Background: Recruiting participants to clinical research studies is challenging, especially when conducted in safety net settings. We sought to compare the efficacy of different recruitment strategies in an NIH-funded study assessing treatment burden in patients with multiple chronic conditions (MCCs).

Methods: Targeted mailing, in-person table-based recruitment (“tabling”) in the waiting room, and telephone calling were used to enroll subjects into one of two studies of treatment burden: a survey study to validate a brief measure of treatment burden for quality assessment (study 1) or a qualitative study to develop a treatment burden clinical communication tool (study 2).

Results: Over 50% of subjects in each study were African American or African immigrants. In study 1, the enrollment goal of 200 was reached within 4 months. Tabling enrolled 78.5% of patients, while the remainder (21.5%) were enrolled from phone calls to eligible patients identified through the electronic medical record (EMR). In study 2, 340 eligible patients were identified through the EMR, and 7 (2.1%) were successfully enrolled via mailed invitations and responses. Retention rates (66% in study 1 and 71% in study 2) were reasonable in all groups.

Conclusions: Study recruiting goals in our safety net population were rapidly reached using the tabling method, which had substantively higher enrollment rates than mailings or telephone calls based on EMR reports. Future trials could compare recruitment strategies across settings and clinical populations.

Keywords: Burden of treatment; Recruitment methods; Underrepresented patient population.
in four are born outside the USA, and public assistance programs account for 74% of payment sources. Health inequity is visible in how our patients overwhelmingly have difficulties accessing care and managing treatment due to poverty, immigration status, involvement in the criminal justice system, and mental health concerns.

Components of the overall project required recruitment of patients for surveys and focus groups. Historically, recruiting racially diverse populations, including patients of low socioeconomic status who are highly mobile, can be challenging. To adequately represent the patient population, meet ambitious recruitment goals, and ensure that performance measures would be generalizable to a range of patient settings, we tested multiple recruitment strategies in an effort to fit the needs of the unique patient population and address their specific barriers. By tailoring enrollment strategies to our patients and making research involvement accessible to them, we moved closer to our study goals of measuring treatment burden and promoting health equity within HHS and the many diverse groups of patients we serve. This paper will discuss the recruitment of patients from the Medicine Clinic in General Internal Medicine at HHS for two studies of the project.

**METHODS**

Research teams at Mayo Clinic in Rochester, MN and Hennepin Healthcare System in Minneapolis, MN led the multisite project. We highlight the recruitment of Medicine Clinic patients with MCCs at HHS for two studies—one to adapt and validate a brief measure of treatment burden to assess person-centered healthcare quality (study 1, phases I and II) and another to develop a patient-centered clinical tool of treatment burden for use in clinic settings at the point of care (study 2). The two studies represent work completed in two different aims of the overall project. The Institutional Review Board (IRB) at each participating institution (HHS and Mayo Clinic) approved the protocols for both studies.

**Patient Selection**

Qualitative and quantitative research methods were used to conduct these studies. We sampled patients who were at least 21 years old, understood English, were diagnosed with two or more chronic conditions confirmed by the EMR, and received their care in the Medicine Clinic. We excluded persons with severe cognitive impairments (e.g., dementia, stroke) or other conditions that would make it difficult to complete a survey (e.g., psychoses). Presence of a chronic condition was determined by the International Statistical Classification of Diseases (ICD) codes in the EMR. Patients considered eligible for the study had received an ICD diagnostic code from a healthcare provider for at least two or more of 20 chronic conditions identified by the US Department of Health and Human Services, 2010). Both studies used a convenience sampling process stratified by number of conditions. Patient incentives in the form of gift cards were utilized in both studies.

**Study 1**

Study 1 had two phases. In phase I, structured interviews with patients were used to winnow items from a previously developed long-form measure of treatment burden (the Patient Experience with Treatment and Self-management [PETS]) to a short-form adaptation that measured patient-centered healthcare quality in primary care. This phase aimed for balanced representation across gender and to recruit at least 20% of participants into each of three pre-planned strata based on the number of EMR-confirmed chronic conditions (2–3, 4–5, 6+); to attain balance in the number of conditions diagnosed. Based upon the literature and prior experience, an enrollment goal of 30 participants was assumed to provide an adequate range of patient perspectives. Recruitment occurred between October and November of 2016. Eligible participants were identified through EMR review of having more than two chronic conditions and having regularly scheduled appointments with a primary care provider (e.g., every 6 months); with eligibility confirmed by patient self-report at the time of interview. After drafting of the brief pilot measure, in phase II, a prospective survey study was implemented to test and validate the new measure and determine its acceptability with a different pool of 200 patients in a clinical setting enrolled between December 2017 and March 2018. Enrolled patients returning to the Medicine Clinic within 6 to 12 months of the baseline assessment completed a follow-up survey (from June 2018 to February 2019). Participants for phase II were eligible if they had at least 2 visits with a primary care provider within the last 18 months.

**Study 2**

Study 2 was a qualitative study involving two rounds of discussion groups for patients with MCCs to develop a patient-centered communication tool of treatment burden for use in clinic settings. The objective of the first round of discussion groups was to identify domains from the PETS measure that were deemed by patients as important to discuss with their healthcare providers during clinic appointments. A second round of discussion groups was used to test the interface and user acceptability of the electronic tool developed and provide overall feedback on its appearance. The methods used are based on a previous study to create a brief patient-reported outcomes quality of life (PROQOL) instrument to improve the care of diabetes patients. The prior study used a series of patient discussion groups to (a) prioritize questions to include in a novel electronic PROQOL tool for use at the point of care and (b) review and comment upon a mock-up of the pilot PROQOL tool. We have used similar qualitative procedures with patients to vet and finalize the content of the original version of the PETS measure, consistent with current best
practice for deriving new patient-reported outcome instruments. In addition to a diagnosis of two or more chronic conditions, participants were eligible if they had at least two appointments within the health system in the past 12 months and were able to travel for in-person discussion groups. The study aimed to enroll between eight and ten patients per group, a number considered as adequate representation of patient perspectives. The same patients were asked to participate in both rounds of the discussion groups. Based on our prior experience recruiting patients for similar focus group studies, we estimated that we would need to contact ten patients for every one patient successfully recruited to an in-person group. We anticipated a high number of eligible patients; therefore, we queried the EMR and stratified by age (<65 vs. 65+) and number of chronic conditions (2–3 vs. 4+ chronic conditions). Complete results of this study, including a pilot test of the derived clinical tool, will appear in a forthcoming manuscript.

**Enrollment Strategies**

Several factors were considered to determine which recruitment strategy would work best and provide the highest yield to the study, including study population, resources, time, and staff availability. Both studies demonstrated the utility of several strategies in recruiting a diverse, underserved, and underrepresented patient population.

**Contact Based upon EMR Reports.** EMR reports, which provide a valuable mechanism for assessing potential research trial populations, recruiting patients into trials, and enhancing trial efficiency, cost-effectiveness, quality, and accuracy, were utilized in both studies 1 and 2. In phase II of study 1, pre-screened weekly reports from the EMR identified eligible patients with upcoming appointments in the Medicine Clinic. Study staff used the report to call eligible patients and assess their interest in participation. In study 2, EMR reports were utilized to identify eligible patients stratified by age and number of chronic conditions. Sets of eligible patients on the report were mailed recruitment letters.

**Tabling.** Tabling is an active, face-to-face method of recruitment. It allows study staff to have personal contact and converse with patients by strategically establishing a presence in a high traffic area. This method was utilized in both phases of study 1, where study staff set up a table and a colorful poster with study details and eligibility criteria in the Medicine Clinic waiting room and invited entering patients to participate. To effectively apply the tabling method, study staff picked a variety of days and times to appeal to the most diverse and broadest number of possible participants. Interested patients that approached the table were screened for eligibility using on-the-spot EMR review, followed by self-reported confirmation of eligibility.

**Targeted Mailing.** Targeted mailing was utilized in study 2 only. Once eligible patients were identified via pre-screened EMR reports, targeted mailing was used to send a recruitment letter to identified patients inviting them to participate and instructing them on how to contact the study team by phone or email to be scheduled for a discussion group. Recruitment letters included research study information, a description of participant tasks, and study coordinator contact information, and were signed by the study principal investigator. A total of 340 recruitment letters were sent in three waves of about a hundred each in May 2017.

Recruitment methods were evaluated in terms of participant yield, representativeness of the participant pool, and study retention rates. Participant yield was assessed in terms of the number of target participants screened, contacted, and enrolled.

**RESULTS**

Descriptive characteristics of participants from both phases I and phase II of study 1 are presented in Table 1. Participants were diverse and representative of the Medicine Clinic’s patient population, especially in regard to race and income level. Enrolled patients were medically complex and socially vulnerable. They were predominately male, middle-aged, and identified their race as Black (African American or African). They had a high number of chronic conditions. Most participants from both phases of study 1 were divorced, separated, widowed, or never married; had less than a high school education or were high school graduates; were on disability or leave; and had an annual income of less than $20,000. About half reported having six or more clinic visits in the past year. A majority lived in a house or apartment, but a notable percentage (23.4% in phase I; 24.5% in phase II) reported being homeless or having other living arrangements. Limited demographic data were collected from study 2 participants; half were female, and half were Black (African American or African). Their average age was over 60, and they had an average of three diagnoses.

Phase I of study 1 (structured interviews) reached the enrollment goal of 30 participants using only the tabling method. Recruitment occurred over six non-consecutive days in a 1-month period. Daily enrollment numbers ranged between one to ten participants with a gradual decline of participants recruited per day from the initial recruitment day to the last, as recruitment became more targeted towards filling underrepresented strata. Informational and statistical data on patients screened were not available.

Figure 1 displays a flowchart detailing the recruitment process for phase II of study 1 (survey validation). A pool of 335 patients were screened for eligibility. The targeted enrollment goal of 200 participants was reached in 4 months. We screened and called 174 patients using EMR reports and successfully enrolled 43 (24.7%). Two-thirds (66.7%) of the
calls was unsuccessful where staff were not able to speak with the patient. We screened 161 patients while tabling and successfully enrolled 157 (97.5%). While more total patients were screened using EMR reports (51.9%) compared to tabling (48.1%), more patients were successfully enrolled through tabling (78.5%) versus EMR reports (21.5%).

Over 9 months, follow-up attempts were made to participants who had scheduled appointments 6–12 months from the date of their baseline survey. Most participants were contacted by phone (n = 136) and only a few were approached at their scheduled appointment without prior contact (n = 26). Some did not have scheduled appointments and did not have the opportunity to complete follow-up surveys (n = 38). The retention rate for the 6–12 month follow-up survey was 66.0% (n = 132), the majority of which (n = 106) were successfully reached by phone.

The recruitment flowchart for the discussion groups of study 2 is outlined in Fig. 2. For round one of the discussion groups of study 2, prescreened EMR reports identified 804 eligible patients stratified by age (< 65 vs. 65 +) and number of chronic conditions (2–3 vs. 4 + chronic conditions). To ensure representativeness of the population, we oversampled for race in the EMR reports. To recruit 8–10 patients, a total of 340 invitations were mailed. Invitations were mailed in three batches a couple of weeks apart to allow for variability, with 100 invitations mailed in the first batch and 120 in each of subsequent 2 batches. Overall, we received 23 positive responses (6.8% response rate) and successfully enrolled seven patients (2.1% of total invitations), with comparable distribution across the four strata. Of the seven patients who participated in the round one discussion group, five of them returned to participate in the second round of discussions (71.4% retention).

### Discussion
Historically marginalized groups, such as minority populations and those of low socioeconomic status, are largely underrepresented in research studies, likely due to barriers to participation and lack of accessibility to studies. The literature supports the use of creative strategies and recruitment methods to overcome these obstacles. We implemented three recruitment methods to capture a representative sample of the patient population served in a safety net hospital Medicine Clinic and found positive results with timely recruitment, meeting enrollment goals most effectively with a method referred to as “tabling” compared to other methods.

Pre-screened EMR reports provided a useful set of eligible patients to recruit. However, recruiting patients by phone using the EMR reports was not as effective as the tabling method for the survey study (phase II of study 1). A large portion of the calls failed to make direct contact with the patients, while all but four of the patients screened during tabling were successfully enrolled. By setting up a recruitment table in a high-traffic area such as a waiting room where patients are checked in for scheduled appointments, it offered convenience to patients without prior commitment or effort on their part, and it offered research staff the opportunity to converse with patients who may otherwise be unreachable via other methods. The findings of both phases of study 1 demonstrate that allowing patients access to research staff at their own discretion and having staff readily available to converse with patients appears to be an effective means of recruitment in a safety net clinic setting. Furthermore, establishing a warm presence in a clinic waiting room may promote

### Table 1. Descriptive Characteristics of Study Participants per Sub-Study

| Characteristic                        | Study 1 structured interviews (N = 30) | Study 1 survey validation (N = 200) |
|---------------------------------------|--------------------------------------|-------------------------------------|
| Female: N (%)                        | 14 (46.6%)                           | 99 (49.5%)                          |
| Age, mean (SD)                       | 57.5 (9.7)                            | 54.3 (9.6)                          |
| Number of diagnoses: median (range)  | 6.0 (2–15)                            | 5.0 (1–13)                          |
| Race/ethnicity                        |                                       |                                     |
| American Indian (Native American)     | 0 (0.0%)                             | 16 (8.0%)                           |
| Asian                                 | 1 (3.3%)                             | 2 (1.0%)                            |
| Hispanic (Latino)                     | 0 (0.0%)                             | 2 (1.0%)                            |
| Black (African American or African)   | 17 (56.7%)                           | 142 (71.0%)                         |
| White (Caucasian, non-Hispanic)       | 12 (40.0%)                           | 38 (19.0%)                          |
| Marital status                        |                                       |                                     |
| Never married                        | 12 (40.0%)                           | 96 (48.0%)                          |
| Married/living with partner          | 1 (3.3%)                             | 26 (13.0%)                          |
| Separated, divorced, or widowed       | 17 (56.7%)                           | 77 (38.5%)                          |
| Missing                               | 0 (0.0%)                             | 1 (0.5%)                            |
| Education                             |                                       |                                     |
| High school graduate                 | 12 (40.0%)                           | 123 (61.5%)                         |
| College/associate’s degree            | 5 (16.6%)                            | 11 (5.5%)                           |
| Occupational status                   | 13 (43.3%)                           | 66 (33.0%)                          |
| Full-time/part-time employed          | 4 (13.3%)                            | 35 (17.5%)                          |
| Full-time student                     | 1 (3.3%)                             | 1 (0.5%)                            |
| Homemaker/retired or unemployed       | 9 (30.0%)                            | 56 (28.0%)                          |
| On disability or leave                | 16 (53.3%)                           | 102 (51.0%)                         |
| Missing                               | 0 (0.0%)                             | 6 (3.0%)                            |
| Yearly household income               |                                       |                                     |
| < $20,000                             | 26 (86.7%)                           | 170 (85.0%)                         |
| $20,000 to $40,000                    | 2 (6.7%)                             | 24 (12.0%)                          |
| $40,000 to $60,000                    | 0 (0.0%)                             | 2 (1.0%)                            |
| $60,000 +                             | 1 (3.3%)                             | 3 (1.5%)                            |
| Missing                               | 1 (3.3%)                             | 1 (0.5%)                            |
| Number of visits last year            |                                       |                                     |
| 1 visit                               | 1 (3.3%)                             | 1 (0.5%)                            |
| 2–5 visits                            | 10 (33.3%)                           | 99 (49.5%)                          |
| 6 or more visits                      | 18 (60.0%)                           | 100 (50.0%)                         |
| Missing                               | 1 (3.3%)                             | 0 (0.0%)                            |
| Living situation                      |                                       |                                     |
| Living in a house/apartment           | 22 (73.3%)                           | 139 (69.5%)                         |
| Assisted living or nursing home       | 1 (3.3%)                             | 11 (5.5%)                           |
| Homeless or other                     | 5 (17.2%)                            | 49 (24.5%)                          |
| Missing                               | 0 (0.0%)                             | 1 (0.5%)                            |

N/A not applicable data

The recruitment flowchart for the discussion groups of study 2 is outlined in Fig. 2. For round one of the discussion groups of study 2, prescreened EMR reports identified 804 eligible patients stratified by age (< 65 vs. 65 +) and number of chronic conditions (2–3 vs. 4 + chronic conditions). To ensure representativeness of the population, we oversampled for race in the EMR reports. To recruit 8–10 patients, a total of 340 invitations were mailed. Invitations were mailed in three batches a couple of weeks apart to allow for variability, with 100 invitations mailed in the first batch and 120 in each of subsequent 2 batches. Overall, we received 23 positive responses (6.8% response rate) and successfully enrolled seven patients (2.1% of total invitations), with comparable distribution across the four strata. Of the seven patients who participated in the round one discussion group, five of them returned to participate in the second round of discussions (71.4% retention).
visibility and acceptance of research within a community that is often underrepresented and may be hesitant to participate in research studies.

From study 2, it appears that the targeted mailing of invitations to participate in research may not be the most effective means of reaching a socially vulnerable, under-represented patient population. Previous studies have reported an association between specific factors and the decision not to participate in studies for underrepresented populations. Barriers included the fear and perceived harms of clinical trial participation, lack of trust for research and medical systems (patient-provider relationship and negative perception of providers), loss of control (uncertainty about treatment allocation), nature of the intervention, time commitment, loss of income, cost of participation, transportation, and family considerations. Although we cannot determine which of these factors directly contributed to the low participant yield in study 2, it is important to consider the study design and how it may have contributed. The study, while low risk, required identified patients to make a concerted effort to participate in a discussion group over two points in time. Once they received the mail invitation to the study, they were asked to respond via email or phone, make themselves available on the days of the groups, and transport themselves to the clinic, as well as commit to returning for a second group discussion. These multiple requirements on the patient end might have contributed to a decision not to participate, leading to low participant yield.

Limitations to our study include the inability to directly compare the various recruitment methods used. This was a supplementary descriptive analysis of an ongoing project, not a discrete study aim. This limits the generalizability of the findings. A more definitive future study would randomize patients to recruitment methods. Second, the assessed recruitment methods were designed principally for survey-based studies. These methods may be less effective when used with other study designs. Furthermore, self-selection was inherent to the recruitment which could have resulted in bias in the samples. Additionally, non-English speaking patients were not included in this analysis, further limiting generalizability of our findings. Finally, this study was performed prior to the COVID-19 pandemic; tabling may understandably be minimized during such times.

In conclusion, tabling in the waiting room of a safety net clinic had a higher recruitment yield than targeted mailings or phone calls to patients after EMR screening. However, all recruitment efforts did yield a range of research participants from traditionally under-represented groups.
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Declarations:

Conflict of Interest: The authors declare that they do not have any meaningful conflicts of interest. Dr. Linzer is supported through Hennepin Healthcare for training and research in physician burnout prevention by the American Medical Association (AMA), Institute for Healthcare Improvement (IHI), American Board of Internal Medicine (ABIM), American College of Physicians (ACP), the Optum Office for Provider Advancement, and the Agency for Healthcare Research and Quality (AHRQ). He consults on a grant for Harvard University on work conditions and diagnostic accuracy. Ms. Audi was supported through Meaningful conflicts of interest. Dr. Linzer is supported through Hennepin Healthcare for training and research in physician burnout prevention by the American Medical Association (AMA), Institute for Healthcare Improvement (IHI), American Board of Internal Medicine (ABIM), American College of Physicians (ACP), the Optum Office for Provider Advancement, and the Agency for Healthcare Research and Quality (AHRQ). He consults on a grant for Harvard University on work conditions and diagnostic accuracy. Ms. Audi was supported through

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