Policy Brief

Gene drive approaches for public health

Vector-borne diseases account for over 17% of infectious diseases globally and disproportionately affect populations in low- and middle-income countries (LMICs). Malaria remains the deadliest parasitic vector-borne disease, causing an estimated 249 million cases and more than 600,000 deaths each year. Dengue is the most prevalent viral vector-borne disease, with an estimated 96 million cases and approximately 40,000 deaths annually. Meanwhile, chikungunya, Zika, and yellow fever continue to expand in scale and geographic reach, placing increasing pressure on already strained public health systems in LMICs.

POLICY RECOMMENDATIONS

- **Increase investment in research for innovative public health tools**: Recent funding cuts for vector-borne diseases, combined with growing challenges such as climate change and insecticide resistance, are eroding progress toward their elimination and underscore the need for innovative technologies. Simply increasing funding for existing tools is unlikely to eliminate vector-borne diseases by 2030. Greater and sustained investment is needed to advance the research, testing, and regulatory readiness of new tools, including gene drive technologies.
- **Recognize gene drive technologies as a potential complementary public health tool**: Genetic approaches, including gene drive technologies, should be considered as part of integrated national strategies for the control of vector borne diseases. They could complement existing vector control tools, such as bed nets and indoor residual spraying, and offer a potentially cost-effective and sustainable approach to disease control.
- **Support implementation of existing guidance and country-led decision-making**: The research, development, and potential future use of gene drive technologies require strengthened national and regional capacity to support informed decision-making. Efforts should focus on enabling countries to implement existing guidance, such as the Convention on Biological Diversity (CBD)'s Additional voluntary guidance materials to support case-by-case risk assessments of living modified organisms containing engineered gene drives, in line with their national circumstances, public health priorities, and regulatory systems. Strengthening capacity is essential to ensure that affected countries can research, develop, and potentially use gene drive tools.

Why new tools are needed for vector-borne disease control

Despite important progress in recent decades in reducing the burden of vector-borne diseases such as malaria, existing interventions face growing challenges. Insecticide and drug resistance are increasingly limiting the effectiveness of prevention and treatment efforts. Inadequate coverage of current interventions in hard-to-reach areas, including rural and informal settlements, continues to place populations at greater risk. Climate change is compounding these challenges and increasing the populations at risk. Modelling suggests that rising temperatures could enable *Aedes aegypti* to establish in southern Europe and the US Midwest by 2050, while *Anopheles stephensi* is already spreading into urban areas of the Horn of Africa.

As current tools struggle to meet the 2030 disease control and elimination targets proposed by the World Health Assembly through the Global Vector Control Response (GVCR) 2017–2030 (GVCR) and the 2021–2030 Neglected Tropical Diseases (NTD) Road Map, there is increasing recognition of the need for new and innovative tools. Gene drive technologies are one potential option being explored, but it is not a "silver bullet". If proven to be safe and effective, they will work alongside rather than replace existing vector control and broader public health interventions.

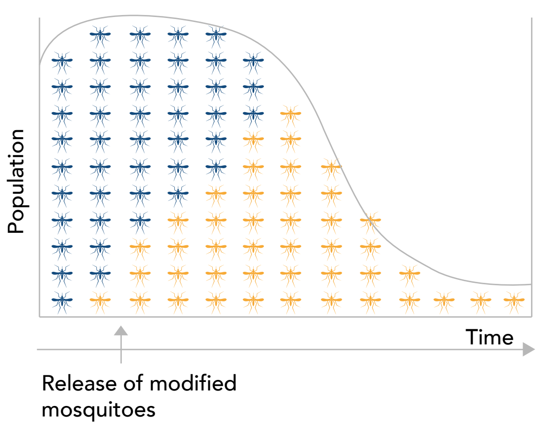
Gene drive technology: mechanism, benefits, and potential applications

Gene drive is a naturally occurring phenomenon that increases the likelihood that a specific trait will be inherited and spread through a target species over generations. Under typical Mendelian inheritance, a gene has a 50% chance of being inherited. Gene drive systems can raise this probability up to 99%. While different gene drive technologies operate through distinct mechanisms, they share this core feature of biased inheritance.

For vector-borne diseases control, researchers are currently investigating two approaches that harness the characteristics of gene drive: population suppression, which reduces or eliminates vector populations by introducing traits that lower fertility or survival; and population replacement, which modifies mosquitoes to block pathogens transmission while largely maintaining population size. By enabling beneficial traits to become established through specific mosquito populations, these technologies have the potential to support long-term disease control and elimination efforts.

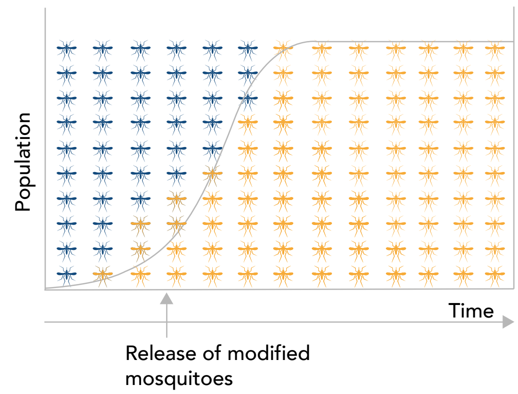
Population supression

Releasing modified mosquitoes into the population can cause transient or permanent population supression



Population replacement

Releasing modified mosquitoes into the population can lead to the spread of a gene that blocks malaria transamission



Gene drive tools are part of an array of new techniques that are being developed to control vector-borne diseases. These include *Wolbachia*, which uses a naturally occurring bacteria to stop transmission of dengue, and various forms of sterile insect technique (SIT). These approaches differ in mechanism and application, but all seek to provide complementary tools that reduce the need for individual uptake and behavior change while reducing the need for repeated interventions. This could lower long-term implementation costs and help reach hard-to-access areas where current interventions are difficult to maintain reliably.

Research on gene drive technologies is most advanced in malaria control. In this context, the technology could potentially be used in two scenarios. In a "first mile" context, in high burden countries, it could help reduce transmission to lower levels, strengthening the impact of existing interventions to significantly reduce malaria cases and the cost of malaria control. In a "last mile" context, it could support countries that have made substantial progress but remain just short of elimination by targeting residual transmission in remote or hard-to-reach areas and helping to reduce the risk of re-introduction from neighboring regions.

CURRENT GENE DRIVE RESEARCH FOR VECTOR-BORNE DISEASES

Gene drive research has been underway for more than 20 years, with substantial progress made in advancing laboratory methods, genetic tools, and contained testing systems. Research is conducted by multiple scientific groups worldwide, targeting different mosquito species and vector-borne diseases, including malaria and dengue. However, no gene drive technology has been released into the environment to date, and field trials are not expected to be proposed for at least another five years. Progress toward potential deployment will depend on several conditions, including continued technical and scientific advances, social acceptance, political will, and robust regulatory evaluation and approval.

- The **Transmission Zero** research program is co-led by scientists at the Ifakara Health Institute, the Tanzania National Institute for Medical Research, Swiss Tropical and Public Health Institute, and Imperial College London. They are developing innovative gene drive approaches to reduce malaria transmission by disrupting the mosquito's ability to carry *Plasmodium falciparum,* the primary malaria parasite in Africa. In 2023, the program achieved a major milestone by being the first to develop a genetically modified mosquito in situ in Africa. Researchers in Tanzania have since demonstrated in laboratory containment that the modified mosquitoes could effectively block the development of malaria parasites, potentially reducing disease transmission. Current efforts are focused on advancing technology development, risk assessments, regulatory engagement, and community consultation ahead of any potential future field testing.

- The **Target Malaria** consortium is developing gene drive technologies to control the population of malaria mosquitoes – either by biasing the sex ratio (male to female) or reducing the number of offspring. The consortium brings together close to 200 experts in 8 partner institutions - the University of Oxford, CDC Foundation, Imperial College London, Liverpool School of Tropical Medicine, Polo d'Innovazione di Genomica, Genetica e Biologia, Uganda Virus Research Institute, and previously Institut de Recherche en Sciences de la Santé (IRSS), University of Ghana and L'université des Sciences, des Techniques et des Technologies de Bamako (USTTB). A key milestone was the 2019 small scale release of sterile, non-gene drive, modified male mosquitoes in Burkina Faso, supporting early field research and strengthening regulatory systems. The project has consistently demonstrated the potential to reduce *Anopheles* mosquitoes under laboratory conditions and has successfully imported modified mosquitoes into Burkina Faso, Mali and Uganda. Researchers are now conducting contained laboratory studies in Uganda. Current efforts focus on technology development, regulatory readiness, and continued engagement with communities and governments ahead of potential future trials.

- Researchers at the **Alphey Lab** at the University of York are investigating "local gene drive" technologies to help address mosquito-borne diseases such as dengue, Zika, and chikungunya, which are transmitted by *Aedes aegypti* mosquitoes. The research focuses on reducing the mosquitoes' ability to spread viruses by using gene drive systems designed to spread only within a limited target population, rather than across the entire species range. They still bias inheritance like other gene drives, but they build in features that make the effect fade out over time or space. The research team aims to develop a prototype ready for potential field testing within the next 10 years.

- The University of California Malaria Initiative **(UCMI)** is an international research collaboration involving scientists from four University of California campuses, Johns Hopkins University, and Cornell University, with partners in São Tomé and Príncipe, Equatorial Guinea, and at the Lisbon Institute of Hygiene and Tropical Medicine (IHMT). The program focuses on population modification approaches that enable mosquitoes to carry genes that block the development of malaria parasites, thereby preventing transmission. In São Tomé and Príncipe, UCMI has conducted detailed ecological and genetic studies of *Anopheles coluzzii*, generating critical data on mosquito habitats to inform the design of future field trials. The collaboration has also strengthened national research capacity by establishing molecular biology laboratory infrastructure at the University of São Tomé and Príncipe (USTP) and supporting training opportunities, including advanced degrees for local researchers in medical entomology and molecular biology.

Gene drive governance and regulation

Gene drive research falls under the same regulatory frameworks that apply to genetically modified organisms, with oversight at local, national and international levels. International guidance provides mechanisms for stepwise assessment and public engagement throughout the research process and any potential future release. This includes the CBD's voluntary guidance materials designed to support case-by-case risk assessments of engineered gene drive organisms, particularly mosquitoes, and the World Health Organization's guidance for testing genetically modified mosquitoes. Other relevant frameworks include the African Union Development Agency (AUDA-NEPAD) recommendations to support research and regulatory development of gene drives for malaria control and elimination in Africa, and the European Food Safety Authority (EFSA)'s guidance on environmental risk assessment and post-market environmental monitoring.

At the national level, oversight frameworks are established by governments through biosafety authorities, relevant ministries, and other bodies responsible for issuing research permits and monitoring compliance. Research institutions and universities provide the first and most immediate layer of oversight, ensuring that research is conducted in accordance with national biosafety and ethical regulations. They also supervise day-to-day research activities and maintain compliance with relevant standards and guidelines.

In many cases, appropriate regulatory frameworks for gene drive research already exist. The key challenge is ensuring that countries have the technical expertise and institutional capacity to implement them effectively. Strengthening technical expertise, institutional capacity, risk assessment capabilities, and governance systems is critical to enable national governments to make informed decisions aligned with their priorities, needs, and concerns.

CONCLUSION

Gene drive technologies could provide a transformative addition to the fight against persistent vector -borne diseases. While still at the development stage, it is important to foster an enabling environment for continued research so that potentially valuable innovations are not prematurely excluded from consideration. This includes strengthening local scientific and regulatory capacity, fostering government support and public trust, ensuring meaningful community engagement and consent processes, and supporting informed, evidence-based decision-making. Continued research is essential to generate the data needed to assess the safety, effectiveness, and potential role of gene drive technologies as part of integrated approaches to addressing vector-borne diseases.

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