

Title: Regional Data Exchange to Improve Care for Veterans After Non-VA
Hospitalization

NCT number: 02689076

Last update/approval date: July 17, 2019

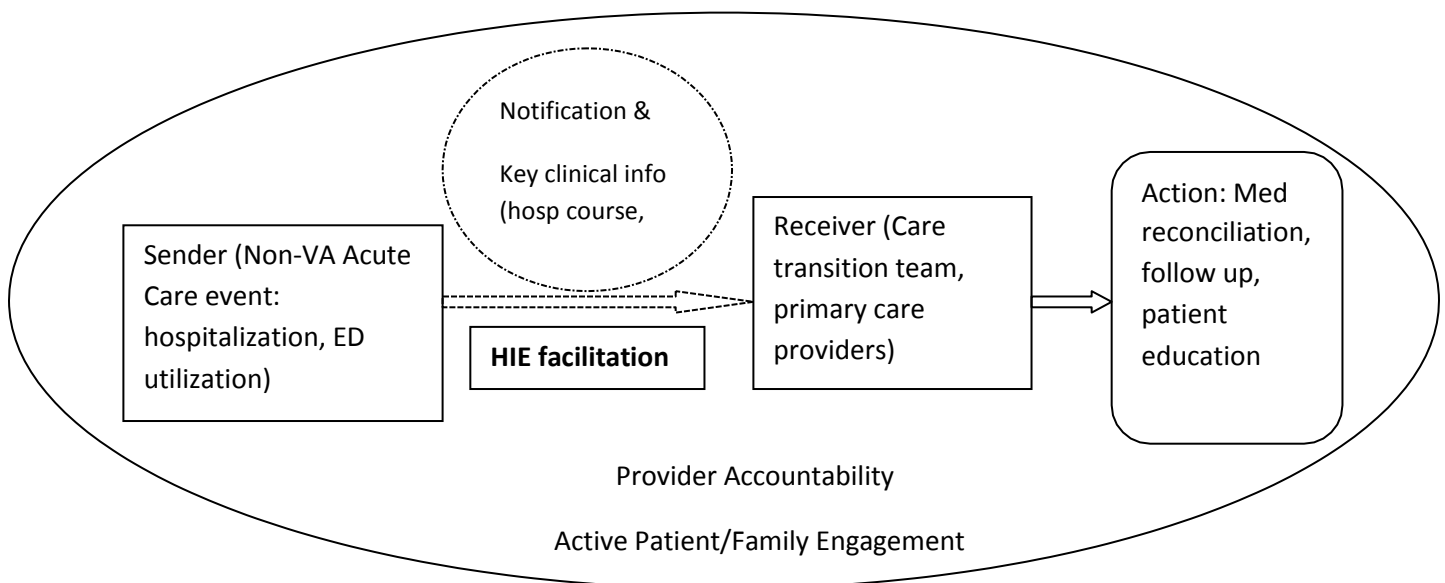
Approved Proposal Narrative

B. BACKGROUND

B.1 VA and non-VA service use and risks of cross-site transitions to older veterans. Among 2.6 million VA-Medicare dually-eligible veterans, nearly 1 million annually receive medical care in both the VA health care system and in systems outside the VA.¹ A common circumstance is when veterans with VA primary care utilize non-VA acute care because of an acute condition that requires urgent triage; e.g., a veteran with suspected myocardial infarction who is taken by ambulance to the nearest hospital, a non-VA facility. Among VA primary care patients who receive non-VA care, care services are often poorly coordinated, and in general VA providers are not aware of non-VA encounters until notified by providers, patients or families. As a result, dual system use is associated with higher hospital admission and readmission rates and greater adverse events.^{2,3} Furthermore, as a result of their multiple chronic diseases, medications, and poorer health, older adults discharged from acute to outpatient care are at higher risk than younger patients for hospital readmission, emergency department (ED) visits, and medication errors.⁸⁻¹² Among all Medicare beneficiaries, 30-day and 90-day hospital readmission rates were determined to be 20% and 34%, respectively.¹³ Recognizing the importance of cross-site transitions for this population, the VA Office of Care Coordination and Centers for Medicare and Medicaid (CMS) have supported projects to improve documentation, medication reconciliation, and patient education to avert adverse outcomes.¹⁴

B.2 Health information exchange’s potential to improve care transitions for older veterans. Health information exchange (HIE) has the potential to bridge an information gap by improving VA providers’ access to non-VA medical information, and the VA’s Virtual Lifetime Electronic Record (VLER) program was initiated to implement HIE between VA and non-VA providers. The value of HIE may be magnified at care transitions, during or near when patients move across health care settings and information is needed in a timely fashion by providers. A model of care transitions (Figure 1) adapted from the National Transition of Care Coalition Work Group¹⁵ suggests that HIE can facilitate notification and transfer of clinical information from one organization to another. Our proposed study is designed to test key aspects of this model -- HIE notification and intensity of the coordination response -- and measure their effects on veteran health.

Figure 1. Transition of Care Model



B.3 Rationale for both HIE-notification and delivery of a geriatric care coordination intervention. VA providers who do not learn of non-VA acute care events until later told by patients, families or non-VA providers miss the time window where actions in Figure 1 (e.g., medication reconciliation and patient education) may be helpful. Thus, notification is necessary for a timely response. However, notification without an obligatory, structured intervention may not significantly impact post-hospital outcomes. This is because studies have not consistently demonstrated an impact of HIE-access alone on outcomes important to patients,¹⁶⁻¹⁹ in part because of research showing provider HIE-access frequencies in only 2.4% of encounters.²⁰ *Since the last submission our own data support the notion that notification and HIE-access by themselves may not result in provider action or result in benefit. At the Bronx VA, data from a study of the effect of HIE on medication reconciliation demonstrated that the HIE identified only 5% of medication discrepancy errors that would not have otherwise been identified, and 2/3 of these had little or no potential for harm, suggesting relatively low impact.²¹ Separately, at the Indianapolis VA, veterans enrolled in the VLER Health program had \$1152 higher annual costs than those who were not, even after adjusting for covariates using propensity scores.²² This finding is concordant with inconsistent associations between HIE and healthcare utilization in other studies.^{19,20}*

In contrast, in randomized controlled trials, short-term (e.g., 30-90 day) post-hospital geriatric care coordination interventions led by dedicated transitions coordinators (nurse, social worker, or nurse practitioner) have been shown to be effective in reducing hospital readmission after hospital discharge by 25-45% and improving care from the patients' perspective.^{23,24} Studies have shown that interventions targeting medication counseling, patient education, and telephone follow-up reduce readmission rates for older adults discharged from the ED.^{25,26} Such interventions are multi-component in nature,²³⁻²⁶ and often include education, medication reconciliation, and care coordination. These services are more intense than what primary care providers -- whose work-time burden for patients with chronic illness is high²⁷ -- can provide to address unmet needs and improve processes and outcomes for older patients.

B.4 HIE in the Bronx and Indianapolis. The current proposal takes advantage of 2 VA partnerships with regional health information-exchange organizations (RHIOs) in the Bronx and Indianapolis covering urban, suburban, and rural areas. The Bronx Regional Health Information Organization (Bronx RHIO) was established in November 2005 to develop and operate a secure clinical data information exchange county-wide in the Bronx. It is a secure, interoperable system that makes it possible for patients' medical records to be accessed wherever they go for health care services in the Bronx. The system enables credentialed and authorized clinicians, including VA providers, to access in real-time and at the point of care clinical information about patients for whom they are providing care. It employs clinical data repositories located behind institutional firewalls as its source data. When a query is made to identify a specific patient, the technology assembles information from data repositories and delivers a profile to the requesting clinician at the point of care. An alert service is available to notify providers of hospital admissions and ED visits for patients for whom they have an identified responsibility (Appendix 1). The Indiana Health Information Exchange (IHIE) is a non-profit organization formed by the Regenstrief Institute, private hospitals, local and state health departments, and other community health organizations in Indiana in 2004. It operates one of the nation's largest health information exchanges, providing a secure and robust health information technology network that connects over 90 hospitals, long-term care facilities, rehabilitation centers, community health clinics and other healthcare providers in Indiana. IHIE provides information in a secure, standardized and electronic format, enabling information to be accessed wherever the patient is seen. IHIE and Regenstrief have been VLER participants since 2010. In FY13 IHIE and the Indianapolis VA exchanged over 6,525 clinical documents in support of patient care. IHIE has developed a service for notifying its ACO members of hospital admissions, discharges and transfers (ADTs), which this project will extend to the VA.

B.5 Previous work by investigators.

The investigative team has experience in studying care transition processes,²⁸⁻³² implementing and evaluating health care models,^{29,33,34} chronic illness care,^{35,36} informatics interventions,³⁷⁻⁴⁰ health information exchange tools and implementation,^{16,41-44} and cost analysis.^{45,46} It has experience in multiple study designs, including

intervention studies with randomized and non-randomized designs, and qualitative evaluations.^{32,47} The current proposal builds on the investigators' and the Bronx and Indianapolis VAs' experience with clinical demonstrations of geriatrics service models and studying informatics systems (see sections D.4 and D.6).

C. SIGNIFICANCE

C.1. Seriousness of the problem of fragmented care. Dual VA and non-VA system use is highly prevalent^{1,48,49} and veterans obtain a significant proportion of inpatient and outpatient primary and specialty care outside the VA.⁵⁰ Dual system care exposes veterans to the risk of adverse events due to the lack of communication between providers^{2,3} and inpatient-to-outpatient transitions are particularly risky for older adults.⁹⁻¹¹ Because of the high frequency of non-VA inpatient use and the risk of transition-related adverse events among older veterans, improving non-VA hospital to VA transitions among older veterans is crucial to achieving improved care across sites for the growing numbers of older veterans. Veterans aged 65-69 are currently the largest veteran age group and veterans aged 70-74 will become the largest veteran age group by 2017.⁵¹ This project has gained salience as a result of the Veterans Access, Choice, and Accountability Act of 2014, which will further expand veterans' access to non-VA care.

C.2 Contributions of the proposed research. *This study will produce information on the effectiveness, cost, safety, and implementation of VA provider notification of non-VA hospital admission or ED visit followed by a geriatric care transitions intervention, as compared to notification alone, and as compared to no notification, tested in a broad demographic and in distinct geographic areas. Findings from this research will inform VA's approach to improving service delivery for older veterans and inform its approach to implementing HIE alerts to VA providers as its HIE capabilities expand. The study is designed to balance generalizability and innovation. First, we decided to implement notification for all study enrollees in order to provide benefit to all study participants and because we expect notification of non-VA care episodes to become a national standard when it becomes technically feasible. Though the study site VAs have more advanced HIE than most VAs, currently ADT alerting, upon which our proposed intervention is based, is not an advanced HIE technology. ADT messages are the basic building blocks of all enterprise level systems integration, and are used to connect, for example, the laboratory information system with the electronic health record. Second, our selected geriatric care transitions intervention is evidence-based (see Section B.3) and has early VA adopters but has not been tested in a rigorous fashion in the VA nor implemented widely. The notification-plus-coordination package goes beyond what is currently provided by PACT teams in that it provides post-hospital follow-up in real-time after a non-VA hospital encounter, enabled by HIE, and it provides targeted, short-term (30-day) geriatric care transitions coordination at an intensity that PACT teams are not staffed to provide. If shown to be effective, it could be integrated into services provided by PACT teams, Home Based Primary Care (HBPC), and/or telehealth/care coordination. In this way the intervention is innovative to the VA: an informatics tool provides PACT teams with previously unavailable information at the right time and a care coordinator responds by addressing fragmentation in older veterans who receive VA and non-VA care and have unmet geriatrics needs. We selected older dual VA and non-VA service users as a target population for this trial because of a) their added risk of poor outcomes from care fragmentation, b) the applicability of HIE in these circumstances, and c) VA operations' interest in this group.*

This project will extend our prior research in the following ways: 1) a prior pilot with 54 non-VA hospital encounters at 1 site will be expanded in this study to 466 non-VA hospital encounters at 2 sites, 2) notification of non-VA hospital encounter will be given directly to the PACT provider electronically, as opposed to through the research team, and 3) there will be 3 groups, one with the notification plus geriatric care transitions coordination, one with notification alone, and one with no notification (usual care). Our rationale for using 2 sites is to ensure sufficient numbers of subjects and to test the intervention in two different environments to help ensure robustness of the findings. In the study's qualitative aim, we will examine how providers report receiving and responding to HIE-notification, and their suggestions for improvement, to contribute to better implementation design. This study will also advance knowledge of potential pitfalls such as patient privacy concerns with HIE in the VA setting, which is an important issue for the entire veteran population using dual

systems. Long-term objectives include disseminating the results so that similar approaches can be adopted in VAs across the nation.

C3. Audience. VA has invested substantial resources in the development and implementation of programs and systems to improve care for veterans across sites, notably via the Computerized Patient Record System (CPRS) and VistaWeb (which now includes access to VLER information from the Department of Defense and non-VA sites). Quantitative and qualitative findings on the use of HIE notifications to improve care of older veterans who utilize non-VA services would be of interest to several VA operations audiences, including the Office of Geriatrics and Extended Care and the VLER Program Office. VA hospital administrators have an interest in determining how using regional HIE and care coordination can improve outcomes and reduce costs of care for veterans in their medical center. VA providers, including primary care providers, specialists, hospitalists, care coordinators, and nurses will see the direct relevance of this research to their practice. Providers and health systems outside of the VA will be interested in study findings because of its potential to be applied in new models of care delivery, such as ACOs. Other VAs which have implemented or are soon to implement HIE with non-VA providers can potentially adopt this proposal's approach.

C4. Responsiveness to an HSR&D priority area. The proposed research responds to the priority area on utilizing healthcare informatics to improve veteran care. Electronic provider notification of non-VA hospital admission and ED visit can enable VA providers and teams to respond in new ways to improve care during this high risk period. We will study providers' natural response to this notification as well as test the impact of a structured geriatric care coordination intervention known to be effective in improving care transition outcomes. Since it is possible that HIE notification by itself may not lead to responsive action on the part of VA primary care providers or PACT teams, in this study we propose in half of enrollees to test a standardized care transitions intervention as a response to HIE notification, while at the same time obtain information on the PACT team response in a notification-only group. We have conducted a pilot study at the Bronx VA of this approach and demonstrated its reliability and feasibility. The proposed controlled trial will provide a rigorous test of its value to the VA.

D. RESEARCH DESIGN AND METHODS

This is a mixed methods study. For Aim 1 we will conduct a trial in which notifications of non-VA hospital admissions and ED visits for older veteran participants will be communicated to their VA PACT providers in the Bronx and Indianapolis from the local Regional Health Information Organizations (RHIOs). In the first phase of Aim 1, enrolled veterans will be cluster-randomized by PACT to receive a geriatric post-hospital care transitions intervention n=155 or notification-alone n= 155. In the second phase of Aim 1 we will identify and collect data on a third, no notification control group (n=300). We will compare effects on hospital admission and readmission 90 days after discharge, VA provider follow-up, patient's condition self-knowledge, and medication discrepancies after discharge, using data obtained from record review, interview, and warehouse sources. For Aim 2 we will compare effects on VA and non-VA costs using VA administrative data and RHIO service use data. For Aim 3 we will conduct interviews with stakeholders, including veteran participants, and examine implementation barriers and facilitators to the notification and coordination interventions at the two sites.

D.1 Aim 1 Patient identification, recruitment, and informed consent: To meet the trial's initial inclusion criteria a veteran must 1) be a PACT patient in a Bronx VA or Indianapolis VA geriatrics or primary care clinic, 2) be 65 years or older, 3) be consented in the local RHIO, and 4) have utilized any non-VA services (including nursing, lab, physician, pharmacy, and/or hospital services) in the previous two years according to the RHIO record. RHIO consenting of veterans at the Bronx and Indianapolis VAs has been occurring for over 3 years as a local administrative activity when veterans visit the VA for business or clinical purposes. In Aim 1 Phase 1, patients fulfilling these criteria will be approached for study enrollment during a VA outpatient encounter. This will be facilitated, after approval by human subjects committee(s), by obtaining clinic appointment dates in advance

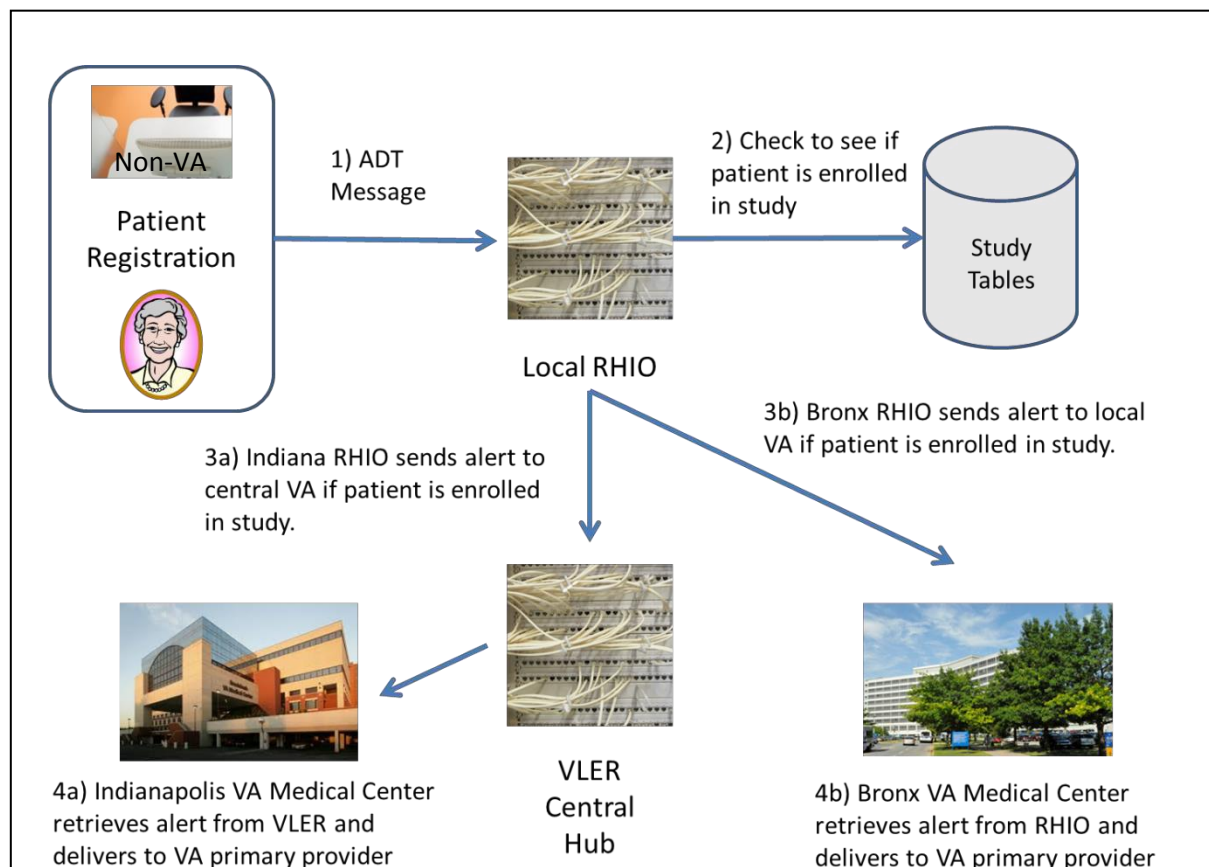
and augmented by initiating contact with patients by phone. To obtain informed consent, a research assistant (RA) will determine whether eligible patients have the capacity to provide informed consent to participate in the study using a screen that assesses the four elements required for capacity: understanding study procedures, appreciation of what will happen to him or her if enrolled, communication of a choice to enroll or not, and demonstration of a rationale for that choice. For patients without capacity, a legal surrogate, identified from query of the patient's provider or caregiver, will be contacted. Recruitment and written informed consent will take place in a location that ensures privacy and convenience for the patient (a private clinic or hospital room).

D.2 Cluster assignment by PACT. We will randomize patients by PACT in order to prevent a team from having patients in both treatment groups and to reduce contamination. Prior to initiating enrollment, the project manager will assign PACTs to notification-plus-coordination or notification-only groups, using lists of computer-generated random numbers in a 1:1 ratio, with separate lists for Bronx VA and Indianapolis VA, in order to maintain balance in groups within each study site. There are 25 primary care PACTs in the Bronx and 41 in Indianapolis, and each PACT will keep their group assignment for the duration of the study. In Aim 1 Phase 1, enrolled patients will be assigned to notification-plus-coordination or notification-only groups according to PACT assignment.

D.3 Non-VA hospital admission and ED visit notifications. After study enrollment, a real-time notification protocol will be set up for veterans in both treatment groups who might experience a non-VA hospital admission or ED visit, which in our prior experience with this population will occur in approximately half of study patients per year. We decided to provide notification to both treatment groups 1) to enable us to study the natural response of PACT providers to notification in the notification-only group, and 2) we anticipate that notification of non-VA encounters will become standard care when feasible. The proposed technical infrastructure and flow is depicted in Figure 2. In brief, RHIOs (the Bronx RHIO and IHIE) receive ADT electronic messages (Step 1) from non-VA health care facilities when patients register for treatment at the facility. Electronic flags in patients' RHIO-managed medical records will be used to identify patients who are veterans enrolled in the proposed study (Step 2), according to study tables. Each RHIO will maintain up-to-date study tables by adding patients as they are enrolled as communicated by study staff.

For study enrollees the system will generate and transmit a message to the VA of a non-VA event. In the case of Indianapolis (Steps 3a and 4a), the message will utilize established communications protocols between VA and non-VA providers afforded by the VLER program and the eHealth Exchange, the nationwide network upon which VLER operates. VLER systems will securely deposit notification messages that will be retrieved at the Indianapolis VA on a daily basis and delivered to the patient's PACT provider. A flag in CPRS will be set to notify the provider that there is an event that can be viewed in VistaWeb. This aligns with a current VLER functionality that provides a CPRS notification to providers when non-VA data is present. The new method will notify them of a non-VA encounter when it occurs, and where. The VA provider will then be able to review the encounter diagnosis codes and past non-VA medical history in VistaWeb. The proposed infrastructure at Indianapolis has been provisionally approved by the IHIE governance board pending grant award and human subjects approval, and the implementation will be accomplished in the first 6 months of the project, utilizing technical support from the Regenstrief Institute and IHIE engineering teams, which have accomplished this implementation in this timeline for other organizations⁵. In the case of the Bronx (Steps 3b and 4b), the RHIO will deposit the notification message in the Bronx RHIO message inbox of the VA PACT provider (Appendix 1) who will retrieve it by logging in to the RHIO, using secure logon and communications protocols. The Bronx RHIO delivers notifications to a subscriber's account as soon as it is received (within hours of the non-VA admission and discharge). If the patient's provider has not undergone Bronx RHIO training or has lost his or her logon or password, the project manager will facilitate rectifying these issues.

Figure 2. Technical infrastructure to support VA provider notification of non-VA admissions and ED visits



In this study, we will do two things to detect false positives (e.g., alerts to the VA for patients without non-VA encounters, or alerts for wrong patients) and improve VA-HIE matching processes. First, RAs will check demographic information of each matched patient to ensure he or she is a VA patient, is enrolled in the study, and had a qualifying non-VA admission. If there is a false positive, the RA will log the mismatch and its reason. Second, to reduce false alerts, investigators and operations staff will review reported mismatches on a regular basis and the details will be investigated. Improvements to the matching algorithms as well as the alerting function will be suggested and implemented. Lessons learned will be shared in study publications as well as in reports to the VLER Program Office for review with other VA-HIE partners.

D. 4 Preliminary data in support of enrollment procedures and expected rates of non-VA hospital and ED use:

In a pilot study over 12 months in 2010-11 (HSRD PPO 10-064; PI, Hung), 244 of 612 (40%) patients in the Bronx VA geriatrics clinic reported using both VA and non-VA services in the past 2 years or had an identity match in the Bronx RHIO, and were approached to participate in a pilot study of a geriatric care transitions intervention following non-VA hospital or ED use. Of these 100 (41%) consented. The reasons for non-consent were: uninterested (45 patients), only used VA services (44), non-VA services used were outside the Bronx (34), refused Bronx RHIO consent (5), no-show/left before approaching (12), and lacked capacity and unable to contact surrogate (4). Enrolled patients were 81 years old on average, 98% male, 37% white, 36% black, and 20% Hispanic. Fifty-four percent reported non-VA hospital use in the prior 2 years and 76% non-VA outpatient service use. Followed for a median of 390 days, these patients experienced non-VA hospital admissions and ED visits at a rate of 0.50 per patient per year and VA hospital admissions and ED visits at a rate of 0.34 per patient per year. Of those with a non-VA hospital or ED encounter, 25% experienced a VA or non-VA hospital readmission within 90 days after non-VA discharge. The reliability of ADT notifications from

non-VA facilities in the Bronx RHIO was at least 98%. Of 54 known non-VA hospital admissions and ED visits, there was 1 missed admission alert from a facility that had an expected temporary interruption in data feeds to the Bronx RHIO, and 1 case in which we initially could not match the patient in the Bronx RHIO because of a birth date discrepancy, resulting in a short delay in being able to subscribe to this patient's ADT alerts.

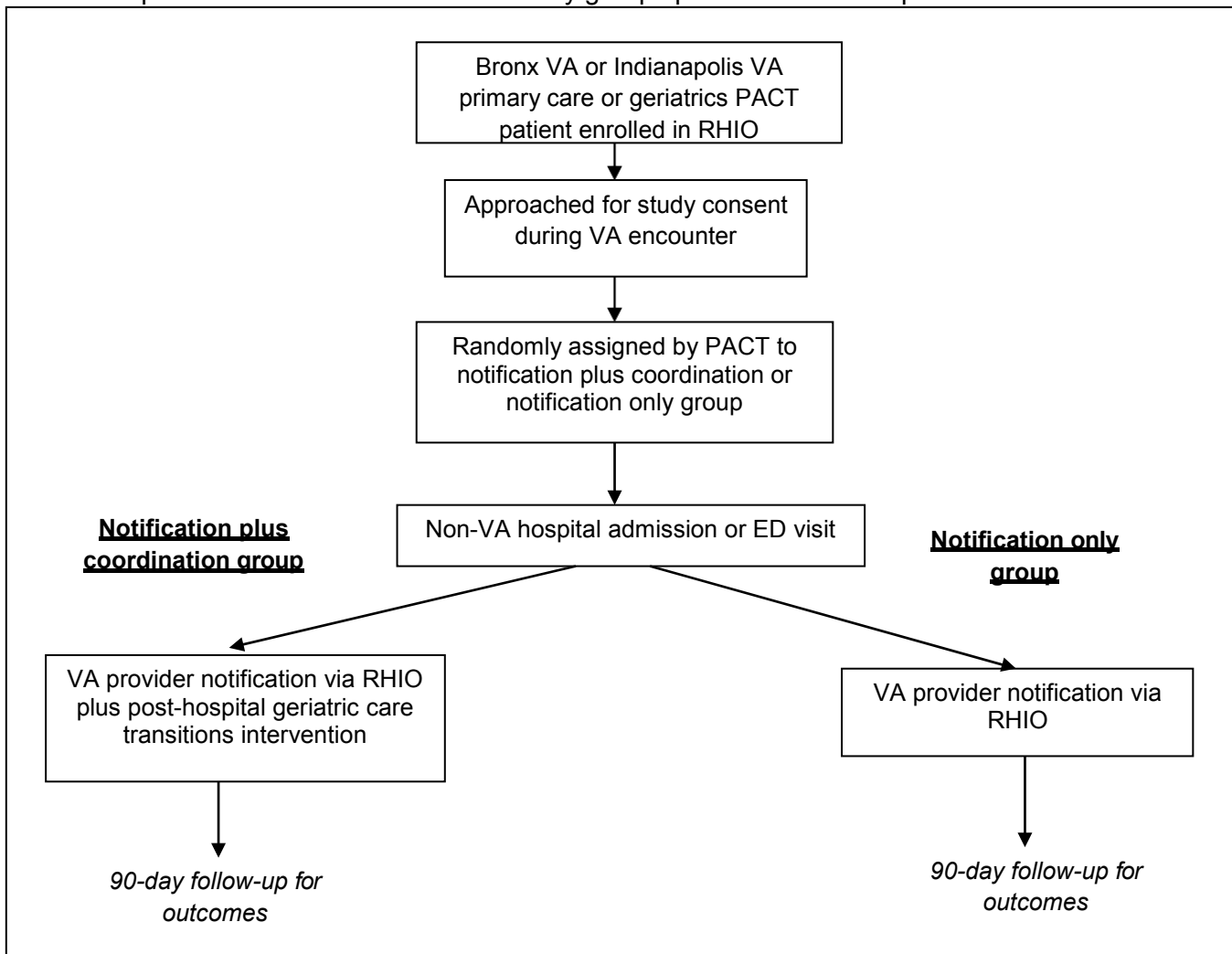
In another study at the Bronx VA testing the impact of HIE on hospital medication prescribing (HSRD IIR-10-146; PI, Boockvar), 1429 of 6202 (23%) admitted veterans had Bronx RHIO identity matches. 862 of these were approached to participate in the study and 400 (46%) consented. The most common reasons for not enrolling were: 1) discharged before approaching, 2) lacked capacity and unable to contact surrogate, and 3) patient refusal. The 112 study enrollees age ≥ 65 years (to match this proposal's eligibility) were 77 years old on average, 50% black, 24% white, and 21% Hispanic. Looking back over the previous year, the non-VA hospital admission rate was 0.32 per patient per year, not including ED visits. Of those with a non-VA hospital admission in the previous year, 33% experienced a VA or non-VA hospital readmission within 90 days after non-VA hospital discharge. We reviewed the CPRS records of those with known non-VA hospitalizations and found that in 48% of cases either there was no documentation of the non-VA hospitalization in CPRS or documentation was present but 0.5-2.5 months delayed, hindering a timely PACT response.

In Indianapolis, among 3468 VLER/RHIO-consented veterans 65 years or older, 1138 (33%) had 1 or more and 626 (18%) had 2 or more non-VA hospitalizations in the past 2 years, for a rate of 0.41 non-VA hospital admissions per patient per year. Our proposed study builds on these preliminary data in the Bronx and Indianapolis first by proposing to examine a sample of 466 non-VA hospital and ED encounters across the 2 sites using the same eligibility criteria, second by implementing direct notification of non-VA hospital encounter to the PACT provider, and third by testing a geriatric care transitions intervention response.

D.5 Geriatric care transitions intervention (notification-plus-coordination) versus notification-only. Patients assigned to notification-plus-coordination will receive a geriatric care transitions intervention for 30 days after non-VA hospital discharge or ED visit based on standardized protocols⁶ (Appendix 2). In brief, a care transitions coordinator will receive electronic notification of a patient's non-VA hospital admission or ED visit, when it occurs, in the same way as the patient's PACT provider. After notification, the care coordinator will review relevant clinical information from the local RHIO about the veteran's duration of stay in the non-VA hospital and diagnostic reason(s) for hospitalization or ED visit. The care coordinator will contact the patient (by telephone, or, if feasible with a visit to the patient in the non-VA hospital) to arrange a home visit within 1-5 days of non-VA hospital discharge or ED visit. If a patient is discharged to a rehabilitation setting, the home visit will occur within 1-5 days after rehabilitation facility discharge. During the home visit, the care coordinator will provide specific, structured activities corresponding to the 4 pillars of transitional care,⁶ including 1) reconciliation of VA and non-VA medications, 2) diagnosis-specific education and counseling, 3) creation of a patient-centered record folder containing contact information, conditions, medications, and advance directives, and 4) coordination of follow up appointments in the VA and non-VA systems. MyHealtheVet will be introduced to the older veteran if he or she is receptive and capable. The care coordinator will communicate with VA and/or non-VA providers if there are high-risk medication discrepancies⁵²⁻⁵⁴ or other questions that require timely clarification or decision-making. After the home visit, the care coordinator will remain in contact via telephone for follow up patient education and counseling for 30 days. The care coordinator will also be available to be called by patients for questions regarding diagnoses, medications, and follow up information. All encounters between the care coordinator and patient will be documented in CPRS. Thus, the transitional care coordinator will provide services that are not directly provided by PACT staff or non-VA nurses, and at a reasonably low staffing cost.

Veterans in the notification-only group, aside from provider notification, will receive usual care. In usual practice, PACT staff call the veteran after a VA hospitalization or ED visit, but may or may not call the veteran after a non-VA hospitalization or ED visit, and do not provide home visits. We hypothesize that the more intensive response (notification-plus-coordination) will reduce 90-day VA and non-VA hospital readmission and will be cost-effective from the system perspective.

Figure 3. Aim 1 Phase 1 patient enrollment, assignment and follow-up. PACTs will be randomly assigned to notification-plus- coordination or notification-only groups prior to initiation of patient enrollment.



D.6 Prior experience with geriatric care coordination activities. Both Bronx and Indianapolis VAs have experience with geriatric care transitions interventions for veterans discharged from the hospital through VA Transformation-21 (T21) initiatives, and have experience with both social workers and nurses staffing the transitions coordinator position. In 2010, the Bronx VA established a Care Transitions Program for veterans discharged from VA and non-VA hospitals. The program served 340 unique veterans through 471 hospital visits and 245 home visits. The rate of 30-day readmission to the VA hospital was 17.8%, compared with 24.4% among veterans referred to the program and eligible but who did not receive the intervention, and 23.5% in an HBPC comparison group (potential effect size range: 0.24-0.27). In Indianapolis, the Geriatric Resources Assessment and Care of Elders (GRACE) program⁵⁵—an interdisciplinary geriatric team that collaborates with PACT in the care of high-risk veterans—was adapted to the VA and as of 2012 served 179 unique veterans. GRACE patients were followed for an average of 13.6 months and versus a non-randomized comparison group had lower readmission rates at 30 days (9.5% vs. 18.2%; $p=0.05$; effect size 0.48) and a lower mortality rate (11% vs. 26%, $p<0.01$; effect size 0.58). Our study builds on these prior experiences by proposing to evaluate the geriatric care transitions intervention in a large sample at 2 sites in a cluster-

randomized design, which has not been done before in the VA setting and not in the context of VA patients who experience non-VA hospital admissions and ED visits.

In this proposal we chose to staff a social worker as the care transitions coordinator as opposed to a nurse because in our experience after hospital discharge many of the care needs of older veterans are unmet social support needs. Among 142 veterans receiving the care transitions intervention in the Bronx, of the average 1.15 unmet care needs per veteran, 51% were about arranging follow up and 27% were needs for help with activities of daily living at home. To address these gaps the transition coordinators referred 32% of patients and caregivers to VA programs such as HBPC, VA respite, VA caregiver groups and other VA services -- a total of 74 referrals. The transition coordinators also referred 23% of patient and caregivers served to community-based programs such as home delivery meal programs. In addition, we anticipate that veterans discharged home from a non-VA hospital with skilled nursing needs (e.g., needing wound care) would have a visiting nurse service already arranged, reducing a need for VA nurse visits. Of note, the Care Transitions Intervention features educational and empowerment activities that can be delivered by a social worker. Our planned sample size predicts a care transitions coordinator caseload of 5-10 per month, which in our experience is a reasonable caseload for a half-time transitions coordinator, in particular since these cases will involve coordinating VA and non-VA services and will be more complex than average.

D.7 Measures. Our evaluation design derives from a care coordination evaluation model published by the Agency for Health Research and Quality, with measures chosen to reflect the perspectives of veteran patients and family members, health care professionals, and the health care system.⁵⁶ We will also be performing a cost evaluation (Aim 2) and an implementation evaluation (Aim 3).

Primary outcome measure (patient/family and system perspective): Percentage of patients with VA and non-VA hospital admission or readmission 90 days after non-VA hospital or ED discharge (or, if the patient is not discharged home, 90 days after discharge home from a rehabilitation facility). Data on VA and non-VA hospital use will be retrieved through the local RHIO (Bronx RHIO or IHIE), CPRS, and data warehouses. *We chose hospital admission or readmission as the primary outcome because 1) it is the most commonly reported outcome in studies of geriatric care transitions interventions^{7,23,24,57,58} and a common outcome reported in studies of HIE,^{19,20} enabling comparison of our study findings with others, 2) it is frequent, 3) it is important to veteran patients, providers, and policymakers, and 4) it can be ascertained objectively with low risk of bias.*

Secondary outcome measures. Our secondary measures were selected to provide information on intermediate outcomes addressed by the HIE and care transitions intervention components.

a) Scheduled follow-up. Timely VA follow-up will be defined as a VA follow-up visit with any VA provider within 30 days of non-VA hospital discharge or ED visit. Timely phone call will be defined as VA PACT phone call within 7 days of non-VA hospital discharge or ED visit. Unscheduled ED visits will be defined as any VA or non-VA ED visits that occur during the follow up period that do not result in hospital admission. We will obtain VA encounter and phone call dates from CPRS, and non-VA encounter dates from the local RHIO.

b) High-risk medication discrepancies. These are defined as the number of discrepancies in medications classified as high risk for hospitalized older adults, including opioid analgesics, insulin, non-steroidal anti-inflammatory drugs, digoxin, antipsychotics, sedatives/hypnotics, and anticoagulants.⁵²⁻⁵⁴ In multivariate logistic regression, the number of high-risk discrepancies was a significant predictor of an adverse drug event with an odds ratio of 1.71 (95% confidence interval 1.28-2.28; p=.0003), indicating an additional 71% risk of an adverse drug event with each additional high-risk discrepancy.⁵⁹ We will obtain a count of high-risk discrepancies based on medical record review and patient or caregiver interview 30 days after non-VA hospital discharge.

c) Care Transitions Measure. This measure of condition self-knowledge and transitional care quality from the patient's perspective is ascertained by patient or caregiver interview 30 days after non-VA hospital discharge. Among 60 patients it had good construct validity; inter-item Spearman correlations with a gold standard

instrument ranged from 0.388–0.594. No significant floor or ceiling effects were detected.⁶⁰ We will use an adapted 3-item version which includes items such as: “After I left the hospital, I had all the information I needed to be able to take care of myself” with the response options strongly agree, agree, disagree, strongly disagree, and don’t know. We chose to use the 3-item rather than a 15-item version as the shorter instrument demonstrates excellent correlation with the longer version but with lower respondent burden.

d) Electronic Health Record meaningful use. In both groups we will ascertain the following process measures associated with CMS’ Meaningful Use program that are relevant to HIE notification and care transitions coordination.⁶¹ 1) percentage of patients in whom a medication reconciliation is documented in CPRS within 30 days after non-VA hospital discharge and the reconciliation includes non-VA medication information (by medical record review; CMS goal > 50%); 2) percentage of patients in whom documentation of non-VA hospital encounter is present in CPRS within 30 days after non-VA hospital encounter (by medical record review; CMS goal > 50%); and 3) percentage of patients who received patient-specific education resources within 30 days after non-VA hospital discharge (by patient interview; CMS goal > 10%).

Process measures. Our process measures provide information on processes influenced by HIE-notifications and by care transitions intervention components. We will calculate frequency of HIE-access by providers (login percent per encounter; login duration; tabs browsed) through system audits provided by Bronx RHIO and IHIE. We will calculate frequency of veteran contacts (in person and telephone) by PACT team and care transitions coordinator, using CPRS record review and coordinator logs. We will calculate percentage of care transitions intervention components delivered that were indicated using coordinator logs. At the Indianapolis VA only we will quantify information/message flow non-VA-to-VA and VA-to-non-VA using data from the VLER Office.

Patient characteristics. Descriptive or prognostic patient variables will include demographics (age, gender, ethnicity, marital status), location (Bronx or Indianapolis), socioeconomic status (Medicaid enrollment, income), chronic conditions count (modified RAND conditions⁶²), number of medications, VA and non-VA hospitalizations in the past year, and characteristics of the index non-VA hospital encounter (length of stay [ED=0], diagnoses, intensive care). The latter information will be extracted from IHIE or the Bronx RHIO. As exploratory health measures, patients at the time of enrollment and 30 days after non-VA hospital discharge will be interviewed to assess physical function (Katz Activities of Daily Living [ADL] scale⁶³ and Lawton Instrumental ADL scale⁶⁴) and cognitive function (Short Portable Mental Status Questionnaire⁶⁵) and changes calculated. All deaths will be recorded.

D.8 Data collection.

Measurement data will be obtained from electronic record review (CPRS, Bronx RHIO, IHIE), patient/family interview in person and by telephone, and data warehouses (i.e., VA Informatics and Computing Infrastructure (VINCI), Bronx RHIO, and IHIE). Study investigators have extensive experience with collecting primary patient data and with requesting and obtaining data from VA and RHIO warehouses. For electronic record review, an RA will be trained on the content and coding of each data element and data handling and transmission procedures. Before beginning record abstraction and periodically during the study, the RA will code 5-10 previously coded records. We will retrain if accuracy per chart is less than 95%. The RA will enter data into a data management program that contains prompts to correct out-of-range and inconsistent entries. For patient/family interviews, the RA will be trained to administer demographic, socioeconomic, and cognitive and physical function questions, and, 30 days after non-VA hospital discharge or ED visit an outcomes questionnaire that includes the Care Transitions Measure and medication discrepancy ascertainment. We will train the RA on the content and coding of each item and protocols to handle possible problems. Training sessions will include an overview of issues relevant to health care of older veterans, interpersonal skills, and troubleshooting (e.g., pausing or rescheduling an interview at a later date if needed). Training will also cover referral procedures for respondents who indicate symptoms that might require immediate medical assistance.

Data management and protection of confidentiality. We will create computer programs for: 1) tracking patients for eligibility, enrollment, and follow-up, 2) entering data obtained from medical records, patient interview, and

other sources, and 3) tracking receipt and completeness data. Programs will have flags for out-of-range and inconsistent entries, and double entry of data as appropriate. Data will be automatically backed up on a network VA system for storage. Scanning for computer viruses will be done routinely. To protect confidentiality, any hard copy data will be stored in a locked cabinet in a locked office. Electronic data will be stored on password-protected computers. Subject identifying information will be stored separately from other data.

After completing Aim 1 Phase 1 enrollment of 155 veterans in each of 2 groups (total n= 310), we will initiate Aim 1 Phase 2. In Aim 1 Phase 2 we will identify 300 veterans not approached in Phase 1 who fulfill study eligibility criteria, including having experienced a non-VA hospital admission or ED visit between March 2016-March 2020, but for whom no notification of the non-VA hospital encounter was provided to the PACT team. There is a pool of veterans in excess of 300 who will not have not been approached during Aim 1 Phase 1 because research assistants had competing study responsibilities (e.g., were recruiting other eligible veterans) or because of gaps in recruiting (e.g., weekends or vacations when project staff were absent). With our HIPAA waiver, we will utilize VA and HIE data warehouses at Bronx and Indianapolis to identify this pool and randomly select 150 from each site (total n=300). Then, with IRB approval for waiver of informed consent, we will conduct a review of the electronic medical records for the study outcome measures that can be obtained from record review alone (see also Section D.7.): 1) VA and non-VA hospital admission or readmission 90 days after non-VA hospital or ED discharge (primary outcome); 2) VA follow-up visit with any VA provider within 30 days of non-VA hospital discharge or ED visit; 3) VA PACT phone call within 7 days of non-VA hospital discharge or ED visit; 4) unscheduled VA or non-VA ED visit 0 days after non-VA hospital or ED discharge that does not result in hospital admission; 5) medication reconciliation documented in CPRS within 30 days after non-VA hospital discharge and the reconciliation includes non-VA medication information; and 6) documentation of non-VA hospital encounter in CPRS within 30 days after non-VA hospital encounter. We will also conduct review of medical records for patient characteristics that can be ascertained from record review alone (see also Section D.7.): demographics (age, gender, ethnicity, marital status), location (Bronx or Indianapolis), socioeconomic status (Medicaid enrollment), chronic conditions count (modified RAND conditions⁶²), number of medications, VA and non-VA hospitalizations in the past year, and characteristics of the index non-VA hospital encounter (length of stay [ED=0], diagnoses, intensive care). We will use the same data collection procedures (i.e., form, database, and data management) as that used for the prospectively enrolled participants.

D.9 Aim 2 cost data

VA costs will be ascertained for the 90 days after non-VA hospital or ED discharge. For our analyses we propose summing the direct costs for hospital, laboratory, pharmacy, radiology, nursing, surgery and other departments to yield a total direct cost variable. We will use the VA Decision Support System (DSS) National Data Extracts (NDEs) to identify these costs. We propose using only direct costs because the notification and care transitions interventions are most likely to influence care processes and costs directly associated with patient care. In addition, direct costs can be increased or decreased by changes in practice patterns and are thus amenable to change in the short run. In contrast, indirect costs usually are not changed by practice patterns and instead require major facility changes such as opening or closing a unit or clinic. The Corporate Data Warehouse contains utilization information extracted from Vista at all VAs. Subsets of this information are available in SAS datasets through VINCI. We will match patients to records using social security numbers (SSNs) of enrolled patients and dates of service. VA's Health Economics Resource Center (HERC) reports that by using patients' SSN, VAMC station identifier, admission and discharge dates, 99.8% of records in the DSS discharge NDE can be matched to the Medical SAS Inpatient Datasets,⁶⁶ indicating that this matching procedure is reliable.

Non-VA costs for the 90 days after non-VA hospital or ED discharge will be estimated from non-VA health care utilization data in the Bronx RHIO and IHIE using a method developed by investigators at HERC.⁶⁷ This method entails using multiple regression from other datasets in which costs are known to calculate beta

coefficients for predictor variables, to enable predicting costs when costs are unknown. Using this method, if a regression beta-coefficient for length of stay is 2500 from an analysis in which costs are known, then a 5-day admission is predicted to cost \$12500 when length of stay is known but not costs. Other variables shown to predict cost in models of veterans similar to our proposed participants include age, gender, marital status, ethnicity, physical function limitations, number of chronic conditions, and ICU use,⁶⁷⁻⁶⁹ variables that will be measured in our study. We will apply these models' beta coefficients to our patient data to estimate 90-day non-VA costs for each patient in our sample. A 1-2 year delay between Medicare claims and when Medicare data becomes available to VA researchers⁷⁰ prevents us from using Medicare data during this grant period.

D.10 Aims 1 and 2 data analysis: First, a descriptive summary of demographics, chronic illness count (RAND62), medication use, prior hospital use, and index hospitalization characteristics, will be generated via univariate analyses. We will use frequency tables and plots to examine the data for unusual or missing data points. To assess the balance of distribution of patients we will compare baseline information between study treatment groups (notification-plus-coordination vs. notification only vs. no notification), with analysis of variance (ANOVA) for continuous variables (if normally distributed) or the Wilcoxon rank-sum test (if not normally distributed), and the Chi-square test or Fisher's exact test for binary/categorical variables. We will compare the characteristics of patients for whom we have complete data with those for whom we have only partial study data. These analyses will indicate the extent to which missing information could affect our analyses. All tests will be 2-sided at a significance level of 5%.

D.11 Analysis of main effects. The analysis of effectiveness will test the following primary research questions:

- Does the frequency of VA or non-VA hospital readmission 90 days after non-VA hospital discharge or ED visit differ between notification-plus-coordination and notification-only plus no notification groups?
- Are the sum of VA plus non-VA costs, or either VA or non-VA costs separately, lower with notification plus coordination than with notification alone or no notification?

Secondary effects:

- Is the rate of timely VA follow-up higher with notification (with or without coordination) than without notification?
- Does the frequency of ED visits after non-VA hospital discharge or ED visit differ between the 3 groups?
- Does the incidence of high risk medication discrepancies differ between notification-plus-coordination and notification-only groups?
- Are the Care Transitions Measure score or CMS meaningful use frequencies higher with notification plus coordination than with notification alone or no notification?

All analyses will be performed as intention-to-treat, i.e. all outcomes will be included on patients assigned to treatment groups, even if they deviate from the group's intervention. We will use a generalized linear mixed model to test the effect on the primary outcome of 90-day hospital admission or readmission (0=no, 1=yes). The logit link of the binary outcome for each observation will be modeled as a linear model, with PACT as a random effect and group assignment (e.g., 0=notification only or no notification, 1=notification-plus-coordination) as a fixed effect. Inclusion of random effects in the model accounts for possible within-cluster correlation of the outcome since patients will be clustered by PACT. To estimate the intervention effect after accounting for patient characteristics, especially those found to be imbalanced between study groups from the preliminary analyses, other covariates will be added as fixed effects to the model. These covariates may include: age, gender, number of pre-admission medications, chronic illness count, and diagnosis and length of stay for the index admission (with ED visits coded as 0 days). In addition to bias reduction, this analysis may increase the power for detecting the intervention effect by reducing the unexplained variance of the outcome and add insight into factors that predispose these patients to the outcome. A similar approach will be used to test the intervention effect on secondary outcomes. For each secondary outcome, an appropriate distribution or link function will be chosen for the generalized linear mixed model, e.g. logit link for the binary outcome of scheduled follow-up, Poisson or Negative Binomial distribution for the counts of high-risk medication

discrepancies, identity or other links for Care Transitions Measure depending on the distribution of scores. For Aim 2, the cost outcome will be assumed to have a gamma distribution, with a log link in the generalized linear mixed model, since gamma is a general class of skewed distributions that include Poisson and exponential as special cases. Goodness-of-fit of each model will be assessed graphically and numerically using the method of Pan and Lin.⁷¹

Sensitivity analyses. Patients may die or leave the region during the study. The primary analyses assume that observations in drop-out periods are missing at random. To investigate whether this assumption affects the main findings, we will first analyze these patients' outcomes in additional generalized linear mixed models. If there is imbalance between groups, we will use different ways to impute missing data to make sure the overall findings are not affected. One way is to use the patients' observed data to randomly generate potential new episodes during the drop-out period (analogous to last-observation-carried-forward but making it probabilistic rather than deterministic), generate a multiple imputed dataset, and estimate the intervention effect using multiple imputation techniques. Another way is to generate probability rules using data from all similar patients. Effects of other imputations using worst case and best case scenarios may also be investigated.

Power calculations and sample size. *Our sample size estimates are based on the primary outcome. Reports of randomized studies of geriatrics care transitions interventions have reported 25-45% reductions in hospital readmissions^{6,7,65} and our own pilot data demonstrated an effect size range of 0.24-0.48 (Section D.6). Based on these figures, we postulate that the notification-only and no notification groups will have a 40% primary outcome rate while the notification-plus-coordination group will have a 26% rate in the 90-day post-discharge period, i.e. a clinically significant 35% reduction. There are several features of the study that support this large potential effect. First, the targeted patients are at very high risk of readmission because they are older utilizers of both VA and non-VA services, who have been shown in previous studies to have significantly higher readmission rates after acute illness, likely because of greater severity of illness and fragmentation of care between systems (Section B.1). Second, in contrast to veterans hospitalized in the VA who routinely receive PACT post-discharge telephone calls and follow-up, this group is naïve to any coordination intervention because PACT teams normally do not respond to non-VA hospital encounters because they do not know about them (Section C.2). Thus, we postulate more than an incremental effect. To account for possible dependence of the outcome among patients cared for by the same PACTs (clustering), we estimated the design effect⁷² based on an*

average number of subjects per PACT = 7. Assuming this intraclass correlation is 0.05 (based on our own pilot data and published literature⁷³), we need to observe a total of 466 patients with non-VA hospitalizations or ED visits (155 in the notification-plus-coordination group and at least 311 in the notification-only plus no notification groups) to detect an effect size of 0.35, with 80% power and a two-tailed test at 5% significance. If the intraclass correlation is smaller (e.g., 0.04), which may be the case for a group of patients whose care is fragmented and perhaps less influenced by PACT, then the power will be higher (Table 1). In order to achieve this sample, we will enroll 300 patients per year across the two sites for 3.25 years, with approximately 25-30% experiencing non-VA hospital encounters. Thus we will enroll 5.7 patients per week between the 2 sites; i.e., 3 per week in the Bronx VA and 3 per week in the Indianapolis VA, assuming a few drop out. Our staffing of a full time RA at each site should be able achieve that. For costs, with a sample size of 466, we will have 80% power to detect between-group differences in cost greater than 0.25 SD at 5% significance. If the variance of the distribution of cost is equal between both groups, then the difference in mean log cost is due only to the difference in the difference in mean cost.^{74,75} The effect size then reflects 80% power to detect the difference if care coordination can reduce cost by 25%. Finally, our power is 80% to detect effect sizes of 0.30 or smaller in our secondary outcome measures, which will ensure that we can identify other important effects of the intervention if they occur (Table 1).

Table 1. Power to detect effect sizes from 0.3-0.375, with cluster size = 7 (466 subjects divided among 66 PACTs) and intracluster correlation coefficient (ICC) = .04 or .05

Effect Size	ICC	Power (%) by outcome		
		90-day hospital admit or readmit (primary outcome)	Care Transitions Measure (secondary outcome)	High risk medication discrepancies (secondary outcome)
.375	.04	87	94	96
.33	.04	77	89	90
.30	.04	68	81	84
.375	.05	85	93	94
.33	.05	75	87	88
.30	.05	66	80	81

D.12 Aim 3 Overview. For Aim 3 we will collect information from the perspectives of patients and staff members to inform future approaches to implementation of HIE between VA and non-VA facilities and VA care transitions interventions. This summative evaluation will be guided by the Consolidated Framework for Implementation Research (CFIR).⁷⁶ CFIR provides an overall typology for understanding the implementation of health services research interventions, describing five interrelated major domains (intervention characteristics, outer setting, inner setting, individual characteristics, and implementation process); each domain has an additional 4 to 12 constructs attached to it. The CFIR framework is both theory-based and evidence-based, and represents the cumulative result of decades of research on implementation and diffusion.^{76,77} We hypothesize that the intervention will be perceived to be important and useful by respondents. However, implementation barriers will exist, including possible concerns about patient privacy that have been voiced in national public surveys of HIE⁷⁸ as well as challenges to effective integration of HIE into clinical workflow as identified in previous studies.^{79,80} Findings can be used 1) to refine our approaches for future implementation and 2) to inform future surveys or research with veterans on the topics of HIE and care transitions.

D.13 Interview participants and procedures. Patient participants: One out of every 20 patients will be asked 5 closed and open-ended questions at the time of telephone interview 30 days after non-VA hospital discharge, after the Care Transitions Measure, medication discrepancy questions, and cognitive and physical function questions. Patients will be selected at random from both treatment groups using computer-generated random numbers, to yield a total of 21 patients over years 2-4 of the study. Our proposed questions are adapted from

questions on health information technology in the 2011 Cornell National Social Survey⁷⁸ and are: “How do you feel about computers being used to share medical information between the VA and non-VA places where you received medical care? How do you think that affected the quality of medical care? Do you think it: improved/worsened/ had no effect [closed-ended]? Given medical information was shared electronically between the VA and non-VA places where you received medical care, how do you think that affected the privacy and security of medical information? Do you think it: improved/worsened/had no effect [closed-ended]?” Patient interviews will take 15-30 minutes and responses will be recorded by the RA by hand.

Staff participants: Bronx and Indianapolis VA staff will be recruited for interview in the last 6 months of the study, including the care coordinators, physician and non-physician PACT providers whose patients participated, primary care practice managers, administrative staff who had knowledge of the program, and VA and non-VA hospital managers -- since non-VA system representatives are stakeholders in this approach. The projected sample size is 40 staff (20 each in the Bronx and Indianapolis). Interviews will be overseen by Boockvar and Dixon, who are experienced in qualitative informatics evaluations. Questions (Appendix 3) will be adapted from the VA’s After Action Review⁸¹ and will address the perceived purpose and effectiveness of the notification of non-VA hospital and ED use, the care transitions intervention, and the importance of each component of the intervention, including the role of HIE in supporting access to non-VA information. Questions will further ask about their experiences and perspectives related to the implementation of the notification, with special emphasis on perceived strengths and weaknesses of the implementation strategy. Staff will answer questions regarding barriers and facilitators, suggestions for improvement, and the value of the intervention to the VA. Early interview questions will be broad and open-ended, followed by more specific probes, allowing participants to respond from a variety of perspectives and the researcher to uncover perceptions, attitudes, and beliefs in the respondents own words.⁸² Respondents will be encouraged to report positive and negative impressions. Staff interviews will take 30 minutes and will be audio recorded and transcribed.

D.14 Interview analysis: Notes and transcripts will be analyzed using standard social science methods for qualitative data.⁸³⁻⁸⁶ Major coding domains will be taken from the CFIR, will parallel the interview questions, and will include: 1) goals and expectations for notification of non-VA hospital or ED use, 2) goals and expectations for transitional care processes, 3) degree that the notification and coordination interventions altered or achieved those goals, 4) barriers to effective use of notification and coordination, and 4) suggestions for improvement. Investigators will apply the coding criteria to notes and transcripts by labeling each word, phrase, or line. A random 5% of transcript lines will be coded by 2 independent coders and inter-rater reliability will be assessed using percentage agreement. Disagreement will be reconciled by discussion and transcripts recoded as appropriate. In an iterative fashion, observations will be sorted into themes, similar themes will be collapsed, and others will be split into logical subthemes. A report will be produced that summarizes themes in narrative with illustrative quotes from respondents and includes tables of barriers, facilitators, and suggestions.

D.15 Safety monitoring: The Principal Investigator and Human Subjects committees will monitor the safety of the project. The chance that serious or severe adverse events will occur due to the interventions (VA provider notification of non-VA hospital admission or ED use and the care transitions intervention) or the data collection procedures (medical record review, interview, and data warehouse access) is small. However, there are risks of loss of privacy and confidentiality, concerns about which may emerge during Aim 3 interviews. We will report severe adverse events immediately to the Human Subjects committees as per policies, regardless of the events’ relationship to the research. In addition, all non-severe adverse events that are unexpected or occur at an unexpectedly high frequency will be reported immediately to the Human Subjects committees. Finally, all adverse events will be summarized annually to the Human Subjects committees in continuation or termination applications (see Human Subjects document for additional details).

D.16 Study challenges and alternate plans: Are there possible unintended adverse consequences of the intervention? Notification of non-VA hospital and ED use plus transitional care coordination is designed to increase VA providers’ awareness of veterans’ non-VA service use and improve care coordination across

settings. There exists the possibility that veterans will consider this a breach of privacy, and that VA staff will consider it an additional task burden that competes with completing other tasks. Our qualitative study will enable us to identify these issues if they occur to inform future implementation. Overall, we predict that these approaches will reduce the amount of time needed to reconcile VA and non-VA information and improve outcomes at a reasonable time tradeoff.

Will results be broadly applicable if the study is being conducted at 2 sites, the Bronx VA and Indianapolis VA, which are unusual in their partnering with local RHIOs and experience with care transitions services? HIE alerting capabilities are going to increase as a result of nationwide roll-out of HIE and VLER, as well as initiatives to address non-VA service use by veterans. The 2 sites also provide a diverse racial, ethnic, economic and geographic distribution, suggesting our findings may be applied to a number of different veteran populations.

How will we address the potential for contamination? The possibility arises that a provider (physician, nurse, or other PACT member) in the notification-only group will become aware of the transitional care coordination intervention and that this awareness will change the way that the provider manages patients in the notification-only group. At the extreme, such contamination could so improve care that the coordination intervention would falsely appear to have had no effect on study outcomes. We expect that such a degree of contamination is unlikely, however. First, providers will have patients in one group or another, but not both, throughout the study. Second, providers in the notification-only group would find it difficult to provide the level of care coordination proposed for the care transitions intervention -- due to their existing clinical care demands and because it is substantially outside standard PACT practice. Nevertheless, to detect contamination we will examine CPRS notes to determine to what extent PACT providers in either group deliver coordination components (such as post-hospital home visits). If this suggests contamination, in a re-analysis we will incorporate independent variables in our multivariable models that mark the extent of contamination; e.g., number of home visits delivered by the PACT, and attempt to control for it.

E. DISSEMINATION PLAN

We plan to distribute our study findings on HIE provider-notification of non-VA hospital use and on the care transitions intervention, their business cases, and their implementation barriers to VA operations partners -- including the Virtual Lifetime Electronic Record Program and the VA Office of Geriatrics and Extended Care -- so that findings can be used to inform decisions about intervention spread within the VA. Investigators have extensive experience presenting in VA forums such as Geriatrics Research Education and Clinical Center (GRECC) Directors meetings and HSRD meetings that will facilitate this dissemination. Investigators also have longstanding relationships with decision-makers in a variety VA operations offices that will facilitate rapid communication of study findings. We will also share our findings on the HIE needs and challenges of geriatrics patients, care coordinators, and other providers with the Indianapolis HSRD Center for Health Information and Communication (CHIC), to inform their research approaches and triangulate their findings. Finally, We will share potentially generalizable findings with non-VA stakeholder groups, such as the American Medical Informatics Association, the American Geriatrics Society, the Agency for Health Research and Quality, and CMS. This dissemination plan will be implemented in year 4 of the project and maximize the project's impact.

F. PROJECT MANAGEMENT PLAN

F.1 Research team and roles. The project will be managed from the Bronx VA GRECC and the Indianapolis VA CHIC offices. Dixon and Baker will oversee HIE alert implementation at the Indianapolis VA. Two RAs will recruit, interview, and track patient participants, and perform medical record reviews. A project manager will oversee day-to-day activities, ensure processes are harmonized between Bronx and Indianapolis, and assist with report writing and study monitoring. Care coordinators at each site will deliver the care transitions interventions, led by Boockvar and Hung at the Bronx VA and Schubert at the Indianapolis VA. Travel is scheduled for RAs, and separately the care coordinators, and project manager to come together either at Indianapolis VA or Bronx VA to ensure fidelity to study procedures. The statistical programmer and data

manager will collaborate on the provider randomization and on data entry, cleaning, and analysis. Dr. Penrod will oversee the quantitative and cost analyses. The research working group (Boockvar, Hung, Dixon, Schubert, Penrod) will meet weekly initially and then twice monthly. This group will a) oversee the conduct of the study; b) resolve implementation and methodologic problems; c) refine study procedures; d) overcome intervention difficulties and barriers; e) handle questionable outcome events and missing data; and f) oversee analyses, publications, and dissemination. Drs. Boockvar and Dixon will conduct qualitative data collection and analysis. All investigators will be involved in completion of reports and dissemination.

F.2 Timeline. This is a 4-year project (Table 2). Aim 1 will have 3 months startup for hiring staff and finalizing protocols. At Indianapolis, the system engineering team at the Regenstrief Institute that is responsible for the IHIE infrastructure will create the mechanisms necessary to enable the notifications of non-VA hospital admission and ED visit. This capability is already in place at Bronx VA through the Bronx RHIO. Patient enrollment can start beginning month 3 for Bronx VA and month 6 for Indianapolis VA. Data collection, entering, and cleaning will be conducted simultaneously months 3-45 (total enrollment and follow-up time = 3.5 years). Aim 2 obtaining VA cost data and generating non-VA cost estimates will occur in month 45 followed by data analysis and report writing. Aim 3 interviews of patients will occur at their exit interview 30 days after non-VA hospital discharge. Interviews with staff members and other stakeholders will occur months 45-46, followed by interview transcription and qualitative data analysis and report writing (Table 2).

Table 2. Project timeline

Activity		Project Period (by quarter): Total Duration = 54 Months																			
		Project Y1				Project Y2				Project Y3				Project Y4				Proj Y5			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2		
Pre-project	IRB application																				
	Bronx notification service																				
Aim 1	Indianapolis notification service	X	X																		
	Finalize data collection protocols	X																			
	Pilot & refine recruitment protocols	X	X																		
	Identify, enroll, assign patients		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X				
	Collect follow-up data		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X				
	Clean and enter data			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
	Identify usual care patients and collect data																		X		
Aim 2	Obtain / generate cost data																		X		
Aims 1&2	Analyze quantitative data																		X X		
Aim 3	Conduct patient interviews					X	X	X	X	X	X	X	X	X	X	X					
	Conduct staff interviews														X	X					
	Transcribe staff interviews														X	X					
	Analyze qualitative data															X	X				
Overall	Reports/dissemination activities																		X		

F.3 Facilities and resources contributed by others (see facilities document and letters of support). The project will be administered from the Bronx VA, within the GRECC. The GRECC will supply office space for Boockvar, Hung, Penrod, the Bronx VA research assistant, the project manager, the statistical programmer, and the data manager. Desktop computers linked to central servers are available for accessing and entering study data into a server-based database that will be accessible to Indianapolis and Bronx research staff. GRECC computers are equipped with software for data entry, management, and analysis, including SAS and STATA. The Bronx RHIO is supported by membership fees, CMS, and New York State, and has offices close to the Bronx VA. The project will be supported by the Indianapolis VA HSRD CHIC, where an RA and Dr. Dixon will have workstations. The Indianapolis VA HIE-provider notification will be provided by IHIE. In the Bronx and Indianapolis the care transitions coordinators will have workstations either in research or clinical practice areas.