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Opinion Article

Malaria: What does the RTS,S/AS01 Vaccine Mean for Children in Africa?

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Opinion

Malaria is an example of an infectious disease which if not diagnosed appropriately and treated promptly can devastate the life of a child. Globally it also has a major impact on quality of life, educational potential, and economic productivity, particularly in resource-poor settings.

The scale of the problem remains enormous; 229 million cases were recorded in 2019 [1]; and malaria kills more than 1 million people a year worldwide, perhaps closer to 3 million when its role in deaths related to other diseases is included. Much of the mortality is concentrated among children under the age of five years; WHO estimates > 260,000 African children under the age of five die from malaria annually. Mortality among school-aged children (ages 6-15 years) is not known, but in many Low- and Middle-Income Countries (LMICs) malaria is reported to be the main reason a school-aged child will die. Morbidity too is far reaching; one important measure is the fact that infection is cited as the principal reason why a child will be absent from school [2]. Here the adverse effects go far beyond compromised attendance. Even an attack of uncomplicated malaria can cause impairment of cognitive performance that often persists for weeks, and adverse effects are cumulative with repeated attacks [3]. In addition, where the principal infecting agent is Plasmodium falciparum, 'cerebral' malaria is common, and infection can be associated with permanent loss of cognitive and fine motor function from complications, especially where diagnosis is delayed and/or treatment is sub-optimal [4]. Consequently, even where children survive malaria, a significant negative effect on their academic potential and, by association, quality of life results.

A vaccine against malaria has long been searched for. Vaccines are a central element in the control of infectious diseases as has been underscored by the current Covid 19 pandemic. But in the case of malaria, because of the complexity of the parasite and its numerous immune evasion mechanisms, an effective vaccine has proved elusive [5].

The announcement by WHO October 6th 2021

In an historic announcement, WHO has recommended widespread use of the RTS,S/AS01 (RTS,S) malaria vaccine among children in sub-Saharan Africa, and in other parts of the world with moderate to high P. falciparum malaria transmission. The recommendation follows research trials in Ghana, Kenya and Malawi that have involved more than 800,000 children [6].

In his announcement, the WHO Director-General quite rightly said, "This is a historic moment. The long-awaited malaria vaccine for children is a breakthrough for science, child health and malaria control." And WHO's endorsement of RTS,S comes at a crucial time in malaria control, as it must be remembered that in recent years, WHO and its partners have been reporting a stagnation in progress against malaria. Between 2000 and 2015, widespread deployment of simple but innovative control measures did turn the tide against malaria; insecticide-treated bed nets, vector control programs, rapid diagnostic testing, new treatments and prophylactic strategies are estimated to have averted 7·6 million deaths since 2000. However, more recently this initiative has been lost, in part due to evolving mosquito and parasite populations and developing resistance to insecticides and antimalarials. Only last year, WHO warned that global targets of reducing malaria case incidence and mortality rates by at least 90% by 2030 would be missed [1].

So, while the announcement of a vaccine is important and historic, in my opinion there is a global imperative to act on two caveats included by the Director-General in the announcement, as both underscore unique but different opportunities that the availability of vaccine now provides. He put the role of the vaccine in perspective by adding that its use "on top of existing tools to prevent malaria" could save tens of thousands of young lives each year, and then stating that the hope of WHO was that the historic RTS,S/AS01 recommendation "can reinvigorate the fight against malaria." These caveats are important reminders that because of the nature of malaria and the resource-poor settings in which it predominates, the vaccine is not in itself a 'silver bullet', and a renewed (reinvigorated) multi-faceted approach to prevention, in which vaccination programs play an integral part, offers the best chance of significantly and permanently decreasing malaria related mortality and morbidity among children. The vaccine will in and of itself improve the situation of course, but in addition all vaccine initiatives must also drive greater efforts to engage children and the communities in which they live in more effective ways to fight malaria.

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In welcoming the announcement, Dr Matshidiso Moeti, WHO Regional Director for Africa also qualified his remarks. While he reiterated that, "We have long hoped for an effective malaria vaccine, as for centuries, malaria has stalked sub-Saharan Africa, causing immense personal suffering," his perspective was, that WHO's recommendation of widespread use of a vaccine "offers a glimmer of hope for the continent" and we expect many more African children to be protected from malaria and grow into healthy adults.

A Lancet editorial also expressed cautious optimism, stating broad roll-out of the vaccine across sub-Saharan Africa is now eminently achievable, but "challenges remain;" adding, this scientific triumph could be one of the most monumental opportunities in child health for a generation, and, "there is hope that the vaccine can turbocharge malaria control" [1].

The RTS,S vaccine

RTS,S is the first parasite vaccine to have obtained regulatory approval; it is designed to induce antibodies against the sporozoite phase of the lifecycle; this blocks infection of the liver, where the parasite would normally mature and multiply before re-entering the bloodstream to further infect erythrocytes [1,5]. This malaria vaccine is the result of 30 years of research and development. The Malaria Vaccine Implementation Program is coordinated by WHO and supported by in-country and international partners. Early studies showed modest efficacy, leading to a positive scientific opinion by the European Medicines Agency; Phase 3 trials between 2009-14 showed that children receiving three doses of RTS,S plus a booster dose, would have a 29% reduced risk of severe malaria [7].

Implementation programs in Kenya, Ghana, Malawi, Burkina Faso, and Mali will continue to be evaluated until 2023, principally to understand the added value of the 4th vaccine dose, and to measure longer-term impact on child deaths. Significantly, it has already been confirmed that, with the additional protective element provided when vaccination is combined with seasonal malaria chemoprevention (monthly administration of sulfadoxine-pyrimethamine and amodiaquine to young children during the transmission season), RTS,S can reduce death from malaria by over 70% [1,8]. In other words, to be this effective, the vaccine will need to be given in parallel with a program which provides vaccinated children with an additional prophylactic drug regimen. This requirement adds further complexity to the already substantial public health challenge of protecting children with a vaccine which requires multiple doses.

Key findings from the phase 3 trials [6,9]

- Vaccination improves health and saves lives: In particular, a significant reduction in deadly severe malaria, even when introduced in areas where insecticide-treated nets are widely used and there is good access to diagnosis and treatment. Children who are not sleeping under a bed net are also benefitting
- Strong safety profile: To date, more than 2.3 million doses of the vaccine have been administered in 3 African countries.
- Feasibility of delivery: using the trial model of introduction in child health clinics.
- No negative impact on uptake of bed nets, other childhood vaccinations, or health seeking behavior for febrile illness.
- Highly cost-effective: Modelling estimates that the vaccine is cost effective in areas of moderate to high malaria transmission.

Limitations noted [5,7-9]

- Early studies showed modest efficacy.
- Possible safety issues: due to an increased incidence of meningitis, cerebral malaria cases, and increased female mortality in malaria vaccine groups.
- Questionable feasibility of effectively delivering a vaccine requiring a four-dose schedule.
- Lack of clarity how the vaccine will fit into wider programs of malaria control remains unclear: Understandably, there are questions over who will pay to make the vaccine available to all who need it, many of whom live in countries with fragile health systems.

The WHO recommendation for the vaccine

Based on the advice of two WHO global advisory bodies, one for immunization and one for malaria, WHO recommends that in the context of comprehensive malaria control the RTS,S/AS01 malaria vaccine be used for the prevention of P. falciparum malaria in children living in regions with moderate to high transmission (as defined by WHO). With the vaccine provided in a schedule of 4 doses from 5 months of age with the aim of reducing malaria disease and burden.

Important and historic though vaccine use will be, as WHO it indicates, there is a need to reinvigorate the fight against malaria using existing tools in parallel with vaccine rollout programs. In my opinion, as the prevalence of infection peaks in school-age children and an estimated 200 million are at risk, this is also the time to respond more effectively than in the past to the repeated calls made to scale up and improve malaria control in this population [2].

Reinvigorating the fight against malaria

Schools obviously provide ready access to children aged 6-15 years, and there are precedents where other health concerns have been effectively controlled through school programs. Hence it makes sense to base initiatives to reinvigorate the fight against malaria in the schools themselves. Importantly there is good evidence that where school children are engaged effectively in health promotion, in addition to benefiting individually, there is a 'trickle down' effect into the community. Siblings and parents within the school child's household are especially likely to gain knowledge and adopt beneficial health practices [10,11], meaning that in the context of malaria, younger children who remain the age group most at risk of death from malaria, and the adults who care for them would likely also benefit to some degree from school-based programs.

In my experience, in many sub-Saharan African cultures there used to be no specific word for malaria, and terms still used are often simply variations of 'fever,' so many parents also need to acquire a practical understanding of what malaria is and what having it means. If this knowledge became universal, vaccine uptake rates would likely benefit, and more parents would take children with symptoms suggestive of malaria for diagnosis and medical care. As a consequence, onward parasite transmission would decrease, the burden of malaria would reduce, and care of children would more often meet the WHO guidelines for accurate diagnosis and treatment within 24 of symptoms developing than occurs currently.

School-based initiatives for malaria

In any given community local needs and resources will differ, so school-based initiatives need to be tailored accordingly; accommodating for example differences between urban and rural settings. Ideally each initiative will be broad and multifaceted enough to leverage as many components of the malaria prevention/treatment equation as are required to comprehensively provide for the needs of the target population. It is clear for instance that in addition to any specific diagnostic and therapeutic measures, educational components_are required to address the lack of knowledge that exists about key facts related to malaria. Among primary school children in rural Uganda one study identified that less than 20% knew mosquitoes transmitted the disease, that bed nets are a preventive measure, or that clinics provide diagnosis and medical treatment [15]. Unless children understand what causes malaria, that it can be prevented, which symptoms should lead to diagnostic testing, and the importance of prompt and effective treatment, they are unlikely to be able to benefit fully from any government driven prevention initiatives.

A valid model to consider as the foundation for upscaling school-based malaria prevention is the WHO Health Promoting School approach; in this model, additions to the curriculum that provide essential health knowledge are combined with activities that promote health related skills and practices [11]. For example in class education on how mosquitoes carry and transmit malaria can be combined with practical measures to promote vector control, such as getting children involved in environmental clean-up of the plastic bags and bottles, bottle caps and cans that provide breeding sites for mosquitoes in the rainy season. In turn, this combination of knowledge and engagement will make the logic of a preventive element such as sleeping under a bed net more obvious, and lead to greater buy in and use by children than just delivering nets to communities and saying they should be used.

Now there is a malaria vaccine for children, what needs to be done?

In my opinion, if the widespread use of the malaria vaccine WHO recommends is to effectively reinvigorate (WHO) and turbocharge (Lancet) efforts to reduce the burden of the disease among children, action is needed to provide multi-faceted programs able to complement and synergistically enhance the effects of vaccination; the following components are relevant:

Education

The goal must be for all children to achieve 'health literacy.' To do this, key facts must be included in the curriculum of all schools in endemic areas about the cause, prevention and clinical features of malaria, and how and why diagnosis and prompt treatment are necessary.

Policy

National strategies need to be established to develop and promote local programs that incorporate child vaccination. This will require new levels of leadership and inter-sectorial collaboration, funding, and support to enable individual communities to participate successfully. Communities will need specific recommendations and direction on how to deliver and sustain the components of the scaled up programs the availability of the vaccine now requires. The 2017 Lancet Commission on the future of health in sub-Saharan Africa provides sound advice in this regard, and constructive direction on approaches to innovative education and training of personnel which correspond to local needs, and hence lend themselves to the strategies required [12].

One obvious policy decision required is whether or not to provide children with prophylaxis to accompany vaccination; to date, the one chemo protective regimen trialed has proved very beneficial [8]. Prior to the vaccine, two prophylactic approaches were utilized to some degree; chemoprophylaxis - the regular administration of antimalarial drugs to those at risk of infection with the aim of maintaining protective levels within the blood stream, and Intermittent Protective Treatment (IPT) - the periodic administration of a full therapeutic dose of an antimalarial drug or combination of drugs at predefined intervals to those at high risk of malaria, regardless of their infection status [2]. Chemo protection through IPT is deemed preferable to chemoprophylaxis for children due to problems with adherence to prescribed regimens, compliance due to cost, and the significant risk of emergence, or increased risk of drug resistance.

Accurate diagnosis and prompt treatment for symptomatic children

During the rollout of vaccination programs, and pending high rates of immunization, greater advocacy is required for the use of current WHO approved diagnostic and treatment methods; for example, those employing Rapid Diagnostic Testing (RDT) and Artemisinin combination therapy (ACT) [13]. In addition, to facilitate effective intervention, logistic improvements are required to ensure the availability of adequate quantities of testing and treatment supplies to outlets providing these services, and to promote 'task shifting' as advocated by WHO [14] where access to; for example, by training personnel other than health care professionals to use RDT and provide ACT, such as pharmacists [2], and teachers in school-based health service delivery programs [15,16].

Prevention

(a) A public health strategy must be developed to provide information on the preventive benefits of the malaria vaccine. To do this requires involvement from across society, and especially engagement of the target end users, many of whom will be young parents whose preferences and beliefs reflect their youth and the extent of their education and life experience. Gender and culture will also be factors. Three elements to be capitalized on are the love of music, influence of social media and ubiquity of cell phone use among African youth these days. Key messages from songs with positive health and behavioral content have been shown to be retained by rural school children, and the impact of health promotion music videos recorded by celebrities has been documented [17]; especially where video production follows the Education Entertainment format proven to be effective in health promotion. Celebrity advocates and female role models should be sought to 'champion' the vaccine and lead online 'chat' via social media. Appointments and reminders for child vaccination can be texted via phones. Past mistakes of using a 'top down' strategy to develop generic public health messaging, and 'outdated' means of dissemination must be avoided.

(b) All established preventive measures should be promoted further, and especially the use of insecticide treated bed nets; the aim should continue to be that as many children as possible sleep under one in malarial areas. To achieve this, school programs should teach all children about vector control and actively involve pupils (and their siblings) in local measures to control mosquitoes and reduce their breeding habitat.

Time for malaria control in children

The vaccine offers a real opportunity to translate these frequently published words into action. For too long, the concept has been repeated, but meaningful practical action has not been forthcoming [3]. Leading authors need to do more to drive change. The latest Lancet commentary asks "why is there no policy to address the high prevalence of malaria infection in school-age children?" [18], but stops short of advocating for specific interventions able to form policy, and revisits cost as being a barrier. This is no way to inspire action by policy makers.

If as the authors say, inaction relates to the pool of funding to support malaria control being insufficient, how will legislators be engaged to endorse vaccination? Clearly advocacy by experts and the weight of public opinion are essential, and briefing policy makers should include how school-based programs are a synergistic factor in the equation. As to recommending specific interventions, of course, it would be desirable if these could be based on the 'gold standard' of randomised controlled clinical trials. But with data from such trials consistently failing to provide consensus, flexibility is required, with openness to recommend solutions from successful intervention models where smaller size or elements of study design do not meet the inclusion criteria for systematic reviews. It is short sighted not to include published evaluations of successful, locally valid solutions in commentaries and reviews. Inclusion would offer a way for individual communities, especially those with unique epidemiologic, geographic, cultural or public health issues, to identify novel interventions with the potential to benefit their children. Broader evaluation of ideas deemed sound could then follow, which in turn would aid policy development.

For example, the International Pediatric Association recently endorsed a school-based teacher-driven testing and treatment model as applicable globally. As far back as 2005, it was proposed that children's access to treatment would be improved by engaging teachers [19], and data from a 2-year trial in 4 schools in rural Uganda show that when volunteer teachers were taught how to use rapid diagnostic test kits to evaluate all children found to be sick at school, and administer prompt artemisinin combination therapy to those testing positive, absence from school, a surrogate measure for malaria morbidity, was greatly reduced [15]. It was the teachers who identified the high impact of malaria on their pupils and called for intervention; their insight and collaboration were integral to the approach chosen and the sustained delivery of the program. Subsequently, a similar approach in Malawi was comparably effective [16]. Importantly this approach reflects government policy in many sub-Saharan countries that promotes RDT use by non-medical personnel. It also incorporates diagnostic and treatment entities advocated by WHO. Arguably, in terms of cost, where RDT and ACT are part of national clinic programs, making these entities available 'down stream' does not require a new funding strategy. The approach also responds directly to the 2017 Lancet Commission directives to use 'non-traditional outlets,' 'people-centered approaches,' and 'improved tools' to address health challenges [12], and is a practical way to make progress towards the broader aim of achieving the UN sustainable development goals for health [14].

Hence, this teacher driven model would be a logical addition to a vaccine rollout strategy, and for policy makers, there are two incentives for its inclusion:

1) The substantial, direct improvement of malaria management for participating children in the short term, and

2) The probability that this model would be a synergistic enabler within the vaccination program.

This is because increased participation in management and prevention within the broader community follow the improvement in knowledge and skills about malaria that children participating in school-based programs acquire [2,11,17]. Consequently there is the potential for greater awareness about malaria in the community as a whole to drive vaccine uptake.

Task shifting

Centering malaria programs on children in schools is called for by the WHO Commission on Social Determinants of Health to support health behaviors; this approach is an example of an innovative, content specific intervention shown to empower young people to take control of their lives [14]. Such 'task shifting' to school-based programs has already increased the delivery of other essential health services for children. Successful teacher-administered programs in LMICs include provision of intermittent anti-malarial therapy in Kenya, prophylactic chloroquine in Sri Lanka, and nationwide anti-helminth treatment in Uganda and in Ghana. Importantly, cost-benefit analysis shows that costs for delivering such health services to children can be reduced by having teachers implement such programs [2]. These are all examples of approaches applicable to ensuring African children benefit comprehensively from vaccine rollout, and which exemplify ways to address health challenges like malaria mortality and morbidity by using the concepts advocated by the Lancet Commission for innovative education and training of personnel that correspond to local needs [12].

Address vaccine hesitancy

Cultural and social factors will impact whether or not a child receives the malaria vaccine. To optimize uptake, lessons must be learned from the experience in sub-Saharan Africa over Covid vaccination. This indicates that a lack of awareness of the need for and benefits of immunization, widespread mis-information, scepticism, and mistrust of the authorities will have to be overcome in order to achieve 'buy in' for malaria vaccination. In Uganda, for example, widespread rumors that the Astra Zeneca Covid vaccine compromised male potency crippled programs offering that vaccine. However, Pfizer's version did not attract this erroneous stigma, and so achieved better uptake.

Promotion of education for girls

Countries who commit to educating their girls will likely see better vaccine uptake, as mothers who can read and write are already more likely to have their children immunized against common childhood infections than those who are uneducated. The children of educated mothers also have other significant advantages relevant to malaria prevention; six years of maternal schooling is associated with lower odds of a mother's children developing malarial parasitemia in eight sub-Saharan countries [20]. And not only does a child of an educated mother have fewer siblings and tend to be healthier, he/she also has a greater likelihood of attending school and will have more active maternal encouragement to do so; hence such children are more likely to benefit from the school initiatives that are now essential to upscale malaria prevention.

Further vaccine development

RTS,S is the first vaccine to be recommended, but other vaccines are in the pipeline, including a version developed by the Oxford vaccine group. Trials already indicate that one, the R21/MM vaccine, appears safe and very immunogenic in African children and shows promising high-level efficacy [5]. The long expressed aim for vaccines advocated by the Gates Foundation vaccines that agents should be stable without refrigeration and able to be effective following a single dose may not be realized in the context of a malaria vaccine, but it is certain that future generations of African children will benefit from progressive advances in vaccine development.

Conclusion

In my opinion the announcement of the first malaria vaccine, while historic and very important, is in no way the 'silver bullet' that will do away with the scourge of malaria. It seems likely that for the foreseeable future, achieving optimum vaccine efficacy will require some form of chemoprophylaxis to be administered to children in parallel with them being vaccinated. And the epidemiologic and public health complexities of malaria will still require effective overarching measures related to vector control, prevention, accurate diagnosis and effective pharmacologic treatment in order to contain the burden of malaria on children.

In providing these measures governments and communities should heed the call to employ 'non-traditional outlets,' 'people-centered approaches,' and 'improved tools' to address the challenges involved and, in this context, base many initiatives in school-based settings. Schools must also be the drivers of the efforts and innovation required to achieve the universal health literacy regarding malaria that is necessary in parallel. Only with African children informed, engaged and in receipt of the benefits of advances such as vaccination can malaria mortality and morbidity be reduced sufficiently for them to be able to enjoy the quality of life, level of educational attainment, and economic productivity the UN development goals call for, and which they deserve.

Conflict of interest

The author has no conflicting interests to declare

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