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Scientists' Views on Scientific Self-Governance for Human Genome Editing Research

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As research on human gene editing has grown, a variety of prominent international organizations are considering how best to govern such research. But what role do scientists engaged in genome editing think they should have in developing research governance? In this study, we present results from a survey of 212 U.S.-based scientists regarding views on human genome editing governance. Most did not believe that scientists should be allowed to self-govern human genome editing research. Open-ended responses revealed four main reasons: conflicts of interest, the inevitability of rare “bad apples,” historical evidence to the contrary, and the limitations of scientific expertise. Analyses of open-ended responses also revealed scientists' views on how human gene editing research should be governed. These views emphasize interdisciplinary professional and public input. The study results illustrate a noteworthy shift in the scientific community's traditional vision of professional autonomy and can inform ongoing efforts to develop research governance approaches.

Keywords: gene editing, governance, oversight, survey

INTRODUCTION

SINCE THE FAMOUS Asilomar Conference addressing the regulation of newly developed recombinant DNA techniques in 1972, the molecular genetics community has taken pride in publicly anticipating the risks of intentional genetic modifications, both in humans and other species.^{1,2} In the United States, this professional initiative helped develop a multilayered system of governance for genetic engineering research, through institutional biosafety committees, the National Institutes of Health (NIH) Recombinant DNA Advisory Committee, and the Food and Drug Administration (FDA). This system collectively provided public accountability and oversight but was largely operated by the scientific community itself. This model helped ensure that the field preserved what sociologists of science have called the “grand bargain” between

science and society: the scientific community was given license to govern itself in large measure, with the expectation that society would benefit from the medical, agricultural, and environmental advances that this science seemed to promise.³⁻⁵

For human gene therapies, this model of governance produced a conventional framework for evaluating new research based on two widely shared views: (1) human genetic engineering research should avoid efforts to make heritable changes by modifying germline cells, and (2) somatic cell modifications should be limited to efforts to treat disease rather than attempts to improve or enhance human traits.⁶ This framework remained steady until the advent of more precise and efficient gene editing techniques using CRISPR-Cas systems and the 2015 proof of principle that they could be used to induce stable DNA

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changes in human embryos.^{7–9} These developments opened a new round of attempts at self-governance by the molecular genetics community, with calls for voluntary moratoria on germline human gene editing and the organization of formal efforts to develop governance by national scientific bodies in multiple countries.^{10,11}

In contrast to the 1970s, this time the scientific community faced the fact that these developments were spread across global networks of laboratories and institutions, complicating the challenge of reaching consensus within the scientific community about even the “softest” forms of guidance for human gene editing research and highlighting a related concern about societal support from countries around the globe.^{2,12–17}

It was in this new global context that, in 2018, He Jiankui announced the birth of two babies whose *CCR5* genes had been targeted for deletion with CRISPR-Cas9 when they were embryos, in an attempt to convey protection against HIV disease.¹⁸ This event surprised the gene editing community, potentially destroying its credibility with the public and derailing the grand bargain that it was seeking to preserve. As a result, efforts to reestablish a viable social contract for this area of research intensified, including an International Commission sponsored by leading national academies of science, an Expert Committee of the World Health Organization, and a report from the Ethics Group of the European Union.^{19–21} In addition to attempting to provide scientific guidance for the responsible development of clinical research, these initiatives and others all call for increased public involvement in the development of human gene editing governance.^{19–23}

While this call for more public involvement may be seen as an attempt to restore public confidence that human gene editing research is adequately monitored, it also represents a retreat from the commitment to relative scientific autonomy that has traditionally characterized this field. If high-level policy initiatives are successful in widening public involvement, an important next question is how scientists who use gene editing in their work will respond. Among possible stakeholders in gene editing governance, scientific opinion leaders have been well represented in recent public discussions and governance initiatives; some would argue that the scientific community has been overrepresented in those fora.²⁴ At the same time, however, the potential users of genome editing, such as patients, clinicians, and the public have been the focus of most empirical research on stakeholder views,^{25–34} leaving scientists’ views of gene editing governance largely understudied.

An interview study of scientists who use genome editing in their research found that while scientists believe the introduction of CRISPR has changed the translational potential of their research, they have limited understanding of the needs of the patient populations whom their

research might affect.³⁵ This interview study, however, did not explore the implications of these findings for the governance of genome editing research.

The purpose of this article is to report qualitative findings from a recent survey of scientists regarding their views on the governance of human gene editing research. Since bench and clinical scientists are the professionals whose work will be governed by the outcomes of the ongoing discussions, their views on the continued applicability of the traditional norms of scientific freedom and accountability in the era of gene editing are especially important to understand. We use the metaphor of the grand bargain as an analytic lens to illuminate the ways in which the gene editing techniques and the new international scientific landscape in which they are being cultivated are shifting traditional understandings of scientific freedom and autonomy at the level of practicing scientists.

MATERIALS AND METHODS

In May through June of 2020, we surveyed 212 U.S. scientists about their views on human gene editing applications and research oversight.³⁶ These scientists were recruited from 69 member institutions of the NIH Clinical and Translational Science Consortium and used gene editing in their own work, which ranged from basic bench science on nonhuman animals and human cells to clinical trials. The survey methods and participant demographics have been described elsewhere.³⁶ The Institutional Review Board at the University of North Carolina at Chapel Hill reviewed this study and determined it to be exempt.

Our survey included questions about oversight for gene editing research.³⁶ In this study, we report on scientists’ views on governance, which come from a closed-ended question, “Do you think scientists can oversee gene editing research themselves?” followed by open-ended questions to explain their answers (Table 1). Respondents who indicated that they thought scientists could oversee gene editing research themselves were asked to explain how they envisioned scientists doing so. Likewise, respondents who said they did not think it possible for scientists to oversee gene editing research themselves were asked to explain why not.

Table 1. Survey questions about scientists’ ability to self-govern

Do You Think Scientists Can Oversee Gene Editing Research Themselves?	n (%)	Open-Ended Follow-Up Question
Yes	45 (23)	How do you envision scientists overseeing gene editing research themselves?
No	150 (77)	Why do you think it is not possible for scientists to oversee gene editing themselves?

We used an inductive, conventional content analysis approach to analyze the responses to the open-ended questions.³⁷ We transferred responses into an Excel spreadsheet and all team members read the responses in their entirety. We then met to discuss initial themes that emerged in the responses and developed a codebook of 12 codes based on these themes. Coding began with two team members coding a subset of responses independently. The coders met twice to discuss how they were applying codes, resolve any discrepancies, and refine the codebook when necessary. The lead author finished coding the excerpts, identifying any problems that were then discussed and resolved with a second coder.

When coding was complete, we compiled every response for each code and team members met to discuss themes that emerged within each code and, when applicable, across codes. We also collapsed themes at this step based on any thematic overlap found among the coded material. After discerning these final themes, we compiled the open-ended responses for each theme. We report in this study on the results of this final thematic analysis, with particular attention to respondents' views on the grand bargain, scientists' potential to oversee gene editing research, and references to other players who should have a say in gene editing research governance.

RESULTS

One hundred ninety-five out of 212 total respondents answered our close-ended question (Table 1). Of these, 45 (23%) answered yes, they thought scientists can oversee gene editing research themselves, and 150 (77%) answered no. Thirty-two (71%) of the 45 who answered yes and 130 (87%) of the 150 who answered no responded to the open-ended question. Below, we divide our findings from analysis of the follow-up open-ended questions into two sections: (1) respondents' reasoning for why scientists cannot oversee gene editing research themselves, and (2) respondents' views on how gene editing research should be governed, for which data come from both those who said yes and those who said no to our initial question.

Perspectives on why scientists cannot oversee gene editing research themselves

Four themes emerged from the open-ended responses that explained why scientists cannot oversee gene editing research themselves: conflicts of interest, "rotten apples," evidence to the contrary, and "not their job."

Conflicts of interest. Most scientists who responded that scientists cannot oversee gene editing research themselves cited conflicts of interest. For example, one noted, "Scientists are too often motivated by hopes of career advancement and reputation enhancement, not to mention monetary compensation. Conflict of interest is a major

problem." Another commented, "Scientists are swayed by potential personal gains from success of their research, which is an inherent conflict of interest regarding self-regulation." A third lamented:

Because they [scientists] believe in their own hypotheses too much before they are tested and still believe in them [even] after the results are negative. Also individual scientists can be bought. I support the governing of gene editing by the organization(s) least likely to be influenced by conflict of interest. Currently, that sadly appears to be almost no organization on earth.

"Rotten apples". Respondents also pointed to the idea that a small number of wayward scientists ruin the opportunity for self-governance for the larger scientific community. For instance, one commented: "There is always going to be that rotten apple in the barrel." Others referred to "bad actor[s]" and "rogue scientists." One respondent expanded on this sentiment, arguing:

Without oversight, a small fraction of scientists will behave irresponsible [sic]. In particular, they will seek financial reward for ethically questionable approaches. The vast majority of scientists would not behave this way, but, as with any collection of humans, society needs protections from those who would put personal gain above protection of the interests of society.

Another remarked, "Most scientists are very aware and concerned about this issue, however we have already seen that it only takes one careless or overzealous scientist to carry out dangerous work. While I know that I am responsible, do I feel confident that every single other individual has the same moral code, no." This comment also touches on a similar theme that emerged: In terms of scientists responsibly overseeing gene editing themselves, evidence exists to the contrary.

Evidence to the contrary. In this study, respondents offered evidence of scientists behaving badly, including reference to He Jiankui's experiments with human embryos. One respondent succinctly wrote, "Two words: He Jiankui." Another offered more explanation:

The case of the Chinese scientist who used CRISPR for genome editing in embryos to protect against HIV is a prime example of why scientists cannot be completely trusted to make these decisions alone. There were plenty of individuals (even American scientists) who knew what He Jiankui was doing and although "concerned" no one blew the whistle when they should have. So even bystander scientists could not be trusted to do the right thing or even push back strongly.

Other respondents referenced changing notions of morality as reasons why scientists cannot oversee gene editing research: "History shows that what one generation of scientists views as acceptable is not necessarily viewed as acceptable by future scientists." Another commented, "We have over 150 years of data showing scientists CANNOT handle the responsibility, going back to the

basis of eugenics.” Similarly, another noted, “I am not aware of any precedent that would suggest [scientific self-governance] is feasible.”

“Not their job”. Some respondents pointed to the nature of science as a reason scientists cannot oversee gene editing research themselves. One simply wrote, “Not their job,” and another commented, “There is more to consider than just the science of gene editing.” Indeed, respondents evoking this theme emphasized that science is about discovery, not the social or ethical aspects of discovery. For example, one said that “many scientists are primarily interested in discovery, and the limits of what can be done. Whether it should be done is not necessarily at the top of their priorities.” Another noted:

Scientists don’t necessarily see the big picture. Gene editing research has implications far beyond the lab or any individuals who may be the immediate beneficiaries of gene editing. There are also important societal implications that need to be carefully considered and scientists are not positioned for this.

Similarly, a respondent wrote that “most of us spend most of our time thinking about the science involved with genome editing and spend less effort on topics that may be related to or impacted by the research.”

Views on how gene editing research should be governed

Of the respondents who said that scientists can oversee gene editing research themselves, virtually none argued that *individual* scientists could oversee themselves. But many comments from those who answered either *yes* or *no* to our question of whether scientists could oversee gene editing research themselves offered ways that *groups* of scientists could be involved in oversight.

The strongest version of this view, which came only from respondents who said that scientists *could* oversee themselves, was that *only* scientists should be involved in oversight, suggesting a certain allegiance to the original concept of the grand bargain. For example, one respondent commented, “Scientists are the ones with more understanding of gene editing research, and they are very well positioned to understand, and evaluate protocols, goals and risks.” Another noted, “There must absolutely be some kind of oversight from a federal committee made up 100% of gene editing scientists. We need to remove religious and political considerations from the equation if we are to make rational medical decisions on gene editing moving forward.” Yet another respondent expanded on this notion:

Form committees by scientists who will evaluate the proposed research and discuss potential flaws as well as ways to improve the suggested research. As this can be significant work load these committees should be formed by dedicated scientific personnel and also have an additional advisory committee formed by active

research scientists in the field. It is key to have diverse scientific personnel (meaning diverse based on research work) and have transparency.

While various responses suggest that only scientists involved in gene editing should comprise these committees, one respondent felt quite the opposite: “Scientist[s] [who are] not themselves involved in human gene editing could constitute oversight bodies.”

However, more respondents pointed to the idea that scientists working in interdisciplinary groups with other nonscientific stakeholders should provide oversight of gene editing research. Reasoning for this view included that “the consequences of gene editing, especially germ line editing, are so great that decisions about gene editing should not be left to any individuals but emerge from the consensus of a larger body.” A few respondents referred to this as ensuring “checks and balances,” like one who said, “I believe oversight has to include patients, international officials, government officials, and scientists so that there are a set of checks and balances to mitigate biased agendas.” Taken together, these various respondents argue that governance requires diverse input to ensure that gene editing research is conducted ethically, reflects social values, and has the support and trust of the public. As one respondent commented, “There are so many possible societal issues, not just scientific issues, and we need a breadth of perspectives to proceed in a way most likely to establish and maintain trust with the public.”

The groups and perspectives most frequently discussed as important to include in oversight were ethicists, funders (the NIH was mentioned repeatedly), and the FDA or other regulatory officials. As one respondent cautioned, “Whether or not gene-editing research should be carried out is not a purely scientific question. Scientists can address purely scientific questions and oversee the related process. When a question is a mixture of science and a political/public policy/ethical issues, scientists will need help from relevant experts.”

Among both the group of respondents who said that scientists could oversee gene editing themselves and the group who said they could not, several respondents mentioned that including international scientists, physician scientists, and clinicians was important. The group who said scientists could not oversee gene editing themselves more often advocated for also including patients, advocacy groups, and the public in oversight. One respondent commented, “No research or treatments for human disease should be conducted in the absence of input from patients, families, and/or laypersons (if all affected persons are unable to participate in oversight). Science should not be conducted in a vacuum away from the people it will affect.”

DISCUSSION

These open-ended statements from scientists reveal an important awareness of the limitations of scientific

self-governance in an era of globalized research, and the reality of rare but dangerous rogue behavior. The scientists we surveyed are not all likeminded, however. Some thought that scientists could and should collectively oversee human gene editing research themselves, on purely scientific grounds, in the tradition of the grand bargain. This optimism about the prospects for collective self-regulation echoes the experience of other scientific communities like stem cell researchers in developing and periodically updating models for voluntary international harmonization of research practices.^{38–40}

But far more saw their role as one of several different stakeholders involved in governance, including patient advocates, other professionals, and the public. Respondents argued that a wider set of perspectives is required to anticipate and respond to the ethical implications of human gene editing, indicating that even those who think scientists can self-govern do not think that scientists should do so alone. Like other recent commentators on these governance issues,^{13,14,17,41–44} they see this diversity of perspectives as necessary to mitigate conflicts of interest, respect public concerns, and incorporate the wide scope of relevant social, ethical, and legal considerations that responsible governance should entail.

For much of the 20th century, this conclusion would have been surprising coming from the scientific community, which operated under the professional autonomy granted by conventions like the grand bargain. As our findings suggest, changes in how science is conducted, such as the dramatic rise in global networks of laboratories and institutions that transcend national boundaries, increasingly challenge this traditional understanding of science as a self-governing, nationally based profession.^{2,12,13,16,41} Instead, these changes reflect a move toward transnational professionalism, a new model of scientific work.⁴⁵ This model suggests that as scientific occupations have become more market oriented, the direction, pace, and scope of research increasingly reflects the influence of commercial forces rather than purely epistemological values and norms.³⁵

This finding is not unique to scientists who use gene editing. A survey of stem cell researchers also revealed the sway of commercialization and clinical translation on researchers' perceptions of their field.⁴⁶ Moreover, as the professional contexts of scientific work and the entities that regulate it become increasingly global,^{4,5} the traditional social contract between scientists and their own countries is changing. As a result, scientists are increasingly less like members of closed self-governing guilds or experts in the service of particular national governments, and more like transnational entrepreneurs.

Against this backdrop, it is perhaps not surprising to see considerable evidence of scientists' attitudes moving away from the grand bargain. The most likely motivations

for this shift were He Jiankui's experimentation and the concerns about conflict of interest that entrepreneurial science provokes.

But there are other hypotheses that could be important to explore as gene editing research evolves. For example, the rise of transnational professionalism in science has prompted a growing endorsement of public engagement and input in gene editing governance in the policy literature.^{21,23,47} As opposed to either self-governance or the governmental control of science, advocates of the democratization of science seek to mitigate the increasingly commercial focus of globalized science by incorporating public values and concerns directly into transnational scientific governance.^{12–14,21,41,42,44} As a result, scientific agencies like NIH increasingly move to include diverse disciplinary perspectives in scientific initiatives like the Human Genome Project and the All of Us Precision Medicine Initiative, normalizing the view that science can no longer be responsibly pursued in a societal vacuum.^{48,49}

Our survey findings should be considered in light of our study's limitation that respondents included only academic researchers working at U.S. institutions. Future research should examine the influence of location, international collaborations, and private-sector employment on scientists' views on gene editing research governance and the role of public engagement.

CONCLUSION

Whatever forces drive the scientific gene editing community's doubts about their capacity for effective self-governance, these doubts have interesting implications for the ongoing governance debates. They reinforce notions that the most plausible forms of governance for this field will certainly not be self-policing.⁵⁰ Instead, some dynamic combination of global professional norms,¹³ institutional review processes,¹⁶ and national funding and regulatory policies¹⁵ are likely to evolve, all of which may involve public engagement and anticipatory planning. At the same time, the diversity of cultural values and interests constituting society at the international level make it more difficult to know which voices should have standing in negotiating governance plans.

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