An effective vaccine against malaria would be a very important addition to the armamentarium of malaria control measures and the field evaluation of a vaccine has to be done in the context of other control measures. Recent years have seen a scaling-up in the implementation of existing malaria control measures. Preventive measures include insecticide treated bed-nets (ITN), long lasting insecticide treated nets (LLIN) and more recently, a revival in the use of indoor residual spraying (IRS). Diagnosis and treatment measures include microscopy, rapid diagnostic tests and the more widespread adoption of artemisinin-based combination treatments. Intermittent preventive therapy of malaria in pregnancy (IPTp) is recommended and widely implemented [1] and similar preventive therapies in infants (IPTi) [2] and children (IPTc) [3] are under evaluation as possible additional interventions. At least in part due to more widespread implementation of malaria control measures, there has been a reduction in the malaria disease burden in some endemic countries [4] and this has implications for the design and size of malaria vaccine trials.

An increasing number of malaria vaccine candidates have entered Phase 1 trials and some have progressed to field efficacy trials in populations where malaria is endemic. The most advanced malaria vaccine candidate is RTS,S, which in a field efficacy trial, with AS02 adjuvant, in 2,022 Mozambiquan children aged 1–4 years at the time of vaccination has shown efficacy, over 18 months of follow-up, of 35.3% (95% CI 21.6–46.6; \( p < 0.0001 \)) against clinical malaria and 48.6% (95% CI 12.3–71.0; \( p = 0.02 \)) against severe malaria [5]. A phase 3 pivotal trial for potential licensure of the vaccine was at the pre-initiation stage as of November 2008. Other promising candidate vaccines are at least 3–5 years behind in their clinical development programmes.

The Malaria Vaccine Technology Roadmap was constructed to provide a global strategic framework for accelerating the development of a vaccine to aid malaria control [6]. Within this framework, the World Health Organisation (WHO) convened a meeting in 2006 to formulate guidance on the selection of case definitions and analysis methods for the evaluation of vaccine efficacy against malaria in clinical trials. In June 2008, the Initiative for Vaccine Research and Global Malaria Programme, WHO, convened a further joint
scientific meeting to consider the current state of malaria vac-
cines in the context of changes in the epidemiology and control of
malaria; to reflect on complexities in the interpretation of measures
of efficacy in field trials of partially efficacious malaria vaccines; and
to consider the implications of different measures of efficacy with
respect to vaccine licensure and public health impact. The meet-
ing included those with expertise in a variety of areas, including:
malaria epidemiology, clinical trials, statistics, vaccine research and
development from academia and industry, vaccine safety, regu-
larity affairs, and malaria control, together with representatives
of funding agencies. Recommendations from the meeting were
directed to the WHO Malaria Vaccine Advisory Committee (MAL-
VAC). We outline here the discussions and recommendations from
the latter meeting.

2. Malaria vaccine trials

Candidate malaria vaccines are conventionally classified into
one of three groups according to the stages of the parasite life-
cycle at which they are directed. Pre-erythrocytic candidates target
sporozoites or liver-stage parasites or both, blood stage vaccines
target merozoites or antigens expressed on the surface of infected
red blood cells, and transmission blocking vaccines aim to induce
antibodies which, after a blood meal, act within the mosquito vec-
tor to target sexual stages of the parasite. Discussions at the meeting
focused on the first two vaccine classes.

Sporozoite challenge trials have been used as a screening
procedure to select pre-erythrocytic candidate vaccines to take for-
ward into field trials. In these challenge trials, small numbers of
malaria-naive vaccinated volunteers, and unvaccinated controls,
are experimentally exposed to mosquitoes infected with drug sen-
sitive parasites. Volunteers are treated as soon as they are shown to
have malaria parasites in their blood. Generally, all of the volunteers
in the control groups develop infection and the proportion of vacci-
nees in whom infection is prevented has been the primary efficacy
endpoint, although in some studies delay in the time to the appear-
ance of malaria parasites in the blood has also been used to assess
the effect of the vaccine. In such studies using the RTS,S/AS02A
vaccine the appearance of parasites following challenge has been
prevented in 30–50% of volunteers [7–9].

Malaria is a major cause of under-5 mortality in sub-Saharan
Africa. In malaria-endemic areas, non-immune infants or children
develop blood stage infections after natural challenge with sporo-
zoites by infected mosquitoes and a proportion of those infected go
to on to develop clinical malaria or severe malarial disease, and some
die of the infection. A substantial degree of immunity to severe
disease and death occurs after a limited number of infections, and
many exposed, semi-immune, individuals will show evidence of
malaria parasites in their blood without obvious clinical symp-
toms. In vaccine trials conducted in malaria-endemic communities,
it is possible to estimate efficacy against infection by taking blood
smears at repeated intervals from a few hundred vaccinated (and
control) children or adults throughout the malaria transmission
period in the year. Larger field trials, generally involving over 1000
children, are required to obtain precise estimates of efficacy against
mild or uncomplicated clinical malaria disease. Much larger trials,
generally involving in excess of 10,000 children, are required to
provide information on the impact of the vaccine against the rarer
malaria sequelae of severe disease or mortality.

3. Measures of the efficacy of a vaccine against malaria
infection and clinical malaria disease

Conventionally, the efficacy of a vaccine is defined as the per-
centage reduction in the risk of the disease it is designed to prevent
among people who have received the vaccine compared to the risk
in unvaccinated people. This definition derived from situations in
which a vaccine was considered to reduce the proportion of people
who were susceptible to disease if challenged by the infectious
agent. Typically, it was applied in disease situations in which nat-
ural infection with the causative agent provided near complete
protection against a second infection with the same agent, such as is
the case with measles infection. The situation is more complicated
for infectious diseases for which the first infection (or vaccination)
may only provide partial protection against re-infection and for dis-
eases which may affect the same individual multiple times, such as
c clinical malaria [10]. In recent reports of malaria vaccine field tri-
als the estimates of efficacy have been derived by comparing the
incidence rates of the first appearance of malaria parasites in the
blood, or of the first occurrence of symptomatic malaria disease,
in vaccinated and unvaccinated groups [5,11–15]. These analyses
have included approaches based on the comparison of malaria
incidence rates, Cox proportional hazards regression models and
Poisson regression models. There seems to be agreement among
leading statisticians in the malaria field that basing analyses on
time-to-event is the most appropriate method to analyse both inci-
dent infection and clinical malaria data from field trials of malaria
vaccines [6] and that this is generally a better approach than com-
paring the proportion of individuals remaining “event-free” at a
specific time post-vaccination—the approach generally used to anal-
yse the results of experimental challenge trials. This has caused
some confusion among non-statisticians working in the field.

Most malaria vaccine field trials have generally reported time-
to-first-event as the primary efficacy endpoint. Questions have
been raised as to whether focussing on the first event is really the
most appropriate end-point in studies to assess the public health
impact of a malaria vaccine. It has been suggested that the reduction
in the total number of events in some defined time period following
vaccination might be a more appropriate measure. At the meeting
it was agreed that a clear exposition was required of the merits and
disadvantages of different measures.

The high incidence of malaria in many endemic areas, in con-
junction with the often substantial variation in risk from person to
person in a given trial, makes estimation of efficacy more complex
than in the case of diseases in which the incidence is rare. Het-
erogeneity in exposure (or susceptibility) and waning of efficacy
cannot be distinguished by examining conventional Kaplan-Meier
plots of the proportion of individuals remaining disease free at
different times post vaccination. Furthermore, estimation of effi-
cacy at a period distant from vaccination is challenging and it was
considered that presentation of long-term follow up data should
include division into distinct time periods (for example 0–1 years
from vaccination, 1–2 years etc.) as a secondary analysis.

Data on the total number of episodes of malaria reflects the true
community disease burden and are of more public health relevance
than first episode data. However, multiple episodes of malaria in the
same individual are not independent and this complicates the sta-
tistical analysis of such data. Further statistical research is needed
to inform the selection of optimal analysis strategies for multi-
ple episodes data. Nonetheless, there was consensus that these
data should be collected and reported for phase 3 trials of malaria
vaccines. Another view expressed at the meeting was that the pro-
portion free from clinical malaria, or from malaria infection, at the
end of follow-up should also be reported and analysed for field tri-
als. Because, in most trials, periods of follow-up vary from subject
to subject, the proportion disease free at a given time post vacci-
nation would have to be estimated by Kaplan-Meier methods. The
regulatory requirement for licensure of a vaccine is demonstration
of clinically relevant benefit using agreed, ethically and statistically
appropriate trial designs, data collection and analysis methods. In
Data sharing will increase understanding of the likely public health impact of any new vaccine in the context of existing control measures.

Evaluation of the impact of possible interactions between interventions is a priority area for assessment of public health impact.

Examination of vaccine impact on malaria transmission is a central part of assessment of any potential new malaria intervention.

Post-licensing evaluation of vaccine efficacy and effectiveness: Long-term efficacy data from phase 3 trials and phase 4 clinical trial designs.

Use of comparator after licensure before policy recommendation?

Post licensure, what data can be derived on efficacy/effectiveness in multiple transmission settings and age groups, in the context of the variable background of changing control measures and epidemiology?

Pharmacovigilance and strengthening monitoring & evaluation for long-term safety (long-term efficacy also relates to safety through possible deferred increased morbidity by interference with acquisition of immunity).

Challenges in interpretation of time to event analysis and duration of efficacy for malaria.

Challenges in the analytic approaches for multiple/cumulative episodes.

Methods paper outlining the design and planned analysis of any phase 3 trial to be published prior to unblinding.

WHO MALVAC committee recommendation to enhance sharing of all data from malaria vaccine clinical trials

WHO MALVAC committee recommendation that development science activities to gain further insight into the area of interactions between malaria preventive interventions are a priority

WHO MALVAC committee recommendation to highlight need for assessment of impact of any new malaria vaccine on malaria transmission

Subject of future WHO meeting

To be included in future WHO meeting

An explanatory paper to be written by leading statisticians with WHO involvement as a resource for policymakers and regulators

Funding support required for further statistical research.

Vaccine developers requested to publish such a paper to allow policymakers to be prepared for the efficacy and safety data that will become available.

Table 1

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<td>Data sharing will increase understanding of the likely public health impact of any new vaccine in the context of existing control measures.</td>
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<tr>
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the case of a malaria vaccine evaluated in paediatric populations, there is general agreement that demonstration of efficacy against time to first episode of uncomplicated malaria disease, over a sufficiently long time period, may be appropriate for licensure [16]. At the meeting regulatory representatives confirmed that in most previous licensure submissions for non-malaria vaccines, only first episode data have been analysed, incidence of endpoints has been much lower than in malaria, immune or functional correlates have sometimes been available and vaccine efficacy has usually been high. The assessment of a relatively low efficacy malaria vaccine will therefore present new challenges from a regulatory point of view.

In general, the decision as to whether or not to license a vaccine depends principally upon its safety and its efficacy against the disease it is primarily designed to protect against. The decision as to whether or not to implement a vaccine in a public health programme will, in addition, be influenced by considerations of cost and the likely impact of the vaccine on outcomes such as all-cause and malaria-related mortality, severe malaria, malaria-related hospitalisations, incident anaemia, multiple episodes of malaria, all-cause clinic attendance data and on the duration of protection against these various measures. While the primary endpoint(s) will provide the focus of efficacy assessment, all of the above efficacy data taken together will be essential for evaluation of likely public health impact and, in so far as is possible, the other end-points listed should be measured and reported on in vaccine trials.

4. Malaria vaccine implementation

One aspect of the post licensure requirements for a vaccine is national regulatory authority (NRA) registration. WHO’s African Vaccine Regulatory Forum (AVAREF) is working to strengthen African NRA capacity. AVAREF was represented at the meeting by Ghana, Kenya, Malawi and Tanzania NRA staff. Following WHO policy recommendation and prequalification, government endorsement, financing mechanisms, pilot implementation projects, and a strengthened monitoring and evaluation (M&E) programme will all be necessary for introduction of a new vaccine. M&E requirements include both a pharmacovigilance network and a sustainable disease burden monitoring system. The need for a strengthened developing country pharmacovigilance system was identified at the meeting as a priority given that new products are emerging which may be implemented only in such resource-poor settings. Current work by the Global Malaria Programme (GMP) to improve country health information system (HIS) inputs forms part of efforts to accurately estimate trends in malaria disease and death.

It was agreed that pilot implementation and improved M&E systems would be critical to provide information on possible interactions between the co-existing malaria control measures. Strengthening government health systems was thought to be the appropriate way to ensure M&E improvements are sustainable.

5. Key questions in malaria vaccine field safety and efficacy

The group reached general agreement on some key questions for interpretation of safety and efficacy of a malaria vaccine and made recommendations for each which were agreed by the MALVAC committee (see Table 1). A number of issues were raised in addition (also see Table 2). It was agreed that further research was required to address the issues of evaluation of allele-specific immunity with polymorphic candidate vaccine antigens and of allele-specific vaccine-related immunity. The impact of co-infections with other pathogens on both malaria vaccine efficacy and on other disease states such as pneumonia, meningitis, bacteraemia and severe gastroenteritis also requires research.

6. Discussion

At a previous meeting, a WHO expert group confirmed that the enormous public health burden of clinical malaria justified licensure based on demonstration of efficacy against this end-point alone [16]. First generation malaria vaccines that will become available for implementation are likely to be of relatively low efficacy compared to other vaccines currently in routine use in developing countries, perhaps in the range of 30–60% efficacy against clinical malaria. In order to build consensus for policy change and implementation of a low effectiveness intervention, there will be a need for a comprehensive, transparent body of evidence covering all necessary aspects for programme implementation. There were strong calls from many experts for all of the safety and efficacy data submitted for licensure to be made available to decision-makers. However, more data may be needed for large-scale implementation.
Table 2
Additional questions posed by the Scientific Forum.

Safety and efficacy in infants. EPI co-administration.
How essential would it be that a malaria vaccine does not interfere with classical EPI vaccines? Would a modest degree of interference be acceptable, or should the vaccine rather be administered outside of the EPI schedule, in situations where interference is noted?

Safety in subgroups
How should safety, immunogenicity and efficacy of a malaria vaccine be established prior to introduction in special groups (HIV positive and/or severely malnourished infants)?

Duration of efficacy
How long should duration of vaccine efficacy be evaluated in phase 3 trials?
How long should protection last for significant public health impact?
How can the impact of boosting from natural infection be assessed?
What are the indications for vaccine booster doses?

Drug pre-treatment
Are we getting different information according to whether or not antimalarial drugs are administered as pre-treatment before vaccine administration?

Modelling and role of a vaccine in the context of other control measures
It will be essential to put the use of a malaria vaccine in the context of existing control measures in targeting malaria control/elimination/eradication. How will simulation modelling be applied for predicting potential beneficial effects of a hypothetical malaria vaccine at the country level? How can modelling be used to estimate cost-effectiveness when vaccination is implemented with other control strategies?

Impact on malaria transmission
One of the properties of an even imperfect malaria vaccine might be to reduce transmission of *P. falciparum*. How should trials be designed to allow evaluation of this indirect potential beneficial effect?

Combination vaccines
When should vaccine candidates be combined with other malaria antigens?

List of participants

<table>
<thead>
<tr>
<th>Expertise</th>
<th>Name</th>
<th>Organization</th>
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<tbody>
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decisions than the submission package for licensure alone. Some of this additional data may have to be collected in post-licensure (Phase 4) studies. Further consultation is required on the key questions that will need to be addressed, the data needed to inform the decisions on whether implementation of any given candidate is appropriate in a given setting, and what study designs might be used to assemble such data. WHO will facilitate a continuous dialog bridging scientific, regulatory and public health perspectives with the vision of reaching consensus on the information needed for implementation. Involving malaria control programmes in the process for assessment of new vaccines for possible implementation will be necessary. This scientific forum, and the consultation process leading up to it, has helped define some of the needs of the joint malaria control and malaria vaccine communities going forward towards possible registration of a first generation vaccine.

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Table 2 (Continued )

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References

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