

**Department of Veterans Affairs
Quality Enhancement Research Initiative (QUERI)**

Chronic Heart Failure QUERI Center Application

Strategic Plan
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I. CHF QUERI Center Mission, Goals and Scope

1.1 Clinical Focus and Scope

The mission of our CHF QUERI center is to improve survival and quality of life for all VA patients with heart failure and those at risk for heart failure through collaboration with other VA organizations to implement best practices. We believe the best way to achieve this mission is through **increased use of care known to prolong survival** and other interventions that **reduce hospitalization rates**. An additional objective is to **contribute to implementation science** while we work toward the above goals. We have designed our implementation projects accordingly using formative evaluations and randomized trials of different implementation strategies.

Once the use rates of life-prolonging treatments are at a high level and readmission rates are low, we plan to focus on identification and treatment of patients with unsuspected reduced left ventricular ejection fraction (LVEF) in order to prevent subsequent heart failure. The medical treatment of heart failure and preserved systolic function (diastolic dysfunction) is also not a current focus of our QUERI due to the lack of relevant clinical practice guidelines. However, this may change if specific treatment guidelines for patients with diastolic heart failure (Step two) become available.

The VA is already doing well on the four mission critical performance measures related to heart failure. These 2006 data include 1) measurement of left ventricular ejection fraction (99%) in patients presenting with heart failure, 2) use of angiotensin converting enzyme inhibitors in appropriate patients (88% use in those with a left ventricular ejection fraction < 40%), 3) documentation of patient education (89%) and 4) smoking cessation counseling (88%). All of these rates are at least significantly higher than mean rates reported by the Joint Commission for non-VA hospitals (Figure 1, 2005 data).

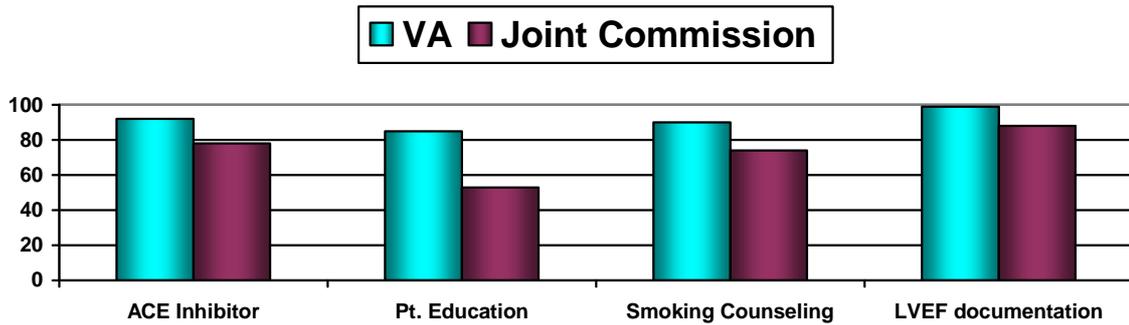


Figure 1. 2005 Performance data for VA and the Non-VA (Joint Commission mean) for heart failure mission critical measures.

These measures are the same as those used by the Joint Commission (ORYX) and the Center for Medicare and Medicaid Services (CMS). However, the measures only focus on inpatient care. Additional performance measures that can be applied to outpatients have been proposed and endorsed by the National Quality Forum (Table 1).

Table 1. National Voluntary Consensus Standards For Ambulatory Care, July 2007, National Quality Forum.

MEASURE TITLE	MEASURE DESCRIPTION
Heart Failure (HF): Assessment of Activity Level	Percentage of patient visits or patients with HF with assessment of activity level.
HF: Assessment of Clinical Symptoms of Volume Overload (Excess)	Percentage of patient visits or patients with HF with assessment of clinical symptoms of volume overload (excess).
HF: Beta-blocker therapy	Percentage of patients with HF who also have LVSD who were prescribed beta-blocker therapy.
HF: Warfarin Therapy Patients with Atrial Fibrillation	Percentage of patients with HF who also have paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy.
HF: Weight Measurement	Percentage of patient visits for patients with HF with weight measurement recorded.

Of these emerging measures we believe that appropriate use of **beta-blockers deserve special attention**. Of those measures listed above only beta-blockers are documented to improve survival. Beta-blockers deserve our focus because the number of eligible patients is high, and use is suboptimal (<60% of patients are treated with a

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recommended beta-blocker). We plan to evaluate rates of other measures based on available data. This will be possible without chart review for warfarin use for those with atrial fibrillation and weight documentation. Determining assessment of activity level and fluid status will need to be done through a chart review mechanism such as the External Peer Review Program (EPRP).

We believe CHF QUERI should not only work toward improving existing measures, but also continuously scan the published science and advocate for other measures that will lead to better heart failure care. One such emerging performance measure is likely to be aldosterone antagonists which are not yet endorsed by NQF having only recently been shown to improve survival in patients with highly symptomatic heart failure. Recent data from the Office of Quality and Performance (OQP) has demonstrated that only 40% of candidates receive this medication at hospital discharge.

With all of the measures of performance we plan to look for disparities in care based on race, gender, age, history of mental health issues, and location (urban/rural) and academic status of the medical center.

Although use of implantable cardioverter defibrillators (ICDs) is of interest to the VA given their high cost, potential for improvement in survival, and increased attention paid to them by U.S. society, CHF QUERI will not work actively to increase use unless the cost-effectiveness is demonstrated clearly for veterans. CHF QUERI believes a better measure of quality would be documentation of a discussion with the appropriate patient regarding ICD implantation. We are currently working with the OQP to better understand the number of patients eligible for ICDs through the use of the External Peer Review Program (EPRP). In the past, VA has trailed the rest of the U.S. in performance of invasive procedures such as coronary angiography (both necessary and unnecessary). (1) We are defining appropriate VA populations for treatment (based on cost-effectiveness) as part of an HSR&D funded project.

Our interest in **prevention** has potential overlap with work by the **Ischemic Heart Disease (IHD) QUERI**. The majority of patients with heart failure have ischemic heart disease and treatment of this condition will help prevent heart failure. We are working closely with IHD QUERI to develop methods to identify patients with ischemic heart

disease that have asymptomatic left ventricular dysfunction and are candidates for treatment. We are also working with IHD QUERI projects examining rates of ischemic heart disease events in those with very low LDL cholesterol levels.

The impact of **alcohol dependence** on incidence, treatment and outcome of heart failure in the VA is not well understood. We plan to collaborate with **Substance Use Disorders (SUD) QUERI** to better understand the epidemiology of alcohol related cardiomyopathy and its impact on quality of heart failure care.

1.2 Significance and Consequences: Epidemiology, Morbidity / Mortality, Quality of Life and Costs

Epidemiology. Heart failure is a common condition associated with high mortality, poor quality of life, and is the number one reason for discharge from the VA Medical Service. (2) The life-time prevalence for those without antecedent myocardial infarction is 1 in 9 for men and 1 in 6 for women. The prevalence of heart failure in the U.S. in 2002 was 4.9 million with an incidence of 550,000 cases per year. It is primarily a disease of the elderly with a prevalence approaching 5% for those aged 65 and older. Admissions for heart failure in the U.S. have risen several fold since 1970 (399,000 to over 1,000,000 per year in 2004) due in part to an aging population. (3) Approximately half of all patients with heart failure have systolic dysfunction (left ventricular ejection fraction below $\leq 40\%$) and are candidates for life prolonging treatments. (4,5)

Morbidity/Mortality. Mortality among Medicare beneficiaries is 25% at one year following a first admission for heart failure. Patients with heart failure have a six to nine fold greater chance of suddenly dying than patients of similar age and gender. In 2001 there were 52,828 deaths in the United States attributed to heart failure. (4) Mortality increases with severity of symptoms and inversely with the left ventricular ejection fraction. (5) Morbidity is also significant. Over half of patients with heart failure have daily symptoms of fatigue and shortness of breath. Approximately 5% of patients will have symptoms with minimal activity. (5)

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Cost. There were an estimated 1,099,000 hospital discharges for heart failure in the U.S. in 2004 with a cost per hospitalization of \$5,000 to 6,000. In 1999, Medicare paid \$3.6 billion for heart failure related care. It was estimated that total costs (direct and indirect) will have reached 33.2 billion in 2007 dollars. (4)

Quality of Life. In addition to its impact on mortality, chronic heart failure is associated with decreased quality of life. Using the time-tradeoff method for utility assessment Fryback and colleagues found that subjects rated symptomatic heart failure as 0.71 (i.e. they were willing to give up 29% of their life expectancy in order to be returned to normal health). (6)

I.3 Treatment / Management Evidence Base

Numerous large multicenter randomized trials have established that angiotensin converting enzyme (ACE) inhibitors, beta-blockers, aldosterone antagonists, ICDs and biventricular pacemakers improve survival in certain patient populations with heart failure. (5) These trials have identified the left ventricular ejection fraction and level of symptoms as the primary determinants of benefit from treatment (Table 2).

Table 2. Life Prolonging Treatments by Stage of Heart Failure. (5)

Stage	Description	Left Ventricular Ejection Fraction (LVEF)	Guideline Recommended therapy
A	Risk factors for heart failure (e.g. hypertension, ischemic heart disease)	≥ 40% (by definition)	Treatment of the underlying disease
B	Asymptomatic, abnormal left ventricular function	≥ 40%	No heart failure specific therapy
		< 40%	ACE inhibitors, beta-blockers
C	Symptomatic NYHA class I (minimal)	≥ 40%	No specific therapy
		< 40%	ACE inhibitors, beta-blockers
	class II (moderate)	≥ 40%	No specific therapy
		35-39%	ACE inhibitors, beta-blockers
		< 35%	ACE inhibitors, beta-blockers, ICDs
	class III (moderate-severe)	≥ 40%	No specific therapy
		35-39%	ACE inhibitors, beta-blockers, aldosterone antagonists
< 35%		Above plus ICD (with biventricular pacemaker if QRS > 120ms)	
D	Symptomatic NYHA class IV (severe)	≥ 40%	No specific therapy
		35-40%	ACE inhibitors, beta-blockers, aldosterone antagonists
		< 35%	Above plus biventricular pacemaker if QRS > 120ms (no ICD)

ICD= implantable cardioverter defibrillator, ACE=angiotensin converting enzyme, NYHA= New York Heart Association, QRS = the QRS wave on the electrocardiogram

Heart failure stage. Patients in the first stage (A) have risk factors for the development of heart failure including hypertension and coronary artery disease.(5) Stage B occurs when the left ventricle is not functioning normally but symptoms have not occurred. Left ventricular function is often quantified using the fraction of blood expelled with each beat (ejection fraction). One large randomized trial found that treatment of patients who had a low ejection fraction with ACE inhibitors reduced progression to symptomatic heart failure. (7) Stage C occurs when symptoms have developed. Multiple randomized trials of patients with reduced left ventricular ejection fraction (<40%) have found that treatment with ACE inhibitors and beta-blockers improve survival. Patients with severe symptoms (New York Heart Association class III or IV) receive additional survival benefit with aldosterone antagonists. Stage D occurs when heart failure is considered end-stage and the patient is near death. The vast majority of patients are in stage A (risk factors for heart failure). Thus, collaboration with leaders in improving treatment of ischemic heart disease (IHD QUERI) and hypertension (Mary Goldstein, Executive Committee member) is important. Prevalence studies have found that Stage B and Stage C patients are similar in number. (8-10) At any one time there are relatively few stage D patients but they are at the highest risk of death. Thus, all stages have either a high prevalence, or high risk of death.

Left ventricular systolic function. Current evidence indicates that heart failure is due to left ventricular systolic dysfunction (LVEF < 40%) in approximately 50% of cases. (10) Patients with systolic dysfunction have worse survival after adjustment for other clinical characteristics. (10,11) Furthermore, life prolonging heart failure therapies have only been demonstrated for patients with systolic dysfunction.

New therapies. Two therapies may soon become established as cost-effective treatments for heart failure but have yet to be incorporated into treatment guidelines since the data have only recently been published (hydralazine/nitrate combination and cardiac resynchronization therapy). (12) It is important for CHF QUERI to monitor the literature and be ready to develop implementation strategies should they become recommended treatments.

Hydralazine/nitrates. A prior study in the VA demonstrated an improvement in survival for patients taking the combination of hydralazine and long acting nitrates compared to

those taking placebo, but the Food and Drug Administration did not approve the combination for heart failure treatment. (5) Further studies found that ACE inhibitors were superior to the combination of hydralazine and nitrates. (5) A recent trial has found that the combination of hydralazine and nitrates improves outcome in black patients who are already receiving standard treatment (e.g. ACE inhibitors and beta-blockers). (12) The data have yet to be incorporated into treatment guidelines and a major controversy exists regarding the appropriate population for use. Many clinicians believe any recommendation should be limited to black patients since they were enrolled in the trial while others believe there is a biologic plausibility that all patients with heart failure will benefit.

Cardiac resynchronization therapy (CRT). Patients with advanced heart failure often have reduced contraction of the left ventricle due in part to intra-cardiac conduction delays. Conduction can be improved with the implantation of a pacemaker that paces the left and right ventricle simultaneously (biventricular pacemaker). Several randomized trials have found that with the pacing function on, clinical status is improved and heart failure admissions are reduced. In a recent meta-analysis, survival also appeared to be improved. (13) Medicare pays for these devices if the ejection fraction is severely reduced, the patient is in New York Heart Association class III or IV (moderate to severe symptoms), and the conduction through the ventricle (QRS duration) is prolonged.

Disease Management Programs. Many (but not all) randomized studies have found that multidimensional programs reduce hospitalizations and may improve outcome including survival. (14-18) They commonly include several of the following interventions: nurse case management, self-management, home monitoring, patient education, frequent phone follow-up, and multidisciplinary team evaluations. Unfortunately, these programs used multiple and often different interventions and it is difficult to determine which components of the heart failure programs are responsible for the success. **CHF QUERI and IHD QUERI have a joint proposal to evaluate a disease management program with a focus on depression treatment** that includes collaboration between the generalist, cardiologist and psychiatrist.

Other therapies. Diuretics and digoxin are frequently used to treat heart failure although there are no randomized trials indicating improved survival. Digoxin has been evaluated in randomized trials of symptomatic patients with depressed ejection fraction and found to improve symptoms and exercise capacity. (5) Thus, it is recommended for patients who remain symptomatic on life-prolonging therapy. Most patients eventually develop severe fluid retention without the addition of diuretics. Thus they are standard of care (5) even though they have not been evaluated in a large randomized trial.

Identification of Candidates for Prevention. No trials of screening for asymptomatic left ventricular dysfunction (Stage B, for which treatment reduces the progression to symptomatic heart failure) have been performed. However, community studies have documented the sensitivity and specificity of several screening tests including echocardiography, electrocardiography and B-type natriuretic peptide (BNP). Dr. Heidenreich recently published a cost-effectiveness analysis indicating that BNP followed by echocardiography in those with a positive test is a reasonable screening strategy if the prevalence of low ejection fraction (<40%) is over 1%. (19) Echocardiography (more accurate but more expensive) was found to be a cost-effective screening strategy if the prevalence of depressed ejection fraction is near 10%.

I.4 Current Practices and Quality / Outcome Gaps

There are limited data regarding the current VA treatment of heart failure (Table 3). Through our EPRP review we know the VA is doing well for two recommended guideline interventions for patients with symptomatic heart failure (Stage C): measurement of left ventricular ejection fraction in patients with a diagnosis of heart failure, and use of ACE inhibitors in patients with a depressed ejection fraction. However, the use of guideline recommended beta-blockers (carvedilol, metoprolol XL, bisoprolol) has been sub-optimal. In addition, EPRP data collected at our request in 2006 indicates that aldosterone antagonist use in appropriate patients is also low (<50%).

Table 3. Current VA and Non-VA Heart Failure Practices.

	VA Palo Alto	VA National (2006 EPRP)	Joint Commission Mean
Asymptomatic Patients (%)			
ACE Inhibitors	77	Unclear	Unclear
Beta-Blockers	70	Unclear	Unclear
Symptomatic Patients (%)			
Ejection Fraction Measurement	--	99	88
ACE Inhibitors	--	92	78
Recommended Beta-Blockers (carvedilol, metoprolol XL)	--	55	Unclear, <33 in Medicare
Aldosterone Antagonists	--	40	Unclear
ICDs	12	No Data	Unclear
Readmission Rate	--	23% at 90 days	8.4 at 30 days
Mortality at 1 year	--	26%	Unclear 34% in Medicare

Palo Alto data provided when National VA data are unavailable.

Denominator for treatment is appropriate candidates. (EF <40% and creatinine < 2.5 mg/dl for ACE inhibitors; EF <40% for beta-blockers; EF<40%, creatinine < 2.5 mg/dl and severe symptoms for aldosterone antagonists). The denominator for ICDs excludes patients with dementia, limited prognosis, or those receiving comfort care only.

Readmission data for the VA are all cause admissions, while for non-VA are for heart failure only, thus it is difficult to compare values.

Disease Management

CHF and IHD QUERIs have recently completed a survey of Cardiology section and Medicine Chiefs throughout the VA system that requested data regarding disease management for heart failure. Preliminary results indicate the structured disease management programs are rare. Although some form of home telehealth is used, the number of patients enrolled with heart failure is very low.

I.5 Significant Influences on Current Clinical Practices and Outcomes

At the VA Palo Alto Health Care System half of all patients with heart failure are managed exclusively in primary care clinics. The other half is primarily managed by cardiologists and cardiology based nurse practitioners. In non-tertiary care VA centers the prevalence of primary care management is likely to be greater. In addition, VA hospital and VISN leadership influence clinical practice through funding and promotion of standards of care.

1.5.1 Conceptual Model of VA Implementation for Heart Failure

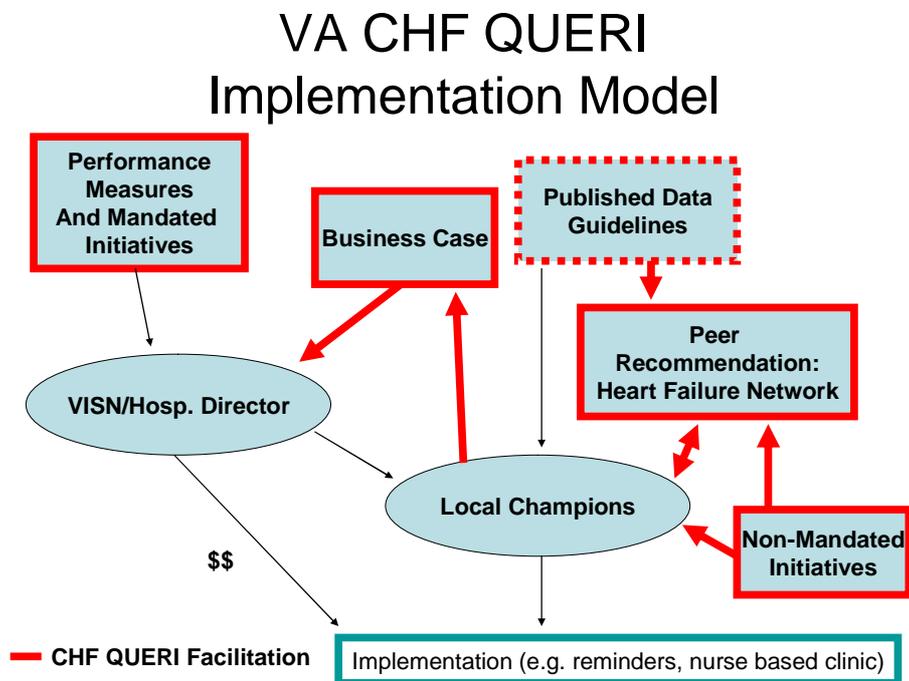


Figure 2. Conceptual model of implementation of heart failure related interventions within the VA system is shown along with the areas of facilitation by CHF QUERI. A key component is the Heart Failure Network which will serve to educate providers on facilitators and barriers at other facilities. Other impacts of CHF QUERI include the creation of quality indicators/performance measures and the development of the business case for each intervention, both general and individualized for the institution.

Our conceptual model of implementation for the VA (**Figure 2.**) incorporates the three elements of **evidence, context, and facilitation** of the **Promoting Action on Research Implementation in Health Services (PARIHS) Model** (20). Evidence for effectiveness is crucial for provider acceptance, and development of performance measures, while evidence for cost-effectiveness (a component of the business case) will be needed for acceptance by the medical center administration. The organizational context or environment must be understood and will vary depending on the complexity and cost of the intervention. CHF QUERI will facilitate implementation of optimal heart failure care through development and promotion of appropriate performance measures (e.g. for beta-blockers or aldosterone antagonists), promotion of heart failure guidelines and peer recommendations through the VA Heart Failure Provider Network we have established, and development of the business case for each intervention.

We are validating our model (and in the process contributing to implementation science) with randomized trials focusing on the interaction of non-mandated initiatives, the HF Network and the local champions. We test different methods of interaction to determine the most efficient means of implementation.

1.5.2 Other Influences on VA Heart Failure Practice and Outcome.

A recent survey of VA primary care providers and cardiologists found that the most frequently reported influences on ischemic heart disease practice were **local cardiologists, cardiology journals, and cardiovascular professional organizations.** (21) It is highly likely that these are the main influences in heart failure practice as well. Outside of the VA three specialty organizations exert a strong influence on heart failure care in the United States. The American College of Cardiology and the American Heart Association jointly create and publish a clinical practice guideline for heart failure. These two organizations also publish the two premier cardiac journals (Circulation and the Journal of the American College of Cardiology) and hold annual meetings where results of heart failure treatment trials are first released. The Heart Failure Society of America is a smaller specialty organization that maintains a website where clinical treatment guidelines are available. The journal produced by the Heart Failure Society of America is also a source of results of clinical heart failure research and clinical guidelines (Dr. Barry Massie serves as Editor-in-Chief, and Dr. Paul Heidenreich is an associate editor).

The treatment of heart failure patients is also influenced by several VA offices (Table 4). The **Office of Quality and Performance** abstracts data from all heart failure admissions and a random subset of outpatient visits for heart failure through the External Peer Review Program (EPRP). Performance on several heart failure specific quality measures are reported back to each VISN and VA center in the form of performance measures. The National Clinical Practice Guidelines Council produces a guideline for heart failure care that is available over the internet. Care may also be influenced via the clinical reminder package of the medical record (CPRS). Heart failure specific reminders exist for patient education, however national measures for life-prolonging treatments are not available since treatment is specific to patients with depressed left ventricular ejection fraction and ejection fraction data are currently not retrievable from CPRS. CHF QUERI has written a white paper that has been shared with the **Office of Information** proposing how this can be accomplished. The association of different VA offices with CHF QUERI projects is shown in **Figure 3**.

The affiliated medical schools are likely to contribute to current clinical practice. We have shown that academically affiliated VA hospitals have higher rates of compliance with clinical practice guidelines for heart failure than non-affiliated VA hospitals. (21)

Finally, **patients can be a major force** in receipt of quality of care. Many therapies are now patient initiated. Therefore, we are initiating interventions directed at the patient but on the national level through **My Health E-Vet**. We plan to provide patients with tools to examine their health status and quality of their heart failure care. By making patients educated partners in their care there will be a higher probability that quality care will be delivered.

Table 4. VHA Programs/Entities

VHA Program or Entity	Influence on Heart Failure Practice and Outcome
Office of Quality and Performance (OQP)	This office oversees guidelines and creates performance measures for heart failure.
Performance Management Workgroup (PMWG)	This committee has developed performance measures for heart failure.
Office of Information	Within the computerized medical record (CPRS) several reminders have been

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	developed to improve care for heart failure.
Committee on Pacemaker and Implantable Cardiac Defibrillator Placement (ICD)	This committee develops guideline for placement of ICDs for patients with heart failure.
Deputy Under Secretary for Health and Operations Management	This office provides support and guidance to the VISN directors.
Office of Care Coordination	This office is overseeing the distribution of various telemonitoring devices and algorithms for care for patients with heart failure.
National Program Director for Cardiology and Patient Care Services	The Director (Robert Jesse) works closely with the CHF and IHD QUERIs to improve care
Collaborative on Advanced Clinical Access	This national group of VA providers and administrators is sharing ways to improve access to heart failure care.

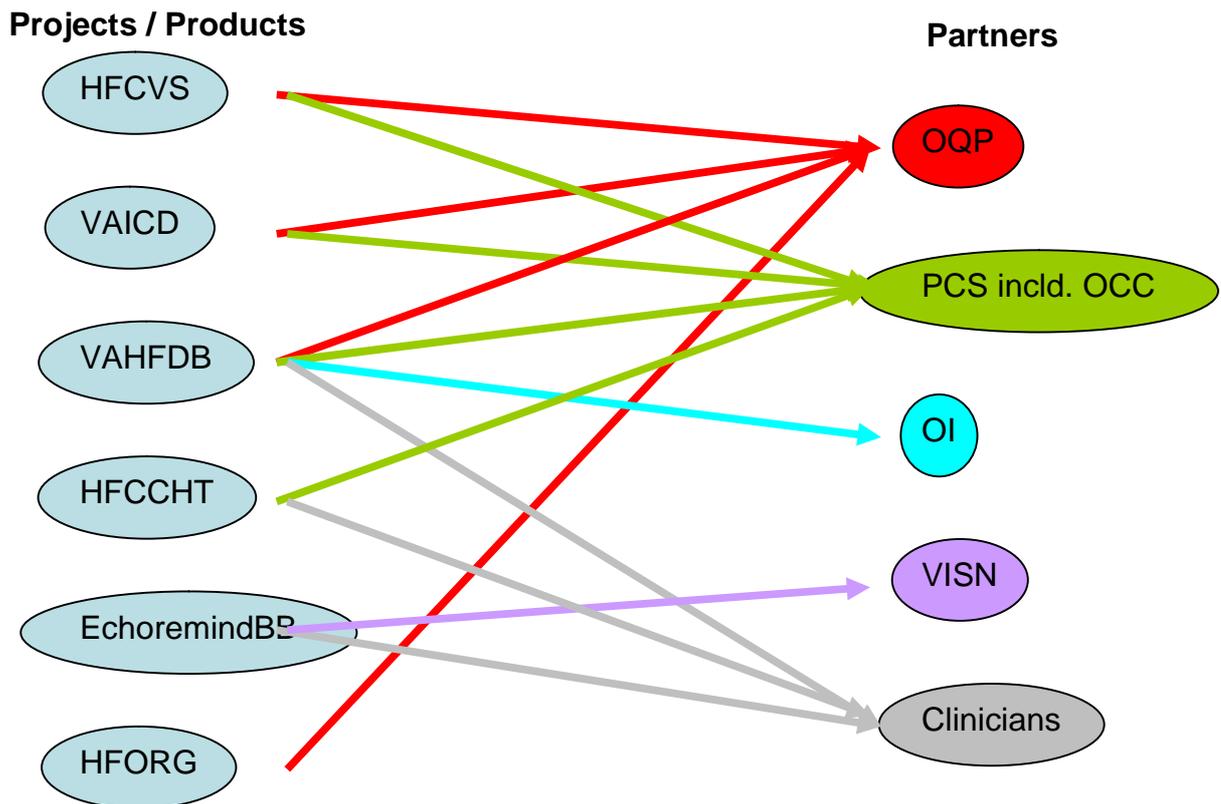


Figure 3. This wiring diagram demonstrates the relationship between different CHF-QUERI projects and other partnering VA organizations and stakeholders. Only selected projects are shown. **HFCVS:** Variation in VA compliance with heart failure guidelines;

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VAICD: Optimal use and cost-effectiveness of ICDs in the VA Health Care System;
VAHFDB: VA Heart Failure Database; **HFCCHT:** High Risk HF Identification for Care Coordination; **EchoremindBB:** Trial of clinical reminders for beta-blockers; **HFORG:** Impact of organizational factors on quality of heart failure care. **OQP:** Office of Quality and Performance; **PCS:** Patient Care Services; **OI:** Office of Information; **VISN:** Veterans Integrated Service Network.

I.6 QUERI Center Coals

1.6.1 Clinical Goals

Based on our review of randomized trials, clinical guidelines and published performance measures, we have rank ordered heart failure related issues and display those we feel are of the highest priority. Those practices that improve survival, apply to a large proportion of the population, and for which the VA is known to be below optimal use receive highest priority. We recognize that clinical issues that have never been tested or known not to prolong survival may have substantial value but we give them lower priority. We expect this ranking to change over time as the VA improves care and more clinical trial data are published and guidelines are revised.

Rank Order of Clinical Issues

- 1) Life-prolonging treatments
 - 1.a) **Beta-blockers**: large population will benefit, not at target usage
 - 1.b) Aldosterone antagonists: smaller population for benefit but not at target usage, not yet NQF performance measure.
 - 1.c) Hydralazine/nitrate combination for African-Americans: smaller population for benefit but not at target usage, not yet NQF performance measure.
 - 1.d) ACE inhibitors: already at a high level based on EPRP data and high compared to non-VA benchmarks.
- 2) Readmission rates: Disease management and home based monitoring and education not widely used.
- 3) Prevention and identification of those with unrecognized heart failure
- 4) Other therapies: Unclear impact on survival or quality of life
 - 4.a) Measurement of Left Ventricular Ejection Fraction: VA already doing well based on EPRP data.
 - 4.b) Patient education at discharge: VA already doing well based on EPRP data.
 - 4.c) ICDs, cardiac resynchronization, unclear if cost-effective, not available at each VA center.
 - 4.d) Digoxin: no mortality benefit
 - 4.e) Diuretics: not studied in large randomized trials
- 5) End of life care: No specific guideline recommendations

Based on the above ranking we have identified three clinical goals that span all time horizons: increasing the use of life prolonging treatment, preventing and identifying unrecognized heart failure and reducing hospitalizations through patient centered care coordination.

Goal 1: Increase the Use of Life-Prolonging Treatment

The first goal of our QUERI Center will be to increase compliance with evidence based treatment guidelines for patients with heart failure. Results from randomized trials indicate that survival, hospitalizations and quality of life improve with appropriate use of medications (first priority: beta-blockers). (5) We have chosen **beta-blockers** as the first target because of their high impact on survival, the large number of eligible patients and the sub-optimal use in the VA system. A 2nd target will be aldosterone antagonists, given their sub-optimal use and recent addition to published guidelines.

A related focus of our center will be to improve care for **patients who historically have been undertreated**. Specifically, we will examine disparities in heart failure care based on race, gender, age, rural vs. urban location, mental illness, alcohol dependence and renal insufficiency. A related focus will be the use of the hydralazine/nitrate combination in African-Americans. The impact of mental illness on heart failure treatment is poorly defined and this effort will be led by Dr. Susan Frayne (co-investigator). Poor quality of care for patients with renal insufficiency and heart disease has been documented by Dr. Michael Shlipak (co-investigator) (22, 23) and he will work with CHF-QUERI to develop interventions aimed at improving their care. We will collaborate with **SUD QUERI** in better understanding treatment and quality of care for heart failure patients with **alcohol dependence**.

Although there are many potential candidates for ICDs and biventricular pacemakers within the VA system, we will not focus on increasing their use at this time given the uncertain cost-effectiveness of the devices. Instead we have focused on understanding the cost and benefit of these devices on different groups of VA patients based on certain clinical characteristics. This HSR&D funded study will take advantage of the VA ICD Surveillance Center which is affiliated with CHF-QUERI and located at VA San Francisco Medical Center in order to determine clinical effectiveness and cost-effectiveness of ICDs as currently implanted. In addition CHF QUERI will work with

Patient Care Services to **develop data systems to track ICDs** for purposes of identifying patients rapidly if and when a device recall occurs

Goal 2. Reduce Admission Rates

We have chosen reduction in readmission as our second goal because it is a major economic burden for the VA due to the high cost of care (\$1000 per day, for a typical 5-6 day stay). (4) Success with this goal will be highly correlated with success with our first goal given that the life-prolonging medical treatments (ACE inhibitors, beta-blockers, aldosterone antagonists) also reduce admission rates. (5) However, there are specific interventions that can be employed to reach this goal, such as optimal use of **disease management including home based monitoring and patient education**. (24-31) Many of these interventions are promoted as part of the **Save 5 Million Lives Campaign** of the **Institute for Healthcare Improvement (IHI)** that the VA has joined. These interventions are used sporadically with varying components in the VA system, and additional trials are needed to document which programs work best within the VA system. We recognize that initiating disease management programs throughout the VA will be a challenge due to their initial upfront costs including the requirement for additional employees. However, the current bed shortage and need to pay for outside hospitalizations should make effective interventions attractive to hospital and VISN directors.

Goal 3: Prevention and Identification of Unrecognized Heart Failure

We believe important targets for improvement of VA heart failure care include the identification of Stage B (asymptomatic) patients with ischemic heart disease, and unrecognized Stage C patients with symptoms of heart failure (dyspnea). Dr. Heidenreich has previously examined the cost-effectiveness of **screening high risk patients to identify those with reduced left-ventricular ejection fraction**. (19) CHF-QUERI will build upon this work by developing methods for system wide identification of VA patients who should be screened for reduced left-ventricular ejection fraction so that treatment can be initiated to prevent the symptoms of heart failure.

A related goal of CHF-QUERI is the prevention of heart failure (Stage B-D) through improved treatment of ischemic heart disease and hypertension (Stage A). Our QUERI center will have a close collaboration with IHD QUERI through common executive

committee members and joint research projects. In addition, Mary Goldstein MD, MS of VA Palo Alto who is currently evaluating measures to improve treatment of VA patients with hypertension serves as a CHF QUERI co-investigator.

Availability of Ejection Fraction Data. Current evidence for heart failure therapy is predominantly in patients with reduced left ventricular ejection fraction (LVEF). (5) To be effective and accurate, quality improvement interventions require that patients' LVEF be recorded in an electronically accessible format. Currently, ejection fraction is not systematically recorded and usually appears as text in diagnostic test reports. Therefore, detailed chart review (as performed by the External Peer Review Program-EPRP) is required to determine which patients with heart failure have a depressed ejection fraction, a practice that is both expensive and time consuming and that leads to delays in measurement and intervention. Furthermore, there is no automated method to identify *asymptomatic* patients with a reduced ejection fraction who will benefit from treatment with ACE inhibitors. Dr. Heidenreich has been working to create an electronic field for ejection fraction at the VA Palo Alto Health Care System. CHF QUERI has developed a white paper along with IHD QUERI and Patient Care Services, and is working with the Office of Information to have the ejection fraction captured as part of the VA electronic medical record.

Initial Work (Year 1). We have already met some short term goals during the first year including a 1) review of published guidelines and recent trials, 2) evaluation of current gaps in care using EPRP data and 3) creation of a Heart Failure Provider Network. During **Year 2**, the Heart Failure Provider Network was expanded and a related Echocardiography Network was created. Through these networks we have tested several implementation strategies for a beta-blocker reminder. We also successfully piloted a patient survey to identify high risk candidates and those appropriate for home telehealth.

Short Term Horizon. During the next few years we plan to work with our network of heart failure champions at each VA center to continue to implement different strategies (Including formative evaluations) to improve use of beta-blockers and potentially other medications. We will focus on improving the transition from inpatient to outpatient care

for patients with heart failure as part of the **IHI Save 5 Million Lives campaign**. We continue our efforts to develop methods to allow each VA to create a database of heart failure patients using the existing VISTA file structure. In addition, we will create a national database of heart failure patients to be used to document any disparities in heart failure care. We will push for a beta-blocker quality indicator and if still needed, a performance measure. We will determine the business case including cost-effectiveness of any proposed treatment or other intervention. As with all interventions we plan to contribute to implementation science through formative evaluations and randomized trials when possible.

Long Term Horizon

Ultimately we expect our efforts will lead to a reform of the practice of heart failure where more patient-monitoring and symptom reporting take place from home and not in the clinic, where databases are used to track and triage patients for appropriate care, freeing cardiologists to deal with the more challenging patients. We expect the VA to lead the country in appropriate use of heart failure treatments.

Table 5. CHF QUERI Goals (Underlined=Joint Commission and Mission Critical VA Measures).

Goal	Description
1	Improving Use of Life-Prolonging Therapy
1A	Improving Use of Life-Prolonging Medications (<u>measure ejection fraction, ACE inhibitors/angiotensin receptor blockers</u> , beta-blockers, aldosterone antagonists, <u>smoking cessation counseling</u>).
1B	Determine Cost-Effectiveness of Life-Prolonging Devices (Defibrillators, Bi-ventricular pacemakers/Cardiac Resynchronization Therapy or CRT).
1C	Improve Use in Vulnerable / Historically Undertreated Populations
1D	Evaluate Trends in Use of Life-Prolonging Treatment Inside and Outside the VA.
2	Decrease Hospitalization Rates
2A	Identify and Increase the Use of Optimal Care-Coordination/ Disease Management
2B	Improve Transition from Hospital to Outpatient Setting, including <u>patient education</u> and early follow-up
2C	Evaluate Proactive Cardiology Review /Collaborative Care for Heart Failure Patients
2D	Develop Heart Failure Databases
2E	Document trends in hospitalization and other outcomes for VA and Non-VA Patients
3	Identify Unrecognized Heart Failure (lower priority)

1.6.2 Implementation Science Goals.

The implementation science goals of CHF-QUERI (Table 6) include evaluation of different methods of implementation, the impact of performance measures, the impact of distributing a business case to local champions, and the use of formative evaluations.

Table 6. Implementation Science Goals

Goal	Description
1	Understand the structural characteristics of VA centers and cardiology sections that are associated with adoption of evidence-based practices for heart failure.
2	Determine the impact of a Heart Failure Provider Network on implementation.
3	Determine the impact, cost and cost-effectiveness of different implementation strategies for heart failure related health services interventions.
4	Test the effectiveness of distributing a business case to local champions to aid in their implementation of interventions requiring substantial up-front or continuing costs.
5	Develop trials of health services interventions that focus on effectiveness wherever possible (e.g. designs that allow enrollment of all eligible subjects/centers).
6	Document the impact of new performance measures on implementation.
7	Perform formative evaluations on all implementation strategies for heart failure interventions.

1.7 Plans for Achieving QUERI Center Goals

1.7.1 Clinical Goals

Our plans for achieving our Center goals follow the six step QUERI process. In addition, our approach to selecting interventions for implementation (QUERI step 4) is based in part on the **Chronic Care Model of Wagner**. (32-34) Below we describe how the six QUERI steps are followed to reach each of our three goals. We believe that facilitation of implementation will be most effective when performed through collaboration between CHF QUERI and different VA offices (e.g. Patient Care Services). Accordingly, we have developed working relationships with Patient Care Services, the Office of Quality and Performance, and other QUERI groups. Our **pipeline of projects** is outlined in **Figure 4** at the end of this section.

We have completed much of the work of QUERI steps 1 and 2 during our first two years. Thus, most of our future work will center on Steps three and higher. As with our selection of goals, our plans to achieve them are prioritized based on: 1) impact on quality-adjusted survival; 2) evidence for effectiveness of health services interventions; 3) the number of patients eligible for the intervention; and 4) feasibility of implementation within the VA. We give top priority to interventions designed to improve the use of treatments known to prolong survival (and quality-adjusted survival) in a large number of patients. Health services interventions that have been shown to be effective in randomized trials will receive high priority. Those interventions yet to be tested in trials must be supported by **Wagner's Chronic Care Model**. The VA's current system of care will guide our implementation efforts. For example, reaching goal on any new mission critical performance measures will receive highest priority.

Goals 1 and 2: Increase the use of life-prolonging treatment and reduce admission rates.

Many interventions we propose will help the VA reach both of these goals since life prolonging treatment also reduces rates of hospitalization. Thus, we will discuss these goals jointly as we review the QUERI steps toward implementation. In certain cases, (e.g. disease management) we note that an effect on admission rates is more likely than an effect on survival.

Goals 1,2 - Step 1) Select Diseases/Conditions/Patient Populations

We have completed a review of the large amounts of literature identifying systolic left ventricular dysfunction as high risk condition in heart failure where treatment improves survival and reduces hospitalization. (5)

Goals 1,2 - Step 2) Identify Evidence-Based Clinical Practice Guidelines / Recommendations

We have completed a review of the published clinical practice guidelines. This review has contributed to a list of quality indicators for the elderly (35) The VA, the American College of Cardiology/American Heart Association and the Heart Failure Society of

America have well known guidelines that are consistent in their recommendations for managing heart failure.

Goals 1,2 - Step 3-Documentation of current practice.

EPRP reports have data for several years on the use of ACE inhibitors and beta-blockers. CHF QUERI has completed a review of beta-blocker and ACE inhibitor use and has worked with the EPRP to begin to document the use of aldosterone antagonists. We will document other areas of practice including follow-up post discharge from hospitalization for patients with heart failure, readmission rates, and survival. The process of care and outcome link will be examined for different heart failure treatments. To determine the potential for improvement we will compare VA values to community standards using Medicare and large national registries- the Acute Decompensated Heart Failure National Registry (ADHERE) and OPTIMIZE-HF. (36, 37) Disparities in care among patients with heart failure will be determined through work by several Executive Committee members including Peter Groeneveld, Anita Deswal, and Susan Frayne in addition to the Coordinating Center.

Goals 1,2 - Step 4) Implement best practices

The **Chronic Care Model** (32-34) fits well with the implementation of VA heart failure treatment guidelines, and we propose interventions during the first year that span the six model dimensions. We recognize that evidence for effectiveness of the different elements for improving heart failure care varies. We focus on areas for which there is the greatest evidence base and potential for success.

CCM Element 1: Organize patient and population data to facilitate efficient and effective care: We are piloting a local registry of all patients with an outpatient diagnoses or inpatient diagnoses of heart failure or a depressed left-ventricular ejection fraction at the Palo Alto VA Healthcare System. Ultimately we plan to provide a tool-kit to individual sites that will guide them in using VISTA files directly or a data warehouse (if available) to create their own registry.

We have completed our **survey of VA Cardiology sections** to determine current use of disease management and capacity to implant devices. Ongoing work on our HSR&D funded study evaluating the effectiveness and cost-effectiveness of **ICD use**

will inform us on how to best approach the use of these devices within the VA system.

We are working with Patient Care Services and the Office of Information to create a field within CPRS to capture ejection fraction. Until this is available we will work to implement our method of electronic capture of ejection fraction from the echocardiography laboratory at other VA centers.

CCM Element 2: Promote clinical care that is consistent with scientific evidence and patient preferences. We have completed the HSR&D Funded Project titled Clinical Reminders in Test Reports to Improve Guideline Compliance (IIR 01-108) This study has randomized 1500 patients to either a reminder or no reminder for beta-blockers. The results show a significant benefit of the reminder, and we are now promoting this method throughout the VA with the help of our Heart Failure Network. Specifically we have randomized VA facilities to receive different levels of effort at implementation of the reminder by CHF QUERI.

Our Executive Committee members have unique experience with development of inpatient tool kits for heart failure. Dr. Fonarow is the Chair, and Drs. Heidenreich and Rumsfeld are members of the Steering Committee for the Get With the Guidelines Program of the American Heart Association. The heart failure component of this program has already been adopted by several hundred hospitals in the US. We will work with Patient Care Services to determine if widespread adoption of this program is feasible within the VA. We will work with IHD-QUERI to refine our collaborative care intervention using successful features of their comparable HSR&D study for patients with stable angina (PI Stephan Fihn).

CCM Element 3: Create a culture, organization and mechanisms that promote safe, high quality care. A potentially important route for implementation is our newly created network of heart failure champions across the VA system. Through periodic live meetings, conference calls, a website, and in-person meetings, we will make available all successful interventions (e.g. nurse initiation of beta-blockers, reminders attached to echocardiography reports for medications) to this network. (38) We will perform formative evaluations during the implementation process to better understand barriers and facilitators of implementation.

CCM Element 4: Assure the delivery of effective, efficient clinical care and self-management support. We will continue to work on implementation of the nurse based initiation clinic. This project includes a cost-effectiveness and budget impact analysis. (Goal 1A)

Collaborative and proactive cardiology review. We are initiating a pilot study of proactive cardiology review in collaboration with general internal medicine at VA Palo Alto. We will work with IHD-QUERI to develop this collaborative care intervention since they have an ongoing comparable HSR&D funded study for the care of patients with stable angina (PI Stephan Fihn). We are currently pursuing funding for a **multicenter trial of collaborative care and disease management** for heart failure patients with a focus on depression (PI Rumsfeld, Co-PI Heidenreich).

CCM Element 5. Empower and prepare patients to manage their health and health care. We have created educational material that has been incorporated by the My Health E-Vet Program. In addition we are working with the My Health E-Vet group to add a health status measure for heart failure, and a tool to allow the patient to assess the quality of their heart failure care. Both of these interventions should improve patient-physician communication and lead to higher quality of care.

CCM Element 6. Mobilize community resources to meet needs of patients. Our Executive Committee members and Heart Failure Provider Network will facilitate the use of resources from the American Heart Association, The American College of Cardiology, The Heart Failure Society of America, and other community sources for use by all patients with heart failure. We will have identified many patient education materials from these sites and now provide links for providers from our website to these sources. In addition, we are working with the My Health E-Vet Program to provide patients direct links to these resources.

Goals 1,2 - Step 5). Document that best practices improve outcomes.

For patients enrolled in randomized trials all of the life-prolonging treatments (practices) by definition improve outcome. (5) Some uncertainty exists for other populations that were excluded from the trials such as those with alcohol dependence, significant renal disease (39) or psychiatric disease. For these populations, we plan to use VA data (e.g.

Decision Support System, Pharmacy Benefits Management) to estimate the impact of treatment on those excluded populations.

Other practices, such as disease management and care-coordination are less well studied, and we work with the Office of Care Coordination to evaluate home based monitoring on outcome. We will take advantage of the variation in implementation that has occurred across VISNs to estimate the optimal implementation method.

Goals 1,2 - Step 6. Document that improved patient outcomes are associated with improved health-related quality of life.

Quality of life is markedly reduced in patients with end-stage heart failure. (40, 41) However, the main improvement in quality-adjusted life years (survival*quality of life adjustment) with treatment will be through increased length of life. We are committed to systematically reviewing the current knowledge on heart failure and health status and will use health status measures such as the Kansas City Cardiomyopathy Questionnaire (KCCQ, 42) as a secondary outcome in our proposed quality improvement interventions. Dr. John Spertus (creator of the KCCQ) and Dr. John Rumsfeld both have expertise in the evaluation of health related quality of life and serve on the Executive Committee of CHF QUERI.

Goal 3: Prevention and Identification of Unrecognized Heart Failure

We plan to focus on goal three after sufficient progress is made with Goals 1 and 2. We plan to achieve this goal by first identifying patients at risk for heart failure or with unrecognized heart failure through the use of local data systems. One major barrier to success is a lack of a field for left ventricular ejection fraction in CPRS. As noted above, we have created a white paper describing our proposal and will continue to work with other interested VA offices (Patient Care Services, OQP) to make this change.

For patients without a known ejection fraction there are several screening tests available with varying accuracy. It is unclear if screening with a particular test or combination of tests is a cost-effective use of resources. We have obtained pilot data from single sites, and plan to initiate multicenter projects to examine the cost-effectiveness of screening

patients at risk for heart failure (e.g. ischemic heart disease, diabetes mellitus, hypertension) to find those with reduced ejection fraction that will benefit from additional treatment. If patient identification and screening by a well defined program is shown-to be cost-effective then we will push for implementation of the screening program through our network of heart failure specialists, through incorporation of screening into the relevant VA clinical guidelines, through creation of national CPRS reminders, and through the VISN and hospital leadership with the help of Patient Care Services.

Definition of Success

The success of our implementation efforts will be measured at two levels. First, the intervention must be adopted. This will be evaluated by surveying local facilities including champions of our heart failure provider network, through formative evaluations during the implementation. Second, the interventions must succeed. Success will be evaluated by measuring use of life-prolonging medications from EPRP and if needed PBM review (where increased use of these treatments is the aim as with our first goal). Rather than employing a simple before-after approach to data analysis we plan to use a controlled design or a time-series approach. We recognize that confounding, bias, and lack of power may limit our ability to detect a real effect of the intervention on process of care and outcome. Thus, we will not automatically label an intervention as ineffective if we are unable to show an improvement in outcome following implementation.

For those interventions shown to be effective the cost-effectiveness including a budget impact analysis (43) will also be addressed. For example, even if a new clinic of nurse-initiated medication improves care, the improvement must be worth the cost of staffing and running the clinic. Thus, we will use cost-effectiveness of implementation efforts as an additional measure of success.

Barriers to Implementation

We have examined barriers to implementation of heart failure interventions through a survey to Cardiology Section Chiefs. Their comments indicated that the initial cost of implementation is the most significant barrier. We believe the hospital and VISN leadership will recognize that the proposed interventions may be cost neutral or savings for several reasons. First, heart failure hospitalization is a costly illness (\$1000 per day), and second, a significant number of hospital days at outside hospitals are being paid by

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VA centers due lack of local staffed beds. Thus, any savings in hospitalization days will have a direct and positive effect on the hospital's budget. The potential for these interventions to be cost-neutral or even savings, their positive impact on heart failure specific performance measures, and the resultant improvement in quality of care should make any effective intervention attractive to local VA administrators.

There is an additional barrier to implementation activities that do not address a current VA performance measure (e.g. beta-blockers for heart failure). Therefore, we are working with the Office of Quality and Performance to align the VA's quality indicators for heart failure with other performance measures endorsed by the National Quality Forum indicating they are based on the best available evidence.

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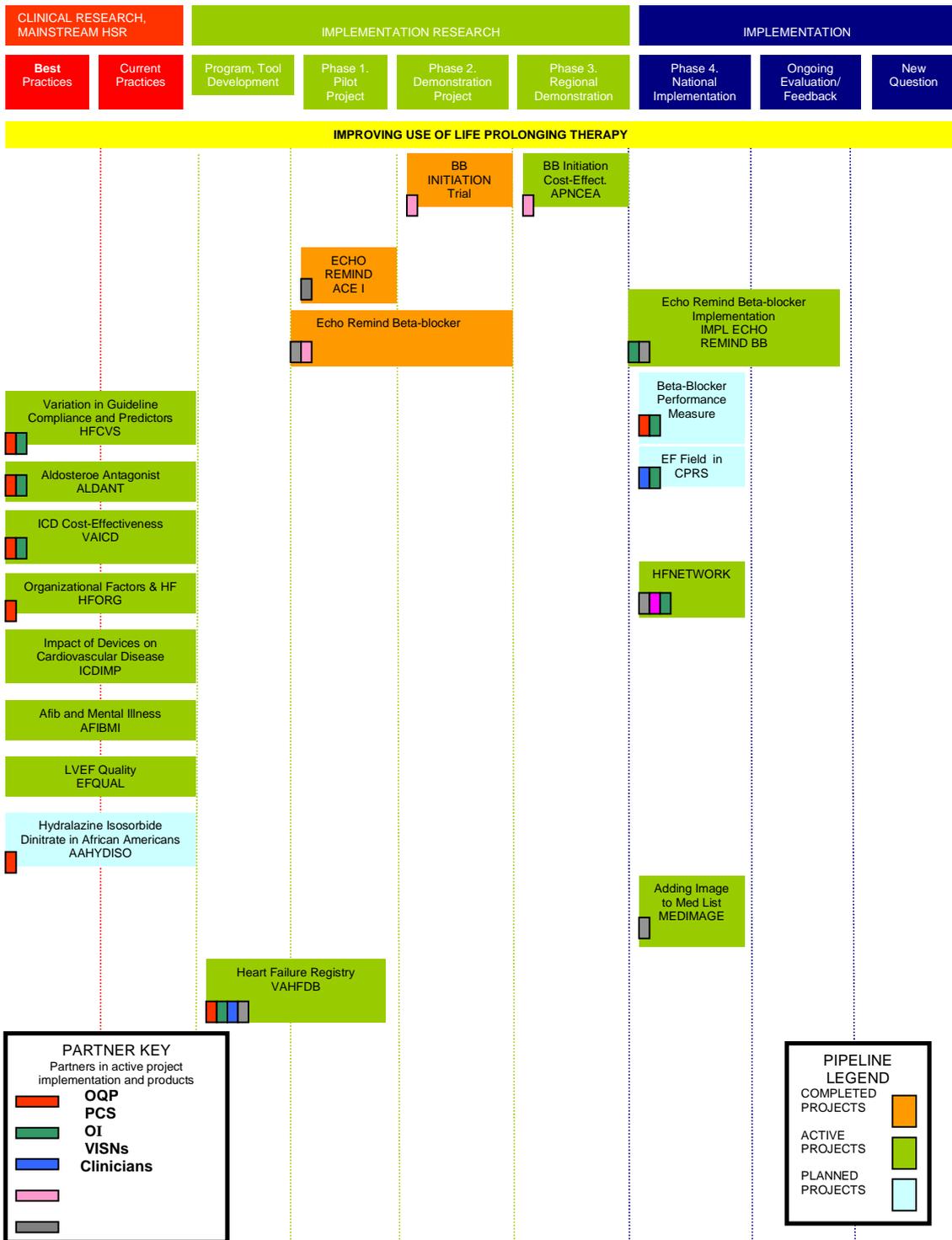


Figure 4. Pipeline of CHF QUERI Projects (continued on next page). This diagram displays the current, completed and planned projects of CHF QUERI and how they related to the different steps of the QUERI process. For details of each project please see the 2007 Annual Report.

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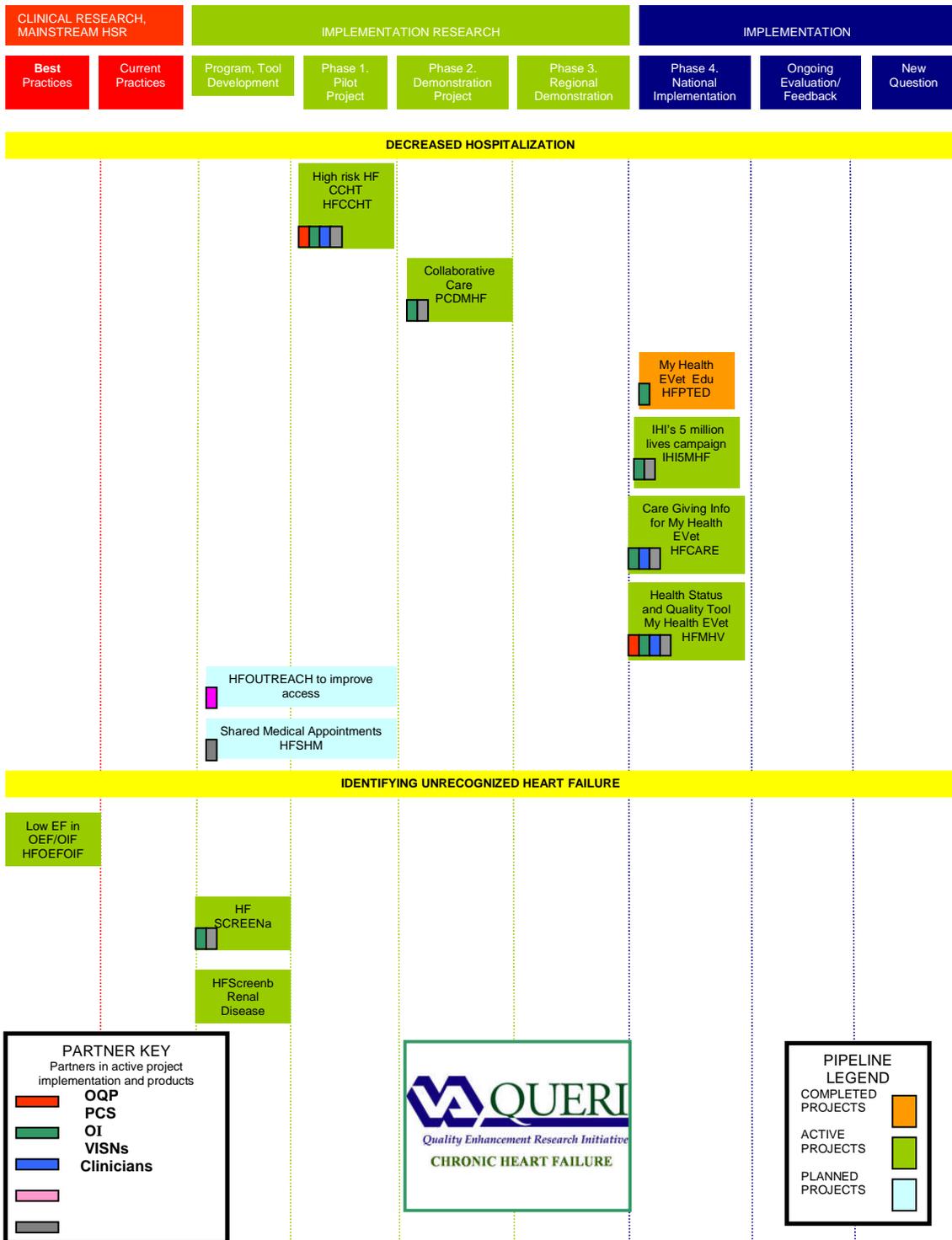


Figure 4. (Contd.) Pipeline of CHF QUERI Projects. This diagram displays the current, completed and planned projects of CHF QUERI and how they related to the different steps of the QUERI process. For details of each project please see the 2007 Annual Report.

II. Management Plan

II.1. Overview of Management Plan

CHF QUERI is organized into nearby Coordinating Centers. Although labeled as Research and Clinical, the centers work jointly with the Coordinators serving as Co-Principal Investigators on most projects.

The **Research Coordinating Center:** is affiliated with the Center for Health Care Evaluation (CHCE), the HSR&D Center of Excellence based at the VA Palo Alto Health Care System. The CHCE is closely affiliated with the Health Economics Research Center (HERC), a national center that assists VA health economics researchers, and the VA Cooperative Studies Program (CSP). The integration with CHCE allows the CHF-QUERI to have access to a wide array of experts in health services research, health economics, statistics, medical sociology and implementation research. Dr. Paul Heidenreich is the Research Coordinator, Dr. Anju Sahay PhD is the Implementation Research Coordinator and Drs. Mary Goldstein, and Susan Frayne serve as co-investigators.

The **Clinical Coordinating Center** is located at the San Francisco VA Medical Center and affiliated with the Interdisciplinary Research Program to Improve care for Older Veterans, a HSR&D Research Enhancement Award Program. The REAP, directed by Mary-Margaret Chren PhD provides a source of expertise in health services research. Dr. Massie, the Clinical Coordinator, Theresa Marsh, the Administrative Coordinator, Dr. Michael Shlipak and Dr. Edmund Keung (co-investigators) all contribute to CHF-QUERI. Drs. Massie, Shlipak and Keung are faculty members at the University of California at San Francisco. The Clinical Coordinating Center works closely with the VA National Defibrillator Surveillance Center, based at the San Francisco VA Medical Center and Directed by Dr. Edmund Keung. Work with the defibrillator center assists CHF-QUERI to determine trends in use of ICDs, outcome and cost of care for Veterans receiving defibrillators.

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