Exploring the intersections of governance, constituencies, and risk in genetic interventions

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Abstract
In June 2020, Revive & Restore hosted the Intended Consequences Workshop to explore how the field of conservation can realize the benefits of genetic interventions and address concerns about unintended consequences of these actions. A group of 57 participants from eight countries representing government, academia, and conservation practice discussed how implementation of genetic interventions designed to achieve conservation objectives can be optimized to both address concerns about risk and achieve the intended consequences. Genetic interventions are efforts designed to manipulate the genetic composition of a conservation target at a species or population level. The planning and implementation of genetic interventions in conservation raises questions about how key constituencies are involved in the process and how risks and benefits are characterized and evaluated. Governance frameworks are critical to structuring dialogue and decision-making among interested parties around the development of these conservation efforts in a manner that addresses risks, benefits, and equity considerations. In this article, we explore related issues of policy and governance, key constituencies, and risk as raised during discussions at a 2020 workshop on “Intended Consequences” of conservation interventions. We examine how different constituencies characterize risks of genetic interventions within particular sociocultural contexts. We then revisit the characterization and framing of risks to suggest ways that the perspectives of different constituencies can be visualized in a manner to inform resulting policy decisions.

KEYWORDS
biotechnology, conservation, engagement, governance, intended consequences, intervention, policy, risk, stakeholders

1The findings and conclusions in this article are those of the author(s) and do not necessarily represent the views of the National Invasive Species Council or the U.S. Fish and Wildlife Service.

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1 | INTRODUCTION

In June 2020, Revive & Restore hosted the Intended Consequences Workshop to explore how the field of conservation can realize the benefits of genetic interventions and address concerns about unintended consequences of these actions. A group of 57 participants from eight countries representing government, academia, and conservation practice discussed how implementation of genetic interventions designed to achieve conservation objectives can be optimized to both address concerns about risk and achieve their intended consequences (see Phelan et al., 2021 for a framework proposed by workshop participants to guide conservation interventions from an Intended Consequences perspective). Genetic interventions are efforts designed to manipulate the genetic composition of a conservation target at a species or population level. This definition includes both traditional and advanced techniques and may include activities such as augmentation of wild populations, hybridization, gene editing, and synthetic biology.

The workshop addressed commonalities across these approaches, while recognizing heightened attention and concern around the use of advanced biotechnology. In this article, we focus on this more controversial subset of genetic interventions for conservation benefit, which could include creation of hybrids to increase viability (Hirashiki, Marvier, & Kareiva, 2021), genetic modifications for invasive species control (Teem et al., 2020), and facilitated adaptation (Newhouse & Powell, 2021). These newer practices can complement conventional conservation methods (Novak, Maloney, & Phelan, 2018; Supple & Shapiro, 2018). However, concerns about greater uncertainty regarding the potential intended and unintended outcomes of genetic modifications has prompted calls for greater scrutiny of these approaches (see Novak, Phelan, & Weber, 2021; Redford, Brooks, Macfarlane, & Adams, 2019).

Advancing the dialogue and enabling sound decision-making around these approaches as well as their evaluation and potential application in the field requires attention to their governance frameworks, the key constituencies involved, and how risks and benefits are characterized. This article provides some perspectives from the workshop on these three areas and their intersections. Regarding governance, we briefly explore both the formal legal structures regulating research and applications along with the broader set of informal policies and normative rules that influence activities in this area. We highlight the perspectives of three particular constituencies—researchers, land managers, and stakeholders including affected communities—and their different orientation to policy and risk. We then propose an approach to characterize risks associated with genetic interventions and a method to visualize how groups prioritize different types of concerns that can help inform decision-making, enable learning between groups, and address a wider range of viewpoints.

2 | GOVERNANCE AND POLICY

Genetic interventions are developed and implemented within a policy context that can influence activities from research to deployment. Development of new conservation approaches that utilize advanced techniques like gene editing offers the opportunity to examine whether current policy and broader governance structures are well suited to guiding these approaches towards achieving desirable outcomes. Indeed, new biotechnology approaches and products have prompted broad review of policy frameworks regulating their development (see NASEM 2017 for an example in the U.S.), and can drive their reconsideration (Evans & Palmer, 2018).

The notion of governance extends beyond the formal policies and statute-driven regulations, and refers to the broader set of formal and informal processes used to resolve conflicts and to make decisions (Rudenko, Palmer, & Oye, 2018). Governance thereby encompasses governmental regulations, organizational requirements from academic and scientific institutions, as well as informal guidance and codes of practice that reinforce broader norms. How and when these considerations come into play can vary by technology, application, and where they are developed and implemented.

Governmental policies are a major element of governance, and a variety of policies come into play in considering genetic interventions, including those that relate to habitat protection, endangered species, regulation of products of genetically modified organisms, biosafety, and intellectual property (for a recent review see Reynolds, 2020). Formal national regulatory processes and their supporting structures (e.g., the U.S. Coordinated Framework for the Regulation of Biotechnology, New Zealand’s Hazardous Substances and New Organisms Act, Australia’s Gene Technology Act) often receive considerable attention given their profile and scope (Gilna, Kuzma, & Showalter Otts, 2014; Meghani & Kuzma, 2018; Rudenko et al., 2018; Showalter Otts, 2014). National level considerations are also often influenced by intergovernmental processes. Because aspects of research, implementation, and potential outcomes can cross borders, multilateral agreements, notably the Convention on Biological Diversity and its Cartagena Protocol on Biosafety, have been focal points for discussions of the governance of genetic interventions in conservation (Convention on
Biological Diversity, 2017; Keiper & Atanassova, 2020; Reynolds, 2020). Conversely, at the state or local level, planning and implementation occur within complex political environments where considerations and decisions often extend beyond what is regulated at both national and international scales.

Formal regulation addressing the research that produces genetic strategies for natural ecosystems is evolving; these areas may intersect with and apply lessons from the regulation of other biotechnology applications. One strategy for accommodating genetic interventions is clarifying and/or extending the authority of existing agencies and statutes that may be well established and familiar to the constituencies involved. For example, in the U.S., the Food and Drug Administration regulates genetically modified animals used for food or drugs, yet interpretation of their jurisdiction includes the authority to regulate genetic interventions for recovery of endangered species. Other conservation topics related to endangered species fall under the authority of the U.S. Fish and Wildlife Service or National Atmospheric and Oceanic Administration. These agencies have more appropriate processes for assessing conservation efforts, but they have no direct oversight of biotechnological applications. Existing regulatory pathways for conventional conservation interventions, like translocation, could be adapted to biotechnology applications for conservation.

Working across agencies does run the risk of perpetuating the complexities of multi-agency coordination and communication that can diffuse effective engagement with stakeholders. A more dramatic strategy would be to consolidate regulatory coordination in a single conservation-focused agency that could address the unique risk factors associated with wild organisms and natural systems.

Moving beyond the bounds of the regulatory sphere, it is important to look at other issues that directly and indirectly affect decision-making and the resolution of conflicts. Those conflicts and decisions often revolve around how intended benefits, as well as associated risks, are characterized, evaluated, and weighed. For genetic interventions, there are several related areas of concern and procedural considerations that impact how potential risks are determined and managed, including:

- the reliability and efficacy of advanced biotechnologies in achieving a lasting species or population-level outcome,
- the ecological and social impacts of an intervention,
- how regulatory agencies will handle new technologies and fields of application, and
- how stakeholders regard the objectives and approaches of particular conservation interventions.

In the regulatory arena, environmental statutes may not allow for the consideration of benefits or equity issues in decision-making. In exploring governance processes surrounding genetic interventions we must therefore consider not only the objectives, risks, and techniques involved, but also who ultimately has the ability to influence decisions about those factors within different timescales and geographies. An in-depth exploration of these frameworks and their applicability to genetic interventions is beyond our scope; rather we focus on how researchers, land managers, and stakeholders including affected communities influence and are influenced by policy processes. Technological advancement is forcing regulatory frameworks to address and potentially accommodate genetic applications that serve increasingly critical conservation needs (Evans & Palmer, 2018; Redford et al., 2019). Such adjustments will take time, practical experience, and further engagement with key constituencies.

3 | KEY CONSTITUENCIES

The Intended Consequences workshop included perspectives related to three particular constituencies: (a) researchers, (b) land managers, and (c) stakeholders including affected communities. The sections below characterize some of the concerns and challenges for these groups as the governance of genetic interventions evolves. We provide illustrative examples that are biased to the U.S. as a reflection of the authors’ dominant experiences, but the workshop included international participants who highlighted how similar issues manifest across geographies.

3.1 | Researchers

Research and development of genetic strategies that can be applied to conservation are well underway (Kolodziejczyk et al., 2019). Researchers in laboratories around the world are exploring a spectrum of basic and applied science. These projects are often motivated by potential applications to conservation, even when these are very long-term goals and their work may have applications outside of conservation. Much of this research takes place in universities and government agencies, often supported by government funding that can be tied to regulatory requirements. The complexity of navigating nested rules and regulations can increase when applied conservation is the designated end goal.

Early research phases can be delayed when the future regulatory landscape is unfamiliar; many lab-based scientists do not know when or how to engage the appropriate regulators. In 2016, the U.S. National Academies of
Science, Engineering and Medicine recognized challenges posed by biotechnology applications for conservation, where there may be fewer or ambiguous comparators (NASEM, 2016). Lacking sufficient examples and accessible guidance, committed researchers can spend significant time trying to navigate policy frameworks and attempting to interact with regulators from different agencies with seemingly overlapping jurisdictions. Meanwhile, regulators with limited resources and capacity will need to handle an increasing number of inquiries as technologies offer new prospects in conservation, often with limited budgets and resources.

Most concerns about unintended consequences of conservation interventions lie downstream from lab-based biotechnology research, as the more serious concerns are generally associated with ecosystem impacts and the health of engineered organisms post-release. Approval pathways will need to address these questions, which will require identifying appropriate forms of evidence. The development and regulatory consideration of a transgenic American chestnut is one case in point (Newhouse et al., 2020; Steiner et al., 2016). Researchers considering biotechnology approaches may thus seek to proactively engage in questions related to downstream risks to help inform later decision-making and de-risk their early research investments. While such endeavors may be useful, burdening early-stage research development with formal requirements to consider hypothetical risks related to subsequent, field-based stages of the project may discourage researchers and delay critical initial research activities. Similar delays have been observed in the genetic engineering research of animal food products (Laible, Wei, & Wagner, 2015; Maxmen, 2012; Tizard et al., 2016; Van Eenennaam, De Figueiredo Silva, Trott, & Zilberman, 2021). Moreover, oversight costs may not be warranted if early research stages are functionally equivalent to research exploring uses outside of conservation that would not trigger similar oversight. In these cases, early informal guidance and codes may be more appropriate.

Ongoing dialogue between researchers and regulators throughout the research and development process is important to facilitate the effective and timely evaluation of biotechnology applications for conservation and achieve conservation outcomes. These interactions can also facilitate new research programs that can build a better evidence base for assessing risk and tools to monitor for indicators of both intended and unintended outcomes.

3.2 | Land managers

Land managers are always seeking more effective tools to accomplish management objectives as defined by their agency’s mission and authorities. This mission and underpinning policies direct how and to what degree other factors are weighed in a management approach. It is important that these policies be based on science and codify agreed upon preferred outcomes that guard against catering to any particular stakeholder. These safeguards avoid the risk of sending conflicting messages or preventing the use of a tool that may present little risk, yet substantial benefits.

Similar to pesticides, where application is based on maximizing benefits and minimizing adverse impacts, genetic interventions offer a spectrum of tools for resource management that could be approached in the same context. Instead of a ban or blank check on the use of pesticides, land management agencies adopt a policy of integrated pest management (Flint & van den Bosch, 1981). Land managers focus on understanding the range of possible tools and methods to control a pest and then develop a strategy to incorporate relevant methods, including pesticides, to maximize positive impact and minimize risk. New types of genetic interventions should be considered among the tools in the toolbox; however, this requires both the expertise and the policy space to consider their potential risks, benefits, efficiency, and efficacy. The current lack of clarity on governance that impacts researchers, also impacts land managers.

Lack of an agency policy or position regarding acceptable conservation techniques can also have repercussions. Without a stated policy or overarching guidance, many of the in-depth deliberations surrounding use of genetic interventions are left to be worked out at the individual project level. This presents difficulties where institutional, ethical, and social engagement questions extend beyond a specific land manager’s geographical scope or area of expertise. At the project level decisions should focus on the specific means to protect a conservation resource, and not be used as a forum to address an agency’s broader position on a technology. These considerations suggest the need for a conscious approach by land management agencies that can balance larger institutional concerns around genetic interventions with the practical needs of achieving their mission on the ground. This process needs to align with the research community’s work, the regulatory environment, and engagement of stakeholders in achieving conservation goals.

3.3 | Stakeholders, including affected communities

In addition to researchers and land managers, there are a wide range of other potentially interested stakeholders...
across the public and private sectors. We recognize that there is a broader discussion on terms like public, community, and stakeholder (NASEM, 2016), but for the purposes of this article, the term “stakeholders” is intended to encompass a broad scope, particularly affected communities, that may have an interest in conservation interventions. Transparency and engagement are essential in the adoption of formal policies as well as in informal decision-making. Conservation actions require the support and cooperation of many types of stakeholders that have: (a) different levels of knowledge concerning ecology, genetics, and potential genetic interventions; (b) different reasons for supporting or opposing conservation interventions; and (c) diverse sets of ethical values.

Stakeholders have two common concerns with the development of policies governing use of biotechnology in conservation: transparency of the decision-making process and engagement in decision-making activities. Both justice and practical wisdom require that communities of interest be informed about conservation projects that affect them. Stakeholder engagement, however, goes beyond transparency about decision-making to include active engagement that solicits input during the decision-making process. Engagement is an important part of both traditional interventions (Smith & Peterson, 2021) and genetic interventions (Newhouse & Powell, 2021) and has been defined as “Seeking and facilitating the sharing and exchange of knowledge, perspectives, and preferences between or among groups who often have differences in expertise, power, and values” (NASEM, 2016: 131). In the context of this article, it should include discussion about the nature of genetic interventions, their consequences, risks, and permanence, and whether they can be reversed or halted. Stakeholder engagement offers an opportunity to: learn about local conditions that may affect a project’s success; tailor interventions to perceived needs; build trust in conservation researchers and practitioners; and build support for conservation goals.

Successfully engaging stakeholders in the decision-making process requires considering who to involve when shared environments are at stake, how early to engage them, and how to manage disagreement (NASEM, 2016). Consensus need not be the goal of these interactions. An early element of the discussion should be to address decision-making and whether options exist to geographically delimit where and how these specific genetic interventions may be deployed. These challenges are not unique to applications of biotechnology, but they are likely to elicit questions of ethics and values. Ethical concerns are divided between principled concerns about biotechnology and the relationship between humans and nature (Preston, 2018; Sandler, 2019), and concerns about consequences for human and ecological health (Brister & Newhouse, 2021; Rohwer & Marris, 2018). Values affect stakeholders’ evaluation of how much risk is acceptable (Brister, Holbrook, & Palmer, 2021).

Workshop participants discussed various approaches to engage stakeholders in discussions about the intersections of risk and values and how these are reflected in formal policy and broader governance processes (Barnhill-Dilling & Delborne, 2021; Carter, Mankad, Zhang, Curnock, & Pollard, 2020). How values are interpreted in a given context often evolves over time, particularly with the incorporation of new knowledge (Baumgaertner & Holthuijzen, 2017). Therefore, tools to enable discussions about risk categories and prioritization are an important part of planning for effective engagement.

4 | VISUALIZING RISK FOR ENGAGEMENT AND CONSULTATION

One approach for facilitating explicit and comparative evaluation of risk could consider that any project proposing a genetic intervention for conservation will have a number of attributes, relating to what is being proposed and the degree of confidence around outcomes. Such attributes would be of concern to researchers, land managers, and stakeholders. Examples of such attributes are:

- Extent of the genetic modification—from negligible (e.g., directed captive breeding) to significant (e.g., creating genetically engineered hybrids),
- Spatial scale of intended effects—from a captive population to local, regional, and even global scales,
- Degree of certainty that desired outcomes can be achieved,
- Likely severity of unwanted outcomes or unintended consequences, and
- Confidence in the ability to mitigate unwanted outcomes—involving exit strategies, mitigation techniques, and detection of deleterious outcomes.

Each attribute could sit on a scale from least to most concern, and any project could be scored along these scales. At some point along each scale a project might go from being acceptable to being unacceptable. Where this zone of unacceptability lies will depend on the particular attribute and the value system of the constituency considering that attribute. For example, some people might be less concerned by the degree of genetic modification and more worried by possible unwanted outcomes. The attributes under consideration could be changed or modified according to regulatory environment, project, technological change, or other factors, but the underlying purpose
is to represent concerns in a transparent manner using the same set of metrics.

Attribute ratings could be displayed by stacking them from most concern to least concern, using a calculated weighting. By linking the different zones, we could visualize a landscape of acceptability specific to any stakeholder group (example in Figure 1). By assessing a project along the five attribute scales, one could identify at what point a project enters a zone that might be a deal-breaker for project approval for some constituents, and thus which aspects need to be addressed through a regulatory or other process. Zones of acceptability might shift according to the urgency of the conservation need and the consequences of “business as usual” or taking no action. Cohesive and transparent presentation and assessment of risk such as this could facilitate engagement and discussion.

A flexible risk visualization strategy would facilitate transparent, collaborative decision-making by providing a framework for conversations about risks, values, and trade-offs. It would not take the place of regulatory approval or policy decisions but could inform required decision-making processes and help identify where concerns are not being addressed within the governance framework.

5 | REVISITING CHARACTERIZATIONS OF RISKS

In addition to the focus on visualizing risk, the Intended Consequences workshop discussed the risks and benefits specifically associated with genetic interventions. There was a recognized need to further explore how different constituencies might assess the risk attribute that we have identified as “the likely severity of unwanted outcomes or unintended consequence” in the previous section.

In the midst of the governance landscape, the frameworks we use to assess risks essentially codify what is valued. These aspects are framed by policy regarding: how stakeholders are formally engaged in the process and what additional assessment mechanisms may be necessary; the formal risk assessment needs required by regulatory agencies versus broader representations of risk that can readily be informed and used by a range of different actors; and the strategic communication of this information to the public. Interaction with regulators and stakeholders will be most advantageous while projects are still under conception. A case-by-case approach will be necessary until sufficient examples of these interventions exist for communities, practitioners, and regulators to have developed confidence, trust, and accepted approaches.

Once a decision has been made about which factors to include in risk assessment, the question becomes how best to reduce the sources of risk of a planned intervention strategy while maximizing benefits and minimizing costs. Both risks and benefits should be assessed against other options for achieving the conservation objective, including taking no action. By combining elements of the risk categories described below, stakeholders and regulators could evaluate risks and benefits using parameters specific to a given project. Here, we consider three categories of risk common to genetic interventions that may be used to systematize and simplify risk assessment:

- Project risk: the potential failure of a genetic intervention to achieve an impact,
• Genetic risk: the potential unintended effects of added/altered biological functions, and
• Ecosystem risk: the potential unintended effects of added (or subtracted) species interactions.

All genetic interventions for conservation include project risk, as no intervention is completely guaranteed to achieve the desired outcome. This requires careful genetic analyses in the design stage, as well as long-term monitoring of the target population.

Interventions that involve the introduction of new genetic elements to the gene pool of a target population have genetic risk. The added genetic risk stems from uncertainties associated with the techniques used and unknown genomic interactions or reversions. Some of this risk can be mitigated by precise gene editing techniques and lab-based experiments conducted on model organisms. However, as with project risk, long-term monitoring of phenotype, behavior, and population genetics is necessary.

Some genetic interventions may aim to produce ecosystem-wide effects, as in efforts to repair degraded ecosystems. These may involve the intentional modification or introduction of interspecific interactions, such as genetic controls to reduce or eliminate populations of an invasive species, modified microbes that are designed to degrade environmental pollutants, or restoration of a vacated ecological niche. Risks associated with ecosystem intervention might be realized over multiple timescales, so monitoring plans must account for near- and long-term effects. Containment methods for modified organisms and exit strategies will be essential if ecosystem risk is considered high. Field trials, predictive mathematical models, and mesocosm studies will become especially important to anticipate the likelihood of negative impacts (e.g., Long et al., 2020; Mozelewski & Scheller, 2021).

The degree of genetic and ecosystem risk for any given project should be assessed early, using quantitative risk assessment strategies appropriate to stakeholders. Risk mitigations, including field trial design should be informed by those early assessments. Projects that are inherently riskier require more stringent risk mitigation. A flexible risk assessment strategy, as described in this section, would allow for scenario-based analyses that consider alternative approaches, as well as the risks associated with inaction. Such side-by-side comparisons will highlight the trade-offs that are important in deciding if and how to intervene for conservation purposes.

## 6 | SUMMARY

Many policy considerations are common across genetic interventions, even though the embedded technologies may be handled differently by existing governance structures. Additionally, formal regulatory processes may only address a portion of the issues raised by these new conservation technologies, which emphasizes the need for clarity and guidance for different constituencies. Existing guidance might apply more broadly and we should identify where additional guidance and best practices might advance decision-making processes. IUCN’s Guidelines for Reintroductions and Other Conservation Translocations (IUCN/SSC, 2013), engagement guidelines around vector control (Thizy et al., 2019), and potentially new codes of practice as discussed during the Intended Consequences Workshop might be relevant places to start. The resulting clarification of issues and substantive guidance could then be considered in the context of more formal national and local regulatory systems.

Recognition of the different constituencies involved in and affected by genetic interventions is inherent to the consideration of how risks and benefits are characterized, assessed, and weighed. While we focus on researchers, land managers, and stakeholders, including affected communities, those are still broad categories and there are serious challenges in enabling and structuring constructive dialogue.

Finally, considering the conservation benefits of genetic interventions in tandem with their relative risk is critical. For each constituency, those risks should also be evaluated against an alternative of non-intervention, which may have its own costs in terms of ongoing adverse impacts and/or management resources. Parameterized risk landscapes and specific framing of genetic and ecosystem risks can be useful tools for weighting conservation benefits against potential risks for specific genetic interventions.

The workshop and this article outline a number of policy and governance issues and opportunities around incorporating genetic interventions using biotechnology into the toolkit of approaches necessary for advancing conservation objectives. The intersection between these ideas and key constituencies and risks requires further attention. With careful consideration underlying policy and governance structures can be used to support proper assessment and appropriate implementation of genetic interventions for conservation.

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The authors have no conflict of interest to declare.
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All authors have contributed and have given final approval of the version to be published.

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