

From Here to There

Going Beyond Common Metrics

From
Here

Evaluation
Science

CTSA
Context

To
There

Cynthia L. Blitz, PhD

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from here.

Why are these types of evaluations not particularly helpful?

Who is responding?
What is it based on?

Are we capturing what a student has learned and/or how teaching pedagogy has played a role in this outcome?

How might the results from these prove to be more useful for a program, a specific course, a professor?



“I’ve been meaning to tell you ... some of the students have given you really negative evaluations.”

our focus.

1

From Here

what, who, why, when, how

2

Evaluation Science

principles of effective evaluation, types, translational

3

CTSA Context

evaluation, logic model, expectations, measures, common metrics

4

To There

process & procedures, expectations, core metrics, discussion, next steps

about me.

- PhD, University of Pennsylvania
- Pre-doc fellowship, Penn Center for Mental Health
- Postdoc, Rutgers Institute for Health
- Assoc Director, Center for Behavioral Health Services & Criminal Justice Research
- Research Professor, Rutgers Grad School of Education
- Executive Director, Center for Effective School Practices



about CESP.

The Center for Effective School Practices

integrity in research & education

Rutgers CESP is a research and evaluation center within the Graduate School of Education that aims to bridge the persistent research-practice gap through implementation, adaptation, and dissemination of evidence-based practices.



ALTERNATE ROUTE



GRANT SERVICES



RESEARCH & EVALUATION



TECHNICAL ASSISTANCE



TRAINING AND EDUCATION

relevant projects.



why evaluate?



NIH Requirement



External Advisory
Committee



Improvement



Internal Decision-
Making



Reporting



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evaluation.

What kind of evaluation
did you need?



Our 3 year project is coming
to an end and were told we
needed an evaluation.

What kind is that?



freshspectrum.com

Rigorous
Evaluation

Evaluation
Planning

Logic
Model

Implementation
Frameworks

Translational
Research

principles of rigorous evaluation.

Clear goals and objectives for the evaluation

- Independent, systematic investigation into **how, why, and to what extent** the stated goals and/or objectives of the program/intervention are achieved (as per the logic model)
- Adopt a broad perspective on program effects (**individual, team, organization, network, and community**) and focus centrally on the mechanisms and processes that link program inputs to program outcomes (**how works, not only what works**)
- Sensitive to the complexity of **tracking a dynamic change process** and also **consider potential unintended effects** (positive or negative)

principles of rigorous evaluation.

Reasonable scope

- Not everything can be evaluated or is worthy of evaluation, so strategic decisions about scope need to be made up front
- Function of the resources available to the evaluation
- Function of what key stakeholders (program leadership, funders, the scientific community, etc.) are most interested to learn about to inform their own evaluation of program efficacy and/or cost-effectiveness
- May also be limited to those questions that can be answered through scientific inquiry

principles of rigorous evaluation.

Theory- and context-grounded evaluation framework

- Grounded in theories that are relevant to the particular level (individual, team, organization) and context (e.g., clinical, org, community) of the intervention/program
- Theories provide an organizing framework to guide evaluation research and connect it with the relevant scientific knowledge base, specifically regarding:
 - Mechanisms and processes that connect specific program inputs and activities to specific outcomes at each level (e.g., linking training to knowledge and practice)
 - Influence of inter-organizational structures (e.g., leadership model), formal and informal relationships (e.g., coordination vs. competition), and differential capacity (e.g., resources, staff with relevant skills, etc.) on implementation and outcomes
 - Major and/or common moderators of implementation (i.e., barriers and facilitators) and effects (subgroup differences)

principles of rigorous evaluation.

Relevant methodology

- Appropriate mix of qualitative and quantitative methods to balance confirmation (testing and corroborating theoretical predictions about underlying mechanisms, causal processes, and effects) with discovery (generating new or unexpected insights)
- Use of valid (level- and context-appropriate) and reliable measurement instruments
- Transparency regarding the methodology and methodological choices made (to facilitate peer-review and replicability/reproducibility)

principles of rigorous evaluation.

Quality of data and communication of findings

- The ability to investigate indirect pathways that connect inputs to outcomes as well as monitor potential unintended effects is a function of the completeness & quality of data (qualitative and quantitative)
- Offers specific answers to specific questions about the program
- Reflect on consistency regarding the overall pattern of findings to contextualize an individual finding
- Ethical, honest, and professional (be aware, and guard against, external pressures and internal biases)

types of program evaluation.

Formative - ensures that a program or program activity is feasible, appropriate, and acceptable before it is fully implemented (e.g., needs assessment, readiness for implementation, etc.)

Process/implementation - determines whether program activities have been implemented as intended (e.g., fidelity, dose, barriers, reach, acceptance, etc.)

Outcome/effectiveness - measures program effects by assessing progress in outcomes (e.g., answer questions about effects on knowledge, capacity, motivation, and behavior/practice)

Economic (cost-effectiveness) - assesses what resources are being used in a program and their costs (direct and indirect) compared to outcomes

Impact - assesses program effectiveness in achieving its ultimate goals (e.g., improving patient care and health outcomes)

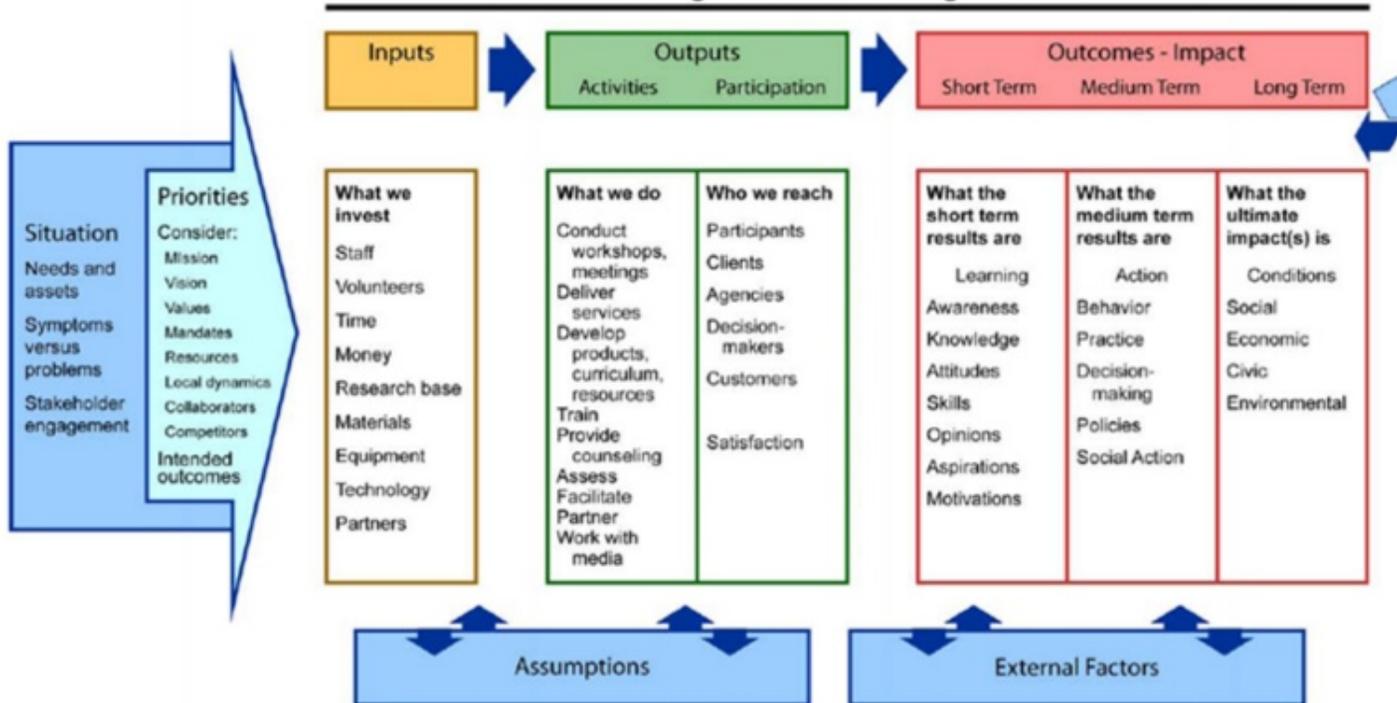
evaluation planning.

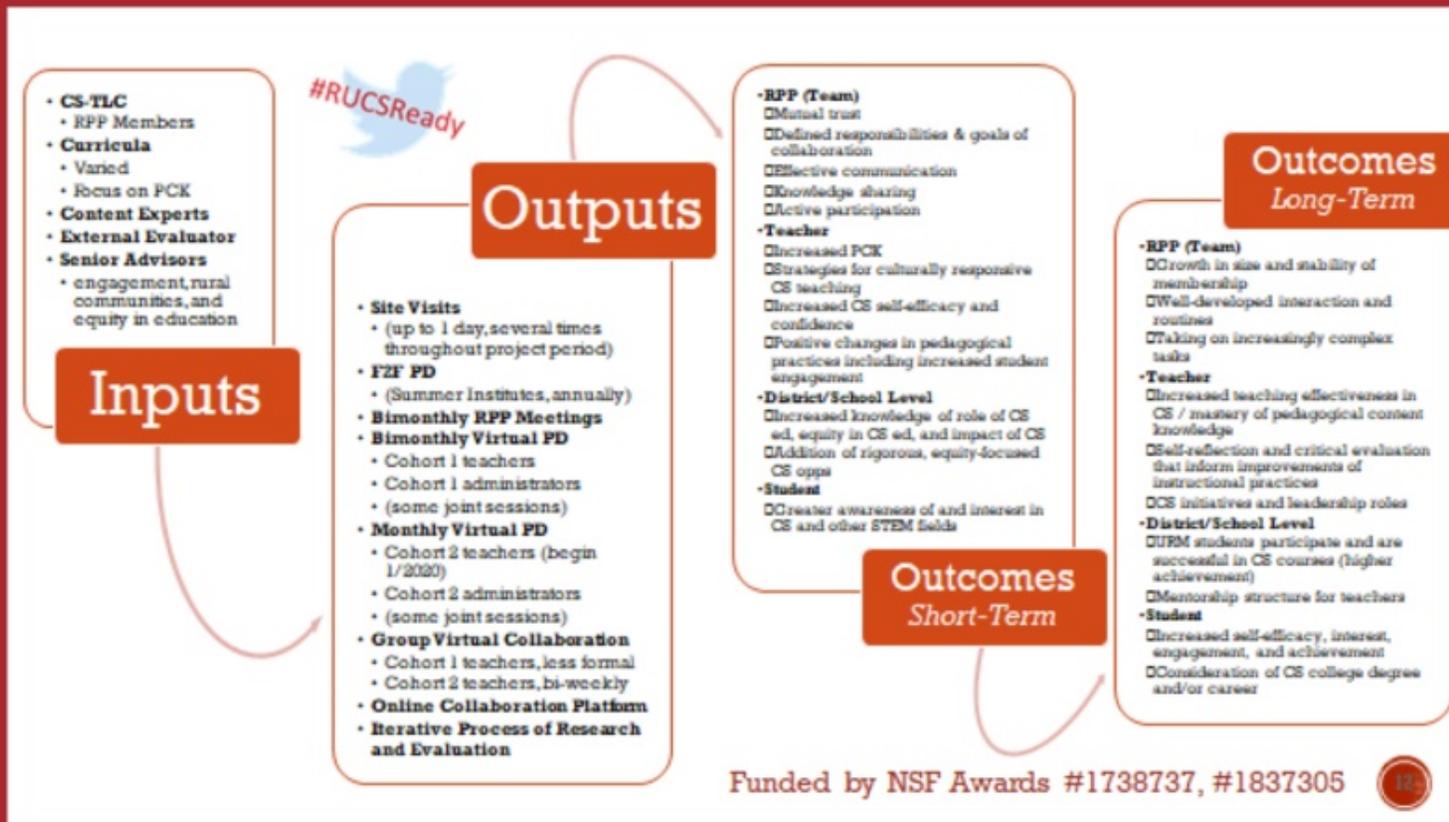
- Develop evaluation questions based on outcomes of interest
- Identify relevant evaluation measures for answering each question
- Design logic model (or theory of action) to guide the evaluation
- Determine relevant data collection methods
- Decide timing for research activities and deliverables

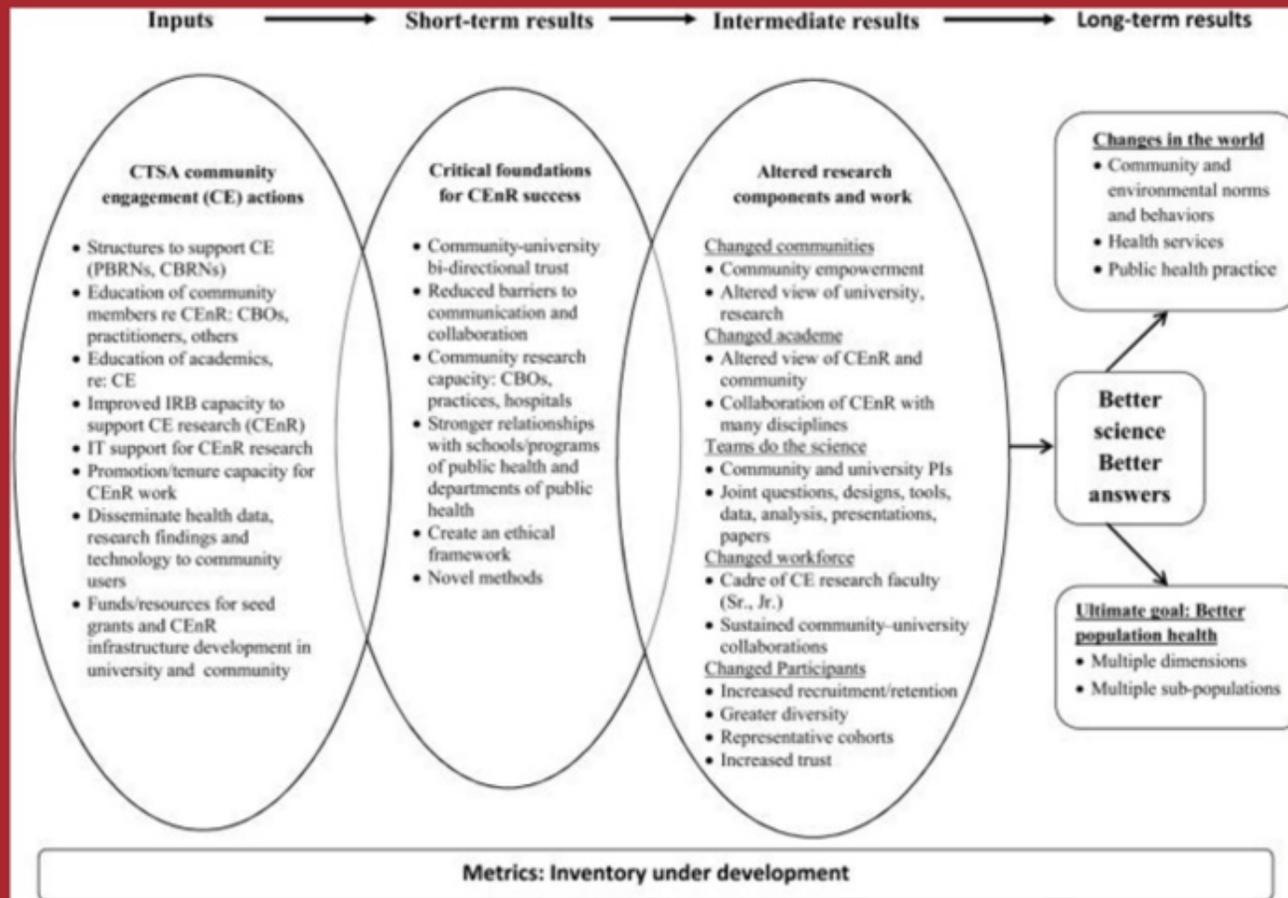
logic models.

- Presents hypothesized relationship between program inputs, intervention activities and the desired outcomes – it describes how the intervention is expected to work (theory of change)
- Five core components of logic models:
 - Inputs (resources, contributions)
 - Outputs (activities, services, events that reach people targeted)
 - Outcomes (anticipated results or changes)
 - Assumptions (rationale)
 - External Factors

Program Action - Logic Model

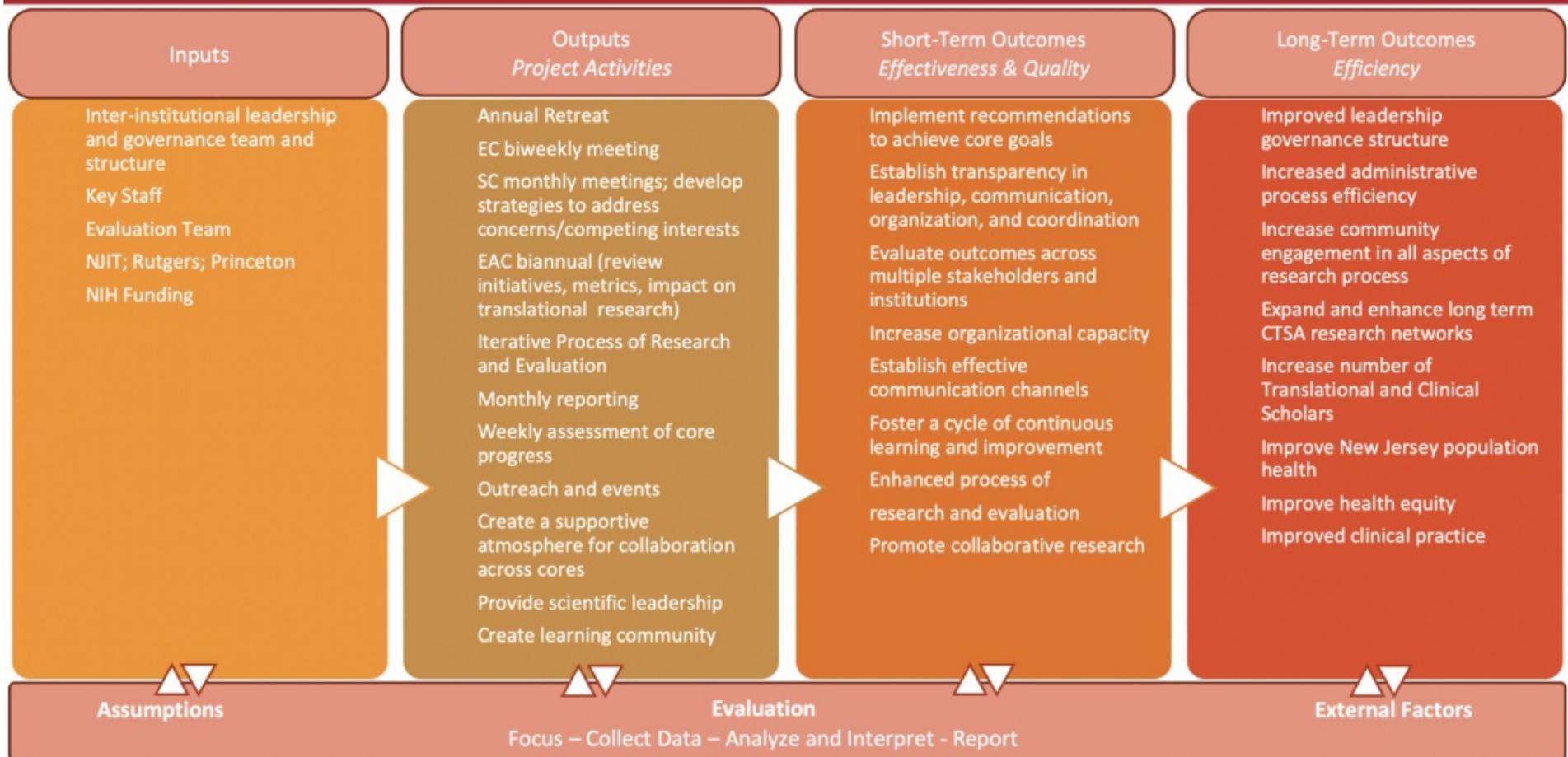






Eder, M. M., Carter-Edwards, L., Hurd, T. C., Rumala, B. B., & Wallerstein, N. (2013). A logic model for community engagement within the Clinical and Translational Science Awards consortium: can we measure what we model?. *Academic medicine: journal of the Association of American Medical Colleges*, 88(10), 1430–1436. doi:10.1097/ACM.0b013e31829b54ae

preliminary administrative core logic model.



implementation evaluation frameworks.

RE-AIM framework

Reach

Efficacy or effectiveness

Adoption (by target staff, settings, or institutions)

Implementation

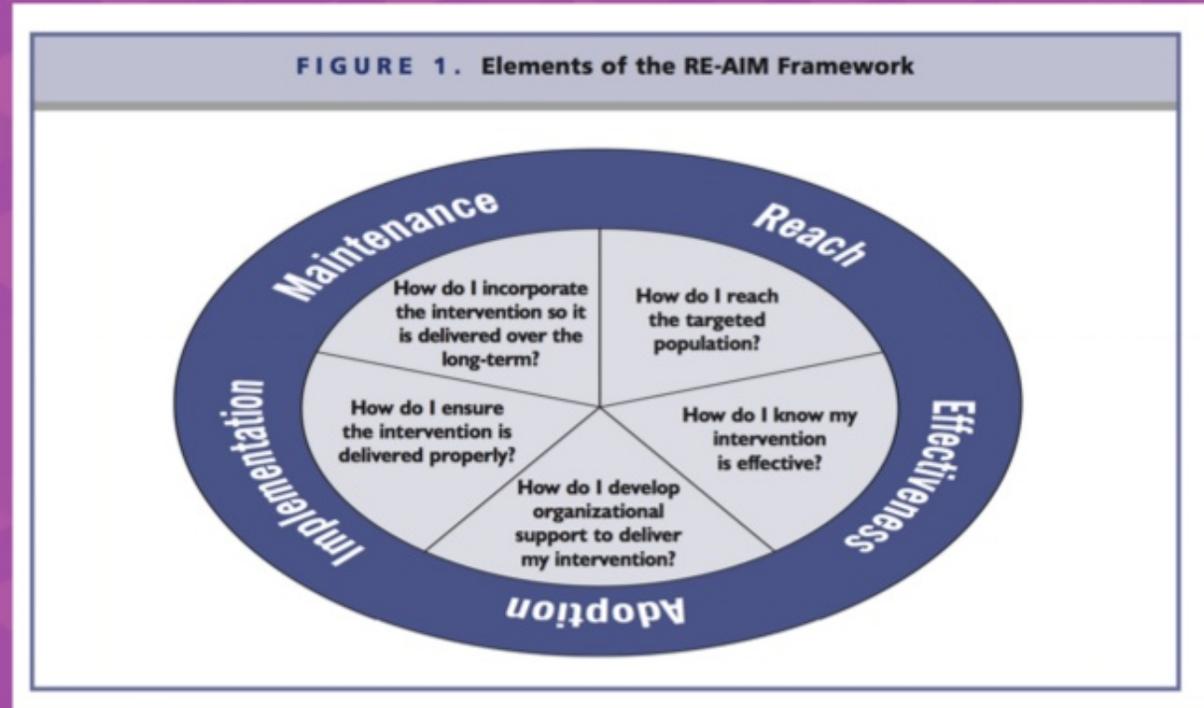
Maintenance



Glasgow, R. E., Vogt, T. M., & Boles, S. M. (1999). Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *American journal of public health, 89*(9), 1322–1327. doi:10.2105/ajph.89.9.1322

re-aim framework.

| Dimension | Original RE-AIM Definition |
|----------------|--|
| Reach | The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative |
| Effectiveness | The effect of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes |
| Adoption | The absolute number, proportion, and representativeness of settings and intervention agents who are willing to initiate a program |
| Implementation | At the setting level, implementation refers to the intervention agents' fidelity to the various elements of an intervention's protocol |
| Maintenance | The extent to which a program or policy becomes institutionalized or part of the routine |



CFIR: intervention characteristics.

I. INTERVENTION CHARACTERISTICS

| | | |
|---|------------------------------|--|
| A | Intervention Source | Perception of key stakeholders about whether the intervention is externally or internally developed. |
| B | Evidence Strength & Quality | Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes. |
| C | Relative advantage | Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution. |
| D | Adaptability | The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs. |
| E | Trialability | The ability to test the intervention on a small scale in the organization [8], and to be able to reverse course (undo implementation) if warranted. |
| F | Complexity | Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement |
| G | Design Quality and Packaging | Perceived excellence in how the intervention is bundled, presented, and assembled |
| H | Cost | Costs of the intervention and costs associated with implementing that intervention including investment, supply, and opportunity costs. |

Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science*, 4(1), 50.

CFIR: characteristics of individuals.

IV. CHARACTERISTICS OF INDIVIDUALS

| | | |
|---|---|--|
| A | Knowledge & Beliefs about the Intervention | Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention. |
| B | Self-efficacy | Individual belief in their own capabilities to execute courses of action to achieve implementation goals. |
| C | Individual Stage of Change | Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention. |
| D | Individual Identification with Organization | A broad construct related to how individuals perceive the organization and their relationship and degree of commitment with that organization. |
| E | Other Personal Attributes | A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style. |

CFIR: outer setting.

II. OUTER SETTING

| | | |
|---|------------------------------|---|
| A | Patient Needs & Resources | The extent to which patient needs, as well as barriers and facilitators to meet those needs are accurately known and prioritized by the organization. |
| B | Cosmopolitanism | The degree to which an organization is networked with other external organizations. |
| C | Peer Pressure | Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or in a bid for a competitive edge. |
| D | External Policy & Incentives | A broad construct that includes external strategies to spread interventions including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting. |

CFIR: inner setting.

III. INNER SETTING

| | | |
|---|-------------------------------------|--|
| A | Structural Characteristics | The social architecture, age, maturity, and size of an organization. |
| B | Networks & Communications | The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization. |
| C | Culture | Norms, values, and basic assumptions of a given organization. |
| D | Implementation Climate | The absorptive capacity for change, shared receptivity of involved individuals to an intervention and the extent to which use of that intervention will be rewarded, supported, and expected within their organization. |
| 1 | Tension for Change | The degree to which stakeholders perceive the current situation as intolerable or needing change. |
| 2 | Compatibility | The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems. |
| 3 | Relative Priority | Individuals' shared perception of the importance of the implementation within the organization. |
| 4 | Organizational Incentives & Rewards | Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary and less tangible incentives such as increased stature or respect. |
| 5 | Goals and Feedback | The degree to which goals are clearly communicated, acted upon, and fed back to staff and alignment of that feedback with goals. |
| 6 | Learning Climate | A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation. |

CFIR: process.

V. PROCESS

| | | |
|---|--|---|
| A | Planning | The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance and the quality of those schemes or methods. |
| B | Engaging | Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities. |
| 1 | Opinion Leaders | Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention |
| 2 | Formally appointed internal implementation leaders | Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role. |
| 3 | Champions | "Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]" [101](p. 182), overcoming indifference or resistance that the intervention may provoke in an organization. |
| 4 | External Change Agents | Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction. |
| C | Executing | Carrying out or accomplishing the implementation according to plan. |
| D | Reflecting & Evaluating | Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience. |

translational research.





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CTSA context.

- transform biomedical research
- speed translation
- engage communities
- train researchers

need quality evaluation to show program is well implemented, efficiently-managed and effective

data

cores, leads, staff, ALL engaged, responsive and in agreement with process

Common Metrics

Beyond Common Metrics

NJ ACTS Planning

Core Metrics

TL1 & KL2

NIH common metrics.

- collect and report data annually in August
- incorporate a component of RBA by including a "turn-the-curve" plan with each common metric report
- Use hub-specific strategies to engage in performance management practices to improve the values for each of the common metrics over time

while common metrics are necessary, they are not sufficient for high-quality and meaningful evaluation





careers in clinical & translational research.

The purpose of this metric is to measure and develop strategic management plans to enhance the extent to which CTSA Program hubs and the Consortium as a whole are training and supporting scientists to remain engaged in clinical and translational research into the future



informatics common metric.

The purpose of this metric is to Improve the interoperability of data within multiple systems by making the data adhere to the FAIR data principles to ultimately enable rich machine readable data.

This common metric will improve local as well as network capacity to efficiently use data to conduct research. Specifically, the metrics on different data types will aid local hubs in prioritizing additions to their data repositories. Improving the CTSA Program's clinical research data ecosystem can enhance the effectiveness of collaborative initiatives within and outside of the CTSA Program to provide tools to identify patient cohorts.



median IRB review duration.

The purpose of this metric is to measure IRB duration and develop strategic management plans, including collaborations, to shorten the time it takes to receive IRB approval. Long IRB review duration can delay study start, prolonging the time until benefits of clinical and translational science findings can be realized.



pilot funding publications and subsequent funding.

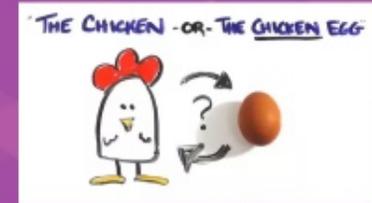
The purpose of this metric is to measure and develop strategic management plans to ensure that important findings from research studies supported by the CTSA Pilot Programs are being disseminated in the scientific literature.



median accrual ratio metric.

The purpose of this metric is to estimate the current accrual ratio for clinical trials in order to enhance our ability to develop performance interventions that increase actual participant accrual into clinical trials within the planned time period

beyond the CMI.



Common metrics compare high-level program performance

What explains the differential in program performance?

Need to consider causal mechanisms that connect program inputs to program outcomes via specific actions/activities implemented

NJ ACTS evaluation planning process.

- Determine goals, objectives, & scope of evaluation
- Formulate set of focal questions for evaluation
- Develop logic model collaboratively decide on most useful framework for guiding the evaluation
- Identify a set of standard data collection instruments and measures to be employed
- Designate responsibilities for data collection, analysis, and reporting
- Determine sensible timeline and list of deliverables

core-specific metrics.

Breaking the overall objectives of the NJ ACTS Hub into a network of cores allows the hub to leverage expertise and resources to divide desired outcomes into achievable, measurable units. Cores allow the hub to support a wide range of clinical and translational research.

From an evaluative stand point, cores should be measured using a "value added" approach, where metrics should reflect a core's progress on individual aims, "value added" to the core, and "value added" to the NJ ACTS Hub as a whole.

Core
B

Core
C

Core
D

Core
E

Core
F

Core
G

Core
H

B1: bioinformatics core.

AIMS

Integrate data from clinical research sources

Enhance informatics to foster rapid deployment of findings into practice

Augment analytic capabilities

Link science of informatics to workforce training

METRICS

Establish a CRDW

Data Integration (# EHR's, patient records, and research data sets)

Support for Clinical Research (# studies using CRDW or informatics tools)

Research Outcomes (# publications and support interventions)

C1: community engagement core.

AIMS

Engage community stakeholders in research

Facilitate knowledge transfer and disseminate engagement strategies

METRICS

Number of...

- 1. faculty recruited**
- 2. thematic retreats**
- 3. pilot funding proposals**
- 4. extramural peer-reviewed applications**
- 5. clinical scholars promoted**
- 6. hubs implementing team science**

C2: collaboration and multi-disciplinary team science core.

AIMS

Expand and assess team science in translational research

Bolster multi-disciplinary team science training

METRICS

Number of...

1. committed community stakeholders
2. new or enhanced partnerships
3. grants including community engagement
4. media site downloads
5. papers
6. presentations

D1: translational workforce development core.

AIMS

Provide training to advance translational research

Advance workforce through evaluation, implementation, and dissemination

METRICS

Number of...

1. personalized training plans
2. personalized and programmatic assessments
3. program participation and completion rates
4. translational science certificates and degrees
5. pubs, presentations, citations
6. grant submissions, funding, and pilot funds
7. promotions and tenure
8. Etc.

D2: pilot translation & clinical studies program core.

AIMS

Advance team research to promote novel methodologies in translational medicine

Foster interdisciplinary research to support novel hypotheses

Inspire new methodologies to assess processes to improve outcomes

METRICS

Number of...

1. applications received and funded
2. applications using NJ ACTS Cores
3. external grant submissions based on pilot data
4. publications supported by pilot grants

Evidence of collaboration after conclusion of pilot grant

E1: biostatistics, epidemiology, and research design core (BERD).

AIMS

Facilitate the translation of science into practice

Promote development, implementation, and sharing of study design

Provide educational opportunities to researchers

METRICS

For consultations number of...

1. consultations per year
2. time between request and meeting
3. hours allotted per consultation
4. peer-reviewed publications post-consultation
5. professional presentations post-consultation

For training, number of...

1. BERD-provided training sessions
2. trainees in each session
3. clinical scholars participating in methods courses

For methodological developments, number of...

1. submissions resulting from pilot work
2. submissions funded
3. funded and indirect dollars from pilot work
4. mini-grant recipients receiving external funding

E2: regulatory knowledge and support core.

AIMS

Expand infrastructure to provide regulatory support

Broaden training of investigators and clinical researchers

METRICS

IRB review duration

Number of...

1. sponsored trials
2. investigator-initiated trials
3. IRB revisions/study protocol
4. IND/IDE exemptions
5. FDA submissions
6. clinicaltrials.gov, non-compliance
7. consultations
8. trained interns joining CTSA
9. participants in in-person training

Confidential user feedback via survey

F1: integrating special populations core.

AIMS

Develop a shared focus on special populations in a full range of research strategies

Enhance linked data resources to expand translational research on special populations

METRICS

Number of...

1. proportion of studies incorporating individuals at either end of life
2. projects include a stretch goal % of health-disparities populations
3. studies including environmental and social health determinants
4. policy changes prompting research across special populations

F2: participant and clinical interactions core.

AIMS

**Establish the Trial Accelerator
and Recruitment Office**

**Optimize efficiency in
conducting clinical studies**

METRICS

Timeline Tracking

1. regulatory milestones
2. budgeting/contracting milestones
3. first subject on trial
4. achievement of recruitment goal-time

Clinical Trial Activity

1. Number of CTSA-wide trials, protocol violations, registered studies
2. compliance on registration and reporting

Increasing Investigator Participation

1. number of new PIs across rank and specialty
2. PI utilization of CRU infrastructure
3. number of initiated human-subjects research

Special Populations

1. number of studies in special populations
2. recruitment of subjects from special populations

Number of publications

G1: liaison to trial innovation center.

AIMS

Expedite initiation of clinical studies

Develop a core Liaison Team to increase successful site participation and network studies

METRICS

Change

- 1. policy revisions facilitating study start-up**
- 2. use of CTSA network resources**

Study Start-Up

- 1. multi-institutional network studies**
- 2. time from receipt to study start-up**

Quarterly NJ ACTS surveys with metrics regarding service efficacy

G2: liason to recruitment innovation center.

AIMS

Increase success through
Individualized Recruitment
Plans

Foster recruitment of vulnerable
populations

METRICS

Studies meeting recruitment
milestones

Time from initiation to subject
recruitment

Participant recruitment
pathways

Quarterly NJ ACTS surveys with
metrics regarding service
efficacy

H1: biomarker discovery.

AIMS

Assay definition

Assay implementation

METRICS

Number of...

1. consultations with investigators
2. pilot assays performed
3. diverse diseases considered
4. departments/institutions
5. assays in development
6. preclinical assessment assays
7. 520k device submissions
8. clinical trials
9. participants enrolled
10. manuscripts submitted

Amount of external funding received

H2: machine learning.

AIMS

Discover patterns in clinical data

Compare clinical data to neuro-computational measures

METRICS

Number of...

1. patient records and identified features
2. patients and tasks tested

Cross-validated goodness-of-fit models

TL1: institutional training core.

AIMS

Provide translational training
Break down barriers and create bridges

Identify new opportunities for research collaboration

Provide opportunities to address key translational/clinical research issues

Create an environment in which our basic/translational and clinical trainees can work together

METRICS

Program activities completed
Progression in course work
Number/quality of publications
Number/quality of internal presentations
Attendance/presentation at national/international science conferences
Individual fellowships, honors, and awards
Time to thesis presentation/degree
Post-graduate positions/career
General satisfaction of student upon completion of the program

KL2: institutional career development core.

AIMS

Recruit and retain committed, talented scholars, to careers in the translational sciences with an eye on the need to recruit URMs

Develop an individualized career development plan (ICDP) to allow each scholar to accelerate their career in the translational sciences and move towards independence

Construct a curriculum with the learning tools essential for translational research

Organize an Academy of Mentors as a multi-disciplinary team to develop translational research+ collaborations

Provide NJ ACTS and CTSA network a trained workforce

METRICS

Grant activity

Publications

Completion of courses or training events

Participation in professional organizations/meetings

Awards



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what's next.

We need to begin a conversation about evaluation and begin the process of planning

This requires everyone to participate and contribute thoughtfully so we have the best possible outcome from the evaluation

**Questions
for You**

**Questions
for Us**

**To be
continued**

RU ready for the evaluation.

Do you already have a good sense of what you may want to learn from the evaluation?

Do you have a sense of how you would use the findings from the evaluation to improve the program and activities?

Who is going to be involved in providing data for the evaluation?

What resources do you have available to support the evaluation?

questions for us.





thank you.

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citations.

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