

# Genome Editing for Human Benefit: Ethics, Engagement and Governance

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## Case study: Co-developing community-wide acceptance model with affected stakeholders for genetic approach of vector control

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### Brief description of the research project

Target Malaria is a non-for-profit research consortium developing an innovative vector control against malaria using gene drive technology.<sup>1</sup> This consortium has partners from three continents: Africa, Europe and North America. The aim is to release genetically modified mosquitoes that will ultimately reduce the malaria vector population. While there is significant progress in the laboratory<sup>2</sup>, there is still a long way before the field evaluation of this technology and its ultimate deployment as a complementary tool for malaria elimination is ready. As part of its development pathway, this project works on a step-by-step approach to building strong scientific knowledge, trust and co-development with stakeholders.

### Background

The resident population of Burkina Faso is estimated at 19 034 397 inhabitants in 2016. The natural growth rate is estimated at 3.1%. Women represent 51.8%. Children under 5 represent 18.14% of the population and expected pregnancies represent 5.49% of the total population (2011-2020 population projections for Burkina Faso's health regions and districts, August 2009, INSD). In Burkina Faso, notwithstanding all the strategies and interventions deployed on the ground, malaria remains a major public health concern and the country is considered as high-risk malaria incidence. Several environmental and climatic factors influencing vector proliferation are associated with the endemicity of malaria, such as rainfalls, temperature and vegetation cover. Malaria is therefore the first cause of consultation, hospitalization and death in health facilities in Burkina Faso. Children under five and pregnant women are the most affected.

The project is working in the Hauts Bassins region, Burkina Faso. In this region, malaria case incidence in 2018 was estimated at 474 per 1,000 inhabitants for all ages and 1,443 per 1,000 children under 5. Malaria continues to be the main cause of mortality and morbidity and an important cause of disability at both the national and regional (Hauts-Bassins) level, despite important achievements over the last decade in reducing the number of malaria cases and the number of deaths caused by malaria.

### Ethical issues

As part of its step-by-step research, the project is proposing to carry-out small-scale releases of sterile male mosquitoes (not gene drive but nonetheless genetically modified) in a village of Burkina Faso. This is a first step of research aiming at better understanding mosquito populations but also at building trust and engagement with stakeholders.

As this strain of mosquito is clearly a Living Modified Organism, it is regulated as such by national authorities and therefore an application to carry-out the release was made to the appropriate authority in Burkina Faso with appropriate data provision for the authority to carry its own risk assessment. Existing regulation in Burkina Faso is limited in terms of the role of the affected community in decision making, although it makes provision for public consultation during the regulatory process – that took place in this case.

For a project like Target Malaria, the question of an appropriate level of community acceptance to proceed to a small-scale release is therefore a very central ethical issue. The guidelines for the

scope and extent of community acceptance is limited to analysis confirming that individual informed consent is not appropriate for the release of genetically modified mosquitoes<sup>3</sup>. The WHO framework for testing genetically modified mosquitoes<sup>4</sup> clearly states that unless specific data collection is done with human subjects (such as blood sample for epidemiology study), the appropriate consent level is a community level one. More recently, the NASEM report on gene drive did not provide any specific comment on the consent model but only highlighted the importance of a meaningful engagement going beyond a deficit model engagement.<sup>5</sup>

Existing guidance documents and publications offer very little example or practical guidance for researchers on how such community acceptance should be obtained, measured and recorded. The team of Target Malaria has consulted other projects and looked at their approaches<sup>6</sup>, in particular the successful model by Eliminate Dengue (now World Mosquito Programme). In agreement with its value of co-development, the project has also decided to co-develop its acceptance model in collaboration with directly affected communities to take their knowledge and experience to respond to the question of what constitutes fair and legitimate authorisation for field studies of genetically modified mosquitoes and ultimately gene drive mosquitoes.<sup>7</sup>

Through this process, different governance mechanisms were put in place with stakeholders trying to address several challenges – for example, grievance management, research monitoring, and national level engagement. The ethical question about balancing alignment with existing governance mechanisms in the community and other ethical considerations – such as gender or minority representations – has challenged the process and led to some interesting learning along the way. Once implemented, it has been interesting to reflect on this co-development process and how it challenges external perceptions. In other words, can a process co-developed between the project proponents and a community, be legitimate considering the context where the project operates and the values that are being introduced by external critical stakeholders?

### Conclusions and recommendations

While projects can co-develop community acceptance models with communities where their research is taking place, the question of legitimacy of this model remains and is often challenged from outside. It appears critical that a collaborative and reflexive process takes place with guidelines on how to establish appropriate acceptance models while still ensuring that these can be co-developed with communities to ensure they are respectful and context specific. A second recommendation would be to engage in cross-sectorial dialogue to ensure that bioethics considerations around community acceptance are shared with other sectors and that the ethical considerations of those sectors (e.g. conservation communities) are put in perspective to elaborate a common ethical framework for area-wide public health interventions.

### References

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