

Strengthening Organizations to Implement Evidence-Based Clinical Practices

Carol VanDeusen Lukas, EdD

Center for Organization, Leadership & Management Research
VA Boston Healthcare System

June 2011



COLMR study team

- Ryann L. Engle, MPH
- Sally K. Holmes, MBA
- Victoria Parker, D.B.A.
- Marjorie Nealon Seibert, MBA
- Michael Shwartz, PhD
- Jennifer L. Sullivan, PhD

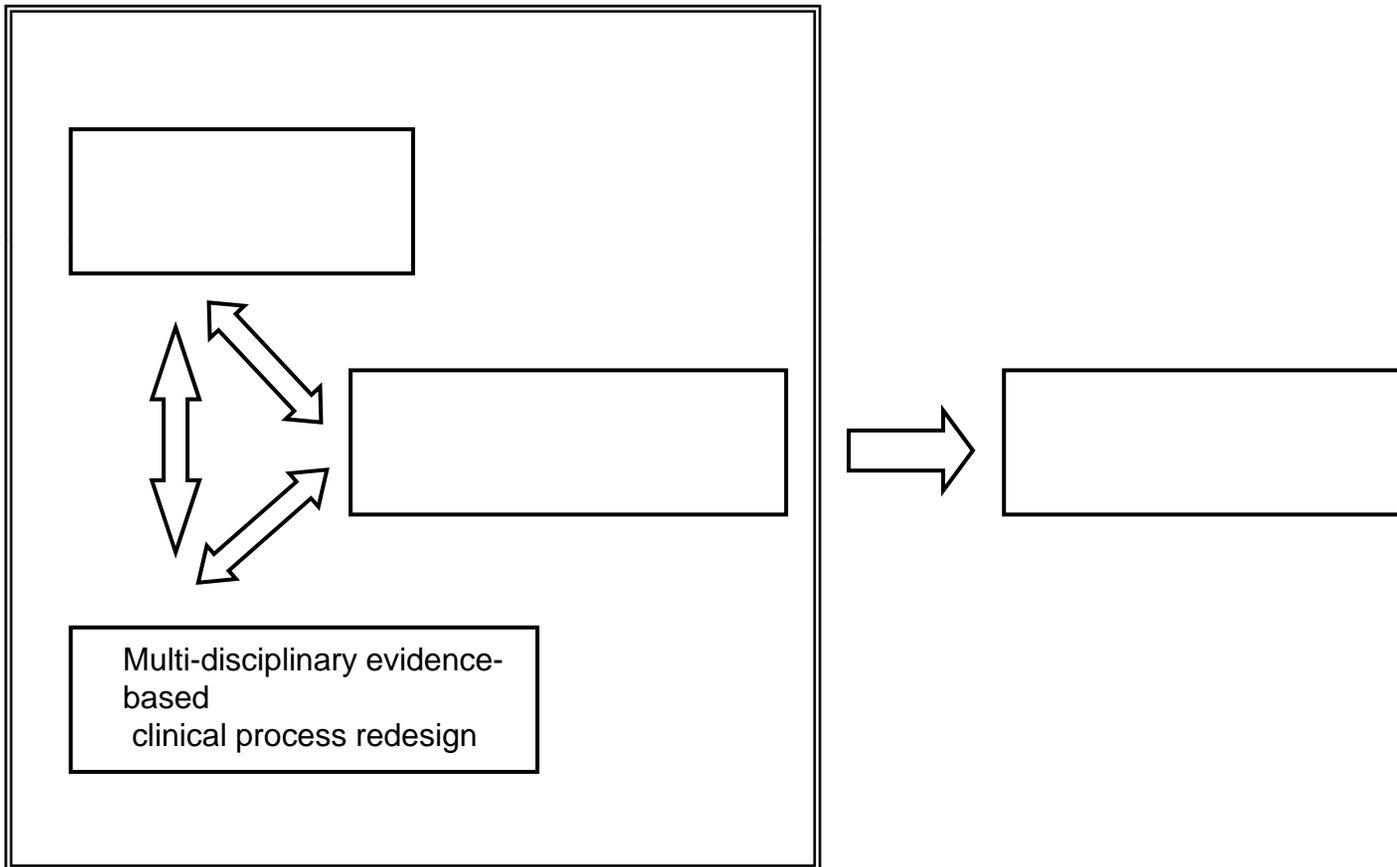
+

VISN leaders

Study aim

- To implement & evaluate an organizational model hypothesized to strengthen the ability of healthcare organizations to bring evidence-based clinical practices in routine operations.

Organizational model tested



Examples of operational elements of model

- Senior leadership commitment
 - Set high expectations for improvement
 - Invest own time on improvement-related activities
- Linkages to senior leadership
 - Appoint a leadership champion
 - Identify clear path for team reporting to senior leadership for accountability & support
- Multi-disciplinary evidence-based redesign team
 - Appoint members from affected disciplines & units
 - Use systematic methods to analyze processes & performance

Study questions

- Is the organizational model implemented with high fidelity to the model design?
- Are medical centers that implement the model with high fidelity more successful in improving performance of a targeted evidence-based clinical practice than medical centers that implement fewer elements?
- Why is the organizational model implementation successful or not successful?

Study design

- Designed in collaboration with directors and chief medical officers of 3 participating VISNs, or Networks, in Dept of Veterans Affairs (VA)
- Original study design: Mixed-methods pre-post comparison group intervention in 16 medical centers in 3 networks
 - 1 Network randomly selected to implement the organizational model
 - Other 2 Networks served as comparison group

Clinical focus is hand-hygiene

- Clinical redesign process component required specific clinical focus to engage staff
- Compliance with evidence-based hand-hygiene guidelines evidenced-based and high priority:
 - Fundamental aspect of infection control
 - One of the simplest yet most effective processes shown to reduce nosocomial infections
 - Requirement of The Joint Commission
 - New high priority for improvement in VA at time of study design

Intervention in 7 medical centers

- Initial site visit for introduction of the project and assessment of baseline state of the model components;
- Follow up to work with site to complete implementation plan
- Repeat visits/phone calls every 4-6 months over 2 ½ years
- VISN-wide support
 - Shared learning groups monthly
 - Leadership consortium quarterly

Three data sources

- Local observations of hand-hygiene compliance
 - compliance rates
- Semi-structured interviews by research team during site visits
 - fidelity ratings
 - factors affecting implementation fidelity
- Site-visit impressions journals kept by research team
 - factors affecting implementation fidelity

Fidelity of implementation

Data source: Notes from semi-structured interviews used as basis for ratings and narrative evidence of fidelity to each model element, completed by site-visit research team at end of each visit

Measures:

- Ratings on a 0-4 scale (0= element not present; 4= element in place and consistently used as intended)
 - Component scores created by aggregating elements and calculating an unweighted mean
 - Overall site fidelity ratings calculated mean of 3 component scores
- Narrative evidence analyzed qualitatively by cross-site comparisons structured by fidelity instrument

Example of fidelity rating tool

II. Management Structures and Processes	Rating	Narrative:	Examples
<p>1. Alignment and accountability</p> <p>a. Create incentive and reward structures to encourage use of hand-hygiene guidelines and, where needed, fundamental redesign of clinic processes</p>			<p>Successes are recognized and celebrated. Where hand-hygiene performance varies from target, individual(s) are charged with taking action and reporting back.</p>
<p>b. Establish structures to link the hand-hygiene improvement efforts to senior management such that senior management gives the initiative high priority and holds the design team accountable.</p> <ul style="list-style-type: none"> • Reporting relationship to senior leadership team • Member of senior management and chief or comparable service line leader in infectious disease as formal champions to advocate for redesign and help the design team solve problems 			<p>Structures and processes, such as an oversight committee with direct reporting paths to senior leadership, monitor hand-hygiene improvement progress regularly to hold the improvement team accountable and to provide support.</p> <p>A member of facility leadership is charged as formal champion for the project and liaison to senior leadership. S/he assures that facility leadership reviews measures and corrective action is taken as needed. Project champion assures that the redesign team has needed resources and helps them resolve problems.</p>
<p>2. Integration and resource support</p> <p>a. Link improvement efforts to senior management such that senior management facilitates cooperation across organizational boundaries and provides other resources to design team.</p>			<p>Project champion and facility leadership are actively engaged support the project as needed in obtaining resources across the organization. <i>For example:</i></p> <ul style="list-style-type: none"> ▪ Protected time to work on initiative ▪ Staff, equipment and space as needed ▪ IT support as needed

Quantitative fidelity scoring

Facility	Fidelity: leadership	Fidelity: management links	Fidelity: redesign efforts	Fidelity: overall	Fidelity: overall change from baseline	Fidelity rank order
A	4.00	4.00	3.85	3.95	2.82	1
B	4.00	3.20	2.95	3.38	2.11	2
C	3.75	2.60	3.35	3.23	1.99	3
D	3.00	3.00	3.50	3.17	1.84	4
E	2.00	2.20	2.25	2.15	1.21	5
F	2.50	1.80	1.65	1.98	0.41	6
G	2.50	1.25	0.50	1.42	-0.05	7

Note: Facilities A-D are high-fidelity sites, E-G are lower fidelity sites.

Hand-hygiene compliance

Data source: Observations of hand-hygiene compliance measured through structured observations by medical center staff

Measures:

- Percent compliance for each observation period at site level.
- Effect size of improvement in compliance calculated by comparing the baseline 3-month periods to the last 3-month periods of the study
- Statistical significance tested through a weighted least squares regression model with:
 - time (i.e., month) as independent variable
 - compliance percent as dependent variable
 - sample size in each data collection period as weight.

Hand-hygiene compliance ordered by fidelity ranking

Facility	Adherence pre-period	Adherence post-period	Effect Size: 3 months pre-post	Effect Size: 6 months pre-post	Regression model: time coefficient	Regression model: time coefficient p value	Regression model: r-squared
A	67.6	92.9	.67	.69	1.29	0.00	0.72
B	74.2	91.5	.48	.40	0.98	0.00	0.57
C	37.4	80.9	.92	.22	1.41	0.01	0.36
D	81.7	96.8	.52	.53	0.97	0.00	0.53
E	69.1	75.2	.14	.07	0.20	0.11	0.62
F	61.5	68.3	.14	-.27	-0.40	0.47	0.03
G	80.1	70.8	-0.22	-0.29	-0.47	0.17	0.08

Note: Facilities A-D are high-fidelity sites, E-G are lower fidelity sites.

Factors affecting fidelity

Data source: Notes from semi-structured interviews and impressions journals completed by research team during site visits

Measurement: Notes coded by members of team who did not visit the particular site being coded

- Thematic analyses beginning with individual site cases
- Data organized into matrices for cross-site comparisons

Limitations

- Implementation in one Network in VA
- Hand-hygiene observations done locally
- Different team members interacted with each site; thus the intervention team actions might have differed in unmeasured ways
- Weak commitment in comparison Networks

Study implications

- Confirms expectations that implementation of EB practices that cut across multiple processes of care is a complex process with many possibilities for failure
- Implementation is strengthened by presence of 3 model components that interact and are mutually reinforcing:
 - Active leadership commitment to improving the targeted practices,
 - Robust clinical process redesign to engage staff and incorporate evidence-based practices in routine operations
 - Links to management structures and processes to support, align and integrate redesign
- Implementation is strongly influenced by organizational elements and context

- Lukas, C.V., Engle, R.L., Holmes, S.K., Parker, V.A., Nealon, Seibert, M., Petzel, R.A., Shwartz, M., Sullivan J.L. (2010). Strengthening organizations to implement evidence-based clinical practices. *Healthcare Management Review*, 35(3), 235-245.



Guidance for the Design of Implementation Trials

Brian S. Mittman, PhD

Director, VA Center for Implementation
Practice and Research Support

VA Greater Los Angeles Healthcare System

June 9, 2011



Implementation research in health

Implementation research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services.

It includes the study of influences on healthcare professional and organizational behavior.

Studying implementation program effectiveness

Two very different questions

1. Does it work? Is it “*effective*”?
Should I use it?
2. How, why, when and where does it work?
How should I use it?

Evaluating implementation program effectiveness: Debates regarding research approaches

- Most large-scale implementation studies are trials (experimental or quasi-experimental evaluations) of implementation programs – QUERI Steps 4/5/6
- Implementation trials are the focus of considerable debate and ongoing development regarding research approaches, designs, methods and reporting

Guidance for implementation program evaluations: *QUERI Service-Directed Project (SDP) Template*

Motivation

- implementation projects are hybrid research/practice initiatives involving complex social/behavioral phenomena
- implementation projects require a unique set of design features, methods, skills and competencies

SDP Template goal

- provide guidance in designing, conducting and documenting implementation trials

Poll question: Audience Composition

1. Have you served as PI or key investigator for an implementation trial submitted for VA funding?
 - Yes, and it was funded

Poll question: Audience Composition

2. Have you served as PI or key investigator for an implementation trial submitted for non-VA funding?
 - Yes, and it was funded
 - Yes, but it was not funded
 - No

Disclaimer; no warranties expressed or implied

The views and recommendations contained in this presentation are based on interactions with untold numbers of VA and non-VA implementation researchers and research stakeholders, but do not necessarily represent their opinions, nor those of any VA or non-VA funding agency or official.

QUERI Service-Directed Project Template

A. Specific aims

- Implementation *and* science aims (short-, long-term)
- Hypotheses: intervention impacts *and* processes; conceptual model

B. Background and significance

- Clinical issue (morbidity, mortality, burden)
- Effective practice (clinical evidence): strength, acceptance, implementation gaps (magnitude, potential to close) (*QUERI Steps 2, C, E, 3A*)
- Implementation processes: evidence, insights

QUERI SDP Template

C. Previous studies

- Current practices: determinants, barriers and facilitators to change (*QUERI Step 3B, D*)
- Implementation strategy: appropriateness (*QUERI Step 3C*), theory, empirical evidence base and status (phase in 4-phase framework)

QUERI SDP Template

D. Design and methods

- Theoretical/conceptual framework and its basis
 - Results of (or plans for) diagnostic analysis (*QUERI Step 3B,C,D*): practice determinants; barriers and facilitators to change
 - Discussion of key conditions, requirements for change
 - Legitimacy of clinical evidence
 - Motivation for change (expectations, pressure)
 - Norms (organizational, professional, consumer)
 - Clinician, staff, consumer education and skills
 - Financial, administrative, logistical and technical barriers and facilitators

QUERI SDP Template

D. Design and methods (continued)

- Theoretical/conceptual framework (continued)
 - Applicable theory(ies) or framework(s) based on current practice determinants and barriers/facilitators to practice change, e.g.,
 - organizational delivery requires organization theory; individual clinician practices require theories from social psychology
 - knowledge gap requires education
 - gaps in practice norms, attitudes, beliefs require social influence

QUERI SDP Template

D. Design and methods (continued)

- Implementation *program* details and theoretical basis
 - Overview; table of key elements relative to theoretical framework
 - Details of operationalization of each element
 - education program design, delivery
 - social influence strategy
 - delivery system redesign; distinguish care model from change strategy (as applicable)
 - Formative evaluation, tailoring/adaptation, monitoring, refinement
- Implementation generally requires multi-level, multi-component *programs* rather than *interventions*

QUERI SDP Template

D. Design and methods (continued)

- Usual care (comparison) condition
- Evaluation details
 - Experimental design (RCT, ITS, pre/post)
 - Sites, sampling, recruitment, randomization
 - Balance between internal and external validity (and artificial vs. real-world conditions): decisions regarding sites and sampling, implementation program delivery (e.g., staffing), etc.; driven, in part, by Phase 1 vs. 2 vs. 3 status of trial

QUERI SDP Template

D. Design and methods (continued)

- Evaluation details: impact evaluation
 - Outcomes (patient, system outcomes)
 - Contextual factors
- Evaluation details: formative/process evaluation
 - Identify mechanisms of impact and measures: variables, measures, data collection protocols
 - Influences on mechanisms: variables, measures, data
 - Analysis plans and methods
- Evaluation details: other
 - Sustainability, spread/scale-up potential and pathway
 - Economics
 - Clinical intervention effectiveness (*if hybrid E/I study*)

QUERI SDP Template

D. Design and methods (continued)

– Management plan

- Intervention management plan
- Evaluation management plan
- Staff qualifications: intervention, evaluation

Studying implementation program effectiveness

Two very different questions

1. Does it work? Is it “*effective*”?
Should I use it?
2. How, why, when and where does it work?
How should I use it?

Implementation research challenges

- What is the nature of the desired evidence, knowledge, insights, understanding (*and the associated learning, skills and abilities*)?
- How is this understanding generally produced? *Mechanism- vs. impact-oriented approaches*
- Is our current portfolio producing this understanding and generating this learning? (*Are prevailing research approaches, designs and methods – and projects – appropriate?*)
- Must we rebalance our portfolio? *How?*