ELEMENTA
Science of the Anthropocene

Roberts, P, et al. 2020. Responsible innovation in biotechnology: Stakeholder attitudes and implications for research policy. *Elem Sci Anth,* 8: 47. DOI: https://doi.org/10.1525/elementa.446

RESEARCH ARTICLE

Responsible innovation in biotechnology: Stakeholder attitudes and implications for research policy

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This article explores attitudes of stakeholders involved in biotechnology towards the Responsible Innovation (RI) framework. As a framework for governance, RI has received increasing scholarly attention but has yet to be successfully integrated into U.S. research and innovation policy. Using a mixed methods approach, we analyzed the attitudes of different biotechnology stakeholders, particularly those working in areas related to genetically modified organisms (GMOs) in agriculture and the environment, towards the principles and practices of RI. Homogenous focus groups (organized by stakeholder affiliation) and pre- and post-focus group surveys were used to measure attitudes towards RI. We designed the survey questions according to the Advocacy Coalition Framework (ACF) and examined the agreement of stakeholders with policy core beliefs (general principles of RI) and secondary beliefs (implementation practices of RI). Although all stakeholder groups had neutral to positive attitudes towards RI general principles, we found significant differences in their reactions to the scholarly definitions of RI and in their attitudes towards practices to implement RI. In comparison to government and advocacy groups, stakeholders promoting biotechnology innovations–industry, trade organizations, and academics–had more negative reactions to social science definitions of RI and to RI practices that relinquish control to people outside of technology development pipelines. Qualitative analysis of focus-groups revealed barriers for implementing RI practices. For example, innovators were cynical about including external voices in innovation pathways due to inflexible funding programs and were concerned about potential delays to innovation given the highly competitive environments for financing and patents. In order to help address these tensions, we call for the co-design of RI practices between biotechnology innovators and other stakeholders. The opening-up of biotechnology innovation to RI practices of anticipation, inclusion, responsiveness and reflexivity will likely be important for future, public legitimacy of emerging genetic engineering applications such as gene editing and gene drives.

Keywords: Responsible innovation; Biotechnology; Governance; GMOs

1. Introduction

Co-production emphasizes the way in which the technical and social are intertwined and mutually reinforcing; that is, science and innovation do not exist in an autonomous sphere shielded from the social context in which they occur (Jasanoff, 2005). Social construction theories have spurred interest in the ways in which societal concerns, values, and diverse points of view can be incorporated into innovation pathways. Responsible innovation (RI) has emerged as a framework to meet this challenge (Stilgoe et al. 2013; Owen et al. 2013). RI brings science and technological innovation into line with the democratic principles of transparency, accountability, and meaningful public input. While RI has gained traction in the European Union (EU) and UK in national policies (e.g. Macnaghten et al. 2016), the U.S. has yet to embrace it in research and innovation systems.

An area that could benefit from an integration of RI is biotechnology. In particular, agricultural biotechnology, including the development of GMOs in agricultural and environmental systems, has been fraught with controversy. While most RI work has been done with newly emerging technologies like geoengineering (Stilgoe 2015), agricultural biotechnology is a more mature area. It provides an interesting case in which to see the potential of RI to shape a technology that already might be locked into certain paths in society (Collingridge 1980; Macnaghten 2016). The area of agricultural biotechnology, and more broadly, biotechnology applied to agriculture and the environment, seems recalcitrant to the integration of principles and processes associated with RI. For example, Marris (2015) found, through her embeddedness in UK

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biotech communities, that synthetic biologists are hesitant to open up innovation processes to public engagement due to potential public backlash, and they frame "responsibility" as a way to shut down conflict and garner public acceptability. With decades of experience embedded in US agricultural and environmental biotechnology communities, our observations are similar.[1]

At the same time, even the most stalwart supporters and developers of biotechnology recognize a need to change their approach to governance, recalling the mistakes made from the 1st generation of genetically modified organisms (GMOs) in agriculture. They are now seeking to avoid these mistakes with emerging GM methods such as gene editing and gene drives (Jordan et al. 2017; Kaebnick et al. 2016; Kuzma et al. 2016; Kuzma et al. 2018). In this article, we explore whether and how RI might be accepted into U.S. biotechnology innovation. We investigate the attitudes of diverse stakeholders working in areas related to agricultural and environmental biotechnology to see whether they agree with the general principles of RI as articulated by Stilgoe et al. (2013) and ways to implement these principles.

Others have studied RI for biotechnology using global and developing-world case studies and by taking an observational and anthropological approach (reviewed in Macnaghten 2016). They have also written on the practical projects in the UK to integrate RI into synthetic biology research and innovation (Macnaghten et al. 2016). Here we focus on the United States, in which biotechnology (especially GM crops) has had a high level of placement in society over several decades and may be locked in to pathways of innovation that are recalcitrant to change. We also differentiate our work by using social science methods of group interviews (focus groups) and survey methodologies to hear from biotechnology innovators[2] and other stakeholders from government, trade organizations, and consumer or environmental advocacy groups.

We address the following questions: what do different stakeholders in U.S. biotechnology think about existing academic and scholarly conceptions of RI?; where do they find the elements of RI problematic for or complementary to their experiences with U.S. biotechnology innovation systems?; and finally, what are the key societal, institutional, or attitudinal barriers to implementing policies and programs relating to RI?

Ultimately, this paper seeks to examine attitudes towards RI among U.S. biotechnology stakeholders in order to identify opportunities and challenges to implementing new governance policies and programs that could help incorporate public desires and concerns into research and innovation in biotechnology. To our knowledge, we report on the first project to apply mixed-methods (surveys and focus group interviews) to compare U.S. biotechnology stakeholder attitudes towards RI. Before moving to our research approach and results, we summarize the RI framework and related studies upon which we draw, briefly introduce the U.S. biotechnology context, and situate our work within the policy process theory of the Advocacy Coalition Framework (ACF).

2. Background and framing of the analysis

2.1. Responsible innovation

RI has gained growing traction among those involved in fields of science policy, science technology and society, and the social studies of science. In the U.S., RI emerges from previous scholarship including anticipatory governance (Guston 2014) and midstream modulation (Fisher et al. 2006). Perhaps the closest that the U.S. has come to incorporating RI into federal policy has been in reference to "responsible development" in the 21st Century Nanotechnology Research and Development Act (Public Law 108–153). In contrast, in the EU, principles of RI or its companion Responsible Research and Innovation (RRI) have been incorporated into several supra-national and national funding programs for over a decade. Recently, the adoption of RI goals, terminology, and ethos have been incorporated into the Europeans Union's Programme for Research and Innovation Horizon 2020 and Norway's BIOTEK2021 program (von Schomberg 2013).

One of the earliest definitions of RI describes it as

> an interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society) (von Schomberg, 2011).

This moves the obligations of scientists and innovators beyond the typical research integrity (e.g. animal care ethics, anti-plagiarism, anti-falsification) to ensuring that science is "for, with, and in" society (Owen et al. 2013). Four key tenets of RI have been developed in the most widely cited paper in this area: anticipation, reflexivity, inclusion and responsiveness (Stilgoe et al. 2013). In this paper, we use these four elements to structure our study of stakeholder attitudes and describe each below:

- ***Anticipation*** has been adapted from concepts such as anticipatory governance (Guston & Karinen, 2010; Guston, 2014) and midstream modulation (Fisher et al. 2006; Schuurbiers, 2011), but adds a forward-looking dimension where potential consequences are explored and analyzed before technologies are fully developed.
- ***Reflexivity*** moves governance of science and technology away from solely a risk-based approach to one that encompasses reflection on the underlying goals, motivations, limits of knowledge, assumptions, and alternative framings of problems. It goes beyond professional self-critique of scientists and extends to research funders, regulators, and the other institutions involved in technology development and governance (Wynne 2006).
- ***Inclusion*** involves citizens and publics, in addition to stakeholders, in governance of research and innovation (von Schomberg, 2013; Stilgoe et al. 2013). It opens up the processes of reflexivity and anticipation

to voices beyond those of subject-matter experts, moving towards bottom-up policy making. It is built on the notion that science and research are public goods (Bardone & Lind, 2016), and therefore discourse about them should be democratized under a Habermassian ideal of political legitimacy (Held, 1980).

- ***Responsiveness*** in turn takes the "what if" questions from anticipation, the discursive value of inclusive engagement, and the collective process of reflexivity to influence the path of innovation (Bardone & Lind, 2016; Owen et al., 2013). It requires a capacity to change shape or direction of innovation in response to stakeholder and public values, as well as new or changing information or circumstances.

The RI framework is based upon the normative foundation that the goals of science, research, and innovation should be guided by social desirability and legitimized through open discourse. RI can also be characterized as a shift from focusing on products and risk-based outcomes, to the processes of research and innovation (Jasanoff, 2005). Groves (2011) argues in the context of medical technologies that RI involves a care for the future that goes beyond "better rules". Instead, RI requires changes to practices, institutions, and the deep participation of publics in shaping innovation.

It is beyond the scope of the paper to reargue why RI is normatively and substantively justified. For this purpose, we point the reader to a body of previous scholarly work (e.g. Wynne 2006; Jasasnoff 2007; Groves 2011; von Schomberg 2011; Owen et al. 2013; Stilgoe et al. 2013). Rather, we set out to understand stakeholder attitudes towards the predominant scholarly vision of RI as described in Stilgoe et al. (2013) and to identify barriers that exist for implementing RI within the U.S. biotechnology community. We also situate the study of these attitudes within the Advocacy Coalition Framework (ACF) (Section 2.3 below), which is a theoretical framework within the policy process literature that examines how individual and group beliefs relate to the formation of coalitions in policy arenas (Jenkins-Smith et al. 2014).

Despite a large body of scholarly work on RI, few projects have taken a systematic approach to finding out what stakeholders operating within innovation systems think about RI, and even fewer have considered stakeholder attitudes within U.S. biotechnology innovation systems. Our is the first to use both qualitative and quantitative approaches to assess attitudes of stakeholders from different sectors involved in U.S. biotechnology innovation. Two previous studies were found that focused on U.S. *academic* researchers at single institutions. One study interviewed U.S. innovators coming from a biotechnology institution within a university (Doezema & Guston 2018). However, in this study, RRI was framed a bit differently than in Stilgoe et al. (2013). Core RI elements fell into categories of ethics, science education, open science, societal engagement, gender equality, and diversity. In another study, Glerup et al. (2017) interviewed 11 U.S. academic scientists working in synthetic biology and nanotechnology and also embedded themselves in a laboratory using a Socio-Technical Integration Research (STIR) protocol (Fisher & Schuurbiers 2013).

Several other projects have explored innovator attitudes towards RI outside of the U.S., such as in the EU, Canada, and UK. The EU's SMART-MAP project convened researchers in academe and industry, social scientists, and civil society organizations to develop tools for incorporating RI into innovation pathways (EU SMART-MAP 2017). Marris (2015) reflected on her experiences working within the UK synthetic biology community to better understand natural scientists' and engineer's conceptions of RI. Hartley et al. (2017) investigate a case study of academic researchers working in multiple STEM fields at one UK university through face-to-face interviews about RI. Carrier and Gartzlaff (2019) interviewed researchers and research executives across the EU in a variety of technological fields across social and natural sciences, humanities, and engineering to study their understandings of RI. One study in Canada interviewed those who design, develop and commercialize health innovations about practices of RI (Rivard & Lehoux 2020). We reflect on these studies as they relate to our results and conclusions in Sections 4 and 5.

In light of this previous work, our project is unique in the following ways: 1) it draws upon a large sample to compare meanings of RI across several stakeholder groups (over 100 participants from industry, trade organizations, consumer or environmental advocacy groups, academe, and government); 2) it focuses on the United States and on non-medical sectors of biotechnology; and 3) it uses a mixed-method approach with both quantitative surveys and qualitative focus-group data. Our study contributes to the literature in other ways as well. First, we develop and implement a quantitative survey instrument that uses the definitions of RI from a highly cited RI paper (Stilgoe et al. 2013) and that is inspired by ACF theory (see Section 2.3). We also focus on a more specific and controversial field of biotechnology, the agricultural and environmental release of GMOs. Finally, through focus groups, we identify barriers to RI across multiple types of institutions (NGOs, government, industry, academe, and trade organizations), which all influence biotechnology innovation.

2.2. Biotechnology innovation and regulation

Biotechnology has, and continues to be, the subject of much discussion pertaining to questions concerning the integration of the social and the technical. Genetic engineering (GE) technologies are rapidly changing food, medical, public health, and industrial systems (Chakradhar, 2015; Bailey, 2015; Kuzma, 2016). Products of genetic engineering are being released into the environment and agricultural systems at an increasing rate, and despite the public controversies, GE products have been a market success.

GE product and GMO releases in the United States are regulated under the rubric of the 1986 Coordinated Framework for the Regulation of Biotechnology (CFRB) (Fed. Registry 51, 23302; 1986). The CFRB evolved out of a neoliberal political context in the mid-1980s that was predominantly occupied with falling behind in global

competitiveness. Economic growth through science and technology, including through newly emerging biotechnologies, was seen as a panacea for this concern. During this time, the Reagan administration brought with it the philosophy of 'new federalism' which focused on dismantling the bureaucracy, devolving authority to the states, and deregulating in areas of public health, occupational safety and the environment (Steinzor 1996). At the same time, academic and industry relationships were forged to increase the opportunities and incentives for the transfer of technology outside of the lab to the marketplace. Under the Bayh-Dole Act of 1986, universities, scientists, and small businesses receiving federal funds were allowed to retain the ownership of patent rights that came about from government funded projects, a shift towards a free-market approach that would give shape to US science policy for decades to come (Markel 2013).

The solidification of university-industry partnerships has led to what some scholars have termed "academic capitalism", which is the reprioritization of universities towards pursuing knowledge with the potential of revenue generation (Rhoades & Slaughter 2004). Similarly, the Stevenson-Wydler Technology Innovation Act of 1980 allowed federal laboratories to actively engage in technology transfer of their work (Slaughter and Rhoades 2004). The modern academe-government-Industry relationship, with strengthened university-Industry partnerships, was thus born. Government policies emerged that were specifically geared towards incentivizing universities to engage in commercialization with industry (Meyer 2003).

The close-knit relationship between academe, industry, and government prevail today in science and technology development which is still seen as the primary force for economic growth. Responsible Innovation may disrupt these relationships however, with its call for opening the university-government-industry triangle to public input and responsiveness. Thus, it was important for us to explore the attitudes of these stakeholder groups towards RI to identify potential barriers. We expected university, industry, and government groups to hold similar attitudes towards principles and practices of RI. We also thought the views of trade organizations would align with this triad, as they often represent the viewpoints of biotechnology developers (e.g. bioindustry associations); scientific societies; or biotech user communities (e.g. farming associations whose members grow GMO crops). In contrast, we suspected that the attitudes of consumer and environmental advocacy groups towards RI would differ. These groups often strive to be included in the innovation system and have an adversarial relationship with biotech developers. In fact, legal cases and media attention sparked by the activity of advocacy groups have prompted change in the CFRB over time at key junctures (e.g. see Kuzma 2020). These hypotheses and ones from the ACF, as described below, informed the structure of our research study, the survey questions, and the coding of the focus-group results.

2.3. Advocacy coalition framework

Given the complex, interactive, and temporal nature of the policy process, various theories have been developed to make sense of policymaking. The Advocacy Coalition Framework (ACF) considers the policy process as occurring within policy subsystems, like biotechnology innovation, which are bound by topic or scope and contain a variety of actors seeking to exert influence on policy outcomes (Jenkins-Smith et al. 2014). The framework suggests that actors form advocacy coalitions based on shared normative beliefs and strategies for achieving desired outcomes (Jenkins-Smith et al. 2014). Within the ACF, actors' belief systems are described by three levels that move from the deep cultural beliefs to more specific views about policies associated with the policy subsystem and ways to implement those policies. "Deep core beliefs" are the most fundamental to a person's cultural identity and are unlikely to be changed. "Policy core beliefs" are fundamental views about principles under which the policy subsystem should operate, and they are often shared within stakeholder groups or coalitions that work closely together. The third level is composed of "secondary beliefs" that reflect how policies should be implemented to achieve desired outcomes. These are usually the most malleable beliefs, and frequently change in response to new information (Henry, Lubell, & McCoy 2011).

In this paper, we test "policy core beliefs" (aka RI principles) and "secondary beliefs" (aka RI implementation), but not the deepest core beliefs in the ACF. We designed survey questions to reflect the four core principles of RI—anticipation, reflexivity, responsiveness, and inclusion as described in Stilgoe et al. (2013)—at the ACF's level of general "policy core beliefs" (**Table 1**). Our policy core belief questions were specifically designed to capture the four RI principles at the level of ACF policy core beliefs according to Jenkins-Smith (2014). We also chose one possible way to implement those four RI principles from the alternatives discussed in Stilgoe et al. (2013) for our survey questions. These questions were designed to represent ACF "secondary beliefs" and RI implementation practices (**Table 1**).

Our goal was to see whether the different biotechnology stakeholder groups agreed on RI principles (policy core beliefs) and/or implementation (secondary beliefs). ACF posits that if coalitions agree on policy principles (policy core beliefs), they are more likely to form closer and stable working relationships to advocate for policies and programs. This is because disagreements over secondary beliefs (RI implementation) among coalitions or stakeholder groups are easier to manage, as these beliefs can change over time, under different circumstances, or upon new information. Thus, an even deeper motivation of our research was to explore the potential for future advocacy coalition formation that transcends or changes current entrenched U.S. coalitions of "pro-biotech" (largely industry and academic developers) versus "anti-biotech" (largely advocacy groups).

We also examined whether attitudes towards RI principles (ACF policy core beliefs) or implementation (ACF secondary beliefs) shifted after exposure to more information about the predominant scholarly vision for RI (Stilgoe et al. 2013). As described in more detail in Section 3, scholarly definitions for the four tenets of RI as derived from Stilgoe et al. (2013) (Table A3 Appendix) were presented to our participants in focus groups after they took a pre-survey

Table 1: Core elements of RI and survey questions. DOI: https://doi.org/10.1525/elementa.446.t1

RI Dimension	Survey Question RI policy principles (ACF policy core belief)	Survey Question RI policy implementation (ACF secondary beliefs)
Inclusion	Maximizing public participation leads to better biotechnology policy.	Innovators should consult with consumer and environmental advocacy groups during R&D in biotech.
Reflexivity	Reflecting on the underlying purposes, motivations, and uncertainties that surround biotechnology products is important.	Social scientists, environmental and health risk analysis and ethicists should be involved from the early stages of biotech innovation.
Anticipation	Considering potential environmental and social implications of biotechnology products is important in the planning stages of research.	There should be a standard of at least 10% of public funding for research in biotechnology that goes to environmental, social, legal, and ethical implications research.
Responsiveness	The innovation process should respond to changes in public attitudes or values.	The innovation process should respond to changes in public attitudes or values even if this means delaying, modifying or terminating the project.

but before they took the post-survey. The same questions for ACF policy core beliefs and ACF secondary beliefs were asked in the pre- and post-tests to detect possible changes in attitudes towards RI principles and implementation upon this new information. We analyzed the portion of the focus group discussions right after these definitions were presented to explore what the initial reactions of the stakeholders were to scholarly visions for RI. These results are discussed in Section 4.2.

3. Methodology

An approach mixing qualitative and quantitative data was employed to assess stakeholder attitudes towards RI, as well as how they reacted to the academic conceptualization of the RI framework, particularly the four elements of RI from Stilgoe et al. (2013). Survey items were used to capture stakeholder attitudes towards the principles and practices of RI, while focus groups allowed for a more in-depth exploration of how representatives from each stakeholder group reacted to the scholarly definition of RI and the barriers they saw to implementing RI. Following the logic of Kelle and Erzberger (2004), this mixed-methods approach was used to reveal a fuller and richer picture of how the different sectors approached the concepts of RI.

The focus group also served as an intervention: 1) agricultural and environmental biotechnology stakeholders were surveyed prior to the focus groups (pre-survey); 2) during the focus groups they were exposed to definitions of the four elements of RI (Stilgoe et al. 2013) and asked to discuss their reactions to them in the context of biotechnology innovation (intervention); and then 3) surveyed with the same questions (post-survey). We used the intervention to test hypotheses regarding how different stakeholders view RI as it is envisioned in the academic and policy literature and to identify challenges and opportunities different biotech stakeholders perceive to implementing RI as defined by RI scholars.

3.1. Study participants

The participants chosen for the study were selected based on the demographic criteria of profession, which in this case means that they were employed in a capacity related to agricultural or environmental biotechnology innovation: academe, industry, government, trade organizations (related to non-medical biotechnology industries), or consumer/environmental groups (also related to non-medical biotechnologies). Academic and industry participants were chosen based on their conduct of "use-inspired" or applied research related to biotechnology products applied to environmental or agricultural applications. The rationale behind choosing to split non-governmental organizations (NGOs) between trade organizations and consumer/environmental groups was that trade organizations can wield a significant amount of pressure on the political system through lobbying on behalf of private interests in American politics. In contrast, consumer and environmental groups yield pressure outside the system; for example through the media or courts, which can significantly impact the dynamics of policy change in biotechnology oversight (Kuzma 2013; Kuzma 2020). Government representatives were from policy-making or analysis areas related to biotechnology in food, agriculture, health and the environment.

Focus group participants were recruited from a sample of stakeholders in the greater Raleigh-Durham-Chapel Hill area (Research Triangle, NC) whose work related to the application of biotechnology in food, agriculture, and the environment. This area hosts a rich diversity of organizations working in the biosciences. Although chosen in part because of its proximity to the research team for convenience, The Research Triangle region appears as the 2nd to 10th most active biosciences region in the U.S. across multiple reports and metrics. In 2015, it ranked only second to the Boston area as a life sciences hotbed according to the JLL Life Sciences Outlook Report (Rose 2015). Although our participants are not a nationally U.S. representative population, they do reflect a representation of one of the nation's most active biotech regions.

For participant recruitment, we first developed a spreadsheet of contacts from the Genetic Engineering and Society (GES) Center database and listserve and from people with whom we have interacted. We then asked key contacts and collaborators to provide more names through a snowball sampling strategy. For stakeholder groups for which our contacts were limited, we searched website databases for organizations in the area whose work relates to biotechnology (particularly its use in agriculture or the environment). We ultimately developed a spreadsheet of over

700 possible participants and recruited 104 participants (Table A1, Appendix).

Participants were first recruited by an introductory all-group email explaining the project and containing a form outlining their rights as participants (IRB protocol was approved by NC State University as "exempt"). Non-responsive invitations were followed up with a second email reminder, and then, if necessary, targeted phone calls were made to fill stakeholder groups for which participants were lacking.

The demographic composition of the groups in Table A1 (appendix) shows a largely white, middle-aged population of biotechnology innovators and policy makers in academe, government, industry, and trade organizations. This is generally what we observe in our interactions with stakeholders in agricultural biotechnologies as well. The exception was that our consumer-environmental organization participant group tended to include more female participants and had the youngest mean age of about 43. This reflects our observations from our engagement activities with these stakeholders and supports the literature that females tend to place more importance on the environmental and health risks of emerging technologies than males (Finucane et al. 2000). Overall, the demographics reflected our observations of the field as experienced in the Research Triangle, although we do not make the claim that they are representative of U.S. biotechnology sectors.

3.2. Focus group research

The use of homogenous focus group is part of a methodological foundation originating in the tradition of group discussion (Morgan 1997), where discussion groups are taken as examples of the broader communities although they may not be statistically representative. Groups are set up to have commonalities in professional aspects related to the topics under discussion. We hosted three focus groups per sector (with the exception of 2 groups for consumer-environmental NGOs), and on a sector basis, the discussions yielded similar themes across these replicates. Therefore, although our focus groups are not meant to contain a demographically representative sample of U.S. biotechnology sectors, the themes from the discussions seem representative of the sectors.

Homogenous focus groups (as opposed to heterogeneous groups typically utilized in market research) treat the discourse of the focus groups, and consequently the textual data derived from such discourse, as reflective of the group (Bohnsack, 2004). However, discussions emerge in the group that may not emerge from individual interviews, as members of the group build upon and react to others' arguments or points. Focus groups encourage participation by people hesitant to be interviewed on their own or lack confidence that they have anything to contribute (Kitzinger 1995). Homogenous focus groups also capitalize on members' shared experiences (Kitzinger 1995). Employment Sector was selected as the characteristic for dividing participants based upon the idea that policy values and stances on biotechnology are likely to vary by sector since at a broad level sectors tend to play different roles in the innovation process and advocate distinct positions that are associated with biotechnology products. However, they are a construction of a conversation that would not necessarily happen naturally as members are encouraged to react to each others' viewpoints, and thus group effects of dominant personalities or hierarchies need to be considered during the moderation (Kitzinger 1995).

Moderators of our focus groups were graduate students in the biological and social sciences who were trained through a rigorous four-day workshop on RI and focus group methodologies, including ways to minimizing over-bearing or distractive participants and foster positive discussion (Herkert et al. 2017). Limson (2018) also used South African bioscience graduate students to engage with publics and found that they gained a greater sense of motivation to do research that benefits the public which resonated with RRI learning outcomes. Our project engaged graduate students to interact with stakeholders about RI through focus groups and found similar results with regard to RI outcomes, which are reported elsewhere (Herkert et al. 2017).

The focus groups were structured in a way to allow for replicability in terms of the process and structure (Bohnsack 2004). All the focus groups were conducted under the same protocol, which consisted of a discussion moderated by a trained moderator who used the same set of structured questions and followed in the same order. However, moderators were engaged in topical steering rather than being rigid in moving from topic to topic. Topical steering avoids what Merton et al. (1987) refer to as the fallacy of fixed questions, which can cut off fruitful discussion. Moderators were thus given the ability to channel the discussion in the direction needed to obtain relevant data without forcing the group to respond in specific ways. As Morgan (1997) notes, avoiding rigid discussion also keeps the moderator from trying to exert too much influence to produce ideal data.

The questions that moderators used in the focus groups are listed fully in the appendix (Table A2, Appendix). Discussion questions proceeded from general questions about responsibility to questions surrounding the formal RI framework as proposed by scholars (Table A3, Appendix). Two note takers were present to record visual cues and observe larger themes from the conversations. In this paper, we report only on the discussions following question 7, which presented the academic definitions of the four elements of RI—anticipation, responsiveness, inclusion, and reflexivity as described by STilgoe et al. (2013)—and asked for participants' responses to this scholarly definition (Table A2 and A3 in Appendix).

All 14 focus groups (2 for consumer-environmental NGOs, 3 each for the 4 other stakeholder categories,) followed the same set of procedures and were 90 to 105 minutes in length. Focus groups contained between 4 to 12 participants and were conducted in May 2016 and 2017. We detected no significant differences in content depending on group size within a sector, although we note that the consumer-environmental NGO focus groups were smaller in size. Recruitment for consumer-environmental NGO participants was more difficult in the Research

Triangle area as few groups in this region make biotechnology policy a priority. To increase participation in this area, we included sustainable agriculture groups, organic agricultural groups, and general environmental policy groups to help recruit participants.

We focus in this paper on what stakeholders thought about scholarly definitions of RI and what barriers and opportunities they saw for implementing RI practices and policies to achieve the four elements of RI (Stilgoe et al. 2013; Table A2 & A3). Thus, we report in this paper on the qualitative discussions following the question:

> *Here are some key elements of RI from the perspective of social scientists who study emerging technologies: We are not suggesting that these are right or wrong, or recommending them. But we'd like to know what you think about them. Take some time to read examples of these elements: What do you think of these definitions and elements of RI?*

Time spent on this question averaged between 10 to 20 minutes for each focus group. Other analyses and papers are in preparation and will report on stakeholder's bottom-up meanings of RI from the other focus group questions (see Table A2, Appendix).

Iterative thematic coding using NVivo software was used for qualitative analysis of the transcripts. Themes and coding structure were designed by two of the three paper authors in a consensus and iterative coding process. The coding was conducted by one of the coauthors, and a sample of the coding for each theme was evaluated by the second author until agreement was achieved. We based initial themes on the four elements of RI as described in Stilgoe et al. (2013), read the transcripts and coded for them, and then looked for additional themes and subthemes to clarify the participants' attitudes and identify barriers and challenges to implementing RI.

3.3. Quantitative survey methods and analysis

Participants in the study were subjected to a pre-focus group survey and a post-focus group survey. We administered the same instrument before and after the focus group which included formal exposure to the academic definitions of RI. At the time of study design (early 2016), we did not find any developed survey instruments for assessing agreement with RI in the literature. Thus, we developed four survey questions according to the description of RI principles and practices in Stilgoe et al. (2013) (**Table 1**). We justify a focus on the Stilgoe et al. (2013) in our survey and focus groups paper as it is the most highly cited paper when one searches for "responsible innovation" in Google Scholar (over 1236 citations with the next paper at 379 as of April 24 2020). We tested the survey instrument prior to using it on the study participants using a test group of biotechnology stakeholders who serve on our Center's advisory board committee. We revised the questions based on their feedback on the survey.

The final questions in **Table 1** were used for the participants to choose their level of disagreement or agreement with principles or practices (implementation) of RI. Specifically, we drew from Stilgoe et al.'s (2013) textual descriptions of the four elements—anticipation, reflexivity, inclusion, and responsiveness–for RI principle statements (aka policy core beliefs according to ACF) and from their "Indicative techniques and approaches" (Stilgoe et al. 2013, p. 1573) for the questions about policy implementation (aka ACF secondary beliefs). In developing our questions, we made particular choices for RI implementation based on our understanding of the literature and experience with the field of RI.

For example, in the case of anticipation, ethical, legal and societal implications (ELSI) research done upstream of technology development is a cornerstone of this RI principle (Stilgoe et al. 2013), as well as its precursor, anticipatory governance (Guston & Karinen, 2010; Guston, 2014). Anticipation is a "systematic thinking of the many different potential outcomes" from an emerging technology (Felt 2018), which directly ties anticipation to the study of ethical, legal, and societal implications. For ELSI study, one must have resources early on in technology development to do anticipation of downstream consequences. Thus, funding ELSI work is an important component of anticipation. RI scholars and some policy makers have called for greater funding of upstream ELSI research as a component of anticipatory governance (Guston 2014) and now RI (Felt 2018). Funding of ELSI shows *commitment to* implement (through investment) the RI principle of anticipation. Ten percent ELSI funding in a budget for a national technology program seemed a realistic, but ambitious, goal for the U.S., as it increases the amount currently spent on ELSI by about 2 to 10 times over past U.S. programs like the Human Genome Project and National Nanotechnology Initiative (Bennett & Sarewitz 2006).

However, we cannot claim that the questions in **Table 1** are the only choices that could have been made for implementing anticipation and other RI principles. Thus, our results are constrained by the RI principles in Stilgoe et al. (2013) and by our desire to use a reasonable set of questions among the many alternatives for RI that scholars propose. We discuss these and other limitations of our approach in the final section of the paper (Section 5.1).

Participant responses to these questions were measured using a 7-point Likert scale that ranged from strongly disagree to strongly agree. Questions were designed as somewhat general open to interpretation so that priming prior to the focus groups would be minimal. In this case, the RI definitions presented in the focus groups would serve to clarify the meaning of the four terms.

Participants' written survey responses were kept confidential and separated from the participant's name (by assigning them numbers) according to our approved IRB protocol. Pre-surveys were sent 1 week prior to the event and filled out online prior to the focus group. Post surveys were completed immediately in-person after the focus group. Within the focus groups, participants were referred to by a number rather than name to increase confidentiality of oral comments, although we could not avoid some group members knowing each other by name in a professional capacity. Participants were offered a $50 Amazon gift card as an incentive following their completion of

the final, post survey (some stakeholders declined or requested a reduced amount based on their organization's policies).

3.4. One-way analysis of variance (ANOVA): Stakeholder Differences Pre and Post-Test

We expected, due to the features of the biotechnology innovation system discussed in Section 2.2, that industry, trade organizations, government, and academic stakeholders would align in their attitudes towards RI prior to focus groups given the tight relationships and innovation goals in U.S. political systems. Our initial hypothesis was that there would be no significant differences among these groups given the triple helix (with trade organizations representing industry as well). Given the contentiousness of the subject matter and history of the GMO debates (Kuzma et al. 2009; Kuzma 2013), we expected significant differences in pre-test scores between consumer-environmental groups and industry (and likely government, trade orgs, and academe as parts of the triple helix). We used descriptive statistics to observe any differences among groups separately in the pre-test or post-test, and then tested for statistically significant differences by measuring analysis of variance (ANOVA) between pairwise groups. A one-way between-subjects design is commonly used for non-experimental survey research where groups are differentiated by demographic data (in this case sector of employment) and are treated as independent variables (Meyers et al. 2013). Statistical significance was tested for by comparing the F test statistic. A Levene's test for homogeneity of variance was also conducted as ANOVA requires the variance between groups to be homogenous, although this may be relaxed in certain cases. The Levene's test uses an F-test to test the null hypothesis that the variance is equal across groups.

As a one-way analysis test only computes a single p-value indicating whether a difference in mean exists between groups, it does not indicate which ones differ, so we added the Tukey's honest significance difference (HSD) test to perform a single-step multiple pairwise comparison to compare all possible pairs of means. The Tukey HSD test provides a more conservative adjusted p-value to account for family-wise error and is best for groups with different sample sizes (such as our stakeholder groups, Table A1).

4. Results

4.1. Survey results

Our findings suggest (**Figures 1** and **2**, **Tables 2–4)** that: 1) all stakeholder groups showed neutral or slightly positive attitudes towards RI principles (policy core beliefs) prior to the focus groups; 2) scholarly definitions of RI presented at the focus groups in between the surveys may have had a polarizing effect on stakeholder attitudes towards RI, particularly between industry and consumer-environmental groups; 3) with the exception of inclusion, stakeholder groups involved in innovation (industry, trade, and academe) disagreed more with the implementation of RI (secondary beliefs) than general principles of RI (policy core beliefs); 4) the greatest magnitude of disagreement occurred between industry and consumer-environmental advocacy groups with the RI principles of responsiveness and inclusion; 5) the general principle of anticipation (policy core belief) showed little difference among stakeholder groups, especially prior to the focus groups; however, industry strongly opposed the way anticipation was implemented (secondary belief) with greater ELSI funding as the proposed policy tool; 6) government aligned more with consumer-environmental groups than other stakeholder groups and 7) industry, trade orgs, and academe generally aligned in their distaste for inclusion and responsiveness. We describe the above survey results in more detail below and return to the focus groups and identification of policy barriers in section 4.2.

4.1.1. Descriptive statistics for attitudes towards RI

Although our study population was relatively large for exploring expert and stakeholder attitudes in a particular technology domain (n > 100), it was regionally limited to the North Carolina Research Triangle region and does not represent biotech stakeholders across the United States. Descriptive statistics are used in studies with smaller numbers of participants or those that are not representative of the entire population to explore patterns in the data. Thus, we chose to evaluate the data descriptively first, before doing significance testing (Sections 4.1.2 & 4.1.3 below). In **Figure 1**, the mean scores of the participants' rankings of RI principles (policy core beliefs) and RI implementation practices (secondary beliefs) are color-coded according to the level of agreement (green) or disagreement (red) or neutral (white). Both the pre-test and post-test results are shown.

In the pre-test, we found neutral to positive (4 to =7) ratings for *RI principles* (*policy core beliefs*) across all stakeholder groups. However, RI principles of inclusion and responsiveness were rated more neutrally; with greater support for reflexivity and anticipation (**Figure 1**; Table A4, Appendix). Consumer organizations were most supportive of responsiveness, while industry, trade organizations, and academe expressed more neutral attitudes. The RI principle of inclusion was most highly supported

	Industry				Trade Org				Academe				Govt				Consumer			
	core		implementation		core		implementation		core		implementation		core		implementation		core		implementation	
	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post	pre	post
Inclus	4.5	4.0	4.7	4.7	4.7	4.9	4.8	5.0	5.0	5.3	5.6	4.9	5.4	5.8	5.5	5.9	5.3	6.1	6.4	6.4
Anticip	6.0	5.5	3.3	3.1	6.3	5.8	4.5	4.2	6.1	5.9	5.0	4.4	6.6	6.0	5.0	5.5	6.6	6.9	6.1	6.3
Respons	4.2	4.1	4.1	3.9	4.8	4.7	4.4	4.5	5.0	4.5	4.2	4.0	4.7	5.2	4.7	5.3	5.0	6.0	5.3	6.1
Reflex	6.1	5.5	4.3	4.3	5.7	5.8	5.4	5.0	6.0	6.0	5.3	5.0	6.1	6.5	5.7	5.8	6.3	6.6	6.3	6.6

Figure 1: Visualization of scores. Scale of Red-White-Green from 3.0 to 7.0 respectfully. Stakeholder groups in ascending order from left to right for agreement with RI. Core = RI principles or ACF policy core believes; Implementation = RI implementations or ACF secondary beliefs. Pre = survey before focus groups; Post = same survey after focus groups.
DOI: https://doi.org/10.1525/elementa.446.f1

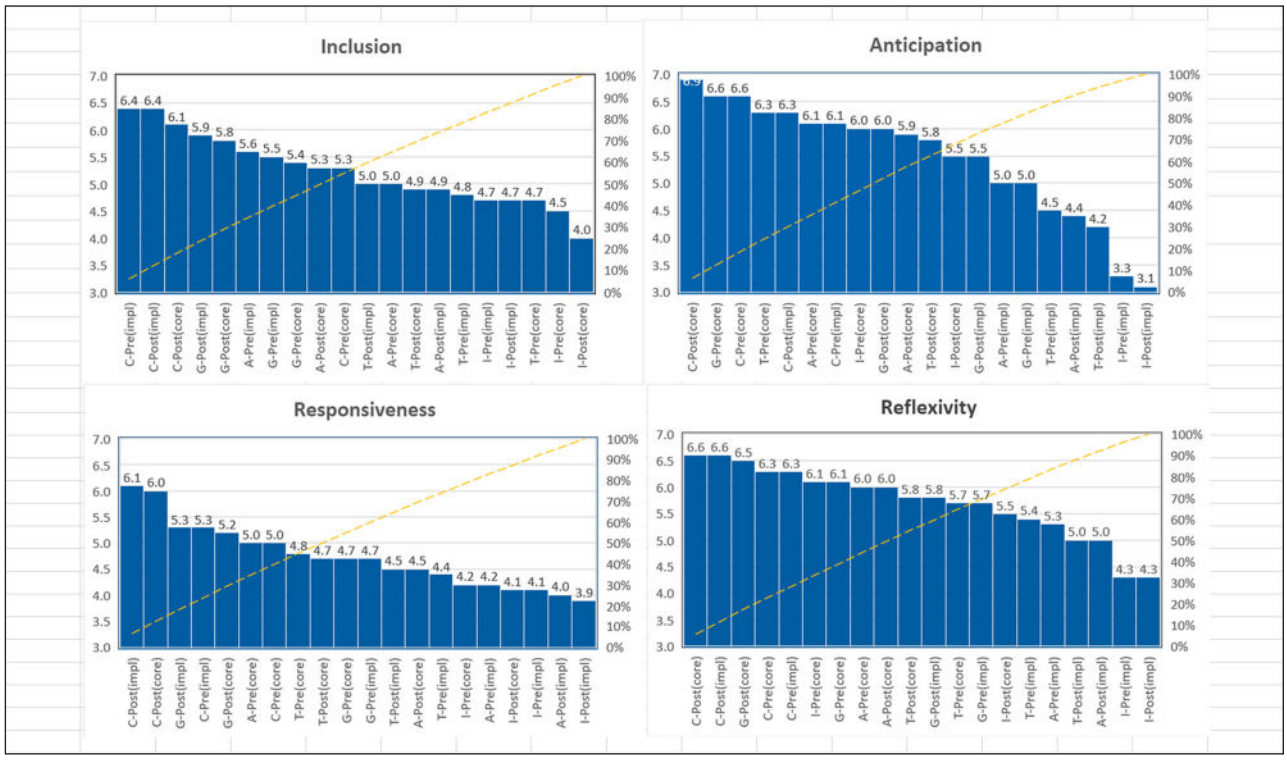


Figure 2: Cumulative graphs of four elements of RI. Groups coded by I = industry, A = academe, T = trade organizations, G = government, C = consumer (and environmental) NGOs. Pre = pre-focus group, Post = post-focus group. Core = core principles of RI, Impl = implementation of RI element. The dashed line shows the cumulative distribution of the scores or percent which are above to the left and below to the right of the line. DOI: https://doi.org/10.1525/elementa.446.f2

by consumer-environmental organizations followed by government, then academe, and finally industry and trade organizations. RI principles of anticipation and reflexivity were favorably rated by all groups (**Figure 1**).

In comparing the post-test with the pre-test for RI *general principles (policy core beliefs)*, we noticed that industry was the only group whose mean score decreased across all four principles; and that consumer-environmental organizations were the only group that saw an increase in mean scores across all four principles (**Figure 1**; Table A4 Appendix). This suggested to us that the focus group, which included a presentation of the scholarly definition of RI (Section 3.2), was an intervention that seemed to polarize the attitudes of industry and consumer-environmental organizations. Interestingly, government scores increased for three of the four principles after the focus groups: all but anticipation.

When the core RI principles were operationalized into RI practices (*secondary beliefs or RI implementation*) (**Table 1**), industry, trade organizations, and academic participants—the developers of biotech products—were less in favor of them (**Figure 1**, Table A5, Appendix) when compared to consumer-environmental and government groups. This suggests to us that it is easier for developers of biotechnology to accept RI in theory, at the level of ACF policy core beliefs, rather than in practice, at the level of ACF secondary beliefs. We note the caveat that our survey questions presented a limited set of choices for implementing RI (discussed more in Section 5.1).

As with the general principles, consumer organizations displayed the most favorable attitudes towards all practices of RI (secondary beliefs) with the highest mean scores (**Figure 1**; Table A5). Conversely, industry ranked each of the practices proposed to implement RI lower than other stakeholder groups. In particular, the implementation of anticipation was scored very low by industry. This is likely due to the specific way we operationalized anticipation, as 10% funding for ELSI research (**Table 1**). The results reveal that biotech innovators in this case do not highly value the integration of social science and humanities scholars in anticipatory governance if it involves funding their work.

For academe, *post-test* scores for implementation of RI decreased; whereas for industry, they stayed largely the same with only slight decreases in anticipation and responsiveness. However, industry scores remained lower than other groups. (**Figure 1**; Table A5). In Section 4.2, we use the focus group discussions that occurred after the scholarly definition of RI was presented to examine why these innovators might be hesitant to endorse the ways we chose to implement RI in the survey questions.

4.1.2. Significance of differences towards RI principles (ACF policy core beliefs)

Through using descriptive statistics, we found differences of means in the *pre-test* scores among stakeholder groups for the general principles of RI of up to 0.8 to 0.9 (**Figure 1**). However, the ANOVA results with a post-hoc Tukey HSD test showed that none of the groups had statistically significantly different mean scores (Table A3, Appendix). This is likely due to the high variation of scores within each group. However, after exposure to the scholarly definition

of RI during the focus groups, in the *post-test*, industry scores for the general principles of RI (ACF core policy beliefs) were statistically different in comparison to other stakeholder groups (**Table 2**).

For the principle of inclusion, industry scores were statistically lower than all groups but trade organizations. The pairwise comparison between academe and industry showed a mean difference of −1.32, between government and industry of −1.77, and consumer-environmental organizations of −2.04 (**Table 2**). Because government, academe (mainly from public universities), and consumer groups represent the public sector, these groups may feel more of an obligation to include external voices in innovation systems, at least in theory if not practice (Sections 4.1.3 & 4.1.4).

Industry differed across the board from consumer groups for all three other principles, ranging from −1.11 for reflexivity, to −1.40 for anticipation and −1.87 for responsiveness. We observed again that responsiveness and inclusion were the most negatively perceived by the key sector of innovation in biotechnology, the industry. For both principles, according to the scholarly definition of RI, industry should share control of innovation by opening up the process to external voices (inclusion) and responding to their concerns (responsiveness). Industry may not want to relinquish their power of the course of innovation (more on this in Section 4.2 and 5).

Consumer-environmental group scores were also significantly higher than academic scores with regard to the RI principle of responsiveness (1.48). Although academics may be inclined to include the public, they may be less receptive to responding to public voices in research and innovation for reasons we discuss in section 4.2, such as inabilities of these researchers to change directions due to inflexible contracts and grant funding.

Overall, it is interesting that the presentation of the scholarly definition of RI in the focus groups brought these differences to light in comparison to the pre-test.

4.1.3. Significance of differences towards implementation of RI (ACF secondary beliefs)

In contrast to the general RI principles, *pretest* scores for RI implementation practices (ACF secondary beliefs) revealed significant differences across some groups (**Table 3**). These were again seen between industry and all groups but trade organizations. Interestingly, implementing anticipatory practices was more problematic to industry in comparison to consumer (–2.88), academe (–1.69), and government (–1.73) groups. We also saw a significant difference between trade and consumer groups in implementing anticipation (–1.61). That is, industry or trade organizations disagreed more than these other groups with increasing ELSI funding as the way to implement anticipation.

Industry and trade organizations also rated the implementation of inclusion significantly lower than consumer-environmental groups (–1.66 and –1.59 respectively). Industry rated reflexivity practices significantly lower than consumer-environmental groups as well (–1.95). Interestingly, there were no significant differences among groups for the RI implementation of responsiveness, in contrast to the significant disagreements over the RI principle of responsiveness discussed above (Section 4.1.2).

In the *post-test*, the above differences in attitudes towards implementing RI remained and additional ones arose (**Table 4**), again indicating the polarizing effect of the focus groups and presentation of the scholarly definition of RI. Industry again differed from consumer-environmental groups across the board on all 4 implementation practices of RI and from government and academe on implementing anticipation. Trade organizations again

Table 2: RI principles after focus groups—significance of differences among stakeholder groups. Tukey multiple comparisons of RI principles – Posttest means, 95% Family-wise confidence Interval: p-value (adjusted mean difference). DOI: https://doi.org/10.1525/elementa.446.t2

Group − Group	Principle			
	Inclusion	**Anticipation**	**Responsiveness**	**Reflexivity**
Consumer – Academe	0.57 (0.71)	0.29 (1.01)	0.014* (1.48)	0.35 (0.60)
Government – Academe	0.88 (0.44)	1.00 (0.15)	0.55 (0.68)	0.67 (0.43)
Industry – Academe	0.008** (–1.32)	0.84 (–0.39)	0.83 (–0.39)	0.32 (–0.51)
Trade – Academe	0.96 (–0.30)	1.00 (–0.10)	0.86 (0.42)	1.00 (0.04)
Government – Consumer	1.00 (–0.27)	0.46 (–0.86)	0.52 (–0.80)	1.00 (–0.18)
Industry – Consumer	0.000*** (–2.04)	0.02* (–1.40)	0.000*** (–1.87)	0.006** (–1.11)
Trade – Consumer	0.29 (–1.01)	0.19 (–1.11)	0.21 (–1.06)	0.36 (–0.64)
Industry – Government	0.002** (–1.77)	0.74 (–0.53)	0.11 (–1.07)	0.03* (–0.93)
Trade – Government	0.59 (–0.74)	0.99 (–0.24)	0.98 (–0.26)	0.66 (–0.47)
Trade – Industry	–0.14 (1.03)	0.96 (0.29)	0.30 (0.81)	0.52 (0.47)
F(Sig.)	6.87 (0.000***)	2.47 (0.05*)	5.12 (0.000***)	4.08 (0.004**)

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

Table 3: RI implementation (ACF secondary beliefs) before focus groups—Significance of differences among stakeholder groups. Tukey multiple comparisons of RI policy implementation–Pretest means, 95% Family-wise confidence interval: p-value (adjusted mean difference). DOI: https://doi.org/10.1525/elementa.446.t3

Group – Group	Policy Implementation			
	Inclusion	Anticipation	Responsiveness	Reflexivity
Consumer – Academe	0.54 (0.80)	0.16 (1.18)	0.24 (1.13)	0.30 (0.97)
Government – Academe	1.00 (–0.03)	1.00 (0.04)	0.88 (0.51)	0.91 (0.41)
Industry – Academe	0.25 (–0.86)	0.000*** (–1.69)	1.00 (–0.09)	0.11 (–0.99)
Trade – Academe	0.48 (–0.80)	0.90 (–0.43)	1.00 (0.19)	1.00 (0.09)
Government – Consumer	0.61 (–0.82)	0.28 (–1.14)	0.84 (–0.62)	0.85 (–0.55)
Industry – Consumer	0.01* (–1.66)	0.000*** (–2.88)	0.15 (–0.93)	0.000*** (–1.95)
Trade – Consumer	0.04* (–1.59)	0.04* (–1.61)	0.51 (–0.93)	0.48 (–0.87)
Industry – Government	0.44 (–0.83)	0.005** (–1.73)	0.77 (–0.60)	0.03* (–1.40)
Trade – Government	0.63 (–0.77)	0.91 (–0.47)	0.98 (–0.31)	0.97 (–0.32)
Trade – Industry	1.00 (0.06)	0.06 (1.26)	0.98 (0.29)	0.13 (1.08)
F(Sig.)	3.52 (0.01*)	9.67 (0.000***)	1.59 (0.19)	5.01 (0.001**)

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

Table 4: RI implementation (ACF secondary beliefs) after focus groups—Significance of differences among stakeholder groups. Tukey multiple comparisons of RI policy implementation–Posttest means, 95% Family-wise confidence interval; p-values (adjusted mean difference). DOI: https://doi.org/10.1525/elementa.446.t4

Group – Group	Policy Implementation			
	Inclusion	Anticipation	Responsiveness	Reflexivity
Consumer – Academe	0.02* (1.48)	0.007** (1.85)	0.000*** (2.14)	0.03* (1.57)
Government – Academe	0.22 (0.99)	0.29 (1.03)	0.66 (1.27)	0.54 (0.00)
Industry – Academe	0.99 (–0.18)	0.03* (–1.31)	1.00 (–0.13)	0.44 (0.00)
Trade – Academe	1.00 (–0.12)	0.98 (–0.26)	0.84 (0.47)	1.00 (0.00)
Government – Consumer	0.89 (–0.49)	0.64 (–0.82)	0.49 (–0.87)	0.69 (0.00)
Industry – Consumer	0.005** (–1.66)	0.000*** (–3.15)	0.000*** (–2.28)	0.000*** (–2.34)
Trade – Consumer	0.07 (–1.35)	0.004** (–2.11)	0.02* (–1.60)	0.06 (–1.57)
Industry – Government	0.08 (–1.17)	0.000*** (–2.33)	0.02* (–1.40)	0.02 (–1.53)
Trade – Government	0.43 (–0.87)	0.16 (–1.29)	0.53 (–0.80)	0.62 (0.00)
Trade – Industry	0.96 (0.30)	0.21 (1.04)	0.65 (0.60)	0.55 (0.00)
F(Sig.)	4.42 (0.003**)	11.36 (0.000***)	7.69 (0.000***)	5.80 (0.000***)

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

significantly differed from consumer-environmental groups in implementing anticipation.

However, in the post-test, we also detected significant differences between consumer-environmental groups and academe across all 4 implementation practices, although they were not as great as the differences between consumer-environmental groups and industry. The most significant difference between consumer-environmental groups and academe was in responsiveness ($p < 0.0000$, 2.4), (this may be explained by the "basic-applied boundary" discussed below in section 4.2.2). Overall, it seems that once academics innovators better understand the concepts behind RI from the scholarly literature (as shown to them during the focus groups), they form more negative attitudes towards RI implementation practices, perhaps because they see them as infeasible or impractical to their mission or goals (see section 4.2 and 5).

4.1.4. Summary of quantitative results

Figures 1 and **2** summarize our results from the survey. Overall, we found more significant differences between groups in the post-test for both the RI principles and RI

implementation practices of RI (**Figure 1**), suggesting that the focus group intervention polarized attitudes between groups inside innovation systems (industry and trade, and sometimes academe) and those outside (consumer groups, and sometimes government). We also found that attitudes among innovators toward the implementation of RI (secondary core beliefs) are generally less favorable than towards the general RI principles (policy core beliefs) in both the pre- and post-test. There were some exceptions, namely inclusion which may have been considered less intensely worded in our survey for RI implementation versus the RI principle (**Table 1**). We discuss the limitation of using one construct for implementation of each RI principle in Section 5.1.

Regardless, across both RI principles and RI implementation, greater knowledge of RI scholarship seems to decrease agreement with it among innovators and their supporters (industry and trade, and sometimes academe). We also found more distaste for responsiveness and inclusion in those responsible for innovating (industry, academe, and trade) than those acting in the realm of public governance (consumer-environmental groups and government) (**Figure 2**). One exception to this was that anticipation in its implementation form had the most negative reaction by industry (**Figure 2**), likely because it involved a commitment of resources to ELSI research (**Table 1**).

Figure 2 breaks down our survey results by the four major elements of RI (Stilgoe et al. 2013) to show which stakeholder groups have the highest ratings for each element. It is another way to visualize the descriptive statistics that aggregates the pre- and post-test scores, as well as RI principles (ACF policy core belief) and RI implementation (ACF secondary belief) scores. Across all four elements of RI, consumer-environmental and government groups hold the top five rankings with one exception (i.e. 19 of 20 spots)—trade organization pre-test scores for implementing anticipation. In contrast, industry, trade, and academic organizations hold all 20 of the bottom ranking spots. From these results, we identify two supra-stakeholder group coalitions in the context of ACF (Section 5.3)—one that consists of innovators and their advocates, and the other that monitor innovators through public governance.

4.2. Focus group results

Below, we analyze reactions towards the RI scholarly definitions (Stilgoe et al. 2013) presented in the focus groups to shed light on the survey results and identify barriers to putting RI to practice. By highlighting these challenges, we hope to contribute to more effective designs for putting the principles of RI into action within biotechnology innovation systems.

4.2.1. Tensions and barriers to implementing RI policies

The thematic analysis and the quantitative attitudinal data were largely supportive of each other in terms of which sectors would be the least or most inclined to implementing the public-empowering concepts of RI, namely inclusiveness and responsiveness. These latent level themes represent the ideas and assumptions that inform the patterns identified in the data (Braun and Clarke, 2006). **Figure 3** summarizes the major themes from the focus group discussions of RI that followed the presentation of the scholarly definition of RI (Stilgoe et al. 2013).

The focus group themes support several of the assumptions and ideas that describe modern institutional arrangements between science, biotechnology, and capitalism as discussed in section 2.2. For example, we found that industry, trade organizations, and academic groups argued for the economic necessity of innovation and worried that it would be threatened by inclusive and responsive RI practices. In contrast, consumer and government groups

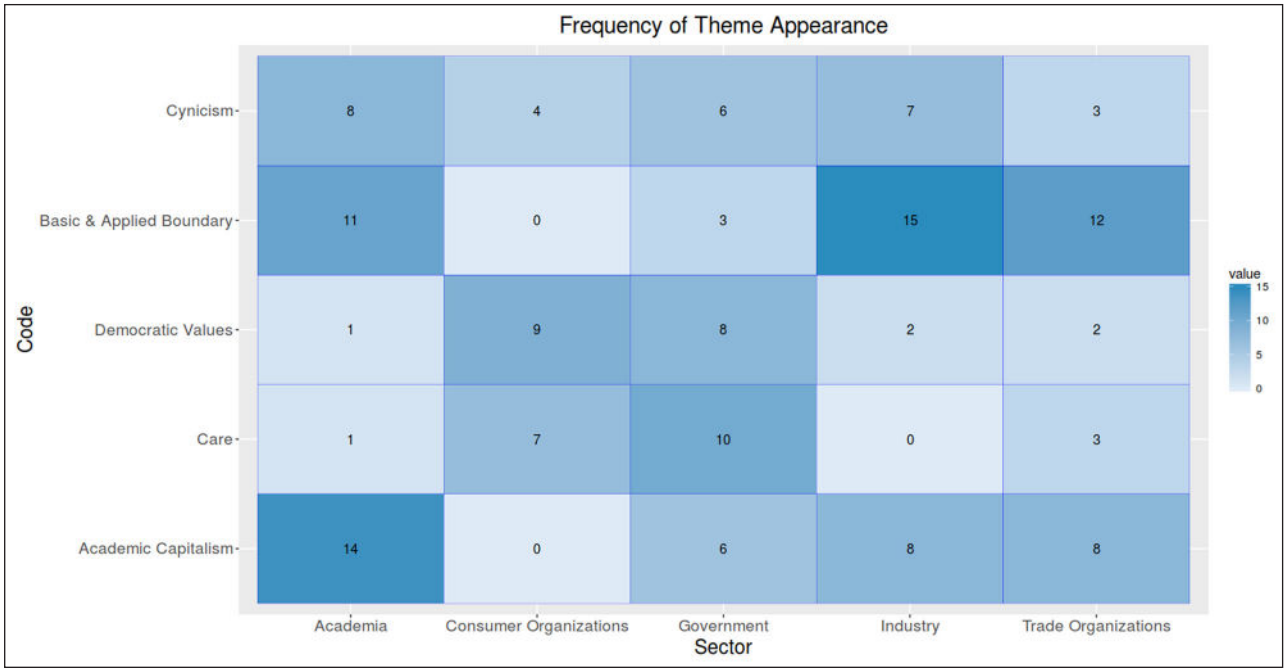


Figure 3: Themes for barriers to RI from focus groups. DOI: https://doi.org/10.1525/elementa.446.f3

tended to mention watchful care for technologies within society and democratic values more often (**Figure 3**). We discuss these and other predominant themes below to explore differences in stakeholder attitudes towards RI and the barriers to implementing RI.

4.2.2. Persistence of the basic-applied boundary

The importance of a delineation between basic research and applied research was evoked repeatedly in the context of RI by all stakeholder groups except for consumer-environmental organizations. Basic scientific research pursues general knowledge, while applied scientific research seeks to produce technologies and techniques to solve social problems. The basic-applied dichotomy has received criticism over the last several years for its promotion of a "value-free" science, and an unrealistic delineation of the steps involved in the research and innovation process (Douglas, 2014; Stokes, 1997). The dichotomy is often used to explain the linear model of innovation, which asserts that innovation comes about as the result of a chronological process that starts with basic academic research. Knowledge derived from basic research is then taken into the applied realm, and through the process of applied research and development, results in innovation.

Asserting the basic/applied dichotomy poses a rather large hurdle for the practicality of RI. Inclusiveness and responsiveness at early stages of innovation are core elements of RI. Under the rationale of the basic/applied dichotomy there cannot exist a participatory procedural process around basic academic research without corrupting the pursuit of general knowledge. Such a process would overstep the autonomy needed by academic scientists to pursue knowledge without others, non-experts, hovering over their shoulders. In the words of a representative from each of these three aligned groups:

> Universities would not be able to research because every fault that a scientist at a University had would be shared with anyone that was critical of it and that research would be driven out of town because those who are absolutely opposed to a particular area of scientific research would have all of the voice. TO[3]

> Also, I do agree that if you do get general public engagement early on where they may not be technically informed that it may actually hamper the innovation process. IND

> I think it is more about applications. I think having this kind of oversight or inclusion in applications of a technology is perhaps better. To restrict in any capacity scientific advancement on an academic scale seems wildly out of place to me. I don't know, I forget who said it, but I just think you just have to be a little bit careful, it is a slippery slope and getting into impeding scientific advancement when you don't even understand or care about what the applications are yet is very dangerous. ACAD

Inserting some procedural participatory mechanism whereby academic researchers are forced to interact and engage with non-expert voices is perceived on one axis to be a threat to autonomy from an ignorant public, and on a second axis a threat to outputs from the research and innovation process.

The traditional linear conception of the research and innovation process with a clean hand-off from basic to applied seemed to underpin the views of academe, industry, government, and trade organizations. In the words of one academic: "It's the commercialization maybe we should be talking about not the research." ACAD. In our focus groups, academic participants tended to see themselves as somehow removed from the conversation around RI. These participants tended to distance themselves from accountability by placing the onus of responsibility on the commercialization of science further downstream, citing lack of control of those steps:

> I don't see a way to incorporate this type of thinking into the political sphere. I mean, I think, we are – we practice a lot of these things or strive for them but as it starts to move out of the university and into the marketplace and then into implementation these things go just by the wayside. It seems. I mean there are so many other factors that enter into policy decisions after that. ACAD

Van Hove and Wickson (2017) also find tensions between RI and basic science in interviews with several nanotoxicology research labs in Norway and Denmark. Responsibility was framed more in terms of laboratory safety, research ethics, and proper waste disposal rather than societal inclusion and responsiveness. Researchers that they interviewed also felt constrained by societal inclusion in innovation in that it would limit scientific freedom and the creativity to do "good science".

4.2.3. Academic capitalism

An extension to the traditional logic of the linear model of innovation, academic capitalism similarly revolves around economic interests and accumulated knowledge capital. Academic capitalism is the submission of universities and subsequently university scientists, to corporate, state, and individual economic interests (Slaughter & Rhoades 2010). Technological innovation has long been held as a necessary condition for economic growth and international competitiveness, and economic growth has proved an enduring rationale for public spending on science. The current dominant policy paradigm has placed universities as key engines of economic growth (Valero and VanReenen 2019).

In the focus groups, academe was the least accepting to the idea of responsiveness and saw its danger in stifling important outcomes from research. In the words of one academic:

> Responsiveness is where I have – I see the potential for that having a troubling outcome. Because as long as attitudes are changing in directions that we

> find favorable responsiveness is fine, but what if they take a left turn and suddenly, we're in a place where things that we find valuable or even critical are completely dismissed as a nonpriority. ACAD

Industry and trade organization participants were also negatively disposed to the idea of responsiveness:

> Responsiveness is really concerning to me simply because a capacity to change shape or direction in response to stakeholder or public values, if you look at the landscape in the U.S. a minority can amplify themselves to a point where they feel and appear to be larger than they are. If we are allowing those voices to drive where innovation goes, I think we are going to stifle ourselves and potentially reverse the progress that we have made. IND

The influence of academic capitalism is also seen in the large number of university-industry relationships and technology transfer offices that construct and shape research and innovation in ways that yield to capital and economic interests from academic research. Biotechnology work is dependent on capital funding often from the private sector and designed for economic output. While individuals may be able to exercise anticipatory and reflective practices in the lab, several academic participants noted that time pressures to produce results in order to attract and retain funding would preclude being inclusive or responsive.

> One of the problems with what you're saying is that the opportunities to get funding was counter to their responsibility we're talking about. If you present a completely tempered view and evenly balanced these may be benefits, but these are the potential dual uses or downside risks. You don't get funded. You don't get funded by the government. You don't get funded by foundations, and you certainly don't get funded by venture capital groups with private money. So, there's a real tension between thoughtfully and properly and fully presenting a full picture and getting the funding to develop the technology. ACAD

In interviews with U.S., UK, and EU academics working in nanotechnology and synthetic biology, Glerup et al. (2017) also found that bottom-up meanings of responsibility were focused on the constant pressure that many research managers and PIs felt themselves to be under to secure further funding for themselves, their groups and their research. They saw a duty to "care" for their research groups by keeping the funding stream going so that scientifically robust work could continue. However, scholarly definitions of RI also include a broader notion of "care" that we turn to below.

4.2.4. Democratic values and care

The concept of care plays an important role in the RI framework as discussed by Stilgoe et al. (2013) who define RI as "taking care of the future through collective stewardship of science and innovation in the present" (p. 1570). Care constitutes a relationship between an individual and something of value whether it be another person, the environment, or a value. To care is to undertake the responsibility for the well-being of another. RI in this light is considered not a set of rules or guidelines, but rather a process through which care is undertaken (Burget et al. 2017). When applied on a macro level, effective care, especially future oriented care, requires attention to a vast number of complex and intertwined social, political, environmental, and economic relationships (Adam and Groves 2011).

The stakeholder groups most concerned with care as a component of RI were government and consumer organizations. Within the focus group conversations, these participants expressed need to consider interdependent relationships, not just economic or health impacts, in the governance of science and technology:

> I have an addendum to the next one where it says the last line proper embedding of scientific and technological advances in our society. That's not the only aspect that needs to be embedded there. You need to also talk about social, personal, emotional, aspects because there are going to changes to social and personal and emotional aspects that need to be taken into account. CO

In addition to the expressed need to consider what are often not readily apparent ramifications, consumer organization and government stakeholders also considered assigning value to future generations a necessary requirement for responsible governance of science and technology:

> I think it functions as a very good guiding principle. Because it's looking down the road. It's important to value subsequent generations and think about the impact, what impact we're having on them. GOV

The discussions of consumer organizations and government around responsibility in science and technology generally showed strong support for the scholarly definitions of RI and closely aligned with the vision of future-oriented care put forth by Stilgoe et al. (2013). Humility and consciousness, attention to and concern for social relationships are a seen as critically important to effective care (Adam and Groves 2011). As one Government participant stated, "I think it is good that we are becoming increasingly conscious, maybe humbler, about technology and innovation." GOV. Coupled with a strong focus on care, consumer and environmental organizations and government groups were also concerned with the need for a valuing diversity and finding substantive value in the lived experiences of others.

The principle of responsiveness, aligning a course of action in response to new information and public perspectives, mirrors the role of policy-making institutions in a democratic political system (Pellizzoni 2004; Stilgoe et al. 2013). Among the government participants, however, there was a greater diversity of viewpoints towards responsivity. An example of one supportive positions is:

> Building on this I thought the responsiveness element was very important. If you are going to be responsible in your innovation you have to understand that different people share different points of view. For example, embryonic stem cells. There are segments of the population where people think an embryo is not a life form, while there are other groups who think it is. There has to be an accommodation to appreciate that different people have different fundamental views of the world. If we are going to live together [we must] recognize that. GOV

Other government participants expressed more apprehension towards the notion of responsiveness. To one participant the concept of responsiveness is already built into technology through market mechanisms:

> This to me is built into innovation. If there's a change of state code in public values, then there's a change in market demand. And so, whereas it—during the—smart companies will do this during the development. Or they'll develop a product for which there is no demand. GOV

Another participant questioned whether there could be negative consequences from being too responsive:

> There may be some downside to that too from the regulatory aspect which is constantly changing. I mean that's a nightmare for the innovators as well. So yeah there must be some kind of balance between responsiveness and stability of policy, I think. GOV

4.2.5. Cynicism

Despite the differing views towards RI among stakeholder groups, a common sentiment expressed by all five groups was cynicism. Cynicism towards the viability of RI was based on lack of funding and institutional support for it, a public that lacks adequate knowledge to engage in participatory discussion, corporate interests, and an imbalance of political power. Consumer and environmental group participants, while supportive of RI, were uncertain of whether financial interests would prohibit other groups from engaging with the RI framework. As members of these stakeholder groups are generally disengaged from direct decision-making, it is not unexpected that there would be reservations about RI implementation given their difficulties in penetrating meaningful policy pathways (Delborne, Schneider, Bal, Cozzens, & Worthington 2013). As one consumer-environmental group participant stated:

> I concur with things that I'm hearing there because the two things I have written down here is the way to limit the influence of potential profits and money to be made because that's an awful strong propellant for development and if it is not balanced by someone who is equally as powerful that can unduly influence your outcome. And so, I fear that there's a broken process which begs a question how there can be someone with an independent oversight or authority who can balance out. CO

Inadequate funding to engage in RI based activities was a feeling echoed by several academic participants, one of which stated that "So circling back to the point [they] made is that our current funding structure whether it's academics or for startup companies is at odds with this model. And one is going to have to give to the other." ACAD. The lack of institutional support available to academic researchers and innovators is something that those working on RI must prioritize for the successful implementation of RI, and this support likely depends on the ability to engage industry, government and private funders. As a trade organization participant noted:

> Our funding for research and our land grants is at a—it's in a crisis now. Funding—public funding for research has continued to go down over the years, and we have had to rely more and more on partnerships—corporate partnerships and funding research and not that there's anything wrong with those type of partnerships but when you lose public funding for that type of research you often lose the ability to have control of the results of the research. TO

Finally, a dearth of public knowledge about science and technology was cited several times as a hurdle to successful RI implementation by industry, trade organizations, academe, and government participants. They expressed hesitancy to open up traditionally technical- and expertise-driven areas. A meaningful implementation of RI for these individuals is stymied by a scientifically illiterate public. Our participants expressed concerns related to the "deficit model" of science communication (Suldovsky 2016); that is, people generally do not understand the science behind biotechnology, and as a result, they cannot form valid viewpoints to inform decision making:

> So, I have a problem with this one from just a pure—what is the word? There's a lot of ignorance about lots of issues. I'm ignorant about a lot of things. You don't want my opinion on quantum theory and physics. It's meaningless. I think you have to have an engaged and informed people helping with the decisions about innovation. IND.

> So, I just get frustrated in the conversation a little bit about who you bring into the conversation. Is it your peers that can see the research and science and they understand that and vetting that to that group of people is something that I think is incredibly important to be responsible. Vetting it beyond that group where you start getting into society and public feelings and all that brings in another factor that to me doesn't really address the responsible factor as it becomes an opinionated factor based on a series of things that you may or may not be able to control. ACAD

While a more scientifically literate public is certainly not harmful, under the "deficit model" there is seldom an indication of what level of technical knowledge is considered adequate to participate, nor is there much consideration given to the idea that other types of knowledge may be valuable. Rather, technical knowledge is used as a means to discriminate against including those outside of the technical areas. Our industry and academic participants expressed a fear of including publics who lack biotechnology expertise and thus may come to fear biotechnology. Expert fear of public fear of biotechnology has been identified in previous literature as "biotechphobia-phobia" (Marris 2015).

Overall, cynicism towards the viability of RI expressed by all five stakeholder groups revealed that an overhaul of the governance paradigm for biotechnology to include RI is a difficult, if not impossible, task. Below we summarize our findings and conclusions from the focus group conversations and surveys and identify possible ways forward to tackle this problem.

5. Findings and conclusions

5.1. Study limitations

Our work is limited in the number of constructs we used for each RI element in the survey, especially for questions about implementation of RI (**Table 1**). Therefore, we view our research as exploratory and hypothesis-generating rather than hypothesis confirming. Future research would benefit from the development of more refined attitudinal constructs for the dimensions of RI. Our work was also conducted with regional stakeholders in the Raleigh NC area. Government stakeholders with higher level policy-making positions in the U.S. federal government and NGOs with closer connections to federal biotechnology policy will need to be studied to test these results. Furthermore, we focused on specific sectors of non-medical biotechnology, particularly environmental and agricultural applications of GMOs. Future studies could compare this contentious policy arena, which includes GM food debates, to other biotechnology sectors such as in medicine and public health. Our results are also limited to the United States. The U.S. biotech sector may be unique in many respects, as there has been a strong market-based push for agricultural biotechnology with nearly 90% saturation of GM commodity crops on the U.S. market today (Kuzma 2017).

5.2. Summary of findings

Despite these limitations, we present significant new empirical results on how U.S. biotechnology stakeholders perceive the scholarly vision of RI. Our findings suggest that diverse stakeholder groups hold relatively positive *a priori* attitudes towards the general principles of RI, yet upon learning more about RI, their opinions diverge. Consumer-environmental groups and industry groups become more polarized, especially when it comes to practices for implementing RI. Attitudes generally break down according to two coalitions—the innovators and their advocates versus those that monitor innovation on behalf of the public.

The greatest disagreements occur with regard to RI principles of responsiveness and inclusion, elements that open-up innovation systems to public voices and values. The negative reaction of innovators (academe, trade orgs, and industry) to inclusion and responsiveness is concerning given that these groups generally wield the direct power in innovation systems and could take steps to open-up decision-making processes. Yet, greater inclusion and responsiveness is viewed as a roadblock among these groups, especially in hyper-competitive funding and intellectual property environments. Brand and Blok (2019) also identify these problems in their work on RI, noting that inclusion could cost significant time and resources, have little direct benefit to innovators, and cause them to fall behind their competitors.

In contrast, we found that consumer and environmental organizations, groups that hold little direct political and economic power (although they may exert power indirectly through the media and the courts), embrace RI as a way to participate in research and innovation. We also found that government stakeholders were more support of RI. These results should be interpreted with caution however, in that our government participants were located in the Raleigh NC area, and they did not have a prominent role in national regulation of GMOs. We suspect that government participants have a commitment to public service that was a factor in rating RI principles and practices more favorably than industry, academe and trade organizations. However, if more federal government representatives were included in our study, these results could have changed as studies have found a bias towards industry and "technological optimism" in federal regulatory agencies when it comes to GMOs (Meghani & Kuzma 2011; Meghani & Kuzma 2018; Kuzma 2019). Regardless our results on the whole reflect the polarization between biotech developers and public watchdogs that we see in action in the biotechnology policy domain.

Our findings are also consistent with the work of scholars who have studied synthetic biology communities in the EU and UK. They found that innovators fear public misunderstanding and early public backlash to their work if the process of research and development incorporates dialogue with diverse publics (Marris 2015; Hartley et al. 2017). As a result, innovators are more inclined to look at public engagement as a way to obtain public acceptance through unidirectional education of an "uninformed" public. Scholars in the UK reflecting on their experiences as part of STS-natural science teams in synthetic biology find that scientists and engineers consider "public acceptance" and "risk perception" as the primary goals of inclusion (Balmer et al. 2015).

5.3. Interpretation within advocacy coalition theory

The Advocacy Coalition Framework (ACF) predicts that groups who agree at deeper core levels (policy core beliefs) will tend to agree more on policy implementation (secondary policy beliefs) and form more stable partnerships to work together (Jenkins-Smith et al. 2014). We did not see this in our study, as general RI principles (policy core

values according to ACF) were agreed upon across two major coalitions of stakeholder groups more so than specific implementations of RI (secondary values) (**Figure 4a**). Using a modification of ACF, Lawton and Rudd (2013) suggest that there can be agreement on secondary policy values (implementation of RI in this study) in the face of disagreement on core policy values (the principles of RI in this study) but that these are likely to result in more transient policy partnerships (**Figure 4b**). In contrast, longer-term policy partnerships result from coalitions that share policy core beliefs (**Figure 4b**).

In the context of ACF, our results suggest a situation that is perhaps more hopeful than not when it comes to policy partnerships among biotech stakeholder groups for designing RI programs. **Figure 4a** shows the two major coalitions we found—the innovation group (light blue—industry, trade organizations, and academe stakeholders) and the monitors of innovation, the civil society group (consumer groups and government stakeholders). Within each coalition, participants generally shared similar attitudes towards RI and responded to the pre- and post-focus-group surveys in similar ways. **Figure 4a** shows our results that these two coalitions diverged more for the implementation of RI (secondary values on the left of the x-axis) and agreed more on general principles for RI (policy core values on the right of the x axis).

Because our two coalitions share policy core values for the most part—that is prior to focus groups, all stakeholder groups rated RI general principles favorably (above 4.0 on a 7 point scale—according to Lawton & Rudd (2013) (**Figure 4b**), it seems that *if* the right designs for RI implementation are found, partnerships among these biotechnology coalitions could be more stable over time. However, these results are preliminary given the limitations of our study discussed above. We also do not analyze the deepest level of values from the ACF framework ("deep core beliefs") which are not sector-dependent and based on cultural predispositions (Jenkins-Smith et al. 2014). Future work could investigate deep core values among stakeholder groups vis-à-vis the policy core values and secondary beliefs about RI tested in this study.

5.4. Barriers and implementation

Finding the right implementation practices of RI requires an identification of the potential barriers to putting RI into action. This study does not offer an exhaustive list of these but begins to illuminate the challenges of implementing RI in U.S. biotechnology innovation systems:

- *Macro level barriers* occur at the national and international levels and include the rigidity of funding structures, pace of innovation within an intensely competitive environment, and drive for economic competitveness.
- *Meso level barriers* present themselves at the institutional level and include lack of institutional capacity for RI (resources), risk of losing investors due to delays, and the possible public backlash if people know of controversial research projects that are in the making.
- *Micro level barriers* include biases at the individual level that experts and innovators have towards the public as not being able to understand biotechnology and therefore thinking that early inclusion of them will lead to poor decisions. Also, many researchers in academe askew responsibility for RI as basic researchers.

Our findings about these barriers are consistent with previous studies on RI in other sectors and national contexts. Carrier & Gartzlaff (2019) studied bottom-up attitudes about RI in the EU through interviews with scientists, engineers, and humanities scholars. They found that the innovators worried about public ignorance, the loss of the autonomy of science, and the additional expenditures required for engaging with societal actors. They call attention to the need to carefully implement RI so that it does not backfire in the future, as we have done in previous

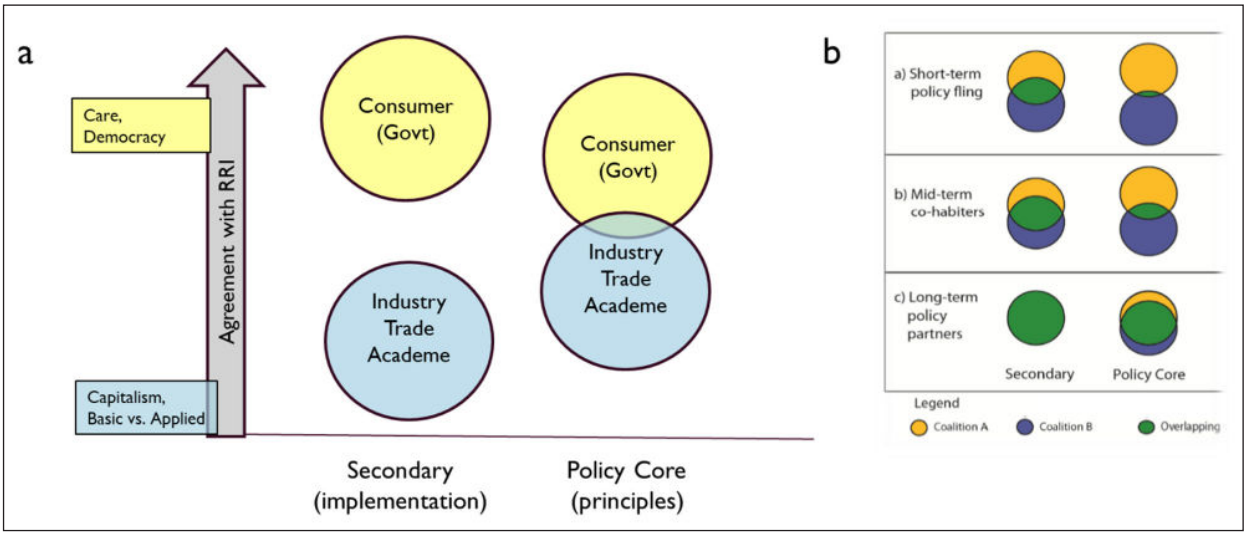


Figure 4: Model for stakeholder biotech coalitions and RI. a) shows model from our results and **b)** adapted from Lawton and Rudd 2013. Circles represent different coalitions. DOI: https://doi.org/10.1525/elementa.446.f4

work (Kuzma & Roberts 2018). Rivard & Lehoux (2020) interviewed diverse health innovators in Canada and found significant concerns about RI related to inclusiveness, especially for slowing down progress in fast-paced innovation systems. They also highlight the need for consideration of the tradeoffs and feasibility issues associated with RI.

While our study centers on U.S. agricultural and environmental biotechnology, Macnaghten (2016) explored attitudes towards RI in the context of GM crops using ethnographic methods and interviews in Brazil, Mexico, and India and through a workshop in the EU and UK. They found that in situations where the crop was not culturally significant to the country, like soybean in Brazil, scientists had "clear and unqualified optimism …on the role of GM crop technologies, with little evidence of a structured and sustained debate with wider society" (Macnaghten 2016, p.284; Carro-Ripalda & Macnaghten 2015). In India, they heard from crop scientists that argued that India "could not afford the risk of falling behind in the development of biotechnology" and that anti-GM groups were "ignorant" (Carro=Ripalda & Macnaghten 2015, p. 25). At all the sites, they found that the barriers to RI were social, cultural and institutional. These results are similar to the barriers identified in our focus groups, especially with respect to "cynicism" of the public's ability to engage in informed conversation and the predominance of "academic capitalism" in U.S. culture and institutions.

Successful implementation of RI requires cooperation and a mutual understanding of responsibility among different stakeholders and institutions, thus there is a need to identify policies and practices through which competing values may be aligned towards responsible governance. The consequences of rejecting RI within innovation systems are large–without buy-in to RI from biotech innovators, especially in academe and industry, there is little chance of outside actors being able to effectively influence decision-making bodies and challenge the current paradigm of science and technology (Macnaghten et al. 2016). Indeed, conflict over inclusion and responsiveness between sectors reflects a broader misalignment between private corporate goals and public values. What is being debated in these practices of RI is control over the framing and saliency of technological and societal issues, and ultimately which solutions are pursued.

Current developers of gene-edited crops and gene-drive organisms in the United States are searching for ways to include public consultation and principles of responsible innovation, as they seek to avoid the mistakes made from the 1st generation of GMOs (Jordan et al. 2017; Kaebnick et al. 2016; Kuzma et al. 2016; Kuzma et al. 2018). The corresponding author has been part of these discussions with industry groups and trade associations trying to develop principles of responsible development for gene editing and thus has first-hand knowledge of the desire for US biotech innovators to improve public transparency and accountability. Yet both in the case of this US community (Kuzma 2016) and in the case of the UK synthetic biology community (Marris 2015), biotech product developers seem to be repeating the same mistakes and still framing responsibility as an endeavor to achieve public acceptance or adoption. Instead, Hartley et al. (2017) argue that conflict must be tolerated, and RRI "must open up possibilities for politicisation on the input side of research governance". We agree that RI, if it is to hold true to its principles, would make space for conflict and public rejection (i.e. politicization) during research and development if public values so warrant.

Yet going forward we also suggest that those looking to implement RI consider the concerns raised by researchers and innovators such as constraints posed by funding sources, regulatory hurdles, institutional capacity, and public backlash. Overlooking such apprehensions runs the risk of alienating researchers and innovators who will then pay lip-service to RI rather than fully engage with it. As a starting point, incentives (such as funding) for anticipation and reflexivity-based practices, the two principles with generally more agreement among stakeholders, could be provided while dialogues are hosted to involve biotech innovators in discussions about overcoming barriers to responsiveness and inclusion.

Based on our work, it is prudent in the long run to obtain "buy-in" from those within the research and innovation process rather than imposing guidelines and practices from the outside. There is a need to ground RI within the specific temporal and structural contexts of real innovation pathways for it to be embraced and succeed. It will be a delicate balance to do this while protecting the core principles of RI. However, with developers of biotechnology recognizing a need to change their approach toward more inclusive and responsive approaches so that emerging GM methods such as gene editing and gene drives are not failures of public confidence (Jordan et al. 2017; Kaebnick et al. 2016; Kuzma et al. 2016; Kuzma et al. 2018), there is an urgent need for more research to understand the barriers for incorporating RI into U.S. biotechnology innovation systems and for pilot programs to put them into practice.

Data Accessibility Statement

Data summaries are reported in the research paper and supplemental files. Anonymized raw data in Excel and NVivo files are held by the PI Kuzma on a secure server under NC State IRB protocol #6157 and are available upon request.

Notes

[1] The corresponding author has been embedded in the US biotech innovation system first as a bench scientist, then government risk assessor, think-tank study director, and policy science researcher for 30 years.

[2] We use the term "innovators" or "developers" to include any participant in our study from academe and industry involved in making biotechnology products or studying biology to enable the making of products. Participants recruited from these two stakeholder groups were engaged in either "use-inspired" research or applied research.

[3] TO = trade organization, IND = industry, CON = consumer/environmental, GOV = government, ACA = academe.

Supplemental file

The supplemental file for this article can be found as follows:

- **Text S1.** Appendices. DOI: https://doi.org/10.1525/elementa.446.s1

Acknowledgements

We'd like to thank colleagues Jason Delborne, David Berube, Erin Banks, David Garson, Jeff Diebold, Nicole Gutzmann and Fred Gould at NC State for helpful input to the project. The authors also appreciate the reviewers for their helpful comments. This study was reviewed by the IRB at North Carolina State University as exempt.

Funding information

The research in this paper was supported by NSF grant 1540244 and the Genetic Engineering and Society Center at NC State University.

Competing interests

The authors have no competing interests to declare.

Author contributions

- Contributed to conception and design: PR, JH, JK
- Contributed to acquisition of data: PR, JH, JK
- Contributed to analysis and interpretation of data: PR, JK
- Drafted and/or revised the article: PR, JH, JK
- Approved the submitted version for publication: PR, JH, JK
- Revised paper during review and approved revisions: JH, JK

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How to cite this article: Roberts, P, Herkert, J and Kuzma, J. 2020. Responsible innovation in biotechnology: Stakeholder attitudes and implications for research policy. *Elem Sci Anth*, 8: 47. DOI: https://doi.org/10.1525/elementa.446

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Knowledge Domain: Sustainability Transitions

Part of an *Elementa* Special Feature: Gene Editing the Food System

Submitted: 09 February 2020 **Accepted:** 17 July 2020 **Published:** 31 August 2020

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ELEMENTA Science of the Anthropocene

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