Exploring the value of a global gene drive project registry

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*Riley I. Taitingfong[1], *Cynthia Triplett[1,2], Váleri N. Vásquez[3,4], Ramya Rajagopalan[2], Robyn Raban[5], Aaron Roberts[6], Gerard Terradas[7], Bridget Baumgartner[8], Claudia Emerson[6], Fred Gould[9], Fredros Okumu[10], Cynthia E. Schairer[1], Hervé C. Bossin[11], Leah Buchman[12], Karl J. Campbell[13], Anna Clark[14], Jason Delborne[9,15], Kevin Esvelt[16], Joshua Fisher[17], Robert M. Friedman[18], Gigi Gronvall[19,20], Nikos Gurfield[21], Elizabeth Heitman[22], Natalie Kofler[23], Todd Kuiken[9], Jennifer Kuzma[9,24], Pablo Manrique-Saide[25], John M. Marshall[26,27], Michael Montague[28], Amy Morrison[29], Chris C. Opesen[30], Ryan Phelan[8], Antoinette Piaggio[31], Hector Quemada[32], Larisa Rudenko[33,34], Natéwinde Sawadogo[35], Robert Smith[36], Holly Tuten[37], Anika Ullah[38], Adam Vorsino[17], Nikolai Windbichler[39], Omar S. Akbari[5], Kanya Long[1], James V. Lavery[40,41], Sam Weiss Evans[42], Karen Tountas[43] &
+Cinnamon S. Bloss[1,2]

*Denotes Co-first authorship

+Denotes Corresponding Author cbloss@ucsd.edu

[1] Herbert Wertheim School of Public Health and Human Longevity Science, University of California, San Diego, La Jolla, CA, USA

[2] Center for Empathy and Technology, Institute for Empathy and Compassion, University of California, San Diego, La Jolla, CA, USA

[3] Energy and Resources Group, Rausser College of Natural Resources, UC Berkeley, Berkeley, CA, USA

[4] Department of Electrical Engineering and Computer Sciences, College of Engineering, UC Berkeley, Berkeley, CA, USA

[5] School of Biological Sciences, Department of Cell and Developmental Biology, University of California, San Diego, La Jolla, CA, USA

[6] Institute on Ethics and Policy for Innovation, McMaster University, Hamilton, ON, Canada

[7] Department of Entomology, the Center for Infectious Disease Dynamics and the Huck Institutes of the Life Sciences, The Pennsylvania State University, University Park, PA, USA

[8] Revive & Restore, Sausalito, CA, USA

[9] Genetic Engineering and Society Center, North Carolina State University, Raleigh, NC, USA

[10] Environmental Health and Ecological Science Department, Ifakara Health Institute, Ifakara, Tanzania

[11] Medical Entomology Laboratory, William A. Robinson Polynesian Research Center, Institut Louis Malardé, Papeete, Tahiti, French Polynesia

[12] Department of Entomology, Texas A&M University, College Station, TX, USA

[13] Re:wild, Puerto Ayora, Galapagos Islands, Ecuador

[14] *Department of Anatomy, University of Otago, Dunedin, Aotearoa/New Zealand*
[15] *Department of Forestry and Environmental Resources, North Carolina State University, Raleigh, NC, USA*
[16] *Media Lab, Massachusetts Institute of Technology, Cambridge, MA, USA*
[17] *Pacific Islands Fish and Wildlife Office, United States Fish and Wildlife Service, HNL, USA*
[18] *J. Craig Venter Institute, La Jolla, CA, USA*
[19] *Johns Hopkins Center for Health Security and Department of Environmental Health and Engineering, Baltimore, MD, USA*
[20] *Bloomberg School of Public Health, Johns Hopkins, Baltimore, MD, USA*
[21] *County of San Diego, Department of Environmental Health and Quality, Vector Control Program, San Diego, CA, USA*
[22] *Program in Ethics in Science and Medicine, University of Texas Southwestern, Dallas, TX*
[23] *Scientific Citizenship Initiative, Harvard Medical School, Boston, MA, USA*
[24] *School of Public and International Affairs, North Carolina State University, Raleigh, NC, USA*
[25] *Laboratorio para el Control Biológico de Aedes aegypti, Unidad Colaborativa de Bioensayos Entomológicos, Campus de Ciencias Biológicas y Agropecuarias, Universidad Autónoma de Yucatán, Mérida, México*
[26] *Divisions of Biostatistics & Epidemiology, School of Public Health, UC Berkeley, Berkeley, CA, USA*
[27] *Innovative Genomics Institute, UC Berkeley, Berkeley, CA*
[28] *Center for Health Security, Johns Hopkins, Baltimore, MD, USA*
[29] *Department of Pathology, Microbiology, and Immunology, School of Veterinary Medicine, University of California, Davis, Davis, CA, USA*
[30] *Department of Sociology and Anthropology, School of Social Sciences, Makerere University, Kampala Uganda*
[31] *United States Department of Agriculture, Animal Plant Health Inspection Service, Wildlife Services, National Wildlife Research Center, Fort Collins, CO, USA*
[32] *Department of Biological Sciences, Western Michigan University, Kalamazoo, MI USA*
[33] *Massachusetts Institute of Technology, Cambridge, MA, USA*
[34] *BioPolicy Solutions, LLC, Cambridge, MA, USA*
[35] *University of Thomas Sankara, Ouagadougou, Burkina Faso*
[36] *Science, Technology & Innovation Studies, School of Social & Political Science, The University of Edinburgh, UK*
[37] *Illinois Natural History Survey, Prairie Research Institute, University of Illinois at Urbana-Champaign, Champaign, IL, USA*

[38] *David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, USA*
[39] *Department of Life Sciences, Imperial College London, London, United Kingdom*
[40] *Hubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta, GA, USA*
[41] *Center for Ethics, Emory University, Atlanta, GA, USA*
[42] *Program on Science, Technology & Society, Harvard University, Cambridge, MA USA*
[43] *GeneConvene Global Collaborative, Science Division, Foundation for the National Institutes of Health*

To the editor:

Recent calls to establish a global project registry before releasing any gene-drive–modified organisms (GDOs) have suggested a registry could be valuable to coordinate research, collect data to monitor and evaluate potential ecological impacts, and facilitate transparent communication with community stakeholders and the general public. Here, we report the results of a multidisciplinary expert workshop on GDO registries convened on December 8–9, 2020 involving 70 participants from 14 countries. Participants had expertise in gene drive design, conservation and population modeling, social science, stakeholder engagement, governance and regulation, international policy, and vector control; they represented 45 organizations, spanning national and local governmental agencies, international organizations, nonprofit organizations, universities, and district offices overseeing local vector control. The workshop aimed to gather perspectives on a central question: 'In what ways could a gene-drive project registry both contribute to and detract from the fair development, testing, and use of GDOs?' We specifically queried the perceived purpose of a registry; the information that would need to be included; and the perceived value of a registry. Three primary findings emerged from the discussion: first, many participants agreed a registry could serve a coordinating function for multidisciplinary and multi-sector work activities; second, doing so may require different design elements, depending on the target end-user group and intended purpose for that group; and third, these different information requirements lead to concerns about information sharing via a registry, suggesting potential obstacles to achieving transparency through such a mechanism. We conclude that any development of a gene-drive project registry requires careful and inclusive deliberation, including with potential end-users, to ensure that registry design is optimal.

Recent advances in gene-drive technologies are enabling potential new strategies for pest management, vector-borne disease control, and conservation[1]. As developers, scientists, policymakers, ethicists, and others debate the risks of harm and potential benefits associated with testing and implementing engineered GDOs, questions remain about how to ensure their safe and ethical development, testing, and use. To coordinate research,

monitor ecological impacts, and facilitate transparent communication with community stakeholders and the general public, some have called for the establishment of a global project registry before any gene-drive release[2,3].

Registries are frequently described as facilitating transparency by making information about experimental biotechnologies or medical treatments publicly accessible to stakeholders. The Genetic Testing Registry was formed in response to calls for enhanced transparency and rigorous review of laboratory-developed genetic tests[4]. Several clinical data registries (e.g., https://clinicaltrials.gov/ or https://www.who.int/clinical-trials-registry-platform) have been created to promote data disclosure and sharing, and several registries have been established to document information on genetically modified organisms (GMOs) (e.g., https://ec.europa.eu/food/plants/genetically-modified-organisms/gmo-register_en, https://bch.cbd.int/en/, and https://www.isaaa.org/gmapprovaldatabase/). The World Health Organization's (WHO) Human Genome Editing (HGE) registry is described as following principles of transparency and inclusivity by making information about clinical trials using genome-editing technologies accessible to stakeholders[5]. More recently, some scholars have called for a consumer-targeted registry for gene-edited crops to earn greater public trust and transparency and facilitate community-led governance[6].

Many experts have identified a gene-drive registry as an important tool for both democratizing access to information and facilitating transparency around the research and development involving gene drives[2,3,7,8]. There is evidence for broad enthusiasm for such a registry among many stakeholders; for example, at the 4th Gene Drive Research Forum — cohosted by the African Union Development Agency (AUDA-NEPAD) and Foundation for the NIH in Addis Ababa, Ethiopia in 2019[7] — 68% of participants agreed with the statement that "a registry of [gene drive] projects would help with transparency". Others have outlined how such a gene-drive registry could be designed in tiered levels to address different end users[2].

Value and purpose of a registry. A review of transcripts of audio-recordings and rapporteurs' notes from the workshop suggests that many participants saw a registry as an opportunity to standardize documentation across the field and collate relevant information in a central location. It was noted that a registry may promote situational awareness, including of who is leading projects around the world, particularly if they become more numerous, and specific details pertaining to those projects. In this way, participants discussed a registry as potentially serving a valuable coordinating function for multidisciplinary and multi-sector work activities and tracking of stakeholder engagement.

For technical end-users, such as developers (researchers working to develop GDOs) and scientists (biologists, geneticists, entomologists, and others who work in the gene-drive field but are not necessarily developing gene drives themselves), it was discussed that a registry could document vital technical information, including features of a gene drive's 'target product profile,' which could spur learning and collaborations among various scientific teams. In later stages of gene-drive use, a registry was seen as a way to help developers anticipate potential cross-interactions between

GDOs released into the environment (e.g., adding a drive to an area where another drive using the same Cas endonuclease gene has already been implemented) or, potentially, to track negative results.

For government stakeholders, a registry could tie cases to countries' expressed goals to clarify lines of accountability, as well as promote surveillance and monitoring of potential ecological and health risks, as well as benefits and societal impacts. A registry could also be a potentially valuable resource for documenting different technologies under development for the purposes of horizon scanning and facilitating earlier information sharing amongst other stakeholders.

A registry was also perceived to serve important ethical purposes with respect to community stakeholders. We note that the term 'community' was used frequently throughout the workshop to reference a variety of different groups: local residents of regions where a GDO may be trialed or released or the general 'lay' public; scholarly or academic communities (e.g., developers referred to as 'the gene-drive community'); or simply without specification). Participants discussed communities' rights to know (and inform decisions about) whether a GDO is planned for release in their environment and advocated for a registry that would include detailed information that might inform local decision-making and authorization by impacted communities. For example, a registry could document engagement efforts, including the names of laboratories or organizations undertaking stakeholder engagement, the communities or groups they are engaging, and descriptions of the activities undertaken through engagement. Some participants also thought a registry might help to build relationships and trust with publics and communities, particularly those who have historically had little or no access to information about emerging technologies that may impact them. In addition, a registry could serve as a coordination point for funders or journals to require a minimum degree of early disclosure and information about community engagement efforts.

Information to include in a registry. Types of information to be included in a registry designed for different types of end-users (i.e., community groups, government stakeholders, and scientists/developers) fell into four main categories of information about the project: people, science, planning, and safeguards (see Table 1). There was some overlap among the categories of information recommended for each end-user group, with just three examples of inputs recommended for all three groups: two types of scientific inputs (details about the target organism and the drive) and one safeguard-related input (measures taken to mitigate risks associated with release).

Sharp distinctions in the types of information participants felt would be useful for different end-user groups also emerged. For a community end-user (e.g., residents in potential release sites, local community groups or civil society organizations), attendees imagined a less technical registry featuring accessible information about plans for release and potential impacts of releases, such as observable changes to community vector control activities. Some participants also highlighted the need to consider the socio-cultural values of community stakeholder end-users (e.g., local and Indigenous communities) in considering what types of information should be included, as well as the extent to which access could be limited due to

structural barriers (e.g., internet connectivity) that could limit the utility of a registry for some groups. For a government end-user, attendees felt that a registry should provide comprehensive technical information and list safeguards being pursued to mitigate potential harms. For technical end-users such as a scientist or developer, attendees imagined that fewer types of information would be included in a registry.

Concerns about a registry. Across participants, three principal concerns were raised: timing of information release; misrepresentation and misinterpretation of data or projects; and authority and legitimacy of the registry. Each of these may hinder a gene-drive registry's utility in providing transparency, potentially offering a veneer of, rather than a substantive contribution to, transparency or accountability.

In terms of timing of information release, views differed concerning the stage at which developers should be expected to share information about their work. Releasing information too soon could lead to public concern or controversy about ideas that never progress beyond the conceptual stage; conversely, releasing information at a later stage might lead to mistrust with community stakeholders, who may then conclude that scientists are withholding information. Some workshop participants discussed how a registry requiring scientists to share early-stage ideas (e.g., those not yet supported by robust experimental data) could also cause undue burden, stalling progress and limiting creativity for little benefit, given that many early-stage ideas are ultimately not viable. Participants also noted that early disclosure of information may present challenges related to intellectual property and patents. One participant noted that confidential business information (CBI) and other proprietary information have proven to be substantial barriers to transparency in regulatory registries.

The second concern of misrepresentation and misinterpretation arose among participants because the disclosure of highly technical information in a registry might lead to misinformed or false narratives about gene-drive technology. Apart from the risk of science being intentionally misrepresented, participants noted that out-of-date information or incomplete information related to limits on sharing of proprietary information, could become problematic in terms of how community stakeholders might perceive it. For instance, even if a researcher withholds information to adhere to institutional policy, such withholding could intensify public perception of a lack of transparency. For this reason, participants suggested that the nature of the information and reason for withholding it be provided within a registry, although others felt that describing the nature of the information would be akin to disclosing it. Participants also recognized that some level of science translation would be needed to make technical information accessible to the general public (in the case of a registry designed for communities/publics) and wondered how much bias would be introduced in the process of translation.

Authority and legitimacy. Another line of debate centered around whether some end-users may associate the data from experiments carried out by scientists and developers with the organization in charge of governing the registry. How then might the registry be presented as a reputable source of information without conveying any sort of approval about the data contained within it? Even more generally, there were questions of who

would be responsible for hosting and designing the registry, compliance, data curation and content moderation, maintenance, and funding. Additional questions included whether or not a registry is even the appropriate concept (e.g., a registry versus a repository) and whether it is feasible, given the current landscape of actors, organizations, funders, and others in the gene-drive field. Further to this point, participants also raised questions about how a registry would be positioned in the broader institutional landscape. Participants wondered whether a gene-drive registry might overlap with existing registries and repositories, such as the Biosafety Clearing House (https://bch.cbd.int/en/) and several questioned whether an additional, gene drive–specific registry was even necessary. This prompted further discussion about whether a gene-drive registry would be meant to function as a form of self-governance, versus a mandatory instrument backed by international law.

Conclusions. Three main takeaways emerged from the structured discussions in this expert workshop. First, a registry could serve a coordinating function for multi-disciplinary and multi-sectoral activities by standardizing documentation, collating relevant information in a central location, and promoting "situational awareness" of projects around the world. In this way, a gene drive registry might be taken up as a "boundary object," known as a shared object around which multiple diverse contributors or users cooperate, despite having different and often conflicting interests[9].

Second, a registry seeking to serve such functions would require different design elements, depending on the target end-user group and intended purpose for that group. This prompts questions about the degree to which design aimed at meeting the needs of a particular group may in turn help or hinder the needs of another. For instance, although standardization may enable discussion across stakeholder communities, it may also systematically obfuscate some perspectives, particularly those for whom a registry system is not a meaningful information resource (e.g., non-scientists). One approach suggested was to design a single registry with multiple user-specific interfaces, wherein end-users are directed to a version of the site that has been tailored to their information needs. However, a single registry with differing layers of authorization for different groups could also become a source of mistrust, as well as require a level of dedicated data management beyond what any funder might support.

Third, the information sharing embodied in a gene-drive registry was seen as on the one hand ethically valuable and on the other concerning or problematic. Ethical value could come from providing the public with information about GDOs and aiding in the mitigation of harms by making information about potential ecological and health risks visible and accessible. However, different information requirements for different end-users also creates concerns about information sharing via a registry, suggesting potential obstacles to achieving transparency through such a mechanism.

Some of the concerns raised in the context of a registry may be mitigated by drawing on lessons from the development and implementation of other established registries. For instance, challenges and strategies regarding funding, authority, data quality and maintenance are well documented in the context of clinical trials registries[10–13]. Challenges related to transparency and information sharing have also been discussed in connection to the

Biosafety Clearing-House[14,15]. Some resistance was also expressed at the potential obligation to disclose technical information due to concerns about intellectual property, accessibility of this information for lay publics, and potential for miscommunication. Although science communication remains challenging, a registry may actually provide an opportunity to promote accessible communication and shared language across diverse stakeholder groups. In addition, more discussion is needed about the governance implications of a gene-drive registry, as it remains unclear how a registry would connect to (or potentially be in tension with) existing governance approaches.

Importantly, the majority of participants in this workshop were based in the United States and other Global North countries; all presentations and discussions were conducted in English. Our findings will thus have limited generalizability to Global South contexts. Additionally, the workshop was conducted virtually over Zoom due to the COVID-19 pandemic, which embeds limitations and opportunities alike with respect to accessibility, including scheduling challenges for different time zones and the need for stable internet access to participate.

Findings from the workshop suggest that any development of a gene-drive project registry needs careful and inclusive deliberation due to its likelihood of serving one set of stakeholder needs more than another. We recommend that a next reasonable step would be to conduct a more formal needs assessment with members of each perceived end-user group. Such evaluation is needed because value and utility are seen as being end-user-specific and dependent, and there are evident challenges in designing objects that will be used by diverse stakeholders for a variety of shared and distinct purposes. Considering the overrepresentation of the United States and other Global North nations in the workshop, future work should also strive for more diverse representation. We also recommend that future work seek to learn from other designers' and end-users' experiences creating and navigating registries, bringing those insights to bear on the design of a gene-drive project registry. Finally, one possibility for continued work on the design of a gene-drive project registry might start from the shared categories of information identified in this exercise.

For this work to proceed further, potential funders need to be identified. In addition, institutional actors would need to be recruited to oversee the creation and upkeep of a registry, including hosting, compliance, content moderation, and maintenance. Should these steps continue to point to value and utility, end-users' feedback will then be critical in designing the registry to achieve its goals of democratizing access to information and facilitating transparency around gene-drive research.

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Competing interests

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249 **Table 1.** Three example types of GDO registries by end-user*.

Information to be included	**Type of end user**		
	Communities	**Governments**	**Scientists and developers**
Registry aim	Feature information and materials to help inform local decision-making and authorization by impacted communities.	Tie cases to expressed goals of countries and clarify lines of accountability. This registry could also promote surveillance and monitoring.	Feature components of technology's 'target product profile,' which would in turn help researchers identify and anticipate potential cross-interactions between GDOs.
People			
Funders of specific projects/Other declarations (e.g., stock held, financial interests, patents associated with GDOs)	x	x	
Profiles of scientists (e.g., affiliations, past research)	x		
List of stakeholders involved with a particular project and their respective roles (e.g., risk assessors, modelers)	x	x	
Points of contact for more information on a specific project		x	
Science			
Details about technology (e.g., type of drive)	x	x	x

Blueprint level genetic details (e.g., Cas being used, target locations, toxin-antitoxin system that could impact efficacy of other drives)		x	x
Details about target organism (e.g., type of organism and its local and global distribution)	x	x	x
Publications associated with specific projects	x	x	
Alternative interventions	x	x	
Anticipated ecological changes	x	x	
Use cases		x	
Plan			
Planned field releases	x		x
Goals and intentions of specific releases	x		
Local vector information (e.g., other mosquito species in the area, other possible hosts of pathogen, other organisms in the ecosystem that could affect the GDO, organisms with application relevance (e.g., mosquitoes, mice, pests) to anticipate cross-interactions among drives		x	x
Engagement activities undertaken in relation to specific projects	x		
Safeguards			

Risk assessment processes pursued/Updates on oversight processes (e.g., regulatory, local approval, risk assessments)	x	x	
Risk mitigation processes pursued/Anticipated risks of release/Safeguards implemented to prevent unintended spread	x	x	x
Information to inform international policy decision-making		x	

*It should be noted that participants conceived of various information types for different end-users, however, these information categories are not mutually exclusive. For example, scientists would likely agree that it would be beneficial to see who was funding what, but that was not an information type that was mentioned for scientists as the end-users.