Translational Bioethics and Public Health

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Modern public health science and practice are characterized by innovation in such areas as prevention, surveillance, data analysis, policy development, and delivery of health services on a population level. Public health officials also need to respond to new scientific developments amid a crisis, as exemplified during the COVID-19 pandemic by efforts to vaccinate much of the population using novel mRNA-based vaccines. Translational bioethics, a type of research ethics, analyzes the societal implications of innovative scientific methods and discoveries with the goal of improving individual and public health. Although translational bioethics is designed to augment the ethics programs of National Institutes of Health (NIH)–funded translational science awardees, its emphasis on the societal implications of transformative research may be applied more broadly.

This article deals with three related concepts: translational research, translational science, and translational bioethics. Translational research involves scientific exploration using innovative techniques and technologies to expedite and enhance the development, testing, and implementation of diagnostics and therapeutics across human diseases and conditions.[1] Translational science is the systematic study of translational processes used to accelerate and increase the significance of research progressing from the bench to the bedside.[2] Translational bioethics, the focus of this article, analyzes the societal implications of novel scientific methods and discoveries. With the aims of translational research extending to adoption of innovative discoveries, it is appropriate for translational bioethics to consider the broader implications of the research, including policy analysis and development.

TRANSLATIONAL BIOETHICS

Since 2012, the National Center for Advancing Translational Sciences (NCATS) at the NIH has coordinated the translational science activities conducted or funded by the NIH.[3] NCATS also coordinates the efforts of 60 leading medical institutions funded to conduct research using translational science principles.

Research ethics is a required component of federally funded translational science grants, but, at present, this usually involves such traditional elements as the selection and recruitment of participants, balancing of risks and benefits, informed consent, and other criteria for institutional review board (IRB) approval. Although these issues are important, a narrow view of research ethics represents a missed opportunity. To parallel the ambitious, disruptive goals of translational science,[4] translational bioethics also should "address fundamental societal issues, including the effects of translational science on public health, health equity, and human flourishing."[5(p603)]

The customarily limited focus of research ethics is related to the regulatory process. The research regulations of the US Department of Health and Human Services ("Common Rule") explicitly prohibit IRBs from considering societal risks and implications of proposed research: "The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility."[6] It would be necessary to revise the Common Rule to require IRB consideration of societal risks and benefits of proposed research.

Regardless of the federal regulations, IRBs are not well structured to consider broader societal issues because they often lack broad multidisciplinary perspectives and seek to produce reviews in a relatively short timeframe.[7] Presidential bioethics commissions, government entities such as the Office of Science and Technology Policy, and independent research organizations such as the National Academies of Science, Engineering, and Medicine could assess societal implications of innovative biomedical research. Nevertheless, there is merit in establishing wide-ranging bioethics assessments as part of the translational science process to take advantage of embedded, interdisciplinary collaboration and expertise. Importantly, the study of societal issues by institutions undertaking translational research should not be seen as preempting consideration of these often-complex issues by other entities and individuals. An unresolved issue is

whether translational bioethics programs should be funded by the NIH, individual research institutions, or some other source.

In briefly describing the substance of translational bioethics, a logical starting point would be the three common morality principles contained in the Belmont Report[8]—respect for persons (autonomy), beneficence, and justice—and their application to societal implications of innovative research.[9] As for autonomy, the balancing of individual and population interests is a foundational concern of public health ethics. Beneficence would assess the costs and benefits of innovative research on a societal level. Justice serves as the moral grounding for health equity, an essential principle in ethical implementation of health research.

The risks, benefits, and consequences of research on public health have been explored in other contexts by academics, practitioners, and public health officials with diverse professional backgrounds and perspectives. Translational bioethics, with its focus on the societal implications of translational research, is congruent with traditional public health ethics scholarship and policy development.

RESEARCH FUNDED BY THE NATIONAL INSTITUTES OF HEALTH

Translational bioethics, at least as envisioned as a part of the 60 academic medical institutions funded by NCATS at the NIH to conduct translational research, has four distinctive characteristics:

1. Integrated: Where appropriate, translational bioethics faculty and affiliated researchers (e.g., from social sciences and humanities) should work with translational scientists from the outset of new research undertakings. In collaboration with researchers, bioethics personnel should learn the goals, methods, and intended applications of the research; review the technical obstacles; ponder the societal risks, benefits, and challenges; and explore possible unintended consequences and long-term implications of the research.
2. Timely: By working with translational scientists, bioethics faculty and affiliated researchers are well situated to generate analyses of ongoing research activities, explore the societal challenges they present, and develop relevant policy options for clinical integration and public health. In many instances, the evaluation can take place much sooner than typical scholarly assessments of novel research, which often occur after a scientific publication or public disclosure of research findings.
3. Interdisciplinary and collaborative: Translational bioethics should be broadly interdisciplinary and, depending on the nature of the scientific research, could include the collaboration of experts with backgrounds in public health, humanities, social sciences, law, theology, and other disciplines. Individual bioethics scholars do not have expertise in all these areas, and, consequently, directors of translational bioethics programs should coordinate the efforts of a multidisciplinary team of investigators, as needed. For example, surveys, interviews, focus groups, and other methods can be used to explore public attitudes about ongoing research, including the views and concerns of diverse racial, ethnic, religious, and other groups. Because a single medical institution may not have all the necessary expertise, and because some issues are likely to arise in multiple research projects, collaborations among the NIH-funded clinical and translational science awardees should be developed.
4. Internally and externally oriented: In reviewing early-stage research design and implementation, bioethics personnel might identify concerns, such as privacy, economic consequences, or health equity, at a time when the research methodology can be modified more easily than would be possible at a later stage. Thus, the research itself might be improved by internal bioethics review. At the conclusion of the research, translational bioethics collaboration also could help identify the need for regulatory action, health education, health communication, or other externally directed strategies to inform policy development.

Translational bioethics should be constructive, collegial, and complementary. Its ultimate purpose should not be to discourage, delay, or defund research, but to advance the traditional research ethics principle of beneficence by minimizing risks and maximizing benefits, with an emphasis on societal issues. Nevertheless, translational bioethics scholars must be vigilant in maintaining their objectivity and independence from translational scientists. The credibility of any bioethical and policy perspectives developed would be seriously jeopardized by the perception or reality that

bioethics faculty and affiliated researchers are subordinate to translational scientists or serve only to legitimize their research.[10] At the same time, embedded bioethics personnel must develop and maintain collegial relationships with translational researchers.

TRANSLATIONAL BIOETHICS IN PRACTICE

Conceptually, translational bioethics is extremely broad, and, therefore, assessments should be tailored to specific research. Some criteria for assessing translational research protocols and practices are the likelihood of success and significance of the research in advancing public health, the degree to which the research is likely to promote health equity, the projected economic and opportunity costs in implementing the research, the ease of integration of discoveries into the health care system, the public acceptability of the research, and the possibility of unintended consequences.

Translational bioethics programs linked to institutions funded to conduct translational science are similar in some respects to the Ethical, Legal, and Social Implications (ELSI) Research Program of the NIH.[11] Since the launch of the Human Genome Project in 1990, the ELSI program has funded numerous grants addressing the societal implications of genomic research, clinical genetics, and nonmedical applications of new technologies, such as DNA forensics. ELSI researchers are primarily funded by individual grants awarded and administered by the National Human Genome Research Institute.

Although the ELSI program is one model,[12] it has some drawbacks in the context of translational science. For example, separate research grants would lack continuity and integration with NCATS-funded research, and the process of obtaining grant funding likely would make the research process much longer than research conducted by embedded personnel. Other models also could be considered, including Belmont Report–type panels on various issues such as gene therapy and neural implants, and incorporating substantial public input.[13]

To be successful, translational bioethics programs need to be endorsed and supported by the NIH, institutional research administrators, and translational research investigators. Translational bioethics program leaders should approach their roles with humility and understand that multidisciplinary collaboration among and aside from NCATS-funded institutions is essential.

CASE STUDY: COVID-19

The recent experience with vaccines for COVID-19 illustrates how social and political factors can affect the uptake of novel public health interventions developed by Clinical and Translational Science Awards (CTSA)-supported or other researchers. At the height of the COVID-19 pandemic, when the first two mRNA vaccines received emergency use authorization from the Food and Drug Administration,[14] the public response varied widely. The hope and relief of public health officials and most of the public were met with ambivalence or outright hostility by a significant and vocal minority of the population.[15] The resulting, suboptimal vaccination rate led to an estimated 234 000 unnecessary deaths in the United States[16] and presented stark lessons to learn.[17]

Widespread vaccine hesitancy and refusal, however, should not have been a surprise. The United States has a long history of political divisions regarding public health interventions, including vaccination. For example, during the H1N1 influenza outbreak in 2009, millions of people refused vaccination, and millions of doses of vaccine had to be destroyed, with political party affiliation highly correlated with the likelihood of vaccination.[18]

Opponents of COVID-19 vaccination asserted libertarian arguments against coercive vaccine mandates, claims that the emergency use authorization was rushed, and even claims that the mRNA platform was genotoxic.[19] The technology used in the mRNA vaccines was developed over decades, and the COVID-19 vaccine was formulated and tested for the better part of a year.[20] This time period provided an opportunity for multidisciplinary research in psychology, sociology, political science, and other fields to consider possible personal, religious, and political objections.

It is debatable whether embedded bioethics analyses concurrent with vaccine development would have increased the uptake of the vaccine in the United States, but such an analysis and possible policy recommendations would have been justified by the gravity of the situation. With mRNA cancer vaccines and similar technologies on the horizon,[21] comparable issues undoubtedly will arise again.

The pandemic also presented numerous other important issues for translational bioethics assessments, including international cooperation in research to develop emergency preparedness strategies, open access to essential data such as genome sequences of emerging pathogens and epidemiological data, new surveillance measures such as wastewater studies, digital passports and other measures to monitor individual disease status,

intellectual property laws and reimbursement policies on access to therapeutics, and a range of health equity issues—both domestically and globally. Although these vital issues have been and continue to be the subjects of ethical and policy analysis, integrating social sciences, humanities, bioethics, and public health policy with innovative translational science research is a strategy worth pursuing.

CONCLUSION

A major rationale for translational bioethics is recognition that scientific advances are not discovered, produced, and adopted in a vacuum. The value of even spectacular scientific discoveries is not self-evident to many nonscientists, and unintended negative social and economic consequences of innovative research are always possible. Individuals and institutions undertaking groundbreaking translational research have a moral obligation to support academically rigorous consideration of the societal implications of their research.

Translational bioethics aligns well with the traditional goals of public health ethics.[22] Although many questions remain about the funding, structure, and scope of translational bioethics, it has the potential to provide valuable, timely, multidisciplinary perspectives on significant societal issues. A highly beneficial outcome of translational bioethics programs would be aiding the seamless adoption and integration of impactful translational research that improves public health. AJPH

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PUBLICATION INFORMATION

Full Citation: Rothstein MA. Translational bioethics and public health. *Am J Public Health*. 2023; 113(10):1055–1058.

Acceptance Date: June 3, 2023.

DOI: https://doi.org/10.2105/AJPH.2023.307362

ACKNOWLEDGMENTS

Kelly Carty Zimmerer provided excellent research assistance.

CONFLICTS OF INTEREST

The author has no conflicts of interest to declare.

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