

## **Highlights from the Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization 5- 7 October April 2020**

(Full report will be published in the Weekly Epidemiological Record on 4 December 2020, and only the wording of the full report should be considered as final)

### **Global Report**

- The global report focused on 2019 progress and how COVID-19 impacted immunization programmes globally in 2020. It highlighted how countries have already responded to the current pandemic and how they could continue to respond in the future so that major, purposeful shifts can emerge from this crisis.
- SAGE underlined the opportunities for integration in the current situation. SAGE further emphasised the importance of taking into considerations gender aspects as enablers and barriers to vaccination.
- Gavi 5.0 Priorities remain critical and COVID-19 creates a greater need to be agile and innovative. Gavi will prioritize 1) Continuity of immunisation, 2) Reaching zero dose, 3) Pacing breadth of protection, 4) Safeguarding domestic financing, and 5) COVID-19 vaccine access and delivery.

### **Immunization in context of the COVID-19 pandemic and other disruptive events with regional and country focus**

- SAGE was updated on the impact of the COVID-19 pandemic on immunization activities. All six regions reported measurable disruptions of immunization activities with notable setbacks for mass vaccination campaigns, outreach services, and surveillance activities. Global and regional surveys revealed that the underlying reasons for disruptions included supply and demand constraints as a result of the pandemic, re-assignment of health workers from immunization activities to COVID-19 response, travel restrictions, shortage of personal protective equipment (PPE), and fear among communities of becoming SARS-CoV-2 infected while seeking services.
- However, Regions also reported signs of recovery and resumption of immunization activities.
- SAGE encouraged countries and immunization partners to document and share the rich lessons learned from these pandemic experiences of disruption and recovery.
- As immunization programmes continue to recover, they will likely primarily be reaching the children with access to services before the pandemic. Communities with unimmunized, or “zero dose” children are likely to continue to be missed despite being more vulnerable and susceptible to outbreaks. Attention to these communities needs to be particularly emphasized during the recovery period as well as beyond.
- SAGE advised all countries to urgently prioritize implementation of catch-up vaccination strategies, including mass vaccination campaigns, assuring proper planning and adequate financial resources for effective infection prevention control measures to protect health workers and the community. Undertaking catch-up vaccination activities now is particularly critical in anticipation of possible near-term events that may again impact usual immunization services, including the potential introduction of COVID-19 vaccines.
- SAGE endorsed the statement *‘Immunization as an Essential Health Service: Guiding principles for immunization activities during times of severe disruption, including during the COVID-19 pandemic’* which supersedes the previous guiding principles issued in March 2020. The statement enhances prior principles regarding the importance of preserving immunization as an essential health service, the necessity of catch-up vaccination policies and strategies, and the importance of prioritization of activities to address outbreak-prone vaccine preventable diseases and to protect

vulnerable populations. The statement is newly broadened to be relevant to any major disruption event, to recognize the dynamic nature of such shocks to the immunization system and thus the need for flexibility and constant re-assessment, and to use the disruption as an opportunity to integrate with and strengthen primary health care and attain equity goals.

- With much admiration and appreciation, SAGE applauded national immunization programme staff, frontline health workers, and National Immunization Technical Advisory Groups (NITAGs) in their extraordinary efforts during the challenges of the COVID-19 pandemic to sustain and restore immunization services on behalf of the children and communities they serve.

## COVID-19 vaccines

- SAGE was presented with COVID-19 disease epidemiology, the COVID-19 vaccine landscape, the COVAX Facility, modelling efforts to help develop vaccination policies, and a report from the Global Advisory Committee on Vaccine Safety (GACVS).
- SAGE has undertaken a three-step process to provide guidance for overall programme strategy as well as vaccine-specific recommendations:
  - 1. A Values Framework.** The *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*, issued on 14 September 2020, outlines six principles and 12 public health objectives.
  - 2. A Prioritization Roadmap.** To support countries in planning, the Roadmap suggests public health strategies and target priority groups for different levels of vaccine availability and epidemiologic settings.
  - 3. Vaccine-specific recommendations.** As licensed vaccines become available, specific recommendations for the use of these vaccines will be issued in the future. Evidence will be retrieved and assessed through a living systematic review.<sup>1</sup>
- SAGE recommended that overall public health strategies should be grounded in ethical values as outlined in the Values Framework.
- SAGE endorsed the **Prioritization Roadmap** and recommended that Regional Immunization Technical Advisory Groups (RITAGs) and subsequently countries in consultation with their NITAGs start using this Roadmap. An ongoing dialogue with SAGE, RITAGs and NITAGs should be maintained which will assist SAGE in further adapting the Roadmap once data on vaccine performance data become available. SAGE recommended that the Roadmap be considered a living document and be published as interim guidance.
- SAGE highlighted the need for early, comprehensive preparedness planning for post-licensure surveillance of COVID-19 vaccines impact, which should include planning for vaccine safety monitoring and effectiveness studies using different methodologies and in different populations. SAGE also acknowledged the ongoing work of GACVS on pharmacovigilance preparedness.
- SAGE strongly endorsed strict adherence to Good Clinical Practice (GCP) with the focus on robust regulatory oversight, careful monitoring of safety by independent data safety monitoring boards in phase III clinical trials of COVID-19 vaccines, and the rights to medical confidentiality of all trial participants.

## Influenza and pneumococcal vaccination in the context of COVID-19

- There are currently limited data on COVID-19 comorbidity with influenza or pneumococcal disease or on benefits of influenza or pneumococcal vaccination in the COVID-19 context.

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<sup>1</sup> Cochrane. <https://covid-nma.com/vaccines/>, accessed October 2020

- In the context of the COVID-19 pandemic, SAGE reconsidered the prioritization of risk groups for influenza vaccination as outlined in the 2012 WHO vaccine position paper. SAGE recommended that during the COVID-19 pandemic, highest priority groups for influenza vaccination are health and care workers and older adults. In no particular order, additional groups for influenza vaccination are pregnant women, individuals with underlying health conditions, and children (6-59 months of age).
- SAGE noted that evidence is insufficient to support a recommendation to introduce an adult pneumococcal vaccination programme in response to the COVID-19 pandemic. However, in countries with existing adult pneumococcal vaccination programmes, improving vaccine coverage and thereby reducing pneumococcal disease may be expected to alleviate the related burden on health systems.

## Polio

- SAGE acknowledged the certification of the WHO African Region as wild polio virus-free on 25 August 2020 by the African Regional Certification Committee, however, expressed serious concerns about the eradication effort. Specifically, SAGE expressed concern about continuing circulation of wild poliovirus in Afghanistan and Pakistan and by the inability of the program to effectively control outbreaks of vaccine-derived polioviruses in Africa.
- SAGE endorsed a second inactivated poliovirus vaccine (IPV) dose to be introduced into all 94 countries that currently administer one IPV dose and bivalent oral poliovirus vaccine (bOPV) in their routine immunization schedules and provided recommendations regarding preferred and alternative schedules for the two IPV doses. Introduction of the second IPV dose will not reduce the number of bOPV doses used in the routine immunization schedule.
- SAGE was updated on the progress of the novel oral poliovirus vaccine type 2 (nOPV2) which is currently being submitted for Emergency Use Listing (EUL); nOPV2 is the first vaccine to go through the EUL process.
- SAGE re-affirmed its April 2020 recommendation on the nOPV2 initial use criteria under EUL and made new recommendations related to nOPV2 assessment and safety monitoring to support decision-making for subsequent phases of nOPV2 use.
- In principle, SAGE endorsed that nOPV2 becomes the vaccine of choice for response to circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreaks after the interim recommendation for EUL is issued and after review of the initial use period is completed and all requirements for use are met.
- SAGE does not recommend IPV to be used for poliovirus outbreak response.

## Measles

- SAGE endorsed the Measles and Rubella Strategic Framework, 2021-2030, a document to guide the strategic priorities and programmatic efforts toward measles and rubella elimination. SAGE welcomed this major multi-partner initiative which frames an approach to tackle both immediate challenges, such as the COVID-19 disruption, and medium-term challenges, such as achieving elimination targets.
- The reported global annual number of measles cases of 872, 872 in 2019 is the highest that it has been in 15 years. Measles vaccine delivers the highest returns on investment in immunization by a large margin, and the benefits of continuing measles vaccination during the COVID-19 pandemic exceed all other antigens when considering overall child deaths averted through routine immunization. SAGE echoed concern that the COVID-19 pandemic is creating large immunity gaps that will inevitably lead to future outbreaks if not proactively and urgently addressed.

## **Rotavirus vaccines**

- Since SAGE last reviewed rotavirus vaccines in April 2012, global progress with rotavirus vaccination has occurred. Currently, 112 or 58% of countries have introduced rotavirus vaccines. Rotavirus vaccine impact is evident from the 40% reduction in rotavirus prevalence documented by the Global Rotavirus Surveillance Network during 2008-2016 as well as studies in a variety of countries that show reductions in hospitalizations and mortality due to rotavirus. Additional safety and effectiveness data have accrued for Rotarix™ and RotaTeq™ and in 2018, WHO prequalified two more rotavirus vaccines, Rotavac™ and Rotasiil™.
- As a result of the current updated review, SAGE recommended all four live oral rotavirus vaccines (Rotarix™, RotaTeq™, Rotavac™, and Rotasiil™) for use.
- SAGE re-affirmed 2013 recommendations that rotavirus vaccines should be included in all national immunization programmes and be considered a priority, particularly in countries with high rotavirus gastroenteritis-associated fatality rates, that use of rotavirus vaccines should be part of a comprehensive strategy to control diarrheal diseases, and that first dose of rotavirus vaccine should be administered as soon as possible after 6 weeks of age.
- SAGE noted that the considerable rotavirus disease burden during the second year of life supports catch-up vaccination for children not vaccinated on time, particularly in high-mortality and crisis contexts, including recent disruptions to immunization services related to the COVID-19 pandemic. Because of the typical age distribution of rotavirus gastroenteritis, rotavirus vaccination of children >24 months of age is not recommended.

## **Development of the Immunization Agenda 2030 Monitoring, Evaluation, and Action (IA2030 ME&A) Framework and the Ownership and Accountability (OA) Mechanism**

- SAGE was presented with the IA2030 ME&A Framework as well as with the current development of the OA Mechanism based on the results of country and stakeholder consultations. Different options were reviewed with an emphasis on leveraging existing structures and mechanisms.
- SAGE commended the progress made so far and raised questions and points to consider while finalising the IA2030 ME&A Framework which will be submitted for the May 2021 World Health Assembly.
- SAGE discussed the possible targets for the Impact Goal indicators for global and regional vaccine preventable disease control. For the OA Mechanism, SAGE discussed the possibility of using existing national health observatories and how to better integrate and leverage civil society organizations by formalizing and structuring their role, in particular with regards to reaching unreached communities.

## **Pneumococcal vaccines**

### *Considerations for use in national programmes to vaccinate older adults*

- Mature pneumococcal conjugate vaccine (PCV) childhood programmes provide indirect protection to older adults for most PCV10 and PCV13 serotypes.
- Introduction of a childhood PCV programme, ensuring optimal uptake of PCV in children, and sustaining high coverage should be prioritized over initiating an older adult vaccination programme.
- For countries that already have mature PCV childhood programmes and would like to provide direct protection to older adults, general considerations for national vaccine introduction should include:
  - Population structure and demographics amongst older adults to guide the age at which introduction should be considered;
  - Operational factors, including cost and cost-effectiveness, to ensure that optimal coverage can be achieved in the target population.

### *Use of pneumococcal vaccines in outbreak settings:*

- Sustained ( $\geq 5$  years) high PCV coverage in children is likely to reduce the risk of pneumococcal outbreaks.
- While there is insufficient data to recommend a reactive vaccination campaign in response to Serotype 1 outbreaks, further research needs to be encouraged.

## **Vaccine Innovation Prioritization Strategy (VIPS)**

- SAGE agreed with the three product innovations prioritized by VIPS, namely, micro-array patches (MAPs), heat thermostable formulations, including controlled temperature chains (CTC) and the use of barcodes on both secondary and primary vaccine packaging. If available and implemented, these innovations could have significant programmatic impact and increase vaccine acceptability.
- SAGE recommended that VIPS continue to assess the product innovation landscape in the context of COVID-19 vaccines to identify potential, additional priorities for VIPS. Additionally, beyond advancing development and use of 'supply-side' product innovations, SAGE noted that attention to developing 'demand-side' innovations is also needed in order to reach the unreached (e.g., innovations to identify the location of/coverage status of target populations).