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National Academies report on gene drives recommends field trials but not environmental release

The National Academies of Sciences, Engineering and Medicine has published a [report](#) on the responsible use of gene drives; techniques which ensure a gene spreads through a population, often using CRISPR-based gene editing. The report reviews the basic science, ethical and social considerations, and governance models of gene drives. In its conclusion the report finds gene-drive modified organisms are not ready to be released into the environment, but recommends strictly controlled field trials.



Dr. Todd Kuiken, Senior Program Associate and Co-Director Biology Collectives, Science and Technology Innovation Program, Wilson Center ([webpage](#)):

Expertise: Environment, biodiversity, environmental security, governance, science and

technology, synthetic biology, U.S. Domestic Policy

“Tasked with evaluating the non-human impacts of gene drives, the NAS report does an excellent job laying out the vast unanswered research questions that should be evaluated prior to the release of a gene drive into the environment. Their conclusion that there is not yet enough evidence to support releasing gene-drive modified organisms into the environment, but that there is enough evidence to support further research and field trials suggests that the committee recognizes the potential benefits of gene drives but is not comfortable with the state of the science in relation to the ecological implications of such an application.

“I was encouraged that the report cautioned against reliance on reversal drives to counteract any negative effects of gene drives. This is important as many in the gene drive community point towards reversal drives as the solution to potential negative impacts of gene drives. This recommendation qualifies the need to address the statement found in the beginning of the report that “research on molecular biology of gene drives outpaced research on population genetics and ecosystem dynamics.” Unfortunately the report does not call for increased funding in these areas nor suggests how funding agencies might develop a research agenda to address this gap.

“One area the report missed was the infrastructure (both physical space and intellectual knowhow) that will be needed in order to conduct the field trials that are called for throughout the report. While the report presents a detailed framework for the stages you would need to go through before getting to a field trial, it fails to identify the scale in which these field trials would need to be conducted, where they would take place or who is responsible for conducting them and paying for them.

“Finally, the report seems to suggest that the Convention on Biological Diversity is the best mechanism to deal with the international implications of releasing a gene drive but falls short on suggesting how the U.S. should be more engaged in those deliberations. How the U.S. engages at the international level around gene drives will be critical in building the social acceptance the report calls for before any gene drive is released.”

Dr. Kevin Esvelt, Leader, Sculpting Evolution Group, Assistant Professor, MIT Media Lab, Massachusetts Institute of Technology ([webpage](#)):

Expertise: CRISPR-based gene drives, genome engineering, ecological engineering, directed evolution

“There’s much to admire in the NAS report on gene drive systems. The committee eloquently covers all of the major issues across many different areas. While I disagree on minor topics here and there—and very much so with the absence of a specific recommendation—they make excellent points in each area. If I had to pick a single take-home, it would be that a one-size-fits-all approach will not work with gene drives because

outcomes will depend on the organism, the type of alteration, the ecosystem, and affected communities.

“Yet despite getting so much right, the report fails to acknowledge the implications of the primary reason why a CRISPR-based gene drive is worthy of an NAS study in the first place. Namely, adding a gene drive changes our default expectation from ‘this alteration is unlikely to spread in the environment’ to ‘this is likely to spread in the environment’.

“Current CRISPR-based gene drive systems are self-sustaining ‘global’ drives. There is a nontrivial chance that they will spread from a single organism released into a wild population into most or all members of the local population—and very possibly into every population of the target species around the globe. This makes field trials of global drives unwise. But more importantly, it means that a single laboratory accident could lead to the unauthorized release of a gene drive system into the environment.

“Following the report’s own recommendations on ethics, this means we cannot even make gene drive organisms in the laboratory without ensuring that all of the people who could be affected—that is, every person living in an ecosystem harboring the target species—is informed, because we are obligated to give them a voice. In other words, laboratories should publicly describe what they are proposing to do before any gene drive experiments begin. Any scientist proposing to make a drive system, no matter the kind, no matter where in the world, should publicly disclose their plans before performing experiments.

“Everything in the Academy report points to this same conclusion about public disclosure. They just don’t explicitly acknowledge it. And that’s a pity, because gene drive systems are intrinsically about altering the shared environment. We should at the very least have the courtesy to inform people what is being planned—and let them voice their opinions—before we begin.”

Dr. John Marshall, Assistant Professor in Residence, Division of Biostatistics and Epidemiology, School of Public Health, University of California, Berkeley ([webpage](#)):

Expertise: Genetic control of mosquito-borne diseases, GM mosquitoes, malaria epidemiology

“The title of the NAS report sets the scene nicely—gene drives are on the horizon, where the Earth and sky meet. The reality of the technology is quickly approaching and the aspirations are exciting; but are we prepared for its arrival?

“The development of proof-of-principle CRISPR-based gene drive systems in four species in quick succession along with recent developments of homing endonuclease genes and Medea-based systems poses the question of whether the science is developing more quickly than our ability to respond to the ethical, legal, social and cultural issues. The NAS report does a commendable job of initiating a much-needed national discussion of how we deal with these issues alongside the science.

“The first conclusion—that there is insufficient evidence to release gene drive systems into the environment at this point—is a good one and a well-known fact in the field. Gene drive technology has developed much more quickly than anyone anticipated a decade ago; but even at an engineering level, the current systems are affected by design features that remain to be addressed. Furthermore, as the committee points out, there are knowledge gaps in a) our understanding of the ecosystems into which transgenes are intended to spread; b) how we engage the public and incorporate their input into the decision-making process; and c) how we regulate the technology.

“The report states that, in the U.S., gene drive systems will likely fall under the federal remit of the Coordinated Framework for the Regulation of Biotechnology; but the title of this framework seems to be quite a euphemism with respect to gene drive, as neither the FDA, USDA nor EPA have clear authority over the technology. Given recent scientific progress, this warrants urgent consideration.

“As some gene drive systems are designed to spread into populations with disregard for national borders, international regulatory considerations become relevant. The report rightly points out that the US not being a party to the Cartagena Protocol—the UN protocol on the international movement of GMOs—hinders international governance.

“This is a complex, multi-disciplinary issue, and the report does an impressive job at identifying knowledge gaps and recommending how we address these prior to the arrival of a technology that promises many potential benefits for global society.”

Dr. Austin Burt, Professor, Evolutionary Genetics, Imperial College, London and Principal Investigator, Target Malaria ([webpage](#)):

Expertise: Population genetic engineering via selfish genetic elements, gene drives, homing endonuclease genes

“The NAS report is an important contribution to the global discussion on gene drive technology. It offers a timely analysis of the current questions scientists, regulators and policy makers need to ask themselves as we consider the potential use of gene drive.

“The report accurately notes that current research on gene drive is at an early stage, and so definite decisions about release cannot yet be made. Scientists have been thinking about the potential of gene drive for some time, but it is only recently that we have seen proof of principle experiments for specific applications of the technology. The reality is that we will have more than 5 years before a product based on gene drive technology could reasonably be expected to be ready for use. This gives us all time to consider the important questions outlined by the NAS report on regulations, risk assessment, and engagement. We need this time, and the pace of discovery does not need to be seen as dictating the pace at which the technology may be put to use.

“One of the most important messages from the report is that each application of gene drive technology will need to be assessed individually for its potential benefits and risks. One size does not fit all because gene drive is a tool that can be applied in many ways to many different issues. In some cases, its application may be deemed desirable and positive, in others it might not. This is a key message that should be the starting point for a constructive dialogue about how to regulate and use gene drive-based technologies, and will help ensure we have a discussion that is balanced and not built on fears.

“Another element which is particularly welcome is the emphasis placed on a staged approach to testing and the importance of engagement. Engagement needs to go hand in hand with the research process to be meaningful. Proceeding stage by stage allows researchers to work with stakeholders in a manner that builds trust and offers an opportunity for them to participate in decision-making about how the research proceeds. Seeing this embedded in the recommendations is very positive.

“Overall, the NAS report clearly outlines both the tremendous potential of the tools that could be created and the challenges we face in realizing this potential. It will provide a useful basis for guiding researchers while pointing out the many areas where more work is needed.”

Dr. Zach N. Adelman, Associate Professor, Department of Entomology, Virginia Tech ([webpage](#)):

Expertise: Molecular and genetic interactions between arboviruses and their mosquito hosts; molecular biology and genetic manipulation of the vector mosquito, Aedes aegypti

“The NAS report on gene drive technology superbly summarizes the complicated nature of defining, regulating and predicting this form of synthetic biology. For those just entering the field, this document represents an excellent access point, written in plain language for a general audience while getting the details right.

“I share the report’s ultimate tone that neither a crisis-mode of thinking nor a purely precautionary mode is appropriate for gene drive applications, as exciting (or as terrifying) as they may be. Instead, scientists (and their funding agencies) in a broad array of disciplines such as ecology, biology, genetics, computational modeling and the social sciences have been challenged by the NAS committee to obtain the data to inform risk assessments sorely needed to truly evaluate the potential for deploying gene drive technology for the benefit of public health, agriculture or conservation biology.

“It was indeed striking how strongly the NAS committee argued for the use of ecological risk analysis in place of other methods, thus allowing consideration of benefits in addition to risks (a seismic shift considering the benefits of some applications include the elimination of malaria!). The sections on governance illustrate clearly how unclear the regulatory pathway is for gene drive technology as its developers seek to move into field-based trials.

“Hopefully shining a national spotlight on some of these issues, long discussed by the vector biology community, will finally bring sufficient clarification to allow the predictable and consistent evaluation of each particular gene drive-containing organism on its own merits.”

Dr. Megan J. Palmer, Senior Research Scholar and William J. Perry Fellow in International Security, Center for International Security and Cooperation (CISAC), Stanford University ([webpage](#)):

Expertise: Societal aspects of biotechnology; biotechnology policy and practices; biological safety, security, and governance

“The National Academies has done a remarkable job describing a wide array of critical issues raised by gene drives. Their well-rounded examination reflects the diversity of expertise and backgrounds of the committee members and contributors to the report. Their interdisciplinary and value-centered approach to the issues sets a good precedent.

“The report opens with central challenges posed by advances in biotechnology, and positions gene drives as an extreme example: the rapid pace of change and increasing scale of effects of biotechnology are stressing our strategies and capacities for governance.

“The report concludes that there is currently insufficient evidence to support release into the environment, and that there are significant gaps in our knowledge and systems of governance. Despite these limitations, they conclude that the potential benefits justify proceeding cautiously with research in carefully confined and contained settings.

“The exact steps needed to proceed responsibly remain unclear. The committee outlines techniques that may reduce – but will not eliminate – the possibility of unintended consequences. The committee also wisely states that “the outcomes of community engagement may be as crucial as the scientific outcomes” and that “a one-size-fits-all approach to governance is not appropriate”. Improving our systems of governance – including clarifying the process and authorities for consent – is a massive challenge on a global scale. While gene drives may not respect political boundaries, society does. We need new and improved strategies to manage the complex interfaces between technology and society.

“The committee exposes critical gaps in current oversight including a lack of clarity on how gene drives fit within regulatory frameworks and guidelines. It is significant that the committee concludes that oversight even at the earliest stages of research is inadequate. Our systems of oversight currently rely heavily upon researchers and their institutions being willing and able to flag emerging issues. There has been little rigorous examination of the effectiveness of these systems.

“I hope that the response to this report will be increased attention to and support for work on risk management, public engagement and international governance. This work must proceed both before and alongside technology development.”

Dr. Omar Akbari, Assistant Professor of Entomology, University of California, Riverside ([webpage](#)):

Expertise: Genetics and physiology of mosquitoes, genetic control technologies for limiting mosquito-borne diseases

“The NAS report does a commendable job at overviewing the technologies and identifying the knowledge gaps and barriers that will be important to address before any gene drive approach can be tested and utilized in the environment.

“As they conclude, and I agree, the potential applications of gene drives are quite exciting, however, the science is still premature and there are far too many unanswered questions to justify the release of a gene drive beyond the laboratory or contained field trials. Therefore, the committee urges caution until we understand better the ethical, regulatory, scientific, social and environmental consequences of unleashing gene drive containing organisms freely into the environment.

“To address these issues, the committee recommends that phased field testing, robust ecological risk assessments, and public engagement will be essential components for moving any gene drive from the laboratory to the field, and I generally agree with these recommendations. The committee also points out that regulation of gene drives will likely fall under the Coordinated Framework for the Regulation of Biotechnology. However, the federal agencies included in the current Coordinated Framework (FDA, USDA, EPA), do not have clear lines of authority over the potential applications of gene drive research.

“This issue of who will govern a technology that has no boundaries and can persist in the environment long-term will be very important address as this technology develops further in various species. Overall, this is a highly complex issue and the committee’s recommendations for a cautionary, collaborative, and multi-disciplinary, approach to future research and governance of gene drives is a good one.”

Declared interests ([see GENeS register of interests policy](#)):

Dr. Kevin Esvelt: Dr. Esvelt is the author of several patents filed by MIT and Harvard University involving the use of RNA-guided nucleases (e.g. CRISPR systems) to build gene drive systems. He is on the record as stating that he would like to see those patents used to ensure that early applications of the technology are restricted to not-for-profit groups.

Dr. Austin Burt: Dr. Burt served as a reviewer of the draft NAS report.

Dr. Zach Adelman: Dr. Adelman is a developer of gene drive technology and gave several presentations to the NAS committee during the fact-finding portion of this report.

Dr. Megan Palmer: Dr. Palmer has previously worked with individuals who served on the National Academies committee and presented at one of the public meetings.

No further interests declared.

Reference:

“[Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research With Public Values](#)” published by the National Academies of Sciences, Engineering and Medicine on Wednesday, June 8, 2016.

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wjohnallen • 4 months ago

If Eugenics is a set of beliefs and practices that aim at improving the genetic quality of the human population, what is it called when applied to non-human organisms?

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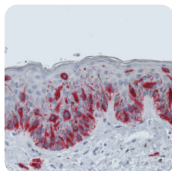
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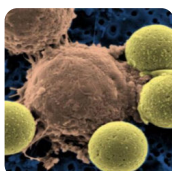
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