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Experiences at a Federally Qualified Health Center Support Expanded Conception of the Gifts of Precision Medicine

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In "Obligations of the Gift," Lee (2021) argues that ethical thinking regarding return of genetic research results has been too narrowly focused on individual consent and participants' "right to know" their genetic information. Early data collected in our NIH-funded study of All of Us Research Program recruitment at a Federally Qualified Health Center support Lee's claim that return of results should be understood within the context of a moral community engaged in delivering precision medicine. This community is composed not only of researchers and participants but also funders, insurers, healthcare policymakers, lawmakers, and others within the "healthcare enterprise." Lee argues that we should understand research participation as a gift "infused, not unfettered, by obligation" (59). Importantly, obligations expressed and created through research participation extend beyond the researcher and participant to others within the larger moral community implicated in precision medicine. Our preliminary results suggest two related findings: first, that the moral community implicated in precision medicine may include participants' family members, too; and second, that return of results to un/underinsured individuals raises serious questions about health justice and the distributed responsibility to ensure care related to medically actionable findings.

Our study [NIH R21 HG010531] examines participation in the National Institutes of Health's All of Us Research Program (AoURP), an unprecedented precision medicine initiative with the goal of collecting genetic, health, environmental, and other data from at least one million diverse individuals living in the United States. Through qualitative inquiry at one federally qualified health center (FQHC) serving as an All of Us recruitment, enrollment, and engagement site, our study seeks to understand what motivates individuals to enroll or not enroll in AoURP, why people do or don't continue participating over time, and how enrollees understand AoURP's stated commitment to engaging research participants as "partners." Our data collection has been on pause since March 2020 when AoURP suspended in-person recruitment due to the coronavirus pandemic. However, in January and February of 2020, we were able to complete key informant interviews with 14 FQHC staff involved in AoURP activities. The staff shared insights into participants'

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motivations for signing up or declining to participate. This is admittedly a small sample; nonetheless, some emergent themes support Lee's core claims.

First, our research suggests that FQHC patients are sometimes motivated to participate in precision medicine research because of anticipated health benefits not just to themselves, but to their current or future family. As one staff member told us, "they're saying, 'I want to do this for my family, for my grandkids.'" This seemed to be especially true for older participants. As Lee notes, access to one's genetic results is often framed as a benefit of participation in research. Several interviewees affirmed that FQHC enrollees in All of Us indeed are motivated by accessing their genetic information. One staff member, frustrated by delays in returning results, told us: "They want their genetic results back. They want what they signed up for." But the impact of these results was often framed in familial terms, such as the mother with a genetic disease who enrolled with the hope that research would help create better care options for her impacted children. Other enrollees expressed hopes for generational or community benefit from their participation. As one staff member put it, "a lot people are saying 'I want to do it for future generations, or for my community … I want the people that I'm around to benefit from this'."

These findings suggest that participants in precision medicine consider their kin as part of the moral community engaged in precision medicine research. When considering the return of genetic research results, research programs must consider that recipients of this information may include siblings, children, or other current or future relatives of the participant. Expectations of future benefit from research discoveries also extend to actual and future kin. What does it look like to situate the participants' kin within the moral community created through precision medicine research participation? Lee's paper does not answer this ethical question, but it provides a conceptual lens on research participation that permits its asking. This constitutes a step forward from narrow framings of the relevant ethical relationship as between the researcher and a single participant.

Second, precision medicine research must confront the challenges of returning genetic results to patients who are un/underinsured, as many FQHC patients are. Little consideration has been given to precision medicine research participants (or their families) who will struggle to receive care for potentially serious conditions they learn about through research participation. Three percent of AouRP participants are expected to receive medically actionable genetic results. While AoURP provides free genetic counseling to all participants, it does not cover the cost of confirmatory testing or follow up medical care.

FQHC staff expressed uncertainty and distress about the prospect of appropriately caring for patients who might receive actionable results. Staff are aware of existing barriers to accessing even the necessary confirmatory testing from a clinically certified lab, much less accessing ongoing and/or specialty medical care. They felt the obligation to ensure follow-up care should not be borne by the clinic alone. One staffer put it this way: "We have 1700 people in [AoURP] right now, and if 3% are going to test positive for an actionable medical genetic trait, then what? How is that thrown back on us?" She imagined what would happen for patients testing positive for Lynch syndrome, which carries an elevated risk of colon cancer, or for the BRCA1 or BRCA2 genes correlated with high risk for

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breast and ovarian cancers: “With Lynch, you should get colonoscopies every so often. If you’re BRCA1, BRCA2, maybe you’d go the route of double mastectomy and prophylactic hysterectomy. Those are all very costly operations, and I can’t imagine where we are going to come up with the money to support that.”

In its sample consent form on its website, AoURP states regarding medically actionable research results: “If you do not have insurance, or if your insurance will not pay, you will be responsible for the cost of followup care” (National Institutes of Health 2018, 8). Although this wording meets the obligation of informed consent, it leaves un/underinsured participants —and their health care providers—in a tight spot. To be fair, this is the norm for precision medicine research studies, and AoURP goes beyond most studies by offering free genetic counseling to participants. Still, one unique aspect of AoURP is its commitment to enrolling people who are underrepresented in biomedical research and to recruit at FQHCs, where patientparticipants, and their families, are more likely to be un/underinsured. These patients are typically left of out advances in genomics and other fields because they face myriad financial and structural barriers to accessing follow-up testing and specialized care for lifelong disorders. This reality puts into question the possibility of conducting just precision medicine research in the context of an unjust health system and profound social inequity. Precision medicine is premised largely on the promise of knowledge in the present and benefit in the future. This is, in the words of one of our interviewees, “an unsure promise.”

Lee’s article, citing Iris Marion Young’s work on justice and reciprocity, picks up on this issue and helpfully distributes the obligation to respond to this problem among a variety of sectors and actors: funders of precision medicine research, the medical centers where research takes place, clinicians and their professional organizations, policymakers crafting health law, and health insurers, to name a few. It’s important, too, to recognize that accessing the potential benefits of precision medicine (namely, improved health status and management) is inextricably linked with occupational status and safety, safe and consistent housing, food security, immigration policy, carceral policy and transportation, among other institutions and systems that structure our lives and influence our health. Securing the benefits of precision medicine for all demands that we see these connections. Our data show that they are already obvious to patients and staff on the front lines of precision medicine research. These same people should not have to shoulder the burden of overcoming structural inequities and injustice.

“Gifts are always about long-term relations, creating collective associations, and opening futures,” writes anthropologist P. Wenzel Geissler (2011, 59). This resonates with our research, where enrollees framed the benefits of their participation in generational terms that extended the obligations of their “gift” long into an imagined future in which (in the words of one staff member) “I can make sure that other people in my family or my neighbors don’t have the same health challenges that I face.” Yet, long before these hoped-for scientific discoveries may arise, participants may receive information about their own genetics that carry serious negative implications for their own health and demand medical attention beyond their means. Fulfilling the moral obligations of precision medicine requires collaboration across actors and sectors to address both present challenges to care and to

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deliver on futures promised—and hoped for—by those whose genetic “gifts” make research possible.

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