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Contents

1. Applying Frameworks, Theories, and Models ................................................................. 1
   A. The Science of Implementation .................................................................................. 1
   B. Frameworks, Theories, and Models Types of Theories ........................................... 2
   C. Types of Theories ..................................................................................................... 4
   D. Levels and Theories ................................................................................................. 4
   E. Applying Theory to Implementation Studies ......................................................... 5

2. Diagnosing a Gap and Designing an Intervention ....................................................... 7
   A. An Introductions to Systems Thinking .................................................................... 7
   B. What Does Systems Thinking Contribute to Diagnosis and Intervention Design? ...... 11
   C. Conducting Diagnosis and Intervention .................................................................. 12
   D. Tools for Implementation Strategy Design ............................................................ 18
   E. Web Resources ........................................................................................................ 20

3. Methods Used in Implementing Research into Practice .............................................. 22
   A. The QUERI Process and Methods ......................................................................... 22
   B. Four Phase Framework of QUERI Implementation Projects .................................. 25
   C. Methods for Implementing Research Into Practice .................................................. 30

4. Formative Evaluation ................................................................................................... 34
   A. The Role of Evaluation in QUERI ........................................................................... 34
   B. The Need for FE in Implementation Research ......................................................... 35
   C. Purposes .................................................................................................................. 35
   D. Data Collection Methodologies .............................................................................. 36
   E. FE Research Process ............................................................................................... 37
   F. Challenges to Conducting FE ................................................................................ 38
   G. Writing About FE ................................................................................................... 38
   H. Resources Related to Evaluation ............................................................................. 39

5. Tools and Toolkits ....................................................................................................... 41
   A. VA HSR&D Cyber Seminars on Tools and Toolkits ................................................. 41
   B. Links to Implementation Toolkits, Conferences, Consortiums, and Trainings .......... 44

6. Resources for Implementing Research into Practice .................................................. 52

7. References .................................................................................................................... 57

1. Applying Frameworks, Theories, and Models

A. The Science of Implementation

B. Frameworks, Theories, and Models

C. Types of Theories

D. Levels and Theories

E. Applying Theory to Implementation Studies

A. The Science of Implementation

Please see the following National Institutes of Health (NIH) website for a succinct definition of implementation science, as well as information on dissemination of implementation science:

http://www.fic.nih.gov/News/Events/implementation-science/Pages/faqs.aspx

Implementation is a “wickedly” complex sociological process (Conklin, 2005) that interacts significantly with multiple dimensions of the context in which it occurs. Implementation researchers seek to discover relationships between key constructs that underlie this process. Implementation science is a relatively new scientific field. In order for the science to advance and for findings to be generalizable, implementation science must incorporate the characteristics of good and/or rigorous science.

Underlying science is a theoretical understanding of the phenomena being studied. Characteristics of good science include (Sabatier, 2007):

1. Data collection and analysis methods should be presented publicly, and in a way that can be replicated by others.
2. Concepts and propositions should be logically consistent, clearly defined, and, in general, lead to empirically falsifiable hypotheses.
3. Propositions should be as general as possible and relevant uncertainties explicitly addressed.
4. Methods and concepts should intentionally be subjected to criticism and evaluation by subject area experts.

Underlying these imperatives is the need for coherent sets of propositions referred to as “theories.”

The following are valuable resources that you may wish to review. They are related to the role and value of theory in implementation research and include cyberseminars, articles, and books.

- QUERI Enhancing Implementation Science Cyber Seminar 2012 (slides 8-18)

Generalizing through consistent use of theory (or frameworks or models) may be more efficient than replicating specific studies in many different settings: (Foy, Ovretveit et al., 2011)

Five roles of theory in designing and testing interventions: (Bartholomew and Mullen, 2011)

Using theory to change individual level behavior: (French, Green et al., 2012)

Role of theory in predicting effects of patient safety practices: (Foy, Ovretveit et al., 2011)

Using theory to guide synthesis of findings across studies: (Damschroder, Aron et al., 2009; Gardner, Whittington et al., 2010)

A widely cited, coherent, and accessible argument for the importance and role of theory in the scientific process, applied to the public policy domain (another highly complex scientific domain of inquiry), is offered in the book edited by Paul Sabatier: (Sabatier, 2007)

Designing theoretically-informed implementation interventions (Improved Clinical Effectiveness through Behavioural Research, 2006).

You also may want to browse the QUERI Implementation Cyberseminar series. Browsing this link will lead you to the audio and video links for each cyberseminar, in addition to the slides:

- http://www.hsrd.research.va.gov/cyberseminars/series.cfm#qi

**B. Frameworks, Theories, and Models**

In implementation science, three commonly used terms are *frameworks*, *theories*, and *models*; each comprising theoretical propositions at different levels of specificity. These terms tend to be used interchangeably in the published literature. This conundrum is complicated by the many layers and contexts in which these terms are applied. It is beyond the scope of this Guide to solve this inconsistency, but the use of terms within this section will be consistent. Elinor Ostrom provides a pragmatic and helpful conceptualization of these terms and illuminates helpful linkages between them in her chapter (Ostrom, 1999) depicted in the Figure below. Frameworks, theories, and models provide three levels of increasing specificity in theory-based research. It is important to clearly describe how theoretical constructs or techniques are defined and operationalized in your project so that others can replicate your results. Selection and use of implementation frameworks, models, or theories is critical not only for guiding data collection and analysis, but also for contributing to advancing the theory of implementation science.
Theoretical or Conceptual Framework. A Framework provides a broad set of propositions that organize diagnostic (what is the nature of the phenomenon being studied, e.g., the context in which implementation happens) and/or prescriptive (e.g., how implementation is planned and carried out) inquiry. Frameworks provide “meta-theoretical” language that promotes comparison across theories. They attempt to identify a comprehensive set of elements that any theory related to the domain (e.g., implementation) would need to consider or include, and help to generate research questions that need to be addressed.

Theory. This is arguably the most contentious term. A “big T” Theory is one that embodies a well-substantiated explanation of some aspect of the natural world, based on a body of facts that have been repeatedly confirmed through observation and experiment. Such fact-supported theories are not unproven “guesses,” but reliable accounts of the real world. The Theory of biological evolution is more than "just a theory." It provides an elegantly simple set of propositions that helps to explain the wide diversity in species over time and space. A “little t” theory is a middle-range set of context-independent propositions that specifies a denser and more logically coherent set of relationships; it may have values applied to some variables, and usually specifies how relationships vary depending on values of specific variables. Normalization Process Theory (NPT) is one of the few implementation theories explicitly characterized as a middle-range theory (May, Mair et al., 2009). Middle-range theories support more specific research questions and provide the basis for working assumptions and testable hypotheses. These theories provide assumptions that make it possible for a researcher to diagnose a phenomenon (e.g., implementation), explain its processes (e.g., the role and value of audit and feedback), and predict outcomes (e.g., more of the desired behavior). Multiple theories can be compatible with a single conceptual framework (see below).

A model is a simplified representation of a complex reality. It is narrower in scope and specifies more precise assumptions; ideally, it is mathematical, though this is not necessarily the case in mixed-methods or qualitative research approaches. Models are context-specific. For example, Klein, Conn & Sorra developed and tested a model of implementation of a software system in a sample of manufacturers. A model was proposed, tested, and refined to include seven defined constructs (including expected outcomes) with defined relationships and statistical associations (Klein, Conn et al., 2001).

A conceptual framework may be broad or narrow. A broad framework might provide guidance in problem definition, purpose, literature review, methodology, data collection and analysis, while a
narrower framework might comprise a collection of constructs with or without relationships specified. For example, the Theoretical Domains Framework (TDF), developed by Susan Michie, provides a taxonomy of constructs known to influence individual-level behavior change (Michie, Johnston et al., 2005; Cane, O'Connor et al., 2012). Another example framework of constructs related to organization-level change is the Consolidated Framework for Implementation Research (CFIR) (Damschroder, Aron et al., 2009).

C. Types of Theories
Whether embodied in frameworks, middle-range theories, or models, theories may be explanatory or prescriptive (Grol, Bosch et al., 2007). *Explanatory* theories (also known as “impact,” “descriptive” or “predictive”) underpin hypotheses and assumptions about how implementation activities will facilitate a desired change, as well as identify potential facilitators and barriers for success. *Prescriptive* theories (also known as “process” or “planned action”) guide how implementation should be planned, organized, and scheduled. The figure below provides a schematic for how these types of theories are related and can be used to guide, design, and test implementation interventions and strategies.

D. Levels and Theories
Another dimension by which to characterize theories is the level they are expected to operate. For example, they may be targeted at individual level change (e.g., Theory of Planned Behavior, an explanatory theory), at the collective or organizational level (e.g., Klein, Conn, and Sorra’s theory and model described above), or at a systems or policy level (e.g., Rogers’ Diffusion of Innovation Theory).

The figure below (based on a manuscript by Ferlie and Shortell, 2001) illustrates the way that clinics or microsystems, where individuals provide clinical care, are nested in larger organizational structures. The circle around the levels encloses the full social system, including both the levels from the provider side (top part of the diagram) and the levels within which patients are embedded (lower part). Patients and
providers meet and interact within smaller sub-units of an organization, with individual providers interacting with individual patients, as well as with each other. Theories apply at all the levels from both the provider and patient sides of the social system.

There is an expanding array of resources to help identify and select appropriate theories. A few are listed below:

- Extensive narrative review and characterization of groundings for multiple levels (Tabak, Khoong et al., 2012)
- Comprehensive list of planned action, cognitive psychology, organizational, and quality improvement theories (see Section 4-Theories and Models of Knowledge to Action): [http://www.cihr-irsc.gc.ca/e/40618.html#toc](http://www.cihr-irsc.gc.ca/e/40618.html#toc).

E. Applying Theory to Implementation Studies

Once appropriate frameworks, models, and/or theories are selected, this will guide the study’s hypotheses generation, data collection, and data analysis (an example using the Normalization Process Model as a conceptual framework to inform qualitative data collection and analyses is provided by Macfarlane and O’Reilly-de Brun, 2012). As noted earlier, it is important to clearly describe how theoretical constructs or techniques are defined and operationalized in your project so that others can replicate your results. Selection and use of implementation frameworks, models, or theories is critical, not only for guiding data collection and analysis, but also for contributing to advancing the theory of implementation science. Doing so promotes systematic building of knowledge across studies and settings; see Gardner, Whittington et al., 2010; Damschroder and Hagedorn, 2011) for more on this topic and:
• General Framework for applying theory to implementation research projects: QUERI Enhancing Implementation Science CyberSeminar 2012
  (see slides 33-54).

Another way of putting models and frameworks together with strategies and tools is described in Sales, Smith et al., 2006). In this paper, the authors describe how all of these interact to support planning and designing interventions, covered in more detail in the next section, and provide an example from Mental Health-QUERI http://www.queri.research.va.gov/mh/default.cfm.
2. Diagnosing a Gap and Designing an Intervention

A. An Introduction to Systems Thinking
B. What Does Systems Thinking Contribute to Diagnosis and Intervention Design?
C. Conducting Diagnosis and Intervention Design
D. Tools for Implementation Strategy Design
E. Web Resources

Clinical research suggests how to effectively improve health and quality of life. Initial steps in translating research findings into improved clinical practice are to diagnose the gap or problem and design an intervention. Diagnosis results in the identification of actionable factors contributing to performance gaps and actionable reasons for failures in implementing innovations. Intervention design is the process of choosing a specific focus (e.g., patients, clinicians, information systems) for initiating change.

For example, while we might first observe a performance gap in a regional-level (or Veterans Integrated Service Network (VISN), in the Department of Veteran Affairs (VA) performance measure, further analysis might show that the problem is most closely related to a lack of patient knowledge or motivation. Still further analysis may indicate that the most effective practical solution would be the development of an intervention to activate patients. Or, we might first identify a failure to fully implement an innovation in individual provider practice, but further analysis might indicate a need to redesign communications between VISN leadership and facility management. Variation studies tell us the relative level of adherence to best practices across observation units (e.g., VISNs, facilities, clinic, practice teams, providers, and patients) and are very useful in identifying performance gaps, which then can be the subject of diagnosis.

Diagnosis and intervention design should always precede change efforts, but sometimes it is not readily apparent. For example, many times diagnosis and intervention design are implicit: a performance gap is observed and a decision is made to focus change efforts at persons or systems based on expert judgment or historical precedent. The problem with implicit methods is they are not transparent -- others who do not share our expertise or culture may not understand why we have made the choices we have. This chapter will focus on explicit, formal diagnosis, and intervention design.

Remember, diagnosis and intervention design are not all-or-none ventures. You can do just enough to determine that you may not need to do more.
A. An Introduction to Systems Thinking

What is a "System?"

A system is an entity that maintains its existence through the mutual interaction of its parts. Systems exhibit emergent properties; these are characteristics that emerge from the interactions between the parts of the system and cannot be found in any of its parts alone. Being aware of how multiple systems and sub-systems might interact will help with relevant aspects of the implementation task. Systems can be described in terms of their goals, inputs, outputs, processes, and component parts or sub-systems. Systems can sometimes be observed or named (for example, the Veterans Health Administration is an integrated system of care made up of many component parts), but they are often not easily observed and not always named. There are many resources on the Internet to help understand systems and systems thinking; we suggest searching using the term “systems thinking.”


We will use a colorectal cancer screening and follow-up system to illustrate a system. A colorectal cancer screening and follow-up system maintains its existence through the mutual interaction of primary care, laboratory, and GI specialty clinics, as well as the more diffuse and external systems of patient adherence to appointments, and interactions with numerous other components of the medical center. Colorectal cancer screening and follow-up includes the referral/scheduling process. Productive communication among lab, GI, and primary care does not wholly reside in any one of these sub-systems, but is an emergent property of their interaction. Any agent (person or organizational entity) may simultaneously be a component in multiple systems. A primary care provider who is part of the colorectal cancer screening system also will play a role in other clinical sub-systems that originate in primary care. The provider also may be a part of administrative systems.

The goal of a colorectal cancer screening and follow-up system is to improve patient survival and quality of life through early detection and prompt treatment of colorectal cancers and pre-cancerous polyps. The inputs into the system are patient health status, patient and provider knowledge and attitudes, and clinic resources, etc. Processes within the system include: patient healthcare seeking, patient-provider shared decision-making, clinical informatics, communication and specialty referral, and patient education. The outputs of the system are screening rate, complete diagnostic evaluation colonoscopy (CDEC) rate, treatment rates, mortality, and quality of life effects.

Formal and Informal Systems

It is important to identify and consider both formal and informal systems when translating research into practice in clinical settings. Formal systems are objective in that they exist apart from any external observer. They are systems that are prescribed, mandated, or formally incorporated and/or organized. They include, but are not limited to, organizational entities (divisions, departments, etc.), professional societies, organized advocacy groups, and so forth. The nominal goals, inputs, outputs, processes, and
component parts or sub-systems of formal systems are typically documented and may evolve over time to differ significantly from the documented components. While documented nominal components are a good introduction to formal systems (see org. chart below for example), effective implementation work requires understanding the functional components; in other words, how a particular system actually operates.

In contrast to formal systems, informal systems are subjective; they only "exist" as observer constructs. They are descriptions of observed goals, processes, interactions among entities, and behaviors. Some examples of formal and informal systems may serve to illustrate. VHA is made up of multiple embedded, overlapping, and interacting systems, both formal and informal.

Examples of formal care systems that exist within VHA include VISNs (Veterans Integrated Service Networks), the regional organizations for VHA, service lines, facilities (i.e., medical center and affiliated community-based centers), stations (specific community-based outpatient clinics or medical centers), care units within a facility (e.g., clinics such as primary care or gastroenterology), and support units (chaplaincy, patient education, pharmacy, etc.).

Examples of informal care systems may be groups of providers who interact regularly, but are not part of a formal organizational network, or patient social support during regular transportation to clinics or in waiting rooms. The goals, processes and behaviors represented by both formal and informal systems have profound effects on healthcare and outcomes. Both are vital mediators of change, and both formal
and informal systems should be considered in diagnosis and in intervention design.

**Examples of formal systems**

*Formal management systems:*
- Veterans Health Administration (VHA)  [http://www.va.gov/health/default.asp](http://www.va.gov/health/default.asp)
- Patient Care Services (PCS)  [http://www.patientcare.va.gov/](http://www.patientcare.va.gov/)
- Operations and Management (10N) (available on VA Intranet only:  [http://vaww.dushom.va.gov/index.asp](http://vaww.dushom.va.gov/index.asp))
- Office of Information & Technology (OI&T)  [http://www.oit.va.gov/](http://www.oit.va.gov/)

*Formal provider systems:*
- Professional groups organized by discipline (i.e., dentistry, nursing, physicians, psychology, and osteopathy)
- Professional groups organized by practice specialization (i.e., primary care, mental health, and surgical)
- Clinic care teams or firms
- Gastroenterology department

*Formal patient systems:*
- Biological and legal family units
- Patient advocacy groups

**Examples of informal systems and system resources**

*Informal care systems:*
- Patient social support
- Friends
- Spiritual community
- Neighbors
- Under some circumstances, patient self-care can be viewed as a system

*Informal staff networks:*
- Patient-focused ad hoc teams; for example, the nurse refers the patient to a specific patient care representative, or the physician says "you ought to talk to nurse X in extended care." These represent how knowledge moves across local experts.
- Sometimes merely acting like one has knowledge is equally valuable. This leads to secretive, defensive behavior to preserve the illusion of power.
Informal provider systems:
- Provider-focused systems to improve job satisfaction and/or performance.
- Social support on and off the job.
- Dysfunctional cases may include implicit or explicit manipulation of others.

B. What Does Systems Thinking Contribute to Diagnosis and Intervention Design?

Systems-thinking helps us with problem diagnosis and intervention design by allowing us to recognize when a system is not functioning as designed.

How to diagnose: We can map out a task model and/or performance model (also called a process map). Analysis of the effectiveness of the system at each point in the system tells us what needs to be fixed. We may find that a specific observation unit (i.e., clinic) has skipped a step in the process.

Intervention design or targeting: The results of diagnosis point to specific individuals or points in the system or process that need to be addressed. Sometimes the entire system needs to be redesigned. Understanding inputs, outputs, and goals of embedded sub-systems will help:
- Identify low-hanging fruit,
- Point to mutual dependencies that may require sequencing of interventions, and
- Identify missing sub-systems or stakeholder groups that need to be involved.

If there are serious deficits at each step in the performance model, redesigning the system may be necessary. Repair may not be feasible, especially if the deficits are restricted to a specific sub-system. What appear to be isolated large deficits will have so many downstream consequences and sub-system interdependencies to work through that system redesign would be called for in these cases, too.

Systems thinking allows us to understand how the normal functioning of an intact system may result in performance gaps or innovation lags.

If we map out the system’s functional goals, inputs, outputs, processes, and component parts or sub-systems, we can often find logical errors, barriers, or resource deficiencies.

We can perform virtual "tests" on potential interventions using our system models to determine how much improvement we might reap from each potential intervention.

Systems thinking allows for understand how normal functioning of multiple systems can produce performance gaps through conflict.

If we map out the system’s functional goals, inputs, outputs, processes, and component parts or sub-systems, conflicts can often be found between dependent inputs and outputs, conflicting goals, or
attempts to access the same limited resources. Using systems models, check to see if proposed interventions resolve one set of conflicts only to create new conflicts.

C. Conducting Diagnosis and Intervention Design

How Do You Conduct Diagnosis and Intervention Design? How Do You Map Out Systems?

Identify the problem

There is usually some trigger that leads to the effort to conduct diagnosis and subsequent intervention design. Implementation efforts may be triggered either by observations of substandard or sub-optimal performance, or by observations that proven innovations are not being applied in the field. Diagnosis and intervention design efforts are often influenced by the impetus for the implementation effort. Some examples:

The observed performance gap:
The performance gap is a deficiency in one of the outputs of the main system of interest. In the colorectal cancer screening example, fewer than one-third of patients with positive fecal occult blood test (FOBT) findings received necessary complete diagnostic evaluation colonoscopy (CDEC).

Identifying an innovation lag or problem:
A new device, drug, policy, or process is deployed to a setting and is not being used, is being used incorrectly, or is being used and is having undesirable effects.

Specify the task model

Use means-ends analysis to develop a basic sequential task model or sub-goal structure. For example,

- We want patients to complete CDEC after positive FOBT findings.
  - What conditions must they satisfy immediately prior to the CDEC?
    - They must be adequately prepped and show up for the appointment.
    - What must they do to be adequately prepped?
      - They must do the at-home prep protocol,
      - Have the materials for the prep, and
      - Understand how to do the prep.

Specify the performance model

How is each node of the task model accomplished or represented in each setting? Representation of concepts such as nodes in a task model is called instantiation.
Describe how each step in the task model is accomplished at each setting.

Identify the appropriate formal systems that provide input or processes to the system.

Identify and document informal systems.

List the inputs and processes that link the sub-goals of the task model.

Construct a decision-tree to model choice processes that connect each sub-goal to the next

Decision-trees are frameworks for making explicit decisions when choices must be made, and for differentiating the frequency with which different paths between sub-goals are pursued. For example, with CDEC at Facility A: Patients are assessed for transportation support at the time of scheduling and are diverted to flexible sigmoidoscopy or barium enema, if no escort is available and the patient is considered low-risk. High-risk, unescorted patients have CDEC done as inpatients. This represents a decision point at which three different things may happen, depending on the circumstances:

1) If transportation is available, proceed with outpatient CDEC;
2) If no transportation is available and the patient is deemed low-risk, divert to outpatient flexible sigmoidoscopy or barium enema; or
3) If no transportation is available but the patient is at higher risk, schedule an inpatient CDEC.

Sometimes decision-tree models incorporate the cost or value associated with each choice as an aid in making new decision rules. For an example, go to: 
http://www.mindtools.com/dectree.html

Measure outputs at each step of the performance model

- Identify the desired output at each step.
- Identify sources of data for determining output at that step.
- Collect data.
- Include outputs in description of the performance model to assist in diagnosis.

Don’t overlook the possibility of using existing datasets and using the VA Information and Resource Center (VIReC) http://www.virec.research.va.gov/ to find out more about VA datasets. These datasets have a wealth of information that may already be sufficient to estimate performance levels at each process node, and they include*:

- Veterans’ Integrated Health Systems Technology and Architecture (VistA),
- Data approval access through Data Access Request Tracker (DART), http://www.virec.research.va.gov/DART/Overview.htm
- Decision Support System (DSS), and
- External Peer Review Program (EPRP).
*Note that VA datasets change consistently, so please consult the VIReC website for up-to-date information.

In the CDEC example, we obtained data on:

- Number of FOBTs processed (NPCD),
- Number of positive FOBTs (VistA),
- Number of referrals for CDEC (VistA),
- Number of completed CDECs (NPCD),
- Endoscopic prep adherence rate (VistA),
- Endoscopic appointment adherence rate (DSS),
- Clinic wait times (DSS),
- Clinic staffing levels (DSS),
- Mapping of providers to clinics (NPCD), and
- Number of other endoscopic procedures (NPCD).

The benefits of using existing data include:

- Financial economy;
- Availability, although getting data may require specialized knowledge of the databases and data extraction techniques; and
- Data collection will not affect clinic operations.

Another tool that uses existing data to identify potential targets for interventions and resource utilization is Systems Dynamics Modeling. Dr. Kristen Hassmiller Lich presented a VA Cyberseminar on System Dynamics Modeling on January 25, 2011 entitled, “Using System Dynamics Tools to Integrate Evidence in VA Stroke Care.”


VA’s Stroke-QUERI http://www.queri.research.va.gov/str/default.cfm utilized System Dynamics Modeling for its Center strategic planning. Briefly, originally coined by Jay Forrester at MIT (Industrial Dynamics, 1961), System Dynamics Modeling is a tool that utilizes mathematical models to inform strategic planning. The modeling describes trends and anticipates new trends and policy consequences. It is a tool that may be utilized to facilitate stakeholder discussions about resource allocations and strategic plans.

However, if there are no existing data sources that meet the needs, then primary data collection will be necessary to complete this part of the diagnosis. However, perhaps not all steps require the output measures. Think about potential sources of data broadly. Having some information through discussions with clinic staff may offer an estimate that is enough to serve your purposes for determining the extent of the problem. For example, in the tale of two CDECs, there are no data on the proportion of persons
for whom having an escort is an issue – so we don’t know how much of a problem this presents. Perhaps asking patients and tracking this for a short period of time would be sufficient for purposes of the diagnosis.; or a discussion could begin with those persons who do the scheduling, and who may already be able to estimate whether it is 5% or 30% of persons who have a problem.

**A Tale of Two CDECs**

Hypothetical data for two imaginary healthcare facilities are presented in the table below (data are taken from actual findings across multiple facilities). There are performance gaps at both facilities. At Facility A, 30% of persons with a positive FOBT receive a CDEC, and at Facility B, 34% of persons with a positive FOBT receive a CDEC. Performance models (how each facility accomplishes each step in the task model) for each facility were determined using the questions above. Effectiveness at each step is included if known.

<table>
<thead>
<tr>
<th>Performance Model, Facility A</th>
<th>Performance Model, Facility B</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Provider looks up CPRS lab result (rate unknown).</td>
<td>• Lab result emailed to all providers (100% of FOBT-positive, unknown whether all are noted by providers).</td>
</tr>
<tr>
<td>• Provider issues CPRS consult request to GI endoscopy (50% of FOBT-positive cases).</td>
<td>• Provider issues CPRS order to GI endoscopy (75% of FOBT-positive cases).</td>
</tr>
<tr>
<td>• GI clinic schedules patients (100% of orders are scheduled for either flexible sigmoidoscopy or CDEC).</td>
<td>• GI clinic schedules patients (100% of orders are scheduled for either flexible sigmoidoscopy or CDEC).</td>
</tr>
<tr>
<td>• Nurse educator instructs all patients in home prep (100% of those scheduled receive instruction).</td>
<td>• No pre-CDEC education.</td>
</tr>
<tr>
<td>• No other prep support is given (90% of patients who arrive in the clinic are properly prepped).</td>
<td>• No other prep support is given (70% of patients who arrive at the clinic are properly prepped).</td>
</tr>
<tr>
<td>• Patients are assessed for transportation support at the time of scheduling and are diverted to follow-up using flexible sigmoidoscopy or barium enema if no escort is available and the patient is considered low risk. High-risk, unescorted patients have CDEC done as inpatients.</td>
<td>• No transportation support or screening is offered.</td>
</tr>
<tr>
<td>• An appointment reminder phone call is made three days before the CDEC appointment (67% of patients arrive for their appointment).</td>
<td>• No appointment reminders are used (65% of patients show up for the appointment).</td>
</tr>
<tr>
<td>• 50% referral rate * 67% appointment adherence * 90% adequate prep = 30% successful CDEC</td>
<td>• 75% referral rate * 65% appointment adherence * 70% adequate prep = 34% successful CDEC</td>
</tr>
</tbody>
</table>
Preliminary conclusions (Kochevar and Yano 2006)

Although the performance gaps are similar, the contributions of subtasks in the performance model are different between Facility A and Facility B. Facility A needs to improve its referral system more than Facility B, while Facility B needs to improve patient completion of prep. Both facilities could improve appointment adherence. Facility A has already implemented several strategies in these areas that Facility B has not yet deployed, and Facility B has implemented a change in how providers are notified of positive results.

Before making the diagnosis: Is it really sub-standard performance?

Before making final conclusions, let’s investigate further. Pick up where the diagnosis left off, then diagnose a little more. The referral rate for Facility B was 75%. Is this adequate? Additional probing identified known causes of lower GI bleeding in half of the non-referred cases, a recent colonoscopy in another 10% of cases, and significant comorbidities that ruled out colonoscopy in another 15% of cases. So providers were appropriately excluding approximately 20% of patients with positive FOBTs from the referrals. The suspected failure rate for referrals is probably closer to 5%, and providers may be able to justify these exclusions as well. While we may need to come back to this in the future, changing referral patterns at Facility B is not recommended. The referral rate at Facility A was 50%. Only about 10% of the non-referral cases could be explained by adequate referral exclusion reasons. Therefore, referral rate improvement at Facility A should be targeted.

Identify actionable factors for intervention

In the tale of two CDECs, the overall performance gaps were found to be similar, but there were differences in the contributions of subtasks – so that the factors identified for intervention were as follows:

- Facility A needs to improve the referral system and appointment adherence.
- Facility B needs to improve completion of prep and appointment adherence.

Intervention design

An intervention target is specified in the following way – it includes both the target people/system involved (patients, clinicians, clinic system) and the subtask. Start with diagnosis of a gap in performance and other possible gaps. However, some performance gaps are not readily amenable to "repair" approaches, and may require more extensive work – sometimes full-scale system redesign. The following is a brief discussion of instances in which more extensive work is required.
Intervention design: How do I do this? (A tale of two CDECs continues.)

Intervention design is the process of choosing a specific focus for initiating change. An intervention target is specified in the following way – it includes both the target people/system involved (patients, clinicians, clinic system) and the subtask. For example, an intervention might target patients’ contributions to appointment adherence, providers’ contributions to making patients aware of the required prep for the exam, clinic systems’ contributions to setting up appointments, or providers’ contribution to ordering colonoscopy exams.

Low hanging fruit: What is the easiest course of action?

The rate at which providers in Facility A look up lab results is unknown. It could be measured, and if we find out that the rate is low, an intervention to change the providers’ behavior could be undertaken. But emailing results to providers (feedback intervention) is associated with a higher referral rate in Facility B. Targeting a system change that supports providers by lessening the effort required to do their jobs is an example of low-hanging fruit.

Sometimes you don’t cross a chasm in two steps.

In Facility B, the diagnostic analysis shows a diffuse set of gaps across the GI prep and appointment adherence part of the process. No single intervention target stands out as a major contributor to the performance gap. If both prep adherence and appointment adherence in GI at Facility B need to be changed, then this may be more readily accomplished as a single system redesign effort, rather than successive piecemeal interventions.

Staging sequential interventions -- Sometimes you DO cross a chasm in two steps (but do so carefully).

Think about what effect the proposed intervention will have on downstream nodes in the task model. You may need to target your first intervention at a point further along in the task model to prepare for increased demand that may result from the main intervention. For example, Facility A’s low referral rate and the availability of a low-cost intervention make the referral system a reasonable intervention target. But what effect will this have on nodes further along in the process model? Facility A has a 67% appointment adherence rate and a 90% prep adherence rate, and increased referrals will put more demand on the prep education and appointment reminder systems. Will the current rates hold up or decline? What kind of intervention targeted at the prep education and appointment reminder systems will maximize their ability to deal with demands generated by increased referrals?

“How-to” summary:

Diagnosis:

- Construct a generic task or process model.
- Construct a performance model that shows how the task model is accomplished in each setting.
• Evaluate the level of performance at each node in the task model in each setting.

*Intervention design:*

• Harvest low-hanging fruit and, when possible, take the course of least resistance.
• Look for opportunities to combine multiple interventions into a cohesive system re-design, BUT.....
• Make sure the observed deficits don’t have a rational explanation, and
• Make sure the fix for one problem doesn’t cause another problem downstream – fix the downstream problems first.

The case study, as illustrated, shows the process after completion, but how do you generate a diagnosis and intervention-targeting plan from scratch? Some tools discussed later in this section were implicitly used in the above example (i.e., use of existing data, means-ends analysis, and decision-trees). However, the fundamental concept running through this example is the necessity of systems-thinking. The task model represents the generic system. The performance model represents a setting-specific system. Evaluating effectiveness at each process step is a systems approach. Making the business case, finding the low-hanging fruit, and knowing how to sequence sequential interventions are all systems concepts.

**D. Tools for Implementation Strategy Design**

There are multiple tools available for implementing strategy designs. Some are identified below, although the literature in this area is evolving rapidly, and it is important to search for current literature.

- Tools/process models – Tools and process models are available to assist with implementation strategy design. (Gaglio B., 2012)
- Intervention Mapping (Bartholomew, 2006)
- Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) (Thorpe, Zwarenstein et al., 2009)
- Use of theory/frameworks to guide implementation targeting/planning
  - Implementation Intervention Mapping and Design – Intervention mapping is a planning framework that utilizes theory, evidence, and practical strategies to design implementation interventions and may target multi-level changes. The tools/process models include steps to target and design an intervention.
    - Developed originally for Health Promotion Programs (Bartholomew, 2006)
      - Includes 6 Steps:
        1. Needs Assessment
        2. Create Matrices of Expected Change Objectives and Specify Determinants
        3. Identify theory based methods and practical strategies to design intervention strategies
        4. Program plan – develop and pretest materials
5. Specify adoption and implementation plan
6. Generate an evaluation plan

- Applied across fields, including healthcare (Schmid, Andersen et al., 2010)

- Example Change Matrix (Step 2) on Secondary Stroke Prevention (Schmid, Andersen et al., 2010): http://www.implementationscience.com/content/5/1/97

<table>
<thead>
<tr>
<th>Provider Performance Objectives</th>
<th>Community Resources for Stroke Risk Management</th>
<th>Delivery System Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assesses patient stroke risk factors during hospitalization for acute stroke</td>
<td>Access to local resources available to assess stroke risk factors</td>
<td>Work flow of discharge planning includes stroke risk factor assess/education</td>
</tr>
<tr>
<td>Orders lab tests as needed</td>
<td>Access to lab tests and interpretation of results</td>
<td>System alerts lab results; prescribes based on results</td>
</tr>
<tr>
<td>Prescribes appropriate medications</td>
<td>Access and provides patient education materials on medications</td>
<td>Medication reconciliation prior to discharge</td>
</tr>
<tr>
<td>Motivates patient to modify lifestyle</td>
<td>Write orders for home equipment</td>
<td>Motivational interviewing is built into patient education</td>
</tr>
<tr>
<td>Refers patient to local programs</td>
<td>Recommends and refers patient to local support programs</td>
<td>Access to local programs is available and up to date</td>
</tr>
</tbody>
</table>

- Example Change Matrix (Step 3) Theory based methods and practical strategies (Schmid, Andersen et al., 2010) http://www.implementationscience.com/content/5/1/97

<table>
<thead>
<tr>
<th>Provider Performance Objectives</th>
<th>Theoretical Strategies of (Theory of Planned Behavior)</th>
<th>Practical Strategies (From provider interviews)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess patient stroke risk factors during hospitalization for stroke</td>
<td>Perceived Social Norms – clinical champion promotes; added into annual competency evaluation Attitudes, Beliefs, Values – training Self-efficacy – role playing to</td>
<td>Stroke risk factor assessment template is included in electronic medical record; Checklist available at neurology workstation where discharge</td>
</tr>
</tbody>
</table>
**E. Web Resources**

**Web Resources for Systems Thinking**
- [http://www.thinking.net/index.html](http://www.thinking.net/index.html)
- [http://www.systems-thinking.de](http://www.systems-thinking.de)

**Engineering/Design/Quality Management Methods**
Theory of Constraints/Throughput Analysis: Systems models that are focused on converting "inputs" to "outputs."
- [http://www.ciras.iastate.edu/library/toc/](http://www.ciras.iastate.edu/library/toc/)

**Task Theories/Task Analysis:** A variety of concrete methods for deriving task and performance models.
- [http://www.cdc.gov/niOSH/mining/content/taskanalysis.html](http://www.cdc.gov/niOSH/mining/content/taskanalysis.html)

**Risk Analysis and Systems Analysis:** Methods based on the concept of risk. Although usually applied in a safety context, "demand" is a type of risk. How might risk analyses be used to represent demand for services? How does this view differ from throughput analysis?
- [http://www.sra.org/](http://www.sra.org/)
- [http://www.hcra.harvard.edu/](http://www.hcra.harvard.edu/)

**Root Cause Analysis Methods** of attributing causation to sequential processes within systems. Root causes are best candidates for interventions.
- [http://www.systems-thinking.org/rca/rootca.htm](http://www.systems-thinking.org/rca/rootca.htm)

**Performance Theories/Behavior Analysis:** Behavior analysis and behavioral task analysis focus on motivational factors (i.e., stimuli, reinforcement, etc.) in system processes.
- [http://www.coedu.usf.edu/~behavior/tlall397.html](http://www.coedu.usf.edu/~behavior/tlall397.html)

**Knowledge Engineering/Knowledge Acquisition:** Knowledge engineering and acquisition methods seek to understand the basis of decision-making within system processes, which might include motivational and factual components.
- [http://kremer.cpsc.ucalgary.ca/courses/CG/](http://kremer.cpsc.ucalgary.ca/courses/CG/)
Means-Ends Analysis: Means-ends analysis may be used as a tool to map out system sub-goals, or as a problem solving method.

Social Cognitive Theory seeks to understand system processes as part of a social context. This is useful for mapping out goals and relationships among persons who are active participants in multiple systems; also useful for understanding conflicting goals. Pajares gives a good overview of social cognitive theory and of self-efficacy at the following link: http://www.uky.edu/~eushe2/Pajares/eff.html

Management Science/Operations Research Methods: Cost-effectiveness analysis is a diagnostic measurement approach that considers resource utilization. Effectiveness may include estimates of the "utility" or value of outcomes.

Technical Efficiency Analysis: A diagnostic measurement approach that considers resource utilization, but allows each observation point to optimize different criteria. For example, some clinics may produce shorter wait times given the number of patients they see, while other clinics might complete more procedures annually given their patients’ multiple comorbidities. This helps identify different strategies of approximating "best practice" when there are multiple system inputs and outputs, as well as scaling relative efficiency of observational units.
3. Methods Used in Implementing Research into Practice

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.

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 HealtheVet 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.
### Step 1: Select conditions per patient populations associated with high risk of disease and/or disability and/or burden of illness for Veterans

<table>
<thead>
<tr>
<th>Description</th>
<th>Typical Methods</th>
<th>QUERI Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1A</strong>: Identify and prioritize (via a formal ranking procedure)</td>
<td>• Epidemiological studies (e.g., incidence and prevalence)</td>
<td>• QUERI group conditions identified as priorities for VA based on epidemiologic evidence, incidence, and prevalence within VA healthcare system</td>
</tr>
<tr>
<td><strong>1B</strong>: Identify high-priority clinical practices and outcomes within a selected condition</td>
<td>• Measurement of disease burden (e.g., cost, health status)</td>
<td>• Identification of lipid and blood pressure management as important clinical targets for diabetic care</td>
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<tr>
<td></td>
<td>• Observational studies of behaviors/practices</td>
<td>• Measurement of recommended antiretroviral drug use for VA patients with HIV/AIDS</td>
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</table>

### Step 2: Identify evidence-based guidelines, recommendations, and best practices

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<thead>
<tr>
<th>Description</th>
<th>Typical Methods</th>
<th>QUERI Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2A</strong>: Identify evidence-based clinical practice guidelines</td>
<td>• Large-scale clinical trials</td>
<td>• Meta-analyses of antiretroviral drug trials</td>
</tr>
<tr>
<td><strong>2B</strong>: Identify evidence-based clinical recommendations</td>
<td>• Formal systematic research reviews or syntheses of best practices</td>
<td>• Development of VA diabetes evidence-based guidelines</td>
</tr>
<tr>
<td><strong>2C</strong>: Identify evidence-based clinical practices</td>
<td>• Empirical validation of best practices</td>
<td>• Guideline modifications made for eye care in diabetics</td>
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### Step 3: Measure and diagnose quality and performance gaps

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<tr>
<th>Description</th>
<th>Typical Methods</th>
<th>QUERI Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3A</strong>: Measure existing practice patterns and outcomes across VHA and identify variations from evidence-based practices (&quot;quality/performance gaps&quot;)</td>
<td>• Measurement of practice variation</td>
<td>• Baseline measurement of HIV screening prevalence</td>
</tr>
<tr>
<td></td>
<td>• Modeling determinants of clinical practices</td>
<td>• Cost analysis of staffing requirements for HIV/Hep C care delivery model</td>
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<tr>
<td></td>
<td>• Observational, cross-sectional, and longitudinal studies</td>
<td>• Cost effectiveness analysis of an HIV screening program</td>
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<tr>
<td></td>
<td>• Focus groups (e.g., providers)</td>
<td>• Modeling facilitators and barriers to improving practice for HTN treatment and control</td>
</tr>
<tr>
<td><strong>3B</strong>: Identify determinants of current practices</td>
<td></td>
<td>• Measurement of delays in laser therapy for diabetic retinopathy and reasons for delays</td>
</tr>
<tr>
<td><strong>3C</strong>: Diagnose quality/performance gaps</td>
<td></td>
<td>• Survey of variations in HIV provider</td>
</tr>
<tr>
<td><strong>3D</strong>: Identify barriers and facilitators to improvement</td>
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## QUERI Implementation Guide

### Step 4: Implement improvement programs

| 4A: Identify improvement/implementation strategies, programs, and program components or tools | Literature reviews  
Experiments or quasi experiments to evaluate QI interventions  
Development or adaptation of educational materials or decision support tools | 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 |
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<tbody>
<tr>
<td>4B: Develop or adapt improvement/implementation strategies, programs, and program components or tools</td>
<td>See descriptions below for QUERI Implementation Activity Phases.</td>
<td></td>
</tr>
</tbody>
</table>
| 4C: Implement improvement/implementation strategies/programs to address quality gaps | Single site pilots  
Small-scale multi-site evaluations  
Region-wide demonstrations  
National rollouts |

### Step 5/6: Evaluate Improvement Programs

| 5: Assess improvement program feasibility, implementation, and impacts on patient, family, and healthcare system processes and outcomes | Experiments or quasi-experiments to evaluate QI interventions  
Development of QI toolkits  
Cost analyses |
|---|---|
| 6: Assess improvement program impacts on health-related quality of life (HRQOL) | 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

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**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

**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 measurable 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
- Overview of Evaluation in Implementation Science: Jeffrey Smith
- Measuring Implementation Outcomes and Fidelity: Carol VanDeusen Lukas
- Studying Implementation Contexts: Ann Chou
- Measuring implementation Mechanisms: Dave Aron
  Scale Up & Spread and Sustainability: Wynne Norton
- Observational Studies: Ann Chou
- 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).
<table>
<thead>
<tr>
<th>Intervention Focus</th>
<th>Implementation Approaches</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Clinical Effectiveness</strong></td>
<td><strong>Hybrid Type II:</strong> Test clinical intervention, test implementation intervention</td>
</tr>
<tr>
<td>YES</td>
<td><strong>Hybrid Type III:</strong> Test implementation intervention, observe/gather information on clinical intervention and outcomes</td>
</tr>
<tr>
<td>NO</td>
<td><strong>Implementation Study</strong></td>
</tr>
</tbody>
</table>
## Study Characteristic Hybrid Type 1 Hybrid Type II Hybrid Type III

<table>
<thead>
<tr>
<th>Research Questions (examples)</th>
<th>Primary Question: Will a clinical treatment work in this setting/these patients?</th>
<th>Primary Questions: Will a clinical treatment work in this setting/these patients? Does the implementation method show promise?</th>
<th>Primary Question: Which method works better in facilitating implementation of a clinical treatment? Which core components are critical? Secondary Question: Is the clinical treatment effective in this setting/these patients?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Secondary Question:</strong> What are the potential barriers/facilitators to a treatment’s implementation?</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
4. Formative Evaluation

A. The Role of Evaluation in QUERI
B. The Need for FE in Implementation Research
C. Purposes
D. Data Collection Methodologies
E. FE Research Process
F. Challenges to Conducting FE
G. Writing About FE
H. Resources Related to Evaluation

A. The Role of Evaluation in QUERI

In general, there is a lack of agreement about the differentiation or association between research and evaluation. While some define this relationship as evaluation research, others see the two terms as separate concepts with different purposes and techniques. The argument arises from the fundamentally different paradigms that guide these seemingly disparate activities: the research paradigm is one of hypothesis testing, while evaluation is geared toward improving rather than proving.

Paradigmatic differences notwithstanding, a combination of the terms is an accurate reflection of an important type of investigation that is conducted in QUERI. Within this context, traditional research methods provide the means to obtain credible summative information, while standard evaluation modes are used to elicit a better understanding of why interventions succeed or fail. The importance of this understanding becomes more self-evident the closer the research objective is to enabling system-wide change, especially in regard to evidence-based healthcare delivery.

More specifically, within QUERI, formative evaluation (FE), at times also referred to as process evaluation, is an important segment of quality improvement research and has been characterized by Stetler (Stetler, Legro et al., 2006) as “a rigorous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts.” FE is oriented towards understanding the process rather than the outcomes of implementation, as is more typical in research-related efforts. However, FE is seldom an end in itself; on the contrary, its greatest value lies in the information it yields to understand study outcomes or summative evaluation.
B. The Need for FE in Implementation Research

FE allows you to understand the context in which implementation of a program or intervention may occur, as well as to assess program/implementation process as it is happening. This permits the capture of information on factors that shape (e.g., facilitate or impede) successful implementation in “real-time,” and also can offer insight into strategies that could be used to amplify (in the case of facilitating factors) or mitigate (in the case of impeding factors) the implementation effort.

FE findings can be used to modify an intervention and/or the process by which the intervention is implemented. They allow for the identification and assessment of local factors that may not be generalizable to all facilities, but that nonetheless exert an important influence on the success of a given implementation effort. FEs also can help: avoid “implementation assessment failure” (erroneous study results because an intervention was not implemented as planned); avoid “explanation and outcome attribution failure” (failure to establish what was accomplished/not accomplished in implementation plan and factors that influenced implementation); and enhance understanding of study outcomes, which provides further support for study replication and further dissemination.

For more information on the benefits of utilizing formative evaluation please see Stetler, Legro et al., 2006) and Smith, Williams et al., 2008).

C. Purposes

FE is unique in that it occurs during the research project, not after. Consequently, results can be used to describe and inform the process. One use of FE is to identify parts of the process that need refinement to maximize the effect of the project. While FE can be used during the research project, the data may be analyzed in relation to summative findings (outcomes) to better interpret findings. What influenced the degree of success or failure? What was required to “make the change happen?” How did the stakeholders feel about the process?

Whereas the general purpose of FE is to prepare for and assess the process of implementation, the literature is replete with other identified purposes, including:

- Assessing whether a program or intervention addresses a significant need;
- Modifying a proposed program or intervention, as needed;
- Detecting and systematically documenting unanticipated events;
- Optimizing/controlling implementation to improve potential for success;
- Obtaining ongoing input for short-term adjustments;
- Documenting continual progress;
- Informing future similar implementation efforts, e.g., to other healthcare sites or to a larger system;
• Understanding the extent/dose, consistency, usefulness, context, and quality of an intervention;
• Assisting interpretation of program outcomes or worth; and
• Fostering an understanding of the causal events leading to change and the specific components
  of the intervention that most influenced it.

D. Data Collection Methodologies Utilized in FE

a. Quantitative

Quantitative assessments can be used to collect data regarding a broader group of participants or
stakeholders (e.g., frontline providers or other staff). In many cases, the participants or stakeholders
targeted are the individuals who will be using the intervention in their daily practice.

Quantitative assessments may include, but are not limited to:

- Structured surveys and tools that assess organizational culture, readiness to change (i.e.,
  Organizational Readiness to Change Assessment–ORCA) (Helfrich, Li et al., 2009), and provider
  receptivity to evidence-based practices (EBPs). (See Tools and Toolkits section)
- Intervention fidelity measures offer information on the extent to which elements of the
  intervention are implemented in the precise way in which they are meant to be implemented.
  For example, an intervention may include a patient assessment and recording that patient
  assessment in the medical record. The completeness of the patient assessment and the way in
  which the assessment is recorded in the patient medical record offer potential areas where a
  fidelity measure might be helpful.

b. Qualitative

Qualitative assessments can offer a “deeper-dive” with a smaller group of individuals to provide specific
information about barriers and facilitators, as well as strategies and best practices for utilizing
facilitators and overcoming barriers.

The best way to capture this data depends on the perspective(s) you are interested in exploring.
Qualitative assessments may include, but are not limited to:

- Semi-structured or open-ended interviews may be used in cases where there is a smaller group
  of clinical stakeholders whose individual perspectives are needed.
- Focus groups may be used in cases where you are interested in exploring group perspectives
  and team dynamics.
Direct observation of clinical structure and process during site visits may provide additional insight into processes/structures that may facilitate or hinder implementation.

Of course, in many cases using a solely qualitative or quantitative assessment will not be sufficient to meet the needs of a FE. For this reason, many implementation projects also take advantage of mixed-method approaches to FE, in which multiple data collection strategies from both the quantitative and qualitative paradigms are utilized. Drawing on both quantitative and qualitative approaches supports the gathering of diverse data that can yield robust FE findings to inform a given implementation effort.

For more information on mixed methods, please refer to Creswell J., 2007) and Greene, 2007).

c. Implementation as the dependent variable

In the realm of FE, the extent to which a practice/intervention has been assimilated into an organization is what is being measured. The extent of assimilation can be framed in three broad categories:

- Widespread avoidance/non-use,
- Meager or unenthusiastic use (compliant use), and
- Skilled, enthusiastic use (committed use) of the practice/intervention.

E. FE Research Process

FE, like most any research or evaluation endeavor, is characterized by a series of choices that must be made regarding what to study and how to most effectively study it. More than likely, resources (e.g., person power, finances, time) will limit the ability to assess and understand all of the factors that could be potentially relevant to a particular implementation effort. For this reason, the ability to make thoughtful choices about what the focus of a particular FE should be is critical.

An important first step involves identifying the aims of the FE. The aims identified will depend, in large part, on the overarching goals of the broader intervention effort, including what is already known about the intervention based on the published literature and existing evidence base. Any theoretical or conceptual framework that is informing the study also is critical to consider at this stage, as it will likely represent or account for factors that could influence implementation and by extension are potential targets for the FE.

Subsequently, researchers must:

- Identify the primary questions that derive from the FE aims,
- Develop instruments and methods to collect data,
- Conduct systematic data collection, and
- Analyze and report the data collected.
As noted above, both qualitative and quantitative methods are commonly used in FE. Qualitative approaches to data collection and analysis may uncover things that are working and not working well, and the extent to which program elements are being implemented as intended. Quantitative approaches to data collection and analysis may be used to gauge the extent to which specific changes are being realized. For example, in a project that involves having providers use computerized clinical reminders, the extent to which those reminders are accessed could be tracked to determine whether change occurs following targeted educational activities.

Ultimately, what is most important is identifying and effectively applying approaches to FE data collection and analysis that are appropriate to the FE and the broader intervention effort.

F. Challenges to Conducting FE

As a unique aspect of implementation research, FE also presents its own unique set of challenges. We categorize these challenges as follows: 1) data collection considerations; 2) participant considerations; 3) regulatory considerations. Each of these challenges are addressed briefly.

Challenges associated with data collection pertain primarily to selecting and effectively applying the appropriate approaches to data collection and analysis. A related issue pertains to issues of entrée (e.g., how can rapport be established with participants? How can support of leadership be gained?) within the settings where data for the FE will be collected.

Challenges associated with participant considerations generally pertain to the engagement of special or potentially vulnerable populations in research. For example, in many cases, unions and/or other employee organizations may have to be consulted before hospital staff can be approached and asked to participate in a research or evaluation effort.

Finally, challenges associated with regulatory considerations pertain to describing FE to organizational entities like research and development committees, institutional review boards, and other bodies that may not be familiar with its purposes and associated activities.

Researchers are encouraged to consult the resources referenced at the end of this section for more information on strategies that may be effective in addressing the challenges presented here.

G. Writing about FE

When writing about FE, researchers must remember the potentially different needs and perspectives of their audiences.
In the context of proposal development and grant writing, researchers need to thoroughly describe the elements of their FE, justify their appropriateness, and cogently articulate their plans for carrying out the FE. A compelling proposal will describe FE in terms of:

- Data collection techniques to be used and the ways that the data collection techniques relate (e.g., hopefully highlighting synergies);
- Settings and participants (i.e., subjects) from which data will be collected including sampling and recruitment plans;
- Envisioned processes and procedures for collecting data; and
- Plans for processing, organizing, and ultimately, analyzing the data that is collected.

The level of detail included to address these topics should be sufficient so that potential funding agencies and reviewers can gauge the appropriateness of the proposed FE, its feasibility, and the capability of the researcher or research team to conduct the proposed FE.

In the context of research oversight and institutional review board protocol writing, researchers need to similarly address the enumerated points above, providing sufficient detail to support the assessment of participant (i.e., subject) understanding of the research, the associated burdens for participants, potential risks to participants, and the management and security of the data that is collected.

Researchers interested in the intersection of FE and writing should turn to texts on writing successful grants and proposals, and to their local institutional review boards for exemplary protocols.

H. Web-based resources related to evaluation

US Government Resources


The National Science Foundation’s Directorate for Education and Human Resources, Division of Research, Evaluation and Communication has a web-published User-Friendly Handbook for Mixed Method Evaluations (http://www.nsf.gov/pubs/1997/nsf97153/start.htm). While the examples and content are related to education and learning evaluations, the handbook has information related to evaluation that can be applied to other settings. Other features include an example evaluation plan, tips for analyzing qualitative data, and example materials – such as example observation guides, interview guides, and so forth.

The Bureau of Justice Assistance is committed to the importance of program evaluation and to developing and enhancing evaluation capabilities at the state and local levels. Evaluation results provide policy makers and program managers with information for future program development and can be
used to modify and improve existing programs. The Evaluation Website: [https://www.bja.gov/evaluation/](https://www.bja.gov/evaluation/) is designed to provide State Administrative Agency staff, criminal justice planners, researchers and evaluators, as well as local practitioners with a variety of resources for evaluating criminal justice programs, and it has a page with links to a variety of evaluation resources.

**Other Resources**

The [American Evaluation Association](http://www.eval.org) is an international professional association of evaluators devoted to the application and exploration of program evaluation, personnel evaluation, technology, and many other forms of evaluation. The site includes Guiding Principles for Evaluators, meetings and events related to evaluation, and links to resources for evaluators, including a listing of online texts and books with "how-tos" related to evaluation. ([http://www.eval.org/publications/guidingprinciples.asp](http://www.eval.org/publications/guidingprinciples.asp)).

[RE-AIM](http://www.re-aim.org) is a systematic way for researchers, practitioners, and policy decision-makers to evaluate health behavior interventions. It can be used to estimate the potential impact of interventions on public health. The group is affiliated with Kansas State University, and the Robert Wood Johnson Foundation has provided funding for the workgroup and for developing the website. RE-AIM stands for: Reach into the target population; Efficacy or effectiveness; Adoption by target settings or institutions; Implementation—consistency of delivery of intervention; and Maintenance of intervention effects in individuals and populations over time.

[Resources for Methods in Evaluation and Social Research](http://gsociology.icaap.org/methods/) is a website supported by ICAAP (The International Consortium for the Advancement of Academic Publication) and lists free resources for methods in evaluation and social research. The focus is on "how-to" do evaluation research and the methods used: surveys, focus groups, sampling, interviews, and other methods. Most of these links are to resources that can be read online. A few, like the GAO books, are available for free (via U.S. mail), as well as being available for online reading.

The [Action Evaluation Research Institute](http://ww35.aepro.org/) is a site with information on action research and evaluation.

[FE Research Associates (FERA)](http://www.feraonline.com) is an evaluation group that has 25 years of experience with non-profit organizations. The site includes general information on FE, as well as links to other resources.
5. Tools and Toolkits

A. VA HSR&D Cyber Seminars on Tools and Toolkits

B. Links to Implementation Toolkits, Conferences, Consortiums, and Trainings

This section of the Guide is devoted to tools and toolkits that focus on the implementation of evidence-based practices to improve the quality of care for Veterans.

As QUERI groups have conducted projects focusing on translating evidence-based practices into routine care, many groups developed their own tools to assist in the implementation of these projects.

Additionally, other tools, toolkits, and resources are available from a number of organizations outside VA. In this section of the Guide, brief descriptions of the tools and resources are presented, with links to these items themselves, which may be useful for future implementation projects – either as tools to be adopted or to serve as models for new product development. The Guide also provides the names of contact persons.

A. VA HSR&D/QUERI Cyber Seminars on Tools and Toolkits

Suicide Prevention Interventions and Suicide Risk Factors and Risk Assessment Tools


Date: 6/11/2012

Series: ESP (Spotlight on Evidence-based Synthesis Program)

Presenters: Bradley, John; Haney, Elizabeth; O’Neil, Maya; and Valenstein, Marcia

Description: This cyberseminar presented two systematic reviews on suicide risk and prevention. The body of research on suicide prevention approaches has been reviewed previously by Gaynes et al., and Mann et al., which were updated in these reports. Suicide Risk Factors and Risk Assessment Tools: Risk factors for suicide in Veteran and military populations identified in more than one study include: white race, bipolar disorder, and substance abuse, and for suicide attempts include: PTSD, depression, psychiatric conditions, prior suicide attempt, alcohol misuse, and history of sexual abuse. Few studies evaluated emerging risk factors, such as traumatic brain injury, among current military personnel and Veterans. There is limited research on the predictive power of suicide risk assessment tools, particularly in populations of Veterans and members of the military. Civilian research has highlighted tools such as the Beck Hopelessness Scale, among others, as showing the most promise for prediction of self-directed violence. Future research should emphasize assessment tools that are brief, conducive to primary care settings, and commonly used in VA and military settings. Suicide Prevention Interventions and Referral/Follow-up Services: Research on pharmacological and psychotherapeutic interventions, as well as referral and follow-up services, was reviewed and summarized. Overall, there is limited evidence
supporting the effectiveness of pharmacological interventions and referral and follow-up services in preventing suicidal self-directed violence. The best available evidence supports the use of problem-solving therapy with patients who have a history of hospitalization for repeated self-harm and dialectical behavior therapy with patients who have a diagnosis of borderline personality disorder.

Aligning Patient Needs with Self-Management Programs


Date: 5/16/2012
Series: PACT (Patient Aligned Care Teams (PACT) Demonstration Labs)
Presenters: Holtz, Bree and Long, Judith

Description: In this cyberSeminar, investigators from two PACT Demonstration Labs presented examples of supporting behavior change in Veterans. Dr. Holtz discussed the Navigator System, a tool for linking patient preferences, goals, and needs to enhanced care and self-management programs. Dr. Long then described a model of supporting behavior change in Veterans using peer mentors to improve diabetes control.

Delirium: Screening, Prevention, and Diagnosis

http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/esp-101311.cfm

Date: 10/13/2011
Series: ESP (Spotlight on Evidence-based Synthesis Program)
Presenters: Wilt, Timothy and Greer, Nancy

Description: Delirium is a common syndrome in hospitalized adults and is associated with adverse outcomes including increased mortality, morbidity, and length of stay. Strategies to detect delirium earlier and to prevent the development of delirium in patients at risk have been advocated. Investigators presented a review of the evidence regarding screening for delirium, strategies to prevent delirium, and the comparative diagnostic accuracy of tools used to detect delirium.

Introducing the VA Quality Improvement Toolkit: Colorectal Cancer Care

http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/qip-042711.cfm
Description: What is the Quality Improvement Toolkit: Colorectal Cancer Care? The Toolkit is the second in a new series of web-based resource guides being developed for quality improvement professionals trying to improve care for a number of high-priority conditions. The Toolkit is available on the VA Intranet: 
https://vaww.visn11.portal.va.gov/sites/Indianapolis/verc/occ/Pages/toolkit_homepage.aspx

The CRC Toolkit offers technical, organizational, and clinical innovations (tools) that may help your facility improve performance on national VA quality metrics. Every tool included has been carefully matched to relevant OQP quality indicators or monitors. This makes it easy for you to identify the particular Tools that may help improve performance on specific metrics.

Intended audience: Clinicians and other staff involved in the diagnosis and treatment of CRC (e.g., leadership and staff from oncology, pathology, radiation oncology, palliative care, primary care); VISN and medical center staff involved in quality management and systems redesign; VISN and medical center leadership; and EPRP coordinators.

Quality Improvement Toolkit: Lung Cancer Care

Description: What is the Quality Improvement Toolkit: Lung Cancer Care? The Toolkit is the first of a series of web-based resource guides being developed for quality improvement professionals trying to improve care for a number of high-priority conditions.

Each toolkit will offer technical, organizational, and clinical innovations (tools) that may help your facility improve your performance on national VA quality metrics. Every tool included has been carefully matched to one or more relevant OQP quality indicators or monitors. This makes it easy to identify the particular tools that may help improve performance on specific metrics.
QUERI Implementation Guide

Intended audience: Clinicians and other staff involved in diagnosis and treatment of lung cancer (e.g., leadership and staff from oncology, thoracic surgery, pathology, radiation oncology, pulmonology, palliative care, primary care); VISN- and medical center staff involved in quality management and systems redesign; VISN and medical center leadership; and EPRP coordinators.


AHRQ’s Health Literacy Universal Precautions Toolkit: A Sine Qua Non for a Patient-Centered Medical Home


Date: 11/9/2010

Series: QIR (QUERI Implementation Research)

Presenters: Brach, Cindy and Noonan, Laura

Description: Cindy Brach, the lead for health literacy at the Agency for Healthcare Research and Quality, described a new toolkit designed for primary care practices to promote better understanding by all patients. The cyberseminar addressed the need for health literacy universal precautions (i.e., minimizing risk for everyone when it is unclear which patients may be affected), and reviewed several of the 20 tools that address spoken and written communication, self-management and patient empowerment, and supportive systems. Laura Noonan, a pediatrician from North Carolina, shared her experiences in piloting the toolkit and using it in a health literacy collaborative. Input into the development of health literacy quality improvement and performance measures will be sought from cyberseminar participants.

B. Links to Implementation Toolkits, Conferences, Consortiums, and Trainings

Resource: AHRQ Innovations Exchange

Description: The Innovations Exchange helps solve problems, improve healthcare quality, and reduce disparities by helping researchers to find evidence-based innovations and QualityTools, view new innovations and tools published biweekly, and learn from experts through events and articles.

Innovations & QualityTools
- Disease or Clinical Category
- Patient Care Process
- Setting of Care
- Patient Population
- Stage of Care
- IOM Domains of Quality
Resource: Heart Failure Toolkit for Providers

Description: The Heart Failure (HF) Toolkit for Providers [http://www.queri.research.va.gov/chn/products/hf_toolkit/default.cfm](http://www.queri.research.va.gov/chn/products/hf_toolkit/default.cfm) has been developed by VA’s Chronic Heart Failure (CHF) QUERI [http://www.queri.research.va.gov/chn/default.cfm](http://www.queri.research.va.gov/chn/default.cfm). It offers a comprehensive set of resources to assist providers in managing heart failure, and focuses on several key areas in the management of HF with downloadable documents. The tools are organized by their source: Veterans Affairs (VA), non-VA, or other.

HF Tools are available in the following categories:
- Practice guidelines
- Clinical pathways
- Clinical algorithms
- Screening forms and chart reminders
- Admission order sets
- Discharge process, orders, and instructions
- Best practices
- Related provider education tools
- Related patient education materials
- Related caregiver materials
- Related communication tips for patients
- Related quality of life measures
- Mortality risk models


Contact: Anju Sahay PhD at [Anju.Sahay@va.gov](mailto:Anju.Sahay@va.gov)
Description: The PACT Toolkit is part of the VA Quality Improvement Toolkit Series. The goal is to produce and disseminate quality improvement resources nationally. This is an interactive site designed to help implement the Patient Aligned Care Team (PACT) initiative at VA facilities to improve their performance measures and quality improvement efforts.

This toolkit is a centralized library offering access to a range of innovations, or "tools," in care delivery and organization that have been developed by VA colleagues nationwide. To help identify the innovations to be adopted, each one has been matched to one or more of the three main PACT Pillars:

Access
- Offer same day appointments
- Increase shared medical appointments
- Increase non-appointment care

Care Coordination & Management
- Focus on high-risk patients (identify, manage, and coordinate)
- Improve care (prevention and chronic disease)
- Improve transitions between PACT and inpatient, specialty, and broader teams

Practice Redesign
- Redesign teams (roles and tasks)
- Enhance communication and teamwork
- Improve processes (visit work and non-visit work)

Link: VA’s Intranet (SharePoint) site may be accessed only from a VA network computer: https://vaww.visn11.portal.va.gov/sites/VERC/va-case/info/PACTToolkit/SitePages/Home.aspx
Contact: Laura York at Laura.York@va.gov

Resource: Stroke Toolkit

Description: This toolkit has been created by the VA’s Stroke-QUERI http://www.queri.research.va.gov/str/default.cfm to provide resources and materials to help improve stroke care. This toolkit provides examples of specific tools for stroke quality indicators through the continuum of stroke care or by a specific type of resource or tool.
Stroke Quality Indicators

Emergency Room/Early Admission

- Dysphagia Screening before Oral Intake
  http://www.queri.research.va.gov/tools/stroke-quality/dysphagia.cfm
- Early Ambulation
  http://www.queri.research.va.gov/tools/stroke-quality/early-ambulation.cfm
- Fall Assessment by End of Hospital Day 2
  http://www.queri.research.va.gov/tools/stroke-quality/fall.cfm
- NIH Stroke Scale
  http://www.queri.research.va.gov/tools/stroke-quality/nih-stroke-scale.cfm
- Pressure Ulcer: Braden Scale within 24 hours of Admission
  http://www.queri.research.va.gov/tools/stroke-quality/pressure-ulcer.cfm
- Thrombolytic Therapy Administered
  http://www.queri.research.va.gov/tools/stroke-quality/thrombolytic.cfm

Hospitalization

- Antithrombotic Therapy by end of Hospital Day 2
  http://www.queri.research.va.gov/tools/stroke-quality/antithrombotic-day2.cfm
- Deep Vein Thrombosis (DVT) Prophylaxis by End of Hospital Day 2
  http://www.queri.research.va.gov/tools/stroke-quality/dvt.cfm
- Initial Functional Assessment (FIM) Completed
  http://www.queri.research.va.gov/tools/stroke-quality/fim.cfm

Discharge

- Anticoagulation for Atrial Fibrillation
  http://www.queri.research.va.gov/tools/stroke-quality/anticoagulation.cfm
- Antithrombotic Therapy at Discharge
  http://www.queri.research.va.gov/tools/stroke-quality/antithrombotic-discharge.cfm
- Discharge on Cholesterol Reducing Medication
  http://www.queri.research.va.gov/tools/stroke-quality/cholesterol.cfm
- Smoking Cessation/Advice/Counseling
  http://www.queri.research.va.gov/tools/stroke-quality/smoking.cfm
- Stroke Education
  http://www.queri.research.va.gov/tools/stroke-quality/stroke.cfm

Resources and Tools

- Data Collection and Reporting Tools
- Guidelines
  http://www.queri.research.va.gov/tools/stroke-quality/guidelines.cfm
- JC Stroke Performance Measurement Guide
QUERI Implementation Guide


- NIH Stroke Scale
  http://www.queri.research.va.gov/tools/stroke-quality/nih-stroke-scale.cfm
- Order Sets
  http://www.queri.research.va.gov/tools/stroke-quality/order-sets.cfm
- Pathways
  http://www.queri.research.va.gov/tools/stroke-quality/pathways.cfm
- Patient Education
  http://www.queri.research.va.gov/tools/stroke-quality/patient-edu.cfm
- Policies
  http://www.queri.research.va.gov/tools/stroke-quality/policies.cfm
- Process Flow Diagrams
  http://www.queri.research.va.gov/tools/stroke-quality/process-flow.cfm
- Professional Education
  http://www.queri.research.va.gov/tools/stroke-quality/pro-edu.cfm
- Stroke ICD-9 Codes
- VA Inpatient Stroke Processes of Care Data Collection Tool

Link: http://www.queri.research.va.gov/tools/stroke-quality

Contact: Laurie Plue at Laura.Plue@va.gov

Other U.S. Government Resources

- **Agency for Healthcare Research and Quality (AHRQ)**([http://www.ahrq.gov/](http://www.ahrq.gov/)) website provides practical healthcare information, research findings, and data to help consumers, health providers, health insurers, researchers, and policymakers make informed decisions about healthcare issues.

- **Cancer Control Planet**([http://cancercontrolplanet.cancer.gov/](http://cancercontrolplanet.cancer.gov/)) is a jointly sponsored site (by CDC, NCI, ACS, SAMHSA) that offers informative cancer information and has links to resources for collaboration and disease control programs.

- **Centers for Disease Control and Prevention (CDC)**([http://www.cdc.gov/](http://www.cdc.gov/)) is the leading federal agency for the protection of people’s health and safety, providing information to enhance health decisions, and promoting health through strong partnerships. CDC serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion, and its education activities are designed to improve health.
  - Replicating Effective Programs (REP) and Diffusion of Effective Behavioral Interventions (DEBI) [http://www.cdc.gov/hiv/topics/research/prs/prs_rep_debi.htm](http://www.cdc.gov/hiv/topics/research/prs/prs_rep_debi.htm)
HHS Centers for Medicare & Medicaid Services (CMS) (http://www.cms.hhs.gov/), formerly HCFA, administers the Medicare and Medicaid programs.

Department of Health and Human Services (HHS) (http://www.hhs.gov/) is the U.S. government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. Most of the other government agencies listed here are under HHS.

National Guideline Clearinghouse ™ (NGC) (http://www.guideline.gov/), sponsored by AHRQ, is a database of clinical practice guidelines and related materials. The NGC mission is to provide physicians, nurses, and other health professionals, healthcare providers, health plans, integrated delivery systems, purchasers, and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation, and use.

The National Institutes of Health (NIH) (http://www.nih.gov/) is the major national funding source for health-related studies. The goal of NIH is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability.

National Heart, Lung, and Blood Institute (NHLBI) (http://www.nhlbi.nih.gov/) provides leadership for a national program in diseases of the heart, blood vessels, lung, blood, and sleep disorders. NHLBI plans, conducts, fosters, and supports an integrated and coordinated program of basic research, clinical investigations and trials, observational studies, and demonstration and education projects. For health professionals and the public, the NHLBI conducts educational activities, including the development and dissemination of materials in the above areas, with an emphasis on prevention.

Substance Abuse and Mental Health Services Administration (SAMHSA) (http://www.samhsa.gov/) is the Federal agency charged with improving the quality and availability of prevention, treatment, and rehabilitative services in order to reduce illness, death, disability, and cost to society that results from substance abuse and mental illnesses.

Non-Governmental Resources

AcademyHealth (http://www.academyhealth.org/) is a professional organization for health services researchers, policy analysts, and practitioners, and is a resource for health research and policy. The organization promotes interaction across the health research and policy arenas by bringing together a broad spectrum of players to share their perspectives, learn from each other, and strengthen their working relationships.

American Health Quality Association (AHQA) (http://www.ahqa.org/pub/inside/158_716_2487.CFM) represents Quality Improvement Organizations and professionals working to improve healthcare quality and patient safety. AHQA focuses on improving healthcare quality through community-based, independent quality evaluation and improvement programs.

American Society for Quality (ASQ) Healthcare Division (http://asq.org/health/) encourages research, innovation, and the formation of learning
partnerships to advance the knowledge of healthcare quality. ASQ disseminates information relating to applications, research, and innovations in quality theory and practice in healthcare.

- **Center for the Evaluative Clinical Sciences** (CECS) ([http://www.tdi.dartmouth.edu/](http://www.tdi.dartmouth.edu/)), at Dartmouth, is a group of scientists and clinician-scholars who conduct research on critical medical and health issues with the goal of measuring, organizing, and improving healthcare systems.
  - CECS’s Clinical Improvement of Health Care ([http://www.dartmouth.edu/~cecs/clinical_improvement.html](http://www.dartmouth.edu/~cecs/clinical_improvement.html)) section works to translate research into tangible action throughout the healthcare system. One of their clinical initiatives is Clinical Microsystems ([http://www.clinicalmicrosystem.org/](http://www.clinicalmicrosystem.org/)), which focuses on understanding those systems that provide care to a population.

- **Centre for Health Evidence** (Canada) ([http://www.cche.net/che/home.asp](http://www.cche.net/che/home.asp)) is a non-profit organization funded by grants and service contracts that engages in projects and partnerships that promote evidence-based practice. Their emphasis is the use of Internet technologies. Within the CHE site, the [Users’ Guides to Evidence-Based Practice](http://www.dartmouth.edu/~cecs/clinical_improvement.html) section offers a series of articles on clinicians’ use of the medical literature to find evidence for practice.

- The **Health Services Research Projects in Progress** (HSRProj) ([http://wwwcf.nlm.nih.gov/hsr_project/home_proj.cfm](http://wwwcf.nlm.nih.gov/hsr_project/home_proj.cfm)) database contains descriptions of ongoing health services research projects funded by government and state agencies, foundations, and private organizations. Use HSRProj to access information about ongoing health services research projects before results are available in published form.

- The mission of **Improving Chronic Illness Care** (ICIC) ([http://www.improvingchroniccare.org/](http://www.improvingchroniccare.org/)) is to help the chronically ill through quality improvement and research. The site describes the Chronic Care Model and provides some tools and examples of how it has been used in quality improvement efforts. Dr. Ed Wagner is its National Program Director.

- The **Institute for Health Care Improvement** (IHI) ([http://www.ihi.org/](http://www.ihi.org/)) is a not-for-profit organization focused on the improvement of health by advancing the quality and value of healthcare. IHI offers resources and services to help healthcare organizations make improvements that enhance clinical outcomes and reduce costs. The site includes a variety of tools, resources, and links to other resources. Within the IHI site, you may want to look at Pursuing Perfection ([http://www.ihi.org/offerings/Initiatives/PastStrategicInitiatives/PursuingPerfection/Pages/default.aspx](http://www.ihi.org/offerings/Initiatives/PastStrategicInitiatives/PursuingPerfection/Pages/default.aspx)).

- The mission of the **Institute of Medicine** (IOM) ([http://www.iom.edu/](http://www.iom.edu/)) is to advance and disseminate scientific knowledge to improve human health. The Institute publishes information and advice concerning health and science policy to government, the corporate sector, the professions, and the public.
The Joint Commission (http://www.jointcommission.org/) works to continuously improve the safety and quality of care provided to the public through the provision of healthcare accreditation and related services that support performance improvement in healthcare organizations.

The National Committee for Quality Assurance (NCQA) (http://www.ncqa.org/) is a non-profit organization whose mission is to improve healthcare quality everywhere. This site is a source for information about the quality of our nation’s managed care plans. NCQA is perhaps best known for its work in assessing and reporting on the quality of the nation’s managed care plans through its accreditation and performance measurement programs.

The National Patient Safety Foundation (NPSF) (http://www.npsf.org/) is a resource for individuals and organizations committed to improving the safety of patients.

The Stanford Patient Education Research Center (http://patienteducation.stanford.edu/index.html) has developed the Chronic Disease Self-Management Program, which is a series of workshops for people with chronic health problems to help them deal with and manage their chronic conditions. Workshops are meant to be participative, and participants’ mutual support and success build confidence in managing their health and maintaining active and fulfilling lives.
6. Resources for Implementing Research into Practice

Selected Organizational Units of the Department of Veterans Affairs Relevant to Implementation Research

The Department of Veterans Affairs (VA) and the Veterans Health Administration (VHA) are large, complex organizations. Understanding some of the key offices and important functions of the agency may help implementation researchers determine whom they should consult about projects they are considering, and where to go for information about this system of healthcare. Below is a listing of VA organizational units with links to more information about each unit, as well as examples of QUERI Centers and projects that have collaborated with these units.

VA Program Offices (Intranet Only) (http://vaww1.va.gov/health/programs.asp)

Office of the Under Secretary for Health (10) (http://vaww.ush.va.gov/)
VHA is a major component of the Department of Veterans Affairs. The top official in VHA is the Under Secretary for Health, who is appointed by the President of the United States and confirmed by the Senate, reporting to the Secretary of the Department of Veterans Affairs. The Office of the Under Secretary for Health is organized into several departments; you may view the organizational chart by clicking the link below. Biographies of current senior leaders within VHA, who serve under the Under Secretary for Health, can be viewed by following the links for each person in the organization.

Org chart (VA Intranet Only) (http://vaww.ush.va.gov/docs/VHAOrgChart071612.PDF)

Office of the Deputy Under Secretary for Health for Policy and Services (10P)
The Office of the Deputy Under Secretary for Health for Policy and Services includes several other Offices with interests in collaborating on implementation research.

- Office of Research and Development (ORD)
  - The Office of Research and Development (ORD) (http://www.research.va.gov/) includes Health Services Research and Development (HSR&D) (http://www.hsrd.research.va.gov/).
  - The Quality Enhancement Research Initiative (QUERI), a program within HSR&D, consists of nine disease-specific Centers: chronic heart failure (CHF), diabetes, HIV/hepatitis, ischemic heart disease (IHD), mental health, polytrauma and blast-related injuries (PT/BRI), spinal cord injury (SCI), stroke, and substance use disorders (SUD) – as well as the eHealth QUERI which works with VA program offices to implement into practice and evaluate ehealth as a model of care. Each QUERI Center is organized with a Research Coordinator, a Clinical Coordinator, an Implementation Research Coordinator (IRC), an Administrative Coordinator, and an Executive Committee. Links to each group’s web page can be found on the national QUERI (http://www.queri.research.va.gov/) page.
HSR&D and QUERI also include several Resource Centers that may assist with implementation research efforts:


- **Veterans Information Resource Center** ([http://www.virec.research.va.gov/](http://www.virec.research.va.gov/)): VIReC develops resources and provides guidance to VA researchers using VA data. The Center’s mission is to improve the quality of VA research that utilizes databases and information systems.

- **Health Economics Resource Center** ([http://www.herc.research.va.gov/home/default.asp](http://www.herc.research.va.gov/home/default.asp)): HERC is a national Center located in Menlo Park, CA that assists VA researchers in assessing the cost-effectiveness of medical care, evaluating the efficiency of VA programs and providers, and conducting high-quality health economics research.

**Assistant Deputy Under Secretary for Health for Policy and Planning** ([http://vaww.va.gov/vhaopp/](http://vaww.va.gov/vhaopp/))

As the second largest Federal agency with employees working at locations throughout the United States, its territories, and the Philippines, it is imperative to have one source of information that is easily accessible, up to date, and describes VA and its many component organizations. To meet this need, VA’s Office of Policy and Planning formed a working group, including employees from across VA. The newly developed Functional Organization Manual (FOM) ([http://vaww.va.gov/opa/publications/VA-Functional-Organization-Manual-Version-1-0-MASTER-01JUN2013.pdf](http://vaww.va.gov/opa/publications/VA-Functional-Organization-Manual-Version-1-0-MASTER-01JUN2013.pdf)) is the product of the working group and will serve as the single authoritative reference that documents VA’s most current organizational structure, missions, functions, and tasks. It describes what gets done, by whom, for whom, and under what authorities, and it serves as a quick but thorough VA reference guide.

**Patient Care Services** ([http://vaww.patientcare.va.gov/](http://vaww.patientcare.va.gov/))

Patient Care Services (PCS) is organized into a number of Program Offices which have interests and active partnerships with QUERI Centers and implementation research projects. All of the PCS Program Offices are listed here: [http://vaww.patientcare.va.gov/Programs.asp](http://vaww.patientcare.va.gov/Programs.asp). Below is a listing of PCS Program Offices and sub-programs with links to several examples of QUERI implementation project collaborations with the sub-programs.

- **Primary Care Program Office** ([http://www.va.gov/primarycare/pcmh/](http://www.va.gov/primarycare/pcmh/))
  - Members of the Diabetes- and IHD-QUERIs are collaborating with the VA Primary Care Program Office in the implementation of the Patient-Aligned Care Teams (PACT) initiative — a team-based, medical home model in VA
primary care. Members of Diabetes-QUERI work with the VISN 11 PACT Demonstration Laboratory to adapt mobile technologies to support patient self-management, and to identify how they can be implemented within the PACT model. Members of IHD-QUERI are helping identify the most prevalent barriers and facilitators of PACT implementation, and assess the effect of PACT on employee satisfaction and burnout. This work provides insights into the challenges and opportunities for implementing new evidence-based practices created by this new model of care.

- **Cyberseminars on PACT**
  - Patient Aligned Care Teams (PACT) Demonstration Labs: PACT Implementation: Findings from primary care surveys
    
  - Patient Aligned Care Teams (PACT) Demonstration Labs: Provider and Staff Experience with PACT: Results and recommendations from national and regional primary care surveys
    

- **Preventive Health Services, National Center for Health Promotion and Disease Prevention**
  - Diabetes QUERI: RRP 10-177 Evaluation of CCHT-Weight Management Program Implementation
    
  - Diabetes QUERI: RRP 12-440 VA Diabetes Prevention: Epidemiology of Pre-Diabetes and Implementation Pilot
    
  - SDP 12-549 & Clinical Funding XVA 41-048 for the Diabetes Prevention Program Demonstration

- **Office of Specialty Care Services/Office of Specialty Care Transformation (SCS/OSCT)**
  - IHD-QUERI and Diabetes-QUERI: Specialty Care Evaluation Center
    

- **Office of Telehealth Services**
  - Diabetes-QUERI: RRP 10-177 Evaluation of CCHT-Weight Management Program Implementation
    
Office of Mental Health Services (http://vaww.mentalhealth.va.gov/)
- MIRECCs, Evaluation Centers, National Suicide Prevention Program, National Center for PTSD, Center for Integrated Healthcare

Office of Geriatrics and Extended Care Services (http://vaww.patientcare.va.gov/PCS/Geriatrics.asp)
- Community-Based Long Term Care, VA Community Living Centers, Geriatric Care, Home-Based Primary Care, Hospice & Palliative Care

Office of Informatics and Analytics (http://vaww.vhaco.va.gov/oia/)
  - Analytics and Business Intelligence (http://vaww.vhaco.va.gov/oia/abi-org.html)
    The function of the OABI includes: comprehensive analytic and business intelligence support; reporting functions to support clinical, functional, financial and administrative business decisions; analytic training for delivery system; and developing Web applications to support access and usability of data.
    - Clinical Assessment and Reporting Tool (CART)
      - IHD-QUERI: RRP 11-014 Veteran Exposure to Radiation in the Cardiac Catheterization Laboratory (http://www.hsr.gov/research/abstracts.cfm?Project_ID=2141701106)

Office of Public Health (http://vaww.publichealth.va.gov/)
- Clinical Public Health Group (http://vaww.publichealth.va.gov/about/pubhealth/index.asp)

Office of the Deputy Under Secretary for Health for Operations and Management (10N) (http://vaww.dushom.va.gov/index.asp)
The Office of the Deputy Under Secretary for Health for Operations and Management oversees field operations, providing broad and general operational direction and guidance to each Veterans Integrated Service Network (VISN).

The Office of Healthcare Transformation (OHT) is spearheading a transformation of healthcare for Veterans that will align it with a vision for the future. OHT was created to apply seven of the VHA initiatives to transform healthcare in alignment with a vision of transforming Veterans healthcare into the future.

• **Rural Health Operations**

• **Mental Health Operations** ([http://vaww.mentalhealth.va.gov/](http://vaww.mentalhealth.va.gov/))

• **Patient Centered Care** ([http://vaww.infoshare.va.gov/sites/OPCC/default.aspx](http://vaww.infoshare.va.gov/sites/OPCC/default.aspx))

• **VISNs** ([http://vaww.va.gov/health/visns.asp](http://vaww.va.gov/health/visns.asp))

• **Office of Homelessness** ([http://vaww.va.gov/homeless/](http://vaww.va.gov/homeless/))

**Principal Deputy Under Secretary for Health (10A)** ([http://vaww.pdush.med.va.gov/](http://vaww.pdush.med.va.gov/))

  o Veterans Engineering Resource Centers (VERCs) ([https://srd.vssc.med.va.gov/Committee/verc/default.aspx](https://srd.vssc.med.va.gov/Committee/verc/default.aspx))

• **Office of Nursing Services** ([http://vaww.va.gov/nursing/](http://vaww.va.gov/nursing/))

The Office of Nursing Services (ONS) provides leadership, guidance, and strategic direction on all issues related to nursing practice and nursing workforce for clinical programs across the continuum of care, and across the spectrum of care delivery sites that impact Veterans.


  (*also with Office of Telehealth Services, Health Economics Resource Center (HERC) and HSR&D’s Center for Health Equity Research and Promotion (CHERP)*)
7. References


