COMMENTARY

PUBLIC ENGAGEMENT AND THE GOVERNANCE OF GAIN-OF-FUNCTION RESEARCH

Monica Schoch-Spana

The White House recently called for a “robust and broad deliberative process” to assess the risks and benefits of select gain-of-function studies, pausing current experiments and further grants until new federal policy on research funding and oversight is developed. At issue is whether and under what conditions laboratory studies that enhance the transmissibility and/or virulence of potential pandemic pathogens such as the H5N1 avian influenza virus should go forward. To date, professionals from medicine, public health, and the life sciences have dominated the debate, and each side of the controversy has cited the public’s well-being as the principal motivator for their position. A major stakeholder, the general public, has not yet actively and systematically weighed in on the matter. This commentary considers in what form and with what benefit public participation may materialize in the current debate regarding the governance of gain-of-function research.

ON OCTOBER 17, 2014, THE WHITE HOUSE OFFICE of Science and Technology Policy declared the start of a “robust and broad deliberative process” to assess the risks and benefits of select gain-of-function studies, pausing current experiments and further grants until new federal policy on research funding and oversight is developed.¹ More technically nuanced than described here, the fundamental issue is whether and under what conditions laboratory studies that enhance the transmissibility and/or virulence of potential pandemic pathogens such as the H5N1 avian influenza virus should go forward.

Together, the National Academies (NAS) and the National Science Advisory Board for Biosecurity (NSABB) are serving as the main institutional mechanisms for incorporating stakeholder input in the year-long decision-making

process, and several public meetings have already been convened, webcast, archived online, and reported in national news and scientific news outlets.^{2,3} Though held openly, with procedures for public comment, these meetings have principally engaged individuals with backgrounds in the life sciences, public health, security, biosafety, risk analysis, and the drug and vaccine industry.

Their voices largely absent, the general public has still been at the center of the gain-of-function debate. Prominent figures on each side of the controversy have invoked the public’s well-being as motivating their position: They hope to diminish the chances and impacts of a pandemic, some by restricting certain gain-of-function studies to prevent an accidental or intentional pathogen release, others by assuring continued work under safe conditions to

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help enhance pandemic detection and vaccine development.⁴⁻⁷ In this context, it is worth reflecting on whether the general public should have greater opportunity to take part in the unfolding deliberations about gain-of-function research risks, benefits, and mitigation approaches.

Are traditional public comment periods, virtual participation in expert-centric discussions, and access to journalistic reports of the debate and risk-benefit assessment sufficient to the task of determining how best to govern the life sciences in society's best interests? Should more sophisticated, resource-intensive deliberative sessions be held with people outside of the present circle of vested parties? This essay provides some thoughts for the NSABB, the National Academies, the life sciences community, public health experts, and federal sponsors and regulators to consider on the topics of public engagement and gain-of-function research risk-benefit deliberations.

WHO IS THE PUBLIC?

In the broadest sense, and relying on the democratic philosophy of John Dewey, "the public" in this case comprises the people interested in or affected by gain-of-function research governance decisions.⁸ This group, of course, depends on perspective. Political jurisdictions, complex disease processes, and many other factors complicate definitions, as illustrated by just a few global, national, and local "publics" relevant to this debate.

In the way that most scientific and medical experts in the gain-of-function debate use it, "the public" is that population of individuals who could become ill or die due to infection with a pathogen of pandemic potential, whether through natural, accidental, or intentional means. In the pandemic context, this kind of public—the population at risk—is global. Immunologically naïve, world citizens in the abstract are equally in danger of infection, and they are equally in need of medical countermeasures potentially informed by gain-of-function research (or alternatives). Despite reductionism that would conflate disease with the infectious agent, however, pandemics do not affect people in equitable ways.

Arguably, additional publics reside within the one of "global" public health. As Paul Farmer and others have demonstrated, inequalities across and within countries "structure not only the contours of the AIDS pandemic but also the nature of outcomes once an individual is sick with complications of HIV infection."^{9(p52)} Quinn and colleagues propose that US racial and ethnic minorities were at a 3-fold disadvantage during the 2009 H1N1 influenza pandemic: enhanced exposure to the H1N1 virus because of social, economic, and behavioral elements; greater susceptibility to flu's complications due to a high prevalence of chronic conditions and immunosuppression; and impaired access to timely and trusted health information, vaccination, and treatment.¹⁰

Other national publics, beyond those understood in strictly public health terms, also come to mind. While the US Congress may authorize and the National Institutes of Health (NIH) and other agencies may invest finite dollars in science, ultimately the US taxpayer underwrites the cost of government-sponsored research. The US public, too, confers authority and operating budgets on the federal public health and regulatory bodies implicated in the biosafety systems that keep researchers and the public safe in the context of gain-of-function and other research of concern.¹¹

Another potentially relevant public resides at the local level: place-based communities that host facilities for current and future gain-of-function research. This public, in the case of a laboratory release, could be on the front lines of an emerging pandemic. As a result, they could have a strong interest in biosafety and biosecurity measures to avert any release and, should prevention fail, in locally robust measures to treat the sick and to interrupt transmission. Expansion of high-containment labs in the US has already elicited a range of public reactions, from broad support to organized opposition that has stymied some proposed facilities.¹² Not confined to perceived health threats, motivators for local resistance have also included issues of environmental justice, community empowerment, and urban development.¹³

Even a short list of "publics" suggests some basis for potential engagements at global, national, and local levels, and it suggests that the terms of the debate may be broader than what has unfolded in professional journals as well as the NSABB and NAS meetings covering the debate.

WHAT DOES ENGAGEMENT MEAN?

The term *engagement* typically refers to processes by which citizens influence the public policy and program decisions that affect them.¹⁴ In a representative democracy, people have a variety of ways to make their voices heard by officials: voting, letter writing, lobbying, and demonstrating. But over the past 50 years, more direct means of public participation in the process of decision making have developed as citizens have become less deferential toward authorities, policy issues have become more complex, theory in deliberative democracy has flourished, and practical experience with engagement activities has accumulated.¹⁵

Scholars and practitioners have often modeled public engagement or participation in terms of the flow of information and influence between authorities and constituents, with the public's increasing say in decisions and their implementation.^{16,17} A continuum comprised of communication, consultation, and collaboration represents a simple model of public involvement in policy making, for the purpose of illustration:

Communication: An official or agency conveys information to members of the public in one-way fashion, often

for education or informational purposes. Public responses are not required or specifically sought out. In the gain-of-function research context, this would take the shape of press releases, educational websites, or summary reports on the proceedings of NAS and NSABB gain-of-function meetings.

Consultation: Authorities solicit opinions through use surveys, polls, and focus groups or, in the gain-of-function context, through the comment period for the draft NSABB recommendations to the US government on future funding and oversight policy. Again, the communication is one-way, from citizens to decision makers. The public's points of view, criticisms, and constructive advice may inform policy options and their implementation, but as one input among many.

Collaboration: Citizens and authorities are engaged in a dialogic, 2-way flow of information that supports deeper understanding of a complex issue on all sides. Collaboration presents the chance for collective learning as part of honest, respectful interaction among formal authorities and their diverse constituents, and for the iterative exchanges that are necessary to approach policy problems with ethical and cultural complexities. Authorities have not yet initiated this level of engagement with the general public, but they have diligently reached out to the life sciences community where careers and their contributions to public health are at stake.

WHY IS ENGAGING THE PUBLIC VALUABLE?

Theoretical discussions have offered substantive, pragmatic, and normative rationale to justify the public's active deliberation and co-production of policy decisions.¹⁸ As summarized in the National Research Council report *Public Participation in Environmental Assessment and Decision Making*, the most important justifications for this position fall into categories of improving quality, enhancing legitimacy, and building capacity,¹⁹ a conclusion borne out by the committee's review of 1,000 empirical studies, practitioner reports, and theoretical analyses from across the social sciences.²⁰

Improving Quality: Public participation (ie, collaborative engagement) enhances decision quality by helping "get the science right."²¹ First, people who are not typically considered "experts" nonetheless hold local knowledge that is sensitive to context. Their grounded input has often corrected technical analyses that have misapplied the science in local conditions. Second, public input—not encumbered by technical presuppositions—can prompt new lines of inquiry that in the end improve the technical competence of policy decisions.¹⁹

Enhancing Legitimacy: Public participation can serve as a venue to inform and elicit the consent of the governed on complex issues in more ways than elections and other traditional methods can provide. Participatory, deliberative

forms of engagement, when performed in good faith, can help build trust between officials and the public, enable officials to consider different points of view including those of otherwise disenfranchised people, and provide evidence even to dissenting participants as well as nonparticipants that officials have acted in a fair and accountable manner.¹⁹

Building Capacity: If executed well, public participation builds a foundation of trust, mutual understanding, and practical experience with dialogue that can benefit future policy formulation, implementation, and evaluation. The public derives greater facility with the science and the political process, and scientists and governing officials develop a better understanding of public concerns. Deliberative exchanges help citizens, scientists, and governing officials understand aspects of a problem that reach beyond their immediate circumstances, providing opportunities for refined and altered views.¹⁹

Navigating Uncertainty: A fourth crosscutting justification, navigating uncertainty, has also been proposed in the case of techno-science policymaking. Involving the public can strengthen the capacity of civil society, technical experts, industry, and government for analysis and reflection on the uncertain and ambiguous nature of many scientific and technological developments. However confident experts may be in their predictive models of risk, chronic and acute failures in today's complex systems demonstrate the limits of human foresight²² (as do unanticipated life-enhancing scientific discoveries). Judgments, informed by scientific facts and social values, are necessary in the context of unforeseen consequences that can be good, bad, or in between and that can unfold for decades or more.²⁰

SOME POTENTIAL APPROACHES

The initial question to consider promptly is whether broader public engagement is to be a feature of the proposed gain-of-function benefit and risk assessment. Principals from NIH, NSABB, and NAS might seek advice on this question from leading practitioners, such as those represented in the Deliberative Democracy Consortium. This fundamental "go, no go" question will hinge in large measure on interrelated matters of good faith effort, practical feasibility, and issue framing:

- Will broader public input play a genuine role in the development of federal policy concerning the governance of gain-of-function? Decision makers who accord weight to, and consciously plan to integrate, the outputs of public engagement set the process up for greater success. In light of evidence that their reflections and analysis matter, participants approach deliberations in a more thoughtful and evenhanded manner.¹⁹
- Decision makers and their advisors must also address head on the question of logistics. Practically speaking, can a robust public engagement process occur in the

time frame currently allotted for the risk-benefit assessment, and, if not, should the timeline be adjusted to allow for this (even given the public health and professional career effects associated with a delay)?

- On what question(s) do decision makers wish to elicit public input? Current contours of the debate suggest the core dilemma about whether gain-of-function experiments of concern (a category now in flux and needing technical precision) should go forward. A corollary issue is whether the present biosafety regime engenders sufficient public confidence for experiments of concern to go forward and, if not, what concrete measures might warrant greater trust.

Should more systematic involvement of publics beyond the life sciences community be desirable, then some considerations for moving forward might include:

Nested Engagements: As illustrated early on, broad “publics” at local, national, and global levels exist. Practically, where does one begin?

The US already has precedents—involving the National Academies and many other entities—for public engagement exercises that are local and national in scope, diversely populated, and involving technically and ethically complex health security matters (eg, allocation of scarce medical resources in a disaster).²³ Based on these past experiences, one can envision a 2-tier process to engage the public in the gain-of-function risk-benefit assessment: a series of local deliberative sessions across the country, followed by a national stakeholder meeting.

To engage citizens with a stake in the result, one could consider holding deliberations in locales hosting gain-of-function laboratories and recruiting participants who already evidence interest in community well-being through involvement in public health and safety initiatives. Concrete examples are local emergency planning committees, citizen corp councils, and public health boards and advisory councils—extant bodies that ideally represent broad sectors of the community (including underserved populations), are conversant in hazard and disaster management challenges, and are mindful of the value of epidemic controls such as disease surveillance and medical countermeasures.

A meeting of national stakeholders could similarly be populated with public health and safety-oriented entities, including those specifically committed to addressing the health disparities aspects. Background “briefing” materials on gain-of-function studies, their potential risks and benefits, and the current US biosafety regime developed to facilitate local and national deliberations could serve as important legacy materials. Documents that crisply lay out the key issues and that can be incorporated into mass media reports and educational curricula can be productive of an informed citizenry outside the bounds of the formal deliberation venues.

NIH, federal partners, the National Academies, and other interested entities could encourage their international

counterparts to develop their own deliberative processes.¹⁵ In 2009, a citizen consultation on climate policy was organized simultaneously in 38 countries on 6 continents.¹⁸

Enduring Structures: Public engagement on this issue should not be limited to a “one-and-done” performance. Engagement procedures on this specific issue can serve as the foundation for the development of more enduring “popular” deliberative systems to tackle analog dilemmas certain to emerge in the future.²⁴ Such participatory endeavors, and the diffusion of well-crafted communication products emanating from them, are an investment in democratic governance in an era of accelerated bio-science and technology developments. Such deliberations can strengthen the scientific literacy of citizens as well as the capacity of scientists, their sponsors, and regulators to represent their respective work in broadly meaningful terms.

CONCLUSION

At this moment in the debate, federal officials and their advisors need to do a risk-benefit analysis as to whether to incorporate the wider public in the gain-of-function deliberations. A well-designed process promises the potential for enhanced decision quality, legitimacy, and capacity building—the last 2 of which are most pressing for gain-of-function governance questions. Other unintended consequences are also possible. Not providing for broad public engagement, however, carries its own risk. People have the capacity to self-organize and issue what Sheila Jasanoff has called a “popular technology assessment” when formal channels fail “to deliver the level of accountability desired by the public.”^{22(p238)} How policy decisions are made about the public’s well-being vis-à-vis science and technology can prove just as important as what the final decision is.

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