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Engaging heart failure patients from a clinical data research network: A survey on willingness to participate in different types of research

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Abstract

The willing participation of patients in clinical research is a critical element in national efforts to collect health data for precision medicine and large cohort studies. However, recruiting patients is challenging. Clinical data research networks (CDRN) have primarily been used for observational studies, but may be able to enhance recruitment efforts. We need a better understanding of patient motivation and preferences for research participation and their interest in different types of research activities, particularly among those who are already represented in CDRNs. We surveyed a heart failure patient cohort constructed from EHRs in a CDRN to assess research participation. Results showed that CDRN recruitment is feasible. Respondents were most interested in completing a one-time survey and giving a blood sample one time. They were least interested in a study about weight control that require surgery. We found statistically significant associations between race and research activity interests.

Introduction

The goal of precision medicine research is to better understand the impact of individual variability in genes, environment, and lifestyle on disease prevention and treatment. The success of this type of research is heavily dependent upon the willingness of large numbers of volunteers to join research initiatives and share their genetic, health and lifestyle data. Electronic health records (EHR) from multiple health care centers, when aggregated under a standard data model, can facilitate identification of large-scale cohorts. The establishment of clinical data research networks (CDRNs) offers an opportunity to leverage EHR resources and lower the technical and regulatory barriers for research. However, first generation CDRNs such as the Health Maintenance Organization Research Network (HMORN) Virtual Data Warehouse[1] and the U.S. Food and Drug Administration (FDA) Sentinel Initiative research network[2] have primarily utilized retrospective observational data from existing clinical data and did not engage participants directly.

Enrolling patients into research studies has traditionally been challenging. In fact, Williams et al. reported that insufficient accrual rate was one of the major reasons for terminated clinical trials reported in ClincalTrials.gov database.[3] In other types of research, such as studies based on surveys, which require less effort than clinical trials on the part of participants, response rates are quite low, hovering around 9% for telephone surveys.[4] A number of studies have shown that racial and ethnic minorities in the US are less likely to express willingness to participate in a health-related studies[5,6] Underrepresentation of minority groups has also been identified in previous clinical trials.[7,8] Several studies have shown that people with higher education level were more willing to participate in medical research.[9,10] In addition, participants were more likely to share data via a research network if requests came from hospitals, universities, or medical groups, as they had trust in such organizations.[11] Thus, one concern is whether CDRNs can effectively engage diverse patients and enroll them in research studies.

The purpose of this study was to examine if a cohort of patients with heart failure identified from the EHRs of a large CDRN could be engaged to participate in new research, and to assess what type of research activities they preferred. We surveyed patients from the patient-centered SCAlable National Network for Effectiveness Research (pSCANNER) on their willingness to participate in future research. pSCANNER is a stakeholder-governed, privacy-preserving, distributed CDRN with access to EHRs across institutions and on over 30 million patients from all 50 states[12,13] that was initially supported by the PCORnet.[14] Our rationale for surveying participants was that understanding challenges from their perspectives could help CDRNs improve recruitment and retention for future studies.

Methods

In the pSCANNER network, heart failure was a condition of interest to investigators, and several future studies in this condition were planned. We first identified a cohort of patients with heart failure by running a query written against the Observational Medical Outcomes Partnership Common Data Model (OMOP) using ICD-9/ICD-10 code and the following inclusion criteria: (1) Age ≥ 18 years old; (2) Two reported diagnoses (inpatient or outpatient) related to HF (ICD-9 CM codes 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 414.8, 428.x.) between 2011 and 2016; OR one principal hospital discharge diagnosis of heart failure between 2011 to 2016, for patients not known to be deceased.

The identified participants were recruited first via e-mail (if the email address was available), using a consistent template identifying the study as conducted by pSCANNER and signed by a local investigator. A telephone outreach firm conducted phone recruitment and completion of the survey for patients for whom a valid email address was not available, or who did not respond to an email. A total of five attempts were made to contact participants. IRB approval was obtained at each of the pSCANNER sites that participated in the study: five University of California health systems (UC San Diego, UC Davis, UC Los Angeles, UC Irvine, and UC San Francisco), Veterans Administration Health System in San Diego, and the University of Southern California, Keck School of Medicine including AltaMed, a USC-partnered community clinic. For one of the sites, only in-person recruitment with paper and pencil survey collection was conducted.

The survey was developed by the PCORnet Survey Team (KK was a member), a collaborative group of investigators from multiple CDRNs participating in PCORnet. Items on the survey were intended for used by cohorts of people who were overweight/obese and by those with other common chronic conditions, such as cardiovascular disease. The items included: (1) key demographics and self-reported health status, (2) participants' interest to participate in a variety of research activities (19 activities rated using a 3-point Likert response scale from 1=not interested to 3=very interested), and (3) preferred mode of contact for future research with yes/no response categories. The order in which each of the research activities were presented was randomized to reduce bias. The survey took approximately 5 to 7 minutes to complete. The survey was implemented in a centralized Qualtrics server and de-identified, individualized links created for each participant candidate. Participants who accessed the survey website could review the purpose of the project, the elements of consent, and the process for withdrawing from the cohort and for completing the survey. The survey responses collected by the phone interviewer were entered into Qualtrics using the unique, de-identified link. There was no time limit to the survey. All survey data were collected and stored in standardized formats under rigorous security protocols. Survey responses, including self-reported identifiers, were retained by each site's research personnel on a password-protected secure server. Non-identifiable survey responses were attached to the pSCANNER database for individuals who responded. Direct identifiers reported on the survey (email address and phone number) were not attached to the electronic record.

All statistical analyses of data were performed in SPSS (SPSS, Chicago, IL, USA). The socio-demographics and health characteristics and mode of contact questions were summarized as numbers and percentages. Two-way analysis of variance (ANOVA) with post-hoc Tukey honest significant difference (HSD) was performed to compare the mean total scores of Research Activity Interest questions and to check for a difference between groups for two categorical demographic covariates: race and education. Statistical significance was accepted as $p \leq 0.05$.

Results

Completion rates for the survey are noted in Table 1. The survey was completed by 2,444 respondents (10.2%) of the total 23,955 heart failure cohort. Of the 2,444 people who completed the survey, 68 were aged under 18 and did not meet the eligibility criteria. Therefore their survey data were excluded from further analysis, leaving 2,376 completed surveys. Table 1 shows response rates by each of the 7 pSCANNER organizations.

Table 1: Survey cohort breakdown by recruiting organization (A-G)

Heart Failure Cohort Survey	A	B	C	D	E	F	G	Total
HF Total	6,575	2,012	3,324	5,460	4,244	2,100	240	23,955
# Surveys Completed	406	143	653	677	269	145	151	2,444
% Completed	6.2%	7.1%	19.6%	12.4%	6.3%	6.9%	62.9%	10.2%

Table 2 summarizes the socio-demographic and health characteristics of survey respondents (n=2,376). The mean age was 63 years (*SD*=15.2, range 18-97) and majority were male (59%). The respondents were likely to be Caucasian (58%) and college educated (69%). About half of respondents (44%) were married at the time of completing the survey. Most of the respondents (60%) were overweight or obese (having BMI ≥ 25) and 867 (36.5%) were diagnosed with diabetes. Among the 2,376 respondents, 756 (32.2%) indicated that they had previously participated in research.

Table 2: Socio-Demographic and Health Characteristics of Responders

Characteristic	***n***	***%***
Age in Years, *M*, (*SD*), range	2,376	
63.0, (15.2), 18-97		
Gender		
Female	963	40.5
Male	1,395	58.7
Other	2	0.1
Ethnicity and Race (Self-Report)		
White	1,376	57.9
Hispanic	447	18.8
Black	294	12.4
Asian	104	4.4
Other	64	2.7
Native American	28	1.2
Pacific Islander	23	1.0
Middle Eastern	4	0.2
Prefer not to answer	23	1.0
Education		
8th grade or less	134	5.6
Some high school	138	5.8
High school graduate or GED	444	18.7
Some college or 2-year degree	843	35.5
4-year college graduate	391	16.5
More than 4-year college degree	400	16.8
Currently Married	1,048	44.1
Physical Activity Level[a], M (SD)	2,413	
3.5 (1.5)		
Obese (BMI ≥ 30)	917	33.4
Overweight (BMI 25 to <30)	653	27.5
Diabetes Diagnosis (Yes/No)	867	36.5
Previous participation in research	756	32.2

[a] Rated from 1 = very inactive, 2 = a couple times a month, 3 = active most weeks, 4 = several days a week, 5 = most days

Table 3 shows participants' interest in future research and their interests in different research activities, from 1= not interested to 3=very interested. Among the participants, the top five research activity interests were (1) completing a one-time survey or list of questions (very interested=48.6%), (2) giving a blood sample one time (45.1%), (3) giving a blood sample that is used to study your DNA(43.6%), (4) testing a treatment given by phone or over the Internet (43.5%) and (5) completing a survey two or more times (40.4%). Participants were least interested in participating in a study about weight control that required surgery (not interested=69.2%), a study that uses a medicine to help control weight (44.6%), and a project that involved other members in the family (42.3%).

The mean and standard deviation was calculated for each research activity to conduct a two-way ANOVA to examine the effect of race and education level on interest in research activities. There was a statistically significant association between the effects of participant race and the mean score for interest in all research activities ($F(8,2134) = 4.70$, $p < 0.0001$). However, no significant association was found between education and the total mean score ($F(6,2134) = 0.63$, $p = 0.71$).

Table 3: Willingness to Participate in Research

Interest in Research Activity[a] (n[b])	*Not interested, %*	*Somewhat interested, %*	*Very interested, %*
Completing a one-time survey or list of questions (n=2,369)	5.5	45.9	48.6
Giving a blood sample one time (n=2,370)	12.1	42.8	45.1
Giving a blood sample that is used to study your DNA (n=2,353)	16.0	40.5	43.6
Testing a treatment given by phone or over the Internet i.e. like getting advice about your health (n=2,368)	14.6	41.9	43.5
Completing a survey two or more times (n=2,364)	12.9	46.7	40.4
A study about weight control that focuses on working on your diet or how active you are (n=2,317)	24.3	35.5	40.2
Taking part in a project that requires you to wear a device or monitor that collects information about your activities (n=2,363)	16.7	44.9	38.4
A study about weight control that tried to understand the genetics of obesity, and would require a blood sample from you (n=2,310)	31.4	31.0	37.6
Completing a weight related survey two or more times (n=2,306)	22.9	42.9	34.2
Testing a treatment where you need to come to clinic one or more times (n=2,365)	20.9	46.9	32.1
Taking part in a project where you have to respond to phone calls or text messages to provide information about what you are doing with diet or exercise or other issues about your health every day (n=2,370)	25.1	44.2	30.6
A study that uses medicines to help control weight (n=2,311)	44.6	28.6	26.9
Taking part in a project that involves meeting at a local community center or school (n=2,367)	28.9	45.2	25.9
Testing a treatment where you have to take a medicine or other treatment, come for clinic visits, AND give blood samples (n=2,366)	35.8	40.7	23.5
Testing a treatment where you have to take a medicine or other treatment, and come for clinic visits (n=2,366)	33.9	43.0	23.2

Taking part in a project that involves you and other people in your family (n=2,363)	42.3	37.1	20.6
Taking part in a project in which you would stay in the hospital for 1 or more days (n=2,366)	41.9	37.8	20.2
Taking part in a project which involves a procedure such as a special x-ray or new type of surgery (n=2,362)	39.9	42.0	18.1
A study about weight control that required surgery (n=2,292)	69.2	18.8	12.1

[a] Each activity was rated from 1 = not interested, 2 = somewhat interested, 3 = very interested
[b] Total number of people who responded to the survey item

Participants indicated the preferred modes of contact to learn about potential research studies (**Table 4**). Half of respondents (50%) preferred to be contacted by personal phone call from research staff or doctor. Patients were also willing to be contacted by email (35%), and letter or postcard in the mail (29.9%). Less than 2% of respondents did not wish to be contacted for future studies. The least preferred mode of contact was through social media (0.8%).

Table 4: Mode of Contact (n=2,376)

Interest in Research Contact, by Mode[a]	***n***	***%***
Personal phone call from research staff or my doctor.	1,192	50.2
E-mail	821	34.6
Letter or post card in the mail	678	28.5
Cell phone text messaging	359	15.1
Talking face-to-face with research staff or my doctor when I am visiting the clinic	345	14.5
Other	147	6.2
A computer-created phone message	99	4.2
Do not contact me	42	1.8
Social media (such as Facebook, Twitter, or Pinterest)	20	0.8
[a] Percentages do not add up to 100% because multiple responses were allowed.	3,703	

Discussion and Lessons Learned

The design and administration of our survey demonstrated the feasibility of identifying a clinical cohort from EHRs in a large CDRN and engaging them to participate in a new research topic.

Lessons Learned for the CDRN. While the IRB protocol was identical at the sites except for site G, where only in-person survey completion was approved, there were variations in implementation that may account for the differences in the response rate. At site G, the number of completed responses was the lowest due to the need for in-person staffing to recruit respondents during clinic hours. However, the in-person engagement appears to have resulted in very high response rate. Additionally, the overall response rate of 10.2% was comparable to the other surveys of CDRN cohort that incorporated broad recruitment approaches such as unsolicited e-mails to eligible patient population.[15] Site A was the first site to field the survey. At this site, all patients were emailed at the same time with the letter signed by the pSCANNER PI and a physician, but not one who was associated with Cardiology. A number of calls were received from patients questioning why they had been contacted and whether the study was a legitimate research project from that institution. Based on the experience of site A, site C revised its invitation email to be co-signed by a cardiologist and sent out emails in four batches one week apart to allow for any

adjustments needed. After the first batch, cardiology clinics at site C also received a few calls and questions during clinic visits asking about the legitimacy of the study. Hence, site C developed an informational brief about the study and distributed it to all clinic staff and physicians so that they could respond knowledgeably to any patient questions. This was distributed before the second batch of emails was sent.

Discussion among the pSCANNER team highlighted the importance of centralized coordination in accomplishing this study efficiently and effectively. First, one site tracked coordinated the project, created template invitations and letters, tracked responses and communicated with all site project managers and with the telephone survey firm. There was one contract for the survey firm that covered all sites. A different site developed and hosted the Qualtrics survey, delivering unique survey links that each site could match to their participant records. This allowed for efficient site-level tracking while allowing patient privacy to be maintained at the local site.

Patients' willingness to participate in clinical studies is critical for advancing precision medicine research. As we learn more about patients' attitudes and preferences toward enrolling in research, the information can be useful in designing future studies and improving patient recruitment and retention. Overall, the majority of patients in our survey showed favorable attitudes towards participating in future research studies. High interest level was shown for one-time completion of survey/questionnaire or one-time submission of a biospecimen. On the other hand, it is not surprising that respondents were less enthusiastic about participating in research that involved more invasive, higher burden processes, or research that involved family members. This is in line with other studies that investigated factors influencing clinical research participation.[16,17] The high level of hypothetical participation among respondents maybe due to the fact that the respondents were already enrolled in this survey study. Also, respondents might already have established trust in research conducted by state-supported, large research universities and their academic medical centers.

While we did find a significant association between participant race and interest in all research activities, we were not able to make interpretations on each race factor and the research interests. Some studies have reported that racial/ethnic minorities tend to have reduced willingness to participate in research due to skepticism or fear toward medical research.[8,18,19] On the contrary, other studies have shown that participants with minority identity showed greater willingness to participate in medical research.[15,20] Prior studies have also reported that women, elderly, and minorities were consistently under-represented in cardiovascular disease (CVD) clinical trials.[21–23] However, more recent online survey of 504 respondents with CVD showed that there were no significant differences in willingness to participate in clinical research based on sex.[24] Further analysis documented that willingness to participate in clinical research were similar among patients with CVD and patients with other chronic conditions.[24] Unlike our study which assessed participants' willingness to participate in different types of research activities, this survey used a single-item to measure willingness to participate in clinical research. Cohort studies must be able to recruit participants who are representative of the population in order to be meaningful.

The majority of our survey respondents preferred to be contacted by research staff or their physician by personal phone call for future trial participation. This finding is similar to other studies reporting a great willingness to participate in research if asked by their own doctor.[18] Although still at an early stage, using social media as a tool for clinical trial recruitment has shown some promising results in several clinical trials;[25,26] even showing effectiveness in reaching historically hard-to-reach populations.[27,28] Interestingly, social media was the least preferred means of contact among our survey respondents. This may be because our mean age of respondents were 63 years old and they may not embrace social media platforms as much as their younger counterparts. Future studies that assess age and cultural differences in the use of social media for recruitment tool may provide additional insights.

Several limitations must be noted. First, the survey respondents were limited to heart failure patients who were primarily treated in academic healthcare facilities in California. Thus, given geographic and cultural differences, these findings may not be generalizable to patient populations in other health settings or regions of the United States. Additionally, this was a self-report survey and therefore data regarding willingness to participate in research may be prone to social desirability biases. It is possible that participants reported higher willingness for future research participation to make a favorable impression. Furthermore, the cross-sectional design of this study makes it difficult to draw casual inferences about factors affecting respondents' willingness to participate in research. Despite these limitations, our results suggest that CDRN infrastructure is able to support prospective enrollment of patients into future clinical studies.

Conclusion

The willing participation of patients is a critical element in ongoing national efforts to construct cohorts for precision medicine and other health research. However, enrolling and retaining patients to clinical research studies can often be challenging. This survey demonstrates that CDRNs can be a source for recruiting for large study cohorts among a geographically diverse population and engaging patients into participating in future studies. Yet, identification with the local institution and investigators may be an important element in garnering patient willingness to engage in future research. Overall, most of the survey respondents showed interest in participating in future studies. The lessons learned in this CDRN may be useful for other cohort studies and network-based research efforts.

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