BMC Emergency Medicine

RESEARCH

Open Access

Barriers to recruitment of an observational SARS-CoV-2 emergency department cohort at Boston Medical Center

Sarah J. Thomson[1*], Roxanne Mistry[2], Henry Bayly[3], Victoria Overbeck[1], Manish Sagar[1,4,5], Elissa M. Schechter-Perkins[6], Laura F. White[3], Karen R. Jacobson[1,4] and Tara C. Bouton[1,4]

Abstract

Background Successful recruitment of study participants is a challenging component of research, and recruitment barriers are amplified in safety-net hospital (SNH) settings. However, engaging historically underrepresented groups in research is critically important to improve health disparities and outcomes. We summarize challenges we encountered while recruiting patients with COVID-19 from the emergency department (ED), actions to improve inclusivity, and implementation hurdles in an SNH setting.

Methods We conducted an observational study at the largest safety-net hospital in New England, recruiting patients in the ED with confirmed COVID-19. Investigators prioritized recruitment inclusivity through language translations of study materials, compensation (including transport and travel reimbursement), flexible sample delivery options, and clinical staff engagement. We identified and categorized major impediments to recruitment success.

Results Recruitment and retention efforts were largely unsuccessful ($n=4$ enrolled of $n=113$ eligible by electronic medical record (EMR) review). Barriers to recruitment success included clinical teams' perception of good candidacy, persistent language barriers, limited consent capacity, burden of participation, and ED discharge logistics.

Conclusions Despite efforts to improve opportunities to participate in research, SNH EDs present unique challenges for recruitment. Study teams should prioritize clinical staff engagement and work with institutions to promote inclusivity and community engagement efforts to improve research engagement in these settings.

Clinical trial number Not applicable.

Keywords Recruitment, Recruitment barriers, Safety-net hospital, Emergency department

*Correspondence:
Sarah J. Thomson
sarahthomson27@gmail.com
[1]Section of Infectious Diseases, Boston Medical Center, Boston, MA, USA
[2]Department of Surgery, Icahn School of Medicine at Mount Sinai, New York, NY, USA
[3]Department of Biostatistics, Boston University School of Public Health, Boston, MA, USA
[4]Department of Medicine, Boston University Chobanian & Avedisian School of Medicine, Boston, MA, USA
[5]Department of Virology, Immunology and Microbiology, Boston University Chobanian & Avedisian School of Medicine, Boston, MA, USA
[6]Department of Emergency Medicine, Boston Medical Center, Boston University Chobanian & Avedisian School of Medicine, Boston, MA, USA

Background

Successful recruitment of participants is widely acknowledged as one of the most challenging components of clinical research studies [1, 2]. Recruitment and enrollment issues are often the primary reason for project terminations, and nearly 80% of global trials require extensions due to insufficient enrollments [3]. There are a number of factors that affect recruitment success, including institutional barriers, the nature of the research being conducted, and the characteristics of the research setting [4]. Barriers to recruitment success are further amplified when recruiting individuals who are hospitalized, specifically in the emergency department (ED) [5], and safety-net hospital (SNH) settings may present additional challenges.

In the United States, SNHs and hospital systems provide health services to millions of under or uninsured patients, including those on Medicaid, regardless of the patients' ability to pay [6, 7]. Due to this, SNHs serve as a vital resource for low socioeconomic status (SES) areas and underserved communities. This is especially true of SNH EDs. The majority of those receiving care in SNH ED settings are often deemed "hard-to-reach" as a result of social vulnerabilities, stigma, mistrust of research processes, language, and cultural barriers [8, 9]. As such, engagement of SNH ED patients in research will be a potentially critical bridge to improving understanding of health disparities and outcomes for those historically underrepresented in research [10, 11].

However, despite widespread acknowledgment of and interest in closing the research gap that exists for underrepresented groups, there is a general lack of prioritization among funders, institutions, and researchers to increase research access and recruitment inclusivity [12]. This is likely due to the additional resources and efforts needed to establish successful research studies in SNH settings. To successfully recruit SNH patients, researchers must account for language diversity, variable levels of health literacy, potential mistrust, perceived and actual discrimination, time and schedule constraints, transportation logistics, lack of access to technology, and other factors when designing study protocols [8, 9, 12]. Addressing each of these barriers requires additional funding support to create and provide supplemental recruitment resources. Given these barriers, sponsors are more likely to conduct research at medical centers that serve privately insured, and therefore higher SES, patient populations, limiting research generalizability [13].

SNH ED settings were also particularly susceptible to the clinical and research challenges presented by the COVID-19 pandemic, with a significant intensification of hospital staffing shortages and drastically reduced health system capacity [14]. Given the disproportionate impact of the pandemic on people of color (POC) and low-SES populations [15], we were interested in recruiting patients with COVID-19 from an SNH ED setting to improve disease surveillance among those historically underrepresented in research. This paper aims to summarize the persistent barriers and challenges we faced recruiting this cohort from the ED, along with actions taken to improve inclusivity, and implementation hurdles in an SNH setting.

Methods

Setting

Boston Medical Center (BMC) is the largest SNH in New England, and the hospital ED serves over 130,000 patients each year [16, 17]. Urban SNHs, like BMC, provide care for a higher proportion of racial and ethnic minorities than other urban hospitals [6]. More than 70% of BMC patients identify as minorities [18] and more than 30% of patients speak a primary language other than English [16, 19]. Additionally, a high proportion of BMC patients are vulnerable, with 25% of the patient population reporting unstable housing and 57% living in underserved areas [20].

BMC also sits at the epicenter of the opioid and homelessness crises in Boston [21]. The hospital cares for a large proportion of patients with substance use disorders (SUDs) [22], with over 2,500 addiction-related patient visits per month [23]. Additionally, approximately 25% of patients admitted to BMC are unstably housed/experiencing homelessness [24], and these populations frequently utilize the BMC ED for care.

Study design and justification

The Boston Medical Center *Dy*namics of *S*ARS *Co*V-2 Study (BMC DySCo) was an observational cohort study that launched in October 2022 and aimed to enroll patients with COVID-19 from the BMC ED. Patients were eligible if they were 18 years of age or older, had a positive polymerase chain reaction (PCR) test for SARS CoV-2 within the past 96 h, experienced symptom onset within the past 96 h (if symptomatic), were living within 10 miles of BMC, and spoke a language accommodated by either study material translations or institutional review board (IRB) short form consents (see the "Language inclusivity" section below). Participants were identified through Epic, BMC's electronic medical record (EMR) system, and were enrolled via in-person electronic consent (e-consent). Participants completed an initial 1-hour study visit and were then instructed to complete symptom questionnaires daily and collect anterior nasal swabs for fourteen days. Daily questionnaires and sample collections were designed to take about 10 min per day. Participants had the option to self-complete symptom questionnaires via emailed Research Electronic Data Capture (REDCap) links, or complete with a study

staff member via phone each morning. Participants also underwent three, 10-minute study blood draws over the three-month study period and completed a follow-up questionnaire at the 90-day mark.

The design and procedures were largely based on a successful observational cohort study previously conducted by the research team on the Boston University (BU) undergraduate and medical campuses. The SARS-*Co*V-2 *Vi*ral *D*ynamics *Post-vaccination* Study (CoViD Post-vax) enrolled BU students, faculty and staff who tested positive for COVID-19 by PCR and were identified as part of the BU SARS-CoV-2 screening program, which included routine COVID-19 testing one to two times per week [25]. While CoViD Post-vax was successful in rapidly recruiting its target sample size, the study's generalizability is limited; most participants were white, young, and vaccinated [26]. Students testing positive for COVID-19 were also required to isolate in a specific set of dormitories, streamlining research sample collection and pick-up. The BMC DySCo study was designed to evaluate similar outcomes, including within-host viral dynamics, immune response, and viral genomic diversity among the more heterogeneous and historically underrepresented populations cared for by BMC.

Inclusivity efforts

To mitigate potential recruitment challenges in this SNH ED setting, we attempted to be proactive and intentional, and held meetings to brainstorm methods for study inclusivity and engagement. These steps were implemented prior to study launch and were amended throughout the enrollment period based on feedback from team members.

Language inclusivity

Given that over 30% of BMC patients speak a primary language other than English [19], we provided consent forms and surveys in four additional languages: Spanish, Portuguese, Vietnamese and Haitian-Creole. These languages were selected because the IRB provided feedback that these are the most common languages encountered in BMC hospital research and previous BMC COVID-19 trials. Additionally, we made use of all available IRB-approved short-form language consents (Albanian, Arabic, Burmese, Cambodian, Cape Verdean, Chinese, French, Greek, Hindi, Igbo) and secured hospital interpreter services to accommodate the breadth of linguistic diversity in our patient population and allow for more inclusive enrollment and retention of non-English speakers and those with limited English proficiency. Enrolled participants that preferred a language other than the five main study languages were able to participate via live telephone interpretation of study procedures.

Consent form flexibility and teach back

Consent form flexibility was necessary to ensure success of this project. As the study team was interacting with participants who had SARS-CoV-2, we aimed to limit paper utilization for infection control purposes. While fully remote consent without in-person engagement may deter patients from research [27, 28], the literature suggests that in-person e-consent is generally regarded by participants as accessible and engaging [29]. Therefore, we opted for an in-person e-consent process. E-consent would allow for legally authorized representatives (LARs) to remotely consent on behalf of intubated patients with COVID-19 as necessary. To promote accessibility, the consents were drafted at an eighth-grade reading level per institutional policies [30].

Additionally, we implemented teach-back methods during our consent process to improve understanding and information retention. Teach-back encourages participants to verbally demonstrate their understanding of the relayed consent information in their own words. Clinical settings that implement teach-back report better comprehension and recruitment success [31].

Transportation and sample pick up

Provision of transportation resources, vouchers, travel reimbursements, and/or parking validation improves participant retention and reduces perceived travel burdens [32–35]. To reduce the travel burden associated with the follow-up blood draw visits, we offered free transportation through a local taxi service and travel reimbursements to participants who transported themselves to these visits.

Additionally, we collaborated with a local courier service with the intention to coordinate biological sample pick-up from participant homes upon hospital discharge. The courier offered flexible pick-up times to accommodate participant schedules, and reduce transportation burdens and time commitment concerns. The courier service was able to communicate with participants via text message in their preferred language. We also provided an on-site freezer for participants who opted to drop off their samples or for those who were unstably housed and close to the hospital. Study staff were also available to pick up study samples at the hospital for inpatient participants prior to discharge.

Compensation

Incentives are one of the most commonly cited drivers of research participation [35]. Financial incentives are the most common, and monetary compensation acknowledges time contributed to the research activities, motivates participation, and improves participant retention [32, 34]. Study compensation was prorated, and participants were eligible to receive compensation

upon completing initial enrollment in the study at the ED visit. Participants would receive compensation up to $250 if they completed all study procedures. This amount reflects what is considered to support the contributed time without being coercive, which would make it more difficult for a participant to refuse inclusion. Participant compensation was issued in the form of reloadable debit cards as required by the hospital.

Daily communications

Consistent communication from research staff helps promote participant engagement and can aid in retention by sustaining commitment to study procedures, specifically in underserved populations [34, 36]. Automatic emails were sent to participants daily with instructions to complete daily symptom surveys online, and we provided a phone number and email address should participants have questions or require assistance with daily procedures. Participants also had the option to complete their daily symptom surveys with a study staff member via phone, and by retaining the same staff over time, we were able to build rapport with participants, which has been shown to encourage further participation [36].

Engaging hospital staff

Clinical teams are valuable partners in hospital research, and warm hand-offs from clinical staff to research staff have an immediate positive impact on a patient's perception of research [37]. When clinical staff engage in a warm hand-off, they explain the research team's goals to their patient and provide a justification for research participation before the study staff's initial patient contact. This transfers patient trust in their clinical care team to the research team and guides the patient to view their clinical and research teams as a cohesive group [38].

We engaged clinical staff in the BMC ED and educated them on our research goals and procedures. We collaborated with the hospital's ED Research Director who provided input on study procedures prior to study launch and during study enrollment, and informed ED providers about the study at regular intervals and in various formats during study enrollment. We hung staff-oriented flyers in the ED to raise awareness for our research, attended ED staff huddles prior to study launch to explain the study, displayed promotional materials with headshots of team members to improve recognition, and made contact with clinical teams prior to approaching patients to prevent encroachment by research staff on clinical care duties.

Pre-screening procedures and patient approach

Each morning, the study research assistant (RA) identified all new ED patients with COVID-19 via the hospital's EMR system. The RA pre-screened all identified patients for study eligibility by assessing age, language preference, ZIP code, and timing of PCR and symptom onset (both needed to be within 96 h), as applicable. All eligibility information was maintained in a locked spreadsheet. If the RA identified an eligible patient, they would review the patient's EMR to rule out individuals that were not 'good candidates' for research (incapacitated, intoxicated, blood disorder, etc.). To prevent undue interference with ED patient discharge, the study team did not approach individuals who were to be discharged within the next hour.

Additionally, patients and their clinical teams were not approached if they had been marked as unapproachable for research in their EMR or by hospital research operations. Patients were not approached if the patient did not have the capacity to consent, if translated materials were not yet available for early non-English speaking recruits, if the patient's clinical team could not be successfully contacted by study staff, if the patient was located outside the main hospital ED (e.g., in the pediatric ED (PED)), or if the patient did not have access to a phone or email address for consistent study follow-up.

If a patient was deemed eligible based on EMR review, the RA would go to the ED, locate the eligible patients' clinical care team, request permission to approach the patient for research, and confirm study eligibility. The clinical care team included the attending or resident physician, physician's assistant, and nurse(s). No patients were approached without permission from at least two members of the clinical care team. The RA kept a spreadsheet of reasons why they were not given permission to approach the patient by clinical staff, if applicable. Reasons included patient ineligibility for the research project, planned patient discharge within the next hour, the patient being deemed not a 'good candidate' for research (due to psychosis, altered mental status, dementia, aggravation, or other unspecified reason), the patient not having the capacity to consent, and patient refusal of blood draws. If the clinical team gave permission and confirmed eligibility, the RA donned the appropriate personal protective equipment (PPE) and approached the patient for research using an IRB-approved contact script to introduce the study's purpose and procedures. The RA noted where uninterested participants stopped them in the contact script and recorded reasons not enrolled, if applicable. The RA also recorded all languages encountered in the ED setting that were not accommodated by the IRB short-form language list.

Eligibility amendments

The original study design required participants to have a positive PCR test and symptom onset both within 48 h to be eligible; these criteria were amended within the first two months of study initiation to allow for symptom onset and positive PCR test within 96 h in an effort

to expand the pool of eligible ED patients. Additionally, the original study design precluded staff from approaching patients that were set for discharge within two hours, but this window was reduced to one hour after consulting with the ED Research Director to allow for a greater number of patient approaches by study staff.

Results

Recruitment success

The study team identified and pre-screened 416 BMC ED patients with COVID-19 through the hospital's EMR system, of whom 4 (0.96%) were successfully enrolled into the study. Study pre-screening and recruitment outcomes are detailed in Fig. 1.

We approached approximately 70% ($N=79/113$) of clinical care teams for patients deemed eligible based on EMR review and pre-screening. Once in the ED, clinical teams denied study staff permission to approach 40 patients (50.6%). The most common reasons for clinical teams refusing permission to approach a chart-review eligible potential participant ($N=40$) was lack of consent capacity (40%, $N=16$), imminent hospital discharge (27.5%, $N=11$), and determination that the potential participant was not a 'good candidate' for research (22.5%, $N=9$). Study staff approached 28 patients, with an enrollment success rate among those approached of 14.3% ($N=4$; Fig. 1).

An overview of contact script progress and patient interest/eligibility attrition during the recruitment procedures using the contact script is detailed in Fig. 2. The RA approached 21 eligible patients; a large proportion of eligible and approached participants refused participation after the RA's general introduction to research (15.8%, $N=3/19$) and after the overview of study procedures (43.8%, $N=7/16$; Fig. 2).

Persistent barriers to success

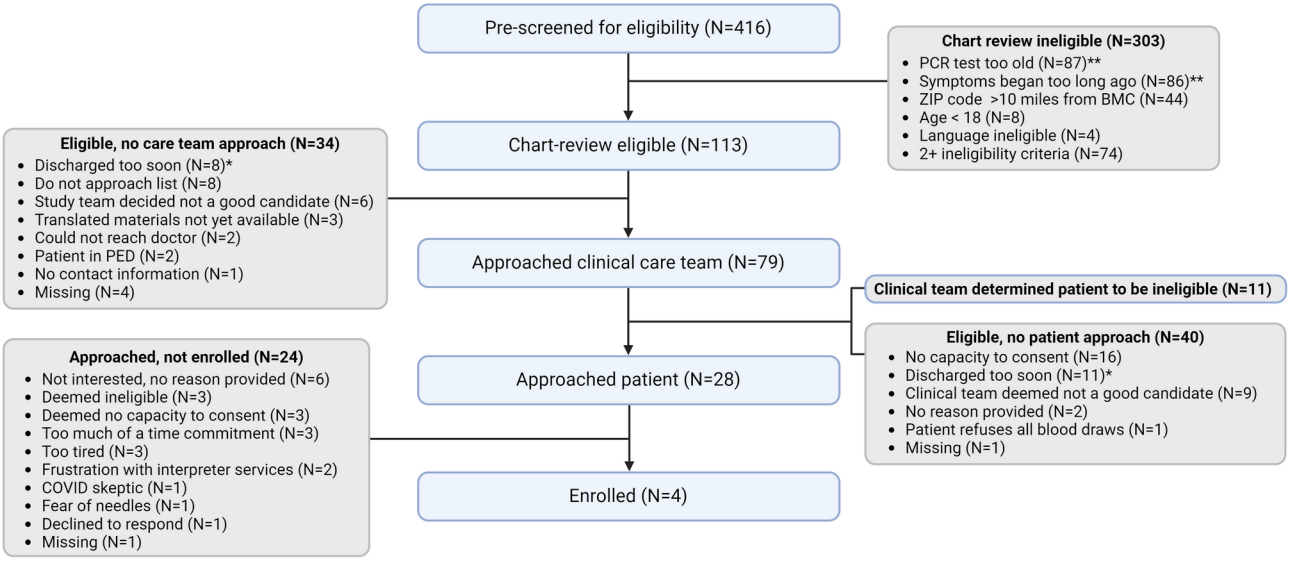
Our recruitment efforts were largely unsuccessful in this SNH setting. During the recruitment process, we identified four major barriers to research success in the ED.

Clinical team engagement and perception of good candidacy

Clinical ED teams caring for potential participants did not give the study team permission to approach a large proportion of patients (50.6%, $N=40$) that were eligible for the study based on EMR review. 22.5% of these denials were on the basis of the patient not being a 'good candidate' for research despite eligibility and consent capacity.

Language barriers

The institution's IRB offered short-form consents in 15 different languages, four of which were the main languages used in our study. However, we encountered an additional five languages (Ethiopian, Japanese, Nepali, Toinese, Yoruba) that were not accommodated by short-form, resulting in seven patients that could not be approached. Both non-English speaking patients we approached had issues with our telephone interpreter services, including frustration with interpretation pace and refusing to work with an interpreter.



*Participants who were "discharged too soon" may have been set for discharge within 1 hour or 2 hours depending on whether they arrived in the ED before or after amending inclusion criteria.
**Participants who whose PCR test was too old, or whose symptoms began too long ago may have tested positive or reported symptom onset beyond 48 hours prior, or beyond 96 hours prior depending on whether they arrived in the ED before or after amending inclusion criteria.

Created with BioRender.com

Fig. 1 Pre-screening and study recruitment summary

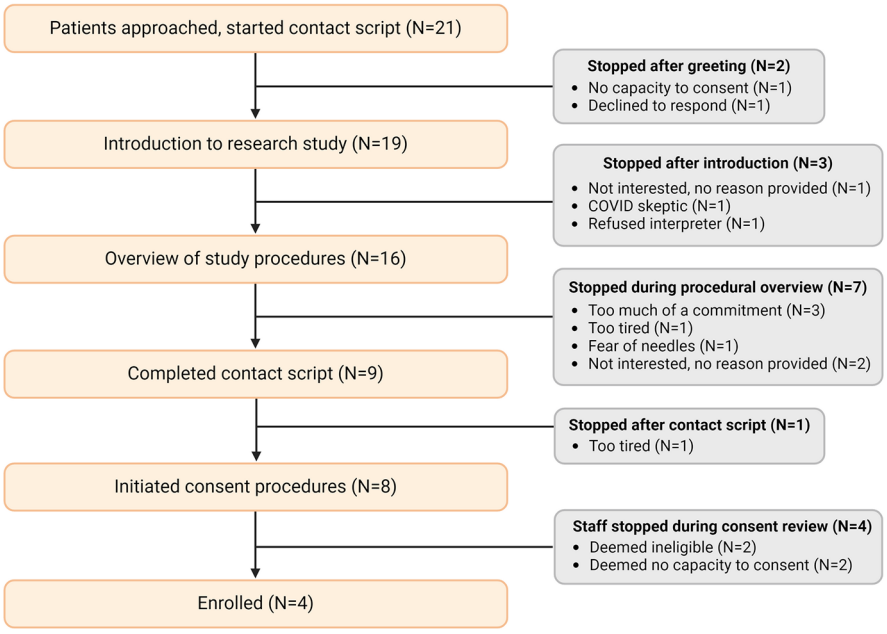


Fig. 2 Patient interest attrition during contact script. Note: An additional 7 patients were approached by study staff and contact script was initiated. However, the study staff was not yet collecting data on where these patients stopped during the initial approach. Reasons these patients were not enrolled: not interested, no reason provided ($N=3$), frustration with interpreter ($N=1$), too tired ($N=1$), deemed ineligible ($N=1$). Reason not enrolled is missing for one patient

Limited consent capacity

Capacity to consent was a consistent barrier in the ED, and clinical teams expressed to the research staff that 40% ($N=16$) of eligible patients should not be approached for this reason. Some clinical teams provided additional detail as to why their patient lacked capacity, including psychosis ($N=3$), dementia ($N=2$), and altered mental status ($N=5$), which was largely due to psychiatric distress or acute intoxication.

ED discharge logistics

Discharge time from the ED was another consistent barrier throughout the recruitment process. BMC is the largest and busiest provider of emergency services in New England [17] where ED overcrowding is common. Overcrowding was especially problematic throughout the COVID-19 pandemic. As such, ED operations staff work to discharge patients as swiftly as possible. To avoid interference with discharge procedures, we did not approach patients that were going to be discharged within the next hour and were therefore unable to offer study participation to many otherwise eligible patients.

Discussion

Here we describe barriers to ED recruitment of patients with COVID-19 in an SNH ED setting. The goal of this review is to ensure future projects anticipate some of these challenges and consider how to build improved systems to overcome them. We encountered institutional, clinical staff, and patient-level barriers during the recruitment process (Fig. 1).

While 113 screened patients were chart-review eligible, approximately 30% of these patients were deemed unapproachable due to discharge time, intoxication, behavioral and consent capacity issues, comorbidities, and other logistical factors. Once in the ED, clinical care teams did not give permission to approach a subset of chart-review eligible patients, most often due to discharge time, lacking consent capacity, or the determination that the patient was not a 'good candidate' for research.

Most approached patients were also reluctant to participate; a majority were not interested, too tired, concerned about study time commitment, or lacking consent capacity. Additionally, about 25% of approached patients stopped us after or during a general introduction to research, and another 30% stopped us after an overview of the study procedures, possibly indicating hesitancy

surrounding research in general, as well as our proposed project (Fig. 2). EDs generally aim to expedite patient discharge [32], and this setting was no exception. Some of the most consistent barriers to research success in this setting included lacking clinical staff engagement, language and cultural barriers, widespread issues with consent capacity, and ED discharge logistics.

Clinical staff engagement remains one of the most important, and challenging, components of a successful recruitment strategy in an SNH ED setting. Our study team recognized the importance of engaging clinical staff to ensure recruitment success in this setting and we had hoped to implement warm handoffs between clinical staff and the study team to facilitate patient trust in recruiting staff. However, engaging and building rapport with clinical staff in the BMC ED proved consistently difficult. It is well documented that the ED is a difficult place to build rapport with and maintain buy-in from clinical staff as a result of competing clinical responsibilities, staffing shortages, skepticism surrounding research, and the shift-based nature of ED work [39, 40]. Clinical staff in certain settings may perceive research recruitment as burdensome [40–42], or feel that they have to identify the "perfect patient" when referring individuals to research teams for study participation [43]. There is also evidence in the literature of bias among clinical staff as well, who may perceive minority patients as less likely to adhere to requirements of more complex studies, and therefore are less likely to identify these patients as 'good candidates' for research [44].

While our team was unable to achieve our recruitment goals in this setting, there are several facilitators to clinical staff engagement in research that may aid research teams in future recruitment success. Our team made active efforts to educate clinical teams and ensure staff buy-in prior to study launch, but we were unable to maintain consistent, in-person engagement efforts and communications with clinical staff during the study course due to limited project staffing and clinical staff responsibilities. Other studies have highlighted the importance of actively engaging clinical staff throughout the study course to ensure recruitment success and protocol adherence [40, 45]. While properly executed warm hand-offs between clinical staff and patients promotes recruitment success, specifically among historically underrepresented groups [37, 46], staff in our SNH ED did not have the capacity to provide these hand-offs for patients in COVID-19 isolation. Other studies also stress the importance of incentives for clinical staff to maintain engagement and improve perceptions of research among clinical staff [40, 41, 45], which we were unable to provide due to budget constraints.

Recruitment of non-English speakers was also a consistent challenge due to institutional and research team barriers. While the hospital serves a linguistically diverse patient population, we identified several patient languages in the ED that were not accommodated by the IRB short-form consents, which prevented us from approaching eligible, non-English speaking patients. Language inclusivity is key when promoting equity in research proposals and recruitment strategies, and should be an institutional priority, especially in SNH settings [47]. Additionally, non-English speaking patients expressed frustration with interpreter services, which were only made available via phone given that eligible patients had COVID-19. The pushback we observed from patients when recommending interpreters highlights the need for multi-lingual and linguistically diverse research staff in this setting, which our study lacked. Given the language diversity in this clinical setting, full linguistic representation would have been challenging, but increased cultural competency and representation would have been beneficial. The literature supports this, as cultural and linguistic congruence are key to ensuring recruitment success among and meaningful engagement with minority communities [36, 37, 48]. Future studies should consider potential language barriers and solutions carefully when establishing recruitment methods in similar settings.

As an SNH ED with a high prevalence of patients with substance use and mental health disorders [22] capacity to consent was a persistent barrier and something for future studies to consider in ED settings. Some of those approached exhibited acute intoxication, altered mental status, and psychosis, and while research staff made efforts to re-approach patients with acute issues later in the day, approach was still deemed inappropriate by clinical staff as capacity issues persisted. While research is limited on consent capacity in SNH ED settings, the ED environment generally makes for a more complex informed consent process. Patients should have adequate time to review the consent and consent procedures should take place in private, distraction-free spaces whenever possible [49]. However, this is difficult to achieve in an ED setting, in which private space is often not available, and clinical conditions such as acute intoxication or other comorbidities impact capacity and create additional barriers to eligibility [44, 50]. When a patients' capacity to consent is questionable, other studies have made use of cognitive scales to make capacity determinations [49] but there are mixed results regarding scale accuracy when implemented among those with SUD [50, 51]. Our study also aimed to make use of LARs to consent on patients' behalf if they did not have capacity, but due to COVID-19 policies in the ED, visitors were limited and it was often difficult to determine next of kin. While capacity to consent issues can be expected in the ED, validated cognitive capacity scales may be a promising tool for standardized consent capacity determination.

Additionally, we would be remiss not to address these findings in the context of the COVID-19 pandemic and associated infection control procedures in the ED. We followed infection control guidelines set forth by the hospital when entering participant rooms for recruitment, which required donning of masks, face shields, gowns, and gloves. PPE was essential to prevent disease transmission during participant interactions; however, research suggests that seeing providers in head-to-toe PPE induces heightened anxiety and fear surrounding COVID-19 among patients [52], and the stress surrounding recent COVID-19 diagnosis may have been aggravated by PPE requirements. Establishing meaningful and trusting relationships with potential participants is crucial to ensuring recruitment success, however, our ability to achieve this may have been hindered by PPE requirements.

Analysis limitations include this research context of the COVID-19 pandemic, and the lack of resources needed to conduct in-depth qualitative interviews with (1) approached patients to understand their hesitancy, (2) approached clinical staff to understand why they deemed certain patients "not good candidates" for research participation, and (3) members of the communities served by BMC to inform protocol planning and implementation considerations in this setting prior to study launch.

A common theme across the identified barriers to recruitment in the SNH ED is the importance of funder and institutional support of clinical research. COVID-19 highlighted the need for improved access to research opportunities for all, without which there is no access to the newest therapeutics and vaccines for underserved communities. A research-supportive culture is one of the most important facilitators of research success [45] and cannot be established by clinical and research teams alone. Institutional commitment is key, and while we identified recruitment barriers in the ED setting, BMC has demonstrated a commitment to research by advocating for inclusion of underrepresented populations in COVID-19 clinical trials and hiring its first chief scientific officer during the pandemic. Upstream support by funding organizations is also crucial, as there are increased costs and resources associated with engaging those historically underrepresented in research, such as those incurred for transportation, language translations and reimbursements. Funders' acknowledgment of the increased participation burden for these communities, as well as the value of investing in engagement efforts to promote trust, is essential to research success.

Conclusion

The SNH ED is a particularly challenging setting to recruit patients for clinical research. More qualitative work is needed to understand at the patient, provider, and community level how to create a successful research environment. However, continued clinical staff engagement, linguistic accommodations, standardized consent capacity tools, and a research-supportive culture at the institutional level may promote recruitment success. Recruitment success in this setting is an upstream issue, and requires action by funders, institutional leadership, and investigators to expand research inclusivity efforts and engage communities.

Abbreviations

BMC	Boston Medical Center
COViD Post-vax	SARS-CoV-2 Viral Dynamics Post-vaccination Study
COVID-19	Coronavirus disease 2019
DySCo	Dynamics of SARS CoV-2 Variants
E-consent	Electronic consent
ED	Emergency department
EMR	Electronic Medical Record
IRB	Institutional Review Board
LAR	Legally authorized representative
PCR	Polymerase chain reaction
PED	Pediatric emergency department
POC	People of color
PPE	Personal protective equipment
RA	Research assistant
REDCap	Research Electronic Data Capture
SES	Socioeconomic status
SNH	Safety-net hospital
SUD	Substance use disorder

Acknowledgements

We would like to acknowledge the support of our BMC Section of Infectious Diseases and Emergency Department colleagues, particularly Dr. Benjamin Linas, Dr. Mari-Lynn Drainoni, Autumn Tamlyn, and Dr. Stephanie Smith, all of whom provided feedback on study design and procedures when we encountered recruitment challenges in the BMC ED. We would also like to acknowledge our colleagues at MassCPR for their funding support of this research.

Author contributions

SJT led manuscript writing efforts, coordinated data collection activities and led data management and interpretation efforts. RM led study data collection and aided in data management and interpretation efforts. HB aided in data management and analysis efforts. VO led data auditing efforts and aided in data interpretation. MS led sample analysis procedures and aided in study design, data analysis, and data interpretation. EMS led efforts within the BMC ED and aided in study design, data collection, and data interpretation. LFW and KRJ aided in study design, data analysis, and data interpretation. TCB served as study principal investigator, led study design, oversaw data collection, management, and analysis, and was a contributor to manuscript writing. All authors read, provided feedback on, and approved the final manuscript.

Funding

Funding for this research study was provided by the Massachusetts Consortium on Pathogen Readiness (MassCPR) and Boston Medical Center. TCB is supported by the National Institute of Health (NIAID K23 grant AI152930).

Data availability

The datasets generated and/or analyzed during the current study are not publicly available as details on individual participant's eligibility and reasons not enrolled may compromise individual privacy. However, data are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The BMC Dynamics of SARS-CoV-2 Variants (BMC DySCo) study obtained approval from the Boston Medical Center Institutional Review Board (H-42603). Participants provided informed consent to the use of their data and samples for health-related research purposes. This study was conducted in accordance with all relevant guidelines and regulations.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Received: 7 January 2025 / Accepted: 15 April 2025
Published online: 20 April 2025

References

1. Kadam RA, Borde SU, Madas SA, Salvi SS, Limaye SS. Challenges in recruitment and retention of clinical trial subjects. Perspect Clin Res. 2016;7(3):137–43.
2. Treweek S, Lockhart P, Pitkethly M, Cook JA, Kjeldstrøm M, Johansen M, et al. Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis. BMJ Open. 2013;3(2):e002360.
3. Desai M. Recruitment and retention of participants in clinical studies: critical issues and challenges. Perspect Clin Res. 2020;11(2):51–3.
4. Newington L, Metcalfe A. Factors influencing recruitment to research: qualitative study of the experiences and perceptions of research teams. BMC Med Res Methodol. 2014;14:10.
5. Price D, Edwards M, Carson-Stevens A, Cooper A, Davies F, Evans B, et al. Challenges of recruiting emergency department patients to a qualitative study: a thematic analysis of researchers' experiences. BMC Med Res Methodol. 2020;20(1):151.
6. Fantasia KL, Wirunsawanya K, Lee C, Rizo I. Racial disparities in diabetes technology use and outcomes in type 1 diabetes in a Safety-Net hospital. J Diabetes Sci Technol. 2021;15(5):1010–7.
7. Sutton JP, Washington RE, Fingar KR, Elixhauser A. Characteristics of safety-net hospitals, 2014. In: Healthcare Cost and Utilization Project (HCUP) Statistical Briefs [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2006 [cited 2023 Dec 18]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK401306/
8. Savard I, Kilpatrick K. Tailoring research recruitment strategies to survey harder-to-reach populations: A discussion paper. J Adv Nurs. 2022;78(4):968–78.
9. Rockliffe L, Chorley AJ, Marlow LAV, Forster AS. It's hard to reach the hard-to-reach: the challenges of recruiting people who do not access preventative healthcare services into interview studies. Int J Qual Stud Health Well-Being. 2018;13(1):1479582.
10. Cummings LC, AcademyHealth. 2016 [cited 2023 May 17]. Health services research: Challenges and opportunities in safety net hospital systems. Available from: https://academyhealth.org/sites/default/files/CummingsSummaryBriefMarch2016_1.pdf
11. Hefner JL, Hogan TH, Opoku-Agyeman W, Menachemi N. Defining safety net hospitals in the health services research literature: a systematic review and critical appraisal. BMC Health Serv Res. 2021;21(1):278.
12. Wambua M, Vang M, Audi C, Linzer M, Eton DT. Lessons learned: recruiting research participants from an underrepresented patient population at a safety net hospital. J Gen Intern Med. 2022;37(4):922–7.
13. Tamlyn AL, Tjilos M, Bosch NA, Barnett KG, Perkins RB, Walkey A et al. At the intersection of trust and mistrust: A qualitative analysis of motivators and barriers to research participation at a safety-net hospital. Health Expect [Internet]. [cited 2023 Mar 14];n/a(n/a). Available from: https://onlinelibrary.wiley.com/doi/abs/https://doi.org/10.1111/hex.13726
14. Magoon R, Ohri R. Compounded research challenges amid the COVID-19 pandemic. Anaesth Crit Care Pain Med. 2020;39(6):689–90.
15. Tai DBG, Sia IG, Doubeni CA, Wieland ML. Disproportionate impact of COVID-19 on Racial and ethnic minority groups in the united States: a 2021 update. J Racial Ethn Health Disparities. 2022;9(6):2334–9.
16. Advancing key performance indicators with pre-visit navigation - a case study with Boston Medical Center [Internet]. Philips. 2020 [cited 2023 Jun 5]. Available from: https://www.philips.com/c-dam/b2bhc/master/landing-pages/medumo/resources/philips-boston-medical-center.pdf
17. Boston Medical Center [Internet]. 2021 [cited 2023 Aug 30]. Emergency Medicine. Available from: https://www.bmc.org/emergency-medicine
18. Boston Medical Center - Delivery System Transformation Initiatives Proposal for the Massachusetts Sect. 1115 Waiver Demonstration Years 15–17 [Internet]. Boston Medical Center; 2012 Jun [cited 2023 Jun 5]. Available from: https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/MassHealth/ma-masshealth-boston-medical-dsti-06142012.pdf
19. Boston Medical Center [Internet]. [cited 2023 May 10]. About BMC. Available from: https://www.bmc.org/about-bmc
20. Calner P, Sperring H, Ruiz-Mercado G, Miller NS, Andry C, Battisti L, et al. HCV screening, linkage to care, and treatment patterns at different sites across one academic medical center. PLoS ONE. 2019;14(7):e0218388.
21. McDonald D. A million roads to Mass. and Cass 'and they're all horrible and scary'. Boston Globe [Internet]. 2023 Jul 2 [cited 2023 Oct 16]; Available from: https://www.bostonglobe.com/2023/07/02/metro/mass-and-cass-boston-homeless/?event=event12
22. McLaughlin A, Burns R, Ryan M, Abbasi W, Harvey L, Hicks J, et al. Comparing COVID-19-related morbidity and mortality between patients with and without substance use disorders: A retrospective cohort study. Subst Abuse Res Treat. 2023;17:11782218231160014.
23. Boston Medical Center [Internet]. 2024 [cited 2024 Apr 10]. Grayken Center for Addiction. Available from: https://www.bmc.org/addiction
24. Boston Medical Center [Internet]. [cited 2024 Apr 17]. BMC invests $6.5 million to help combat homelessness. Available from: https://www.bmc.org/about-us/stories/bmc-invests-65-million-help-combat-homelessness
25. Testing at BU. | Student Health Services [Internet]. [cited 2023 Dec 18]. Available from: https://www.bu.edu/shs/covid-19/testing-at-bu/
26. Bouton TC, Atarere J, Turcinovic J, Seitz S, Sher-Jan C, Gilbert M et al. Viral dynamics of Omicron and Delta SARS-CoV-2 variants with implications for timing of release from isolation: a longitudinal cohort study. Clin Infect Dis Off Publ Infect Dis Soc Am. 2022;ciac510.
27. Price JR, Mookerjee S, Dyakova E, Myall A, Leung W, Weiße AY, et al. Development and delivery of a Real-time Hospital-onset COVID-19 surveillance system using network analysis. Clin Infect Dis Off Publ Infect Dis Soc Am. 2021;72(1):82–9.
28. Dommaraju SR, Robinson D, Khosla S, Pobee R, Del Rios M. Challenges with text-based messaging platform to perform social needs assessments of patients presenting with COVID-19-like illness at an urban academic emergency department. Public Health Pract. 2022;3:100249.
29. Skelton E, Drey N, Rutherford M, Ayers S, Malamateniou C. Electronic consenting for conducting research remotely: A review of current practice and key recommendations for using e-consenting. Int J Med Inf. 2020;143:104271.
30. HRPP Policies | Office of Human. Research Affairs [Internet]. [cited 2023 May 17]. Available from: https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#8.4.5.1
31. Tamariz L, Palacio A, Robert M, Marcus EN. Improving the informed consent process for research subjects with low literacy: A systematic review. J Gen Intern Med. 2013;28(1):121–6.
32. Cofield SS, Conwit R, Barsan W, Quinn J. Recruitment and retention of patients into emergency medicine clinical trials. Acad Emerg Med. 2010;17(10):1104–12.
33. Gilmore-Bykovskyi A, Jackson JD, Wilkins CH. The urgency of justice in research: beyond COVID-19. Trends Mol Med. 2021;27(2):97–100.
34. Langer SL, Castro FG, Chen ACC, Davis KC, Joseph RP, Kim W (Sunny), editors. Recruitment and Retention of Underrepresented and Vulnerable Populations to Research. Public Health Nurs Boston Mass. 2021;38(6):1102–15.
35. Spears CR, Nolan BV, O'Neill JL, Arcury TA, Grzywacz JG, Feldman SR. Recruiting underserved populations to dermatologic research: a systematic review. Int J Dermatol. 2011;50(4):385–95.
36. George S, Duran N, Norris K. A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders. Am J Public Health. 2014;104(2):e16–31.
37. Epps F, Brewster G, Phillips JS, Nash R, Shah RC, Hepburn K. Using a warm Hand-Off approach to enroll African American caregivers in a Multi-Site clinical trial: the handshake protocol. J Appl Gerontol Off J South Gerontol Soc. 2022;41(1):142–7.

38. Schottenfeld L, Petersen D, Peikes D, Ricciardi R, Burack H, McNellis R et al. Creating patient-centered team-based primary care [Internet]. Rockville (MD): Agency for Healthcare Research and Quality; 2016 [cited 2023 May 10]. Available from: https://www.ahrq.gov/sites/default/files/wysiwyg/ncepcr/tools/PCMH/creating-patient-centered-team-based-primary-care-white-paper.pdf
39. Johnson R, Kuczawski M, Mason S. Why is it so difficult to recruit patients to research in emergency care? Lessons from the AHEAD study. Emerg Med J. 2016;33(1):52–6.
40. Segre LS, Buckwalter KC, Friedemann ML. Strategies to engage clinical staff in subject recruitment. J Res Nurs JRN. 2011;16(4):321–32.
41. Stiell IG, Perry JJ, Brehaut J, Brown E, Curran JA, Emond M, et al. How to conduct implementation trials and multicentre studies in the emergency department. CJEM. 2018;20(3):448–52.
42. El-Menyar A, Asim M, Latifi R, Al-Thani H. Research in emergency and critical care settings: debates, Obstacles and solutions. Sci Eng Ethics. 2016;22(6):1605–26.
43. Lamb KA, Backhouse MR, Adderley UJ. A qualitative study of factors impacting upon the recruitment of participants to research studies in wound care – The community nurses' perspective. J Tissue Viability. 2016;25(3):185–8.
44. Nazha B, Mishra M, Pentz R, Owonikoko TK. Enrollment of racial minorities in clinical trials: Old problem assumes new urgency in the age of immunotherapy. Am Soc Clin Oncol Educ Book. 2019;(39):3–10.
45. McRae AD, Perry JJ, Brehaut J, Brown E, Curran J, Emond M, et al. Engaging emergency clinicians in emergency department clinical research. Can J Emerg Med. 2018;20(3):443–7.
46. Vranceanu AM, Jacobs C, Lin A, Greenberg J, Funes CJ, Harris MB, et al. Results of a feasibility randomized controlled trial (RCT) of the toolkit for optimal recovery (TOR): a live video program to prevent chronic pain in at-risk adults with orthopedic injuries. Pilot Feasibility Stud. 2019;5:30.
47. Curt AM, Kanak MM, Fleegler EW, Stewart AM. Increasing inclusivity in patient centered research begins with Language. Prev Med. 2021;149:106621.
48. Hernandez ND, Durant R, Lisovicz N, Nweke C, Belizaire C, Cooper D, et al. African American Cancer survivors' perspectives on Cancer clinical trial participation in a Safety-Net hospital: considering the role of the social determinants of health. J Cancer Educ. 2022;37(6):1589–97.
49. Schmidt TA, Salo D, Hughes JA, Abbott JT, Geiderman JM, Johnson CX, et al. Confronting the ethical challenges to informed consent in emergency medicine research. Acad Emerg Med Off J Soc Acad Emerg Med. 2004;11(10):1082–9.
50. McCormack RP, Gallagher T, Goldfrank LR, Caplan AL. Including frequent emergency department users with severe alcohol use disorders in research: assessing capacity. Ann Emerg Med. 2015;65(2):172–e1771.
51. Martel ML, Klein LR, Miner JR, Cole JB, Nystrom PC, Holm KM, et al. A brief assessment of capacity to consent instrument in acutely intoxicated emergency department patients. Am J Emerg Med. 2018;36(1):18–23.
52. Amin S, Chin J, Terrell MA, Lomiguen CM. Addressing Challenges in humanistic communication during COVID-19 through medical education. Front Commun [Internet]. 2021 [cited 2023 Mar 8];6. Available from: https://www.frontiersin.org/articles/https://doi.org/10.3389/fcomm.2021.619348

Publisher's note