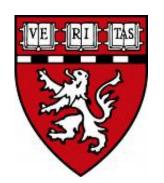
Implementation Science and Serious Illness Care Research

Stephen J. Bartels MD, MS
James J. and Jean H. Chair of Health Policy
and Community Health
Professor of Medicine, Harvard Medical School
Director, Mongan Institute





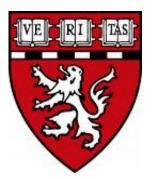


Disclosures

No Relevant Disclosures







Why Implementation Matters: The Research "Problem"

Pace, Relevance, and Pipeline of Translating Research into Practice



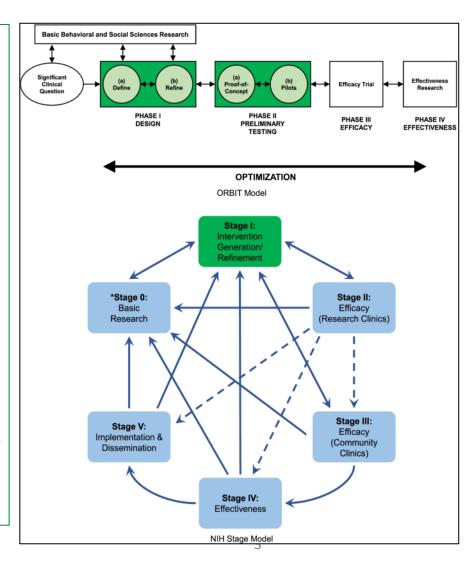




• PACE: 17 years to implement 14% of research in practice

Balas & Boren, 2000

- RELEVANCE: Health care systems and communities often view academic research as too incremental, cumbersome, and siloed to be helpful
- PIPELINE: Inadequate pipeline of applied population and health care delivery scientists and applied real-time projects



Why Implementation Matters:

An Evidence-Based Serious Illness Intervention Story

Even if the intervention is 100% effective...

It is only so good as how and whether:

- it is adopted
- practitioners are trained to deliver it
- trained practitioners choose to deliver it
- eligible populations receive it
- it can be sustained

If we assume 50% threshold for each step... (even with perfect access/adherence/dosage/maintenance)

Impact: .5x .5x .5x .5 x .5 = 3% benefit

Adapted from Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: The RE-AIM framework. *Am J Public Health*. 1999;89(9):1322.

Why Implementation Matters: Impact on Key Outcomes



What is Implementation Science?

"...the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practice into routine practice, and, hence, to improve the quality and effectiveness of health services."

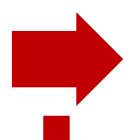
Eccles & Mittman, Implementation Science, 2006

Implementation Science Domain and Methods

	Efficacy Trials	Effectiveness Trials	Implementation Trials	Hybrid Effectiveness- Implementation Trials
HYPOTHESIS	Treatment will be effective over control	Treatment will be effective over control	Treatment will be adopted and sustained	Treatment will be effective, adopted, and sustained
SETTING	Research	Real world	Real world	Real world
CONTEXT	Not considered	Real world	Real world	Real world
SAMPLE	High exclusions	Few exclusions	Real world No exclusions	Real world No exclusions
OUTCOMES	Health outcomes Mechanisms	Health outcomes	Adoption, Fidelity Organizational Change Spread, Sustainability	Health outcomes, Adoption, Fidelity Organizational Change Spread, Sustainability
INTERVENTIONIST	Highly trained research staff	Practitioners	Practitioners Organizations	Practitioners Organizations
RESEARCH ROLE	High involvement	Some involvement	Limited involvement	Limited Involvement
VALIDTY EMPHASIS	Internal	Internal and External	External	Internal and External

Accelerating Evidence of Effectiveness AND Implementation Hybrid Effectiveness-Implementation Trials

Effectiveness Research



Implementation Research

Hybrid Type 1

- Test clinical effectiveness
- Observe/assess implementation barriers and facilitators

Hybrid Type 2

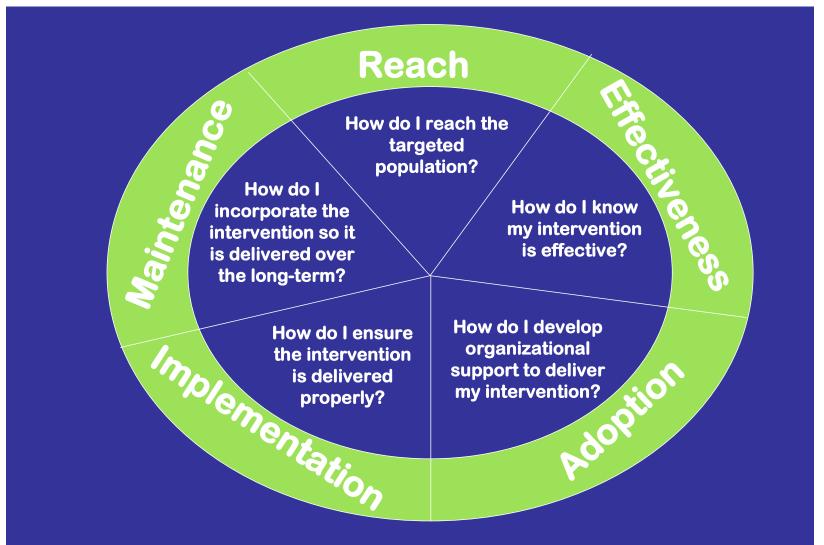
- Test clinical effectiveness
- Test implementation strategies

Hybrid Type 3

- Test implementation strategies
- Observe/assess clinical outcomes

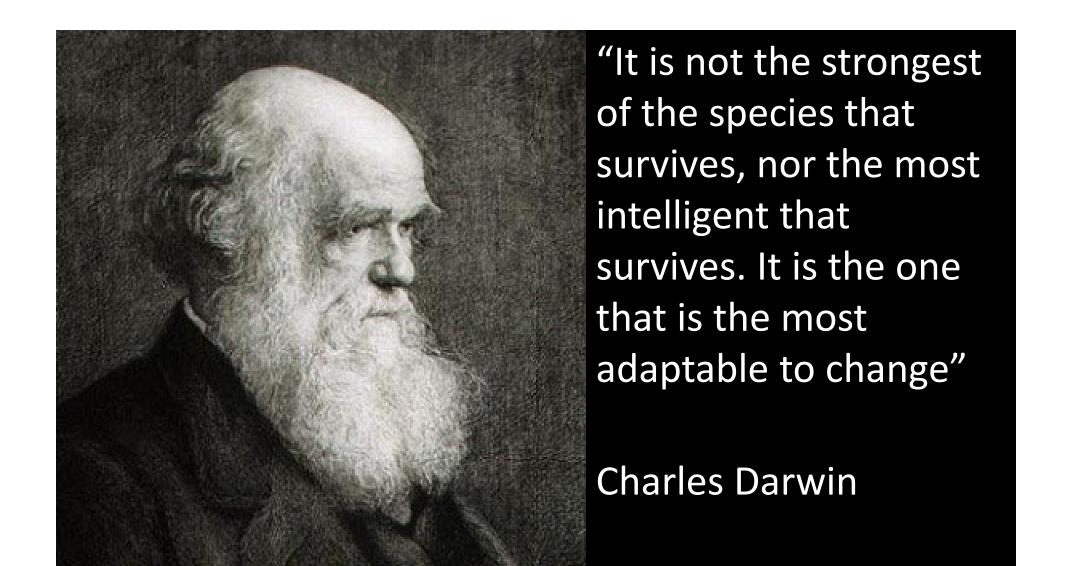
Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care. 2012

Example of an Implementation Framework for Outcomes: RE-AIM



Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: The RE-AIM framework. *Am J Public Health*. 1999;89(9):1322.

Fidelity vs. Adaptation



Why Do We Need to Adapt Implementation and Delivery of Interventions for Serious Illness? Selected Examples

- Lack of access to serious illness communication and care delivery
 - -Adaptations: Community heath workers, peers, digital delivery, Electronic Health Record/AI/behavioral nudges
- Health disparities in serious illness communication and care delivery
 - -Adaptions: Co-designed to advance equity with respect to race/ethnicity, culture, language, sexual and gender minorities, disability, SES, SDOH
- Tailoring for different populations and providers
 - -Adaptations: Tailoring for different populations (e.g., cancer, heart failure, COPD, dementia); translation of palliative care skills and competencies to other specialties (primary palliative care)

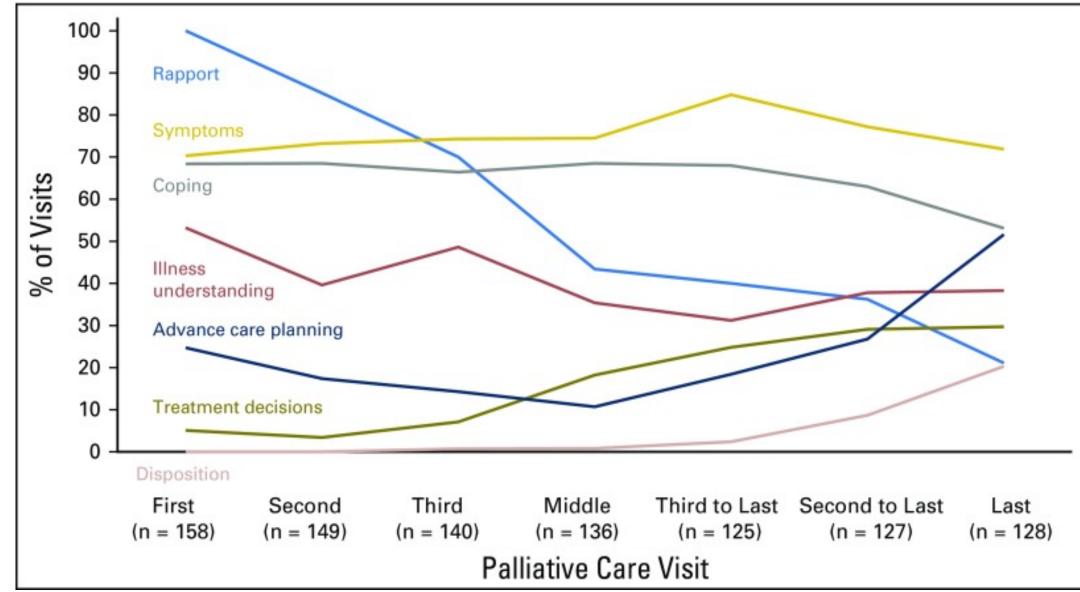
Adaptations are changes to the design, delivery or form of an evidence-based intervention with the goal of improving uptake, fit, reach, efficiency, effectiveness, equity and/or sustainability

Importance of identifying "core elements" that are empirically or theoretically associated with the desired outcome and cannot be modified

Fidelity to Function vs. Form (Mittman 2018)

But What are the Core Components of Palliative Care?

Changing
Content of
Palliative
Care Visits
Across
Illness
Trajectory





Hoerger M, Greer JA, Jackson VA, Park ER, Pirl WF, El-Jawahri A, Gallagher ER, Hagan T, Jacobsen J, Perry LM, Temel JS. Defining the Elements of Early Palliative Care That Are Associated With Patient-Reported Outcomes and the Delivery of End-of-Life Care. J Clin Oncol. 2018 1096-1102.

Contextual Drivers of **Implementation** and Adaptations

Example: Serious Illness Conversation **Implementation**

Paladino J, et al. Serious Illness **Care Programme-contextual** factors and implementation strategies: a qualitative study. **BMJ Support Palliat Care. 2022**



Conceptual Framework of Factors that Influence SICP Implementation ORGANIZATIONAL CONTEXT

LEADERSHIP PRIORITZATION

- Engagement, messaging, and longitudinal involvement
- Modeling desired behaviors
- Celebrating successes and addressing obstacles

INCENTIVES AND REWARDS

- Value-based payment models (emphasis on populations with serious illness)
- Quality incentives for training
- · Quality incentives for having and documenting serious illness conversations

PROGRAM RESOURCES

- Financial resources for an implementation team (clinical leader(s) and administrative colleagues)
- Availability of data analyst/information technology support

EHR / DATA INFRASTRUCTURE

- · Accessible, structured EHR documentation template
- · Reliable reporting and data feedback on documented serious illness conversations

FACILITATION

- Active involvement of implementation teams and motivated specialty-specific champions INTERVENTION
- Inclusive interprofessional clinician skills training to use a Conversation Guide
- · Longitudinal social, communication, and adaptation support for clinicians

ADAPTATION

- Modifying the Serious Illness Conversation Guide
- Customizing EHR documentation workflows to streamline access
- Tailoring patient identification and data feedback approaches to contextspecific needs

LOCAL CONTEXT (CLINIC, SITE)

SICP

Guide

Training

Coaching Patient identification

Reminders

Reporting & data

feedback

EHR template

QUALITY IMPROVEMENT/TEAM CULTURE

- · Team cohesiveness and psychological safety
- Use of data to drive improvement
- Degree of burnout or low morale

PROGNOSTIC VARIABILITY

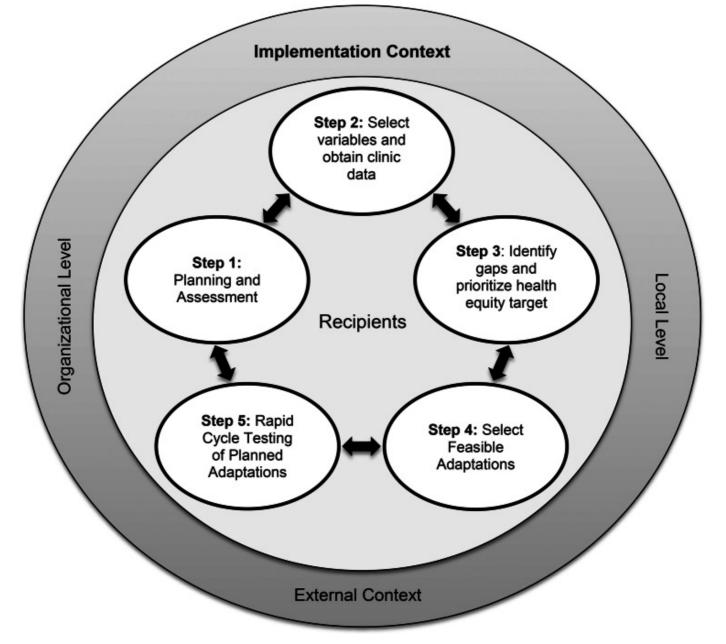
- Perceived relevance or value of the intervention for patient populations with different prognoses (e.g. patients with curative intent or long-term chronic illness) Degree of baseline comfort with difficult conversations

INTERVENTION EXPERIENCES

- Motivation and accountability for practice improvement
- Feeling heard and supported
- Self-efficacy and comfort with serious illness conversations
- Adoption and sustainment of conversations

Engaged, Data-Driven Selection of Indicators and Adaptations to Improve Health Equity

SEDDI:
Stakeholder and
Equity Data-Driven
Implementation



Stakeholder and Equity Data-Driven Implementation: a Mixed Methods Pilot Feasibility Study. Aschbrenner KA, Kruse G, Emmons KM, Singh D, Barber-Dubois ME, Miller AM, Thomas AN, Bartels SJ. Prev Sci. 2022 Oct 4:1–11.

Achieving the Goal of Equity-focused Serious Illness Intervention Implementation

- 1) Focus on reach and equity from the very beginning;
- 2) Design and select interventions for complex conditions and needs, and low-resource communities with implementation in mind;
- 3) Implement what works, and develop implementation strategies that are scalable, sustainable and able to reduce inequities in care;
- 4) Develop the science of adaptations for equity and complex health challenges associated with serious illness;
- 5) Use an equity lens for implementation outcomes.

Adapted from Reframing implementation science to address inequities in healthcare delivery Baumann and Cabassa; BMC Health Services Research 20:190; 2020

Summary Points

- Advance implementation research methods to accelerate uptake, spread, impact, and sustainment of Serious Illness Interventions.
- Identify the essential core components of interventions that cannot be changed (*fidelity to function vs. form*) and embrace community-engaged adaptation to improve uptake, fit, acceptability, feasibility, reach, sustainability of serious illness interventions.
- Engage diverse patients and families representing a spectrum of health inequities in intervention co-design to improve the likelihood of successful implementation, spread, and impact.
- Focus on engagement, equity, and reach from the beginning.

Selected Examples: Serious Illness Implementation Research

- Evaluating the implementation and impact of navigator-supported remote symptom monitoring and management: a protocol for a hybrid type 2 clinical trial. Rocque G et al., BMC Health Serv Res. 2022
- Long-term Effect of Machine Learning-Triggered Behavioral Nudges on Serious Illness Conversations and End-of-Life Outcomes Among Patients With Cancer: A Randomized Clinical Trial. Manz CR et al. JAMA Oncol. 2023
- Early Integrated Telehealth versus In-Person Palliative Care for Patients with Advanced Lung Cancer: A Study Protocol. Chua IS et al. J Palliat Med. 2019
- Acceptability of a Serious Illness Conversation Guide to Black Americans: Results from a focus group and oncology pilot study. Sanders JJ et al., Palliat Support Care. 2022
- African American Recruitment in Early Heart Failure Palliative Care Trials: Outcomes and Comparison With the ENABLE CHF-PC Randomized Trial. Stockdill et al. J Palliat Care. 2023
- Adaptations to the Serious Illness Conversation Guide to Be More Culturally Safe. Beddard-Huber et al., 2020 International Journal of Indigenous Health