Denver Health Medical Center
Department of Emergency Medicine
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Denver, Colorado 80204

10/6/2025

To whom it may concern,

Please find below the protocol and statistical plan our study entitled: “Emergency Department Linkage to Care for Patients Experiencing Homelessness”. This is the second part of a two-arm study funded by the Agency for Healthcare Research and Quality (AHRQ, F32HS030344).

The arm of this study aims to actively link patients to follow up care with the Colorado Coalition for the Homeless Street Medicine team as compared to standard of care follow up with a rapid follow up clinic at Denver Health Medical Center.

The NCT number is NCT07209072.

Please feel free to contact us directly by electronic mail at Kathleen.Joseph@dhha.org or Carol.Lyle@dhha.org if the investigators can provide any further information. The investigators look forward to hearing from you.

Sincerely,

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Study Title: Emergency Department Linkage to Care for Patients Experiencing Homelessness -- Aim 2

Protocol (COMIRB) Number: 24-1764

Principal Investigator: Joseph, Kathleen MD

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1. Study Rationale

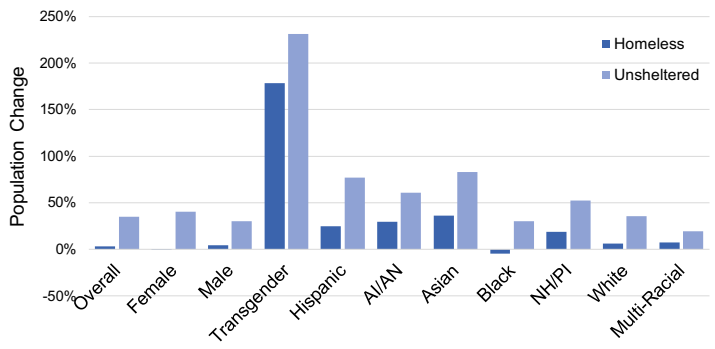
Less than 8% of PEH report having a primary care doctor and only 28% report having a regular clinic,[1] emphasizing the challenges of follow up and the fragmented care these patients receive. Street outreach is a growing and promising solution as it brings social workers, clinicians, and nurses directly to patients, rather than expecting patients to present to clinic. Thus far, no studies have examined an intervention to directly link PEH to street medicine from the ED. Therefore, we propose to conduct a pilot evaluation of a street medicine linkage-to-care intervention, which is hypothesized to offer a novel and effective solution to care coordination for PEH. We propose utilizing a custom build within the DHMC electronic health record (**EHR**) to create a discharge referral order linked to certain diagnoses. During odd numbered weeks, this order will automatically generate a referral to the Colorado Coalition for the Homeless physician-led street medicine program (intervention), and during even weeks, it will automatically generate a referral to standard-of-care conventional follow up at the DHMC Comprehensive Care Clinic (control, **CCC**).

Aim: To implement and evaluate the feasibility and effectiveness of an ED-based intervention referring PEH to direct follow up with a physician-led street medicine clinic at ED discharge
Hypotheses: (**1**) At least 60% of eligible participants will be successfully identified in the ED and receive either referral to the street medicine program or usual follow up care; and (**2**) referral to street medicine by ED clinicians will be significantly associated with successful follow up compared to referral to usual care.

2. Background

In the U.S. there are over 650,000 persons experiencing homelessness (**PEH**), of which over 250,000 are unsheltered, living on the streets, in vehicles or abandoned buildings.[2] Nationally, homelessness has continuously increased since 2017, and in 2023, reached record highs.[2] These national trends are mirrored in the Denver metropolitan area, where unsheltered homelessness rose by 32% in 2022,[3] prompting the mayor to declare a state of emergency.[4] Furthermore, marginalized racial and ethnic groups are over-represented in the homeless population compared to the general population.[2,5] There are rising rates of homelessness among minority racial, ethnic, and LGBTQ+ groups, suggesting unequal access to shelters and housing.[6] Since 2015, homelessness in transgender individuals has increased by 178% and unsheltered homelessness has increased by 231% (**Figure 1**).

Figure 1. Subgroup population shifts in US homelessness since 2015.



Abbreviations: AI/AN, American Indian or Alaska Native; NH/PI, Native Hawaiian or Pacific Islander

Similar increases have been seen in Asian, American Indian, and Hispanic populations. Thus, homelessness disproportionately affects historically disenfranchised populations and is perpetuated by systemic inequity and racism.

PEH are a uniquely vulnerable population due to high rates of chronic, environmental, and infectious diseases, substance use, mental illness, and trauma.[7] In one study, 43% of participants reported a chronic medical problem, 53% a serious mental health problem, and 49% a substance use disorder.[8] Homelessness is also an independent risk factor for mortality.[7,8] The average life expectancy of PEH in the U.S. is 48 years[9] and mortality rates are 3 to 6 times that of the general population.[7] Thus, access to both comprehensive primary and specialty care may significantly improve overall health of PEH.

Emergency departments (**ED**s) provide a critical healthcare safety-net for our society, with an estimated 131 million visits annually in the U.S.[10] EDs exist at the confluence between acute health and social needs. In one survey of patients in an urban ED, 42% reported financial difficulty meeting essential expenses, 36% reported food insecurity, 25% reported housing instability, and 14% reported homelessness.[11] The high prevalence of social needs contributes to poor health outcomes, repeat ED utilization, and frequent hospital readmissions.[12] As such, acute care needs of patients in the ED exist in conjunction with, and are inextricably linked to, social needs, and both must be addressed to improve patient care and population health.

PEH are 3 times more likely to utilize the ED than the general population,[13-16] and are more likely to have repeat ED visits.[17] High rates of comorbidities, difficulty navigating the healthcare system, lack of transportation, increased reliance on EMS, lack of health insurance, and the perception of limited options contribute to frequent ED use.[8,18] Discharge to the street and to shelters is associated with ED recidivism within 30 days,[19] suggesting that housing status drives a component of ED use. Thus, discharge from the ED without intervention perpetuates a cycle of continued reliance on EDs for primary care, preventable acute care, and social needs, contributing to high healthcare system costs and ED crowding.

PEH suffer from complex medical needs but often lack access to primary care and obtain fragmented care from multiple healthcare systems and EDs.[20-23] Unfortunately, most EDs lack meaningful ways of coordinating with outpatient clinicians at discharge for PEH. However, in many cities, including Denver, there are dedicated healthcare for the homeless clinics that include physician-led, team-based street medicine programs, which provide primary care to PEH on the streets, in shelters, and in encampments. Street medicine programs have been shown to enhance patient engagement, improve access to housing, and decrease ED utilization and hospitalizations.[24] Engagement with street medicine and other healthcare for the homeless programs are promising solutions to fractured care and avoidable ED utilization among PEH; however, to date there are no studies on care coordination interventions between EDs and street medicine.

3. Objectives and Endpoints

The outcome for Hypothesis 1 will be inclusion of eligible patients over the study period (*Reach)*. The outcome for Hypothesis 2 will be successful linkage-to-care as defined by completion of 1 follow up visit within 30 days with either a street medicine clinician (intervention) or a CCC clinician (control) (*Effectiveness*). Patients without a documented follow up visit will be considered not linked to care. Secondary *effectiveness* outcomes will include the number of repeat ED visits, hospitalizations, and primary care visits within 6 months after the initial ED visit. Secondary *adoption* outcomes will include characteristics of referring ED clinicians.

4. Study Design

We will perform a prospective equivalent time-samples quasi-experiment in the ED at DHMC to include a total of 390 patients, 130 allocated to the intervention and 260 allocated to the control. Eligible participants will be either (**a**) actively linked to care through a referral to a physician-led street medicine program (intervention) by the patient's treating ED clinician or (**b**) undergo standard-of-care referral to

usual follow up care through the DHMC CCC (control) by alternating weeks at the time of ED discharge.

Participants will be selected using convenience sampling as part of routine ED care. All clinicians in the ED and CDU will be educated on the intervention and flyers deposited throughout the department will remind staff to enroll eligible patients. This will ensure that patients are enrolled regardless of timing of presentation to the ED. Additionally, weekly emails will be sent to all ED clinicians to remind them of intervention and control weeks according to an equivalent time sample protocol. Participants will be referred for either street medicine follow up through a standardized electronic communication with the Street Medicine nurse manager or the Comprehensive Care Clinic through an electronic referral (see **Intervention**). This aim will use RE-AIM, an implementation science framework, to specifically evaluate the reach, adoption, and effectiveness of this intervention with a focus on feasibility. The proportion of successfully enrolled patients out of all eligible patients and the proportion of enrolled patients who successfully complete at least 1 follow-up visit will be determined via structured medical record review and data abstraction obtained from the electronic health records (**EHR**s) of CCH and DHMC. The number, timing, diagnoses, and length of stay of ED visits, primary care visits, and hospitalizations will also be measured for 6 months after the index ED visit via chart abstraction.

5. Study Population

Population: Adult patients discharging from the ED, who do not have a primary care doctor and are identified as homeless according to the DHMC Homeless Registry. We will aim to enroll 390 patients over 1 year.

Inclusion Criteria:

(**1**) adult (≥18 years of age) DHMC ED patient,
(**2**) currently unsheltered, defined as living on the streets, in a vehicle, or in another place not fit for human habitation,
(**3**) anticipating ED discharge, with
(**4**) a diagnosis listed in **Table 1** that requires short-term follow up, and
(**5**) a stable location (i.e., an intersection, landmark, or encampment where they can be located by the street medicine team) within Denver County for at least 2 weeks.

Table 1. Diagnoses requiring short term follow up after discharge from the ED.

- COPD or asthma exacerbation
- Bacterial or viral pneumonia
- CHF with volume overload
- SSTI
- Dehydration requiring IV fluids
- Hyperglycemia secondary to DM
- Frostbite
- First- and second-degree burns
- Bacterial ENT infections
- Diabetic foot infection
- Traumatic head injury
- Pregnancy
- Opioid overdose

Abbreviations: COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; SSTI, skin and soft tissue infection; DM, diabetes mellitus; ENT, ear, nose and throat

Exclusion Criteria:

Patients will be excluded if they:
(**1**) have altered mentation (e.g., intoxication, or secondary to medical, psychiatric, or behavioral conditions) that are unable to communicate their location, contact information, or agree to follow up.
(**2**) are prisoners,
(**3**) previously enrolled.

Strategies for Recruitment and Retention:

Enrollment will occur 24 hours per day and all ED staff will be trained on patient eligibility and referral procedures by the PI prior to initiation. Weekly in-person communications will target all ED clinicians and unit clerks to remind them of alternating intervention and control weeks in accordance with the equivalent time samples design. The street medicine team will attempt to follow up with patients referred for 2 weeks. As participation in this aim is limited to referral with subsequent follow-up as standards of care, and future visits measured as outcomes of this study, a retention plan is not applicable.

6. Study Intervention

Utilizing a custom build within the DHMC electronic health record (**EHR**) (Epic Systems Corporation, Verona, WI), we will create a discharge referral order linked to the diagnoses listed in **Table 1**. During odd numbered weeks, this order will automatically generate a referral to the CCH physician-led street medicine program (intervention), and during even weeks, it will automatically generate a referral to standard-of-care conventional follow up at the DHMC CCC (control). Clinicians will still be able to place a referral to the DHMC CCC if the patient does not meet inclusion criteria. The structured EHR referral for the intervention will be modeled after the current existing referral to the CCC). The intervention referral will include the patient's diagnosis, contact information, and planned geographic location. ED clinicians will be educated that contact information should be updated by the patient and that information from the chart should not be used as it is often out of date and unreliable. ED clinicians will educate the patient on what the street medicine team looks like through a standard discharge instruction stating the following: "The street medicine team will try to follow up with you as soon as possible at the location you specified. They will keep trying for 2 weeks. The street medicine team is 2-5 people. They are usually walking around and carry red backpacks. They have Colorado Coalition for the Homeless nametags."

The referral order will send a standardized electronic notification to the CCH street medicine nurse coordinator. **The street medicine team will attempt to follow up with the patient within 2 weeks of ED discharge**, with the expectation that the team may have to visit the same location several times to successfully locate the patient. Patients referred to the intervention will be given instructions on the dates and approximate times of street medicine clinician visits. During control weeks, CCC appointments will also be scheduled according to current standard of care processes. Due to staffing limitations, the street medicine program is limited to accepting 5 referrals per week. Thus, if the maximum of 5 referrals is reached before the end of the intervention week, all additional eligible patients will be referred to the CCC automatically. For pregnant people specifically, follow up with the street medicine team will **augment** standard of care referrals to the Women's Care Clinic (Obstetrics and Gynecology), which is standard of care for patients without prenatal care who present to ED.

7. Discontinuation and Participant Withdrawal

Participants may choose not to follow up with either clinic and utilize the patient connect to care hospital appointment line at any point. No strict criteria for withdrawal will be used.

Dr. Joseph and her primary mentor, Dr. Haukoos will systematically assess for safety concerns, including review of ED recidivism and inpatient hospitalization rates after every 10 patients enrolled. A designated clinician outside of our study team with appropriate expertise in linkage to care will be asked to review aggregated safety data. If they determine that there is concern for safety in either arm, the study will be stopped.

8. Study Assessments and Procedures

Data collection will be performed by the PI and a trained RA using standard medical record review methods and structured data collection tools (REDCap, Research Electronic Data Capture, Vanderbilt University, Nashville, TN).[44] ED data will include patient identifier (medical record number, **MRN**), demographics (age, sex, race/ethnicity), primary language, comorbidities, details of the ED visit (i.e., date, arrival and discharge times, diagnoses), payer, ESI, arrival mode, and referral details, including clinician characteristics (clinical role, age, and gender). Outcomes will be obtained by trained RAs blinded to the intervention using structured chart abstraction from the CCH and DHMC EHRs and the Colorado Regional Health Information Organization (**CORHIO**), a health information exchange network that provides patient information from many hospital systems. Outcomes will include primary care, ED, and inpatient visits during the 6 months following the index ED visit (e.g., date, time, frequency, diagnoses, length of stay). To determine the *total number of eligible participants* for Hypothesis 1, every ~48 hours the PI or RA will review charts of all ED patients included in the Homeless Registry to determine their diagnostic eligibility for inclusion. We anticipate this will overestimate the number of eligible patients as there is no standardized clinical documentation for the other inclusion criteria. In the future, to address this, we will perform a survey of 100 randomly identified PEH in the ED to estimate the percentage that are unsheltered and have a stable geographic location and will use this to adjust the estimate. For this survey, we will obtain informed consent. **We will submit an application to the IRB for this survey separately in the future.**

9. Risk/Benefit Assessment

Risks: The primary risks to patients breach of confidentiality prior to the de-identification of data. All PHI will be stored on RedCap and the de-identified data will be stored on the Denver Health T drive. The de-identified databases will be accessible only by study investigators. All PHI will be immediately destroyed upon completion of analysis and final reporting of the results. All patient data collected is part of routine clinical care and obtained through chart review. Additionally, there is a risk that patients in the intervention arm will have decreased access to follow up compared to the control arm as this intervention is novel and its feasibility and efficacy have not been determined. However, current evidence suggests that street medicine programs enhance follow up compared to standard of care, particularly in this patient population where there is limited access to transportation, multiple competing needs, and poor baseline rates of follow up.

Benefits: We anticipate that patients will benefit directly from participation in Aim 2 secondary to improved linkage to follow up care and primary care. Current standard of care is to provide all patients who present to the ED with a hospital appointment line number to call to request an appointment for follow up. This will continue to be practiced with ALL patients enrolled in this study. However, we hope to elevate the care provided by ensuring all patients meeting inclusion criteria are referred for additional follow up through either the CCC or CCH street medicine team. Currently, use of the CCC for referrals is determined by provider discretion, and providers can still refer patients directly to the CCC if they so choose. Additionally, by demonstrating feasibility of the intervention, broader application of the intervention could result in future benefits to both participating patients and future patients.

10. Safety Monitoring Plan

Adverse Events and Serious Adverse Events

Adverse event (AE) means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related. An AE or suspected adverse reaction is considered a "serious" adverse event (SAE) if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or

require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

All AEs will be captured on a study case report form (CRF). Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study procedures and/or intervention (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

A clinician with appropriate expertise in linkage to care will be responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected, and an unanticipated problem (UP), if the nature, severity, or frequency of the event is not consistent with the risk information previously described or provided for the study procedures. UPs will be reported to the IRB as soon as possible, but in no event later than 5 working days after the PI first learns of the event.

Dr. Joseph and her primary mentor, Dr. Haukoos will systematically assess for safety concerns, including review of ED recidivism and inpatient hospitalization rates after every 10 patients enrolled. A designated clinician outside of our study team with appropriate expertise in linkage to care will be asked to review aggregated safety data. If they determine that there is concern for safety in either arm, the study will be stopped.

11. Data Analysis

Data will be entered into a standardized data collection instrument, REDCap, hosted at Denver Health, and transferred into native SAS format. All analyses will be performed using SAS Enterprise Guide (SAS Institute, Inc., Cary, NC). Descriptive statistics will be calculated for all variables. Bivariate statistical tests (e.g., Wilcoxon rank sum, Fisher's exact) will be used to compare variables between study groups. A prevalence estimate and its corresponding 95% confidence interval (**CI**) will be estimated for Hypothesis 1. Both unadjusted and adjusted measures of association will be estimated for Hypothesis 2. Using both exact methods and multivariable logistic regression, we will report unadjusted and adjusted risk ratios (**RR**s), the latter based on the following model framework: [outcome] = f(intervention) + (age, sex) + (Charlson Comorbidity Index) + (time of day) + (day of week) + (week of year) + (probability of referral to street medicine). Inclusion of time, day, and week will help adjust for secularity in ED visits, as well as seasonality. To estimate the probability of referral to street medicine and to adjust for potential referral bias, we will use propensity score methods that includes all patient- and clinician-level data with referral site as the dependent variable. Collinearity will be assessed although no assessment of effect modification is planned. The unit of analysis will be the patient, no adjustments for multiple comparisons will be made, and statistical significance defined as $p<0.05$. We anticipate producing at least one manuscript and one abstract from these data.

Using Hypothesis 2 to drive the sample size estimation for this aim and assuming 25% linkage-to-care for the control group, 40% linkage-to-care for the intervention group (absolute increase of 15%), and an allocation ratio of 2:1 (based on a maximum of 5 street medicine referrals per week), we estimate requiring a minimum of 198 and 99 patients, respectively, for a total of 297 to achieve a power of 80% ($\alpha=0.05$). However, to ensure sufficient numbers to minimize overfitting of the multivariable logistic regression model based on a 10:1 ratio of outcomes-to-variables, we plan to enroll 260 and 130 patients, respectively, for a total of 390 patients (90% power). Such enrollment will occur over a 12-month period, 26 weeks devoted to the intervention and 26 weeks to the control.

12. Informed Consent Process

We will request a waiver of written informed consent and a waiver of HIPAA Authorization from COMIRB. This request for waiver is based on the following in accordance with 45 CFR 46.116(f)(3)(i-v):

(1) The research involves no more than minimal risk to the participants and if the research involves using identifiable private information, the research could not practicably be carried out without using such information in an identifiable format. The study performed as Aim 2 is minimal risk because the only risks include breach of confidentiality, which is viewed as minimal. PHI data will be collected retrospectively and will not affect the clinical care that patients receive. The PI and her sponsor will assume full responsibility for the protection of all study-related documents and datasets, including those that contain PHI. The PI will oversee all data collection. All electronic data containing PHI will be held on a protected network. A de-identified database used for analysis will be password protected and stored in the PI's separate folder on the mainframe networks at DHMC. These networks include firewall protection and the folder will only be accessed by members of the study team.

(2) The waiver will not adversely affect the rights and welfare of the participants. It does not violate patients' rights. The risks involved in this study are no more than what the patient would experience in standard care because participation in the research will occur concurrently with their clinical care, and referral to follow up is standard of care.

(3) The research could not practicably be carried out without the requested waiver. Separate written informed consent cannot practicably be carried out without a waiver because of the provider-based referral system that is integral to capturing a representative sample of patients and assessing the true feasibility of this type of intervention. Without a waiver, there is the potential for biased participation in the study and an inaccurate assessment of the feasibility of this intervention. It is essential that we determine whether this type of referral system can feasibly be deployed from the ED and utilized by providers. We believe this waiver of consent will not adversely affect the rights and welfare of the subjects involved in this project, as they will only be subjected to current standards of care or enhanced follow up care, and they will all have the right to refuse to participate without adversely affecting their care.

13. Confidentiality and Privacy

All study-related materials will be accessible only by study investigators and authorized study personnel. Chart review data will be entered directly into RedCap and only de-identified data will be used for analysis and stored on the Denver Health T drive. Procedures will be implemented to ensure patient confidentiality in gathering and recording all study-related data, with close oversight of all collection and data storage by the PI. The de-identified databases will be accessible only by study investigators. All PHI will be immediately destroyed upon completion of analysis and final reporting of the results for each aim. All electronic files will be password protected and stored in restricted access folders maintained within Denver Health secure T drive that comply with local and federal HIPAA regulations.

14. References

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