A Brief Introduction to Implementation Science in the Context of Pragmatic Trials : An NIH Perspective

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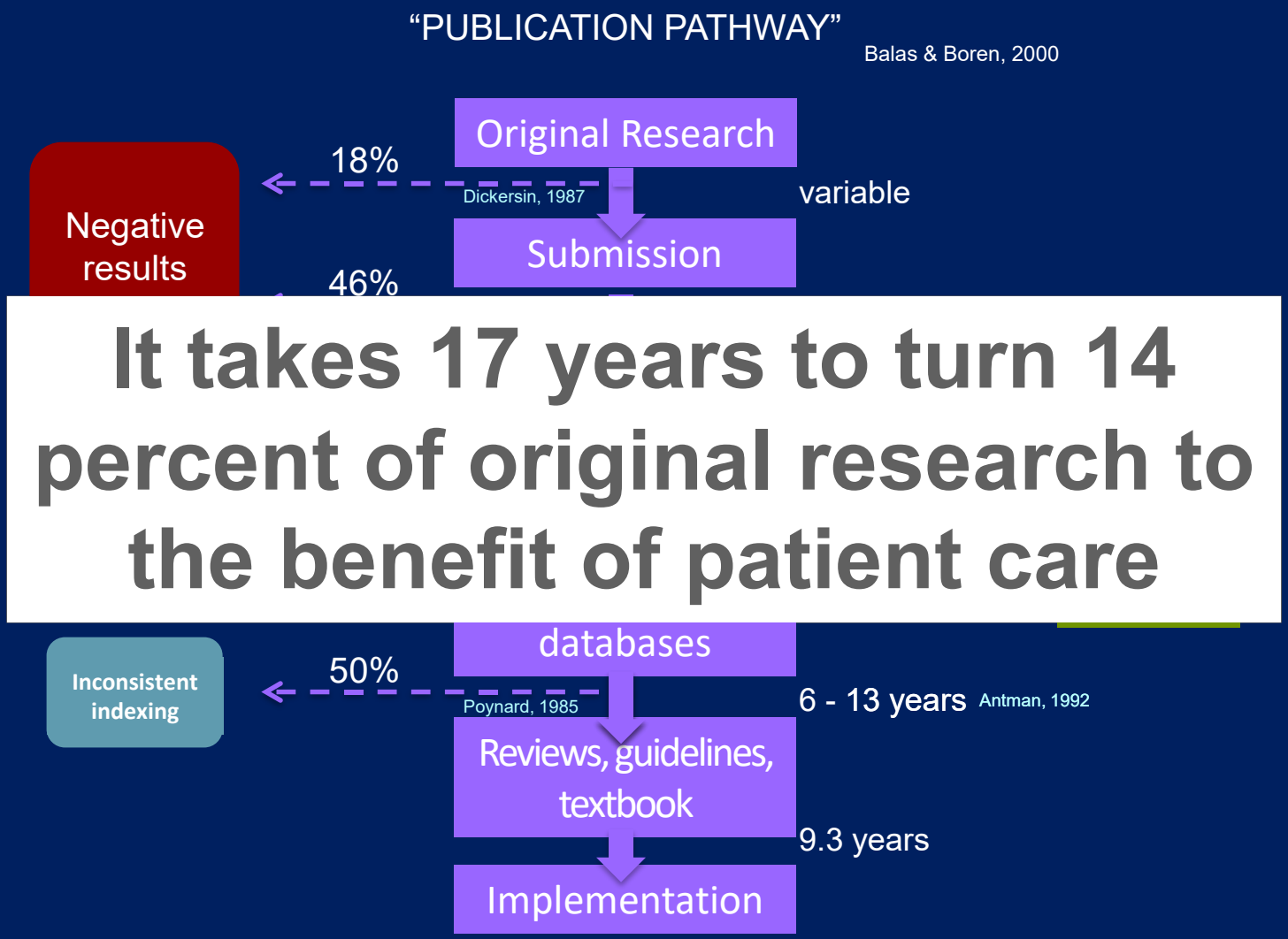
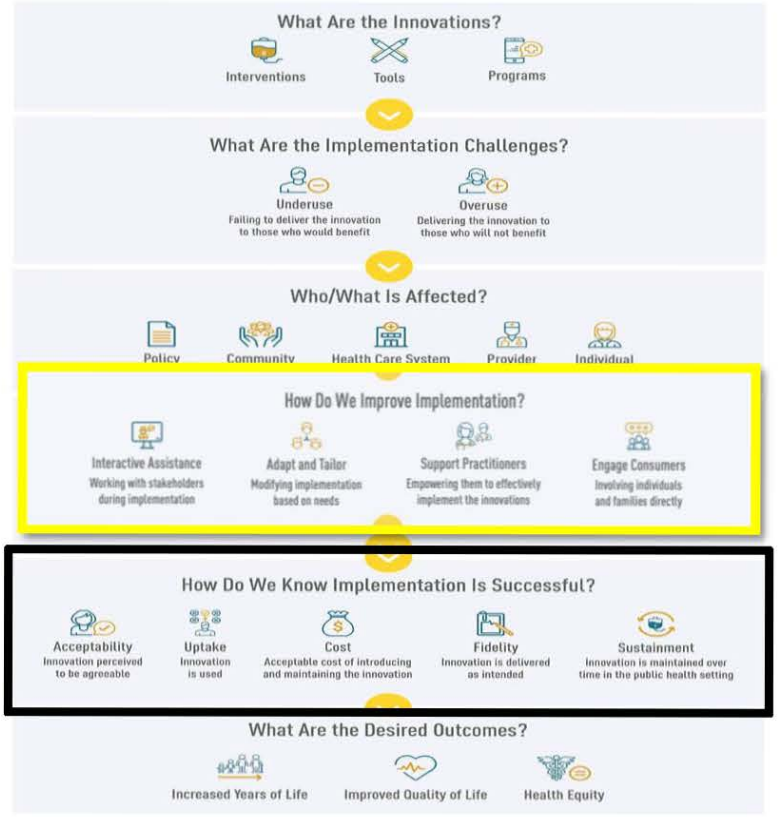
NIH NATIONAL CANCER INSTITUTE

Session Outline

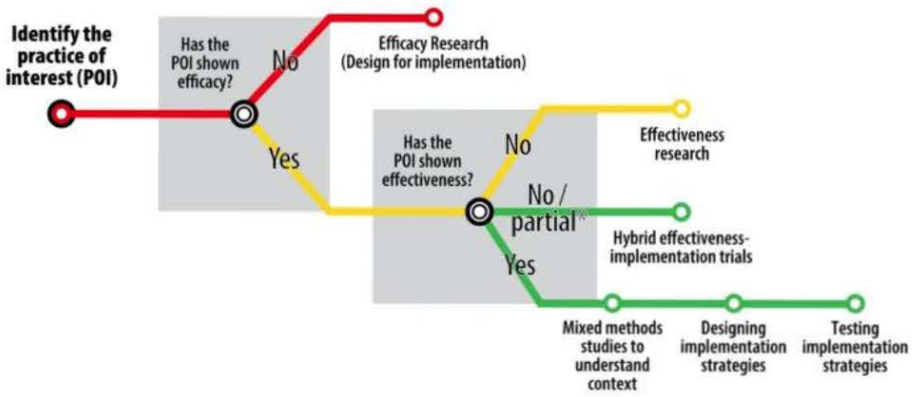
- What is Implementation Science and How Does it Relate to Health Research?
- Considering IS in the context of Pragmatic Trials
- Assumptions, Implications, and Opportunities


"PUBLICATION PATHWAY"
Balas & Boren, 2000
Original Research
18%
Dickersin, 1987
Negative results
variable
Submission
46%
It takes 17 years to turn 14 percent of original research to the benefit of patient care
databases
Inconsistent indexing
50%
Poynard, 1985
6 - 13 years
Antman, 1992
Reviews, guidelines, textbook
9.3 years
Implementation

A Brief Intro to Implementation Science



NCI Annual Plan 2021

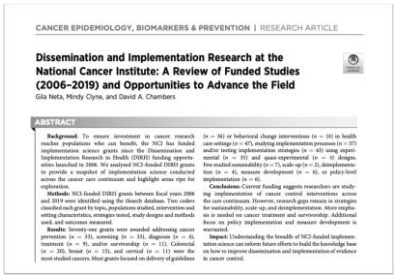


"Subway" schematic to guide researchers contemplating implementation studies of evidence-based interventions

Lane-Fall, Curran, & Beidas, *BMC Medical Research Methodology* (2019)

Trans-NIH PARs: Dissemination and Implementation Research in Health

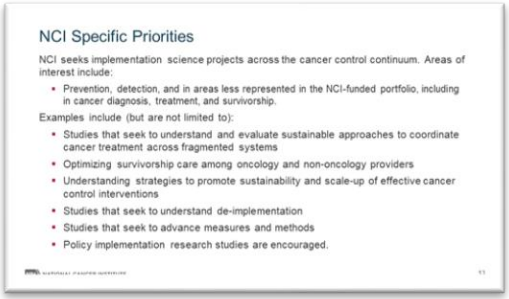
PAR-22-105 (**R01**, Clinical Trials Optional)	PAR-22-109 (**R21**, Clinical Trials Optional)	PAR-22-106 (**R03**, Clinical Trials Not Allowed)
NCI, NCCIH, NHGRI, NIA, NIAAA, NIAID, NIAMS, NICHD, NIDA, NIDCD, NIDCR, NIEHS, NIMH, NIMHD, NINDS, NINR, ODP, OBSSR, ORWH	NCI, NCCIH, NHGRI, NIA, NIAAA, NIAID, NIAMS, NIDA, NIDCD, NIEHS, NIMH, NINDS, NINR, Fogarty (FIC), ODP, OBSSR, ORWH	NCI, NHGRI, NIA, NIAAA, NICHD, NIDA, NIDCR, NIEHS, NIMH, NINDS, FIC, ODP, OBSSR, ORWH


CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION | RESEARCH ARTICLE

Dissemination and Implementation Research at the National Cancer Institute: A Review of Funded Studies (2006–2019) and Opportunities to Advance the Field

Gila Neta, Mindy Clyne, and David A. Chambers

ABSTRACT

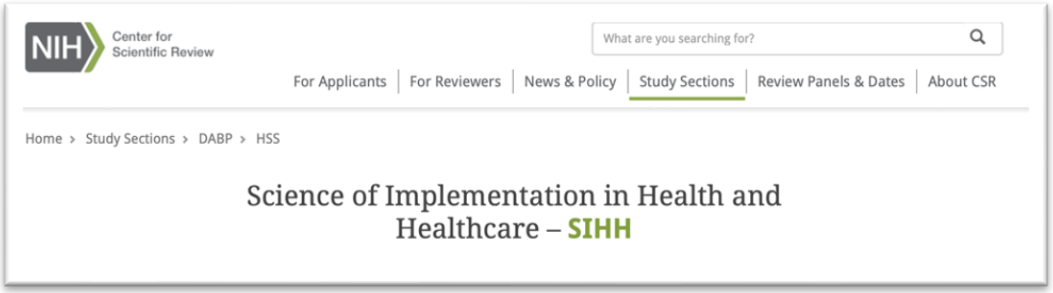

NCI Specific Priorities

NCI seeks implementation science projects across the cancer control continuum. Areas of interest include:

- Prevention, detection, and in areas less represented in the NCI-funded portfolio, including in cancer diagnosis, treatment, and survivorship.

Examples include (but are not limited to):

- Studies that seek to understand and evaluate sustainable approaches to coordinate cancer treatment across fragmented systems
- Optimizing survivorship care among oncology and non-oncology providers
- Understanding strategies to promote sustainability and scale-up of effective cancer control interventions
- Studies that seek to understand de-implementation
- Studies that seek to advance measures and methods
- Policy implementation research studies are encouraged.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Science of Implementation in Health and Healthcare – SIHH


Notice of Special Interest

Dissemination and Implementation Science for Cancer Prevention and Control in Low Resource Settings

The purpose of this Notice is to inform potential applicants of the interest of the National Cancer Institute (NCI) in supporting implementation research related to cancer prevention and control in low- and middle-income countries (LMICs). NCI encourages applications that pursue innovative approaches to identifying, understanding, and developing strategies for overcoming barriers to the adoption, adaptation, integration, scale-up, and sustainability of evidence-based interventions, tools, policies, and guidelines in low-resource settings.

Earliest Submission Date: 5 October 2022 | Expiration Date: 8 May 2024

- NCI Team Leads: Gila Neta, Wynne Norton
- Reissued most recently in May 2022
- IC-specific priorities in each announcement

Select NCI-Funded IS Grants

R01: Implementing Tobacco Use Treatment Guidelines in Community Health Centers in Vietnam

Principal Investigator

Donna Shelley, MD, MPH
NEW YORK UNIVERSITY*

FOA**
PAR 13-055

Award Number
R01#CA175329-01A1

View Funded Grant (PDF, 2.21MB)

R01: De-implementation of low value castration for men with prostate cancer

Principal Investigator

Ted Skolarus, MD, MPH, FACS
UNIVERSITY OF MICHIGAN AT ANN ARBOR*

FOA**
PAR 16-238

Award Number
R37#CA222885-01

View Funded Grant (PDF, 828.73KB)

R01: Disseminating an Evidence-Based Tobacco Control Intervention for School Teachers in India

Principal Investigator

Glorian Sorenson, PhD, MPH
HARVARD SCHOOL OF PUBLIC HEALTH*

FOA**
PAR 13-055

Award Number
R01#CA200691-01A1

View Funded Grant (PDF, 1.26MB)

R21: Effective Training Models for Implementing Health-Promoting Practices Afterschool

Principal Investigator

Rebekka Mairghread Lee, ScD
HARVARD SCHOOL OF PUBLIC HEALTH*

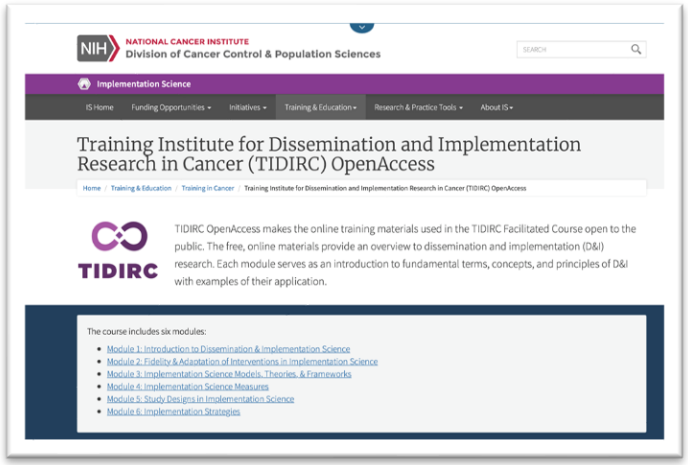
FOA**
PAR 13-054

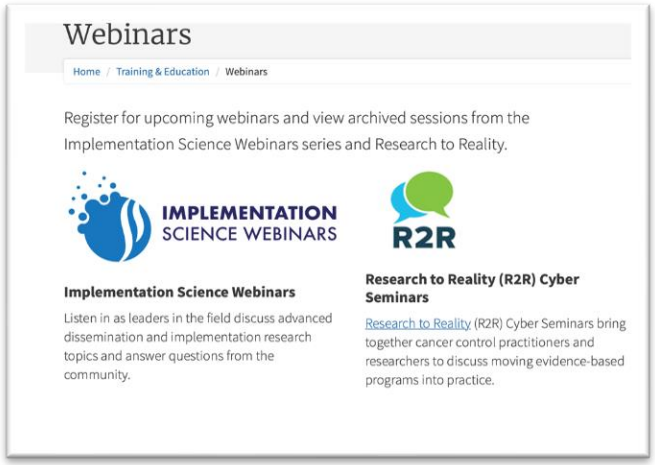
Award Number
R21#CA201567-01A1

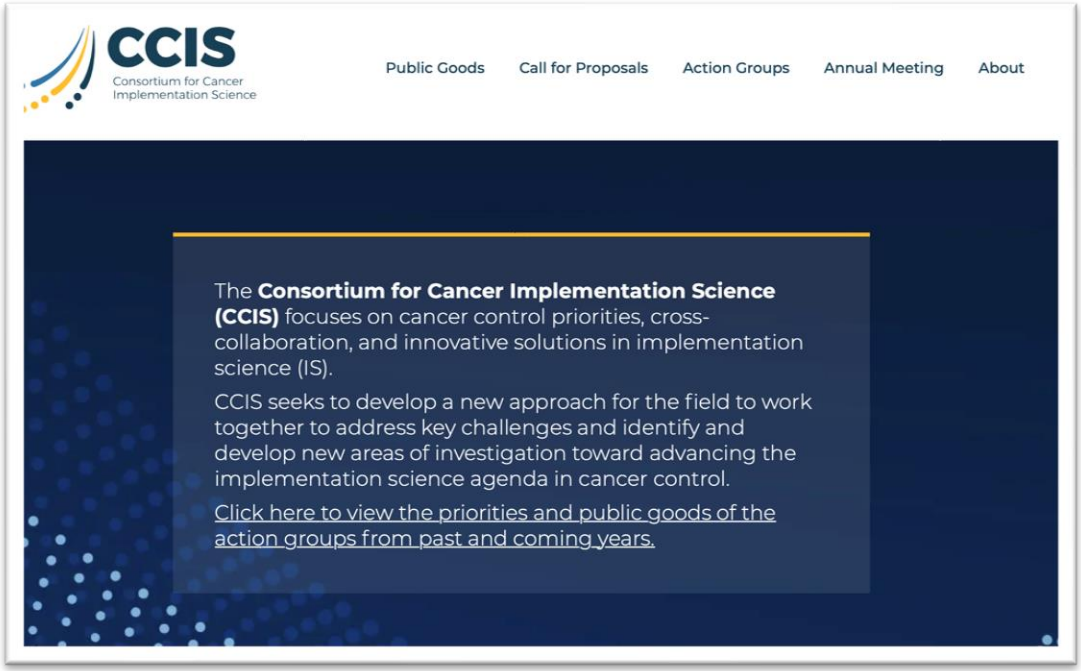
View Funded Grant (PDF, 836.74KB)

https://cancercontrol.cancer.gov/is/funding/sample-grant-applications

Implementation Science Resources







The Importance of What…

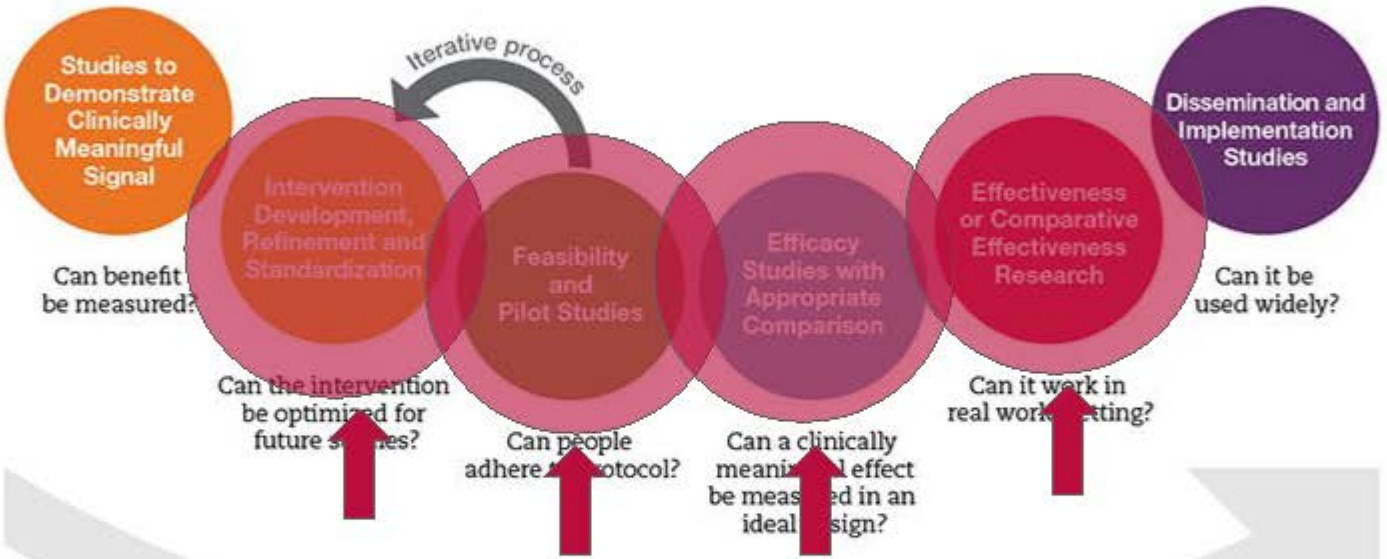
What is the intervention that needs to be implemented?

A. Genetic/genomic tests
B. Information Dissemination/educational intervention
C. Monitoring and Follow-up
D. Preventive Care
E. Treatment
F. All of the above?

The fish-bicycle conundrum…

Ref: Paraphrased from Irina Dunn, 1970

Adjusting When We Study Implementation



https://ncc

An earlier focus on…

- Who's going to deliver it?
- Fit with ultimate patient population
- Building in tests of training, support, adherence, mediators and moderators to high quality delivery
- Hybrid designs

Selecting a Hybrid Design

PERSPECTIVE article

Front. Health Serv., 08 December 2022
Sec. Implementation Science
Volume 2 - 2022 |
https://doi.org/10.3389/frhs.2022.1053496

This article is part of the Research Topic
Hybrid Effectiveness-Implementation Trial Designs: Critical Assessments, Innovative Applications, and Proposed Advancements
View all 3 Articles >

Reflections on 10 years of effectiveness-implementation hybrid studies

Geoffrey M. Curran[1,2*], Sara J. Landes[3,4*†], Sacha A. McBain[4], Jeffrey M. Pyne[2,4], Justin D. Smith[5], Maria E. Fernandez[6], David A. Chambers[7] and Brian S. Mittman[8]

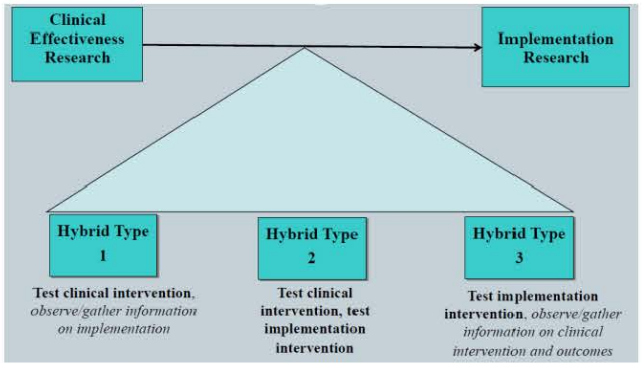


Figure 1

1. What is the nature of the effectiveness data on your intervention of interest?
   - Very-to-moderately strong, especially if not a lot of intervention adaptation needs to take place? Consider type 3 or type 2 depending on how much you expect the intervention will need to be adapted (Question 2).
   - Mixed results? Missing (strong) effectiveness data? Consider types 1 or 2.
2. How much do you expect the intervention will need to be adapted for where you want to study/use it?
   - A little? Consider type 2 or 3, including adaptation process as a step in an implementation-focused project.
   - A lot? Consider focusing on effectiveness in a type 1 or type 2.
3. How much do you already know about implementation determinants for the intervention in your context of interest?
   - Not much? If you also need to focus on effectiveness data, consider type 1.
   - If the effectiveness data are strong, and you know enough already to develop/select a strategy or package of strategies to evaluate? Consider type 2 or 3.
4. How ready are you to evaluate a "real world" implementation strategy or package of strategies?
   - Not ready? A type 1 is indicated, where you collect information on implementation determinants to help you prepare for developing strategies later.
   - Ready, and you need to focus as well on effectiveness of the intervention (Question 1)? Consider a type 2.
   - Ready, and your effectiveness data are strong (Question 1) and you don't need to adapt a lot (Question 2)? Consider a type 3.

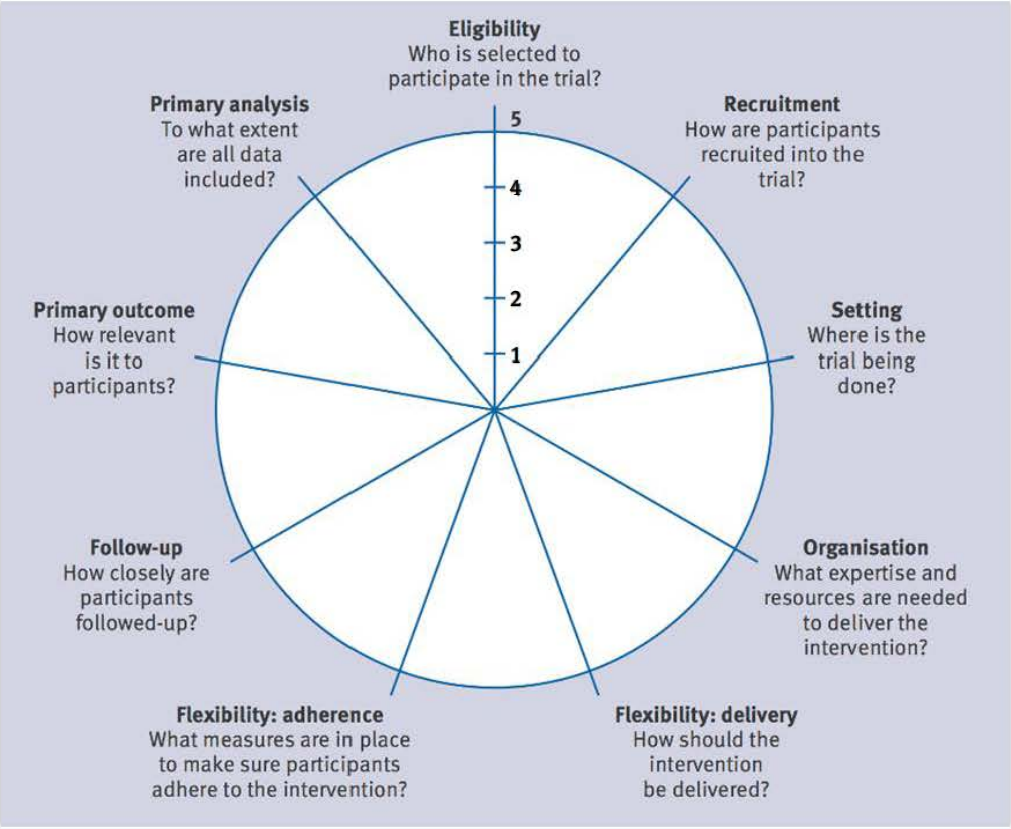
Figure 1. Four questions to consider when selecting a hybrid study type.

Challenge: Well meaning efforts can exacerbate inequities…

- Choice of sites
- Inclusion/exclusion criteria for individuals
- Level of IT/Practice Infrastructure
- Targeted outcomes
- Organizational Context and Climate
- Ecological Characteristics…

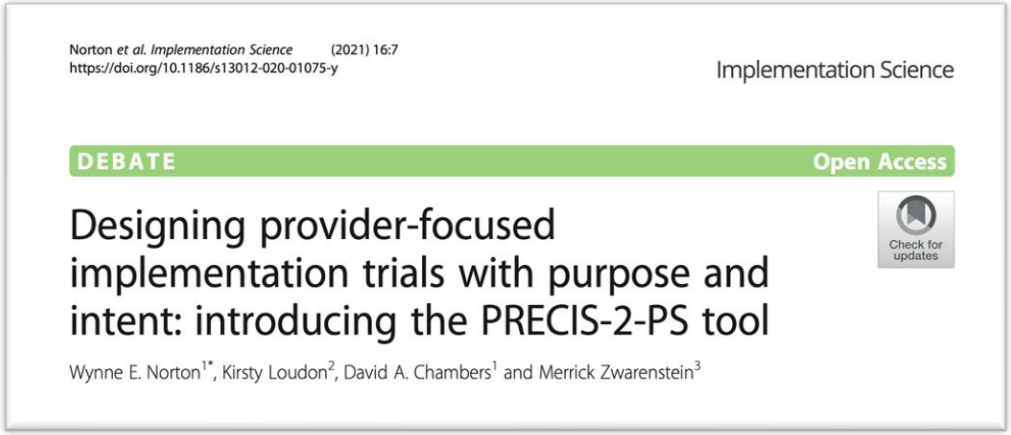
How we Design our Trials:

The PRagmatic-Explanatory Continuum Index Summary 2 (PRECIS-2) wheel



Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. **The PRECIS-2 tool: designing trials that are fit for purpose.** *BMJ.* 2015;350:h2147.

Extending PRECIS-2 to Consider Provider-Strategies to Support Practice Change



Norton *et al. Implementation Science* (2021) 16:7
https://doi.org/10.1186/s13012-020-01075-y

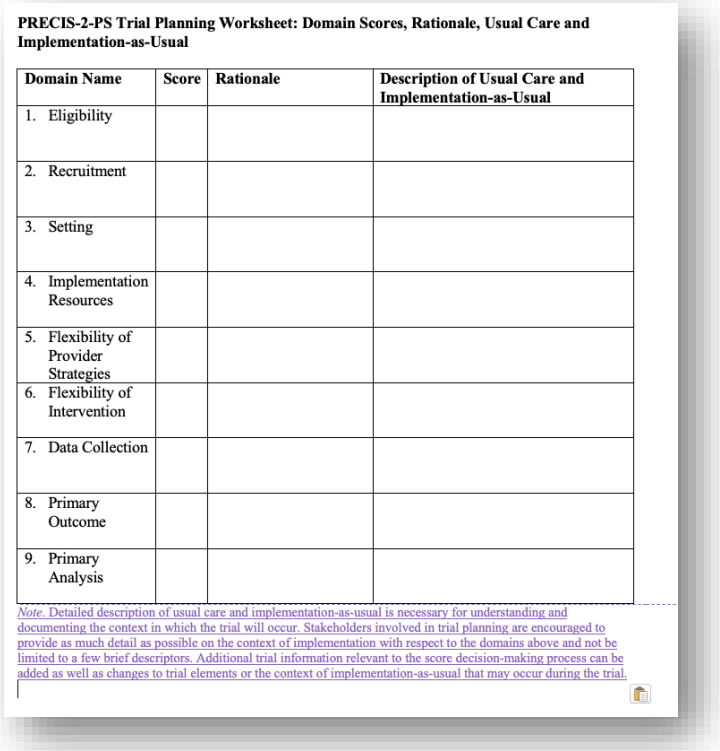
Implementation Science

DEBATE Open Access

Designing provider-focused implementation trials with purpose and intent: introducing the PRECIS-2-PS tool

Wynne E. Norton[1*], Kirsty Loudon[2], David A. Chambers[1] and Merrick Zwarenstein[3]

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7791810/pdf/13012_2020_Article_1075.pdf



PRECIS-2-PS Trial Planning Worksheet: Domain Scores, Rationale, Usual Care and Implementation-as-Usual

Domain Name	Score	Rationale	Description of Usual Care and Implementation-as-Usual
1. Eligibility			
2. Recruitment			
3. Setting			
4. Implementation Resources			
5. Flexibility of Provider Strategies			
6. Flexibility of Intervention			
7. Data Collection			
8. Primary Outcome			
9. Primary Analysis			

Note. Detailed description of usual care and implementation-as-usual is necessary for understanding and documenting the context in which the trial will occur. Stakeholders involved in trial planning are encouraged to provide as much detail as possible on the context of implementation with respect to the domains above and not be limited to a few brief descriptors. Additional trial information relevant to the score decision-making process can be added as well as changes to trial elements or the context of implementation-as-usual that may occur during the trial.

TOWARDS A DYNAMIC VIEW

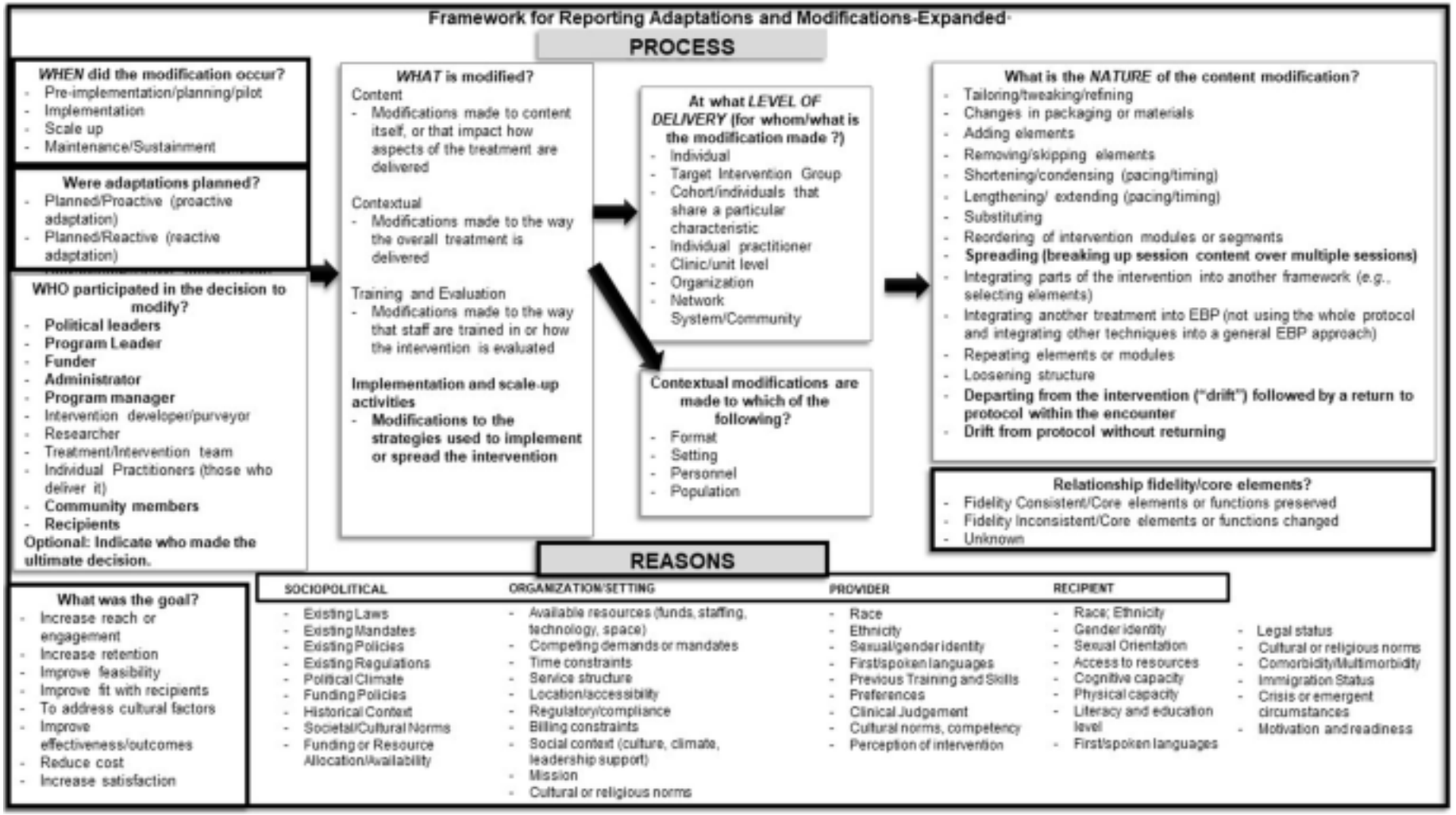
Challenging Traditional Assumptions

- EBPs are static
- System is static
- Implementation proceeds one practice or test at a time
- Consumers/Patients are homogeneous
- Choosing to not implement is irrational

Fidelity vs Adaptation?

Variable use for variable populations, settings, and purposes…

The FRAME (Stirman et al, 2019)



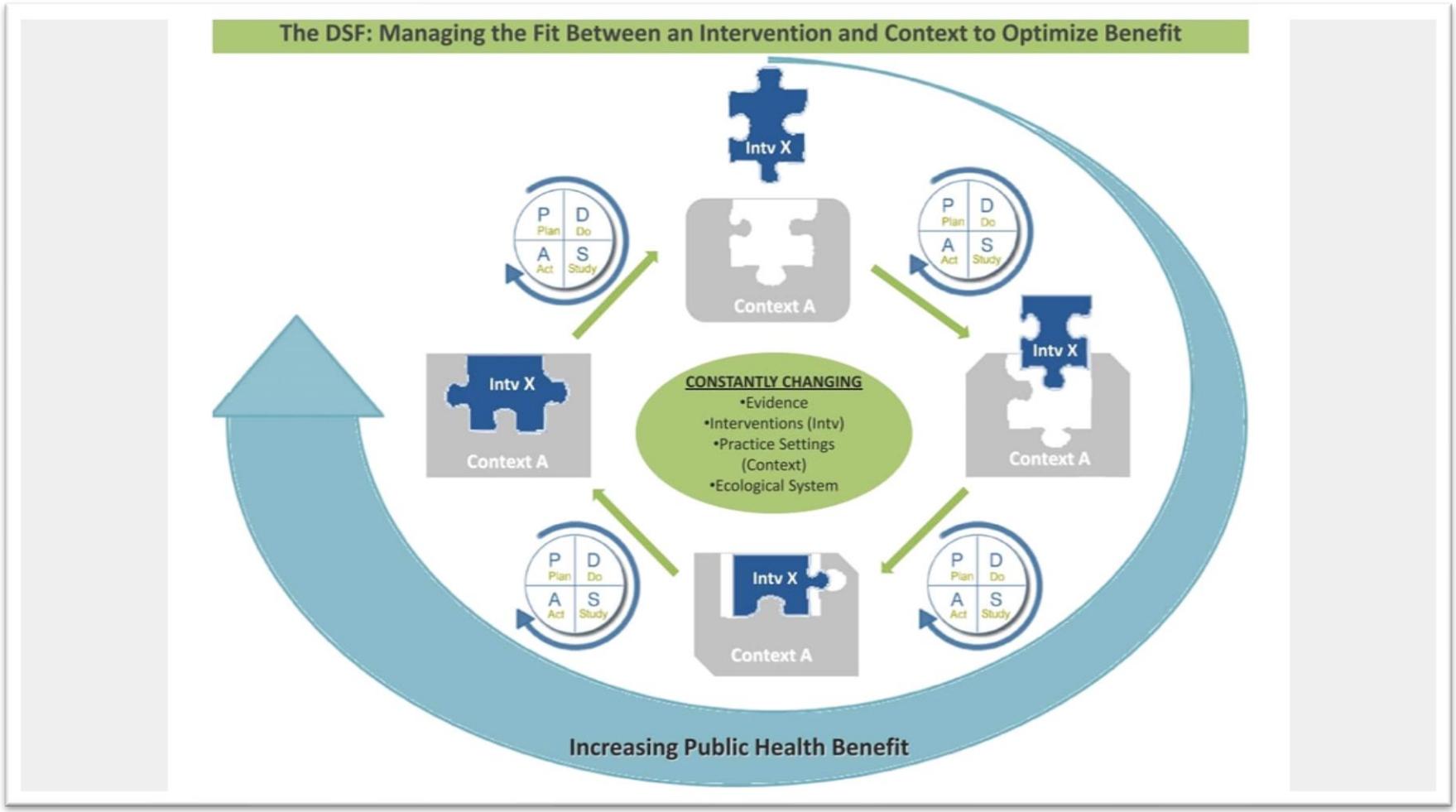
See also: **Frame-IS**, Miller et al, 2021

Sustainability or Evolution?

- IF MEDICINE CONTINUES TO EVOLVE, SHOULD EXISTING INTERVENTIONS BE SUSTAINED IN THE SAME FORM THAT WE'VE CREATED THEM?
- HOW DOES THE SYSTEM COPE WITH A DYNAMIC FIELD THAT IS CONSTANTLY CHANGING?
- WHERE DO WE GO FROM HERE?

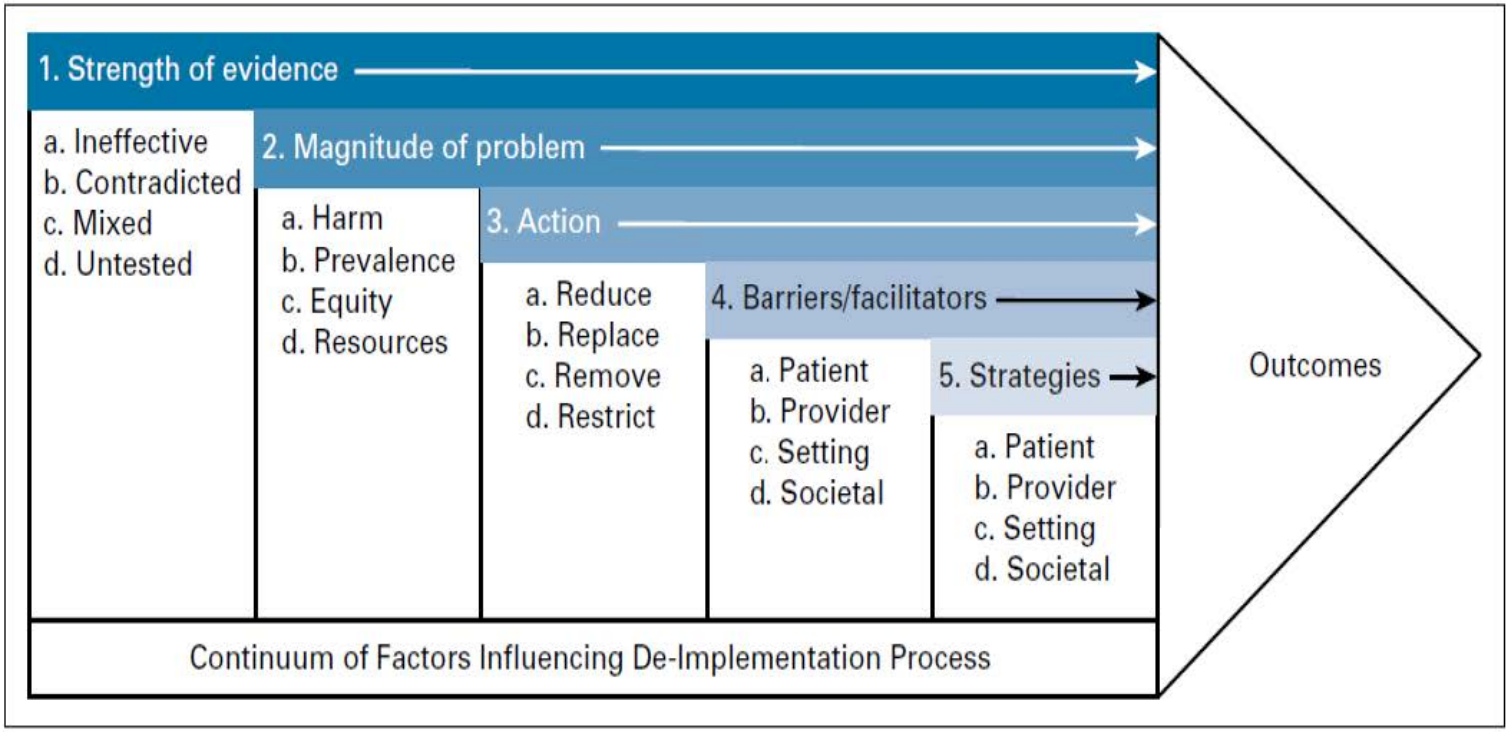
http://www.thestrut.com/2012/12/19/the-evolution-of-the-beatles-hair/

A Dynamic Approach to Sustainability…



Chambers, Stange, & Glasgow, *Implementation Science,* 2013

Need: Understanding De-Implementation



Norton, Chambers, & Kramer, *JCO,* 2018

CODA: Picking up the Pace

Sarah Fisher (Indy Car racer)
Source: Indystar.com

J Clin Transl Sci. 2019 Jun;3(2-3):53-58. doi: 10.1017/cts.2019.386. Epub 2019 Jul 30.

Designing for Accelerated Translation (DART) of Emerging Innovations in Health

Alex T Ramsey [1], Enola K Proctor [2], David A Chambers [3], Jane M Garbutt [4 5], Sara Malone [2 4], William G Powderly [5], Laura J Bierut [1]

Affiliations + expand

PMID: 31528365 PMCID: PMC6746422 DOI: 10.1017/cts.2019.386

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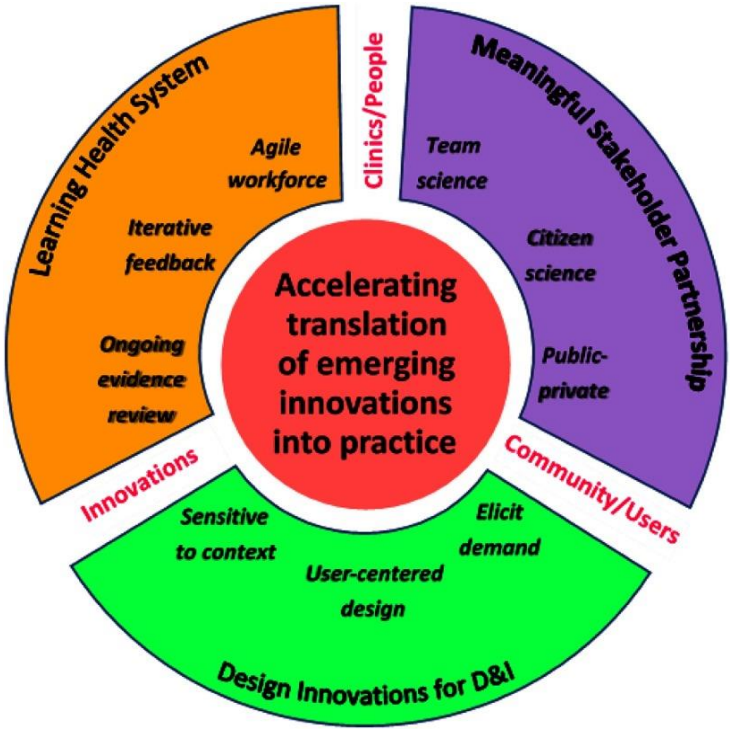


Table 2.

Design for Accelerated Translation (DART) strategies to optimize the implementation of emerging health innovations

	Current State: "Where We Are"	Optimal State: "Where We Want to Be"	Improvement Strategies: "What It Will Take"
Meaningful Stakeholder Partnership	Disconnected from customers; Lab silos	Utilizing team science	Develop partnerships between investigators across the translational spectrum early in design/development
	Small/restrictive samples	Leveraging citizen science	Harness power of public for scientific activities
	Disconnected from industry	Partnering with private industry	Partner with those primed to bring innovations to market
Design Innovations for D&I	Pushing out innovations	Eliciting demand and performance needs from users	Understand user motives and context; demonstrate value added and simplicity
	Researcher-driven development	Engaging in human/user-centered design	Involve diverse group of end-users as partners throughout design/development
	Efficacy over effectiveness	Implementing robust, context-sensitive innovations	Better packaging of research evidence for translation to practice and policy; focus on pragmatic and adaptive trials to optimize adoption potential
Learning Health System	Rigid/narrow use of evidence	Ongoing and efficient review of evidence	Use existing data to add to evidence on intervention impact; conduct rapid reviews; use create–trial–sustain approaches to guide ongoing adaptation
	Static delivery systems	Supporting the use of iterative feedback	Give real-time feedback on key outcomes to providers
	Resistant to change	Promoting an agile workforce with change-oriented mindset	Train workforce in core concepts that apply across technologies

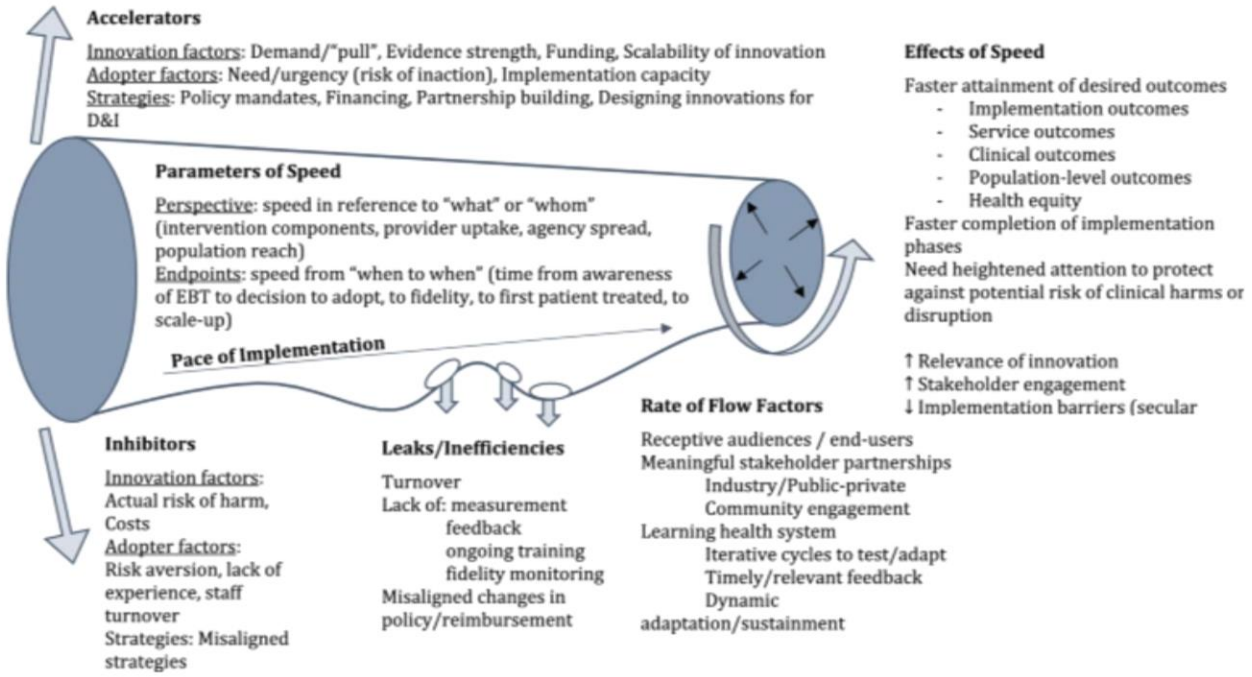
Commentary | Published: 02 June 2022

FAST: A Framework to Assess Speed of Translation of Health Innovations to Practice and Policy

Enola Proctor, Alex T. Ramsey ✉, Lisa Saldana, Thomas M. Maddox, David A. Chambers & Ross C. Brownson

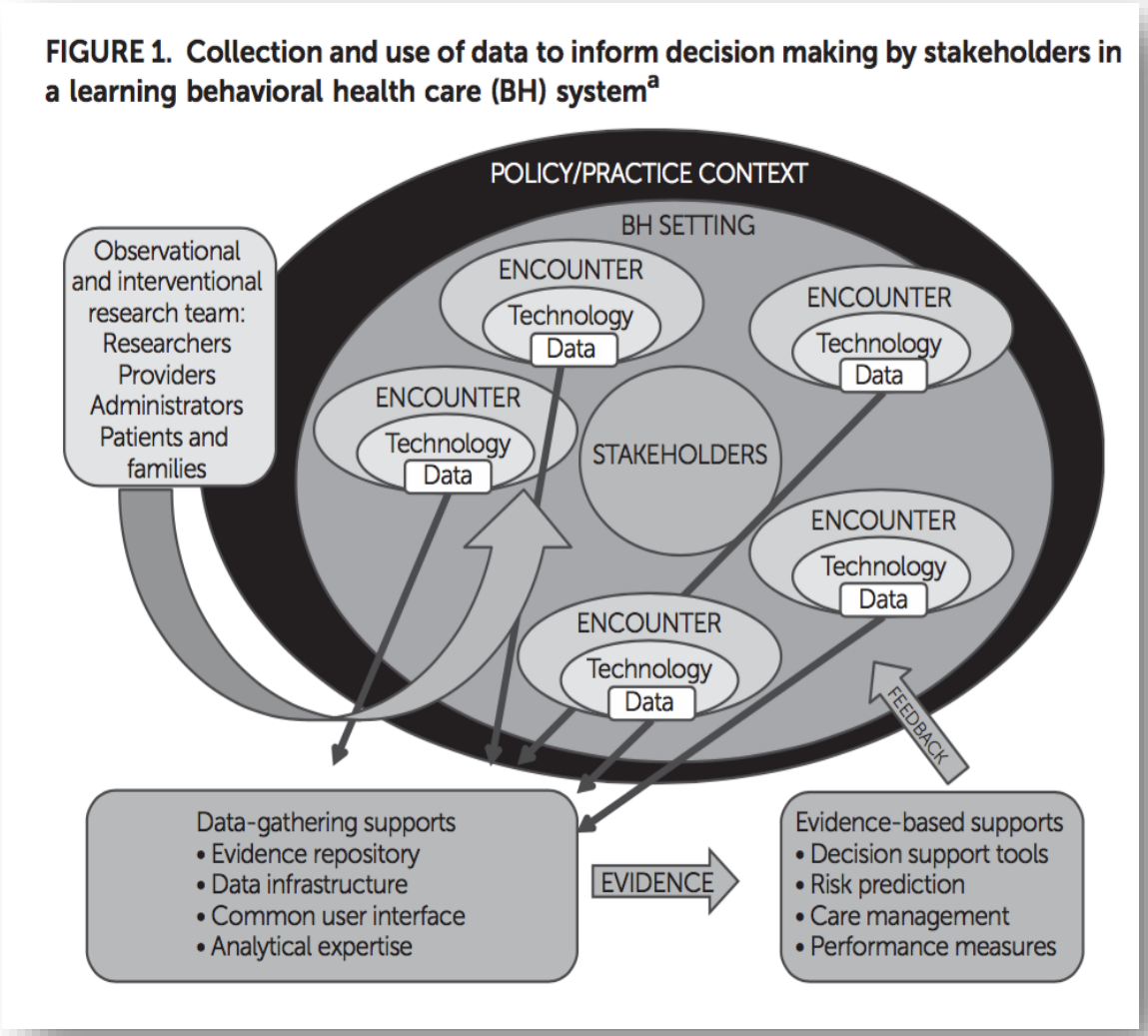
Global Implementation Research and Applications **2**, 107–119 (2022) | Cite this article

Fig. 1



Depiction of the determinants of implementation pace in the framework to assess speed of translation (FAST)

Can Pragmatic Trials be framed in the context of Learning Health Care Systems?



- What is your health system landscape? (e.g. practice partners)
- High priority questions of partners?
- Data and research infrastructure?
- Communication among partner sites?
- What can we learn?

Stein, Adams, Chambers. *Psychiatric Services,* 2016.

Opportunities for Collaboration/Learning

- Studying Implementation Strategies across Pragmatic Trials
- Contributing to the Science of Adaptation
  - *Tracking Adaptations to Interventions*
  - *Adaptive Designs*
- Gathering long-term data on use of interventions
  - *Sustainment or De-implementation*
  - *Evolution or Substitution of Interventions*
- Learning about the context in which interventions are delivered
  - *Common measures*
  - *High-priority questions of partners*

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