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 The “Meeting Date” column displays the date of the SAGE meeting during which the recommendation was originally made.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 HQ is working closely with regional offices to obtain subnational level data. Surveillance data for measles and rubella as well as for new vaccines is collected on district level on regular basic and there are efforts to collect sub-national level coverage data. Currently this is happening in AFR on monthly as well as annual basis; and in SEAR and EUR on, it is done on annual basis. In October 2016, at the Global monitoring meeting 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. We are exploring ways to analyse and visualise the data.
General	SAGE recommended strengthening national vaccination programs, integrating health services and strengthening health systems to promote universal health coverage.	Apr 2013	Completed	A teleconference was held on May 13 2013 with J. Abramson, P. Figueroa, and N. Arora and EPI (M. Zaffran and T. Goodman) to discuss the issue and provide briefing on the integration activities that historically and presently Expanded Programme on Immunization (EPI) is working on. Subsequently, in early June a draft typology was produced and shared that summarizes this area of work. The topic was discussed at the Apr 2014 SAGE meeting. SAGE concluded that addressing integration, by its very nature, requires a broader discussion beyond SAGE. In this regard, it was proposed that the SAGE working group on the Decade of Vaccines (DoV) consider options for moving forward, as integration is reflected as both a guiding principle and a strategic objective of the Global Vaccine Action Plan (GVAP). The Department secured funding at the end of 2014 to establish a position dedicated to the issue of integration. Recruitment has been completed and the recruited staff started in Oct 2015. At the Apr 2016 SAGE meeting, session on 'Implementation in the context of health system strengthening (HSS) and universal health coverage' was held. It was proposed that improvement of immunization services within the broader health services should be a third dimension of vaccine programmes alongside safety and effectiveness.
General	SAGE 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 that started in that direction.

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General	SAGE requested that a paper be developed, highlighting the circumstances under which off-label use of any vaccine can be recommended, while clarifying the differences between regulatory decisions and public health recommendations. Legal and programmatic implications of off-label recommendations and the need for clear communication should be considered.	Apr 2012	Ongoing	Advice was sought from the Expert Committee on Biological Standardization (ECBS), and added to the agenda of meeting on 15-19 Oct 2012. SAGE had previously requested a paper that highlights the circumstances in which off-label use of any vaccine could be recommended, while clarifying the differences between regulatory decisions and public health recommendations. During the Nov 2012 SAGE meeting, SAGE further requested ECBS to prepare guidance for national regulatory authorities on studies needed to support evidence-based, off-label use of vaccines which would benefit public health. It was noted that for regulators, product specific data are paramount. SAGE requested that an additional document to be prepared to advise the national immunization technical advisory committees about the type of data that might support a policy recommendation to use a vaccine outside its licensed schedule in order to achieve public health benefits such as operational simplicity or cost savings. Guidelines on procedures and data requirements for changes to approved vaccines were adopted by ECBS in Oct 2014 (TRS 993, annex 4). Preliminary consultations took place around the 2015 ECBS meeting for specific guidance on Labelling information of inactivated flu vaccines for use in pregnant women. This document was prepared, taken through public consultation, finalized and adopted by ECBS in Oct 2016. The document can be found here: http://www.who.int/biologicals/expert_committee/Label_after_ECBS_HK_28_Oct_2016.clean.pdf?ua=1 A paper clarifying the differences between regulatory decisions and public health recommendations was commissioned. Unfortunately, there were delays in finalization of the publication but the paper has finally been published in Vaccine and is available online with open access www.sciencedirect.com/science/article/pii/S0264410X17302694 .
AEFI reporting	SAGE urged that efforts be pursued to enhance Adverse Events Following Immunization (AEFI) reporting worldwide.	Apr 2016	Ongoing	With Gavi support, 30 African countries have established work plans. A first analysis of the new Global Vaccine Action Plan (GVAP) indicator for Adverse events following immunization (AEFI) monitoring has identified 84 member states that meet the recommended level of at least 10 AEFI cases reported per 100,000 surviving infants per year. A manuscript is currently submitted that describes the AEFI reporting ratio through Joint Reporting Form (JRF).
AEFI reporting	SAGE commented on the passive surveillance data from the Uppsala Monitoring Centre (UMC) and raised concerns that the safety signal detection was not undergoing appropriate peer review. SAGE concurred with GACVS on the need to increase collaboration and to implement a strong review process.	Apr 2016	Ongoing	The Global Advisory Committee on Vaccine Safety (GACVS) concluded that signals documented by the Uppsala Monitoring Centre (UMC) provide useful information in monitoring the safety of vaccines from worldwide sources. It was proposed that a strengthened process of collaboration with UMC would allow use of the expertise on vaccine safety available within the GACVS and partner agencies for the review of this information before it is communicated to the network of pharmacovigilance centres and to vaccine manufacturers. This review should take into account the limitations of signal detection methods along with the reviews performed routinely by the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA), given their extensive experience and access to more complete information with the Individual Case Safety Reports (ICSRs) they receive and that may not all be shared with UMC. The GACVS Secretariat will liaise with UMC to identify mechanisms for such collaboration. UMC revised its signal assessment guideline in April 2015. In March 2016, UMC was recommended to establish a review group for the vaccine signals. So far this has not happened though and new signals are being generated. The WHO Essential Medicines and Health Products (EMP) Department is currently examining the issue. During a recent visit to Uppsala, a reply from UMC Director was requested by the WHO Safety and Vigilance team.

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Decade of vaccines/GVAP	SAGE recommended that the 2016 GVAP assessment report be presented at the World Economic Forum in Davos where the Decade of Vaccines was launched.	Oct 2015	Closed-not implemented	The recommendation made at the Oct 2015 SAGE meeting arrived too late to be included to the Davos 2016 agenda. Therefore, it has been agreed upon with Decade of Vaccines (DoV) partner agencies to include at World Economic Forum in Davos in Jan 2017. It will allow us to share the 2016 mid-term SAGE assessment report and also to be able to include some inputs from both SAGE recommendations on MNTE and Measles-Rubella Elimination revised strategies (to be presented to SAGE in Oct 2016). This topic has been discussed with the Bill & Melinda Gates Foundation (BMGF) in June during which a principle agreement has been reached. A concept note detailing the objectives, message and format of a possible Davos session were developed by WHO to engage the discussion but it was finally decided by WHO and the BMGF not to have the event. Focus is rather on the organization of a DoV leadership meeting in Apr 2017 which is in active preparations through discussions between the 5 lead agencies.
Decade of vaccines/GVAP	The SAGE working group should continuously review the need for reformulation of the indicators or mechanisms for collection and reporting of data.	Nov 2012	Ongoing	The SAGE Decade of Vaccines (DoV) Working Group (WG) continues to review the need for reformulation of the indicators and mechanisms for data collection. In 2016 the WG has specifically discussed safety and demand side indicators as well as discussed indicators to be used as part of the Sustainable Develeopement Goals (SDGs). The SAGE report of progress with the Global Vaccine Action Plan (GVAP) for 2016 i.e. the midterm progress report was published online and is available at: http://www.who.int/immunization/global_vaccine_action_plan/en/ This report was tabled at the Executive Board in Jan 2017 together with a draft GVAP resolution sponsored by Australia, Brazil and Colombia. A teleconference of the SAGE WG took place on 27 Mar 2017 with specific focus on the selection of the SDGs indicator for Immunization (3.8), on discussing data quality and on selecting priority countries for the 2017 GVAP Secretariat report. The SAGE DoV WG will meet from 29-31 August for the yearly revision of progress in the implementation of GVAP for the year 2016.
Diphtheria	SAGE expressed its deep concern over the reported lack of diphtheria antitoxin and encouraged WHO to take on a strong leadership role in resolving this shortage globally.	Oct 2016	Ongoing	A session will be held at the upcoming April 2017 SAGE meeting which will tackle the issue of diphtheria antitoxin supply shortages.
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 will take 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 is available. The emerging data and draft recommendations were discussed during the face to face meeting of the WG which took place Mar 2017. The WG will present to SAGE in Apr 2017.

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Hepatitis A	Long-term protection from single or 2-dose schedules should be regularly monitored by countries and reviewed by SAGE.	Apr 2012	Ongoing	Post-market surveillance continues in Argentina and a detailed report on the recent epidemiological situation was provided to WHO in Mar 2017. In 2014, in the context of a localized outbreak in a border area, 8 potential breakthrough cases were identified. For 5 of them there is uncertainty about the vaccination status and/or conditions (cold chain) in which vaccination was administered. Seven of these cases are in the 5-9 age group (distributed throughout the period) and one in the 1-4 age group. This resulted in an enhanced vigilance in the country. As exemplified by the outbreak in San Martin, the risk persists in the population. 73% of of hepatitis A virus (HAV) acute infection cases reported occurred in individuals over >10 years. All cases reported occurred in unvaccinated individuals. After now 11 years of follow-up, there is currently still no evidence of waning immunity and the outbreak experienced in 2014 was compatible with very high vaccine effectiveness. Hepatitis A cases have remained low in 2014, 2015, and 2016. Although a reduction in hepatitis A rates was experienced in all age groups, there is an increasing proportion of the remaining cases occurring in persons > 14 years of age in the post vaccination period. Most of these represent non-vaccinated adolescents or adults that escaped HAV-infection in previous outbreaks. Both Colombia and Paraguay also introduced a single dose national immunization schedule for 1 year old children. Yearly review of the Argentinian surveillance data will continue as Argentina was the front runner country to introduce a 1 dose schedule with the inactivated vaccine. A third phase immunogenicity study is ongoing in Argentina, to assess long term protective antibodies in children more than 9 years following single dose vaccination. The results of the phase 2 study conducted in 2013 with a median post-vaccination interval of 7.7 years were quite reassuring with a prevalence of protective antibodies of 97.4% (95% CI: 96.3-98.3) still protected. More recent analysis (phase 3) indicates that the prevalence of protective antibodies in children > 9 years following a single dose of hepatitis A vaccine was still 87.6% but a decrease was observed in all centers with decreased GMCs. It is still unclear if different samples or differences in methodology or recall bias in seronegative individuals could actually account for the difference, but this requires continued follow up. For the time being epidemiologic surveillance continues to show very low infection rates in all regions and age groups with sporadic cases occurring mainly in frontier regions and non-vaccinated adolescents.
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	To date, WHO has not received any application from hepatitis B vaccine manufacturers to support the label change of prequalified hepatitis B vaccine.

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Hepatitis B	SAGE recommended that the timely delivery of a birth dose of hepatitis B vaccine (that is, within 24 hours of birth) should be used as a performance measure for all immunization programmes. Reporting and monitoring systems should be strengthened to improve the quality of data on the birth dose.	Apr 2009	Ongoing	A new indicator for Hepatitis B birth dose has been added to the WHO /UNICEF Joint Reporting Form (JRF) 2017 - this new indicator will allow the distinction between timely (24 hours) and late birth dose administration. In Nov 2016, AFRO held consultation on hepatitis B control and included discussing barriers, actions and support needed towards hepatitis B birth dose introduction. This was part of joint meeting held with viral hepatitis counterparts. A consultation on implementation of a new universal birth dose recommendation was conducted in Dec 2010 with special focus on countries with a high percentage of home births. Outputs include a monograph documenting the systematic review and best practices from the consultation. Immunization Practices Advisory Committee (IPAC) reviewed this work in early 2011 and again in Apr 2012, and endorsed the 2013 publication of 'Practices to Improve Coverage of the Hepatitis B birth dose vaccine.' From this, work is ongoing to develop field guidelines for scaling up Hepatitis B birth dose. The JRF and associated materials have been revised to improve reporting of birth dose with a particular focus in Western Pacific Regional Office (WPRO). The WHO/UNICEF estimate process was piloted in 2012 in WPRO and was applied globally for the first time to the 2013 JRF birth dose data. Analysis of timely birth dose data for 2008 shows no significant changes from 2006 analysis and the major issue is lack of data quality. A study of the cost of scaling up the birth dose by country has been completed, based upon previously published methodology estimating the cost of implementing the Global Immunization Vision and Strategy (GIVS) goals. In 2012, WPRO convened Expanded Program on Immunization (EPI) and Maternal and Child Health (MCH) managers from the five priority countries to jointly propose actions towards improving birth dose uptake. In Jan 2015 the African Regional Office (AFRO), and in Mar 2015 WPRO, held Hepatitis B birth dose consultations to improve birth dose coverage. In Feb 2015, An AFRO workshop on birth dose introduction was conducted in Brazzaville; this workshop included guidance on birth dose monitoring. An assessment of birth dose implementation has taken place in Sao Tome Principe in July 2015 and Nigeria in September 2015 and in the Gambia in Dec 2015. Senegal held a Hepatitis B birth dose training workshop in Dec and introduced birth dose in Jan 2016. Guidance for hepatitis B birth dose introduction was published on June 2016 ('Preventing Perinatal Hepatitis B Virus Transmission: A Guide for Introducing Hepatitis B Birth Dose Vaccination', available from: http://www.who.int/immunization/documents/general/ISBN9789241509831/en/ in English, French and Spanish. An Arabic version is under development). The guidance includes a chapter on reporting and monitoring birth dose vaccination. In July 2016, a proposal to revise WHO/UNICEF JRF report on birth dose was submitted (suggesting to report late and timely birth dose globally).

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Hepatitis B	All regions and associated countries should develop goals for hepatitis B control appropriate to their epidemiologic situations. Serologic surveys of hepatitis B surface antigen (HBsAg) prevalence, representative of the target population, will serve as the primary tool to measure the impact of immunization and achievement of the control goals.	Nov 2008	Ongoing	As of Jan 2017, all regions have had the regional committees (RCs) on immunization endorse hepatitis b control goals, except for the South East Asian Regional Office (SEARO) which as noted below had a 2016 ITAG recommendation to establish a goal. Regional goals slightly differ in target dates, threshold prevalence and specific ages in which to measure prevalence - but are largely similar nonetheless. In Sept 2016, the European Regional Office (EURO) held a consultation to discuss establishing a regional verification mechanism. In June 2016, the SEARO's ITAG recommended to establish a Regional control goal of less than or equal to 1% HBsAg sero prevalence by 2020 among children aged 5 years. In August 2015, an HQ mission took place to discuss HepB control targets. In August 2016, the The African Regional Office (AFRO) Regional Committee discussed adopting a viral hepatitis strategy in line with the Global Health Sector Strategy (GHHS) for viral hepatitis which includes a hepatitis B control target in-line (although more ambitious) with the target endorsed as part of the immunization strategy at the 2014 RC meeting. In 2014, the AFRO RC meeting adopted resolution to reduce Hep B infection to <2% among children under 5 years of age by 2020 and adopted hepatitis B activities as part of the RVAP that was also endorsed at the same RC meeting. The Eastern Mediterranean Region (EMR) has a RC goal of reducing childhood hepatitis B prevalence to <1% among children <5 years by 2015. Its regional office, EMRO is working with Member States to ensure achievement of this goal. The Western Pacific Region (WPR) established a RC goal to reduce hepatitis B infection to <1% among children at least 5 years of age by 2017. The EURO will consider a regional hepatitis B control goal as proposed by ETAGE. The Pan American Health Organization (PAHO) has resolved to eliminate hepatitis B virus transmission and is formulating a regional strategy. Documenting the "Impact of Hepatitis B Immunization: best practices for conducting a serosurvey" (WHO/IVB/11.08) was published in 2011 by the department of Immunization, Vaccines and Biologicals. In 2012, WHO HQ has published a framework for global action to control viral hepatitis (http://www.who.int/csr/disease/hepatitis/Framework/en/index.html). The 2016 WHO Executive Board approved a global health sector strategy on viral hepatitis 2016-2021 that proposes an impact target of less than 1% HBsAg prevalence among children by 2020 and 0.1% by 2030.
HIV	SAGE requested regular updates on the progress of HIV-vaccine research.	Apr 2010	Ongoing	The recent start of a phase 2b efficacy trial in South Africa constitutes an important progress in the HIV vaccine research and development area, building on the promising results from the RV144 Phase 3 trial in Thailand (which showed 31 % protection against new HIV infection during the 3.5 years after vaccination, 60 % during the first year), and favorable results from a preparatory study in South Africa. The vaccination regimen in the upcoming HVTN 702 trial in South Africa will, like RV144, be based on a canarypox-based vaccine called ALVAC-HIV and a bivalent gp120 protein subunit vaccine, but will also include a new adjuvant, target HIV subtype C and include the addition of booster doses. Other live-attenuated candidate vaccine constructs are under evaluation in early clinical development. Finally there are major, and promising, vaccine science initiatives underway to attempt to induce broadly neutralising antibodies through re-engineered antigens. These have a longer time frame, but raise the prospect of cross-clade protection. WHO IVR is considering the value of organizing a consultation on preparation for success, downstream access and use.

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Immunization schedules	SAGE requested a critical appraisal of alternative schedules for pneumococcal conjugate vaccine, rotavirus vaccine and Hib vaccine in 2011.	Nov 2010	Ongoing	The funding grant from Bill & Melinda Gates Foundation (BMGF) for schedules-related work to inform SAGE discussions on immunization schedules is now over. All delays in regard to this work were due to the Ebola outbreak and the R&D Blueprint on staff responsibilities. - Pneumococcal Conjugate Vaccine (PCV): evidence was reviewed by SAGE in November 2011. A new position paper was published in 2012. - Rotavirus: evidence was reviewed by an ad-hoc group of experts in February 2012 and presented to SAGE in April 2012. An updated vaccine position paper was published in February 2013. A new review of evidence is ongoing. - Haemophilus influenzae type b (Hib): The issue was revised during the April SAGE 2013 meeting. A new position paper was issued. - Pertussis: evidence was reviewed by SAGE in 2015. A new position paper was issued. - Hepatitis B: evidence was reviewed by SAGE in Oct 2016. A new position paper is expected in 2017. - HPV: evidence was reviewed by SAGE in in Oct 2016. A new position paper is expected in April 2017. - TT vaccine: evidence was reviewed by SAGE in Oct 2016. A new position paper is expected in 2017. February 2017 - Diphtheria: evidence will reviewed by SAGE in Apr 2017. A new position paper is expected in 2017. A consultation to develop analytic tools to support countries with the selection and/or adjustment of vaccine schedules in different epidemiological and operational scenarios took place in December 2016.
Immunization schedules	SAGE requested that IVIR-AC assess optimal immunization schedules based on both direct and indirect effects and not only direct effects.	Oct 2015	Ongoing	As part of any vaccine impact evaluation, IVIR-AC reviews and encourages studies of optimal schedules on both direct and indirect effects. Study projects and meetings have been held and are planned on HPV, Hep B vaccines, rotavirus vaccines among others.
Implementation	SAGE recommended that WHO promote further progress in the arena of implementation more actively, and that a preparatory team continue the dialogue and develop a more targeted agenda.	Apr 2016	Ongoing	WHO is currently implementing multiple World Health Assembly (WHA) resolutions that mandate integration of disease-specific programs, using a Health Systems Strengthening (HSS) framework. This aims to seek universal immunization coverage as part of Universal health coverage (UHC). Within the Gavi sphere, the Alliance has committed to having HSS be the framework for each country, under which all Gavi grants will be managed as a single investment. This is captured in the new Country Engagement Framework, which WHO Health Systems and Innovation (HIS)/Health Sys Governance, Policy & Aid Effectiveness (HGS) has assisted the Gavi Alliance Partners and Gavi Secretariat in developing.

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Implementation	SAGE recommended the formation of an implementation group that had a broad array of expertise in this area.	Apr 2015	Closed	In April 2015, SAGE stressed the importance of applying the rigour and science in implementation programme design and evaluation of delivery of vaccines, in order to maximize the impact of current and future vaccines and delivery technologies. SAGE had further elaborated the above in a two page concept note. This document was then discussed within WHO. It was proposed and agreed upon by SAGE that instead of forming a SAGE working group, the Department of Immunization, Vaccines and Biologicals would first work with the Department of Health Systems Governance and Financing, which is involved with health systems strengthening (HSS), and the Department of Service Delivery and Safety group to organize a session on Implementation in the context of health system strengthening and universal health coverage at the April 2016 SAGE meeting. This session was successfully held. SAGE noted the advancements in knowledge in the field of HSS, which should support the attainment of immunization goals in a sustainable manner. The need to embed health systems thinking in every initiative and action, without losing goals so far attained, was appreciated by SAGE as a way forward. SAGE emphasized the importance of ensuring the visibility of immunization goals in planning HSS efforts. A system to generate data for evidence-based decision-making, with a focus on implementation research, is a route to achieving this. It was proposed that implementation research take up specific challenges that lead to strengthening of health systems. Improvement of immunization services within the broader health services should be a third dimension of vaccine programmes alongside safety and effectiveness, and this will need appropriate long term funding. SAGE recommended that WHO more actively promote further progress in this arena and that a preparatory team continue the dialogue and develop a more targeted agenda. For the time being it was concluded that no SAGE working group would be established, but that SAGE would be kept informed of meaningful developments.
Implementation research	The implementation research agenda should define equity beyond traditional economic money metrics such as social economic status gradients, to include other measures of inequity such as the multidimensional poverty index or impacts on marginalized populations. SAGE suggested that studies to examine the integration of immunization with other health interventions should be included in the implementation research agenda.	Nov 2013	Ongoing	This recommendation is now part of the new Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) agenda under research to minimize barriers and improve coverage of vaccines currently in use. Since 2014 research topics on the non-specific effects of vaccines, missed opportunities and community vaccine acceptance have been part of the agenda of IVIR-AC.
Implementation Research	SAGE outlined some considerations for IVIR-AC to include in their deliberations – assessment of the use of high quality randomized controlled trials where feasible (noting the substantial ethical and methodological challenges involved), with sufficient power to explore sex differences, and a priori defined and standardized immunological endpoints designed to answer the specific question of non-specific effects– and emphasized that future research should draw on a broad investigator pool and from a wide range of geographic locations using a standardized protocol.	Apr 2014	Ongoing	During the Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) June 2015 meeting, IVIR-AC endorsed the designing of one or more protocols to assess the prospective non-specific effects (NSE) of immunization on mortality. The work of the WHO Secretariat needs to be completed in preparing the protocols for the questions identified and trials outlined during the ad-hoc expert consultation of Feb 2016. These generic protocols would enable harmonized implementation of the trials across multiple settings. While further development of all the proposed trial designs is important, IVIR-AC recognizes that full evaluation necessitates a complete protocol. IVIR-AC will help inform decisions on feasibility and the selection of designs, and formulate questions. At the Feb 2017 meeting IVIR-AC reviewed the final proposals for 2 trial designs suggested by the ad-hoc Working Group on NSE. It will be presented at the SAGE Apr 2017 meeting as part of the briefing of IVIR-AC by chair Rob Breiman.

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Implementation Research	SAGE identified the conditions necessary for pertussis resurgence and the effective strategies for prevention of resurgence as important topics for modelling research.	Apr 2014	Ongoing	The June 2015 meeting of the Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) meeting agreed on the plan for phase 1 of the comparison of pertussis models from Australia, England & Wales and the United States of America, which is meant to be a rapid assessment on the relative contributions of vaccine formulations, waning immunity, vaccine coverage and schedule to the observed pertussis resurgence in these countries. If successful, phase 2 offers further opportunities to test whether existing models are sufficiently robust to changes in factors such as demographics, spatial heterogeneity, immunity and contact matrices across multiple settings. In many countries using aP vaccine in the national immunization programme, aP vaccine is used in the private sector which represents a variable proportion of infant immunizations, so these complexities will need to be reflected when the models are extended to low and middle income settings. Phase 1 has been implemented and preparations are under development for Phase 2 and implementation will depend on funds being made available. Pertussis surveillance and laboratory capacity are still extremely poor in LMICs (particularly in Africa), and beyond the scope of the model comparison exercise to address. The committee noted that data are expected to be forthcoming through ongoing studies and follow-on analysis of maternal influenza trials, and strongly endorses the identification or further opportunities to add pertussis markers (primarily PCR on respiratory specimens) to studies such as Gavi– or the BMGF– supported vaccine impact studies. There were concerns that the opportunistic process by which the 3 models were identified may not have included all relevant parameters or modelling approaches. The feasibility of taking into account other models and parameters identified through a literature review and/or open call should be assessed, focusing on the main results of the different models for phase 1, and if they are interested to include them in phase 2. The work under Phase 1 has recently been completed by the modelers and will be shared with SAGE Chair soon for further follow up. Meanwhile the WHO burden of pertussis disease estimates have been updated by the WHO secretariat in collaboration with Hong Kong University. The global pertussis estimates for age under 5 will be published soon in Lancet Infectious Diseases.
Integration	WHO should discuss and develop guidelines on how to fully integrate vaccination (GVAP) into the operation of all aspects of the health-care system and to reduce missed opportunities to vaccinate.	Oct 2014	Ongoing	During the April 2016 SAGE meeting, SAGE members were successfully updated on the ongoing work in AFRO, PAHO and SEARO on using the missed opportunities for vaccination (MOV) strategy to facilitate the integration of immunization with other health services. Following the SAGE session, WHO has received multiple requests from countries for technical assistance to implement the MOV strategy in additional countries. Based on the two MOV assessments conducted in Chad and Malawi in 2015 (draft manuscripts prepared for peer reviewed journal submission), the package of methodology materials will be finalized/published by Q2-2017. These include: a planning guide, the assessment methodology (including the MOV protocol, sample questionnaires and generic field guides) and an intervention guidebook. In the meantime, WHO has launched a web page with the DRAFT guidelines for easy access. Having strengthened the capacity of AFRO to implement MOV assessments (in Chad, Malawi and Kenya; planning phases for DRC, Nigeria, and Mauritania), collaboration is now ongoing with SEARO where MOV assessments have been completed in Timor Leste (interventions are ongoing) and are being planned and supported in Cambodia (WPRO, in collaboration with CDC). To establish a network of partners engaged in MOV, an informal coordination meeting was established in March 2016 to provide regular briefing 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 third partner coordination call took place on January 26, 2017, to elicit opportunities to collaborate on upcoming country activities. WHO contracted one of the partners (AMP) to lead the assessment in Burkina Faso. WHO is planning a partner training on the MOV methodology for Q2-2017, to enable more rapid scale up of impact.

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IVIR-AC	IVIR-AC should seek linkages with the WHO Alliance for Health Policy and Health Systems Research as they might be useful in priority setting and discussions.	Oct 2014	Ongoing	The Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) secretariat have had initial discussions with WHO staff of the Alliance for Health Policy and Health Systems Research (HPSHR) to update on the IVIR-AC deliberations in September 2014. Discussions for concrete steps for their involvement in vaccine implementation research are ongoing. The WHO Alliance for HPHSR will have a seat in the WHO Secretariat of the IVIR-AC. In addition, Initiative for Vaccine Research (IVR) was involved in a call for proposals issued by the WHO Alliance with financial support from Gavi and UNICEF on implementation research studies in low and middle income countries (LMICs) in 2015. Seven proposals have been selected for funding and being implemented with a one year timeline until 2016. A new funding proposal is being prepared for 2016-2017 with support from Gavi and UNICEF. New projects have been granted and a workshop on implementation research protocol development took place in August 2016.
IVIR-AC	SAGE noted that a sub-group of IVIR-AC members and external subject experts should make recommendations on the types of prospective studies to assess the non-specific effects of vaccines.	Oct 2014	Ongoing	An ad-hoc consultation on clinical trials for non-specific effects of vaccines (NSE) was held on 16–17 February 2016. Eighteen experts (including 3 IVIR-AC members) contributed to this consultation, whose main objectives were to reach a consensus on priority trial questions and to propose trial designs for each of the priority questions. Protocol synopses for the six different trials that the experts proposed were prepared for review and discussion at June 2016's IVIR-AC meeting. At the February 2017 meeting IVIR-AC reviewed the final proposals for 2 trial designs suggested by the ad-hoc working group on NSE. It will be presented at the SAGE April 2017 meeting as part of the briefing of IVIR-AC by the chair, Rob Breiman.
Japanese encephalitis	Guidance is needed on how to approach Japanese encephalitis (JE) vaccine impact assessments. This guidance should address surveillance data sources and analysis to measure JE vaccine impact, design of surveillance and special studies for impact measurement, JE laboratory diagnostics, and data collection and analysis for observational studies to measure vaccine effectiveness	Apr 2015	Closed	The guidance document is now available on WHO website: 'WHO guide to measuring effectiveness and impact of Japanese encephalitis vaccination' (available at http://www.who.int/immunization/diseases/japanese_encephalitis/JE_effectiveness.pdf).

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Lower middle-income countries: sustainable adoption and financing for new vaccines	SAGE requested that WHO facilitate the establishment of a partnership among all relevant stakeholders to consider: pooled procurement; tiered pricing; greater transparency of pricing; and exploring the role that UNICEF, the Pan American Health Organization and foundations can have in assisting these countries with procuring and financing vaccines.	Nov 2010	Ongoing	WHO set up a Middle Income Countries (MIC) Task Force in June 2014 with main immunization stakeholders (WHO, UNICEF, World Bank, Gavi Secretariat, BMGF, AMP, Sabin, Task Force for Global Health), which led to the creation of the "MIC strategy", presented at SAGE in April 2015. The strategy aims at improving sustainability of immunization programmes and access to vaccines in non-Gavi MICs. The MIC strategy is based on four pillars : i) Strengthening evidence-based decision-making; ii) Enhancing political commitment and ensuring financial sustainability of immunization programmes; iii) Enhancing demand for and equitable delivery of immunization services; and iv) Improving access to timely and affordable supply. The timeline for the strategy is up to 2020 to align with the GVAP timeframe and up to 2025 for a longer term horizon. In the longer term, the MIC strategy could provide a platform to ensure sustainability of Gavi's investments in fully self-financing countries. Following SAGE endorsement of the MIC Strategy in Apr 2015, the WHO-led MIC Task Force initiated a country engagement process: in collaboration with key immunization partners WHO started multi-partner dialogues with four countries struggling with raising or maintaining high immunization coverage and/or introducing new vaccines. With each of these countries, the MIC Task Force has identified obstacles to achieving and sustaining the immunization system performance and potential solutions to reaching GVAP targets through plans of action. The MIC Task Force selected four countries for the MIC strategy implementation based on potential for impact (birth cohort, coverage of traditional vaccines, status of new vaccines introduction) and feasibility of engagement. Selected countries are Romania, Swaziland, Jordan and Philippines. Countries are at different stages of implementation of their plan of actions. Also, some efforts to support all MIC countries in the area of access to timely and affordable supply have been implemented. Notably, the creation of a mechanism for access to supply in humanitarian emergencies in MICs not supported by Gavi; set up of a peer platform and regional workshop to strengthen country procurement capacity; work on price transparency continues successfully with 70% of world (n. of countries and birth cohort) sharing vaccine product, price and procurement information since the beginning of WHO price transparency efforts. 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. As it close, the MIC TF made the following recommendations: 1- The TF expressed important concerns regarding funding for implementation of the MIC Strategy and called for fundraising efforts by its member organisations or other appropriate coalition of partners. For these purposes it proposed continued awareness raising on the MIC issue through: A- Development of an advocacy tool to be developed starting from technical background documents prepared for the SAGE April 2015 meeting. A time limited and informal Steering Committee of some TF members (WHO, UNICEF, TFGH and other as interested) could be set up to follow work by external consultants. B- Regular monitoring & reporting on MIC progress against GVAP as well as monitoring of implemented activities against intended activities under the MIC strategy (dashboard). 2-The TF agreed on the importance to ensure completion of pending tasks and enhance smooth transitioning as the TF sunsets. 3- 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.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Malaria Vaccine	SAGE requested continued review of the planning of the pilot implementations and to receive regular updates on the results.	Oct 2015	Ongoing	In November 2016, the Global Fund to Fight AIDS, Tuberculosis and Malaria approved US$ 15 million from its catalytic funds for the malaria vaccine pilots. Together with previous funding commitments made by Gavi, the Vaccine Alliance (up to $27.5 million, matching other sources 1 to 1) and UNITAID ($9.6 million), a total of $49.2 million has now been pledged for the first four years of the Programme (2017-2020). These commitments enable the Programme to start. Initial visits by a joint delegation from WHO, PATH and GSK to each of the 3 shortlisted countries took place in October-November 2016. The proposed Malaria Vaccine Implementation Programme was discussed with senior representatives from the Ministry of health, including the National Malaria Control Programme, the Expanded Programme on Immunization, regulatory authorities, research organizations and partners. The visits confirmed continued interest and suitability to participate in the programme for all three countries. Kenya, Malawi and Ghana have been formally notified of their selection in February 2017. A public announcement of the country selection will be made in the coming weeks. SAGE members are requested not to reveal the country names until publication of the WHO press release. Intensive preparation activities have now started with the aim to introduce the RTS,S malaria vaccine in pilot areas in 2018. The national regulatory agencies of the 3 countries have been convened under African Vaccine Regulatory Forum (AVAREF) on 18-19 February 2017 to explore a potential joint regulatory review and shared or collaborative oversight mechanisms for RTS,S use in the pilots.
Maternal immunization	SAGE recommended that WHO endorse the importance and ethical imperative of clinical trials in pregnant women for potentially life-saving interventions such as RSV vaccine (and future vaccines against other targets currently in development, such as group B streptococcal disease).	Apr 2016	Ongoing	WHO is promoting vaccine trials be conducted in pregnant women. Updated TRS guidance for vaccines includes a section on trials in pregnant women. WHO Draft Preferred Product Characteristics for Next Generation Influenza Vaccines includes advocacy for clinical trials in pregnant women. Also, IVR has supported two efforts evaluating the ethics of maternal immunization: 1) Beeler JA, Lambach P, Fulton TR, Narayanan D, Ortiz JR, Omer SB. A systematic review of ethical issues in vaccine studies involving pregnant women. Hum Vaccin Immunother. 2016 May 31:1-8. [Epub ahead of print] PubMed PMID: 7246403, and 2) Verweij M, Lambach P, Ortiz JR, Reis A. Maternal Immunisation: Ethical Issues. In press at Lancet Infectious Diseases. Both publications advocate for the ethical imperative of clinical trials in pregnant women.
Maternal Immunization	SAGE encouraged the Regional Office for the Americas to document the successful regional experience of delivering influenza vaccine to pregnant women.	Apr 2015	Ongoing	Regarding the Regional Office for the Americas/Pan-American (PAHO)/WHO's documentation of the successful regional experience of delivering influenza vaccines to pregnant women, PAHO has progressed significantly: - We have submitted a manuscript describing influenza uptake in the Latin America and Caribbean Region since the pandemic, highlighting the improvements in targeting pregnant women for vaccination in 29 countries. - During 2015 PAHO conducted, a survey among 14 Latin American countries (LAC) countries that aimed at describing the process from vaccine introduction decision, to implementation among pregnant women. It also tackled obstacles and enabled vaccine promotion and uptake. - In order to complement this survey, we are planning another in-depth survey to develop case-studies with key countries that have acquired a lot of experience in maternal immunization. As part of these case-studies, countries will share lessons learned. - During 2016, PAHO collaborated with the Ministry of Health of Nicaragua to document factors associated with their successful expansion of influenza vaccination among pregnant women in Nicaragua in 2013. Findings from this experience were published in Vaccine in Feb 2016. - PAHO convened a multi-disciplinary, inter-institutional working group to develop a field guide for maternal immunization which is in its finalization phase. This field guide targets EPI managers, EPI staff, and other healthcare workers involved in maternal and child health care. Currently the maternal and neonatal immunizationfield guide is in the final round of editing. It will be published in English and Spanish in the course of Mar 2017. - In 2017 PAHO has been stressing, at various meetings held in country and at the regional level, the importance of offering influenza vaccines to pregnant women though routine healthcare services throughout the season, especially in tropical countries where influenza circulation tends to last.

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Maternal Immunization	SAGE concluded that the recommending bodies, including WHO, need to engage in a dialogue with regulators and manufacturers to review current regulatory practices against the evidence on risks and benefits and biological plausibility on product safety. SAGE requested WHO to develop a process and a plan to move this agenda forward in support of an increased alignment of data safety evidence, public health needs and regulatory processes.	Nov 2013	Ongoing	WHO has completed evaluations of product monograph language regarding safety and use during pregnancy, as well as a survey of health care provider's perceptions of the specific product monograph language regarding use in pregnancy. WHO has reviewed various regulatory approaches to labelling of the pregnancy and lactation sections of product inserts and has produced a document titled, "Labelling information of inactivated influenza vaccines for use in pregnant women." The document was reviewed and endorsed by Expert Committee on Biological Standardization (ECBS) in late 2016.
Maternal Immunization	SAGE encouraged WHO to promote more implementation research to generate generalizable data on the best ways to integrate maternal immunization into routine antenatal care in low resource settings	Apr 2015	Ongoing	WHO's Initiative for Vaccine Research (IVR) is in the process of producing many implementation research tools and guidance regarding: 1) assessment of vaccine confidence/hesitancy in pregnant women; 2) maternal influenza immunization program costing tool; 3) guidance document to estimate the influenza economic burden of a country; 4) guidance document to estimate the cost effectiveness of influenza vaccines in a country; 5) field guide for the evaluation of influenza vaccine effectiveness; 6) maternal immunization adverse events following immunization surveillance guidance; and 7) implementation guidance document. IVR is collaborating with the US CDC to pilot some of these tools in low and middle income countries.
Measles	SAGE requested evidence on the need for measles revaccination of HIV-infected adolescents and adults. Further research is needed to monitor the long-term immune responses to measles vaccine in HIV-infected children revaccinated after starting HAART and in HIV-infected children starting HAART prior to receiving their first dose of MCV.	Oct 2015	Ongoing	Compiling the evidence on the need for measles revaccination of HIV-infected adolescents and adults is expected to be completed by July 2017. Professor William Moss at Johns Hopkins University is taking the lead on this work. Research on the long-term immune responses to measles vaccine in HIV-infected children revaccinated after starting HAART needs to be taken up by clinical research groups.
Measles	SAGE supported the development by WHO of a standardized method to categorize countries based on their level of disease control and likelihood of achieving and sustaining measles and rubella elimination, and tailoring immunization and surveillance strategies to the country categorization.	Oct 2016	Ongoing	The categorization is currently being discussed by the Measles and Rubella SAGE Working Group via the monthly teleconferences and the next version will be shared with regions and regional vaccine advisory committees to ensure alignment. The final categorization will be completed and reported on at the October 2017 SAGE meeting.
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 draft updated measles position paper (to be published in 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 and it is expected that they will report on this at the October 2017 SAGE meeting.
Measles	SAGE recommended further clinical, immunological, epidemiological and modelling studies regarding the impact of different measles vaccination schedules.	Oct 2015	Ongoing	The RIVM in the Netherlands (the same group that did the systematic review of use of measles vaccine under 9 months of age) are expected to have the results from their clinical studies of the immune response to an early dose of MMR vaccine in 2017. Modeling work is being done at US CDC to explore the effect of different vaccination schedules on the epidemiology of measles. An update on this work will be provided to the SAGE Measles and Rubella Working Group by end of June 2017.

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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	Pending approval of financial support, a Measles and Rubella/ micro-array patch (MAP) Working Group (WG) will be set up in 2017 to develop a clinical regulatory pathway. The outcomes and recommendations from this WG will be shared with SAGE later this year.
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/. Eight of the 26 meningitis belt countries have received approval from Gavi, the Vaccine Alliance for introduction of the meningococcal A conjugate vaccine into their routine immunization programme, with a single dose at 9, 15 or 18 months of age concomitantly with the administration of the first or second dose of Measles/Rubella vaccine. Among them, 4 countries have launched their introduction at the age of 9 months (Sudan, July 2016 and Mali, Feb 2017); at the age of 18 months (Ghana, November 2016) and at the age of 15 months (Burkina Faso, Mar 2017), respectively. The remaining four countries (Central African Republic, Chad, Niger and Nigeria) intend to do so in 2017. Another 2 countries (The Gambia and Guinea) have applied to Gavi in 2016. Other meningitis belt countries intend to apply for the introduction of the vaccine into their routine programme at the next Gavi application windows in May and Sep 2017.
Middle Income Countries Strategy	SAGE called upon WHO Secretariat to report back on progress in implementation of the Middle Income Strategy.	Apr 2015	Pending	The SAGE Secretariat has proposed reporting to SAGE in writing for the moment through the SAGE issue tracker. See other item in the SAGE tracking sheet on this topic.
MNTE	UNICEF, UNFPA and WHO should work with countries to generate and sustain political commitment to maintaining elimination of MNT, in order to guard against complacency once a country has been declared to have achieved elimination.	Oct 2016	Ongoing	All opportunities including the Regional Immunization Technical Advisory Group (RITAG) meetings and Immunization Managers' meetings are being utilized to advocate for efforts by countries to sustain their Maternal and Neonatal Tetanus Elimination (MNTE) status. MNTE was one of the few topics the African RITAG focused on during its meeting in Dec 2016. Additionally, efforts are being made to finalize the guidelines on sustaining MNTE to ensure that countries are guided through the appropriate steps to take to sustain their achievements.
MNTE	UNICEF, UNFPA, and WHO should urgently develop an MNTE investment case and resource mobilization strategy to secure predictable and timely funding support for the remaining 18 countries, if the 2020 elimination timeline is to be met.	Oct 2016	Ongoing	There is currently a collaborative work by WHO, UNICEF and The United Nations Population Fund (UNFPA) that has led to the establishment of the Terms of Reference for the work on the investment case, and the recruitment of a consultant has been finalized. The target is to complete elimination section of this work by mid year.
MNTE	WHO should re-emphasize the previous recommendations on the number of doses needed in women of reproductive age if SIAs or routine immunization of pregnant women are needed and clarify that pregnant women are protected when they have had 5–6 documented doses (by card, immunization registry and/or history) by the time of reproductive age. Updated WHO recommendations should reinforce the need for booster doses for both males and females throughout the life course, opportunistic catch-up immunization, individual and community education on clean wound care and following standard surgical protocols as per the WHO infection prevention guidelines.	Oct 2016	Completed	Following the recommendations from SAGE in October 2016, the position paper on tetanus vaccines has been revised and updated. This position paper was published in the Weekly Epidemiological Record (WER) on 10 February 2017.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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	This recommendation has not yet progressed much as yet. We have, however, initiated discussions with CDC on the feasibility of combining some of the MNTE validation surveys with serosurvey.
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	Efforts are currently going on to submit a proposal to the Gavi Alliance Policy and Programme Committee to request for financial assistance to support the production and availability of this critical device aimed at markedly increasing access to the Tetanus Toxoid vaccine to very remote parts of some selected countries where currently access is seriously compromised as a result of insecurity, active conflicts and lack of human resources.
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	A stakeholder's meeting was convened at the end of Nov 2016 to follow up on this. Other efforts include the concept note produced to follow up on funding for Tetanus Toxoid Uniject from Gavi, the Vaccine Alliance and the work on the investment case that is anticipated to facilitate resource mobilization to help support countries to implement their elimination activities.
MNTE	WHO should re-emphasize and track adoption of the recommendation that age-appropriate combinations of tetanus and diphtheria toxoids should be used to promote and sustain diphtheria immunity throughout the life course and for both sexes, and should clarify that tetanus antigen combined with low-dose diphtheria antigen (Td) is the preferred programme option for children aged 4 years and older.	Oct 2016	Completed	The WHO position paper on Tetanus vaccine has already been revised to reflect this recommendation on the use of age-appropriate combinations of tetanus and diphtheria toxoids. It was published in the Weekly Epidemiological Record (WER) on 10 Feb 2017. Opportunities are being used during Immunization Managers' meetings to emphasize on this.

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
Multiple injections	SAGE noted the need for further research on multiple injections during the same visit and recommended the following research topics and activities: (i) impact of multiple injections in the same visit on vaccine coverage, disease reduction, vaccine programme success and caregiver and provider experience; (ii) development of a standardized monitoring protocol for acceptance and acceptability by caregivers and providers and for prevalence of adverse events; (iii) development of optimal provider and infant caregiver communication approaches; (iv) optimal multiple injection administration techniques, and (v) development of new technologies, such as intradermal patches and new combination vaccines, which would decrease the number of vaccine injections in a single visit.	Apr 2015	Ongoing	Multiple injection studies have been conducted in collaboration with US CDC in South Africa, Gambia, and Albania, with studies ongoing in the Philippines, Sudan, and Columbia. Studies are primarily designed to evaluate healthcare provider and infant caregiver attitudes and practices regarding administration of multiple injectable vaccines in the same visit, in most cases following the introduction of IPV and PCV. A separate work stream in WHO IVB, in conjunction with WHO EMP and external partners (PATH, AMP), is investigating the development of microarray patch technologies, see respective tracking sheet items.
Pain mitigation	SAGE recommends that WHO: 1) includes pain mitigation recommendations with WHO immunization practice guidance materials; 2) disseminates pain/distress mitigation recommendations through the usual dissemination channels, immunization managers, National Immunization Technical Advisory Group (NITAG) and partner organizations; 3) monitors and evaluates the implementation success of pain mitigation measures; 4) works with industry, ECBS and regulatory agencies to advocate that grading of pain experienced during the vaccine injection be included in data for licensing and in the product monograph.	Apr 2015	Ongoing	Internal discussions have taken place on how to move forward across relevant WHO departments. A brief position paper was drafted based on the SAGE recommendations and published in the Weekly Epidemiological Record on 25 September 2015. This formed the basis for additional proactive communication activities. As example of actions in response to points 1 and 2, WHO ensured that information in WHO guidance on multiple injections and IPV was consistent with the SAGE recommendations on reducing pain, specifically in two documents: Practical considerations for the successful introduction of IPV, and Multiple Injections: Acceptability and Safety, both available on this web page. The PP on reducing pain was also added on the same web page. In relation to the training aspects for IPV introduction, we updated training modules for health workers, also to reflect the recommendations from the latest PP. The Immunization in Practice recently published has in module 5 ‘Managing immunization sessions’, recommendations on vaccine sequence (increasing pain- oral before injection, rota before OPV), positioning the recipient, no aspiration etc. IIP has been distributed to countries and the last edition was also translated into several local languages. Work is also ongoing to ensure appropriate incorporation of pain mitigation in WHO guidance documents when they get updated and to ensure that any recommendation posted on the web at odds with SAGE's guidance be adjusted/removed. The pain mitigation guidance has been included in the NITAG resource center. As a further example of use and integration in WHO documents, reference to the pain mitigation position paper has been made in the recently published updated tetanus position paper. PDVAC will consider pain mitigation within their preferred product characteristics to guide target product profiles and include the topic in their envisage Vaccine special issue on the PDVAC pipeline analyses for 25 pathogens. Steps have been taken and discussions started to also reflect the measurement of pain at time of injection in the updated Guidelines on clinical evaluation of vaccines to be discussed and endorsed by ECBS in October 2016. More specific activities still need to be implemented with respect to points 3 and 4.
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. The SAGE Polio WG and SAGE issued a statement in Mar and made recommendations during the Apr 2016 SAGE meeting regarding IPV supply. This issue was further reviewed during the SAGE Polio Working Group meeting in August 2016 and during a conference call in Dec2016. An update from the meeting, including on discussions with vaccine producers, will be provided during the Apr 2017 SAGE meeting (or earlier if needed).

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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	The 'GAPIII Containment Certification Scheme' (CCS) was endorsed by SAGE in Oct 2016 and published. The Containment Working Group (CWG) was established in Jan 2017 to support the Global Commission for the Certification of Poliomyelitis Eradication in their new global containment oversight role. WHO is now training GAPIII auditors nominated by the national authorities for containment (NACs) to assess poliovirus-essential facilities (PEFs) against the implementation of GAPIII. PEFs are expected to engage in the containment certification process, following CCS. As of Feb 2017, only 15 of 30 countries planning to retain type 2 polioviruses have nominated a national authority for containment.
Polio	SAGE requested the Polio Working Group to evaluate options for catch-up vaccination for cohorts born after 1 May 2016 in countries where IPV introduction will be delayed or regular supply disrupted.	Apr 2016	Completed	The topic was discussed at the SAGE Polio WG in August 2016 and reported to the SAGE in October 2016. SAGE recommended that when sufficient supplies of IPV become available countries with delayed IPV introduction or stock-outs should prepare for catch-up vaccination of children who could not receive IPV in the routine schedule.
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 draft 'Guidance for completion of Phase I of GAPIII' has been circulated for comments.
Polio	SAGE advised GPEI to accelerate implementation of the WHO Global Action Plan for containment (GAPIII) including: a) all countries completing phase I; b) regional focal points closely monitoring country activities and ensuring each country completes its inventories of facilities that hold or handle polioviruses, and destroys or commits to destroying WPV2 by end 2015 and any other type 2 containing materials including Sabin poliovirus by July 2016.	Oct 2015	Ongoing	As of 17 Jan 2017, all 205 countries and territories have completed their reports on the first part of Phase I. 28 countries or territories have reported not retaining any OPV2/Sabin2 materials. The completion of this second part of Phase I will follow the publication of WHO's 'Guidance for the completion of Phase I of GAPIII', pending endorsement by the Containment Advisory Group (CAG). The release of mOPV2 in 6 countries for post-switch outbreak response further delays the completion of Phase I in these areas. Altogether, 30 countries reported the intention to retain PV2 materials (WPV2 or OPV2/Sabin2) in 78 designated poliovirus-essential facilities.
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 NITAGs. The WHO secretariat is advocating the use of fIPV at both regional and country TAGs.
Polio	SAGE noted that the IPV supply situation is further deteriorating. Therefore, the programme should explore the possible use of devices facilitating intradermal administration (e.g. jet injectors, intradermal adapters).	Oct 2016	Ongoing	WHO is working on pre-qualification of both jet injectors and intradermal adapters. In addition, WHO is conducting several pilots of the use of these devices in immunization campaigns (e.g. Karachi, Pakistan).

Topic	Recommendations/Action item	Meeting Date	Status	Comments and Follow up
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	Inter-Cluster Transition Committees have been established in both WHO Regional Office for Africa (AFRO) and WHO Regional Office for the Eastern Mediterranean (EMRO). They are Chaired by the Directors Programme Management of the respective Regions. The Regional Offices are also members of the WHO Global Polio Transition Steering Committee established by the Director-general's Office. Headquarters (HQ) and Regional Colleagues are members of the Global HR Working Group that is planning for the effective and efficient reduction in the Polio Staffing levels in countries, regions and HQ. Guidance on Transition Planning, and Budget Rampdown figures for 2017 - 2019 have been provided to AFRO, EMRO and Regional Office for South-East Asia (SEARO), and the 16 polio priority transition countries by the Global Polio Eradication Initiative (GPEI) through the Transition Management Group (TMG). Financing has also been provided through the TMG to support Consultants, selected by the Regional Offices, who are assisting transition countries in conducting asset mapping, identifying country priorities and needs, and developing transition plans. Both AFRO and EMRO are also involved in the development of a Business case for Immunization in the African continent as a follow-up to the Addis Declaration on Immunization. Polio transition and its consequences will inform this business case.
Polio	The documentation for ‘legacy planning’ should include contributions from communities and front-line health workers on their experiences with the polio programme, what it has meant for them and how lessons learnt could further improve the routine vaccine and health programme.	Apr 2013	Ongoing	Capturing this information is integrated into the country-level transition planning guidelines, and the work of the Transition Management Group of the Global Polio Eradication Initiative is emphasizing the importance of this. All Transition Planning consultants are briefed/ trained on the Transition Guidelines.
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	Malaria Vaccine Preferred Product Characteristics (PPCs) are finalized and available on WHO website: (http://apps.who.int/iris/bitstream/10665/149822/1/WHO_IVB_14.09_eng.pdf). Respiratory Syncytial Virus PPCs are now under development. In addition, 2 Ebola vaccine Target Product Profiles (TPPs) have been developed for reactive and prophylactic use, and these are available from WHO website: (http://www.who.int/immunization/research/target-product-profile/ebolavaccine/en/). The Zika vaccine TPP was updated through a 2nd public consultation, and is available on WHO website since 17 Feb: (http://www.who.int/immunization/research/development/zika/en/index2.html).
Regulatory	SAGE recommended that the further development of the Emergency Use Assessment and Listing procedure being developed by WHO, which would allow use of a vaccine in the context of a Public Health Emergency of International Concern, be done in close consultation with relevant regulatory authorities, including those of the affected countries.	Apr 2015	Ongoing	Regarding the Emergency Use Assessment and Listing (EUAL) procedure, the WHO Prequalification Team took note of SAGE recommendation and further development of the EUAL will consider relevant regulatory authorities including those of impacted countries. Further, a document entitled, “Vaccine evaluation in public health emergencies – review of regulatory pathways in selected countries” was prepared and presented to SAGE working group (WG) on Ebola vaccines in Aug 2015. In Oct 2015, the document was submitted to the Expert Committee on Biological Standardization (ECBS) for review and advice. The Committee considered that a guidance document might be of value to National Regulatory Authorities (NRAs) and other public health organizations. However, it also recognized the complexity of emergency situations, each of which is essentially unique, and that decisions ultimately rest on a benefit/risk assessment. The ECBS reviewed the document's progress in 2016. Evaluation of vaccines for public health emergencies was discussed in the 3rd meeting of the WHO Collaborating Centers Network on Vaccines in Seoul, in July 2016. Lessons learned from the Ebola crisis in West Africa and the Middle East respiratory syndrome coronavirus (MERS-CoV) outbreak in Korea were discussed and several activities of the CC network were proposed. In addition, new initiative called the Coalition for Epidemic Product Innovation (CEPI) was discussed as a framework in which a number of partners will work together to assure better preparedness for public health emergencies in future. The ECBS was also briefed about the CEPI in Oct 2016. In that context, further work on the development of regulatory standards has been undertaken and progress will be reported to the ECBS 2017.

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Reports from other advisory committees on immunization	WHO and NIBSC should develop with other stakeholders, a business plan to assure long-term security of the development of WHO reference preparations as a global public health resource and additional efforts should be undertaken to disseminate outcomes of the committees deliberations and to explain the relevance of its work to the broader immunization community.	Nov 2006	Pending	A network of WHO Collaborating Centres (CC) on the Standardization of Vaccines has been established. At its 3rd meeting, the network agreed to establish a “Core Expert Group (CEG)” to assist the Expert Committee on Biological Standardization (ECBS)to review selected proposals for measurements standards. Proposals for replacement measurement standards are usually straightforward, with few strategic or scientific issues, and they would be the initial focus of the CEG. The ECBS agreed that the CEG could pre-review selected measurement standards in the vaccines area and thus help to streamline the ECBS review process. This process will be piloted in 2017.
Reports from other advisory committees on immunization	SAGE recommended appointment of appropriate programmatic and implementation expertise to IVIR-AC membership including representation of experts from low and middle-income countries.	Nov 2011	Ongoing	Since 2013, Immunization and Vaccines related Implementation Research Advisory Committee (IVIR-AC) includes 2 programmatic and implementation research members from the African Region (AFR) and the South East Asian Region (SEAR). Since 2014, IVIR-AC includes a mathematical modeler/economist from SEAR and a medical anthropologist from AFR. Currently 2 seats are vacant for health economists with experience in vaccine implementation research. Recruitment of new members is ongoing. There was a call for new members in 2015. Three potential candidates were selected to attend the June 2015 meeting. The mathematical modeler was selected to become a member but the two health economists were not selected as they did not meet the expectations. A new call for Committee Members was issued in Q3-Q4/2016. The selection process is still ongoing with another call for nominations issued in Mar 2017, as further members will be rotating off in 2017.
RSV	SAGE asked for preparations to be made to support global policy-making for respiratory syncytial virus (RSV) maternal immunization as well as passive immunization with long-acting mAb. SAGE emphasized the need to link maternal immunization platform strengthening with influenza, tetanus and pertussis vaccines along with preparations for potential country introductions of RSV vaccine.	Apr 2016	Ongoing	Further discussions have been held with the WHO Prequalifications (PQ) team with regard to prequalification processes for both respiratory syncytial virus (RSV) vaccines and monoclonal antibodies (mAbs). The ECBS Guidelines for RSV vaccines are planned for development and possible adoption at Expert Committee on Biological Standardization (ECBS) 2018, as these are a prequisite for consideration for PQ. The Essential Medicines and Health Products (EMP) department is considering an approach to PQ of mAbs. Intensive discussions continue about the most appropriate way to prepare for policy-making in Low and Middle Income Countries (LMICs), without any results yet available for efficacy trials in these settings. A Phase 3 trial of the Novavax RSV F Vaccine in 11,856 older adults (60 years of age and older, enrolled in the USA), did not meet the pre-specified primary or the secondary efficacy objectives, and did not demonstrate vaccine efficacy. Efficacy may differ between elderly and healthy pregnant women target groups. The Novavax Phase 3 trial in late 2nd/early 3rd trimester pregnant women continues with endpoints accruing in neonates and young infants. The RSV vaccine pipeline remains very robust and can be accessed at the IVR Vaccine Pipeline Tracker: http://who.int/immunization/research/clinicaltrials_newvaccinepipeline/en/ (open the page then navigate to the RSV tab of the spreadsheet)
Second year of life (2YL)	A recommendation was made for consideration of a platform for immunization coverage in the 2nd year of life, in view of potential necessary booster doses and opportunities to catch up with incomplete vaccination, and removing the artificial barrier often experienced after the 1st birthday.	Apr 2014	Ongoing	Two country case studies (Zambia, presented to SAGE in April 2016, and Senegal) (WHO, JSI) and a global landscape analysis and literature review (UNICEF) have been conducted; learnings from this have been used to inform the draft global guidance on Establishing and strengthening a healthy child visit in the second year of life (2YL) for immunization and other health interventions. An advanced draft of the guidance document will be shared with and reviewed by the Immunization Practices Advisory Committee (IPAC) in Feb 2017. Country demonstration projects are also ongoing in Ghana and Malawi (CDC) and will continue to inform the global guidance.
Smallpox vaccines	SAGE recommended that WHO initiate discussions with countries in possession of smallpox vaccine to establish mechanisms for replenishment of the WHO stockpile in case of need.	Nov 2013	Ongoing	Discussion with the French Government for the donation of 5 million doses and Japanese Government for 10 000 doses have been put on hold until there will a be a quality advice from the WHO Prequalification (PQ) team whether these vaccine would be acceptable. WHO is working on smallpox vaccine prequalification for the emergency stockpile. A WHO meeting took place in Geneva 7-8 Sep 2015 to discuss with the National Regulatory Authorities and vaccine manufacturers what would be the minimum criteria to pre-qualify smallpox vaccines in case of re-emergence of variola virus. The report is envisaged to be published in Q1 2017.

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Strengthening of NITAGs	SAGE requested a regular update on the number of established National Immunization Technical Advisory Groups (NITAGs).	Apr 2016	Ongoing	This information is collected via the WHO/UNICEF joint reporting form and analyzed every year. The figures are included in the GVAP secretariat report, which is made available to the SAGE DoV working group and then to SAGE. Although some data verification is still pending, in 2015 127 countries reported the existence of a NITAG and 77 countries the existence of a NITAG that meets all 6 basic process indicators included in the JRF and used as part of the GVAP indicator. These figures can also be included in the global report on a yearly basis. A specific NITAG session will be held at the April 2017 SAGE meeting.
Supply shortages	SAGE proposed as immediate action to communicate effectively to countries on causes of shortages and current mitigation and long term activities.	Apr 2016	Ongoing	Shortage discussion was integrated into the GVAP secretariat report and regular quarterly calls with regions. More actions have been conducted regarding specific vaccines, such as YF or IPV, for which clear impacts of the current shortages have been identified and are being addressed with both short and long term strategies.
Supply shortages	SAGE recommended that WHO could play a key role in setting up an “Exchange Forum”, helping to collect demand information from all Member States and to enhance dialogue between countries’ demand (including anticipation of schedule evolution and new introductions) and manufacturers’ supply availability and risks.	Apr 2016	Ongoing	Concerns about ongoing shortages of vaccines persist. Internal WHO discussions and discussions with partners are in progress, in light of the SAGE session on vaccine shortages held in April 2016 and of resolution 69.25 on "Addressing the global shortage of medicines and vaccines." These discussions are also well aligned with the fifth objective of the Global Vaccine Action Plan (GVAP), the Middle Income Country (MIC) Strategy endorsed by SAGE in April 2015, the 68th World Health Assembly (WHA) resolution on the GVAP in May 2015. WHO IVB Department, in collaboration with Essential medicines and health products (EMP) and with support from Linksbridge consulting funded by the Bill & Melinda Gates Foundation, is leading a Vaccine Shortage Project. The aim of the project is 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 intends to develop 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) to prototype 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 will be developed. Draft Terms of Reference for the operating model -with related resource assumptions- will be made available by Q3 2017.

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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 2016, we have made significant progress toward strengthening the Networks and meeting those goals. In 2016, the Global Rotavirus Surveillance Network comprised 101 sentinel surveillance sites in 48 countries and the Global IB-VPD Surveillance Network comprised 111 sentinel sites in 51 countries. Data management processes continue to be improved toward a more systematic approach in reporting, cleaning, analysing and interpreting data. The reference laboratories are appropriately supporting sites and network laboratory performance has been successfully monitored by the global external quality assessment program as well as quality control programmes. Sentinel site and laboratory assessments are ongoing at priority sites. The most recent data available is from 2016, and it reflects the strength of the data and the network. Network data has contributed to vaccine introduction decisions, such as choice of pneumococcal conjugate vaccine (PCV) formulation, and the surveillance networks have been used as platforms for vaccine impact evaluations, particularly for rotavirus vaccines (RV). The surveillance platform has also been leveraged to monitor other VPDs, such as typhoid using the IB-VPD surveillance sites and other enteric pathogens such as norovirus, Shigella, and ETEC using the rotavirus network. Moving forward, the rapid introduction of PCV and RV by Member States now requires the surveillance networks to focus on improving baseline data for sites in non-vaccine using Member States and to ensure consistent surveillance practices to monitor impact for sites that meet inclusion criteria in vaccine-using Member States. A web-based data management tool is being rolled out in one Region (PAHO) and has great potential to improve data quality and sharing across the Network. We are discussing how to better integrate IB-VPD meningitis surveillance with existing meningococcal meningitis surveillance systems. We conducted a meeting in December 2016 to evaluate the cost of surveillance to help countries and funders develop sustainable surveillance plans, including other VPDs such as measles. We also continue to support sites where PCV and/or RV vaccine impact evaluations may be feasible due to sufficient pre- and post-vaccine introduction data, including using secondary data sources such as hospital administrative data. We have an ongoing evaluation of what sites to include in the Network and how to incorporate countries conducting surveillance outside of the Network. Finally, one of our main activities is to work with countries on making surveillance sustainable in the long term.
Sustainable Development Goals	Approval of a vaccination coverage indicator under the child mortality target of the Sustainable Development Goals (SDGs) has not yet been obtained. SAGE urged WHO and countries to request an aspirational immunization indicator under the SDGs.	Apr 2016	Ongoing	Several immunization partners (Gavi, Unicef, BMGF, US-CDC, WHO, Center for Vaccine Ethics and Policy NYU) have worked together to explore possible indicators to be added to the SDGs monitoring framework in addition to currently included ones (Target 3.8.1 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 4th meeting of the Inter-agency and Expert Group on Sustainable Development Goal Indicators (IAEG-SDG) accepted the new immunization indicator 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 definition of the indicator and the proposed measurement needs to be developed and validated by SAGE Decade of Vaccine working group. A call is scheduled for May 2016 to further discuss potential options. The definition needs to finalized or IAEG meeting scheduled for fall 2017 in order to include the indicator to 2018 SDG report.

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Tuberculosis vaccines	SAGE endorsed the establishment of a WHO TB vaccine technical expert group with representation from SAGE. An annual written report on TB vaccine developments should be provided to SAGE. SAGE would be provided with two-page summaries of progress every year. TB would only be included on the agenda of SAGE when there is a meaningful development of decision from SAGE required.	Nov 2011	Ongoing	Progress in TB vaccine development was reviewed by PDVAC in June 2016. Since the adolescent/adult population carry the heaviest disease burden, there is consensus within the TB vaccine community that prioritizing this target population will have the highest and most immediate public health impact from reduction in transmission. The most advanced vaccine candidates are GSK's M72/AS01E, the recombinant BCG VPM1002, M. VaccaeTM. M.vaccae is a heat killed homogenized lysate developed by Anhui Zhifei Longcom, China, which has been evaluated in Phase 3 for prevention of tuberculosis in healthy adults with latent TB infection, as well as as adjunctive immunotherapy with the aim to shorten TB treatment. Results have not been communicated. VPM 1002 is a recombinant BCG, originally developed by the Max Planck Institute; now licensed to the Serum Institute of India (SII) and being developed with Vakzine Projekt Management (VPM), Hannover, Germany. It is currently in Phase IIb/III trials, being compared to BCG in neonates in South Africa, as well as being tested for prevention of TB recurrence in adults in India. M72/AS01E a GSK adjuvanted protein vaccine candidate in phase IIb evaluation in Southern Africa, being tested for prevention of pulmonary TB, in previously infected adults. Primary results are awaited in the coming months. Secondary endpoints include safety and immunogenicity. H4/IC31 is an adjuvanted recombinant protein under development by Sanofi Pasteur, SSI and Aeras, currently in a Phase II prevention of infection study in adolescents (Phase II) with data expected in 2017. Upon PDVAC recommendation, WHO IVR is driving an effort to generate guidance on preferred product characteristics for TB vaccines targeted to adults and adolescents, with support from the Gates foundation.
Typhoid	Establish a SAGE working group on typhoid conjugate vaccines in 2016 to prepare for a SAGE review of the evidence in 2017.	Oct 2015	Ongoing	The SAGE Working Group (WG) on Typhoid Vaccines was established in Mar 2016 and the evidence review to support policy recommendations is ongoing. The Working Group will hold its face-to-face meeting 29-31 May. An ad hoc WHO meeting was scheduled for 3 Apr (including some SAGE WG members as well as non-SAGE WG experts) to review specific policy related issues and data to inform the SAGE WG process; a particular focus of the meeting will be to review the burden of disease in infants and young children and key considerations for optimum vaccination strategies using typhoid conjugate vaccines. Data on the safety of typhoid vaccines was reviewed by Global Advisory Committee on Vaccine Safety (GACVS) in Dec 2016. SAGE review of the draft recommendatiosn form the SAGE WGrp is scheduled for Oct 2017. One licensed typhoid conjugate vaccine is undergoing WHO prequalification review.
Un/under-immunized children	SAGE requested that WHO quickly roll out tools so that other countries can address low coverage of vaccination.	Nov 2010	Ongoing	Work is ongoing on the tool to assess "Missed Opportunities for Vaccination" (see item 284). On a broader level, a companion document to the Global Vaccine Action Plan (GVAP) focusing on Routine Immunization entitled "Global Routine Immunization Strategies and Practices" (GRISP) has been presented to the SAGE WG on DoV twice, and in Aug 2016 was published
Vaccination during humanitarian emergencies	SAGE also suggested that the framework approach to vaccine decision-making could be considered for other health interventions in emergencies.	Apr 2012	Ongoing	Possibilities of using the SAGE framework in other public health areas and emergency settings are being explored.

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Vaccination during humanitarian emergencies	SAGE emphasized the need to advance work on refining guidance in delivering continuous immunization services during humanitarian conflicts. A session on human emergencies will tentatively be slotted at the April 2016 SAGE meeting.	Oct 2015	Ongoing	A WHO meeting on implementation of vaccination during humanitarian emergency situations was convened in Cairo from 12-14 January 2016. The objectives were to: -reflect on the experience of EMR countries in implementing vaccination in humanitarian emergencies and the issues, challenges, best approaches and existing country guidance documents to ensure satisfactory vaccination of the target populations. -reflect on countries experience using vaccination in acute humanitarian emergencies: a framework for decision making. -build on countries experience to initiate development of a draft guidance document on the implementation of vaccination in humanitarian emergency situations. A draft guidance document on implementation issues has been initially produced by EMRO. This document is being adjusted some as a result of limited preliminary peer-review and will soon be distributed for a much broader peer review. 'Vaccination in acute humanitarian emergencies: a framework for decision making' has also been adjusted/updated based on the feedback received during the Cairo meeting and a draft operational manual is being developed. Work is ongoing for the development of web based interactive tools to support its use and facilitate further updating. Attempts will be made to have a proactive dissemination and communication plan to ensure adequate distribution. Finally, although there was no separate specific session during the Apr 2016 SAGE meeting an update was featured in the IVB Director's global report at this meeting. A meeting was jointly organized with MSF on 20 June to tackle the issue of supply and procurement obstacles in humanitarian emergencies: a. Discuss/map the obstacles to necessary access to affordable vaccines in a timely manner in emergency and humanitarian crisis situations. b. Discuss proposed solutions for addressing the key barriers to timely provision of affordable vaccines in humanitarian crisis situations. c. Agree upon a set of priority issues to be addressed by partners with a proposed plan of action/timeframe for follow up. A follow-up meeting took place on 10-11 Oct to develop consensus on the various guidance and priorities mentioned above and discuss how to best communicate and advocate for their implementation. Feedback form the meeting included that the envisaged operational manual missed important features while still being too long. Therefore the participants concluded that with having the revised and edited framework for decision-making along with the web-based tools, the operational manual was obsolete. The implementation guide and the framework for decision-making are currently with the editor. Further, a kick-off meeting took place with the software company to initiate the development of the web-based tools.

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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 (Africa and South East Asia). Particularly the operational feasibility of using POCT/OF in a field setting needs to be determined. Currently, besides the measles IgM assay for oral fluid, capillary blood and serum, a POCT for rubella IgM is being developed. POCT for measles and tetanus IgG are being evaluated for the use on oral fluid and dried blood spots on filter paper.
Vaccine coverage	WHO to identify appropriate methods and develop guidelines for collecting, analysing, and interpreting biomarkers for validating coverage.	Nov 2011	Ongoing	Currently, WHO is developing global guidelines on conducting serosurvey studies on measles and rubella and primarily to be applicable in a pre- and post-SIA (supplementary immunisation activity) setting. An expert working group has been assembled and based on the expertise in the various fields of each of the members, needed to conduct such studies, including statisticians, epidemiologists, laboratory experts, and program experts, given sub-tasks in developing parts of these guidelines that pertain to their respective expertise. A working draft has been circulated for comments and was finished by the end of 2015. It was tested subsequently in pilot studies in two different settings, pre- and post-campaign, for its applicability. The data collection part of a pilot study has been conducted in Mongolia in 2016. Analysis of the survey results is underway. Based on the outcome, the working draft guidelines will be adjusted, amended and corrected where needed. The second pilot study is being planned to take place in Bhutan in February and is a joint seroprevalence study measles-rubella and hepatitis b and c. The final document is planned to be ready and published by end of 2017 and to be rolled out as a tool to evaluate the immune status of the target or targeted population.

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Vaccine coverage	SAGE recommended that WHO explore alternative survey methods to improve the precision, reduce the cost and improve the usefulness of survey results to national and local immunization programmes.	Nov 2011	Ongoing	To improve the quality, precision and usefulness of survey results and to reduce the cost of surveys, the Global Immunization Monitoring and Surveillance Group (GIMS) explored recent advances in sampling methodology; new technologies for constructing sampling frames, supervision of field work, data collection, and analysis; and alternative content, collection, analysis, presentation and linkages An initial meeting was convened of the Department of Immunization Vaccines and Biologicals (IVB) Informal Advisory Group on Monitoring Immunization Programme Performance through Household and Community Surveys. The first meeting addressed the need to modify Demographic and Health Surveys (DHS) implemented by ICF International; and the UNICEF Multiple Indicator Cluster Surveys (MICS) and the WHO Immunization Cluster Survey to accommodate changes in immunization system strategies. In 2012, following a meeting with representatives of ICF and the MICS team, WHO and UNICEF provided written recommendation to these agencies to propose modifications to their standard recommendations on data collection, analysis and presentation of immunization coverage data. An informal working group was created to review and revise WHO guidance on measuring immunization coverage through household and community surveys. In 2013, the working group met to agree on the scope of work, to identify initial products, and establish a plan of document production, review, pilot testing, and clearance. Draft guideline was circulated to external reviews in 2014-2015. The proposed methods were reviewed in September 2014 by Immunization and Vaccines Related Implementation Research Advisory Committee (IVIR-AC). IVIR-AC agreed that the revised method for coverage surveys is the proper way forward, but that statistical expertise will be required to implement the survey in the field and provided other considerations, including the importance of using GPS technology, the need for qualitative studies and piloting of surveys in hard-to-reach settings. IVIR also noted that difficulties in monitoring progress and comparing cross-sectional data across methods and time must be addressed. Protocol for pilot testing was used in Bangladesh. In mid-2015, a working draft of the WHO Vaccination Coverage Survey Reference Manual was distributed and posted on the departmental website. Between 2015 and 2016, all or some aspects of the recommendations included in the new Survey Manual were used in Burkina Faso, Lao PDR, and to a lesser extent in Lebanon and for surveys following supplementary immunization activities (SIA) in Kenya, Swaziland, to name a few. Nigeria combined a MICS with a vaccination coverage survey and Pakistan planed its 2017 Vaccination Coverage Survey using the new Manual. In Dec 2015, a briefing workshop on the methodology for regional focal points and consultants was conducted. In 2016, countries in the African and Eastern Mediterranean regions were briefed. Between 2016 and early 2017, WHO in collaboration with UNICEF and CDC conducted trainings that brought together statisticians from developing countries (one Anglophone and one Francophone training), along with immunization program officers and consultants were conducted for countries from all regions, except EUR. A separate training was done in China for all provinces. It is expected that the WHO Vaccination Coverage Survey Reference Manual will be finalized in 2017, after experiences and lessons learned are shared and discussed. The revised recommendations will likely improve accuracy, by decreasing selection bias and reliance on maternal recall, and should also increase likelihood for adequate power, increase rigor and quality. The cost of the various trade-offs needs to be further explored.
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.

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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. The in-depth tool, "A Guide to Tailoring Immunization Programmes (TIP)" is being used in at least 6 countries by WHO-EURO (European Regional office), with at least 3 additional countries starting TIP projects in 2017, one of which in the Western Pacific Region. An evaluation of TIP implementation in the European Region from 2013-2016 was conducted in the second half of 2016. Findings will inform development of a new updated version of TIP in 2017. Additionally, the Univ. of Witwatersrand in South Africa has been contracted to adapt the TIP method for developing countries, with less intensive consultant-based inputs. This is being finalized and will be published in the first half of 2017. The Health Worker KAP tool has been completed and piloted with the assistance of JSI in Kenya. The final version will be published also in the first half of 2017. Lastly, in 2017 a range of new activities and materials are planned, with a focus on: 1) promoting and scaling up use globally of the various tools and guidance developed by EURO on boosting acceptance and addressing hesitancy, 2) developing a range of tools targeted to health workers covering multiple injections, contraindications, and pain mitigation, and 3) a conversation guide informed by the latest evidence from the behavioural and social sciences. 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, and other partners is also taking place to ensure alignment of efforts.
Vaccine Hesitancy	SAGE underlined the importance of distributing the matrix of determinants, the definition of hesitancy and the other deliverables to countries and partners.	Oct 2014	Ongoing	Discussions and presentations were held in the context of the immunization managers' meeting in the Eastern Mediterranean Region (EMR) and the African Region (AFR) Task force on immunization(TFI) meetings in 2014 and 2015. A Special Issue on Vaccine Hesitancy has been published in Aug 2015 in the journal Vaccine with a series of 10 full papers plus one editorial. In conjunction, a WHO press briefing was held on 18 Aug 2015 to emphasize WHO initiatives addressing vaccine hesitancy. This generated much positive media coverage. A compilation of centers to assist countries in addressing vaccine hesitancy has been finalized and sent to WHO regions to disseminate to countries. A paper which outlines the results of the 2015 Joint Reporting Form (JRF) indicators on vaccine hesitancy and contains the matrix of determinants and the definition of vaccine hesitancy was published open access on 1 Mar 2017: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0172310.
Vaccine Hesitancy	SAGE encourages validation of the developed compendium of survey questions on vaccine hesitancy, which have been assessed and validated only in some high-income countries or not at all.	Oct 2014	Ongoing	Discussions with various stakeholders are ongoing (Centre for Disease Control CDC, WHO EURO, Middle Income Countries MIC task force) on the ways forward to identify partners to take on the validation of the survey quesions. The MIC task force framework was presented to SAGE during the April 2014 meeting, which highlighted the importance to advance this initiative. Currently, how to secure funding from donors in support of the listed activities and advance validation of the questions in LMIC settings is being explored. The survey questions have been translated in Arab and French and are available on the WHO hesitancy website: http://www.who.int/immunization/programmes_systems/vaccine_hesitancy/en/ The necessity to validate the research questions has been flagged to a newly established International Collaboration on Vaccine Acceptance.

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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 has actively promoted the research agenda, and several relevant studies are in planning or execution phase. Fractional dose non-inferiority studies for all 4 prequalified vaccines will be conducted (funded, Africa), and long term immunogenicity will be assessed in a Brazilian cohort (funded). Immunogenicity study in DRC is on track.