Genome Editing for Human Benefit: Ethics, Engagement and Governance

Singapore, 12 – 13 November 2019

Global Forum on Bioethics in Research

Guidance and policy paper: Guiding community acceptance processes for gene drive research – available guidance, gaps, and experiences from Mali, Burkina Faso and Uganda

Delphine Thizy, Target Malaria (Imperial College London), Bakara Dicko, Target Malaria Mali (MRTC), Léa Paré Toé, Target Malaria Burkina Faso (IRSS), Elinor Chemonges Wanyama, Target Malaria Uganda (UVRI)

Brief description of the context

The session will address guidance for community acceptance for field studies in gene drive research for vector control. Specific and formal guidance on community consent for field studies of gene drive organisms is currently absent. It is a relatively novel area of research which presents specific and distinct challenges for engagement and consent, and as such there are still questions and unresolved issues about what constitutes adequate processes and models for community consent. Recent efforts to inform this issue, mostly led by researchers[1,2], provide elements for consideration but need further development.

The session will present the current landscape and recent developments, consider what are the gaps and what differentiates acceptance for gene drive from acceptance in other fields, and look towards existing standards in other relevant fields for lessons and a way forward in informing guidance. The discussion will be international in relevance, though with applicability at national level.

Commentary, conclusion and recommendation

Gene drive research has made significant progress in the past four years. As a result, the prospect of gene drive organisms being proposed for field evaluation is growing more likely. This field of research is relatively new, but researchers have been able to draw on existing standards and best practices to guide their work throughout the technology development process, in order to ensure the safety and integrity of their research and results. This has included biosafety procedures for containment, building standards for laboratories, etc. It also includes drawing on guidance established for the development of gene-edited organisms, which although not specific to gene drive, are highly relevant, notably the WHO's Guidance Framework for testing genetically modified mosquitoes.[3] In addition, groups working on gene drive for public health are able to engage with the WHO Vector Control Advisory Group (VCAG) to present their progress and receive guidance from VCAG on how to conduct their research. This has enabled gene drive researchers to proceed with laboratory research and to plan the technical and scientific aspects of possible field evaluations with the support of well-established guidance and best practices.

One aspect that does not currently benefit from similarly established and recognised guidance is the topic of consent for gene drive research. Most groups working in this field have established stakeholder engagement programmes that support core research activities and enable community engagement in the technology development process. But once a gene drive organism is sufficiently advanced as to be proposed for field evaluation, the research groups will need to seek community acceptance (or consent) for those activities.

Gene drive organisms are "area-wide" in their application and so do not offer the possibility of individual opt-out. Individual residents in an area where a field evaluation would take place would not be in a position to opt-in or opt-out as they may do for a drug or vaccine trial. Instead, it is the

community as a whole that needs to come to a decision about whether to allow or not a field evaluation to proceed.

Researchers need to have clear guidance to help structure their programme and ensure they are setting up an appropriate mechanism for seeking acceptance, and to help regulators and policy-makers assess whether the acceptance given (if it is), was adequately sought and obtained.

Research groups have been thinking through this issue proactively and have started to develop models for community decision-making. Given the diversity of context in which research is taking place, there is great awareness that a 'one size fits all' approach would not be productive, and that at the same time, decision making should remain as much as possible with those directly affected, rather than be entrusted to more removed mechanisms, diminishing the voice of those at the heart of the matter. But in order to ensure there is a level of quality and confidence in the decisions reached, a set of principles endorsed by researchers, funders and major organisations in the field would help provide clarity to researchers and policy-makers.

Questions and concerns

There are several questions that need to be addressed by developing guidance on acceptance:

- What process should researchers follow when seeking community acceptance for an activity?
- How can regulators and other bodies overseeing the research be confident the decision made by the community was well informed and legitimate?
- How can guidance offer sufficient specificity while at the same time acknowledging the very different social and cultural context in which consent may be sought?
- Who needs to be involved in the acceptance process?
- What is the responsibility of the researchers, vs. that of other actors?
- What is the "threshold" for support that is deemed sufficient?
- Are there international standards that need to be met or incorporated into the acceptance governance, such as Free Prior Informed Consent?

Conclusions

This gap is an important one that needs to be addressed to ensure research proceeds ethically and public confidence in the research is maintained. A collaborative process, led by WHO or another institution, to draft such principles or guidance, would be a positive step forward to address this governance gap.

References

1. James, S., Collins, F. H., Welkhoff, P. A., Emerson, C., Godfray, H. C. J., Gottlieb, M., … Touré, Y. T. (2018). Pathway to Deployment of Gene Drive Mosquitoes as a Potential Biocontrol Tool for Elimination of Malaria in Sub-Saharan Africa: Recommendations of a Scientific Working Group†. *The American Journal of Tropical Medicine and Hygiene*, *98*(6_Suppl), 1–49. https://doi.org/10.4269/ajtmh.18-0083
2. Thizy, D., Emerson, C., Gibbs, J., Hartley, S., Kapiriri, L., Lavery, J., … Robinson, B. (2019). Guidance on stakeholder engagement practices to inform the development of area-wide vector control methods. *PLOS Neglected Tropical Diseases*, *13*(4), e0007286. https://doi.org/10.1371/journal.pntd.0007286
3. WHO/TDR and FNIH. (2014). Guidance Framework for testing genetically modified mosquitoes, 159. Retrieved from http://r4d.dfid.gov.uk/Output/197475/Default.aspx