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Research and Applications

Demographic differences in willingness to share electronic health records in the All of Us Research Program

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ABSTRACT

Objective: Participant willingness to share electronic health record (EHR) information is central to success of the National Institutes of Health All of Us Research Program (AoURP). We describe the demographic characteristics of participants who decline access to their EHR data.

Materials and Methods: We included participants enrolling in AoURP between June 6, 2017 and December 31, 2019 through the Trans-American Consortium for the Health Care Systems Research Network (TACH). TACH is a consortium of health care systems spanning 6 states, and an AoURP research partner.

Results: We analyzed data for 25 852 participants (89.3% of those enrolled). Mean age = 52.0 years (SD 16.8), with 66.5% White, 18.7% Black/African American, 7.7% Hispanic, 32.5% female, and 76% with >a high school diploma. Overall, 2.3% of participants declined to share access to their EHR data (range across TACH sites = 1.3% to 3.5%). Younger age, female sex, and education >high school were significantly associated with decline to share EHR data, odds ratio (95% confidence interval) = 1.26 (1.19–1.33), 1.74 (1.42–2.14), and 2.44 (1.86–3.21), respectively. Results were similar when several sensitivity analyses were performed.

Discussion: AoURP seeks a dataset reflecting our nation's diversity in all aspects of participation. Those under-represented in biomedical research may be reluctant to share access to their EHR data.

Conclusion: In our data, race and ethnicity were not independently related to participant decision to decline access to their EHR information. Results suggest that the value of the AoURP dataset is unlikely to be constrained by the size or the racial/ethnic composition of this subgroup.

Key words: Trans-American Consortium for the Health Care Systems Research Network, African American, All of Us Research Program, electronic health record, diversity

KEY POINTS

Question: What demographic characteristics are associated with participant decision to decline access to their electronic health record (EHR) for the All of Us Research Program (AoURP)?

Findings: Younger age, female sex, and higher education emerged as characteristics related to a decision to decline access to the EHR. Race and ethnicity were not significantly related to this decision.

Meaning: Few AoURP participants enrolled through Trans-American Consortium for the Health Care Systems Research Network (TACH) declined access to their EHR information. In our study, racial and ethnic minoritized groups were not over-represented among those who decided to decline this access.

INTRODUCTION

The development of electronic health records (EHRs) has created new avenues for health and wellness at the health system level, while concomitantly expanding research potential through infrastructure that allows for the sharing and monitoring of patient care across healthcare networks.¹ The increased usage of EHRs has not gone unnoticed by patients. According to the Kaiser Family Foundation Tracking Poll, the number of persons reporting their physician's use of EHRs has doubled from 46% in 2009 to 88% in 2019.² Accompanying this expansion of health information technology is public scrutiny and concern with the security and privacy of patient data and health information.² This concern is within reason. In 2009, the Department of Health and Human Services' Office for Civil Rights began publishing summaries of healthcare data breaches on its website and has shown an upward trend of data breaches.³ Between 2009 and 2018, there were 2546 breaches, each involving more than 500 records.³ These data breaches resulted in the exposure of 189 945 874 healthcare records, representing more than 59% of the US population.³ While increased security measures have helped to reduce easily preventable breaches, hacking and unauthorized access and disclosures are not infrequent.^{2,3}

Knowledge of data breaches may serve to undermine the trust that patients have in healthcare research, especially racial and ethnic minoritized groups, who can easily summon historic episodes of the mistreatment of Black/African-American and other minoritized populations in research studies.⁴ This history is believed to have contributed to a reluctance of racial/ethnic minoritized groups to participate in research and an under-representation of minoritized populations in clinical trials.⁵ Relevant to diversity in research participation and the expansion of using the EHR for research purposes, the willingness of patients to share their EHR data for research is also reportedly lower among racial and ethnic minoritized groups.⁶⁻⁹ Studies conducted from 2011 to 2017 in which there was sufficient participant diversity for comparisons, have shown this to be true. In these studies, Black/African Americans and other groups under-represented in biomedical research (UBR) were more likely to have concerns about security of EHR information.^{7,8} Some of these studies have found differences not only by race, but found that people with low education^{6,8} and females⁶ were less likely to consent to sharing their EHR.

This article focuses on data from the All of Us Research Program (AoURP), a nationwide program funded by the National Institutes of Health, whose mission is to accelerate health research and medical breakthroughs, enabling individualized prevention, treatment and care for all of us. The goal is to recruit 1 million or more persons in the United States to share their unique health data, including surveys, physical measurements, biospecimens, and access to EHR data. Participant willingness to share EHR information is central to program success.

Participation of minoritized populations in the AoURP is a priority. AoURP will oversample those traditionally UBR to ensure sufficient "statistical power to make robust inferences within each group"—a key objective of the program.¹⁰

This analysis includes participants from the Trans-American Consortium of the Health Care Systems Research Network (TACH), an AoURP research partner, comprising the following institutions: Baylor Scott and White Health (Dallas, TX), Essentia Institute for Rural Health (Duluth, MN), Henry Ford Health System (Detroit, MI), Reliant Medical Group and the University Massachusetts Medical School (Worcester, MA), and Spectrum Health (Grand Rapids, MI). (TACH member HealthPartners, Minneapolis, MN, started enrolling participants after these data were obtained and analyzed.) Each TACH site represents a potentially different demographic profile (Table 1), creating an important opportunity to assess demographic trends in EHR information sharing. Each of the 6 TACH sites is described briefly below:

Essentia Health is an integrated, not-for-profit, 501(c)(3) healthcare delivery system with facilities in 3 states: Minnesota, Wisconsin, and North Dakota. About 84% of Essentia's geographical service area is classified as rural. In 2020, there were 1.6 million clinic encounters, 154 000 emergency room visits, 223 500 telehealth visits, and 37 350 inpatient hospital admissions. *Spectrum Health System* is Spectrum Health, is a not-for-profit, integrated, managed care health care organization based in West Michigan with subsidiaries including 14 hospitals, treatment facilities, urgent care facilities, as well as physician practices that serve the western Michigan area. Priority Health is a subsidiary health plan with 1 million members. *HealthPartners*, a 501c (3) nonprofit organization, is the largest consumer-governed nonprofit health care organization in the United States, providing care, health plan coverage, research, and education to its more than 1.8 million medical and dental health plan members and more than 1.2 million patients at over 300 locations across more than 50 specialties throughout Minnesota and western Wisconsin. *Reliant Medical Group* is a 500-provider community-based multi-specialty group practice at 20 locations in central Massachusetts. Reliant provides care to more than 300 000 patients with more than 1 million clinic visits each year. *Scott & White Healthcare* and *Baylor Health Care System* merged in October of 2013 to create *Baylor Scott & White Health* (BSWH). As the largest not-for-profit healthcare system in Texas, providing exceptional care at sites across 46 Texas counties, with over 7.5 million patient encounters annually. The *Baylor Scott & White Quality Alliance/Scott & White Health Plan* represents over 906 000 covered lives.

The objective of this article is to describe the demographic profiles of AoURP participants enrolled through TACH sites who provided consent to share their EHR, in comparison to those who declined to do so. This report not only allows some reflection on patient attitudes toward research but provides valuable insight into the

Table 1. Characteristics of the study sample

Variable	Overall n = 25 852	Baylor n = 9226	Essentia n = 1246	Henry Ford n = 6812	Reliant n = 1828	Spectrum n = 6740
Mean age (SD)	52.0 (16.8)	54.6 (16.6)	50.2 (16.9)	52.0 (16.3)	56.4 (17.4)	47.5 (16.4)
Age ≥65, n (%)	6865 (26.6)	2976 (32.3)	292 (23.4)	1705 (25.0)	686 (37.5)	1206 (17.9)
Female, n (%)	8402 (32.5)	3253 (35.3)	339 (27.2)	2067 (30.3)	632 (34.6)	2111 (31.3)
≤High school diploma, n (%)	6208 (24.0)	2686 (29.1)	152 (12.2)	1672 (24.5)	319 (17.5)	1379 (20.5)
Race, n (%) ^a						
White	17 186 (66.5)	5375 (58.3)	1119 (89.8)	3549 (52.1)	1570 (85.9)	5573 (82.7)
Black/African American	4846 (18.7)	1814 (19.7)	21 (1.7)	2487 (36.5)	45 (2.5)	479 (7.1)
Hispanic/Latino	1986 (7.7)	1337 (14.5)	<20 (1.5)	223 (3.3)	101 (5.5)	306 (4.5)
Am Indian/Alaska Native	114 (0.4)	38 (0.4)	<20 (1.4)	32 (0.5)	<20 (0.2)	24 (0.4)
Asian	456 (1.8)	141 (1.5)	23 (1.8)	146 (2.1)	37 (2.0)	109 (1.6)
More than one race	1264 (4.9)	521 (5.6)	47 (3.8)	375 (5.5)	72 (3.9)	249 (3.7)
Declined to share EHR, n (%)	581 (2.3)	118 (1.3)	44 (3.5)	175 (2.6)	64 (3.5)	180 (2.7)

^aRace and ethnicity are shown here according to how the question was presented to participants using the 2010 Census format.

general acceptance of tenets essential to the success of this large, national study.

METHODS

Study population

The work described here was proposed by Consortium members and was confirmed as meeting criteria for “non-human subjects research” by the All of Us Institutional Review Board. The population for this study was drawn from participants in the All of Us Research Program at the 5 TACH sites described above who enrolled in All of Us between June 6, 2017 and December 31, 2019.

The primary consent process had 2 components. The first consent covered surveys and collection of biospecimens. A second consent asks participants to share access to their EHR information whereby participants are given the opportunity to select “agree” or “disagree.” For the TACH consortium, participants that decline to share their EHR are not invited to donate biospecimens and consequently will not have their genetic information analyzed. To address questions regarding identifiable data, the Frequently Asked Questions section of the All of Us website contains information about encrypted data and the removal of “obvious identifiers from data used for research [. . .]. This means names, addresses, and other identifying information is separate from the health information.” The consent process is digital, and while FAQs are available, person-to-person discourse between program staff and potential participants is only available if the potential participant were to reach out to local email/phone numbers or to the national support center.

The study sample for the analysis was categorized into 2 groups: (1) those who consented to share their EHR data and (2) those who declined to share their EHR data. Participants who did not view or complete the EHR consent document were not included in this analysis. Between June 6, 2017 and the official launch date of May 6, 2018, institution employees, friends, and family were encouraged to participate (pre-launch participants). Final analyses were conducted with and without pre-launch participants.

We present race/ethnicity the way it is presented to participants in the Basics Participant-Provided Information (PPI) module in which demographic information is provided. The question format is based on the race/ethnicity question asked prior to when the race and ethnicity questions were separated in the 2020 Census.¹¹ In our analysis, we have modeled race and ethnicity according to participant self-report of Hispanic versus Non-Hispanic + selected race.

Statistical analysis

For this analysis, we compared demographic characteristics (age, ethnicity, race, sex, and education) by declining EHR access. Cells counts of <20 persons are suppressed in all tables (<20), in accordance with the AoURP Data and Statistics Dissemination Policy.¹² Data are presented as the mean and standard deviation for continuous variables, and as the frequency and percentage for categorical variables. Two-sample *t*-tests or Chi-square tests were used as appropriate to compare demographic differences in age, sex, race/ethnicity, and education between these 2 groups within each site in the TACH consortium. As patients were nested within their health system, multilevel logistic regression models with random intercept allowing for variability across systems, were used to examine the associations of demographic variables with decline to share EHR. Odds ratios (ORs) were reported with 95% confidence intervals (CIs). Any *P*-value <0.05 was used to determine statistical significance. All analyses were done using SAS version 9.4 (SAS Institute, Cary, NC, USA). Several sensitivity analyses were also performed. First, dummy variables were created for missing sex, missing race/ethnicity, and missing education in logistic regression models. Second, we performed the analysis using imputed values for the missing race/ethnicity, sex, and education. We used a multiple imputation approach with chained equations (MICE) to create 10 imputed data sets. Missing values in the original dataset were replaced by plausible imputed values, taking imputation uncertainty into consideration. ORs of willingness to share EHR were calculated from each imputed dataset and then pooled into final estimates. Results appear in [Supplementary Materials, Tables S1–S4](#).

RESULTS

As of December 30, 2019, TACH had recruited 28 960 patients, of whom 1521 had no recorded decision on sharing their EHR information. Another 1587 persons had incomplete data in the PPI module (*n* = 770 missing sex, in addition to *n* = 7 intersex, which was not categorized at this time, *n* = 1092 missing race/ethnicity, and *n* = 864 missing education). As shown in [Figure 1](#), this left an analytic sample of 25 852 participants (89.3% of the total participants recruited) with a recorded decision to decline or share their EHR information with researchers. [Table 1](#) shows demographics overall, and by TACH site. The study sample is predominantly non-Hispanic White (66.5%). Most participants are in their 50s, younger than 65 years of age, male, and are post-high school educated

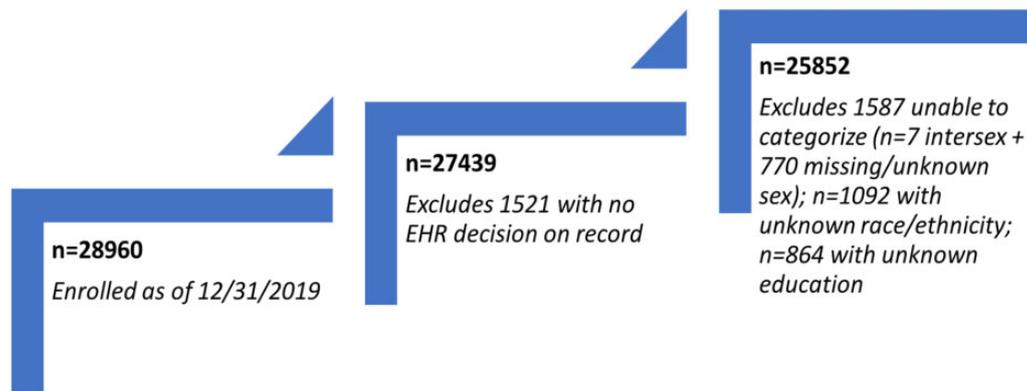


Figure 1. Steps to arriving at sample used in analysis

*Participate-provided information

Table 2. Active decline status by race/ethnicity category at each Trans-American Consortium of the Health Care Systems Research Network (TACH) study site

	Total Active decline		White Active decline		Black/African American Active decline		Hispanic Active decline		Other Active decline	
	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)
Baylor	118	(1.28)	61	(1.13)	29	(1.60)	<20	(1.42)	<20	(1.29)
Essentia	44	(3.53)	41	(3.66)	<20	(0.00)	<20	(0.00)	<20	(3.45)
Henny Ford	175	(2.57)	102	(2.87)	47	(1.89)	<20	(3.14)	<20	(3.44)
Reliant	64	(3.50)	55	(3.50)	<20	(8.89)	<20	(0.99)	<20	(3.57)
Spectrum	180	(2.67)	154	(2.76)	<20	(1.25)	<20	(4.25)	<20	(1.83)
Total	581	(2.25)	413	(2.40)	86	(1.77)	40	(2.01)	42	(2.29)

(>high school diploma). Some notable differences in demographics were observed across TACH sites. Spectrum had the fewest persons ≥ 65 years (17.9% versus 26.6% overall). Baylor had the highest proportion of females (35.3% vs 32.5% overall), persons with less than a high school diploma (29.1% vs 24.0% overall), and Hispanic patients (14.5% vs. 7.7% overall). Henry Ford Health System (HFHS) had the highest percentage of Black/Black/African American participants (36.5% vs 18.7% overall).

Overall, about 2.3% of participants ($n = 581$) actively declined to share their EHR (Table 1). Across TACH sites, Essentia and Reliant/UMass had the highest percentages of active decline (3.5% and 3.5%, respectively), while Baylor had the lowest (1.3%). As shown in Table 2, Whites had the highest percentage of decline (2.4%), and Black/Black/African Americans had the lowest (1.8%).

We investigated differences by demographics (age, race, gender, and education) using multilevel logistic regression models in which declined access to the EHR was the dependent variable (Table 3). Looking at individual TACH sites, results were in the same direction across sites for age, sex, and education, with some site variation in the strength of the association. For several individual TACH sites, CIs and corresponding P -values did not meet our criteria for statistical significance, but absolute values suggest larger sample sizes may be needed to fully investigate an association between race/ethnicity and the decision to decline to share access to the EHR for Black/African-American race at HFHS and Spectrum and for Hispanic ethnicity at Reliant. Overall, decline of access to EHR data was associated with younger age, OR (95% CI) = 0.79 (0.84–0.75); female

sex, OR = 1.74 (1.42–2.14); and higher education level, OR = 2.44 (1.86–3.21). All P -values for these associations were < 0.001 .

We examined how declining EHR access varied by site using HFHS as the referent category. Baylor, with the highest percentage of persons with lower education and the highest percentage of Hispanic participants decline EHR access than HFHS. Running the models separately by site yielded similar results (data not shown). The analysis was also conducted restricting the sample to those participants that enrolled on or after the national launch (May 2018). Resulting patterns were similar (Table 4).

We also investigated race as an effect modifier of the relationship between demographic variables (age, sex, and education) and active decline status. In general, race did not change the direction of relationships observed between the outcome of EHR decline and age, sex, or education. Among Hispanic and Other race/ethnic categories, sex was either not associated with decline to share the EHR, or participants that declined to share were more likely to be male, but these aberrant associations were not statistically significant. Finally, we conducted a sensitivity analysis using 1587 that had missing/uncategorized demographic data (race, sex, and education). While addition of this group did not appreciably change the original results, the proportion declining to share the EHR was 4.5% (71/1537) versus the 2.3% for the analytic sample reported above. Persons with missing sex were more likely to decline sharing their EHR

Table 3. Results of multilevel logistic regression models describing relationship between demographic variables and EHR decline

	All TACH sites			Baylor			Essentia			Reliant			Henry Ford			Spectrum		
	aOR ^a (95% CI)	P		aOR ^a (95% CI)	P		aOR ^a (95% CI)	P		aOR ^a (95% CI)	P		aOR ^a (95% CI)	P		aOR ^a (95% CI)	P	
Age ^b	0.79 (0.84-0.75)	<0.001		0.74 (0.83-0.66)	<0.001		0.78 (0.94-0.65)	0.011		0.75 (0.88-0.65)	<0.001		0.85 (0.93-0.78)	0.001		0.80 (0.88-0.73)	<0.0001	
Race/ethnicity ^c																		
Black/AA	0.95 (0.73-1.22)	0.67		1.54 (0.98-2.42)	0.059		0.62 (0.04-10.92)	0.746		2.54 (0.89-7.21)	0.081		0.82 (0.57-1.17)	0.273		0.69 (0.31-1.52)	0.355	
Hispanic	1.00 (0.71-1.41)	0.99		1.14 (0.68-1.93)	0.620		0.51 (0.03-9.13)	0.650		0.26 (0.05-1.36)	0.111		1.17 (0.55-2.51)	0.681		1.48 (0.83-2.65)	0.182	
Other	1.07 (0.78-1.49)	0.67		1.00 (0.50-1.99)	1.000		0.88 (0.29-2.69)	0.825		0.91 (0.34-2.45)	0.859		1.26 (0.77-2.06)	0.366		0.69 (0.33-1.45)	0.328	
Female vs male	1.74 (1.42-2.15)	<0.001		1.46 (0.96-2.22)	0.076		1.01 (0.51-1.96)	0.988		2.83 (1.42-5.64)	0.003		1.97 (1.33-2.91)	0.001		1.59 (1.10-2.31)	0.015	
≥HS vs. ≤HS ^d	2.44 (1.86-3.21)	<0.001		2.37 (1.45-3.89)	<0.001		1.08 (0.41-2.84)	0.873		1.04 (0.53-2.04)	0.902		2.74 (1.65-4.56)	<0.001		3.24 (1.81-5.80)	<0.001	

^aAdjusted odds ratio (95% confidence interval).

^bAge included in the model as an ordinal variable 18-25, 25-35, 35-45, 45-55, 55-65, 65+.

^cWhite is the reference category, AA = Black/African American.

^dHS = High School.

Table 4. Results of sensitivity analysis (multilevel logistic regression model) describing relationship between demographic variables and EHR decline restricted to participants enrolling on or before national launch (May 6, 2018)

	All TACH sites		
	Adjusted odds ratio	(95% CI) ^a	P
Age ^b	1.30	(1.22–1.37)	<0.001
Race (<i>White is reference category</i>)			
Black/AA ^c	1.11	(0.83–1.47)	0.48
Hispanic	1.08	(0.75–1.58)	0.67
Other	1.08	(0.75–1.56)	0.68
Female vs male	1.73	(1.37–2.17)	<0.001
>HS vs. <HS ^d	2.42	(1.81–3.23)	<0.001

^a95% confidence interval.

^bAge included in the model as an ordinal variable 18–25, 25–35, 35–45, 45–55, 55–65, 65+.

^cBlack/African American.

^dHigh School.

information when compared with the reference group of male sex, OR = 1.98 (1.06–3.68); and persons with missing education were more likely to decline sharing the EHR information compared to the reference group of less than a high school education, OR = 4.88 (2.84–8.38). Analyses using multiple imputation for missing race/ethnicity, sex, and education also did not appreciably change the results. Both the sensitivity analysis and the analysis using multiple imputation appear as [Supplementary Material, Tables S1–S4](#).

DISCUSSION

We describe the relationship between demographic factors and the participant decision to decline access to their EHR among persons enrolled in the AoURP across 5 institutions in the TACH consortium. The analysis differs from comparisons of survey respondents to non-respondents or study participants versus non-participants often used to assess external validity and inform recruitment strategies.^{13,14} In contrast, our analysis focuses on participant willingness to participate in one aspect of the study and is perhaps more relevant to internal validity.¹⁵ We found the proportion of patients declining to share access to their EHR information to be a low 2.3%, and that the racial and ethnic make-up of this group does not skew toward UBR. We also found that persons declining EHR access were more likely to be younger, female, and more educated. This demographic pattern of declining EHR access was similar across the consortium. As AoURP nears its goal of 1 million participants, our data suggest that the size and demographic composition of those declining to share their EHR information are unlikely to be the factors that limit the internal validity of the AoURP.

The percentage of participants declining EHR access is similar to current literature, for which estimates of participants unwilling to share one or more aspects of their EHR with researchers or other end-users range from 3.7% to 15.3%.^{16–18} The California study conducted by Kim et al,¹⁸ with the highest estimate of decline (15.3%) is from a random digit dialing telephone survey in which investigators raised the issue of sharing de-identified versus identified data. Investigators found that significantly more respondents would share de-identified data for research than would share identified information for healthcare.¹⁸ Later, this same group of investigators (Kim et al), reported that participants who believed sharing

EHR information improves research quality (vs those that did not hold this belief) increased the odds of consent more than 10-fold, OR = 11.26 (4.13–30.73).⁶ In the more recent California study of 1246 participants (Kim et al), investigators also reported that 72.6% of study participants were willing to share at least one item in the EHR along with their biospecimens, preferably with their home institution (the institution that holds their EHR), and 67.1% were willing to share all items with researchers in the home institution.¹⁶ In this study, participants found for-profit organizations the least preferable in terms of sharing their patient information.¹⁶

Racial/ethnic minoritized groups seem less influenced by the *reason* for sharing.^{6–8} One large study found that White participants were more likely to be influenced by the end-user of the EHR (eg, research, quality improvement, or marketing) than were Black/African Americans and Hispanic patients.⁷ Some site variations that were observed in our analysis for the association of race/ethnicity to sharing access to the EHR could be investigated further to understand site-specific factors contributing to the potential differences.

We found that women were more likely to decline to share access to their EHR information than men. Several reports from the United States and abroad suggest that women are more concerned about security and privacy than their male counterparts.¹⁹ In one study, the gender effect was less pronounced in older age groups.²⁰ Polls suggest that younger age groups do not have the same level of concern regarding security than older age groups.² Younger persons are also more likely to be adept at technology, a characteristic that was associated with greater likelihood of consent to share EHR information in a previous study,⁶ but differs from our results. In a German study, in which being healthy was associated with greater concern about privacy of health information, authors speculated that sicker patients may feel that ready access to the EHR is necessary and beneficial.²⁰ Along these lines, we might expect that racial/ethnic minoritized groups with high morbidity would be more likely to share their EHR.

For the AoURP and other studies cited above, most participants are willing to give access to their EHR information.^{16–18} While results of this study could inform the content of recruitment and consent materials that address the concerns of identified subgroups, recent results from Harle et al are not entirely supportive.¹⁷ In the Harle randomized trial, enhanced interactive consent features targeting trust, knowledge, and volunteerism were not effective in increasing consent to share EHR information. This was also true among non-White participants, who remained less engaged in all aspects of the consent process compared to their White counterparts,¹⁷ regardless of the intervention arm. Auxiliary assessments by this group did suggest that trust messaging may be helpful, specifically for participants from minoritized populations, but the relationships were complex and need further exploration.¹⁷

It is important to acknowledge that our study sample includes only persons willing to enroll in the AoURP, and therefore, results are only applicable to this group. In addition, some patients may not have realized that participation was possible without EHR consent, and with this knowledge may have increased the proportion of EHR decline in our analysis. Personal or face-to-face discourse may have helped some potential participants better understand the pros and cons of sharing their EHR or how their participation in the program may be limited by declining to share their EHR. We can speculate that personal discourse could be viewed more favorably by participants than enhanced online features and trust messaging as examined in the Harle study.¹⁷ In addition, research suggests that an “all or nothing” approach to consent to share health information reduces the likelihood of participation.¹⁶ In the Kim et al study,

sexual history, pregnancy history, and income were among the items that participants were least likely to share.¹⁶

We also note that about 9.4% (25 852/27439) of participants were excluded from our main analysis due to missing data or data that could not yet be categorized. A sensitivity analysis showed that this group was more likely to decline a request to share their EHR information with researchers, suggesting the group may represent a different demographic profile than that of our analytic sample. Their inclusion in the regression model, however, did not change the direction of our overall associations. Analyses using imputed values also did not change the direction of our associations (Supplemental Materials, Tables S1–S4). Other factors (eg, health status previous participation in research, beliefs about research benefit) as well as social factors (eg, socioeconomic status and income) may influence willingness to share access to the EHR, and there is room for more research on this topic as our sample size is steadily increasing.

External validity is compromised when a study sample differs from that of the population from which it was drawn.²¹ Overrepresentation of racial and ethnic minoritized groups in the sample of persons that decline to share the EHR could indicate that future AoURP results based on EHR findings could be biased if the exposure and/or the outcome being studied are related to race/ethnicity. While the results of our study are not meant to provide evidence that AoURP study participants are representative of the US population, our findings do suggest that racial and ethnic minoritized populations are not over-represented among those participants that decline to share the EHR.

In summary, the use of EHRs in medicine is growing exponentially and with that growth comes an expansion of research capabilities. Achieving a sample that reflects the diversity of the US is a high priority for the AoURP. While the number and characterization of persons that decline access to their EHR information could inform the potential for bias, we found that the majority of persons willing to participate in the Program are also willing to share access to their EHR information. Estimation across TACH sites suggests that this is true even for racial and ethnic minoritized groups. In general, the results of this analysis bode well for the AoURP, suggesting that the AoURP dataset is unlikely to be constrained by the UBR representation in the group of participants who decline access to their EHR information, although differences in the distribution of age, education, and sex in this subgroup will need to be considered.

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AUTHOR CONTRIBUTIONS

CLMJ co-designed the analysis framework, interpreted analysis results, and co-wrote the manuscript. AT conducted the analyses, interpreted results, co-wrote, reviewed, and edited the manuscript. DWC, MME, PAP, ABS, and SCW provided on-site supervision, participated in study design and analysis interpretation, and reviewed/edited the manuscript. CCJ and BKA provided overall supervision and oversight to study design, data collection, data analysis and interpretation, and reviewed/edited the manuscript. CDPR developed the research question, co-designed the analysis framework, interpreted analysis results, and co-wrote the manuscript.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Journal of the American Medical Informatics Association* online.

CONFLICT OF INTEREST STATEMENT

The authors have no competing interest to declare.

DATA AVAILABILITY STATEMENT

The data underlying this article will be shared on reasonable request to the corresponding author.

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