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Ethical perspective on malaria research for Africa

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Abstract

Malaria is a leading cause of death and illness in Africa, afflicting mainly young children, infants and young pregnant women, especially in rural areas where access to health services is often limited.

Resistance to the safest and most affordable antimalarials, the threat of insecticide resistance, demand for research and development of new malaria treatment, prevention and control tools in the form of new antimalarials, vaccines, diagnostics, insecticides and devices.

New antimalarial tools must be tested on the most afflicted groups (young children, infants and pregnant women) whose autonomy especially in tradition African rural settings is severely impaired or diminished. They, therefore, deserve special protection by the researcher; thorough ethical review ensuring genuine informed consent is therefore crucial.

The testing of new products, particularly with novel vaccine formulations and new adjuvants in the vulnerable groups, age de-escalation, trial of transmission blocking vaccines, the initial testing (Phases Ia and IIa) of vaccines and drugs in non-endemic populations all pose ethical dilemmas, as do bioprospecting (biopiracy) and the standard of care during and after the research. Besides these concerns, ethical issues relating to epidemiological research are also addressed.

Keywords: Malaria vaccines; Antimalaria tools

1. Introduction

Malaria has been variously described as Africa's public health enemy number one, and as the greatest shackle to Africa's socio-economic development. The untold historical havoc and destruction imposed on Africa by malaria each year is 400 times greater than that resulting from the 9/11 attacks on New York city, which has completely changed world history. Yet malaria remains a mere statistic, mainly because it kills, maims and impoverishes residents of resource poor countries, who lack the means to adequately address it. Most of the deaths and suffering are of voiceless young children, infants and pregnant mothers; the latter mainly in their first and second pregnancies. These mainly live in remote rural areas, where access to health services is often limited, and where the father, husband, mother-in-law, and even the extended family have veto power on these most vulnerable dependents. It is also

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these powerless vulnerable groups who are often the main research participants.

Although there are such other high-risk groups as non-immune short-term travellers, refugees and other displaced persons, expatriate staff and migrant laborers, itinerant and foreign consultants, investigators, and investors, they are not include in the presentation, mainly because they usually do not constitute participants in malaria research in Africa.

The suffering and deaths from malaria are further compounded by the failure of the safest and most affordable antimalarials, due to drug resistance. Consequently there is urgent need to develop and deploy new antimalarial drugs that are accessible. Under these circumstances the need for new antimalarial drugs and an efficacious malaria vaccine is obvious.

During the malaria eradication era of the 1960s malaria control and even malaria eradication could be achieved through vector control. Intradomiciliary residual spraying, for example, eradicated malaria in some epidemiological settings in Africa (Koutzetsov, 1977), whereas source reduction and source treatment made many African urban areas malaria free. These effective vector control methods were abandoned on various pretexts including the threat of perceived insecticide resistance and sustainability. In urban areas, proven mosquito control measures ceased after the departure of the former colonial masters, the overwhelming majority of whom lived there.

The staggering malaria statistics, the failing malaria treatment, prevention and control, dictate undertaking research aimed at sharpening existing tools and the discovery, development and eventual deployment of improved and new antimalaria tools. At the same time the ongoing genomic revolution and other scientific discoveries are likely to reveal promising leads to the development of new malaria control and prevention tools in the form of potential malaria vaccines, antimalarial drugs, diagnostics, insecticides, devices and other products for the treatment, management, prevention and control of malaria.

The anticipated new products will of necessity be tested on humans, or in the human environment. Furthermore many other studies particularly in the various branches of epidemilogy and will involve studies in, for example, malaria epidemiology, parasitology, mosquito entomology, molecular biology, immunology, sociology and behavioral sciences, and the like. Furthermore, research collaboration involving “guest” researchers will continue. All these have ethical implications.

If the history of research with human subjects in the world is anything to go by, there is need and indeed concern that the rights and welfare of research participants should be protected. This is especially the case in sub-Saharan Africa where malaria is mainly a disease of the poor, the ignorant, and those particularly vulnerable to exploitation. It is also in many parts of Africa where human rights abuses are rife, ignorance is wide-spread, health systems are generally poor and poorly managed. The need to safeguard the rights and welfare of these research participants in therefore paramount.

Much of the presentation will naturally focus on the ethics of involving children in trials of new intervention tools; in some cases, reference will be made to the involvement of pregnant women. Near the end reference will be made to ethics of new vector control measures and ethics in epidemiological studies. The presentation will address a few specific issues related to dilemmas encountered in research particularly in malaria intervention trials. Given the great breadth of the issues at hand, the presentation will mainly focus on current areas of ethical concerns, particularly informed consent, standard of care, benefits and risks inherent in various trial strategies, mosquito intervention trials and epidemiological studies, ethical review, and finally examine issues at the end of a trial or research endeavor. Throughout the presentation reference will be made to current international guidance, so as to update the audience since the last MIM conference. Given the above limitations the presentation will not cover such important areas as ethics in trials of traditional medicines; compensation, insurance and indemnity; intellectual property rights; capacity strengthening in research and ethical review; dissemination and utilization of research results.

2. Informed consent

To most ethicists informed consent is the cornerstone of bioethics. All guidance documents acknowledge the over-riding importance of individual informed consent. As stated earlier malaria in many parts of