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

**VA Ann Arbor Healthcare System**
**VA Center for Clinical Management Research**
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# Diabetes QUERI Center
## 2011 Strategic Plan

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## 1. EXECUTIVE SUMMARY

Nearly 25% of Veterans in the Veterans Health Administration have been diagnosed with diabetes. Diabetes is a leading cause of blindness, end stage renal disease, and amputation in the US and in the VA. The mortality rate among VA patients with diabetes averages approximately 5% per year, compared with an average of 2.6% among patients without diabetes, and the majority of deaths and hospitalizations related to diabetes, both inside and outside VA, are due to macrovascular complications such as heart attack and stroke. Among people with diabetes, the presence of specific risk factors such as elevated glucose levels, poorly controlled hypertension, and dyslipidemia, can increase the probability of such devastating consequences, whereas appropriate management of these risk factors (both medical management and self-management), along with the early recognition and treatment of foot ulcers, retinal disease, and renal impairment are known to be successful in reducing end organ complications and death. This is especially true among those who develop diabetes at a younger age and those who have not yet developed complications. Consequently, the Diabetes QUERI is committed to research and collaborations to promote the use of effective care strategies that will decrease the number of patients who experience these complications and help Veterans with diabetes live longer and better lives.

Additionally, preventing type 2 diabetes through lifestyle changes and the use of medication in persons at high-risk for developing diabetes, particularly those who are overweight or obese, is also of great importance to the Diabetes QUERI. Approximately three-quarters of Veterans are overweight and nearly 40% are obese. Approaches to preventing diabetes share many of the same characteristics as those to prevent and treat obesity and other cardiovascular risk factors. Therefore, our research and implementation programs focus not only on diabetes prevention, but more broadly on obesity prevention and treatment, promotion of physical activity, and cardiovascular risk prevention.

Accordingly, Diabetes QUERI has 2 overarching goals, crafted in collaboration with our key operational partners in Patient Care Services (PCS) (and in particular the Office of Specialty Care), Offices of Primary Care, National Center for Disease Prevention and Health Promotion (NCP), and Office of Informatics and Analytics (OIA), to ensure that our efforts are closely aligned to their operational priorities and that the products of our research can be readily implemented in routine practice. These goals are:

1) To work with operations partners to promote evidence-based approaches to reduce diabetes risk factors and the incidence of diabetes among Veterans (Diabetes Prevention/Primary Prevention); and,

2) To work with operations partners to promote evidence-based approaches to improve treatment and reduce complications of diabetes (Diabetes Management/Secondary and Tertiary Prevention).

Our driving vision for Goal 1 is to help Veterans improve physical activity, decrease obesity and decrease cardiovascular risk by developing efficient and effective programs to identify Veterans at risk for diabetes and related conditions, help match Veterans with programs and treatments that best suit their risk, needs, preferences and resources, and provide self-management support that allows Veterans to meet their health goals. We will achieve Goal 1 by: A) developing and using individualized assessments to tailor recommendations and enhance uptake of prevention programs; and B) developing and implementing low-cost scalable approaches to support self-management for diet, exercise, and weight maintenance or loss.

Our vision for Goal 2 is to help Veterans improve their quality of life and reduce complications from diabetes by developing Veteran-centered programs that integrate identification of patients at high risk, provide decision support to patients and providers that allow for individual goal setting and that match patients' needs and preferences with available programs, and support patients' self-management goals. We will achieve Goal 2 by: A) developing and implementing individualized assessments and decision support tools to enhance the use of appropriate diabetes treatments and decrease inappropriate treatments; and B) developing and implementing innovative programs to improve diabetes self-management.

The Diabetes QUERI takes a population based and Veteran-centered approach to improving the health and healthcare of Veterans with diabetes and Veterans who may be at risk for diabetes. This approach encompasses the spectrum of primary, secondary and tertiary prevention, with a special focus on personalizing care for Veterans based on their risks, needs and preferences. Of particular importance for Diabetes QUERI is recognizing the need to balance the benefits of treatment with its risks. This approach enhances appropriateness of therapy, decreases potential for harm, and improves outcomes, including quality of life. We recognize that most Veterans with or at risk for diabetes receive the majority of their care in the primary care setting, and therefore a large portion of our interventions are either primary care based or center on improving effective communication and coordination strategies between primary and specialty care.

As a result of the work of the Diabetes QUERI, as well as the work of our key partners, the VISNs and facilities participating in QUERI programs, we anticipate several important long and short term impacts. The work that we will forward in Goal 1 should result in a significantly

larger percentage of eligible Veterans participating in lifestyle change programs through better access (expanding services through automation), by providing more program choices, and by better methods of matching Veterans with beneficial prevention programs (making them aware of programs, considering program and individual characteristics, encouraging shared decision making between the Veteran and their clinical team). Within our 3-year planning horizon, impacts for participants in our QUERI studies include: increased physical activity, improved diet, weight loss/maintenance, increased self-monitoring, as well as higher engagement in lifestyle programs and weight maintenance/loss. For Goal 2, we anticipate several major impacts in the next 3 years, including the integration and use of new diabetes performance measures in routine care, the integration and use of the CarePartners program in VISN 11 even after program funding ceases, the successful implementation of the Peer-to-Peer/SMA programs in 2-3 VISNs, recommendations for new patient centered measures and decision tools that are individualized and balance overuse and underuse. Finally, within the next 3 years, Diabetes QUERI, in conjunction with operations partners, will be ready to launch and evaluate a Diabetes Self-Management Platform that incorporates assessments of individualized patient risk, decision support, and self-management support options.

Diabetes QUERI has been an active part of VA diabetes quality improvement initiatives, evaluations and expertise to inform policy since 1998. During this time, VHA has seen tremendous improvements in diabetes care. While the reasons for these improvements are multifactorial, including the work by our partners in Central Office, individual VISNs and facilities, and committed VA clinicians, members of the Diabetes QUERI have helped to forward these efforts both practically and intellectually. Our work in improving diabetes management has reached a stage of maturity such that we can focus on expanding self-management approaches and personalizing care for Veterans, in order to fulfill the vision of patient-aligned care. Our work in diabetes prevention is only beginning but has tremendous future impact.  We are looking forward to working with our partners, clinicians in the field, and Veterans, to implement and evaluate a variety of strategies to achieve further improvements in VA diabetes care and prevention.


## 2.  CLINICAL FOCUS AND SCOPE

Diabetes mellitus is a chronic condition characterized by elevated glucose levels (i.e., hyperglycemia) due to the body's inability to use blood glucose for energy.  There are several different types of diabetes but the primary form that affects patients in the VA is type 2 diabetes. Type 2 diabetes results either because the pancreas is not producing enough insulin (which is

needed to metabolize blood glucose), or the body is not able to use insulin correctly. While there may be some VA patients with type 1 diabetes, a condition in which the pancreas is no longer making any insulin, this number is very low as type 1 diabetes generally develops in younger people, thus excluding a person from military service.

Diabetes is the seventh leading cause of death in the U.S.[1] Among people with diabetes, the presence of specific risk factors over time can lead to severe and devastating complications including blindness, end-stage renal disease, amputation, heart attack and stroke. These risk factors include persistently elevated glucose levels, poorly controlled hypertension and dyslipidemia. Appropriate management of these risk factors (both medical management and self-management), along with the early recognition and treatment of foot ulcers, retinal disease, and renal impairment are known to be successful in reducing end organ complications. This is especially true among those who develop diabetes at a younger age and those who have not yet developed complications. Consequently, the Diabetes QUERI is committed to research and collaborations to promote the use of effective care strategies that will decrease the number of patients who experience these complications and help Veterans with diabetes live longer and better lives.

Additionally, preventing type 2 diabetes through lifestyle changes and the use of medication in persons at high-risk for developing diabetes, as demonstrated in the U.S. Diabetes Prevention Project (DPP) and Finnish Diabetes Prevention Study (DPS),[2-4] is also of great importance to the Diabetes QUERI. Approaches to preventing diabetes share many of the same characteristics as those to prevent and treat obesity and other cardiovascular risk factors. Therefore, our research and implementation programs focus not only on diabetes prevention, but more broadly on obesity prevention and treatment, promotion of physical activity, and cardiovascular risk prevention. Specifically, in collaboration with the VA National Center for Health Promotion and Disease Prevention (NCP) we are developing, testing and evaluating interventions and implementation strategies to promote weight loss and increase physical activity both for patients with diabetes as well as those at risk for diabetes.

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These interventions involve clinical system redesign, use of clinical information systems, and decision support to help providers and teams identify patients in need of additional or different management and assist both providers and patients in making decisions about treatment options. We also stress that improving management of obesity, pre-diabetes and diabetes must focus on enhancing patients' ability for self-management. While the health system can provide the infrastructure and support to promote effective self-management, patients must implement that support at home and in the community. Therefore, providing effective and efficient self-management support is an extremely important focus of the Diabetes QUERI.

## 3. SIGNIFICANCE AND CONSEQUENCES

### 3.1 Obesity and Pre-Diabetes

The incidence of overweight and obesity among Veterans is high and likely to be increasing rapidly, as it is in the general US population.[5] This moving target makes it difficult to get accurate current estimates on the prevalence of overweight and obesity. Using NHANES data from 1999 to 2008, Koepsell et al. found that approximately 75.4% of Veterans were

overweight and 32.8% were obese.[6] These rates were similar to rates seen in age and sex adjusted non-Veterans from the same cohort.   In a study of 1.8 million Veterans seeking care in the VA system in 2000, 68% of women and 73% of men were overweight or obese.[7] Statistics on younger Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) Veterans are particularly alarming.  In one recent study of OEF/OIF Veterans who were frequent users of the VA health care system, 86% were overweight or obese at initial presentation for care in the VA.[8] These statistics raise significant concerns about an increasing number of Veterans who may develop obesity related diseases, such as heart disease, diabetes, and hypertension, as well as disabling disorders related to degenerative joint disease.[1,9]

According to 2005–2008 NHANES data, 35 percent of U.S. adults ages 20 years or older and 50 percent of those ages 65 years or older had pre-diabetes. Applying this percentage to the entire U.S. population in 2010 yields an estimated 79 million Americans ages 20 years or older with pre-diabetes.[10] The incidence of pre-diabetes among Veterans is currently unknown. However, among Veterans with a body mass index (BMI) > 30 who enrolled in a Diabetes QUERI weight loss clinical trial, 45% had pre-diabetes based on VA criteria. Treating pre-diabetes with either lifestyle interventions or with metformin has been shown to reduce the risk of developing type 2 diabetes.[2] One study documented cost savings over 5 years with early identification and treatment of pre-diabetes.[11]


**3.2 Diabetes**

Diabetes is a prevalent condition, affecting about 25.8 million people or 8.3% of the US population.[1] In addition, the number of individuals with diabetes is on the rise worldwide, which is attributed in part to the aging population and other general risk factors including obesity and sedentary life-styles.  The prevalence of diabetes in the VA population, however, is considerably higher.  In FY2000 about 18% of Veterans (600,000) using the VA healthcare system had diabetes (36% under age 65). In FY2010, this number rose to 24% (1.45 million Veterans, 52% under age 65), including over 620,000 Vietnam Veterans (personal communication, Leonard Pogach, MD).  Although this increase may be attributed in part to the health-related factors listed above, this increase within VHA is also the result of policy changes, such as those that granted category 8 Veterans access to VA healthcare and added type 2 diabetes to the list of presumptive conditions associated with herbicide exposure, including Agent Orange. Rules permitting eligible Veterans to apply for and receive compensation for type 2 diabetes related to herbicide exposure went into effect July 9, 2001.

The high prevalence of diabetes has significant clinical impact on the US and Veteran population. Diabetes is a leading cause of blindness, end stage renal disease, and amputation in the US[1] and in the VA. For example, a single site assessment of nearly 800 Veterans who received a diabetes eye exam found that over one-third had early disease or were at high risk for potentially preventable visual loss or blindness.[12] In 2000, the prevalence of stage 3-5 chronic kidney disease (CKD) among Veterans with diabetes was approximately 30% and of particular concern was the 11% of Veterans with diabetes <55 years of age with CKD.[13] Finally, at least three quarters of non-traumatic amputations in VA involve patients with diabetes.[14] The mortality rate among VA patients with diabetes averages approximately 5% per year, compared with an average of 2.6% among patients without diabetes,[15] and the majority of deaths and hospitalizations related to diabetes, both inside and outside VA, are due to macrovascular complications such as heart attack and stroke.[16-18]

Although the use of inpatient hospital care provided by VA facilities for Veterans with diabetes decreased from 1.68 discharges per person in 1994 to 1.61 discharges per person in 1998,[19] the use of VA outpatient care among Veterans with diabetes has been on the rise. It is estimated that in FY1998, the total cost of VA inpatient and outpatient use by Veterans with diabetes was over $1.6 billion or approximately 3.9% of total VA expenditures.[19] In 2010, the number of visits to diabetes clinics alone was 280,235 at an annual cost of over $75 million (VISN 1 VERC, communication Leonard Pogach MD). Annual VA pharmacy costs for patients with diabetes have also been increasing. As of FY2000 VA patients with diabetes received 30% of all VA pharmacy prescriptions, which accounted for approximately 28% of all pharmacy dollars expended.[20] In 2007, diabetes (not including treatment of complications) was the 4th most expensive disease (combined inpatient and outpatient costs), and in FY2008, the estimated cost of glycemic treatment alone was approximately $450 million (VSSC Diabetes Clinical Cohort, communication Leonard Pogach MD).

Although the direct medical costs related to diabetes are certainly important, the indirect costs associated with this condition are also of significant concern. A study by Diabetes QUERI affiliated investigators found that costs associated with diabetes-related mortality, disability, early retirement and work absenteeism, based on a national household sample of Americans, was more than $133 billion over the lifetime of the study cohort.[21] It is estimated that in 2007, diabetes cost the United States $174 billion, with $58 billion due to disability, work loss, and premature mortality and an additional estimated $20 billion due to reduced productivity while at work.[22] Aside from the staggering cost, this study draws attention to the increased prevalence of physical and cognitive disability among persons with diabetes, which often lead to absenteeism

and early retirement. An increased risk of disability among individuals with diabetes has been found in a number of studies,[16] and is of concern not only because of the cost implications but the impact on quality of life.

## 4. TREATMENT/MANAGEMENT EVIDENCE BASE

### 4.1 Prevention of Type 2 Diabetes

Individuals who are at high risk for type 2 diabetes can prevent or at least substantially delay the onset by making small changes in diet and exercise behaviors that result in moderate amounts of weight loss. In the Diabetes Prevention Program study (DPP), individuals at high risk for developing diabetes who were randomized to a lifestyle modification program promoting moderate intensity physical activity for 150 minutes each week, decreased fat intake to less than 30% of daily intake, and a 7% reduction in weight, reduced the incidence of developing type 2 diabetes by almost 60% compared to controls.[2] The number needed to treat to prevent one case of type 2 diabetes in this trial was 7. Other large randomized controlled trials have confirmed these results.[23,24]

Diet and exercise changes that yield weight loss are not the only interventions that have been shown to prevent type 2 diabetes. Even in the absence of weight loss, adopting elements of the Mediterranean diet, including increased consumption of olive oil and nuts accompanied by a reduction in saturated fats, resulted in a reduction in incidence of diabetes similar to that seen in the DPP.[25,26] Medications can also reduce the incidence of diabetes. One arm of the DPP was given daily low dose metformin and these participants were 30% less likely to develop type 2 diabetes than the controls. While metformin is effective, it is only half as effective as lifestyle interventions and does not yield the same non-diabetes related benefits seen in lifestyle change interventions. Specifically, lifestyle interventions aimed at reducing the incidence of diabetes also improve outcomes for other health conditions, including coronary artery disease, depression, osteoarthritis, and some cancers.[27]

While the DPP was expensive – costing approximately $3500 per person over 3 years – recent studies have shown that similar results with respect to intermediate outcomes such as weight loss can be achieved with less costly interventions. Both group-based and internet-mediated interventions modeled on the DPP curriculum have been shown to yield significant weight loss at a substantially reduced cost.[28,29] Simulated cost effectiveness analyses of these lower cost versions of the Diabetes Prevention Program show that they have the potential to be cost-saving while simultaneously improving the health of Veterans.[30]

**4.2 Diabetes Management**

The evidence base for optimizing diabetes care and patient outcomes is extensive. This evidence is the foundation for the VA/DoD Management of Diabetes Mellitus Clinical Practice Guideline.[31] The Diabetes QUERI has a long-standing linkage to the guideline development process with four Executive Committee (EC) members serving on the VHA/DoD Diabetes Mellitus Clinical Practice Guideline Workgroup.[31] The fact that so much is known about how to improve outcomes for patients with diabetes is what provides the true impetus for the Diabetes QUERI, since our goal is to help implement strategies that efficiently deliver state-of-the-art evidence-based care in VHA. Due to the vast nature of the literature, much of which is fully summarized in the 2010 Guidelines, in our discussion below we only highlight key studies, especially recent ones, and those findings that are especially relevant in defining the Diabetes QUERI focus areas.

During the past two decades, efficacy studies have demonstrated that improving processes of care can substantially delay or prevent both microvascular and macrovascular complications of diabetes. Microvascular disease, which affects small blood vessels in the eye, kidney and nerves, is influenced by both level of glycemic control (i.e., blood sugar control) and blood pressure control.[32-37] While some studies have suggested that tight glycemic control may decrease macrovascular complications for type 2 diabetes,[36,38] more recent studies have shown that glycemic control is unlikely to play a large role in reducing macrovascular events. This is perhaps in part because most current patients are also receiving risk reduction strategies with appropriate blood pressure control, lipid therapy and aspirin treatment.[34,39,40]

Although most Veterans now have at least acceptable glycemic control, the relatively smaller percentage of patients (~16%) who continue to have persistently poor control (A1c >9% or no measure) remain a high-risk population of interest for the Diabetes QUERI. Consistent with our population and risk based approaches, we are especially concerned about younger Veterans with poor glycemic control, because they are at highest risk for developing downstream consequences. A complicating factor of particular interest is that while glycemic control is important in reducing complications of diabetes, we now know that overly aggressive ("tight") glycemic control is not only unnecessary for the majority of patients, it may even be dangerous for some.[39,41] Aggressive management of patients with type 2 diabetes was halted in the ACCORD trial because of increased incidence of death in the intensive treatment group (median achieved A1c 6.4% vs. 7.5%).[41] Intensive treatment was also associated with a higher risk of hypoglycemia. In the ADVANCE trial,[34] although intensive treatment (median achieved A1c of 6.5%) resulted in decreased incidence of nephropathy, severe hypoglycemia occurred

more frequently than in the conventionally treated group.  Indeed, ensuring the safety of insulin and other glycemic control regimens, and avoiding hypoglycemia, particularly in the elderly, is an important focus of the Diabetes QUERI because of the adverse consequences of severe or recurrent hypoglycemia.[42,43]

In sum, current evidence emphasizes the importance of appropriate approaches to glycemic control – targeting more aggressive control for younger patients without microvascular complications, and focusing on more moderate control among older patients, those at risk for hypoglycemia, or those with current microvascular complications who are less likely to benefit from tight control.[31,44-47] Our work in this area emphasizes our overall focus on interventions that promote individualized approaches so as to take into account risk, benefit and patient preferences.

As discussed above, glycemic control may not be the most important factor in improving macrovascular outcomes.  Control of blood pressure to about 140/80 mmHg decreases the risk of macrovascular complications and microvascular complications, as well as nephropathy incidence and progression.[18,48] Moreover, work by the CDC Diabetes Cost-effectiveness Group suggests that hypertension control not only improves health outcomes but is also cost-saving.[49] VHA supports treatment targets of <140/80 and advocates individualizing care based on tolerance of regimens.[50] Although VA guidelines for hypertension control have differed from JNC-7 and ADA recommendations based upon the strength of the evidence, the VHA-DoD Guidelines did acknowledge that a target of <130/80 mmHg could be considered, taking into account patient factors and safety and the presence or absence of microvascular disease.  In contrast, JNC-7 and ADA established a strict <130/80 mmHg target.  More recently, the ACCORD Trial results did not show a benefit of reducing blood pressure (BP) from an average of 134 to 119 systolic, except for a decrement in strokes.[40] The ongoing SPRINT trial will evaluate tighter blood pressure control in patients without diabetes, or diabetes of shorter duration, but will not be complete until 2018.

Treatment with lipid lowering agents is another important part of decreasing the risk of cardiovascular complications among patients with type 2 diabetes,[51] even among those with low baseline low-density lipoprotein cholesterol (LDL) levels.[52] The most important factor may well be the use of moderate dose statins in the majority of patients, rather than focusing strategies on intensifying therapy to reach thresholds, except possibly among those at highest cardiovascular (CV) risk.[52-55] Further, because high dose statins have higher rates of complications like myopathy and rhabodmyolisis,[56-61] it is advisable to use the doses with

greatest efficacy and lowest complications, individualized based on patient characteristics and risks.

In addition to the benefits associated with improved glycemic control and management of cardiovascular risk factors, early detection and treatment of eye and foot complications also have proven efficacy.[37,62-64] Evidence suggests that 90% of visual loss due to diabetic retinopathy can be prevented through optimal medical (including good blood pressure and glycemic control) and ophthalmologic care, with early detection and optimally-timed laser therapy playing a key role in this prevention strategy.[65] However, while laser therapy for established diabetic retinal complications is an effective treatment, there has been controversy surrounding the timing of routine retinal screening. Work conducted by the Diabetes QUERI, as well as in the United Kingdom, shows that conducting routine annual screenings for most diabetes patients is inefficient (as the majority of those undergoing frequent examinations are patients with previously normal fundoscopic examinations) and closer monitoring of those with known disease is likely more effective in preventing blindness due to diabetic retinopathy and macular edema.[66-69]

It is estimated that up to 50% of amputations are preventable,[70] with a number of observational, quasi-experimental and randomized controlled studies to show that foot complication rates can be substantially reduced through the use of certain practices.[71,72] However, research (including a study by Diabetes QUERI affiliated investigators) also suggests that the application of specific clinical practices in isolation (e.g., educating patients to inspect their feet on a daily basis) is not enough. Decreasing ulcers and amputations requires a coordinated, multi-disciplinary systems approach that includes screening, surveillance and salvage.[73,74]

Besides the clinical aspects of treating patients with diabetes, individuals with chronic conditions, including diabetes, are expected to engage in a number of daily behaviors, such as taking medications, following nutrition and exercise plans, and monitoring disease control, which are generically referred to as "self-management." The literature on interventions designed to improve self-management, well summarized in the 2010 VA-DoD Diabetes Guidelines,[31] is vast and varied. Unfortunately, whether the delivery of these interventions is through group visits, pharmacists or electronic means, many show initial but often not sustained benefit.[31] It is essential that VA develop and implement methods to improve diabetes self-management that are sustainable and efficient. Consequently, we firmly believe this is an important area of continued research for the Diabetes QUERI.

A final Diabetes QUERI related treatment issue is the inpatient management of glycemic control. There are several studies that suggest survival benefits and decreased morbidity with intensive glucose monitoring and management of critically ill and post-surgical patients.[75-78] Perhaps even more important is the institution of appropriate insulin management protocols in the inpatient setting that avoid wide swings in glycemic control, including extreme hyper- and hypoglycemia.[79,80] Although clearly an important area, at present this issue is considered outside the main focus of the Diabetes QUERI, in part, because this topic is being addressed by others within VHA. Specifically, the VA Inpatient Evaluation Center (IPEC) has been involved in inpatient care related to hypo- and hyperglycemia for several years. Dr. Mercedes Falciglia (member of the Diabetes Program Field Advisory Committee) at the Cincinnati VAMC has been the primary lead in this area, and continues to work with IPEC on inpatient-focused issues. There may be future opportunities for implementation research in this area in collaboration with IPEC.

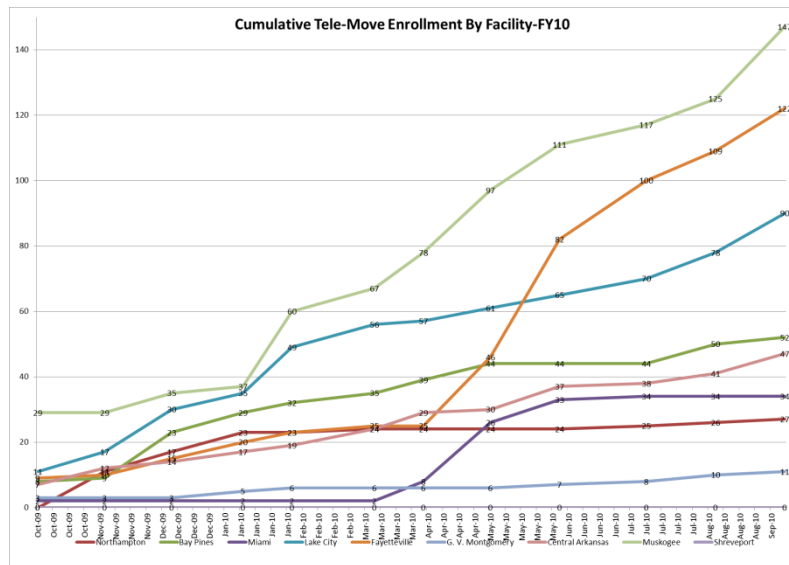## 5. CURRENT PRACTICES AND QUALITY/OUTCOME GAPS

### 5.1 Veterans at risk for diabetes

Although to date the primary focus of the Diabetes QUERI has been on Veterans with diabetes, as already noted we are expanding our focus to include Veterans at risk for diabetes with a specific emphasis on obesity and lifestyle modification. To address the high rates of obesity and the associated high rates of chronic illness, the VA developed an innovative and broad reaching weight loss program called MOVE!, which targets Veterans with BMI > 30 or those with BMI > 25 who have additional cardiovascular disease risk factors. The program includes a large screening component and evolving intervention components. The intervention components focus on facility-based group classes with some telephone counseling. Technology mediated intervention components such as the CCHT-Weight Management (TeleMOVE) program have recently been implemented. FY2010 data show that MOVE! screening is now being completed in approximately 95% of target individuals across the VHA. This screening percentage has increased steadily in the 5 years since MOVE! was rolled out as a national program, especially after introducing a screening performance measure. Veterans who enroll in the MOVE! program and continue to participate do benefit. The average weight loss among one cohort of engaged MOVE! participants was 3.5 lbs in 6 months, with approximately 20% achieving a 5% weight loss.

However, impact of the MOVE! Program is limited by low enrollment rates and high drop-out rates. In FY2010 only 10% of individuals identified as eligible for MOVE! attended at

least one session, down 2% from the previous year.[81] It is tempting to interpret the low attendance rates as evidence that Veterans are not interested in weight management interventions. However, about half of facilities report that capacity of existing MOVE! programs is limiting participation and this was confirmed in our own evaluation.[82] Travel time and costs, access and scheduling issues typically associated with facility-based group programs prohibit participation by many Veterans.

TeleMOVE is a relatively new program that has been rolled out to VA medical centers across the country over the past 2 years. While at this time there is limited data regarding the effectiveness of the program, preliminary data from a qualitative implementation study conducted by Diabetes QUERI investigators suggests that



Cumulative Tele-Move Enrollment By Facility-FY10

unexpectedly high staffing requirements due to frequent in-person or telephone based patient contact, along with technical barriers, have limited the dissemination of a potentially effective intervention. As can be seen in the enrollment graph above, there was substantial variability in recruitment success between the 9 sites that participated in the pilot intervention study. Preliminary quantitative results indicate that the automated TeleMOVE program is as effective as traditional MOVE! for weight loss and that women, rural veterans and whites are more likely to enroll in TeleMOVE than are men, urban veterans and African Americans. Additionally, those enrolled in TeleMOVE are significantly more obese on average than those enrolled in MOVE!.

MOVE! data and early experiences with TeleMOVE in FY2010 suggests that the following quality gaps need to be addressed:

a) Delivering MOVE! interventions to more eligible Veterans by expanding the capacity of existing programs and leveraging those programs using automation and technology-mediated interventions as well as exploring options such as peer-to-peer programs.

b) Improving access for all Veterans by providing effective and low-cost interventions that do not require frequent face-to-face visits with travel to a medical center for participation.

c) Increasing the effectiveness of MOVE! interventions by incorporating more sophisticated self-monitoring and goal setting tools including objective monitoring of physical activity and automated goal setting algorithms.

d) Enhancing patient centeredness of MOVE! by providing autonomy supportive interventions that accommodate personalization and Veteran choice.

As the MOVE! program evolves, quality measures are evolving as well. Initial quality measures focused on screening rates rather than weight loss outcomes. This was due in part to the difficulties associated with accessing and using BMI data. As stated in the recent FY2010 Evaluation Report for MOVE! "numerous limitations in using and interpreting these data continue," referring to BMI data used to evaluate the program. Over half of individuals seen in MOVE! clinics did not have BMI components recorded in CPRS.[81] Ideally, future quality measures would address the ultimate patient-oriented outcome of success in weight loss (or prevention of weight gain) rather than process measures such as screening and participation rates. In shifting to a more prevention focused agenda, we also advocate broadening performance measures to include Veterans who are not yet obese but who are at risk of becoming obese. This would include Veterans whose BMI is 25-30, and especially those with additional cardiovascular risk factors. Moreover, while improvements in BMI tracking and prevention indices will help us improve evaluation of obesity prevention interventions, in the future more detailed real-time objective measures of weight, diet and physical activity behaviors and preferences should be tracked and incorporated into patient medical records. These data would allow the identification and personalization of diet and exercise program recommendations, and feed automated tailoring algorithms, thereby efficiently delivering the right type of intervention to the right patient.

**5.2 Veterans with diabetes**

Over the past 15 years, the quality of diabetes care in VA has significantly improved, making VHA a model of care within the US and worldwide.[83-85] For example, a comparison of VA performance data for FY2009 with corresponding information on patients in Medicare managed care plans indicates substantially better results for VA patients:

- Received an annual HbA1c test: 97% of VA patients vs. 90% of Medicare beneficiaries

- HbA1c > 9%: 15% vs. 28%
- Blood pressure measure < 140/90mmHg: 80% vs. 61%
- Received an annual eye exam: 88% vs. 64%
- Had an LDL cholesterol measure: 96% vs. 87%
- LDL measure of < 100 mg/dl: 69% vs. 50%

Although there is some variation across VISNs and facilities, in general, performance on most traditional diabetes measures is high across VHA.[86,87]

These high rates of achievement on traditional measures of care undoubtedly reflect the high quality of care provided for Veterans with diabetes within VHA. However, these metrics are not without limitations and as the VHA moves to a more patient-centered approach to care, there is the potential to more finely hone the measurement of the quality of care to take into account the distinct needs of VHA's diverse patient populations. This would include putting particular emphasis on improving glycemic, blood pressure and lipid management for patients at high risk for poor outcomes (e.g., young Veterans, those with high CV risk, and high risk for nephropathy). Equally important, new measures should help insure that treatment is not unnecessarily intensified for those who are less likely to benefit or who may even be harmed by increased medication.

For example, young Veterans with diabetes but without other comorbid conditions have worse glycemic control than young Veterans with co-morbid conditions. This has a major impact upon the estimated 650,000 Veterans of the Vietnam Era with diabetes (about 31% of that era, FY10 data, personal communication Lynette Nilan RN, Patient Care Services), the majority of whom are service connected. However, while there may be a need for more intensive treatment in certain patient subgroups such as these younger Veterans, we must also be cognizant of the potential for harm of intensive treatment among other patients.[43] Indeed, we have found that from 2000 to 2004, over 10% of diabetes patients in VHA had a hypoglycemic event each year.[88] This estimate, however, only includes events captured through codes available in administrative data and, with average A1c levels among VHA diabetes patients consistently declining by 0.5% per year, there are concerns that rates of hypoglycemia may actually be increasing. Another recent study demonstrated high rates (30%) of coded hypoglycemia for older Veterans on insulin with cognitive impairment or dementia (prevalence about 18% ).[89] Consequently, much work remains in the development of measures and interventions that focus on identifying patients at high risk from poor control, hypoglycemia, or potential overtreatment, and on implementing approaches that focus on the appropriateness of treatment while incorporating patient preference.

Similar to the issues discussed above in regard to glycemic control, the drive toward achieving ever more ambitious control targets for blood pressure and LDL, without considering measurement variability and the suitability of the goal for a particular patient, raises significant concerns about the appropriateness of current measures and potential harm to patients through overtreatment.[90-92] The Diabetes QUERI's development of tightly-linked clinical action measures, using national VA data (from the Corporate Data Warehouse – CDW, 2009-2010), demonstrates that among diabetes patients age 18-75, 82% had a BP <140/90, while an additional 12% had a higher BP but appropriate clinical management.[93] However, in the cohort of diabetes patients aged 18 and older (n=976,898), 25.5% had a BP < 140/65 and 30.8% of these were potentially overtreated, defined as having a BP < 140/65 and BP medication intensification within 90 days or being on ≥ 4 BP medications at moderate or high dose. Among the 263,492 patients 76 and older, 40.1% had a BP < 140/65 and 30.6% of those were potentially overtreated (12.2% of all diabetes patients 76 and older).[94]

There is also evidence that hyperlipidemia management would benefit from a focus on use of moderate dose statins rather than achieving a target LDL. Approximately 76% of Veterans with diabetes aged 50-75 have an LDL < 100 or are on at least a moderate dose statin. Despite the problem of the over 20% who are not on a moderate dose statin, we find evidence of potential overtreatment with high dose statins. For example, 116,462 of the 564,392 diabetic patients without ischemic heart disease (IHD) were on high dose statins and thus potentially overtreated – representing 20.6% of diabetic patients without IHD and 13.3% of all diabetic patients.[95] Although specific harms associated with overtreatment have yet to be conclusively demonstrated in this population, these data certainly suggest that additional work on improving appropriateness of care for glycemia, blood pressure and lipid management is warranted.

Another avenue for improvement in the care of VHA diabetes patients involves specific sub-populations, such as women and patients with potentially complicating co-morbidities, such as mental health conditions. Research continues to show less improvement in some clinical outcomes among women and some racial/ethnic groups despite, in many cases, high performance on process of care measures.[96-99] Similarly, potential disparities in care processes and/or outcomes continue to surface for patients with various mental health conditions. Recent research suggests gaps in receipt of guideline-concordant medical care for VA patients with mental disorders, particularly for diabetes services that required coordination between providers.[100] A study by Copeland and colleagues of Veterans with psychosis, with or without

concomitant diabetes, found that Veterans with psychosis were more likely to have decreasing use of primary care over time, and this was associated with decreased survival.[101]


6.  **SIGNIFICANT INFLUENCES ON CURRENT PRACTICES AND OUTCOMES**

The significant improvements in diabetes care observed over the past several years are unquestionably due to the combined efforts of many within VHA.  In particular, programs and initiatives of Patient Care Services (PCS), the performance monitoring activities by the former Office of Quality and Performance (OQP) (now incorporated as part of the Office of Informatics and Analytics - OIA) and the development and dissemination of the VA/DoD diabetes clinical practice guidelines are all notable factors contributing to improvements in diabetes care quality VA-wide. Diabetes QUERI researchers and EC members have worked directly with these offices to help inform and evaluate many of these efforts. Research conducted by the Diabetes QUERI and other investigators shows that performance measurement has been a critically important tool for improving care, including diabetes care, in VHA.[83] However, as discussed in the previous section, research also suggests that the proliferation of measures and focus on 'meeting the measures' may have unintended consequences. This underscores the importance of continuing our close partnership with OQP/OIA to develop new measures that re-focus attention on providing appropriate care.[102-104]

In addition, we look forward to extending this partnership to support efforts by OIA in the area of informatics as they work to create registries and management tools as well as the Integrated Electronic Health Record (iEHR), which will have greater functionality for chronic disease management. Similarly, we expect that new efforts by the Offices of Primary and Specialty Care (described below) as well by Patient Care Services, will further change the face of diabetes care in VA. Diabetes QUERI is working closely to help inform and advance these efforts, with our co-clinical coordinators anchored in the Office of Specialty Care (Dr. Len Pogach) and Primary Care (Dr. Susan Kirsh), and with the addition of new members to the EC from the Office of Primary Care (Ms. Joanne Shear) and OIA (Dr. Jonathan Nebeker).

Over the past decade, the National Center for Disease Prevention and Health Promotion (NCP) has led VHA emphasis on and improvements in prevention of obesity and thus, diabetes. We have worked closely with NCP for the past several years to evaluate and enhance NCP's efforts related to MOVE! and TeleMove (described above) and the Director of NCP (Dr. Linda Kinsinger) has been an active member of the Diabetes QUERI EC since 2005. Future improvements in prevention that focus on ways to deliver obesity prevention interventions in

efficient and effective ways will surely result from the combined efforts of NCP, PCS, Primary Care, and OIA, among others. Diabetes QUERI is working closely with all these partners as part of our research effort to improve diabetes and obesity prevention practices by making them more accessible, less costly, and more effective.

Two newer initiatives that are expected to have a significant impact on diabetes care within VHA over the next several years are the Primary Care Program Offices' Patient Aligned Care Team (PACT) initiative and the Office of Specialty Care Services (SCS) transformational initiatives, such as the VA Specialty Care Access Networks (SCAN). PACT involves implementing a patient-centered medical home (PCMH) model at all VHA primary care sites. This redesign effort will enhance self-management support for diabetes patients, as well as those at risk for the condition. Dr. Kerr is the Director, and Dr. Krein co-director, of the VISN 11 PACT Demonstration Laboratory, funded by the Office of Primary Care. As part of the lab, we have engaged Diabetes QUERI investigators to focus on ways to identify high risk patients, match them with available and novel technology-facilitated self-management programs, and incorporate programs that focus on efficiently involving caregivers and peers in the self-management activities of Veterans with diabetes. In addition, the Diabetes Primary Care Systems Redesign Committee, chaired by Dr. Susan Kirsh, is helping to inform sub-initiatives related to PACT further emphasizing the focus on diabetes patients and diabetes care as part of this effort. The PACT redesign effort and patient-centered approach also provide the ideal foundation for prevention related activities, through increased staffing for preventive services and the incorporation of health psychology and health behavior change clinical providers. Indeed, this model embodies a wellness approach as endorsed in the Department of Veterans Affairs Strategic Plan Refresh 2011-2015, which notes that "Nationwide, chronic diseases are being diagnosed at earlier ages. This trend will require reorientation of U.S. health care away from the acute care model, and toward a more patient centered model that focuses on wellness and disease prevention."

As part of the VHA mission of creating a patient-centered healthcare system, SCS is launching several initiatives, which among other things, are designed to improve Veteran access to specialized services and build a strong interface with PACT. One of these initiatives is VA SCAN, an innovative healthcare program that uses telehealth technology to allow healthcare specialists to provide expert advice to primary care providers in rural and remote settings as they treat of patient with complex medical conditions such as diabetes. There are currently five SCAN sites focusing specifically on diabetes. Diabetes QUERI researchers, led by David Aron, a longtime Diabetes QUERI member, will be involved in helping to evaluate local

SCAN and other SCS transformational efforts. As both PACT and SCAN are relatively new initiatives, their influence on VA diabetes care and outcomes is yet to be determined. However, both hold great promise for promoting advances in diabetes care and prevention across VHA.

In addition to the many internal efforts just described, VA diabetes care has also been influenced by a number of groups outside VHA. For example, VHA performance measures are generally consistent with those used outside VHA in order to facilitate comparisons between VA and non-VA care. Likewise, guidelines and practice standards disseminated by the American Diabetes Association or various professional societies can influence care within VA. However, while it is important to recognize the likely influence of these external groups on VA diabetes care, it is also important to note the influence of VA and QUERI investigators on helping to inform the recommendations and decisions made by these external entities. For example, in 1996 Dr. Pogach proposed the first VA EPRP measures, which become the basis for the first measure set of the Diabetes Quality Improvement Project. Additionally, Diabetes QUERI members have been instrumental in publicizing their disagreements with some of the recommended measures in HEDIS,[43,105-107] and have influenced VA performance measurement policy on multiple occasions. In 2007, work by Drs. Pogach and Aron, which was presented to the Performance Management Work Group, led to the removal of A1c < 7% (and BP <130/80 mmHg) as mission critical. In 2010, this work also led OQP to comment to the National Quality Forum that the <7% (modified) and <8% measures were not suitable for the Veteran population due to safety issues. OQP ceased scoring the measures in December 2010.

Also of note, Dr. Pogach, as the VA Representative to the Diabetes Mellitus Interagency Committee, has championed the VA evidence-based approach, as well as the importance of accurate A1c reporting. He is also the VA representative to the AHRQ Diabetes CER Stakeholders Panel, while Dr Aron represents the Endocrine Society on the AMA-NCQA Diabetes Measurement Group. Recently, Dr. Kerr participated in an American Diabetes Association (ADA) consensus development conference on the future of performance measurement in diabetes. Among the conclusions and recommendations of the participating experts was a specific focus on measures that encourage more patient-centered care, considering risks and benefits of treatment for the individual patient. This philosophy is strongly aligned with the views of the Diabetes QUERI and VHA diabetes clinical leaders and is largely based on the continuous measure conceptual model proposed by Drs. Aron and Pogach in a series of publications,[107-109] as well as the clinical action measures work developed by Dr. Kerr.[103,104]

Last but not least, all the committed VA clinicians who, along with facility and VISN leaders, have developed and implemented a variety of strategies to achieve the tremendous improvements in VA diabetes care must be commended.  Too often we focus on how care can be improved and what clinicians can or should do better.  However, in this case it is appropriate and worthwhile to highlight successful performance in so many areas of diabetes care as an example of what can be achieved when a system works together and leverage this success to motivate further collegial work to improve patient outcomes.

## 7.  DIABETES QUERI CENTER GOALS

As discussed in section 2, Diabetes QUERI takes a population-based and Veteran-centered approach to improving the health and healthcare of Veterans with diabetes and Veterans who are at risk for diabetes and related conditions. Consequently, Diabetes QUERI has 2 overarching goals:

1. To work with operations partners to promote evidence-based approaches to reduce diabetes risk factors and the incidence of diabetes among Veterans (Diabetes Prevention/Primary Prevention); and,

2. To work with operations partners to promote evidence-based approaches to improve treatment and reduce complications of diabetes (Diabetes Management/Secondary and Tertiary Prevention).

The ultimate outcome of Goal 1 is an expanded portfolio of effective approaches that can be used in VHA to decrease the incidence and prevalence of obesity, promote physical activity, reduce cardiovascular risk, and reduce the incidence of diabetes. This is a newly formalized goal for Diabetes QUERI and we are working closely with the NCP, as a primary partner, to ensure the approaches pursued can be implemented in future derivations of MOVE! as well as other prevention programs. Because this research area is less mature, a good deal of our focus over the next several years will be on identifying gaps in care, variations in practice, and testing novel interventions (QUERI steps 2-4). In addition, we will continue evaluating program uptake and testing implementation strategies for new or existing programs like MOVE! and the soon-to-be piloted Health Risk Assessment (HRA) tool (QUERI steps 5-6), which are both under the purview of NCP. Our driving vision for Goal 1 is to help Veterans improve physical activity, decrease obesity and decrease cardiovascular risk by developing efficient and effective programs to identify Veterans at risk for diabetes and related conditions, help match Veterans with programs and treatments that best suit their risk, needs, preferences and resources, and

provide self-management support that allows Veterans to meet their health goals. We will achieve Goal 1 by: A) developing and using individualized assessments to tailor recommendations and enhance uptake of prevention programs; and B) developing and implementing low-cost scalable approaches to support self-management for diet, exercise, and weight maintenance or loss.

The ultimate outcome of Goal 2 is an integrated portfolio of effective programs to identify patients at high risk for poor outcomes, provide decision support to patients and providers focused on effective therapies to decrease poor outcomes, and support Veterans in their self-management efforts. In this way, we hope to reduce the complications of diabetes and its treatments. Goal 2 is a more mature goal than Goal 1, and focuses on secondary and tertiary prevention. As such, a larger proportion of our work in this area involves testing, evaluating and implementing effective interventions (QUERI steps 4-6). However, because Diabetes QUERI work emphasizes enhancing the appropriateness of care, we have also expanded our focus to include examining not only undertreatment but potential overtreatment in certain diabetes populations (e.g., the elderly), as well as addressing disparities, particularly among younger Veterans and women. Our vision for Goal 2 is to help Veterans improve their quality of life and reduce complications from diabetes by developing Veteran-centered programs that integrate identification of patients at high risk, provide decision support to patients and providers that allow for individual goal setting and that match patients' needs and preferences with available programs, and support patients' self-management goals. We will achieve Goal 2 by: A) developing and implementing individualized assessments and decision support tools to enhance the use of appropriate diabetes treatments and decrease inappropriate treatments; and B) developing and implementing innovative programs to improve diabetes self-management.

**Conceptual Framework**

The Conceptual Framework for Diabetes QUERI has been adapted from the Chronic Care Model (CCM),[110,111] which is a foundational model for enhancing care delivery. This framework, shown in Figure 1, identifies the components and vision based on an ideal context within which to reduce diabetes incidence and help diabetes patients better manage their condition. This framework is aligned with our ultimate goal of providing population-based, Veteran-centered approaches to improving the health and healthcare of Veterans with diabetes and preventing diabetes and related conditions. In addition, it is aligned with VHA's real-world system re-design for primary care including interfacing with specialty care to best serve and support patients. We used this framework to help us: 1) conceptualize sub-goals that have mid-
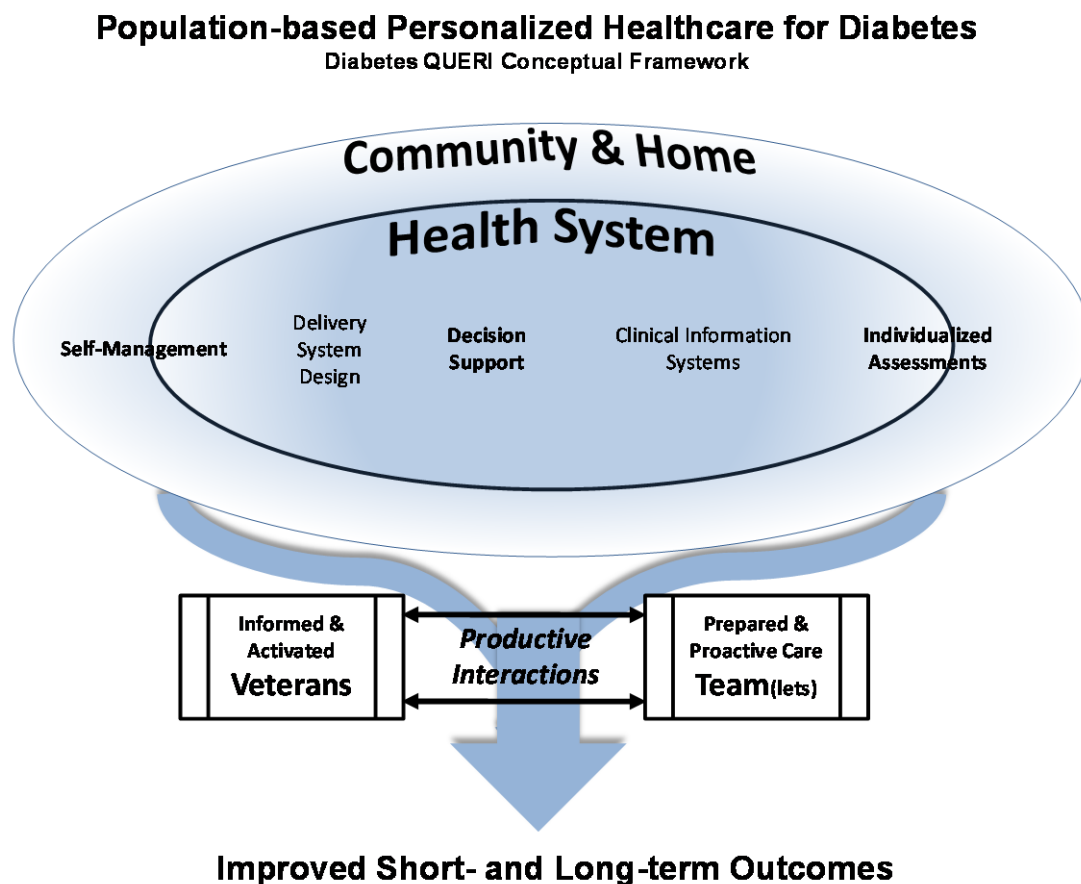
and short-term impacts; and 2) identify gaps in our current research portfolio that should be addressed in the next three years. Thus, our planned projects are designed to address gaps we identified based on the degree of alignment of our completed and current projects to components in the care delivery conceptual framework, along with discussions with our operational partners as discussed in more detail below. This framework will continue to guide prioritization of future projects.

Our conceptual framework highlights a few notable features and adaptations as they relate to Diabetes QUERI goals. First, it is important to note that while interventions will usually be initiated at the level of the health system (in our case, VHA), to be effective (and efficient) most programs that improve outcomes for patients with chronic conditions rely on informed and activated patients who are engaged in self-management activities that need to be supported, in part, through community and home venues as well as through the healthcare system. Therefore, our framework emphasizes that the health system is embedded within the broader environment consisting of community and home.

Second, to be truly personalized, care must be tailored to risks, needs, preferences and resources. Risks and needs may be based on clinical and health status, as well as risks and benefits of therapies, while preferences and resources determine a Veteran's desire for therapies, goals related to their health and ability to engage in programs. The original CCM explicitly includes informed and activated patients but does not include individualized assessments as a system component, which we believe are essential to identify patient risks, needs, preferences, and resources. Thus, we have explicitly added Individualized Assessments to the framework. This individualized assessment function may span the health system (e.g., via on-site kiosks and PACT teamlet member assessments), community (e.g., at Veteran service organizations), and home (e.g., web-based interface). The inclusion of this feature emphasizes the need to personalize individual Veterans' care using a variety of approaches. In addition, we have highlighted three areas (self-management, decision support, and individualized assessments) where we believe the Diabetes QUERI can have the most impact in the next 3 years and where we intend to focus the majority of our work. As mentioned, Individualized Assessments use patient specific data (self-reported and/or through clinical information systems) to generate information about Veterans' risks, needs, preferences and resources. Decision Support includes tools to help Veterans and providers make informed decisions about appropriate therapies and programs. Self-Management focuses on providing support for Veterans to achieve their goals. While Delivery System Design and Clinical Information Systems are important foundational components and can help to support the three highlighted

components, Diabetes QUERI does not have ultimate jurisdiction in these areas and thus we rarely focus on interventions that rely <u>only</u> on Clinical Information Systems or Delivery System Design. However, Diabetes QUERI recognizes the importance of these components and is committed to working with operational partners who are responsible for these functions as evidenced by our work to help inform system redesign efforts (e.g., PACT) and by adapting our programs to changes in clinical information systems (e.g., rolling out new electronic versions of performance measures).

**Figure 1. Diabetes QUERI Conceptual Framework.**

**Population-based Personalized Healthcare for Diabetes**
Diabetes QUERI Conceptual Framework

**Community & Home**

**Health System**

| Self-Management | Delivery System Design | Decision Support | Clinical Information Systems | Individualized Assessments |

| Informed & Activated **Veterans** | *Productive Interactions* | Prepared & Proactive Care **Team**(lets) |

**Improved Short- and Long-term Outcomes**

By focusing our work on Individualized Assessments, Decision Support and Self-Management, and by coordinating these efforts with those who work on system design and information technology components, we can make the greatest impact with our implementation efforts. This strategy allows us to leverage our work to enable productive interactions between informed and activated Veterans and prepared and proactive team(let)s. We break this

framework down into specific components, mapping completed, current, and planned projects to components in the framework in Sections 7.1 and 7.2. Specific linkages that show how individual projects build on one another in several streams of research, are delineated in the Pipeline Diagram in our Annual Report (Appendix A). Our implementation science framework, which spans both goals, is described in section 7.3.

**7.1 Goal 1: Diabetes Prevention**

Using the conceptual framework described above, and in collaboration with the Diabetes QUERI EC and operational partners in NCP and PCS, we developed the following two sub-goals for Diabetes Prevention:

A. Develop and use individualized assessments to tailor recommendations and enhance uptake of prevention programs

B. Develop, test, and implement low-cost scalable approaches to support self-management for diet, exercise, and weight loss

7.1a Plans for achieving Goal 1

Primary prevention of diabetes and related risk factors is a new goal for our center, first introduced last year and further developed since then. Our portfolio of research is just beginning. Table 1 lists completed, current, and planned projects that have been mapped to the components from the conceptual framework to which they contribute. We have laid out a roughly 3-year strategy, keeping in mind that some planned projects will likely not be completed in this timeframe but we anticipate making significant progress. The sub-goal is also indicated for each project. For completed work, we focus on those studies in the last 3 years that have directly contributed to current and planned work. For past and current studies, the project names match the short names in the project tables. It is worth noting that many of our current projects will continue and have impact in the next 3 years.

To illustrate, we conducted an evaluation of the MOVE! program in 2007 (MOVE! Evaluation) that identified the need for telephone-based self-management support services for weight management. We then developed ASPIRE-VA, which includes a phone based intervention as one of the study arms. ASPIRE-VA recently finished recruiting 479 patients and will work with the patients for another two years. Concurrently, NCP contracted with a vendor to provide phone-based coaching on six lifestyle topics, three of which are related to weight management. NCP is funding an evaluation of this program that will be conducted by Diabetes

QUERI staff in collaboration with the Durham HSR&D COE (Telephone Lifestyle Coaching (TLC) Evaluation). We have embedded a randomized control trial of a feedback tool to test its effectiveness in improving uptake as part of this evaluation. These projects are mapped to self-management support and delivery system design because they provide this support to Veterans and, if shown to be effective, will change the delivery system by providing previously unavailable services.  While the Diabetes QUERI programs that focus on prevention have the ultimate goal of weight loss, enhanced physical activity and lower incidence of diabetes, many also benefit patients with diabetes. For example, 36% of ASPIRE-VA participants have diabetes.

As discussed in section 5.1, there are a number of barriers to delivering effective diet and exercise programs to at-risk Veterans on a large enough scale to decrease the incidence and prevalence of diabetes at the population level. The demand (and need) for diet and exercise programs is high among Veterans and many of those who truly engage in the MOVE! program benefit significantly. However, participation in at least 1 MOVE! visit by at-risk Veterans is exceedingly low (~10% of those identified by MOVE! screening as at risk or about 2% of all VHA veterans), and sustained engagement (patients with 6+ MOVE! visits) is even lower (~24% of those who enroll or about 0.5% of all veterans).[81] Even with this low level of participation, however, most of the on-site programs at local facilities have backlogs and are unable to meet the burgeoning need.

To address this challenge, our QUERI is committed to developing programs designed to give Veterans a choice of programs with guidance about which programs might work best for them based on their own risks, needs, preferences, and resources. Our priority is to work with our operational partners to develop and implement low-cost scalable interventions and make them maximally effective and accessible for Veterans. Providing options, enabling choices, and matching Veterans to accessible prevention programs are the bedrock principles that inform our two sub-goals. Matching veterans to programs requires that we know key information about the Veteran and this necessitates individualized assessments (Prevention Sub-goal 1A) of Veterans' risks, needs, preferences and resources. This assessment information will feed into a matching algorithm designed to provide a set of choices that have the best chance of helping individual Veterans successfully meet their goals. However, before this process can be operational, additional work is needed to identify, develop, test and implement a variety of effective programs that target specific Veteran subgroups and can be tailored based on individual characteristics (Prevention Sub-goal 1B).

Our two sub-goals are linked in several ways, with projects often contributing toward achieving both sub-goals simultaneously. For example, the OEF/OIF Weight Loss Pilot is testing

the effectiveness of several automated diet and exercise programs while simultaneously eliciting qualitative feedback from participants about their experiences in the different programs.  The ultimate goal is to use this information to help us match Veterans to appropriate automated or home-based weight loss programs. We mapped this project to both of our sub-goals (1A &1B) but most of our projects are mapped to a single sub-goal though they may have linkages to both sub-goals.

**Table 1. Diabetes QUERI Goal 1 Framework table.**

| Goal 1: Diabetes Prevention | | | | |
|---|---|---|---|---|
| **Self-Management Support** | **Delivery System Design** | **Decision Support** | **Clinical Information Systems** | **Individualized Assessments** |
| **Veterans Walk for Health (B)** | | | | **OEF/OIF PA Survey (A)** |
| **MOVE! Evaluation (B)** | | | | |
| **Life Goals (B)** | | | | |
| **Diet Preferences to Optimize Weight Loss (A)** | | | | |
| **TeleMOVE Evaluation (A&B)** | | | | **Self-Assessment Kiosks  (A&B)** |
| **ASPIRE-VA (B)** | | | | |
| **Veterans Walk to Beat Back Pain (B)** | | | | |
| **OEF/OIF Weight Loss Pilot  (A&B)** | | | | |
| **Web-based MOVE! for SMI  (B)** | | | | |
| **Telephone Lifestyle Coaching (TLC) Evaluation  (B)** | | | | **HRA Assessment (A)** |
| **Life Goals Implementation (B)** | | | | |
| **Counseling for Weight Loss Maintenance (B)** | | | | |
| **OEF/OIF Stay Strong (Internet) (B)** | | | | |
| | **Obesity CEA Simulation (B)** | | | **Pre-diabetes Prevalence  (A)** |
| | **DPP CEA Simulation (B)** | | | |
| **Mediterranean Diet Pilot Study (B)** | | | | |
| **Diabetes Prevention Program Demo Project (B)** | | | | |
| **Self-Management Platform: Patient Matching to Prevention Programs  (A&B)** | | | | |
| *Wiki: Resource Guide* | *Navigator Function* | | | *HRA Linkage* |

**\* Funded in conjunction with Operations**

| Completed Projects |
|---|
| Current Projects |
| Planned Products/Projects |

(A) Sub-goal A: Develop and use individualized assessments to tailor recommendations and enhance uptake of prevention programs
(B) Sub-goal B: Develop, test, and implementation automated approaches to support self-management for diet, exercise, and weight loss

As indicated by the phrasing of our sub-goals and the Diabetes QUERI prevention portfolio, our specific  focus is on lifestyle approaches to prevent diabetes, which means that in general, we are *not* focusing on approaches involving use of medication (e.g., initiating metformin for patients with pre-diabetes) or bariatric surgery. While these approaches may be of benefit for some patients, we feel there is a significant need to systematically focus the efforts of a cadre of highly capable researchers on ensuring that lifestyle behavior change interventions are in place for Veterans so they can be empowered and equipped to manage their own lives, to achieve their own goals. As one of our EC members and key operational partners, Linda Kinsinger quoted from the Harvard Review:[112]

"In the bottle before you is a pill, a marvel of modern medicine that will regulate gene transcription throughout your body, helping prevent heart disease, stroke, diabetes, obesity, and 12 kinds of cancer – plus gallstones and diverticulitis. Expect the pill to improve your strength and balance as well as your blood lipid profile. Your bones will become stronger. You'll grow new capillaries in your heart, your skeletal muscles, and your brain, improving blood flow and the delivery of oxygen and nutrients. Your attention span will increase. If you have arthritis, your symptoms will improve. The pill will help you regulate your appetite and you'll probably find you prefer healthier foods. You'll feel better, younger even, and you will test younger according to a variety of physiologic measures. Your blood volume will increase, and you'll burn fats better. Even your immune system will be stimulated. There is just one catch. There's no such pill. The prescription is exercise."

Similar statements can be made about the benefits of a healthy diet. This, in a nutshell, is why we are choosing to focus our diabetes prevention efforts on engaging Veterans in lifestyle change to improve their health and well-being and avoid the debilitating diagnosis of diabetes.

***Sub-goal 1A: Develop and use individualized assessments to tailor recommendations and enhance uptake of prevention programs***

Veterans differ in their risks, needs, preferences and resources for diet and exercise programs. For example, we recently published a paper examining attitudes and preferences toward various types of physical activity among OEF/OIF Veterans (OEF/OIF PA Survey). Results of a survey of this Veteran cohort shows that, in contrast to older Veterans, this group tends to be comfortable with computer-mediated interventions, prefer vigorous modes of physical activity, and particularly like resistance exercise such as lifting weights.[113]

We have two on-going studies contributing to this sub-goal. The Self Assessment Kiosks project provides a kiosk where patients with serious mental illness enter information about their interest in returning to work, need for wellness services, and their current weight. One goal of this assessment is to prevent diabetes and reduce cardiovascular risk. This kiosk is geared for low-literate patients and provides an example of eliciting information from patients to guide treatment and referral decision-making. In addition, the kiosk provides tailored educational content. The second project is the, Diet Preferences to Optimize Weight Loss study, which is testing two weight loss approaches (low-carb versus low-fat) with an additional arm allowing patients to choose the program in which they want to participate. Information from this trial will

inform us about Veterans' preferences for diet approaches, in addition to testing the effectiveness of these two approaches; this information will provide guidance for better matching patients to available weight loss programs.

Table 2 shows the list of planned projects along with general status and timelines for each. Because so little is known about pre-diabetes in the Veteran population, one of our planned projects is geared toward better understanding the prevalence of pre-diabetes among Veterans in order to be able to target future diabetes prevention interventions more appropriately (Pre-diabetes Prevalence). This project is a sub-study related to our ASPIRE-VA project. We have a unique opportunity to estimate pre-diabetes (along with undiagnosed diabetes) among the nearly 500 overweight/obese Veterans participating in ASPIRE-VA. Also, in order to refine individualized assessments, we plan to collaborate with NCP in evaluating roll out of their Health Risk Assessment (HRA) tool and with testing approaches (e.g., whether and how financial incentives may increase Veterans' willingness to provide information through the HRA) to maximize uptake of this important new tool in VHA (HRA Evaluation). Information available through the HRA will be a key data source to link to the Navigator tool that will help to match patients to prevention programs. Our close collaboration with NCP on the HRA and with PACT on the Navigator tool (explained in more detail under Sub-goal 2A, below) will allow us to continue our work toward the goals of both individualized assessments of patients' needs for diet and exercise programs, and their preferences for how these interventions should be delivered.

### Sub-goal 1B: Develop and implement low-cost scalable approaches to support self-management for diet, exercise, and weight loss

As described in section 7.1a, VA needs to expand the choices with which Veterans can engage in diet and exercise programs. In particular, given limited resources and vast need, VA needs to find ways to implement low-cost, scalable and effective approaches to support self-management for diet, exercise and weight loss in order to lessen the incidence and prevalence of diabetes, as well as other comorbidities, on a population level. Expanding capacity, increasing engagement and adherence and reducing cost of diet and exercise programs can all be accomplished simultaneously by adding automated computer-mediated options to the MOVE! program portfolio, along with continuing to develop cost-effective group approaches. Younger veteran cohorts (OEF/OIF/OND) often prefer non-facility based technology mediated services, such as programs delivered over the internet or by cell phone.

**Table 2. Planned Projects for Diabetes QUERI Goal 1, Sub-goal 1A.**

| Planned Project's Label | Title/Description | Submitted | Planned Submission Timeline | Planned Project Timeline |
|---|---|---|---|---|
| **Diabetes QUERI Goal 1:** <br> *To work with operations partners to promote evidence-based approaches to reduce diabetes risk factors and the incidence of diabetes among Veterans (Diabetes Prevention/Primary Prevention).* | | | | |
| **Sub-goal 1A:** <br> *Develop and use individualized assessments to tailor recommendations and enhance uptake of prevention programs.* | | | | |
| Pre-Diabetes Prevalence | Estimate prevalence of pre-diabetes in a cohort of Overweight/Obese Veterans | | Component of SDR for submission to NCP 11/2011 | 06/2012-06/2013 |
| HRA Evaluation (IIR) | Trial of Health Risk Assessment & Link to Prevention Programs | | 06/2012 | 06/2013-06/2015 |
| Self-Management Platform: Patient Matching to Appropriate Programs (LIP + Operations)* | Develop a platform that brings together various self-management tools for diabetes management and obesity/PA | 06/2012 | | 2013-2017 |

\* Applies to Sub-goals A & B

Diet and exercise programs are particularly well suited to automation and mediation using technology. Self-monitoring is a critical component of most effective diet and exercise programs and is enhanced by newer technologies, which can provide more accurate, individualized, and timely feedback, goal-setting guidance, and reinforcing messages. In particular remote objective monitoring and online coaching has been shown to increase physical activity in patients with diabetes, heart disease, obesity, and COPD.[114] While upfront costs to develop and test automated interventions are high, significant economies of scale may be realized if the intervention is rolled out on a national scale.

We are currently testing a wide array of such diet and exercise programs. Some are home based and computer-mediated, for example, in our OEF/OIF Weight Loss Pilot study, we are testing the feasibility of three different low-cost home based automated interventions to improve diet, exercise and weight loss. Each of the three interventions tested in this study has a different focus; one leverages a large web based online community to provide social support

for health behavior change, another employs an uploading objective physical activity monitor to improve self-monitoring and the third emphasizes high intensity resistance exercise rather than moderate intensity walking programs that are more commonly recommended for weight loss. ASPIRE-VA, on the other hand, is comparing phone- and group-based weight management interventions with usual care provided through MOVE!. Several programs (e.g. Life Goals and Life Goals Implementation) specifically target patients with serious mental illness (SMI), addressing concerns about the weight gain effects of anti-psychotic medications and delivering low cognitive load content for those veterans with SMI who also have cognitive impairment.

The variety of service-delivery options being explored by the Diabetes QUERI is representative of our desire to understand the program characteristics most useful in matching veterans to programs they are most likely to engage in and in which they will be most successful. Veterans Walk for Health, a former Diabetes QUERI project, was one of our first studies to test an automated way to track physical activity objectively among Veterans. This study showed that more objective and detailed web-supported monitoring resulted in more weight loss than monitoring using a simple pedometer or time-based walking goals with manual logging on a paper calendar. We are continuing our work in this domain by developing the Staying Strong application, targeting OEF/OIF Veterans (OEF/OIF Stay Strong).

We are testing 5 different interventions to help Veterans lose weight: 1) ASPIRE-VA targeted to any Veteran who is a candidate for MOVE!, being tested at two VAMCs and is designed to promote small weight loss with the aim of helping Veterans *continue* weight loss or maintenance over the longer-term; 2) the OEF/OIF Weight Loss Pilot which is testing 4 automated approaches; 3) the Life Goals Implementation study which targets serious mental illness (SMI) patients to encourage wellness behaviors while managing their condition; 4) Web-Based MOVE! which is a low-literacy web-based version of MOVE! also targeted to SMI patients; and 5) Diet Preferences, a program comparing two dieting approaches (low carb v. low fat) using an on-site group format. These interventions will all provide insight into what works and what works best for whom. The latter study, especially, will provide valuable information about patient preferences (some participants will be allowed to choose the program in which to participate) and how choice may or may not influence effectiveness. We are also completing a comprehensive evaluation of the TeleMOVE! Program (TeleMOVE Evaluation) being rolled out by our partners at NCP and the Office of Telehealth Services (OTS). Preliminary results indicate that implementation of this "automated, home-based" program was very challenging for most of the medical centers; workload actually increased compared to traditional MOVE!. Despite these challenges, however, participants did lose weight.

Our planned projects are focused primarily on implementing evidence-based programs. For example, a project was recently funded to test implementation approaches for integrating the Life Goals program into PACT (Life Goals Implementation). In addition, we are planning a pilot study based on evidence demonstrating the effectiveness of the Mediterranean Diet in diabetes prevention even without associated weight loss (Mediterranean Diet Pilot Study). Another area of focus for planned projects is how to maintain or continue weight loss over the long term.  Along with the ASPIRE-VA study mentioned above, another study (Weight Loss Maintenance; PI: William Yancy) is focusing on weight loss maintenance, randomizing patients to standard weight-loss counseling versus counseling targeted toward weight loss after completing an initial weight loss program.

The Diabetes QUERI is also planning to launch a cluster of projects with the primary aim of implementing a version of the Diabetes Prevention Program (DPP) lifestyle intervention on a broad scale in VHA.  In the first year, we will conduct three studies focusing on: 1) establishing the prevalence of pre-diabetes among veterans (mentioned in sub-goal 1A); 2) the costs associated with obesity in the VA (Obesity CEA Simulation); and, 3) the cost-effectiveness of implementing the DPP in VHA (DPP CEA Simulation).  Results of these studies will inform subsequent cost-effectiveness analyses as well as intervention demonstration projects.  In collaboration with NCP, we have been discussing a proposal for a DPP-like demonstration project that would be funded through a Service Directed Research mechanism incorporating both facility based group programs, similar to MOVE!, as well as automated online tools to support self-monitoring and remote delivery of the DPP curriculum.

The ultimate goal of this cluster of projects is to lay the foundation for broad scale implementation of the diabetes prevention program lifestyle intervention in VHA. A final component of the Goal 1 strategic plan incorporates products from both sub-goals and involves developing systems and algorithms to guide veterans and providers in matching individual veterans to appropriate lifestyle intervention that take into account their risks, needs, preference and resources.  Specifically, within the next 3 years we propose to develop a self-management platform where patients can be matched to prevention programs that are most likely to benefit them. This is a Diabetes QUERI-wide project that spans both Goals 1 and 2, and is more fully described in section 7.2b.

**Table 3. Planned Projects for Diabetes QUERI Goal 1, Sub-goal 1B.**

| Planned Project's Label | Title/Description | Submitted | Planned Submission Timeline | Planned Project Timeline |
|---|---|---|---|---|
| **Diabetes QUERI Goal 1:** *To work with operations partners to promote evidence-based approaches to reduce diabetes risk factors and the incidence of diabetes among Veterans (Diabetes Prevention/Primary Prevention).* | | | | |
| **Sub-goal 1B:** *Develop and implement low-cost scalable approaches to support self-management for diet, exercise, and weight loss.* | | | | |
| TLC Evaluation (OPS) | Telephone Lifestyle Coaching Evaluation | 09/2011 | | 2011-2012 |
| Life Goals Implementation (IIR) | Primary care psychosocial wellness services for mood disorders and CDV risk | 06/2011 (Approved) | | 01/2012-03/2015 |
| OEF/OIF Stay Strong (IIR) | "Staying Strong" Trial: A physical activity program for returning Veterans from Afghanistan and Iraq to reduce the prevalence of obesity | | LOI due 06/1/2012 | 2012-2015 |
| Weight Loss Maintenance (IIR) | Maintenance After Initiation of Nutrition TrAINing (MAINTAIN) | 01/2011 (Approved) | | 2012-2015 |
| Obesity CEA Simulation (LIP) | Cost Simulation of obesity in VHA | 10/2011 | | 2012 |
| DPP CEA Simulation (SDR + OPS) | Cost-Benefit Simulation of Diabetes Prevention Program in VHA | | 06/2012 | 2012-2015 |
| DPP Demonstration Project (SDR + Ops) | Group plus web based Diabetes Prevention Program demonstration in the VA | | 11/2011 | 2012-2013 |
| Mediterranean Diet Pilot Study (RRP) | Feasibility of Promoting the Mediterranean Diet Among Veterans | | 06/2013 | 2013-2016 |

7.1b Anticipated Key Impacts for Goal 1

A key impact we anticipate is that a significantly larger percentage of candidate Veterans (individuals who are at high risk for diabetes or who would significantly benefit) would participate in a lifestyle change program due to improvements in access (expanding services through automation) and the availability more treatment options. Most importantly, we believe that developing better methods of matching Veterans with beneficial prevention programs, including making them aware of programs, considering program and individual characteristics, and

encouraging shared decision making between the Veteran and their clinical team will increase the likelihood of sustained patient involvement in lifestyle change programs. The hope is that this involvement will lead to longer term changes in behavior, including increased physical activity and improved nutrition. These changes in lifestyle can, at the least, prevent further weight gain but can often lead to weight loss and, very importantly, keeping lost weight off.[115]

In the shorter term, including our 3-year planning horizon, we expect the impact on participants in our studies to include: increased physical activity, improved diet, weight loss/maintenance, reductions in CVD risk profiles, increased self-monitoring, as well as higher engagement in lifestyle programs and weight maintenance/loss.

More detail is provided on the Diabetes QUERI Metrics table (see Table 7 on page 58).

7.1c Primary Partners for Goal 1

We have a long-standing and close relationship with our primary partners in the VHA National Center for Health Promotion and Disease Prevention (NCP). Linda Kinsinger, MD, MPH, is an active member of our EC and our Diabetes Primary Prevention Work Group and Dr. Michael Goldstein recently joined the EC.  Ken Jones, PhD, is also a member of the Primary Prevention Working Group and we are active participants in his National Obesity Research Network. In addition, we are working with the Office of Telehealth Services, along with NCP, in our evaluation of the Tele-MOVE program. Finally, our work with the Offices of Primary Care on the focus of prevention activities will continue to expand, with the addition of Ms. Joanne Shear (National Clinical Program Manager, Primary Care) to the EC, and the naming of Dr. Susan Kirsh (Chronic Disease Consultant for PACT, who reports to the Chief Consultant of Patient Care Services) as the new Co-Clinical Coordinator.

7.1d Implementation Science Contributions for Goal 1

We will use hybrid study designs,[116] in trials of interventions to more quickly get interventions proven to be effective into wider use.[117] For example, in our ASPIRE-VA effectiveness trial, which we characterize as a Hybrid Type 1 trial, we are incorporating process evaluations into the study, keeping field notes about potential implementation issues that are unique to each site and conducting interviews with a purposively selected sample of participants for more insight about their experiences with the program.[118] This information will be useful to inform next steps in testing or implementation if the intervention is proven effective. In addition, in many studies, we are using the Consolidated Framework for Implementation Research

(CFIR), developed by our QUERI,[119] to systematically identify barriers and facilitators to implementation. For example, our completed evaluation of the MOVE! program and current evaluation of TeleMOVE have both used the CFIR to guide our analyses. Consistent use of the CFIR across studies will better enable synthesis and translation of findings regarding which modalities work in which environments and the reasons for any differences, information that is useful for both researchers and our operational partners. Please refer to Section 7.3 for more information about our planned contributions to implementation science across both Diabetes QUERI goals.

7.1e Cross-QUERI contributions for Goal 1

      Our investigators are actively collaborating with several other QUERIs on studies related to prevention. In addition, we are collaborating with several QUERIs on implementation science goals. This latter work is described in Section 7.3. Dr. Caroline Richardson is affiliated with eHealth QUERI and is a member of the eHealth QUERI's Patient Facing eHealth subcommittee that recently delivered a report on the current state of patient facing eHealth initiatives in the VA. Dr. Amy Kilbourne is actively collaborating with the Mental Health QUERI in her work related to Life Goals. Dr. Alexander Young, another EC member, is also part of the Mental Health QUERI. Our collaborations with the Mental Health QUERI are important in addressing the rising prevalence of diabetes and diabetes-associated risk factors (e.g., rapid weight gain) as a result of treatment regimen used to treat certain mental illnesses.

7.1f Disparities for Goal 1

      Disparities in the prevalence of diabetes among certain subgroups of Veterans (and the general population) are well documented. In particular, prevalence of diabetes is higher among American Indians, non-Hispanic blacks and Hispanics as compared to non-Hispanic white adults. The epidemiology of pre-diabetes is less clear; however, we can presume these disparities would similarly apply.[120] Thus, we are particularly interested in targeting these important Veteran constituencies. In the ASPIRE-VA study, for example, we have succeeded in recruiting a much higher proportion of non-white Veterans (42.8%) than are present in VA overall. This is also true for women (14.8%), though not as dramatic. We plan to conduct sub-group analyses to assess whether there are differences in end-point and process outcomes for ASPIRE-VA for women or non-white Veterans compared to male or white Veterans.  Two other patient sub-groups of particular interest are patients with mental health conditions and rural Veterans. As just discussed, we have a number of projects that focus specifically on addressing

potential disparities in care among patients with mental health conditions and we believe that further development of automated services and matching based on needs and resources are critical for addressing potential disparities in care and access to services for rural Veterans.

7.1g Health Information Technology and Data Development

We will work with our partners at NCP to evaluate the Health Risk Assessment tool that was recently awarded to a vendor. This is a key information technology and information source to link into the self-management platform for diabetes prevention. Information from the HRA can be used to help match patients to prevention programs. Though we may not succeed in actually linking the HRA with a Navigator function within our 3-year planning horizon, we do plan to explore approaches or prototypes for doing so, setting the stage for linking HRA data in the future.

**7.2 Goal 2: Diabetes Management**

Our second goal is to work with operations partners to promote evidence-based approaches to improve treatment and reduce complications of diabetes; secondary and tertiary prevention of diabetes. Guided by our conceptual framework and discussion with our EC and operational partners, we are focusing on two sub-goals for Diabetes Management:

A. Develop and implement individualized assessments and decision support tools to enhance the use of appropriate diabetes treatments and decrease inappropriate care.

B. Develop and implement innovative programs to improve diabetes self-management.

7.2a Plans for achieving Goal 2

While the descriptions of current, past and planned projects are well captured in this year's and past years' Annual Reports, we highlight in the Goal 2 Framework table (Table 4) primarily the key work that has contributed to our current sub-goals and that will be the focus of the next three years. As with Goal 1, the table for Goal 2 depicts previous, current and planned projects that address these sub-goals – and show which areas of our conceptual framework these projects address.  We have listed only a small fraction of completed work, focusing instead on those studies in the last 3-5 years that are directly contributing to current and planned work. For past and current studies, the project names refer to the names in the Annual Report (Table 3-Current and Completed Projects). For each sub-goal, we also provide a table

with more detail on the projects we are planning to conduct in the next 3 years. It is worth noting that many of our current projects will also continue and have impact in the next 3 years.

### Sub-goal 2A: Develop and implement individualized assessments and decision support tools to enhance the use of appropriate diabetes treatments and decrease inappropriate treatments

As described in detail in sections 4.2 and 5.2, Diabetes QUERI feels it is essential to focus our efforts in making sure that the patients receive interventions that are tailored for their risks, needs and preferences. This includes ensuring that those at high risk for poor outcomes and who are not receiving evidence based therapies (i.e., young persons with poor glycemic control; patients at high risk for CV events who are not on statins) have the opportunity for intensive treatments, while those at high risk of complications (or who achieve no additional benefit despite accruing additional real or transactional costs) *because* they are receiving intensive therapy (e.g., older patients on high dose insulin) have the opportunity for de-intensification. We have a significant body of past and current work related to individualizing assessments, but a smaller set of studies that focus on developing decision support tools and programs for both providers and patients. Therefore, our goals in the next three years are to implement individualized assessment tools, to develop and implement innovative decision support tools, and importantly, to integrate these tools with each other to enhance the use of appropriate diabetes treatments and decrease inappropriate care. Our past work has helped to develop and apply the knowledge base to enable us to assess individual patient characteristics related to diabetes treatment and risk for poor outcomes (e.g., QALY DM; DM/Depression Cost; Chronic Kidney Disease)[66,68,121-123] and to understand utilization and costs related to diabetes care in VA (Diabetes Costs; DM/Depression Cost).

This work has enhanced our ability to stratify patients with diabetes according to risk for poor outcomes (QALY DM; Summary Measures of Quality); understand the benefit of therapies for patients at different levels of risk (QALY DM); and understand glycemic control factors among Veterans of different ages (Hypoglycemia Predictors). Additionally, we have focused on evaluating tools that can be used to better assess patient risk in real time (Cube Utility). In the area of decision support, Dr. Aron's telemedicine study (DM Telemedicine) and his and Dr. Kirsh's assessment of best practices in outpatient diabetes care (OP Diabetes Care) provided a foundation for evaluating future specialty care initiatives (e.g., SCAN) now ongoing in diabetes. Additionally, the Wound Care Teleconsultation project, led by Dr. Lowery, in collaboration with Dr. Gayle Reiber (EC member), along with other work to improve diabetes footcare (Footcare

Collaborative) have provided a platform for the development of decision support tools to improve management of diabetes patients at high risk for lower limb and wound related complications.

**Table 4. Diabetes QUERI Goal 2 Framework table.**

| Goal 2: Diabetes Management | | | | |
|---|---|---|---|---|
| Self-Management Support | Delivery System Design | Decision Support | Clinical Information Systems | Individualized Assessments |
| | | | | Summary Measures of Quality (A) |
| | | | Cube Utility (A)  QALY DM (A) | |
| Footcare Collaborative (A) | | | | |
| | | Wound TeleConsultation (A) | | |
| | OP Diabetes Care (A) | | | |
| DM/Depression (B) | | DM Telemedicine (A) | | |
| SMA Benefits (B) | | | | |
| Peer Support (B) | | | | |
| DM CarePartners (B) | | | | |
| | | | | Diabetes Costs (A) |
| | | | | Interplay (A) |
| | | | | CV Risk Predict (A) |
| | | | | Hypoglycemia Predictors (A) |
| Wound Care Access (A) | TeleRet (A) | | | Tight Glycemic Control Consequences (A) |
| | | A1c Numeracy* (A) | | VA Diabetes Trial Follow-up (A) |
| CarePartners ORH (B) | | | Action Measures (A) | |
| SMA Collaborative* (B) | | | | |
| AIM (B) | | | | |
| | | PACT Demo Lab: Navigator & Registries (A) | | |
| | | | | Patient Goals (A) |
| | | | | CKD Preventable Hospitalizations (A) |
| | TeleWound Provider Toolkit (A) | | | Cardiac Risk Score (A) |
| | | | Unintended Consequences (A) | |
| | SCAN/Specialty Care Evaluations* (A) | | Next Generation Measures (A) | |
| | Diabetes Personalized Counseling (A) | | | |
| Peer-to-Peer/SMA Implementation (B) | | | | |
| | Health Coaching Decision Support (A) | | | |
| Self-Management Platform: Patient Matching to Appropriate Programs (A & B) | | | | |

\* Funded in conjunction with Operations

| Completed Projects |
|---|
| Current Projects |
| Planned Products/Projects |

(A) Sub-goal A: Develop and implement individualized assessments and decision support tools to enhance the use of appropriate diabetes treatments and decrease inappropriate treatments
(B) Sub-goal B: Develop and implement innovative programs to improve diabetes self-management

Building on this work, we have also recognized the need for better tools to help providers understand the varying risk for adverse outcomes among Veterans with diabetes – i.e., an approach that helps providers use individualized assessments of care. Therefore, we are currently engaging in a number of funded projects that are creating and refining the foundational tools necessary to better identify and assess individualized patient risks, needs and preferences.

First, Dr. Pogach is working on a number of projects that better define the role of chronic comorbidity in glycemic control (Interplay) as well as the consequences and costs of tight glycemic control (Glycemic Control). Second, Dr. Hayward conducted a pilot study, which

demonstrated the feasibility of using VA-specific data to predict cardiovascular risk and the need for tools to tailor treatments to individual Veteran circumstances (CV Risk Predict). Subsequently, he has submitted an IIR (Cardiac Risk Score) to further develop the risk prediction methods and infrastructure as a prerequisite for developing automated decision support tools that can be integrated into the VA EMR or a web-based interface (such as MyHealtheVet) to aid clinicians and patients in optimizing and personalizing cardiac and cerebrovascular (CCV) risk reduction treatment decisions in the outpatient setting. He is also integrally involved in a study that examines the long term effects of intensive glycemic control in the Veterans Affairs Diabetes Trial (VADT follow-up).

While more work clearly needs to be done to develop accurate, sophisticated and usable tools to stratify patients by risk for poor outcomes, Drs. Kerr and Krein are currently applying the finding from previous Diabetes QUERI projects to create a diabetes registry as part of the Ann Arbor PACT Demonstration Laboratory (Navigator and Registries). In that capacity, we are implementing registries that identify patients at high risk for poor outcomes from both undertreatment (e.g., younger persons with poor glycemic control) and overtreatment (older persons with tight glycemic control or use of complex or intensive medical regimens). In addition, we have developed and are implementing a navigator system for patients with diabetes. The system uses proactive outreach to patients identified as high risk, with a nurse-led assessment of Veterans' self-reported needs and preferences, to match patients to appropriate programs such as intensive care management, MOVE!, facilitated self-management (see below), nutrition, or other available programs, thus spanning both the areas of individualized assessments and decision support. The Navigator system is a major innovation that has been funded through the Demonstration Laboratory. We are working closely with EC member Dr. Jonathan Nebeker (Associate National Director for Clinical System Design, Medical Informatics Office, OIA), to ensure that this tool can be translated to routine functions through the next generation electronic health record (iEHR). We are also working with EC member Dr. Linda Kinsinger, Director of NCP, to interface the navigator system with the planned health risk assessment tool (HRA).

QUERI investigators are also working closely with the VA Office of Analytics and Business Intelligence (OABI) to transfer work done on tightly-linked clinical action measures (Action Measures) and glycemic continuous measures (Summary Measures of Quality) for operational use as e-measures. Once in the field, this work, which builds on individualized assessments but taps into clinical information systems (CDW) and decision support, should significantly impact that way providers approach hypertension, dyslipidemia and glycemic

control for patients with diabetes. Drs. Pogach, Conlin, Aron and Kirsh are working on an operational initiative to increase the understanding of variability in A1c measurement (A1c Numeracy), in order to decrease unnecessary intensification of medications for patients whose values are near goal. This project, which is not a research project but instead an operations funded initiative that builds on previous research, spans individualized assessments, use of clinical information systems, decision support to providers, and delivery system design.

In addition to completing ongoing work described above in the next 3 years, for Sub-goal 2A, our new work will focus on developing and implementing an individualized assessment tool for cardiovascular risk that can be used by patients and providers; developing, testing and evaluating tools and programs that can be used to help providers and patients make informed decisions about diabetes treatment, including overtreatment; and developing the next generation of patient-centered performance measures. Table 5 lists our planned projects, which are further summarized below. In the area of individualized assessments, as mentioned above, Dr. Hayward's project to develop a VA-specific tool that can be used by providers to assess CCV risk is progressing, and will be further pursued by an IIR (Cardiac Risk Score). This will result not only in a model but a fully formed decision tool that can be integrated with the VA electronic health record (iEHR), thus leading to real-time decision support for providers. Dr. Nebeker, a member of the Diabetes QUERI EC, is also a collaborator on this project to ensure transferability to future iterations of the iEHR. Second, Dr. Pogach and colleagues are developing and evaluating models to identify veterans with diabetes and chronic kidney disease who are most likely to benefit from subspecialty care to assist clinicians in referral decisions for this high risk patient subgroup (CKD Preventable Hospitalizations). Third, Ms. Damschroder has been funded to examine the unintended consequences of diabetes performance measurement to inform future derivations of quality, performance and surveillance measures (Unintended Consequences).

**Table 5. Planned Projects for Diabetes QUERI Goal 2, Sub-goal 1A.**

| Planned Project's Label | Title/Description | Submitted | Planned Submission Timeline | Planned Project Timeline |
|---|---|---|---|---|
| **Diabetes QUERI Goal 2:** *To work with operations partners to promote evidence-based approaches to improve treatment and reduce complications of diabetes (Diabetes Management/ Secondary and Tertiary Prevention).* | | | | |
| **Sub-goal 2A:** *Develop and implement individualized assessments and decision support tools to enhance the use of appropriate diabetes treatments and decrease inappropriate care* | | | | |
| CKD Preventable Hospitalizations (IIR 11-077-2 ) | Ambulatory Care and Preventable Hospitalizations in Diabetic Kidney Disease | 06/2011 Approved | | 01/2012-12/2016 |
| Cardiac Risk Score (IIR) | Developing and Validating a Veterans Affairs Cardiac Risk Score | | 12/2011 | 06/2012-05/2015 |
| Telewound Provider Toolkit (LIP) | Develop procedure document for implementing tele-consultations for wound care | | 12/2012 | 12/2012-12/2013 |
| Unintended Consequences (RRP) | Implementation of Diabetes Performance Measures: Focus on Unintended Consequences. Phase II of this project (an SDP) will evaluate uptake of new Clinical Action Measures | 05/2011 Approved | | 01/2012-01/2013 |
| SCAN/ Specialty Care Evaluations (QUERI) | Conduct quantitative and qualitative evaluation of 4 specialty care initiatives in collaboration with Cleveland, Denver, and Seattle | 10/2011 Approved | | 12/2012-12/2014 |
| Next generation measures (IIR or SDP) | Develop and evaluate new personalized measures for diabetes care, including surveillance measures of overtreatment | | 06/2013 | 06/2013-06/2016 |
| Patient Goals (RRP) | Characterization of Elicited Patient Goals for Integration into Goal-Driven Care Coordination Solution | | 01/2012 | 05/2012-04/2013 |
| Diabetes Personalized Risk Counseling (IIR) | Testing personalized decision counseling in patients with diabetes – focus on decreasing overtreatment | 12/2011 | | 06/2012-5/2016 |
| Health Coaching Decision Support (IIR) | Technologically Enhanced Delivery of Personalized Diabetes Treatment Information – translation to VA using PACT Clinical Associates | | 06/2012 | 06/2013-05/2017 |

We also expect that this work will lead to a partnered evaluation with OABI of the implementation of new diabetes performance measures in VA, as well as future work by Drs. Kerr and Pogach on Next Generation Measures, which will examine more patient centered approaches to monitoring and improving quality of care. These approaches will include focusing measures on patients who are most likely to benefit, using what we know about variability of clinical measurement (e.g., for A1c and BP) to generate actionable assessments of these intermediate outcomes, balancing overuse and underuse, and incorporating shared decision making and evaluations of patient preferences in areas where benefits are unclear. Thus, we plan to use performance measures to motivate appropriate decision making in diabetes care, and to be explicit about the processes of care that need additional patient inputs. As part of this effort, we are working with Dr. Nebeker who will be submitting an RRP to assess how to incorporate patient goals into the EHR and care coordination (Patient Goals).

Our ultimate vision is that quality measurement will not be a stand-alone, retrospective assessment of quality but rather a dynamic component of care coordination that supports appropriate decisions and patient-centered care. Further, in the area of decision support, we have several exciting projects planned to enhance both provider and patient understanding of and decisions about diabetes care. First, the SCAN/Specialty Care evaluation led by Dr. Aron, with co-investigators Drs. Anne Sales (a member of the Diabetes QUERI EC), Dr. Julie Lowery (co-IRC), Len Pogach, and Susan Kirsh (co-Clinical Coordinator) will commence in 2012. The SCAN and complementary specialty care initiatives will support primary care clinicians in their decision making about complex diabetes care patients. Similarly, Drs. Lowery and Reiber plan to develop a TeleWound provider toolkit to assist in decision making and treatment of diabetes patients at high risk for lower limb related complications, including amputation.

We are also very excited about 2 projects that will start in the next 3 years that are expected to help drive the science in shared decision making for diabetes. The first project (Diabetes Personalized Risk Counseling), led by QUERI investigators Drs. Sandeep Vijan and Angie Fagerlin, develops and tests a decision tool that will be implemented within PACT to help older patients with tight glycemic control make decisions about de-intensification of therapy. Clinical associates will be trained to discuss these issues with patients identified at risk for poor outcomes from hypoglycemia, and will use a web-based tool to help guide health coaching and patient goal setting, and to empower patients to discuss the topic with their primary care physicians. Second, also using PACT health coaching as a platform, Dr. Heisler will examine the use of a veteran-focused web-based decision tool that helps younger patients with diabetes set goals about their diabetes care, make informed decisions about medications and self-

monitoring, and assist with self-management support (Health Coaching Decision Support). The project will focus specifically on those with high risk of poor outcomes, including patients in historically socially disadvantaged inner city VAMCs.

Finally, even as we develop new tools that can be used for individualized assessments and decision support, the cornerstone of our work in the next 3 years will be to build a platform, with our partners, that integrates what is already known and available through various VA offices and through research, to enhance individualized assessments, decision support and self-management support. This "Diabetes Self-management Platform" is more fully discussed under sub-goal B, below.

### Sub-goal 2B: Develop and implement innovative programs to improve diabetes self-management

For our second diabetes management sub-goal, our focus will be to work with operations partners to translate programs that have been developed by Diabetes QUERI and others into routine practice. Our work in self-management among diabetes patients has a long history. QUERI investigators' work in the use of interactive voice response (IVR) – a form of telehealth - to improve care management (Carepartners ORH), and the use of shared medical appointments to enhance both care management and self-management (SMA Benefits), have all led to innovations in self-management support. Most recently, Dr. Heisler's randomized controlled trial that used both group visits and IVR mediated phone calls that connected Veterans with one another to support self-management, showed a significant improvement in glycemic control among patients with poor initial control (Peer Support). Dr. Heisler has submitted an SDP to conduct an implementation study of the peer-to-peer program, together with shared medical appointments (Peer-to-Peer/SMA Implementation). Dr. Kirsh is continuing her work on implementing shared medical appointments which began in 2007 (Shared Medical Appointments), originally funded through QUERI, throughout VA, and is participating in a SMA collaborative in VISN 7 (SMA Collaborative). An evaluation of this collaborative is awaiting further funding through PCS. Additionally, through the AIM program, we focused on improving self-management related to blood pressure control for patients non-adherent with their medication. In this implementation study, veterans with persistent poor BP control and non-adherence received a pharmacist-based intervention based on motivational interviewing principles. Our results show that intervention team patients achieved improved systolic BP control more quickly than control team patients, but by six months post-intervention control team patients had achieved similar levels of better control. Thus, the AIM program was successful in

more rapidly lowering BP for "resistant" hypertensive patients – but in a system with high baseline levels of control (>80%), multiple programs in place to enhance control, and even possible overtreatment, we may have reached the maximum threshold of safe BP intensification. Nonetheless, several aspects of the AIM project have been incorporated as part of the Ann Arbor PACT Demo Lab. For example, the informatics tools developed for AIM to identify and track patients are the foundation for the navigator system.

Another important effort that focuses on self-management, developed in part through QUERI funding, is Dr. John Piette's CarePartners program. The program uses accessible technology to link the veteran, his/her informal caregiver (who may be living in another city or state), and the patient's care manager. Using telehealth technology (interactive voice response – IVR), patients receive regular calls to assess their self-management goals, caregivers receive reports of these calls (as well as training on how to support their patient), and care managers receive alerts if patients report critical values (for example, very high or low blood sugars). We are currently implementing and evaluating the Diabetes CarePartner program throughout all VISN 11 rural CBOCs (Carepartners ORH), and as part of the Ann Arbor PACT Demonstration Laboratory. Indeed, one of the principal goals of the Ann Arbor PACT Demo Lab is to enhance patient self-management through the use of technology-facilitated self-management. The Lab uses the Registry and Navigator system (described under sub-goal A) to match patients with available facilitated self-management (including CarePartners, Peer-to-Peer, teleMOVE and CCHT), as well as other programs, depending on patients' risks, goals and preferences.

We are also continuing to stress self-management among patients with serious mental illness (SMI). In particular, Dr. Kilbourne is funded to conduct an RCT to determine whether VA patients with SMI receiving Life Goals Collaborative Care (Life Goals Implementation), a program that combines customized behavioral change strategies with chronic care management for SMI, will experience improved medical outcomes (including CVD and glycemic risk factor control), improved mental health outcomes, and improved health behaviors. As a result of the work of Diabetes QUERI, as well as the many programs that have been implemented in VHA (e.g., MOVE!, CCHT, etc), we are in a unique position to begin to integrate these programs to make them available to care managers, and to patients, to support diabetes self-management goals. Currently, while there are many programs available, there is not a single portal or platform through which care managers can learn about these programs, enroll appropriate patients, or obtain additional information. We have begun to build such a platform locally in our Demonstration Laboratory, and, with our partnership with the Offices of Primary Care, we are now poised to develop and evaluate such a platform nationally.

**Table 6. Planned Projects for Diabetes QUERI Goal 2, Sub-goal 2B.**

| Planned Project's Label (project type) | Title/Description | Submitted | Planned Submission Timeline | Planned Project Timeline |
|---|---|---|---|---|
| **Diabetes QUERI Goal 2:** _To work with operations partners to promote evidence-based approaches to improve treatment and reduce complications of diabetes (Diabetes Management/ Secondary and Tertiary Prevention)._ | | | | |
| **Sub-goal 2B:** _Develop and implement innovative programs to improve diabetes self-management_ | | | | |
| Peer-to-Peer/SMA Implementation (SDP) | Implementation Study of the Peer-to-Peer (P2P) Program for Patients with Diabetes | 09/2011 | 01/2012 (resubmit) | 08/2012-08/2015 |
| Self-Management Platform: Patient Matching to Appropriate Programs (LIP + operations) | Developing a platform that brings together various self-management tools for diabetes management and obesity/PA | 11/2011 | | 12/2012-04/2013 |
| Evaluating and testing Self-Management Platform (SDP) | Testing the use of the self-management platform in 2 VISNs | | 05/2013 | 09/2013-09/2016 |

The goal of the diabetes self-management platform is three-fold. The first is to assemble in one place various tools and programs that have been developed or are in use in VA, including those developed through research, so that care managers, and ultimately patients, can access them to help diabetes patients improve their self-management. While the tools that will be assembled first are those that are currently in use through clinical or research venues, we view the platform as being dynamic, and believe it will help us identify gaps that can be the subject of additional research. The second goal is to identify gaps in the implementation of currently available tools, so that we can work with appropriate partners to enhance their utility. For example, we anticipate working closely with informatics in order to make tools more readily accessible to care managers on the intranet, and for patient tools through MyHealth*e*Vet. Third, through close partnership with PCS, our goal is to assess the implementation and effectiveness of the self-management platform.

The self-management platform spans Diabetes QUERI Goals 1 and 2 and builds upon our previous work in self-management and in PACT. In particular, we will build upon our PACT Demonstration Laboratory innovation to create a platform that includes 1) an intranet based resource guide for clinicians that describes available self-management programs (including

those in the community) and how to access them; 2) a "navigator function" which, based on patient risks, needs, characteristics, and preferences will match patients to programs; and 3) linkage to (and ultimately integration of) NCP's Health Risk Assessment (HRA) tool with the navigator. In this way, we will be able to create and test a unified platform that allows for individualized assessments and matching to appropriate self-management programs, as well as a resource guide that brings together available programs in one "place".

The development of the Diabetes Self-Management Platform will be led by EC member Joanne Shear, who is the National Clinical Program Manager in the Office of Primary Care, and by Co-Clinical Coordinator Susan Kirsh, who is also the Chronic Disease Consultant for PACT and reports to the Chief Consultant of Patient Care Services. Members from NCP, Office of Telehealth, Office of Patient Centered Care, Office of Nursing Services, as well as from research (including from Diabetes QUERI Drs. Kerr, Heisler, Piette and Richardson) are currently being invited to form a joint PCS-QUERI workgroup as the first step of the Diabetes Self-Management Platform development. This will be a major activity for Diabetes QUERI in the next 3 years.

7.2b Anticipated Key Impacts for Goal 2

We are very proud of our accomplishments thus far, and particularly excited that new performance measures developed through the Diabetes QUERI were endorsed by the national Performance Measurement Workgroup and will be incorporated into routine care nationally in VHA. A major downstream impact from Diabetes QUERI work will be the use of more appropriate therapies for BP, dyslipidemia and glycemic control, and a decrease in overtreatment, as a result of these measures.

One of the goals of the Diabetes QUERI is to develop, through our research, tools and products that can be implemented broadly. One example is the SMA training manual, developed with QUERI support, including the initial funding to assess the effectiveness of the SMA model. This manual has been widely distributed throughout VA to assist with the implementation of SMAs as part of PACT.

Over the next three years, we anticipate several major impacts:

      1) The integration and use of new diabetes performance measures in routine care.

      2) The integration and use of the CarePartners program in VISN 11 even after ORH funding ceases.

      3) The successful implementation of the Peer-to-Peer/SMA programs in 2-3 VISNs.

      4) The development of a CVD risk decision tool.

5) The development and successful testing of glycemic shared decision making tools.

6) Recommendations for new patient centered measures that are individualized and balance overuse and underuse.

7) Evaluation tools and insights related to the interface between primary care and specialty care for patients with diabetes.

8) Finally, within the next 3 years, Diabetes QUERI, in conjunction with operations partners, will be ready to launch and evaluate a Diabetes Self-Management Platform that incorporates assessments of individualized patient risk, decision support, and self-management support options.

More detail is provided on the Diabetes QUERI Metrics table (see Table 7 on page 58).

### 7.2c Primary partners for Goal 2

The Diabetes QUERI has several primary partners in our work to improve secondary and tertiary prevention efforts for Veterans with diabetes, many of which are identified above. These partners include the VA Office of Analytics and Business Intelligence (OABI – formerly OQP), a primary partner for over a decade which continues to play an instrumental role in our work to define and implement clinical action measures. Dr. Nebeker, a member of our EC, is part of OIA with a focus on informatics. This is critically important for us because many of our tools and interventions are based on informatics platforms. Another primary partner in this work has been Patient Care Services, which has provided the requisite clinical expertise for measure development. The partnership of PCS and the Diabetes QUERI also includes the participation and overlap between members of the Diabetes QUERI, including Drs. Pogach, Conlin, and Aron as part of the Diabetes Program, Dr. Kirsh and Ms. Shear as part of the Offices of Primary Care. Our relationship with the Diabetes Program has been in place since the Diabetes QUERI began with Dr. Pogach serving as Clinical Coordinator. Dr. Aron has been Co-Clinical Coordinator for the past several years, and Dr. Conlin, Chair of the Field Advisory Committee for Endocrinology, is Chair of the EC. We are especially pleased with our expanded partnership this year with the Offices of Primary Care. Dr. Kirsh, who has assumed the role of co-Clinical Coordinator (in place of Dr. Aron) is a consultant with the Office of Primary Care. Our newest EC member, Ms. Joanne Shear, is National Clinical Program Manager in the Office of Primary Care. Because most diabetes management occurs within primary care, and because almost all of our interventions are either primary care based or rely on integration with primary care, our EC

advised us to expand the primary care role within our EC. We therefore made the proactive decision to balance our co-clinical coordinator roles between specialty care (Dr. Pogach) and primary care (Dr. Kirsh). We rely on our relationships with PCS to ensure that our projects and activities are aligned with key operational priorities, such as implementation of the diabetes guidelines, current concerns related to hypoglycemia, the imperative to improve self-management, PACT integration, and a more interactive health record. Another more recent primary partner is the VA Ann Arbor Healthcare System PACT Demonstration Laboratory, as well as the National Coordinating Center for the Demonstration Labs. This partnership provides us with a unique opportunity to implement and evaluate many of the interventions and strategies that have been developed by the Diabetes QUERI and QUERI Investigators within the VA Ann Arbor Healthcare System. It is hoped that the most successful of these interventions can then be implemented on a broader scale in collaboration with the National Coordinating Center and the other four PACT demo labs.

Other partners with which the Diabetes QUERI has had some continuing involvement during the past year include the Office of Systems Redesign, Inpatient Evaluation Center (IPEC), Office of Telehealth, Office of Rural Health and other QUERI groups as described in more detail under cross-QUERI contributions.

7.2d Implementation Science Contributions for Goal 2

As stated for Goal 1, we also plan to use hybrid study designs in trials of interventions related to Goal 2 to more quickly get the interventions proven to be effective into wider use.[116,117] For example, the AIM-VA study was a Hybrid Type 4 design in which implementation strategies were tested while concurrently assessing the effectiveness of the AIM program in terms of clinical outcomes. Information from our comprehensive, multi-stage formative evaluations has guided development of our toolkit to help others implement AIM program components in their own clinics. We used the CFIR in this study, as well as in multiple other studies, to systematically identify barriers and facilitators to implementation. We are promoting consistent use of the CFIR across our studies to better enable synthesis and translation of findings about what works where and why; information that is useful for both researchers and our operational partners. Please refer to Section 7.3 for more information about our planned contributions to implementation science.

7.2e Cross-QUERI contributions for Goal 2

Our cross-QUERI activities with respect to management of patients with diabetes include ongoing involvement with the Stroke QUERI, through Dr. Krein's role as a member of the Stroke QUERI EC and through consultation and discussions with Stroke QUERI investigators in two specific areas of shared interest: risk prediction for individualized assessment and the development of decision support tools. In addition, we have a close partnership with the Mental Health QUERI to identify ways to better address the significant challenges of patients with diabetes and co-morbid mental health conditions. The work of two members of the MH QUERI is closely aligned with our own: Dr. Alexander Young, a member of our EC, and Dr. Amy Kilbourne, an investigator in Ann Arbor, are both working in areas that are closely tied to our two goals for patients with diabetes. We have also had discussions with the IHD QUERI about translating our performance measurement work to patients with IHD. Finally, we have extensive collaboration with several QUERIs with respect to Implementation Science, further described in section 7.3.

7.2f Disparities for Goal 2

Diabetes QUERI continues to work to identify and reduce racial/ethnic, gender related and mental health disparities within VHA as well as disparities related to geographic access to care. As already discussed, we have taken specific steps to better address mental health disparities by forging closer ties with the Mental Health QUERI. Our linked clinical action measures work also includes a specific focus on women veterans through an association with Drs. Miller and Vimalananda, based at the Bedford VA. We have continued work to improve access to self-management in rural areas through the CarePartners ORH project. Our future projects to improve glycemic control and shared decision making will have a particular focus in urban VAs, where there are greater treatment and outcome disparities (Health Coaching Decision Support). Furthermore, we expect that development of the self-management platform will include an explicit focus on identifying or adapting tools that address potential disparities.

7.2g Data development, implementation, and evaluation for Goal 2

A primary component of the Ann Arbor PACT Demonstration Laboratory is the development of a patient registry system, similar to the Diabetes Cube, that would be used by care managers to identify and monitor specific patients and serve as a 'navigator' to help match patients with programs that best meet their medical needs and preferences. The PACT Registry and Navigator are the culmination of work by the Diabetes QUERI going back to back 1999,

including our initial work to develop a diabetes registry/database, subsequent work on how to identify people with diabetes and, most recently, the Cube Utility project and other projects that focus on identifying patients with specific risk factors. We anticipate that findings from this project will make important contributions to the development of future VA registries.

<u>7.2h Health Information Technology (HIT) development, implementation, evaluation for Goal 2</u>

Health Information Technology is a key part of several of the programs and interventions that have been developed and tested with support from the Diabetes QUERI. This includes the Peer to Peer intervention described above, which uses a telephone based platform to securely link peers with one another without compromising privacy. Potential plans to extend the Peer to Peer program are described above, including how to expand the current system for broader use. The CarePartner program uses both interactive voice response technology and the Internet to monitor patients and provide information to the Caregiver. Currently, the CarePartner program is being used throughout VISN 11 and as part of the Ann Arbor PACT Demonstration Laboratory. Finally, for implementation of our newly developed navigator system beyond the Demonstration Laboratory, we working closely with the iEHR care coordination integrated product team to ensure that the tool or elements of the tool can be integrated with the iEHR. We are also engaged in efforts by PCS through the Office of Informatics and Analytics (OIA) and the Office of Health Information (OHI) to analyze the current capabilities of tools and projects that focus on care plans, care management and care coordination. While there are many steps in the process to make the navigator a sustainable product, we are encouraged by our close ties with the iEHR team and the enthusiasm expressed by the many groups, including OIA, the Office of Nursing Services, Primary Care, NCP, OHI, who have viewed the tool.
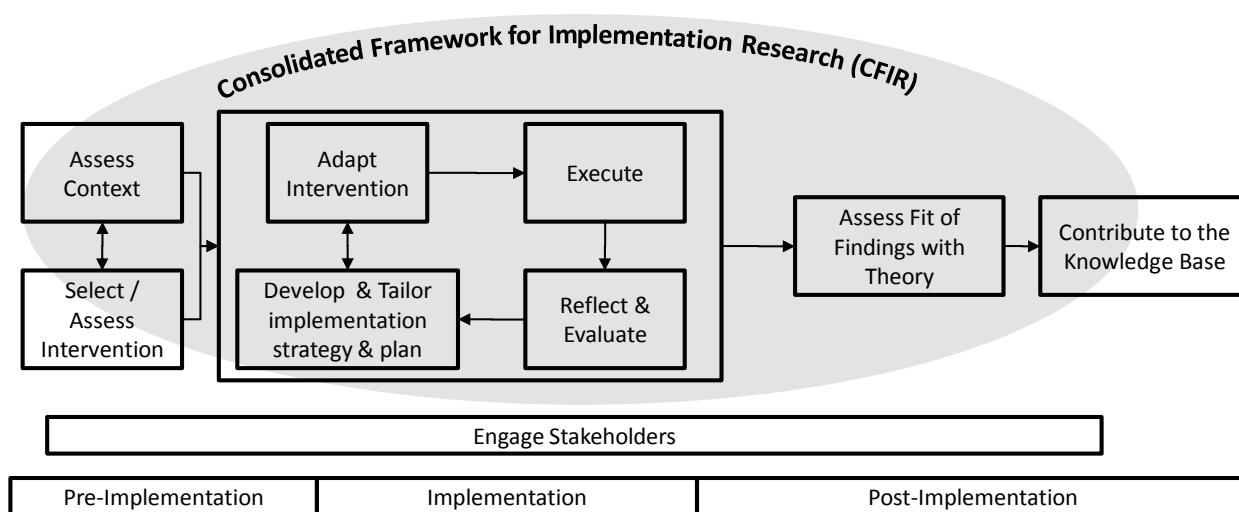
**7.3 Contributions to Implementation Science**

Our conceptual framework, presented in Section 7, helps to guide and prioritize the interventions and studies needed to accomplish our goals. To complement this framework, we have an implementation framework to guide our implementation work, which is essential for implementing interventions and for contributing to implementation science. The centerpiece of our implementation framework is the Consolidated Framework for Implementation Research, developed by our QUERI.[119] The CFIR helps to guide context and intervention assessments, assessment of implementation progress during implementation, coding and analysis of data, interpreting findings, and providing a structure by which to contribute to the implementation science knowledge base. The CFIR is an "explanatory" framework, identifying and defining

constructs that influence implementation (akin to independent variables). We complement the CFIR by enveloping it in a "process" or "planned action" framework that helps guide how to plan, organize, and schedule activities, using the CFIR where appropriate, to accomplish implementation.[124]

Our approach to implementation, as depicted in our Implementation Conceptual Framework, also reflects in the content of the Enhancing Implementation Science (EIS) curriculum which our staff has taught for the last two years.  It is also consistent with our published work.[117] In our prospective implementation studies, the CFIR will be used to guide our assessment of context and, as appropriate, to refine the intervention being implemented.

**Figure 2. Diabetes QUERI Conceptual Framework for Implementation**



These activities are done before implementation begins. The central part of the framework features an iterative four-step process that embodies the spirit of PDSA (Plan-Do-Study-Act), which is a widely used approach in organizational change (e.g., Institute for Healthcare Improvement)[125] including the VA's System Improvement Framework.[126] The CFIR is used to guide adaptation of the targeted intervention or practice and to tailor an implementation strategy and plan based on findings from the context assessment and the characteristics of the intervention. A cyclical process of execution (ideally through piloting or smaller cumulative incremental changes) with time for reflection and evaluation, which then informs refinement of the plan and potentially, adjustments in the intervention, is done until implementation goals have been achieved.

In our retrospective implementation studies (i.e., when an intervention has already been implemented, and we are trying to understand the determinants of implementation success post-hoc), the CFIR guides our data collection and analysis (see below). In all of these studies, it is essential to assess the fit of our findings with the CFIR and other theories used to guide the implementation, to validate and improve on these theories. Too often, this step is lacking in published implementation science literature.[127] Lastly, we are committed to contributing to the knowledge base related to implementation science; both academically (e.g., through publication in peer-reviewed journals) and operationally (e.g., by translating those findings back to our operational partners). Our on-going and planned contributions to implementation science are not goal-specific but rather cut across both goals. We have two major goals in the implementation science domain:

## Continue to Develop CFIR Definitions, Methods, and Tools

An important role of the CFIR is as "an organizational framework for synthesizing and building knowledge about what works where, across multiple settings".[119] In order to fulfill this role, we are encouraging and supporting its use in a wide range of studies and settings.

| | Low Implementation | | | High Implementation | |
|---|---|---|---|---|---|
| **III. INNER SETTING** | | | | | |
| **Structural Characteristics** | | | | | |
| Networks and communications | -2 | -2 | 1 | 2 | 2 |
| **Culture** | N/A | N/A | N/A | N/A | N/A |
| **Implementation Climate** | N/A | -2 | N/A | N/A | N/A |
| Tension for change | 0 | 0 | 2 | 1 | 1 |
| Compatibility | -2 | 1 | 0 | 1 | 1 |
| Relative priority | -2 | -2 | -2 | 1 | 2 |
| Organizational Incentives & Rewards | 0 | -1 | 0 | 0 | 1 |
| Goals and feedback | -2 | -1 | 1 | 2 | 2 |
| Learning climate | N/A | -1 | -1 | 1 | 2 |
| **Readiness for Implementation** | | | | | |
| Leadership Engagement | -2 | -1 | 2 | 2 | 2 |
| Available resource | -2 | -2 | -1 | 2 | -1 |
| Access to knowledge and information | -1 | N/A | N/A | 2 | 1 |

There is great interest in documented methods and tools to help researchers use the CFIR in their studies. Evidence of this interest is reflected in the published article's status as Highly Accessed, the number of times it has been cited (nearly 70 publications as of October 2011), and the dozens of requests for consultation on the application of the CFIR, from both VA and non-VA researchers and from the U.S. and abroad.

To meet this challenge, we are committed to developing methods and tools to help researchers apply CFIR in their work. We have already shared example interview guides that were developed based on the CFIR (see "CFIR in Action" on www.wiki.cfirwiki.net). We will document our approach in more detail, as a Toolkit, to help research teams code and analyze qualitative data for their study. Lastly, we have developed an approach for assigning ratings for

each construct using qualitative data. The table shows an excerpt from one of our studies. In this example, we had 2 "low implementation" and 2 "high implementation sites" plus a "transition" site (center column) which exhibited characteristics of both. For example, it appears that high implementation sites have strong positive presence of the construct "networks and communications" and low implementation sites have a strong negative presence, with the transition site falling in between. Our qualitative data reveal more specifically, that team formation or "teamness" was one of the driving forces behind this construct. We are especially excited about this way of analyzing the data because it allows us to build a repository of findings across studies. Our vision is to build sufficient sample size to use qualitative comparative analyses techniques, accompanied by qualitative insights (e.g., through realist synthesis) to understand specifically how constructs manifest themselves. This process can generate specific recommendations for sites attempting implementation, which moves us toward being able to better predict likely success or failure in implementations before investing time and resources, and to target weak/negative but important constructs (e.g., use strategies to build "teamness" in sites lacking this feature) to improve a site's prospects for success. So far, we have used this approach in three studies and plan to continue to use it in all of our future implementation studies.

In addition to developing these methods and tools, we will continue to refine the CFIR based on our own experience and input from other researchers. Our Wiki has the functionality to support this kind of input. Discussion pages are available for users to suggest refinements, coding guidelines, and more. We have collected input already and will continue to do so. Our work uses mixed methods whenever possible, using the strengths of qualitative and quantitative data sources. Several IRCs have been working together, with Dr. Anne Sales, on the CIFR Development Initiative (CDI) work group to

| CDI Work Group |
| --- |
| Laura Damschroder, Diabetes QUERI |
| Hildi Hagedorn, SUD QUERI |
| Carmen Hall, PT/BRI QUERI |
| Christian Helfrich, IHD QUERI |
| Julie Lowery, Diabetes QUERI |
| Anne Sales, Acting Director, IPEC |

make progress toward building a repository of measures and develop methods related to implementation research. The CFIR provides the organizing framework for this effort. We are broadening the goals of this group, which were outlined in an earlier work plan, to include the identification of quantitative measures (and develop new items when necessary) mapped to CFIR constructs. Quantitative measures will allow us to more efficiently measure and assess constructs by, for example, administering surveys remotely to stakeholders at many sites

instead of being limited to conducting phone or in-site interviews. Laura Damschroder has already been working with Dr. Carmen Hall (PT/BRI QUERI) on mapping the Organizational Change Manager (OCM)[128] instrument to the CFIR. Two researchers affiliated with the developers of the OCM are also involved in this effort. Next, the group will map Organizational Readiness to Change Assessment (ORCA) items to the CFIR and apply this to a set of data (from a SUD QUERI study) that have already been collected and will be analyzed using methods developed as part of this effort. Constructs from another implementation model developed by Klein and Sorra[129] have been mapped to the CFIR as well.[82] Complementary to our efforts, Laura Damschroder is a member of the Instrument Review Taskforce (IRT), affiliated with the Seattle Implementation Research Conference (SIRC) and funded by NIMH among others, who are engaged in a comprehensive synthesis of measures (http://www.seattleimplementation.org/sirc-projects/sirc-measures-project/). This group envisions an organized battery of rated measures, organized by the CFIR.[130] This is a valuable and serendipitous opportunity to take advantage of our congruent efforts in this domain.

**Expand Collaborations and Capacity**

In addition to the collaborations described above, we plan to continue and expand on collaborations with other QUERIs in the implementation science domain. For example, Laura Damschroder is consulting on the RE-INSPIRE project (the "Stroke Collaborative" evaluation) with the Stroke QUERI. In addition to providing guidance on applying the CFIR in this evaluation, she will work with Dr. Edward Miech to map the Competing Values Framework Cultural Assessment to the CFIR. Based on the meeting of the IRCs in Santa Monica in July, we have identified several other QUERIs interested in working with us to apply the CFIR for data collection and analysis, including SUD, eHealth, HIV/Hepatitis and CIPRS.

Our wiki (www.wiki.cfirwiki.net) is an online collaborative tool which most of the QUERIs have accessed. We will continue to develop this tool and encourage others to use this important resource. We do not have the capacity to respond to the increasing number of inquiries and requests for consultation on using the CFIR; thus, our goal is to develop the wiki as a means for addressing many queries. We have already directed a number of researchers to this site who have found it to be helpful.

In addition to the growing number of collaborations within VA, we are also networking outside of VA. Our first priority is to meet VA needs and to meet goals related to our own work; however, seizing selected opportunities will help to bolster positive visibility for VA, and ensure that our contributions to implementation science are generalizable beyond VHA. We have

already described our participation with SIRC, a good example of the mutual benefits accrued by making measures widely available. Another example is Laura Damschroder's planned collaboration, through the SIRC, to author a paper that will incorporate dependent measures into the CFIR.

Building capacity for conducting implementation research is an important sub-goal for our QUERI. Laura Damschroder and Julie Lowery are both on faculty with the EIS training sessions that are sponsored by CIPRS. They will continue their involvement in this capacity. In addition, they are developing mechanisms to support and mentor local researchers new to implementation through a monthly "lab" session during which work in progress will be presented for feedback and pertinent journal articles will be reviewed and discussed. We will also continue to present our work at VA and non-VA conferences (e.g., NIH's Dissemination and Implementation). Another small effort related to capacity-building is our administration of the Mixed Methods Special Interest Group. This group has recently expanded to include interested researchers affiliated with AHRQ. Many, if not most, members of this group are interested and/or engaged in implementation research. This takes little effort to manage but provides a wide-ranging network of VA, and some non-VA, researchers. We will continue to support this.

## 8.  MANAGEMENT PLAN

### 8.1 Leadership and Staffing

The Research Coordinating Center, under the direction of Dr. Eve Kerr and co-direction of Dr. Sarah Krein, is housed at the VA Ann Arbor HSR&D Center of Excellence. The Clinical Coordinating Center, under the direction of Dr. Len Pogach, is housed at the VA New Jersey Healthcare System in East Orange. In the past, Dr. Pogach shared clinical coordination duties with Dr. David Aron at the Louis Stokes Cleveland VAMC. Starting in late 2011 and ongoing, Dr. Susan Kirsh (also at the Louis Stokes Cleveland VAMC) replaced Dr. Aron as Co-Clinical Coordinator. Because most patients with diabetes, or at risk for diabetes, receive the majority of their care in the primary care setting, the EC felt it was essential to establish closer connections with primary care clinical and policy representatives. Therefore, adding Dr. Kirsh as Co-Clinical Coordinator helps to anchor our QUERI leadership team both in primary care and specialty care (through Dr. Pogach).

As Research Coordinator, **Dr. Kerr** is responsible for the overall leadership of the Diabetes QUERI Research Coordinating Center. Dr. Kerr is a nationally recognized health services researcher in the area of quality measurement and improvement for diabetes and other chronic conditions and has a long track record of HSR&D and QUERI funding. **Dr. Krein**, also a

health services researcher, is often the initial Diabetes QUERI point of contact in assisting researchers and others throughout VA on diabetes issues. Her expertise in data systems, implementation science, cost analyses and organization of care, contributes greatly to Diabetes QUERI expertise. Additionally, we have added **Dr. Caroline Richardson** to our core management team for the Diabetes QUERI.  Dr. Richardson, a family and women's health physician at the VA and respected health services researcher in the area of physical activity, will lead our Goal 1 work as the Prevention Coordinator. **Dr. Pogach** is actively engaged in numerous Diabetes QUERI studies. In addition, Dr. Pogach's many roles within VHA serve to keep the Diabetes QUERI up-to-date on important clinical and operations developments. For example, as the VA National Program Director for Diabetes, Dr. Pogach provides a vital link between the Diabetes QUERI and Patient Care Services. **Dr. Kirsh** is a primary care physician at the Louis Stokes Cleveland VA, a trained implementation researcher, and the Chronic Disease Consultant for PACT, Patient Care Services, VA Central Office.  Dr. Kirsh leads initiatives that are coordinated with the Offices of Primary Care, and will keep us up-to-date on policies and plans for primary care as they relate to diabetes.

**Dr. Julie Lowery and Ms. Laura Damschroder**, the Co-Implementation Research Coordinators, lead our implementation science efforts. They also participate actively in the planning and execution of the overall portfolio, lead several QUERI studies and are very involved with cross-QUERI implementation science activities. Leah Gillon, M.S.W. and Douglas Bentley, MPH, serve as the Co-Administrative Coordinators and project managers for several Diabetes QUERI projects.

The Diabetes QUERI has a number of affiliated investigators who have active research programs that advance Diabetes QUERI goals. In addition to investigators in Ann Arbor, New Jersey and Cleveland, we have a number of core investigators from around the country (see Table 5, Staff and Executive Committee Roster in the Annual Report).  We want to particularly highlight our growing collaboration with investigators from the Durham VA HSR&D Center of Excellence who have expertise in diabetes, obesity and diabetes prevention activities. For example, we have had a long standing collaboration with Dr. Hayden Bosworth on various diabetes studies. This past year, we added Dr. William Yancy to our EC, because of his expertise in dietary interventions for patients with, and at risk for, diabetes. We have also started to work closely with Dr. Matthew Maciejewski on pilot work examining cost-effectiveness of diabetes prevention programs. We expect these collaborations to continue and expand.

**8.2 Executive Committee**

The Diabetes QUERI Executive Committee consists of individuals with diabetes research and clinical expertise and includes members from key stakeholder groups within VHA (see Annual Report, Table 5). We continually look for opportunities to expand Diabetes QUERI linkages to bring new ideas and inspiration to the Diabetes QUERI functions. Dr. Paul Conlin currently serves as our Executive Committee Chair and leads discussion in our quarterly EC meetings. In the past 2 years, we have added Dr. Jonathan Nebeker (OIA), Dr. Alexander Young (MIRECC and MH QUERI), Dr. Michael Goldstein (NCP), Ms. Joanne Shear (Offices of Primary Care), Dr. Sharon Watts (ONS; replacing Linda Haas, who is retiring),  and Dr. William Yancy. We view the role of the Executive Committee as vitally important for generating project ideas, research strategic planning, keeping us informed of new developments in the clinical, operations and research worlds, and creating bridges to other stakeholders.

**8.3 Meetings and Communication**

Internal to the Research Coordinating Center, meetings are held weekly with the Research, Implementation Research and Administrative Coordinators for purposes of developing and collaborating on pilot projects and new proposals, review of projects progress, and reports on field-based projects. Additionally, we meet with the Clinical Coordinators monthly. Our administrative coordinators communicate regularly with the members of the EC and affiliated investigators to get updates on their projects – with full reports due prior to the annual report. All Coordinators and executive committee members participate in conference calls on at least a quarterly basis, and attempt to meet face-to-face whenever practical (e.g., at the HSR&D, QUERI, or ADA meetings). Further, QUERI EC members, Coordinators and other experts are part of Diabetes QUERI workgroups to address specific developmental topics. The most recent of these is the workgroup to develop the proposed self-management platform.

**Table 7. Diabetes QUERI Performance Metrics.**

| Goal 1: To work with operations partners to promote evidence-based approaches to reduce diabetes risk factors and the incidence of diabetes among Veterans (Diabetes Prevention/Primary Prevention) | | | | |
|---|---|---|---|---|
| **Sub-Goals:** | | | | |
| **A. Develop and use individualized assessments to tailor recommendations and enhance uptake of prevention programs** | | | | |
| **Objectives:** | **Scope (VAMCs, VISNs, Patients)** | **Project** | **Metric Data Source†** | **Timeline** |
| Estimate the prevalence of pre-diabetes among Veterans (Project Outcome) | 2 VAMCS | ASPIRE | Lab, clinical, self-report | 2012 |
| Evaluate and support testing and roll-out of Health Risk Appraisal (HRA) Tool (Project Outcome) | Pilot Study | Planned | | 2012-2014 |
| Adapt "Navigator" tool to interface with Health Risk Appraisal (HRA) Tool (Applies to Sub-goal 1A & 1B) (Project Outcome) | 1-2 VAMCS | LIP | Study Data | 2013-2014 |
| **B. Develop, test, and implement low-cost scalable approaches to support self-management for diet, exercise, and weight loss** | | | | |
| Double the level of participation (in terms of attended sessions) of Veterans in a weight management program compared to usual care (MOVE!) (Process Outcome) | 2 VAMCs 1000 patients | IBB 09-034 | IBB 09-034 | 2013 |
| Increase weight loss among Veterans over a 12-month period compared to usual care (Usual care estimate ~ 1.5 kg) (Process Outcome) | 2 VAMCs 468 patients | IBB 09-034 | IBB 09-034 | 2013 |
| Improve sustainability of weight loss/maintenance over 12-24 months among Veterans compared to usual care (Project Outcome) | 2 VAMCs 500 patients | *Planned* | Study Data | 2012-2015 |
| Estimate potential cost savings from diabetes prevention strategies (e.g., DPP) in VA (Process Outcome) | VHA | LIP | Admin & Literature | 2012 |
| Evaluate and support testing and roll-out of the Telephone Lifestyle Coaching (TLC) program (Project Outcome) | 4500 Veterans | Ops/RRP | Study Data | 2012+- 2012 |
| Promote weight loss/maintenance among OEF/OIF Veterans through automated objective monitoring of physical activity (Clinical Outcome) | 216 Veterans | Planned IIR | Study Data | 2012-2014 |
| Implement Diabetes Prevention Program Demonstration in VA to reduce incidence of diabetes among high-risk Veterans (Project Outcome) | 100 Veterans | SDP or SDR | Study Data | 2012-2014 |
| Understand preferences and satisfaction of OEF/OIF Veterans with multiple modes of automated interventions (Project Outcome) | 1 VAMC | LIP | Study Data | 2011-2012 |
| Identify barriers and successful strategies for implementing TeleMOVE! (Project Outcome) | 9 VAMCs 3 VISNs | RRP | Study Data | 2011-2012 |

| **Goal 2:** To work with operations partners to promote evidence-based approaches to improve treatment and reduce complications of diabetes (Diabetes Management/Secondary and Tertiary Prevention) | | | | |
|---|---|---|---|---|
| **Sub-Goals:** | | | | |
| **A. Develop and implement individualized assessments and decision support tools to enhance the use of appropriate diabetes treatments and decrease inappropriate care** | | | | |
| **Objectives:** | **Scope (VAMCs, VISNs, Patients)** | **Project** | **Metric Data Source†** | **Timeline** |
| Develop clinical prediction tools to personalize Cardiovascular Care for Veterans (Project Outcome) | National | Planned IIR | Study Data | 2014 |
| Work with OABI to implement and evaluate new clinical action measures for diabetes (Clinical Process Outcome) | National | RRP 09-111 and approved RRP | CDW and Study Data | 2012-2013 |
| Identify unintended consequences of current diabetes performance measures (Clinical Process Outcome) | 4 VAMCs | Approved RRP | Study Data | 2012 |
| Develop and test shared decision-making tools to improve glycemic management (Project Outcome) | 4 VAMCs | Planned IIRs | Study Data | 2014 |
| Assess and enroll high risk diabetes patients in clinical and self-management programs using Navigator system (Project Outcome) | 1 Health System ~ 1000 patients | PACT Demo Lab | PACT registry & Navigator Tool | 2012 |
| Provide recommendations to Office of Specialty Care for improving dissemination of specialty care initiatives (Project Outcome) | National | Approved SDR | Study Data | 2013 |
| Develop and disseminate procedure document for implementing tele-consultations for would care (TeleWound Provider Toolkit) (Project Outcome) | National | LIP | Study Data | 2013 |
| Identify veterans with diabetes and chronic kidney disease most likely to benefit from subspecialty care (Project Outcome) | National | Approved IIR | Study Data | 2013-2014 |
| **B. Develop and implement innovative programs to improve diabetes self-management** | | | | |
| Improve Hemoglobin A1c values among Veterans with diabetes using Peer-to-Peer and shared medical appointments (SMAs) approaches (Clinical Outcome) | 8 VAMCs | Planned SDP | Study Data | 2014 |
| Improve self-management support among Veterans participating in Diabetes CarePartners program as part of the Rural Health Initiative (Clinical Process Outcome) | VISN 11 | FY09RFP-V11-A | Study Data | 2012- 2013 |
| Develop a Toolkit for Motivational Interviewing Approaches to improve adherence to BP medications (Project Outcome) | 3 VAMCS | SDP 06-128 | Study Data | 2012 |
| Implement and evaluate SMAs in VISN 7 (Project Outcome) | 1 VISN | LIP | Study Data | 2012-2013 |
| Develop and evaluate self-management Platform (Project Outcome) | 2 VISNs | Planned | Study Data | 2013-2014 |

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