3. Methods Used in Implementing Research into Practice

A. The QUERI Process and Methods
B. Four Phase Framework of QUERI Implementation Projects
C. Methods for Implementing Research Into Practice

In describing methods that are appropriate to use across the pipeline of activities involved in moving research evidence into practice, it is helpful to understand the larger context of the QUERI program and its current portfolio of activities. QUERI targets nine conditions/diseases for quality improvement that are prevalent among Veterans, including: chronic heart failure (CHF), diabetes, HIV/HCV, ischemic heart disease (IHD), mental health (MH), poly-trauma and blast-related injuries (PT/BRI), spinal cord injury (SCI), stroke (STR), and substance use disorders (SUD). A tenth QUERI focuses on e-health, with an initial emphasis on adoption and implementation of the My Health***e***Vet personal health record and its features. Additional conditions may be added periodically.

Most health services researchers have received a significant amount of training in study design, and are generally prepared to use the texts and references cited throughout and at the end of this section. Rather than attempt to replicate or reproduce the work of literally hundreds of texts and articles, we refer you to them. If these are not easily understood, we recommend working closely with a seasoned methodologist or researcher with a background in implementation science, quasi-experimental and other non-randomized controlled trial designs, or in program evaluation.

A. The QUERI Process and Methods

It would be difficult to describe appropriate methods used in QUERI-related research and program evaluation outside of the context of the Six-Step Process that has guided QUERI activities since QUERI's inception. The steps in the table below have been slightly modified from their original form in order to better reflect the current understanding of how classic research methods complement the process of implementation (Stetler, Mittman et al., 2008). The table also includes methods that would be appropriate in addressing each step, as well as examples that have been or could be used by QUERI groups. The original Six Steps have been supplemented by two foundation steps – Step M and Step C that are considered to be outside of the core QUERI process, although they support the process. Step M Projects may be conducted through QUERI if viewed as critical for subsequent steps. Step C projects are generally funded through the Clinical Science and Health Services Research and Development programs.

Descriptions	Typical Methods	QUERI Examples
Step 1: Select conditions per patient populations associated with high risk of disease and/or disability and/or burden of illness for Veterans		
1A: Identify and prioritize (via a formal ranking procedure) **1B**: Identify high-priority clinical practices and outcomes within a selected condition	• Epidemiological studies (e.g., incidence and prevalence) • Measurement of disease burden (e.g., cost, health status) • Observational studies of behaviors/practices	• QUERI group conditions identified as priorities for VA based on epidemiologic evidence, incidence, and prevalence within VA healthcare system • Identification of lipid and blood pressure management as important clinical targets for diabetic care • Measurement of recommended antiretroviral drug use for VA patients with HIV/AIDS
Step 2: Identify evidence-based guidelines, recommendations, and best practices		
2A: Identify evidence-based clinical practice guidelines **2B**: Identify evidence-based clinical recommendations **2C:** Identify evidence-based clinical practices	• Large-scale clinical trials • Formal systematic research reviews or syntheses of best practices • Empirical validation of best practices	• Meta-analyses of antiretroviral drug trials • Development of VA diabetes evidence-based guidelines • Guideline modifications made for eye care in diabetics
Step 3: Measure and diagnose quality and performance gaps		
3A: Measure existing practice patterns and outcomes across VHA and identify variations from evidence-based practices ("quality/performance gaps") **3B**: Identify determinants of current practices **3C**: Diagnose quality/performance gaps **3D:** Identify barriers and facilitators to improvement	• Measurement of practice variation • Modeling determinants of clinical practices • Observational, cross-sectional, and longitudinal studies • Focus groups (e.g., providers)	• Baseline measurement of HIV screening prevalence • Cost analysis of staffing requirements for HIV/Hep C care delivery model • Cost effectiveness analysis of an HIV screening program • Modeling facilitators and barriers to improving practice for HTN treatment and control • Measurement of delays in laser therapy for diabetic retinopathy and reasons for delays • Survey of variations in HIV provider

		attitudes and facility policies for HIV care
Step 4: Implement improvement programs		
4A: Identify improvement/implementation strategies, programs, and program components or tools **4B**: Develop or adapt improvement/implementation strategies, programs, and program components or tools **4C**: Implement improvement/implementation strategies/programs to address quality gaps	• Literature reviews • Development of QI toolkits • Experiments or quasi experiments to evaluate QI interventions • Development or adaptation of educational materials or decision support tools See descriptions below for QUERI Implementation Activity Phases. • Single site pilots • Small-scale multi-site evaluations • Region-wide demonstrations • National rollouts)	• Pilot test strategies to identify and care for patients with diabetes who have at-risk feet • Multi-site evaluation of scheduling strategies to improve optimal timing of diabetes retinopathy follow-up and therapy • Trial of clinical reminders to improve HIV patient outcomes and guideline concordance
Step 5/6: Evaluate Improvement Programs		
5: Assess improvement program feasibility, implementation, and impacts on patient, family, and healthcare system processes and outcomes **6**: Assess improvement program impacts on health-related quality of life (HRQOL)	• Experiments or quasi-experiments to evaluate QI interventions • Development of QI toolkits • Cost analyses See descriptions below for QUERI Implementation Activity Phases. • Single site pilots • Small-scale multi-site evaluations • Region-wide demonstrations • National rollouts	• Evaluation of a foot care intervention for patients with diabetes • Eye care intervention trial to study improvements in diabetic patient and system outcomes • Evaluation of eye and foot care interventions for reducing blindness, amputation, and improvements in HRQOL
Step M: Develop measures, methods, and data resources		

M1: Develop, refine, and validate patient registries and databases documenting healthcare organizational features, clinical practices and utilization, and outcomes **M2**: Develop and/or evaluate case-finding or screening tools **M3**: Develop and/or evaluate measures of healthcare structures, processes and outcomes	• Develop databases • Develop measurement tools	• Development of HIV patient research database • Design of HIV case-finding algorithm • Design of provider perceptions/attitudes survey instrument
Step C: Develop clinical evidence		
C1: Develop and evaluate evidence-based clinical practices and recommendations (clinical research) **C2**: Develop and evaluate evidence-based health services interventions (health services research)	• Systematic research reviews • Panels of experts • Delphi Method for consensus building	• Construction of guidelines for treatment of depression in HIV patients on antiretroviral medication regimens

B. Four Phase Framework of QUERI Implementation Projects

The QUERI Four Phase Framework provides a method for describing QUERI implementation projects, conducted largely under Steps 4, 5, and 6 of the QUERI process described above. This framework incorporates the necessary phases to assure adequate development, refinement, evaluation, and assessment of innovative evidence-based implementation programs and strategies. It maximizes the likelihood of successful identification and implementation of beneficial programs to diffuse clinical findings and minimize failed large-scale implementation efforts and, thus, the ineffective use of resources. In addition, use of these labels fosters a consistent understanding and communication among QUERI stakeholders, including QUERI Coordinating Center leaders, investigators, reviewers, HSR&D/Central Office program managers, and VA, as well as non-VA partners. The following descriptions of the phases are based on Table 2 in Stetler, Mittman et al., 2008).

http://www.queri.research.va.gov/default.cfm
http://www.queri.research.va.gov/SDP-submissions.pdf

Phase 1: Pilot project to develop/refine an improvement/implementation program and assess basic feasibility

A potential improvement program, strategy, or tool that is designed to systematically address quality

gaps in the provision of evidence-based care should be implemented in a relatively brief study with a fairly short timeline (e.g., 12-18 months) within a single clinic or facility, when first proposed, developed, or imported into the VA healthcare system. This allows initial feasibility testing and refinement or adaptation to the VA environment. These projects:

- Identify incompatibilities between a new program and the underlying structure, operations, and culture;
- Describe important "lessons learned" that permit refinements to the program;
- Produce basic information regarding program acceptance, feasibility, and impacts in a rapid, low-cost manner; and
- Require formative evaluation as part of the initial feasibility testing to permit full delineation of barriers and facilitators, and to increase the opportunity to export into *Phase 2.*

Phase 2: Small clinical trials to further refine and evaluate an improvement/implementation program

Activities of this type represent a modest level of investment and commitment, and are designed to produce valid evidence regarding program operations and impacts in a rigorous manner. They also are designed to permit continued refinement of program designs and features. These types of projects:

- Involve 4-8 facilities within 1-2 VISNs;
- Are conducted within a formal research and evaluation framework, and often use a hybrid design, such as a traditional intervention design plus a descriptive formative evaluation (Curran et al., 2012);
- Require active research team support and involvement, plus modest real-time refinements to maximize the likelihood of success and to study the process for replication requirements;
- Develop and test measurement tools and evaluation methods; and
- Include evaluation of costs and benefits to allow assessment for the feasibility of continuing on to *Phase 3*.

Phase 3: Regional roll-out projects

Projects of this type use a larger number of facilities and/or VISNs to prepare for national implementation and incorporation into VHA operations on a regular basis. They should include a sufficient number of sites to permit assessment of feasibility, acceptance, and consistency within regional conditions in order to produce valid evidence of program performance and impacts. Elements include:

- Implementation within 10-20 facilities in 3-5 VA regions;
- Should require less need for real-time refinements of the implementation strategy;
- Measurement of impacts on key patient and caregiver outcomes (e.g., clinical, functional status,

psychosocial outcomes such as satisfaction and quality of life, etc.);

- Evaluation of program costs and cost effectiveness; and
- Decreased research team support at local sites and greater involvement of stakeholders, both nationally and locally to prepare for "hand-off" to national rollout.

Phase 4: "National roll-out" effort

These projects represent a type of "post-marketing" phase, using Food and Drug Administration (FDA) terminology, in which an innovative implementation program is deployed system-wide by a VHA operations entity or program. QUERI research teams, Coordinating Centers, or other health services researchers may provide some support through technical assistance for implementation and evaluation. Hallmarks of these projects include:

- Implementation of a tested, refined strategy throughout VA,
- Existing operations or designated leadership entity delivers the program,
- Research team support as determined per Phase 3 evaluation, and
- Concurrent and ongoing evaluation per Phase 3 evaluation.

Understanding Implementation Success within VA: The Translating Initiatives in Depression into Effective Solutions (TIDES) Example

Many VA researchers hope to ensure that their investigations result in measureable improvement of the care delivered to Veterans. However, the pathway from accumulated research knowledge to system improvement and back again is typically circuitous and may be difficult to map. By focusing on the QUERI research projects related to the Translating Initiatives in Depression into Effective Solutions, or TIDES, initiative over the decade between 2001 and 2011, we aim to illustrate some of the potential benefits and challenges of attempting to follow such a pathway.

TIDES began as a research/clinical partnership among clinical managers in three VA regions (VISNs 10, 16, and 23) and depression care researchers based in VISNs 20 and 22. From the start, these researchers and clinical managers agreed that major depressive disorder was a serious condition that was not being cared for adequately in VA settings. In particular, depression screening was being initiated across the VA system, and these clinical managers were concerned that patients screening positive for depression were not receiving guideline-concordant care. With approximately 5 to 10% of patients potentially being identified with depression in VA primary care settings per year, it was becoming apparent that the system for initiating treatment and appropriate follow-up for patients in primary care, in particular, was likely to require enhancement.

Researchers, on the other hand, had assembled substantial evidence that collaborative care for depression was effective and cost-effective. A plethora of publications in a wide variety of settings

substantiated the potential positive impacts of this approach. Collaborative care for depression involves a trained, designated care manager in providing comprehensive, protocol-based assessment and follow-up, self-management support, and links to mental health specialists when needed for patients with symptoms of major depression in primary care.

Together, TIDES researchers and clinical managers assembled a pilot collaborative care intervention using Evidence-Based Quality Improvement as a partnership quality improvement approach. This approach was funded by an initial $150,000 QUERI grant. Separately, and a year later, the researchers garnered HSR&D funding for a rigorous, randomized, qualitative and quantitative evaluation of an expanded implementation of the initial model.

While not initiated originally through Mental Health-QUERI http://www.queri.research.va.gov/mh/default.cfm , which at the time was focused mostly on serious mental illness and mental health specialty care, the TIDES initiative soon began to engage a broad set of QUERI researchers with interests in depression in primary care through Mental Health-QUERI networks. Additional research projects investigating related aspects of depression care, such as TIDES care for patients with HIV, TIDES care for depressed patients in contract clinics, economics of TIDES depression care, and others were proposed and funded by an enlarging group of health services researchers and linked clinical partners.

Meanwhile, in about 2004, the regional directors and other leaders from the initial three TIDES VISNs pushed the project to focus on how learning from the initiative could be incorporated into VA policy. Over the following two years, TIDES researchers introduced an enlarging group of VA clinical managers to the problem of depression in VA, and potential methods for improvement. Project participants also focused specifically on developing methods for sharing information from the project with both new spread sites and VA leaders. A project to further spread TIDES to an additional VISN and to additional sites in the initiating VISN was funded by QUERI in 2005, with an accompanying evaluation.

In 2006, the issue of depression care rather suddenly arose as a political concern among Veterans and Congress. A call to TIDES leaders to pull together a website that would provide needed information and tools for collaborative care, hosted by VA's mental health leadership, went out in March of 2006, with a short-term due date of June 2006 for broad dissemination. Primary care and mental health central leadership next developed a request for proposals to develop and test models for improving care for depression, and about 20 of these projects were funded after review across nearly all VA regions.

By 2008, TIDES collaborative care was available to approximately 300,000 - 500,000 Veterans receiving primary care at clinics in the 17 medical centers where TIDES had been fully implemented. Additional sites had implemented linked improvement methods, including the Behavioral Health Laboratory and the White River Junction co-located collaborative care model; these models had both been featured along with TIDES on the newly-developed website. Nearly 50 researchers and their clinical partners were engaged in implementing some aspects of TIDES. Policymakers meanwhile included the use of one or

more of these models as mandatory elements of site-level primary care/mental health integration in VA nationally.

The TIDES efforts demonstrated that collaboration among health services researchers from around the country could influence patient care and policy under the right circumstances. Collaborative care models became routine care in VA and spread throughout many VA regions. Additional components, conditions, and changes to the basic TIDES initiative in primary care continue to be developed and investigated through QUERI and related projects to this day. At the same time, TIDES identified a number of barriers to the implementation process.

Barriers to depression care improvement included a variety of pre-existing institutional policies within the clinic and healthcare system, a legacy of local culture and turf issues between mental health and primary care, and the need to re-educate frequently due to turnover of key clinical leaders. Limited skills and training related to achieving initiative goals and time constraints on team members also presented implementation challenges. Additionally, VA's centralized information technology (IT) services proved difficult to navigate effectively. This was true despite development of three alternative IT models, one of which involved no external software, for implementing collaborative care. While two of these models rose to the top of the IT innovation implementation list, none were actually implemented nationally. The lack of electronic guidance and reporting for the initiative has continued to reduce its accountability and transparency of the collaborative care approach.

In summary, despite a variety of challenges, TIDES and TIDES-linked researchers and clinical partners joined in promoting a set of improvements in care that they believed had salience and a strong prior research base. This initial work entrained additional linked projects and care models over the succeeding decade. Ten years after its inception, TIDES and its partner models continue to provide a substrate for ongoing improvement, and also can provide a working example for QUERI and other VA researchers as they consider new approaches to improving VA care through partnership. See:

- Rubenstein, Williams et al., 2009)
- Rubenstein, Chaney et al., 2010)
- Luck, Hagigi et al., 2009)
- Fickel, Yano et al., 2009)
- Liu, Rubenstein et al., 2009)
- Smith, Williams et al., 2008)
- Liu, Bolkan et al., 2009)
- Liu, Fortney et al., 2007)
- Kirchner, Edlund et al., 2010)

C. Methods for Implementing Research Into Practice

While a variety of research methods are used at various stages in the QUERI process, particularly at Steps 4, 5 and 6, quasi-experimental designs may be most appropriate. This is because of inherent difficulties created by having small numbers of sites for study, and limitations in randomizing sites and/or individuals. With careful attention to selecting controls or comparison groups, and consideration of threats to validity, quasi-experimental designs can provide the rigor needed to determine whether a quality improvement project had positive effects. Additionally, methods in formative and process evaluation become important at these steps, both for improving the intervention itself and for documenting the intervention processes. The specific resources (e.g., surveys, focus groups) will be driven by the nature of the proposed project.

The QUERI Center for Implementation Practice and Research Support (CIPRS) http://www.queri.research.va.gov/ciprs/ hosted a series of conferences on "Enhancing Implementation Science" from 2010-2012. Many of the presentations from these conferences can assist investigators in gaining basic knowledge about evaluating implementation trials, including: measuring implementation outcomes and fidelity, studying implementation contexts, observational studies, and cost analysis in implementation research.

Copies of presentation slides and audio and video of presentations are available at (www.queri.research.va.gov/meetings/eis/2011).

Specific relevant talks include:

- Hybrid Study Designs: Alison Hamilton
  http://www.queri.research.va.gov/meetings/eis/2011/Novice-Hybrid-Hamilton.pdf
- Overview of Evaluation in Implementation Science: Jeffrey Smith
  http://www.queri.research.va.gov/meetings/eis/2011/Smith.pdf
- Measuring Implementation Outcomes and Fidelity: Carol VanDeusen Lukas
  http://www.queri.research.va.gov/meetings/eis/2011/MidAdvOutcomes-VanDeusenLukas.pdf
- Studying Implementation Contexts: Ann Chou
  http://www.queri.research.va.gov/meetings/eis/2011/MidAdv-Context-Chou.pdf
- Measuring implementation Mechanisms: Dave Aron
- Scale Up & Spread and Sustainability: Wynne Norton
  http://www.queri.research.va.gov/meetings/eis/2011/Norton.pdf
- Observational Studies: Ann Chou
  http://www.queri.research.va.gov/meetings/eis/2011/MidAdv-ObsStudies-Chou.pdf
- Cost Analysis in Implementation Research: Patricia Sinnott

Also see the section in this Guide on formative and process evaluation.

Appropriate levels of intervention

Part of the design of an intervention to implement best practices and its evaluation must include a

careful analysis of the appropriate level of the intervention. The unit – and level of analysis in the accompanying evaluation – must conform to the nature of the intervention and its level. For example, if an intervention is conducted at the organizational level, such as the clinic, then the most appropriate unit of analysis is the clinic. However, it may be feasible to analyze data at the individual patient level as well. In order to make appropriate statistical inferences using frequently used approaches (e.g., regression analysis) the hierarchical nature of the data—the fact that patients are nested within clinics, which may be nested within facilities, which may be nested within VISNs—must be taken into account.

Whether an implementation investigator has the ability to randomize subjects to intervention arms in a trial design is a related issue for consideration. Researchers are strongly advised to include a methodologist/statistician who is experienced in the design and conduct of these analyses on the research team.

Hybrid designs

QUERI researchers were instrumental in the development and early use of hybrid designs which combine traditional effectiveness research with implementation research. Hybrid models 1 through 3 are defined based on the emphasis of the project on effectiveness or implementation. Hybrid 1 models focus on effectiveness, but also collect process evaluation information during the clinical trial to inform future implementation. Hybrid 2 designs focus equally on testing a potential implementation strategy and testing the effectiveness of the intervention. Finally, Hybrid 3 designs focus primarily on testing an implementation strategy, but also collect effectiveness information on the population/setting of interest, which may be slightly different from the population or setting from which the primary effectiveness data for the intervention were collected. For example, a Hybrid 3 design might implement a nurse case manager intervention for depression that has previously been shown to be effective in primary care into an HIV specialty clinic. For details on the various hybrid designs, please see Curran, Bauer et al., 2012).

Intervention Focus		Implementation Approaches	
		YES	**NO**
Clinical Effectiveness	**YES**	**Hybrid Type II:** Test clinical intervention, test implementation intervention	**Hybrid Type I:** Test clinical intervention, observe/gather information on implementation
	NO	**Hybrid Type III:** Test implementation intervention, observe/gather information on clinical intervention and outcomes	**Observational Studies**
		Implementation Study	

Study Characteristic	Hybrid Type 1	Hybrid Type II	Hybrid Type III
Research Questions (examples)	**<u>Primary Question</u>:** **Will a clinical treatment work in this setting/these patients?** **<u>Secondary Question</u>:** **What are the potential barriers/facilitators to a treatment's implementation?**	**<u>Primary Questions</u>:** **Will a clinical treatment work in this setting/these patients?** **Does the implementation method show promise?**	**<u>Primary Question</u>:** **Which method works better in facilitating implementation of a clinical treatment? Which core components are critical?** **<u>Secondary Question</u>:** **Is the clinical treatment effective in this setting/these patients?**