International Research and Philanthropy: Ethical Concerns with Malaria Research

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ABSTRACT

This paper analyzes ethical issues arising from malaria research. These issues stem from the use of human landing catches, the medical treatment provided to human landing catch participants, participants misunderstanding their role in research, the conflicts of interest between the Gates Foundation and its evaluation policy, and the genetically modified mosquito release. This paper reviews the relevant ethical issues and recommends ways to prevent these problems from re-occurring and similar issues from arising.

Keywords: Target Malaria, Gates Foundation, Human Landing Catch, Conflict of Interest, Gene-Drive

INTRODUCTION

Malaria research poses complex ethical issues. The potential for unanticipated and anticipated harm to research subjects is high and the areas of research are often where the general population is socioeconomically disadvantaged. The type of data collection and the role of human research subjects are problematic. Issues concerning the release of genetically modified mosquitoes include participants misunderstanding their role in the research, community consent, mosquito migration, and the cost of re-occurring release. This paper reviews these ethical concerns and uses a rule utilitarian approach to provide recommendations to prevent ethical problems from recurring. Policies and protocols surrounding international research and philanthropy as a primary funding source need to be strengthened and further developed; otherwise, unethical research practices in low-income resource-poor settings will likely continue.

I. Rule Utilitarianism

John Stuart Mill's work is part of classical utilitarianism, which describes the principle of utility.[1] The principle of utility states, "actions are right in proportion as they tend to promote happiness, wrong as they tend to produce the reverse of happiness."[2] Rule utilitarianism, a contemporary form of utilitarianism, still seeks to produce the most happiness for the most people. It considers the consequences that would occur

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during the implementation of an act as a general rule where everyone in similar circumstances did the same thing.[3] It judges whether an action is good by asking whether it conforms to a rule that consistently maximizes utility or happiness. Applied rule utilitarianism demonstrates how some of Target Malaria and the Gates Foundation's current practices could not be implemented as general rules for similar circumstances.

II. Human Landing Catches

Human landing catches are a mosquito collection method for research involving studying behaviour and physiology, and population.[4] Human landing catches use human subjects as bait to attract mosquitoes, which are then caught as they land on an exposed limb. Medical treatment for human landing catch participants is inadequate.

Human landing catches are a mosquito collection method used in research settings. Human subjects are placed in an area with an exposed limb to catch mosquitoes as they land.[5] When participating in a human landing catch, researchers may expose subjects to roughly 70 mosquito bites per night.[6] When conducting these catches in areas with malaria, repeated mosquito bites put participants at risk of contracting malaria or other mosquito-borne diseases. Furthermore, the individuals recruited to be human landing catch subjects frequently come from financially disadvantaged backgrounds, with limited or no other means to generate an income.[7] Senior researchers often do not participate in catches because they understand the associated risks.[8]

A mosquito electrocuting trap, which electrocutes and kills the mosquitoes, was explicitly designed as a safer alternative to human landing catch.[9] The continued use of human landing catches when other methods of collecting mosquitoes are available may place participants at undue risk. Under rule utilitarianism, it would not be possible to implement a generalizable rule that allows human subjects to be placed at undue risk when safer alternatives are available. Therefore, the use of human landing catch should not continue.

III. Medical Treatment for HLC Subjects

Malaria is a parasitic disease spread by the *Anopheles* species of mosquitoes.[10] Four parasites cause malaria*, P. vivax, P. ovale, P. malariae,* and *P. falciparum*, the latter causing the most severe form of the disease.[11] The incubation period for malaria is usually 7 to 30 days. However, symptoms can first show as late as one year after exposure.[12] Two parasites, *P. vivax* and *P. ovale,* can cause a relapse of illness because they can remain dormant in the liver, with relapse occurring up to four years after infection.[13] Recurrent malaria infections can have severe consequences: recurrent *P. falciparum* and *P. malariae* infections can lead to severe anemia and nephrotic syndrome, respectively.[14] Human research subjects must be monitored and given adequate treatment for any illnesses or complications of human landing catches.

IV. Terms: Gene-Drive and Genetically Modified

Gene drives are self-replicating DNA. In male mosquitoes, they would spread infertility with the potential to wipe out the entire species. As male mosquitoes do not bite, the research assumes that using gene drives will shrink female mosquito populations in areas with high malaria rates, reducing the incidence of the disease.

Target malaria does not use gene-drive mosquitoes outside of labs at all. This paper refers to d the release of non-gene-drive genetically modified mosquitoes in Burkina Faso. (Gene drive mosquitoes are genetically

modified mosquitoes,[15] but not all genetically modified mosquitoes are gene drive.) There is no evidence that any researcher has released any gene-drive mosquitoes.

V. Target Malaria in Burkina Faso

Target Malaria is a non-profit research consortium that aims to limit malaria incidence in sub-Saharan Africa by reducing populations of malaria-transmitting mosquitoes. Target Malaria, based at Imperial College London, is researching gene-drive mosquitoes (only in labs in the UK and Italy) and non-gene drive mosquitoes to reduce mosquito populations and the incidence of malaria in high-burden areas.[16] Target Malaria has released mosquitoes, although those released were sterile, do not bite, and do not carry malaria. Currently, Target Malaria is using non-gene drive genetically modified mosquitoes in its research. Target Malaria's goal is to eventually use gene drive genetically modified mosquitoes engineered with a genetic mutation designed to reduce the number of female offspring. Target Malaria receives its primary funding from the Gates Foundation.[17] Researchers at Imperial College London develop genetically modified mosquitoes and ship the eggs to partner institutions which carry out the research.[18] For example, in one instance, mosquitoes were developed at Imperial College London and shipped to Italy and Atlanta, where researchers test them; eggs were then shipped from Italy to Burkina Faso.[19] According to Target Malaria, the partner institution's research in Burkina Faso aims to determine the species of mosquitoes located in the area and the seasonal dynamics and behaviour of these mosquitoes.[20] Target Malaria and its partner institution in Burkina Faso use human landing catches and the release of genetically modified mosquitoes in their research.[21]

Target Malaria uses several methods to collect the mosquitoes used for research. The methods include human landing catches, swarm collections, and spray catches.[22] The collection method used depends on the type of research.[23] Target Malaria uses mosquitoes caught through human landing catches in various ways, including creating eggs for their insectary, studying insecticide resistance, and studies involving mosquito releases.[24] During human landing catches, the research team collects the mosquitoes before they bite. Swarm collections are conducted using a net in areas where mosquitoes swarm; this method captures live adult mosquitoes.[25] Spray catches are used inside and involve insecticides; this method collects dead mosquitoes.[26] Target Malaria's release of genetically modified mosquitoes used swarm collection and spray catches as the methods of recapturing mosquitoes.[27]

According to Target Malaria, individuals participating in human landing catches are monitored for symptoms of malaria for 21 days after participating in a catch.[28] As the incubation period for malaria can be much longer, Target Malaria's current policy for medical treatment of human landing catch participants does not adequately protect them. Burkina Faso has a fee-based healthcare system that uses out-of-pocket payments, although pregnant women and children under five receive free health care and medications.[29] As a result, human landing catch participants diagnosed with malaria after the 21-day period observed by Target Malaria would be responsible for paying for healthcare and medications themselves.

Furthermore, Target Malaria provides treatment only once a participant shows symptoms of malaria;[30] there is no mention of preventative treatment in its guidelines. As part of an unrelated study on malaria, human landing catch participants were given Malarone as a preventative treatment.[31] According to the authors, not providing the treatment would have been unethical.[32] If preventative treatments are available, human landing catch participants should receive those treatments, as withholding preventative treatments put participants at undue risk of catching malaria. Following rule utilitarianism, a formulated rule would state that researchers should give human landing catch subjects preventative medicine and medical treatment that aligns with incubation periods.

VI. Burkina Faso

Burkina Faso is one of the world's poorest nations,[33] and it is part of a group of seven African countries which account for roughly half of all yearly malaria deaths globally. [34] The village of Bana in Burkina Faso is where Target Malaria conducts much of its research.[35] Bana consists of mud huts with no electricity or sewage system; significant health concerns in the village include malaria and water pollution.[36] While indigenous populations reside in Burkina Faso, the country's constitution does not recognise indigenous persons as existing.[37]

Burkina Faso may not have an ethical code or straightforward regulations for human research. There is limited information on the country's research regulations. The council on Health Research for Development noted in a 2008 document that there were no regulations at the time of publication.[38] Attempts to find new documents or ethical codes since the 2008 publication has been unsuccessful, partially due to difficulties in accessing websites such as Burkina Faso's governmental sites. Burkina Faso initially drafted an ethical code in 2005; however, Burkina Faso does not appear to have implemented the code.[39] Burkina Faso utilizes Research Ethics Committees for determinations on research projects. An order was implemented in 2004 to guide the organization and function of ethics committees but does not include any regulations on research ethics.[40] The Health Research Ethics Committee, created in 2002, primarily follows International ethical guidelines, combined with guidelines from various medical professions due to the lack of a research code of ethics.[41] All health research projects conducted within Burkina Faso must receive approval from the Health Research Ethics Committee; when a project is approved, the committee issues an ethics certificate, researchers cannot conduct research.[42] Yet, gaining the ethics certificate does not mean the research can initiate: once the certificate is issued, researchers are required to gain ethics approval from a regional department.[43] The reasoning for this is that the higher-up officials serving on the national ethics committee cannot authorise the operational aspects of a project; representatives from these regional departments believe that their authorisation is more determinate than the national ethics committee concerning ethical standards.[44] The requirement of a project to receive two different levels of approval raises the question of whether the initial guidelines approved will still be implemented in research projects if the regional department believes they are not feasible from an operational standpoint. The Health Research Ethics Committee does not have the resources available to oversee the research activities it approves.[45] Although the status of Burkina Faso's ethical codes is currently unknown, international codes of ethics, such as the Declaration of Helsinki and the Nuremberg Code, should protect international research subjects if followed.

VII. Informed and Community Consent

The elements required for informed consent to be valid are disclosure, understanding, voluntariness, and capacity.[46] The researcher must ensure that subjects have a sufficient understanding of the study information prior to signing the consent forms.[47] In low-resource settings, it may be beneficial to determine the potential subjects' willingness to participate in the study prior to disclosing financial incentives. This may help to alleviate the issue of subjects agreeing to participate in research studies only because of financial incentives. Under rule utilitarianism, if outside motivation such as free treatment or financial compensation biases consent in one situation, it is biased in all similar situations.

The element of disclosure could be expanded in international research to further protect research subjects. Disclosure agreements should include information about the study, including risks and benefits, the right to withdraw, and the reason for consent.[48] But, suppose Target Malaria had been required to disclose to potential participants that human landing catches would likely not be approved in a high-income country.

Even if they would be approved, they could not be ethically done without providing participants with a preventative treatment.[49] Such disclosure would make the potential subjects aware that they were not getting the same protections as their counterparts in other countries. This information would have allowed them to make a more fully informed decision.

Rather than using the same individual consent-based model that researchers used with human landing catch participants, Target Malaria decided to develop a community agreement model for the release of genetically modified mosquitoes in Bana.[50] Target Malaria seemed to believe that consent did not apply to their work because the organization does not work in areas with recognised indigenous peoples.[51] However, in previously published research, Target Malaria stated that indigenous populations reside in and around the village of Bana.[52] The decision not to use a consent-based model may have been because Burkina Faso does not recognize indigenous peoples.[53] However, by definition, an indigenous person is indigenous regardless of whether their government recognizes them as such. Under rule utilitarianism, disregarding a population as indigenous and using community agreement in place of free and prior informed consent implies a general rule that this could apply in similar circumstances. This would likely result in the rights of officials disregarding indigenous persons in many instances.

VIII. Participants Misunderstanding Their Role in Research

Researchers from Target Malaria conducted a qualitative study in Bana to determine what factors motivated individuals to participate in their research activities. There is an apparent conflict of interest with the researchers conducting the study themselves. While Target Malaria attempted to reduce potential bias by using a researcher who was not part of the primary research team in Bana to conduct the qualitative study,[54] it may not have been enough. The study participants were aware that Target Malaria was conducting the study; the researcher gathering the qualitative data spent three months in Bana.[55] Target Malaria felt that this would allow the residents to trust the researcher and limit the potential of participants tailoring responses based on what they thought the researcher would want to hear.[56] However, because the participants knew the researcher was from Target Malaria, they may not have given the same information they would have given to a researcher not affiliated with Target Malaria. A study conducted by a researcher unaffiliated with Target Malaria may have yielded different results.

The study also showed participants misunderstood their role in the research. One of the more prominent misconceptions was that they thought they were learning how to do a trade;[57] this belief indicates that they did not understand their role as research subjects. The issue was further confused because participants were paid, making them believe that it was their job.[58]

Another misconception concerned the responses of individuals who participated in indoor spray catches. The common misconception in the participant responses was that indoor spraying offered malaria protection and a direct benefit to health by reducing the number of mosquitoes in the home.[59] The researchers mention that even after repeatedly explaining that these methods were purely scientific, were not meant to control mosquitoes, and were not methods that would give long-term protection, subjects continued to believe that indoor spraying offered malaria protection and a direct health benefit.[60]

The researcher's concluded that residents of Bana had better knowledge of malaria and how transmission occurs because of Target Malaria's work.[61] Mosquito collectors listed the skills they gained through the projects and believed that entomological research could be a long-term job prospect because of other local research groups; they welcome the chance to earn income through the project.[62] The researchers do not discuss the gravity of the misconceptions or their implications on the informed consent to Target Malaria's

main project activities. Researchers have a duty to ensure that study participants give fully informed consent. Their gaining what they believed to be skills and work experience may have affected participants' perceptions and judgments and led them to consent when they otherwise would not have.

IX. Available Research on Participant Misunderstanding

The conflict of interest may become more apparent considering one of the researcher's previous publications, which, after reviewing a study that had issues similar to Target Malaria's qualitative study, still reached differing conclusions. One of the Target Malaria researchers involved in the qualitative study had previously reviewed malaria research involving participant misunderstanding. The research in this instance was a clinical study comparing two malaria medications in children.[63] The study found that parents decided to enroll their children in the study prior to receiving any information from the researchers conducting the study.[64] The parental motivations to enroll their children included free medication.[65] The study also shows that parents did not understand the research being conducted or its procedures.[66] The researchers concluded that lack of understanding and motivations, such as free treatment to participate, might compromise the informed consent.[67] In areas with socioeconomic vulnerability, the decision to participate may be strategic: participants receive access to health care that otherwise would be unattainable.[68] Strategies to ensure voluntary informed decision making are needed.[69] Furthermore, sometimes when an individual's main reasoning for participation in a research project is financial compensation, they have not made an autonomous choice because the financial compensation is a controlling influence that determines their decision to participate. This conclusion is quite different from the one provided in Target Malaria's qualitative study, which emphasized the benefits to the participants, such as improved knowledge about malaria.

X. Financial Backing: The Gates Foundation Evaluation Policy

The Gates Foundation provides an evaluation policy; however, the policy may not adequately cover scientific research. The foundation designed the policy to assist the foundation and its partners in determining what needs evaluation.[70] In most circumstances, the foundation works with prospective partners within the grant proposal process to determine measurable outcomes, progress and success indicators. The foundation believes this will allow partners to work instead of constantly needing to measure and report.[71]

The Gates Foundation has set priorities for evaluation. Projects are a "high priority for evaluation when outcomes are not easily observable, and a low priority when the results are easily observed."[72] In these cases of low priority for evaluation, the foundation believes that the "partners' self-reported progress data and existing protocols (such as for clinical trials) provide sufficient feedback for decision making and improvement."[73]

Aside from the context of Target Malaria, the Gates Foundation has funded ethically questionable research projects, including cheaper cervical cancer screening in India that left some women in the control group without any screening,[74] and a demonstrational study giving HPV vaccines to adolescent girls, and failing to provide medical care to those participants who experienced severe adverse effects.[75]

By not evaluating the protocols, the Gates Foundation is at continued risk of funding research that does not adequately protect research subjects. Relying on existing protocols is insufficient, primarily when researchers are conducting the research in low-income countries. Not all countries have research ethics protocols equal to those of the United States, and some lack protocols altogether. As the foundation has

already provided funding to at least three international studies that have included unethical practices, it must strengthen its evaluation policy to prevent funding more studies that may be prone to unethical practices.

XI. Funding Example: Gates Foundation Conflicts of Interest

The Gates Foundation funding has inherent conflicts of interest. As of 2016, the Gates Foundation gave $75 million to Target Malaria for the gene-drive mosquito project.[76] In early 2018, the foundation pledged $45 million to Burkina Faso, with $34 million designated for government programs.[77] This is a conflict of interest because the Gates Foundation is simultaneously providing significant funding to governing bodies, such as the United Nations and the Burkina Faso government, and asking these same bodies to approve research for a project that is also significantly funded by the foundation.

NGOs and activists proposed a moratorium on releasing entities with gene-drives at the 2018 Convention on Biological Diversity Conference, which was not adopted.[78] Burkina Faso's National Biosafety Agency approved the release of 10,000 genetically modified mosquitoes in August 2018.[79] The decision of Burkina Faso and the United Nations to allow the release of modified mosquitoes and reject the moratorium may be due to the "Bill Chill,"[80] such as not speaking out against the Gates Foundation for fear of repercussion.[81] Funding recipients such as Burkina Faso and the United Nations may fear the loss of further funding if they do not allow Target Malaria's work to continue.

XII. Mosquito Migration

Mosquitoes can migrate. A 2019 study showed that mosquitoes could migrate over long distances.[82] This study determined that *Anopheles* mosquitoes, including *Anopheles coluzzii,* the species Target Malaria used for its release, can potentially travel up to 300km per night at high altitudes with strong winds.[83] It should be noted that it was published roughly four months after Target Malaria's release of genetically modified mosquitoes, meaning Target Malaria's researchers may have been unaware of the potential for mosquito migration. However, this study does affect several of Target Malaria's notions surrounding the release of modified mosquitoes.

Target Malaria's mosquito release consisted of both modified and non-transgenic male *Anopheles coluzzii* mosquitoes, with 14,850 total dust-marked mosquitoes released.[84] Although the goal was to release male mosquitoes, Target Malaria did account for and initially noted before the release occurred that there was a possibility for the incidental release of a small number of female mosquitoes.[85] Attempts to recapture the mosquitoes began just two hours after the release and lasted for twenty days.[86] The re-collection efforts resulted in the recapture of just 527 (3.55 percent) of the released dust-marked mosquitoes[87] meaning that 96.45 percent of the released dust-marked mosquitoes were not recaptured. This brings up the question of where 96.45 percent of the released dust-marked mosquitoes went. Researchers estimated that the modified mosquitoes had a lifespan of roughly 2.6-3.9 days,[88] equaling roughly 1.6-2.9 nights. As these mosquitoes can potentially travel 300km per night,[89] the modified mosquitoes may have travelled roughly 480-870km from the release site. Furthermore, the potential for mosquitoes to migrate over long distances denotes that Target Malaria's community agreement to obtain agreement from "relevant communities before engaging in research that may impact them"[90] would need to be expanded to include all communities in potential migration paths to be considered relevant communities that their research may impact. When investigative journalist Zahra Moloo travelled to Burkina Faso prior to the genetically modified mosquito release, she determined that communities surrounding Bana were not adequately informed and, in most cases, opposed to the release occurring.[91] If

Target Malaria had accounted for mosquito migration and sought consent from all communities that could be affected by the release, the opposition from the communities surrounding Bana would have likely resulted in the release not occurring. A further implication of mosquito migration is that once the efforts to reduce the population cease, it is likely that the mosquito population will resurge from mosquitoes migrating into the area.

XIII. Cost of Re-occurring Releases

Controlling mosquito populations would require multiple releases of modified mosquitoes.[92] Payment for the ongoing method of malaria prevention could fall on the communities, challenging the feasibility of the long-term project. As mosquitoes can migrate over long distances,[93] mosquito populations will likely resurge once releases of modified mosquitoes cease, and subsequent releases of modified mosquitoes will continuously be needed.

When looking at implementing this initiative on a large scale, it becomes a more significant issue. As the village of Bana is where Target Malaria is conducting this research, the village should have access to this method of combating malaria once the research has concluded; they should not be left in a position to pay for access to this method, which is likely one that they could not afford. While Bana should have access to the method to combat malaria, there is still the question of how other communities and countries would access it. When implementing the strategy on a large scale, say for all sub-Saharan Africa, the cost of accessing the project should be factored into the research itself. Without this, it is likely that the low-income countries and communities that need this technology the most will be the same ones who cannot afford it.

XIV. Recommendations

Burkina Faso must strengthen its ethical approval process. If there is no formal code of ethics, one must be implemented to ensure all regulatory bodies involved in the ethical approval of research follow the same standards. If an ethical code is in place, the documents must be publicly available to ensure regulatory bodies, researchers, and the public have access. The resources of the National Health Research Ethics Committee need to be increased to provide oversight of approved projects to ensure that they are not deviating from the approved guidelines.

The Gates Foundation must prioritize evaluating scientific research to ensure funds are only distributed to projects without ethical concerns.

Indigenous populations need to have full rights and respect in medical research regardless of if the country they reside in.

Community consent needs to account for the long-distance migration of mosquitoes, especially as it is a new technology with unknown factors such as ecological effects and chances of mosquito mutations.

Human landing catches should not be used as a mosquito collection method. (If they do occur, participants need to be given medications proven to prevent malaria and need to be given treatment for any vector-borne diseases present in the area they may acquire through participation.)

Participant understanding of the research needs to be given a higher priority. Research should be temporarily stopped if it is determined participants do not understand. When a project includes aspects such as healthcare treatment, researchers must ensure that the treatment is not the only motivation for participation. Financial incentives should be introduced after a determination that the potential subject wants to participate in the research. This may help reduce the occurrence of individuals agreeing to

participate only because of the financial benefits. Disclosure should include notifying potential research subjects of study elements that would not be approved in the researcher's home or high-income country. Disclosing this information would help ensure potential research subjects are making fully informed decisions.

CONCLUSION

Current ethical rules and regulations are not adequately protecting research subjects. Human landing catch participants are not receiving adequate treatment or preventative measures. Informed consent is invalid when research subjects do not understand the nature of their engagement in the project, the risks, or the benefits. Conflicts of interest between researchers and subjects may explain the researchers' willingness to overlook the participants' misconceptions. The additional conflict of interest at the level of funding must be resolved. Any foundation should engage in due diligence and robust evaluation of research projects. Using a rule utilitarianism approach demonstrates how current practices need improving as they could not be implemented as a general rule for similar circumstances. While applied rule utilitarianism exposes insufficient policies, it can also be beneficial in developing new policies that protect individuals participating in research. Stricter organizational oversight, local regulation of research on human subjects, and improved evaluation policies would create rules that protect research participants and result in the greater good.

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