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 The “Meeting Date” column displays the date of the SAGE meeting during which the recommendation was originally made.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. In 2017, for 2016 data, 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. In 2018, for 2017 141 countries reported subnational data, for a total of about 23,000 districts. Detailed analysis and reported data are available 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. AFRO continues to work with countries on updating their pre service curriculum.
AEFI reporting	SAGE urged that efforts be pursued to enhance Adverse Events Following Immunization (AEFI) reporting worldwide.	Apr 2016	Ongoing	Progress with adverse events following immunization (AEFI) surveillance is sustained with 114 countries reporting at least 10 AEFI per 100,000 surviving infants during 2017 as compared to 45 in 2010 and 97 in 2016. In order to further analyze national capacity, more refined indicators related to serious AEFI, timeliness and completeness of reporting are now being developed and evaluated.
Analysis of national legal framework on immunization	Legal frameworks: A comprehensive global audit should be undertaken to document the ways in which legislation and regulation have been used to promote or undermine immunization at a national level, to identify how legal and regulatory instruments can be best applied in different contexts and for different purposes to strengthen immunization systems	Oct 2017	ongoing	The University of Dalhousie Canada is currently conducting a study to assess the impact of legislative frameworks on immunization, particularly in the context of establishment and governance of national immunization technical advisory groups (NITAGs). Preliminary results were presented at Decade of Vaccines (DoV) Working Group meeting in Aug 2018 and at the meeting of the Global NITAG Network in December 2018. Additional analysis is ongoing. Sabin Vaccine Institute conducted a landscape analysis of immunization legislation in the European region and developed case studies. Potential follow up studies to assess the impact of the legislation in select countries is under discussion.
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, but one member resigned. The terms of reference were split into 6 and a member was assigned as a lead each. Several teleconferences have been held, nine members participated in the “Data Partners Meeting” organized by EPI/WHO in October 2017 and the first face-to-face meeting took place in July 2018 (sharable report is available upon request). The Working Group explored coordination with other WHO programmes collecting subnational data. The Working Group will report to SAGE in April 2019.

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Decade of vaccines/GVAP	The SAGE working group should continuously review the Progress on GVAP and 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 2018 was published online and is available at: http://www.who.int/immunization/global_vaccine_action_plan/en/ This year the SAGE DoV WG will be overseeing the development of the overall GVAP review and lessons learnt. A highlevel interim lessons learnt item will be presented at SAGE in April 2019 (after the post 2020 Global immunization strategy development multistakeholder meeting in March 2019). The full GVAP report report will be prepared for the October 2019 SAGE meeting. The GVAP review will replace the formal annual GVAP secretariat report and SAGE assessment report.
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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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 2018 WHO coordinated the procurement of DAT among different procurement agencies and partners. DAT was supplied to Yemen, Bangladesh, Indonesia, Venezuela and Haiti. Around 20,000 vials have been deployed between WHO, PAHO and MSF. DAT-WG is now looking for solutions to establish either procurement mechanism to make agreement in advance or a stockpile to meet the urgent or unexpected demand during outbreaks. WHO is now evaluating the quality of the available DAT 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 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	Completed	The English version of the new surveillance standards was released in September 2018; the French version was released in December 2018. The WHO/UNICEF Joint Reporting Form (JRF) was modified for 2019 requesting age and vaccination status of diphtheria cases to assist SAGE in future decisions.
Ebola	SAGE reiterated that WHO should support the national regulatory authorities of countries endemic for ebola virus disease (EVD) to reach consensus on pathways for the evaluation and marketing authorization of candidate EVD vaccines.	Oct 2018	Ongoing	Work is ongoing within WHO in order to ensure continous support to national regulatory authorities and to reach consensus on pathways for new candidate vaccines.

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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. In October 2018, SAGE discussed a review of data submitted by developers of candidate vaccines and of published data.
Full public health value of vaccines	SAGE requests update on progress and implementation of the concept, and on a more public health related terminology.	Apr 2018	Ongoing	On the recommendation of SAGE, the term value proposition has been removed and the new terminology for the concept is the 'Full public health value of vaccines (FPHVV)'. Efforts to socialize the concept are continuing, and the PFHVV was discussed at the 2018 PDVAC meeting. Efforts and collaborations to develop components of FPHVVs are underway for Herpes Simplex Virus, Group B strep and Group A strep vaccines.

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Hepatitis A	Long-term protection from single or 2-dose schedules should be regularly monitored by countries and reviewed by SAGE.	Apr 2012	Ongoing	Post-market surveillance continues in Argentina and a detailed report on the recent epidemiological situation was provided to WHO in 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. 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. Currently, a study is ongoing to assess the immunological response after ten years of vaccination. Results are anticipated by the end of 2019.
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 August 2018, one Hepatitis B vaccine manufacturer, LG Chem, has obtained licensure approval from the Korean Ministry of Food and Drug Safety for their Hepatitis B vaccine product, Euvax B Injectable vaccine (single dose, thimerosal containing 0.5ml presentation) to be stored up to 37°C for 28 days and up to 45°C for 4 days. The latter parameters are compatible with Controlled Temperature Chain (CTC) requirements, however this product has yet to be WHO Pre-qualified. In November 2018, LG Chem informed WHO PQT of their decision to withdraw their request for pre-qualification and not proceed with a CTC label variation. The main reason for the latter concerned the low potency preferred by the manufacturer which was not meeting the approval of PQT. A second manufacturer, Biological E. Ltd, is actively testing its birth-dose Hepatitis B vaccine with a view to seeking a label variation for licensed and WHO Pre-qualified use in a 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.

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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 Jan 2015 the African Regional Office (AFRO), and in Mar 2015 WPRO, held Hepatitis B birth dose consultations to improve birth dose coverage. In February 2015, an AFRO workshop on birth dose introduction was conducted in Brazzaville; this workshop included guidance on birth dose monitoring. An assessment of birth dose implementation has taken place in Sao Tome Principe in July 2015 and Nigeria in September 2015 and in the Gambia in December 2015. Senegal held a Hepatitis B birth dose training workshop in Dec and introduced birth dose in 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.
Hexavalent IPV-based combination vaccines PQ and supply	Track progress on Hexavalent IPV-based combination vaccines prequalification and supply	Oct 2017	Ongoing	This work is ongoing through the Gavi market shaping team who is leading on collecting information on hexavalent supply as well as communication with manufacturers on potential future demand. Gavi is launching a market shaping roadmap with partners on Hexavalent vaccine.
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 responses are starting. Several other approaches are being tested in translational research. WHO IVR organized a consultation on HIV vaccine development in 2018 to discuss the status of HIV vaccine research and the need for the global health community to prepare for the outcome of ongoing efficacy trials in highly endemic countries. A meeting report is submitted for publication. Partner discussions are ongoing to update WHO recommendations on research priorities.
HPV	SAGE urged that a globally more equitable distribution of the available HPV doses be encouraged to ensure optimal global public health access to vaccines.	Oct 2018	Ongoing	A workplan for the assessment of options to achieve more equitable allocation of HPV vaccine under supply constraints is currently ongoing.

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HPV	The secretariat is developing a pathway, milestones and indicators towards that goal that will require careful consideration of the role of HPV vaccination, besides screening and care components. To guide WHO on this, it was agreed that a SAGE working group would be needed, with an initial reporting back to SAGE in October 2018. SAGE should consider new data in terms of cost-effectiveness, defining long- and interim- goals, identifying indicators for the elimination strategy as related to vaccination.	Jun 2018	Ongoing	SAGE established a Working Group in 2018. In October 2018, SAGE reviewed the latest evidence on the immunogenicity, efficacy and effectiveness of HPV vaccines, their administration schedules, number of doses and intervals, and use in HIV-infected and in male populations. SAGE also reviewed the results of 3 models showing the impact and effectiveness of various HPV vaccination and screening strategies, and the potential for cervical cancer elimination. SAGE also expressed concern about the constrained HPV vaccination supply forecast until at least 2024. Work is being done by the SAGE Working Group to assess options for more equitable distribution of HPV vaccines.
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/ The Working Group deliberations are ongoing in 2019.
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	In Q1 2018, UNICEF issued an update on IPV supply which provides the current understnading of IPV supply. this is available upon request. UNICEF does not anticipate a market with multiple suppliers and sufficient supply capacity to fully meet programmatic requirements of at least 2 doses of IPV to materialize before 2023.

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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. 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. Selected countries were Romania, Swaziland, Jordan and Philippines. AAlso, 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. With the development of Gavi 5.0 strategy and development of post GVAP strategy, WHO and partner are exploring opportunities of complementary, coordinated approach to support access to vaccines in MICs.

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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	Preparations continued at global, regional and country levels towards start of pilot malaria vaccine implementation in Ghana, Malawi, Kenya, expected in Q1 – Q2 2019. The national EPI Programmes have intensified stakeholder engagement activities and finalization of information/communication materials for health workers and communities. The first national Training of Trainers for regional health officials was held in Ghana – marking the start of a series of trainings for sub-national officers and health workers. Risk communications plans for global and local handling of potential vaccine safety issues, and key information products for community, national and global stakeholders were finalized, and crisis management trainings for stakeholders were conducted in Ghana and Malawi. An update was provided to MPAC in October 2018 and included a report from the long-term follow-up study (MAL-076) conducted in a subset of the phase 3 trial sites. MPAC was pleased to note that children living in areas with moderate to high perennial malaria transmission who receive three or four doses of RTS,S appear to benefit for at least seven years after vaccination and do not have an excess risk of clinical or severe malaria. The results were found to provide further reassurance that the period of rebound in immunized children was limited and to reinforce the safety profile of the vaccine. As suggested by MPAC and SAGE, a working group for the development of the Framework for Policy Decision on RTS,S has been constituted (including 2 SAGE members) and met for the second time in December 2018. The proposed Framework will be presented to SAGE and MPAC in their upcoming meetings. A progress update was also provided to RITAG on 15 January 2019.
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. SAGE requested WHO to follow-up with a broad based consultation on vaccination of pregnant and lactating women.	Apr 2015	Ongoing	WHO's Initiative for Vaccine Research (IVR) is in the process of producing many implementation research tools and guidance regarding: 1) Service delivery of Maternal Tetanus Immunization and Antenatal Care in collaboration with the WHO Maternal Child and Adolescent Department ; 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 (all influenza risk groups); 5) field guide for the evaluation of influenza vaccine effectiveness and influenza programme evaluation tool (all influenza risk groups); and 6) implementation guidance document for HWs (guidance for pregnant women is available), and 7) literature review and multicenter study assessing of vaccine confidence/hesitancy in pregnant women and/or health care workers. IVR is collaborating with several research and public health groups to pilot some of these tools in low and middle income countries.
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	Completed	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.
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 vaccine(MR) / micro-array patch (MAP) Working Group (WG) was set up and has had five conference calls. A face to face consultation with the MR-MAP WG, vaccine manufacturers, MAP developers and other stakeholders took place in April 2018 and the outcomes and recommendations will be shared with SAGE (report to be published in Q1 2019). The MR-MAP Target Product Profile (TPP) has been posted for public consultation until end of Jan 2019 and will be finalized shortly thereafter. A background paper on the applicability of MAPs to LMICs has been submitted to Vaccine (currently under review).
Measles	SAGE requested feedback on the utility of the M&R immunity gap guidance.	Oct 2018	Ongoing	Assessments are ongoing and feedback to SAGE will be provided as soon as available.

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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 and again additional findings discussed in July 2018. The results of this work were presented to the IVAR-AC. IVIR_AC have created a sub working group that would continue to review the modelling work and provide feedback to the whole of the IVIR-AC. Additional work is needed to validate the models and revise the recommendations. This work is ongoing and will be presented to SAGE in October 2019.
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 prioritize research areas in order to increase interest of donors to fund and of research institutions to carry out the needed research
Measles rubella investment case	SAGE requests update on measles rubella investment case as per recommendations from April 2018 meeting	Apr 2018	Ongoing	The work on the measles and rubella investment case is ongoing. The draft concept paper of the feasibility of measles and rubella eradication (which includes the investment case) was presented at the October 2018 SAGE. IVIR-AC raised a number of concerns with the model, therefore alternatives are being pursued in order to complete this work for presentation at the October 2019 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 surveillance and outbreak investigations in country.
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/. Eleven 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, 8 countries have launched their introduction at the age of 9 months (n= 6 countries: Sudan, July 2016; Mali, February 2017; Central African Republic, June 2017; Chad, July 2017; Niger, October 2017; Cote d'Ivoire, August 2018); or at the age of 18 months (n= 1 country: Ghana, November 2016); or at the age of 15 months (n= 1 country: Burkina Faso, March 2017), respectively. The remaining three countries intend to do so in 2019 (The Gambia, Nigeria) and in 2020 (Togo). Another 2 countries (Guinea and Guinea Bissau) have applied to Gavi through its new country engagement framework for an introduction in 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 January and May 2019, except for 4 countries located in the east end of the meningitis belt who intend to wait for the availability of affordable multivalent vaccines to consider an introduction into their routine programme while enhancing surveillance in the meantime. Further, one additional country has conducted its initial mass vaccination campaign in 2018 (Burundi) while Kenya has planned to do so in Q1-2019 and Eritrea in Q2-2019.
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	This important item has been highlighted again in the 2018 GVAP assessment report. The approach to address this item is currently being discussed by SAGE secretariat in liaison with IVB senior management.

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Missed opportunities for vaccination (MOV)	WHO should discuss and develop guidelines on how to reduce missed opportunities to vaccinate.	Oct 2014	Ongoing	During the April 2016 SAGE meeting, SAGE members were 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. Based on pilot MOV assessments conducted in Chad and Malawi in 2015 (PLOS ONE, 2019) and Kenya in 2016 (manuscripts in preparation), WHO published a set of updated MOV guidance documents and field tools in Q3-2017. These include: a planning guide and the assessment methodology (including the MOV protocol, sample questionnaires and generic field tools). The intervention guidebook is currently under review and will be published in Q1-2019. WHO launched a MOV web page which contains links to all the available materials for easy access to countries and is regularly updated with country experiences, MOV related documents and publications. Having strengthened the capacity of AFRO to implement the MOV strategy (MOV assessments completed in: Chad, Malawi, Burkina Faso (led by partner AMP), Kenya, DRC, Nigeria, Mozambique (led by partner VillageReach), Zimbabwe and Uganda), collaboration is ongoing with SEARO (MOV assessment completed in Timor Leste 2016), EMRO (MOV assessment completed in Jordan (led by partner UNICEF) in 2017) and WPRO (MOV lite model completed in Cambodia (in collaboration with CDC) in 2017). Since March 2016, a network of partners engaged in MOV has been established 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 sixth partner coordination call took place in September, 2018. WHO priorities include supporting countries to implement and monitor actions to reduce MOV; evaluate and document the impact of these interventions on coverage and timeliness; and continue building capacity in regions and countries to support additional assessments and MOV reduction strategies. To date, WHO has provided support to AMP in Burkina Faso to implement MOV activities in 2018/2019 and are supporting a consultant in Malawi to assist the country office and MoH with MOV activities in 2018/2019. Through monitoring and evaluation, the impact of post-MOV assessment country intervention action plans will be assessed and reported back to SAGE at a future date. In December 2018 WHO published a resource guide on integration named "Working together: An integration resource guide for planning and strengthening immunization services throughout the life course". This document brings together a range of resources to provide an overview of the global policies, potential interventions and strategies related to the integration of immunization services. It also provides guidance and country examples on the integration of immunization with additional health interventions throughout the life course.
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	Despite the rejection by the Gavi PPC of the proposal submitted to it to request for financial assistance to support the production and availability of compact pre-filled autodestructive device (cPAD) to increase access to the Tetanus Toxoid vaccine in remote parts of some selected countries, the use of the devises and costs were clearly included in the investment case and highlights presented to donors at the Nov 2018 recent conference in NY. BD indicated some interest in funding Uniject procurement for some of the countries. The initiative will continue to follow up with this and other donors for funds to support financing of the devise in the most difficult-to-reach parts of countries. WHO/HQ will continue to advocate with partners and donors to fund the procurement of cPAD for use to deliver TTCV in remote and hard-to-reach areas during SIAs.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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 maternal and neonatal tetanus elimination (MNTE) investment case that focuses on the remaining countries yet to attain elimination (14 at the moment) has been completed and both online and hard copies disseminated to all levels. The investment case highlights the areas of resources' need, and is being used for resource mobilization, especially from partners and donors as well as domestically mobilized resources. In addition, WHO/HQ is working closely with UNICEF/HQ to ensure that country tetanus toxoid (TT) supplemental immunization activities (SIAs) plans submitted are timely and adequately funded. Country SIAs plans were recently received from Central Africa Republic, Guinee, Nigeria and South Sudan to conduct rounds of TT SIAs in 2019. Disbursement of funds by UNICEF/HQ has been done for Guinee, Nigeria and South Sudan, while plan for Central African Republic is being reviewed.
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	WHO/HQ working closely with with the US CDC/Atlanta to integrate tetanus immunity assessment into the ongoing HIV serosurvey in some high-risk districts in Nigeria and in the Lymphatic Filariasis (LF) serosurvey in Cambodia. WHO/HQ is facilitating the collaboration work between CDC Offices and coutnry offices in Nigeria and Cambodia for the integration of the two aspects of serosurveys.
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	As part of efforts to generate and sustain political commitments to sustaining elimination, a regional workshop was conducted in Aug 2018 for 19 countries in the African region including those that have already eliminated maternal and neonatal tetanus (MNT), to develop their sustainability plan. Similar workshops will be conducted in other regions in 2019, immediately aftet the Global maternal and neonatal tetanus elimination (MNTE) sustainability guideline is finalized and disseminated to countries. Post-validation surveys, which were commenced in 2018 will continue in priority countries in 2019, as part of efforts to sustain MNTE. 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 MNTE status. Update on the status of implementation of the AFR RITAG recommendations were presented at the annual meeting of the AFR RITAG in January 2019. Official announcement of MNT elimination in Kenya was made in a high profile event involving key country stakeholder with wide media coverage. A joint WHO/UNICEF HQ assessment and planning mission to Papua New Guinea discussed MNTE progress and challenges in that country. Participants were updated on the status of MNTE in the Central & West Africa RWG meeting in March 2019. The WHO guidelines on sustaining MNTE was finalized and access link pasted on WHO website. Several countries have developed or are in the process of developing their MNTE sustainability plans, which will be mostly funded through domestic resources.
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	The investment case for the 14 countries that are yet to eliminate has been finalized, online link and hard copies shared with stakeholders. Highlights were presented to MNTE donors during a Donor conference in Nov 2018 in New York. Work is ongoing for the investment case for the countries that have eliminated, as there is the need to incorporate findings from the post-validation missions that were conducted in Algeria, Timor Leste, Cameroon and Djibouti during 2018.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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 was published in February 2019 (Traicoff et al. Developing standardized competencies to strengthen immunization systems and workforce). A new menu option has been created on WHO website called 'Workforce' which will host all related document in this area of work including the framework document of staff functions and competencies.
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 third Global NITAG Network (GNN) meeting was successfully held from the 6th to 7th of December 2018 in Ottawa, Canada. The meeting was attended by 35 NITAG country representatives (NITAG Chair, member or secretariat) from a total of 26 countries. The next meeting is scheduled in October 2019/February 2020 in Atlanta and will be hosted by the US-CDC. The simplified evaluation tool and the training material package are being reviewed following the pilot testing in several countries. The NITAG Resource Center will be revamped in 2019.
Non-specific effects of vaccines	SAGE requested to be updated on the finalization of statement and publication on non-specific effects (NSE) of vaccines as well as finalization of study protocols.	Oct 2018	Ongoing	Feedback received from the public consultation on the protocols has been collated. A meeting to discuss and finalize the protocols is envisaged in 2019.
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 that will be published in February 2019. We have launched activities to analyze available pneumococcal and meningitis surveillance data and a systematic literature review to describe known outbreaks. This and disease modeling will be used to devise a strategy for responding to pneumococcal outbreaks, since the existing data is sparse. This was discussed at the ICG meeting and African meningitis meeting in Q3 2018. We plan continued work in this area in 2019.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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	Phase I of GAPIII (Preparations for containment of poliovirus type 2 (PV2)): As of September 2018, countries have been informed that the 'Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses' is available and that Global Commission for Certification of Poliomyelitis Eradication (GCC) recommended its implementation by April 2019. Phase II of GAPIII (PV2 containment period): 27 countries reported the intention to retain PV2 materials (WPV2 or OPV2/Sabin2) in 79 designated poliovirus-essential facilities (PEFs).Surveys of facilities retaining type 2 infectious materials are complete. Surveys of facilities that may retain type 2 potentially infectious materials are ongoing. 24 of these countries have nominated a national authority for containment (NAC). Lately, Three designated facilities (one in Sweden, one in South Africa and one in Indonesia) have currently been recognized by their NACs and the GCC as suitable candidates to become PEFs and have been issued certificates of participation (CPs).
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	Documentation and dissemination of lessons learned from polio eradication is one of the three objectives of transition planning. Through different initiatives (e.g. GPEI History Project,Johns Hopkins Curriculum Project, Multimedia Project, documentation of polio lessons-learned at the country level) contributions of frontline workers involved in polio eradication efforts are being captured. These projects involve 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.
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 joined the Polio Eradication Department. South Africa and Indonesia have submitted to the Global Commission for Certification of Poliomyelitis Eradication (GCC) the second and third certificate of participation (CP) in the containment certification activities. WHA adopted resolution WHA71.16 on containment in May 2018. A meeting between the Chairs of national authorities for containment (NACs) and GCC Containment Working Group (CWG) members to discuss progress, gaps and needs with containment certification activities is planned at WHO in October 2018.
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 are an integral part of the polio transition planning exercise at the country level, providing guidance and 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, Regional Immunization Technical Advisory Group recommendations, discussions at the Regional Committees). In addition, the “Strategic Action Plan on Polio Transition”, which was presented to the World Health Assembly in May 2018 was prepared with substantive input from AFRO, EMRO and SEARO. The Strategic Action Plan focuses on functions that need to be sustained to keep the world polio-free, to strengthen immunization and to strengthen outbreak preparedness, detection and response capacity and 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 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). In China, WHO supports sIPV manufacturers to carry out clinical trials with fsIPV for in-label use.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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). SAGE also requested reconsideration of terminology from fractional IPV to intradermal; explore if PEF safety monitoring can be linked to IH regulation (April 2018)	Oct 2016	Ongoing	IPV supply has improved in Q3 2018 and all countries now have sufficient supply of IPV for routine immunization. Pre-qualification of Tropis jet needle-free injector was achieved in June 2018 and is now available for use in the polio program. First IPV campaign was carried out using Tropis in Karachi in February 2019. Discussions on change of terminology of fractional dose and IH procedures are ongoing.
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	The 'Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses' (PIM Guidance) has been finalized and published on the GPEI website in April 2018. PIM Guidance implementation workshops have already been organized in 3 Regions, and action is already being taken to ensure the collection of facility data and compilation of national progress reports on preparations for poliovirus containment and completion of Phase I of GAPIII.
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 February 2019 Polio Working Group meeting, will be provided during the April 2019 SAGE meeting.
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 the previous update, the PPCs for new tuberculosis and Group A streptococcus vaccines have been finalized and published on the PDVAC website. The PPC for Herpes Simplex Virus vaccine, and the first target product profile for a product in combination with a new delivery technology (MR vaccine with microarray patch) is near finalization.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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	The Regulation and other health Technologies (RHT) aims to strengthen regulatory preparedness for public health emergencies through: • Strengthening of regulatory procedures for risk-based evaluations during public health emergencies (PHEs) • Reinforcing RHTs capacity to support regulatory preparedness for PHEs • Assist countries in adapting their regulatory requirements for PHEs and using networks for expedited assessments during PHEs The scope and activities for WHO regulatory work includes support for WHO's R&D Blueprint, development of technical guidelines and standards, Regulatory Systems Strengthening, Emergency Use Assessment and Listing (EUAL), Safety monitoring and ensuring communication and coordination with different stakeholders. RHT has mapped regulatory provisions for emergency clinical trial and marketing authorization in 40 countries In November 2017, RHT organised a tabletop exercise on regulatory preparedness in a simulated emergency setting. Several activities under the norms and standards have been implemented/planned as follows: • Publication of the Guidelines on the quality, safety and efficacy of Ebola vaccines endorsed by ECBS in May 2018 and implementation workshop is planned in 2019. • Discussion of the Guidelines of Nucleic acid based vaccines of importance for priority pathogens for PHE during the ECBS meeting October 2018. • A meeting of collaborative centers networks of vaccines for standardization of priority pathogens. Following Ebola outbreaks in DRC, RHT convened a meeting with regulators of the AVAREF in June 2018 to review and discuss key regulatory considerations to facilitate implementation of EUAL for Ebola vaccine. additional work is still ongoing. Regarding the Emergency Use Assessment and Listing (EUAL) procedure, the WHO Prequalification Team took note of recommendations made during a public consultation in May 2017 and also by SAGE and initiated revision of the EUAL. The main principles of the revision includes: • a pre-emergency phase to concentrate most of the assessment activities and allow a rapid decision when the emergency is declared and a post deployment monitoring phase • Involvement of NRAs responsible for oversight of the products and NRAs of potentially affected countries at different stages of the procedure The document was published in the WHO website for comments and disseminated to several stakeholders.Comments are under collection and will be published Q1 2019. WHO has continued working with CEPI, which support product development and CT phases 1 and 2 for vaccines for emerging pathogens, with as priorities Lassa fever, MERS and Nipah. WHO ensures liaison with CEPI via a Biostandard and Assay Working Group co-chaired by WHO and CEPI and via specific Task Forces for the 3 prioritized diseases. This work addresses in particular the need to coordinate between different donors and partners. CEPI funding should accelerate the development of reference standards and reference materials for vaccines in a two-stage approach with intern standards with fast-track development paving the way to the future adoption of WHO official standards. CEPI will also support a better coordination of the collection of clinical samples for emerging diseases, which should facilitate the development of products and standards

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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	WHO and NIBSC have been working on the plan for dissemination of the outcomes of the ECBS deliberations since the ECBS 2017 meeting. Workshops/ consultations on typhoid conjugate vaccines and RSV vaccines have been organized to explain the relevance of recently adopted WHO standards to the broader immunization community in 2018 and 2019. Publication of the articles on these topics as well as on a broader range of vaccine standards in relevant journals for immunization community is planned in 2019 and 2020.
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	The Essential Medicines and Health Products (EMP) department is holding an informal consultation of experts on “Guidelines on the quality, safety and efficacy of human Respiratory Syncytial Virus vaccines” in September 2018, which should lead to published guidelines for manufacturers by the end of the year. The EMP department has created a standard for a microneutralization assay, and is currently working on standardization assays for RSV antibodies. A Phase 3 trial of the Novavax RSV F protein 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. In contrast, Novavax announced that a planned informational analysis in December 2017 of a Phase 3 trial in late 2nd/early 3rd trimester pregnant women, using the same vaccine, was favorable, supporting trial continuation, with a planned interim analysis in Q1 2019, which could be the final analysis depending on the results. Other candidate RSV vaccines including pre-fusion F protein vaccines, gene-based vector vaccines and live, attenuated vaccines are in phase I and II clinical trials. Regarding long-acting mAbs, one product (MEDI8897) will complete phase IIb trial in late 2018, planning to undertake a phase III study in normal term infants in 2019. The WHO prequalification (PQ) department has begun a pilot for PQ of similar biotherapeutic products for the anticancer mAbs, rituximab and trastuzumab, as the test cases for PQ of mAbs for LMICs; the results of which could lead to a pathway for PQ of RSV mAbs in the future. 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. With funding support from the Gates foundation, WHO is supporting systematic reviews, impact modelling, and an expert consultation on evaluation of the long-term impact of early RSV infection on subsequent wheeze/asthma, with the objective of contributing to policy-related decisions regarding RSV vaccines/mAbs.
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	Completed	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 have also been developed, in collaboration with UNICEF. The guidance document “Establishing and strengthening immunization in the second year of life: Practices for vaccination beyond infancy” has been published and is available online in English, French and Portuguese (http://www.who.int/immunization/documents/WHO_IVB_ISBN9789241513678/en/) and a companion implementation handbook will be published in January 2019. WHO and UNICEF are moving ahead to finalize 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.

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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	In December 2017, WHO published the 'Operational framework for the deployment of the WHO Smallpox Vaccine Emergency Stockpile (SVES) in response to a smallpox event.' This document lays out the considerations and processes needed for countries to request vaccine in the event of a smallpox outbreak. It also describes the processes by which donors can deploy vaccine to the WHO SVES, and WHO can deploy vaccine to requesting countries. WHO continues discussion with countries for their donation and replenishment of the stockpile. The Regulation and other health Technologies RHT is developing mechanisms to ensure timely deployment in countries of smallpox vaccines through development of a procedure that provides acceptable assurance of the quality, safety and efficacy of smallpox vaccines, providing technical assistance to WHO member states in building capacities for the import, registration and emergency use of smallpox vaccine and developing the capacity in member states to monitor, oversee, the safety of the vaccines for emergency use. A procedure for assessment of smallpox vaccine was developed as well as a safety monitoring guidelines. The Pre-Emergency phase of the revised EUL, will be considered for the assessment of smallpox vaccine. WHO is also mapping regulatory provisions for emergency use of medical countermeasures.
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	Review of the evidence for characterization of BCG strains for vaccine production is being conducted and will be reported in 2019.
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. A total of 134 countries now report the existence of a NITAG and 98 report a NITAG meeting six functionality process criteria – a 20% increase over 2016. These figures are included in the global report on a yearly basis. NITAG side meetings are organized back to back to SAGE meetings.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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 through 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. A report on ‘Addressing the global shortage of, and access to, medicines and vaccines’ was presented to the 71st World Health Assembly in May 2018.2 As a result, WHO was requested to develop a roadmap to outline the programming of WHO’s work on access to medicines and vaccines, including activities, actions and deliverables for the period 2019-2023. Efforts on addressing supply shortages will be part of the post GVAP strategy. 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. MI4A undertook its first market study on global availability of HPV vaccines to inform the WHO Call for Action on Elimination of Cervical Cancer. The second study focused on Meningococcal meningitis vaccines with the public summary to be available on the MI4A page by February. The study focuses on short term analysis of demand and supply and an update on long term forecast will be developed later in 2019, in line with the development of the Defeating Meningitis disease control strategy. In 2019 two additional global studies will be conducted – with decision on vaccines selected later in Q1.

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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 2018, 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 and 2018. 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 (Global Pediatric Diarrhea Surveillance). 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 used in one Region (AMRO/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. Indicator was reported for DTP3, MCV2 and PCV3 in February 2018 and is part of the indicator database. https://unstats.un.org/sdgs/indicators/database

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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 vaccine expert working group, with further advise from PDVAC, continues to progress its activities on new TB vaccines development. Major new developments have been recently noted in the field. M72/AS01E a GSK adjuvanted protein vaccine candidate in phase IIb evaluation in Southern Africa, being tested for prevention of pulmonary TB. Two doses of M72/AS01E administered one month apart to HIV-negative adults showing evidence of latent Mycobacterium tuberculosis infection, provided 54% protection (90% CI, 13.9 to 75.4; 95% CI, 2.9 to 78.2; P = 0.04) against pulmonary TB, over approximately two years of follow-up. The study, still blinded at an individual level, showed no concerning imbalance in the occurrence of serious adverse events, with more local and flu-like general reactogenicity, including some grade 3 reactions reported in the vaccinated group. This result constitutes a major progress and provides an unprecedented opportunity to advance the field of TB vaccine towards potential public health impact. WHO is engaging leading stakeholders aiming to define the best pathway forward for accelerated availability of an effective, affordable, new TB vaccine for public health impact. H4/IC31 is an adjuvanted recombinant protein under development by Sanofi Pasteur, SSI and Aeras. A Phase II prevention of infection study in adolescents (Phase II) showed no significant protection against infection induced by H4/IC31. In the same trial, a secondary analysis showed indication that BCG revaccination induced moderate protection against sustained infection. Possible next steps following this observation are being discussed. The Gates foundation has shown interest to fund follow-up research to further understand the significance of this result. 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. Upon PDVAC recommendation, WHO has developed guidance on preferred product characteristics for TB vaccines. The document is now publically available through the WHO IVR website: http://www.who.int/immunization/research/development/tuberculosis/en/.
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	A range of new and updated tools are being developed on the topic of strategic communications, service quality and health worker capacity, and new documentation on 'Tailoring Immunization Programmes'TIP. All will be published on a soon to be expanded version of the WHO vaccine hesitancy web page.

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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	Following a thorough review of sampling methodologies; 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, WHO published, in 2018, its "Vaccination Coverage Cluster Survey Reference Manual", see http://www.who.int/immunization/documents/who_ivb_18.09/en/. A tool named "Vaccination Coverage Quality Indicators (VCQI)" – a 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 – was developed in 2016-2017 and is being expanded to include additional analysis. VCQI allows conducting analysis not only from surveys done using WHO Vaccination Coverage Cluster Surveys, but also from existing survey databases, such as DHS and MICS. Going forward, WHO envisions providing this tool VCQI for others to code it in R and other statistical packages. Other survey support material, like model questionnaires, model protocols, reports, etc, as well as practical "how to" guides have been developed; one practical with a focus on post campaign surveys is underway. Another important survey-related activity was, in 2018, the development of a White Paper to standardize and support the generation of immunization-related survey indicators, along with model questionnaires. Several capacity building activities around vaccination coverage surveys have been conducted since 2015. These have included briefings with all regions (but EUR) and selected countries, and trainings for regional focal points, consultants, statisticians and immunization program officers. The largest initiative to develop capacities on the new WHO survey recommendations was the design and successful implementation of the Survey Scholar distance-learning initiative, using an approach that is based on evidence-based adult-learning methodologies for distance learning. The distance-based portion of this training initiative, Modules A was conducted in 2017. Survey Scholar participants, from almost 50 countries, were engaged. In mid-2018, a repeat of module A3, on survey analysis and interpretation was conducted. The French version of the distance-based Survey Scholar, Module A1 on planning a survey, was done in Q4 2018 and the material for the rest of the training is being adapted to francophone Africa, for running modules A2 and A3 in 2019. A community of Survey Scholar Alumni has been created and, in partnership with Gavi, activities to further develop survey consultants are underway. Finally, in collaboration with countries and partners, a research agenda related to surveys was developed and published, see: https://www.ncbi.nlm.nih.gov/pubmed/30041880 and efforts are undergoing to start supporting that research. All WHO survey related-materials are available here: http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/index2.html

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Vaccine coverage	SAGE recommended that WHO support new research for biological specimen collection including rapid on-site diagnostics that could improve coverage and susceptibility estimates. Improved serological surveillance techniques could be integrated with existing population-based surveys such as DHS or MICS. These research topics should be included on the QUIVER (now IVIR-AC) agenda.	Nov 2011	Ongoing	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 (India, Uganda, Malaysia) with further two countries being planned for 2019 (Cameroon and Ghana) to determine the operational feasibility of using POCT/OF in a field setting. 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.
Vaccine coverage	WHO to identify appropriate methods and develop guidelines for collecting, analysing, and interpreting biomarkers for validating coverage.	Nov 2011	Ongoing	Currently, WHO is finalizing global guidelines on conducting serosurvey studies on measles and rubella to identify immunity gaps in the population. An expert working group has been assembled, based on the expertise in the various fields of each of the members needed to conduct such studies, including statisticians, epidemiologists, laboratory experts, and program experts, given sub-tasks in developing parts of these guidelines that pertain to their respective expertise. It was tested subsequently in pilot studies in two different settings (post campaign/post outbreak in Mongolia, and at elimination in Bhutan). The data collection part of a pilot study has been conducted in Mongolia in 2016 and in Bhutan 2017; this latter study was an integrated study alongside hepatitis B/C. Based on the field work, the working draft guidelines are being adjusted, amended and corrected where needed. Also, give several advances in field of diagnostics mainly, the current draft is being finalized and is to be rolled out as a tool to evaluate the immune status of the target or targeted population.
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. At the March 2018 IVIR-AC meeting a proposal was presented for a WHO Guidance document on the standardization of delivery costing of vaccines to facilitate comparison of delivery costs across vaccines and to improve the quality of these costing tools/studies. Currently a Typhoid Costing Tool is under development to help countries to plan and costs the roll out of TC vaccines. At the March 2019 IVIR-AC meeting, IVIR-AC will continue to discuss research to minimize barriers and improve coverage of vaccines currently in use.

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Vaccine Hesitancy	SAGE acknowledged the necessity to develop core capacities at headquarters and regional level for gaining behavioural insights that can be applied in an integrated fashion for prevention of many communicable and non-communicable diseases, as well as vaccine hesitancy. This will require the involvement of sociologists, psychologists, anthropologists, experts in social marketing, communication experts, and specific disease and vaccine experts.	Oct 2014	Ongoing	A range of activities are now ongoing in this area. There is now 1FTE at WHO HQ focused on this area, and a number of initiatives are now scaling up, both in terms of guidance being published on the WHO Vaccine Hesitancy web page, as well as jointly coordinated initiatives with UNICEF and CDC. 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.
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 have been conducted (results pending), and fractional dose studyies in infants have been launched (both Africa). Immunogenicity study in DRC is on track, and 1 month immunogenicity data have been published, 1 year data to follow soon (already presented at WHO meetings). In June 2018, Martins et al. published 8 year follow-up immunogencity data from a YF vaccine dose finding study in military personal, with very encouraging results. Fractional dose was extensively used during 2018 campaigns in Brazil, which will allow to gather more data on programmatic aspects and safety.