Original Report: Precision Medicine in Health Disparities Research

Participatory Genomic Testing Can Effectively Disseminate Cardiovascular Pharmacogenomics Concepts within Federally Qualified Health Centers: A Feasibility Study

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Objective: We assessed feasibility of an educational program designed to enhance stakeholder knowledge and perceptions of pharmacogenomics at a federally qualified health center (FQHC).

Design: FQHCs have a rich history of providing care to the underserved, but often are not represented by studies evaluating cutting-edge concepts. We used a novel educational platform to provide participatory genomic testing and classroom education. We assessed participant knowledge and perceptions using questionnaires between May and July 2018.

Setting: We partnered with a FQHC affiliated with an academic medical center in Chicago.

Participants: Using convenience sampling, we recruited 20 providers and 10 community members for a feasibility study. Providers included physicians, physician extenders, community health workers, and patient health navigators. Community members were patients, supporters, and/or FQHC advisory board members.

Intervention: Participants had the option to undergo personal genomic testing. Online educational modules included basic genetics, cardiovascular pharmacogenomics, and personalized medicine. Education concluded in a 2-hour live course with case-based discussions.

Main Outcome Measures: Our main outcome was testing pilot feasibility. Baseline knowledge and perceptions were compared with post-intervention assessments using descriptive statistics, t tests (or Wilcoxon rank-sum) for continuous variables and chi-squared (or Fisher's exact) for categorical variables.

Results: We found that attitudes toward the intervention were positive and remained so after intervention. Our intervention was both feasible and acceptable. Genomics knowledge increased for nearly all participants.

Conclusions: We have determined that a pharmacogenomics educational program tailored for an underrepresented community is feasible and acceptable. Outcomes will advise methodology for larger implementation studies. *Ethn Dis*. 2020;30(Suppl 1):167-176; doi:10.18865/ed.30.S1.167

Keywords: Community-Based Participatory Research; Community Health Partnerships; Cardiovascular Disease; Pharmacogenomics; Genomics Research; Participatory Genomics Testing

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Introduction

Racial and ethnic disparities in prevalence, morbidity, and mortality of cardiovascular disease (CVD) continue.[1] Among ethnic minorities, African Americans, tend to carry the highest rates of CVD and CVD-related risk factors.[2] Since the discovery of the human genome, researchers have been striving to understand the clinical translation of genomics to risk of poor CVD outcomes. Pharmacogenomics (PGx) involves the study of the human genome with regard to pharmacokinetics and pharmacodynamics. The integration of PGx with clinical practice for CVD will allow for the application of personalized medicine, and hopefully, improved medication efficacy with lowered side effects.[3]

The evidence supporting PGx in the medical management of CVD has grown substantially over the past decade.[4] A well-known example is the association between guanine nucleotide-binding proteins beta-3 subunit (*GNB3*) TT genotype and an improved therapeutic effect of fixed-dose isosorbide dinitrate and hydralazine in clinical outcomes among African Americans with advanced heart failure.[5] Additionally,

people of African descent are more likely to carry distinct genetic variants that affect the metabolism of the anticoagulant warfarin, leading to clinically significant differences in therapeutic dosing compared with other ethnicities.[6] Given the documented ethnic contributions to CVD, PGx promises to help clinicians and researchers better understand outcomes in diverse populations. To date, genomics research participants have disproportionally included people of European descent. Therefore, it is imperative that people of diverse backgrounds be identified for participation in PGx research so that the available data are reflective of the populations as a whole. Furthermore, PGx studies must be conducted in ways that justly represent these underrepresented populations.[7,8] Several issues limit the integration of PGx into clinical practice, with lack of provider knowledge about genetics being one of the most commonly cited barriers.[9,10]

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Given the perceived barrier of knowledge about genetics testing, the implementation of an educational program for both CVD clinical providers and community leaders of genetically diverse populations should improve the overall understanding of pharmacogenomics and augment the recruitment of underrepresented groups in pharmacogenomics research. To date, little is known about the feasibility or acceptability of implementing genomics educational tools for underrepresented groups. In this study, a novel educational platform was developed that used participatory genomic testing (PGT) to increase baseline knowledge and awareness of pharmacogenomic concepts in a federally qualified health center (FQHC) setting. PGT has been shown to improve understanding of genomics concepts in academic settings.[11,12] Our primary objective was to determine if adaptation of a PGT intervention to an underrepresented community was feasible and acceptable. A secondary goal of this project was to preliminarily assess the effect of the intervention on knowledge and attitudes toward PGx concepts. The outcomes of this study will advise best practices on implementation, engagement, and recruitment of diverse participants in larger research studies.

Methods

Setting

Mile Square Health Center is a network of 11 FQHCs affiliated with the University of Illinois Hospital and Health Sciences System and has a rich history of providing comprehensive health care services to underserved communities since 1967. Mile Square clinics are situated in neighborhoods with disproportionate morbidity and mortality associated with chronic conditions. The clinics serve a predominately African American population (74%). We targeted providers from five of the primary care Mile Square clinics: Near West, Back of the Yards, Cicero, Englewood, and South Shore. Recruitment began in May 2018 and the course intervention occurred on July 13, 2018.

Participants

Our goal was to recruit 20 providers and 10 community member participants. Because this was a pilot feasibility study, our goal sample size was based on practical considerations including participant availability and predicted workflow in the clinical setting. Our multidisciplinary work group determined that this sample size would be sufficient to detect clinically meaningful outcomes to further guide future work. Our reach included 103 providers and 132 community members who represented more than 30 community partner organizations (total N=103 + 132=235).

Participants were recruited using flyers, and direct invitations through electronic communication (via email) or direct communication (via phone, presentations at provider meetings and community board meetings, and announcements at center events). Recruiters designated pre-specified times for face-to-face interactions

with clinic providers at each of the clinics in addition to direct phone calls to each of the providers not available for face-to-face interactions. Recruited community stakeholders included individuals who responded with interest to the community members' recruitment emails, and those informed about the study during community events and community board meetings. Participants were offered optional genomic testing through 23andMe. Community members received a $60 cash incentive for participation. The recruitment phase of this study lasted four weeks.

The eligibility criteria used for health care providers included, being: aged ≥18 years, employed as a health care provider at a Mile Square Health Center in Chicago, IL and employed with one of the following employment titles: physician, physician extender, nurse, medical assistant, community health worker or patient navigator. The eligibility criteria applied for community stakeholders included, being: aged ≥18 years and either identified as a community leader from a community served by Mile Square Health Clinics in Chicago, IL or identified as a member of the Mile Square Health Center FQHC Community Board.

All procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all participants included in the study. The University of Pittsburgh ceded review to the internal review board of the University of Illinois at Chicago who approved this study.

Educational Platform

The Test2Learn™ program (www.test2learn.org) is a validated pharmacogenomics curriculum developed in 2014. The program has improved PGX knowledge, confidence in understanding test results, and empathy for patients in academic settings.[12] In addition to the Test2Learn platform, other programs have emerged that strive to enhance learner's knowledge of and comfort with PGx concepts.[13-16] We adapted the program to the needs of FQHC providers by emphasizing health aspects unique to the underserved community, with a special emphasis on heart disease. We developed a separate educational process for providers and community members to enhance the applicability of the materials.

Most of the educational videos and online materials were adapted

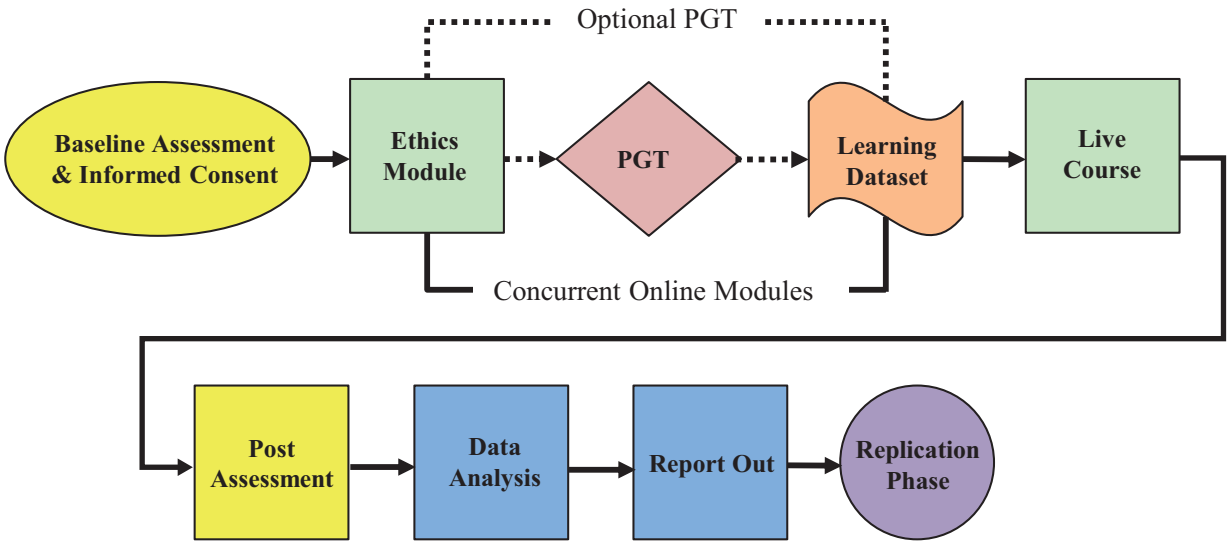

Figure 1. Overview of study design
The educational intervention consisted of online modules, online educational materials, optional participatory genomics testing, and a 2-hour live course. The yellow box represents our baseline and post-course assessments that were compared with t-tests or chi squared analyses.

from previously existing educational content designed at the University of Pittsburgh School of Pharmacy.[12] Course objectives were based on a formal review process and integration of PGx competencies and curriculum standards, then adapted to the needs of primary care providers. This process of curriculum development has been used previously for teaching pharmacy, family medicine, and internal medicine trainees (unpublished data). For providers, the online modules included ethics, basic genetics, pharmacogenomics, and personalized medicine. Community members had online access to the ethics video but did not receive the provider-level educational materials.

Online content also included access to personal genomics test results for all participants who had opted into PGT. Both community members and providers were eligible to participate in genomics testing. Personal results were available only to the participant. Course instructors were blinded to whether learners underwent testing. Both community members and providers had the ability to review their results on the Test2Learn website. Alternatively, provider and community participants could access an anonymous test dataset from the Harvard Personal Genome Project in high-fidelity learning exercises within the platform.

The PGT education ended with a two-hour, face-to-face, live course with in-depth, interactive, case-based discussions. The live course was led by project members including a genomics expert, a pharmacist, and a cardiologist. For the provider group, the live course included an overview of the concepts that had been covered in the online educational modules in addition to a discussion of unique issues impacting the use of PGx in diverse settings. The live course for community members included a basic introduction to genetics, PGx, and personalized medicine as well as a discussion of involvement of racially diverse communities in cardiovascular pharmacogenomics research (Figure 1).

Feasibility Measures

We assessed five feasibility outcome measures and criteria for success, including: 1) training motivation (session attendance, follow-up completion); 2) user experience (retention rates, reasons for dropout); 3) website deployment (website fidelity); 4) ease of PGT participation (participant ratings pre-and post-intervention); and 5) assessment of participation (duration of live course, feedback). These components were assessed via open-ended survey responses. We also determined barriers to participant recruitment.

Survey Instruments

Questions were developed to capture the following content areas: knowledge; skills; attitudes and concerns of PGx; perception of educational intervention; and research engagement. Many of the questions were adapted from prior validated assessments of the Test2Learn materials.[12] We measured demographic characteristics categorically. Provider questions included age, gender identity, professional background, and credentials as well as training specific to genetics. Community members responded to questions regarding age, race, gender identity, income, occupation, and level of education (contact the corresponding author for the complete set of questions). The post-intervention suruveys included the same items for knowledge, attitudes, and perceptions of PGx concepts, but also asked about participant perceptions of the intervention itself.

We asked providers 14 knowledge questions, most of which were similar to those asked of the community but with added questions reflecting the greater level of detail of the PGx education for providers. One of the provider knowledge questions was eliminated from the analysis because of lack of clarity. We asked seven knowledge questions of the community member participants. These knowledge questions were measured using binary "True" or "False responses, for example, "Humans are over 99% identical at the DNA level."

Provider attitudes/perceptions regarding pharmacogenomics and precision medicine included questions to understand the utility of testing, knowledge and capacity to interpret results, efficacy to educate patients about risks and benefits, beliefs about provider testing, and prior use of genetic testing. Similarly, community members were asked to respond to their providers' level of understanding, perceptions, and ability to educate patients about testing.

Because our study goal was to determine feasibility and acceptability, these response options will be refined after this initial pilot phase. All items were reviewed for reading level, avoidance of jargon, avoidance of double-barreled questions, and item length.

Contact the corresponding author for a a full listing of knowledge, attitudes and perceptions questions.

Statistical Analysis

We preliminarily explored differences in provider and community knowledge, perceptions, and attitudes toward PGx at baseline and after the course. Evaluation of the pre- and post-assessments occurred after all survey responses had been returned for analysis. Questions with five or more answer choices were treated as continuous variables.[17] We used t tests or Wilcoxon rank-sum to compare means. Variables with non-normally distributed responses were dichotomized into high versus low using a median cutoff. We also dichotomized Likert questions with less than five answer choices into high vs low (or "useful" vs "not useful"). The true-or-false questions and dichotomized answer choices were treated as categorical variables and compared with either chi-squared or Fisher's exact tests. Statistical analyses were performed using Stata version 15.0.

Results

Baseline Characteristics

We successfully recruited 20 providers and 10 community members for participation in the live course. Of the participating providers, 14 (70%) providers submitted their baseline assessments and 11 (55%) completed the post-course assessment. Of the community members, there were eight (80%) community members who submitted their baseline assessments and seven (70%) who submitted the post-course assessment.

Participant demographic characteristics are as follows. Providers (n=14) included physicians, physician extenders, community health workers, and patient navigators/advocates. Community participants (n=10) included patients and board members. Participants comprised diverse racial and ethnic backgrounds including African American (35.7%), Latinx/Hispanic (42.9%), European American (14.3%), and Asian American (7.1%). Community members were representative of local community-

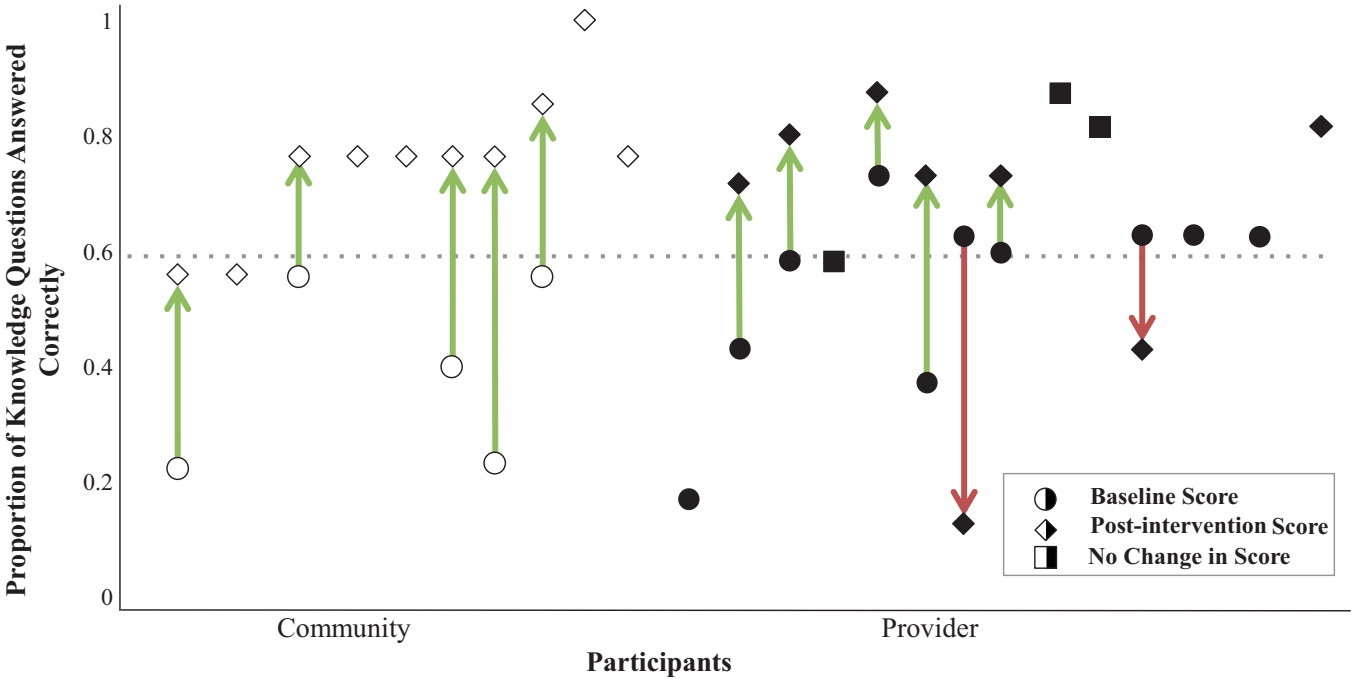

Figure 2. Knowledge increased from baseline
We found that cardiovascular pharmacogenomics knowledge increased with the educational intervention. Proportion of knowledge questions answered correctly appears along the vertical axis. Community members are represented by white dots and providers by black dots. The dashed line marks 60% of questions answered correctly.

Table 1. Comparing means from baseline with post-intervention

	Community			Provider		
	Baseline	**Post**	**P**	**Baseline**	**Post**	**P**
Self-rate knowledge						
PGx	1.75	3.0	.0036[a]	2.88	3.33	.089
Basic genetics	2.88	3.43	.048[a]	3.13	3.83	.064
Precision medicine	1.88	3.57	.0015[a]	2.14	3.18	.0034[a]
AA ancestry and PGx	3.13	3.86	.045[a]	2.0	3.27	.0005[a]
Attitudes						
PGx in the clinical setting	3.0	2.86	.67	3.42	3.45	.46
DTC testing in the clinical setting	3.38	2.83	.90	2.93	3.09	.34
PCPs should have PGx knowledge	4.38	4.57	.29	4.21	4.36	.30
PCPs should counsel based on PGx knowledge	4.38	4.57	.24	3.93	4.18	.22
PGx will be routinely used in the future	4.25	4.29	.46	4.14	4.45	.13
Knowing my genetic info will change my behavior	4.38	4.57	.24	4.14	4.0	.67
DTC companies provide accurate results	3.63	3.86	.24	2.79	3.27	.096
Lay people are capable of interpreting their results	2.75	2.86	.41	2.29	2.45	.32

AA, African American; DTC, direct to consumer; PGx = pharmacogenomics.
a. statistically significant.

based organizations and all self-identified as African American or Black.

Feasibility of Educational Intervention and Methodology

We had 100% live course attendance. All participants were highly motivated, especially the community members. We found that during the live courses, participants were engaged. They interacted with course instructors positively and voiced interest in the material. Community members engaged in the PGT session were receptive to sharing information about the benefits of genetic testing and personalized medicine with their clients, friends, and family. Community participants also expressed the desire to participate in joint training sessions and dialogue along with health care providers.

User experience was generally positive as evidenced by survey responses regarding perceptions of the intervention. Retention rates were high as evidenced by full participation in live courses and more participants submitting post-intervention surveys after completion of the course materials. Suspected reasons for not returning surveys were inconvenience of paper surveys and lack of time for completion.

Website deployment went smoothly. There were no reported systems failures by participants. Three participants reported difficulty logging in to the website, but after troubleshooting, this was found to be secondary to user error (forgotten password) rather than website fidelity.

PGT participation was generally favorable as determined by baseline and post-intervention survey results as described in subsequent sections. Feedback regarding the course materials, burden of the intervention, and barriers to participation were gleaned via face-to-face conversations and open-ended survey responses. As an additional measure of recruitment feasibility, we determined an enrollment ratio of 30 out of the potential 235 (13%) Mile Square provider and community population.

Knowledge of PGx

Providers

Mean baseline knowledge for providers was 7.86 questions correct out of 13, which increased to 8.64 questions post-intervention (P=.21). With the exception of two participants, all respondents who provided both baseline and post-intervention data had scores that showed an increase in knowledge or stayed the same. Three participants' scores remained unchanged,

and the remaining providers had an increase in scores (Figure 2).

Providers' self-described knowledge increased in the areas of personalized medicine and the contribution of African American ancestry to PGx (Table 1). There were no differences in whether a provider would refer a patient for PGx testing. Interest in referral was high (12/14, 86%) at baseline and stayed high post-intervention (9/11, 83%).

Community

Mean baseline knowledge for community members was 3.63 and increased to 5.42 questions correct out of 7 after intervention. Community members' self-described knowledge of PGx concepts, basic genetics, precision medicine, and the contribution of African American ancestry to PGx increased (Table 1).

Attitudes toward PGx

Providers

When asked which testing providers had ordered in the prior year, one participant replied that he or she had ordered multiple gene panels. Another participant responded as having ordered testing technologies of an unknown type. None of the other providers had ordered testing within the preceding year. At baseline, four of the providers had used genetic services to manage patients: PGx and diagnostic testing being used rarely (less than five times in a year), cancer risk testing being used rarely by three providers, and cancer risk testing being used frequently by one provider (more than 10 times in a year). Ten out of 11 providers (90.9%) said that the course motivated them to seek additional PGx training. The top two preferred learning methods that providers identified were online and in-person continuing medical education. The providers' biggest concerns for their own personal genomic testing were regarding data security and the potential impact PGx results could have on eligibility for health or life insurance. Otherwise, the provider attitudes and perceptions regarding PGx and precision medicine did not change from baseline to post-intervention.

Community

Most community member participants had not been offered genomics testing, except for one who had undergone PGx testing and another three who had genetic cancer risk testing. Community members felt that prenatal carrier testing became more useful for understanding and managing personal health after educational intervention compared with baseline (1-sided Fisher's exact=.007). After intervention, community members agreed more strongly that they would feel comfortable having a primary care physician explain the process of PGx testing. The community's biggest concerns for genomic testing were regarding data security and the potential impact PGx results could have on health insurance eligibility.

Discussion

We have determined that a PGx educational program tailored for an underrepresented community is feasible and acceptable. Our educational intervention has the potential to increase awareness and promotion of PGx and genomics research concepts in diverse settings. In this post-genomic era, the availability of commercial genomics testing has created a unique opportunity for patients to access unprecedented amounts of health-related data. We have found that members of traditionally underserved communities are eager to learn more about their personal risk and PGx data. This community desire has the potential to outpace primary care providers' ability to counsel patients. To best accommodate this growing need, health care providers must gain a foundation of knowledge regarding basic genomics and PGx concepts.[10,18]

Our educational intervention has the potential to increase awareness and promotion of PGx and genomics research concepts in diverse settings.

To our knowledge, this is the first study to incorporate PGT in a FQHC. Others have recognized the importance of fostering a community-based approach to genomic research and education.[19,20] Collab-

orative research relationships with underserved populations should be a fundamental tenet in future genomics research. Concerns about the potential for the scientific community to misuse genetic information has historically been a barrier for many African Americans to participate in genetic research.[7]

However, education efforts that emphasize the value of such information for improving the health of African Americans could overcome many of these barriers.[8] We found that confidence in interpreting results increased with our educational intervention. We also showed that confidence in the accuracy of testing with direct to consumer tests did not change from baseline. Notably, all of our participants opted to undergo the optional personal testing.

Providers had a baseline interest in PGx and precision medicine. Similar to providers, community members described interest in PGx concepts. Also, like providers, the community's biggest concerns for genomic testing were regarding data security and the potential impact PGx results could have on health insurance eligibility. After intervention, community members agreed more strongly that they would feel comfortable having a primary care physician explain the process of PGx testing; however, providers' level of comfort did not significantly increase. The desire to pursue precision medicine likely exceeds the current level of comfort providers have in discussing these important concepts.

Our findings are also promising in demonstrating that, by engaging communities, we can increase the interest in participation in future research projects. Community-based participatory research experts have shown that through genuine collaborative efforts, academicians can gain the trust of the communities with which they want to work.[8,21] To date, genetic consortia have been the primary source of information on the contribution of genetics to CVD risk. As more cohorts that include racial/ethnic minorities join these collaborative efforts, the prevalence of risk alleles in minority cohorts can be determined, as well as their relationship with incident CVD risks.[22] Finally, if the goals of personalized medicine are realized, these genomic findings may be combined with phenotypic information to provide precise characterizations of individual risk for CVDs.

There are some limitations to our study. Despite recruiting efforts, the number of provider and community member participants who enrolled and completed both assessments, was small. We could not account for missing data and are underpowered to detect pre-post changes in some meaningful effect sizes. In addition, we relied on convenience sampling, rather than random sampling. Participant responses may be subject to self-selection bias. Our results may not be applicable to patient populations in other locations that do not share a similar socioeconomic and ethnic/racial makeup as the underserved communities of Chicago represented in this study. Nevertheless, for a pilot study, we had an adequate sample to achieve our goal of determining feasibility. There is no benchmark for intervention adherence as measured by survey completion rates.[17] We successfully recruited all 30 participants to complete the live course intervention, of which 24/30 (80%) submitted either their baseline and/or post-intervention survey data. Additionally, a single PGT program was utilized for PGx education, which does not allow for direct comparison of other currently available modalities. It should be noted that these factors could limit the scope of the majority opinion, educational value, and assessment results among participants included in this study. Nevertheless, the findings herein should be viewed as hypothesis generating and will help guide future research.

Conclusion

In studies where racial and ethnic minorities are recruited, some findings may be compromised by small sample sizes.[23] Historical issues of misuse and abuse of disenfranchised communities for the benefit of science have likely contributed to medical mistrust, which has then led to low rates of research participation.[24,25] This pilot study has provided a critical opportunity to understand the acceptance of the African American community regarding genomics research.

We have created a cardiovascular PGx educational program tailored for an underrepresented population. By educating providers and community members of the benefits of precision medicine in a culturally sensitive way, we hope to enhance trust in the medical system and en-

courage future research participation.[26-28] We plan to replicate the program at another FQHC site to bolster data collection. Future assessment of the fidelity of our intervention will require evaluation of community member engagement via social network analysis and monitoring referrals via the electronic medical record. Through implementation of successful educational interventions, we eventually hope to counteract historical discrimination and underrepresentation in medical research. With greater involvement of racially diverse communities in cardiovascular pharmacogenomics research, the field will more accurately reflect at-risk populations.

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Conflict of Interest

No conflicts of interest to report.

Author Contributions

Research concept and design: Johnson, Massart, Empey, Reis; Acquisition of data: Da Goia Pinto, Aponte-Soto, Watson, Massart; Data analysis and interpretation: Johnson, Massart, Empey; Manuscript draft: Broughton, Empey, Massart, Da Goia Pinto, Aponte-Soto, Reis, Watson; Statistical expertise: Johnson; Acquisition of funding: Johnson, Reis, Winn; Supervision: Reis, Watson, Winn, Massart

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