

**Mitigating ethnic disparities in access and engagement in spine pain rehabilitation –
STEPPT Mixed Methods Pilot Study**

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Study Objectives

The purpose of this pilot study is to assess the feasibility, acceptability, and preliminary effectiveness of the STEPPT intervention to improve ethnic disparities in physical therapy referral and adherence between Hispanic and Non-Hispanic White patients with spine pain. We expect the intervention will be feasible and acceptable, with suggested modifications from patient and clinic staff stakeholders that will inform a larger clinical trial. Compared to standard care, we expect STEPPT to reduce ethnic disparities in physical therapy referral and adherence outcomes.

Design & Methods

STEPPT is a health system, quality improvement intervention. Our research team developed the preliminary STEPPT intervention based on available evidence, to promote physical therapy referral and attendance for Hispanic patients with spine pain. Our team then adapted the STEPPT intervention based on insights gained from feedback from Federally Qualified Health Center (FQHC) administrators and co-development workshops conducted with FQHC clinic directors, primary care physicians, nurses, medical assistants, and patient health navigators. The pilot single-arm clinical trial will allow our research team to implement and assess the adapted STEPPT intervention in a single FQHC clinic prior to initiating a larger clinical trial.

Participant Eligibility and Enrollment

Because this is a health system quality improvement intervention, all patients at the FQHC pilot clinic will be included in the study if they: (1) are 18 years of age or older, (2) identify as Hispanic or Non-Hispanic White ethnicity/race, (3) have signed a broad consent for use of de-identified health information for research, and (4a) identify a new spine pain problem at a visit with a primary care physician (new diagnosis of neck or back pain added to the problem list during the visit) OR (4b) have an existing spine pain problem (existing diagnosis of neck or back pain on the problem list) and their physician generates any referral for the spine problem at the visit. Patients with a possible non-musculoskeletal etiology for spine pain (e.g. infection, cancer, urological disorder, pregnancy) or conditions requiring urgent medical intervention (e.g. fracture, cauda equina syndrome) will be excluded.

Upon completion of the STEPPT pilot study, the research team will conduct post-intervention interviews with a purposive sample of Hispanic patients who meet study eligibility criteria. Participants will be contacted via phone by Research staff who are FQHC

employees or who are onboarded as FQHC volunteers to offer them the opportunity participate in interviews. To ensure a diverse and representative sample, we will purposively sample 20 participants based on age, sex, pain region (low back, neck), language preference, and referral and adherence status. Participants who agree to participate in interviews will be scheduled for an in-person or Zoom interview based on their preference.

Informed Consent

A waiver of consent was granted for enrollment in the STEPPT pilot intervention because it meets the requirements outlined in 45 CFR 46.116, section f3 i) the research involves no more than minimal risk to the subjects, ii) the research could not practicably be carried out without the requested waiver or alteration, iii) only patients who have signed the a broad consent for use of de-identified health information from the electronic health records will be included in the study, iv) the waiver will not adversely affect the rights and welfare of the subjects. The STEPPT intervention is a minimal risk health systems quality improvement intervention including education and enhanced care navigation to improve physical therapy referral and adherence to physical therapy for Hispanic/Latino patients with neck /back pain. No additional pertinent information will be provided to subjects after participation as it would be impractical to do so, however, if effective the approaches will be implemented more broadly across the health system.

Patients who agree to participate in post-intervention interviews will be asked to provide written informed consent prior to participation in the interview. Bilingual study team members will obtain written informed consent from participants and then conduct the interviews.

STEPPT Pilot Intervention

The pilot STEPPT intervention includes: (1) auto-referrals to physical therapy in the electronic health records (EHR) system, (2) delivery of health literacy materials through multiple channels (after visit summary, text message, link to educational video, etc.), and (3) enhanced health care navigation. Prior to commencing the pilot trial, STEPPT research staff will conduct trainings with clinic staff including medical providers (primary care provider (PCP), nurse, medical assistant (MA)) and study patient health navigators.

Auto-Referrals to Physical Therapy: The first component of the STEPPT intervention is an auto-generated physical therapy referral in the EHR system for all patients with a new low

back or neck pain problem (added to the problem list at the physician visit). The physician must sign the auto-referral before the patient can be scheduled for physical therapy. During STEPPT intervention, Non-Hispanic White (NHW) participants with a new spine pain problem will also receive an auto-generated PT referral (similar to Hispanic participants) based on administrator and health system preferences.

Patient Education Materials: Patient education materials that were developed include: (1) neck/back pain fact sheet, (2) information on what to expect in physical therapy for neck/back pain and the FQHC physical therapy referral and scheduling process, (3) instructions on postural exercises for spine pain relief, and (4) an educational video on how physical therapy can help with neck/back pain and information on physical therapy services at the FQHC. These materials have been culturally tailored for Hispanic patients and are available in both English and Spanish, based on patient-preferred language. These materials will be delivered via two different channels to Hispanic patients with a new or existing spine pain problem who are referred to physical therapy. First, the custom EHR system will be leveraged to auto-order printed education materials (#1-3) for Hispanic patients, to be included in the “After Visit Summary” provided to the patient by the nurse or medical assistant. Second, electronic copies of the education materials (#1-3) and a link to the educational video (#4) will be sent via automated text message within 24 hours of the physical therapy referral. Patients will be encouraged to share and discuss these informational resources with their family members to solicit social support for engaging in physical therapy. During STEPPT intervention, NHW participants with a new or existing spine pain problem will only receive education materials that are ordered by their physician. Consistent with current practices at FHCS, the neck/back pain fact sheet will be the only education material that will be available for physicians to order for NHW patients.

Enhanced Healthcare Navigation: Enhanced healthcare navigation will be administered by the STEPPT Patient Health Navigators (PHN) utilizing the STEPPT Registry, an interface within the HIPAA-protected FQHC network, specifically tailored to track and provide personalized enhanced care navigation to Hispanic participants. The study PHN will contact each participant individually. First, they will provide a brief (~1-2 min) semi-scripted explanation of how physical therapy can help patients manage their pain and improve function. This will help reinforce the health literacy component of STEPPT by providing information about the benefits of physical therapy from multiple sources. Next, the PHN will schedule the patient for their first physical therapy visit, at a time and location that is convenient for the patient. Last, the PHN will ask the patient if they anticipate any challenges to attending physical therapy, proactively assist the patient in developing a plan to overcome any identified barriers and will refer the patient to additional resources (e.g.,

transit, childcare, etc.) as necessary. If needed, the PHN can also manually deliver a follow-up text message with a link to electronic educational materials. To address linguistic barriers, all STEPPT PHNs will be bilingual (Spanish/English). During STEPPT intervention, NHW patients who are referred for physical therapy will be contacted by centrally located FQHC staff who will process the referral and reach out to the patient to schedule an appointment consistent with current practice.

Standard Care Control

Standard Care reflects the existing care coordination pathway at the FQHC and will serve as the control condition. During standard care, a centrally located Referral Specialist will verify insurance authorization when a physical therapy referral is made, and three call attempts will be made to schedule the PT evaluation. If no contact is made after 30 days, a letter will be sent to inform the patient that they are responsible for calling the clinic to follow up on the referral. During Standard Care, the FQHC providers and staff will not receive any education on the benefits of physical therapy referral for spine pain or culturally responsive strategies to facilitate patient engagement. Consistent with standard practice, patients will only receive a fact sheet on neck or back pain if manually ordered by their PCP and will not receive personalized enhanced care navigation.

Outcomes

Physical Therapy Referral and Adherence Rates (Primary)

The primary outcomes that will be gathered from the electronic health record (EHR) are rates of physician referral to physical therapy (within 3 months of index visit) and patient adherence to physical therapy referral (within 6 months of referral) for spine pain before (3-month baseline) and after (3-month intervention) implementation of STEPPT. Patient sociodemographic characteristics will also be collected from the EHR for descriptive purposes.

Involvement Rating

During STEPPT intervention, a formal process evaluation also will be conducted by the study team to assess clinic involvement in STEPPT training and implementation activities. The study team will conduct monthly audits including reviews of data from all levels of the STEPPT program, and structured observations of the clinic workflow. Process evaluation measures will include a quantitative Involvement Rating Score (range 0 to 11 points, with higher scores indicating greater involvement in STEPPT implementation), supplemented by the qualitative analysis of structured observations and field notes. Based on this evaluation, the research team will provide monthly feedback to clinic staff, which will include a summary report of progress toward equitable rates of physical therapy referral

and adherence. Research staff will support uptake and adherence to STEPPT with regular outreach to FQHC clinic staff to share lessons learned, help problem-solve barriers, and suggest customized strategies.

Patient Interviews

The study team will conduct post-intervention interviews with a subsample of participants to evaluate acceptability and feasibility of the STEPPT intervention. A semi-structured interview guide with open-ended questions was developed using the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) Framework. The interview guide includes questions regarding Hispanic patients' opinions of the materials they received during the pilot intervention, the delivery of the materials, and their experience receiving Enhanced Care Navigation. Interviews will take approximately one hour and will be conducted in the patient's preferred language by trained moderators.

Interviews will be audio-recorded and transcribed for qualitative analysis. Patient recommendations identified in the interviews will inform the need for additional adaptations before finalizing the STEPPT intervention procedures and materials prior to a larger clinical trial.

Data Processing and Storage: All participant data will be retained in the password-protected, HIPAA-compliant FQHC system. Power BI will be used to extract participant data from EHR and referral systems, and a registry will be used to track participants for enhanced care navigation. Only research team members who are employees or onboarded volunteers at the FQHC, and who have met all HIPAA and patient privacy training requirements, will have access to these data. When participant data are exported from the FQHC system for analysis, data will be coded by an FQHC Data Scientist using a unique identifier such that only deidentified data will be shared and used for analysis. De-identified data that is shared will be stored on password-protected HIPAA-compliant servers at San Diego State University. A Data and Safety Monitoring Plan will be implemented to maintain the safety and confidentiality of all study participants and to ensure data integrity.

Statistical Analysis Plan

The primary outcome of interest is the change in rates of referral and adherence to physical therapy before and after the STEPPT intervention between Hispanic and NHW participants with spine pain, which will define the overall effect of STEPPT on ethnic disparities. Descriptive statistics will be summarized at each time point (baseline vs. intervention) separately for each group (Hispanic vs. NHW). Effect size estimates for change in referral

and adherence rates before and after intervention will be calculated to conduct a power analysis for a larger clinical trial of the STEPPT intervention.