Five things you need to know about the new R21 malaria vaccine

Ghana is the first country to approve a new malaria vaccine that could save millions of lives in the world’s most malaria-ridden regions. Here are five things you need to know about the new vaccine.

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Ghana has become the first country in the world to approve the highly anticipated R21 malaria vaccine that could save millions from the mosquito-borne disease. The disease kills a child every minute worldwide and in Ghana itself there were 5.3 million cases and 12,500 deaths in 2021.

The R21/Matrix-M malaria vaccine, developed by the University of Oxford and manufactured and scaled up by the Serum Institute of India (SII), is only the second vaccine the world has seen for a disease that has caused untold suffering for millennia.

The R21/Matrix-M vaccine targets the plasmodium ‘sporozoite’, which is the first form of the malaria parasite entering the human body.

Despite the lack of a vaccine, between 2000 and 2015 such significant progress was made in reducing infections and deaths through vector control and antimalarials that it prompted talk of moving beyond the aim of elimination towards malaria eradication. However, since 2015 progress has been backsliding, and this was deeply exacerbated by the COVID-19 pandemic. Now, the hope is that using vaccines alongside other approaches to reduce infection will be a game-changer.

1. Early reports show the vaccine could have a significant impact

While the phase 3 data for the R21 vaccine has not been published yet, phase 2 data was published in September showing high effectiveness following a fourth booster dose.
unpublished phase 3 data shows a similar vaccine performance as in the phase 2 trial, according to lead scientist Adrian Hill, at the Jenner Institute, Oxford University.

Ghana's Food and Drugs Authority (FDA Ghana) has assessed this trial data and approved the vaccine for use in children aged 5 to 36 months, who are at highest risk of death from malaria.

This new vaccine comes hot on the heels of the RTS,S vaccine which was approved in October 2021 by the World Health Organization (WHO). Four doses of RTS,S vaccine reduce clinical malaria cases by 39% and severe malaria by 30%. Given the extreme burden malaria puts on families, communities and economies across the world, this is not insignificant, and the vaccine has already been given to one million children in pilot roll-outs since 2019. A second efficacious new vaccine could transform the world's malaria response.

2. The vaccine targets the first stage of the parasite's life cycle

When the anopheles mosquito that carries the malaria parasite bites a person, it sends the parasite through the bloodstream, where it shapeshifts through stages of its life cycle. The complexity of the malaria parasite's life cycle has meant vaccine development has been hampered for years. The R21/Matrix-M vaccine targets the plasmodium 'sporozoite', which is the first form of the malaria parasite entering the human body.

Only a few (10–100) sporozoites are injected by infected mosquitoes before the parasite multiplies, making them the ideal target for a vaccine. R21 is a subunit vaccine that delivers parts of a protein secreted by the sporozoite that are bundled up with a part of the hepatitis B virus that is known to trigger a strong immune response.

The vaccine also contains Novavax's Matrix-M, an "adjuvant" which boosts the immune system response to make it more powerful and long-lasting. Vaccines work by putting the antigen, which is the piece of the virus or bacteria that our system recognises and responds to, in front of our immune cells. This technology – that was used in Novavax's COVID-19 vaccine – induces the influx of antigen-presenting cells at the injection site and enhances antigen presentation in local lymph nodes, which means that the immune system is triggered as strongly as possible.

3. Vaccine roll-out could start as soon as WHO gives the go-ahead

Formal results from the ongoing phase 3 trial of 4,800 children across Burkina Faso, Kenya, Mali and Tanzania are expected to be published by the end of the year. WHO is currently assessing whether to prequalify the vaccine for wider use. If WHO does recommend it, Gavi and UNICEF could begin funding and procuring doses immediately to protect children across Africa as soon as possible.

However, the idea is not to replace RTS,S but to be complementary – Gavi has already approved funding for a malaria vaccine programme and is ready to support rollout of R21 alongside RTS,S.

4. Supply should be able to meet demand

The Oxford team have a deal with Serum Institute of India to produce up to 200 million doses annually, which will mean the vaccine won't face the same bottlenecks in manufacturing hurdles that many vaccines – including the COVID-19 vaccines – have encountered.
This is critical because vaccinating those at high risk of malaria simultaneously will be important in stemming the spread of disease, as well as protecting the vaccinated.

5. Tech transfer could mean local production in Ghana

Serum Institute of India have announced a technology transfer deal to produce the vaccine in Ghana. This can start as soon as a manufacturing facility is completed in Accra.

The COVID-19 pandemic made it acutely clear that relying on vaccine production in a few countries that then ship doses to where they are needed is fraught with potential issues, and is often more costly. Countries like Brazil and India already have robust manufacturing capacity, but building local vaccine production capacity across Africa is critical.