

IMPACT EVALUATION PROTOCOL

TABLE OF CONTENTS

ABSTRACT	2
A BACKGROUND	3
B STUDY OBJECTIVES	4
C INTERVENTION: INTENSIVE MANAGEMENT PATIENT ALIGNED CARE TEAM ¹	5
D EVALUATION DESIGN	6
D1 DESIGN SUMMARY	6
D2 SUBJECT SELECTION AND WITHDRAWAL.....	6
2.a Inclusion Criteria for ImPACT Program	6
2.b Exclusion Criteria for ImPACT Program	7
2.c Randomization.....	7
2.d Recruitment for Evaluation.....	7
2.e Withdrawal from ImPACT Program	7
D3 RISKS AND BENEFITS	7
D4 DATA COLLECTION	7
E EVALUATION AND STATISTICAL ANALYSIS PLAN	8
E1 POWER CALCULATION	8
E2 AIM 1. FEASIBILITY AND IMPLEMENTATION EVALUATION	8
2.a Feasibility Evaluation	8
2.b Implementation Evaluation.....	8
E3 AIM 2. IMPACT’S EFFECT ON UTILIZATION AND COSTS OF CARE.....	9
3.a Data Sources and Outcomes	9
3.b Data Analyses	9
E4 AIM 3. IMPACT’S EFFECT ON PATIENT-REPORTED OUTCOMES	10
4.a Data Sources and Outcomes	10
4.b Data Analyses	10
F DATA HANDLING AND RECORD KEEPING	10
F1 CONFIDENTIALITY AND SECURITY	10
F2 TRAINING.....	11
F3 RECORDS RETENTION	11
G PROTOCOL MODIFICATIONS	11
G1 AIM 1 MODIFICATIONS	11
1.a Feasibility Evaluation Modifications	11
1.b Implementation Evaluation Modifications.....	12
G2 AIM 2 MODIFICATIONS	12
2.a Patient Population.....	12
2.b Outcomes	12
2.c Data Analyses	13
G3 AIM 3 MODIFICATIONS	14
H REFERENCES	14

Abstract

Background: VA's highest-utilizing patients generally have complicated health care needs—including complex and multiple chronic conditions, comorbid mental health conditions, and social stressors—that contribute to high rates of hospitalization, emergency services, and specialty care use. Inspired by emerging intensive primary care models for high-utilizers, VA Palo Alto obtained FY2012-FY2013 Office of Specialty Care Transformation (OSCT) funding to launch a novel program that augments the existing PACT model with intensive care delivered by a multidisciplinary team. The Intensive management PACT¹ intervention encompasses a number of evidence-based strategies, including a comprehensive intake process, coordination of specialty care, chronic condition case management, provision of social services, rapid response to deteriorations in health, and facilitation of transitions after high-acuity events.

Objectives: We aim to evaluate ImPACT's feasibility, implementation, and effectiveness, and lay the groundwork for future larger-scale efforts and evaluations within the VA system.

Methods: We will partner with the implementation team of VA Palo Alto's ImPACT clinic to conduct a Hybrid Type 1 evaluation of the program's feasibility, implementation, and effectiveness. For the first phase of ImPACT, VA Palo Alto identified PACT patients who were among the most costly 5% or among the 5% highest risk for future hospitalization for the facility, but who were not enrolled in other intensive management programs. A random sample of 150 patients were selected for immediate enrollment in ImPACT, and 433 were assigned to continue to receive usual PACT care, thereby serving as a control group for our analyses. The evaluation will focus on the following goals:

- **Aim 1: Evaluate the feasibility and implementation of the pilot ImPACT intervention.** Using semi-structured interviews with ImPACT and PACT team members and leadership, we will evaluate the success of intervention delivery, including patient identification, recruitment, and retention; provision and uptake of planned services; and monitoring of patient participation and key outcomes.
- **Aim 2: Evaluate ImPACT's effect on utilization and costs of care.** We will use a difference-in-differences approach, wherein we compare changes in VA health care costs (total, as well as inpatient, outpatient, and fee-basis) and utilization (including hospitalizations, emergency department visits, and specialty care) among ImPACT patients and high-utilizing patients who are receiving usual PACT care.
- **Aim 3: Examine the association between ImPACT participation and patient-centered outcomes.** Using data from surveys administered in the ImPACT clinic, we will assess patient satisfaction with the ImPACT intervention and overall care, as well as changes in patient-reported outcomes, including health status, symptom burden, and function.

A Background

Nearly half of VA's total health care expenditures are generated by its highest-utilizers (the most costly 5% of patients with regard to total VA health care costs) (Figure 1); a pattern that is also observed in the general population^{2,3} and in Medicaid recipients.⁴ These patients generally have complicated health care needs—including complex and multiple chronic conditions, comorbid mental health conditions, and social stressors—that contribute to high rates of hospitalization, emergency services, and specialty care.² Patients who are among the highest-utilizers in a health system frequently remain in that category.^{3,5} For example, one analysis of data from the Medical Expenditure Panel Survey indicated that 38% of patients in the top 5% in 2008 maintained this ranking in 2009.³

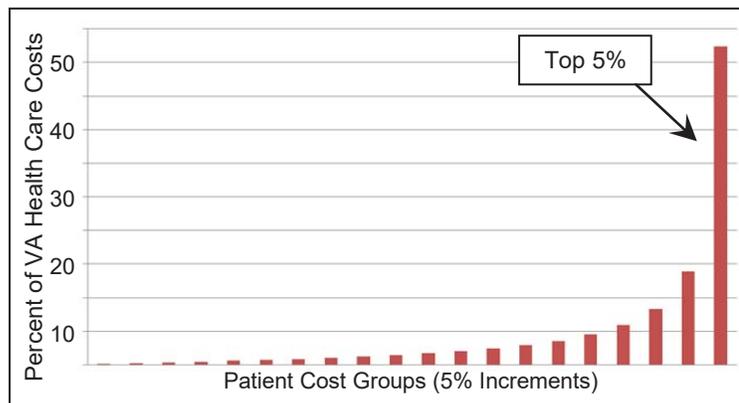


Figure 1. Proportion of health care costs generated by VA's 5% highest-utilizing patients in FY2010

Preliminary work (described under I.B. below) has shed light on the complexity of VA's most costly patients, including the prevalence of multiple chronic conditions in this population (e.g., 45% have conditions that involve 5 or more different organ systems, and 48% have a comorbid mental health condition) (HERC, unpublished data). This level of multimorbidity has been associated with increased rates of functional decline⁶ and rehospitalization,⁷ and poor clinical outcomes⁸ including high mortality rates.⁹ The presence of comorbidities affecting different systems (e.g., depression and diabetes) can negatively impact quality of care and self-management for all conditions;¹⁰⁻¹³ a phenomenon that is especially prominent when a mental health comorbidity is present.^{14,15} Single-disease-oriented approaches are often not effective for these patients,^{16,17} and may result in inefficient, fragmented care that increases health care costs.¹⁸

A number of intensive primary care models have emerged with the goal of improving outcomes and containing utilization in very high risk patients. One of the earliest models, in Camden, New Jersey,¹⁹ was highlighted memorably by Atul Gawande in his *New Yorker* article entitled, "The Hot Spotters."²⁰ Gawande describes how an extremely time- and resource-intensive multidisciplinary approach for a small group of Camden's most costly patients reduced their health care costs by more than 50%.²¹ This strategy of intensive management for high-utilizers (or patients thought to be at risk for high-utilization) has been tested in a number of other settings in recent years,²²⁻²⁷ including clinics serving older adults (e.g., Guided Care).²⁸⁻³¹ Some models, such as CareMore (a for-profit corporation that provides intensive management for frail and chronically ill members) and the Ambulatory-Intensive Care Unit (developed for Boeing employees and later disseminated to other settings such as Atlantic City and rural Humboldt County in California), report savings as high as 15-20% in non-peer-reviewed observational studies.^{22,32,33} These savings are generally attributed to lower spending for emergency care and hospitalizations.

The evidence supporting intensive management programs for high-utilizers is more mixed when these models are implemented in patient populations with complex mental health and

socioeconomic challenges.^{34,35} For example, a Washington State program focusing on older and disabled Medicaid patients with mental illness and/or chemical dependency did not generate significant savings in overall Medicaid or inpatient costs in intention-to-treat analyses. The lack of savings was attributed in part to low rates of service usage (only 45% of clients engaged in services offered). Secondary analyses focusing on patients who participated in the intervention (compared with propensity score-matched controls), revealed some promising findings for this subgroup, including increased access to care and more intense use of certain services (such as outpatient mental health care), as well as reduced inpatient medical costs and fewer deaths.²³ These findings suggest that intensive primary care programs that focus on especially high-risk patients may need to overcome heightened challenges to implementation and patient engagement.

Drawing conclusions from the literature on intensive primary care programs is challenging because of the heterogeneity of interventions, settings, and patient populations. A comprehensive evidence brief for a recent HSR&D mini-State of The Art³⁶ conference about intensive primary care found that few RCTs and observational studies could be generalized to Veterans.³⁷ However, there have been several noteworthy attempts to synthesize findings from the most promising models and to identify the key components,^{27,38,39} such as exceptional individualized caring for chronic illness,³⁸ frequent in-person contact,²⁷ and care coordination during transitions between hospital and home.³⁹ Recently, VA Palo Alto, supported by the Office of Specialty Care Transformation (OSCT), developed a new clinic that incorporates many of the promising elements of early, non-VHA intensive primary care models. The resulting program—ImPACT (Intensive management PACT)—offers an opportunity to study the feasibility, implementation, and effectiveness of a VHA-tailored care model that augments PACT services with intensive primary care.

B Study Objectives

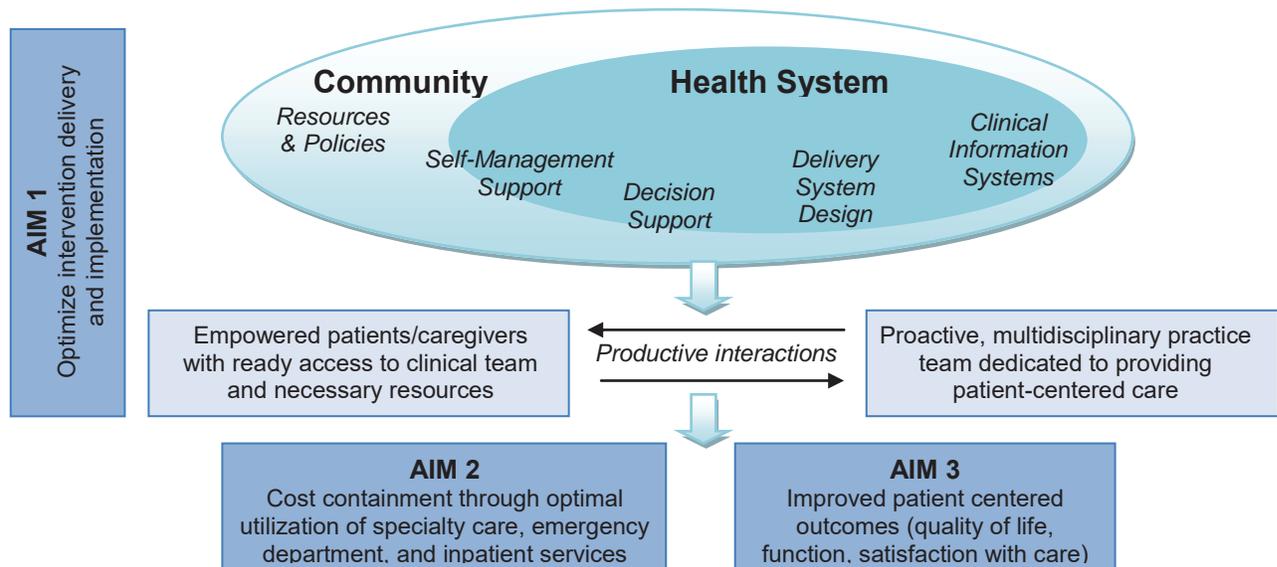
For the proposed HSR&D pilot, we will partner with the implementation team of VA Palo Alto's ImPACT clinic to conduct a Hybrid Type 1 evaluation of the program's feasibility, implementation, and effectiveness. Our specific objectives are:

- **Aim 1: Evaluate the feasibility and implementation of the pilot ImPACT intervention.** Using semistructured interviews with ImPACT and PACT team members and leadership, we will evaluate the success of intervention delivery, including patient identification, recruitment, and retention; provision and uptake of planned services; and monitoring of patient participation and key outcomes.
- **Aim 2: Obtain preliminary estimates of ImPACT's effect on utilization and costs of care, and refine analytic techniques for a subsequent multi-center study.** In order to evaluate the effectiveness of the ImPACT pilot, we will use a difference-in-differences approach, wherein we compare changes in VA health care costs (total, as well as inpatient, outpatient, and fee-basis) and utilization (including hospitalizations, emergency department visits, and specialty care) between ImPACT patients and high-utilizing patients receiving usual PACT care.
- **Aim 3: Examine the association between ImPACT participation and patient-centered outcomes, and refine survey instruments for future evaluations.** Using data from surveys administered in the ImPACT clinic, we will assess patient satisfaction with the ImPACT

intervention and overall care, as well as changes in patient-reported outcomes, including health status, symptom burden, and function.

C Intervention: Intensive Management Patient Aligned Care Team¹

The ImPACT care model augments the existing PACT model with intensive care delivered by a multidisciplinary team (including a physician, nurse practitioner, social worker, recreational therapist, and program coordinator). It encompasses a number of strategies that have been described in syntheses of peer-reviewed and gray literature,^{27,37-41} and also adapts some of the elements of early intensive primary care models described above in Section 1.A.^{21-24,26,29,33} Its theoretical roots lie in the Chronic Care Model (CCM) (Figure 4), which was designed to help practices improve patient health outcomes by focusing on essential elements at the community, organization, practice, and patient levels. A systematic review of studies published since 2000 suggests that redesigning care using the CCM leads to improved patient care and better health outcomes, although effects on cost may take time to be realized.⁴²



Conceptual framework for ImPACT, guided by the Chronic Care Model⁴³

Components of the ImPACT intervention aim to improve care within the following CCM domains, which have been adapted to reflect the needs of very complex and high-utilizing patients:

- **Health System:** ImPACT was developed with strong support from OSCT and facility leadership. The intervention aims to improve care through a multidisciplinary team effort that is patient-centered, well-coordinated, evidence-based, and efficient.
- **Delivery System Design:** ImPACT's intensive management strategies include:
 - An intensive intake process, including a home visit if deemed appropriate
 - Frequent contact (in-person, telephone, or secure messaging) tailored to a patient's needs
 - After-hours access to on-call team member in order to avoid unnecessary emergency care
 - Optimization of chronic condition management using evidence-based protocols
 - Navigation of transitions between hospital and home
 - Coordination of specialty care, including contact with specialists when indicated

- Rapid response to signs of health status deterioration or other stressful events
- Assess patient goals, advance directives, Physician Orders for Life-Sustaining Treatment
- **Self-Management Support:** The ImPACT team uses patient-centered health coaching to encourage patients, and their caregivers when appropriate, to set goals, identify barriers and challenges to self-care tasks, and monitor and communicate changes in condition status.
- **Decision Support:** ImPACT team members provide care recommendations based on evidence-based protocols, help patients navigate specialty care, and ensure that advanced directives are complete.
- **Clinical Information Systems:** Supported by OSCT, ImPACT developed a patient registry that tracks patients by condition, care needs, and health status, thereby promoting proactive, individualized care, and facilitating assessments of the program's effectiveness. ImPACT staff will take advantage of VA's new Patient Care Assessment System to develop care plans, and streamline team members' activities.
- **Community Resources & Policies:** ImPACT helps patients identify and access community resources that enhance social support and encourage healthy activities.

D Evaluation Design

D1 Design Summary

We propose to conduct a Hybrid Trial (Type 1), which is designed to test a clinical intervention while also gathering information about its delivery and implementation.⁴⁴ While a modest program evaluation of ImPACT is planned for OSCT, the proposed HSR&D pilot will provide a more comprehensive assessment of ImPACT that will inform current efforts to identify the optimal intensive primary care model for VHA. We plan to assess the intervention's feasibility, delivery, and implementation through semi-structured interviews with ImPACT and PACT team members (Aim 1); we will evaluate ImPACT's influence on utilization and costs by comparing changes in key outcomes among ImPACT patients and patients receiving usual PACT care (Aim 2); and we will examine pre-post changes in patient-centered outcomes among patients who participate in ImPACT (Aim 3). In conjunction with these steps, we will evaluate and refine our assessment tools and analytic methods in preparation for a subsequent multi-center RCT of ImPACT (Table 2).

D2 Subject Selection and Withdrawal

VA Palo Alto used the following criteria to identify patients for the first cohort of the ImPACT program.

2.a Inclusion Criteria for ImPACT Program

- Receive care from one of 14 primary care providers (MDs, NPs) who have at least three half-days of clinic per week
- Total VA healthcare costs in the top 5% for the facility during the 9-month eligibility phase (10/1/11-6/30/12)
AND/OR
- Risk for one-year hospitalization in November 2012 in the top 5% (using the VA's Care Assessment Need risk-prediction algorithm).⁴⁵

2.b Exclusion Criteria for ImPACT Program

- Enrollment in VA's mental health intensive case management, home-based primary care, or palliative care programs
- Recipient of inpatient care for over half of the 9-month eligibility phase (10/1/11-6/30/12).
- Total VA healthcare costs in the lowest cost decile in the 9-month eligibility phase (10/1/11-6/30/12)
- Risk for one-year hospitalization in November 2012 in the lowest risk quartile (using the VA's Care Assessment Need risk-prediction algorithm).⁴⁵

2.c Randomization

Given limited resources, VA Palo Alto facility leadership offered ImPACT to 150 of the 583 eligible patients (using simple random sampling without replacement). The ImPACT clinical team contacted selected patients by mail followed by telephone during an enrollment period from 2/1/13 through 8/31/13. The remaining 433 patients received standard PACT care.

2.d Recruitment for Evaluation

The Stanford/VA Palo Alto IRB designated the original ImPACT intervention and its associated program evaluation as "non-research" quality improvement. The evaluation will not involve additional contact with patients beyond the clinical contact that is planned as part of the ImPACT program. For the implementation evaluation (Aim 1), Dr. Zulman or a trained research assistant will obtain informed consent from ImPACT and PACT team members and all other VA staff prior to interviews.

2.e Withdrawal from ImPACT Program

Patients who are invited to enroll in the ImPACT QI intervention have the option of declining participation or withdrawing from participation at any time in favor of usual PACT care.

D3 Risks and Benefits

For the implementation evaluation in Aim 1, risks associated with participation are minimal and are primarily limited to potential breaches of confidentiality of the information shared during interviews.

For the feasibility study in Aim 1, and for the evaluations proposed in Aims 2 and 3, no data will be collected from patients beyond that which are collected as part of their clinical care and as part of the planned, internal program evaluation for ImPACT. We therefore do not anticipate that the proposed evaluations will pose research-specific risks to patients.

D4 Data Collection

For the feasibility study in Aim 1, we will analyze data collected by the ImPACT team (e.g., proportion of patients who choose to participate, number of contacts made with these patients, patient engagement with different components of the intervention). Additional details may be obtained during interviews with ImPACT clinical team members.

For the implementation study in Aim 1, data will be obtained through semi-structured interviews with key VA staff members.

For Aim 2, we will obtain data for ImPACT patients and PACT patients from VA Palo Alto's Decision Support System Office.⁴⁶ DSS data contain cost estimates of all VA hospital stays and

health care encounters. Data will also be extracted from the VA National Patient Care Database (outpatient utilization, including emergency department visits, and primary and specialty care encounters), VA Patient Treatment File (inpatient utilization, including hospitalizations), and VA Fee Basis files (covered care provided outside of VA facilities). These files also include clinical and demographic information.

For Aim 3, we will obtain data from patient surveys that the ImPACT clinical team is administering at time of enrollment, as well as approximately 6 months after enrollment.

E Evaluation and Statistical Analysis Plan

E1 Power Calculation

Because baseline cost data for ImPACT-eligible patients were approximately gamma distributed, we assumed that the coefficient of variation will remain constant with a decrease in mean cost over follow-up in the ImPACT group. Based on the cost of care (mean \$77,087, S.D. \$62,975) for ImPACT-eligible patients and anticipating a 20% average decline in costs among ImPACT patients similar to that achieved by previous intensive primary care programs,^{22,32,33} we forecast 88.6% statistical power to reject the null hypothesis of no difference in mean change in costs over 9 months between the ImPACT group (n=150) and PACT group (n=433) (assuming a correlation of 0.5 among repeated measurements within patients over follow-up and a one-tailed Type I error of 5%).

E2 Aim 1. Feasibility and Implementation Evaluation

2.a Feasibility Evaluation

To evaluate feasibility, we will examine the success of ImPACT’s sampling strategy (e.g., patient identification, eligibility criteria, stratification by providers), including the proportion of patients who choose to participate and whether this varies by PACT provider. We will also assess intervention delivery by analyzing data from the ImPACT patient registry, which includes frequency of patient contact, patient participation with different components of the intervention, and whether the ImPACT team meets pre-specified goals such as contact with patient within 24-hours of hospital discharge, emergency room visit, or an after-hours phone call.

2.b Implementation Evaluation

We will structure our implementation evaluation on the Reach-Efficacy Adoption Implementation Maintenance (RE-AIM) Framework.⁴⁷ We will conduct semi-structured interviews 4 months after program launch with key individuals, including ImPACT team members (n = 6), ImPACT-affiliated PACT providers (n = 14), PACT team members from nursing, behavioral health, and social work (n = 10), and VA Palo Alto’s ACOS for Ambulatory Care. Our evaluation will be purely descriptive, and the goal will be to identify implementation challenges that should be addressed and studied in our subsequent multi-center RCT. The evaluation will focus on the following domains:

- **Reach.** We will assess the number of patients in the top 5% who meet ImPACT eligibility criteria, differences between ImPACT participants and eligible patients who opt out (e.g., utilization, chronic conditions, and sociodemographic characteristics), and drop-out rates among participants.

- **Effectiveness.** Our proposed evaluations of ImPACT's effect on utilization and costs, and its effect on patient-centered outcomes are described below under Aim 2 and Aim 3 methods, respectively.
- **Adoption and Implementation.** We will assess facilitators and barriers to ImPACT's adoption and implementation at VA Palo Alto through interviews with ImPACT and PACT providers and team members. We will evaluate the number of ImPACT contacts with patients and explore the relationship between number of contacts and outcomes, adjusting for baseline patient characteristics (described in Aim 2). We will also determine the cost of the intervention based on quarterly reports prepared by the ImPACT implementation team.
- **Maintenance.** We will explore patient attrition rates over time, as well as change in PACT provider satisfaction with ImPACT at 4 and 9 months. At the end of the ImPACT pilot, we will observe whether the facility decides to continue/expand the program, and will interview program and facility leadership to understand the reasons underlying this decision.

E3 Aim 2. ImPACT's Effect on Utilization and Costs of Care

We will evaluate changes in cost and utilization among ImPACT participants vs. comparable patients receiving usual PACT care.

3.a Data Sources and Outcomes

We will obtain cost and utilization data for ImPACT patients and PACT patients from VA Palo Alto's Decision Support System Office, with whom we are already partnering to create a patient registry for the ImPACT pilot. DSS data contains cost estimates of all VA hospital stays and health care encounters. Data will also be extracted from the VA National Patient Care Database (outpatient utilization, including emergency department visits, and primary and specialty care encounters), VA Patient Treatment File (inpatient utilization, including hospitalizations), and VA Fee Basis files (covered care provided outside of VA facilities). These files also include clinical and demographic information.

- **Primary Outcome.** Our primary outcome is the cost of VA care (including inpatient, outpatient, and fee-basis costs)
- **Secondary Outcomes.** Secondary outcomes will include utilization of the hospital, emergency department, and outpatient primary and specialty care.
- **Covariates.** Analyses will adjust for patient age, sex, race, and eligibility. We will examine different approaches to adjusting for patient complexity, including counts of conditions and Diagnostic Cost Groups (DCGs, a diagnosis-based case-mix measure that classifies patients based on their clinical complexity and the associated expected need for health care resources).⁴⁸ We will also adjust for patient-level Care Assessment Need (CAN) scores,⁴⁹ which reflect the estimated probability of a patient's admission or death within 90 days or 1 year. CAN scores for all ImPACT-eligible patients have been obtained from the Office of Informatics and Analytics.

3.b Data Analyses

- **Primary Intention-to-Treat Analyses.** We will evaluate the effectiveness of the ImPACT pilot through a difference-in-differences approach, wherein we compare changes in VA health care costs and utilization among ImPACT patients and patients who are receiving usual PACT care. All analyses will account for patient clustering at the provider level. We will also examine whether number of contacts with the ImPACT team mediates the relationship between the intervention and outcomes, using causal mediation analysis.⁵⁰
- **Secondary Efficacy Analyses Using Propensity to Participate.** Because patients may choose whether or not to engage in the ImPACT intervention, the baseline sample in the intervention group may be highly self-selected. We will therefore complement the

intention-to-treat analyses with an efficacy evaluation of “active participants” (e.g., patients who completed the ImPACT intake process and have at least three additional contacts with the team during their first three months in the program; additional definitions of “active participant” will be explored). We were unable to identify a strong instrumental variable for these analyses, so we will use propensity scores, avoiding features that could act even weakly as instruments and generate bias.^{51,52} We will match those who participate in ImPACT with a subgroup in PACT using propensity to participate. Propensity scores will be calculated using information about patient age, sex, race, eligibility, previous VA utilization, and risk of future utilization (as assessed by DCGs or CAN scores). Because race is frequently missing, we will include “missing race” as a category for this pilot evaluation, but will consider using multiple imputation by chained equations⁵³ as well as other methods that have been used to impute race with VA data.⁵⁴

E4 Aim 3. ImPACT’s Effect on Patient-Reported Outcomes

We will evaluate patient satisfaction with the ImPACT intervention, as well as changes in enrolled patients’ satisfaction with their general care and with their chronic illness care. We will also assess changes in patient-reported outcomes, including health status, symptom burden, and function.

4.a Data Sources and Outcomes

We will obtain data from patient surveys that the ImPACT clinical team plans to administer at time of enrollment, as well as after 4 to 9 months of enrollment.

- **Patient Satisfaction.** We will assess patient satisfaction with the ImPACT intervention, as well as changes in satisfaction with overall care (Patient Satisfaction Questionnaire select subscales)^{55,56} and changes in assessment of chronic illness care.⁵⁷
- **Patient-Centered Outcomes.** We will evaluate changes in patient-reported health status,⁵⁸ symptom burden (fatigue, pain, sleep problems, stress),⁵⁹ and functional status.⁶⁰
- **Patient Care Needs.** We will examine changes in patient-centered outcomes for subgroups of patients who have greater levels of need in four domains, as assessed by the ImPACT clinical team during patient enrollment interviews: medical status and health trajectory (i.e., overall health status), social support, self-management and mental health, and medical neighborhood (i.e., access to care, coordination of care).

4.b Data Analyses

We will use paired t-tests to evaluate pre-post changes in ImPACT patients’ satisfaction with their care and changes in patient-centered outcomes. We will also conduct secondary subgroup analyses to evaluate pre-post changes in outcomes for patients with high levels of need in domains of interest, including patients with poor social support, those with mental health conditions, and those who report particular difficulty accessing and coordinating care.

F Data Handling and Record Keeping

F1 Confidentiality and Security

VA Palo Alto Ci2i investigators have considerable experience in maintaining the confidentiality of patient information and have established procedures in place to ensure data confidentiality. For the implementation evaluation in Aim 1, the primary risk associated with participation by VA staff is breach of confidentiality. For this reason we have chosen to interview all staff members

individually rather than as a group. Research staff will conduct interviews using a VAMC encrypted laptop in conjunction with a USB-attached audio-recording device. Typed notes and audio recordings will be immediately uploaded to a secure, password-protected server, and then removed from the laptop disk drive. We will remove identifiers (names, dates) from the file names and interview notes.

F2 Training

All investigators and research staff will have met training requirements for handling protected health information as outlined by the Health Insurance Portability and Accountability Act (HIPAA).

F3 Records Retention

All electronic data will be housed on a secure server behind the VA Palo Alto firewall, and all paper forms will be stored in a locked file cabinet in the PI's office. Study datasets will use confidential case identifiers. Data will be confidential, but not anonymous, since individual SSNs will be needed to link individual data across data sources. For this purpose, an electronic cross-walk file will be stored on a secure, access-limited folder on the Center's server at the VA Palo Alto. Access to the cross-walk will be restricted to authorized personnel who have met the security criteria necessary for access to patient identifier mapping files at the VA's Austin Automation Center.

G Protocol Modifications

The following sections describe changes that were made to the ImPACT evaluation protocol after patient enrollment began in February, 2013.

G1 Aim 1 Modifications

1.a Feasibility Evaluation Modifications

Feasibility evaluation measures were expanded to include measures of care continuity, access, and patient-centered care services (described in detail in the table below).

Process Measure	Domain	Description
Assigned PCP encounters	Care continuity	Proportion of primary care visits with the patient's assigned primary care provider.
Telephone encounters	Care access, increasing options for visit modality	Proportion of telephone visits out of all primary care encounters.
Appointment no-shows	Care continuity, also care access for general patient panel through increased scheduling efficiency	Proportion of no-show appointments out of all appointment types for primary care encounters Percent of no-show appointments out of all appointment types for specialty care encounters
Discharge follow up visit	Care continuity through improved care transitions	Proportion of discharges where patient follow-up visit occurred within two business days of discharge out of all discharges.
Personal health record registration/in-person authentication	Patient-centered, responsive to individual preferences for viewing/managing health record and services, communicating with care team	Rate of new patients registered for myHealtheVet during the time period. Rate of new patients that completed in-person authentication during the time period.
Advance directives completion/discussion	Patient-centered, through planning/ documenting preferences for advanced care	Rate of patients with new signed AD documentation during the time period Rate of patients with new signed AD documentation or

Telehealth referral	Patient-centered, responsive to preferences for monitoring and management	documentation of an AD discussion during the time period Rate of patients referred to telehealth services during time period (one referral maximum per patient)
---------------------	---	--

For each measure, we compared rates among ImPACT and PACT patients. Difference-in-differences regression models were used to evaluate whether ImPACT is associated with changes in access and continuity measures, adjusting for baseline group differences. Since measures of patient-centered care identify the occurrence or non-occurrence of a one-time event (e.g., telehealth referral), chi-squared tests were used to compare differences in new telehealth referrals, advance directive discussions and completion, and personal health record registration and authentication during the intervention period.

1.b Implementation Evaluation Modifications

Although the original protocol for the implementation evaluation was guided by the RE-AIM framework,⁴⁷ the interview guides were ultimately developed using the Consolidated Framework for Implementation Research (CFIR).⁶¹ CFIR delineates five domains (Intervention Characteristics, Outer Setting, Inner Setting, Characteristics of Individuals involved in implementation, and the Process of implementation) that influence the implementation of complex interventions. The decision to change the guiding framework from RE-AIM to CFIR was made because the qualitative domains of the CFIR framework would provide insight that complemented quantitative findings from other components of the evaluation.

G2 Aim 2 Modifications

2.a Patient Population

The original protocol specified a study population of 150 ImPACT and 433 PACT patients. Final analyses excluded patients who died or left the facility before the intervention start date (February 1, 2013) (8 in ImPACT, 23 in PACT), and patients who were identified in retrospective chart review as not meeting study eligibility criteria, e.g. because they were enrolled in a community nursing home at time of patient selection (2 in ImPACT, 5 in PACT).

2.b Outcomes

Analyses adhered to the primary and secondary outcomes described in the original protocol.

- **Primary Outcome.** Our primary outcome is the cost of VA care (including inpatient, outpatient, and fee-basis costs)
- **Secondary Outcomes.** Secondary outcomes will include utilization of the hospital, emergency department, and outpatient primary and specialty care.

In addition, final analyses examined costs of specific inpatient services (i.e., acute and extended medical/surgical care and acute and extended mental health/residential care), and outpatient services (i.e., ED, primary, specialty, and mental health care). For primary analyses, we included average monthly ImPACT encounter costs (~\$136/patient) to capture personnel effort and workload; in sensitivity analyses we replaced encounter costs with average monthly ImPACT personnel costs (\$240/patient) to reflect program costs incurred by the facility. Utilization measures included admission frequency and length of stay for each inpatient service, and number of primary, mental health, specialty care, and ED visits.

2.c Data Analyses

Statistical Power. The original evaluation design assumed that program sustainability would require demonstration of superiority under one-tailed testing; however for the final evaluation we used a more conservative two-tailed test. Power from the one-tailed and two-tailed calculations for an analysis of covariance to detect a 20% reduction in mean costs (comparable to savings achieved by previous intensive outpatient programs over 12-18 months)^{22,33,62} was 88.6% and 81.3%, respectively, equivalent to a superiority margin of 8.5% and 6.2% reduction in mean costs, respectively.

Mortality Data. Because mortality data can be delayed, we obtained updated data after the evaluation period (9/15/2014), and validated these data through independent chart review by three reviewers. Charts were reviewed for all patients who were either 1) flagged as deceased by the facility, or 2) flagged as having monthly VA costs of \$0 for two or more months at the end of the evaluation period (n=153).

Descriptive Analyses. The original protocol focused on primary intention to treat and secondary efficacy analyses to evaluate the effects of ImPACT on specified outcomes. Prior to conducting these analyses, we first compared characteristics of patients in ImPACT and PACT using t-tests for continuous variables and chi-square tests for dichotomous and categorical variables. We examined differences in attrition (i.e., departure from the health care facility) across the two groups using linear regression. We examined differences in mortality, including among patients who had left the facility, using Kaplan-Meier analysis. In descriptive analyses, we examined changes in average ImPACT vs. PACT person-level aggregate costs and utilization over 16-month baseline and follow-up periods.

Primary Intention-to-Treat Analyses. As described in the original protocol, primary intention-to-treat analyses used a difference-in-differences framework to compare monthly VA health care costs and utilization among ImPACT and PACT patients during baseline and follow-up periods. We included fixed effects to account for fixed differences across patients.⁶³ In sensitivity analyses, we replaced person fixed effects with covariates for baseline characteristics and found similar results. For patients who died during the study period, we included monthly costs after death (\$0); for patients who left the facility, we set monthly costs to missing after they were no longer receiving care from the VA facility.

Secondary Efficacy Analyses. Although we initially intended to use propensity scores to match ImPACT participants with a subgroup in PACT, our final model used an instrumental variable approach to address potential unobserved confounders. Specifically, we used randomization as an instrument for participation in order to estimate the effect of the intervention on patients who actively engaged in ImPACT (defined *a priori* as completing an intake and at least three additional encounters with the team).⁶⁴⁻⁶⁶

Subgroup Analyses. We conducted pre-specified and post-hoc exploratory analyses to examine variation in program effects for key patient subgroups, with the goal of refining the program's future patient selection criteria. Pre-specified subgroups, defined before evaluation was initiated, included patients with and without mental health diagnoses, patients < and ≥ 65 years of age, and patients who were eligible for ImPACT based on high-cost vs. high-risk for hospitalization (non-mutually exclusive groups). Post-hoc stratified analyses focused on characteristics that the clinical team perceived as potential candidates for future patient selection: the presence of heart failure, diabetes or COPD; hospitalization in the 6 months prior

to program implementation; and high-risk for hospitalization with an admission in the 6 months prior to program implementation.

G3 Aim 3 Modifications

Aim 3 survey development and analyses adhered to the original protocol. The only exceptions are as follows:

1. The ImPACT team modified their baseline and follow-up survey instruments prior to patient enrollment, adding the Patient Activation Measure (PAM), and removing the Patient Assessment of Chronic Illness Care. After piloting the survey with several patients, the team replaced the original 13-item PAM (PAM-13) with the 6-item low literacy version (PAM-6).⁶⁷
2. The final evaluation did not include planned subgroup analyses because the evaluation team was concerned that the response rate was too low for these to be meaningful.

H References

1. Williams JW, Jr., Katon W, Lin EH, et al. The effectiveness of depression care management on diabetes-related outcomes in older patients. *Ann Intern Med.* 2004;140(12):1015-1024.
2. Conwell LJ, Cohen JW. AHRQ Statistical Brief #73: Characteristics of persons with high medical expenditures in the U.S. civilian noninstitutionalized population, 2002. 2005; http://meps.ahrq.gov/data_files/publications/st73/stat73.pdf. Accessed 11/28/12.
3. Cohen S, Yu W. Statistical Brief #354: The concentration and persistence in the level of health expenditures over time: Estimates for the US population, 2008-2009. 2012; http://meps.ahrq.gov/mepsweb/data_files/publications/st354/stat354.pdf. Accessed 11/28/12.
4. Mann C. Medicaid and CHIP: On the Road to Reform. Alliance for Health Reform/Kaiser Family Foundation. 2011; www.allhealth.org/briefingmaterials/KFFAlliance_FINAL-1971.ppt. Accessed 11/28/12.
5. Garber AM, MaCurdy TE, McClellan MB. Persistence of Medicare expenditures among elderly beneficiaries. In: Garber AM, ed. *Frontiers in Health Policy Research*. Vol 1. Cambridge, MA: MIT; 1998:153-180.
6. Anderson G. Chronic care: Making the case for ongoing care. 2010; <http://www.rwjf.org/content/dam/web-assets/2010/01/chronic-care>. Accessed January 26, 2015.
7. Friedman B, Jiang HJ, Elixhauser A. Costly hospital readmissions and complex chronic illness. *Inquiry.* 2008;45(4):408-421.
8. Lehnert T, Heider D, Leicht H, et al. Review: Health care utilization and costs of elderly persons with multiple chronic conditions. *Med Care Res Rev.* 2011;68(4):387-420.
9. Lee TA, Shields AE, Vogeli C, et al. Mortality rate in veterans with multiple chronic conditions. *Journal of general internal medicine.* 2007;22(Supp 3):403-407.
10. Kerr EA, Heisler M, Krein SL, et al. Beyond comorbidity counts: How do comorbidity type and severity influence diabetes patients' treatment priorities and self-management? *Journal of general internal medicine.* 2007;22(12):1635-1640.
11. Turner BJ, Hollenbeak CS, Weiner M, Ten Have T, Tang SS. Effect of unrelated comorbid conditions on hypertension management. *Ann Intern Med.* 2008;148(8):578-586.
12. Wang PS, Avorn J, Brookhart MA, et al. Effects of noncardiovascular comorbidities on antihypertensive use in elderly hypertensives. *Hypertension.* 2005;46(2):273-279.
13. Redelmeier DA, Tan SH, Booth GL. The treatment of unrelated disorders in patients with chronic medical diseases. *N Engl J Med.* 1998;338(21):1516-1520.
14. Frayne SM, Halanych JH, Miller DR, et al. Disparities in diabetes care: Impact of mental illness. *Arch Intern Med.* 2005;165(22):2631-2638.
15. Krein SL, Hofer TP, Holleman R, Piette JD, Klamerus ML, Kerr EA. More than a pain in the neck: How discussing chronic pain affects hypertension medication intensification. *Journal of general internal medicine.* 2009;24(8):911-916.
16. Boyd CM, Darer J, Boulton C, Fried LP, Boulton L, Wu AW. Clinical practice guidelines and quality of care for older patients with multiple comorbid diseases: Implications for pay for performance. *JAMA.* 2005;294(6):716-724.
17. Tinetti ME, Bogardus ST, Agostini JV. Potential pitfalls of disease-specific guidelines for patients with multiple conditions. *N Engl J Med.* 2004;351(27):2870-2874.
18. Vogeli C, Shields AE, Lee TA, et al. Multiple chronic conditions: Prevalence, health consequences, and implications for quality, care management, and costs. *Journal of general internal medicine.* 2007;22(Supp 3):391-395.

19. Brenner J. Reforming Camden's health care system - One patient at a time. *Prescriptions for Excellence in Health Care*. 2009(5):1-3.
20. Gawande A. The hot spotters: Can we lower medical costs by giving the neediest patients better care? *The New Yorker*. New York, NY 2011.
21. Green SR, Singh V, O'Byrne W. Hope for New Jersey's city hospitals: The Camden Initiative. *Perspect Health Inf Manag*. 2010;7:1d.
22. Reuben DB. Physicians in supporting roles in chronic disease care: The CareMore model. *Journal of the American Geriatrics Society*. 2011;59(1):158-160.
23. Bell J, Mancuso D, Krupski T, et al. *A randomized controlled trial of King County Care Partners' Rethinking Care Intervention: Health and social outcomes up to two years post-randomization*. Seattle, WA: Center Healthcare Improvement for Addictions Mental Illness and Medically Vulnerable Populations;2012.
24. Milstein A. Can health care quality improve and cost decrease? Pilot project in Atlantic City may show the way. 2009; <http://pweb1.rwjf.org/reports/grr/056351.htm>. Accessed 11/28/12.
25. Brown KE, Levine JM, Fiellin DA, O'Connor P, Sledge WH. Primary intensive care: Pilot study of a primary care-based intervention for high-utilizing patients. *Dis Manag*. 2005;8(3):169-177.
26. Raven MC, Doran KM, Kostrowski S, Gillespie CC, Elbel BD. An intervention to improve care and reduce costs for high-risk patients with frequent hospital admissions: A pilot study. *BMC Health Serv Res*. 2011;11:270.
27. Brown RS, Peikes D, Peterson G, Schore J, Razafindrakoto CM. Six features of Medicare coordinated care demonstration programs that cut hospital admissions of high-risk patients. *Health Aff (Millwood)*. 2012;31(6):1156-1166.
28. Boulton C, Reider L, Leff B, et al. The effect of guided care teams on the use of health services: Results from a cluster-randomized controlled trial. *Arch Intern Med*. 2011;171(5):460-466.
29. Dorr D, Wilcox AB, Brunner CP, Burdon RE, Donnelly SM. The effect of technology-supported, multidisease care management on the mortality and hospitalization of seniors. *Journal of the American Geriatrics Society*. 2008;56(12):2195-2202.
30. Counsell SR, Callahan CM, Clark DO, et al. Geriatric care management for low-income seniors: A randomized controlled trial. *JAMA*. 2007;298(22):2623-2633.
31. Counsell SR, Callahan CM, Tu W, Stump TE, Arling GW. Cost analysis of the Geriatric Resources for Assessment and Care of Elders care management intervention. *Journal of the American Geriatrics Society*. 2009;57(8):1420-1426.
32. Milstein A, Kothari P. Are higher-value care models replicable. *Health Affairs Blog* October 20, 2009; <http://healthaffairs.org/blog/2009/10/20/are-higher-value-care-models-replicable/>. Accessed 11/28/12.
33. Blash L, Chapman S, Dower C. The Special Care Center - A joint venture to address chronic disease. *Center for the Health Professions Research Brief*. 2011(11/28/12).
34. Sledge WH, Brown KE, Levine JM, et al. A randomized trial of primary intensive care to reduce hospital admissions in patients with high utilization of inpatient services. *Disease Management*. 2006;9(6):328-338.
35. Shumway M, Boccillari A, O'Brien K, Okin RL. Cost-effectiveness of clinical case management for ED frequent users: Results of a randomized trial. *Am J Emerg Med*. 2008;26(2):155-164.
36. Choi J, Tasota FJ, Hoffman LA. Mobility interventions to improve outcomes in patients undergoing prolonged mechanical ventilation: a review of the literature. *Biol Res Nurs*. 2008;10(1):21-33.
37. Peterson D, Helfand M, Humphrey L, Christensen V, Carson S. *Evidence Brief: Effectiveness of Intensive Primary Care Programs, VA-ESP Project #09-199*. 2012.

38. Milstein A, Gilbertson E. American medical home runs. *Health Affairs*. 2009;28(5):1317-1326.
39. Boulton C, Murphy EK. New models of comprehensive health care for people with chronic conditions. In: IOM, ed. *Living Well with Chronic Illness: A Call for Public Action*. Washington, D.C.: The National Academies Press; 2012:285-318.
40. Smith-Spangler C, Jenchura E, Sundaram V, et al. Care Coordination: In Search of the Active Ingredients of Interventions Reported in Systematic Reviews. 2012 VA HSR&D/QUERI National Conference; July 17, 2012; Washington, D.C., Oral Presentation.
41. Bodenheimer T. Building teams in primary care: 15 Case Studies. 2007; <http://www.chcf.org/~media/MEDIA%20LIBRARY%20Files/PDF/B/PDF%20BuildingTeamsInPrimaryCareCaseStudies.pdf>. Accessed 11/28/12.
42. Coleman K, Austin BT, Brach C, Wagner EH. Evidence on the Chronic Care Model in the new millennium. *Health Affairs (Project Hope)*. 2009;28(1):75-85.
43. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: Translating evidence into action. *Health Affairs*. 2001;20(6):64-78.
44. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: Combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care*. 2012;50(3):217-226.
45. Wang L, Porter B, Maynard C, et al. Predicting risk of hospitalization or death among patients receiving primary care in the Veterans Health Administration. *Med Care*. 2013;51(4):368-373.
46. Plenge RM, Seielstad M, Padyukov L, et al. TRAF1-C5 as a risk locus for rheumatoid arthritis--a genomewide study. *N Engl J Med*. 2007;357(12):1199-1209.
47. Glasgow RE, McKay HG, Piette JD, Reynolds KD. The RE-AIM framework for evaluating interventions: What can it tell us about approaches to chronic illness management? *Patient education and counseling*. 2001;44(2):119-127.
48. Rosen AK, Loveland S, Anderson JJ. Applying diagnostic cost groups to examine the disease burden of VA facilities: Comparing the six "Evaluating VA Costs" study sites with other VA sites and Medicare. *Med Care*. 2003;41(6 Suppl):II91-102.
49. Fihn S. Overview of the Office of Analytics and Business Intelligence. HERC Health Economics Cyber-Seminar. 9/18/12; http://vaww.hsr.d.research.va.gov/for_researchers/cyber_seminars/archives/hmcs-091912.pdf. Accessed 11/17/12.
50. Imai K, Keele L, Tingley D. A general approach to causal mediation analysis. *Psychol Methods*. 2010;15(4):309-334.
51. Bhattacharya J, Vogt W. Do Instrumental Variables Belong in Propensity Scores? *National Bureau of Economic Research Technical Working Paper* 2007;343.
52. Pearl J. Understanding Bias Amplification *American Journal of Epidemiology*. 2011;174(11):1223-1227.
53. White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and guidance for practice. *Statistics in Medicine*. 2011;30(4):377-399.
54. Trivedi AN, Grebla RC, Wright SM, Washington DL. Despite improved quality of care in the Veterans Affairs health system, racial disparity persists for important clinical outcomes. *Health Aff (Millwood)*. 2011;30(4):707-715.
55. Marshall GN, Hays RD. *The patient satisfaction questionnaire short-form (PSQ-18)*. Santa Monica, CA: RAND;1994.
56. Health R. Short-form patient satisfaction questionnaire (PSQ-18). 2011; http://www.rand.org/content/dam/rand/www/external/health/surveys_tools/psq/psq18_survey.pdf. Accessed 9/13/12.

57. Glasgow RE, Wagner EH, Schaefer J, Mahoney LD, Reid RJ, Greene SM. Development and validation of the Patient Assessment of Chronic Illness Care (PACIC). *Med Care*. 2005;43(5):436-444.
58. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res*. 2011;20(10):1727-1736.
59. Ritter PL, Gonzalez VM, Laurent DD, Lorig KR. Measurement of pain using the visual numeric scale. *Journal of Rheumatology*. 2006;33(3):574-580.
60. Lorig KR, Sobel DS, Ritter PL, Laurent D, Hobbs M. Effect of a self-management program on patients with chronic disease. *Eff Clin Pract*. 2001;4(6):256-262.
61. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implement Sci*. 2009;4:50.
62. Milstein A, Kothari P. Are higher-value care models replicable? *Health Affairs Blog*. 2009; <http://healthaffairs.org/blog/2009/10/20/are-higher-value-care-models-replicable/>. Accessed 11/28/12.
63. Greene WH. *Econometric Analysis*. 7 ed: Pearson Education, Inc.; 2012.
64. Heckman JJ. Randomization as an Instrumental Variable. *The Review of Economics and Statistics*. 1996;78(2):336-341.
65. Angrist JD, Imbens GW, Rubin DB. Identification of Causal Effects Using Instrumental Variables *Journal of the American Statistical Association*. 1996;91(434):444-455.
66. Angrist JD, Krueger AB. Instrumental Variables and the Search for Identification: From Supply and Demand to Natural Experiments. *Journal of Economic Perspectives*. 2001;15:69-85.
67. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. *Health Serv Res*. 2005;40(6 Pt 1):1918-1930.