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ResearchMatch on FHIR: Development and evaluation of a recruitment registry and electronic health record system interface for volunteer profile completion

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Abstract

Background: Obtaining complete and accurate information in recruitment registries is essential for matching potential participants to research studies for which they qualify. Since electronic health record (EHR) systems are required to make patient data available to external systems, an interface between EHRs and recruitment registries may improve accuracy and completeness of volunteers' profiles. We tested this hypothesis on ResearchMatch (RM), a disease- and institution-neutral recruitment registry with 1357 studies across 255 institutions. *Methods:* We developed an interface where volunteers signing up for RM can authorize transfer of demographic data, medical conditions, and medications from the EHR into a registration form. We obtained feedback from a panel of community members to determine acceptability of the planned integration. We then developed the EHR interface and performed an evaluation study of 100 patients to determine whether RM profiles generated with EHR-assisted adjudication included more conditions and medications than those without the EHR connection. *Results:* Community member feedback revealed that members of the public were willing to authenticate into the EHR from RM with proper messaging about choice and privacy. The evaluation study showed that out of 100 participants, 75 included more conditions and 69 included more medications in RM profiles completed with the EHR connection than those without. Participants also completed the EHR-connected profiles in 16 fewer seconds than non-EHR-connected profiles. *Conclusions:* The EHR to RM integration could lead to more complete profiles, less participant burden, and better study matches for many of the over 148,000 volunteers who participate in ResearchMatch.

Introduction

Recruiting the right patient for the right clinical study remains a challenge for advancing clinical and translational research [1]. Researchers are often limited to patient populations that are accessible through their affiliated healthcare providers or organizations. Moreover, recruiting a cohort of participants for a clinical trial with stringent inclusion criteria often results in an underpowered study [2]. Retrieving reliable patient information related to inclusion and exclusion criteria from sources such as the electronic health record (EHR) can be time-consuming and may lack the detail needed for trial eligibility assertion [3]. There may also be institutional limitations regarding what patient information can be accessed for preparatory research activities and which patients can be contacted if inclusion and exclusion criteria are met.

Community-driven clinical research registries can help address these recruitment barriers. ResearchMatch (RM) is a disease- and institution-neutral, national recruitment registry that facilitates enrollment of participants for clinical studies [4]. RM currently serves approximately 148,000 self-registered "volunteers" and over 13,000 researchers from 218 research institutions in the United States. RM enables researchers to send institutional review board (IRB) approved recruitment messages to cohorts of volunteers with select eligibility criteria. When joining RM, volunteers complete a profile, providing information about their location, demographics, conditions, and medications. These online forms are designed to be as user-friendly as possible, but accuracy is dependent on a volunteer's memory and willingness to disclose.

The 21st Century Cures Act requires EHR systems to allow patients to share their health data with external applications through Application Programming Interfaces (APIs) that conform to HL7 Fast Healthcare Interoperability Resources (FHIR) standards [5]. The Cures Act presents an opportunity to streamline the creation of RM profiles by enabling new volunteers to pre-populate their RM registration form with demographic, condition, and medication data pulled directly from the EHR. To assess the acceptability of pulling EHR data into RM and inform the design of the EHR to RM interface, we sought input from the community through a community engagement studio comprised of potential RM volunteers. After developing the

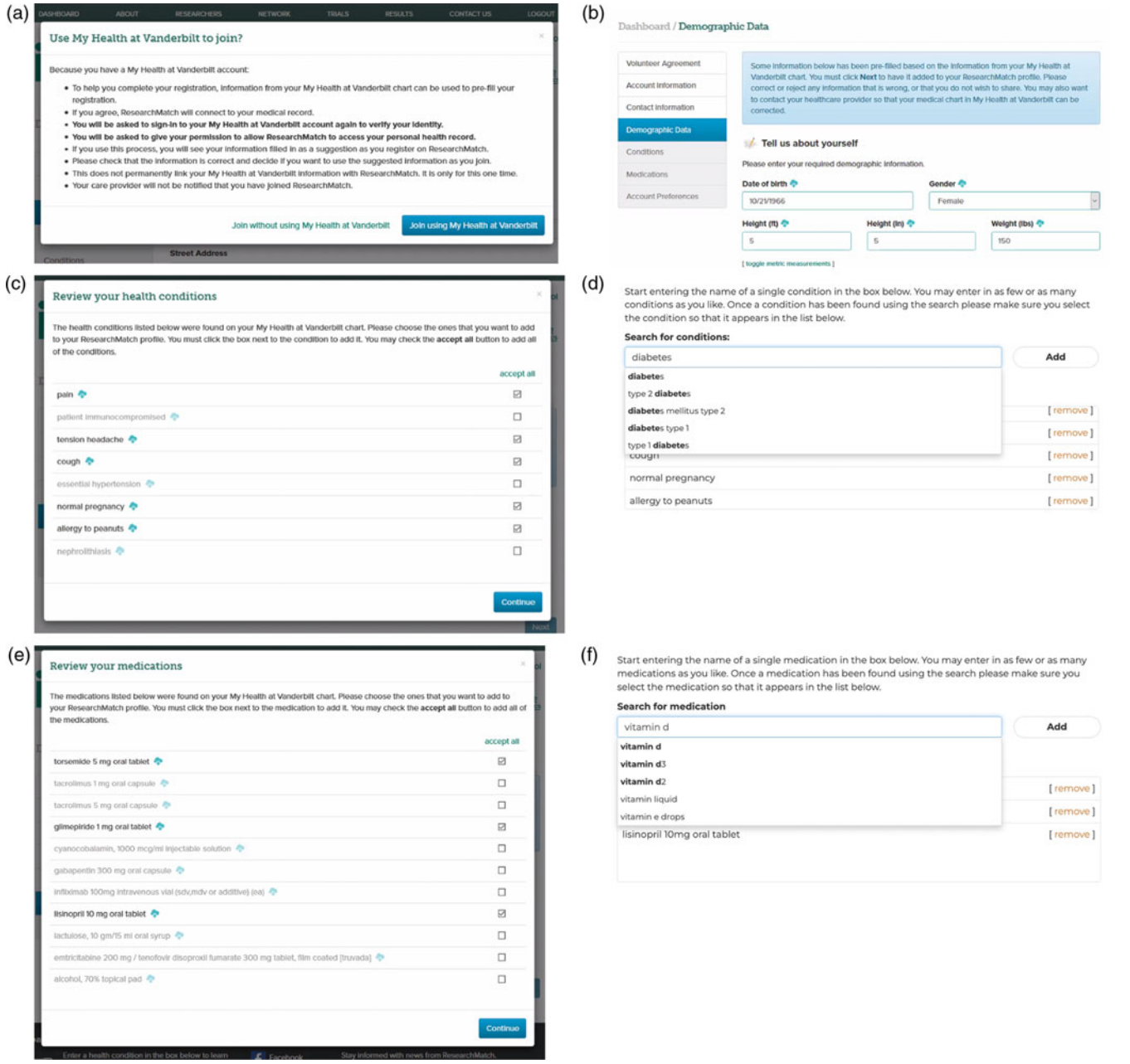

Figure 1. User interface for importing demographic, condition, and medication data from electronic health record to ResearchMatch profile.

interface based on feedback from this studio, we performed a study to assess whether participants included more information about their conditions and medications when the EHR interface was available.

Methods

Community Engagement Studio

In April 2020, we conducted a Community Engagement Studio (CE Studio) at Vanderbilt University Medical Center (VUMC) to provide feedback on the integration of RM with the EHR. The CE Studio is a structured approach that facilitates project-specific input from community and patient stakeholders [6]. Individuals were recruited to take part in the Studio through a database of past CE Studio experts, as well as through local community-based organization contacts. Participants in the Studio, called community experts, provided input on the project design, implementation, and dissemination of the potential EHR integration with RM. The 2-hour session was led by a neutral facilitator and scribe who was not involved with RM or the evaluation study. Community experts were presented with a storyboard of the proposed EHR integration and then discussed barriers to use and preferences to optimize user experience. The facilitator summarized the recommendations from the community experts and presented them to the RM team. The RM software development team then created the EHR to RM integration based on recommendations of the CE Studio participants.

EHR to ResearchMatch Interface

Screenshots for the final product were developed based on feedback from the CE Studio (Fig. 1). The integration was

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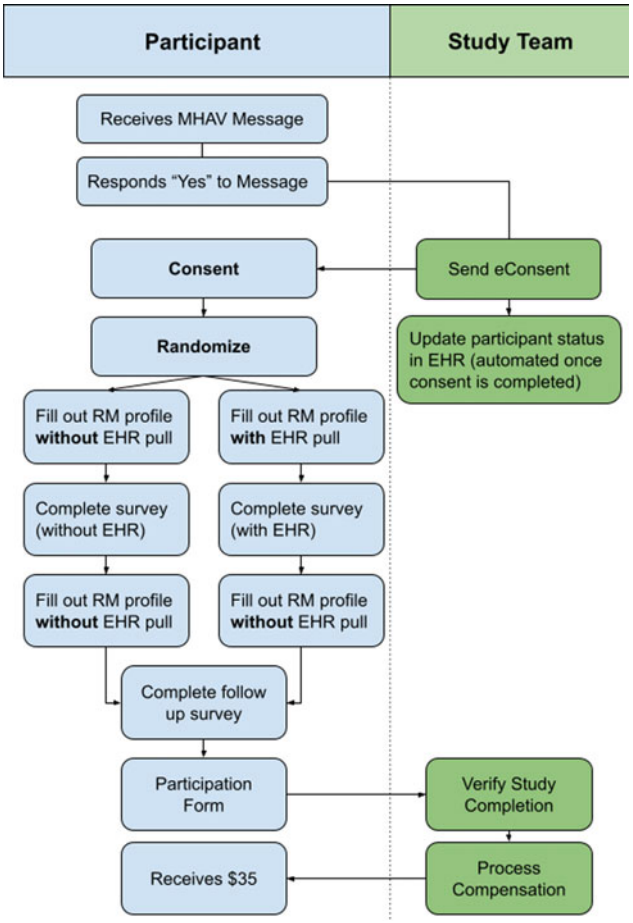

Figure 2. Study flow. EHR = electronic health record; MHAV = MyHealth at Vanderbilt patient portal; RM = ResearchMatch.

implemented as an application through Substitutable Medical Applications, Reusable Technologies (SMART) on FHIR, which is a framework for third-party applications interfacing with EHR systems [7]. When initiating an RM profile, the volunteer was provided information about pulling their data from the EHR and was given the option to join RM using the EHR connection (Fig. 1a). The EHR connection to RM at VUMC uses Epic's FHIR APIs and OAuth2 authentication. When enabled, the user is redirected to log in to their MyChart account and asked to grant RM permission to read their demographics from the Patient resource; height, weight, and smoking status from the Observation (Social History) resource; problem list conditions from the Condition resource; and active medication list medications from the MedicationStatement resource. Each of these resources came from the DSTU2 version of FHIR, which is what our Epic instance was using when we developed the interfaces. Other FHIR resources, such as Encounter and Immunization are available in Epic, but were not relevant for ResearchMatch profiles and therefore not requested from the user [8]. If the user approves, they are returned to the RM registration process. In the background, RM makes several FHIR API requests to obtain information from the relevant resources. The FHIR payload includes conditions and medications as SNOMED codes, which are linked to patient-friendly labels in an existing ResearchMatch database based on the Unified Medical Language System (UMLS) [9]. This terminology mapping is updated every month using the latest UMLS release. This information is pre-loaded in the registration dialogs (Fig. 1b, c, e), where users are given the option to include any of the suggested EHR data before they are added to their form. Users can also add additional conditions and medications that were not suggested from their EHR data by manually entering them with a keyword search (Fig. 1d, f).

Evaluation Study

In April 2022, the VUMC IRB approved a study to evaluate the EHR to RM interface (IRB #220121). Our primary hypothesis was that individuals enter more conditions and medications into their RM profile when using the automatic EHR data transfer compared to the traditional, manual-entry method. Our secondary hypothesis was that the EHR-connected RM profile would take participants the same or less time to complete than an RM profile without the EHR connection. Inclusion criteria were being 18 years of age or older, having at least two healthcare encounters, conditions, and medications within the last year in the VUMC EHR, and having an active My Health at Vanderbilt (MHAV) account. MHAV is VUMC's Epic MyChart patient portal. We excluded patients with an existing RM profile (based on matching their RM email address to their email address Epic), and who were pregnant or incarcerated.

Fig. 2 outlines the evaluation study. We invited patients who met criteria to participate in the study using MHAV research messages. We sent invitations to 350 patients per week who met inclusion criteria proportional to remaining recruitment goals by gender and race. If patients indicated they were interested in the study in MHAV, their research status in Epic was automatically updated to "interested" and their medical record number was sent to the REDCap electronic data capture system where all study data, documentation, and communications were managed [10].

Once they indicated interest, patients would receive a link to the eConsent form in REDCap. If the patient agreed to participate, they were randomized to either complete the EHR-connected RM profile first or the non-EHR-connected RM profile first. Participants then received instructions on how to complete the RM profile and a link to a special campaign in RM that allowed for the EHR connection. Prior to and during this evaluation study, the EHR connection was not available to the public. Additionally, we tracked the time it took for people to complete the profile by logging the time they began the sign-up process in RM and when they submitted the completed profile. After a 2-week washout period, REDCap sent another email to participants with instructions on how to complete the second RM profile, this time via the alternative method (EHR or non-EHR-connected, respectively). After completing both profiles and a post-study survey, participants were compensated with a $35 gift card.

In November 2022, VUMC updated the institutional default for patient research contact preference, stored in Epic, to "Okay to contact." As such, we revised our inclusion criteria from having 2 encounters, medications, and problem list conditions in the last year to being on Epic's "active patient" registry. This includes patients that are alive and meet one of the following criteria: (1) have had an encounter within the past 3 years, (2) are on a specified registry, (3) have an upcoming appointment in the next 3 months, (4) has had a managed care coverage within the last year, and/or (5) are a patient created within the past year. We also increased the number of MyChart research messages sent to 500 messages per week.

In our statistical analysis, we sought to determine if participants were more likely to include more conditions and medications in their RM profile using the EHR connection than in their profiles

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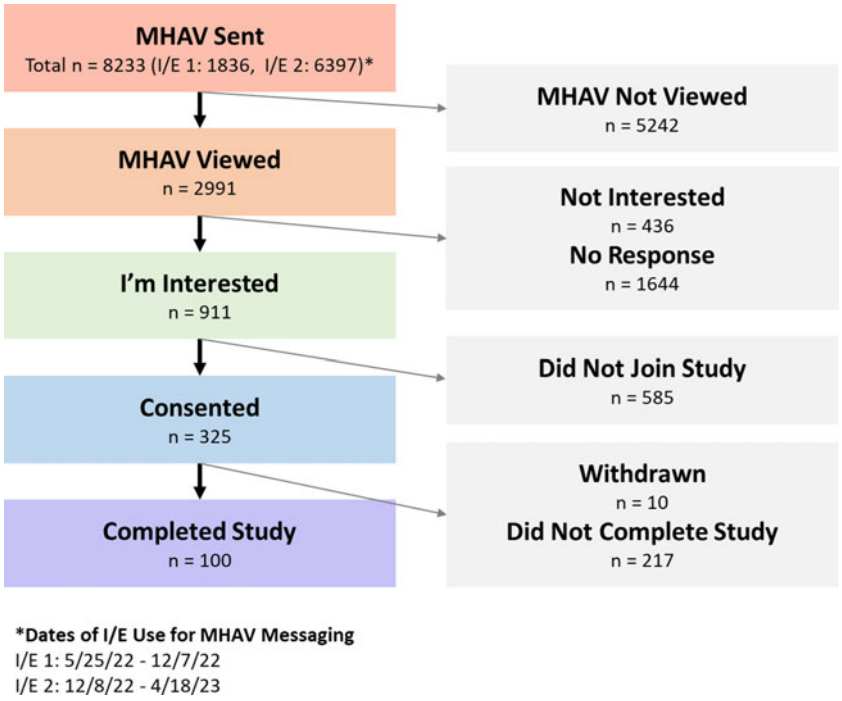

Figure 3. CONSORT diagram. MHAV = My Health at Vanderbilt patient portal.

created without the EHR connection. With a binomial test of null hypothesis 0.5, we needed to recruit 153 participants to detect a 0.1 increase in proportion of participants with more conditions or medications in their RM profile with 0.8 power. We also analyzed the output from the follow-up survey asking which profile creation method they preferred and the overall ease of creating an RM profile using the two methods.

Results

Community Engagement Studio

Five experts agreed to participate in the CE Studio. Overall, experts were supportive of the workflow and language describing the new EHR to RM data. They stressed the importance of clearly conveying information about individual choice and revocability of permission during the presentation to new RM volunteers. Experts advised that we emphasize the relationship between VUMC and RM to increase trust and clearly explain privacy options and workflows with visuals. Experts also believed that information about how much time completing a profile might take, including the effect of the EHR integration, would be helpful.

Evaluation Study

We sent 1,836 participants invitations under the original inclusion criteria (2 or more encounters, medications, and problem list conditions) and 6,397 invitations with the updated inclusion criteria (active patient registry). Most invitations went unread or did not receive a response, but 911 patients indicated interest in MyChart and had their email addresses transferred to REDCap (Fig. 3). Among those, 325 completed the eConsent form and 100 completed both RM profiles and the follow-up survey. 53 out of 161 (33%) consented participants randomized to filling out the EHR-connected profile first completed the study. 47 out of 164 (29%) randomized to fill out the non-EHR-connect profile first completed the study.

Among the 100 participants who completed the study, the majority (75%) entered more conditions in their EHR-connected RM profile compared to their non-EHR-connected profile (Table 1). This effect was true across all demographic groups except for the 8 participants who had a race other than White or Black from the EHR. Participants also included more conditions in their EHR-connected profile regardless of whether they completed that profile first or second. In their EHR-connected profile, participants were presented with a mean of 11 conditions, chose to include a mean of 8 of those conditions, and manually added a mean of 0.8 conditions. 58 participants accepted all conditions that were presented to them.

As with conditions, participants had more medications in the EHR-connected profile across all demographic groups, except for non-White non-Black participants (Table 2). In their EHR-connected profile, participants were presented with a mean of 8 medications, chose to include a mean of 7 of those medications, and manually added a mean of 0.8 medications. 55 participants accepted all medications that were presented to them. 38 participants accepted all medications and conditions presented to them.

The median time to complete an RM profile was 4.8 minutes. 62 of the 100 participants completed the EHR-assisted profile in less time (binomial test p-value .010) and the median time difference between completion time of the profiles was 16 s less time for the EHR-connected profile.

In the post-study survey, most participants described creating a RM profile, regardless of the EHR connection, as "Very Easy" or "Somewhat Easy." 87 out of 98 participants who responded to the question (89%) preferred the EHR-connected account creation method as shown in Figure 4.

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Table 1. Participants with more conditions in their electronic health record profile by demographic group and sequence of profiles

Conditions		# Participants	# Participants with more conditions in EHR profile	Binomial test p-value	EHR values entered Median (IQR)	Non–EHR values entered Median (IQR)
All Participants		100	75	<0.001	6 (4–11)	4 (2–5)
Race	Black	16	15	<0.001	8 (7–10)	3 (2–4)
	White	76	56	<0.001	6 (4–11)	4 (2–6)
	Non-Black/White	8	4	0.637	4 (4–5)	4 (3–4)
Age	<30	13	8	0.291	4 (2–8)	4 (1–9)
	30–64	67	51	<0.001	7 (4–10)	3 (2–5)
	65+	20	16	0.006	10 (5–14)	4 (1–5)
Sex	Female	61	41	0.005	6 (4–9)	3 (2–6)
	Male	39	25	0.054	7 (4–13)	5 (2–8)
Sequence of profiles	EHR first	53	44	<0.001	6 (5–9)	3 (2–5)
	Non-EHR first	47	31	0.020	7 (3–13)	4 (2–6)

EHR = electronic health record; IQR = interquartile range.

Table 2. Participants with more medications in their electronic health record profile by demographic group and sequence of profiles

Medications		# Participants	# Participants with more medications in EHR profile	Binomial test p-value	EHR values entered Median (IQR)	Non-EHR values entered Median (IQR)
All Participants		100	68	<0.001	6 (3–12)	4 (1–6)
Race	Black	16	13	0.011	7 (4–9)	4 (1–6)
	White	76	51	0.002	6 (3–14)	4 (1–8)
	Non-Black/White	8	4	0.637	4 (2–6)	4 (2–4)
Age	<30	13	8	0.291	6 (1–10)	4 (2–7)
	30–64	67	47	0.001	6 (3–10)	4 (1–5)
	65+	20	13	0.132	9 (5–14)	5 (1–10)
Sex	Female	61	43	0.001	6 (3–12)	3 (1–5)
	Male	39	25	0.054	7 (4–13)	5 (2–8)
Sequence of profiles	EHR first	53	38	0.001	6 (3–8)	2 (1–5)
	Non-EHR first	47	30	0.039	7 (4–15)	5 (2–9)

EHR = electronic health record; IQR = interquartile range.

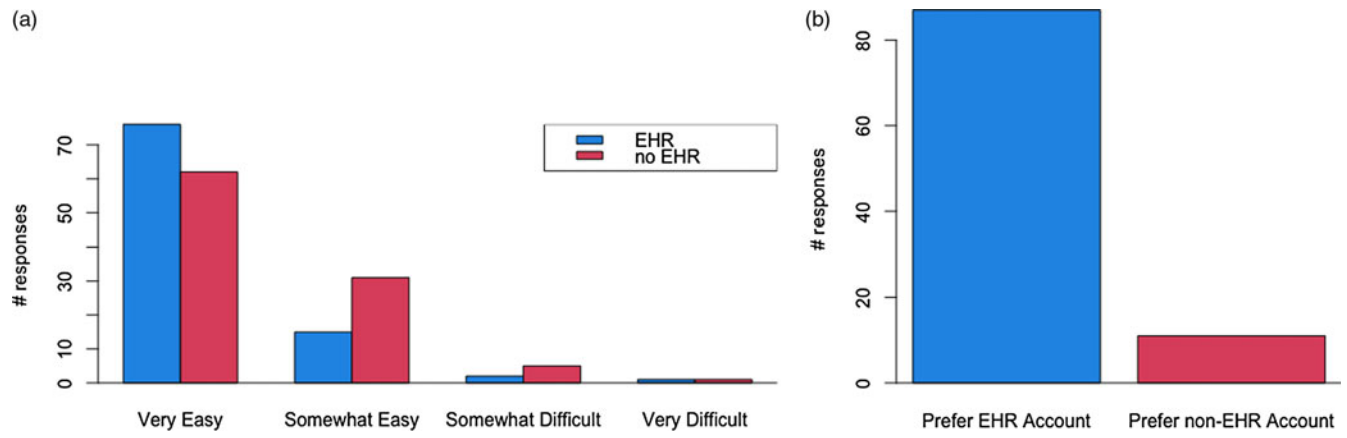

Figure 4. (***a***) Post-study survey regarding ease of RM profile creation (EHR $n = 94$, no EHR $n = 99$) and (***b***) preferred EHR creation method ($n = 98$). EHR = electronic health record; RM = ResearchMatch.

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Discussion

Our CE Studio revealed that the community was generally supportive of connecting personal EHR data to RM to facilitate easier and more complete volunteer registration, so long as communication was clear and participant choice to utilize this connection was preserved. The positive response to this integration indicates potential for widespread adoption at other institutions. Preliminary results from the evaluation study show promise for obtaining more conditions and medications, and thus greater precision about volunteers' eligibility criteria compared to recall-based profile completion. While the effect was small, using the EHR connection also decreased the amount of time it took to complete an RM profile. Reduction in volunteer burden is important for improving participants' perception of the clinical research experience [11].

Most participants (62%) removed at least one condition or medication from the lists that were presented to them. This result would suggest that volunteers are taking the time to adjudicate the appropriateness of their EHR information for RM, removing conditions they have recovered from or medications they are no longer taking. While we would expect patients who interact with the healthcare system frequently to have up-to-date medication and problem lists, there are often discrepancies between these lists and the current state of the patient [12,13]. Since volunteers are accountable for the information they provide to RM, the opportunity to adjudicate their information improves the accuracy of the data for trial matching.

The CE Studio we conducted is one method of soliciting usability and acceptability feedback for participant-facing research applications. Much like focus groups in commercial software development, CE Studios with trained moderators have the potential to obtain efficient and low-cost community feedback. Soliciting community engagement early in the development process can reduce costs later in evaluating, revising, implementing, and disseminating software for research. An iterative approach with multiple points of community feedback at various points in the development process would have been ideal, but we were limited by budget and timelines.

Most participants entered more conditions and medications in the EHR-connected account regardless of whether they were randomized to complete the EHR-connected or non-EHR-connected profile first. Although we designed a washout period between registration of profiles for individual participants, we anticipated there might be recall bias among those who completed the EHR-connected profile first, as participants might remember the conditions pulled from the first EHR-assisted profile and enter those into their second profile. The greater number of medications and conditions in the EHR-connected profiles demonstrates how the amount and complexity of health-related data can pose a challenge for research registry volunteers relying only on recall alone.

The EHR patient portal (MHAV) was the means of contacting potential participants for the study since having an account was a requirement and all inclusion criteria could be assessed using reports in the EHR. However, the low response rate for research recruitment messages and lack of diversity of patients with MyChart accounts proved to be a challenge. We sent messages to participants proportional to the racial makeup of the metro Nashville area where VUMC is located. Our lack of diversity and low response rate may have biased our results toward individuals who are likely to support new technologies like the EHR connection. These challenges also highlight the need for better outreach and engagement of underrepresented populations in patient portals and in research [14].

Conclusion and Next Steps

Community Experts responded favorably to an EHR-to-registry connection for easier RM profile completion, provided options for denial and adjudication are presented clearly. The EHR connection demonstrated effectiveness in increasing the number of conditions and medications entered in RM profiles, which could lead to improved trial matches for RM volunteers. Additionally, participants spent less time completing their RM profile with the EHR connection and most preferred the EHR-connected RM profile creation method compared to manually entering their information.

The findings of this study helped inform VUMC's offices of privacy, cybersecurity, legal affairs, and the IRB to approve a permanent integration between MHAV and RM at VUMC. Interested patients with MHAV accounts at VUMC may select to join RM using the workflow refined through our CE Studio and evaluated through our study. We are also working to make the ResearchMatch SMART on FHIR app available to other RM partner institutions so that volunteers who receive care at any RM organization may take advantage of the streamlined process. This will require institutional buy-in and attention to user experience. Given RM volunteers may have received treatment at various healthcare systems, we will need to model choice architecture in a way that prompts initiation from the most recent system. We are also considering regional and state-wide Health Information Exchanges with FHIR interfaces as a central source of RM profile data, allowing one connection for all new volunteers in a particular region.

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Competing interests. Leah Dunkel is currently acting as a contractor for VentureWell where her work is unrelated to the topics discussed in this paper. All other authors have no conflicts to declare.

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