Frameworks/Approaches used in Clinical Settings, Part 1 (Re-Aim and CFIR)

Margaret Handley, PhD MPH

November 7, 2013

Outline

1. Introduction to Evaluation Thinking for Designing, Implementing and Evaluating Interventions in Clinical and Public Health Settings

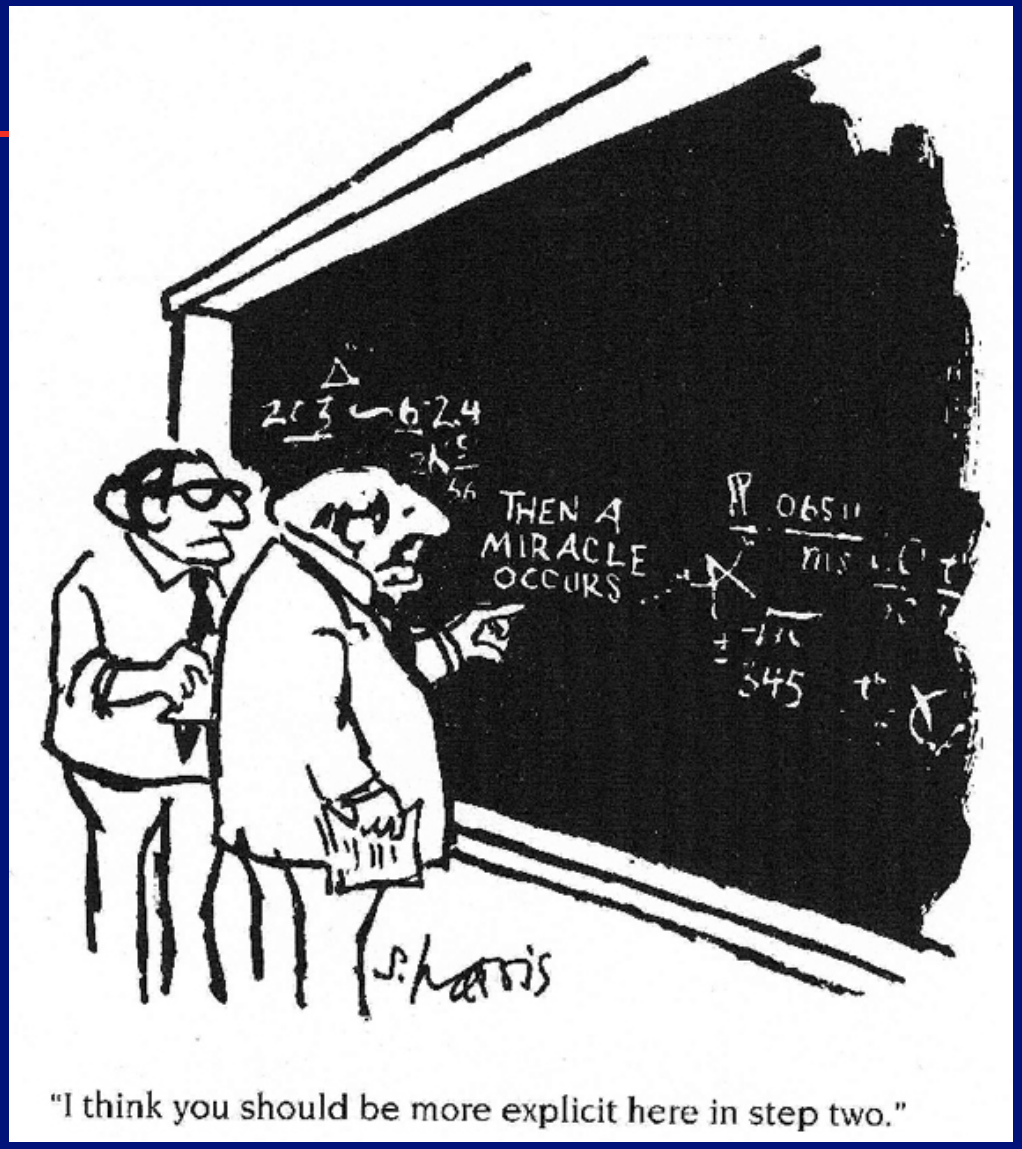
2. RE-AIM Framework and Examples

3. Consolidated Framework for Implementation Research (CFIR) and Examples

1. Evaluation Thinking and Implementation

Evaluation Thinking Can Improve Interventions and Translation of Research into Practice

Can identify 'active' ingredients, adaptive processes, and non-essential components

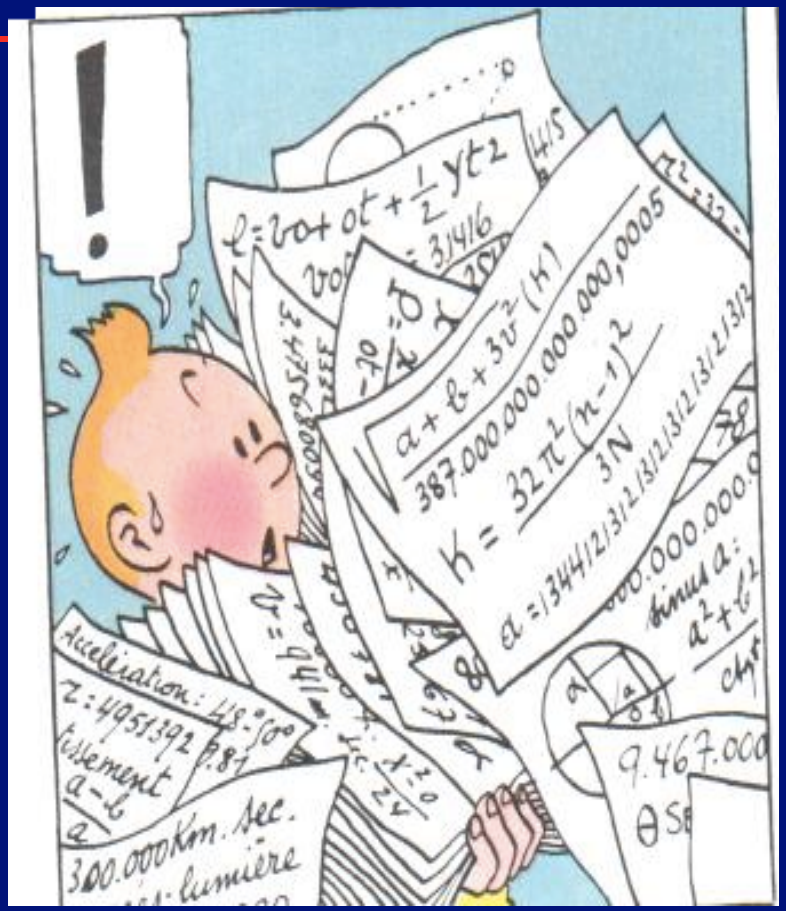


"I think you should be more explicit here in step two."

Importance of Bringing Evaluation Thinking into Planning

To allow for modifications prior to full-scale implementation and subsequent evaluation, i.e.
–'Evaluability' assessment

To apply a realist approach –
identify how, and for whom,
a program might work, as well as
understanding the implementation
of the program as proposed



Leviton LC, et al. 2010. Evaluability Assessment to Improve Public Health Policies, Programs, and Practices. Annual Rev. Public Health. 31:213-233. Pawson, R, Tilley N. Realistic Evaluation. Thousand Oaks, CA: Sage Publications; 1997. **Adapted from Gaglio 2012.

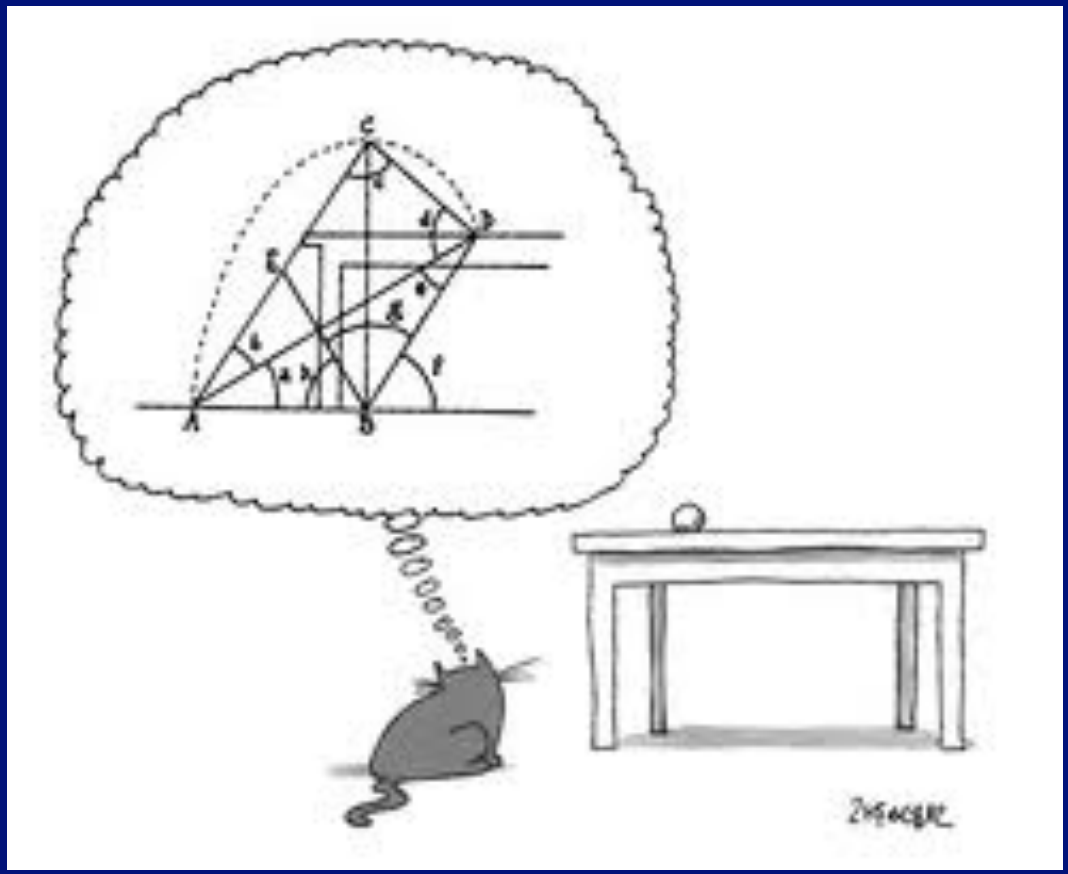
Role of Evaluation

– to identify, describe, and understand the context in which a program or policy is implemented in order to understand outcomes.

Intuitive Goal	Evaluation Concept
Am I making a difference?	Describe/Summarize
What have we done?	Quality; Importance; Accountability; Cost-effectiveness
How well have we done it?	
What is the value of it?	Effectiveness; Social equity
How effective have we been, and for whom?	Evidence-based planning; Outcomes-focusing
What are we going to do now that we have this info?	

Evaluation thinking– How to get from here….

To more like here….modeling implementation



In General…..Implementation Frameworks

Provide a way of thinking about a study/project/ implementation

Guide timing of stages of intervention implementation

Develop a plan for formative evaluation

Select and tailor interventions to promote the use of evidence [e.g. Intervention mapping]

Guide development of hypotheses to test

Facilitate interpretation re: influences and meanings

Identify concepts that may be important in data analysis

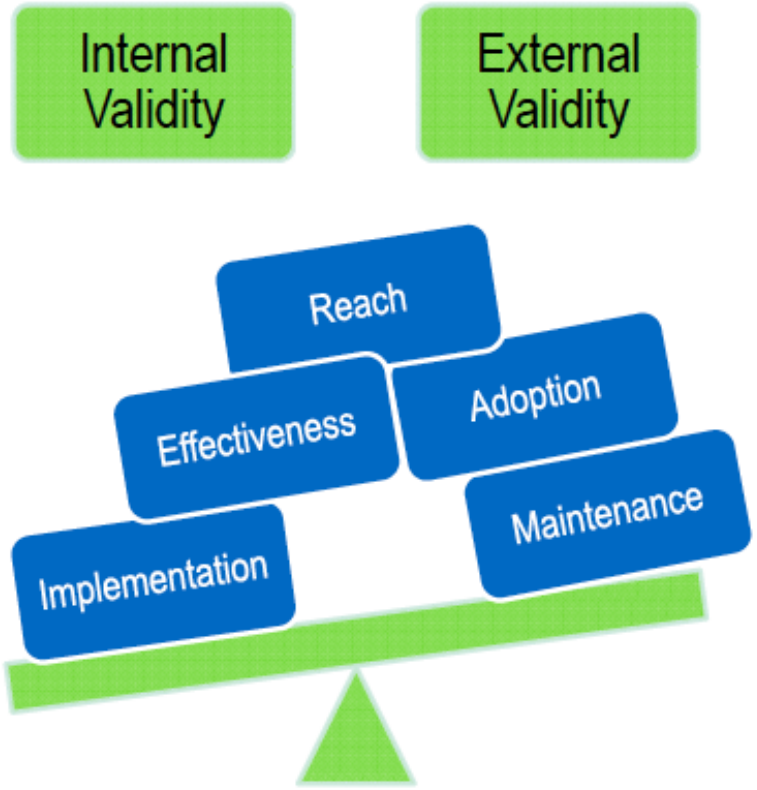
Help with measurement

Identify boundaries around the project/study

Provide a framework for summarizing, reporting findings

2. RE-AIM

RE-AIM Framework



Glasgow, Vogt & Boles, Am J Public Health. 1999 Sep;89(9):1322-7

RE-AIM TO HELP PLAN, EVALUATE, AND REPORT STUDIES

R	→ Increase	Reach
E	→ Increase	Effectiveness
A	→ Increase	Adoption
I	→ Increase	Implementation
M	→ Increase	Maintenance

Glasgow, et al. ***Ann Behav Med*** **2004;27(1):3-12**

http://www.re-aim.org/

UNDERLYING PREMISE OF RE-AIM

Indicators of internal and external validity will enhance the evidence base for effectiveness of interventions in real world settings

PURPOSES OF RE-AIM

- To broaden the criteria used to evaluate programs to include external validity
- To evaluate issues relevant to program adoption, implementation, and sustainability
- To help close the gap between research studies and practice by:
  - Informing design of interventions
  - Providing guides for adoptees
  - Suggesting standard reporting criteria

RE-AIM Guidelines for Developing, Selecting, and Evaluating Programs and Policies Intended to Have a Public Health Impact

RE-AIM ELEMENT	GUIDELINES AND QUESTIONS TO ASK
REACH Percent and representativeness of participants	Can the program attract large and representative percent of target population? Can the program reach those most in need and most often left out (i.e., the poor, low literacy and numeracy, complex patients)?
EFFECTIVENESS Impact on key outcomes, quality of life, unanticipated outcomes and subgroups	Does the program produce robust effects across sub-populations? Does the program produce minimal negative side effects and increase quality of life or broader outcomes (i.e., social capital)?

Gaglio B and Glasgow RE. Evaluation approaches for dissemination and implementation research In Handbook of Dissemination and Implementation Research. Editors: R Brownson, E. Proctor, G Colditz. Oxford Univ. Press. 2012.

RE-AIM Guidelines for Developing, Selecting, and Evaluating Programs and Policies Intended to Have a Public Health Impact (cont.)

RE-AIM ELEMENT	GUIDELINES AND QUESTIONS TO ASK
ADOPTION Percent and representativeness of settings and staff that participate	Is the program feasible for majority of real-world settings (costs, expertise, time, resources, etc.)? Can it be adopted by low resource settings and typical staff serving high-risk populations?
IMPLEMENTATION Consistency and cost of delivering program and adaptations made	Can the program be consistently implemented across program elements, different staff, time, etc.? Are the costs—personnel, up front, marginal, scale up, equipment costs—reasonable to match effectiveness?

RE-AIM Guidelines for Developing, Selecting, and Evaluating rograms and Policies Intended to Have a Public Health Impact (cont.)

RE-AIM ELEMENT	GUIDELINES AND QUESTIONS TO ASK
MAINTENANCE Long-term effects at individual and setting levels, modifications made	Does the program include principles to enhance long-term improvements (i.e., follow-up contact, community resources, peer support, ongoing feedback)? Can the settings sustain the program over time without added resources and leadership?

http://www.re-aim.org/forms/re-aim_framework_constructs_checklist.pdf

Examples of RE-AIM in Design/Evaluation

1. Diabetes Self-Management Program

Q: Does the diabetes self-management program attract who we want it to?

Q: Was it effective – for who? What outcomes?

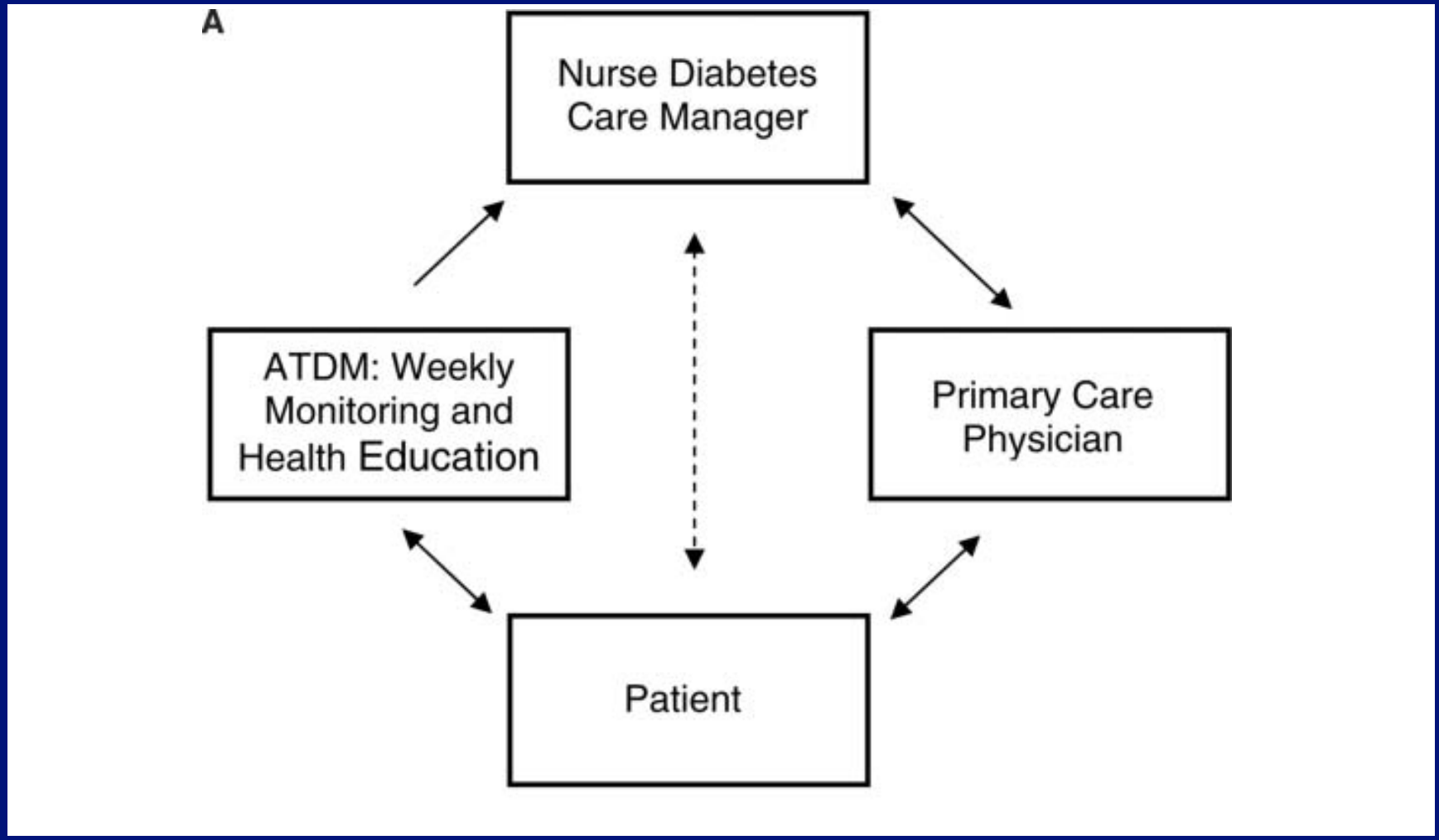
Q: Did we reach those with limited resources?

Q: How much did it cost to do this?

Schillinger, et al 2009; Handley et al 2007

IDEALL STUDY RE-AIM Design/Evaluation Qs

Examples of RE-AIM in Design/Evaluation-IDEALL



IDEALL STUDY RE-AIM Design/Evaluation Qs

Area	Evaluation questions Included
Reach (setting, sample, recruitment)	What percent of potentially eligible participants a) were excluded, b) took part and c) how representative? WHO? ACROSS WHAT CRITICAL DOMAINS? LANG/LITERACY?
Efficacy or Effectiveness	What impact on a) all participants; b) on process intermediate, and primary outcomes; and c) on both positive and negative outcomes? WHAT HAPPENED? WHY?
Adoption	What % overall and within settings and populations (e.g.,clinics /clinicians/pts.) was there differential adoption? were differences meaningful? WHERE THE MOST IMPACT? THE LEAST IMPACT?
Implementation	**Were** intervention components delivered as intended? FIDELITY, MINUMUM SET OF COMPONENTS?
Maintenance	Long-term effects? who dropped-out? were different intervention components continued? What was modified?

IDEALL STUDY RE-AIM REACH Evaluation Qs

1. Health system/clinic	Proportion of CHNSF clinics participating in IDEALL among clinics approached	CHNSF data on clinics	Four of six clinics (67%), including two community and two hospital-based primary care clinics
2. Clinician	a. Proportion of clinicians participating in IDEALL among clinicians approached	CHNSF data on patients and their clinicians; IDEALL data	a. 122 of 126 eligible clinicians contacted for reviewing patient eligibility sheets completed them (97%)
	b. Proportion of clinicians with ≥1 patient enrolled in IDEALL among those with eligible patients	IDEALL data	b. 102 of 122 clinicians had one or more patient enroll in IDEALL (84%)
3. Patient	a. Proportion of database-eligible patients at the four study clinics among all nine CHNSF clinics	CHNSF data on patients with HA1c ≥8%	a. 1,307 of 2,261 database-eligible patients were affiliated with the four study clinics (58%)
	b. Proportion of clinician-eligible patients at the four study clinics, and reasons for clinician-determined ineligibility	CHNSF data on patients with no HbA1c exclusion combined with clinician eligibility criteria at the four clinics	b. 1,390 of 1,612 potentially eligible patients were clinician eligible (86%) and 222 patients were ineligible (14%) for: incorrect clinician assigned, no longer clinician, or patient moved (8%); patient

Example 2-Plan for Open Notes Evaluation

Table 1 Summary of RE-AIM framework [6] for Evaluation of OpenNotes

Domain	Methods	Outcomes
Reach	Administrative data re: PCP characteristics and panel information; Portal use data; Surveys of patients/PCPs	PCP and patient demographics PCP workload, sessions, visits PCP portal statistics: number patients on portal, number of OpenNotes Patient portal statistics: registered users, logons
Effectiveness	PCP pre- and post- intervention survey, interviews Patient pre- and post- intervention survey PCP/patient portal data	PCP and patient preferences about continuation of OpenNotes PCP reported burden from OpenNotes Patient measures: Perceptions of Benefits/Risks of OpenNotes, ACES Quality of patient-doctor relationship subscale, Perceived Efficacy in Patient-Physician Interactions (PEPPI) short form questionnaire, PCP portal and telephone messages Patient portal: number of notes viewed
Adoption	System level data PCP practice data	Description of systems, PCP practices, proportions using OpenNotes PCP panel size, registered portal users
Implementation	Process data, PCP surveys and interviews, non-respondent surveys	PCP expectations, burden, barriers to participation; detailed descriptions of PCP experiences, comments, recommendations
Maintenance	PCP/system responses	Decision to continue or discontinue OpenNotes

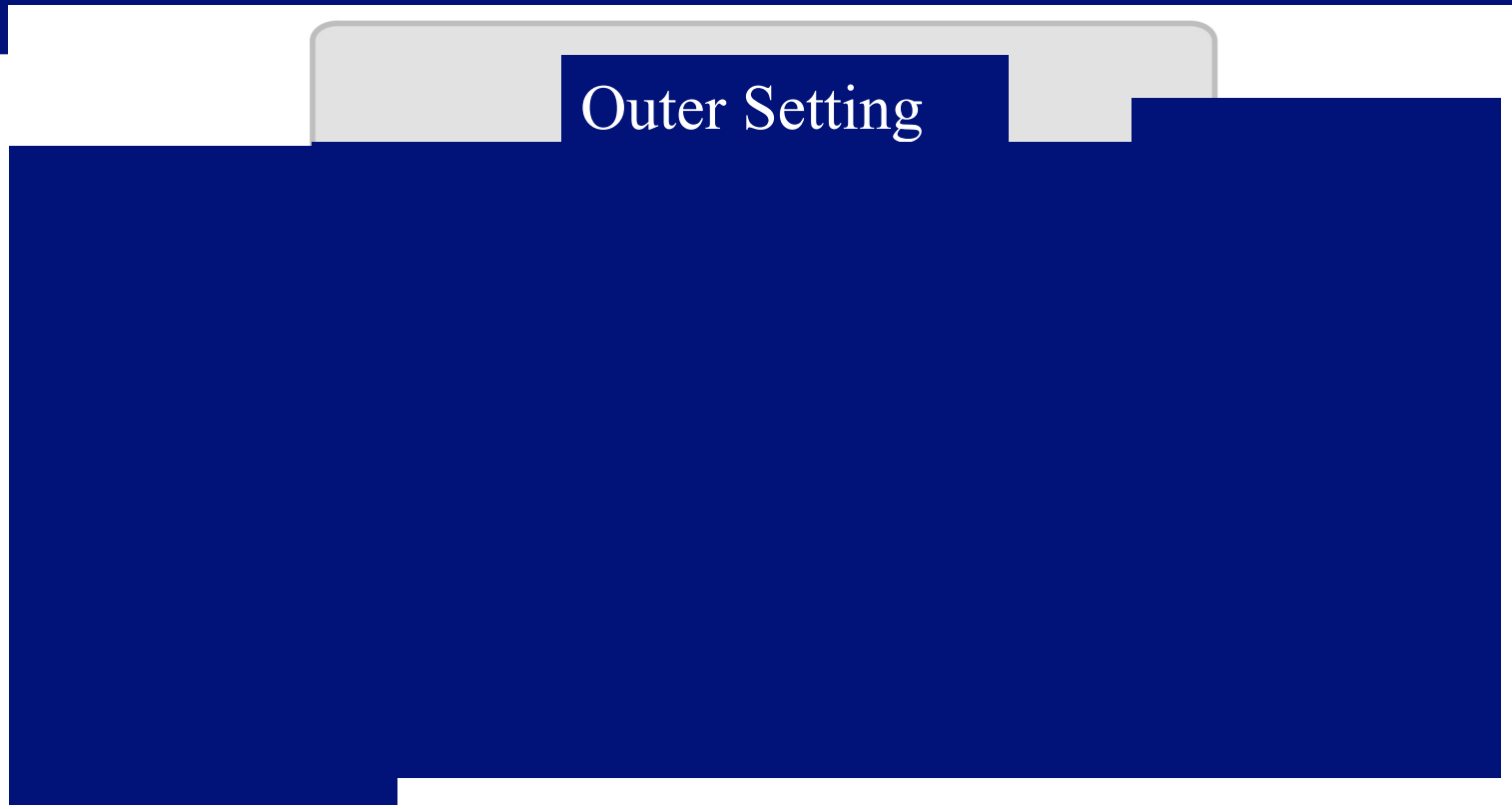
Levelle SG 2012

3. CFIR- Consolidated Framework for Implementation

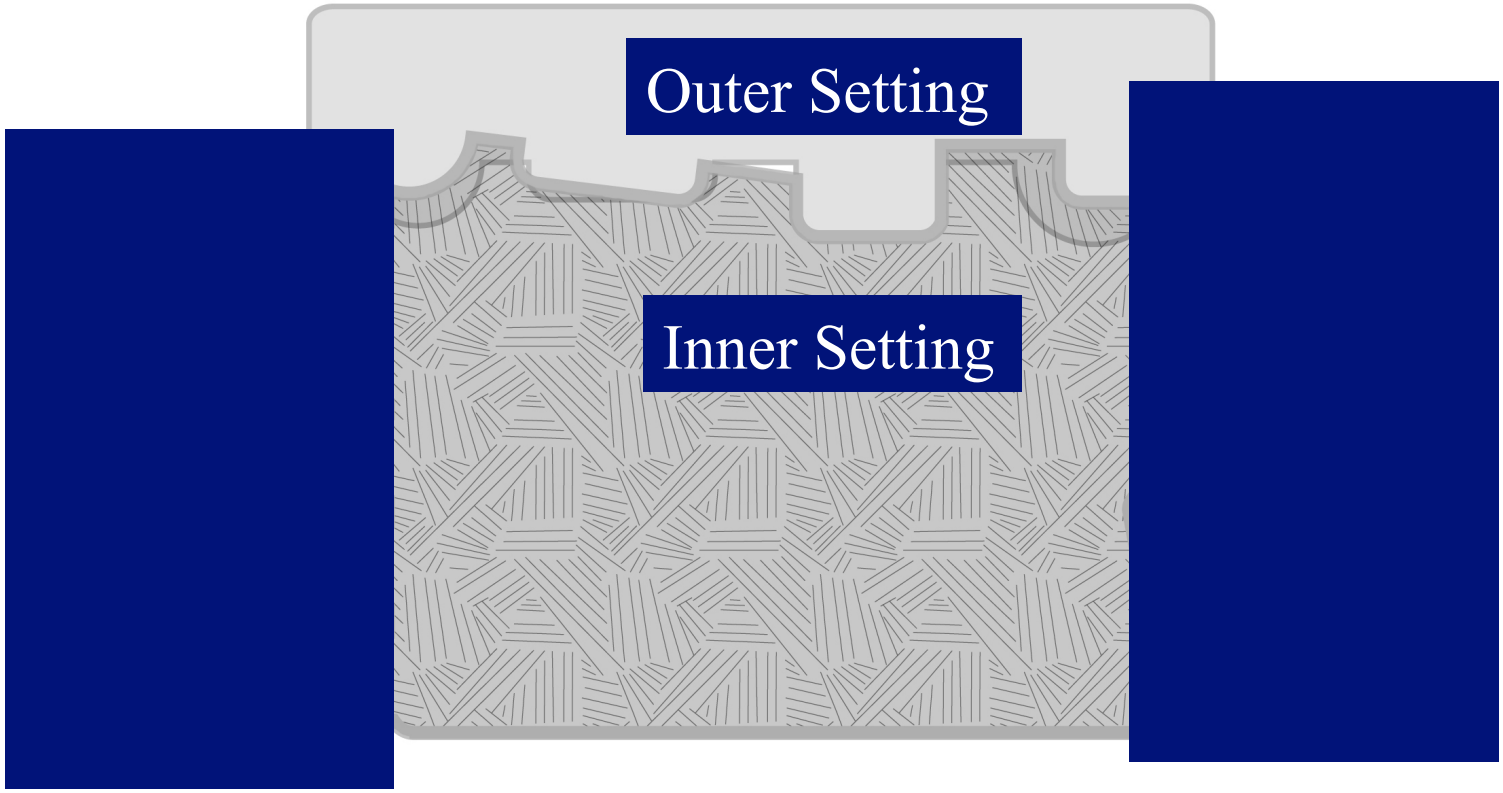
"A comprehensive practical taxonomy of constructs that have an established evidence base in the literature to enable implementation researchers to see further through the complex array of influences on implementation by bringing together constructs across many different scientific disciplines into a single framework for pragmatic and scientific application"

Damschroeder and Hagedorn, 2011

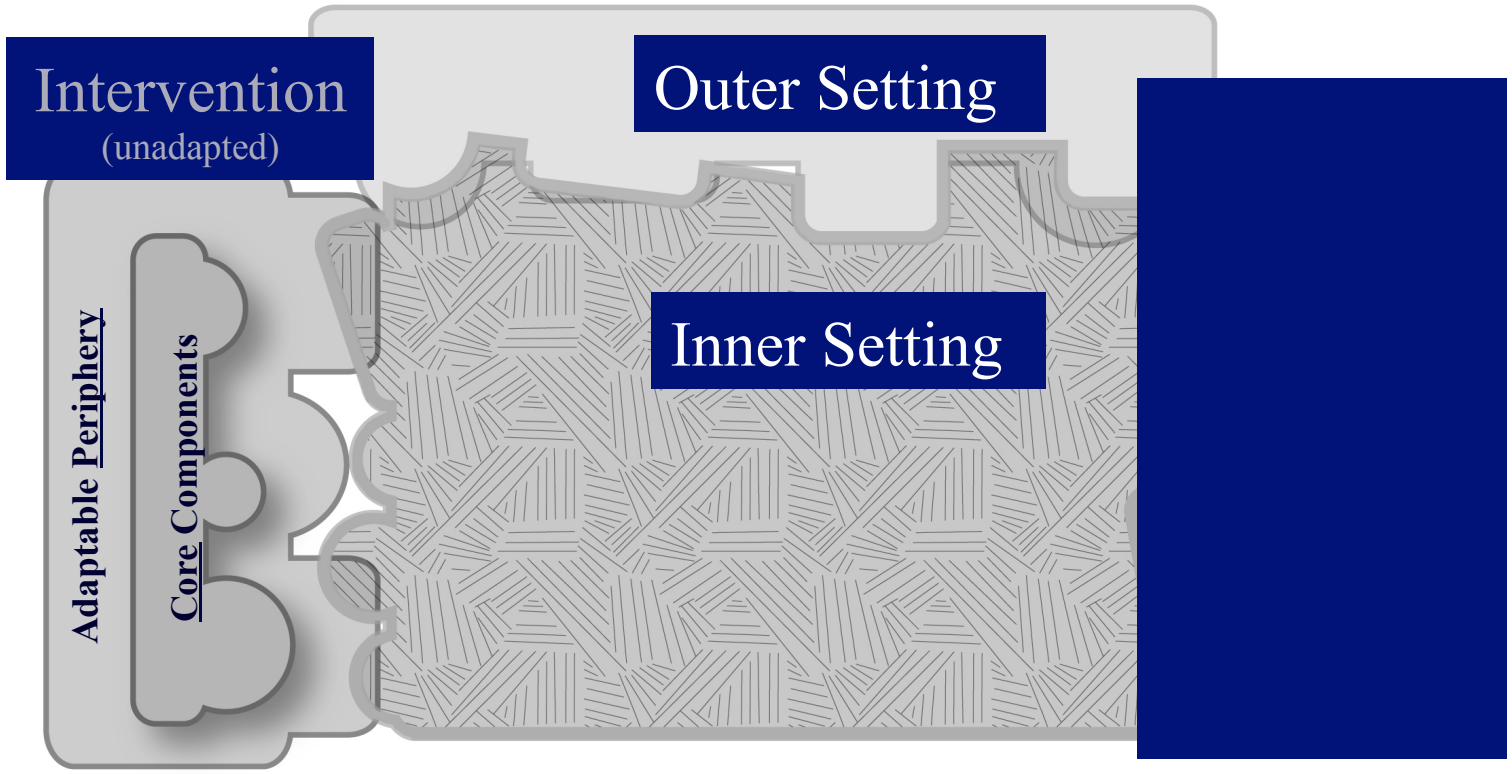
Consolidated Framework for Implementation Research (CFIR)



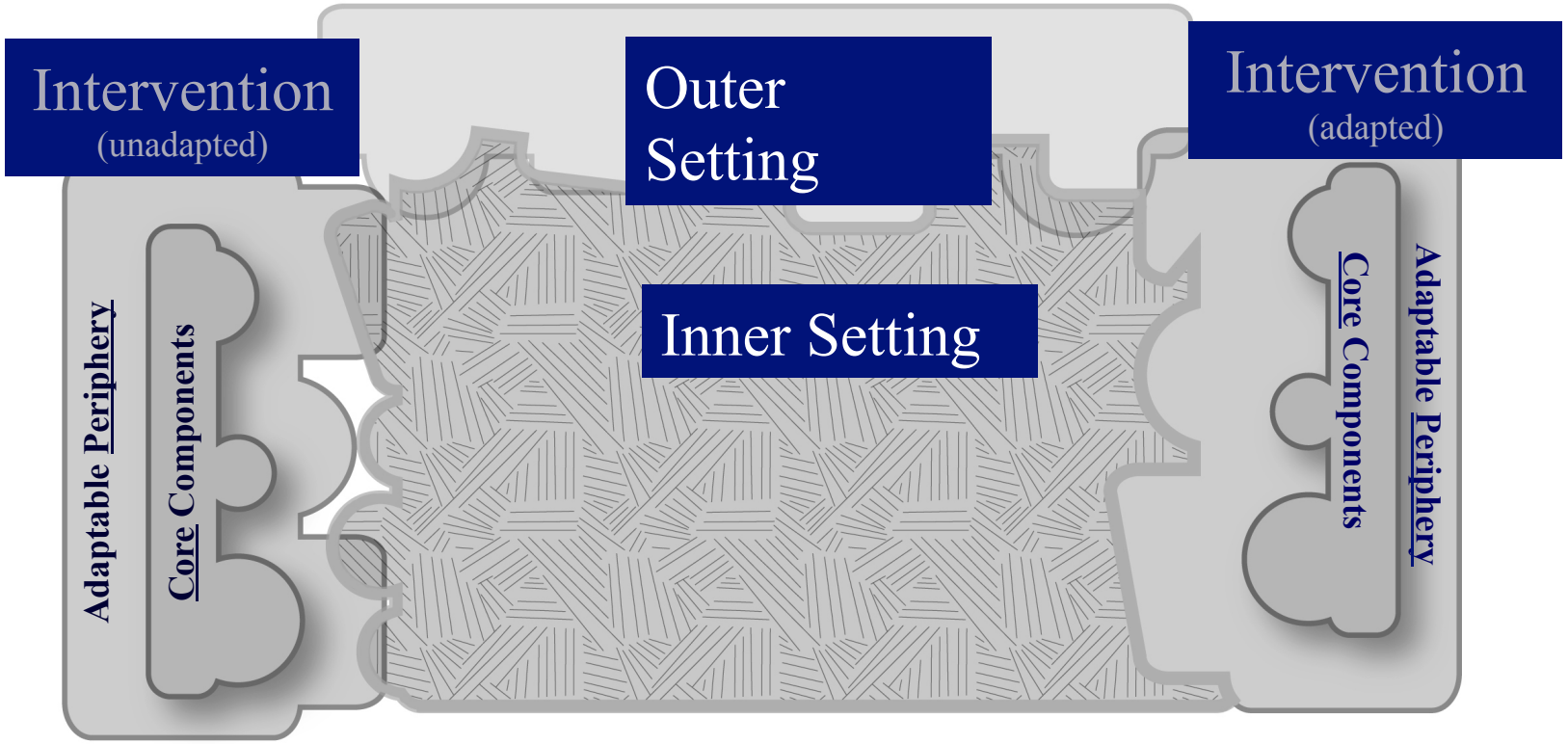
Consolidated Framework for Implementation Research (CFIR)



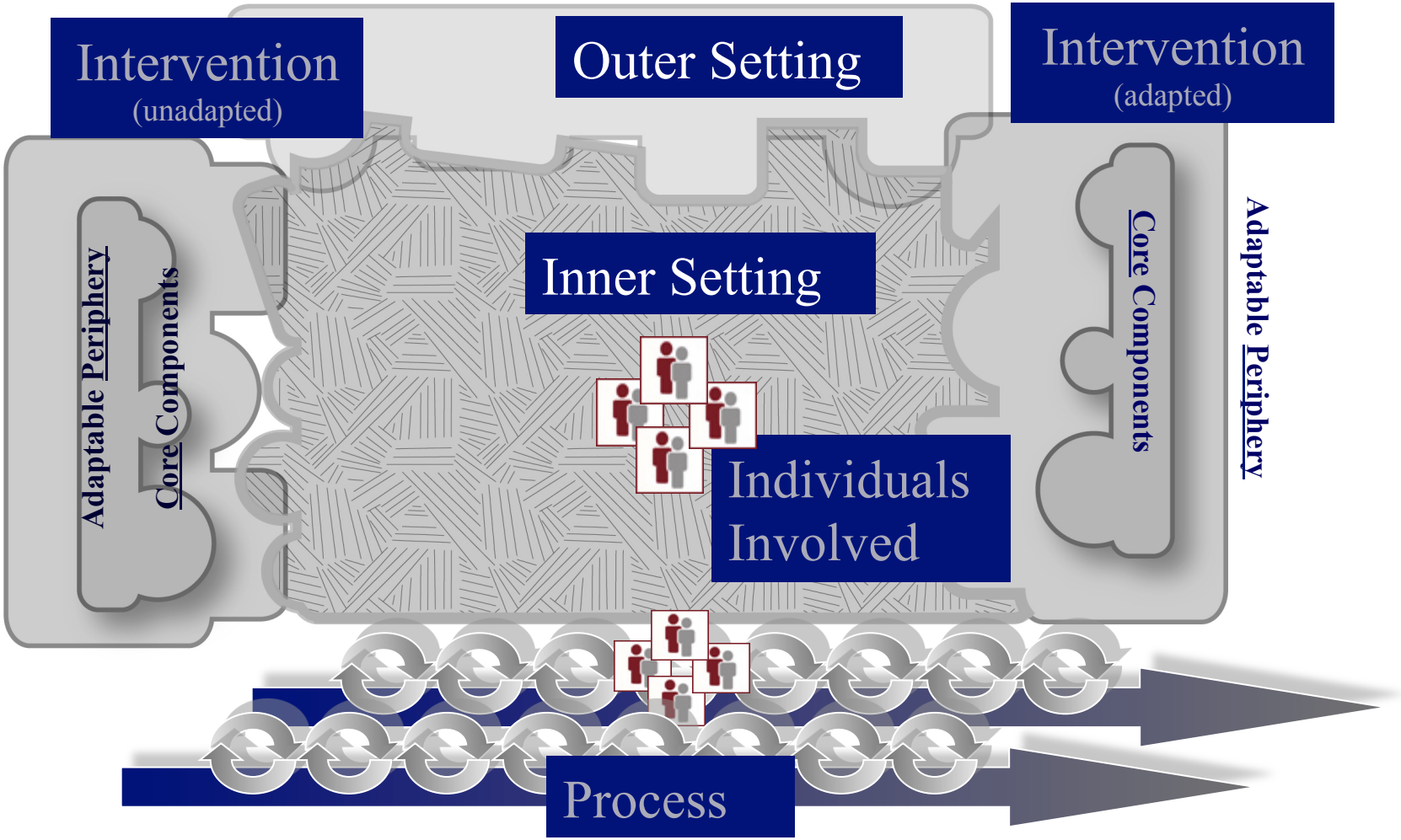
Consolidated Framework for Implementation Research (CFIR)



Consolidated Framework for Implementation Research (CFIR)



Consolidated Framework for Implementation Research (CFIR)



CFIR…

- Embraces, consolidates, and standardizes key constructs from multiple theories
- Agnostic to specific theories
- Provides a pragmatic structure for evaluating complex implementations
- Helps to organize findings across disparate implementations
- Paves the way for cross-study research

CFIR Construct Definitions

	Topic/Description	Short Description
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.

CFIR Construct Definitions

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.
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.

CFIR Construct Definitions

Inner Setting continued

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.
E	Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.
1	Leadership Engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.
2	Available Resources	The level of resources dedicated for implementation and on-going operations including money, training, education, physical space, and time.
3	Access to knowledge and information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.
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 Construct Definitions

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.

CFIR Application

- Consists of 39 individual constructs
- Cannot use them all in every study
- A priori assessment of which constructs to include
    - Modifiable & non-modifiable constructs
- Retrospective ‘fit’ of CFIR constructs
    - Identify gaps, explore variation, develop generalizations
- Determine levels at which each construct may apply
  e.g., teams, departments, clinics, region

CFIR Qualitative Study Barriers and Facilitators to Implementing the VHA Tele-Retinal Imaging Program

2.a. V/F: What is your role in the VISN/clinic? Background Information & Characteristics of Individuals

[*Follow-ups*]

1. What is your job title?
2. To whom do you report (position/title, not name)?
3. What are your main responsibilities and locations?
4. What is your role in the Tele-Retinal Imaging Program specifically? Knowledge & Beliefs about the Intervention*
5. How long have you been involved in the program?
6. VISN Coordinator: In regards to the tele-retinal screening program, is your position a collateral position or is it funded?

2.e. V/F: Thinking about the tele-retinal program specifically, what kinds of communications take place that are important for making the program work? Do you think some methods of communication are more effective than others? Networks & Communication*

2.d. V/F: At what stage of implementation is the Tele-Retinal program in at your VISN/facility? How do you think the program is going? Knowledge & Beliefs about the Intervention*

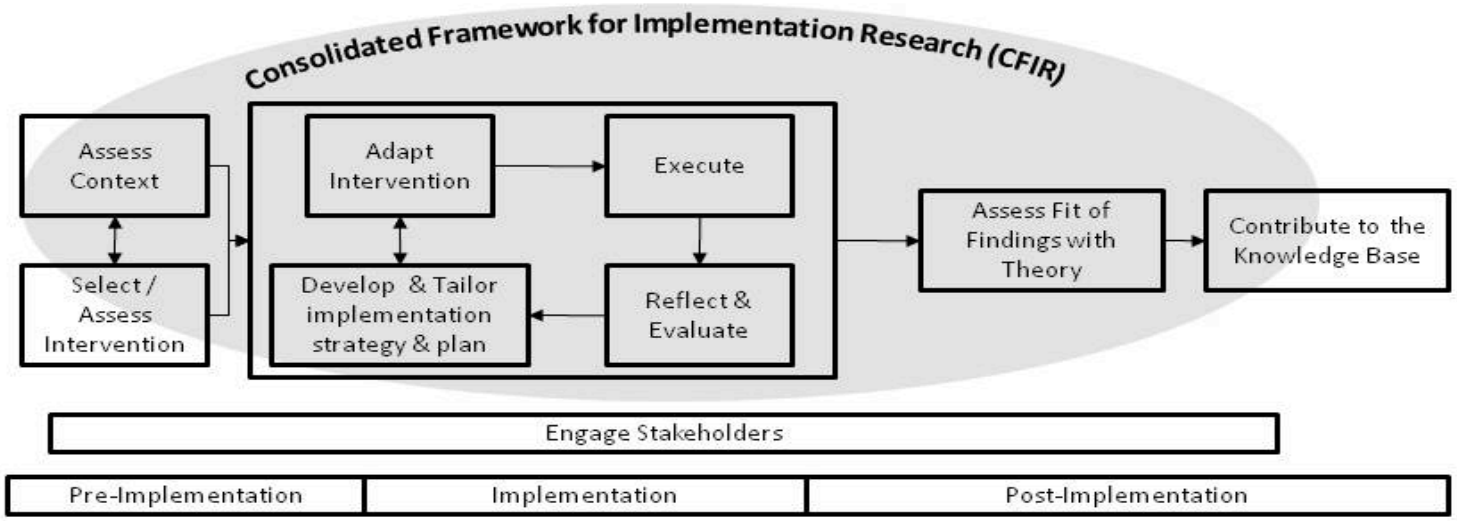
[*Probing*] Why do you say that?

[*Follow-ups*]

1. What are the program's goals?
2. To what extent is it meeting its goals?

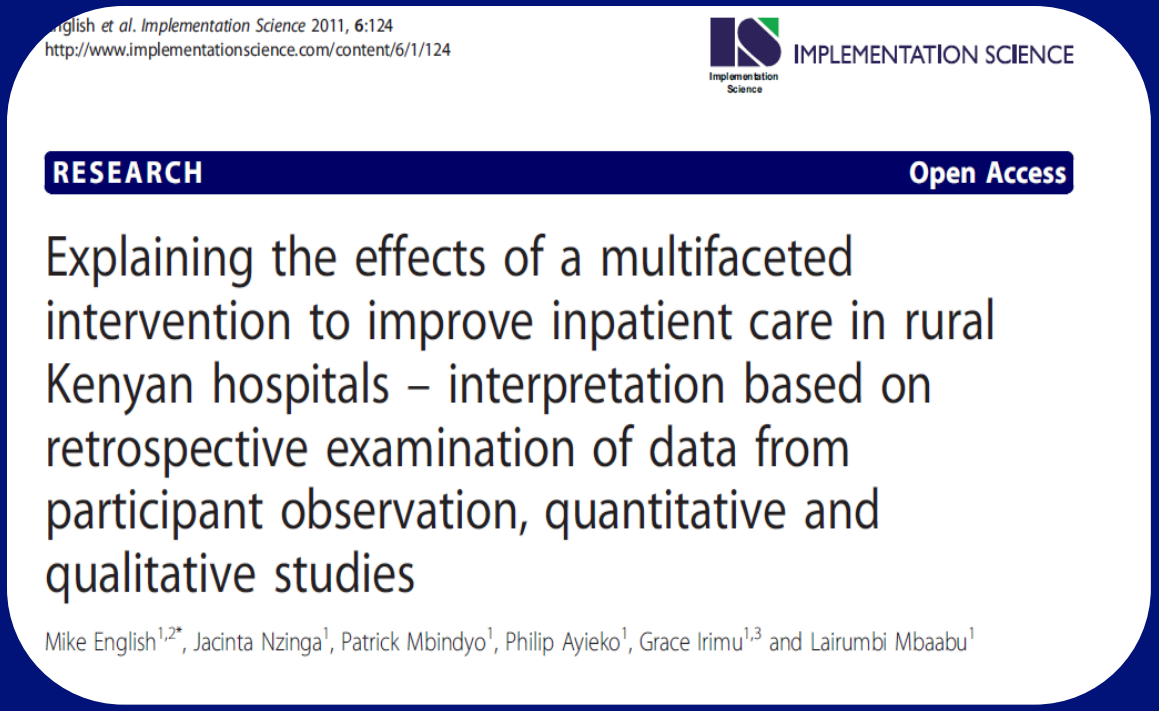
http://www.wiki.cf-ir.net/index.php?title=Main_Page

Framework for Applying CFIR



http://www.wiki.cf-ir.net/index.php?title=Main_Page

Example of Application of CFIR in Rural Kenya –



nglish et al. Implementation Science 2011, 6:124
http://www.implementationscience.com/content/6/1/124

IMPLEMENTATION SCIENCE

RESEARCH Open Access

Explaining the effects of a multifaceted intervention to improve inpatient care in rural Kenyan hospitals – interpretation based on retrospective examination of data from participant observation, quantitative and qualitative studies

Mike English[1,2*], Jacinta Nzinga[1], Patrick Mbindyo[1], Philip Ayieko[1], Grace Irimu[1,3] and Lairumbi Mbaabu[1]

"an ethnography of an intervention"

"a multi-method study with multiple parallel but linked strands of enquiry tackling an overarching question….

…why did performance vary so much between hospitals and between the full and partial intervention groups?"