Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization 5 - 7 October 2020

Conclusions and recommendations*

*Full meeting report will be published in the Weekly Epidemiological Record on 4 December 2020
Agenda items

• Global report

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

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

• COVID-19 vaccines

• Polio

• Measles

• Rotavirus vaccines

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

• Pneumococcal vaccines

• Vaccine Innovation Prioritization Strategy (VIPS)
• The global report presented by the Director of the Department of Immunization, Vaccines and Biologicals 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.
• 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. Programmes have modified service delivery to accommodate IPC measures.

• **Innovative delivery strategies** and increased integration with PHC sought.
Immunization in context of the COVID-19 pandemic and other disruptive events: SAGE recommendations

- As immunization programmes recover, “Zero dose” children are likely to continue to be left out, exacerbating inequity.

- SAGE advised all countries plan for and conduct catch-up vaccination strategies.

- SAGE endorsed the document ‘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 document 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 document is broadened to any major disruption event, to recognize the dynamic nature of such shocks to the immunization system.
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.

- In context of COVID-19, SAGE reconsidered the prioritization of risk groups for influenza vaccination. 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.
• SAGE supports 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.
COVID-19 vaccines

- 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 countries start using this Roadmap. An **ongoing dialogue** with SAGE, RITAGs and NITAGs should be maintained which will assist SAGE in further adapting the Roadmap.

- 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 and safety (GACVS preparation).

- SAGE underlined strict adherence to **Good Clinical Practice** (GCP) with the focus on robust regulatory oversight, monitoring of safety by independent data safety monitoring boards, and the rights to medical confidentiality of all trial participants.
• 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, 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.

• All Polio campaigns were **suspended** in March 2020, and since July 2020 are gradually resuming.

• 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.

**Polio: progress and IPV use**
• 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 multi-partner Measles and Rubella Strategic Framework, 2021-2030, to guide the strategic priorities and programmatic efforts toward measles and rubella elimination.

- The purpose of the MRSF is to create the conditions for eradication through pivots in strategy delivered in a unified approach that strengthens routine immunization.

- The global annual number of reported measles cases of 872,872 in 2019 is the highest in 15 years. MV has the highest RoI in immunization by a large margin.

- The modelled 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, may increase malnutrition and disrupt VitA supplementation leading to higher CFR’s.
Since SAGE last reviewed rotavirus vaccines in April 2012, global progress with rotavirus vaccination has occurred, and four prequalified vaccines are now available. Currently, 112 or 58% of countries have introduced rotavirus vaccines.

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, particularly in countries with high rotavirus burden;
- Use of rotavirus vaccines should be part of a comprehensive strategy to control diarrheal diseases,
- First dose of rotavirus vaccine should be administered as soon as possible after 6 weeks of age.

SAGE noted the considerable rotavirus disease burden during the second year of life warrants catch-up vaccination.

Because of the age distribution of rotavirus disease, vaccination of children >24 months of age is not recommended.
Pneumococcal vaccination: older adults and outbreak settings

- Mature pneumococcal conjugate vaccine (PCV) childhood programmes provide **indirect protection** to older adults for most PCV10 and PCV13 serotypes.
- Childhood PCV programmes with high coverage **should be prioritized** over initiating an older adult vaccination programme.
- For countries with **mature PCV childhood programmes** and would like to provide direct protection to older adults, general considerations for introduction 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.
- Sustained (≥ 5 years) high PCV coverage in children is likely to **reduce the risk of pneumococcal outbreaks**.
- **Catch-up vaccination** for outbreak prone areas recommended
- Insufficient data to recommend a **reactive vaccination campaign** in response to Serotype 1 outbreaks, further research needed.
More information and background documents can be found on the SAGE website

www.who.int/immunization/sage/meetings/2020/october/en/

The full report will be published in the WHO Weekly Epidemiological Record on 4 December 2020
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.
Vaccine Innovation Prioritization Strategy (VIPS)

- SAGE agreed with the **three product innovations** prioritized by VIPS:
  - Micro-array patches (MAPs);
  - Heat thermostable formulations, including controlled temperature chains (CTC);
  - 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).