

Patient Aligned Care Team (PACT) Intensive Management (PIM) Project
Protocol
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Background

In 2013, VHA Primary Care Services submitted a request for proposal (RFP) seeking VA Medical Center (VAMC) participation in a national PACT Intensive Management (PIM) initiative. The specific objectives of the initiative were to 1) reduce preventable hospitalizations and emergency care in persons having complex medical and social needs and who are identified as being at highest risk for unplanned visits, hospitalization, and death, 2) optimize high-risk patient functional status, and 3) maintain high-risk patients in their homes and communities to the greatest extent possible. Through the RFP, five VAMCs were selected to receive funding for up to \$750,000 per year to support demonstration projects to innovate strategies to manage high-risk Veterans in a rigorously evaluated quality improvement project. Through this initiative, the PIM teams at each of the demonstration sites became subject matter experts and valuable advocates for high-risk patients' individual and system-level needs.

Summary of outcome measures

Primary Outcome Measure:

1. VA health care cost

Total costs of VA care, including inpatient, outpatient, pharmacy and fee-basis services.

Secondary Outcome Measures:

2. Healthcare Utilization

VA central repository administrative data will be analyzed to calculate utilization of hospital, emergency and outpatient primary and specialty care. This information will be electronically abstracted through the VA central repository administrative data center.

3. Medicare utilization and cost

Medicare claims data was used to capture utilization and costs for services reimbursed by Medicare. The Master Beneficiary Summary File was used to ascertain patients' Medicare enrollment status.

Other Pre-Specified Outcome Measures:

4. Engagement

The investigators will look at patient PIM enrollment data by utilizing central repository administrative data. The data will be electronically abstracted through the VA central repository administrative data center.

5. Functional status

Patient report of their physical, social, and mental functional status is routinely collected as part of their medical visit. The data will be abstracted through the VA central repository administrative data.

6. Quality of Life Status

Patient assessment of their quality of life collected as part of their medical care. This information will be electronically abstracted through the VA central repository administrative data center.

7. Symptom Burden

Patient assessment of mental health and physical health symptom burden is routinely collected as part of their care and documented in their medical record. This data will be electronically abstracted through the VA central repository administrative data center.

8. Implementation Outcome/ challenges

Information about implementation barriers and facilitators, feasibility, and sustainability will be obtained through two waves of key stakeholder interviews, including demonstration site staff and facility leaders

9. Primary Care Staff Job Satisfaction and Intention to Stay at the VA

The investigators will survey Primary Care Providers (PCPs) (physicians, MDs/DOs; nurse practitioners, NPs; physician assistants, PAs) and nurses (registered nurses, RNs; licensed practical nurses, LPNs; licensed vocational nurses-LVNs) at the five healthcare systems that have a PIM team. They will use both online using RedCap and paper-and-pen versions of the survey to increase response rate. The investigators will survey Primary Care staff at baseline and one year later. The first survey was fielded December 2014 - May 2015 and again from October 2016 - January 2017). Primary Care Staff Job Satisfaction is measured by a single item "Overall, I am satisfied with my job," rated on a 5-point Likert agreement scale.

10. Primary Care Staff Intention to Stay at the VA

The investigators will survey Primary Care Providers (PCPs) (physicians, MDs/DOs; nurse practitioners, NPs; physician assistants, PAs) and nurses (registered nurses, RNs; licensed practical nurses, LPNs; licensed vocational nurses-LVNs) at the five healthcare systems that have a PIM team. They will use both online using RedCap and paper-and-pen versions of the survey to increase response rate. The investigators will survey Primary Care staff at baseline and one year later. The first survey was fielded December 2014 - May 2015 and again from October 2016 - January 2017). Intention to Stay at the VA is measured by a single item "I intend to continue working in PC at the VA for the next two years," rated on a 5-point Likert agreement scale.

Primary and Secondary Outcome Measures Procedures

Sample selection and recruitment

Demonstration Site Selection: Five sites will be selected in a competitive process by reviewers and funders from the VHA Office of Primary Care Services. Selection criteria include sites that: 1) have geographically diverse teams, spanning both rural and urban settings; 2) have teams that include a mental health provider; and 3) provide services that can increase Veteran access to healthcare, including home visits and telehealth.

Inclusion criteria: The evaluation team will collaborate with demonstration sites over six months to define and identify the high-risk Veteran population using the CAN score (Wang et al.) The CAN score is computed weekly for each VHA patient based on multiple electronic data elements (i.e., clinical diagnoses, laboratory data, vital signs, previous inpatient and outpatient utilization over the preceding year) and predicts risk of hospitalization in the subsequent 90 days. The patient lists will include those on the top 10th percentile of the CAN score and that had at least one ED visit or hospitalization in the VHA over the prior 6 months. All patients will have an assigned primary care medical homes in general Primary Care, Women's Health, Geriatrics, or Infectious Disease (mostly caring for patients with Human Immunodeficiency Virus, HIV). The Infectious Disease medical home will be included as a tracer for assessing specialty medical homes, to provide formative information on differences from primary care medical homes.

Table 1. Exclusion Criteria

Exclusion Criteria
<ul style="list-style-type: none">A clinical encounter with specialty primary care teams with comprehensive resources other than those identified in inclusion criteria (i.e., Post-Deployment, Renal, Spinal

Cord Injury, Homeless PACT, Home-Based Primary Care team), in the previous two months

- Outpatient encounters in Mental Health Intensive Care Management programs (VHA-adapted Assertive Community Treatment program), palliative care, and hospice in the previous two months
- Nursing home in the previous two months
- Care Assessment Need Score (CAN) (Wang et al.) < 90th percentile
- Inpatient admission to a residential substance abuse treatment program in the previous two months
- Death

Exclusion criteria: Patients will be excluded if they are managed by an intensive primary care team or have received intensive outpatient services in the past two months, such as homeless primary care services, primary care for home-bound patients, intensive outpatient mental health services. Patients residing in a VHA nursing home facility or residential substance abuse treatment program in the previous two months will also be excluded. Full exclusion criteria are listed in Table 1.

Sample: The evaluation team will randomly identify a sample of high-risk Veterans from among patients assigned to a primary care medical home at a demonstration site. Half of these patients will be randomly allocated to the innovation group and sent to the demonstration teams for recruitment consideration, and the other half will be allocated to usual care in the VA patient-centered medical home. The investigators will stratify by gender to ensure representation of 10% women in both the innovation group and the usual care group to inform future policy. Demonstration teams will receive lists of high-risk patients from the evaluation team through a secure workspace behind VHA firewall. Demonstration patients on this list are considered innovation patients (intent-to-treat), if they receive services from the demonstration teams. Demonstration teams will be blinded to the list of usual care patients in the comparison group as part of the quality improvement design.

Local healthcare providers will be permitted to refer a limited number of Veterans to the intensive primary care programs (up to 10% of the program capacity). To allow usual care patients the opportunity to participate as a demonstration patient, after 12 months, high-risk Veterans in the usual care group will not be excluded from being randomly selected for an invitation to participate in the intensive management innovation.

Based on a univariate comparison, a sample size of 526 patients per evaluation arm (1052 total) will provide 90% power to detect a small effect (Cohen's $d = 0.2$) in ED visits or hospitalizations with a two-sided significance level of 0.05. The investigators estimate that at least 200 patients will have the opportunity to be invited to the intensive management program at each demonstration site over a one-year period, which will provide a sufficient sample size of 1000 patients in the innovation and 1000 in the comparison arm. Sites control the frequency and

quantity of high-risk patients identified to them each month, based on clinical and resource considerations. PIM teams are expected, however, to receive at least 200 names over 12 months, rather than all 200 at the beginning.

Interventions

Selected demonstration sites will span a variety of high-risk patient care approaches, such as a patient-centered medical home for high-risk Veterans, collaborative care model for high-risk patients, and care transitions program. Each site will propose a site-specific intervention. All proposed interventions will use population management models and determined their own approaches to stratifying patients and determining eligibility for and intensity of services. The types of services offered by each team will depend on program staff, local resources, and facility and program priorities. Each site will also develop its own criteria for when to discontinue services for patients.

Measurements

Patient demographics, chronic conditions and other health conditions (Yoon, Scott, Phibbs, & Wagner, 2011), comorbidity score (Charlson), VHA outpatient/inpatient utilization, measures of prescription drug use and mortality will be obtained through the VHA Corporate Data Warehouse. For costs, VHA inpatient and outpatient utilization records will be linked to Managerial Cost Accounting (MCA) cost data to obtain the costs of outpatient and inpatient care. Pharmacy utilization and costs will be obtained from MCA Pharmacy files, and VHA-sponsored care is obtained from Fee Basis files. Implementation costs will be determined through micro-costing methods from site reports. Because these are administrative data, these are collected from each participant regardless if they were not offered services or if they were discontinued from the intervention.

Analysis

The investigators will conduct an intent-to-treat analysis based on patients' allocated group. The investigators plan to compare unadjusted mean utilization counts and costs for different categories of inpatient care and outpatient care and total care. The investigators will estimate the impact of PIM using regression models to obtain the differences-in-differences estimate of the change from the 12-month pre-intervention period to 12-month and 24-month post-intervention period attributable to PIM above and beyond any time trends that occurred in both groups. Our regression models will predict utilization of outpatient encounters and inpatients stays in count data models (Poisson and negative binomial regression models) including a time-varying measure of risk using the Charlson Index and patient fixed effects to account for factors fixed over time. Regression models of costs include the same predictors as the utilization models and will be conducted using ordinary least squares (OLS); sensitivity analyses will be conducted using generalized linear models (GLM) with a log link and Poisson distribution. Mortality will be compared between treatment groups with a log-rank test for equality of survivor functions.

In other sensitivity analyses, the investigators plan to conduct regression models with patient random effects and covariates for patients' age, gender, race/ethnicity, marital status, means test, service connection, homelessness, Charlson Index, and site. The investigators will also measure the treatment effect on the treated by conducting regression analysis using instrumental variables to examine whether more PIM encounters were related to cost and utilization impacts by using randomization to PIM as an instrument for number of PIM encounters. Instrumental Variable models will use the two-staged least squares estimator.

Other Outcome Measures

Functional Status, Quality of life, Symptom Burden

Standardized assessments of symptom burden (mental health and physical health), quality of life, and functional status (physical, social, and mental) will be based on patient-reported outcomes measurement information system (PROMIS) global items. These measures will be obtained only on the innovation patients and entered into the electronic medical record using a standardized assessment template available only to the demonstration staff. Some standardized assessments are available on the entire sample as part of VHA medical records (i.e., pain score, Patient Health Questionnaire (PHQ)-2 for depression) and performance measures.

Implementation Outcome/challenges

Sample selection/ recruitment

The investigators will interview PIM staff about implementation challenges and lessons. The investigators will use PIM staffing lists from the demonstration sites to compile the sampling frame. The investigators will include in the sampling frame the team leaders, team members, and program coordinators. The investigators will select all PIM team leads and program coordinators (if the site has a coordinator), and randomly select 1 of each job title/role from the PIM team members. Team members who refuse or are ineligible will be replaced by randomly selecting another person in the same job title/role, until one completed interview is obtained for each job title/role for each site. Team members will include RNs, NPs, MDs, social workers, psychologists, and intermediate care technicians. The investigators will invite 35 potential respondents by email, and follow up by telephone and using instant messaging for those who do not respond to the initial email.

With approval from site and program leadership, stakeholders will be sent an email describing the interviews and inviting them to participate. If stakeholders do not respond to the invitation email within 2-3 business days, the investigators will follow up by either phone, instant message, or additional emails. Methods of communication will be determined by available contact information and perceived individual stakeholder preferences. The investigators will make 3 follow-up contact attempts.

Instrument Development

Two qualitative team members drew on the Consolidated Framework for Implementation Research (CFIR) and chronic care model to develop the interview guides. The interviews are designed to take approximately 30 minutes, except the program lead interviews which are approximately 60 minutes. Interview guides will be refined through piloting and consultation with PIM and evaluation team clinicians.

Procedures

Interviews will be conducted by telephone. The investigators will analyze the transcripts of these interviews thematically, guided by the Consolidated Framework for Implementation Research and the Chronic Care Model.

Analysis

All interviews will be audio recorded. Audio recordings of the interviews will be transcribed in full. Summaries will be created from the transcripts, or directly from the audio recordings, using standardized templates based on the interview guides, with additional sections included for recording good quotes, emergent themes, and analyst observations. The summarized data will then be organized into Excel matrices to facilitate within and across site comparisons.

The substantive findings from these comparisons will be disseminated to the evaluation team, the PIM sites, and to VA central office via Powerpoint presentations and written reports, providing a richly detailed record of stakeholders' perceptions of the PIM pilot project and PIM program activities and providing timely and specific formative feedback that will be used to shape and improve PIM.

Primary Care Staff Job Satisfaction and Intention to Stay at the VA.

Sample

The investigators will survey all Primary Care Providers (PCPs) (physicians, MDs/DOs; nurse practitioners, NPs; physician assistants, PAs) and nurses (registered nurses, RNs; licensed practical nurses, LPNs; licensed vocational nurses-LVNs) at the five healthcare systems that have a PIM team.

Method

The investigators will use both online using RedCap and paper-and-pen versions of the survey to increase response rate. The investigators will survey Primary Care staff at baseline and one year later. The first survey will be fielded December 2014 - May 2015 and again from October 2016 - January 2017).

Analysis

Longitudinal cohort of staff who responds to both Wave 1 and Wave 2. The investigators will use ordinary least squares regression analysis to examine associations between the independent variable measured at wave 1 and outcome variables measured at wave 2 controlling for wave 1 outcomes among staff who completed both waves. The investigators will focus on Job Satisfaction and Intention to Stay at VA as dependent variables. The investigator will adjust for provider-level covariates (type of staff, location, type of primary care team, gender, length of time at VA) and clustering of respondents within clinics assuming a random effect using robust standard errors. The investigators will use sample weighting for nonresponse based on provider characteristics in both waves and conduct multiple imputations for item-level missing data;

Difference-in-differences between Wave 1 and Wave 2: will treat Wave 1 and Wave 2 as two independent samples and use difference-in-difference regression analysis to assess differences in outcome variables between Wave 1 and Wave 2 among PIM and usual care. The investigators will focus on primary care staff experience (e.g., stress, satisfaction with help received) working with high-risk patients as dependent variables. The investigators will adjust for covariates (type of staff, location, type of primary care team, gender, length of time at VA). The investigators will use sample weighting for nonresponse based on provider characteristics in both waves.

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- Yoon, J., Scott, J. Y., Phibbs, C. S., & Wagner, T. H. (2011). Recent trends in Veterans Affairs chronic condition spending. *Popul Health Manag*, 14(6), 293-298. doi:10.1089/pop.2010.0079