A Novel Patient Recruitment Strategy: Patient Selection Directly from the Community through Linkage to Clinical Data

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Appl Clin Inform 2018;9:114–121.

Abstract

Objective This article presents and describes our methods in developing a novel strategy for recruitment of underrepresented, community-based participants, for pragmatic research studies leveraging routinely collected electronic health record (EHR) data.

Methods We designed a new approach for recruiting eligible patients from the community, while also leveraging affiliated health systems to extract clinical data for community participants. The strategy involves methods for data collection, linkage, and tracking. In this workflow, potential participants are identified in the community and surveyed regarding eligibility. These data are then encrypted and deidentified via a hashing algorithm for linkage of the community participant back to a record at a clinical site. The linkage allows for eligibility verification and automated follow-up. Longitudinal data are collected by querying the EHR data and surveying the community participant directly. We discuss this strategy within the context of two national research projects, a clinical trial and an observational cohort study.

Conclusion The community-based recruitment strategy is a novel, low-touch, clinical trial enrollment method to engage a diverse set of participants. Direct outreach to community participants, while utilizing EHR data for clinical information and follow-up, allows for efficient recruitment and follow-up strategies. This new strategy for recruitment links data reported from community participants to clinical data in the EHR and allows for eligibility verification and automated follow-up. The workflow has the potential to improve recruitment efficiency and engage traditionally underrepresented individuals in research.

Keywords
- clinical trials
- data linkage
- cohort studies
- patient outcomes
- patient recruitment

received
October 19, 2017
accepted after revision
December 21, 2017

DOI https://doi.org/10.1055/s-0038-1625964.
ISSN 1869-0327.

Background and Significance

Since the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009, the increased availability of routinely collected electronic health data created the opportunity to conduct research more efficiently across diverse populations. For example, researchers have increasingly shifted toward the design of pragmatic clinical trials (PCTs), which are comparative effectiveness trials conducted in a real-world setting and embedded within routine clinical care.[1,2] PCTs are designed to improve the applicability and generalizability of trial findings to clinical practice with broad selection criteria, utilization of routine clinical settings and personnel, few follow-up visits, and simple design.[1,3] The use of "real-world evidence" or information obtained outside of traditional clinical research settings is also encouraged in the field of drug development and within the 21st Century Cures Act.[4,5] Real-world evidence includes data from electronic health records (EHRs), claims and billing data, and other data obtained through sensors and health applications. Similarly, in the field of observational epidemiology, The Precision Medicine Initiative (PMI) *All of Us* Research Program plans to use EHR data as part of follow-up of its 1,000,000 person–cohort study.[6]

A challenge to both traditional and pragmatic research studies is the recruitment of underrepresented populations. Many observational cohort studies and clinical trials have traditionally been conducted within academic medical centers, hospital systems, or other institutions focused on clinical care because clinical institutions typically offer increased access to patients, clinical data, and research teams. This process ignores patients who fall outside of clinical care and may benefit from participation in research. Minority patients are generally underrepresented in clinical research because of inadequate outreach, lack of awareness, and/or mistrust of the system.[7–9] This is problematic not only for recruitment, but also because much of the success of medical research is dependent on positive public perception of the value of research.[10] Active community engagement in clinical research may help to increase enrollment of study participants, including those of underrepresented groups, reduce the time of the research project itself, and improve dissemination and adoption of research findings among communities.[10] Additionally, community engagement and recruitment in research allows community members to understand their own health issues, while informing researchers and policy makers of the community priorities and the need for cultural sensitivity in research.[11,12]

Objective

We present and describe our methods in developing a novel strategy for the recruitment of underrepresented, community-based participants, for pragmatic research studies leveraging routinely collected EHR data. We discuss this strategy within the context of two national research projects, a clinical trial and an observational cohort study.

Methods

Conventional clinical research studies often occur within the confines of health care settings, as outlined in ►Fig. 1. Recruitment occurs through the identification of patients at their clinical encounters or prior to visits via EHR data. Following enrollment, data are collected from the patient directly and/or through historical EHR data. In this conventional workflow, patients are either surveyed directly for follow-up or queries are sent to the EHR to gather longitudinal patient data, a protocol incorporated into pragmatic research studies.[13,14]

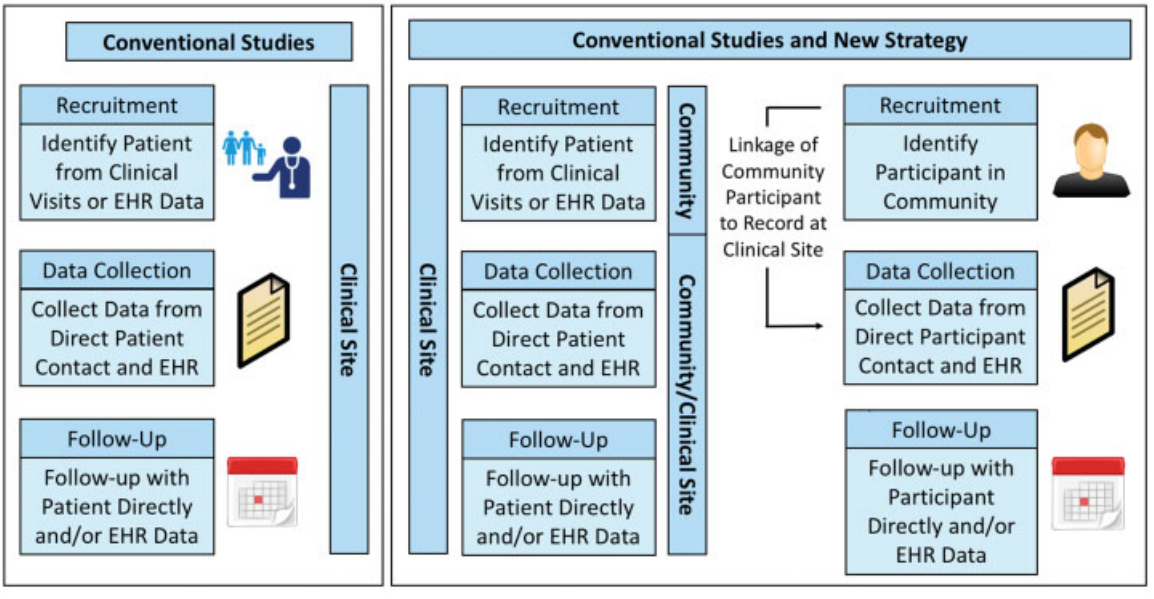

Fig. 1 Conventional stages of clinical research studies versus the new model for community-based recruitment.

Our new model moves outside of the clinical setting and into the community to identify participants for recruitment. Preliminary data are collected from participants at the time of outreach with full consent for their participation and access to clinical records. Utilizing identifiers from the collected data, participants are linked to a record at a clinical site for eligibility verification and continued data collection through EHR queries. Follow-up may occur directly from the patients, but through the linkage to the clinical records, researchers may also query EHR data for longitudinal information. This model facilitates the identification and recruitment of typically underrepresented participants.

Linkage

Linkage of the community participant back to a record at the clinical site is an integral component of the new recruitment model. During recruitment, participants are asked a set of screening questions to ensure eligibility for the clinical trial. The purpose of the linkage is twofold: (1) to verify the eligibility based on clinical evidence; and (2) to enable long-term, passive follow-up of the participant via EHR data. This implementation utilizes a privacy-preserving EHR linkage tool with hashing and matching components, as described by Kho et al.[15] The hashing application deidentifies the user information, which is shared across sites and linked for verification.

Workflow

►Fig. 2 presents an overview of the stages in the community-based recruitment workflow.

Potential study participants are identified by community organizations via community events or other outreach methods. Participants are asked a series of initial eligibility questions and the collected data are encrypted and deidentified using the hashing algorithm. If patients do not meet the initial eligibility, recruitment activities stop and the participant is thanked for his/her time. If initially eligible, this output is sent to the data hub/honest broker to conduct the linkage to clinical data (eligibility criteria/variables of interest are included in the data) using the deidentified hashing output from the participating clinical sites. If a match exists, the participant's eligibility for the study is verified and the data hub/honest broker alerts the community organization and the organization informs the community participant about successful enrollment. Based on the study design, participants are then surveyed for primary data collection directly via telephone, e-mail, or through an online portal. The participant may be contacted directly for subsequent follow-up, or queries may be sent to the clinical site by the clinical study hub to pull participant health information from the EHR.

Below, we discuss two case studies utilizing the community recruitment method in the following sections.

Case Study 1

Background for Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness (ADAPTABLE) Case Study

A. PCORI/PCORnet

In 2010, the Patient-Centered Outcomes Research Institute (PCORI) was established as a nonprofit organization to help patients, providers, payers, and policy makers make informed health care decisions and improve the quality of care by producing evidence-based research supported by all participants in the health care community.[16] With the goal of advancing use of electronic health data in comparative effectiveness research (CER), PCORI developed PCORnet: The National Patient-Centered Network.[17,18] The central

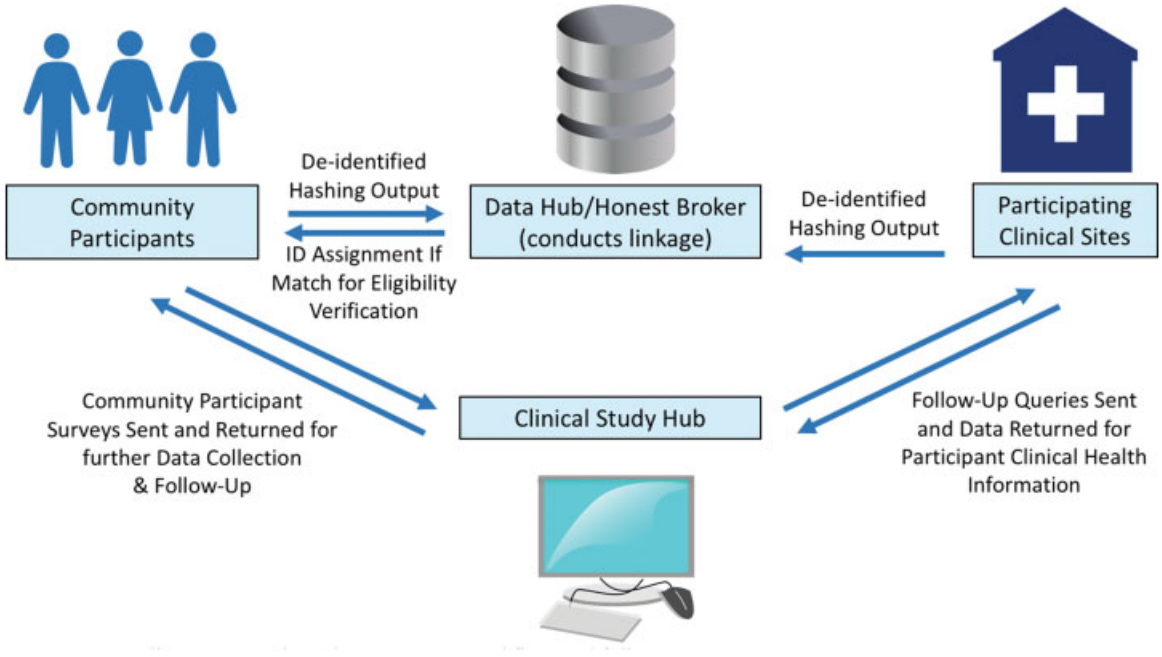

Fig. 2 Overall community-based recruitment workflow and follow-up.

goal of PCORnet is to maintain a "network of networks" of various health care institutions and stakeholder groups and build partnerships for the purpose of collecting and using data for improved CER.[17] PCORnet is a distributed research network conducting research across Clinical Data Research Networks (CDRNs) and People-Powered Research Networks (PPRNs).[17] Each site follows the PCORnet Common Data Model (CDM), a standardized data structure and format utilized by all CDRNs and PPRNs.[19]

B. CAPriCORN

The Chicago Area Patient-Centered Outcomes Research Network (CAPriCORN) is one of the 13 CDRNs within the national PCORnet infrastructure. CAPriCORN is a collaboration among 11 Chicago health care institutions, including private, county, and state hospitals and health systems, Federally Qualified Health Centers (FQHCs) and two Department of Veterans Affairs Hospitals, managed by one neutral nonprofit administrative entity with a subcontract to one nonprofit public health agency to serve as the central hub.[20]

CAPriCORN is a distributed data network; each participating institution maintains a relational data warehouse, including administrative and clinical data across inpatient and outpatient settings.[20] Each institution maintains their own PCORnet CDM and the CAPriCORN CDM. The CAPriCORN CDM includes all components of the PCORnet CDM and other additional data instruments and elements. An independent nonprofit, the Medical Research Analytics and Informatics Alliance (MRAIA) serves as CAPriCORN's data hub and honest broker.[21]

C. ADAPTABLE Background

ADAPTABLE is a demonstration project conducted through PCORnet.[14] This PCT is designed to compare the effectiveness of two aspirin doses, low (81 mg/day) versus high (325 mg/day), in preventing myocardial infarction and stroke among 20,000 individuals with coronary heart disease.[14] The project not only seeks to answer this clinical question, but to test the capabilities of and refine the methods for conducting PCTs through PCORnet.[14] ADAPTABLE presents a new model for clinical trials, aiming to minimize the burden of research activities on patients, clinicians, and institutions, while incorporating patient-reported outcomes (PROs).[22]

The trial assesses patient eligibility through a computable phenotype run against the EHR data mapped to the PCORnet CDM. Computable phenotypes are representations of clinical conditions developed by querying the EHR using a standard set of data elements or expressions.[23] Each site has developed its own methods of patient recruitment, which include direct mail, phone calls, electronic messaging, and in-clinic recruitment. If patients are willing to participate, they are consented and randomized via an online patient portal or via traditional methods for patients without access to the Internet. To access the portal, patients are provided with an access code or "Golden Ticket." Subsequent follow-up occurs from the patient directly through an online portal or phone surveys, through queries of the PCORnet CDM for the patient's health information, and through claims data if available.[24]

D. The CAPriCORN Approach to Community-Based Recruitment

A major aim of PCORI and PCORnet is to involve community organizations and patients in research. On the recommendations of CAPriCORN's Patient-Clinician Advisory Council, we designed and developed a novel recruitment strategy aimed at identifying underserved individuals in nonclinical settings who may be eligible to participate in ADAPTABLE. The strategy involves two community institutions, the Sinai Urban Health Institute (SUHI) and PASTORS4PCOR (P4P), in Chicago.[25,26]

To be eligible for the ADAPTABLE trial, participants must have received care at an institution within PCORnet that is participating in the trial. Potential participants identified by the community site must be linked to a participating CAPriCORN institution for future follow-up queries by the ADAPTABLE coordinating center. The linkage not only allows for assessment of the institution eligibility criteria, but also eligibility validation for patient-reported answers to the Health Screening Questionnaire.

There are five CAPriCORN sites participating in ADAPTABLE: Northwestern University, University of Chicago, Rush University Medical Center, NorthShore University HealthSystem, and the Cook County Health and Hospitals System (CCHHS). Each site maintains its own pool of eligible patients based off of the computable phenotype. At four sites, research assistants are responsible for identifying and inviting eligible patients to participate in the trial. CCHHS provided data for their pool of eligible patients for eligibility verification and follow-up of patients recruited in the community; active recruitment at CCHHS is planned pending finalization of data sharing agreements. As with all participating ADAPTABLE sites nationwide, individuals who are deemed eligible for the study will receive a unique "Golden Ticket" number to access the secure Web-based patient portal for consent and randomization, managed by the central ADAPTABLE Team. The tickets are unique to the CDRN and clinical site within the CDRN where the patient was identified.

Example Workflow

►Fig. 3 presents the workflow for the implementation of the community-based recruitment strategy within ADAPTABLE.

Potential study participants are primarily identified at community events. Community health workers from both SUHI and P4P interview potential participants by asking a series of eligibility questions. The first question asked of the interested participant is whether he/she receives clinical care at a participating CAPriCORN institution. Recruitment ends if clinical care is received outside CAPriCORN, as this is a requirement for eligibility. If care is received within CAPriCORN, the community health worker proceeds with a verbal consent protocol. Once verbal consent is obtained, the potential participant is asked a series of questions related to current aspirin dose, if any, allergy to aspirin, age, cardiovascular health, current medications, and if female, whether she is currently pregnant or nursing. The responses to the set of questions in the initial screening questionnaire

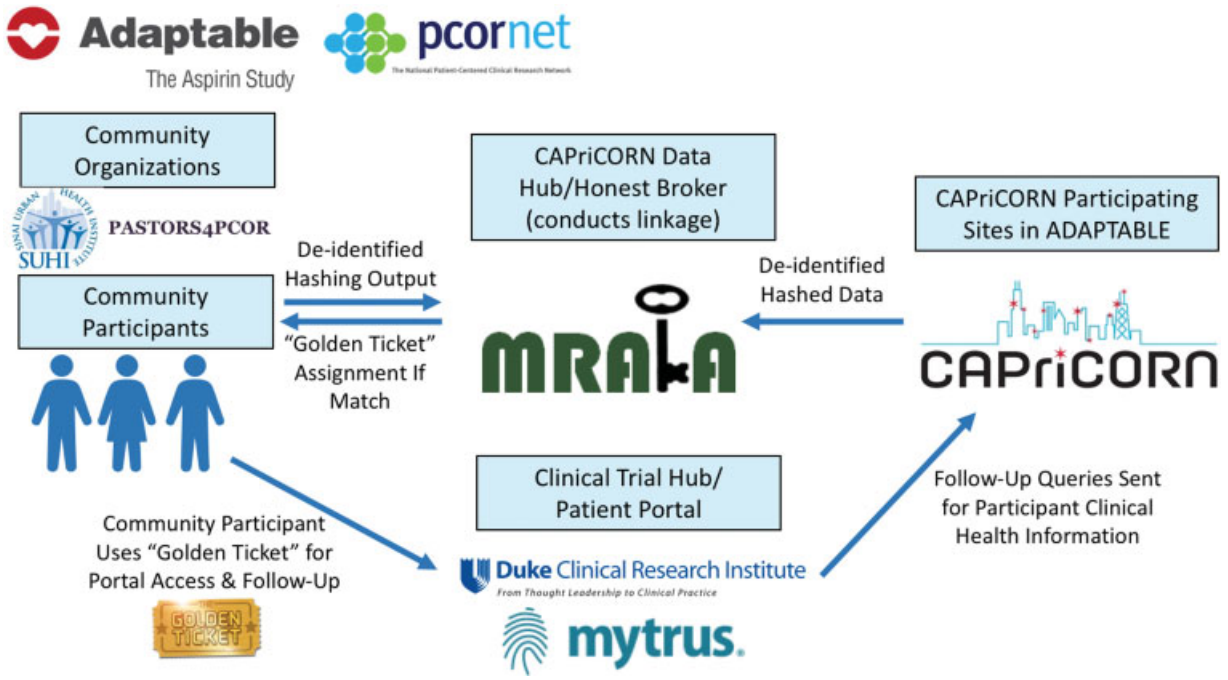

Fig. 3 ADAPTABLE community-based recruitment workflow.

are tied to eligibility logic. If eligible, the participant proceeds to the next questionnaire, which has two parts: (1) collection of provider contact information and (2) personal information from the participant including first and last name, date of birth, social security number, race/ethnicity, gender, and contact information (address, phone number, and preferred method of contact). After this questionnaire is administered, the eligibility interview with the participant is complete.

Data collected during the interview are recorded in REDCap (Research Electronic Data Capture), a secure data collection tool.[27] REDCap may be utilized either through a browser, if an Internet connection is available, or via the REDCap mobile application on a tablet in offline mode with data synced to the REDCap server once an Internet connection is available.

To link the potential participant with an existing record at a participating CAPriCORN site, we used the EHR linkage tool described above.[15] The hashing software is conducted locally at the community institutions and requires a one-time setup to configure the software. The software is installed on a local machine with an environment accessible to the REDCap server. A script is executed directly in the command line to abstract the data elements necessary from the REDCap database. The five inputs needed to create the deidentified Hash ID and 18 hashes are collected during the initial screening questionnaire.

The deidentified hashing output is sent via Secure File Transfer Protocol (SFTP) to MRAIA, the CAPriCORN data hub and honest broker, for linkage to a participating CAPriCORN site. Prior to implementation of the community-based recruitment strategy, the CAPriCORN sites participating in ADAPTABLE generated their hashing output and sent it to MRAIA. MRAIA matches the Hash IDs from the community institutions to the Hash IDs collected from the participating CAPriCORN institutions.

If there is a match to the CAPriCORN Hash ID table, MRAIA assigns a "Golden Ticket" to the participant record and shares the ticket number with the corresponding community site. If the community participant matches multiple CAPriCORN institutions, MRAIA has implemented informatics rules to assign ownership of the community participants, which may vary by project. Examples of ownership rules may be:

- Based on patients' last primary care visit.
- Based on disease focus, last specialist visit.
- Based on equal distribution of credit; that is, if three health systems are matches for one participant, and the first patient is assigned to System A, the next participant will be assigned to System B, and so on.

For ADAPTABLE, MRAIA has opted to implement the third option based on equal distribution of credit. Although community participants must be linked to a CAPriCORN institution to participate, the community institution will receive the monetary credit per randomized participant.

The community institution reidentifies the community participant following the alert from MRAIA that a match was made. The community health workers proceed by informing the participant of the successful match and eligibility verification and provide the Golden Ticket information. After receipt of the Golden Ticket, the community participant utilizes the ticket to login to the secure ADAPTABLE portal, managed by the Duke Clinical Research Team and Mytrus, for consent and enrollment. The community institution is required to follow-up with the community participant until the entire consent and randomization procedure is completed in the portal. Following this step, all future follow-up

occurs by the ADAPTABLE Coordinating Center. Follow-up surveys are sent to participants through the secure patient portal and queries are also sent to clinical sites for longitudinal patient data.

At the time of writing the manuscript, ADAPTABLE work was still underway and final outcomes were still being realized due to its novel design. We expect to have another report/paper in the coming year about the implementation of the community recruitment strategy within the ADAPTABLE case study.

Case Study 2

All of Us Background

The PMI was announced in early 2015 by President Obama and brings together the National Institutes of Health (NIH), National Cancer Institute, and Food and Drug Administration to bring precision medicine to health care.[28] A large focus of the PMI is to better utilize precision medicine to improve treatments, prevention, and care. To expand our knowledge about precision medicine, the PMI developed the *All of Us* Research Program, which will help facilitate the achievement of the PMI's long-term objectives.[6] The goal of the *All of Us* program is to build a research cohort of one million or more Americans to better understand the intersection of environmental, lifestyle, and biologic factors and their impact on health.[6] The size of the *All of Us* cohort will allow researchers to detect associations between gene, environment, and lifestyle factors, determine causes of differences in drug responses, discover biological markers that lead to changes in risk for common diseases, and discover new classifications and relationships between diseases.[6]

Example Workflow

The *All of Us* Research Program is another example of how researchers are leveraging a community-based strategy to recruit typically underrepresented individuals, while also utilizing EHR data for research.[29] The program utilizes two methods for participant recruitment, a community-based direct volunteer (DV) and health care institution-based method.[29] In the DV method, any American can volunteer to participate in the cohort study and consent for participation, reflecting the new community-based recruitment strategy presented above. A major goal of the research team is to ensure that the *All of Us* cohort is representative of the U.S. population, including those from various age, sex, race/ethnicity, socioeconomic, and geographic groups.[29] The institution-based method requires the collaboration of health care provider organizations (HPOs) to recruit participants, similar to the conventional clinical research workflow. The HPOs recruit, consent participants, and conduct the required study activities.

Regardless of the method of recruitment, each participant of the *All of Us* cohort is required to provide a biologic specimen, behavioral data, and health data for better understanding of diseases and their mechanism.[29] The eligibility criteria for potential participants are limited and center around the core requirements above. Those recruited from the community provide health data either from their EHR data, through direct transfer through the novel Sync for Science tool, or by undergoing an initial exam from a provider. For those participants identified at HPOs, it is the responsibility of the HPO to share the EHR data with the *All of Us* Program. At the time of consent, each participant will provide permission to be recontacted for follow-up, through direct contact with the participant and/or longitudinal collection of his/her EHR data.[29]

Data from various sources will be transmitted to the Data and Research Center (DRC) with full consent from the participant. Data approaches considered involve consented identified patient data and anonymized patient data from sources external to the EHR. To aggregate records from different sources for an individual participant, the *All of Us* working group proposed the utilization of a unique identifier (the PMI ParticipantID) and the use of record linkage strategies. The record linkage strategies may incorporate privacy-preserving methods for sensitive information as needed, such as the utilization of hashing algorithm for the patient identifiers prior to transmission to the DRC,[6] although with full patient consent, direct identity verification by participants is anticipated to be the prime method for record linkage.

The project details and methods will be finalized during Phase I of the *All of Us* Research Program. The Research Program has already formed a national team including Enrollment Sites, a DRC, a Biobank, and other partners to engage patients and communicate findings.[30]

Discussion

We developed and piloted a new strategy to recruit participants for pragmatic clinical studies in the community. Engaging patients directly from the community for research is a step toward more efficient recruitment of underrepresented populations for clinical research. This strategy demonstrates the potential for new, low-touch, pragmatic research methods.

Prior studies have discussed the methodology and best practices for clinical research recruitment directly from the community, but do not incorporate methods for eligibility verification and automated follow-up with EHR data.[7,31,32] Pragmatic research studies simplify eligibility criteria and screening to improve study generalizability in comparison to traditional clinical studies. Our strategy utilizes direct recruitment of participants outside of the clinical setting and further addresses the need to simplify screening and follow-up through the linkage of study participants back to records at clinical sites.

In pragmatic clinical research, the intervention of interest often occurs in a real-world setting and study visits are incorporated into routine clinical practice. Without regular interaction through clinical care, follow-up for community-based participants may be difficult. Automated follow-up via EHR data or direct patient contact is recommended for good clinical practice.[33] ADAPTABLE and *All of Us* incorporate follow-up via existing EHR data and direct patient contact (phone or e-mail). While other research studies have utilized

automated follow-up via the EHR,[13] this approach uniquely gathers community participants' clinical information.

The community-based recruitment and data collection protocols could be made more efficient by combining information collected directly from patients in their community with clinical data to provide the complete clinical and social picture of a study participant to researchers. The incorporation of PROs in PCTs is necessary to further increase applicability and generalizability of research evidence to clinical practice. The U.S. Food and Drug Administration defines PROs as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."[34] The utilization of PROs as outcome measures in comparative effectiveness trials has been limited thus far. PROs, combined with clinical data, can provide clinicians, researchers, and policy makers with the complete picture when evaluating interventions in research studies.

The community-partner strategy is not without limitations. As seen within ADAPTABLE, in order for the linkage to occur, the honest broker must have all hashes of eligible patients from the participating clinical sites. Without the hashes, the honest broker will be unable to match the potential community participant data to an existing record at the clinical site. Another limitation is that patients have to be seen at one of the participating institutions or have EHR data there to participate in the study. Study personnel may have to reach out to many individuals before identifying someone with EHR data at a participating institution. Leveraging EHR data for multiple patients and from multiple sites is also complex. Privacy and data ownership issues may arise and need to be addressed. ADAPTABLE was implemented within an existing research network with a common data model, making it easier to aggregate the EHR data. For *All of Us*, this infrastructure does not exist. Participants from the community must provide their own electronic copies of EHR data. This requires their home health care institutions to have technologies available to patients like "Blue Button" or Sync for Science to view, download, and transmit health care data to the Coordinating Center. This technology may not be available at all sites and may also come from multiple sites if one participant receives regular care at multiple institutions. Once received at the Coordinating Center, these data will be in multiple formats, making aggregation difficult before data curation.

Another limitation is the potential for duplication of the patients approached by both the clinical site and community site. To minimize this possibility, patients are asked during recruitment if they have ever been approached about the ADAPTABLE study by phone, letter, or during a visit with a health care provider. Additionally, for the ADAPTABLE project, it is difficult for community partners to identify eligible patients due to the specific eligibility criteria required. This community-based strategy may be better suited for PCTs or cohort studies, such as *All of Us*, seeking a very diverse sample of participants with more general eligibility criteria.

Conclusion

With the widespread use of EHRs and the need to engage a more diverse set of participants, researchers are looking for new and more efficient methods for recruitment and follow-up. We introduce a low-touch method to recruit potential participants from the community and link the participant to a record within a clinical institution. This allows for eligibility verification and automated follow-up by querying clinical information from the EHR. The workflow has the potential to improve recruitment efficiency and engage traditionally underrepresented individuals in research.

Clinical Relevance Statement

We successfully developed a low-touch method to recruit potential participants from the community and link the participant to a record within a clinical institution. This strategy allows for more efficient recruitment and engagement of underrepresented individuals in research and may be adapted to future research studies.

Multiple Choice Questions

1. Where is clinical research traditionally conducted?
   a. Community centers
   b. Academic medical center
   c. Law offices
   d. Public libraries
   Correct Answer: The correct answer is b. Clinical research is traditionally conducted within academic medical centers due to easy access to research staff, access to clinical data, and regular contact with patients. Community centers, law offices, and public libraries do not offer the same resources for clinical research.

2. Currently, how can patient data be linked from multiple data sources in U.S.?
   a. By global/national patient identifier
   b. Comparing common clinical conditions like flu
   c. Through the matching of personal identifiers such as date of birth, name, etc.
   d. Patient data cannot be linked or combined
   Correct Answer: The correct answer is c, personal identifiers are regularly utilized to link data from multiple sources. The United States do not have a global/national patient identifier and common clinical conditions like the flu do not offer the specificity needed for linking patient-level data. Patient data can be linked, therefore option d is not correct.

Protection of Human and Animal Subjects

This study is presenting an alternative design of cohort-based trails with no actual human subject involvement. The case study cited in the design was approved under CAPriCORN's own institutional review board (IRB) of record "CHAIRb" and a study protocol of

PCORI-funded ADAPTABLE, and NSF-funded "*All of Us*" protocols.

Conflict of Interest

Abel N. Kho and Satyender Goel hold equity in Health DataLink LLC, which provides privacy-preserving record linkage software.

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