Are you affiliated with the VA?

- Yes
- No

What is your primary role?

- Researcher
- Clinician
- Manager or Policy Maker
- Student, Trainee, or Fellow
- Other

What is your level of participation in implementation research?

- Have been a PI on an implementation study.
- Have been part of a study team for an implementation study.
- Currently developing an implementation study proposal.
- No hands on experience, just getting started.

The Rewarding Early Abstinence and Treatment Participation (REAP) study

Hildi Hagedorn, Siamak Noorbaloochi,

REAP Study Objectives

1. Test the effectiveness of an incentive program with a large sample of Veterans with alcohol and/or stimulant dependence. Comparing:
   - Rates of negative alcohol and drug screens during the intervention
   - Rates of attendance during the intervention
   - Percent days abstinent out of the past 30 days at 2, 6, and 12 month follow-ups.
2. Assess the costs of the intervention.
3. Complete a process evaluation to inform future implementation efforts.

Relation to QUERI Pipeline

- Mainstream HSR&D Effectiveness Study
- Hybrid Type I design
  - Includes elements of a Pre-Implementation Study (Step 3)
    - E.g., identify barriers and facilitators to implementation.

Study Conditions

- 330 Veterans seeking treatment for alcohol or stimulant dependence at two VA SUD clinics randomly assigned to:
  - Usual Care: Standard care provided at the clinic AND breath and urine testing 2x/week for 8 weeks.
  - Incentive Program: Usual care + draw for incentives (VA canteen vouchers) when negative samples are submitted.

Costs of the Intervention

Vouchers	M = $103 (SD=78)
Rapid Urine Test Cups ($5.25/cup X 11.6 visits)	M = $61 (SD=25)
Alco Sensor mouthpieces ($0.24/piece X 11.6 visits)	M − $3 (SD−1)
Staff Costs ($41,000 base + 30% fringe)	$103 (16 apts. of 15 min. each)
Mean $ per patient	**M=$269 (SD=99)**

* Highest Cost Patient = $462

Evaluation Framework Guiding PE

- RE-AIM
  - Reach: What percentage of patients approached agreed to participate? Did participants differ from those that refused?
  - Effectiveness: Tests of main study hypotheses.
  - Adoption: What will be the greatest barriers to other sites adopting this intervention? How can they be overcome?
  - Implementation: What tools will programs need to deliver the intervention consistently?
  - Maintenance: What resources would be required? What changes, if any, will be needed to integrate the intervention into regular practice?

Theoretical Framework Guiding PE

- PARIHS
  - Evidence: What are the staff's perceptions of the evidence supporting this intervention? Does the intervention fit with their current clinical practice and perceived needs of their patients?
  - Context: What are the characteristics of the culture and leadership in the clinics? What resources are available to the clinics?
  - Facilitation: What types of resources, training, and tools would be of greatest assistance to maintaining the intervention?

Linking Data Collection to Frameworks

RE-AIM Constructs	Data Source
Reach	Recruitment rates. Demographic characteristics of those agreeing vs. those refusing.
Effectiveness	Main study outcomes comparing control to intervention patients: Rates of negative urine screens, rate of study retention.
Adoption	Observations of intervention in clinic. Perceptions of staff and leadership.
Implementation	Perceptions of staff.
Maintenance	Perceptions of leadership.

Linking Data Collection to Frameworks

PARIHS Construct	Data Source
Evidence	Perceptions of staff and leadership.
Context	Organizational readiness measure collected from staff and leadership.
Facilitation	Observation of intervention in the clinic. Perceptions of staff and leadership.

Process Evaluation Tools

- Organizational Readiness to Change Assessment (staff):
  - Knowledge of evidence base, attitudes toward intervention, organizational context (leadership, culture, resources, etc.)
- Research Team Observation Log:
  - Record details of interactions with staff particularly those focusing on reactions of staff to the intervention, barriers to implementation, recommendations for improvements.

Process Evaluation Tools

- Staff Post-Intervention Interviews:
  - Reactions to the intervention, perceptions of the impact of the intervention on the clinic, barriers and facilitators to implementation, recommendations for changes to the intervention.
- Post-Intervention Leadership Interviews:
  - Are they going to attempt to continue the intervention? What lead to that decision? If yes, what modifications will they make?
- Patient Post-Intervention Interviews
  - Likes, dislikes, value, improvements.

Insights from Process Evaluation

- **REACH**: Patients were enthusiastic about entering the program and enjoyed it.
- **EVIDENCE**: Staff were not enthusiastic about the intervention at baseline. Enthusiasm increased dramatically during intervention period.
- **MAINTENANCE**: Staff suggested a group intervention would be more feasible, but patients were not interested in this.
- **FACILITATION**: Change in staff attitudes

Uses of Process/Formative Evaluation

- Effectiveness Trials:
  - Collect information to inform future implementation.
- Implementation Trials:
  - Assess stakeholders' perceptions of feasibility and value of implementation strategy.
  - Understand and adapt implementation process in real time.
  - Assess impact of theoretical constructs on implementation outcome, e.g., the value of your theory.

EQUIP: Implementation Research in Specialty Mental Health

Supported by HSR&D QUERI

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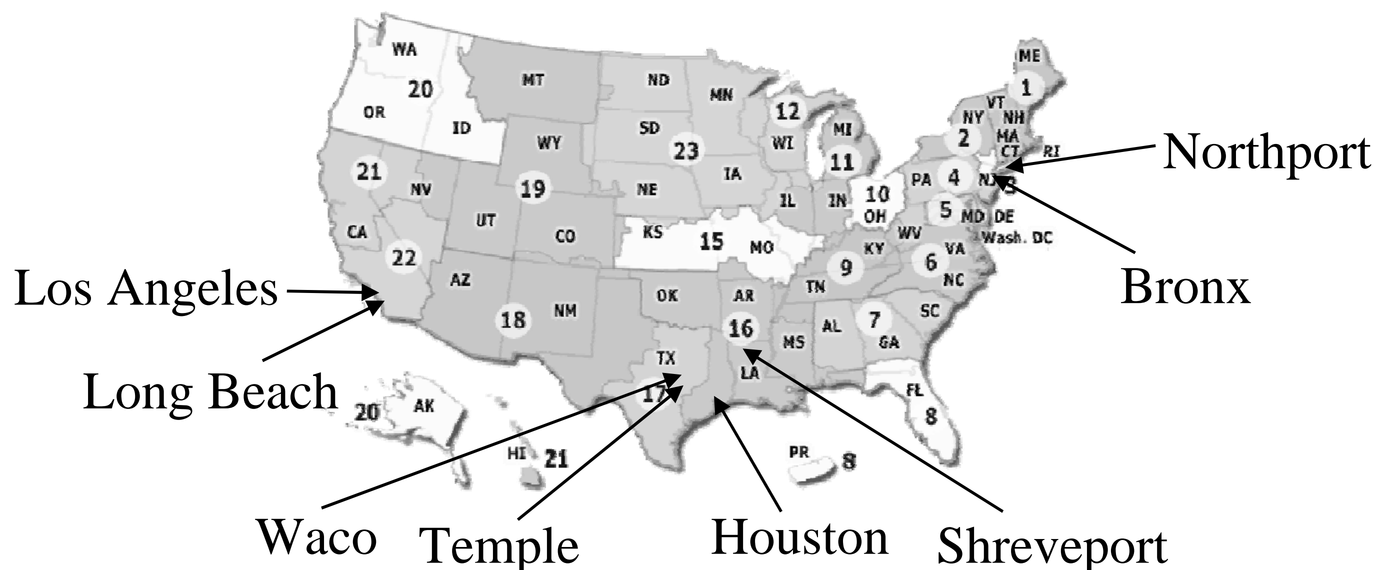
EQUIP Investigators: VISN 3, 16, 17, and 22

VA Desert Pacific Mental Illness, Research, Education, and Clinical Center (MIRECC)
UCLA Department of Psychiatry

EQUIP: Research – Operations Partnership

- Improve care for schizophrenia
  - Evidence-Based Quality Improvement
  - implementation methods & evaluation
- Clinic-level, 15-month controlled trial (VA QUERI)
  - partnership with 4 VA regional networks
  - each with 1 intervention and 1 control site (8 medical centers)
- QUERI Step 4, Phase 2-3
  - evaluation of both implementation and effectiveness



EQUIP: Specific Aims

- Assist VA VISNs to implement evidence-based care for schizophrenia
- Evaluate the effect (relative to usual care) of care model implementation
  - on provider competency, treatment appropriateness, patient outcomes, and service use
- Evaluate processes of and variations in care model implementation and effectiveness

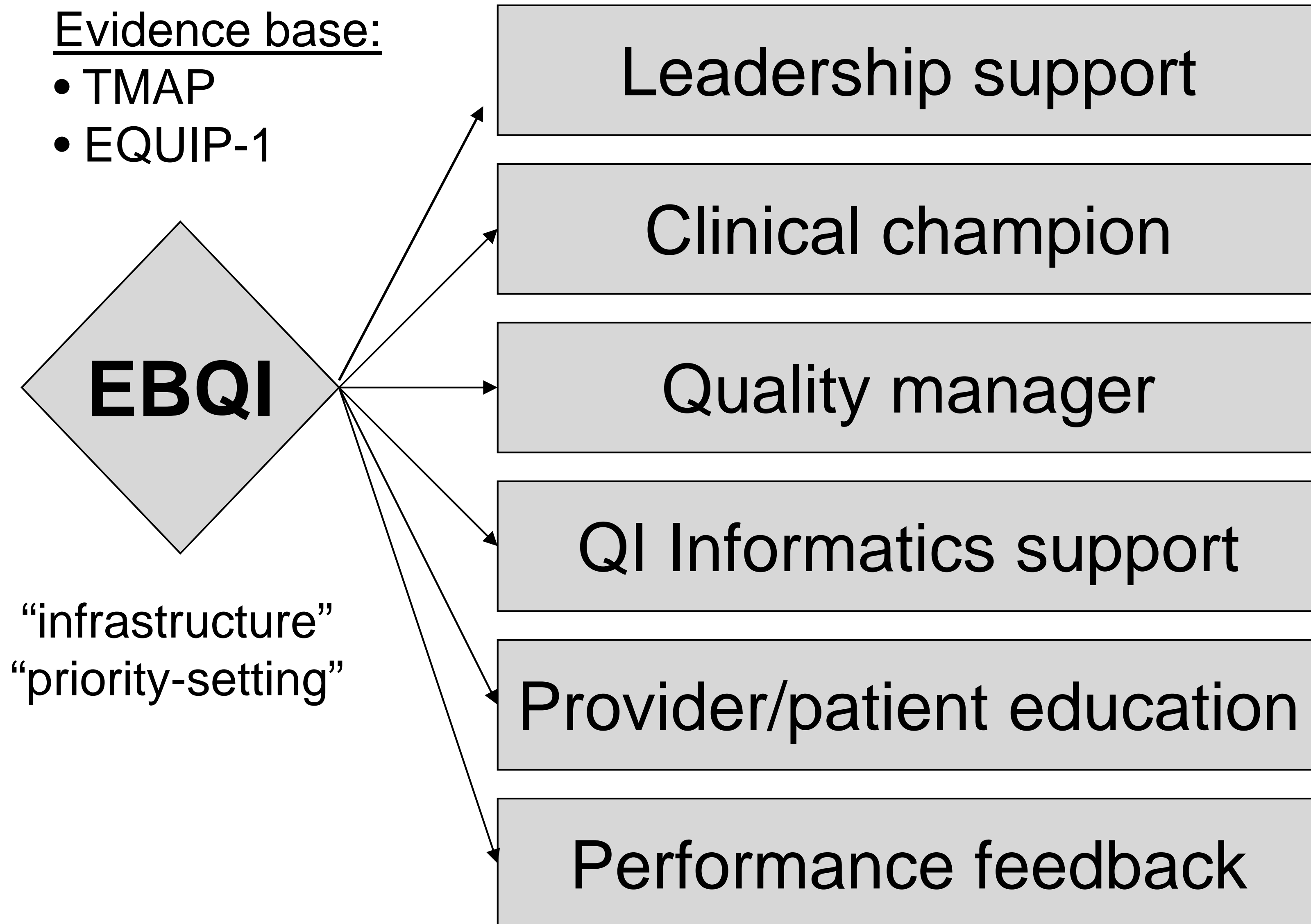
Formative & Process Evaluation

- Using mixed methods, evaluate processes of and variations in care model implementation and effectiveness to strengthen implementation and to:
  - assess acceptability of the care model, and barriers and facilitators to its implementation
  - understand how the project's strategies and tools affect care model implementation
  - analyze the impact of individual care model components on treatment appropriateness

At Baseline

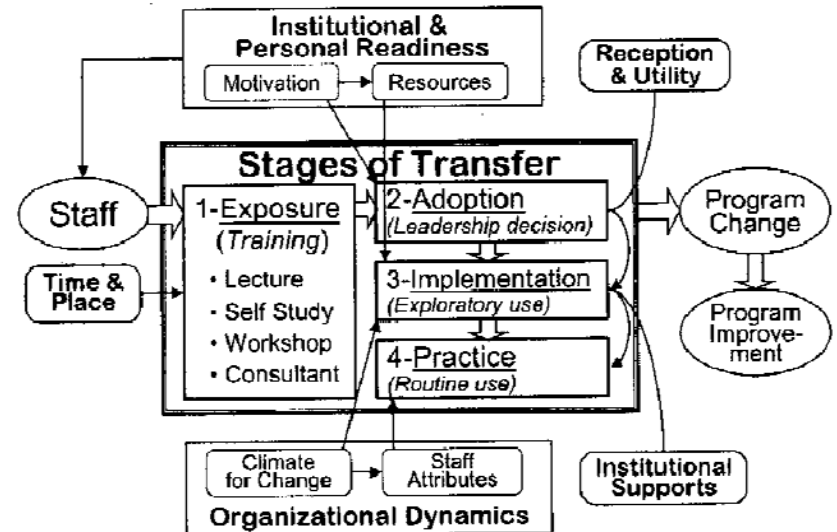
- Strategic planning
  - choice of 2 evidence-based practices for implementation
  - care targets: weight & work outcomes
- Diagnostic evaluation
  - structure of care for patients with schizophrenia varied across sites
  - availability & quality of these care targets varied across sites

Implementation Tools & Strategies: Evidence-Based Quality Improvement (EBQI)



Conceptual Framework: Simpson Transfer Model

- Stages of organizational change
- Validated survey measures for each stage



- 4 Action steps:
  - Exposure: Introduction and training
  - Adoption: Intention to try the care model through a program leadership decision and subsequent support
  - Implementation: Exploratory use of the care model
  - Practice: Routine use of the care model

Intervention Strategies and Formative Evaluation Activities by STM Stages

STM Stages	Intervention Strategies and Tools	Formative Evaluation (time-point)
Exposure ➔	•Secure commitment •Training and Observation of care model by Regional PIs and Project Managers •Review evidence •Address values •Identify and prioritize needs •Begin tailoring intervention	•Program Training Needs •Organizational Readiness for Change •Provider Burnout
Adoption ➔	**Predisposing activities**: •VISN Implementation Teams •Opinion leaders •Continue tailoring •Continue to secure commitment, address values	•Field notes
Implementation ➔	**Enabling activities**: •Patient Assessment System •Assertive care •Discuss and start using provider supports & incentives •Social marketing	•Project documents (Minutes from Implementation Team meetings, Project Managers' field notes, Quality Coordinators' logs) •Provider & Clinic Manager interviews (pre- & mid-implementation)
Practice	**Reinforcing activities (performance monitoring & feedback)**: •Monthly Quality Meeting/Quality Reports •Implementation Team Meetings •Continue tailoring with provider input •Quality Reports	•Provider & Clinic Manager interviews (post-implementation) •Organizational Readiness for Change •Provider Burnout

Data for Formative Evaluation

Pre-Implementation

(STM: Exposure & Adoption)

Implementation

(STM: Implementation)

Post-Implementation

(STM: Practice)

Developmental

- Field notes
- Documents (minutes, etc.)
- ORC & Burnout Inventory
- Key stakeholder interviews

Implementation-Focused

- Field notes
- Quality Coordinator logs
- Documents
- Key stakeholder interviews

Progress-Focused

- QI tools

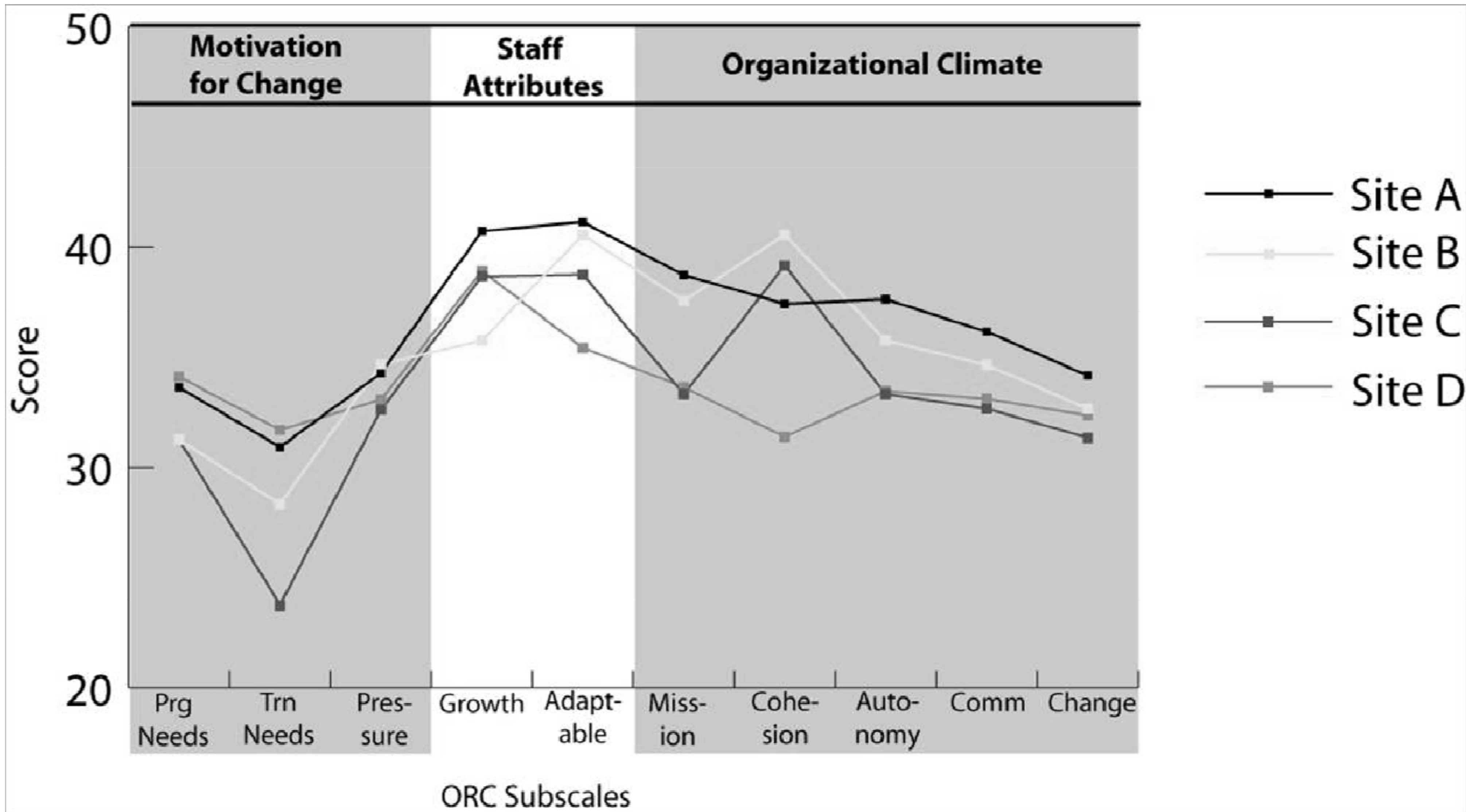
Interpretive

- Field notes
- Key stakeholder interviews
- ORC & Burnout Inventory

Evaluation

- Summative
  - 801 patients
  - 201 providers (clinicians and managers)
  - evaluate effect on provider competency, treatment appropriateness, patient outcomes, service utilization
  - patient interviews at 0 and 12 months
  - VistA data on treatment use
- Process
  - characterize provider competencies, organizational readiness, barriers, facilitators
  - interview providers & managers at 0, 6, and 12 months
  - survey providers and administration at 0 and 12 months
  - monitor use of informatics
  - logs and minutes of implementation team meetings
  - field notes from local QI teams

Institutional and Personal Readiness for Change



TCU Organizational Readiness for Change (ORC) scale

Tailoring of Implementation Based on Readiness

- Sites A and B: more ready to change
  - no specific tailoring
- Site C: less ready to change
  - needs (low): heighten awareness of gaps in care; use clinical champions and educational programs
  - mission (moderate but lowest of all clinics): study staffing kept consistent; consistency of message
  - autonomy (moderate but lowest of all clinics): let clinicians help determine how to implement the care targets

Results: Implementation

- Organization
  - strong support
  - collaboration between services was difficult (nutrition, primary care wellness programs, specialty mental health)
- Clinician competencies
  - improved through education and practice
- Managers used data to reorganize care
  - scales placed in each clinic
  - routine weighing of patients established
  - clinical staff trained to provide services

Results: Summative

- At baseline
  - 45% of patients obese, mean BMI = 30
  - 70% on medications that cause substantial weight gain
  - 22% used services, mean sessions used = 2
- As a result of the intervention, patients were 2.3 times more likely to use services ($\chi^2=14$, $p<.01$)
  - mean sessions used increased to 11
  - no changes at control sites
- Control site patients: 13 pounds heavier at end-point (±7.6 pounds, $F=4.8$, $p=.03$)
  - controlling for: pre-baseline weight, baseline weight, psychotic symptoms, negative symptoms

Reference Slides

Multiple Data Sources: Measuring & Documenting Implementation

	EQUIP	Examples
Semi-structured interviews: leaders, clinicians, managers	✓	participation, level of implementation
Organizational site surveys: administrators & staff	✓	clinic structure, processes, change
Field journals	✓	group-level dynamics, implementation details
Administrative data	✓	visits, prescriptions
patient surveys	✓	kiosk self-assessments
Activity logs	✓	time spent on aspects of study

Stages of Formative Evaluation

Developmental

"Diagnostic" of the existing context (baseline assessment)

- Organizational readiness for change
- Expectations of project
- Existing services and structure of care

Implementation-Focused

"Actuality" of implementation

- Barriers to change
- Adjustments to interventions

Progress-Focused

"Monitoring impacts & indicators of progress toward goals"

- Dose & intensity of intervention

Interpretive

"Uses results of all other FE stages"

- Key stakeholder experiences
- Could "re-diagnose" the context

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- Acknowledgements
  - VA HSR&D and QUERI (MNT 03-213)
  - VA Desert Pacific Mental Illness Research, Education and Clinical Program (MIRECC)
  - NIMH UCLA-RAND Center for Research on Quality in Managed Care

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