In-class Discussion Questions – August 19th 2013

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"Competitive facilitation of drug-resistant Plasmodium falciparum malaria parasites in pregnant women who receive preventive treatment" by Harrington et. al. (PMID 19451638)

1. In the beginning of the discussion, the authors state that it is not ethically acceptable to randomize a control group of women who do not receive IPTp. Read the paragraph below from the Wikipedia article about IRBs. On what grounds might an IRB allow or disallow a "no treatment" control group?

An institutional review board (IRB), also known as an independent ethics committee or ethical review board, is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans. They often conduct some form of risk-benefit analysis in an attempt to determine whether or not research should be done. The number one priority of IRBs is to protect human subjects from physical or psychological harm. In the United States, the Food and Drug Administration (FDA) and Department of Health and Human Services (specifically Office for Human Research Protections) regulations have empowered IRBs to approve, require modifications in planned research prior to approval, or disapprove research. IRBs are responsible for critical oversight functions for research conducted on human subjects that are 'scientific', 'ethical', and 'regulatory'.

2. The article is from 2009; it is now 2013. Read the current World Health Organization (WHO) recommendations for IPTp (below). Does the WHO still recommend using SP?

Malaria infection during pregnancy is a major public health problem, with substantial risks for the mother, her fetus and the neonate. Intermittent preventive treatment of malaria in pregnancy is a full therapeutic course of antimalarial medicine given to pregnant women at routine prenatal visits, regardless of whether the recipient is infected with malaria. IPTp reduces maternal malaria episodes, maternal and fetal anaemia, placental parasitaemia, low birth weight, and neonatal mortality.

WHO recommends IPTp with sulfadoxine-pyrimethamine (IPTp-SP) in all areas with moderate to high malaria transmission in Africa. As of October 2012, WHO recommends that this preventive treatment be given to all pregnant women at each scheduled antenatal care visit except during the first trimester. WHO recommends a schedule of four antenatal care visits. Based on currently available evidence, the preventive efficacy of SP for IPTp persists even in areas where quintuple mutations linked to SP resistance are prevalent in *P. falciparum*.

Among the approximately 780 million persons at risk of malaria in endemic countries in sub-Saharan Africa, an estimated 32 million pregnant women could benefit from IPTp each year. However, during the last few years, WHO has observed a declining effort to scale-up IPTp in a number of African countries. In high-burden countries, IPTp noticeably lags behind other malaria control measures. This does not appear to be due to low levels of antenatal clinic attendance. Uncertainty among health workers about SP administration for IPTp may have also played a role. Simplified IPTp messages and health worker training have been shown to improve IPTp coverage.

Last update: 6 March 2013

3. What is competitive facilitation and what are its implications for this paper? Why might we still be using SP in pregnant women regardless of the obvious problems with building resistance?