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IDOSR JOURNAL OF SCIENTIFIC RESEARCH 11(2):40-45, 2026. ISSN: 2550-794X

https://doi.org/10.59298/IDOSRJSR/2026/11.2.4045 IDOSRJSR11106

Monoclonal Antibody Prophylaxis Against *Plasmodium falciparum* Malaria in Sub-Saharan African Pregnant Women

Mutebi Mark

Department of Pharmacology Kampala International University Uganda
Email: mark.mutebi@studwc.kiu.ac.ug

ABSTRACT

Malaria in pregnancy remained a dominant, preventable driver of maternal anemia, placental inflammation, fetal growth restriction, and preterm birth in Sub-Saharan Africa despite insecticide-treated nets and intermittent preventive treatment in pregnancy with sulfadoxine-pyrimethamine (IPTp SP). Persistent transmission, imperfect antenatal coverage, and drug resistance sustain residual risk. This review evaluated the biochemical and immunologic rationale, emerging clinical evidence, and implementation pathway for monoclonal antibody (mAb) prophylaxis to prevent *P. falciparum* infection and pregnancy-associated malaria in Sub Saharan Africa. A narrative synthesis was developed from peer-reviewed mechanistic literature, major clinical trial reports, and global guidance documents on malaria in pregnancy and antibody-based prevention to write this article. Long-acting anti-sporozoite mAbs targeting circumsporozoite protein, including CIS43LS and L9LS, showed high levels of protection in controlled human malaria infection and field trials, with extended half-life enabling seasonal protection after a single administration. However, pregnancy-specific evidence remained limited, requiring careful bridging of pharmacokinetics, placental IgG transfer biology, and maternal-fetal safety. A pregnancy-centered target product profile must prioritize simplicity of delivery, compatibility with antenatal care schedules, surveillance for rare adverse outcomes, and equity in access. mAb prophylaxis was a credible, biologically rational complement to IPTp SP, not a replacement, and may be strategically deployed for women at highest risk or in settings with high residual transmission while pregnancy-specific trials mature.

Keywords: Malaria in pregnancy, Monoclonal antibody, Circumsporozoite protein, Placental malaria, Sub-Saharan Africa.

INTRODUCTION

Malaria in pregnancy is a distinct clinical and immunopathologic entity in which *Plasmodium falciparum* exploits the placental microenvironment, promoting sequestration of infected erythrocytes, local inflammation, impaired nutrient exchange, and adverse maternal and neonatal outcomes [1–3]. Classical consequences include maternal anemia, low birth weight, preterm birth, stillbirth, and increased infant vulnerability, particularly among primigravidae and adolescents [4]. The World Health Organization recommends IPTp SP, initiated in the second trimester and given at least monthly to achieve three or more doses, alongside vector control measures such as insecticide-treated nets [5, 6]. Yet, programmatic gaps persist: a substantial proportion of pregnant women still do not receive IPTp SP, and the biologic effectiveness of drug-based prevention is threatened by parasite resistance, variable transmission intensity, and delayed engagement with antenatal care.

The core problem is therefore not simply the absence of interventions, but a persistent mismatch between transmission biology and the operational realities of pregnancy care. Pregnant women can acquire infection before the first antenatal visit, adherence can be incomplete, and parasites may evade drug pressure [7]. These constraints justify the evaluation of prevention modalities that provide rapid onset protection, extended duration, and minimal

dependence on repeated dosing. This review argues that monoclonal antibody prophylaxis merits serious consideration as a complementary strategy for Sub-Saharan African pregnant women. Section 1 summarizes the burden, placental pathophysiology, and clinical consequences of *P. falciparum* infection in pregnancy. Section 2 outlines the immunobiology of pregnancy and the mechanistic rationale for passive immunoprophylaxis, including Fc receptor biology and transplacental IgG transfer. Section 3 examines leading antigen targets and engineering principles that determine potency, durability, and functional profile. Section 4 critically appraises the current evidence base for malaria preventive mAbs, with explicit attention to what can and cannot be inferred for pregnancy. Section 5 addresses implementation pathways, integration with antenatal services, and a pragmatic research agenda for pregnancy-centered development. The purpose of this review is to synthesize the current state of science and define the evidence and delivery requirements needed to responsibly translate malaria mAbs into pregnancy protection.

Malaria in Pregnancy in Sub-Saharan Africa (Burden, Pathophysiology, and Clinical Consequences)

Pregnancy-associated malaria is driven by a specific adhesive phenotype of *P. falciparum-infected* erythrocytes that preferentially sequester in the placental intervillous space [8]. This sequestration occurs at densities that can exceed peripheral parasitemia and is central to disease pathogenesis. The molecular hallmark is expression of VAR2CSA, a parasite ligand that binds chondroitin sulfate A on placental syncytiotrophoblast-associated proteoglycans, enabling selective accumulation of infected erythrocytes in placental tissue [9]. The resulting microenvironment is characterized by monocyte infiltration, cytokine activation, fibrin deposition, and impaired placental perfusion, which jointly compromise oxygen and nutrient transfer.

The clinical consequences are both maternal and fetal. Maternal anemia reflects hemolysis, dyserythropoiesis, iron dysregulation, and inflammatory suppression of erythropoiesis. Fetal and neonatal risks include low birth weight and small for gestational age infants from placental insufficiency, as well as preterm birth, stillbirth, and neonatal death. Recent syntheses continue to emphasize the scale and persistence of placental malaria and its association with adverse birth outcomes, reinforcing that malaria in pregnancy remains a major contributor to preventable perinatal morbidity in endemic regions.

IPTp SP reduces maternal parasitemia and improves birth weight in many settings, but its real-world impact is limited by missed antenatal opportunities and heterogeneous effectiveness across regions [10]. WHO has highlighted ongoing gaps in IPTp coverage and has produced operational guidance to improve community deployment, underscoring that a large proportion of pregnant women still do not benefit from this intervention. In this context, a prevention tool requiring fewer contact points and offering durable protection could plausibly reduce the biologic and programmatic residual risk that sustains malaria-related adverse outcomes in pregnancy.

Immunobiology of Pregnancy and Rationale for Passive Immunoprophylaxis

Pregnancy is not an immunosuppressed state in a simplistic sense; rather, it is an immunologically reprogrammed state that balances fetal tolerance with antimicrobial defense [11]. The placenta is an immunologically active interface, and systemic immune adaptations can modify susceptibility and disease expression. First pregnancies are particularly vulnerable to placental malaria because protective antibodies against pregnancy-specific parasite variants, including VAR2CSA-related adhesive phenotypes, are acquired over successive pregnancies.

Antibodies are therefore central to naturally acquired protection in malaria and especially relevant in pregnancy [12]. Protective mechanisms include neutralization of sporozoites, inhibition of hepatocyte invasion, opsonization and phagocytic clearance, complement activation, and Fc-mediated effector functions that shape parasite clearance and inflammation. Passive immunoprophylaxis via mAbs aims to deliver a high concentration of a defined protective antibody at the time it is needed, bypassing the variability of natural immunity, vaccine responsiveness, and exposure history [13, 14].

Pregnancy adds two biologically advantageous features for antibody-based prophylaxis. First, IgG transfer across the placenta via the neonatal Fc receptor provides a plausible route for fetal and neonatal benefit, depending on maternal concentration, subclass distribution, Fc structure, and timing of administration [15]. Second, the same Fc receptor pathways that regulate IgG recycling and half-life can be exploited through Fc engineering to extend antibody durability, potentially supporting protection across a transmission season from a single dose.

The conceptual distinction is important: malaria preventive mAbs developed to date largely target the sporozoite stage, aiming to block infection before blood stage multiplication and before placental sequestration becomes established. This is attractive in pregnancy because it targets the earliest bottleneck in infection and, in principle, prevents downstream placental inflammation and its fetal consequences. However, pregnancy also imposes heightened safety thresholds. Any prophylactic mAb must demonstrate not only absence of teratogenicity and obstetric harm, but also neutral effects on fetal growth, placental function, and immune development. Thus, while the immunobiology of pregnancy supports the plausibility of passive prophylaxis, it also demands a rigorous pregnancy-specific evidence pathway.

Targets and Engineering of Antimalarial Monoclonal Antibodies

The leading targets for malaria preventive mAbs are antigens expressed on sporozoites, most prominently the circumsporozoite protein (CSP) [16]. CSP is abundant on the sporozoite surface and contains conserved epitopes that can be exploited for potent neutralization. CIS43LS and L9LS are long-acting anti-CSP mAbs developed to prevent *P. falciparum* infection, with Fc modifications that extend serum half-life, thereby enabling sustained protective concentrations [17]. The mechanistic premise is straightforward: if sporozoites are neutralized or functionally blocked before hepatocyte invasion, the entire downstream cascade of blood stage infection and placental sequestration is prevented.

Engineering considerations are not decorative details; they determine whether mAbs are deployable for public health use in pregnancy [18]. Key design variables include: (i) epitope specificity and breadth across parasite strains, (ii) binding affinity and functional potency, (iii) Fc-mediated effector profile, and (iv) half-life extension through Fc receptor interactions. Long-acting profiles support seasonal protection, reduce dosing frequency, and improve adherence by design. Route of administration is equally strategic. Subcutaneous delivery is operationally attractive for antenatal clinics and community distribution, provided bioavailability and tolerability remain acceptable.

Beyond sporozoite targets, theoretical targets relevant to pregnancy include antigens mediating placental adhesion (VAR2CSA) and blood stage antigens that could reduce parasitemia and placental inflammation if infection occurs [19]. Yet, targeting placental adhesion is mechanistically complex because VAR2CSA is large, polymorphic, and subject to antigenic diversity. Moreover, blood stage control might not fully prevent placental inflammatory programming once sequestration begins. For these reasons, the current most mature development pathway for pregnancy prevention is likely anti-sporozoite mAbs that prevent infection upstream, while parallel research continues on adhesion and blood stage targets as complementary or rescue strategies.

Evidence Base for Monoclonal Antibody Prophylaxis and Relevance to Pregnant Women

The clinical evidence for malaria preventive mAbs has progressed from controlled human malaria infection to field studies in endemic settings. The phase 1 program for CIS43LS demonstrated feasibility and protection against *P. falciparum* infection with an extended half-life antibody, establishing proof of concept that a single administration can confer protection [20]. Subsequent studies in endemic contexts reported protective effects over a malaria season, strengthening the translational argument that mAbs can prevent naturally acquired infection in high transmission regions. For L9LS, early-phase evidence also demonstrated safety and substantial protection, and field evaluation has extended into endemic settings with subcutaneous administration, which is directly relevant to operational feasibility.

Two implications follow. First, the mAb platform is no longer speculative. Second, the mechanistic target is upstream and therefore aligned with pregnancy prevention goals, since infection prevention should avert placental sequestration and its obstetric sequelae. Nonetheless, the pregnancy relevance remains inferential at present. The pivotal trials to date have largely involved non-pregnant adults or children, and pregnancy-specific pharmacokinetics can differ due to increased plasma volume, altered Fc receptor expression, and changes in antibody distribution and clearance. Therefore, bridging cannot rely on serum concentration alone; it must incorporate maternal exposure, placental transfer kinetics, fetal exposure, and obstetric outcome surveillance.

Safety considerations are multidimensional. mAbs in general have a strong safety record across many diseases, but malaria prevention would require administration to healthy pregnant women, including early gestation once safety is established, and potentially repeated use across pregnancies. Rare adverse events, immune complex effects, and injection site reactions must be monitored, but pregnancy requires additional endpoints: hypertensive disorders, fetal growth, congenital anomalies, preterm birth, stillbirth, and neonatal adaptation. Ethical constraints have historically delayed inclusion of pregnant women in trials, but contemporary frameworks increasingly support carefully staged inclusion when maternal and fetal risks of the disease are substantial and when preclinical and non-pregnant data support safety.

Trial design for pregnancy should prioritize clinically meaningful endpoints. Infection incidence and parasitemia are important, but pregnancy-centered endpoints must include placental malaria (histology or molecular measures), maternal anemia, and birth outcomes [21]. Timing also matters: an intervention administered at first antenatal contact may miss infections acquired earlier. A plausible deployment model could involve administration early in the second trimester, aligned with IPTp initiation, or even earlier once teratogenic risk is excluded. Importantly, mAbs should be evaluated as add-on tools rather than replacements, because IPTp SP and vector control remain beneficial and synergistic.

Strain diversity and antigenic variation can erode breadth if epitopes are not sufficiently conserved. Durability may differ in pregnancy. Cost and supply constraints can limit scalability. Finally, the external validity of trial settings may not capture the heterogeneity of transmission intensity, coinfections, nutritional status, and health system access that characterizes many Sub-Saharan contexts. These limitations do not negate the promise of mAbs, but they define the evidence and implementation thresholds that must be met before routine pregnancy deployment can be justified [22].

Implementation Pathways in Sub-Saharan Africa (Integration, Cost, Equity, and Future Directions)

If malaria mAbs are to protect pregnant women at scale, implementation must be designed around antenatal care realities. The ideal delivery pathway integrates into routine antenatal visits, leveraging existing systems used for IPTp SP delivery and tetanus vaccination. WHO guidance on IPTp SP emphasizes initiation in the second trimester and monthly dosing to achieve three or more doses [23, 24]. This creates a natural scheduling scaffold for a long-acting mAb: a single dose given early in the second trimester could provide extended protection through late gestation, potentially reducing infections that occur between IPTp doses or among women with delayed or inconsistent attendance.

Operationally, subcutaneous administration is likely preferred due to simplicity, reduced need for infusion infrastructure, and easier community deployment. Cold chain needs, training requirements, and pharmacovigilance capacity must be explicitly addressed. A pragmatic approach would prioritize settings with high residual transmission and documented gaps in IPTp coverage, while ensuring that mAb deployment does not displace proven interventions. Instead, it should be integrated as layered prevention: nets, IPTp, prompt diagnosis and treatment, and mAbs where they add value.

mAbs are historically expensive, but large-scale manufacturing, dose-sparing strategies, and targeted seasonal deployment could improve cost-effectiveness [25]. Pregnancy is a compelling prioritization group because the morbidity burden is concentrated and measurable in birth outcomes. WHO has also emphasized community strategies to reduce missed opportunities for IPTp, and a similar community-integrated approach could be envisioned for mAb administration once safety and feasibility are established.

CONCLUSION

Malaria in pregnancy in Sub-Saharan Africa persists because placental pathophysiology, transmission intensity, and operational constraints intersect to sustain residual risk despite proven tools. *P. falciparum* sequestration in the placenta, mediated by VAR2CSA binding to placental chondroitin sulfate, drives inflammation and placental dysfunction that translate into maternal anemia, low birth weight, and preterm birth. IPTp SP remains foundational and WHO-recommended, yet coverage gaps and contextual threats such as parasite resistance and late antenatal initiation limit population-level effectiveness. Against this background, monoclonal antibody prophylaxis represents a mechanistically coherent strategy that targets infection upstream, before blood stage amplification and placental sequestration. Long-acting anti-CSP antibodies such as CIS43LS and L9LS have demonstrated substantial protection in early-phase and field settings, including subcutaneous delivery, suggesting practical feasibility for seasonal prevention. The principal uncertainty is not whether mAbs can prevent malaria, but whether they can be safely, durably, and equitably deployed in pregnant women with demonstrable benefit on placental malaria and birth outcomes. Pregnancy-specific trials, pharmacokinetic studies, and robust surveillance systems are therefore the critical next steps. Health ministries and research sponsors should prioritize phased pregnancy-inclusive trials of long-acting anti-sporozoite monoclonal antibodies integrated with IPTp SP and antenatal care delivery, with parallel pharmacovigilance registries to enable rapid, safe policy translation once efficacy on placental malaria and birth outcomes is confirmed.

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CITE AS: Mutebi Mark (2026). Monoclonal Antibody Prophylaxis Against Plasmodium falciparum Malaria in Sub-Saharan African Pregnant Women. IDOSR JOURNAL OF SCIENTIFIC RESEARCH 11(2):40-45. https://doi.org/10.59298/IDOSRJSR/2026/11.2.4045