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Target product profiles for second-generation childhood malaria vaccines

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Clinical trials of the four-dose RTS,S/AS01 vaccine for *P. falciparum* malaria demonstrated a protective effect in young children and, beginning in 2018, the vaccine will be evaluated through a large-scale pilot implementation program in Ghana, Kenya and Malawi. Recent evidence from a phase 2a challenge study indicates that varying the timing and amount of the fourth dose could further improve the public health impact.

We used a dynamic modelling approach to inform target product profiles (TPPs) for a second-generation malaria vaccine, focussing on the vaccine properties of initial efficacy, duration of protection, dosing schedules and coverage. We simulated the changing anti-circumsporozoite antibody titre following vaccination, related titre to vaccine efficacy, and then implemented this efficacy profile within an individual-based model of malaria transmission. We developed a range of efficacy profiles for different vaccine schedules and used these to evaluate the relative impact of initial efficacy, duration, and fourth dose characteristics. We ran the simulations across a range of epidemiological strata, measuring clinical cases averted children younger than five years.

We found that in the first decade of delivery, a vaccine with high initial efficacy vaccine resulted in more clinical cases averted, compared to a longer duration vaccine, and that the effect was more pronounced in high malaria prevalence settings. However, the low initial efficacy and long duration schedule averted more cases across all age cohorts if a longer time horizon was considered. We also observed that a higher antibody titre resulting from the fourth dose was always advantageous, and that a longer delay between doses three and four averted more cases in older age classes.

Our results indicate that an imperfect malaria vaccine, initial efficacy may be more important than vaccine duration. An optimised malaria vaccine may outperform the current RTS,S, but timing of the fourth dose determines the age group that benefits most. This TPP analysis could provide insight for vaccine developers and policy-makers into how distinct characteristics of a malaria vaccine may translate to public health outcomes.

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