Capacity-building for Gene drive research

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ene drive technology could help address challenges in global health and conservation, in particular vector-borne diseases and invasive species management. However, the responsible development and application of gene drive approaches require capacity-building efforts to ensure countries can participate in this research and benefit from its potential applications.

Capacity-building should enhance the knowledge, skills, infrastructure, and resources necessary to conduct genetic research, including gene drive, responsibly and effectively. By empowering scientists, policymakers, regulators, and stakeholders to understand, evaluate, and leverage genetic approaches, capacity-building efforts foster a robust and inclusive research community that could harness the full potential of genetic technologies.

In <u>decision 15/31</u> on synthetic biology, the Convention on Biological Diversity (CBD) acknowledged the importance of capacity-building and called on international cooperation and support for capacity-building for synthetic biology. The multidisciplinary Ad Hoc Technical Expert Group (mAHTEG) on Synthetic Biology that followed the decision called attention to capacity-building gaps between developing and developed countries, which experts considered one of the main drivers of inequity in the synthetic biology field.

POLICY RECOMMENDATIONS

- Governments need to create an enabling environment and commit resources to build regulatory
 and research capacity. Building the capacity of regulators is crucial as gene drive technologies
 continue to advance. Governments must play a central role in ensuring regulators have the resources,
 expertise, and tools to oversee gene drive research and evaluate its applications effectively. At the
 same time, building researchers' ability to leverage the potential of new genetic approaches, including
 skills and infrastructure, is critical to ensuring new technologies serve national priorities. Creating an
 enabling environment for capacity-building initiatives undertaken by partners and other stakeholders
 is also crucial. This could range from providing technical assistance, such as access to specialized
 laboratories, to policy guidance on regulatory requirements.
- The CBD needs to fulfil its mandate by ensuring the capacity building plan for the Cartagena Protocol is implemented. This will ensure Parties, particularly developing countries, strengthen their biosafety-related human resources and institutional capacities.
- Collaborations and partnerships are vital to maximize gene drive's benefits for society and the environment. By working together, researchers, policymakers, and other stakeholders can harness the potential of genetic technologies and address major priorities and questions. Collaborations and partnerships can leverage multidisciplinary expertise, promote resource-sharing, facilitate risk assessment and management, support capacity-building initiatives and foster stakeholder engagement.

Both external and internal capacity-building are crucial for gene drive research success

External capacity-building initiatives encompass the creation of an enabling environment for the research and application of genetic tools. This includes training regulators, national biosafety and bioethics committees, and raising awareness of the technology to ensure stakeholders can make informed decisions. While developers of genetic tools can participate and contribute to external capacity-building activities - for example, by contributing technical knowledge -, other actors, such as national authorities, need to lead and share the responsibilities for these efforts. Partnerships are essential in ensuring governments, developers, international

organizations, such as the World Health Organization and AUDA-NEPAD, and other stakeholders can benefit from exchanging experience and knowledge.

Internal capacity-building for research happens within institutions or research projects. It is essential to ensure that institutions have the expertise, research infrastructure, and resources needed to conduct research responsibly and effectively. The field of genetic technologies is relatively new, so it is important to address inequalities and gaps in the available skillsets to ensure scientists in different regions can lead research that meets their interests. Infrastructure development requires building new laboratory equipment and facilities, such as insectaries, laboratories with appropriate containment facilities, bioinformatics tools, and other key equipment so that research can be done in situ when desired.

Learning from existing capacity-building efforts

There are existing initiatives that are supporting capacity-building for gene drive research,

especially as research advances and there is more interest from countries wishing to use these technologies. There is need to expand such initiatives to ensure sufficient regulatory capacity, place the right scientists in the right disciplines, support decision-makers, and establish the 'hard' infrastructure needed, such as laboratories, to advance research.

The Pan-African Mosquito Control Association (PAMCA)'s Anopheles Genomics Project Phase II Building Sustainable Capacity in Vector Genomics and Bioinformatics in Africa is a collaboration with Sanger Institute that is promoting skills development and technology transfer for sustainable vector genomics capacity in Africa. The initiative has a Pan-African reach and aims to: establish basic computing and cloud infrastructure; train scientists, students, staff of local institutions, and national disease implementing agencies (NMCP/NMEPs); undertake Training of Trainers (ToT) to support additional vector genomics and bioinformatics trainees in Africa; and increase participation of women in bioinformatics and vector genomics.

The African Genetic Biocontrol Consortium has several capacity-strengthening initiatives, including on risk assessment, safety evaluation, biosafety at research and field sites, and genetic biocontrol technologies. The consortium provides opportunities for international training to strengthen in-country capacity for decision-making on the safety of genetic biocontrol technologies. It also supports broader understanding of genetic biocontrol technologies and increases transparency about gene drive technologies by providing technical training and opportunities to disseminate information, as well as addressing public misinformation.

The International Centre for Genetic Engineering and Biotechnology (ICGEB)'s Regulatory Science Group has worked for over 10 years to enhance the institutional capacities of governments in Sub-Saharan Africa, Central America and the Caribbean, related to national regulation of the products of biotechnologies in alignment with their policy objectives. The Group works in close collaboration with government officials and experts to ensure the resultant procedures and processes are tailored to the national regulatory frameworks and are immediately implementable. It also supports skill development for regional and international networking by regulatory officials and provides free eLearning on biosafety for regulatory authorities in Sub-Saharan Africa.

Transmission Zero is an international research program involving partners from Tanzania, including the <u>Ifakara Health Institute</u> (IHI) and the <u>National Institute of Medical Research</u>, alongside researchers from <u>Imperial College London</u> in the United Kingdom. The project has successfully developed the first transgenic mosquito strain to be made in a lab on the continent. Through this collaboration, Transmission Zero has contributed to building the technical, infrastructure and regulatory capacity of its partner institutions and countries where they are present.

Transmission Zero focuses on training PhD and Masters students to build a critical mass of scientists who will drive research, even after the project concludes. Ifakara is also collaborating with Swiss TPH to develop the capacity of local staff to operate their BSL-2 laboratory facilities. As the project progresses, these partnerships are expected to further develop the capability to conduct genetic modification at IHI.

The <u>University of California Malaria Initiative</u> (UCMI) is a collaborative initiative comprising researchers from four University of California campuses (Irvine, Davis, San Diego, Berkeley) and Johns Hopkins University. UCMI researchers work to eliminate human malaria by modifying mosquito populations to prevent the disease transmission. The project works in partnership and collaboration with scientists, public health officials, government officials and communities in partner countries.

In São Tomé and Príncipe (STP), UCMI and the Ministry of Health developed a partnership agreement to undertake collaborative work in three main areas - mosquito collections and analysis, training and capacitybuilding, and community engagement. Through this partnership, UCMI has built a Molecular Biology Laboratory, located at the University of STP, which provides support to UCMI's ongoing field research on mosquito vectors and training for university students.

CONCLUSION

Capacity-building is essential for advancing responsible and effective gene drive research. It is crucial to ensure that countries can both engage in gene drive research responsibly and reap the benefits of this technology. Capacity-building efforts must be comprehensive, collaborative, and contextually relevant to address the multidisciplinary nature of gene drive technology and its complex ethical, social, and regulatory considerations. Capacity-building is not just about acquiring technical skills or infrastructure — it is about fostering a culture of responsible innovation, ethical stewardship, and equitable participation in genetic research, including gene drive. By prioritizing capacity-building efforts and investing in the necessary resources, policymakers can support the research, development and potential application of gene drive technologies that address pressing global challenges while upholding the highest standards of safety, ethics, and social responsibility.

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