

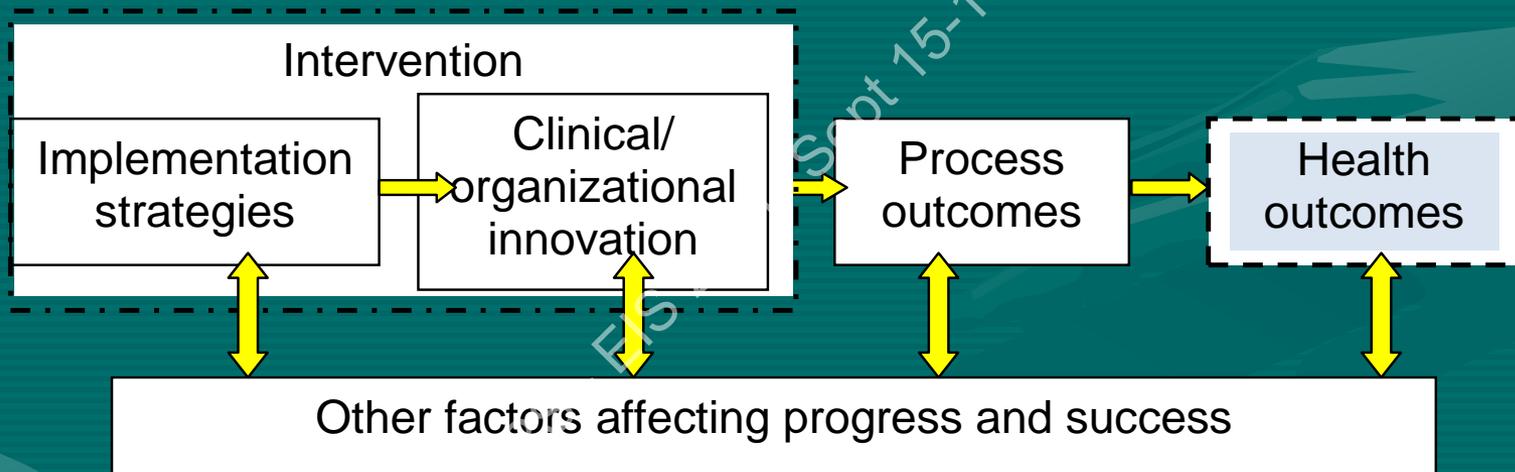
Measuring Implementation Outcomes and Fidelity

Carol VanDeusen Lukas, Ed.D

Center for Organization, Leadership &
Management Research
Department of Veterans Affairs

September 2011

Implementing a clinical or organizational innovation



Why do we care?

- Judging effectiveness of strategies for implementing innovative programs
 - Implementation outcomes as dependent variables
- Analyzing effectiveness of intervention on process outcomes
 - Implementation outcomes as independent variables
- Understanding factors affecting implementation success
 - Implementation outcomes as independent variables

Implementation strategy v. innovation v. outcomes

<i>Study</i>	<i>Implementation strategy</i>	<i>Innovation</i>	<i>Process outcome</i>
Organizational collaboration for hand-hygiene	External facilitation	Organizational model for strengthening implementation of evidence-based practices	Hand-hygiene compliance
Bipolar CCM	Replicating effective programs (REP)	Collaborative chronic care model (CCM)	Guideline concordant anti-manic treatment

Three broad measurement questions to consider

- How do we operationalize a complex innovation to measure it?
- Against what shared standards of success should the implementation strategies and innovation in practice be judged?
- What data collection tools and strategies should be used?

How do we operationalize a complex innovation to measure it?

- Key elements
 - Important for implementation as well as measurement
 - Replication v tailoring/ customization/ adaptation

CIPRS - EIS 2017 - Sept 16, 2017

How do we operationalize a complex innovation to measure it?

- Which features are core to the intervention?
 - Which features have to be present for the intervention to maintain its effectiveness?
 - Which can vary without compromising effectiveness?

Against what shared standards of success should the implementation strategies and innovation in practice be judged? E.g.,

- **Fidelity** -- Adherence, Scope/reliability, Intensity/dose, Quality of program, Participant responsiveness, Sustainability
- **RE-AIM** – Reach, Effectiveness, Adoption, Implementation, Maintenance

Against what shared standards of success should the implementation strategies and innovation in practice be judged?

- Which standards are appropriate for this intervention?
- Are there other standards again which implementation should be judged?

What are appropriate measurement approaches?

- At what levels of the organization is implementation targeted and is data collection needed?
- Are standard instruments available that would fit with the intervention in this context?
- Are secondary data sources available that tap the indicators sought?
- If primary data will be collected, will it be through surveys that cut widely across the organization or through interviews and focus groups that probe more deeply?
- Are validated data collection tools available and appropriate?
- What data collection will be expected of local participants and what will be done by the study team?

A case example:

**Strengthening organizations to
implementation evidence-based
practices**

CIPRS - EIP 2017 - Sept 15-16, 2017

Study aim

- To implement and evaluate an organizational model hypothesized to strengthen the ability of healthcare organizations to implement evidence-based clinical practices.

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 sites

- 7 participating medical centers varied in size, location, services provided & academic affiliation
- Senior leadership in each medical center was a quadrad – medical center director, chief of staff, nurse executive & associate director
- All medical centers part of the same network

The innovation: organizational model based on two premises

- Implementing evidence-based clinical practices is often a complex intervention that requires substantial organizational change
- Substantial organizational change requires balancing organizational strategy & direction from senior leaders with front-line activity & involvement of staff

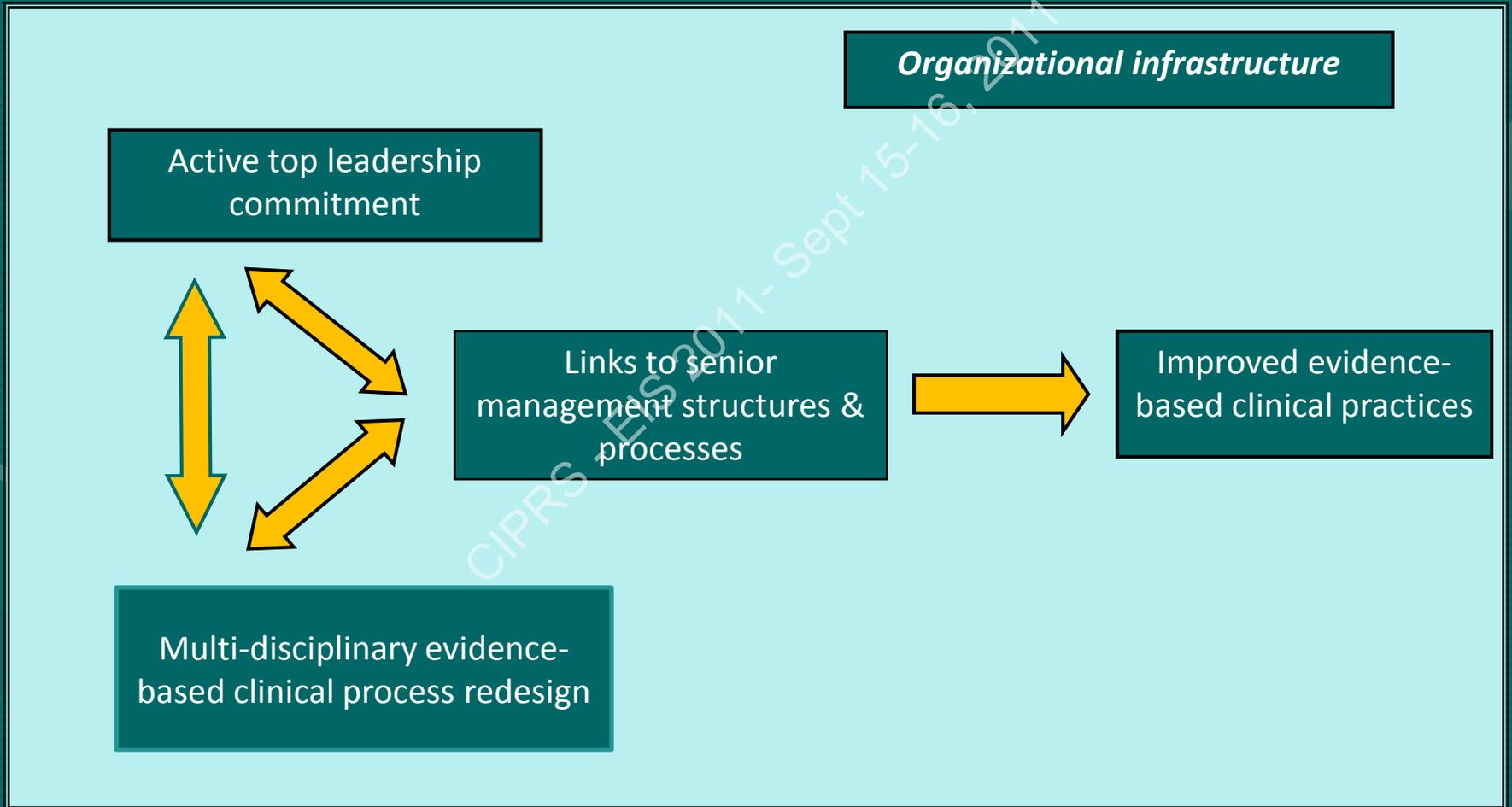
Organizational model developed from Organizational Transformation Model (OTM)

- OTM was developed in evaluation of Robert Wood Johnson Foundation's *Pursuing Perfection* initiative
- OTM identifies five interactive elements that appeared critical to successful transformation of patient care
 - Impetus, leadership, improvement initiative, alignment, integration
 - Individual elements established in literature

Organizational model reflects OTM consolidated

- Expect that organizational elements that drive organizational transformation will facilitate change required to implement evidence-based practices

OTM Consolidated



Operational definition of organizational model

- Organizational model is defined conceptually in broad terms of model components
- But components need to be operationalized in order to be implemented:
 - research team identified key elements in each component
 - medical centers identified details of structures and processes they would use to put each element into place

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

Clinical process outcome: hand-hygiene compliance

- 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 the VA at the time of study design

Implementation strategy

- External facilitation to complement theory of organizational model
 - Assist sites in building own structures and capabilities so intervention will be sustained and spread
 - Start in one area of high importance
- Onsite assessment and introduction to each medical center
 - Tailor model to local structures and culture + local implementation plan
 - Visits every 6 months + extra as needed – feedback/TA
- Network-wide support
 - Shared learning group of POCs & team members monthly
 - Leadership forum for medical center directors & VISN leaders quarterly

Three sets of measures

- Ratings of fidelity of implementation (Q1 & Q2)
- Observations of hand-hygiene compliance (Q2)
- Qualitative analysis of factors affecting fidelity (Q3)

CIPRS - EIS 2017 - Oct 15, 2016, 2017

Fidelity of implementation

Data source: Ratings and narrative evidence of fidelity for 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

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.

Factors affecting fidelity

Data source: Notes from semi-structured interviews and impressions journals completed by research team during site visits and records of telephone conversations and e-mail exchanges

Measures: Notes coded with Nvivo by members of team who did not visit the site

- Thematic analyses using explanation building strategy beginning with individual site cases
- Data organized into matrices for cross-site comparisons

Is the organizational model implemented with high fidelity to the model design?

CIPRS - EIS 2017 - Sept 15-16, 2017

Fidelity to the model varied considerably

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.

Narrative evidence expands on the quantitative findings

- High and low fidelity groups show different patterns of behavior, activities and structures
- Model components interact and are mutually reinforcing.

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 of the model?

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.

Why is the organizational model implementation successful or not successful?

CIPRS - EIS 2017 - Sep 15, 2017

While each site had its own array of forces, patterns emerged across sites

No differences associated with systematic differences in implementation strategy

Sites with *high fidelity*,

- Shared the urgency to improve compliance with hand hygiene
- Had no major aspects of the organizational environment that interfered with implementation
- Had a positive improvement climate including:
 - Staff experience and skills with quality improvement,
 - Organizational values for improvement where staff felt safe trying and speaking about necessary changes

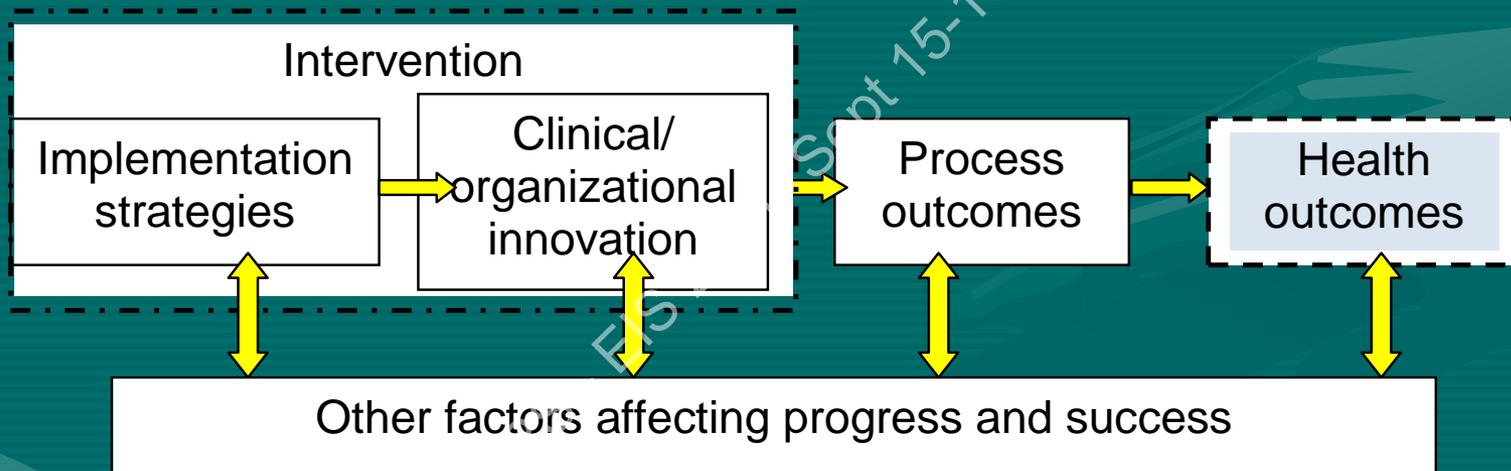
Implications

- Study confirms expectations that implementation of evidence-based clinical practices, particularly those like hand hygiene that cut across multiple processes of care is:
 - Often a complex process in which there are many possibilities for failure
 - Influenced by organizational elements and context
- Study provides refined understanding of relationships among components of the organizational model and with factors in organizational contexts affecting them which provide basis to:
 - Draw practical lessons for future implementation efforts
 - Contribute to the theoretical understanding of the dynamics of the implementation of evidence-based practices

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

Implementing a clinical or organizational innovation:



Three broad measurement questions to consider

- How do we operationalize a complex innovation to measure it?
- Against what shared standards of success should the implementation strategies and innovation in practice be judged?
- What data collection tools and strategies should be used?

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

References

- OTM:

Lukas CV, Holmes SK, Cohen AB, Restuccia J, Cramer IE, Shwartz M, Charns MP. An organizational model of transformational change in healthcare systems. *Health Care Management Review*, 2007; 32(4): 309-320.

- OTM consolidated:

Lukas CV, Engle RL, Holmes SK, Parker VA, Nealon Seibert M, Petzel RA, Shwartz M, Sullivan JL. Strengthening organizations to implement evidence-based clinical practices. *Healthcare Management Review*, 2010, 35(3), 325-245.