



HHS Public Access

Author manuscript

Am J Bioeth. Author manuscript; available in PMC 2019 April 01.

Published in final edited form as:

Am J Bioeth. 2018 April ; 18(4): 34–36. doi:10.1080/15265161.2018.1431328.

Trust, precision medicine research, and equitable participation of underserved populations

Dr. Maya Sabatello, LLB, PhD,

Assistant Professor of Clinical Bioethics and Co-Director, Precision Medicine: Ethics, Politics, and Culture Project, Department of Psychiatry, Columbia University

Dr. Shawneequa L. Callier, JD, MA,

Associate Professor, Department of Clinical Research and Leadership, School of Medicine and Health Sciences, The George Washington University

Dr. Nanibaa' A. Garrison, PhD, and

Faculty at the Treuman Katz Center for Pediatric Bioethics at Seattle Children's Hospital and Research Institute; and Assistant Professor, Department of Pediatrics in the Division of Bioethics at the University of Washington School of Medicine

Dr. Elizabeth G. Cohn, PhD, RN

Rudin Chair of Community Health, Hunter-Bellevue School of Nursing, City University of New York; and Associate Director, Community Engagement Core Resource, Irving Institute for Clinical and Translational Science, Columbia University

Through the use of culturally-appropriate videos on precision medicine research (PMR) that were developed and tailored to 5 racial and ethnic groups of patients, and subsequent focus group discussions, Kraft and colleagues (2018) innovatively explored the role of trust in patients' values, expectations and concerns about PMR at the individual and institutional levels. On the basis of their findings, the authors made suggestions for improving trust and trustworthiness that should serve as a base-line for further investigation. In this commentary, we consider two primary issues that stem from this study: 1) patients' trusting relationships with their physicians may prompt stronger interest to enroll in PMR (a "spillover effect"), and 2) participants may be more vulnerable to the ramifications of an increasingly blurred distinction between research and clinical practice, specifically, the risk of therapeutic misconception and expectations to reap benefits from PMR. These issues raise complex questions given the privatized healthcare system in the U.S. and the promise of PMR as an emerging approach to healthcare provision with an aim to reduce health disparities. Our discussion centers on underserved populations that were not included in the study. We argue that as principles of justice and fairness require that the burdens of participation be shared fairly among the general population, inclusivity in PMR requires a concomitant and diligent consideration of equitable access to research and its benefits for individuals and communities.

Spillover effects in underserved groups

Focusing on recent patients of a healthcare system in northern California, a major finding of Kraft et al.'s study is that willingness to participate in PMR is contingent on patients' perceived trustworthiness of the physicians, researchers, healthcare system, government and corporate institutions that are involved in the research. Although the study did not define or systematically assess levels of trust, which would have been desirable for a systematic comparison across racial/ethnic groups, participants' responses suggested that patient-physician relationships are instrumental for trust and willingness to enroll in PMR, and importantly, that—especially among historically marginalized groups—there is a “spillover effect”: trustworthiness of research is inextricable from patients' personal and group experiences with biomedical research and clinical care.

These findings are consistent with previous reports about the impact of (especially negative) individuals' experiences in medicine on attitudes about research (and vice versa) (King 1998). They are particularly poignant for enrollment into PMR given that the existing healthcare system makes it difficult for patients and potential PMR participants to develop necessary trust-based physician-patient relationships. Besides the market-based privatized healthcare system and its entanglement with industry's interests, the system often fails to provide stable and consistent health insurance coverage (e.g., consider patients who move frequently or experience high provider turnover in low-resourced settings). Consequently, nearly half of all Americans are uninsured or underinsured. Against this backdrop, ongoing health inequities could make it difficult for PMR to win over an already skeptical public.

These deficiencies in healthcare delivery are particularly prevalent among historically marginalized groups in *low-resourced* settings (Sohn 2017)—i.e., African American, Hispanic, and American Indian/Alaska Native populations, and people with disabilities—who were not included in Kraft et al.'s study and for whom, without systemic changes, the status quo with regard to low quality patient-physician relationships is likely to last. This status quo places PMR in a precarious position. Although PMR is expected to extend beyond race and genomics to include environmental and lifestyle factors on health interventions and outcomes, the latter have historically been neglected. Poor social determinants of health remain a major factor for negative health outcomes among African American communities, for example, and yet they are too often ignored (Bentley, Callier, and Rotimi 2017). Similarly, without proactive strategies in place, the prevalence of inaccessible healthcare facilities and equipment (e.g., weighing scales) and researchers' insufficient knowledge about how to design disability-accessible studies will limit the enrollment of persons with disabilities into PMR programs (Sabatello 2017). And, as had occurred with many American Indian and Alaska Native tribes, distrust and concerns about participation in genomic research emerged in the aftermath of misuses of biospecimens, stigmatizing interpretations and privacy violations that may have reflected broader misunderstanding and disrespect for these communities (Garrison 2013). Through careful efforts, trust can be gained by deliberate and meaningful engagement but will remain diminished in the long term if these same barriers continue to block access to the potential benefits of precision medicine.

The role of trust-based physician-patient relationships for PMR enrollment raises two additional interrelated concerns. First, Kraft et al.'s study suggests that patients have considerable trust in their physicians, to the point of a patient granting an automatic 'yes' to a physicians' invitation to enroll in PMR (page 10). Such a response increases the risk of uninformed decision-making. Indeed, while Kraft et al.'s study suggests that patients view their physicians as key messengers, physicians may neither share this expectation nor desire to take on this role. Further, physicians may lack the necessary genomic knowledge to inform participants appropriately (Mikat-Stevens, Larson, and Tarini 2015). Without appropriate measures for closing this "expectations gap," there is a risk that patients' confidence in their physician will erode over time or backfire when it comes to patients' initial enrollment or continued participation in PMR—neither of which is desirable. Second, as research moves out into the community, the use of trusted messengers—who especially in underserved populations may be a community or religious leader—raises the question of participants enrolling based on existing trust in the messenger and not necessarily on the robust nature or clinical objective of the study. The normative requirement that a participants' decision to enroll is well-informed about the risks and benefits is thus heightened.

To alleviate these concerns, we question how to best educate, recruit, enroll and manage participants in PMR. One possibility is a flexible team of interdisciplinary professionals that can be utilized, depending on the need and complexity of the study. Such a team could consist of members with substantial sociocultural and genomic knowledge, including understanding of translational genomics in clinical settings (from genetic counseling to reproductive and preventative care) and would be well equipped to facilitate the expectations and understanding of participants who enroll in PMR.

Vulnerabilities relating to the increasingly blurred research-clinical distinction

As responses in Kraft et al.'s study indicate, participants in PMR are vulnerable to therapeutic misconception (e.g., pg. 10). The increasingly blurred line between clinical care and research is commonly cited as a primary reason for this result. The PMR's ideal of providing the right drug to the right patient at the right dose may further lead to misperceptions of the research. And, investigation into lifestyle behaviors, local environments, diets, and genes could reasonably make participants believe that study results will be tailored to them and their communities rather than the general population.

Concurrently, there is a need to inquire how and which practices by healthcare providers and other personnel involved in PMR may further blur—or clarify—the distinction between medicine and research for all participants. Importantly, there is a need for consideration whether this distinction can, and should, remain if PMR is to ensure equal access to benefits across racial, ethnic and other minority groups.

For instance, PMR enrollment by researchers working within a healthcare system may be confusing for patients, especially those from underserved communities who may hope to receive healthcare services they often lack. The possibility of uncovering—and possibly,

returning—medically relevant results further requires consideration. This issue has been extensively discussed in literature on genomic research and flagged for its role in blurring traditional distinctions between patients and research participants. However, its relevance for underserved populations requires additional caution given Kraft et al.'s report that non-white participants expressed concerns about not reaping research benefits. Studies with Blacks and African Americans, for example, indicate that consideration of potential benefits to themselves, relatives, and community members is integral to their decision-making about enrollment (Halbert et al. 2016; Cohn et al. 2015), and significantly, that some may decline receiving genetic results due to concerns about a lack of access to healthcare that would allow them to follow up on actionable results (Yu et al. 2013). Current guidance recommends anticipating and communicating potential options for return of genomic results at the beginning of a study during the informed consent process. However, this approach may be insufficient for ensuring that participants from underserved communities have equal opportunities to benefit from return of results policies or, for that matter, generalizable knowledge in the future due to the access barriers described above. Such quandaries may exacerbate, not reduce, distrust in PMR enterprises.

In this regard, Kraft et al.'s finding that non-white patients are aware of research harms in particular racial/ethnic groups and that distrust over “group harm” may extend to other racial/ethnic groups is particularly telling. As scholars have argued, the powerful memory of the Tuskegee Study of Untreated Syphilis in the Negro Male is grounded in the *inaction* of the federal government and partner researchers who withheld available treatment from participants (Reverby 2009). During the course of PMR, investigators are likely to uncover details about environmental exposures, genetics, and lifestyle habits that could have an immediate effect on participants' health and health outcomes. Physicians and institutions invested in PMR should consider this potential paradigm shift, the implications thereof for trust and trustworthiness across minority groups, and the necessity of ensuring cost and resources to treat and counsel those involved in PMR enterprises.

The enduring impact of disparate and inaccessible medical treatment in the U.S., coupled with a well-known history of research abuse among marginalized racial and ethnic groups require that concrete efforts to address the concerns raised above be adopted (Kin 1998; Sabatello 2017). Appreciation of cross-cultural perspectives and creative solutions for research arrangements (e.g., data sharing) (Bentley, Callier, and Rotimi 2017; Garrison 2013) that ward off repeating historical wrongs are urgently needed, especially if participation is to be equitable.

Acknowledgments

This work was supported by grant funding from the National Institutes of Health: NHGRI K01 HG008653, K01 HG008818 and P50 HG007257-05S1.

References

1. King, PA. Race, justice and research. In: Kahn, JP., Mastroianni, AC., editors. *Beyond consent: Seeking justice in research*. Oxford & NY: Oxford University Press; 1998. p. 88-110.

2. Sohn H. Racial and ethnic disparities in health insurance coverage: Dynamics of gaining and losing coverage over the life-course. *Population Research and Policy Review*. 2017; 36(2):181–201. DOI: 10.1007/s11113-016-9416-y [PubMed: 28366968]
3. Bentley AR, Callier S, Rotimi CN. Diversity and inclusion in genomic research: Why the uneven progress? *Journal of Community Genetics*. 2017; 8(4):255–266. DOI: 10.1007/s12687-017-0316-6 [PubMed: 28770442]
4. Sabatello M. Precision medicine, health disparities, and ethics: The case for disability inclusion. *Genetics in Medicine*. 2017; 2017doi: 10.1038/gim.2017
5. Garrison NA. Genomic justice for Native Americans: Impact of the Havasupai case on genetic research. *Science, Technology and Human Values*. 2013; 38(2):201–223. DOI: 10.1177/0162243912470009
6. Mikat-Stevens NA, Larson IA, Tarini BA. Primary-care providers' perceived barriers to integration of genetics services: A systematic review of the literature. *Genetics in Medicine*. 2015; 17(3):169–176. DOI: 10.1038/gim.2014.101 [PubMed: 25210938]
7. Halbert CH, McDonald J, Vadaparampil S, Rice L, Jefferson M. Conducting precision medicine research with African Americans. *PLoS One*. 2016; 11(7):e0154850.doi: 10.1371/journal.pone.0154850 [PubMed: 27441706]
8. Cohn EG, Husamudeen M, Larson EL, Williams JK. Increasing participation in genomic research and biobanking through community-based capacity building. *Journal of Genetic Counseling*. 2015; 24(3):491–502. DOI: 10.1007/s10897-014-9768-6 [PubMed: 25228357]
9. Yu JH, Crouch J, Jamal SM, Tabor HK, Bamshad MJ. Attitudes of African Americans toward return of results from exome and whole genome sequencing. *American Journal of Medical Genetics: Part A*. 2013; 161a(5):1064–1072. DOI: 10.1002/ajmg.a.36610 [PubMed: 23610051]
10. Reverby, SM. *Examining Tuskegee: The infamous syphilis study and its legacy*. Chapel Hill: The University of North Carolina Press; 2009.