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Governance of Emerging Technologies in Health and Medicine — Creating a New Framework

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With scientific innovation accelerating and becoming increasingly decentralized, technologies are diffusing rapidly across previously stable boundaries, no longer staying in their assigned regulatory, market, or academic lanes. Genetic testing — no longer confined to the laboratory or clinic — is now available directly to consumers and is used in law enforcement, immigration, and other areas for diagnosis, identification, and entertainment. Neurotechnologies — such as transcranial direct current stimulation, transcranial magnetic stimulation, and transcutaneous electrical nerve stimulation — are being sold to and used by the public for a variety of applications, and they are sometimes even being built by laypeople from kits or according to instructions available online. And artificial intelligence and machine learning have permeated many areas of human endeavor and created new, virtual spaces in which people can operate, interact, and innovate.

Our current laws, regulatory bodies, and other governance structures — both "hard" (such as legally binding laws and regulations) and "soft" (such as voluntary guidelines, standards, and norms) — were largely built for a research, development, and market landscape that has changed substantially over recent years. As a result, our current approach to governance is no longer fit for purpose. Part of the challenge to our current system is encapsulated in the so-called Collingridge dilemma: early in a new technology's development, uncertainty and minimal evidence about its impact impede policymaking, but once the technology has diffused and harmful effects have become clear, it may be too late to act.[1] Furthermore, diffusion across boundaries means that no single regulatory agency has the full picture of a technology or complete jurisdiction over it: the regulation and governance of genetic testing, for example, vary with the domain in which it's used — whether in a research, clinical care, law enforcement, or direct-to-consumer context. Finally, the speed of evolution and diffusion demands iterative, dynamic governance. We need a more comprehensive or coordinated approach to ensure that we have a broad view of the development and evolution of technology across sectors (government, private, nonprofit, academic, consumer, or volunteer), applications, and stakeholders.

ETHICAL CONSIDERATIONS

In addition to acceleration and broader diffusion, there is increasing awareness within many fields (including medicine, public health, bioethics, and policy) that new technologies affect our societies in uneven ways, with some populations or groups receiving benefits, others being harmed, and still others — for good or ill — having no access to the technology at all.[2] Frequently, these patterns recapitulate or exacerbate existing structural inequities, and such effects can play out at national and global levels.

New technologies in health and medicine may not be fundamentally causing structural inequality, and they alone cannot solve this societal problem. However, the shared goal of improving human well-being that undergirds associated government funding, regulation, and oversight and professional commitments creates a responsibility not to exacerbate such inequities and to ameliorate them whenever possible.[3] Beyond questions of equity, it has long been recognized that the development and use of many emerging biomedical technologies can raise fundamental moral and ethical questions (such as questions regard-

ing intervening in the human brain or modifying the genome) as well as concerns related to dignity, civic responsibility, beneficence, and other human values.[4]

But many of our hard governance mechanisms (regulation by the Food and Drug Administration, for example) focus primarily on individual safety and have not historically had the mandate to take such broad principles and values into account. Furthermore, we do not have good tools or frameworks for helping scientists, technologists, policymakers, and other stakeholders translate ethical principles and values such as equity, fairness, and collective good into concrete science and health policy choices. Finally, many emerging technologies will have lasting future effects, but we lack mechanisms for discussing how much weight to place on future uncertainties.

DIVERSITY OF INPUT

Admittedly, shifting our governance approach away from the historically siloed model that expects technologies to stay within an individual regulatory agency's purview and toward a more coordinated approach that includes both hard and soft governance and applies a cross-sectoral lens will be challenging, as will shifting our governance focus away from more narrow concerns such as safety and toward broader principles such as justice and fairness. That said, we are in a moment when real change is necessary and may be possible. In part because of the societal upheaval and reckoning catalyzed by the Covid-19 pandemic and the Black Lives Matter movement, the public, academics, business leaders, and policymakers have recognized the need to build trust and to ensure that advances in technology promote rather than frustrate societal interests. Furthermore, the sudden and radical restructuring of daily life caused by the pandemic has opened our eyes to the possibilities of policy change and flexibility.

To lay the groundwork necessary to facilitate these shifts, we believe that diverse experts from a range of disciplines and multiple sectors should come together to assess the landscape of emerging scientific advances and technologies in health and medicine and to explore their potential societal, ethical, legal, and workforce implications, with the goal of developing a cross-sectoral governance framework that guides and facilitates the translation of ethical principles into meaningful policy choices.

Key to any change in approach or focus will be the views of a diverse set of actors who shape the development and use of new technologies at every stage of the technology life cycle. In particular, the perspectives of three key constituencies will need to be solicited and attended to: individual users and society, those who directly use the technology and live in the world shaped by it; "drivers" of technology, those who play a central role in designing and developing a technology (e.g., scientists, innovators, research funders, and investors); and formal governance actors (e.g., policymakers and regulators).

As noted above, governance of emerging technologies often occurs in technology or sector-specific silos, but the complexity of current technology development and diffusion makes it impossible for any single entity to fully govern emerging technologies.[5,6] The successful development and adoption of new scientific knowledge and technologies for societal benefit depend on an effective and enlightened health-and-medicine governance ecosystem that considers benefits, risks, values, and incentives across sectors from the earliest stages of discovery and innovation to proactively assess and adjust the upstream decisions that shape downstream impact.

Furthermore, we must understand what counts as risks and benefits to individuals and groups and what values they bring to discussions of emerging technologies in health and medicine. Science can tell us whether we can do something and often whether it is safe, but the questions of whether we ought to and how we should proceed are not solely scientific ones. "Ought" questions require information about the values and interests of a given society, which may vary widely, and the scientific community is unlikely to have expertise in these areas. In addition, the scientific community may not have sufficient information at the outset to assess long-term implications.

ESSENTIAL ELEMENTS

It is critical to ground any effort to develop new modes of governance within a real-world context. Three elements that we believe should be part of any comprehensive approach to developing a new

governance framework are the integrative use of case studies, foresight or visioning exercises, and ethical principles and values.

First, a series of case studies that are representative of the landscape of emerging technologies can be useful, particularly if the technologies chosen have both a track record of development and governance and anticipated growth and evolution. Each of the case technologies should undergo an examination of its governance and effects across a range of sectors, such as academia, health care and nonprofit organizations, government, the private sector, and volunteers or consumers. In addition to illustrating the potential implications of new technologies for health and society, case studies can examine how governance has developed in each sector and describe how siloed governance has created challenges or fallen short. These explorations should also consider the multitude of stakeholders, factors, and interactions that shape the translation of technologies within and across sectors, as well as the benefits, risks, and societal implications associated with a technology's development.

Second, although it is critically important to examine the existing evidence base to understand what has worked and what has not, technologies or applications may rapidly evolve in ways that were not anticipated at the outset and that thus pose unforeseen challenges to society. Such evolution can be helpful to imagine and articulate, building on the solid foundation of the case study. A "visioning" component can flesh out one or more plausible futures, describing how a technology might evolve over the next 5 to 10 years and the societal implications of a particular evolutionary trajectory. This type of work typically traces and brings to life additional technological paths, social disruptions, and future contexts that should inform emerging technology governance.

Third, equally important for the comprehensive assessment of a technology are the principles and values that guide and shape its governance. Many governance documents have articulated a set of commonly held principles, but we propose that a new governance framework should take those principles further, to implementation. The principles should be not only the foundation of the framework but also the standards against which we gauge the success of governance.

A resilient framework should permit assessment of a technology along a range of axes (e.g., affordability, access, and distribution of benefits and harms), both at a particular point in time and iteratively as the technology and its use evolve. Assessments of performance on these measures would provide concrete indicators or markers of alignment with the framework's guiding principles and values. By integrating key elements that facilitate systematic and explicit consideration of the many factors that may affect a governance decision, such a framework can inform and encourage important dialogue and help stakeholders clarify what has value, why, and in what context.

Such a framework would not itself impose or imply a particular judgment about the inherent value or benefit of a given technology. Rather, it would guide collection of the information necessary for decision making that would enable the governance ecosystem to be adjusted systematically and routinely to better align the effects of a technology with guiding principles focused on societal benefit.

With these goals in mind, the National Academy of Medicine (NAM) has formed the Committee on Emerging Science, Technology, and Innovation (CESTI) in health and medicine[7] to serve as a platform for convening diverse stakeholders who have insights into the different aspects of emerging technology in order to assess governance in health and medicine and drive collective action. Committee members are drawn from diverse academic disciplines, professional backgrounds, and sectors and have been tasked with developing data-based, principle-driven, key elements of a novel governance framework that can help shape a new governance ecosystem. The NAM effort will assess the existing governance of emerging technologies with a focus on identifying gaps and unintended consequences of the current ecosystem; consider how to empower stakeholders in emerging technologies by ensuring that they have the appropriate incentives to facilitate the development and use of transformative technologies while mitigating risks and enhancing societal benefit; and recommend specific strategies and practical approaches to improve cross-sectoral and coordinated governance (e.g., by means of forecasting mechanisms, principle-based governance levers, and robust public engagement) and to align governance with guiding ethical principles and values. CESTI's foundational work will inform a

consensus study designed to provide concrete, actionable recommendations for implementing a coordinated, cross-sectoral governance ecosystem for emerging science and technologies in health and medicine, focused on societal benefit.

The past 2 years have taught us many lessons, including that trust in science and medicine is tenuous and precious, that existing inequities must be addressed, and that coordinated governance can facilitate the rapid translation of health and medical innovation. We have also learned that dramatic and responsive policy change is possible. These are the lessons that we believe should guide the development of a new governance framework and ultimately a new governance ecosystem for emerging science, technology, and innovation.

Disclosure forms provided by the authors are available at NEJM.org.

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