INTRODUCTION TO IMPLEMENTATION SCIENCE: PART I

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**MY BACKGROUND**

Medical anthropologist

VA health services and implementation researcher for past 14 years

Founding director of the qualitative core at CADRE; Served as the Center’s Associate Director for 3 years

Member of NCI’s Qualitative Methods in Implementation Science Working Group

PI on two VA Quality Enhancement Research Initiative (QUERI) grants

Developing the Engagement, Integration, and Implementation core in the Institute for Clinical and Translational Science (ICTS)
HOW LONG DOES IT TAKE FOR BIOMEDICAL RESEARCH TO GET INTO ROUTINE CLINICAL PRACTICE?
The answer is 17 years, what is the question: understanding time lags in translational research

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Thank you, Dan Livorsi!
WHAT HAVE OUR RESPONSES IN THE SCIENTIFIC COMMUNITY BEEN TO THIS TIME LAG?
T0-T4 Translational Science

Goal: Translating Science into High-Quality Care

- T0: Preclinical and Foundational Research
  - Informs research with humans

- T1: Translation to Humans
  - Clinical interventions and their initial testing

- T2: Translation to Clinical Settings
  - Inform evidence-based guidelines

- T3: Translation to Practice
  - Implementation in real-world settings

- T4: Translation to Populations
  - Population-based outcomes studies
T0-T4 Translational Science
Drug Discovery, Development, and Deployment Maps (4DM)
T0-T4 Translational Science

Drug Discovery, Development, and Deployment Maps (4DM)

Clinical and Translational Science Awards (CTSA)
RESPONSES

T0-T4 Translational Science
Drug Discovery, Development, and Deployment Maps (4DM)
CTSAs
“Real-World”/ Pragmatic Trials

RESPONSES

T0-T4 Translational Science

Drug Discovery, Development, and Deployment Maps (4DM)

CTSA s

“Real-World”/ Pragmatic Trials

Patient and Community Engagement
RESPONSES

T0-T4 Translational Science
Drug Discovery, Development, and Deployment Maps (4DM)
CTSAs
“Real-World”/ Pragmatic Trials
Patient and Community Engagement
Implementation Science (IS)
WHAT IF WE FLIP THE QUESTION?
RESPONSES TO ADDRESSING HEALTH DISPARITIES AND HEALTH EQUITY

T0-T4 Translational Science
Drug Discovery, Development, and Deployment Maps (4DM)
CTSAs
“Real-World”/ Pragmatic Trials
Patient and Community Engagement
Implementation Science (IS)
“the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services”

Eccles MP, Mittman BS. Implement Sci 2006; 1:1
IMPLEMENTATION SCIENCE

“scientific study of methods to promote the systematic uptake of proven clinical treatments, practices, organizational, and management interventions into routine practice, and hence to improve health”

Implementation Science website, 12/7/2020
Implementation science is here.
Health Services Researchers
Organizational Psychologists
Behavioral Psychologists
Economists
Anthropologists
And others
...joined the nurses and physicians already tackling the research-practice gap.
**IMPLEMENTATION SCIENCE**

“scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice”

<table>
<thead>
<tr>
<th>From definition</th>
<th>Other Names</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research findings and EBPs</td>
<td>Interventions, Innovations</td>
<td>Insert your favorite…</td>
</tr>
<tr>
<td>Scientific study</td>
<td>Conceptual model</td>
<td>PARiHS, RE-AIM, CFIR, etc.</td>
</tr>
<tr>
<td>Methods</td>
<td>Strategies</td>
<td>Audit feedback, education, champions, etc.</td>
</tr>
<tr>
<td>Scientific study</td>
<td>Outcomes</td>
<td>Acceptability, adoption, fidelity, etc.</td>
</tr>
</tbody>
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FOUR ESSENTIAL QUESTIONS

1) What is the gap between the evidence-base and clinical practice?
   - What needs to change?

2) What conceptual model best describes how you hypothesize change will occur?
   - How/why will this change occur?

3) What implementation strategies will facilitate that change?
   - What will create the change?

4) What outcomes do we need to measure to evaluate whether the change occurred in practice and clinical outcomes?
   - What changed and by how much?
Implementation science made too simple: a teaching tool

When defining implementation science, some very non-scientific language can be helpful...

- The intervention/practice/innovation is THE THING
- Effectiveness research looks at whether THE THING works
- Implementation research looks at how best to help people/places DO THE THING
- Implementation strategies are the stuff we do to try to help people/places DO THE THING
- Main implementation outcomes are HOW MUCH and HOW WELL they DO THE THING
THE PLAN: A REDESIGN

Building an Optimal HH Bundle: A Mixed Methods Approach (VA CRE 12-289)

Submitting the final report in January

Looking back, it was an implementation research study... kinda.

- How would I design it differently now?
REDESIGN

The Case Study
BUILDING AN OPTIMAL HH BUNDLE: SPECIFIC AIMS

1. Identify combinations of hand hygiene intervention strategies that optimize hand hygiene compliance and that could form an evidence-based hand hygiene bundle for VHA implementation.

2. Identify institutional, organizational, ward/ICU, and individual level facilitators and barriers to implementing hand hygiene interventions.
RESEARCH DESIGN

AIM 1
Cluster-randomized controlled trial that will sequentially test three individual hand hygiene interventions to identify an optimal combination of interventions to increase hand hygiene compliance.

AIM 2
Qualitative evaluation to examine barriers and facilitators to the interventions and develop contextual insight for implementing and scaling-up the intervention.
STUDY DESIGNS

Effectiveness and Implementation
Hybrids
All research designs are utilized in implementation research—from RCTs to stepped wedge to observational—but to be considered implementation research the study must assess several implementation outcomes.

Most studies are mixed methods.
HYBRID DESIGNS


For more info [search “hybrid”]: http://www.hsrdr.research.va.gov/cyberseminars/catalog-archive.cfm
## Hybrid Design: Questions

<table>
<thead>
<tr>
<th>Research Questions</th>
<th>Hybrid Type I</th>
<th>Hybrid Type II</th>
<th>Hybrid Type III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Question:</td>
<td>Will a clinical treatment work in this setting/these patients?</td>
<td>Primary Questions: Will a clinical treatment work in this setting/these patients?</td>
<td>Primary Question: Which implementation strategy works better in the implementation of the clinical treatment?</td>
</tr>
<tr>
<td>Secondary Question:</td>
<td>How was the clinical treatment implemented?</td>
<td>Does the implementation strategy show promise?</td>
<td>Secondary Question: Was the clinical treatment effective?</td>
</tr>
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REDESIGN: STEP ONE

Hybrid Type III
REDESIGN: STEP ONE

Hybrid Type III

Why?
- HH works!
- Semmelweis proved it in 1847 before germ theory was described
Hybrid Type III

Primary Question:
Which implementation strategies (or bundles of implementation strategies) work better in the implementation of the HH?

Secondary Question:
Was the clinical treatment effective?
(Translated to: Was HH still effective at reducing infection rates?)
Discussion of behavioral interventions.
What needs to change?
BACKGROUND: LITERATURE

HCW adherence was an average of 38.7% based on over 75 studies.

What works?
- Multi-faceted approaches

What does not work?
- Single-pronged approaches

Does it need to be the kitchen sink?
- Meta-analysis (Schweizer, et al 2014): Bundles with more interventions did NOT equal better HH compliance.
FOUR ESSENTIAL QUESTIONS

1) What is the gap between the evidence-base and clinical practice?
   - What needs to change? 61.3%

2) What conceptual model best describes how you hypothesize change will occur?
   - How/why will this change occur?

3) What [implementation] strategies will facilitate that change?
   - What will create the change?

4) What outcomes do we need to measure to evaluate whether the change occurred in practice and clinical outcomes?
   - What changed and by how much?