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TRANSLATIONAL BIOETHICS AND PUBLIC INPUT

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ABSTRACT

Translational Science (TS) is justified as advancing the public's interests but has no mechanism for determining these interests. Standard social science approaches would either produce unrepresentative descriptions or a cacophony of data not easily condensed into a concrete conclusion about moving forward with a TS project. I propose to use the simplifying and structuring ethics used in IRBs to create social science reports of the 4-6 most prominent values or principles of the public regarding a biotechnology. A board of bioethicists would weigh and balance these values to conclude whether the public supports a TS innovation.

KEYWORDS

Public engagement
Public views
Social science and bioethics
Translational bioethics
Translational science

According to the NIH, translational science (TS) is dedicated to "interventions that improve the health of individuals and the public."[1] This appropriately makes the public the ultimate beneficiary of translational science, but how do decision-makers know what "improvement" is for the public? After all, what constitutes good health is not objective, and while there would be high consensus that some bodily conditions are diseases, whether the public wants all that TS could provide is not obvious. Note, for example, that a large portion of the TS programs are about human genetics and stem cells, for which the public is decidedly of mixed mind.[2] It is also unlikely that the public would accept all technologies that advance health, because health is not all the public values. For TS to be successful it needs to maximize the public's values in shaping the TS agenda.

Others have identified how the bioethics approaches used in translational science does not include the consideration of societal views. For example, Mark Rothstein argues that TS programs do consider ethics, but “tend to focus on ‘human subjects’ issues, such as community engagement, recruitment strategies, informed consent, and institutional review board (IRB) submissions.” However, he continues, “if translational science is designed to foster ‘disruptive translational innovation,’ then the ethical component should be similarly ground-breaking . . . Translational science presents an important opportunity for bioethics assessments to address fundamental societal issues, including the effects of translational science on . . . human flourishing.”[3] To link to my previous paragraph, TS needs to know what “human flourishing” is and, again, what it means to flourish is not objective – the public’s versions of this are likely to be somewhat different from that of scientists and medical professionals.

Can TS create an ethics that is equally rigorous and applicable to the earlier stages of translation, long before technologies are tested on people, with a method for deciding which technologies would truly result in human flourishing according to the ethics of the public? For this one aspect of translational bioethics (TB) I propose to build on the successes of human research subject ethics.

THE SIMPLIFIED AND STRUCTURING METHOD IN HUMAN RESEARCH ETHICS

The criteria for institutional review boards (IRBs) are contained in the Common Rule, where the ethics of the public are represented as principles taken from the Belmont Report. There are only three principles that need to be maximized – autonomy, beneficence, and justice.[4] IRBs are not to debate whether other principles should be included. This point is critical to my argument. I do not want to downplay the difficult deliberations of IRBs, but this simplified and constrained version of ethics makes it even possible to come to a “yes/no” answer on a research study. There is much we can learn from the sociological realism of this design.

First, IRBs exist in bureaucracies, and bureaucracies need stated rules to structure decision-making.[5] What makes the work of an IRB even possible is that the principles are undebatable and fixed, like rules. If IRB members could add or subtract principles, no conclusion about whether to permit the research could ever be reached because the answer would be based on the values or principles of the committee member. The rules of the game would also change for every case. Moreover, there are three principles, which strongly constrains the range of debate. If there were 100, then there would be no constraints on the debate, and it would be as diffuse as the purely academic ethical debate on a topic.

Second, if it is true that the principles in human research ethics actually do represent the primary values of the public (which I will get to in a minute), then this system also has a modicum of democratic legitimacy, as well as its cousin, public acceptance. Moreover, as historians have noted, in a society that distrusts government, it is best for decision makers to not appear to be following their own ethical judgement, but rather to be following transparent laws or rules.[6] IRBs are enacting government policy, so following rule-like principles and thus minimizing discretion increases public legitimacy.

A METHOD FOR PUBLIC INPUT TO TRANSLATIONAL BIOETHICS

The question of whether a technology should be developed at all, or more realistically the shape of that development, is not allowed to be part of the debate at an IRB. But it needs to be a part of

TB and should follow the public's values. In recent years, the profession of bioethics has recognized it cannot directly represent the public and has called for public consultations to influence public ethics.[7] To determine if a proposed technology in TS would truly result in flourishing, from the public's perspective, bioethicists obviously need to ask the public.

However, there are at least three challenges in asking the public. First, there is at present no method for reaching an ethical conclusion from public input or public engagement, a situation I hope to start remedying with this essay.

Second, if social scientists are simply asked to determine the public's views, they will produce a huge range of analyses that will not obviously allow for a "yes/no" answer. If there were five books reporting studies of the public's views about human brain organoids, the results would not be written in a commensurable way that could be clear input for a decision. This is not a critique of social science. Sociologists like to cite physicist Neil deGrasse Tyson's tweet that "in science, when human behavior enters the equation, things go nonlinear. That's why Physics is easy and Sociology is hard."[8] I have no doubt that physics is hard, but the subject matter of sociology generally precludes binary conclusions like "the public wants this technology vs. the public does not want this technology."

A third problem is that you cannot just ask the public to decide "yes" or "no" because the public does not have the time to be informed about biotechnology. An IRB does not put its decision up for public vote, but rather the public is represented by the principles. Analogously, I want to solve these three challenges in using social science by taking advantage of all of the simplifying and structuring aspects of principlism. This would develop a TB where a relatively transparent conclusion could actually be reached about which technologies should be developed by using the public's principles or values.

Which principles would be established for the public's view of a particular technology? While it has never been demonstrated, I think it is plausible that the existing three principles used for human research are the public's ethics – only when applied to healthcare ethics consultation and human subjects research. However, we should not assume that those principles are what the public would want to maximize in a decision of whether to pursue a TS technology.

We can hypothesize what these values or principles may be for particular biotechnologies. For example, for the question of whether to pursue human germline genetic modification, would the public only want the existing Belmont principles to be our guide, or would they want additional values? I would bet that the public would add a value like "respecting nature's/God's design." This combination of values would probably only rule out what Agar calls "radical enhancements."[9]

IDENTIFYING THE PUBLIC'S VALUES FOR EACH ISSUE

Imagine a TB panel convened by the National Center for Advancing Translational Sciences at the NIH comprised of representatives from TS institutes, or perhaps an independent panel organized jointly by a group of TS institutes. The panel would meet at the conceptual stage of research, long before there are any human subjects. Like a human subjects IRB, the proposed panel would consider a limited number of the public's principles or values in deciding which technologies will truly advance human flourishing. This raises the question of how to identify these values. The public's principles for human research were determined by reflection and discussion by a group of academics in 1978, but it is unlikely that the contemporary society would consider this method legitimate, again suggested by bioethicists' call for public engagement. I am calling for a Belmont Report for each technology or family of technologies under consideration in TS, but with the principles of the public being determined in a more accurate manner using social science.

A typical methodology would be to conduct an in-depth semi-structured interview study of perhaps 80 people with the sample stratified by key demographic dimensions. This allows a deeper understanding of how people talk about their values in relation to a biotech issue. From what is learned from those un-representative interviews, a social survey is produced that is inevitably produces less rich data than the in-depth interviews, but allows for representative claims about the U.S. population. From this, we could identify the values or principles for a technology like human gene editing. Just like the academics at the Belmont Conference Center concluding that having seven principles was not "crisp enough" before settling on three,[10] it is standard fare in social science to identify the most prominent 4-6 features from data. Unlike the more diffuse social science I described previously, the simplifying and disciplining aspect of this version of social science would come from the explicit requirement that the project identify the 4-6 most prominent principles or values that the public uses when discussing a possible biotechnology.

It is true that different teams of social scientists would produce somewhat different sets of principles. But I would venture that they would not be too different, and would be more consistent than what arises from a purely ethical debate. The proper standard to judge this method is not perfection. Rather, it should be compared with what we currently use to represent the public's values, which is reflection by bioethicists and scientists on what the public wants after consulting diffuse and incommensurable social science studies (if they exist).

Some scholars in bioethical debate advocate determining the public's views by way of deliberative events where a group of citizens learn about a technology and then debate.[11] I do not advocate for these for a number of reasons, including that they are not representative of the public. But if the TS community thinks the public deliberative event produces a better measure of the public's values, deliberative events still fit with my overall point, as long as they produce a description of 4-6 most prominent public principles.

DEBATE BY A TRANSLATIONAL BIOETHICS PANEL

As noted, this social science would produce the equivalent of a Belmont Report – for human brain organoid research, for human gene editing, for brain-computer interfaces, or whatever is on the table. In the current IRB system, the public's values are there in the regulations, and then experts who understand topics like exactly how a device would be implanted in someone's brain determine if the public's ethics are being maximized by this particular experiment. This is constraining and simplifying like the section of the Common Rule (46.111 "Criteria for IRB approval of research") that lists a very limited number of criteria for use in deciding the ethics of research on human subjects.[12]

Similarly, the interdisciplinary TB panel, presumably comprised of bioethicists, scientists, lawyers, and social scientists, would have the public's values in a report, and would use its expert knowledge to determine whether the proposed direction of TS would maximize the public's values. My method side-steps the issue of the public not having the time to study the details of a scientific proposal, which would be left to people paid to have this knowledge. While citizens do not have the time to study science, they are quite good at expressing their values.

More realistically, and productively, in the same way that medical researchers shape their research designs to make them compatible with anticipated decision making of the IRB, presumably TS institutes would fine tune their research topics a priori to make sure they fit with the public's values.

We often rely upon bioethics panels such as government bioethics commissions or those of the National Academies or other science societies. One criticism is that the result is primarily determined by the values of those invited to be at the table who are, again, not representative of the public or even of all bioethicists. The outcome of a TB panel would still be dependent on who is invited to be at the table, but less so than with existing methods, because a member of the panel who tried to inset their own principle would have to bend the public's principles. Bending can only go so far. You can make a table, a broom handle, and a sculpture with a block of wood, but you cannot make a pair of eyeglasses.

Some might be fearful that bringing in the public's values would shut down their research, but I have no doubt that the #1 value that would be identified for nearly every possible technology is the relief of suffering from disease. The question will be – how do we relieve the suffering of disease without violating other values the public holds dear? People with very unusual values (e.g., flat-earthers, conspiracy theorists) are indeed so unusual that their values would not make it to the top 4-6 (or probably the top 100) values.

WHY CONSIDER THE PUBLIC'S VALUES?

There are two reasons to bring the public's values into shaping the agenda of TS. First, it is intrinsically right to do so because science is conducted on behalf of the people in a society, who also typically pay for it. Second, it is in the self-interest of TS. I think that TS will find that on the vast majority of issues the values of the public correspond with those of translational scientists and when they do not, a radical shift in the science is not required to make it consistent. To be perceived as ignoring the public's will sets TS up for a backlash that will swing far beyond the adjustments that would likely be required to make TS fit the values of the public. It is better to ask the public ahead of time than later to call for a self-imposed partial or full moratorium, which is a surprisingly common occurrence.[13] My proposed mechanism is one way to bring in the public's values, and I welcome a debate about how the public's values could enter TS.

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ENDNOTES

[1] National Center for Advancing Translational Sciences, Transforming Translational Science, https://ncats.nih.gov/files/translation-factsheet.pdf.

[2] National Center for Advancing Translational Sciences, NCATS Programs & Initiatives, https://ncats.nih.gov/programs.

[3] Rothstein, M.A., "Expanding the Role of Bioethics in Translational Science," *Journal of Law, Medicine & Ethics* 50, no. 3 (2022): 603-07, at 603.

[4] Beauchamp, T.L. and J.F. Childress, *Principles of Biomedical Ethics*, 8th ed. (New York: Oxford University Press, 2019).

[5] I elaborate on this method in Evans, J.H., *The History and Future of Bioethics: A Sociological View* (New York: Oxford University Press, 2012).

[6] Porter, T., *Trust in Numbers: The Pursuit of Objectivity in Science and Public Life* (Princeton, N.J.: Princeton University Press, 1995), at 195.

[7] Scheufele, D.A. et al., "What We Know about Effective Public Engagement on CRISPR and Beyond," *Proceedings of the National Academy of Sciences* 118, no. 22 (2021), https://doi.org/10.1073/pnas.2004835117.

[8] Neil DeGrasse Tyson, https://twitter.com/neiltyson/status/6957597767524496640?lang=en.

[9] Agar, N., et al., *Humanity's End: Why We Should Reject Radical Enhancement* (MIT Press, 2010).

[10] Ibid. at 52.

[11] Dryzek, J.S. et al., "Global Citizen Deliberation on Genome Editing," *Science* 369, no. 6510 (2020): 1435–37.

[12] 45 C.F.R. 46.111.

[13] E.g., National Academies of Sciences, Engineering, and Medicine, *Second International Summit on Human Genome Editing: Continuing the Global Discussion: Proceedings of a Workshop in Brief*, Olson, S., ed. (Washington, D.C.: National Academies Press, 2019); Metz, C. and Schmidt, G., "Elon Musk and Others Call for Pause on A.I., Citing 'Profound Risks to Society,'" *New York Times*, March 29, 2023.