Practical Approaches to Enhancing Fairness, Social Responsibility and the Inclusion of Diverse Viewpoints in Biomedicine

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Workshop Description

In biomedical research and clinical medicine, many of the ethical frameworks and processes focus on benefits and harms at the individual level. However, in biomedicine, there is increasing recognition of a need to implement frameworks and processes that address the social impacts of technologies, such as genomics and AI technologies, and their social benefit for underrepresented populations and communities. For example, studies demonstrating the potential for bias in AI shed light on the need to develop processes to more effectively identify and address downstream impacts of medical AI, as well as engage communities who are stakeholders in the research. Privacy is often envisioned as an individual right, but the collection and use of data also have repercussions at the level of groups and communities. For that reason, there have been recent efforts to arrive at models for data stewardship and data sovereignty. This workshop will provide a forum for discussion of practical approaches to enhancing fairness, social responsibility and inclusion of diverse viewpoints in biomedicine. Interdisciplinary research on ethics and how fairness, social responsibility, and community engagement can be operationalized in biomedical research will provide a foundation for robust discussion on these issues.

The 3-hour workshop will consist of two parts:
- The first part will include a series of 15-minute talks that address fairness, social responsibility & inclusion/community engagement for different areas of biomedicine, followed by an audience Q& A and discussion of the topics such as diversity in precision medicine, ethical and sustainable data stewardship, and public engagement with social and behavioral genomics.
- For the second half of the workshop, weare conducting an interactive exercise with the audience. Focusing on case studies, based on topics from the first half of the workshop, such as community engagement and data stewardship, we will use smartphone-based polling to facilitate feedback from the audience on approaches, challenges and solutions for addressing the ethical issues from the case study.

Learning Objectives

By the end of this workshop attendees will be able to:

1. Understand the social and political context that underlays the need for frameworks and processes that more effectively address the impacts of these technologies on individuals and communities.
2. Explore and analyze efforts to identify and address the downstream harms and benefits of biomedical technologies
3. Locate actors that have the ability to mitigate the downstream harms of biomedical technologies and/or the ability to promote its downstream benefits.

Presenter Information

This workshop brings together rich and interdisciplinary perspectives from medical anthropology, biomedical engineering, education, and bioethics, as well as, legal perspectives. Importantly, our multidisciplinary and multi-institution workshop aims to do more than provide the PSB community with the opportunity to come together to analyze and evaluate efforts to enhance social responsibility and the inclusion of diverse viewpoints in biomedicine. We offer workshop attendees strategies for intervening to assist with promoting fairness, social responsibility, inclusion, and justice in biomedical research and practice.

About the Workshop Organizers

Daphne Martschenko, Ph.D., is an Assistant Professor at the Stanford University Center for Biomedical Ethics and a co-organizer of the international Race, Empire, and Education Research Collective. Dr. Martschenko holds an MPhil from the University of Cambridge in Politics, Development, and Democratic Education and in 2019 received a Ph.D. in Education, also from the University of Cambridge. Dr. Martschenko's work advocates for and facilitates the ethical and responsible conduct of and public engagement with genetic/genomic research.

Nicole Martinez-Martin, JD, Ph.D., is an Assistant Professor at the Stanford Center for Biomedical Ethics. She received her JD from Harvard Law School and her doctorate in social sciences (comparative development/medical anthropology) from the University of Chicago. Her broader research interests concern the impact of new technologies on the treatment of vulnerable populations. Her recent work in bioethics and neuroethics has focused on the ethics of AI and digital health technology, such as digital phenotyping or computer vision, for medical and behavioral applications.

Meghan Halley, PhD, MPH, is a Senior Research Scholar in the Stanford Center for Biomedical Ethics (SCBE) at Stanford University. She completed her doctorate in medical anthropology from Case Western Reserve University in 2012, and additional training in health services research at the Palo Alto Medical Foundation Research Institute from 2012 through 2016. Her current research focuses at the intersection of the ethics and economics of new genomic technologies. Her current projects include examining ethical issues related to sustainability and governance of patient data and relationships when large clinical genomic studies transition to new models of funding; ethnographic work exploring how diverse stakeholders perceive value in

the use of genome sequencing for diagnosis of rare diseases; and the development of new measures for assessing patient-centered outcomes in pediatric rare diseases.

Presentations

- Daphne Martschenko, PhD, Assistant Professor in Biomedical Ethics, Stanford University: "Wrestling with Public Input on Social and Behavioral Genomics" reporting on scholarship gathering the perspectives of members of the public on the risks and potential benefits of social and behavioral genomics.
- Mildred Cho, PhD, Professor in Biomedical Ethics, Stanford University, reporting on the use of hypothetical design exercises in order to examine values in biomedical AI/ML development
- Meghan Halley, PhD, MPH, Senior Research Scholar in Biomedical Ethics, Stanford University: "Toward more ethical and sustainable data stewardship in rare disease research" reporting on the parameters of ethical data sharing and sustainability in rare disease research, involving perspectives on cloud-based genomic databases.
- Krystal Tsosie, PhD, MPH, Assistant Professor, School of Life Sciences, Center for Biology and Society, Arizona State University: "Platforms Not Platitudes: Operationalizing Ethics and Advancing Indigenous Data and Digital Sovereignty" on community data governance and stewardship with digital data tools rooted in machine learning and dynamic consent e-platforms
- Carole Federico, PhD, GSK.ai-Stanford Ethics Fellow, Stanford University: "Synthetic Data for Biomedicine: Epistemic and Ethical Challenges".
  Interactive Hypothetical Design Case Study Presentation:
- Nicole Martinez-Martin, JD, PhD, Assistant Professor in Biomedical Ethics, Stanford University
- Mildred Cho, PhD, Professor in Biomedical Ethics, Stanford University
- Tiffany Bright, Co-Director Center for Artificial Intelligence Research
  Cedars-Sinai, Computational Biomedicine

Speaker Presentations

The speaker presentations will provide examples of how issues of diversity and inclusion, as well as social responsibility, are being engaged in the fields of genomics and machine learning in medicine.

Genes, and the social narratives we tell about them, continue to grip the popular imagination. In particular, claims regarding genetic differences in human behavior and social outcomes have been a pervasive and often ugly feature of American society since the eugenics movement of the twentieth century. Today, researchers in the rapidly growing field of social/behavioral genomics investigate whether and how genetic differences between individuals relate to differences in behaviors (e.g., aggressive behavior) and social outcomes (e.g., educational attainment), as well as how genetic information can inform the design of social/behavioral studies. There is staunch and polarizing academic debate about the risks and benefits of this science. Many researchers are optimistic that this work will increase understanding of human behavior, improve health and well-being,

and reduce societal inequality. Others worry about its potential to be misused in service of racist, classist, and ableist claims.

Defining the harms and benefits of research has traditionally been left to researchers, professional societies, and regulatory bodies. In the US, researchers are regulated by policies such as the Common Rule (45 CFR 46), research ethics committees, and Institutional Review Boards (IRBs). These systems of regulation guide the ethical conduct of research by ensuring studies have an acceptable risk-benefit profile such that potential harms (i.e., risks) are minimized and potential benefits enhanced.

Confining debate about the threats and promises of social and behavioral genomics to the research community is limiting. Academic considerations of the harms and benefits of research, generally neglect to consider the broader social impacts. IRBs are expressly prohibited by the Common Rule from considering any broad social or policy risks. IRBs generally don't regulate risks other than those directly encountered by research participants. However, per the Common Rule, IRBs are allowed to judge the broader social benefits of research; that is, whether research has the potential to enhance health or knowledge. As a result, existing mechanisms for regulating the ethical conduct of research are limited in their ability to appraise the downstream implications of research, especially the potential social harms.

Daphne Martschenko, PhD (Stanford University) will present the results of an 18-month effort to gather input from an 11-member Community Sounding Board comprised of individuals from across the United States on the risks, benefits, and ethical responsibilities of social and behavioral genomics. Attendees will leave this presentation with tools that can help them better elicit and engage public perspectives to produce socially and ethically informed decisions about whether and how to conduct biomedical research, as well as socially and ethically responsible policy decisions and research communication.

The presentation by **Krystal Tsosie, PhD, MPH** (Arizona State University) will provide an overview of how community data governance and stewardship with digital data tools rooted in machine learning and dynamic consent e-platforms have been applied to advance Indigenous Data and Digital Sovereignty.

Mildred K. Cho, PhD (Stanford University) has conducted research regarding the integration of ethical values into medical AI/ML. Her most recent work examines the use of hypothetical design exercises in order to support ethics in the development of AI/ML applications in medicine. **Carole Federico, PhD** (GSK.ai-Stanford Ethics Fellow) will discuss ethical issues relevant to synthetic data, with a focus on representativeness and fairness in synthetic data and practical challenges in applying existing ethical frameworks to synthetic data.

Machine learning predictive analytics (MLPA) are increasingly utilized in health care to reduce costs and improve efficacy. The growth of MLPA could be fueled by payment reforms that hold health care organizations responsible for providing high-quality, cost-effective care. At the same time, policy analysts, ethicists, and computer scientists have identified unique ethical and regulatory challenges from the use of

MLPA in health care, and they have also proposed a variety of principles and guidelines focused on confronting these challenges.

However, critical gaps in knowledge have challenged our ability to assess these potential solutions. Understanding the perspectives of MLPA developers is essential for overcoming the "principles-to-practice" gap. **Meghan Halley, MPH, PhD** (Stanford University) will present a study that sought to better characterize available MLPA health care products, identifying and characterizing claims about products recently or currently in use in US health care settings that are marketed as tools to improve health care efficiency by improving quality of care while reducing costs. The research team conducted systematic database searches of relevant business news and academic research to identify MLPA products for health care efficiency meeting our inclusion and exclusion criteria. Their findings provide a foundational reference to inform the analysis of specific ethical and regulatory challenges arising from the use of MLPA to improve healthcare efficiency.

Mildred Cho, **PhD** (Stanford University) has conducted research examining how developers of machine learning applications in healthcare envision and put values into practice in their work. Using a case study approach that draws from issues from the workshop presentations, Dr. Cho, **Nicole Martinez-Martin, JD, PhD** (Stanford University) and **Tiffany Bright**, **PhD** (Center for Artificial Intelligence Research Cedars-Sinai) will lead the audience in an interactive discussion regarding how values of diversity, representation and social responsibility are put into practice in the work of researchers in genomics and computational biomedicine.