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BRIEF REPORT

Effectiveness and Cost of Recruiting Participants to a Research Registry Using an Emergency Department Research Associate Program

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We identified a novel way to recruit participants into a research registry by using an Emergency Department Research Associate (EDRA) Program. Research associates working in the Emergency Department at Strong Memorial Hospital approached patients and family members to enroll into the University of Rochester Research Participant Registry and for ResearchMatch.org. We found that 73% of individuals (574/781) approached agreed to register for either one or both registries. Those who registered were more diverse than individuals who registered through other methods. Overall, using EDRAs to enroll adult patients and their family members is an effective method for growing research participant registries.

Study Highlights

WHAT IS THE CURRENT KNOWLEDGE ON THE TOPIC?
☑ Although recruitment into registries uses a variety of different approaches, use of emergency departments (EDs) for registry recruitment is absent from the literature.
WHAT QUESTION DID THIS STUDY ADDRESS?
☑ Is registry recruitment in the ED feasible and how does that compare with passive methods?
WHAT DOES THIS STUDY ADD TO OUR KNOWLEDGE?
☑ Use of enrollers based in the ED yielded more subjects than passive recruitment and with a different profile (younger adults; greater racial/ethnic diversity). Family members were also recruited.
HOW MIGHT THIS CHANGE CLINICAL PHARMACOLOGY OR TRANSLATIONAL SCIENCE?
☑ Registries are increasingly relied on to streamline access to subjects interested in research. Increasing their size and diversity (age, race/ethnicity, and sex) has the potential to speed recruitment and shorten study enrollment timelines.

Registries are lists of participants amenable to contact about participation in future health research or clinical studies. Registries are used to directly recruit both healthy participants and participants with various clinical conditions into health research studies.[1–11] The University of Rochester Research Participant Registry (URRPR; https://futurereserarchregistry.urmc.rochester.edu/) created in 2013 was part of an institutional effort to engage with the local community, raise awareness about research, and provide a mechanism for participants to become involved in research. Participants can self-enroll or can enroll someone else (e.g., a parent for a child). After receiving institutional review board approval, investigators can obtain a list of participants to contact for study screening. Prior to this pilot, registry promotion was passive, including radio and TV advertising, posters on the University campuses, at local primary care clinics, and community organization offices or events.

ResearchMatch.org is a free online tool that recruits participants nationally for future research studies.[7] Investigators register their research protocols, and the tool matches participants with studies. Participants receive an email notification asking them if they are interested in the study and can choose to release their contact information to the study investigators.

In an effort to increase and improve enrollment into both registries, we used the University's Emergency Department Research Associates (EDRA) program. The program employs 25–30 undergraduate students, supervised by a faculty administrator and director, to approach, consent, enroll, and engage emergency department (ED) patients into research studies.[12] Established over 20 years ago, this program has enrolled > 20,000 study participants, staffing the ED 16 hours/day, 7 days/week. EDRAs complete human subject protection training supplemented with training to avoid negative patient care impacts and ensure study protocol adherence. ED-based research associated programs are increasingly common, particularly at large academic institutions, such that the work reported herein is highly generalizable.

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This feasibility pilot sought to determine if the EDRA program could increase enrollment in both registries and expand registrant diversity (e.g., race/ethnicity, age, and sex). We compared pilot results, including costs, with previously enrolled participants.

MATERIALS AND METHODS

Participant registries

Participant information collected for the URRPR included: name, date of birth, contact information, preferred mode of contact (mail, email, or phone), race/ethnicity, sex, and preferred language. Additionally, registrants could opt to indicate "conditions of interest" (e.g., healthy volunteer, bones/joints/muscles, heart/circulation, etc.). Registrants also received information on registry withdrawal processes. The University of Rochester Research Subjects Review Board approved the URRPR protocol. For ResearchMatch.org, volunteer registration was completed as described in Harris *et al*.[7]

EDRA training and participant selection

EDRAs were trained using informational materials and demonstrations for both registries, including suggested scripts for approaching patients that explained associated purposes and potential responsibilities. Eligibility (patients and family members) was minimal requiring a local mailing address, email address, or phone number. For ResearchMatch.org, all patients and their families who had a valid email address were eligible. Exclusion criteria for both included non-English speaking unless a translator was present, previously registered, or inability to give informed consent. A convenience sampling approach was used with EDRAs approaching patients and family members present in the ED from December 2017 to February 2018. EDRAs prioritized approaching patients/families based on those who were not in acute distress (based on EDRA's electronic health record review, provider judgement, and visual inspection), not with a provider or undergoing tests (away from room), or were awaiting test results. EDRAs checked every 30–60 minutes on previously unavailable patients. There were 28,800 patients who visited the ED during the pilot, so meeting the goal of approaching 6–10 patients per shift was easily met.

Participant enrollment process

Potential participants were asked first about registering in URRPR. The daily goal was a minimum of six enrollments. Enrollment for both registries occurred through a tablet computer with web connectivity. EDRAs prioritized protocols for open/active studies over registry enrollment. For each patient approached, it was noted on a Shift Chart: EDRA name, date, shift, medical record number, and ED room number. Sex, race/ethnicity, and age were obtained from the electronic health record. For both patients and family members, enrollment status and any relevant notes (e.g., why declined or missed) was recorded. To track ResearchMatch.org, enrollment in a specific weblink was established.

EDRA discussion

As part of our process evaluation, 2 months post-pilot, six EDRAs met to discuss the EDRA pilot implementation, including challenges and successful recruitment techniques. Questions asked included: (i) What was your experience with enrolling people?; (ii) What worked well?; (iii) What did not work?; and (iv) What suggestions are there if this program is continued? Their participation was based on their availability around classes and other commitments. Initial answers were probed for clarification as needed. Detailed notes taken during the discussion were examined by two authors (C.D. and A.D.) for key themes within each question using content analysis.

Cost determination

Costs were based on an annually set hourly rate. Administrative setup costs included a one-time training cost (0.5 hours) for each EDRA (N = 30). The EDRA supervisor's time for data review/communication time totaled 0.7 hours per month. We estimated that EDRAs would spend 6.5 minutes with each potential participant.

RESULTS

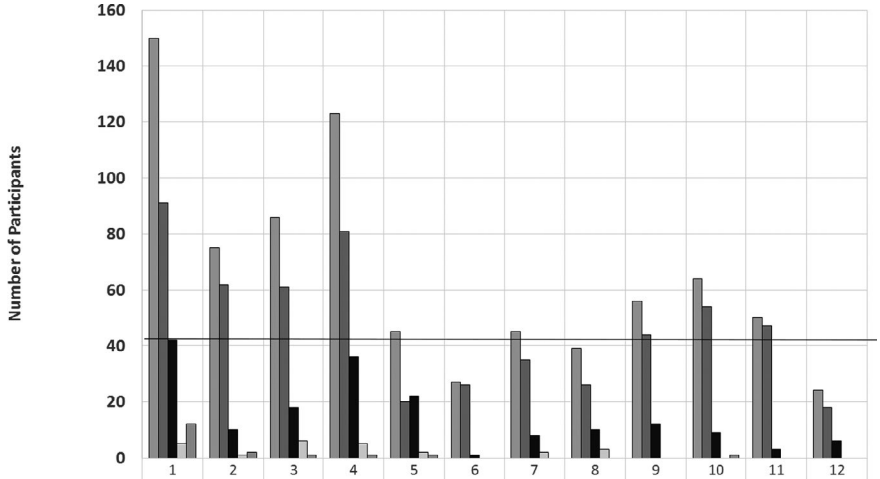
Figure 1 depicts the status of the 784 individuals approached about joining both registries. Enrollment fluctuated over the 3-month period with a decline in January (week 5). The overall enrollment rate was 72% (565/784) with 23% declining (177/784). In the prior year (December–February), passive enrollment methods yielded 196 registrants. The comparable pilot period of active EDRA enrollment yielded 2.88-fold more registrants. The 3-month pilot cost was US $3,348 ($5.93 per registrant).

Those approached were: 64% white, 27% African American, 2.1% Asian, 7% Hispanic, and 39% men. Enrollment for white and non-white race was similar (73%), but higher among Hispanics (88%). Mean age was 38 ± 16 years (median 34 years).

Table 1 shows that among enrollees (vs. decliners) the proportion of white enrollees was similar (65% vs. 64%) but lower than pre-pilot registrants (83%). The proportion of Hispanic participants was higher among enrollees (9.0% vs. 1.7%), and was nearly double that in the pre-pilot registry (4.8%). More men were represented in the pilot (both enrolled (40%) and declined (38%) than pre-pilot (28%)). Although no differences in age were noted, fewer children were enrolled during the pilot. Of the 89 family members approached (11%; 89/784), 73 (82%) enrolled.

Findings from EDRA discussion

Six EDRAs attended the discussion group. They observed that younger individuals were more likely to enroll. Older adults liked to talk about their medical issues; this created rapport and led to enrollment. Older individuals needed more assistance with the tablet registration. Keeping the "pitch" about the registries short resulted in an efficient 10-minute enrollment process. EDRAs found it helpful to explain that patients could enroll while waiting and individuals with any condition or healthy volunteers could participate. Those in less pain and with lower acuity were easier to enroll. Parents were less likely to enroll themselves or their children because they were too concerned about the child's health. Showing the ResearchMatch.org map (of different states represented in the registry) was helpful. In addition, upon entering the room, acknowledging everyone there was beneficial. EDRAs also noted that patients



	1	2	3	4	5	6	7	8	9	10	11	12
Total approached	150	75	86	123	45	27	45	39	56	64	50	24
Enrolled	91	62	61	81	20	26	35	26	44	54	47	18
Declined	42	10	18	36	22	1	8	10	12	9	3	6
Ineligible	5	1	6	5	2	0	2	3	0	0	0	0
Missed	12	2	1	1	1	0	0	0	0	1	0	0

Week

Figure 1 Number of people enrolled per week. The graph depicts the total number of people approached, the number of people who enrolled in the either registry, the number of people who declined enrollment after explaining the purpose of the registry, the number of people who were ineligible, and the number of people who were approached but refused learning more about the registry. The line indicates the targeted enrollment of 42 people per week. Flu season started around week 5.

Table 1 Demographic characteristics of enrolled and declined participants compared with registrants prior to the pilot

	No. Approached	White (%)	Hispanic or Latino (%)	Men (%)	Mean age ± SD	Median age (range)	Age 0–17 years (%)
Enrolled[a,b,c,d]	565	65	9.0	40	37 ± 16	33 (3–92)	1.9
Declined[e,f]	177	64	1.7	38	40 ± 16	37 (14–85)	0.6
Registrants prior to pilot[g]	1,911	83	4.6	28	42 ± 18	40 (<1–90)	5.2

[a]Enrolled in either University of Rochester Research Participant Registry, ResearchMatch.org or both. [b]Sixteen enrolled participants did not have race recorded. [c]Twenty-one enrolled participants did not have ethnicity recorded. [d]Forty-two enrolled participants did not have age recorded. [e]Eleven declined participants did not have age recorded. [f]Thirteen participants who declined did not have race recorded. [g]There were 1,352 people who did not have race recorded and 166 people who did not have ethnicity recorded.

awaiting hospital admission and those in the observation unit were more likely to enroll.

EDRAs also noted several problems. It was harder to get individuals to complete the ResearchMatch.org registration after doing the local registration. The latter process is much shorter. In addition, the ResearchMatch.org registration required creating a username and password, a deterrent for some individuals. EDRAs also identified that potential registrants were confused about the difference between the two registries and the redundancy between the registries' questions. Potential registrants did like that ResearchMatch.org included survey-based research and that they could specify different categories of disease. EDRAs observed that, in some cases, family member interest (or disinterest) was directly related to whether the patient would enroll.

DISCUSSION

This study evaluated a feasibility pilot using EDRAs to recruit individuals into an institutional and a national research volunteer registry. The pilot demonstrated the approach's feasibility. Importantly, this active approach yielded a greater number of participants than comparable time periods using passive recruitment methods. The proportion of male and minority participants increased but was not effective for enrolling children. Seasonal affects were observed, with a dramatic decline during the flu season due primarily to EDRAs' prioritization of studies that recruiting patients with the flu. Had the pilot extended into the spring, the number of individuals approached would have rebounded to those achieved during the first month of the program. Regardless, the overall target (N = 504) for the 3-month period was reached.

Lower burden forms work well in the ED setting where patients are not feeling well. Thus, a significant proportion of individuals declined or did not finish enrolling in the longer process required for ResearchMatch.org.

We were uncertain whether family members/non-patients would enroll. On balance, including them was an effective strategy to increase overall enrollment, despite their potential to be negative, their interest affected the patient's interest.

Recruiting in an ED setting presents unique aspects. As expected, recruitment was negatively impacted by the

patient's acuity, particularly for pediatric patients whose parents were too worried to consider research while their child was ill. By contrast, patients whose illness or injury was less acute were more likely to enroll, likely attributable to the wait times involved in ED care. Another unique aspect was the ability to approach all patients. A higher proportion of under-represented individuals (e.g., African Americans and Hispanics) was recruited through the pilot than through prior passive methods. Several factors likely contributed to this finding. First, passive recruitment may not reach individuals from under-represented groups, they may see it as a burden and not important. Active enrollment that includes personal contact and assistance makes the messages about eligibility and the importance of volunteering clearer and reduces enrollment burden. Younger adult patients, particularly those of lower socioeconomic status and/or without insurance, who may be from under-represented groups, may use ED services more frequently for nonurgent complaints. Given that the nonurgent group was more likely to enroll, this likely increased the enrollment among individuals from under-represented groups.

As with all study recruitment, EDRAs should be trained, processes piloted to determine potential feasibility issues, and tracking and periodic check-ins performed to assess enrollment numbers and implementation issues. Assessing program impact should include overall numbers and patterns by shift, day, week, or season. Further, subgroup recruitment analyses are recommended to assess overall diversity and achievement of program goals.

Cost per registrant was higher than with passive recruitment approaches but accrual occurred at a faster pace. Although EDRAs prioritized studies in active recruitment, registry recruitment can help fill the gaps during down time, thus reducing registry recruitment costs. Training and oversight costs would be minimized in a sustained program (i) with greater volume, the cost per registrant would decline, and/or (ii) would be incorporated into long-term operations (i.e., not requiring dedicated supervisor time).

During this 3-month pilot, there were 28,800 ED visits. The EDRAs approached 784 people or 2.7% (784/28,800) of all patients that visited the ED and some of those approached were patients' family members. A substantially higher number of EDRAs would be needed in order to reach all persons who come through the ED each month.

Registries are of increasing interest locally and nationally as sources of potential research subjects. Registry growth is expected to translate into increase study enrollment. We are unable to demonstrate specifically how the EDRA pilot improved our recruitment as we are only in the early stages of building the URRPR registry. For confidentiality purposes, we did not track registrants' subsequent research study enrollment. Although all registry members receive electronic newsletters informing them of ongoing studies, there is not a centralized way of tracking subsequent study enrollment. Similarly, whereas ResearchMatch.org is used by many investigators and our institution is the number one enrolling site, the system does not provide information on which registrants enroll in the studies.

The best method for registry recruiting is unknown, but like recruitment plans for individual studies, a portfolio of methods is needed to build diverse registry across ages, sexes, races/ethnicities, and socioeconomic backgrounds. An EDRA-like program is one such method for general registry recruitment or to focus on enrolling key subgroups.

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Conflict of Interest. The authors declared no competing interests for this work.

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