

A research-based implementation program in the US Department of Veterans Affairs: Crafting culture, capacity, and infrastructure to enhance the evolution of QUERI.

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Abstract

Background

N.B.: This paper is one in a series of articles for a special Theme Issue on the Quality Enhancement Research Initiative (QUERI) of the Veterans Health Administration in the United States (US).

The significant gap between available evidence and current practice reinforces the fact that effective solutions have been slow in emerging, perhaps because of the sheer complexity of addressing this gap and the lack of active engagement of researchers most familiar with the evidence. In turn, few generic models with the potential to address the multiplicity of barriers to uptake of evidence have been systematically applied in a health care system and few directly involve researchers in the solution.

An approach developed by the US Veterans Health Administration (VHA), called the Quality Enhancement Research Initiative or QUERI, creates an innovative integration of health services research, policy, and clinical care delivery. Specifically, QUERI is designed to enable a shift in the focus of traditional health services research (HSR) portfolios to i) a more active and yet scientifically-focused implementation trajectory and ii) direct partnering with service providers and administrators. As the largest, integrated health care system in the US, VHA has been able to serve as a national laboratory for exploring the relationships, infrastructure, resources and other factors needed to operationalize implementation science in real settings.

Methods Supporting Active Implementation

This paper provides a case description regarding the challenge of re-focusing traditional HSR researchers on an implementation trajectory. It describes organizational efforts undertaken to refine and adapt traditional HSR. These efforts are described primarily through an evidence-based, organizational change framework with three, overlapping components; i.e., refinement of cultural

norms and values; capacity-building efforts; and creation of a supportive and reinforcing infrastructure. Additionally, the critical and supportive context of the broader VHA environment is noted.

Conclusion

Efforts to more actively engage health services researchers in both the active reduction of current “best practice” gaps in care and the study of those processes required a shift in the perspective and activities of those researchers. It also required consistent reinforcement, development of explicit organizational supports, and “substantial malleability.” As a result of concerted efforts over the past eight years, observable differences in HSR activity within the VHA can be reported.

As an introductory part of this *Theme Issue for Implementation Science* on the QUERI program, provision of the above background information is considered relevant to those interested in understanding the environment in which QUERI’s evolution has taken place. Its evolving success in shifting HSR portfolios onto an action-oriented program of implementation research to directly improve care is demonstrated in other papers within this Issue. Organizational strategies used by QUERI also provide working hypotheses for those focusing on implementation of a systems-based approach to routinely enhancing transfer of research knowledge into practice.

Background

N.B.: This paper is one in a series of articles for a special Theme Issue on the Quality Enhancement Research Initiative (QUERI) of the Veterans Health Administration in the United States (US). The purpose of the QUERI program is an innovative integration of health services research, policy, and clinical care delivery, with a focus on implementation and implementation science. See the Issue's Overview for a table of contents and publication timelines for all included papers. [1]

The persistent gap between available evidence and current practice in healthcare reinforces the fact that effective solutions to this problem have been slow in emerging. Although clinician and system barriers to uptake of evidence are generally well identified [2]; and methodological issues such as lack of conceptually grounded research and the need for both better study designs and reporting formats are becoming generally accepted, [3-6] progress in closing the gaps has been frustratingly protracted.

As a potential part of both the problem and solution to this state of affairs, the role of researchers in facilitating implementation of evidence has recently grown. For example, Lavis et al. surveyed directors of applied research organizations and found that only 30% frequently or always developed “actionable messages for decision makers”; only 20-22% frequently or always developed “knowledge-uptake skills in target audiences and knowledge-transfer skills in research organizations”; and only 8-12% frequently or always evaluated the “impact of knowledge-transfer activities.”[7] Others that have noted this issue and suggested needed changes include the following:

- Berwick notes that “health services research has not yet been sufficiently helpful in meeting the challenge of improving care in part because it has over-constrained both its methods and its favorite topic [p. 317].”[8]

- Rubenstein and Pugh, based on a Veterans Health Administration (VHA) sponsored State of the Art Conference with both VHA and non-VHA health services research (HSR) participants, suggest that “clinical organizations should find ways to embed health services researchers as active partners in care delivery [p S61]” [9], even though it might “initially cause discomfort among researchers, managers and policy makers [S62]”[9].
- Sussman et al note that “translation of evidence-based research into practice is not simple and requires substantial malleability among researchers, practitioners, gatekeepers, and policy makers; most particularly among researchers [p. 21]”[10].

Solutions to the research-practice gap and its related barriers/issues are likely to be neither quick nor easy; and although a shift in the role of the researcher looks promising, there are few examples to date in the literature that describe approaches that would create such a change. One exception is the VHA’s QUERI.

QUERI represents a unique effort to achieve suggested changes by embedding researchers into the care delivery system as full partners; encouraging malleability in methods and processes; and employing other approaches recommended by Berwick, Sussman, Rubenstein/Pugh, and others.

The QUERI program consists of nine, independent disease- or condition-focused QUERI Centers [11] and a supporting organizational structure located within VHA’s Health Services Research and Development Service (HSR&D)[12]. Described in-depth elsewhere [11,13-15], QUERI’s overall goals and purpose are outlined in this Issue’s *Overview* article, [1] along with a brief description of a QUERI Center. (See Tables 1 & 2, *Overview* article.) Since QUERI’s inception in 1998, Centers have been expected to put QUERI’s six-step translation framework into action. (See Mittman in this Issue [16].)

QUERI’s evolution has not been a simple, quick-fix process. Required changes did “cause discomfort [S62]”[9], given the needed paradigm shift and necessary knowledge/skills, reporting tasks, and other fundamental innovations in traditional HSR activities. However, QUERI’s unique

collaboration of research and practice offers insights into the challenges and benefits of creating innovative roles for researchers in this field. It specifically offers a potentially instructive model for implementing recommendations emerging in the literature from others grappling with the problems of translation [4,8-10,17].

In summary, this article documents QUERI's unique features and approaches for supporting and facilitating implementation of evidence-based practice (EBP) in a large healthcare delivery system (VHA) via direct engagement of health services researchers. This approach — a strategic, leadership-driven systems change— links research and practice in a way that produces and identifies clinically relevant findings, and then negotiates, disseminates, promotes, implements, and evaluates both the uptake of those findings and requisite implementation processes. By describing and analyzing the manner in which QUERI was designed and guided through its initial 8 years of development, this article aims to provide guidance and insights to other systems striving to employ research expertise and resources in directly enhancing healthcare system quality and performance. The article complements other papers in this *Theme Issue* that highlight QUERI research tools/approaches or describe implementation projects involving specific steps in the QUERI framework [1]. The current paper also describes QUERI tools but focuses primarily on the strategies used to guide the QUERI program itself. The authors played central roles in the design and evolution of QUERI and describe the program from this perspective.

Methods for Creating a Research-based Implementation Program

VHA had long benefited from positive collaborations among researchers, policymakers and management when it recognized in 1998 “the potential for a more systematic role for research in the area of quality improvement [p. I-2]” [13]. In that context, those instrumental in QUERI's development and evolution defined a dual focus for QUERI: (1) realization of more rapid,

scientifically-based implementation of research evidence to reduce gaps in care and (2) development of implementation-related research knowledge that would further support rapid, scientifically valid implementation throughout the VHA and other healthcare settings.

QUERI's goal achievement would require a shift in the perspectives and activities of researchers — i.e., Sussman's substantial malleability [10], as the foci of active/rapid/reality-based implementation were grounded for many in unfamiliar concepts and processes [4,18-24]. This complex challenge is best viewed within the general context of expected norms within the HSR field at that time:

- o Researchers typically engaged in traditional research and development work where RCTs (Randomized Controlled Trials) and other highly controlled research designs or large, quantitative epidemiological designs were employed. This produced a large set of results published by VHA scientists throughout major U.S. and international scientific journals.
- o Few investigators concerned themselves with what happened with their findings. One study in basic or clinical research led to more basic or clinical research. Implementation activity was rarely considered by investigators.
- o Individual study timeframes were often 3-5 years, with the researcher's end responsibility defined as passively reporting in selected peer reviewed journals and presenting at conferences, often attended only by other scientists—and perhaps select clinicians.

An additional challenge was the fact that many health services researchers were not knowledgeable regarding the multiplicity of fields relevant to implementation science, which nonetheless was still a “young” field in the early years of QUERI. Although evidence and theory from various fields relevant to the research-practice gap did exist [18,20,25,26] and, within health care, an increasing amount of relevant information was emerging [27,28], key challenges remained regarding the following:

- o Information was increasingly emerging about what wasn't known regarding potential interventions for enhancing the uptake of research findings among health care providers.

- o Specific guiding tools and substantiated, workable theories for enhancing the uptake of research findings among health care providers, in dynamic and often chaotic health care settings, were not readily available.
- o Methods that would enable implementation of rapid, real-time implementation projects while also providing credible scientific data were unclear and appeared to run counter to the gold standard RCT.

Efforts to operationalize the QUERI framework[16] and adapt related organizational environments thus drew upon the best available evidence regarding organizational change, EBP, and implementation science in the late 1990s/early 2000s [13,14,29-31]. The transition to a new a paradigm and new methods was further facilitated by development of innovative tools linked to programmatic goals. Specific approaches included the following:

- o Expanded expectations of researchers, in terms of scientific and practice-related activities as well as career paths deemed by QUERI as “appropriate and desirable.”
- o Mechanisms to increase researcher ability to enact expectations and achieve program outcomes.
- o Additional infrastructures to support, reinforce, and sustain the increased focus on practice goals in addition to research goals.
- o Other encouraging and reinforcing leadership behaviors.

Leadership monitored and refined goal-related progress through ongoing formative evaluation, identifying issues and barriers and gathering stakeholder suggestions continuously. Input was obtained from a QUERI Research and Methodology Review Committee (R&M) and a project funding application review committee (SDP; described in a later section). The R&M Committee was created to ensure “the scientific quality and feasibility of each QUERI Center’s plans, activities, and products ... while facilitating selected aspects of QUERI’s integration with other VHA programs and activities...[p. 340]”[11]. Committee members included representatives from VHA clinical and operations leadership, thereby providing an important link to the many changes

taking place in the larger VHA environment (e.g., implementation of electronic patient records, development and dissemination of evidence-based guidelines and guideline-based performance measures, and a call, articulated by the VHA Under Secretary and US Congress, to refocus VHA research on the needs of veterans and actions to improve their health.)

An enabling framework

Since 1998, QUERI leadership has employed an iterative, evidence-based series of approaches to operationalize its mission. These efforts can be characterized through an institutionalization or enabling framework that evolved out of organizational redesign efforts, one specifically related to EBP [29,31,32]. The enabling framework's basic premise is that, to become a routine part of a practice-based research system—including its alignment within the overall VHA organization—the QUERI program needed a relevant *culture*, specific *capacities*, and a congruent *infrastructure*. These three organizational components are not mutually exclusive. Rather, like a Venn diagram, the sub-elements of each component inter-relate and thereby provide reinforcement across components. Additionally, a related action or innovation at one point in time may serve a different function at another point in time, and progress is rarely linear [31]. Together, however, these components provide an evidence-based framework to organize the description of QUERI's evolution to its current stage and to better understand the content and context of the articles in this *Issue*. The following sub-sections provide details and the rationale for the QUERI culture, capacity, and infrastructure approach, while Tables 1-2 outline samples of evidence-based efforts to operationalize and institutionalize QUERI.

Refining cultural norms and values

Organizational context is increasingly recognized as a critical factor in implementation of EBP [33-37]. One part of that context is the culture of an organization and its sub-components (e.g., the managerial subculture)[34,38,39]. Basically, the culture of an organization needs to match, support,

and reinforce its mission, vision and strategic goals. Several cultural triggers were perceived as critical to QUERI's evolution. More specifically, in order to reinforce expectations for a more active implementation role for researchers, norm-directed actions were needed relying heavily on social influence; language; symbols; active engagement, partnering, and dialogue. This was operationalized through a multiplicity of actions such as those listed in Table 1.

Active leadership is critical to any sustainable organizational culture-related change in the form of establishing, articulating, supporting, and championing a desired change — particularly and frequently in the initial phases when related organizational infrastructures are absent [30,34,36,40]. Relevant leadership activities within QUERI included regular communications between QUERI administrators and Center Coordinators, which were used to clarify and reinforce expectations and the value of QUERI. In terms of leadership in the VHA beyond the research community itself, provision of monies from the clinical side of VHA to the research-based QUERI was perhaps one of the clearest messages of widespread value for the program.

A second aspect of culture is a common language and views or paradigms of the world, in this case, that related to HSR research [34]. In 2001 a Glossary (see Table 4, in the *Overview* article [1]) was created to enhance communication and a common understanding among leadership and Center researchers. A working definition of “Traditional Versus Translation Research Paradigms” was also circulated in the same year (Table 3). This has more recently been replaced by an operational description of hands-on implementation research (Table 4), akin to the “field-work” recently discussed by Sussman et al [p.16] [10]. Shifting traditional views was assumed to be a slow, incremental effort of “unfreezing” current conceptions of research/researcher roles and refining/changing them to include new and innovative approaches [41]. Dissemination of these innovative documents, along with supportive feedback consistent with the new paradigm, was provided through the regular interactions of leadership with Center Coordinators. Such feedback

was subsequently reinforced more formally via Center performance evaluations, as described in the infrastructure section below.

Collaboration, teamwork, and good working relationships within/across an organization have been suggested as an important contextual/cultural component of quality programs and successful implementation/innovation [34,39,42,43]. Already a general expectation within the VHA, QUERI leadership originally encouraged active research-practice collaboration through recommendations regarding each QUERI Center's Executive Committee (EC) membership (see Table 2 in the *Overview* article [1]) and through publicly spotlighting role model partnerships created by the most innovative Centers. Over time, collaboration-related recommendations regarding two-way communications across VHA organizational lines—especially with clinicians, as well as quality improvement leaders and operations leadership—became increasingly detailed and, again, were eventually formalized through integration into yearly evaluations.

In summary, QUERI leadership initially provided encouragement, direct on-going contact regarding program expectations and progress, and periodic “paradigm” documents — all geared to support the shift to a blending of traditional and implementation research and a more policy/practice-oriented implementation culture. This shift was not always a natural fit [9] as HSR researchers were asked to conduct a new, unfamiliar and at times seemingly “questionable” kind of real-time research and to engage with clinical stakeholders as “integral partners”[44]. Such partners ranged from central VA policymakers to local clinical leadership.

As described by Lavis et al. [45] and Ross et al. [44], many researchers' interactions with decision makers have been limited and more likely focused on how decision makers could help researchers *conduct their own* research. In that traditional paradigm, the health system can be seen as a “supplier” of needed data, space, resources, etc, with the researcher as the “customer.” In contrast, QUERI researchers were asked to focus on the needs of decision makers and clinicians, as well as on related issues with the quality of the health care system. QUERI's research implementation

expectations thus pushed cultural boundaries or, as the current chief of QUERI noted, they “up-ended” the traditional relationship of the health services researcher to the health system. In the new paradigm, the researcher is the “supplier” — of expertise, evidence, facilitation, etc. Such a shift in expected behaviors required more than verbalized expectations and encouraging communications.

Enhancing Capacity for Hands-on Implementation Research

In addition to clear expectations, a common language and collaborative connections, those expected to successfully operationalize desired change must have the capacity, capability, and resources to do so [34]. Within the QUERI program, HSR researchers needed new knowledge and skills to pursue practice-oriented research goals. This required capacity-building, focused on QUERI Centers, so that related individuals and teams would have the ability, the tools, resources and the supports needed to fulfill their operational mission.

The capacity-building strategy used over the years to enhance progress on the part of HSR researchers to some extent reflects the same types of change approaches QUERI Centers employ in clinical implementation projects. Specific examples, based on the best evidence available in the early years of QUERI [22,24,46], focus around educational strategies; multi-faceted incentives; new, collaborative roles; linkages to VHA resources; and methodological guidance. Key points regarding these conceptual categories are briefly described below, with more specific examples in Table 2.

- o Educational programs and materials: Periodic QUERI conferences were held, including several separate QUERI National Meetings with participation by regional clinical and operations leadership. In one such conference (2002), a session was held in which leaders directly addressed QUERI investigators to dialogue about the state of implementation science and the work QUERI researchers’ were conducting to measure and enhance improvements in the quality

of care. By 2004, enough experience had been gained to develop an *Implementation Guide* [12] for use as an orientation resource for those new to QUERI.

- Incentives: Special funding mechanisms were provided to encourage action-oriented implementation/improvement studies that did not fit standard RCT review paradigms yet were rigorous and produced valid and reliable output within a reasonable timeframe. This includes, as described in Table 1, Service Directed Projects (SDPs), other special solicitations, and discretionary/rapid response monies. As further incentive to use of more innovative and risk-taking approaches to action-oriented improvement studies, QUERI created special review committee mechanisms, e.g., for SDPs, where members understood the importance of rigorous methods as well as the nature of implementation science and thus were open to relevant designs, concepts and approaches beyond the traditional RCT. (See Table 2, Guiding Documents below, and Step 4 projects in Mittman [16]). Emerging projects were expected to be rapidly developed and innovation was encouraged. However, QUERI leadership clearly communicated to Center Coordinators the likelihood of a range of project results and the value of both positive and negative findings in the context of continuous learning.

Another significant incentive related to the need for peer-reviewed publication opportunities for this innovative work. VHA/QUERI's response was to directly create such opportunities --- involving the requisite external peer review process--- in the form of periodic journal "Supplements." See Table 5 for the source and content of three such supplements. Most recently, the VHA was instrumental in supporting establishment of the Implementation Science e-journal.

- Collaborative roles: As Sussman, et al recently observed, "different personnel roles are required to facilitate successful translation of research evidence [p.16]"[10]. In that vein, QUERI both created and funded a new role within each QUERI Center (originally titled a *Translation Coordinator* or TC); and encouraged use of a broader VHA initiative on "Academic Experts."

The purpose of the TC role was to facilitate translation efforts and to provide a clear focus within each Center regarding what is now termed implementation science. Since many HSR researchers were not schooled in social/behavioral sciences, the addition of such an individual was expected to enhance capacity. The TCs, now termed *Implementation Research Coordinators or IRCs*, were responsible for the development of the above noted *Implementation Guide*.

Although not specifically a QUERI initiative, Centers more recently were able to obtain additional short-term funding under an HSR&D “academic experts” program. These individuals bring knowledge to QUERI teams, e.g., from the fields of organizational science, educational psychology, health management and policy, anthropology, and business administration.

Through introduction of both the *IRC* role and academic experts not only did QUERI researchers gain specialty knowledge but also expertise in sometimes unfamiliar techniques such as qualitative or mixed methodologies. These innovations collectively address the Sussman et al recommendation that implementation research “sometimes may require communication among different programmatic and scientific roles... [and] may involve persons from rather different academic backgrounds...i.e., transdisciplinary research [p. 18]”[10]. (See Table 2.)

- o Linkage to VHA Resources: Given data needs inherent throughout the QUERI framework, two critical expert resources essential to development and success of implementation studies — and in some cases to on-going sustainability of implementation efforts — are the VHA’s VIREC and HERC. Both are a national resource center funded by the VHA HSR&D. VIREC, or the VA Information Resource Center [47], has a mission is to improve the quality of VHA research that uses databases and information systems. HERC, the Health Economics Resource Center [47], has the mission to promote health economics in VHA through research, education, and service. Details regarding the specific relationship of VIREC and HERC to QUERI are provided in Table 2.

- o Guiding methodological documents: A final, key capacity-building strategy used in QUERI relates to the methodological challenge of implementation research. This includes the challenges and complexities of identifying scientific methods that produce credible and reliable output while accounting for the realities of the real-time, dynamic health care setting; dealing with scientific uncertainties and other variables often ignored in peer reviewed publications; [4,25,48] and overcoming limitations or so-called “failures” in traditional implementation research increasingly described in the literature [6,49,50].

While resolving critical methodological issues is not simple, e.g., those related to lack of control in real world situations, specific measures could be taken to promote rigor in the progressive, goal-directed implementation steps tested by QUERI. The state of the science during QUERI’s early years did not provide sufficient answers to existent challenges; and therefore, to increase QUERI researcher capacity to produce the output needed to bridge research and practice, innovative tools were developed. Some have already been mentioned as they served multi-purposes in QUERI’s institutionalization change strategy and are detailed in Table 2.

Of special note are the SDP and expanded QUERI framework. The Service-Directed Project template (see Table 6) , one of a number of related SDP documents representing an early effort based on current literature, began to introduce QUERI researchers to unfamiliar science and concepts [19,21,22,51,52]. SDP materials were formatively refined through the efforts of the original SDP review group and QUERI implementation experts, as evidenced by the multiple versions in Table 2 and the Mittman paper [16]; and over time these documents were used to introduce and reinforce the importance of intervention mapping, theoretical frameworks, “strength of evidence” issues, diagnostic analysis/formative evaluation, spread and sustainability, and the all-important concept of context [16,36,53,54]. The SDP review process also differentiated evidence regarding best practice (either for a therapeutic process or a delivery system) from evidence regarding different types of change interventions to enhance uptake of

the best practice evidence — and thus differentiated various meanings of the term “intervention” in this regard. See the Brown et al paper for such differentiation [55].

In terms of the QUERI framework, Mittman describes its evolution in detail as well as the current QUERI pipeline and Four-phase Implementation Research Framework [16]. QUERI has thus continuously encouraged innovation and exploration, per Sussman, et al., of new “study design(s), methods, or instruments that will help facilitate translation of existing evidence-based findings, tools, and strategies [p. 27,]”[10]. However, as with the communication of expectations, values and cultural paradigms, such guiding documents and other capacity building approaches were necessary but still not sufficient to achieve AND sustain the desired organizational evolution.

Building a Supportive, Reinforcing, and Sustaining Infrastructure

Those wishing to successfully build upon the momentum of a beginning shift in research paradigms and progress in capacity-building must also make expectations and related activities an integral part of the everyday organization [29,31,56]. To enable a sustainable and thus lasting shift — in the direction of an active and scientifically-focused implementation program of research— requires its institutionalization/normalization. For example, on-going incentives and a day-to-day reinforcing context are needed to “make it happen and keep it happening over time” — as old habits easily reemerge without on-going support and reinforcement.

Creation of a supportive infrastructure in an innovative program such as QUERI, including relevant organizational policies, procedures, operational systems, structures and processes, requires time. This is particularly important as the nature of the desired program itself must evolve and respond to normal institutional pressures. Listed below are a few of the infrastructure-related steps, based on principles of evidence-based management, taken by QUERI and other VHA leadership to facilitate progress toward normalization. Again, these examples may also continue to serve other “change”

functions but relative to infrastructure, they represent an integration of QUERI into the on-going formal functions/standards of VHA/QUERI:

- o QUERI Center accountability for role expectations: At some point in the evolution of an innovation, the “encouraging” words, gentle persuasion/feedback, and flexibility for off-target Center responses need to become a structured set of time-lined expectations for which a player is formally held accountable. Over time QUERI leadership increasingly established such expectations regarding explicit implementation-related activities and products. Coordinators and Centers as a whole are evaluated relative to these expectations for their performance at least annually (more often as needed) and, where appropriate, changes have been made where accountability or a “fit” was not evident, including discontinuation of a QUERI Center or a shift in its leadership. Expectations took two major forms, i.e., a periodic Strategic Plan and an Annual Report, built on the 6-step QUERI process.

Initially, a separate “translation plan” — now integrated back into one consolidated Strategic Plan — was used to underscore the importance of “hands-on, action-oriented research on implementation” and to ensure attention by each Center on Step 4 of the QUERI process.[16]

Relative to the issue of collaboration, the Annual Report now requires Centers to record how they communicate with, engage, involve and partner with various national and regional stakeholder groups such as the Office of Quality Performance (OQP) and the VISN directors.

Figure 1 provides an illustration of such partnerships for one of the QUERI Centers. As of this year, each Center goal now must respond to an explicit goal to “Contribute to implementation science.” In any case, each Center receives a set of actionable recommendations to maintain forward progress toward goal achievement that are subsequently monitored by QUERI leadership.

- o Congruent organizational goals, priorities, and resources: QUERI has existed for eight years and been continuously funded to support its mission. As described previously, this money

comes from both research and clinical operations. Organizations that lose site of the importance of formalized support, and “protection” of innovations such as “QUERI” [57] — which at some point are no longer seen as an innovation requiring basic norm-related groundwork — find that they readily begin to disintegrate and often disappear.

- o Alignment of other organizational systems: To further institutionalize the mission of QUERI, members of QUERI Centers have been placed, as routine members, on centralized VA committees such as the group responsible for guideline development. Various VHA Health Services Research Centers of Excellence (CoE), which have a core group of outstanding investigators and are provided with core funding to pursue their research missions relative to improving care for veterans, are also increasingly shifting to an implementation mindset. See, for example, the VanDeusen Lukas et al [58] CoE-based protocol on an organizational-level implementation intervention.

QUERI Centers, as a recognized formal VHA entity, are establishing on-going working relationships with central VHA offices, which in turn are integrating QUERI Center activities and needs into their routine performance. Examples include adoption of specific performance measures by the Office of Quality Performance and the addition of offerings for spread and sustainability by the Employee Education Office.

Given at least beginning success in the norm-directed groundwork for shifting culture and values, and the enhanced knowledge/skills and supports available to QUERI Centers, the above type of formalization activities are designed to reinforce those gains, embed them in routine VHA work, and thus facilitate QUERI’s continued evolution.

Conclusion

As stated earlier, solutions to the research-practice gap and its related barriers/issues are not likely to be either quick or easy, nor are they likely to be solved by any single approach. The VHA Health

Services Research and Development Service (HSR&D), an intramural research program, includes in its mission the need *to identify and evaluate innovative strategies that lead to accessible, high quality, cost-effective care for veterans and the nation*. Furthermore, the HSR&D home page highlights the fact that *translating research evidence into improved patient care is a priority of HSR&D and the major effort behind the Quality Enhancement Research Initiative (QUERI [59])*. As the largest, integrated health care system in the United States, the VHA has been able to serve as a national laboratory for pursuing this priority and thereby exploring the relationships, infrastructure, resources and other organizational components and processes needed to operationalize implementation science in real settings.

The Institute of Medicine, or IOM, in its sentinel report on *Crossing the Quality Chasm* made a strong case for a focus on quality as a system property [p. 4] [60]. This includes creating systems that “facilitate the application of scientific knowledge to practice, and provide clinicians with the tools and supports necessary to deliver evidence-based care consistently and safely [p. 7-8]”[60]. In 2001, the IOM noted that “one of the strongest examples of synthesizing the evidence base and applying it to clinical care is offered by the ...VHA [p, 97]”[60] through its QUERI program and related frameworks. QUERI’s “system” journey to institutionalize scientific findings through the routine uptake of the results of VHA and other relevant research is ahead of many systems but is still in an early stage of transformation. The journey has not been an easy one and has at times created “discomfort” and required “substantial malleability” among HSR researchers, given additional tasks and responsibilities not typical of traditional research; increased expectations for frequent updates to central office; and related, on-going accountability for strategic plan progress. Yet progress has been made, as indicated for the following objectives:

- o Multiple QUERI Centers are operationalizing the QUERI framework and engaging in active implementation projects, as demonstrated in this *Issue* [e.g., 55,61,62]; and the Re-Tides project

[63-65] is focused on a template for evidence-based national roll-out across the VHA health care systems that can be used by other QUERIs.

- o QUERI Centers are pursuing implementation studies using innovative approaches expected to avoid limitations or “failures” of previous implementation/quality improvement research (e.g., formative evaluation, facilitation, tailored intervention development, anthropological designs, and sustainability measures) and addressing potential implementation issues (e.g., appropriate variations in application of evidence, data base issues, cost-effectiveness, and clarity of intervention-related operational definitions) [66-69].
- o Within the VHA, dissemination of QUERI activities and findings are used to concretize for various stakeholders what EBP is all about. QUERI investigators use their findings to work with quality improvement teams in the VHA to identify the largest gaps between evidence and practice—then collaboratively help to determine a course of action to systematically close these gaps. QUERI Centers have begun to establish on-going working relationships with central VHA offices, which in turn are integrating QUERI Center evidence into routine decision-making and activity. Examples include influence on the development of guidelines (OQP) and the evidence-based removal or addition of targeted medications in VA's formulary.
- o Completed implementation research focusing on factors that facilitate implementation in real settings and on documenting barriers is being published and presented. Papers on methodological issues/solutions are being disseminated through peer-reviewed journals, contributing to international efforts to determine how to link evidence with practice. (See Table 5 for papers beyond this QTI; also see Table 3 in the *Overview* paper [1] in this *Issue*.)
- o Completed implementation projects that have impacted morbidity and mortality issues are started to being published. [See the *Overview* article [1] in this *Issue* and Francis [70].]

In conclusion, one of the things that all nations and all organizations are discovering when they try to structure health care in ways that embed science into clinical decision-making is that it takes concerted, systems-based effort. This may involve a shift in cultural norms and values, which do not change without resolute, ongoing commitment at all levels. Consistent use of best available evidence as the basis for decision making also likely involves on-going resources, innovation, visionary leadership, refinements in infrastructures, an extended period of time, and the efforts of not only those providing and managing care in the clinical setting but also those producing related science. Many questions remain regarding the optimal involvement of HSR researchers and needed organizational components at the different phases of the transfer of research into routine practice [9]. QUERI's efforts to date illustrate that research and practice can be systematically linked, and these efforts will continue to provide both insights and hypotheses regarding innovative research-clinical partnerships as a potential model for others pursuing the realistic integration of evidence into practice.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

CBS conceived of the paper and drafted the initial form and all revisions of this manuscript. All other authors (LM, JGD, BSM) have read drafted components of the manuscript, provided substantial input into initial and final refinements of the manuscript, and agreed to the final manuscript.

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Table 1	
	Sample interventions/approaches
An enabling component: Shifting cultural norms and values	<ul style="list-style-type: none"> • Active reinforcement of the QUERI mission by QUERI leadership, e.g., in terms of both reinforcing its consistency with VHA’s mission to “do the right thing for patients” as well as reinforcing the researchers’ need to keep QUERI on the front burner of their agenda. • Endorsement by top VHA leadership, e.g., during attendance by non-QUERI VHA leaders, from diverse sectors within the organization, at both QUERI educational conferences and R&M meetings to reinforce the criticality of this work • Operational endorsement by the clinical side of the VHA through provision of funds to the HSR&D-based QUERI program for selected activities. • Articulation and use of a common language, with clear and accepted definitions/glossary as well as a standard, articulated “QUERI” framework • Celebration of progress, such as the highlighting of QUERI in the Institute of Medicine’s book on the Quality Chasm [60] • Direct involvement of leadership in reducing barriers confronting QUERI Centers, e.g., through early linking and networking activities.

Table 1, continued	
	<ul style="list-style-type: none"> • Expansion of expectations of HSR researchers plus active communication by HSR&D leadership of those expectations as representative of “acceptable and productive” scientific output and career paths. • Visualization of expected paradigm shifts, e.g., per distribution of the “Traditional Versus Translation Paradigms” table as well as a visual representation of the shift from an investigator-initiated generation of research and individually defined priorities to a phased/pipeline portfolio of implementation focused research [16]. • Expectations regarding enhanced research-clinical partnership: See the Smith et al article on building bridges [63]; the Chaney et al paper on creating partnerships with IRBs [64] ; and the Curran et al [66] description of intervention development through local partnership with clinical staff.
Another enabling component: Capacity building	<ul style="list-style-type: none"> • <u>Educational interventions</u>, including conferences, workshops, consultative visits, and written material such as knowledge transfer and adaptation references as well as pertinent documents (e.g., Tables 3 & 4). • <u>Multifaceted incentives</u>, including the following special funding mechanisms: <ul style="list-style-type: none"> ○ Additional file 1: See for a 2003 form of a QUERI <i>Special Solicitation for Service Directed Projects (SDP) on Implementation of Research into Practice</i>. This funding sought to promote “rapid and systematic implementation of clinical research findings and recommendations into routine practice within the Veterans Health Administration (VHA).”

Table 2, continued

- QUERI Centers have in the past had a small amount of discretionary core funding they could devote to small projects requiring fast reaction capabilities for smaller groundwork projects or pilots — all in line with the action-oriented mission of QUERI. Quick turn around funds were also at times available from QUERI central office for short term projects. These are currently available in the form of Rapid Response Project funds (RRP).
- Additional file 2: For a newer source of funding, see *Special Solicitation for Projects Implementing Research into Practice to Improve Care Delivery*. This funding mechanism seeks to increase collaboration between Research and Operations with a particular emphasis on using the QUERI model to improve care delivery. This recent solicitation notes both SDP funding and Rapid Response Project (RRP) funding per specific, targeted solicitations. The RRP's can include “small pilots or demonstrations, pre-implementation assessments or planning efforts, and studies that follow-up on recently completed implementation activities.... initial testing of improvement tools, such as registries, clinician decision support tools, or education materials for patients and clinicians.”
- Additional file 3: *VISN/HSR&D Implementation Collaborative: Innovations to Implement Evidence-Based Clinical Practice*. This solicitation from HSR&D provided further incentives for directly collaborating with clinical partners.

Table 2 continued

- Availability of credible journals for publication of innovative QUERI work, i.e., a Medical Care Supplement, 2000, 38 (Suppl.); Journal of the American Medical Informatics Association, 2004,11; Journal of General Internal Medicine, 2006, 21(Suppl. 2).

- Collaborative Roles:

- Additional file 4: *Working Paper: Position description: QUERI translation coordinator, September 2001.*
The primary duty and responsibilities of such individuals were to *facilitate translation processes by exploring and developing the structural link between research and clinical practice.* Several of the papers in the *Issue* include *Implementation Research Coordinators* or IRCs as authors [62,66-68,71]; and solicitations for new QUERIs continue to call for this role, which are to be filled by an individual with an appropriate background, e.g., in behavioral, social, managerial, or organizational science.
- HSR&D “academic experts” program, whereby expertise of specific consultants can be obtained that bring new skill sets to the HSR community within the VHA, which had traditionally grown out of the biostatistics/clinical epidemiology/clinical trial tradition rather than behavioral and social sciences. Several authors in this *Issue* were brought into QUERI through the academic experts program, including two authors on the Social Marketing paper [65] and an anthropologist on the Sustainability paper [67].

Table 2 continued

- Formal linkage to VHA Resources:
 - VIREC's specific mission within QUERI is to assist QUERI leadership and groups with implementation efforts by: (1) re-assessing the QUERI Centers' data needs and (2) facilitating and coordinating a collaborative and multidisciplinary approach to meeting these data needs. For example, VIREC provides technical assistance and consultation related to data needs; facilitates dialogue among HSR&D, the Office of Information and QUERI groups; identifies and disseminates information about new and existing data sources that may support QUERI; and provides support and collaboration with the QUERI R&M Committee and consultants [72,73].
 - HERC's specific role within QUERI is to support the QUERI program by offering feedback to QUERI investigators on economic analysis proposals; serving on review committees for service-directed research and rapid-response projects; advising the QUERI R&M Committee; publishing research on economic methods in implementation research; and providing training on health economics methods. HERC staff members are directly involved in several QUERI projects as investigators or as steering committee or executive committee members and the co-authors of the economics paper in this Issue are from HERC [68].

Table 2, continued	
	<ul style="list-style-type: none"> ○ It is also of note that VHA is known for its investment in information technology (IT) to enhance quality care. Hynes, et al provide a description of how such general IT has been key to operationalization of the QUERI program; i.e., QUERI has been able to enhance or expand “several existing VHA information technology resources by developing entirely new databases and informatics tools, validating and refining existing databases, and analyzing and interpreting their contents [p, 348].”[72] ● <u>Guiding documents:</u> <ul style="list-style-type: none"> ○ For examples of use of SDP related concepts in this Issue see Krein et al [61] per a conceptual framework; Wallace & Legro [71] per use of formative evaluation; Bowman et al [67] per focus on sustainability; and Curran et al [66] per a type of intervention mapping as well as diagnostic analysis per formative evaluation. ○ See Mittman’s description of the pipeline and four phase implementation model [16] and the Brown et al [55], Krein et al [61]; and Goetz et al [62] illustrative cases.
<p>A final enabling component: Refining infrastructures</p>	<p>NOTE: See text re: <u>QUERI Center accountability for role expectations; Congruent organizational goals, priorities, and resources;</u> and <u>Alignment of other organizational systems</u></p>

Table 3: Traditional Versus Translation Paradigms	
<i>Traditional Model</i>	<i>QUERI Model</i>
<ul style="list-style-type: none"> ▪ A “hand-offs,” scientific control paradigm is valued where the researcher introduces an intervention in an unbiased manner and, at the end, objectively evaluates its effectiveness in terms of identified outcomes. 	<ul style="list-style-type: none"> ▪ A “<i>rapid, meaningful</i>” quality improvement paradigm is valued where the research translator introduces a research product in a “hands-on” manner that facilitates the likelihood of systematic, objective, active implementation.
<ul style="list-style-type: none"> ▪ Rigor is defined in terms of the gold standard of an RCT with traditional control group. 	<ul style="list-style-type: none"> ▪ Rigor is defined in terms of systematically constructed but variable and/or multi-method, evaluative designs: e.g., <i>research translators</i> <ul style="list-style-type: none"> ○ <i>focus primarily on demonstration or pilot translation projects as preparation for national roll-out of selected research findings. System-wide translation may require a series of iterative demonstration projects to obtain sufficient refinement of a replicable/adaptable implementation plan.</i> ○ <i>are encouraged to choose an evaluation design that matches their translation objectives and the nature of their research product. Designs can range from experimental comparisons to goal-directed program evaluation.</i> ○ <i>evaluate the effectiveness of implementation, both in terms of on-going formative evaluation (re: change process & progress) that enables enhancement of implementation; and in terms of summative evaluation to assess the results or level of goal achievement (re: structure, process, and outcome results).</i>

Table 3: continued	
<ul style="list-style-type: none"> ▪ Primary concern is with “statistical” significance, at times within the context of large sample sizes. Clinical significance may be, but more frequently is not addressed. 	<ul style="list-style-type: none"> ▪ Primary concern is with “clinical significance” but within the context of credible data; new approaches are encouraged, e.g., intensity scoring and goal-attainment scales.
<ul style="list-style-type: none"> ▪ Statistical tools are used, in some cases highly sophisticated inferential methods, to determine “effectiveness” or a best fit predictive model: e.g., with MANOVA or logistic regression. <ul style="list-style-type: none"> ○ <i>Statistical measurement, often in the form of correlations, is used to control a large number of potentially intervening variables, many of which are not modifiable in the practice setting.</i> 	<ul style="list-style-type: none"> ▪ Selection of analytical approaches, including triangulation, should fit the objectives of the demonstration project. Focus should be on production of <i>actionable</i> data that can be: <ul style="list-style-type: none"> ○ <i>Used by the research translator, to understand the extent of success of the implementation of targeted research findings; the extent of success of the translation intervention/strategies used to facilitate implementation; the factors that facilitated or hindered success, for example, the strength of the research finding or the dose of translation intervention; the nature of the change expected of targeted users, the nature of managerial support, or existence of unexpected barriers; nature of internal and external facilitation; and implications for development of a guide for roll-out and sustainability.</i> ○ <i>Used by targeted providers or other potential users to better understand the translation process and QUERI.</i>
<ul style="list-style-type: none"> ▪ There is an acceptance that research “takes time,” with many projects spreading over 3-7years. <ul style="list-style-type: none"> ○ <i>Researchers take the long-view of the need to incrementally and continually build a knowledge base regarding the focus of study. Thus, there usually is a need for a follow-up study to clarify, expand, or confirm findings and/or the related conceptual framework.</i> 	<ul style="list-style-type: none"> ▪ There is an expectation that QUERI projects employ a “<i>rapid</i>” cycle of translation/evaluation more compatible with a quality improvement paradigm. <ul style="list-style-type: none"> ○ <i>QUERI implementation projects should take no longer than 18 months to produce initial results.</i> ○ <i>The goal of QUERI is to convert, disseminate, implement and evaluate substantiated research findings into practice on a routine and rapid basis.</i>

Table 3: continued

<ul style="list-style-type: none"> ▪ The role of the researcher is completed when the results are published and reported/disseminated to self-selecting, interested audiences. 	<ul style="list-style-type: none"> ▪ The role of the QUERI health service researcher/translator is not only to produce new knowledge relevant to improvement of the health of veterans but also to facilitate the systematic translation of those research findings into routine practice.
<ul style="list-style-type: none"> ▪ Traditional networking frequently occurs amongst researchers in the same field of study. 	<ul style="list-style-type: none"> ▪ QUERI research translators are responsible for networking not only with fellow researchers but also with those in a position and responsibility to facilitate evidence-based practice/best practice.
<ul style="list-style-type: none"> ▪ The goal of the researcher, the research system, and related incentives within which the researcher operates, is to publish in the most credible of scientific medical journals, such as NEJM or JAMA (gold standards). 	<ul style="list-style-type: none"> ▪ The goal of the QUERI health service researcher and related research system within which the researcher operates is to disseminate and publish the methods and results of translation efforts in credible, peer-reviewed sources.
<ul style="list-style-type: none"> ▪ Research requires knowledge of the research process and the substantive area under study. 	<ul style="list-style-type: none"> ▪ Translation of research findings requires knowledge of the translation process, including synthesis/conversion of findings into an actionable product; dissemination of findings/related products; use of translation interventions to facilitate uptake of findings; and formative and summative evaluation of translation efforts.

Table 4

Operational Definition of *Hands-on, action-oriented research on implementation**

1. *Hands-off implementation research*, in contrast to hands-on implementation research, is often demonstrated by the following, i.e., the researchers:
 - i) Allow sites to view the study as “your research”
 - ii) Drop intervention/s into the site, then sit back and wait till “end” of trial to see results
 - iii) Delegate site activities to research assistants that are critical to routine best practice maintenance
 - iv) Plan not to interfere with experimental interventions (i.e., given need for maximum control)
 - v) Are primarily concerned with statistical outcomes re: targeted variables rather than with understanding the complex black box of implementation
2. *Hands-on implementation research* includes or is demonstrated by the following actions, i.e., the researchers:
 - i) ENGAGE IN A STRATEGIC, COLLABORATIVE RELATIONSHIP; i.e., they initiate a strategic effort to partner with relevant operational leadership by:
 - Engaging key stakeholders in a mutual relationship
 - Enhancing partner commitment (as thru evidence-based persuasion/gaps evidence, stakeholder needs assessment, and use of a business case)
 - Focusing the partner on the fact that this is not “research as usual” but rather a quality improvement effort with a rigorous study and evaluation approach to enable replication
 - ii) PARTICIPATE IN THE IMPLEMENTATION PROCESS ON SITE, as appropriate, in order to:
 - Understand, real-time, the on-going nature of implementation within the particular setting
 - But not to substitute for roles/activities that will need to be sustained/maintained as part of the routine delivery system or practice
 - Provide formal facilitation to help overcome mutable problems and provide needed support

Table 4 continued

iii) UTILIZE A STEP 4 HYBRID STUDY DESIGN:

- That involves the most realistically rapid timeline, relevant to the complexity of the implementation program,
- That, during the study, focuses on progress and identifies both potential and actual influences on the progress and effectiveness of implementation efforts through use of formative evaluation [50], and
- That plans action during the study, as needed based on formative data, to refine the change intervention, resolve mutable barriers, and enhance available facilitators

...in order to optimize the following:

- Actual implementation of the change intervention to achieve or at least assess its potential
- The goal of clinically meaningful (not just statistically significant) evidence-based practice
- Understanding of the black box of implementation, including cost-benefit
- Understanding of outstanding research questions
- Development of a replicable implementation program

3. Summary: Key words which describe “hands-on” implementation research:

- STRATEGIZE
- ENGAGE/EDUCATE/PERSUADE
- PARTICIPATE
- FACILITATE
- OPTIMIZE

*Memo to Implementation Research Coordinators from C. Stetler, 2006

& A hybrid design combines use of formative evaluation with an experimental study, quasi-experimental study or other appropriate real world design for the question/targeted innovation at hand, within the Step 4 continuum of pilot to national rollout phases. [50].

Table 5 – Additional QUERI-related publications per Journal Issues

Medical Care, 2000, 38(6 Suppl 1)

- Demakis, McQueen, Kizer, Feussner I17-25
- Kizer KW, Demakis JG, Feussner JR. Reinventing VA Health Care: Systematizing Quality Improvement and Quality Innovation. I7-16.
- Ashton CM, Bozkurt B, Colucci WB, et al. VA QUERI in Chronic Heart Failure. I26-37.
- Krein SL, Hayward RA, Pogach L, BootsMiller BJ. Department of Veterans Affairs QUERI for Diabetes Mellitus. I38-48.
- Every NR, Fihn SD, Sales AEB, et al. QUERI in Ischemic Heart Disease: A Quality initiative from the Department of Veterans Affairs. I49-59.
- Bozzette SA, Phillips B, Asch S, et al. QUERI for Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome: Framework and Plan. I60-69.
- Fischer EP, Marder SR, Smith R, et al. QUERI in Mental Health. I70-81.
- Weaver FM, Hammond MC, Guihan M, Hendricks RD. Department of Veterans Affairs QUERI for Spinal Cord Injury. I82-91.
- Oddone E, Brass LM, Booss J, et al. QUERI in Stroke: Prevention, Treatment, and Rehabilitation. I92-104.
- Finney JW, Willenbring ML, Moos RH. Improving the quality of VA care for patients with Substance-Use Disorders: the QUERI Substance Abuse Module. I105-113.
- Rubenstein LV, Mittman BS, Yano EM, Mulrow CD. From understanding health care provider behavior to improving health care: the QUERI framework for quality improvement. Quality Enhancement Research Initiative. I129-41

Table 5 – continued

Journal of the American Medical Informatics Association, 2004, 11(5)

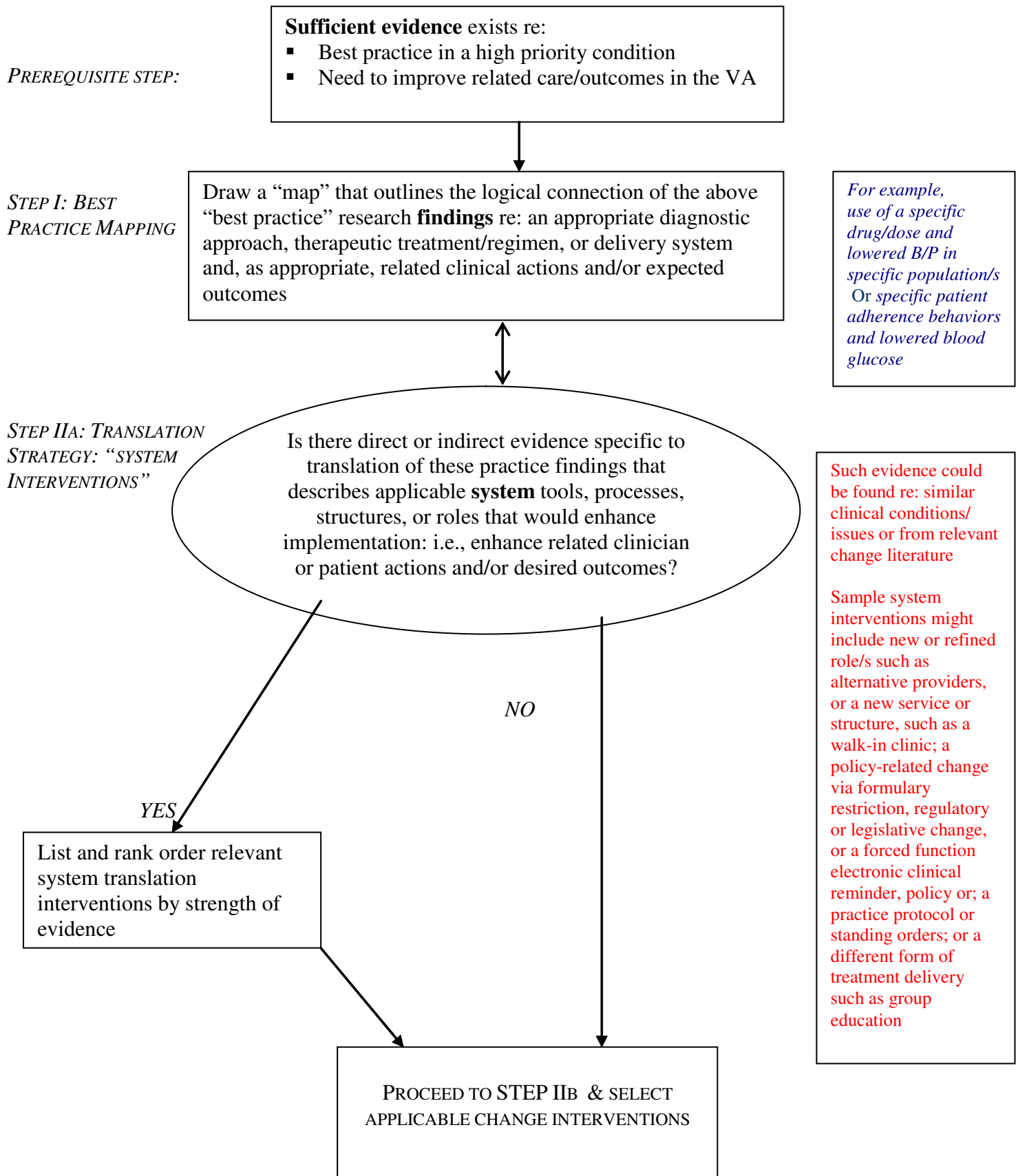
- Owen RR, Thrush CR, Cannon D, et al. Use of electronic medical record data for quality improvement in schizophrenia treatment. 351-357.
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Journal of General Internal Medicine 2006 (21 Suppl 2)

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Table 6
SDP Template

Working SDP INTERVENTION GUIDE (Version 1)



*STEP IIB: TRANSLATION
STRATEGY: GENERAL
INTERVENTIONS*

Given your best practice map, as well as any evidence regarding potential system enablers or barriers specifically related to the current lack of best practice, identify which of the following will likely be needed relative to providers, patients, the organization, etc.:

- Change in awareness (brief knowledge)
- Change in practice knowledge/skill
- Change in attitude/belief or motivation
- Contextual support for change/system enablers
- Change in behavior

- There may be evidence about such issues in the literature
- Site specific diagnostic analysis will also be needed to assess various factors/barriers in targeted locations prior to finalization of the implementation plan

Is there direct evidence specific to translation of the selected practice findings that describes **general change** interventions that would enhance implementation: i.e., enhance related clinician, patient, and/or organization changes?

YES

NO

Use of an explicit translation framework or model, such as PRECEDE, SI = f(E,C,F), change theory, or a combination thereof, can facilitate overall translation decisions.

Consider strength of all related translation evidence, its fit with projected needs for change, other interventions noted on Table 1, and select a set of interventions for SDP implementation of these best practice findings

Use Table 1 to select a set of generic translation interventions that facilitate the type of change/s that will be required to implement the targeted best practice findings and, if applicable, system interventions.

Refine the SDP Map to illustrate the translation strategy, i.e., the expected associations from best practice findings through achievement of desired outcomes

Evidence regarding the selected interventions should be noted in the proposal; see reference list.

Additional files provided with this submission:

Additional file 4 : Draft Position Description TC.pdf : 93Kb

<http://www.implementationscience.com/imedia/2282348461129792/sup4.PDF>

Additional file 3 : Collaboratives Solicitation.pdf : 119Kb

<http://www.implementationscience.com/imedia/1801998244112979/sup3.PDF>

Additional file 2 : SDP-1005-final.pdf : 86Kb

<http://www.implementationscience.com/imedia/1297568271112979/sup2.PDF>

Additional file 1 : SDP-solicitation-implementation-Dec2003.pdf : 185Kb

<http://www.implementationscience.com/imedia/1934496462112979/sup1.PDF>