Update on the RTS,S/AS01 Malaria Vaccine Implementation Programme

Background

The Malaria Vaccine Implementation Programme (MVIP) was developed to act on the 2016 WHO recommendation to pilot the RTS,S/AS01 malaria vaccine in routine immunization programmes (1). The MVIP supports introduction of the malaria vaccine in selected areas of Ghana, Kenya and Malawi, and evaluation of the programmatic feasibility of delivering a four-dose schedule, the vaccine’s impact on mortality, and its safety in the context of routine use. The primary aim of the Programme is to address outstanding questions related to the public health use of the vaccine in order to enable WHO policy recommendations on the broader use of RTS,S/AS01 in sub-Saharan Africa.

The Programme is jointly coordinated by the Global Malaria Programme (GMP), the Immunization, Vaccines & Biologicals (IVB) Department and the WHO Regional Office for Africa, in close collaboration with other WHO departments and country offices, ministries of health in pilot countries, PATH and other partners. Introduction of the malaria vaccine is country-led. Funding for the MVIP is provided by Gavi, the Vaccine Alliance, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and Unitaid.

Update since October 2019

The Ministry of Health of Kenya launched RTS,S/AS01 vaccination on 13 September 2019. This major milestone means that vaccine implementation is underway in all three MVIP countries. Data and feedback received so far suggest good acceptance of the programme by health care workers, caregivers and communities, and generally high demand in areas where adequate communication and sensitization efforts have taken place. While there has been variation in performance across geographic areas, administrative data indicate that all three countries have reached over 60% of their target population with the first dose of RTS,S/AS01. This level of uptake is considered satisfactory and within expectations for a new vaccine with a novel schedule, i.e., targeting children from 5 months of age (in Malawi) and from 6 months of age (Ghana and Kenya) for the first dose. Areas for improvement have been identified through supervisory visits, and measures are being taken by the national immunization programmes, supported by partners, to address identified issues (e.g., health workers’ misunderstanding of the vaccine schedule).

The first round of data collection for the qualitative longitudinal Health Utilization Study (HUS), coordinated by PATH, began shortly after vaccination started in each country. As part of the feasibility evaluation, the HUS assesses issues related to vaccine uptake, community perceptions and acceptability of the vaccine, and service delivery challenges and successes. Early insights from the interactions with caregivers, health personnel and community members have been shared with the ministries of health and partners to help inform programmatic improvements.

The one-year anniversary of the vaccine launch on 23 April 2019 was commemorated in the context of the 2020 World Malaria Day and World Immunization Week (2). An estimated 275 000 children in Ghana, Kenya and Malawi have received their first dose as part of routine childhood vaccination and should be benefiting from the added protection provided by the vaccine.
Data collection through sentinel hospitals and community mortality surveillance are ongoing, with monthly data quality review by WHO and in-country evaluation partners. Opportunities to strengthen the surveillance systems have been identified through this process. Initial data show that the rates of meningitis detected in sentinel hospitals are lower than expected (including in Kenya where diagnostic capacity, i.e., lumbar puncture rate, is high). This may be a consequence of good vaccination programmes and the high uptake of the Haemophilus influenzae type B (Hib) vaccine and pneumococcal conjugate vaccine (PCV).

The MVIP’s advisory bodies continue to meet regularly and provide guidance to the Programme. Since the last update, the Programme Advisory Group (PAG) met three times, on 7 November 2019, 14–15 January 2020 and 15 April 2020; and the Data Safety and Monitoring Board (DSMB) met twice, on 24–25 November 2019 and 3 March 2020.

Recommendation for case-control study and resource mobilization

In light of the data that have emerged since the original WHO position paper on RTS,S/AS01, including the extended follow-up of the phase 3 trial and modelling analyses questioning the value of the fourth dose, and the current levels of RTS,S/AS01 coverage, the PAG recommended a case-control study to evaluate the added benefit of the fourth dose of RTS,S/AS01. A case-control study would also strengthen the evaluation of existing safety and effectiveness endpoints. Efforts are underway to secure funding.

In Quarter 4 of 2019, additional funding commitments for the completion of the MVIP through 2023 were secured from the Global Fund (up to US$ 8 million) and Gavi (up to US $11.6 million). Fundraising to fill the remaining gap of approximately US$ 5.6 million is ongoing.

Gavi has agreed to work with other parties to find a financial mechanism to enable continued production of RTS,S prior to a policy recommendation in order to improve the timeliness and volume of future vaccine supply.

On 18 October 2019, WHO convened a Malaria Vaccine Stakeholder Meeting to brief stakeholders on the malaria situation, the potential role of the vaccine as a complementary control tool, and the pathway to WHO policy review.

Impact of COVID-19

Cases of COVID-19 have been reported in all three MVIP countries. At present, vaccination services (including RTS,S/AS01 vaccination) continue, although demand may decrease due to fear of coronavirus infection, directives for people to stay at home, health worker fears and anticipated absenteeism. The evaluations through sentinel hospital surveillance and community mortality surveillance continue, with close monitoring of the COVID-19 situation and respecting Ethics Review Boards (ERBs) and national guidance. Evaluation partners have instituted measures to reduce the risk of COVID-19 infection among study staff (personal protective equipment, social distancing). In anticipation of potential disruption of activities, they have also introduced measures to collect data retrospectively.

WHO has released guidance on immunization and malaria services in light of COVID-19 (3,4). The guidance calls for countries to prioritize routine immunization of children in essential service delivery and for malaria control interventions to continue as long as they can be safely provided, including with modification as needed.

WHO continues to monitor the potential impact of COVID-19 on the MVIP and is in close contact with local partners to assess risks and implement mitigation measures.
Priorities for the next six months

Key priorities in the coming weeks and months include support to in-country partners to mitigate and monitor the potential impact of COVID-19 on the Programme; continued support of programmatic improvement where needed; continued support to evaluation partners to ensure the hospital- and community-based surveillance systems are fit for purpose with appropriate mitigation measures implemented; coordination and management of the data generated by the MVIP; and continuation of resource mobilization efforts to address the remaining funding shortfall for the completion of the MVIP and for implementation of a case-control study.

References


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