TF comes to a close. Anticipating that considerable time may be needed for funding to become available, the TF proposed that partners focus on i) regular normative/guidance work benefitting all countries including non Gavi MICs and ii) access to affordable and timely supply (continuing working on implementation of ongoing activities and potentially new one as possible). Partners committed to continue information sharing and collaborative spirit in these efforts.

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Malaria Vaccine	SAGE requested continued review of the planning of the pilot implementations and to receive regular updates on the results.	Oct 2015	Ongoing	Critical cross-cutting elements of the Malaria vaccine implementation programme (MVIP) are now in place to move the Programme forward: (1) In October 2017, WHO signed a Collaboration Agreement with PATH and GSK to define roles and responsibilities of these partners in the MVIP. GSK has committed to supply, without charge, sufficient quantities of the vaccine to allow sound implementation of the MVIP, up to a maximum of 10 million doses. (2) Agreements between WHO and the 3 MVIP Funders (Gavi, the Global Fund and Unitaid) have been fully executed and funding is now available for phase 1 of the MVIP, through 2020.(3) The hiring of dedicated staff in AFRO and the three pilot countries (Ghana, Kenya and Malawi) is moving forward. All pilot countries have developed and submitted RTS,S/AS01 vaccine introduction plans and initiated preparatory activities, including on communications, logistics and supply planning, adaptation of monitoring tools and strengthening of routine pharmacovigilance. Use of RTS,S/AS01 in the MVIP will require special approval by national regulatory authorities (NRA) of the three countries prior to vaccine introduction. A joint regulatory review by the three NRAs, convened under the African Vaccine Regulatory Forum (AVAREF) took place in February 2018. Timelines for final decision by regulators about the special approval have been agreed upon. The master protocol for the pilot evaluations received approval by the WHO Research Ethics Review Committee in February 2018. Country-based research partners will be contracted to implement country-specific protocols. The two key advisory bodies for the MVIP have been set-up: the MVIP Programme Advisory Group (PAG), the highest-level advisory body to WHO on MVIP-specific aspects, has been convened for the second time in March 2018. The MVIP Data Safety and Monitoring Board (DSMB), responsible for safeguarding the well-being of children vaccinated in the MVIP by providing advice and recommendations to WHO on issues concerning the safety of RTS,S, has met for the first time in February 2018. A comprehensive update on the MVIP will be provided to SAGE during its meeting in April 2018.
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	Closed	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 the Regional Office for the Americas to document the successful regional experience of delivering influenza vaccine to pregnant women.	Apr 2015	Ongoing	Regarding the Pan-American Health Organization's (PAHO) documentation of the successful regional experience of delivering influenza vaccines to pregnant women, PAHO has progressed with its in-depth survey to develop case-studies with key countries that have acquired a lot of experience in maternal immunization (currently ongoing in three countries). Also, PAHO has published its field guide for maternal immunization (in English and Spanish). It is available from http://www.paho.org/hq/index.php?option=com_content&view=article&id=13445%3Amaternal-and-neonatal-immunization-field-guide-for-latin-america-and-the-caribbean&catid=6774%3Aslide-show&Itemid=40557&lang=en.

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Maternal Immunization	SAGE concluded that the recommending bodies, including WHO, need to engage in a dialogue with regulators and manufacturers to review current regulatory practices against the evidence on risks and benefits and biological plausibility on product safety. SAGE requested WHO to develop a process and a plan to move this agenda forward in support of an increased alignment of data safety evidence, public health needs and regulatory processes.	Nov 2013	Ongoing	WHO has completed 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 has produced a document titled, "Labelling information of inactivated influenza vaccines for use in pregnant women." The document was reviewed and endorsed by Expert Committee on Biological Standardization (ECBS) in late 2016. Future vaccines intended for use by pregnant women will undergo phase III trials in pregnant women. Currently available vaccines recommended for use in pregnancy (influenza, tetanus, acellular pertussis) are unlikely to have phase III trials necessary for an indication for use during pregnancy, however, there is regulatory consensus that pregnant women are not contra-indicated from receiving vaccines merely because a product is not indicated for use in that group.
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	WHO's Initiative for Vaccine Research (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 (not pregnancy specific); 4) guidance document to estimate the cost effectiveness of influenza vaccines in a country (not pregnancy specific); 5) field guide for the evaluation of influenza vaccine effectiveness (not pregnancy specific); and 6) implementation guidance document. IVR is collaborating with several research and public health groups to pilot some of these tools in low and middle income countries.
Measles	SAGE noted that there is a need to address the substantial information gap on the role of factors such blunting and maternal immunity in infants aged <6 months, and the impact of vaccination <6 months of age on subsequent MCV doses.	Oct 2017	ongoing	This is an information gap and research is needed. The SAGE WG is working to priorotize reserach areas in order to increase interets of donors to fund and of reserach institutions to carry out the needed research
Measles	SAGE stressed that the accumulation of susceptible persons at both the national and subnational level should continue to be monitored to identify and address immunity gaps. SAGE requested that the Measles and Rubella Working Group refine the recommendations as to when follow-up SIAs should be conducted.	Oct 2016	Ongoing	The updated measles position paper (published May 2017) stresses the importance of monitoring the accumulation of susceptible persons at both the national and subnational level to identify and address the immunity gaps. The SAGE MR Working Group is looking at refining recommendations as to when follow up supplementary immunization activities (SIAs) should be conducted. Initial modeling results and data analyses were discussed at the SAGE WG meeting in June 2017. The results of this work will were presented to the IVAR-AC and will be presented at the October SAGE in 2018.
Measles	SAGE recommended that the most expeditious clinical development and regulatory pathway to licensure of measles containing vaccines (MCV) micro-array patch (MAP) be determined, and that barriers to the development, licensure, and use of MAPs for measles and rubella vaccine delivery be identified and addressed urgently.	Oct 2016	Ongoing	a Measles and Rubella/ micro-array patch (MAP) Working Group (WG) was set up and has had two conference calls. A face to face mmeeting is planned in April in 2018. The outcomes and recommendations from this WG will be shared with SAGE.
Measles - Transmission	SAGE noted that there is a need to address the substantial information gap on transmission drivers.	Oct 2017	ongoing	This work needs to be addressed through improved survillance and outbreak investigations in country.

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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 Feb 2015: http://www.who.int/wer/2015/wer9008/en/. Ten 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, 7 countries have launched their introduction at the age of 9 months (Sudan, July 2016; Mali, Feb 2017; Central African Republic, June 2017; Chad, July 2017; Niger, October 2017); at the age of 18 months (Ghana, November 2016) and at the age of 15 months (Burkina Faso, Mar 2017), respectively. The remaining three countries intend to do so in 2018 (The Gambia, Côte d'Ivoire, Nigeria). Another 3 countries (Guinea; Guinea Bissau; Togo) have applied to Gavi through its new country engagement framework for an introduction in 2019. Two additional countries have applied to Gavi to conduct their initial mass vaccination campaigns: Burundi in Q4-2018 with the intention to enhance surveillance waiting for availability of affordable multivalent vaccines to consider introduction into routine; and Eritrea in Q2-2019 with the intention to introduce the vaccine into routine in Q4-2019. Other meningitis belt countries intend to apply for the introduction of the vaccine into their routine programme at the next Gavi application windows in May and September 2018.
Migrant Population	Existing knowledge on reaching displaced and mobile populations - including individuals escaping conflict zones or natural disaster, economic migrants, seasonal migrants, those moving to urban centers and traditional nomadic communities - and other neglected populations should be synthesized to identify good practice, innovative approaches and gaps in knowledge.	Oct 2017	ongoing	How to reach migrant populations? Is this considered in microplans or catch-up?
MNTE	UNICEF, UNFPA, and WHO should make all efforts to secure timely supply of the available WHO prequalified TT vaccine in compact single-dose pre-filled auto-disable injection devices to facilitate vaccination of inaccessible populations by community workers. Should the supply of TT vaccine in this latter presentation be less than expected, a clear plan for prioritizing and allocating available doses should be established.	Oct 2016	Ongoing	The proposal submitted to the Gavi Alliance Policy and Programme Committee (PPC) to request for financial assistance to support the production and availability of this critical pre-filled device aimed at markedly increasing access to the Tetanus Toxoid vaccine to very remote parts of some selected countries where currently access is seriously compromised as a result of insecurity, active conflicts and lack of human resources has been rejected by the PPC through a communication in January 2018. It is very unlikely that this very important initiative will ever be funded under the circumstance.
MNTE	UNICEF, UNFPA and WHO should work with countries to generate and sustain political commitment to maintaining elimination of MNT, in order to guard against complacency once a country has been declared to have achieved elimination.	Oct 2016	Ongoing	All opportunities including the Regional Immunization Technical Advisory Group (RITAG) meetings and Immunization Managers' meetings are being utilized to advocate for efforts by countries to sustain their Maternal and Neonatal Tetanus Elimination (MNTE) status. Update on the status of implementation of the AFR RITAG recommendations were presented at the annual meeting of the AFR RITAG in December 2017. MNTE was one of the topics discussed at the SEAR and WPR TAG meetings in June 2017 as well. Additionally, efforts are being made to finalize the guidelines on sustaining MNTE to ensure that countries are guided through the appropriate steps to take to sustain their achievements.
MNTE	UNICEF, UNFPA, and WHO should urgently develop an MNTE investment case and resource mobilization strategy to secure predictable and timely funding support for the remaining 18 countries, if the 2020 elimination timeline is to be met.	Oct 2016	Ongoing	There is currently a collaborative work by WHO, UNICEF and The United Nations Population Fund (UNFPA) that has led to contracting the University of North Carolina to conduct the work on the investment case for MNTE. Work is progressing in earnest, and the first phase of the work focusing on the attainment of elimination by the 16 remaining priority countries is expected to be completed by the end of Q1 2018.Discussions on the second phase of the investment case work on sustaining MNTE have started.

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MNTE	Where feasible, the use of serosurveys to validate assessment of risk identified from other data sources should be considered to guide vaccination strategies, especially in high-risk districts. Close attention should be paid to sampling strategies and laboratory methods to ensure that results are valid and interpretable. WHO should provide guidance on: sampling methods; sample collection and testing; and analysis, interpretation and use of serosurvey data for monitoring. WHO should consider establishing reference laboratories and reference serum panels to support standardization and quality assurance of the laboratory methods used in serosurveys.	Oct 2016	Ongoing	There is a recent effort to integrate tetanus serosurveys with the DHS, and a concept note has been written to that effect. This initiative is to be facilitated by US CDC in collaboration with WHO.
MNTE	UNICEF, United Nations Population Fund (UNFPA), and WHO should support countries in securing the necessary resources to implement their national elimination plans, including procurement of Td vaccine and operational costs for SIAs.	Oct 2016	Ongoing	The first phase of the MNTE investment case that focuses on the remaining countries yet to attain elimination (14 at the moment) is almost completed. This will highlight the areas of resources' need, and will also be used for resource mobilization. UNICEF, UNFPA and WHO have significantly contributed to this.
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	Multiple injection studies have been conducted in collaboration with US CDC in South Africa, Gambia, and Albania, with studies ongoing in the Philippines, Sudan, and Columbia. Studies are primarily designed to evaluate healthcare provider and infant caregiver attitudes and practices regarding administration of multiple injectable vaccines in the same visit, in most cases following the introduction of IPV and PCV. A new time motion study has also been initiated in Uganda. The findings of these studies will feed into the development of future guidance required to address concerns related to multiple injections and pain. For now, to better support countries in this area, new training modules for health workers on addressing pain at the time of vaccination and multiple injections will be imminently published.

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National immunization programme management	SAGE welcomed the initiative and stressed the importance and urgency of developing guidance that can be tailored to each country's unique structure and needs. SAGE emphasized the importance of looking at functions and competencies from a health-system perspective whereby all the immunization functions are adequately addressed with competent staff, regardless of the country's health system structure. SAGE recommended sharing of experiences between countries and regions on immunization workforce planning. SAGE suggested creating tools to assist countries in different aspects of immunization human resources management including: staff turnover and rotation policies, performance evaluations, and design of training. SAGE recommended that this work be piloted in a range of countries.	Apr 2017	Ongoing	A joint meeting with the US CDC and other relevant partners (JSI, BMGF, GAVI)was conducted in November 2017, to review the competencies needed at different level of the programme. A final list of competencies needed at national level will be available by Mar, 2019. The US CDC had drafted an article on this topic for a peer-reviewed journal, which should be published by end of Feb,2019.
National Immunization Technical Advisory Groups (NITAGs)	SAGE recommended that tailored guidance, tools, training, mentoring programmes and sharing of information are needed to assist NITAGs. Therefore, SAGE stressed that initiatives such as the Global NITAG Network and the NITAG Resource Centre are essential and that these would require dedicated financial and human resources. SAGE further noted that NITAG evaluations are important beyond the current process indicators and should be continued and supported by countries and partner institutions. NITAG evaluations need to focus on function, quality and integration.	Apr 2017	Ongoing	The second Global NITAG Network (GNN) meeting was successfully held from the 28th to 29th of June 2017 in Berlin, Germany. The meeting was attended by 38 NITAG country representatives (NITAG Chair, member or secretariat) from a total of 26 countries. During this meeting the GNN was formally established and its strategic document endorsed. The next meeting is scheduled in December 2018 and will be hosted by the Public Health Agency of Canada. The secretariat of GNN is now ensured by WHO HQ and the NITAG Resource Centre is also being managed by WHO.

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Pain mitigation	SAGE recommends that WHO: 1) includes pain mitigation recommendations with WHO immunization practice guidance materials; 2) disseminates pain/distress mitigation recommendations through the usual dissemination channels, immunization managers, National Immunization Technical Advisory Group (NITAG) and partner organizations; 3) monitors and evaluates the implementation success of pain mitigation measures; 4) works with industry, ECBS and regulatory agencies to advocate that grading of pain experienced during the vaccine injection be included in data for licensing and in the product monograph.	Apr 2015	Ongoing	Internal discussions have taken place on how to move forward across relevant WHO departments. A brief position paper was drafted based on the SAGE recommendations and published in the Weekly Epidemiological Record on 25 September 2015. This formed the basis for additional proactive communication activities. As example of actions in response to points 1 and 2, WHO 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 WHO position paper 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 WHO position paper. 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 has been 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. As a further example of use and integration in WHO documents, reference to the pain mitigation position paper has been made in the recently published updated tetanus position paper. PDVAC will consider pain mitigation within their preferred product characteristics to guide target product profiles. 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 were discussed and endorsed by ECBS in October 2016. They allude to pain mitigation. More specific activities still need to be implemented with respect to points 3 and 4.
PCV	SAGE proposed surveillance and research priorities to guide future policy revision, including further assessment of dosing schedules and pneumococcal outbreak epidemiology, particularly epidemics of ST1 disease.	Oct 2017	ongoing	SAGE PCV working group was convened in 2017 and presented results at October 2017 SAGE meeting. One component of this WG was to review available evidence on use of catch-up campaigns, including in the context of pneumococcal outbreaks. This will be written up in a revised WHO PCV position paper in 2018. We will also launch activities to analyze available data and use disease modeling to devise a strategy for responding to pneumococcal outbreaks, since the existing data is sparse.
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	GPEI partner agencies recently have launched two new projects to comprehensively document and disseminate lessons learned from polio eradication. The first one is a 5 year project led by Johns Hopkins Bloomberg School of Public Health document, preserve, and disseminate the polio program's best practices to help inform future global health policy and implementation. Collaborating with academic institutions from around the world, the team will develop short courses and hands-on clinics for public health students and professionals, by conducting a variety of activities from literature review to in-person surveys. Frontline workers involved in polio eradication efforts will be an intricate part of the process to gather "first hand" experience on success and challenges. As a part of a multimedia lessons-learned project, GPEI is also collecting stories focusing on inspiring individuals, who were key to innovations in the history of polio eradication. The project involves interviews with community leaders and front-line health workers, who made a difference in changing strategies, when stakes were high and there was need for a paradigm shift in the programme.

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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	WHO Regional Offices from AFRO, EMRO and SEARO have been an integral part of the polio transition planning exercise at the country level. For the last two years, the Regional Offices have been guiding and providing technical support to the countries to develop their national transition plans. In many cases, Regional Offices have integrated polio transition planning into broader region-specific immunization initiatives and strategies (e.g. Addis Declaration for Immunization). In addition, the Regional Offices are a part of a cross-cluster WHO team set up to finalize the “Strategic Action Plan on Polio Transition” which will be presented to the World Health Assembly in May. As a part of this effort, the regional offices have provided substantive input into a comprehensive planning exercise, looking at functions that need to be sustained to keep the world polio-free, to strengthen immunization and to strengthen outbreak preparedness, detection and response, including the estimated costs of sustaining these functions. The Regional Offices will play an important role in the implementation of the Strategic Action Plan and its Monitoring and Evaluation Framework.
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 officer to focus on containment has been recruited and will join the WHO Containment team in March. Sweden has submitted to GCC the first and so far only certificate of participation (CP) in the containment certification activities. At their meeting of 23-25 Oct 2017, GCC has recommended WHO to consider an EB request for a WHA 2018 resolution urging countries hosting PEFs to accelerate the appointment of a competent NAC as soon as possible and no later than 31 Dec 2018 and to process all CP applications as soon as possible and no later than 30 June 2019, stating that after June 2019, new PEF applications will not be considered unless under exceptional circumstances. the report is published and has been shared with stakeholders in all regions.
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 January 2018, countries still pending completion of Phase I are awaiting the publication of the 'Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for polioviruses'. For Phase II, 28 countries reported the intention to retain PV2 materials (WPV2 or OPV2/Sabin2) in 91 designated poliovirus-essential facilities (PEFs). 18 of these countries have nominated a national authority for containment (NAC). So far, only one designated facility, in Sweden, has requested to engage in the containment certification process.
Polio	SAGE requested WHO to complete the guidance on identification of potentially infectious materials (including stool and respiratory specimens) into 3 groups based on likelihood of being contaminated with VDPV2 or WPV2.	Oct 2016	Ongoing	A revised draft of the ‘Guidance for non-polio facilities to minimize risk of sample collections potentially infectious for polioviruses’ has been approved by the Containment Advisory Group (CAG) at their second meeting of 28-30 November 2017, pending minor adjustments and completion of annex 3 listing country-specific data. The guidance is planned to be completed shortly.
Polio	SAGE urged WHO to facilitate discussions and decision-making by National Immunization Technical Advisory Groups (NITAGs) to introduce IPV intradermal fractional dose use by providing necessary technical information.	Oct 2016	Ongoing	WHO prepared the communication and technical materials to National Immunization Technical Advisory Groups (NITAGs). The WHO secretariat is advocating for the use of fractional dose IPV at both regional and country technical advisory group meetings (TAGs).
Polio	SAGE noted that the IPV supply situation is further deteriorating. Therefore, the programme should explore the possible use of devices facilitating intradermal administration (e.g. jet injectors, intradermal adapters).	Oct 2016	Ongoing	WHO is working on pre-qualification of both jet injectors and intradermal adapters. In addition, WHO has conducted several pilots of the use of these devices in immunization campaigns (e.g. Karachi, Pakistan). These results were presented to the scientific stakeholders in polio program and to countries considering introduction of fIPV.
Polio	SAGE requested its Polio Working Group (WG) 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	The IPV supply situation is being closely monitored. An update from the September Polio Working Group meeting, including on discussions with vaccine producers, was provided during the October 2017 SAGE meeting.

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Polio	SAGE requested that WHO review its tier classification of countries with respect to prioritization of IPV to take into account the size of the population with no IPV protection and the recent VDPV2 events.	Apr 2017	Ongoing	WHO, in collaboration with partners, is working on updating its tier classification of countries with respect to prioritization of IPV. It will be presented to the SAGE Working Group in September 2017 and to SAGE in October 2017.
Preferred Product Characteristics	SAGE noted the utility of Preferred Product Characteristics (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	Since this recommendation, the Product Development for Vaccines Advisory Committee (PDVAC) has been created, and identified as the WHO committee responsible for overseeing the PPC generation process and content. PDVAC has emphasized the need for several PPC documents to be developed by WHO IVR. PPCs for Group B streptococcus and RSV vaccines have been finalized. Target Product Profiles for emerging pathogens have been developed as part of the Blueprint initiative. PPCs for new tuberculosis vaccines, next-generation influenza vaccines influenza vaccines, Group A streptococcus, ETEC, Shigella and Herpes Simplex Virus 2 are under development. PPCs when finalized and ready for public circulation are posted on the WHO IVR website.
Private sector engagement with national immunization programmes	SAGE applauded the development of the draft guidance as an initial step in tackling this area of work and urged WHO to finalize a common framework starting with a set of core principles.	Apr 2017	Completed	As requested by SAGE the "WHO Guidance Note: Engagement of private providers in immunization service delivery. Considerations for National Immunization Programmes" has been revised and particularly shortened. The WHO Guidance Note was published in September 2017 and can be retrieved through the following link: http://www.who.int/immunization/programmes_systems/policies_strategies/Private_sector_immunization.pdf?ua=1
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	Regarding the Emergency Use Assessment and Listing (EUAL) procedure, the WHO Prequalification Team took note of SAGE recommendation and further development of the EUAL will consider relevant regulatory authorities including those of impacted countries. Further, a document entitled, "Vaccine evaluation in public health emergencies – review of regulatory pathways in selected countries" was prepared and presented to SAGE working group (WG) on Ebola vaccines in Aug 2015. In Oct 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 reviewed the document's progress in 2016. Evaluation of vaccines for public health emergencies was discussed in the 3rd meeting of the WHO Collaborating Centers Network on Vaccines in Seoul, in July 2016. Lessons learned from the Ebola crisis in West Africa and the Middle East respiratory syndrome coronavirus (MERS-CoV) outbreak in Korea were discussed and several activities of the CC network were proposed. In addition, new initiative called the Coalition for Epidemic Product Innovation (CEPI) was discussed as a framework in which a number of partners will work together to assure better preparedness for public health emergencies in future. The ECBS was also briefed about the CEPI in Oct 2016. The CEPI initiative led to the establishment of a Regulatory Working Group in 2017 with the focus on data requirements for product development in the absence of an outbreak, regulatory issues related to stockpiling and the use of stockpiled products during the outbreaks.
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 network of WHO Collaborating Centres (CC) on the Standardization of Vaccines has been established. At its 3rd meeting, the network agreed to establish a "Core Expert Group (CEG)" to assist the Expert Committee on Biological Standardization (ECBS)to review selected proposals for measurements standards. Proposals for replacement measurement standards are usually straightforward, with few strategic or scientific issues, and they would be the initial focus of the CEG. The ECBS agreed that the CEG could pre-review selected measurement standards in the vaccines area and thus help to streamline the ECBS review process. A drafting group on Men B guidelines was established as a part of CEG activity on written standard and report will be submitted to ECBS for discussion. Review of measurement standards will be conducted in September and feedback from CEG will be submitted to the ECBS. Further discussion on the activities of the CEG is going to take place at the ECBS meeting from 17 to 20 October 2017.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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 WHO Prequalifications (PQ) team with regard to prequalification processes for both respiratory syncytial virus (RSV) vaccines and monoclonal antibodies (mAbs). The ECBS Guidelines for RSV vaccines are planned for development and possible adoption at Expert Committee on Biological Standardization (ECBS) 2018, as these are a prequisite for consideration for PQ. The Essential Medicines and Health Products (EMP) department is considering an approach to PQ of mAbs. Intensive discussions continue about the most appropriate way to prepare for policy-making in Low and Middle Income Countries (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. 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. Novavax announced that a planned interim data analysis was favorable, supporting trial continuation. Results from a Medimmune candidate vaccine tested in adults showed negative results and the possibility of increased severity in a subset of participants, which led to the discontinuation of an importnat part of this program. The RSV vaccine pipeline remains very active 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). A WHO Preferred Product Characteristics for RSV vaccines document has been finalized under PDVAC oversight, and is now publicly available on the WHO IVR website. WHO is actively developing its activities related to the preparation of policy decisions related to RSV vaccines, with funding support from the Gates foundation.
Second year of life (2YL)	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	Two country case studies (Zambia, presented to SAGE in April 2016, and Senegal) (WHO, JSI) and a global landscape analysis and literature review (UNICEF) have been conducted; learnings from these as well as country demonstration projects in Ghana and Malawi (CDC) have been used to inform the draft global guidance on Establishing and strengthening immunization in the second year of life: practices for immunization beyond infancy. An advanced draft of the guidance document was shared with the Immunization Practices Advisory Committee (IPAC) in Feb 2017 and the document was circulated for a final round of review in September 2017. Advocacy and demand creation packages targeting decision makers, planners, health workers and caretakers are also under development and will be published, along with the guidelines and a companion Handbook for planning, implementing, and strengthening vaccination into the 2YL, in Q1 2018. With the guidelines on track, WHO and UNICEF are moving ahead to develop training materials for country-level staff and for building a pool of consultants trained to identify gaps and facilitate actions needed to maximize coverage of vaccines scheduled in the second year of life.
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 is still ongoing to provide 5 million doses. WHO is waiting for the french regulatory authority to provide the technical information about the vaccine for evaluation. The negotiations with the Japanese Government for 10 000 doses have been put on hold until the Japanese NRA approve the manufacturer to restart production. WHO is working on smallpox vaccine prequalification for the emergency stockpile. WHO restarted the dialogue with the UK for the donation of 4 million doses. A WHO meeting took place in Geneva 7-8 Sep 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 not yet published.
Standardization of BCG strains	SAGE requested ECBS to review and report whether manufacturers have implemented their guidelines for characterization of BCG vaccines on strain, product and batch related characteristics.	Oct 2017	ongoing	

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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. By the end of 2016, 127 Member States reported the existence of a NITAG and 82 Member States (including 27 GAVI-eligible and 25 non GAVI supported Middle Income 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 was held at the April 2017 SAGE meeting.
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. This has been stressed throguh the SAGE session on vaccine shortages held in April 2016, resolution 69.25 on "Addressing the global shortage of medicines and vaccines", the fifth objective of the Global Vaccine Action Plan (GVAP), the Middle Income Country (MIC) Strategy endorsed by SAGE in April 2015 and the 68th World Health Assembly (WHA) resolution on the GVAP in May 2015. WHO IVB Department, in collaboration with Essential medicines and health products (EMP) and with support from Linksbridge consulting funded by the Bill & Melinda Gates Foundation and MMGH consulting, has leading a Vaccine Shortage Project over the years 2016-2017. The aim of the project was to act upon the recommendations and requests of SAGE and WHA by providing concrete proposals on WHO’s role and actions to enhance information sharing for pre-empting and managing vaccine supply shortages. While all countries can benefit from this work, particular attention is paid to countries not supported by UNICEF Supply Division, PAHO, or Gavi. To ensure that any potential solution in this space builds on existing data, knowledge and processes, a first phase of the project, the Analysis of Assets, aimed to understand the extent of information available to WHO to be able to predict, pre-empt and act upon vaccine shortages. This includes both internal and external information. This phase also aimed to understand the extent of current project/mitigation work within WHO, vaccine by vaccine. This phase has been completed and a project report is available upon request. Based on the findings from Phase 1, Phase 2 of the project was focusing on development of concrete solutions to enhance WHO’s ability to address vaccine shortages with a focus on filling current gaps in information sharing and supporting self-procuring countries. Using Bacillus Calmette–Guérin (BCG) and D&T containing vaccines to prototype solutions, an informed proposal on WHO’s functions and operating model with regards to vaccine supply/demand/price data input, market analytics, output material and distribution was developed. The proposal was successfully submitted to the Bill and Melinda Gates foundation for funding and the new project, Market Information for Access to Vaccines (MI4A) was kicked off in January 2018. Under this project, WHO commits to conduct to enhance available GLOBAL vaccine market information to enhance timely access to affordable vaccines. The work will entail: i) two global vaccine market studies per year in collaboration with Linksbridge SPC and MMGH Consulting to assess global supply, demand and pricing challenges of vaccines at risk (availability & affordability). ii) development of tools and materials for countries to improve market knowledge and enhance procurement outcomes. iii) creation of an information sharing ecosystem for enhanced information exchange among key stakeholders. iv) development of guidance and strategies for suppliers and countries aimed at enhancing access.

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Surveillance	SAGE endorsed the recommendations of the ad hoc TAG for improving the quality of the IB-VPD surveillance network and urged that the objectives of this network be more clearly defined, that collaboration with other surveillance systems and laboratory networks (i.e. the polio/measles laboratory networks) be continued, and that, where feasible, activities be linked with other programmes enhancing country capacity, including implementation of the International Health Regulations. SAGE urged greater attention to integration of data systems, which would facilitate real-time analysis and performance monitoring. SAGE also noted the opportunities for integration by building upon the enhanced capacity developed by these networks to conduct surveillance for other diseases using a similar case-definition and personnel trained in applying and adhering to rigorous surveillance protocols. Both networks should continue to share experiences with the polio surveillance network. Integration efforts must be strategically designed in ways that are logical and synergistic.	Nov 2013	Ongoing	Since 2013, significant progress has been made to strengthen the Global IB-VPD and Rotavirus Surveillance Networks through recommendations from the 2013 global strategic review and annual meetings and consultations. By the end of 2017, we have made significant progress toward strengthening the Networks and meeting those goals. In 2016, the Global Rotavirus Surveillance Network comprised 133 sentinel surveillance sites in 58 countries and the Global IB-VPD Surveillance Network comprised 124 sentinel sites in 57 countries. This continued through 2017. 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 complete year of data available is from 2017, 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). The surveillance platform has also been leveraged to monitor other VPDs, such as typhoid using the IB-VPD surveillance sites and other enteric pathogens such as norovirus, Shigella, and ETEC using the rotavirus network. 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 to monitor impact for sites that meet inclusion criteria in vaccine-using Member States, especially for pediatric diarrhea and rotavirus. 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. We are discussing how to better integrate IB-VPD meningitis surveillance with existing meningococcal meningitis surveillance systems. 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. Finally, one of our main activities is to work with countries on making 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 the currently included ones (Target 3.8.1 Universal Health Coverage composite indicator, and the Hepatitis B control strategy, three doses of Hep B vaccine). It was agreed to propose Global Vaccine Action Plan (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 Decade of Vaccine Working Group. In November 2016, at the 4th meeting of the Inter-agency and Expert Group on Sustainable Development Goal Indicators (IAEG-SDG), the new accepted immunization indicator was defined as 3.b.1 Proportion of the target population covered by all vaccines included in their national programme. WHO and UNICEF were identified as co-custodians for this indicator. The indicator definition was presented to SAGE in October and was reclassified to Tier II at IAEG-SDG meeting on 28 November. The indicator definition is: - Coverage of DTP containing vaccine (third dose): Percentage of surviving infants who received the 3 doses of diphtheria and tetanus toxoid with pertussis containing vaccine in a given year. - Coverage of Measles containing vaccine (2nd dose): Percentage of children who received two dose of measles containing vaccine according to nationally recommended schedule through routine immunization services. - Coverage of Pneumococcal conjugate vaccine (last dose in the schedule): Percentage of surviving infants who received the recommended doses of pneumococcal conjugate vaccine. - Coverage of HPV vaccine (last dose in the schedule) : Percentage of 15 years old girls received the recommended doses of HPV vaccine. This indicator aims to measure access to vaccines, including the newly available or underutilized vaccines, at the national level over the life course. Indicatro was reported for DTP3, MCV2 and PCV3 in February 2018 and will be part of next SDG report.

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Tuberculosis vaccines	SAGE endorsed the establishment of a WHO TB vaccine technical expert group with representation from SAGE. An annual written report on TB vaccine developments should be provided to SAGE. SAGE would be provided with two-page summaries of progress every year. TB would only be included on the agenda of SAGE when there is a meaningful development of decision from SAGE required.	Nov 2011	Ongoing	WHO IVR, with the support from an TB vacine expert working group, with further advise from PDVAC, continues to progress its activities on TB vaccine development Several tuberculosis efficacy trial results are awaited in the coming months. The most advanced vaccine candidates are GSK M72/AS01E, the recombinant BCG VPM1002, M. VaccaeTM. M.vaccae is a heat killed homogenized lysate developed by Anhui Zhifei Longcom, China, which has been evaluated in Phase 3 for prevention of tuberculosis in healthy adults with latent TB infection, as well as as adjunctive immunotherapy with the aim to shorten TB treatment. Results have not been communicated. 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 IIb/III trials, being compared to BCG in neonates in South Africa, as well as being tested for prevention of TB recurrence in adults in India. Discussions are ongoing about neonatal BCG comparison phase 3 study design to ensure appropriate data is generated, supporting robust policy decision on possible BCG replacement. M72/AS01E a GSK adjuvanted protein vaccine candidate in phase IIb evaluation in Southern Africa, being tested for prevention of pulmonary TB. Primary results are awaited in the coming months. Secondary endpoints include safety and immunogenicity. 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 the coming months. Upon PDVAC recommendation, WHO has developed guidance on preferred product characteristics for TB vaccines, with support from the Bill and Melinda Gates Foundation. The document has gone though a thorough consensus building consultation process including a vast stakeholder meeting organized late 2017, and is now available for public review through the WHO IVR website: http://www.who.int/immunization/research/development/tuberculosis/en/.
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 (WG) on Typhoid Vaccines was established in Mar 2016 and will report its evidence review and draft policy recommendations for typhoid vaccines to SAGE at the Oct 2017 meeting. Data on the safety of typhoid vaccines was reviewed by the Global Advisory Committee on Vaccine Safety (GACVS) in Dec 2016. New modelling data on the dynamics of diseases transmission and economic evaluation of typhoid burden and of vaccination strategies have also been reviewed by the Immunization and Vaccines Related Implementation Research Advisory Committee (IVIR-AC) in Feb and Sept 2017. Important new data have also been generated in recent and ongoing studies on areas such as the epidemiology and burden of typhoid fever; trends in antimicrobial resistance of S. Typhi and implications for typhoid control. These data have provided critical information to inform the SAGE Working Group's evidence review, or are anticipated to provide data in the next few years to support country level decisions on typhoid control. Currently, one licensed typhoid conjugate vaccine is undergoing WHO prequalification review. The position Paper is published end of March 2018.

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Un/under-immunized children	SAGE requested that WHO quickly roll out tools so that other countries can address low coverage of vaccination.	Nov 2010	Ongoing	Work is ongoing on the tool to assess "Missed Opportunities for Vaccination" (see item 284). On a broader level, a companion document to the Global Vaccine Action Plan (GVAP) focusing on Routine Immunization entitled "Global Routine Immunization Strategies and Practices" (GRISP) has been presented to the SAGE WG on DoV twice, and in Aug 2016 was published. Additionally, a range of additional guidance materials are under development and close to finalization. These include a health worker 'knowledge, attitudes, and practices' (KAP) tool, training materials for health workers on conversations with hesitant parents/caregivers, and addressing concerns regarding multiple injections and pain. A global field guide for 'Tailoring immunization programmes', based on the original guide from EURO, is being finalized. General guidance is also planned for development in 2018 to outline a range of evidence-informed interventions that may be considered when working to identify, assess, and address hesitancy in specific populations.
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	Possibilities of using the SAGE framework in other public health areas and emergency settings are being explored.
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 was initially produced by EMRO, adjusted some as a result of limited preliminary peer-review, and then 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. Finally, although there was no separate specific session during the Apr 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 20 June 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 took place on 10-11 Oct to develop consensus on the various guidance and priorities mentioned above and discuss how to best communicate and advocate for their implementation. Feedback form the meeting included that the envisaged operational manual missed important features while still being too long. Therefore the participants concluded that with having the revised and edited framework for decision-making along with the web-based tools, the operational manual was obsolete. The updated framework for decision-making has been published and is available at http://apps.who.int/iris/bitstream/10665/255575/1/WHO-IVB-17.03-eng.pdf and implementation guide was finalized and is available at http://apps.who.int/iris/bitstream/10665/258719/1/WHO-IVB-17.13-eng.pdf. Work is ongoing with UNICEF for the development of web based interactive tools to support its use and facilitate further updating. These tools should be available by Q3 2017. Attempts are currently being made to have a proactive dissemination and communication plan to ensure adequate distribution of the tools.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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	With the support from the Bill and Melinda Gates Foundation (BMGF), a point-of-care testing (POCT) prototype sample Oralight collection device and POCT test system based on lateral flow and a reader combined with mobile phone, has been developed for the detection of measles specific antibodies in serum and oral fluid. The prototype showed high sensitivity and specificity (91 and 94% respectively for serum and 90 and 96% for OF). On top of that, measles virus genome could be reliably detected in the POCT strips and used for genotyping, even after prolonged storage for more than a month at 20-25°C. The added advantage was that the POCT was highly thermostable and the results showed high concordance with gold standard assay used in the Global Measles Rubella Laboratory Network (GMLRN). The assay is particularly useful in endemic settings as well as in settings near elimination of even post elimination and re-introduction. During a recent meeting of the Measles Rubella Initiative on Research and Innovation POCT came out as one of the top research priorities. It will allow monitoring disease using effective surveillance and evaluate programmatic efforts to ensure progress. It will also aid in developing and maintaining outbreak preparedness, and respond rapidly to outbreaks and manage cases. Field studies are now in phase 2 in different epidemiological and health care settings, including countries in different phases of measles control and with different health care infrastructures (Africa and South East Asia). Particularly the operational feasibility of using POCT/OF in a field setting needs to be determined. Currently, besides the measles IgM assay for oral fluid, capillary blood and serum, a POCT for rubella IgM is being developed. POCT for measles and tetanus IgG are being evaluated for the use on oral fluid and dried blood spots on filter paper.

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Vaccine coverage	SAGE recommended that WHO explore alternative survey methods to improve the precision, reduce the cost and improve the usefulness of survey results to national and local immunization programmes.	Nov 2011	Ongoing	To improve the quality, precision and usefulness of survey results and to reduce the cost of surveys, the Strategic Information Group (SIG) at EPI, Department of Immunization, Vaccines and Biologicals (IVB) explored recent advances in sampling methodology; new technologies for constructing sampling frames, supervision of field work, data collection, and analysis; and alternative content, collection, analysis, presentation and linkages with other health household surveys. An Informal Advisory Group on Monitoring Immunization Programme Performance through Household and Community Surveys was established. The first meeting addressed the need to modify Demographic and Health Surveys (DHS) implemented by ICF International; and the UNICEF Multiple Indicator Cluster Surveys (MICS) and the WHO Immunization Cluster Survey to accommodate changes in immunization system strategies. In 2012, following a meeting with representatives of ICF and the MICS team, WHO and UNICEF provided written recommendation to these agencies to propose modifications to their standard recommendations on data collection, analysis and presentation of immunization coverage data. A new consultation will take place in April 2018. The development of a revised WHO Vaccination Coverage Survey Reference Manual followed a thorough process. In late 2012, an informal working group was created to review and revise WHO guidance on measuring immunization coverage through household and community surveys. In 2014-2015, a draft Survey Reference Manual was circulated to external reviews. The proposed methods, which are aligned with household surveys that use probability sampling and modern statistical techniques for analysis, were also reviewed, in September 2014, by Immunization and Vaccines Related Implementation Research Advisory Committee (IVIR-AC). IVIR-AC agreed that the revised method for coverage surveys is the proper way forward, but noted that statistical expertise will be required to implement the survey in the field and provided other considerations, including the importance of using GPS technology, the need for qualitative studies and piloting of surveys in hard-to-reach settings. IVIR also noted that difficulties in monitoring progress and comparing cross-sectional data across methods and time must be addressed. Protocol for pilot testing of the Survey Manual was used in Bangladesh. In mid-2015, a working draft of the WHO Vaccination Coverage Survey Reference Manual was distributed and posted on the departmental website. Between 2015 and 2016, all or some aspects of the recommendations included in the new Survey Manual were used in Burkina Faso, Lao PDR, and to a lesser extent in Lebanon and for surveys following supplementary immunization activities (SIA) in Kenya, Swaziland, to name a few. Nigeria combined a MICS with a vaccination coverage survey (2016-2017) and Pakistan planed its 2018 Vaccination Coverage Survey using the new Manual. Serosurvey protocols in Bhutan and Mongolia used the Survey Manual recommendations. In April 2017, WHO convened a meeting to review combined feedback and lessons learned from “statistical support outsourcing” with general experience sharing and research agenda setting, the meeting report is available here: http://bit.ly/WHO. In short, several recommendations were made to WHO, countries and partners seeking to improve the quality of surveys and their use. The WHO Vaccination Coverage Survey Reference Manual was finalized at the end of 2017. The revised recommendations will likely improve accuracy, by decreasing selection bias and reliance on maternal recall, and should also increase likelihood for adequate power, increase rigor and quality. The cost of the various trade-offs is being explored. All survey related-materials are available here: http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/index2.html Finally, several capacity building activities around vaccination coverage surveys have been conducted. In Dec 2015, a briefing workshop on the WHO Vaccination Coverage Survey methodology for regional focal points and consultants was done. In 2016, countries in the African and Eastern Mediterranean regions were briefed. Between 2016 and early 2017, WHO in collaboration with UNICEF and CDC conducted trainings that brought together statisticians from developing countries (one Anglophone and one Francophone training), along with immunization program officers and consultants were conducted for countries from all regions, except EUR. A separate training was done in China for all provinces. An additional training was conducted in Nepal in Feb 2017, with the objective to train persons working on Immunization and a cadre of statistics professionals who, in partnership with Immunization Programmes, can conduct secondary immunization analyses from existing surveys. Participants included NSO and Immunization persons from SEAR and WPR countries, as well as consultants that work mainly in Asia. In this hands-on training in Nepal, the tool “Vaccination Coverage Quality Indicators (VCQI)” was introduced. VCQI is set of Stata programs intended to be used by statisticians and epidemiologist to analyze survey data; and for survey analysts to add further modifications and additional indicators. VCQI allows conducting analysis not only from surveys done using WHO

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Vaccine coverage	WHO to identify appropriate methods and develop guidelines for collecting, analysing, and interpreting biomarkers for validating coverage.	Nov 2011	Ongoing	To improve the quality, precision and usefulness of survey results and to reduce the cost of surveys, the Strategic Information Group (SIG) at EPI, Department of Immunization, Vaccines and Biologicals (IVB) explored recent advances in sampling methodology; new technologies for constructing sampling frames, supervision of field work, data collection, and analysis; and alternative content, collection, analysis, presentation and linkages with other health household surveys. An Informal Advisory Group on Monitoring Immunization Programme Performance through Household and Community Surveys was established. 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Between 2015 and 2016, all or some aspects of the recommendations included in the new Survey Manual were used in Burkina Faso, Lao PDR, and to a lesser extent in Lebanon and for surveys following supplementary immunization activities (SIA) in Kenya, Swaziland, to name a few. Nigeria combined a MICS with a vaccination coverage survey (2016-2017) and Pakistan planed its 2018 Vaccination Coverage Survey using the new Manual. Serosurvey protocols in Bhutan and Mongolia used the Survey Manual recommendations. In April 2017, WHO convened a meeting to review combined feedback and lessons learned from “statistical support outsourcing” with general experience sharing and research agenda setting, the meeting report is available here: http://bit.ly/WHO. In short, several recommendations were made to WHO, countries and partners seeking to improve the quality of surveys and their use. The WHO Vaccination Coverage Survey Reference Manual was finalized at the end of 2017. The revised recommendations will likely improve accuracy, by decreasing selection bias and reliance on maternal recall, and should also increase likelihood for adequate power, increase rigor and quality. The cost of the various trade-offs is being explored. All survey related-materials are available here: http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/index2.html Finally, several capacity building activities around vaccination coverage surveys have been conducted. In Dec 2015, a briefing workshop on the WHO Vaccination Coverage Survey methodology for regional focal points and consultants was done. In 2016, countries in the African and Eastern Mediterranean regions were briefed. Between 2016 and early 2017, WHO in collaboration with UNICEF and CDC conducted trainings that brought together statisticians from developing countries (one Anglophone and one Francophone training), along with immunization program officers and consultants were conducted for countries from all regions, except EUR. A separate training was done in China for all provinces. An additional training was conducted in Nepal in Feb 2017, with the objective to train persons working on Immunization and a cadre of statistics professionals who, in partnership with Immunization Programmes, can conduct secondary immunization analyses from existing surveys. Participants included NSO and Immunization persons from SEAR and WPR countries, as well as consultants that work mainly in Asia. In this hands-on training in Nepal, the tool “Vaccination Coverage Quality Indicators (VCQI)” was introduced. VCQI is set of Stata programs intended to be used by statisticians and epidemiologist to analyze survey data; and for survey analysts to add further modifications and additional indicators. VCQI allows conducting analysis not only from surveys done using WHO

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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 (human papillomavirus (HPV), influenza and oral cholera vaccine (OCV)) and vaccine uptake/hesitancy. Non-specific effects (NSE) of vaccination and missed opportunities for vaccination sessions were on the IVIR-AC agenda in 2016 and 2017. Economic tools for influenza vaccines were presented at the June 2016 meeting. A malaria costing tool to help countries cost and plan RTS,S vaccine in their country will be reviewed at the Sep 2017 meeting.
Vaccine demand / acceptance /hesitancy	Acceptance and demand: Each country should develop a strategy to increase acceptance and demand for vaccination, which should include ongoing community engagement and trust-building, active hesitancy prevention, regular national assessment of vaccine concerns, and crisis response planning.	Oct 2017	ongoing	The role of legislation n promoting vaccination - need to review current experiences.
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	A range of activities are now ongoing in this area. With added capacity in this area at WHO HQ since late 2017, a number of initiatives are now scaling up, e.g. development and dissemination of further guidance on applying behavioural insights to assess and address hesitancy, and coordination with a group of global experts to support initiatives and capacity building in a variety of regions and countries. One of the key pillars of this work is "Tailoring Immunization Programmes (TIP)" which is now being used in at least 9 countries in the European Region, and as of December 2017 in Mauritania. A updated TIP guide is due to be published by WHO EURO in 2018. TIP has also been presented at regional meetings and features in regional guidance for WHO SEAR and WHO WPR. Lastly, in 2018 a range of new activities and materials are planned, with a focus on building capacity among regional staff, sharing lessons learned and experiences, and promoting and scaling up use globally of the various tools and guidance developed by EURO on boosting acceptance and addressing hesitancy. Collaborations in this field are also being fostered with a number of experts and researchers from a diverse range of disciplinary backgrounds to informally help support WHO efforts in this area. Coordination with UNICEF, CDC, Gavi, and other partners is also taking place to ensure alignment of efforts.
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/ The promotion of their use and necessity to validate the research questions will be discussed further internally at WHO.

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Vaccine Hesitancy	SAGE underlined the importance of distributing the matrix of determinants, the definition of hesitancy and the other deliverables to countries and partners.	Oct 2014	Closed	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 Aug 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 Aug 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 paper which outlines the results of the 2015 Joint Reporting Form (JRF) indicators on vaccine hesitancy and contains the matrix of determinants and the definition of vaccine hesitancy was published open access on 1 Mar 2017: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0172310.
Yellow Fever	SAGE prioritized head to head non-inferiority studies of all 4 WHO prequalified Yellow Fever vaccines, as well non-inferiority studies in special populations. Of particular importance, given the consequences for international travel involving IHR requirements is the duration of protection with fractional dosing, including the potential need for revaccination. Safety and effectiveness assessments should be put in place when minimal effective doses are used.	Oct 2016	Ongoing	IVR actively promotes the research agenda, and several relevant studies are in planning or execution phase. A technical consultation was held in NOv 2017, and the report is available on WHO's website. Fractional dose non-inferiority studies for all 4 prequalified vaccines will be conducted (funded, Africa), and long term immunogenicity have been studied (manuscript submitted). Immunogenicity study in DRC is on track, and 1 month immunogenicity data have been published, 1 year data to follow soon.