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### Exploring the value of a global gene drive project registry

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1 **Exploring the value of a global gene drive project registry**

2

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59  
60 **To the editor:**

61  
62 Recent calls to establish a global project registry before releasing any gene-drive–modified organisms (GDOs) have suggested a registry could be  
63 valuable to coordinate research, collect data to monitor and evaluate potential ecological impacts, and facilitate transparent communication with  
64 community stakeholders and the general public. Here, we report the results of a multidisciplinary expert workshop on GDO registries convened on  
65 December 8–9, 2020 involving 70 participants from 14 countries. Participants had expertise in gene drive design, conservation and population  
66 modeling, social science, stakeholder engagement, governance and regulation, international policy, and vector control; they represented 45  
67 organizations, spanning national and local governmental agencies, international organizations, nonprofit organizations, universities, and district  
68 offices overseeing local vector control. The workshop aimed to gather perspectives on a central question: ‘In what ways could a gene-drive project  
69 registry both contribute to and detract from the fair development, testing, and use of GDOs?’ We specifically queried the perceived purpose of a  
70 registry; the information that would need to be included; and the perceived value of a registry. Three primary findings emerged from the discussion:  
71 first, many participants agreed a registry could serve a coordinating function for multidisciplinary and multi-sector work activities; second, doing so  
72 may require different design elements, depending on the target end-user group and intended purpose for that group; and third, these different  
73 information requirements lead to concerns about information sharing via a registry, suggesting potential obstacles to achieving transparency through  
74 such a mechanism. We conclude that any development of a gene-drive project registry requires careful and inclusive deliberation, including with  
75 potential end-users, to ensure that registry design is optimal.

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

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

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

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

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

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

105 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  
106 implemented) or, potentially, to track negative results.

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

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

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

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

131 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  
132 a registry should provide comprehensive technical information and list safeguards being pursued to mitigate potential harms. For technical end-users  
133 such as a scientist or developer, attendees imagined that fewer types of information would be included in a registry.

134 **Concerns about a registry.** Across participants, three principal concerns were raised: timing of information release; misrepresentation and  
135 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  
136 transparency, potentially offering a veneer of, rather than a substantive contribution to, transparency or accountability.

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

145 The second concern of misrepresentation and misinterpretation arose among participants because the disclosure of highly technical  
146 information in a registry might lead to misinformed or false narratives about gene-drive technology. Apart from the risk of science being intentionally  
147 misrepresented, participants noted that out-of-date information or incomplete information related to limits on sharing of proprietary information,  
148 could become problematic in terms of how community stakeholders might perceive it. For instance, even if a researcher withholds information to  
149 adhere to institutional policy, such withholding could intensify public perception of a lack of transparency. For this reason, participants suggested  
150 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  
151 information would be akin to disclosing it. Participants also recognized that some level of science translation would be needed to make technical  
152 information accessible to the general public (in the case of a registry designed for communities/publics) and wondered how much bias would be  
153 introduced in the process of translation.

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

157 would be responsible for hosting and designing the registry, compliance, data curation and content moderation, maintenance, and funding. Additional  
158 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  
159 current landscape of actors, organizations, funders, and others in the gene-drive field. Further to this point, participants also raised questions about  
160 how a registry would be positioned in the broader institutional landscape. Participants wondered whether a gene-drive registry might overlap with  
161 existing registries and repositories, such as the Biosafety Clearing House (<https://bch.cbd.int/en/>) and several questioned whether an additional, gene  
162 drive-specific registry was even necessary. This prompted further discussion about whether a gene-drive registry would be meant to function as a  
163 form of self-governance, versus a mandatory instrument backed by international law.

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

169 Second, a registry seeking to serve such functions would require different design elements, depending on the target end-user group and  
170 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  
171 turn help or hinder the needs of another. For instance, although standardization may enable discussion across stakeholder communities, it may also  
172 systematically obfuscate some perspectives, particularly those for whom a registry system is not a meaningful information resource (e.g., non-  
173 scientists). One approach suggested was to design a single registry with multiple user-specific interfaces, wherein end-users are directed to a version  
174 of the site that has been tailored to their information needs. However, a single registry with differing layers of authorization for different groups could  
175 also become a source of mistrust, as well as require a level of dedicated data management beyond what any funder might support.

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

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



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

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

192 Findings from the workshop suggest that any development of a gene-drive project registry needs careful and inclusive deliberation due to its  
193 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  
194 needs assessment with members of each perceived end-user group. Such evaluation is needed because value and utility are seen as being end-user-  
195 specific and dependent, and there are evident challenges in designing objects that will be used by diverse stakeholders for a variety of shared and  
196 distinct purposes. Considering the overrepresentation of the United States and other Global North nations in the workshop, future work should also  
197 strive for more diverse representation. We also recommend that future work seek to learn from other designers' and end-users' experiences creating  
198 and navigating registries, bringing those insights to bear on the design of a gene-drive project registry. Finally, one possibility for continued work on  
199 the design of a gene-drive project registry might start from the shared categories of information identified in this exercise.

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

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## 212 **Competing interests**

213 A.C. is a PhD student supported by Predator Free 2050 Ltd, through a Capability Development grant (<https://pf2050.co.nz/2021-students/>). J.D. has  
214 been a member of the Genetic Biocontrol of Invasive Rodents (GBIRd) partnership since 2017. K.E. is an inventor on patent applications concerning  
215 diverse forms of CRISPR-based gene drive filed by Harvard University and MIT. K.E. has called for the technology to remain non-profit until the  
216 first major public health application is successful. N.K. is a member of a CCA expert committee sponsored by Health Canada to consider genetically  
217 modified animals for pest control, and the founder and director of a non-profit initiative called Editing Nature. R.P. is the co-founder of Revive &  
218 Restore, a non-profit organization, which advocates for the thoughtful use of biotechnology in conservation. O.S.A is a founder of Agragene, Inc. and  
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222 Research Advisory Committee of the NIH.

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**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
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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	
<i>Plan</i>			
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		
<i>Safeguards</i>			

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	

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\*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.