

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.

After reviewing the rationale and the 12-month outcomes for the PIM demonstration in February 2017, the PIM Advisory Committee agreed that PIM is a valuable learning opportunity for managing high-risk patients. The Committee believed that primary care teams, or VHA Patient Aligned Care Teams (PACT), need greater support for the management of high-risk patients, who frequently have psychosocial needs not easily met in primary care. Furthermore, PIM can serve as a bridge to specialized programs (e.g. Home-Based Primary Care (HBPC), Geri-PACT, telehealth, hospice, palliative care, and Mental Health Intensive Care Management (MHICM)) and to community care providers. Since general primary care manages most (88%) of the Veterans at highest risk for hospitalization, there is an urgent need to innovate tools that primary care teams can use to improve their care, including standardized assessments and virtual modalities.

During the phase 2.0, PIM teams will use a standardized approach to high-risk patient populations. The goals of the next phase of PIM (PIM 2.0) include:

- 1) Advancing understanding of how to identify patients who will benefit from PIM, using a combination of population management and referrals;
- 2) Standardizing certain PIM features and processes for future dissemination and developing tools and strategies to support PACT care for high-risk Veterans;
- 3) Providing bridging care to enable high-risk patients to effectively access appropriate specialized VA or community care services; and
- 4) Serve as an expert resource to primary care at the facility-level to promote population-based care.

Identifying patients who will benefit from intensive care management teams remains a challenge. In PIM 2.0, the target patient population will be referred using the following eligibility criteria:

1. Care Assessment Need (CAN) score for 1-year hospitalization/death  $\geq$  90
2. Empaneled in PACT or Women's Health (WH)-PACT
3. 6-month history of VHA emergency room visit or VHA hospitalization
4. At least one ambulatory care-sensitive chronic medical condition (i.e., congestive heart failure, diabetes, hypertension, chronic obstructive pulmonary disease, asthma, angina/atherosclerotic heart disease)
5. Not currently in Domiciliary, VHA or community nursing home, assigned to Homeless (H-PACT), or HBPC

### Summary of outcome measures

#### **Primary Outcome Measure:**

1. VA health care cost  
Total costs of VA care, including inpatient, outpatient, and fee-basis services.

#### **Secondary Outcome Measures:**

2. Healthcare Utilization  
VA central repository of administrative data, or the Corporate Data Warehouse (CDW), will be analyzed to calculate utilization of hospital, emergency and outpatient primary and specialty care.
3. Medicare utilization and cost  
Medicare claims data will be extracted to measure total patient inpatient and outpatient cost for services reimbursed by Medicare. Inpatient cost will be measured as cost for total acute hospitalizations, and subcategories: medical, surgical, psychiatric, rehabilitation, hospice and ambulatory care-sensitive conditions. Outpatient cost will be measured as the cost reimbursed by Medicare in 9 categories: primary care, specialty care, mental health, surgical, home health, nursing home, diagnostic, rehabilitation and ED.

#### **Other Pre-Specified Outcome Measures:**

4. Functional status  
Patient report of their physical, social, and mental functional status is routinely collected as part of their medical visit as health factor data. The data will be abstracted through the VA CDW. The variables used to measure functional status are the following:
  - In general, how would you rate your satisfaction with your social activities and relationships? (Excellent, Very good, Good, Fair, Poor)

- In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.) (Excellent, Very good, Good, Fair, Poor)
  - Administer Katz Index of Independence in Activities of Daily Living (ADL)
  - Administer the Lawton Instrumental Activities of Daily Living (IADL)
5. 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 CDW.

6. 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 CDW.

## Primary and Secondary Outcome Measures Procedures

### Sample selection and recruitment

**Demonstration Site Selection:** Five sites were 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:** Referral patients must meet the following eligibility criteria as that of the target patient population (i.e., CAN composite score  $\geq 90$ , empaneled in PACT/WH-PACT, 6-month history of VHA acute care use, at least one ambulatory care-sensitive chronic medical condition) and may be referred from anywhere throughout the facility, including specialty care clinics (e.g., HBPC) or emergency medicine. Flexibility in eligibility criteria will be up to the PIM team leader's discretion. To further understand who will benefit from PIM, further information will be entered in by a health care staff member using standardized templates in the electronic health record. Patient characteristics may include non-adherence to treatment plan, problems with health literacy, poor social support, fragmented care with multiple specialists or with community providers.

## Sample:

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 be enrolled 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.

## Interventions

The five demonstration sites provided a 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.

***The PIM 2.0 phase will involve standardization of certain PIM features.*** The PIM teams' team will offer a standardized menu of services, ranging from chart review assessment or in-home assessment, to a time limited intensive care management intervention. The following PIM features are standardized across the PIM demonstration sites:

- A. Chart review assessment template in CPRS
- B. Comprehensive assessment template of unmet needs and modifiable risk factors in CPRS
- C. Transitions in care process (eligibility criteria, clinical protocols)
- D. Diagnostic home visits process (eligibility criteria, clinical protocols)
- E. Core risk stratification/Triage process
- F. Discharge criteria and note template in CPRS
- G. Standardized interdisciplinary team (IDT) meeting note procedure and template in CPRS

## 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

We plan to measure the impact of the intervention with propensity score-adjusted multiple logistic regression analysis for the primary outcome measures between comparison and treatment group 12-months after enrollment. The propensity score will be calculated based on demographics, baseline utilization, comorbidities, study site, and enrollment month.

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 inpatient 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.

## 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.

## Patient Satisfaction

To ascertain differences between PIM and PACT high-risk patients in their experiences with VA care by comparing patients who are eligible for PIM at the five PIM demonstration sites versus patients who are eligible for PIM at 16 matched comparison sites (that do not have PIM). Primary outcome measures include domains "experience with VA care", "patient-centered care", and "satisfaction."

## Outcome

- I have a VA healthcare provider who I can trust
- I have a VA healthcare provider who helps coordinate my care from different doctors and services
- I got the service I needed
- It was easy to get what I needed
- In the last 6 months, did someone at the VA talk with you about specific goals for your health
- In the last 6 months, did someone at the VA ask you if there are things that make it hard for you to take care of your health
- Primary care services

## Sampling Specifications

PIM Sites: All estimated 750 PIM 2.0 patients will be sampled, along with 3926 randomly selected patients from all sites (approximately 785/PIM site) based on a list of high-risk patients provided by the PIM evaluation team.)

Comparison sites: All 4197 will be randomly selected from comparison sites based on a list of eligible high-risk patients provided by the PIM evaluation team.

We will build a hierarchical linear model to take into account patient-level observations nested within VA facilities. The investigator will adjust for facility-level characteristics (rural/urban, primary care staffing, primary care team function) and patient-level covariates (demographics).

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