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REVIEW

The Translational Approaches to Personalized Health Collaborative: Pharmacogenomics for African American Older Adults

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Older adults (i.e., 60 years and older), are the leading consumers of medications, and consequently are suffering the most from medication-related adverse events. Not only are older adults the largest consumers of medications, they are more likely to experience an adverse drug event contributing to increased hospitalization, utilization of emergency medical services, and mortality. Translational Approaches to Personalized Health (TAPH) is a transdisciplinary team of researchers conducting community-engaged participatory research focused on the discovery and translation of pharmacogenomic (PGx) data to improve health outcomes. Underserved and ethnically diverse older adults living in urban settings are significantly under-represented in PGx studies. To address the issue of under-representation, our study enrolls older African American adults into a community-based PGx study. Therefore, we will characterize the frequency of actionable PGx genotypes and identify novel PGx response genes in our cohort of older community dwelling African Americans. The translational component of our work is to use the PGx findings to improve therapeutic outcomes for medication management in older adults. Such findings will serve as a foundation for translational PGx studies aimed at improving medication efficacy and safety for older adults. In this article, we describe the process for launching the TAPH collaborative group, which includes the transdisciplinary team, community-engaged participatory research model, study measures, and the evaluation of PGx genes.

Older adults are the leading consumers of medications, and consequently are suffering the most from medication-related adverse events. Older adults are seven times more likely to experience adverse drug events (ADEs) than younger populations.[1,2] Not only are older adults the largest consumers of medications, ADEs in older adults are more likely to contribute to increased hospitalization, utilization of emergency medical services, and mortality.[3] Specifically, community-dwelling older African Americans are more likely than other adults to visit emergency departments, become hospitalized, or suffer death due to ADEs.[4–8] African Americans are significantly under-represented in pharmacogenomic (PGx) studies, but older African Americans are even less represented.[9] Research focused on evaluating the potential of PGx to reduce ADEs and improving therapeutic outcomes for older adults have been lacking. Therefore, efforts in the clinical translation of PGx for older adults are needed. Additionally, the data that informs the PGx recommendations provided in the US Food and Drug Administration (FDA) approved labeling for medications were predominately from studies of European ancestry adults.[8,10] For example, the genotype-based recommendations that were originally provided by the FDA for warfarin were informed by studies where African Americans were under-represented. Therefore, this lack of diversity in PGx studies contributed to suboptimal dose predictions for individuals of African ancestry.[8]

Our study implements PGx in a cohort of community dwelling older African American adults and will also identify novel genetic variants that may impact pharmacologic responsiveness. In this paper, we describe the process for launching the Translational Approaches to Personalized Health (TAPH) collaborative, which includes the transdisciplinary team, community-engaged participatory research model, study measures, and evaluation of PGx genes. We provide preliminary results on the recruitment and retention, participant characteristics, polypharmacy rates, and DNA sample results. The translational component of our work is to use the PGx findings to improve therapeutic outcomes provided through medication management, education, and counseling for participants and healthcare providers.

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This study received support from the African American Cardiovascular Pharmacogenetic Consortium (ACCOuNT), which was designed to discover novel genetic variants in African Americans.[9] ACCOuNT was funded via a U54 mechanism from the National Institutes of Health's National Institute on Minority Health and Health Disparities. The ACCOuNT Transdisciplinary Collaborative Center is focused on gene discovery in African Americans for clinical translation as a way to improve the impact of genetic biomarkers on drug selection, dosing, and clinical outcomes.[9] The Transdisciplinary Collaborative Center supports research studies that center on DNA variant discovery in African Americans with the goal to translate findings of genetic biomarkers on drug selection and clinical outcomes. The TAPH collaborative was funded by the ACCOuNT to introduce PGx testing and counseling to older adults in a community-based setting living in low-income subsidized housing.

TAPH COLLABORATIVE

The TAPH collaborative includes a network of health service delivery and community partners that work synergistically with academic researchers toward improving medication efficacy and safety for older adults. The TAPH collaborative includes stakeholders from diverse backgrounds, communities, and scientific disciplines, and relies heavily on partnership equity between the academic researchers and community partners (see **Figure 1** for the TAPH collaborative process).

Health service delivery partners

Many of the low-income older adults are aging in place in congregate housing settings, specifically designed for independent living with minimal support services.[11] Several Richmond, Virginia, senior apartment buildings were identified as having high utilization rates of healthcare services, such as emergency department visits and hospital admissions. To address the unmet needs of older African American adults in Richmond, VA, faculty from VCU Schools of Nursing, Pharmacy, and Medicine initiated the development of an interprofessional model of care called the Richmond Health and Wellness Program (RHWP) https://nursing.vcu.edu/community-engagement/rhwp/. The RHWP model of care provides integrated services for coordinated care activities to impact healthcare utilization and health outcomes.[11,12] The program has been providing wellness care to low-socioeconomic status community-dwelling older adults living in high-rise low-income housing units since 2012. The RHWP program provides wellness care to older adults, with an average age of 73 years old, and 82% are African American, in the buildings where they live. VCU Geriatric Medicine is a collaborating partner at RHWP. Similarly, VCU Geriatric Medicine cares for a population with an average age of 78 years old, of whom 56% are African American and 40% are white. The five most prevalent chronic conditions at both RHWP and VCU geriatric sites are hypertension, diabetes, dyslipidemia, cognitive impairment, and chronic obstructive pulmonary disease.[11] As shown in **Figures 2** and **3**, the vast majority of older adults served by the RHWP wellness program manage their medications independently. Therefore, the wellness program routinely provides services for participants that are related to medication counseling, medication discrepancies, and medication adherence.

Community partners

We draw heavily on existing collaborations with our housing partners to identify the needs of older adults residing in low-income senior apartment buildings. This approach was developed to mitigate challenges often associated with research in low-income, vulnerable populations that reduce trust related to research within the community and diminish the ability to successfully recruit and enroll participants.[13] We engaged in a process that established the Advisory Council by which relevant stakeholders work collaboratively with researchers to address health issues concerning their community. The Advisory Council was developed to address community concerns around race and culture to advance social equity as an integral dimension of the program stability and research. The Advisory Council meets quarterly to ensure the community's voice is integrated into a sustainable program of research and service. By empowering representatives of the community to actively participate in decision making and honoring

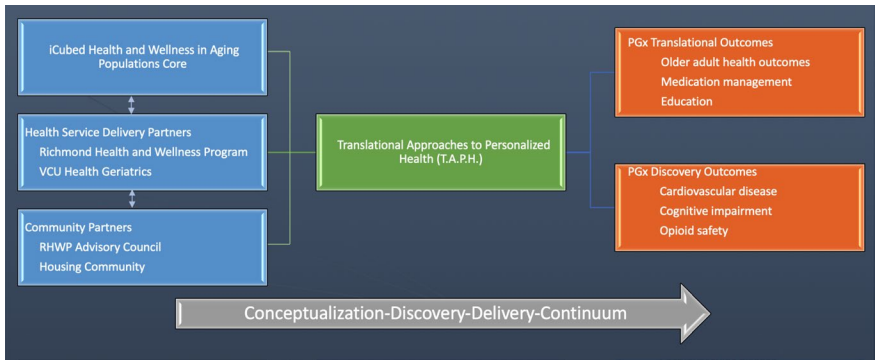

Figure 1 Translational approach to personalized health (TAPH) collaborative process. PGx, pharmacogenomic; RHWP, Richmond Health and Wellness Program. The T.A.P.H. research team works synergistically with iCubed, health service delivery and community partners to engage older adults in sustainable programs of research. T.A.P.H. oversees the engagement of providers and community members in education and participation in PGx research.

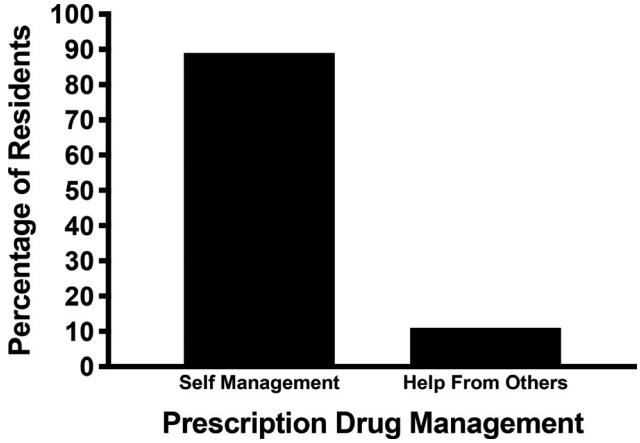

Figure 2 Richmond Health and Wellness Program participant self-report of medication management.

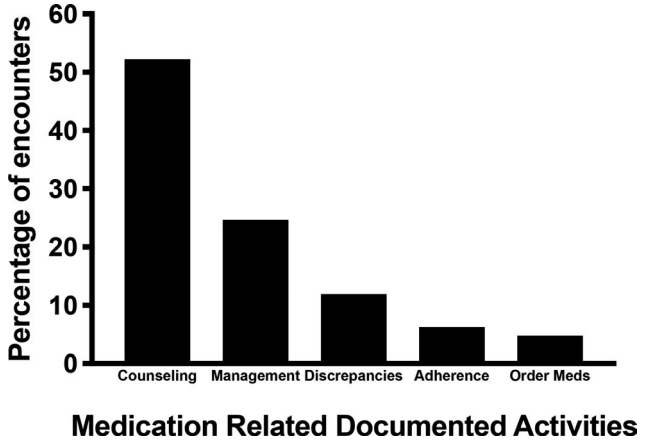

Figure 3 Richmond Health and Wellness Program participant use of wellness center for medication management.

their perspectives and values, researchers can build trust, improve enrollment, and establish sustainable interventions. The Advisory Council is composed of 16 older adult representatives living within federally subsidized housing buildings where RHWP offers wellness care and 2 housing administrative representatives. The Advisory Council meets quarterly with RHWP faculty and researchers with a shared agenda focused on the needs and concerns of the community and to discuss research initiatives. The Advisory Council identified medication safety, ADEs, cardiovascular disease, cognitive decline, and opioid drug use as some of the concerns affecting older adults in their communities. By exploring the needs of the community via the Advisory Council, older adults living in low-income housing have contributed to the development of numerous clinical initiatives and research studies over the past 8 years.[7,11,14–16]

iCubed health and wellness in aging populations core

The Institute for Inclusion, Inquiry, and Innovation (iCubed) Health and Wellness in Aging Populations core (https://icubed.vcu.edu/programs/aging-populations/) is the research initiative successfully built upon RHWP's service delivery operation. The iCubed Health and Wellness core is an initiative formed in 2017 to strategically invest in transdisciplinary teams of academic researchers using community-engaged participatory research approaches to solve challenging and persistent problems in urban environments. The iCubed Health and Wellness in Aging Populations core addresses problems of older and disabled adults "aging in place" within low-income senior housing apartment buildings. Our research approach is focused on the social determinants of health and health disparities facing the population, which is primarily African American and low-income. The iCubed Health and Wellness in Aging Populations core, in collaboration with the RHWP Advisory Council, has identified a shared scholarship agenda addressing medication safety and ADE issues, as determined around social determinants of health, health disparities, and aging in place in low-income urban communities.

TAPH transdisciplinary team

In 2019, academic researchers (Price and Sargent) from the iCubed Health and Wellness in Aging Populations core founded TAPH; a transdisciplinary team of academic researchers from pharmacy, nursing, medicine, and gerontology. The team has a shared mission and goal for the discovery and translation of PGx data to improve health outcomes for underserved and ethnically diverse older adults living in urban settings. The research faculty in the TAPH collaborative work closely with community partners, VCU Geriatrics, RHWP, and the RHWP Advisory Council in the planning, initiating, and translating of research findings. To translate findings into real-world applications, we expect that the team will need to broaden its expertise to incorporate the original research investigators and translational partners, including those whose work influences policy, health organizations, and public health practitioners. **Figure 1** illustrates the TAPH collaborative process. The figure highlights how ideas are conceptualized between academic researchers from iCubed and health service delivery and community partners thereby generating sustainable TAPH research initiatives to address medication safety and ADE issues.

TAPH RESEARCH INITIATIVE

All TAPH research protocols were approved by the VCU institutional review board. In this project, we hypothesize that safety and efficacy outcomes of pharmacotherapy could be optimized for older African American adults if we consider the FDA's guidance on clinically actionable PGx of cytochrome P450 (CYP450) genetic variants within the routine patient care of older adults with multiple chronic diseases.[17] We will characterize the frequencies of clinically actionable CYP450 genetic variants to generate some of the earliest PGx implementation data within older ethnic minorities. Furthermore, we will explore relationships among clinically actionable *CYP450* genotypes, cardiovascular disease, depression, cognitive impairment, and opioid use. Genomic and PGx implementation research studies often focus on a single drug or disease and rarely focus on patient populations with comorbid diseases.[8,18–25] Therefore, older

community-dwelling adults are often left out of large PGx implementation efforts due to having multiple comorbid health conditions. The lack of PGx research in older adults is concerning because they are the largest consumers of medications, many of which have FDA guidance on clinically actionable PGx recommendations. Moreover, a large percentage of the FDA's clinically actionable PGx statements are for drugs that are metabolized by the CYP450 system (see **Figure 4**). This important work will allow us to answer the following questions, "Are clinically actionable PGx variants in older African Americans associated with suboptimal pharmacotherapeutic outcomes (i.e., adverse drug responses)?" and "What is the interest and knowledge of older adults and their providers in using PGx?"

Using a community-engaged participatory research model to facilitate our recruitment process, we have implemented an introductory PGx program through RHWP and VCU Division of Geriatrics with the primary goals:

1. demonstrate the ability to engage low-income, community-dwelling older adults in PGx studies,
2. determine if clinically actionable *CYP450* PGx variants among community-dwelling older adults of racial/ethnic minorities backgrounds are associated with adverse drug responses,
3. determine the impact of pharmacist/advanced practice nursing led CYP450 PGx counseling/consults on participant/healthcare provider knowledge,
4. assess interest/utilization of PGx personalized medicine for cardiovascular disease, cognitive health, and opioid safety for older adults.

We have prioritized goals 1, 2, and 3 as they relate to clinically actionable *CYP450* genotypes. Methods are aimed at characterizing clinically actionable PGx variants, drug-gene interactions, and novel genetic variant discovery. Findings will serve as a foundation for translational PGx studies aimed at improving medication efficacy and safety for older adults as outlined in goal 4. The frequency of clinically actionable genotypes and drug-gene interactions are characterized, then we offer participants counseling on their results as well as provide them with printed information on any identified drugs that have Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines for common clinically actionable variants (i.e., CYP2D6 and CYP2C9). Participants receive wallet-sized copies of their *CYP450* genotypes and are encouraged to share the results with their healthcare providers. Pre-counseling and post-counseling surveys will be collected from the participants to characterize their satisfaction with the PGx counseling and PGx knowledge gained. The wallet-card with *CYP450* genotype results contain our contact information for further consultation. A PGx-trained healthcare professional is available to provide consultations for the participants' healthcare professionals that desire to utilize *CYP450* genotypes to optimize pharmacotherapy. Healthcare professionals are provided consultations and PGx education and given the opportunity to enroll in the study. Healthcare professionals enrolled in the study complete a telephone survey to characterize their responsiveness, knowledge, and satisfaction with the PGx consultation and identified gene-drug interactions.

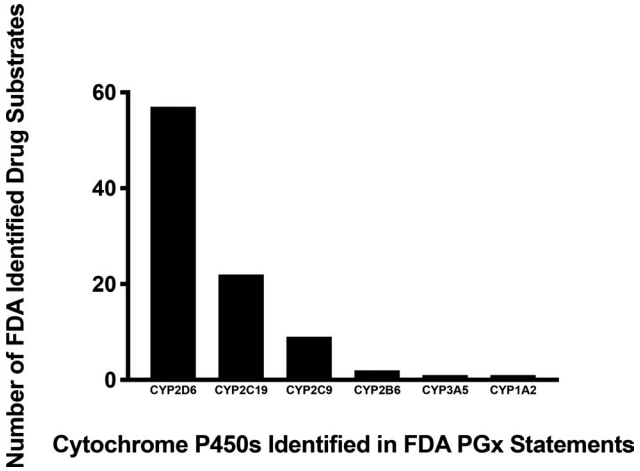

Figure 4 US Food and Drug Administration (FDA) required cytochrome P450 pharmacogenomic (PGx) statements. Note: A large percentage of FDA mandated PGx statements with medication labels are related to CYP450 genetics.

TAPH PGx variables and measures

PGx Sample: DNA is obtained via noninvasive saliva collection using Oragene DNA collection kits (OGR-500). Genetic variants and gene allele quantification within drug metabolism enzymes and transporters will be analyzed using TaqMan Open Array PGx Express and custom panels on the QuantStudio 12K Flex system (Applied Biosystems, Foster City, CA, USA). **Table S1** provides a full list of the genetic variants collected.

Demographic variables: Demographic variables include ethnicity, race, educational level, age, sex, and annual income.

Health history: Chronic disease history is collected as self-report on demographic survey for population/clinical characteristics.

Medication history: The name of the drug, preparation, dose, dosing frequency, and duration of use (i.e., days, months, and years) are collected from medication bottles and/or from the electronic medical record, including over-the-counter medications.

Cognition: Cognitive domains, including orientation, processing speed, visuospatial, and visuoconstructional skill, language, attention and executive function, working memory, episodic memory, and immediate recall will be assessed with the English versions for both the Mini-Mental State Exam-2 and the National Institutes of Health-Toolbox Cognition Measures (NIHTB-CB).[26,27] The NIHTB-CB consists of a comprehensive set of measures to assess cognition and uses a standardized testing process that takes ~ 35 minutes to complete.[27] The NIHTB-CB is administered on an iPad tablet. The Mini-Mental State Exam-2 is a brief cognitive screening tool that consists of 30 items and requires 5–10 minutes to administer on paper.[26,28]

Frailty: The FRAIL scale is a short, self-reported, five-question screening tool that assesses the presence of

fatigue, muscle resistance, aerobic capacity, illness, and loss of weight. Scores range from 0 to 5, participants being classified as robust (0 points), prefrail (1 to 2 points), and frail (≥ 3 points). Psychometric testing of the FRAIL scale has shown it to be optimal for identifying frail persons at risk of mortality and health decline.[29,30]

Anxiety/depression: To assess participants for anxiety and depression, a brief, 4-item survey, the Patient Health Questionnaire-4 (PHQ-4), will be utilized. The first two items are from the validated Generalized Anxiety Disorder-7 Scale.[31,32] The final two items are drawn from the PHQ-4. Internal reliability, construct validity, and factorial validity of the PHQ-4 have been well-established in the literature.[33]

Substance use: To screen for tobacco, alcohol, and illicit substance use two surveys are incorporated. The CAGE questionnaire, which stands for cut-down, annoyed, guilty, and eye-opener, is a brief four-question survey.[34] One question from the Alcohol Use Disorders Identification Test self-report version (and modified Alcohol Use Disorders Identification Test for substances other than alcohol) is also included.[35] Our modified survey also asks that participants quantify the amount of each substance used (never, monthly or less, weekly, daily or almost daily, or refused to state).

Provider engagement/satisfaction: Study participants are first provided with a definition of primary healthcare provider and then asked if they have one assigned to their care and how often they are seen by their provider. To determine the level of satisfaction with their primary healthcare provider, participants are asked the questions from the "Your Personal Doctor" section of the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG CAHPS) survey. CAHPS was developed by the Agency for Healthcare Research and Quality (AHRQ) in 2012 to measure a patients' perception of care received from a primary care provider in an office setting. The CAHPS 1.0 survey was determined to have excellent psychometric properties.[36] A qualitative question was added to gather information on participants' conceptualization of "satisfaction" in relationship to receiving healthcare from a primary care provider.

Participant baseline PGx knowledge: Study participants complete baseline knowledge and interest in PGx questions based on a Likert scale from 0 to 10, where 0 is not knowledgeable and 10 is extremely knowledgeable (see **Figure S1**).

Participant PGx counseling: At the participant follow-up visit, a PGx counseling guide/script is used to ensure that participants receive standardized counseling on their individualized PGx results.

Participant interest in PGx survey: After PGx counseling, the PGx interest survey is completed to determine level of knowledge after counseling, interest in sharing PGx results with their provider, and in learning more information about PGx. Questions are based on a Likert scale from 0 to 10, where 0 is not important and 10 is extremely important, and has yes/no answers (see **Figure S2**).

Providers of participants have the opportunity to enroll in the study, however, if they decline, they still receive provider PGx counseling. If they choose to enroll in the study, they complete a Healthcare Professional PGx Survey to determine PGx knowledge, use in current clinical practice, and interest level in future use. See **Table 1** for the study instruments and data collection visits.

PARTICIPANT RECRUITMENT AND RETENTION

Enrollment is occurring through snowball sampling, a chain-referral method in the community-engaged settings as information about the study was shared by our community partners and RHWP participants. The challenges of recruiting African Americans for clinical research are long standing and lead to under-representation that compromises generalizability of PGx research.[13,37] Snowball sampling was used to overcome some of the barriers to recruitment of African Americans including fear, distrust, limited clinic and research team engagement, and competing priorities and needs (i.e., scheduling and transportation).[13] The TAPH was the first to introduce the concept of PGx and collecting genetic samples to older adults living in low-income housing through the development of clinical initiatives and research studies. This topic area was expected to be associated with a high degree of skepticism among community members. Consequently, the use of snowball sampling provided an opportunity to establish trust and support among community members prior to ascertainment and possible participation.

In 4 months, we were able to recruit and retain 79 participants with 94% (n = 74) of participants enrolling from the community-engaged low-income housing units and 6.3% (n = 5) enrolling from VCU Geriatric clinic. A total of 90 individuals received education and screening for the

Table 1 Study instruments and collection

Participant baseline visit	Participant follow-up visit	Healthcare professional enrollment
PGx saliva sample collection	Participant PGx counseling	Provider PGx counseling
Demographics	Participant interest in PGx	Healthcare professional PGx survey
Medication history		
PHQ-4		
Frailty index		
Substance use profile		
MMSE-2		
NIH cognitive toolbox		
Patient-provider satisfaction		
Participant knowledge in PGx		

Study instruments included baseline assessment, taking 60–90 minutes to complete. Study includes two time points, initial data collection and follow-up education.
NIH, National Institutes of Health; MMSE-2, Mini-Mental State Exam-2; PGx, pharmacogenomic; PHQ-4, Patient Health Questionnaire-4.

research study, resulting in 11 (8 VCU Geriatric clinic and 3 community settings) declining to enroll. Active recruitment efforts, attempting to engage patients during clinic visits, were needed in the VCU Geriatric clinic resulting in lower enrollment numbers. Reported reasons for not enrolling in the VCU Geriatric clinic setting included "system barriers," such as being unable to stay for the study after a provider's appointment, not interested in research, and being unable/unwilling to return to clinic for the research study intake. We recognize the need to adapt the recruitment approach for the VCU geriatric clinic to address reported "system barriers."

Our long-standing partnership with the community that we serve through RHWP is our most notable strength. This partnership has created a mutual trust relationship with older adults in these settings who have responded favorably to a PGx program of research. In addition, many RHWP participants have previously participated in research initiatives by RHWP faculty researchers with favorable outcomes. Faculty researchers in the TAPH collaborative serve as RHWP wellness program clinicians weekly and attend quarterly RHWP Advisory Council meetings to share results from the research thereby, deepening relationships, and building rapport. When conducting research in the community setting, researchers are often able to address system barriers by being mindful to the participants' needs and meeting the participants in the buildings where they live. We can modify schedules to meet the day and time that works for the participant and eliminate transportation issues by completing the research protocol data and sample collection at the housing unit where the participant lives. Steps will be taken to educate and find meaningful strategies to engage clinic staff in the research study, identify ways to maintain flexibility in the research protocol, and work to understand the clinic culture and environment.[13]

PRELIMINARY DATA

Data collection and enrollment for the TAPH study is ongoing with a target goal of 250 participants. The 79 participants enrolled have a mean age of (±SD) 69 years (5.9 uears), 44% men and 56% women, 71% African American and 22% white, and 51% live on < $10,000 a year (see **Table 2** for participant characteristics). As anticipated, polypharmacy is highly prevalent in our cohort. Using the polypharmacy definition of taking 5 or more medications, 78% of participants had polypharmacy, which was higher than participants taking 7 or more medications (60%). A total of 98% of patients agreed to participate in future PGx studies and 97% agreed to the use of stored samples for future research.

Table 2 TAPH participant characteristics

Age (mean, range, SD*)	**69 (60–80)**	**5.9**
Sex	Total N	%
Male	35	44.3
Female	44	55.7
Marital status		
Married	3	3.8
Single-never married	28	35.4
Divorced or separated	30	38.0
Partnered-living together	1	1.3
Widowed	17	21.5
Race		
American Indian or Alaska Native	1	1.3
Black or African American	56	70.9
White	17	21.5
Asian	0	0
Unknown or not reported	1	1.3
Other	4	5.1
Ethnicity		
Hispanic or Latino/a	3	3.8
Non-Hispanic or Latino/a	76	96.2
Education	Total N	%
< 8 grade	6	7.6
High school graduate (not GED) or less	38	48.1
Started or completed college	35	44.3
Income		
< $10,000	40	50.6
Between $10,000 and $14,999	30	38.0
Between $15,000 and $29,999	5	6.3
Between $30,000 and $44,999	0	0
Declined	1	1.3
Smoking		
Current	28	35.4
Never	26	32.9
Former smoker	25	31.6

GED, General Educational Development; TAPH, Translational Approaches to Personalized Health.

CONCLUSION

In order to advance the field of PGx precision medicine appropriate representation of diverse ethnic and racial groups of older adults with multiple comorbid conditions will be critical for translational outcomes.[38] We have described the process for launching the TAPH collaborative group and provided preliminary results on recruitment and retention, participant characteristics, polypharmacy rates, and DNA sample results. Additionally, we have demonstrated the ability to engage low-income, community-dwelling older adults in a PGx study. The connections with community partners and older adults living in congregate housing and Advisory Council have been the driving force in engaging low-income, community-dwelling older adults in PGx research. These relationships were built as the academic researchers spent time providing wellness care with RHWP and attending Advisory Council meetings. Partnership in the community has created synergy and trust, resulting in an opportunity to sustain and expand community-engaged PGx research with ethnically diverse low-income older adults. The transdisciplinary nature of the team and how

information is shared among community partners, health service delivery, and academic partners has resulted in shared ideas that target improving health disparities in innovative ways.

The TAPH collaborative has support to sustain the current research goals with plans for expansion. The VCU iCubed investment within the Health and Wellness in Aging Populations Core provided tremendous support for the launching of TAPH. We have also identified additional opportunities to apply for internal and external funding in various forms to ensure the long-term sustainability of the proposed project. To support the growth of translational initiatives, the team has envisioned a conceptual framework and roadmap for the clinical implementation of PGx within geriatric ambulatory care settings.[39] Translation of PGx requires a broad multilayered approach that includes informatics for electronic medical record integration, insurance coverage, and patient and provider education, including curricula PGx integration for health professionals and providers.[39] Additionally, they will continue to broaden the team's expertise to incorporate partners whose work influences policy, health organizations, and public health practitioners. Studies of this kind provide a unique opportunity to determine the prevalence of clinically actionable PGx variants that could affect the efficacy and safety of medications in an ethnically diverse group of older adults that suffer ADEs at disproportionately higher rates. Such findings will serve as a foundation for improving medication efficacy and safety for older adults.

Supporting Information. Supplementary information accompanies this paper on the *Clinical and Translational Science* website (www.cts-journal.com).

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Conflicts of Interest. All authors declared no competing interests for this work.

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