Dear antenatal care participant:

We congratulate you for your pregnancy and welcome you to the antenatal clinic of Lungwena Health Center. During the coming months, the health center staff will do their best to ensure the health of yourself and your growing fetus. Our team, the Lungwena Child Health Study group, is working with the health center staff to ensure best possible health for the mother and the child. Currently, we are testing if repeated treatment of pregnant women with two different registered drugs could promote maternal health and prevent babies being born too early or too small.

The study is open to 1,320 pregnant women > 15 years of age who have felt the movements of the fetus and whose pregnancy has lasted between 14 and 26 weeks. If you fulfill these criteria, we invite your participation. However, if you have diabetes, tuberculosis, some other chronic disease, pregnancy complications, twin pregnancy, or drug allergies, you may not participate in the study. Additionally, women who have recently taken azithromycin or sulfadoxine-pyrimethamine (SP) antibiotics, those who will be moving out of this area, and those who do not provide a written consent are excluded from the study.

The participants of the study will be randomly divided into three groups. One group will get the normal antenatal care with two doses of presumptive malaria treatment with SP (Fansidar®). The second group will get SP every month. The third group will get SP every month and another antibiotic, azithromycin (Zithromax®), twice during pregnancy. All tablets will be given together with Sobo and biscuits.

If you take part in the study, we will see you at the antenatal clinic of Lungwena Health Center at four-week intervals until the last month of pregnancy and weekly thereafter. At first visit, you will undergo a pelvic ultrasound examination. For a subgroup of 300 women, we will do the ultrasound examination also at each subsequent antenatal visit.

At enrollment, a small amount of blood will be taken from your arm. The blood will be used to diagnose anemia, malaria and your body’s ability to fight it, syphilis and, if you wish, human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS). At all subsequent visits, a few drops of blood will be taken from a finger prick to measure your malaria response and the change in blood hemoglobin content during pregnancy. After delivery, all participants will be asked to give a small urine and a vaginal swab sample, which will be used to check if the study drugs have cured birth canal infections that the participants might have had. Almost all laboratory tests are conducted in Lungwena, but the urine and vaginal swab samples and advanced malaria tests need to be analyzed in Blantyre, Lilongwe and elsewhere because we do not have right equipment here in Mangochi.

Within two days of delivery, a research assistant will visit your home to measure the size of your baby and to interview you and the attendant about your delivery. One month after delivery, we ask you and your baby to come to the health center for a medical examination and we will also make a home visit to interview you about your experience from the study participation. The infants are examined further at the health center at the ages of 3, 6, 9, and 12 months and thereafter at 15, 18, 24, 36, 48 and 60 months. At the 3 and 6 month visits, a few drops of blood will also be taken from your finger prick to measure your malaria response and the change of your blood hemoglobin content after pregnancy.

All participants will be tested for syphilis and some other sexually transmitted infections and treated if found positive. In case of syphilis positivity, you can also ask us to verify cure with another blood sample taken from you after delivery or your baby at six months of age. During pregnancy, we will provide you with iron and vitamin A according to the national recommendations in Malawi. If we find you to be severely anemic, we will treat you with iron and, if needed, refer you to Mangochi. If you opt to have your HIV/AIDS status investigated and your test result is positive, we will provide you and your baby with nevirapine (Viramune®) tablets and suspension. This medication will decrease the possibility of HIV/AIDS transmission to your baby.

Monthly SP is expected to clear malaria better than the traditional two-dose regimen. Azithromycin medication is hoped to cure potential infections that may affect the health of the mother and the newborn. Thus, it is possible, but not certain, that some mothers and their babies benefit from the intensified medication.

Both drugs have proven safe in previous trials and they have commonly been given also to pregnant women. Some participants may get allergic or other adverse reactions, such as abdominal discomfort, vomiting, itching, or skin rash. More severe adverse events are not likely, but their possibility cannot be completely excluded because experience from the current dosing regimen is still limited. Any adverse reactions are treated according to national guidelines at Lungwena Health Center or Mangochi District Hospital. If needed, you will be helped in obtaining appropriate medical care from these facilities.

We will not pay you for participating in the trial but you will receive careful pregnancy follow-up. Additionally, we will compensate your time with a bar of soap at enrollment, at 32-week antenatal visit, after delivery and at the home visit that we make at approximately 4 weeks after delivery. We will also reimburse you with 50 kwacha for informing us rapidly about the delivery when it has taken place. All visits and study medications will be free of charge to you and we will support your baby’s nutritional status by giving her or him a package of likhuni phala at 6 and 12 months of age. For each of the health centre visits after the infant has become 12 months old, we will compensate you for your time with one kg of sugar, 1 kg of rice, and one bar of soap.

All collected information will be stored and treated confidentially by the study team and not disclosed to outsiders, other than national or international authorities who have the right to monitor proper conduct of studies like ours. When talking about the study, we will never tell the names or other personal information from you or any of the other mothers.

(English version, to be translated into Chi-Yao and read aloud to all participants)
Participation in the trial is entirely voluntary and your decision will not in any way influence your other treatment at Lungwena Health Center or elsewhere. Furthermore, if you choose to give your consent now, you may still withdraw it at any point of the trial, without giving any reason for your decision.

After reading or hearing this information, we ask your willingness to take part in the trial. Please feel free to ask clarifications to any unclear issues or to consult your family members or friends about the decision. If thereafter you are willing to give your informed consent, please sign the attached form.

We sincerely thank you for your time and consideration. Please feel free to contact us at any point if you have further questions. Lungwena, originally on November 17, 2003 and modified on May 15, 2004 and on December 22, 2005.

Rose Mzamu, RN, study nurse; Bernard Mbewe, MD, study physician; Per Ashorn, MD, principal investigator