DAY 3

New & emerging vaccines

Malaria Vaccine

Ebola vaccines – Zaire, Sudan
Ebola, Marburg
• Key activities towards access
• Demand and supply projections
• Key messages
MALARIA VACCINE, KEY ACTIVITIES TOWARDS ACCESS

- WHO M4A Malaria Vaccine Market Study
- WHO Recommendation*
- Gavi Board approval for malaria vaccine programme
- UNICEF tender published (2023-2028)
- Tender evaluation, negotiation meetings
- Framework for allocation of limited malaria vaccine
- First malaria vaccine WHO PQ-ed
- First UNICEF award issued (2023-2025)
- First Gavi application window opens (for MVIP countries**)
- Gavi approves special, time limited co-financing policy for Malaria Vaccines
- Malaria vaccine Market Shaping Roadmap published
- Gavi application windows (non-MVIP countries) open
- Negotiation meetings for new malaria vaccines
- Allocation of first malaria vaccine to MVIP + 9 new countries
- Gavi approvals
- Country preparations for introductions start
- Potential WHO recommendation of second malaria vaccine
- Q4: Supply begins
- Malaria vaccine introduction in countries start
- Potential WHO prequalification of second malaria vaccine (if recommended)
- If recommended & prequalified, start of supply of second malaria vaccine

*WHO Recommendation: RTS,S/AS01 malaria vaccine recommended for use for the prevention of *P. falciparum* malaria in children living in regions with moderate to high transmission, as defined by WHO.

**MVIP countries: Countries participating in Malaria Vaccine Implementation Programme - Ghana, Kenya and Malawi.
Demand

- **High interest in introducing malaria vaccine:** 17 countries in total applied to Gavi and were approved for support to introduce malaria vaccine to date, and additional applications for Gavi support are underway.

- Countries applied for Gavi support to introduce the vaccine initially in **highest need category areas**, as defined by Framework for Allocation of Limited Malaria Vaccine Supply.

- However, currently available supply of RTS,S/AS01 vaccine of 18 million doses through 2023-2025 is only sufficient to meet the needs of highest need areas in **9 new countries** in addition to continued vaccination in areas in MVIP countries where vaccine is already in use.

- 25 million children live in areas of moderate to high *P. falciparum* parasite prevalence (current WHO recommendation on use of first malaria vaccine), translating to **steady state demand of ~ 80 - 100 million doses by 2030** with 4-dose schedule.

- Steady state demand for **DR Congo and Nigeria** alone represents approximately 30 million doses annually if used in all areas of moderate to high transmission. Actual demand will be highly dependent on the pace of introduction in these two countries.

- Demand estimates are dependent of WHO policy recommendation.
Supply

- First malaria vaccine - RTS,S/AS01 vaccine is WHO pre-qualified and recommended for use. Technology Transfer of RTS,S to manufacturer in India is ongoing leading to additional supply potentially from 2026-2028.

- All currently available supply of 18 million doses of RTS,S/AS01 through 2025 has been allocated to countries based on Framework for Allocation of Limited Malaria Vaccine Supply.

- Second malaria vaccine – R21/Matrix-M vaccine currently in Phase III trials. Data for this vaccine will be reviewed by SAGE/MPAG on 27th September 2023 and if recommended, WHO Policy Recommendation expected to follow in Q4-2023.

- If R21/Matrix-M vaccine is recommended for use at least in moderate to high transmission areas of perennial as well as seasonal transmission, and if prequalified by WHO, the vaccine will become a second malaria vaccine available through UNICEF potentially from 2024.

- Further pipeline – majority in pre-clinical or Phase I trials.

UNICEF Q&As on malaria vaccines supply, price and market-shaping efforts

https://www.unicef.org/supply/documents/malaria-vaccine-questions-and-answers

Information on the supply availability, including anticipated ramp up of the RTS,S production and product transfer of RTS,S/AS01, pipeline vaccines, price & anticipated price evolution as well as on market shaping activities.
KEY MESSAGES

➢ First generation malaria vaccines will be used as part of overall toolbox for malaria control and prevention. Integration of immunization and malaria control programmes at global, regional and country levels is needed for quality implementation.

➢ Urgent innovation in product improvements and next generation vaccines that better meet countries programmatic preference and context and vaccine with higher efficacy rates and fewer doses required is needed.

➢ Flexibility will be needed from the manufacturers in the initial years of malaria vaccine programme as vaccine becomes progressively introduced in countries’ programmes while countries navigate the challenges of competing health priorities and constrained health systems.

➢ With additional supply on the horizon, reduction in prices, as production capacities increase, is needed to help countries and donors sustain malaria vaccine programmes.

➢ UNICEF and partners are committed to implement the Alliance action plan to improve health of the malaria vaccine market, as agreed in the Gavi Alliance Malaria Vaccine Market Shaping Roadmap.
• Ebola Zaire – Global Stockpile
• Sudan Ebola Vaccine and Marburg Vaccines
• UNICEF Expression of Interest for Sudan and Marburg vaccines
• Key messages
EBOLA ZAIRE - GLOBAL EBOLA VACCINE STOCKPILE

- Two WHO prequalified Ebola Vaccines available – both with documented protection against Ebola Zaire strain only.
- UNICEF currently holds LTA for rVSV-ZEBOV Ebola vaccine, for stockpile of 500,000 doses as per SAGE recommendations.
- Global Ebola vaccine stockpile (ICG Stockpile) established at the beginning of 2021, reached its target level at the end of 2022 and currently at maintenance phase.
- The Stockpile is accessible to any country facing outbreak, with deployment funded by Gavi for Gavi supported countries.
Global Ebola Vaccine Stockpile build up projections

- Today’s stockpile level: **456,810 ds**
- Deployments from stockpile: **145,620ds**
  (of which **6,570 for outbreak**)
- Destroyed due to expiry: **42,620 ds**

Global Ebola Vaccine Stockpile projections, September 2023
Re-emergence of Sudan Ebolavirus Disease (SVD) in Uganda in 2022 after over a decade without new cases.

Current licensed Ebola vaccines against Zaire Ebolavirus strain do not provide cross-protection against Sudan Ebolavirus.

In November 2022 three vaccine candidates were recommended by WHO Prioritization Working Group for inclusion in trials in Uganda.

In December 2022, UNICEF launched Expression of Interest (EOI) on behalf of UNICEF and Gavi with objective to engage with developers/manufacturers of SVD vaccines early on.

In February 2023, following outbreak of Marburg, UNICEF issued “Addendum to the EOI” to 4 developers of Marburg Vaccines and received 4 responses.

In May 2023, UNICEF and Gavi engaged in follow up calls with three developers of Sudan & Marburg vaccines.

Ongoing progress update discussions with developers will continue.
**Sudan Ebola vaccine and Marburg vaccines**

**Expression of Interest, EOI-VC-2022-1, launched on UNGM on 20 December 2022, Purpose of the EOI:**

| Three (3) vaccine candidates in Phase I (completed or ongoing) |
| Three (3) vaccine candidates in pre-clinical/early-stage development |
| Two (2) vaccine candidates - Active/ongoing plans for Phase II for two (2). |
| One (1) Vaccine candidate does not have active Phase II plan yet. |

**Responses received, Sudan Ebolavirus Vaccines:**

- **Six (6) Responses to EOI**
  - Accelerate the availability of licensed vaccine(s), understanding developers’ needs
  - In the interim to potentially make available investigational doses for public health emergency use
  - To help inform the design of UNICEF’s procurement strategy for supply & stockpiling of Ebola vaccines against Sudan Ebolavirus and Marburg vaccines in the future
SAGE learning agenda and future potential recommendations on preventive vaccination will impact the market dynamics, while demand for preventive vaccination is highly uncertain and difficult to forecast.

Ebola vaccines with improved product characteristics as defined under the Ebola vaccine Target Product Profile are needed, including:

- Documentation (product label indication) for use in pregnant women, lactating women and young children;
- Reduced cold chain dependency, including vaccine demonstrating stability at 2-8°C for at least 6 months and vaccines with reduced cold chain storage volume requirements;
- Vaccines that can be administered at a dosage volume of 0.5mL, using standard 0.5 mL Auto-Disable injection device typically readily available at country level;
- Greater flexibility in production systems – due to the nature of the virus, access to surge capacity as and when needed for preventative vaccination.
THANK YOU