

Highlights from the Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization

2-4 April 2019

(Full report will be published in the Weekly Epidemiological Record on 31 May 2019)

Report from Director, IVB and Regional Updates

- The Director of the WHO Department of Immunization, Vaccines and Biologicals provided a preview of what the vision for the next decade of work in the vaccine and immunization field will entail and stressed four key aspects: (1) over the last many decades, the world has been on a trajectory of great advances in the development and health of communities; (2) however, the world in 2019 is increasingly uncertain and volatile with the risk of backsliding; (3) the vaccine and immunization agenda is being re-shaped with a central view toward equity, security and prosperity for all; and (4) vaccines and immunization are central to achieving the Sustainable Development Goals (SDGs), with at least 14 of 17 linked to achieving vaccine goals.
- The next decade is an opportunity for the global community to address key issues and harness new solutions in vaccines and immunization while at the same time contributing to the broader global health agendas including not only the SDGs but also WHO's "triple billion" goal as part of its 13th Programme of Work, Primary Health Care, and Universal Health Coverage.
- Regional Offices highlighted major achievements and challenges. Of concern are the multiple outbreaks of measles and other vaccine-preventable diseases as these reflect weakened immunization systems. Fragile and conflict-ridden countries face challenges in sustaining immunization, as do many lower-middle-income countries in relation to financing. Several regions reported on efforts to increase life-course vaccination and on strengthening country decision-making.

Report from Gavi, the Vaccine Alliance

- Approvals of new and expanded vaccine programmes at the December 2018 Gavi Board reflect a shift from infant vaccination to a life-course approach, which aligns with the priorities of the 13th WHO Programme of Work.
- The Gavi Board retreat on the Gavi 5.0 strategy focused on ways that the Alliance contributes to the SDG vision of leaving no one behind. Four key areas were highlighted including: vaccine introductions; reaching the under-immunized; financial and programmatic sustainability; and healthy markets and innovation.
- In 2019-2020, Gavi will update its core policies on country eligibility and transition, co-financing, health system investment framework and gender. In addition, the policies will focus on a more differentiated approach to accelerate equitable vaccination coverage and use an evolving support model to further unlock domestic resources.

Data use and quality

- Discussed were major findings and knowledge gaps around data quality and use, and possible interventions to strengthen governance, tools, assessment and improvement planning in order to use data for continuous quality improvement (CQI) for immunization program decision-making.
- Considerable amounts of immunization and vaccine-preventable disease surveillance-related data are routinely collected and available nationally, regionally, and globally, though quality and access often remain challenging and more needs to be done to create a “culture of data use”.
- The use of data was emphasized as one of the major drivers of ongoing improvement in data quality. Any information and communication technology solutions require adequate infrastructure, sustainable financing, political will and a skilled and motivated workforce.
- SAGE will further discuss this extensive review of data use and data quality in order to make decisions on recommendations at a future SAGE meeting.

Update on the development of a post 2020 Global Immunization Strategy

(i) Interim review and lessons learnt report

- SAGE welcomed the interim review and lessons learnt report on the Global Vaccine Action Plan (GVAP). The final report will be presented to SAGE in October 2019. This interim report aims to provide a differentiated view on the achievements and shortcomings of GVAP and inform the development of the post 2020 strategy.
- Interim findings highlighted achievements such as the alignment of all global actors, a strong monitoring and evaluation framework, emphasis on data quality and the increased numbers of national immunization technical advisory groups (NITAGs).
- Reported shortcomings included the perception of a top-down plan, little guidance to offer solutions to address challenges, and weaknesses in advocacy and communications.
- Progress towards the GVAP goals occurred mainly in well-funded areas such as new vaccine introduction.

(ii) Post 2020 strategy

- SAGE welcomed the accelerated process to develop the post 2020 global immunization strategy. The strategy should provide a coherent framework allowing alignment with global health agendas and with partner strategies, but especially with regional and country plans.
- The development of the new strategy was officially launched by WHO with the co-creation multi-country multi-stakeholder forum on 19-21 March 2019 which gathered 110 participants from 50 organisations and over 30 countries. At the forum, a three-level approach was adopted with:
 - An overarching vision for the decade through 2030 which would be used by actors within and beyond the immunization community;
 - A framework strategy for immunization stakeholders;
 - A collection of global, regional and country goals, plans, partner strategies and disease strategies.

- The strategy will be developed over the next months and include a wide engagement process to assure that the new strategy is informed by country needs and focus. An advanced draft will be presented to SAGE in October 2019 before submission in 2020 to the WHO Executive Board and the World Health Assembly for endorsement.

RTS,S/AS01 Malaria Vaccine and the Malaria Vaccine Implementation Programme (MVIP)

- The framework for policy decision on RTS,S/AS01 Malaria Vaccine was presented to SAGE for consideration and endorsement. This framework describes how the data from the pilot implementation of the RTS,S/AS01 malaria vaccine in Ghana, Kenya and Malawi will be used to inform future malaria vaccine recommendations.
- SAGE endorsed the step-wise process laid out in the framework for review and use of data from the pilot studies:
 - Step 1: Updated WHO recommendations on use of RTS,S/AS01 vaccine in Africa are possible if and when (a) safety signals observed in the Phase III trial are resolved, and (b) severe malaria or mortality data trends are assessed as consistent with a beneficial impact of the vaccine. This step could be as early as 24 months after vaccinations begin in the first pilot country of the MVIP.
 - Step 2: Adjustments or refinements to WHO malaria vaccine recommendations may be made based on the final MVIP data set which is expected to be available approximately 50 months after the start of vaccination in the last pilot country of the MVIP. The pilots are designed to establish the public health value of the fourth dose of the vaccine schedule.
- The framework will be reviewed on 10 April 2019 by the Malaria Policy Advisory Committee with consideration for endorsement.
- Regional- and country-level consultation will be important in the development of updated WHO recommendations on use of RTS,S/AS01 vaccine.

Polio

- SAGE acknowledged progress towards poliovirus eradication albeit expressed concerns about areas consistently inaccessible for vaccination in parts of Afghanistan and Nigeria.
- SAGE expressed concern about the large number of circulating vaccine-derived polioviruses, and the poor vaccination coverage with IPV in many countries.
- SAGE noted that the IPV supply shortages are abating and will allow swift implementation of catch-up campaigns.
- In anticipation of the certification in 2019 of Wild Polio Virus Type 3 (WPV3) eradication, SAGE discussed the potential switch from bOPV to mOPV1. While no decision was taken at this time, SAGE highlighted the very significant programmatic and regulatory challenges associated with such a switch.

- SAGE endorsed guidelines for surveillance of poliovirus excretion among persons with primary immunodeficiencies.

Defeating meningitis by 2030: Global Roadmap

- Meningitis remains a major public health challenge in regions and countries around the world. Cases and outbreaks continue to be highly feared. The magnitude of the problem varies dramatically between regions, but in all instances deaths and long-term sequelae due to meningitis leave a substantial mark.
- SAGE was presented with the global strategy to 'Defeat Meningitis by 2030' which is being developed by a WHO-led multi-organization initiative that includes partners addressing the specific organisms responsible for most causes of acute bacterial meningitis.
- SAGE praised the development of a global roadmap for Defeating Meningitis by 2030 that will be shared for recommendation at the October SAGE meeting. The initiative was considered timely, as important advances are happening in the field of the bacterial meningitis pathogens.
- SAGE assessed the proposed strategic structure and pillars as promising, albeit advised to review the wording of the visionary picture to ensure it is achievable.
- SAGE acknowledged that there is not sufficient awareness about meningitis globally which results in public complacency, and that the constituency that has driven this global effort is the affected communities.

Ebola vaccines

- WHO Health Emergencies Response provided an update on the epidemiology of the outbreak in the Democratic Republic of Congo (DRC) and on the status of the Ebola response in North Kivu and particularly noted the important contribution of vaccination in reducing transmission.
- SAGE re-visited the possible vaccination strategies by reviewing epidemiological data and impact modelling. It concluded that ring vaccination currently remains the most effective strategy in this DRC Ebola outbreak. Geographic targeting should remain as a fall-back strategy. Mass vaccination and ring plus had less favourable overall impact for the doses used in the modelling.
- SAGE reviewed epidemiological data from North Kivu for children below 1 year of age and for lactating women. Although clinical data on the safety and efficacy of the rVSV-ZEBOV-GP Ebola vaccine for these two specific groups are absent, SAGE considers that the high attack rates and high case fatality rates for these groups, together with the accumulating data on vaccine safety and efficacy for other groups, justify inclusion of children who are above the age of 6 months and of lactating women in the ongoing ring vaccination efforts in North Kivu.
- SAGE strongly urged the implementation of studies to evaluate additional Ebola candidate vaccines, including where possible in pregnant and lactating women and in infants.