

Exploring the value of a global gene drive project registry



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 8–9 December 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, non-profit 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 multisector 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 conservation¹. 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 tests⁴. Several clinical data registries (for example, <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) (for example, 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 registry is described as following principles of transparency and inclusivity by making information about clinical trials using genome-editing technologies accessible to stakeholders⁵. 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 governance⁶.

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 Fourth Gene Drive Research Forum⁷ – cohosted by the African Union Development

Agency (AUDA-NEPAD) and Foundation for the NIH in Addis Ababa, Ethiopia in 2019 – 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 users².

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 multisector 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 scientific teams. In later stages of gene-drive use, a registry was seen as a way to help developers anticipate potential interactions between GDOs released into the environment (for example, 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 and 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

Correspondence

Table 1 | Three example types of gene drive project registries by end-user^a

Information to be included	Type of end user		
	Communities	Governments	Scientists and developers
Categories of information	Feature information and materials to help inform local decision-making and authorization by affected communities	Tie cases to expressed goals of countries and clarify lines of accountability, and perhaps also promote surveillance and monitoring	Feature components of technology's target product profile, which would in turn help researchers identify and anticipate potential interactions between GDOs
People			
Funders of specific projects; other declarations (for example, stock held, financial interests, patents associated with GDOs)	x	x	
Profiles of scientists (for example, affiliations, past research)	x		
List of stakeholders involved with a particular project and their respective roles (for example, risk assessors, modelers)	x	x	
Points of contact for more information on a specific project		x	
Science			
Details about technology (for example, type of drive)	x	x	x
Blueprint-level genetic details (for example, Cas being used, target locations, toxin-antitoxin system that could affect efficacy of other drives)		x	x
Details about target organism (for example, 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 (for example, 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 (for example, mosquitoes, mice, pests) to anticipate interactions among drives)		x	x
Engagement activities undertaken in relation to specific projects	x		
Safeguards			
Risk assessment processes pursued; updates on oversight processes (for example, 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	

^aPlease note that there are likely other information types that could be considered useful for these and other end-users, but this table only reflects what was explicitly mentioned in the workshop. For example, scientists would likely agree that it would be beneficial to see information about funders of gene drive projects, but this did not specifically emerge in the participant discussions.

for the purposes of horizon scanning and facilitating earlier information sharing among 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 (for example, 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 affected 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 affect 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 (that is, community groups, government stakeholders, and scientists or developers) fell into four main categories of information about the project: people, science, planning and safeguards (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 (for example, 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 (for example, 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 (for example, 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 concept 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 (for example, 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 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 and the public) 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 (for example, 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 or as 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 multidisciplinary and multisector 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 interests⁹.

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 (for example, 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, concerns surrounding the timing, representation and interpretation of information shared via a registry complicate the goal of transparent communication with community stakeholders and the general public.

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 trial 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 owing to concerns about intellectual property, accessibility of this information for the lay public, 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.

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 video conferencing 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 because it may serve 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 end-user 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 over-representation 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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