Department of Veterans Affairs
Quality Enhancement Research Initiative (QUERI)

Ischemic Heart Disease QUERI Center

Strategic Plan

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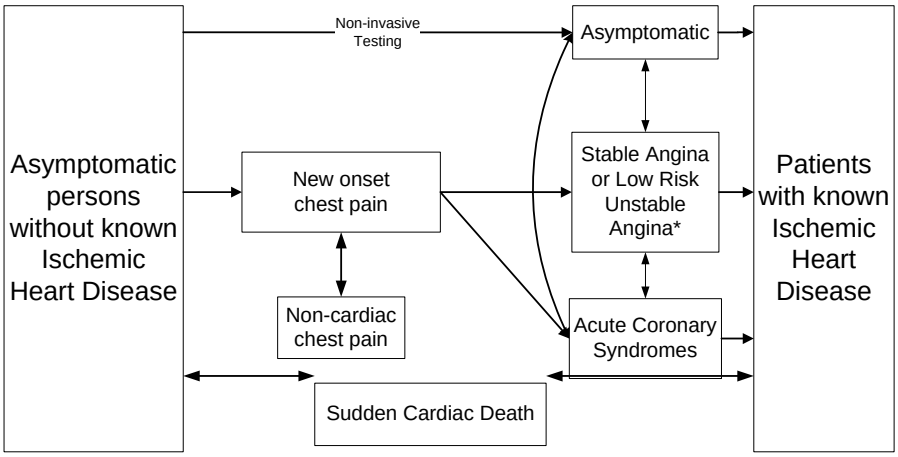
Ischemic Heart Disease QuERI Strategic Plan

Executive Summary

This year we have substantially revised our center goals, while also emphasizing that the updated goals build directly upon prior Ischemic Heart Disease (IHD) QuERI work and successes. For the first decade of IHD QuERI's existence, our goals centered on discrete disease states, i.e., to improve the quality of care and outcomes for patients with specific acute and/or chronic clinical conditions related to IHD. While those objectives remain integral to our mission, several trends over the past five years have transformed the manner in which our investigators and Executive Committee view our current goals. These include:

- Recognition that **IHD is a dynamic continuum** rather than a series of isolated clinical stages. In the past, national IHD prevention guidelines defined recommendations based on presence of known IHD, which is somewhat arbitrary because patients tend to repeatedly go through acute and chronic phases of IHD. (Figure 1) Moreover, many patients with undiagnosed IHD may have a risk of adverse events that is as high, or higher than those with known IHD and need to be treated accordingly. In fact, patients' risk of cardiac events may not correspond with extent of disease. Given that IHD remains the leading cause of mortality in the U.S., the latest IHD prevention guidelines focus instead on **prospective risk-factor management** (*see Figure 1*).

Figure 1: IHD as a Dynamic Continuum



- Increasing emphasis on **assessing the effectiveness and safety** of therapies (e.g., medications, devices, diagnostic testing) applied in clinical practice. Currently, cardiovascular therapies are demonstrated to be efficacious in selected patient populations in clinical trials and then approved for routine use. However, in routine clinical practice, these therapies are often provided to patients or in clinical scenarios not tested in research

trials, potentially leading to differences in effectiveness and safety. This requires development of methodologies to assess the effectiveness and safety of treatments as they are being used in practice.

- Further, there has been increasing focus on **improving systems of care** as opposed to discrete processes of care. The VA has successfully increased provider adherence to many specific processes of care, such as prescribing aspirin and beta-blockers for patients with AMI. Moreover, survival following AMI has improved significantly over the past decade [1]. Yet, new challenges abound, including suboptimal cardiovascular risk factor management, poor patient adherence to medications and behavior changes, and the necessity for **better care coordination across settings**. Improving individual clinical processes or technologies without addressing these large system issues is unlikely to translate into meaningful gains in quality of care.
- A shift to **team-based, patient-centered, coordinated care**. Nationally, there is an increased focus on patient-centered care and outcomes, and the need to solicit and address patients' needs and preferences. The patient-centered medical home (PCMH) model of care, being implemented in the VA as the patient-aligned care team (PACT), aims to establish primary care teams as the hub of care coordination to improve care continuity and access. National implementation of PACT creates opportunities to improve care, but also requires innovative thinking about how research-based practices can be developed, evaluated and integrated into new and evolving models of care. Of particular significance for IHD are goals to improve coordination of care among specialists and with primary care, and to **proactively manage patient risk factors**.

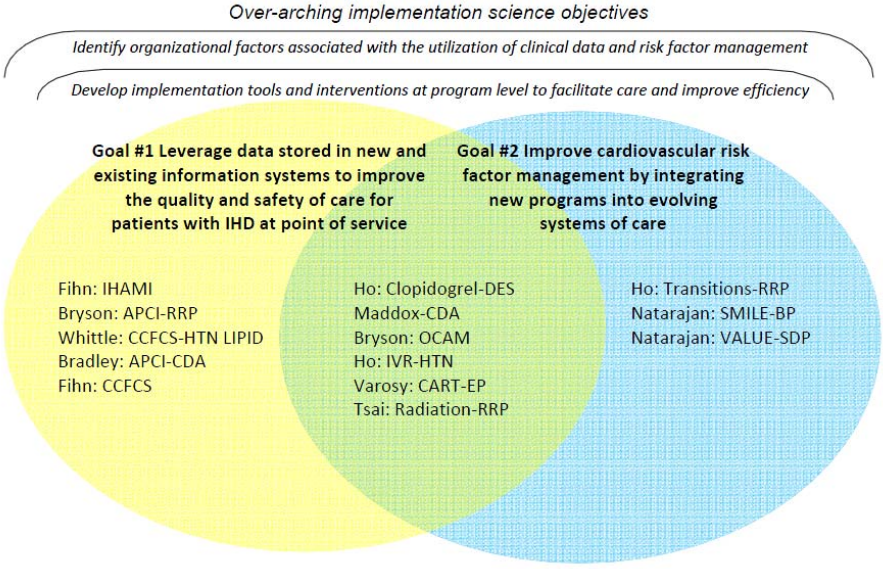
Thus, to reflect the trends described above, and following discussions with our Executive Committee members, affiliated investigators, national opinion leaders, and stakeholders in operations, we have framed the following goals that focus on creating and using change platforms to improve quality of care and clinical outcomes. By **change platforms**, we mean systems or care models that can be used to implement new practices. These change platforms can only be established through close coordination with VHA operational units:

Goal #1: Leverage data stored in new and existing information systems to improve the quality and safety of care for IHD patients at point of service. A major effort over the past five years has been developing data systems in collaboration with VA operations, specifically the CART platform and the Cardiac Care Follow-up Clinical Study (CCFCS) data

repository. IHD QuERI investigators and analysts have also been involved in developing the Quality Information Resource (#XVA 61-040, QIR) for the Office of Patient Care Services. These data systems can serve as powerful resources—as change platforms--for ambitious research studies aimed at improving value and safety. This strategic goal is exemplified by specific projects such as: using CCFCS data to better understand racial disparities in care for ACS, Better Hypertension and lipid care in racially diverse, veterans at risk, (#RRP09-123, HTN-LIPID) combining the existing data in the CCFCS repository with data from systematic medical record abstractions to identify factors related to in-hospital AMI, Predictors and Outcomes of In-hospital Acute Myocardial Infarction (#EPID-006-07F, IHAMI); using the CART platform to systematically track and provide decision-support to reduce radiation exposure, Characterization and Predictors of High Radiation Exposure in the Cardiac Catheterization Laboratory (Radiation RRP); develop and implement an electrophysiology module for CART in order to better track the use of cardiac devices, Implementation of the VA Clinical Assessment, Reporting, and Tracking Cardiac Electrophysiology Module (SDP, CART-EP); and improve appropriate use of PCI (Appropriateness of Percutaneous Coronary Intervention, #RRP 09-140, APCI).

Goal #2: Improve cardiovascular risk factor management by integrating new programs into evolving systems of care. Our vision is to develop and package risk factor management strategies that can be readily integrated into care systems, notably through IT systems, such as CART, and as part of the new models of care in the national implementation of the patient aligned care team (PACT). These include projects to use interactive voice response technology to

Figure 2: Overlapping Major Goals with Projects



support patient self-management, Pilot Intervention to Improve the Transition from Hospital to Home Following Hospitalization for a Cardiac Condition (RRP, TRANSITIONS); improve the coordination of care between cardiology and referring primary care providers (TRANSITIONS); and develop a toolkit for implementing a stage-matched BP management intervention, The Smile BP Toolkit: Implementing VA Research to Improve Hypertension Control (#RRP 11-016, SMILE-BP). IHD QuERI investigators are also involved in the national evaluation of the PACT model, and are well positioned to identify gaps and opportunities to help improve PACT implementation.

Implementation science. In addition to improving clinical outcomes, we endeavor to advance implementation science through a better understanding of how effective change platforms can stimulate large-scale, sustainable implementation of new care practices. This is reflected both in our choice of center goals, which correspond to two of Secretary Shinseki's transformational initiatives, and in overarching implementation science goals (Figure 2). A majority of our planned projects are designed to **develop interventions to be implemented by taking advantage of the CART platform or anticipating developments related to the PACT**. Routine clinical data systems, such as CART, and the new models of care being implemented as the PACT, are two of the most readily exploitable change platforms in VHA. From our work with VACO partners on CART implementation, QIR and the PACT evaluation, we have a better understanding of the needs of clinical operations, and are in a position to test interventions where there is considerable "pull" from the clinical system, and where we are well-situated to evaluate implementation process and outcomes. We also have a range of projects planned to expand our work to **improve measurement and understanding of organizational context**. This includes ongoing research to identify specific clinical structures that influence medication adherence, Organizational Correlates of Adherence to Medication (#IIR 07-068, OCAM) and factors related to organizational readiness to implement new practices, Predicting implementation from organizational readiness to change (IIR-09-067, ORCA testing) and planned work to develop tools and interventions from this work.

We also have two important changes in project management for IHD QuERI. First, John Rumsfeld, MD PhD will share Clinical Coordinator responsibilities with Michael Ho, MD, PhD, a nationally-recognized cardiologist, highly accomplished health services investigator, long-time IHD QuERI-affiliated investigator and member of the IHD QuERI team in Denver. Dr. Ho will

share the responsibilities of the Clinical Coordinator with Dr. Rumsfeld, who has taken on the role of Acting National Program Director for Cardiology for VA Patient Care Services. Second, this year Blake Wood joined our team as our new Administrative Coordinator, replacing Mary McDonell. Mr. Wood will also assume some of the Implementation Research Coordinator duties, and serve as co-IRC with Dr. Helfrich. Mr. Wood studied Industrial and Systems Engineering under QI researcher David Gustafson at the University of Wisconsin, Madison and his background in operations research and biostatistics provides a nice complement to Dr. Helfrich's background in organizational behavior.

Over the next five years, the IHD QuERI will conduct a range of studies that leverage VA systems to improve quality and safety, and integrate cardiovascular risk factor management into care systems. In many cases, these projects will exploit platforms that we have spent the last decade helping to create, and will respond to the needs of the new PACT model to provide integrated, patient-centered care. While these are new goals, they also reflect our long-standing successful collaboration with VA operations, developing interventions that respond to operational needs, and leading to successful implementation effort to improve the quality of care and outcomes of veterans with IHD.

1. Clinical Focus and Scope

For the first decade of IHD QuERI's existence, our goals centered on discrete disease states, i.e., to improve the quality of care and outcomes for patients with specific acute and/or chronic IHD conditions. Our focus and scope were correspondingly defined in terms of these conditions and their care processes, such as emergency care for ACS, hyperlipidemia screening and treatment, and management of chronic stable angina. While these objectives remain integral to our mission, we have reframed our focus and scope to think more broadly and approach IHD as a disease continuum rather than focusing on discrete stages of disease. As a result, our center goals are driven less by specific clinical foci within IHD, but rather more by efforts to develop and exploit specific platforms for interventions with our operational partners. Specifically, we will leverage data systems and integrate new programs into care systems to improve risk factor management which has the potential to improve the entire range of the disease continuum.

Nonetheless, our current and planned projects emphasize specific clinical foci. These include improving quality and safety of cardiac procedures; understanding and addressing influences of patient adherence, risk factor modification, and improving care coordination. The important distinction is that our center goals are not predicated on specific clinical foci, but follow from the priorities developed in concert with our stakeholders and operational partners, and represent the best opportunities to meet our center goals of leveraging data and integrating risk factor management to improve quality and safety. Thus, our clinical foci are not so much drivers of our strategic plan as logical corollaries of it, and consequently can, and probably will, change significantly over the course of the next three years.

There are a number of clinical domains or processes that presently are not a focus of IHD QuERI investigators. Most notably, we are not working on non-medical, behavior-related risk factors, such as improving diet, exercise and weight loss. These are critical factors, but there is currently a more limited evidence-base for effective behavioral change strategies within health settings [2] than for medical interventions (Fihn et al, in press), and much of the most promising work in risk behavior modification involves policy interventions at a population level [3] [4]. In addition, we will not focus on diagnostic testing strategies for IHD (e.g., use of nuclear stress tests, stress echo, etc) or cardiac imaging (MRI, PET scanning, etc.), an area where we have limited resources and expertise. We are presently not studying emergency care for ACS,

an area in which we have already completed substantial work in the past, Evaluating Quality of Care for Acute Coronary Syndromes in VHA (#SDR 03-289, ACS) IHD QUERI Emergency Department Technical Assistance Project (OQP, EDQI-TAP), and where there are a broad range of programs and tools available to support improvement work (e.g., American College of Cardiology's D2B initiative; American Heart Association's Get with the Guidelines program; University of Virginia's Project UPSTART). As IHD-QUERI continues to grow and we form new collaborations with investigators and/or clinical operations, we may target these or other domains for further investigation.

Reason for framing clinical focus and scope differently

Several factors led us to reframe our clinical focus and scope, including some of the larger trends discussed above: the broad recognition that **IHD is a dynamic continuum** in which conditions are inter-related and chronically progressive rather than simply distinct episodes; an increasing emphasis on **assessing the effectiveness and safety** of therapies (e.g., medications, devices, diagnostic testing) applied in clinical practice; increasing focus on **improving systems of care** as opposed to discrete processes of care; and a shift to **team-based, patient-centered, coordinated care**, most notably in the form of the patient-centered medical home (PCMH) model of care, being implemented in the VA as patient-aligned care teams (PACT). These trends all generally require a broader, rather than a narrower, clinical focus and scope.

Second, **IHD QuERI team members can achieve greater synergies through shared focus on developing and exploiting particular platforms and partnerships**, rather than a shared focus on a specific clinical condition (e.g., AMI) or process (e.g. lipid testing). By platforms, we mean specific data systems (e.g., CART, CCFCS) or models of care (e.g., PACT) that are amenable to data-driven interventions. A good example is the CART platform, which we developed in collaboration with PCS, and are now developing new modules to address additional conditions and procedures. An IHD QuERI affiliated investigator is leading development of a CART electrophysiology (EP) module, and planning a quasi-experimental study of CART-EP implementation. CART-EP will standardize data collection of EP procedures (e.g., AICD implantation and ablation procedures) and will be linked to the VA National Cardiac Device Surveillance Program (NCDSP) to improve the quality, safety and monitoring of implanted cardiac devices. The development of CART-EP provides an excellent example of

leveraging our expertise with the CART platform, and addressing the priorities and opportunities identified in collaboration with our partners in operations.

Third, the **VA already has a strong secular trend of improvement, for existing performance measures that focus on discrete IHD clinical processes or cohorts** (e.g., medications for patients hospitalized for AMI, outpatient management of patients with hypertension and hyperlipidemia). Thus, the IHD QuERI team will be focusing energy on improving utilization of data, integrating new programs into evolving systems of care, and systematically planning and measuring implementation of these programs.

How we selected our focus

We redefined the way we think of our clinical focus and scope based on discussions with our EC members and investigators, and with partners in clinical operations.

Our EC met in May 2010 in conjunction with the AHA Quality of Care and Outcomes conference, in addition to holding two conference calls. Our EC members, including Principal Deputy Under Secretary for Health, Robert Jesse MD PhD, encouraged us in shifting our thinking away from disease states toward the continuum of care, and to focus on working with clinical operations to create sustainable quality improvement platforms. Dr. Jesse in particular has emphasized transactional quality improvement: i.e., building quality improvement tracking and interventions into the clinical system, not making it a parallel system. This notion of building quality assessment and improvement mechanisms into clinical and administrative operations is a foundation of the quality movement and systems engineering [5] and a key aim of current health care redesign efforts [6]. National thought leaders in cardiology, including Eric Peterson at Duke University, John Spertus at the Mid America Heart Institute, and Laura Petersen at VA Houston COE, endorsed our new goals and a broader notion of our clinical focus and scope.

In a series of team meetings from June through October 2010, IHD QuERI investigators identified two fundamental clinical areas related to cardiovascular risk reduction: (1) medicine/medication related factors (i.e. blood pressure, lipids), and (2) lifestyle related factors (exercise, smoking, weight loss). Over the past several years, we have consciously elected to concentrate on medication related factors because they are most readily influenced by health care systems through improved delivery, monitoring and adherence, whereas the locus of control for the lifestyle changes is the patient/home, and work on the latter topic would require investigators with a different skill set than we presently have (e.g., health behaviorists, psychologists, etc.)

We also have ongoing collaborations with operations that have underscored the effectiveness of focusing on our core strengths of leveraging data systems, and building upon our partnerships. Our investigators are heavily involved in clinical operations, notably CART management (Drs. Maddox, Rumsfeld, Tsai, Varosy, Fihn, Plomondon and Ms. Box), the Quality Information Resource (Drs. Fihn, Lowy, Maynard, Bryson), and the Patient Aligned Care Team Demo Lab Coordinating Center (Drs. Fihn, Lowy, Maynard, Bryson, Nelson, Helfrich). These operational activities would not have evolved without the QUERI infrastructure enabling collaborations between various units and personnel: research, operations, and quality. The extent and depth of that collaboration has increased over the past two years, and as a result we have new opportunities to develop QUERI projects that meet the needs of our operational stakeholders through these collaborations.

Defining major goals in terms of data and care systems, as opposed to disease states, facilitates prioritizing clinical issues that are most amenable to study and ultimately improvement given our current resources and expertise.

Overlap with other QUERI teams

Our focus and scope overlap significantly with the CHF, DM and Stroke QUERIs, and we manage this overlap through regular communication and collaboration on specific projects, particularly with CHF QUERI. In addition to Paul Heidenreich, the CHF QuERI Director serving on our Executive Committees, the IRCs of the CHF and IHD QuERIs routinely join the others' regular team calls. We have multiple partner collaborations, including our investigators on an quality improvement initiative from PCS to model and anticipate heart failure hospitalizations (QIR project with CHF-QUERI); a study of collaborative care and depression care for heart failure, Patient-Centered Disease Management for Heart Failure Trial (#IIR 06-068, PCDM), an RRP to develop new performance measures for diabetes (DM QUERI); and sponsoring an RRP, with an SDP in development, for blood pressure control (Stroke QUERI).

2. Significance and Consequences

The annual death rates from ischemic heart disease (IHD) in North America have steadily declined in North America since 1968; between 1996 and 2006, the annual death rate declined 36.4%, and the actual number of deaths declined 21.9% [7]. Death rates remain higher for males and African-Americans (relative to females and whites) [7], and IHD remains the

number one cause of death in men and women, accounting for 1 of every 6 deaths in the United States. In the US in 2010, the total estimated cost (direct and indirect) for caring for patients with IHD exceeded $177 billion.[7] Precise figures are not available on the prevalence of IHD among VHA patients, however, over 500,000 VHA patients have a diagnosis of IHD, and it is a leading cause of mortality and hospitalization for Veterans.[8, 9] Each year, there are approximately 9,000 admissions for AMI to VHA facilities, and approximately 2,500 AMIs among patients admitted to VHA facilities for other conditions (unpublished CCFCS data). In FY 2008, chronic IHD was the third most frequent discharge diagnosis for VHA hospitalizations, after affective psychoses and chronic heart failure, accounting for 20,651 of 588,856 hospital discharges {Maynard, In press #2065}. Based on analyses of VA spending on chronic conditions in 2008, VERC calculates that the annual cost of caring for IHD is $3,187 per patient.

At the same time that IHD-related mortality has declined, the prevalence of key risk factors is increasing. Risk factors that promote atherosclerosis in both men and women include hypertension, diabetes mellitus, dyslipidemia, smoking and obesity [10]. The prevalence of obesity [11, 12], hypertension [13] and diabetes mellitus [14] are rapidly increasing in the US. Some projections suggest that the related burden of mortality, greater than 200,000 preventable deaths [15] and accounting for 5.5%-7.0% of all US health expenditures from obesity alone, will be so severe that it will soon reverse centuries of steady improvements in life expectancy [16]. In the general population, Veterans have similar rates of overweight and obesity [17] and higher rates of physical activity as compared with non-Veterans [18]. However, among Veterans who obtain care from VA, the prevalence of obesity is significantly higher [17] and physical activity significantly lower than for the non-Veteran population [18]. The prevalence of diabetes mellitus among Veterans is approximately 20% and appears to be increasing [19].

3. Treatment and Management Evidence Base

The VA/DoD Clinical Practice Working Group updated the guidelines for the management of IHD in November 2003,[20] with a further update in 2004 following the release of updated guidelines for the management of STEMI. A further update of ACC/AHA guideline for management of stable ischemic heart disease will be published in early 2011. The VA document is a large, omnibus guideline covering each of the three foci: acute phase, chronic illness care, and secondary prevention, and synthesizes national guidelines, mainly a joint guideline from the American College of Cardiology (ACC), the American Heart Association (AHA), the American

College of Physicians, the American Society of Internal Medicine (ACP-ASIM), and in part on other national guidelines, such as the Joint National Council on Hypertension VII Report (JNC-VII)[21] and the National Cholesterol Education Program, Adult Treatment Panel III (NCEP-ATPIII).[22, 23] The ACC/AHA also produce guidelines for management of STEMI, NSTEMI/unstable angina, and stable ischemic heart disease [24] and these have been adopted by VHA.

Guidelines for acute coronary syndromes emphasize the importance and timing of revascularization therapy. For patients with STEMI, there is strong evidence to support revascularization with emergency coronary angioplasty within 90 minutes of presentation (Class I, Level B) or thrombolytic drugs within 30 minutes (Class I, Level B) of presentation to restore blood flow in the occluded artery and minimize myocardial injury [25]. The importance of revascularization strategies in the early therapy of patients with NSTEMI or unstable angina is less well defined, with evidence suggesting patients at higher risk for recurrent acute coronary syndromes experience greater benefit from urgent revascularization [26].

Following treatment of the acute event, the focus of ongoing therapy is the management of symptoms (e.g. angina) and prevention of recurrent events, mainly through risk factor reduction. For patients who have experienced an acute coronary syndrome, antiplatelet therapy (notably aspirin), beta blockers treatment, ACE inhibitors use, and lipid lowering therapy (particularly HMG CoA reductase inhibitors) are all known to be effective in reducing mortality [20]. Levels of evidence for these treatments are Class I (Level A) to Class IIa (Level B). VHA has had performance measures for the treatment of IHD with beta blockers, aspirin, and ACE inhibitors for several years. Failure of patients to adhere to these therapies significantly increases risk of adverse events and mortality [27]. Optimizing patient adherence to risk factor reduction therapies are a key component of the IHD guidelines.

In addition to these therapies, treatment goals for hypertension and hyperlipidemia are a part of guidelines for risk factor reduction in patients with IHD. As a risk factor for cardiovascular disease, hypertension is associated with considerable morbidity and mortality. The JNC-VII[21, 28] convenes periodically to synthesize the research on hypertension for busy clinicians and public health workers in the form of a guideline report. In addition, the NHLBI convenes the Adult Treatment Panel (ATP) periodically to synthesize the evidence on hyperlipidemia treatment in the form of a guideline report {Grundy, 2002 #2066}. The latest update (ATP-IV) is

anticipated in late 2011. The guidelines of JNC-VII and ATP are consistent with the recommendations of the risk factor modification goals of ACC/AHA guidelines.

Despite this apparent consensus, there is ongoing debate about the relative merit of treating lipids to a goal level [29]. The majority of randomized trials that demonstrated clinical benefit to lipid lowering therapy treated patients with a therapy at a specific dose and did not treat to lipid goals {Anonymous, 1994 #890}, {Anonymous, 1998 #891}, {Anonymous, 2002 #892}, {Colhoun, 2004 #893}. As a result, the majority of observed benefit of lipid lowering therapy may represent an effective therapy at an effective dose and not the achievement of a specific lipid goal. The IHD QuERI is exploring the impact of a performance measure for lipid lowering using treatment with appropriate lipid lowering therapy as compared to achievement of lipid goal, Process Oriented Validated Electronic Performance Measures Pilot Study (#RRP 09-139, PROVE-PM).

Additional evidence to support previous recommendations that revascularization with coronary angioplasty should not be the primary therapeutic approach for most patients with stable IHD was recently reported from a collaborative VA randomized trial [30]. In this study, angioplasty offered no mortality benefit and only a relatively small and temporary symptom benefit. The primary benefit for elective angioplasty was anginal symptom relief, and no effect was noted in mortality or recurrent MI. Despite this work, the degree to which percutaneous coronary intervention is performed appropriately, as determined by concordance with guidelines, is unclear. Recently published appropriate use criteria are intended to serve as a practical tool to quantify the 'appropriateness' of percutaneous coronary interventions (PCI) for a variety of clinical scenarios and support the effective and efficient use of PCI [31].

Even though more than 1 million percutaneous coronary procedures are performed annually in the U.S., substantial gaps in knowledge remain regarding best practices in the peri-procedural and long term care of patients after PCI. Coronary stents are routinely placed during percutaneous coronary angioplasty with the majority of stents being drug eluting (DES). A key adjunct to coronary stents is use of dual anti-platelet therapy (aspirin and a thienopyridine), both periprocedurally and in long term follow-up. Two more potent thienopyridine medications (prasugrel and ticagrelor) have been demonstrated to reduce post-procedural coronary events compared with clopidogrel. This benefit is offset by an increased risk of bleeding, particularly in patients 65 years or older [32]. In addition to confusion over optimal choice of thienopyridine, the optimal duration of thienopyridine use remains unclear with current guidelines supporting a

minimum of 1 month and ideally up to a year for bare metal stents (Class I, Level B) and a minimum of 12 months for DES (Class I, Level B) [26]. It is unclear how concurrent use of warfarin therapy for separate indications (i.e. atrial fibrillation, deep venous thrombosis, etc) or comorbid conditions influence these recommendations. In addition to the importance of therapies to reduce the risk of coronary thrombosis, increasing attention is being given to reducing risk for bleeding, the most common major complication of the anti-platelet and anticoagulant therapies [33]. Strategies to reduced bleeding include use of a radial access approach for percutaneous coronary procedures, vascular closure devices, and bivalrudin. These strategies appear to significantly reduce risk of bleeding, and in some cases mortality [34]. Recent studies have suggested a risk-treatment paradox in which patients at higher risk of bleeding are less likely to receive treatment approaches designed to reduce bleeding risk [35]. In summary, significant opportunities exist to refine the understanding of optimal use and adjuvant care of patients undergoing percutaneous coronary intervention for coronary artery disease.

In the Veterans Health Administration, about 10,000 PCIs are done annually. The results of these procedures are recorded in the Clinical Assessment Reporting and Tracking - Catheterization Laboratory (CART-CL) system. Data are entered according to specifications from the American College of Cardiology National Cardiac Data Cardiac Registry (NCDR) Catheterization PCI Registry version 4.3.1. NCDR benchmark reports, which are provided to participants, do not currently include appropriateness measures, something that is of considerable interest to VHA. ACC-NCDR personnel are planning to operationalize these measures, but it is not clear when this work will be completed.

Patient safety, particularly in hospitals, remains a high priority. A recent report from the US Office of the Inspector General on adverse events in hospitals among Medicare patients, concludes that adverse events likely contributed to 180,000 deaths in 2008, and 44% of the adverse events were likely preventable. The estimated costs for care related to adverse events was roughly $4.4 billion for 2008, or 3.5% of Medicare inpatient expenditures [36]. There is also increasing recognition of the value of post-market surveillance, i.e., tracking long term outcomes and complications for drugs and devices. For many cardiac devices, safety problems may only become apparent with long term use, after the device has received FDA approval and is on the market. In this situation, adverse events that represent true safety issues may be difficult to detect [37]. Recent studies suggest that clinical registries, like CART-CL, can be used

prospectively for surveillance to identify low-frequency safety signals in the use of new cardiovascular devices [38].

4. Current Practices and Quality/Outcome Gaps

For care in the US overall, there remain significant gaps in the implementation of best practices for IHD. For example, between 10-40% of patients with acute coronary syndromes (depending on the specific measure) do not receive guideline-indicated therapies at discharge even when they are eligible [39], and as few as a third of eligible patients receive cardiac reperfusion therapy within guideline specified timeframes.[40, 41] and a large proportion do not receive guideline-indicated therapies at discharge even when eligible. [39] Moreover, there is consistent evidence of regional variations in care processes and patient outcomes that persists after risk adjustment [42, 43], including for AMI care in the VHA [44].

Within the past seven years, two studies comparing VA to Medicare have raised concerns about worse outcomes for VA myocardial infarction patients and underuse of cardiac catheterization, and coronary revascularization.[45, 46] Prior research has found geographic variation in AMI quality of care and outcomes for Veterans at VHA facilities [44]. In November 2003, the VA launched a multi-faceted cardiac care initiative, in which IHD QuERI played a major role in both support and evaluation. Our subsequent research suggests that the observed outcome differences may be attributable to patients who developed an AMI after presenting to the hospital with another medical condition. These patients have higher in-hospital mortality risk compared to patients presenting with an AMI, and prior studies evaluating outcomes of VA AMI patients may have inappropriately included these patients [47]. Analyses using both the External Peer Review Program data from the VA Office of Quality and Performance, and Medicare and VA administrative data indicate that mortality for AMI among Veterans has steadily declined from 2004 to 2006 and is equivalent between AMI patients treated in VA and Medicare patients treated in the community [1].

A recent review by the VA Evidence-based Synthesis Program also suggests that the quality of care and outcomes for cardiovascular disease in VA is generally equal or better than care in the community [48]. The VA has tracked and reported IHD performance measures for years, and these generally show either a steady trend of improvement or the VHA has maintained a reasonably high, system-wide performance. For example, the 2 top graphs in Figure 3 below, show the proportion of patients admitted with AMI who received an ECG within

10 minutes of arrival, and, among eligible, high-risk (STEMI) patients, the proportion who underwent a PCI within 90 minutes. Both measures have shown a steady improvement over the past three to four years. The bottom 2 graphs show the proportion of patients with AMI who receive aspirin and Beta-blockers within 24 hours of admission, both of which have remained above 95% over a similar period.

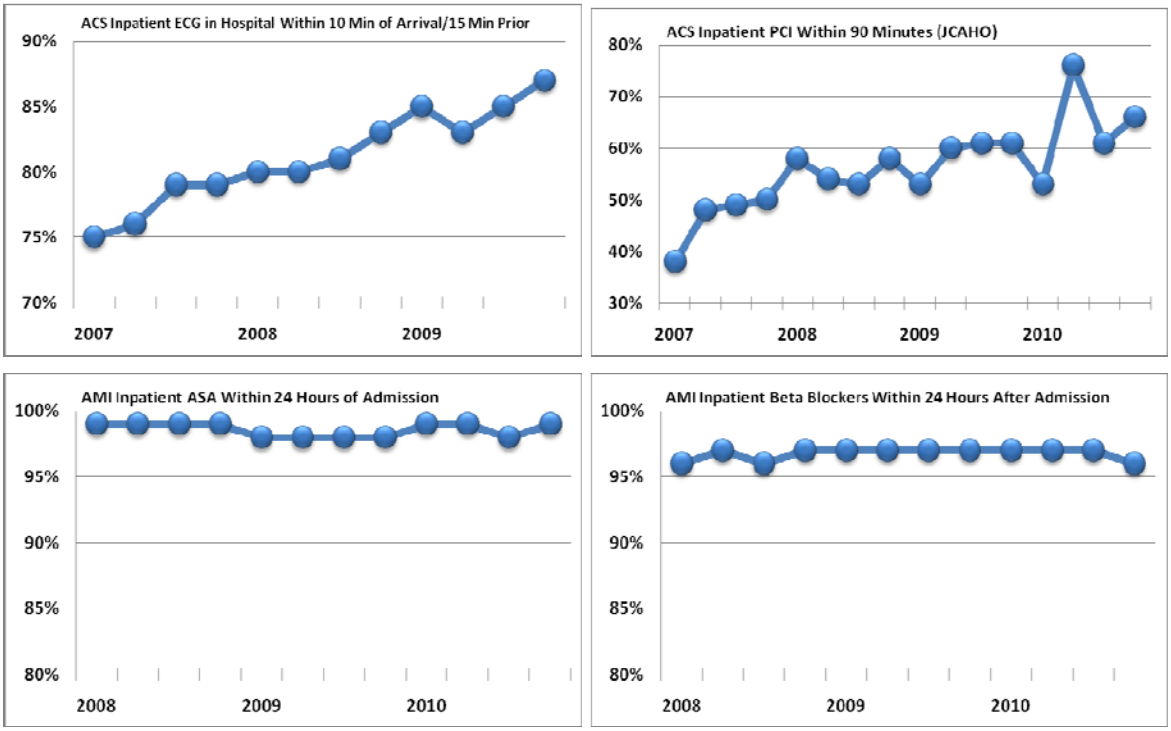


Figure 3: Select performance measures from the External Peer Review Program for acute MI in VHA from 2007 through 2010

IHD mortality in the US overall [7], and AMI mortality in VA specifically [49], have declined steadily. Nationally, the decline in mortality has been associated with both improvements in management of risk factors (i.e., patient behaviors), and improvements in medical treatment [50] [51], with the former accounting for approximately 43% of the observed decline in mortality and latter approximately 47% [7]. Among medical treatments, the largest declines in mortality have been associated with secondary preventive therapies after MI or revascularization (11%); initial treatments for AMI or unstable angina (UA; 10%); and other therapies including antihypertensive and lipid-lowering primary prevention therapies (12%) [7].

However, non-adherence to medications appears to be a common problem for patients with cardiovascular diseases [52]. One study reported nearly a quarter of patients discharged for acute myocardial infarction do not fill their cardiac medications within 7 days of discharge

[53]. Another found 34% of patients discharged with prescriptions for aspirin, statin, and Beta-blockers stopped at least 1 medication and 12% stopped all 3 medications within 1 month of hospital discharge [54]. Poor adherence is associated with a range of negative outcomes including poorer risk-factor management, and increased emergency department visits, re-hospitalization and mortality [52].

5. Significant Influences on Current Clinical Practices and Outcome

VHA Entities and Initiatives

A number of major initiatives and programs in VHA are influencing the future of IHD care, notably the Secretary's Transformation Initiatives which include Transforming Health Care Delivery through Health Informatics, and the Patient Aligned Care Team (PACT) model. Transforming care through health IT seeks to update the VA HIT system and to make it easier to develop and implement innovative new clinical IT applications. CART is seen as a model for new clinical IT platforms. The PACT initiative seeks to adapt a patient-centered medical home model of care to VA, with a particular focus on improving patient-centeredness, care coordination, transitions of care and access to care. These two initiatives have a high degree of overlap with our center goals, and IHD QuERI investigators are integrally involved in both.

IHD QuERI continues to play a central role in CART. Dr. Rumsfeld serves as the CART National Program Director, Drs. Maddox and Tsai serve as CART Clinical Co-Directors, and Dr. Maddox also oversees the CART Research Committee and Dr. Tsai oversees the CART Clinical Advisory Committee. Dr. Varosy is leading the CART-Electrophysiology Workgroup, Dr. Meg Plomondon serves as the CART Analytics Director, and Ms. Box serves as the CART Health IT Manager. Dr. Stephan Fihn serves as CART Executive Committee Chair, and Gordon (Blake) Wood serves, with Mary McDonell, as CART Program Coordinator.

IHD QuERI investigators led by Dr. Fihn are involved in the national evaluation of PACT. Dr. Fihn heads the evaluation and leads the PACT Demo Lab Coordinating Center. Dr. Bryson heads the Outcome Measurement Working Group, Dr. Hebert the Economic Evaluation Working Group, Dr. Helfrich the Organizational Function Working Group and Dr. Maynard the Analytics Working Group. Dr. Elliott is also coordinating the definition of patient cohorts for the initiative.

Several offices have been involved in quality improvement activities related to IHD: Office of Quality and Performance (OQP), Patient Care Services (PCS), the Office of Information (OI), Employee Education Services (EES), the Evidence Based Practice Work

Group, formerly the National Clinical Practice Guidelines Council (NCPGC), the Office of Systems Redesign, and Health Services Research & Development (HSR&D, principally IHD QuERI).

Non-VA Entities

National entities influencing current clinical practice include most notably the AHA and the ACC. Members of the IHD QuERI Executive Committee are involved in national ACC and AHA committees as well as in their scientific sessions. The AHA has conferences throughout the year and the VA has partnered several times with the AHA to co-sponsor an outcomes conference on cardiovascular disease, which occurs in April or May of each year. Most IHD QuERI Executive Committee members participate in this conference, and IHD QuERI typically holds its Executive Committee meeting in conjunction. This permits extensive interactions with leading researchers within and outside VHA.

The ACC has developed measurement systems which have had enormous impact in the field of cardiology. In particular, the National Catheterization Data Registry (NCDR) is the most widely known cardiovascular procedural registry and has been used to improve the quality and care in the catheterization lab. To date, few VHA cardiac catheterization laboratories participate in ACC-NCDR CathPCI registry, but most would prefer strongly to be able to participate in order to understand how their processes of care and outcomes compare with others, and as a tool for quality improvement. Under the leadership of Dr. Robert Jesse, the VHA through the CART program has joined the NCDR CathPCI registry. As a result, data from CART will be used to compare processes of care and outcomes in the catheterization lab between VA sites and between VA and non-VA sites. VHA's participation in NCDR has been met with extreme enthusiasm within the VA catheterization lab community.

6. QUERI Center Goals

The IHD QuERI's overall mission is to improve the quality of care and clinical outcomes for Veterans with IHD and Veterans at risk for IHD through identifying, assessing and promoting implementation of evidence-based best practices; fostering collaboration among researchers and operational units; and advancing the sciences of evidence-based medicine and evidence-based management. This mission remains unchanged.

Our center goals, however, have evolved. Previously, our goals focused on discrete clinical conditions and disease states: treating acute diseases (previously Goal 1) and managing risk factors and chronic disease (previously Goal 2). These goals are still embedded in our program objectives and metrics (*see Table 1: IHD QuERI Major Goals and Objectives*). However, this year we have substantially revised our center goals to focus on change platforms that we believe will impact quality of care at many levels and across the spectrum of IHD:

- **Center goal #1: Leverage data stored in new and existing information systems to improve the quality and safety of care for IHD patients at point of service (aka "Leverage Data")**
- **Center goal #2: Improve cardiovascular risk factor management by integrating new programs into evolving systems of care (aka "Integrating New Programs")**

In Section 2, Clinical Scope and Focus, we described the trends over the past five years that led us to reframe our goals. These include the recognition that IHD is a dynamic continuum rather than a series of isolated clinical stages; the need to assess the effectiveness and safety of therapies as they are being used in practice; and an increasing focus on improving systems of care as opposed to discrete processes of care, which includes a shift to team-based, patient-centered, coordinated care.

The IHD QuERI's revised Center goals reflect and respond to these broader trends, and should not be seen as a shift away from improving clinical outcomes. Rather, we anticipate that focusing on improvements in systems of care represent the best opportunity to improve health outcomes across the continuum of care and across the spectrum of ischemic heart disease conditions.

7. Plans for Achieving Each Goal

We will achieve each of our Center Goals by meeting an overlapping set of 7 objectives, which may be found in Table 1: IHD QuERI Center Goals and Objectives. Our Analytic

Framework, Figure 3, depicts the interlocking relationships among the objectives, Center goals, and intermediate and long term metrics, illustrated using several, key IHD QuERI projects. All of our projects address multiple objectives, with most current and planned projects addressing many objectives, often under both Center Goals. Table 1 lists all projects addressing each objective, but for brevity and clarity, we provide detailed descriptions for a limited number of illustrative projects under each objective. Below, we describe the objectives comprising each Center Goal, and key anticipated impacts, contributions to implementation science and key partnerships. Because of the overlapping nature of our Center Goals, we have a single heading for key impacts, implementation science contributions and partnerships under which we include both Center Goals.

Progress towards the IHD QuERI's first Center goal, **Leveraging Data**, will be achieved through concerted effort on four related objectives:

- **Objective 1-1: Improve the availability of timely clinical information at the point of decision making**
- **Objective 1-2: Track changes in quality of care and outcomes for AMI**
- **Objective 1-3: Develop program-level implementation tools and interventions to facilitate care and improve efficiency**
- **Objective 1-4: Identify organizational factors associated with the utilization of clinical data**

The objective of **increasing the availability of timely clinical information at the point of service** is consistent with the concept of transactional quality improvement, and more generally to tenets of classical quality improvement, proposing that the data to drive quality must be available in real time to the staff, providers and frontline managers who are in a position to act upon them. This is perhaps best captured in one of W. Edward Deming's 14 points, the admonishment to build quality assurance into the production system and end dependence on inspecting products after the fact [5]. Objective 1-1 is central to the IHD QuERI's efforts, and we believe offers one of the best opportunities to translate evidence-based medicine into practice.

A total of 5 current and planned IHD QuERI projects, working at various stages of the QUERI six-step process, are achieving progress on this key objective. Current IHD QuERI projects addressing objective 1-1 include Dr. Bryson's PROVE project which seeks to translate performance measurement from labor intensive manual chart abstraction to extraction of continuously updated electronic data (Steps 1, 3, and M). The APCI-RRP is identifying the data

elements necessary to be able to categorize the appropriateness of PCI procedures, and validating the CART-CL data elements needed to make the appropriate classification (Steps 3 and M) which will lay the groundwork for Dr. Bradley's CDA to examine variation in appropriateness of PCI and the patient, provider and systems factors associated with appropriateness. (For more details on existing projects mentioned here and below please refer to our 2010 Annual Report, Key Impacts and Progress sections.)

Several proposed IHD QuERI projects will also contribute to making progress on this objective and the larger Center goal of Leveraging Data: Dr. Tsai's Radiation RRP project will create a dynamic patient dose monitoring tool and protocol to alert catheterization laboratory teams of effective radiation dose; Dr. Bradley's CDA proposal includes a pilot project to provide appropriateness ratings to patients and providers at the point-of-care in decision support with the hopes of reducing inappropriate PCI; and Dr. Varosy's CART-EP SDP will evaluate the implementation of a new CART module for arrhythmia procedures. This CART-EP module utilizes data elements (based on the National Cardiovascular Data Registry's NCDR-ICD ver 2.0) and plans for the integration of data from the VA Pacemaker Surveillance Programs and the VA National Cardiac Device Surveillance Program (VANCDSP) with the CART platform. This will allow for prospective identification of sentinel safety events, and rapid, systematic identification of patients when safety issues arise.

These new projects, with the shared objective of making essential, timely clinical information available for decision-making, all include plans for the systematic evaluation of implementation processes which are discussed under objectives 1-3 and 1-4 below.

Objective 1-2 is to continue the IHD QuERI's efforts to **track changes in quality of care and outcomes for AMI**. A total of 4 current and planned projects address objective 1-2. The ongoing IHAMI project and CCFCS Repository continue to pull in data from existing VA data resources (EPRP, PBM, and DSS NDE) augmented by abstractions from patient medical records (IHAMI). In collaboration with outside investigators, the IHD QuERI team continues to identify data elements, and provide data extractions and analyses. Active CCFCS-related projects include: HTN-LIPID, Clopidogrel Use in Patients with Chronic Kidney Disease Following Acute Coronary Syndromes, (#CCFCS-Fischer, CLOPIDOGREL-CKD), Incidence of bleeding and death associated with triple antithrombotic therapy after acute coronary syndrome, (IHD-QuERI, TRIPLE-ANTITHROMBOTIC), and Prevalence, Care and Outcomes of ACS Patients with Newly Diagnosed Diabetes (CCFCS, ACS Diabetes).

An excellent example of the utility of the CCFCS data repository is Dr. Ho's line of inquiry on clopidogrel leading to important nationally-recognized manuscripts and funded research that is providing the evidence for future clinical guideline updates. In 2006-07, Dr. Ho began working with the IHD QuERI CCFCS team on an unfunded study investigating the efficacy of clopidogrel therapy for ACS patients. This produced several published papers on the incidence of death associated with stopping clopidogrel after ACS (Ho, JAMA, February 2008) and the risks of adverse outcomes associated with clopidogrel and PPIs following ACS (Ho, JAMA, March 2009). Subsequently, Dr. Ho has submitted proposals and received funding for projects seeking to improve adherence to clopidogrel using automated alerts through CART-CL (Ho-DES-RRP), and a multi-faceted intervention after ACS to improve medication adherence (Ho-PCAI-IIR).

The CCFCS Repository is an active resource that is being updated regularly and which is utilized by many researchers. The IHD QuERI is planning modifications to the CCFCS Repository data systems and SOP that will make the data more readily available in the years ahead. And, as discussed under objective 1-1 above, the IHD QuERI also has ongoing and new projects that will identify new data elements that may be integrated into the research data systems.

The third objective under the larger goal of Leveraging Data is to **develop program-level implementation tools and interventions to facilitate care and improve efficiency.** By program-level tools, we mean tools and interventions that are adopted and implemented by a system (e.g., an IVR system to promote medication adherence), as opposed to an individual (e.g., academic detailing). We note that this objective is shared with both of our Center goals: Leveraging Data and Integrating New Programs (*see Figure 3: Analytic Framework*), and a total of 6 current and planned projects address objective 1-3 and 2-2. . This objective is shared across the two goals because there is a synergistic relationship between data systems and systems of care; to be effectively implemented, tools and interventions must be developed and applied within an existing platform, whether that platform it is a model of care (e.g., PACT) or an IT system (e.g., CART). This objective is also closely linked to objective 1-4: **Identify organizational factors associated with the utilization of clinical data.** For the latter objective, we are trying to identify those generalizable organizational factors that are important across interventions, or across settings, that promote or impede the use of tools or interventions. For objective 1-3, we also want to identify characteristics of the tools and

interventions themselves that promote efficiency and care. 5 of our projects address objective 1-4, and 11 of our projects address both objectives 1-3 and 1-4.

The recently submitted Transitions-RRP (Michael Ho, PI) is intended to improve the VA regional model of cardiac care by identifying best practices for the discharge of patients back to their primary care facility from a tertiary referral center. This project directly addresses QUERI step 4 of implementing quality improvement programs. The work performed in this RRP will provide the preliminary data for an eventual SDP to test a transitions-of-care intervention in a larger number of facilities with the goal of improving the transition period from hospital to home for Veterans discharged with a primary cardiac diagnosis. This proposal directly addresses objectives 1-3 and 1-4 by identifying and pilot testing tools to improve the transition of care from hospital to home and to identify the patient and site level factors associated with specific use of a transition to home tool.

We have three planned SDPs that address objectives 1-3 and 1-4. Dr. Varosy submitted a concept paper to conduct a quasi-experimental implementation study of the planned rollout of the CART-EP module, which integrates the strengths of efficient report generation and field-specific, real-time data collection of the CART program with the VA's well-established arrhythmia device remote monitoring program, VANCDSP. This systematic study of the implementation of this new CART-EP module will include semi-structured assessments of contextual factors building on findings and methods from the CART-CL implementation RRP to assess the compatibility with existing clinical processes and logistics; the role of national leadership; and perceptions of the contribution to patient care and safety.

Dr. Bryson is developing an SDP in collaboration with cardiologist Sunil Rao at the Durham VA, which will develop a training and support program to introduce trans-radial PCI to all VA cath labs. Trans-radial PCI is an alternative to traditional femoral access PCIs, and has been associated with approximately half the risk of major bleeds, which are the most common and serious adverse event associated with PCIs. The SDP will develop and implement a national training program to support introduction of trans-radial PCIs, and will include a systematic evaluation of implementation, including baseline study of organizational readiness to change using an adapted ORCA survey.

Dr. Natarajan just completed a VA HSR&D IIR that tested a telephone delivered stage-matched intervention (SMI) and found a significant improvement in blood pressure control. He is developing a follow-up SDP to further refine, disseminate and test this telephone support

system intervention to improve blood pressure. In this SDP proposal, the VALUE in BP (Veterans Affairs Lowering Uncontrolled Elevation in Blood Pressure) Program, he will build on his previous work to comparatively evaluate if an enhanced SMI delivered through a specialized center, network tailored counseling (NTC) through a hub facility, leads to superior BP control compared to local delivery of the SMILE BP (Stage Matched Intervention to Lower Elevated BP) toolkit. This SDP will formally assess comparative effectiveness, implementation factors, potential sustainability and cost to improve BP control as the work moves from a research setting to actual clinical care.

Among current projects, Dr. Maddox's CDA research includes specific aims to determine hospital, provider, procedural, and patient level factors associated with risk factor control patterns in the year following cardiac catheterization for CAD patients. One of Dr. Maddox's objectives is to determine if systems with formal risk factor management programs have higher rates of control for hypertension and hyperlipidemia. Similarly, Dr. Bryson's current study, Organizational Correlates of Adherence to Medication (OCAM), is examining specific systems characteristics, such as the pharmacy FTE in the clinic, to identify factors associated with greater medication adherence among diabetes patients. The study includes a qualitative component that is examining how the systems factors influence patient adherence, e.g., not just whether involvement of a clinical pharmacist in primary care is associated with improved medication adherence, but what activities that clinical pharmacist engages in.

Progress towards achieving the IHD QuERI's second Center goal, **Integrating New Programs**, will be achieved through concerted effort on three related sub-goals or objectives:

- **Objective 2-1: Identify and understand differences in risk factor management and their causes**
- **Objective 2-2: Identify organizational and contextual factors that influence risk-factor management**
- **Objective 2-3: Develop implementation tools and interventions at program level to facilitate care and improve efficiency**

The objective of **identifying and understanding differences in risk factor management and their causes** is closely related to step three in the six-step QUERI process model and emphasizes our focus on systems of care as the driver and not the disease state.

IHD QuERI has several ongoing projects that are measuring existing risk factor management practice patterns as well as identifying quality gaps and barriers and facilitators to improvement.

Currently, 4 active and planned IHD QuERI projects address this objective. These include Dr. Bryson's OCAM project, which seeks to identify variations in medication adherence at the facility level; Dr. Ho's Transitions RRP, which will assess the critical transition process from hospital to home and pilot an intervention to improve processes of care (e.g., early follow-up and medication reconciliation); Dr. Maddox's CDA, the first two aims of which are to determine BP and LDL control among patients with CAD in the year following catheterization and then, using existing VA data and linking to CART-CL, determine specific factors associated with BP and LDL control; and Dr. Fihn's IHAMI project, which is examining clinical factors that predispose patients to in-hospital AMI.

The second and third objectives both emphasize the importance of implementation science, and overlap with objectives 1-3 and 1-4 under Center Goal 1. Objective 2-2, **identify organizational and contextual factors that influence risk-factor management,** is addressed by 4 current and planned projects, including Dr. Bryson's OCAM study, Dr. Maddox's CDA, Dr. Ho's Transitions RRP, and Dr. Natarajan's SMILE-BP RRP.

As discussed above, Dr. Ho's Transitions project will also identify organizational and contextual factors associated with risk factor management and re-hospitalization. Dr. Ho also plans to follow up the Transitions RRP with an SDP to assess patient outcomes (medication adherence), provider outcomes (e.g., provider satisfaction), and clinical outcomes (e.g., re-hospitalization rates), while assessing contextual factors. It will include a semi-structured qualitative piece building on the qualitative component in the RRP to assess how implementation is affected by contextual factors, such as past experiences with service agreements, and role of VISN-level policies on coordination of services.

Dr. Natarajan's recently funded SMILE-BP RRP builds on his successful trial of a telephone-delivered Transtheoretical Model-based stage-matched intervention (SMI) to improve BP control in Veterans with uncontrolled BP. The RRP will develop and pilot a toolkit, and perform formative evaluation of toolkit implementation. The formative evaluation will test the translated SMI toolkit with different staff (nurses, social workers, pharmacists, PACT or other health care staff) for delivery at other VA sites, and will include describing the barriers, facilitators, and methods of intervention by different health care staff. Dr. Natarajan has begun planning a study to evaluate the comparative effectiveness of SMILE BP toolkit delivered by

local VAMC staff against the SMI delivered from a hub facility through a regional implementation study (e.g., an SDP). If this promising theory-driven approach can work in a clinical setting where improvements in hypertension control are still needed, it will be an important contribution and would allow tailoring and adoption of the tool across VA facilities.

Objective 2-3: **Develop implementation tools and interventions at program level to facilitate care and improve efficiency** is addressed by 4 current and planned projects, including, Ho-Clop-DES, Maddox-CDA, Natarajan-SMILE-BP, Natarajan-VALUE-SDP (see Table 1: IHD QuERI Major Goals and Objectives.)

For example, Dr. Natarajan has begun developing a follow up SDP to the SMILE-BP project that will use the information about organizational and contextual factors gleaned from the RRP to construct a tool that will facilitate wide dissemination. Key information such as the barriers, facilitators, and methods of intervention by different health care staff, patient and provider satisfaction with the translated SMI (with recommendations for improvement); and the training required to achieve high-quality intervention delivery will be obtained as part of the SMILE BP RRP. In the proposed SDP, the VALUE in BP Program, he will build on his previous trial and the RRP to evaluate if an enhanced stage-matched intervention (SMI) delivered through a specialized center (network tailored counseling at a hub facility) or a SMI toolkit delivered by Patient Aligned Care Team (PACT) or other staff is superior. This SDP will formally assess comparative effectiveness, implementation, potential sustainability and cost of the tailored behavioral interventions to improve BP control to inform implementation planning and policy.

b. Anticipated key impacts

We anticipate a number of key impacts from the activities under each Center Goal and objective, many of which are represented by target metrics (Table 2). The largest number of our anticipated impacts relate to implementation outcomes, with a more limited number of short-term clinical outcomes, and finally long-term clinical outcomes.

For Goal 1, leveraging data, anticipated impacts include: identifying factors associated with use of lower effective radiation dose, and reducing unnecessary radiation exposure among a set of pilot sites (Tsai Radiation RRP); adapting appropriate use of PCI criteria for implementation in CART-CL, and reducing adverse events and cost (Bryson, APCI; Bradley CDA); developing computerized alerts to cardiac catheterization labs for patients receiving drug eluting stents (DES) who have not filled prescriptions for clopidogrel, and improving adherence

to clopidogrel (Ho, Clop-DES); systematically implementing a new CART module for cardiac devices, and improving device safety (Varosy, CART-EP); tracking changes in quality of care and outcomes for acute MI (Fihn, IHAMI); and identifying CAD patients who are appropriate for formal, longitudinal risk factor management programs, and improving their long term risk factor management (Maddox, CDA).

In particular, we use two sets of projects and anticipated impacts as examples in our Analytic Framework to illustrate the link from our Center Goals to pilot metrics (Figure 3). First, we expect that Drs. Bryson's and Bradley's studies adapting appropriateness criteria for PCI to allow criteria ultimately to be integrated into the CART system will contribute to more effective use of PCI. By increasing the appropriate use of PCI, first in pilot sites, and ultimately in VA nationally, we will reduce risk from adverse events and reduce costs from unnecessary procedures, while still making this therapy more readily available to those patients who will benefit from it.

Second, Dr. Tsai's planned radiation RRP, and anticipated subsequent work, will help first systematically understand variation in radiation exposure from interventional cardiac procedures, and identify factors associated with lower effective radiation dose. The purpose of the program of research is ultimately to reduce radiation exposure during interventional procedures, and improve long term safety, without sacrificing essential clinical data.

For Goal 2, Integrating New Programs, anticipated impacts include: identifying factors associated with BP and LDL control in year following catheterization (Maddox, CDA); packaging and disseminating an evidence-based, telephone-delivered intervention to improve BP management (Natarajan, SMILE-BP); developing computerized alerts for patients receiving (DES) who have not filled prescriptions for clopidogrel, and improving adherence to clopidogrel (Ho, Clop-DES); and designing risk factor management programs to improve BP and LDL control among CAD patients for the year following catheterization (Maddox CDA).

We use Dr. Maddox's CDA and Dr. Ho's program of work on clopidogrel to illustrate the link from our Center Goal 2 to pilot metrics in our Analytic Framework (Figure 3). First, for Dr. Maddox's work studying factors associated with BP and LDL control in year following cath, we will test the feasibility of a multi-modal intervention. Dr. Maddox's prior research suggests that among patients with non-obstructive disease, more than a third have elevated LDL, and nearly two-thirds with hypertension have uncontrolled LDL or HTN in the year after an index catheterization, and have much poorer odds of having control of their risk factors than patients

diagnosed with obstructive disease. By systematically understanding the factors that contribute to control, we anticipate that we can design a multi-modal intervention will improve BP and LDL control among IHD among patients in the year following catheterization. We believe this improvement may be particularly strong among patients diagnosed with non-obstructive disease.

Second, Dr. Ho's clopidogrel RRP will improve medication adherence among patients receiving drug eluting stents by creating systems to help ensure that patients fill clopidogrel prescriptions in a timely manner and take their medications as prescribed. This will contribute to improving antiplatelet therapy following PCI, and ultimately will improve outcomes following PCI. If the intervention is effective, CART-CL will provide a platform for implementing the intervention nationally.

Dr. Ho's progression of work on clopidogrel, initially using CCFCS data and then developing an intervention, provides a good example for both how our work reflects the six-step QUERI process, and how we view the QUERI model more flexibly in light of changing trends. We see the QuERI process as being fundamentally data driven and evidence-based, but recognize that the evidence is constantly evolving, and one of the ways we can most effectively keep the VA on the cutting edge of evidence-based medicine, and create a system that is receptive to implementing new practices, is by developing integrated data systems that both monitor adherence to current evidence-based best care, and also helps develop the next generation of evidence. This means partnering with operations at every step, including the basic step of identifying the most pressing questions and gaps to be addressed, and deciding how to best address them. This approach has resulted in new data systems, or linking existing data systems, such as CCFCS and CART, that would not exist without QUERI.

Our goals create opportunity for unanticipated impacts. We also expect that in the coming three years we will have impacts unrelated to any current or planned projects. To recapitulate one of the main points in the introduction to our goals: A key reason we invest considerable effort in forging and maintaining partnerships with operations, and in developing and leveraging data systems, is that many of our most important opportunities to impact the system of care have been unpredictable and emergent. While that does not mean these opportunities are random, it demonstrates the value of these change platforms as important strategic targets because they can be used to address a range of clinical and operational issues, including those that we haven't yet considered. Unanticipated impacts are particularly

important in light of the Secretary's Transformational Initiatives in VA, two of which align with our Center Goals: Transforming Health Care Delivery through Health Informatics, and the Patient Aligned Care Team (PACT) model. Work on these initiatives is evolving, and they represent great, but still uncertain opportunities to help elevate the quality of care and the efficiency and effectiveness of the VA. IHD QuERI-affiliated investigators are integrally involved in CART operations (a key piece of the Transforming Health Care Delivery through Health Informatics initiative), and in the Demo Lab Coordinating Center for the PACT initiative. The involvement of IHD QuERI-affiliated investigators in key roles for VACO programs allows us to be more responsive to the needs of the system. It also allows us to strategically develop interventions to fit with the change platforms represented in these initiatives.

c. Primary partners

Patient Care Services (PCS), Office of Patient Safety (OPS), Office of Quality and Performance (OQP), and the Office of Systems Redesign (SR) are key partners. In particular, PCS and OQP are the partners with who we have developed CART and CCFCS, respectively. The VA National Cardiac Device Surveillance Program (NCDSP), and the Outcomes among Veterans with Implantable Defibrillators (OVID) Registry, are key partners for the CART-EP project.

External partners include the Food and Drug Administration (FDA), the American College of Cardiology (ACC) National Cardiovascular Data Registry (NCDR), the Institute of Medicine (IOM), and the Safety of Atrial Fibrillation Ablation Registry Initiative (SAFARI).

We also collaborate with many other QuERI teams, most notably CHF QuERI, but also DM, SUD, SCI and MH QuERIs, as discussed below under cross-QuERI collaborations.

d. Implementation science contribution

Each of our Center Goals includes objectives that make contributions to implementation science: **Develop implementation tools and interventions at program level to facilitate care and improve efficiency** (objectives 1-3 & 2-3); and **identify organizational factors associated with implementation** (objectives 1-4 & 2-2). These are represented in Figure 3, as spanning the two Center Goals.

In all cases, the studies that develop and test implementation tools will incorporate aims to assess barriers and facilitators to implementation, including organizational contextual factors. Where appropriate, we are building on our prior work studying implementation in planning new studies, by adapting past tools and frameworks, such as interview guides, surveys and

secondary data on contextual factors. For example, in the CART-EP SDP, we will adapt data collection tools from the CART-CL implementation RRP, with particular attention to themes of clinical process compatibility that emerged in the RRP findings, and we will include new randomization strategies to enhance the rigor of the evaluation of implementation.

In addition to implementation science contributions specific to each Center Goal, we also have a number of broader contributions to implementation sciences. One of our overarching goals relative to implementation science is to better understand how organizational factors influence the adoption and implementation of new, evidence-based practices. Improving understanding and assessment of organizational context is a shared goal across QuERI teams, and for the nascent implementation science community more broadly. Most of our work in this area is in collaboration with other QuERI teams.

This implementation science work can be thought of as falling into two broad categories: one focused on structures that contribute to specific sets of practices, likely through a fairly prescribed set of mediators, the other focused on psychological or behavioral organizational factors (affective factors) that may affect organizational functioning more broadly and through a range of mediators. Across both categories, we want to understand relationships between organizational factors and implementation outcomes that apply to a range of facilities and settings; we want to understand which lessons translate across most or all of our work, and which lessons are idiosyncratic. Most of our work on organizational context assesses both structural and affective factors, but often emphases one or the other.

Dr. Bryson's ongoing Organizational Correlates of Medication Adherence (OCAM) is an example of a study focusing on structural factors. OCAM is assessing process-specific characteristics of care systems, such as pharmacy staff FTE in primary care, and their relationship with medication adherence among patients with diabetes. The study also includes qualitative data collection that may identify affective factors. Dr. Helfrich's recently funded IIR to systematically validate the organizational readiness to change assessment (ORCA) is an example of a study primarily examining an affective factor (collective readiness to change). The study uses a survey instrument which includes staff perceptions of structural factors (resource availability, staff release time), but it focuses on measuring the effect on perceptions of collective readiness to implementation changes. We believe improving understanding of both structural and affective factors in implementation science is critical, because they each provide different information. Structural factors are often more actionable, but may be highly context

dependent (e.g., adequate staff release time for implementation activities may, on average, be important, but may be more or less important depending on overall staff experience and compatibility of the new clinical practice with existing clinical procedures). Conversely, affective states may be more reliably predictive of implementation outcomes, but may be less actionable (e.g., poor collective readiness to change may be highly prognostic of implementation outcomes, but may not, in and of itself, indicate what changes are required to improve the odds of effective implementation).

Implementation frameworks. We do not use a single, overarching implementation framework, although our work touches on several, and our team, led by Dr. Helfrich, has been involved in a number of efforts to contribute to the conceptual literature (*see Annual Report*). The ORCA is based, in part, on the Promoting Action on Research Implementation in Health Services (PARIHS) framework [55] [56], and a focus of a current cross-QuERI project (*see below*) is to map the ORCA to the Consolidated Framework for Implementation Research (CFIR), a model developed by members of the DM QuERI [57]. The CART RRP adapted elements of Klein and Sorra's model of effective implementation, notably the concepts of implementation climate and compatibility, or fit, of the evidence-based practice change to the intended users' perceptions of their domains of responsibility and expertise.

The essential shared feature of all of these models is that they include constructs representing both characteristics of the practice change (e.g., compatibility with past experiences), and the context in which the change is being made (e.g., culture of openness to change). All three models portray that interaction as critical and non-linear.

e. Cross-QUERI contributions

We are collaborating with CHF QuERI on two planned RRPs, Transitions RRPs (Ho) and a CHF RRP (Heidenreich PI), related to patients' transition and care management following hospital discharge. This work is very timely given the importance to the PACT model of care coordination and communication between primary care and specialty services and following hospital discharge.

Dr. Helfrich is collaborating with Laura Damschroder and Carmen Hall, IRCs for the DM and Poly Trauma QuERIs, respectively, on an initiative to map measurement tools onto the Consolidated Framework for Implementation Research (CFIR). The three will map (i.e., link) ORCA survey items or scales to CFIR constructs, and in process examine where conceptual definitions can be clarified, and where empirical measures have poor representation or lack a

corresponding construct in the CFIR. This is part of a broader effort to improve the validity of measures of implementation barriers and facilitators by sharpening conceptual definitions and standardizing measures. Along with Dr. Cheryl Stetler, a long-time implementation science consultant to the QuERI program currently with the Center for Implementation Practice and Research Support, they have proposed a workshop at the 4th Annual NIH conference on the Science of Dissemination and Implementation.

The group is also developing content for an online Wiki created and coordinated by the DM QuERI, with a linked glossary of implementation science constructs and definitions being headed by Dr. Hall. The goal is to create a central clearing house for conceptual definitions and guidance on measures, including surveys, interview guides and coding manuals, and structural factors or other secondary data operationalized as implementation measures. This work builds on the PARIHS Development Initiative, a cross-QuERI project to assess the evidence-base for PARIHS and provide better guidance to researchers on how to use the framework in implementation projects and research. See annual report section for a description of this work.

Dr. Helfrich will present on implementation frameworks at a Cyber Seminar this Spring. The talk will reprise a presentation developed with Laura Damschoder of DM QuERI, Hildi Hagedorn of SUD QuERI and Cheryl Stetler of CIRPS for the Enhancing Implementation Science conference in Denver. Dr. Helfrich has also been asked to serve as a member of a traveling faculty, based on the Enhancing Implementation Science conference, to provide implementation science training to teams or centers that request it from CIPRS.

Dr. Helfrich's ORCA study is a collaboration with Rick Owen and Jeff Smith of MH QuERI, Hildi Hagedorn of SUD QuERI, and Tim Hogan of SCI QuERI. These partner projects are all intervention studies testing a facilitation intervention. They are sharing data, and in some cases collecting additional data, that will allow for more rigorous, prospective validation of the ORCA instrument. This study represents the only example we know of in which an organizational measure has been studied prospectively across multiple implementation settings and validated against independent outcome measures; organizational surveys are often validated using retrospectively gathered data and self-reported outcome measures, which introduces substantial threat of measurement bias. The study will produce a short form of the survey, a user's guide and important information about specific survey scales that are prospectively associated with implementation effectiveness. Our goal is to promote more valid, operationally relevant assessment of organizational context across a range of settings. We

believe this will ultimately improve the efficiency and effectiveness of implementation of new practices in the VA.

f. Disparities

Dr. Whittle's project HTN LIPID ("Better hypertension and lipid care in racially diverse, veterans at risk" RRP 09-123) is using the CCFCS Repository to examine the pattern of adherence to use of evidence based medical therapy and control of lipid and blood pressure among African-American (AA) and white veterans and evaluate the provider and patient barriers and facilitators to optimizing the use of evidence based therapies and control of lipid disorders (LD) and hypertension (HTN). The overall goal is to determine whether these barriers and facilitators are quantitatively different for AA and white patients.

Dr. Karin Nelson's study ENVIRO examined the relationship between neighborhood characteristics and patient outcomes/quality of life, including ischemic heart disease. She has found that neighborhood socio-economic status (SES) was independently associated with both mental and physical summary measures of health ($p < 0.05$ for both), after adjusting for both individual socioeconomic status, self-reported co-morbid disease and health behaviors, and health care access. Physical health status was also significantly associated with street connectivity, a measure of "walkability" of a neighborhood ($p < 0.05$). (A manuscript is currently under review.)

g. Data development, implementation, evaluation

As previously noted, development of the CART platform and the CCFCS data repository have been key to most projects under our first Center Goal, leveraging data. Our work in this area continues with current or planned projects to implement use of the CART data elements necessary fir appropriateness criteria for PCI (Bryson, APCI RRP; Bradley CDA); electrophysiologic procedures (Varosy, CART EP); peripheral arterial procedures (Tsai, CDA); in-hospital CPR (Bradley); outpatient cardiac clinic visits (Varosy/Maddox, CART Clinic); and cardiac imaging procedures (Maddox). Our investigators are also centrally involved in developing the data resources for evaluation of the PACT initiative.

h. Health IT development, implementation, evaluation

As previously noted, most of our current or planned intervention projects involve HIT in one form, such as developing automated alerts for clopidorel prescriptions (Ho, Clop DES), effective radiation exposure (Tsai, Radiation RRP), and appropriateness of PCI (Bryson, APCI RRP; Bradley, CDA); or using telephone-based, staged-matched intervention (SMI) to improve

blood pressure control (Natarajan, SMILE-BP RRP). We will also continue our evaluation of CART implementation with Dr. Varosy's proposed SDP to conduct an evaluation and quasi-experimental study of the implementation of the new electrophysiology module for CART. CART will also be used in the multi-modal risk factor management intervention proposed in Dr. Maddox's CDA. These efforts relate to both Center Goals.

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Management Plan Update

Coordination

The activities of IHD QuERI continue to be managed across two locations: the IHD QuERI Research Coordinating Center in Seattle, Washington and the Clinical Coordinating Center in Denver, Colorado. Dr. Stephan Fihn continues in his leadership role as Research Coordinator, while the Clinical Coordinator duties will now be shared jointly between Dr. Michael Ho and Dr. John Rumsfeld. Dr. Rumsfeld has taken on the role of Acting National Program Director for Cardiology for VA Patient Care Services. Dr. Ho is a nationally-recognized cardiologist, highly accomplished health services investigator, and long-time IHD QuERI-affiliated investigator and member of the IHD QuERI team in Denver. Dr. Christian Helfrich will continue in his role as the lead Implementation Research Coordinator for IHD QuERI, but he will share these responsibilities with Mr. Blake Wood, who is also taking over Mary McDonell's role as IHD QuERI Administrative Coordinator.

The IHD QuERI Research Coordinating Center works closely with the Clinical Coordinating Center to monitor and support multiple core-funded and independent field-based projects. The number and breadth of these ongoing projects require an ongoing team effort. The bi-weekly IHD QuERI team meetings include standing agenda items for reviewing new proposals as well as progress reports from investigators leading ongoing projects. Affiliated and outside investigators are invited to present at these regular calls, which include multiple IHD QuERI support staff and analysts to offer feedback on data management, study design and analytics.

Investigators

Three investigators joined or have taken new roles with IHD QuERI in 2010. Paul Varosy, MD is a cardiologist and health services researcher at the Denver VAMC.

Steve Bradley MD, MPH, is a cardiologist and health services researcher at the Seattle VAMC. Dr. Bradley completed a post-doctoral fellowship in health services research before beginning a fellowship in interventional cardiology. He is resubmitting a CDA related to on appropriateness of PCI.

Sundar Natarajan, MD, is an internist and health services researcher at the Manhattan VAMC with interest in cardiovascular risk factor management. Dr. Natarajan recently completed

an HSR&D-funded trial of a theory-based intervention to support BP control, is funded by the American Diabetes Association to evaluate the comparative effectiveness of two different behavioral interventions to lower LDL in veterans with diabetes, and is collaborating with Stroke and IHD QuERIs to conduct an RRP to develop an implementation pilot of the successful BP control intervention.

The senior IHD QuERI investigators are also committed to bringing up the “next generation’, that is, those that can and should step into QuERI leadership roles in the future, by involving them on the EC or EC subcommittees. This includes some of our current IHD QuERI investigators at our coordinating centers in Seattle and Denver (Mike Ho, Chris Bryson, Tom Maddox, Tom Tsai, and Steve Bradley), as well as national investigators in cardiovascular outcomes research in the VA (e.g. Brahmajee Nallamothu, Ann Arbor VA; Sunil Rao, Durham VA; Salim Virani, Houston VA: Jeffrey Whittle, Milwaukee VA; and Sundar Natarajan, New York VA.).

Table 1: IHD QUERI Center Major Goals and Objectives

Goal/objective	*Description*	*Project Label*	*Time Frame*
Major Goal #1	**Leverage data stored in new and existing information systems to improve the quality and safety of care for IHD patients at point of service**		**1-5 years**
Objective 1-1	Improve the availability of timely clinical information at point of decision making	Bryson-PROVE, Varosy-CART-EP, Bryson-APCI-RRP, Bradley-CDA, Tsai-Radiation	1-3 years
Objective 1-2	Track changes in quality of care and outcomes for AMI	Fihn-IHAMI, Fihn-CCFCS, Bryson-APCI-RRP, Bradley-CDA	1-5 years
Objective 1-3	Develop implementation tools and interventions at program level to facilitate care and improve efficiency	Bryson-PROVE, Ho-Clop-DES, Ho-Transitions, Natarajan-SMILE-BP, Natarajan-VALUE-SDP	1-5 years
Objective 1-4	Identify organizational factors associated with the utilization of clinical data	Bryson-OCAM, Helfrich-ORCA, Bryson-Radial PCI, Varosy-CART-EP, Natarajan-VALUE-SDP	1-5 years
Major Goal #2	**Improve cardiovascular risk factor management by integrating new programs into evolving systems of care**		**1-5 years**
Objective 2-1	Identify and understand differences in risk factor management and their causes	Fihn-IHAMI, Bryson-OCAM, Maddox-CDA, Ho-Transitions	1-3 years
Objective 2-2	Identify organizational and contextual factors that influence risk-factor management	Bryson-OCAM, Maddox-CDA, Ho-Transitions, Natarajan-SMILE-BP	1-3 years
Objective 2-3	Develop implementation tools and interventions at program level to facilitate care and improve efficiency	Ho-Clop-DES, Maddox-CDA, Natarajan-SMILE-BP, Natarajan-VALUE-SDP	2-5 years

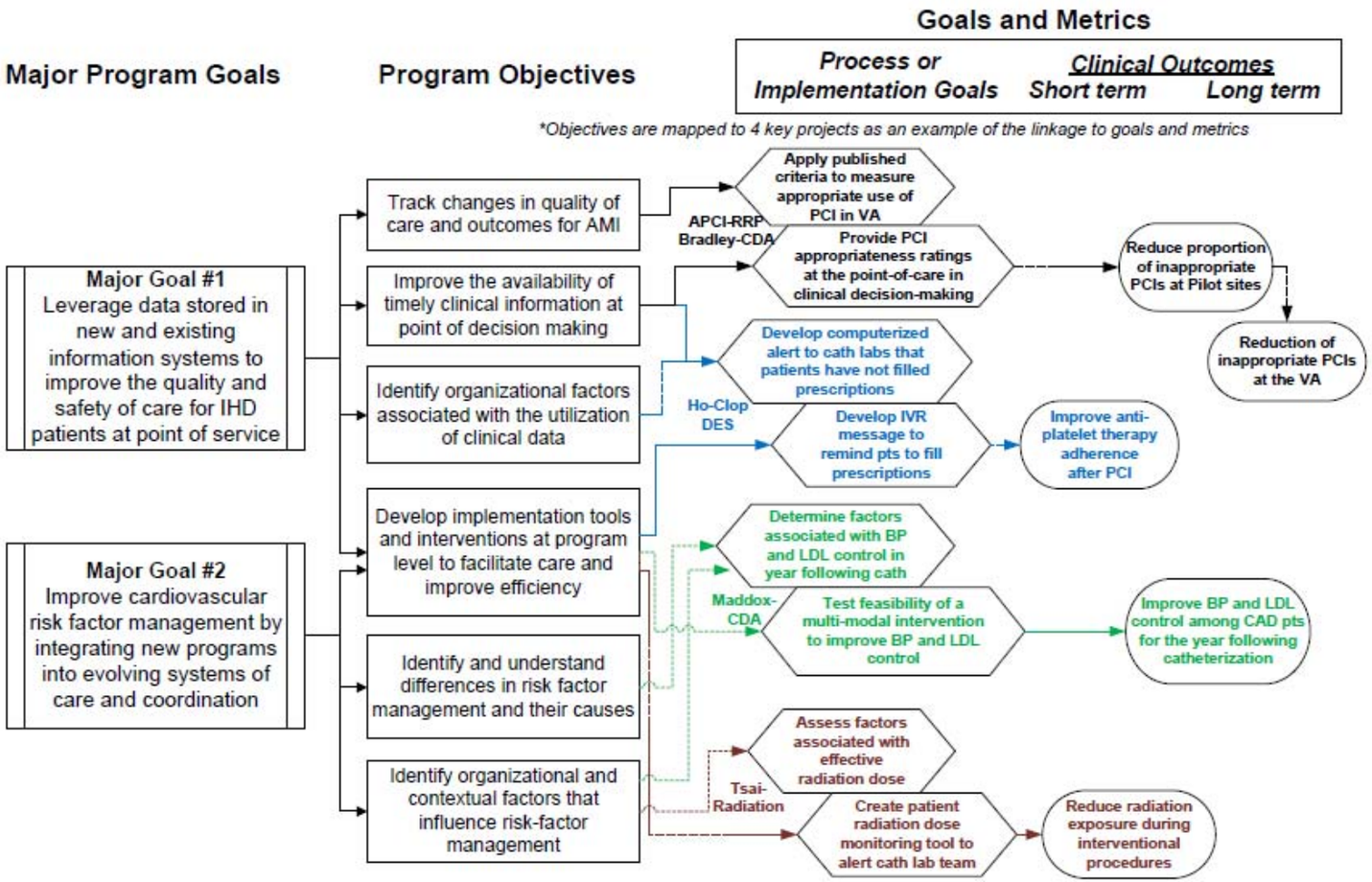
Table 2: IHD QUERI 2010 Pilot Performance Metrics

	Scope	*Project*	*Metric Data Source*	*Timeline*
Major Goal 1: Leverage data stored in new and existing information systems to improve the quality and safety of care for IHD patients at point of service				
Center Activities/Project Outcomes				
1. Apply published criteria to measure appropriate use of PCI in VA	VA	Bryson-APCI, Bradley-CDA	CART-CL	2012
2. Track changes in quality of care and outcomes for AMI	VA	IHAMI, CCFCS, PROVE	CCFCS and pt med records	2012
3. Develop computerized alert to catheterization labs that patients have not filled prescriptions	Pilot sites	Ho-Clop-DES	CART-CL	2011
4. Assess factors associated with veteran radiation dose in the catheterization laboratory	Pilot sites	Tsai-Radiation	CART-CL	2011
5. Develop VA-wide transradial PCI training program	VA	Bryson-Radial PCI	Project admin	2012
6. Increase % of QUERI projects assessing baseline organizational readiness	QUERI teams	ORCA IIR, Core	ART database	2015
Clinical Process Outcomes				
1. Provide PCI appropriateness ratings at the point-of-care in clinical decision-making	Pilot sites	Bradley-CDA	CART-CL	2014
2. Reduce radiation exposure during interventional procedures	Pilot sites	Tsai-Radiation	Project data	2012
3. Increase proportion of trans-radial PCI procedures	VA	Bryson-Radial PCI	Project admin / CART-CL	2013
Clinical Outcomes				
1. Improve anti-platelet therapy adherence after PCI	Pilot sites	Ho-Clop-DES	DSS/Pharmacy data	2011
2. Reduce proportion of inappropriate PCIs at Pilot sites	Pilot sites and national	Bradley-CDA	CART-CL	2016
3. Reduce rate of PCI procedure complications (notably bleeding complications) and attendant utilization (length of stay, utilization of CT scans and transfusions)	VA	Bryson-Radial PCI	CART-CL	2016

Table 2: IHD QUERI 2010 Pilot Performance Metrics (cont.)

Major Goal 2: Improve cardiovascular risk factor management by integrating new programs into evolving systems of care				
Center Activities/Project Outcomes				
1. Determine factors associated with BP and LDL control in year following catheterization	VA	Maddox-CDA	CART analytic database	2011
2. Package and disseminate an evidence-based, telephone-mediated intervention by nurses to improve BP management.	VAMC, VISN	SMILE-BP, VALUE-SDP	Project data	2016
Clinical Process Outcomes				
1. Test feasibility of a multi-modal intervention to improve BP and LDL control	Pilot sites	Maddox-CDA	CART analytic database, direct provider and patient inquiry	2013
Clinical Outcomes				
1. Improve BP and LDL control among CAD patients for the year following catheterization	Pilot sites	Maddox-CDA	CART analytic database	2014
2. Improve anti-platelet therapy adherence after PCI	Pilot Sites	Ho-Clop-DES	DSS/Pharmacy data	2011

Figure 4: 2010 IHD QUERI Analytic Framework



Ischem r 2010

Figure 5: IHD QUERI Collaborations