Today’s Agenda

• Introduction to D&I Research (15 minutes)
• Development of Implementation Strategies (20 minutes)
• Measurement and Evaluation for Implementation (20 minutes)
• D&I Theories/Models/Frameworks (20 minutes)
• Study Design for D&I Research (15 minutes)
• Q&A (20 minutes)
Introduction to D&I Research
And Areas of Confusion

Definitions

*Translational Research* includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.
Definitions

• **Dissemination research** – scientific study of targeted distribution of information and intervention materials to a specific clinical practice or public health audience. The intent is to understand how best to spread and sustain knowledge and the associated evidence-based interventions.

• **Implementation research** – scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health.

• **Dissemination and Implementation (D&I) Research** – studies typically involves both interdisciplinary cooperation and trans-disciplinary collaboration, utilizing theories, empirical findings, and methods from a variety of fields not traditionally associated with health research. D&I research often includes significant and ongoing collaboration with stakeholders from multiple public health and/or clinical practice settings as well as consumers of services and their families/social networks.

Definitions

• **Efficacy** refers to the intervention’s ability to do more good than harm among the target population in an ideal setting (e.g., randomized clinical control trial).

• **Effectiveness** refers to the intervention’s ability to do more good than harm for the target population in a real world setting.

• **Evidence-based intervention**: The objects of dissemination and implementation are interventions with *proven* efficacy and effectiveness.
A Continuum: Diffusion-Dissemination-Implementation

<table>
<thead>
<tr>
<th>Diffusion</th>
<th>Dissemination</th>
<th>Implementation</th>
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<tbody>
<tr>
<td>The passive, untargeted and unplanned spread of new practices</td>
<td>Active spread of new practices to the target audience using planned strategies</td>
<td>Process of adoption, integration and use of new practices within a setting</td>
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Other Terms for “Implementation”

- Knowledge translation
- Knowledge exchange
- Knowledge transfer
- Knowledge integration
- Research utilization
The Translational Research Spectrum

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<thead>
<tr>
<th>T0</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>T4</th>
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</thead>
<tbody>
<tr>
<td>Basic science research</td>
<td>Translation to humans</td>
<td>Translation to patients</td>
<td>Translation to practice</td>
<td>Translation to community</td>
</tr>
<tr>
<td>Preclinical and animal studies</td>
<td>Proof of concept Phase 1 clinical trials</td>
<td>Phase 2 clinical trials Phase 3 clinical trials</td>
<td>Phase 4 clinical trials and clinical outcomes research</td>
<td>Population-level outcomes research</td>
</tr>
<tr>
<td>Defining mechanisms, targets, and lead molecules</td>
<td>New methods of diagnosis, treatment, and prevention</td>
<td>Controlled studies leading to effective care</td>
<td>Delivery of recommended and timely care to the right patient</td>
<td>True benefit to society</td>
</tr>
</tbody>
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Translation from basic science to human studies
Translation of new data into the clinic and health decision making

Evidence Generation → Clinical and Health Benefit

• Finding the “right things to do” (science: evidence generation)
  – closing the “knowledge gap”

• Making the right information easy to access (“sociology”: diffusion/dissemination)
  – closing the “knowing gap”

• Making the right thing easy to do (implementation/uptake)
  – closing the “knowing-doing gap”
What Is the Problem?

- New research takes too long to get adopted
- Research often not aligned to address critical health/health care problems
- Providers lack tools/technical assistance to implement effective Rx
- Large programs being rolled out without adequate planning to maximize effectiveness and learning
  - Effectiveness of implementation and quality improvement programs varies, but is generally low
- Variation and patient-centered care
  - Treatments work differently in different people
What is the Problem?

- It takes 17 years to turn 14 percent of original research findings to the benefit of patient care
- Patients receive 54.9 percent of recommended evidence-based care for prevention and chronic illness care
  - McGlynn EA. NEJM 2003
- Two-thirds of organizations' efforts to implement change fail
  - Damschroder LJ. Implement Sci. 2009

The 17-Year Odyssey

- Priorities for research funding
- Peer review of grants
- Publication priorities and peer review
- Research synthesis
- Guidelines for evidence-based practice
- Evidence-based medicine movement
- Academic appointments, promotion, and tenure criteria
- Funding; population needs, demands; local practice circumstances; professional discretion; credibility and fit of the evidence

Jing Li CHSR

Ultimate Population Impact of Magic Pill

<table>
<thead>
<tr>
<th>Implementation Step</th>
<th>Concept</th>
<th>% Impacted</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% of Clinics Use</td>
<td>Adoption</td>
<td>50%</td>
</tr>
<tr>
<td>50% of Clinicians Prescribe</td>
<td>Adoption</td>
<td>25%</td>
</tr>
<tr>
<td>50% of Patients Take Medication</td>
<td>Reach</td>
<td>12.5%</td>
</tr>
<tr>
<td>50% Follow Regimen Correctly</td>
<td>Implementation</td>
<td>6.2%</td>
</tr>
<tr>
<td>50% of Those Taking Correctly Benefit</td>
<td>Effectiveness</td>
<td>3.2%</td>
</tr>
<tr>
<td>50% Continue to Benefit after 6 Months</td>
<td>Maintenance</td>
<td>1.6%</td>
</tr>
</tbody>
</table>

Glasgow RE. 2011. [www.re-aim.org](http://www.re-aim.org)

Typical Assumptions

- Interventions shown to be effective in one place or under research conditions will be reproducible in large populations at similar costs and effects
- Different interventions of a health system are independent of each other
- Common infrastructure needed for all interventions can be put in place
- Implementation is straightforward: institutions and local context can be overcome by training, standardization of processes, and more funding
- The principles of scientific management
  - Like machine parts, members fulfill specific functions
  - Emphasizes aspects of the organization that are predictable, controllable and reproducible

David H. Peters, Johns Hopkins University
Areas of Confusion: Clinical vs. Implementation Research

<table>
<thead>
<tr>
<th>Study feature</th>
<th>Clinical research</th>
<th>Implementation research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim: evaluate a / an ...</td>
<td>clinical intervention</td>
<td>implementation strategy</td>
</tr>
<tr>
<td>Typical intervention</td>
<td>drug, procedure, therapy</td>
<td>provider, organizational practice change</td>
</tr>
<tr>
<td>Typical outcomes</td>
<td>symptoms, health outcomes, patient behavior</td>
<td>adoption, adherence, fidelity</td>
</tr>
<tr>
<td>Typical unit of analysis, randomization</td>
<td>patient</td>
<td>provider, team, clinic, facility</td>
</tr>
</tbody>
</table>

Areas of Confusion: Quality Improvement vs. Implementation Science

**Quality Improvement (QI)**
- Motivated by quality gaps (gaps in clinical effectiveness, patient safety, value, access)
- Approaches include industrial QI techniques (CQI, TQM, PDSA, Lean, Six Sigma)
- QI research is often **problem-driven**

**Implementation Science (IS)**
- Motivated by recognition that research results and innovations are under-utilized (translational roadblocks)
- Activity guided by clinical research approaches and based on explicit implementation science conceptual, theoretical framework (vs. industrial QI methods)
- Implementation research is often **solution-driven**

Courtesy of Brian Mittman, PhD
Areas of Confusion: Quality Improvement vs. Implementation Science

### Quality Improvement (QI)
- QI often focuses on the “here and now” – immediate, local improvement needs via rapid-cycle, iterative improvement

### Implementation Science (IS)
- IS often attempts to develop, deploy and rigorously evaluate a fixed implementation strategy across multiple sites, emphasizing theory, contextual factors, and (sometimes) mediators, moderators, mechanisms
- IS aims to develop generalizable knowledge

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Arguably, neither has made much headway in achieving either goal

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Courtesy of Brian Mittman, PhD
QI vs. IS: Conceptual, Theoretical Foundations

• The fundamental basis – foundation – for both fields includes theory, empirical research and research methods addressing the:
  – Organization and delivery of healthcare (and other) services
  – Knowledge, beliefs, attitudes and practices (behaviors) of healthcare (and other) professionals and staff

Key Characteristics of D&I Research

• Contextual
• Complex
• Multi-component programs and polices
• Non-linear
• Transdisciplinary
• Multi-level and multi-method
Real World D&I
Influence of Content, Context, and Process

Dissemination and Implementation

Content
• Evidence development and testing
• Evidence interpretation and packaging

Context
External:
• Political and Professional
• Economic (e.g., reimbursement)
• Social (e.g., stigma)

Internal:
• Organizational culture and structure
• Practice setting characteristics
• Local stakeholders (e.g., attitudes and behaviors)

Process
• Behavior change strategies (e.g., client motivation/behavior, provider practices)
• Systemic processes (e.g., supervisory processes, quality improvement)
• Engagement (e.g., teachers, physicians, families)

Adapted from Pettigrew et al., 1997 by Chambers, Ringoisen, Hingwood & Patel, 2002

Addressing D&I Research Questions
Collaboration, Team Science

• Multiple perspectives
• Multiple methods
• Multiple sites and settings
• Diverse expertise
• Need for integration

Stange KC. et al. 2001. Fam Med
Typology of Collaboration

• Multidisciplinary
  – Multiple disciplines
  – Each contributes their piece to solving a problem
    (e.g., an edited book with different chapters)

• Interdisciplinary
  – A conversation between and among disciplines
  – Working together on solving a common problem
    (e.g., a collaborative health care team)

• Transdisciplinary
  – A sustained conversation across and beyond disciplinary boundaries
  – Creates a new shared language (e.g., the emergence of D&I research)

Development of Implementation Strategies
Implementation Strategy

“Methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice”

Or

The “how” of implementation

Getting from “What is happening now?” to “What do you want to happen?”

Characteristics of Implementation Strategies

• Level of complexity
  – Discrete: involve 1 process or action (e.g., system reminder)
  – Multifaceted: use 2 or more discrete strategies (e.g., detailing + reminder)
  – Blended: multiple strategies targeting different levels are interwoven/packaged

• Target(s): Patients, Providers, Organization, Community, Other?

• Top-down vs. Bottom-up

• Phase(s) of implementation

• Dose

• Frequency
Challenges of Selecting Strategies

- Complexity of evidence-based practices & programs
- Complexity of the context
- Lots and lots of potential strategies but lack of operational definitions/conceptual clarity in the literature
  
  e.g., Compendium of discrete implementation strategies in mental health
  
  - Powell, et al. 2012, found 68 → One year later, Michi, et al., found 93
  
  But
  
  Frequently strategies are poorly defined which limits replication
  When defined, use inconsistent terminology
  What strategy works best: within a site specific contextual and cultural environment? for specific innovations?

Challenges of Selecting Strategies

To address some the challenges, do you

- use strategies “off the shelf“?
- tailor them, and how?
- adapt them, and how?
- combine multiple strategies, and how?
Examples of Implementation Strategies

- Education (fact sheets, CPG summaries, presentations, research articles)
- Clinical support tools (pocket cards, clinical reminders)
- Technical Assistance (centralized, local)
- Stakeholder engagement
- Performance monitoring/feedback
- Opinion leaders/champions
- CQI/PDSA cycles
- Formative evaluation (identify barriers/facilitators and modify intervention/implementation)
- Evidence-based QI
- Training/coaching/supervision
- Facilitation

How to Select Implementation Strategy

- Theory and Empirical Evidence
  - Grounded in theory
  - Empirical track record
  - Consensus among informed experts
- Relevance
  - Address the underlying risk and protective factors/conditions that contribute to the problem
- Feasibility / Pragmatic Rationale
  - usually informed by assessment of context and stakeholder input
Your Study:
Tailoring Strategies to Determinants of Practices

• Assessing context to identify determinants of practice (i.e., barriers and facilitators) that may need to be addressed
• Designing or selecting strategies appropriate to the determinants
• Implementing and evaluating the strategies

Examples of Tailoring Strategies to Determinants

<table>
<thead>
<tr>
<th>Identified Determinants</th>
<th>Implementation Strategies</th>
</tr>
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<tbody>
<tr>
<td>Lack of knowledge</td>
<td>Interactive education sessions</td>
</tr>
<tr>
<td>Perception/reality mismatch</td>
<td>Audit and feedback</td>
</tr>
<tr>
<td>Lack of motivation</td>
<td>Incentives/sanctions</td>
</tr>
<tr>
<td>Beliefs/attitudes</td>
<td>Peer influence/opinion leaders</td>
</tr>
<tr>
<td>System of care</td>
<td>Process redesign</td>
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Opportunity

- “...results suggest a mismatch between identified barriers and the quality improvement interventions selected for use” (Bosch et al., 2007)
- e.g., identified organizational barrier but using strategies targeting providers
- There is a need for “systematic and rigorous methods...to enhance the linkage between identified barriers and change strategies” (Grol et al., 2013)

Specifying and Reporting Implementation Strategies

Efforts to Develop Reporting Guidelines

Implementation Science

Editorial
Specifying and reporting complex behaviour change interventions: the need for a scientific method
Susan Michie¹, Dean Fixsen², Jeremy M Grimshaw³ and Martin P Eccles⁴
Implementation strategies: recommendations for specifying and reporting

A Framework for Enhancing the Value of Research for Dissemination and Implementation

What is the extent and quality of documentation and reporting of fidelity to implementation strategies: a scoping review

Simplified Framework & AIMD Framework

Towards a common terminology: a simplified framework of interventions to promote and integrate evidence into health practices, systems, and policies

Aims – What do you want your strategy to achieve and for whom?
Ingredients – What comprises the strategy?
Mechanism – How do you propose the strategy will work?
Delivery – How will you deliver the strategy?
Proctor et al. Framework

<table>
<thead>
<tr>
<th>Prerequisite</th>
<th>Requirements</th>
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</thead>
<tbody>
<tr>
<td>1) Name it</td>
<td>Name the strategy, preferably using language that is consistent with existing literature.</td>
</tr>
<tr>
<td>2) Define it</td>
<td>Define the implementation strategy and any discrete components operationally</td>
</tr>
</tbody>
</table>
| 3) Specify it      | a) The actor: Identify who enacts the strategy (e.g., administrators, payers, providers, patients/consumers, advocates, etc.).
                     b) The action: Use active verb statements to specify the specific actions, steps, or processes that need to be enacted.
                     c) Action target: Specify targets according to conceptual models of implementation; identify unit of analysis for measuring implementation outcomes.
                     d) Temporality: Specify when the strategy is used.
                     e) Dose: Specify dosage of implementation strategy.
                     f) Implementation outcome affected: Identify and measure the implementation outcome(s) likely to be affected by each strategy.
                     g) Justification: Provide empirical, theoretical, or pragmatic justification for the choice of implementation strategies.

Applied Example 1 (Trauma-Focused CBT)

**Multifaceted Strategy (11 Component/Discrete Strategies*)**

- Prepare change package
- Commitment
- Learning sessions
- PDOSA cycles
- Conference calls
- Web support
- Quality improvement technique training
- Metrics reporting
- Coaching calls
- On-site visits
- Revisiting

*Each specified according to Proctor et al. (2013) standards

<table>
<thead>
<tr>
<th>Actions</th>
<th>Target</th>
<th>Temporality</th>
<th>Dose</th>
<th>Outcome</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparatory Work</td>
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</table>
| Prepare Change Package   | Faculty experts prepare   |              |      | Adoption, fidelity, penetration, and sustainment of TF-CBT | Theoretical: Knowledge (CFIR & TDF); planning (CFIR)
|                          | resources on TF-CBT, and implementation strategies |              |      |                                | Empirical: Farmer et al. (2011) |
Reporting on the Strategies Needed to Implement Proven Interventions: An Example From a “Real-World” Cross-Setting Implementation Study

Rachel Gold, PhD, MPH; Arwen E. Bunce, MA; Deborah J. Cohen, PhD; Celine Hallambe, MPH; Christine A. Nelson, PhD, RN; Enola K. Proctor, PhD; EE A. Brown, BA; and Jennifer E. Odlum, MD, MPH

Increase the percentage of patients with diabetes appropriately prescribed cardioprotective medications

Proctor et al's framework domains, applied to describe the overarching strategies

<table>
<thead>
<tr>
<th>In KP: Overarching strategy = Top-down</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actor</td>
</tr>
<tr>
<td>National/regional health plan leadership, and regional ALL “champions” identified to encourage local uptake; protected time to do so</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In CHCs: Overarching strategy = Practice facilitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic/service organization ALL “champions” identified to encourage local uptake; site coordinators/practice facilitators; study research staff</td>
</tr>
</tbody>
</table>

Measurement and Evaluation for Implementation
What Is Successful Implementation?

- Implementation plan and its realization
- EBP uptake: i.e., clinical interventions and/or delivery system interventions
- Patient and organizational outcomes achievement

Key Question in Evaluating Implementation

- How to conceptualize and measure success of implementation processes and their impact on service delivery
- Implementation outcomes need to be identified and assessed, distinct from clinical and health outcomes
Why Distinct Implementation Outcomes?

When services are unsuccessful, is failure due to:

• Services didn’t work (service or treatment failure)?
• Services or treatments weren’t implemented well (implementation failure)?
• Could have an effective treatment, poorly implemented
• Could have an ineffective treatment, successfully implemented
Studying Implementation

Key Concepts

- Acceptability
- Adoption
- Appropriateness
- Feasibility
- Fidelity
- Implementation cost
- Penetration
- Sustainability
Measurement: Acceptability

• Typically brief Likert scales summarized and dichotomized
  – Example: Evidence Based Practice Attitude Scale (EBPAS) (Aarons, 2004)
    ▪ 15-item, 5-point Likert scale
    ▪ Subscales: Appeal, Requirements, Openness, Divergence
  – Administered via interview & questionnaires, trending toward online administration

Measurement: Adoption

• Dichotomous measure
  – Is intervention being used? (Henggeler, 2008)
• Continuous measures of adoption
  – Adding number of program components adopted (Li et al. 2004)
  – Considering adoption intent
Measurement: Feasibility

- Rarely directly measured
- Often inferred or judged by researchers
  - Program may be deemed feasible if highly rated on other implementation outcomes (acceptability)
- Often inferred retrospectively on basis of burden
  - Program, screener, or treatment may require too much time

Measurement: Fidelity

- Typically multiple item, Likert measures
- Summed up scale yields continuous measure of fidelity, often dichotomized
  - Dartmouth Assertive Community Treatment Scale: licensed measure in the public domain
    [https://www.dartmouth.edu/~implementation/page15/page4/files/dacts_protocol_1-16-03.pdf](https://www.dartmouth.edu/~implementation/page15/page4/files/dacts_protocol_1-16-03.pdf)
- Assessment via:
  - Self-report
  - Face-to-face or telephone interviews
  - Observation by research teams
Measurement: Penetration

- Reflects “depth” of implementation in target sites
- Measured as a proportion
  - # sites within agency adopting an EBP / # agency sites exposed to EBP
  - # of providers delivering the EBP / # of providers trained
  - # of providers’ cases receiving the EBP / # of eligible patients served by provider

Measurement: Sustainability

- Little measurement of sustainability, once improvements are introduced in care
- What factors associated with sustainability?
- What does sustainability mean?
  - Continued use of an EBP?
  - Continued capacity to deliver evidence-based care (even if the EBP is changed)
- How long should an EBP be implemented?
  - Sustainability “curves”
Multiple Stakeholders and Multiple Perspectives

- Service consumers
- Families
- Providers
- Administrators
- Funders
- Legislators

Ongoing efforts for measure synthesis and harmonization
SIRC Instrument Review Project

• Comprehensive library of D&I instruments
• Rating system reflecting the degree of empirical validation of instruments
• Consensus battery of instruments.

To date, 450 instruments. Rating is ongoing.

http://www.seattleimplementation.org/sirc-projects/sirc-instrument-project/

The NCI GEM D&I initiative:

• Uses crowd-sourcing approach

130 different implementation science measures across 74 constructs, their associated characteristics and a rating of these measures for quality and practicality.

http://www.gem-beta.org/GEM-DI
One Study Example

Evaluation of Implementation

• **Formative evaluation (FE)**
  - Rigorous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts (Stetler et al, 2006)

• **Summative (impact) evaluation**
  - Systematic process of collecting and analyzing data on impacts, outputs, products, outcomes and costs in an implementation study
  - Used to assess success, effectiveness, or goal achievement of an intervention
Need for FE in Implementation Research

• Capture information on factors that hinder or facilitate successful implementation

• Address interpretive weaknesses
  – Avoid “Type III error” (where intervention not implemented as planned or designed)
  – Identify what did / did not happen in implementation plan
  – Identify factors in setting, anticipated and unanticipated, that influenced implementation
  – Enhance understanding of study outcomes to more accurately interpret project findings and inform future implementation efforts

Four Stages of FE

• Developmental
• Implementation-Focused
• Progress-Focused
• Interpretive
Developmental FE

• aka “local needs assessment”, “organizational diagnosis”
• Involves data collection on...
  - Actual degree of less-than-best practice (need for improvement)
  - Determinants of current practice
  - Potential barriers / facilitators to practice change or implementation of proposed adoption strategy
  - Strategy feasibility, including perceived utility of project

Implementation-Focused FE

• Occurs during implementation of project plan
• Focuses on assessing discrepancies between implementation plan and actual execution
• Enable to...
  - Understand nature and implications of local adaptation
  - Describe and understand major barriers to implementation and what it takes to achieve desired change
  - Identify and implement new components or refine original strategy to optimize potential for success
  - Identify critical details necessary to replicate implementation strategy in other clinical settings
Progress-Focused FE

• Occurs during implementation of project plan (concurrent with implementation-focused FE)
• Focuses on monitoring impacts and indicators of progress toward implementation or clinical goals
  — audit/feedback of clinical performance data
  — progress in relation to pre-determined timelines for implementing intervention components
• Can be used to inform need for modifying or refining original implementation strategy

Interpretive Evaluation

• Uses data: 1) from other FE stages; 2) on stakeholder experiences
• Obtain stakeholder views on:
  — Usefulness / value of intervention (as a whole, or individual components)
  — Barriers / facilitators to implementation success or failure
  — Satisfaction with implementation process
  — Recommendations for further refinements to intervention
• Can provide working hypotheses on implementation success / failure, particularly when implementation and evaluation plans grounded in a conceptual framework (for theory building / refinement)
Stages of FE

Pre-implementation

Developmental
- Identify determinants of current practice
- Identify potential barriers / facilitators
- Assess feasibility of proposed intervention
- Integrate findings into intervention design and refinement prior to implementation

Implementation

Implementation-Focused
- Assess discrepancies between implementation plan and execution, exploring issues of fidelity, intensity, exposure
- Understand and document nature and implications of local adaptation
- Monitor impacts and indicators of progress toward project goals
- Use data to inform need for modifying or refining original strategy
- Provide positive reinforcement to high performers, negative reinforcement to low performers

Progress-Focused
- Assess intervention usefulness/value from stakeholder perspective
- Elicit stakeholder recommendations for further intervention refinements

Interpretive
- Assess satisfaction with intervention and implementation process
- Identify additional barriers / facilitators

Post-implementation

FE Assessment Methods / Tools

- Quantitative
  - Structured surveys / tools
  - Audit / feedback of administrative data on clinical performance on quality measure(s) of interest

- Qualitative
  - Semi-structured interviews
  - Focus groups
  - Direct observation of clinical structure/processes in site visits
  - Document review

- Mixed Methods (i.e., Quantitative + Qualitative)
  - Provide richer explanation of study results to enhance understanding of key factors in implementation success / failure
Theory, Model, and Framework?

- Theories present a systematic way of understanding events or behaviors by providing inter-related concepts, definitions, and propositions that explain or predict events by specifying relationships among variables.
  - They are abstract, broadly applicable and not content- or topic-specific
- Frameworks are strategic or action-planning models that provide a systematic way to develop, manage, and evaluate interventions.
  - Frameworks often contain theories; theories don’t typically have frameworks
- Models is used to describe theories and frameworks collectively.

Why Using Models?

• In implementation research, you are attempting to change something(s)
  • Need a theory of how that change will occur
• Your theory of how change will occur drives what you decide to do:
  • What/who to target (may have multiple targets)
  • How to foster change (may have/need multiple strategies)
• Change is a process: a model can help you parse out your process, e.g., into phases
• Models can enhance interpretability of study findings

Three Aims and Five Categories of Theories, Models and Frameworks

- Describing and/or guiding the process of translating research into practice
- Understanding and/or explaining what influences implementation outcomes
- Evaluating implementation

Theoretical approaches used in implementation science

Process models
Determinant frameworks
Classic theories
Implementation theories
Evaluation frameworks

Wealth of Existing Models for D&I

• 61 models with research focus (Tabak et al., 2012)
• Additional 25+ with practitioner/clinician focus (Mitchell et al., 2010)
• 25 implementation frameworks (Meyers et al., 2012)
• Some commonly used models:
  – PARiHS, CFIR, ISF, RE-AIM, ...

PARiHS – Promoting Action on Research Implementation in Health Services
CFIR – Consolidated Framework for Implementation Research
ISF – Interactive Systems Framework
RE-AIM – Reach, Effectiveness, Adoption, Implementation, Maintenance
Model Categories

1: Broad
Loosely outlined and defined constructs; allows researchers greater flexibility

2

3

4

5: Operational
Detailed, step-by-step actions for D&I research

Dissemination and / or Implementation (D/I)

D only
Focus on active approach of spreading EBIs to target audience via determined channels using planned strategies

D > I
Equal focus on dissemination and implementation

I > D
Focus on process of putting to use or integrating evidence-based interventions within a setting

I only

Socio-ecological Framework (SEF)

System: Hospital system, government

Community: Local government, neighborhood

Organization: Hospitals, service organizations, factory

Individual: Personal characteristics

http://www.cdc.gov/prc/images/dni-models_large.jpg

Figure 2. Case study on use of the Interactive Systems Framework (ISF)^5

ISF (Categorized as D=1, CF=2, SEF=System, Community, Organization, Individual)

Framework Background: The Interactive Systems Framework (ISF) was originally developed to be used by different types of stakeholders (e.g., funders, practitioners, researchers) to better understand the needs of all stakeholders and systems. The ISF identifies three systems: the Prevention Delivery System which implements innovations; the Prevention Support System which provides training; technical assistance (TA) or other support for users; and the Prevention Synthesis and Translation System which relays information and translates it into user-friendly forms. Each of these activities is necessary for the movement of innovations into widespread practice at the community level.

Study: Promoting Science-based Approaches to Teen Pregnancy Prevention project (PSBA)

Study Background: The PSBA program was a multi-site, capacity-building effort that aimed to assist local prevention partners in the use of science-based approaches (SBAs) to prevent teen pregnancy. ISF was adopted to allow for specific and strategic planning about what capacities were needed at the local level and to develop a framework for systematically building these capacities.

Measures: ISF was used to inform the evaluation and its measures for this project. Evaluation questions were developed to document and evaluate the process and outcomes of the PSBA project. Three particular focus areas were selected: the ISF-inspired capacity-building model; ISF-inspired capacity-building model; and the impact of ISF-inspired capacity-building model on local partners.

Use of ISF: PSBA used all three systems of the ISF to facilitate practice improvements. The PSBA Prevention Delivery System included all local prevention partners who agreed to receive intensive TA from the state and regional grantees. The PSBA Prevention Support System included efforts made by CDC's national, regional, and state partners to strengthen their own general organizational capacity, build SBAs-specific capacity to provide training and TA; and assist local partners. The PSBA Prevention Synthesis and Translation System consisted of creating an accessible and comprehensive manual called Promoting Science-based Approaches to Teen Pregnancy Prevention using ISF-inspired capacity-building model (PSOA/GTC).
How to Decide What Model to Use?

Main considerations (Tabak et al. 2012)

• Construct flexibility
  • Broad or operational (detailed, step-by-step)?
• Dissemination and/or implementation
  • Which type of research are you doing?
• Socioecologic framework
  • What level(s) are you interested in: individual, organization, community, system?
• Also consider whether you want to use an existing model or develop a new model
• Examine whether the model you’re interested in has measures associated with it

Dissemination & Implementation Models in Health Research & Practice

This interactive website was designed to help researchers and practitioners to select the D&I Model that best fits their research question or practice problem, adapt the model to the study or practice context, fully integrate the model into the research or practice process, and find existing measurement instruments for the model constructs. The term ‘Models’ is used to refer to both theories and frameworks that enhance dissemination and implementation of evidence-based interventions more likely.

Select
Search, view, and select D&I Models

Adapt
Read strategies for adapting D&I Models to research or practice context

Integrate
Read strategies for incorporating D&I Models into the full spectrum of your project

Measure constructs
Find a list of constructs and links to measurement tools associated with the D&I Models

Jing Li CHSR
http://dissemination-implementation.org/index.aspx
Adapt

 +/- What are the benefits of using existing models?
 +/- Why adapting of D&I models might be necessary?

A researcher will almost always adapt a model in some way; therefore, adaptation is often an important part of using a model. Adaptation often improves the appropriateness of the selected model to the intervention being disseminated or implemented, the population, and the setting. Further, adaptation contributes to the field by testing modifications to existing models, such as disregarding pieces shown to be ineffective or adding ones with additional evidence. Models should be viewed as living documents, or works in progress, not as static entities.

 +/- What should be considered before adapting a D&I model?
 +/- What type of modifications can be made to D&I models?

Modifications that can be made without much hesitation include: wording to suit the audience, timeline (based on adaptation guides), or cultural preferences based on the population.

Adaptations that may be possible, but should be made with caution, include: substituting activities or changing the order of the steps.

Adaptations that compromise the core elements of the model should not be attempted without substantial evidence to support the adaptation. This includes changing the health communication mode/theory of the health topic/behavior; deleting core elements; or putting in strategies that detract from the core elements.

As long as model adaptations do not become a weakness of the proposed study, when drastic changes are made to a model, it provides an excellent opportunity for model testing. In studies that adopt a model, adaptations should be documented and monitored so that the impact of changes on model applicability can be reported and incorporated into the literature.

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Ten Key Ingredients for Implementation Research Proposals

<table>
<thead>
<tr>
<th>Proposal Ingredient</th>
<th>Key Question</th>
<th>Review Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The care gap or quality gap</td>
<td>The proposal has clear evidence that a gap in quality exists?</td>
<td>Significant impact</td>
</tr>
<tr>
<td>2. The evidence based treatment to be</td>
<td>Is the evidence for the program, treatment, or set of services to be</td>
<td>Significance innovation</td>
</tr>
<tr>
<td>implemented</td>
<td>implemented demonstrated?</td>
<td></td>
</tr>
<tr>
<td>3. Conceptual model and theoretical</td>
<td>The proposal delineates a clear conceptual framework/theory/model that</td>
<td>Approach innovation</td>
</tr>
<tr>
<td>justification</td>
<td>informed the design and variables being tested?</td>
<td></td>
</tr>
<tr>
<td>4. Stakeholder priorities, engagement in</td>
<td>Is there a clear engagement process of the stakeholders in place?</td>
<td>Significance impact</td>
</tr>
<tr>
<td>change</td>
<td></td>
<td>Approach Environment</td>
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http://dissemination-implementation.org/index.aspx
### Ten Key Ingredients for Implementation Research Proposals

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<tr>
<td>5. Setting’s readiness to adopt new services/treatments/programs</td>
<td>Is there clear information that reflects the settings readiness, capacity, or appetite for change, specifically around adoption of the proposed evidence-based treatment?</td>
<td>Impact Approach Environment</td>
</tr>
<tr>
<td>6. Implementation and strategy/process</td>
<td>Are the strategies to implement the intervention clearly defined, and justified conceptually?</td>
<td>Significance impact innovation</td>
</tr>
<tr>
<td>7. Team experience with setting, treatment, implementation process</td>
<td>Does the proposal detail the team’s experience with the study setting, the treatment whose implementation is being studied, and implementation processes?</td>
<td>Approach investigator team</td>
</tr>
<tr>
<td>8. Feasibility of proposed research design and methods</td>
<td>Does the methods section contain as much detail as possible, as well as lay out possible choice junctures and contingencies, should methods not work as planned?</td>
<td>Approach investigator team</td>
</tr>
<tr>
<td>9. Measurement and analysis section</td>
<td>Does the proposal clarify the key constructs to be measured, corresponding to the overarching conceptual model or theory? Is a measurement plan clear? Does the analysis section demonstrate how relationships between constructs will be tested?</td>
<td>Approach investigator team</td>
</tr>
<tr>
<td>10. Policy and funding environment; leverage or support for sustaining change</td>
<td>Does the proposal address how the implementation initiative aligns with policy trends?</td>
<td>Impact significance</td>
</tr>
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</table>
Overarching Note: What Drives Your Impact Score?

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Regression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approach</td>
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</tr>
<tr>
<td>Significance</td>
<td>3.3</td>
</tr>
<tr>
<td>Innovation</td>
<td>1.4</td>
</tr>
<tr>
<td>Investigator</td>
<td>1.3</td>
</tr>
<tr>
<td>Environment</td>
<td>-0.1</td>
</tr>
</tbody>
</table>

Based on 32,000+ scored applications submitted for funding in fiscal year 2010

Study Design for D&I Research
Types of Implementation Studies

Moving from observational to interventional studies

• Understand behaviors across multiple groups (providers, organizations, consumers)
• Focus on the “how” and “why” evidence-based practices are used
• Testing implementation strategies
  – Facilitate use of evidence-based practices by providers
  – Multifaceted approaches to promote sustainability

Pragmatic Perspective in Implementation Research

• Explanatory/Efficacy trials or efficacy trials: concerned with evaluation of intervention under optimal conditions that maximize treatment fidelity and adherence.
• Pragmatic/Effectiveness research: concerned with answering real-world questions of relevance to practitioners, policymakers, administrators, and citizens
Study Design: Start with a Question

Typical progression of questions:
• What should be done to address X problem?
• Is an evidence-based practice (EBP) being used?
  – If not, why not?
• What factors influence the EBP being used or potentially being used?
• What else needs to be done to facilitate the use of the EBP?
• How do you know that what you’ve done is effective?


Study Design: Key Differences

• All research designs are possible in implementation research
  – RCTs, comparative effectiveness, quasi-experimental, mixed methods, etc.
• But, your implementation research will assess several implementation outcomes
Study Design: Key Differences

And, your units of analysis might be different

• Units of randomization are often much larger (sites/clinics vs. individuals)
  – May need many sites
• Units beyond individual patients are often measured
  – Climate measures
  – Performance of an entire clinic
• Units of analysis may go back and forth between individual and larger groups

Experimental Study Designs

• Randomized control trial (RCT)
• Cluster RCT
• Pragmatic RCT
• Stepped-wedge cluster RCT
The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) wheel
Loudon et al. 2015. BMJ

The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) wheel
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Stepped-wedge cluster RCT

Quai-Experimental Study Designs

• Regression Discontinuity Design
  – Individuals/groups assigned to intervention or control based on a \textit{priori} score or metric

• Non-Equivalent Control Group Design
  – One group receives intervention, one group is control
  – Can compare groups at baseline (but can’t control for unmeasured differences)

• \textit{Interrupted Time Series (ITS)}
  – Multiple assessments prior to and following introduction of intervention
  – More accurate assessment of outcomes or behavior than single pre-post assessments

Mixed Methods Design

• Collection and integration of qualitative and quantitative data
• Good approach for broader and more comprehensive understanding processes, context and complexity
• Can embed within other types of study designs
• Conduct one study within the other type of study design (e.g., qualitative within quantitative study design or quantitative within qualitative study design)
Utilizing Effectiveness-Implementation “Hybrid Designs”

• Hybrid designs take a dual focus a priori in assessing intervention effectiveness and implementation.
• Advantages: speed translation and more useful information for researchers and decision makers
• Type 1, Type 2, Type 3
• Unlike other designs, the hybrid designs are unique to implementation research
Resources

• The National Cancer Institute (NCI) Division of Cancer Control & Population Sciences webinar series https://cyberseminar.cancercontrolplanet.org/implementationscience/
• The National Implementation Research Network (part of the NIH) website https://www.nlm.nih.gov/hsrinfo/implementation_science.html
• The VA Health Services Research & Development on Implementation Science
• http://www.hsrd.research.va.gov/research_topics/implementation_science.cfm
• The VA Quality Enhancement Research Initiative (QUERI) http://www.queri.research.va.gov
• AHRQ Dissemination Topic https://www.ahrq.gov/topics/topic-dissemination.html
• University of Colorado Center for Research in Implementation Science and Prevention (CRISP) http://www.ucdenver.edu/academics/colleges/medicalschool/programs/crisp/Pages/default.aspx

Textbooks

DISSEMINATION AND IMPLEMENTATION RESEARCH IN HEALTH
Translating Science to Practice

Evaluating Improvement and Implementation for Health

KNOWLEDGE TRANSLATION IN HEALTH CARE
Moving From Evidence to Practice