A methods primer on hybrid effectiveness-implementation studies

Bryan R. Garner, PhD
Professor and Director of Dissemination & Implementation Science
The Ohio State University (OSU) College of Medicine (COM) and
Center for the Advancement of Team Science,
Analytics, and Systems Thinking in Health Services and
Implementation Science Research (CATALYST)

THE OHIO STATE UNIVERSITY

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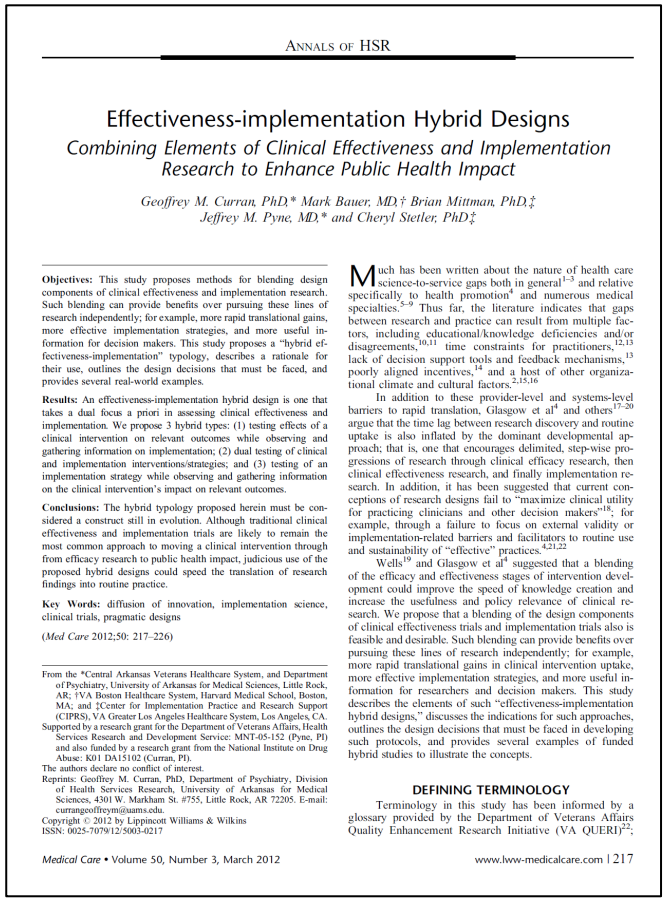
Effectiveness-Implementation Hybrid ~~Designs~~ Studies



ANNALS OF HSR

Effectiveness-implementation Hybrid Designs

Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

Geoffrey M. Curran, PhD, Mark Bauer, MD,† Brian Mittman, PhD,‡ Jeffrey M. Pyne, MD,* and Cheryl Stetler, PhD,‡*

Objectives: This study proposes methods for blending design components of clinical effectiveness and implementation research. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains, more effective implementation strategies, and more useful information for decision makers. This study proposes a "hybrid effectiveness-implementation" typology, describes a rationale for their use, outlines the design decisions that must be faced, and provides several real-world examples.

Results: An effectiveness-implementation hybrid design is one that takes a dual focus a priori in assessing clinical effectiveness and implementation. We propose 3 hybrid types: (1) testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation; (2) dual testing of clinical and implementation interventions/strategies; and (3) testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

Conclusions: The hybrid typology proposed herein must be considered a construct still in evolution. Although traditional clinical effectiveness and implementation trials are likely to remain the most common approach to moving a clinical intervention through from efficacy research to public health impact, judicious use of the proposed hybrid designs could speed the translation of research findings into routine practice.

Key Words: diffusion of innovation, implementation science, clinical trials, pragmatic designs

(*Med Care* 2012;50: 217–226)

From the *Central Arkansas Veterans Healthcare System, and Department of Psychiatry, University of Arkansas for Medical Sciences, Little Rock, AR; †VA Boston Healthcare System, Harvard Medical School, Boston, MA; and ‡Center for Implementation Practice and Research Support (CIPRS), VA Greater Los Angeles Healthcare System, Los Angeles, CA.

Supported by a research grant for the Department of Veterans Affairs, Health Services Research and Development Service: MNT-05-152 (Pyne, PI) and also funded by a research grant from the National Institute on Drug Abuse: K01 DA15102 (Curran, PI).

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Reprints: Geoffrey M. Curran, PhD, Department of Psychiatry, Division of Health Services Research, University of Arkansas for Medical Sciences, 4301 W. Markham St. #755, Little Rock, AR 72205. E-mail: currangeoffreym@uams.edu.

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Much has been written about the nature of health care science-to-service gaps both in general[1–3] and relative specifically to health promotion[4] and numerous medical specialties.[5–9] Thus far, the literature indicates that gaps between research and practice can result from multiple factors, including educational/knowledge deficiencies and/or disagreements,[10,11] time constraints for practitioners,[12,13] lack of decision support tools and feedback mechanisms,[13] poorly aligned incentives,[14] and a host of other organizational climate and cultural factors.[2,15,16]

In addition to these provider-level and systems-level barriers to rapid translation, Glasgow et al[4] and others[17–20] argue that the time lag between research discovery and routine uptake is also inflated by the dominant developmental approach; that is, one that encourages delimited, step-wise progressions of research through clinical efficacy research, then clinical effectiveness research, and finally implementation research. In addition, it has been suggested that current conceptions of research designs fail to "maximize clinical utility for practicing clinicians and other decision makers"[18]; for example, through a failure to focus on external validity or implementation-related barriers and facilitators to routine use and sustainability of "effective" practices.[4,21,22]

Wells[19] and Glasgow et al[4] suggested that a blending of the efficacy and effectiveness stages of intervention development could improve the speed of knowledge creation and increase the usefulness and policy relevance of clinical research. We propose that a blending of the design components of clinical effectiveness trials and implementation trials also is feasible and desirable. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains in clinical intervention uptake, more effective implementation strategies, and more useful information for researchers and decision makers. This study describes the elements of such "effectiveness-implementation hybrid designs," discusses the indications for such approaches, outlines the design decisions that must be faced in developing such protocols, and provides several examples of funded hybrid studies to illustrate the concepts.

DEFINING TERMINOLOGY

Terminology in this study has been informed by a glossary provided by the Department of Veterans Affairs Quality Enhancement Research Initiative (VA QUERI)[22];

Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*, *50*(3), 217.

- **A study that takes a <u>dual focus</u> in assessing clinical effectiveness and implementation.**
- **Hybrid studies <u>typically</u> of 3 types:**

  Type 1: <u>testing</u> effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation

  Type 2: <u>dual testing</u> of clinical intervention and implementation strategy

  Type 3: <u>testing</u> of an implementation strategy while examining information on the clinical intervention's impact on relevant outcomes

- **Such dual foci are <u>always stated a priori</u>**

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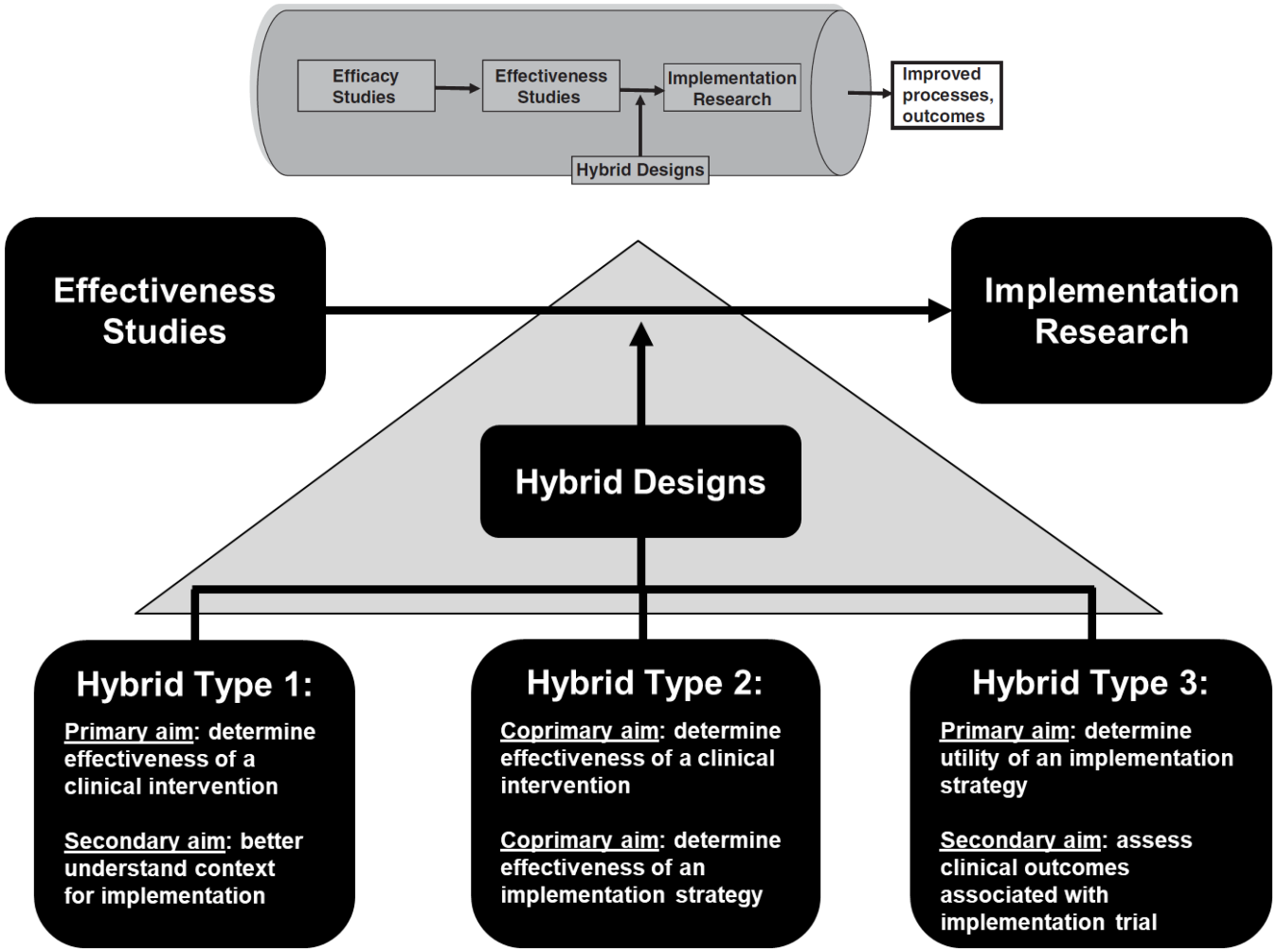
FIGURE 1. Research pipeline.



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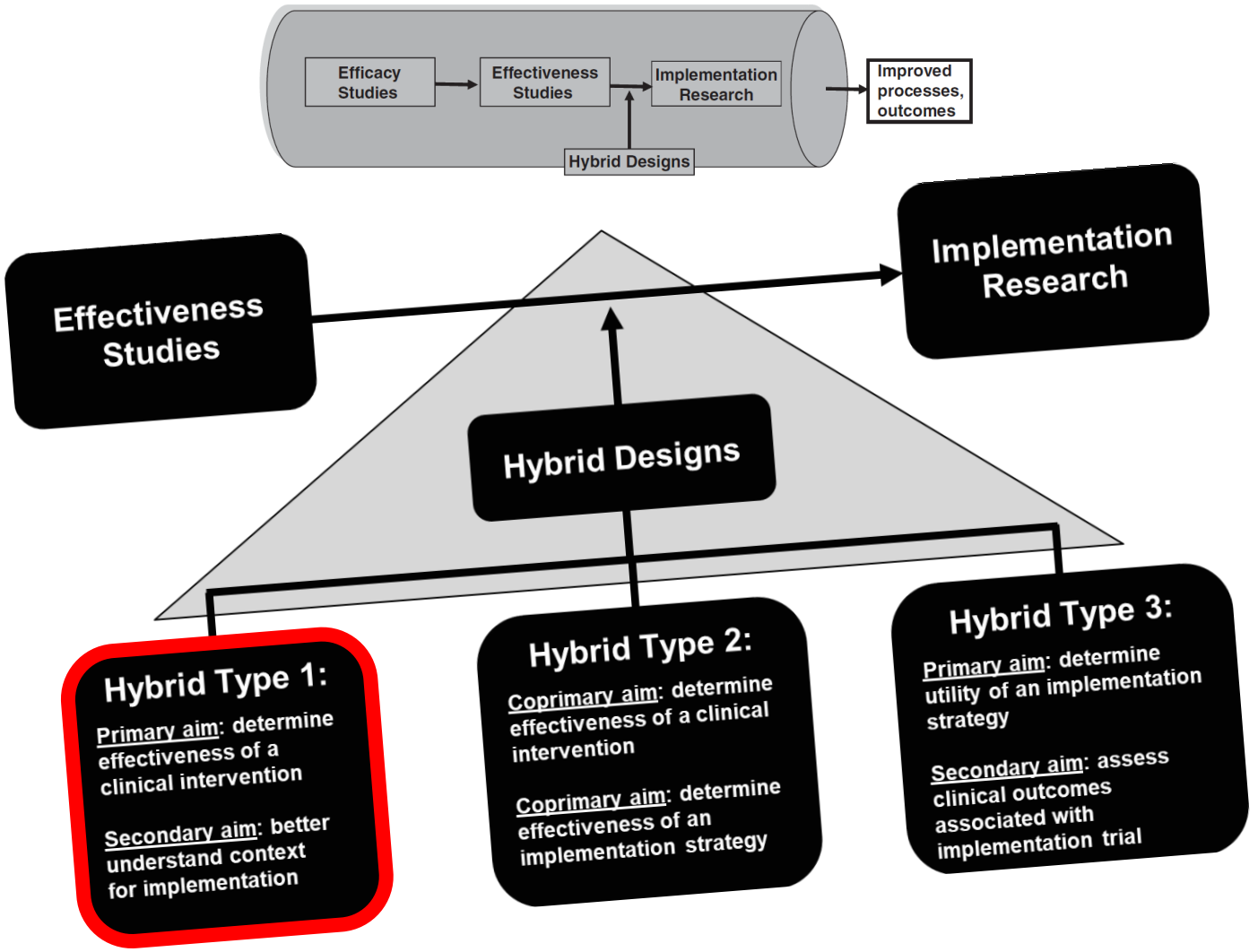

The Implementation Research Logic Model (IRLM)

Smith et al. Implementation Science (2020) 15:84
https://doi.org/10.1186/s13012-020-01041-8

Implementation Science

RESEARCH Open Access

The Implementation Research Logic Model: a method for planning, executing, reporting, and synthesizing implementation projects

Justin D. Smith[1,2*], Dennis H. Li[3] and Miriam R. Rafferty[4]

Abstract

Background: Numerous models, frameworks, and theories exist for specific aspects of implementation research, including for determinants, strategies, and outcomes. However, implementation research projects often fail to provide a coherent rationale or justification for how these aspects are selected and tested in relation to one another. Despite this need to better specify the conceptual linkages between the core elements involved in projects, few tools or methods have been developed to aid in this task. The Implementation Research Logic Model (IRLM) was created for this purpose and to enhance the rigor and transparency of describing the often-complex processes of improving the adoption of evidence-based interventions in healthcare delivery systems.

Methods: The IRLM structure and guiding principles were developed through a series of preliminary activities with multiple investigators representing diverse implementation research projects in terms of contexts, research designs, and implementation strategies being evaluated. The utility of the IRLM was evaluated in the course of a 2-day training to over 130 implementation researchers and healthcare delivery system partners.

Results: Preliminary work with the IRLM produced a core structure and multiple variations for common implementation research designs and situations, as well as guiding principles and suggestions for use. Results of the survey indicated a high utility of the IRLM for multiple purposes, such as improving rigor and reproducibility of projects; serving as a "roadmap" for how the project is to be carried out; clearly reporting and specifying how the project is to be conducted; and understanding the connections between determinants, strategies, mechanisms, and outcomes for their project.

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* Correspondence: jd.smith@hsc.utah.edu; jd.smith@northwestern.edu
[1]Department of Population Health Sciences, University of Utah School of Medicine, Salt Lake City, Utah, USA
[2]Center for Prevention Implementation Methodology for Drug Abuse and HIV, Department of Psychiatry and Behavioral Sciences, Department of Preventive Medicine, Department of Medical Social Sciences, and Department of Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA
Full list of author information is available at the end of the article

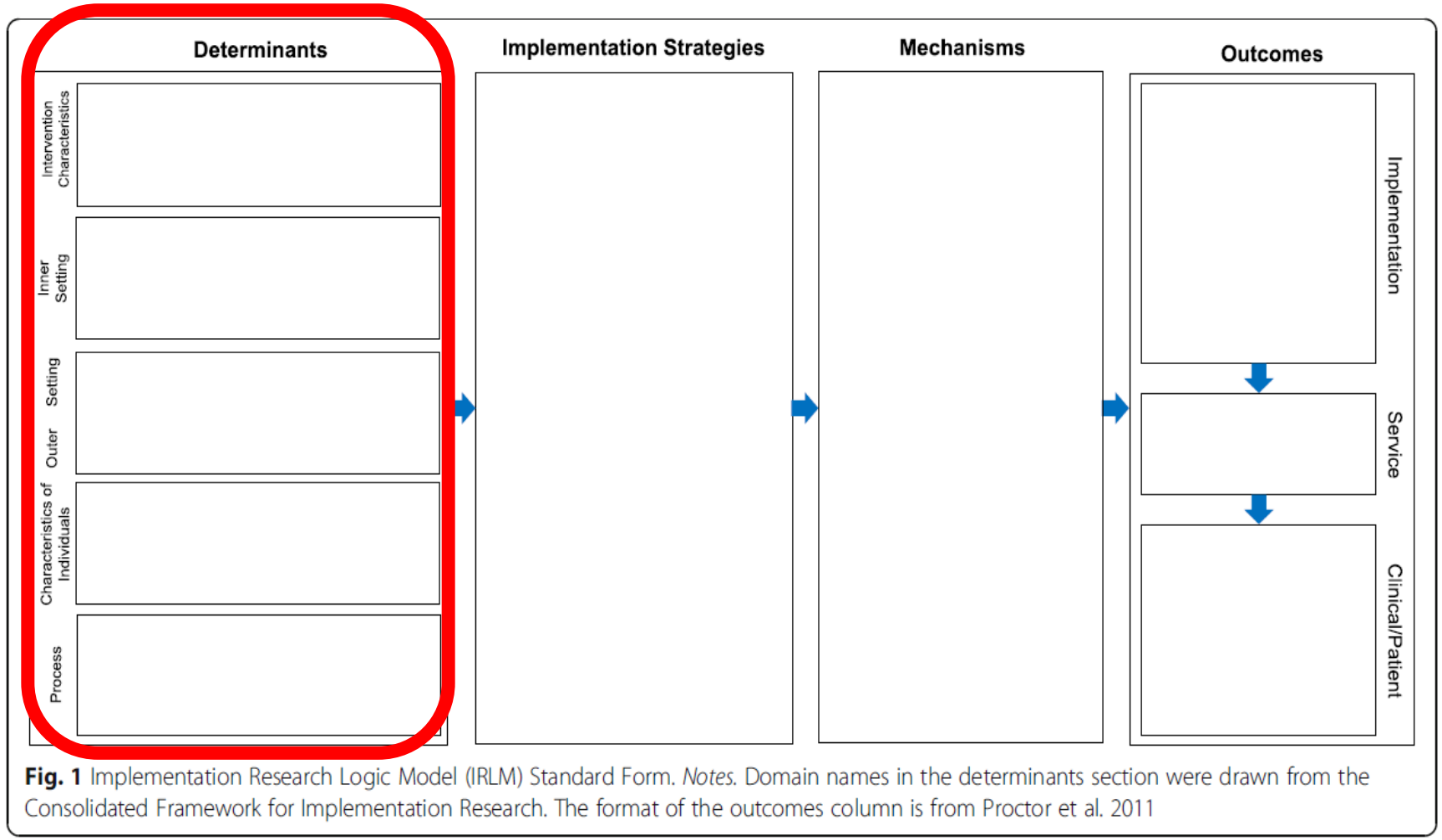

Fig. 1 Implementation Research Logic Model (IRLM) Standard Form. *Notes.* Domain names in the determinants section were drawn from the Consolidated Framework for Implementation Research. The format of the outcomes column is from Proctor et al. 2011

Smith JD, Li DH, Rafferty MR. The implementation research logic model: a method for planning, executing, reporting, and synthesizing implementation projects. Implementation Science. 2020 Dec;15(1):1-2.

Consolidated Framework for Implementation Research (CFIR)

Implementation Science

BioMed Central

Research article

Open Access

Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science

Laura J Damschroder*[1], David C Aron[2], Rosalind E Keith[1], Susan R Kirsh[2], Jeffery A Alexander[3] and Julie C Lowery[1]

Address: [1]HSR&D Center for Clinical Management Research, VA Ann Arbor Healthcare System (11H), 2215 Fuller Rd, Ann Arbor, MI 48105, USA, [2]VA HSR&D Center for Quality Improvement Research (14W), Louis Stokes Cleveland DVAMC, 10701 East Blvd, Cleveland, OH 44106, USA and [3]Health Management and Policy, School of Public Health, University of Michigan, 109 S. Observatory (M3507 SPH II), Ann Arbor, Michigan 48109-2029, USA

Email: Laura J Damschroder* - laura.damschroder@va.gov; David C Aron - david.aron@va.gov; Rosalind E Keith - rekeith@umich.edu; Susan R Kirsh - susan.kirsh@va.gov; Jeffery A Alexander - jalexand@umich.edu; Julie C Lowery - julie.lowery@va.gov

* Corresponding author

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Abstract

Background: Many interventions found to be effective in health services research studies fail to translate into meaningful patient care outcomes across multiple contexts. Health services researchers recognize the need to evaluate not only summative outcomes but also formative outcomes to assess the extent to which implementation is effective in a specific setting, prolongs sustainability, and promotes dissemination into other settings. Many implementation theories have been published to help promote effective implementation. However, they overlap considerably in the constructs included in individual theories, and a comparison of theories reveals that each is missing important constructs included in other theories. In addition, terminology and definitions are not consistent across theories. We describe the Consolidated Framework For Implementation Research (CFIR) that offers an overarching typology to promote implementation theory development and verification about what works where and why across multiple contexts.

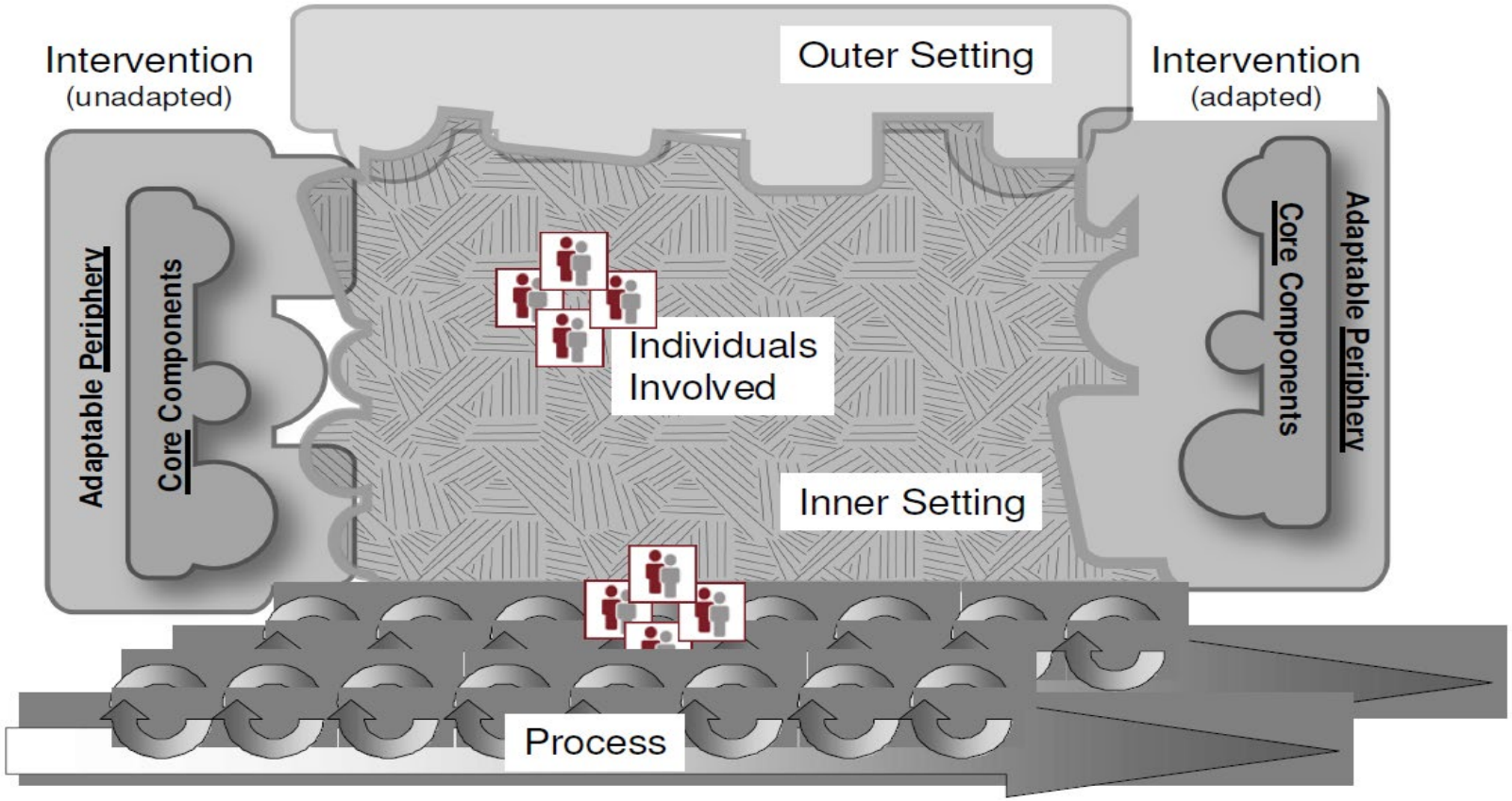
Methods: We used a snowball sampling approach to identify published theories that were evaluated to identify constructs based on strength of conceptual or empirical support for influence on implementation, consistency in definitions, alignment with our own findings, and potential for measurement. We combined constructs across published theories that had different labels but were redundant or overlapping in definition, and we parsed apart constructs that conflated underlying concepts.

Results: The CFIR is composed of five major domains: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. Eight constructs were identified related to the intervention (e.g., evidence strength and quality), four constructs were identified related to outer setting (e.g., patient needs and resources), 12 constructs were identified related to inner setting (e.g., culture, leadership engagement), five constructs were identified related to individual characteristics, and eight constructs were identified related to process (e.g., plan, evaluate, and reflect). We present explicit definitions for each construct.

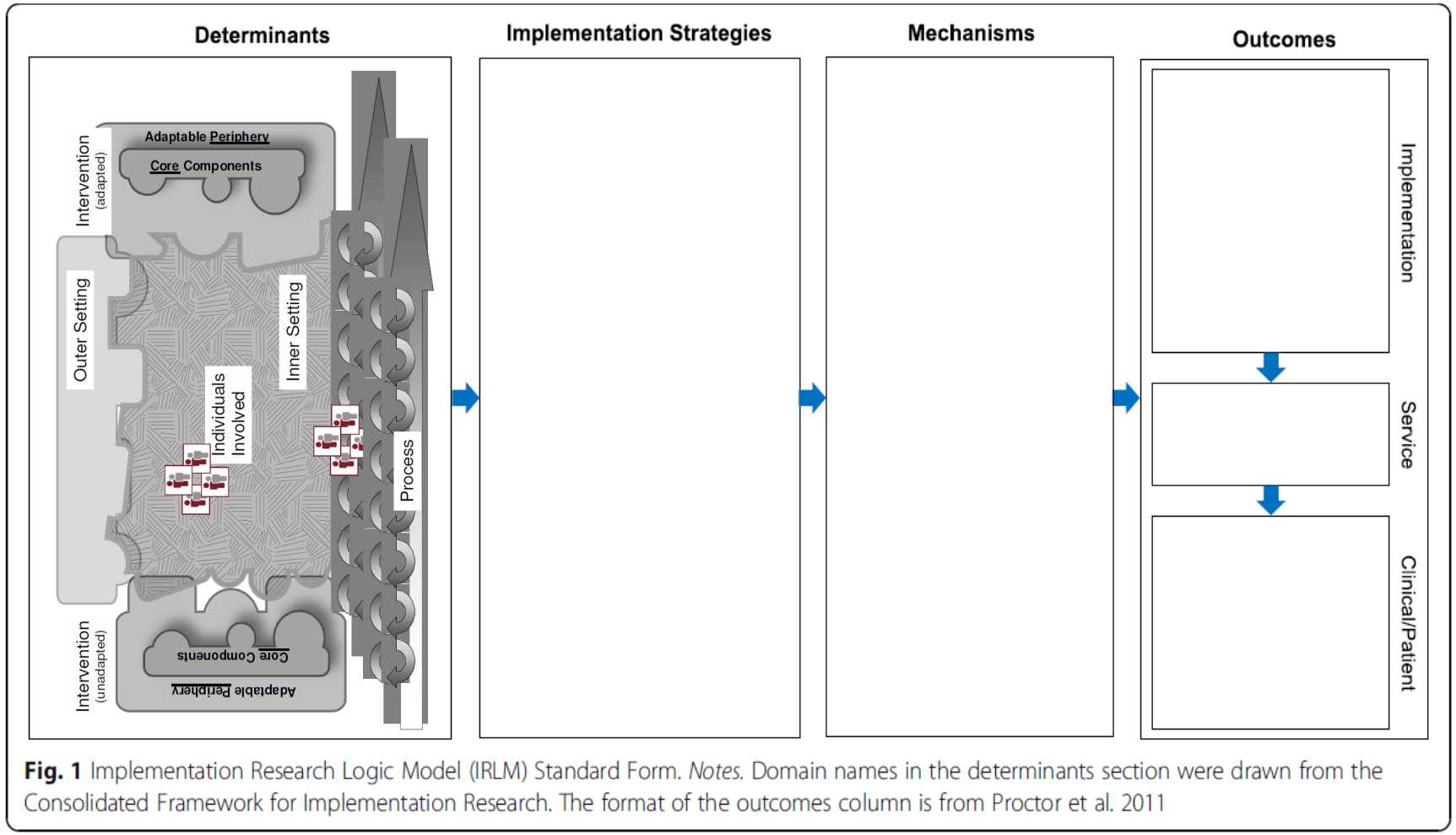
Conclusion: The CFIR provides a pragmatic structure for approaching complex, interacting, multi-level, and transient states of constructs in the real world by embracing, consolidating, and unifying key constructs from published implementation theories. It can be used to guide formative evaluations and build the implementation knowledge base across multiple studies and settings.

Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implementation science. 2009 Dec;4(1):1-5.

Figure 1: Major Domains of the CFIR



CFIR within the IRLM



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Note the CFIR has been updated

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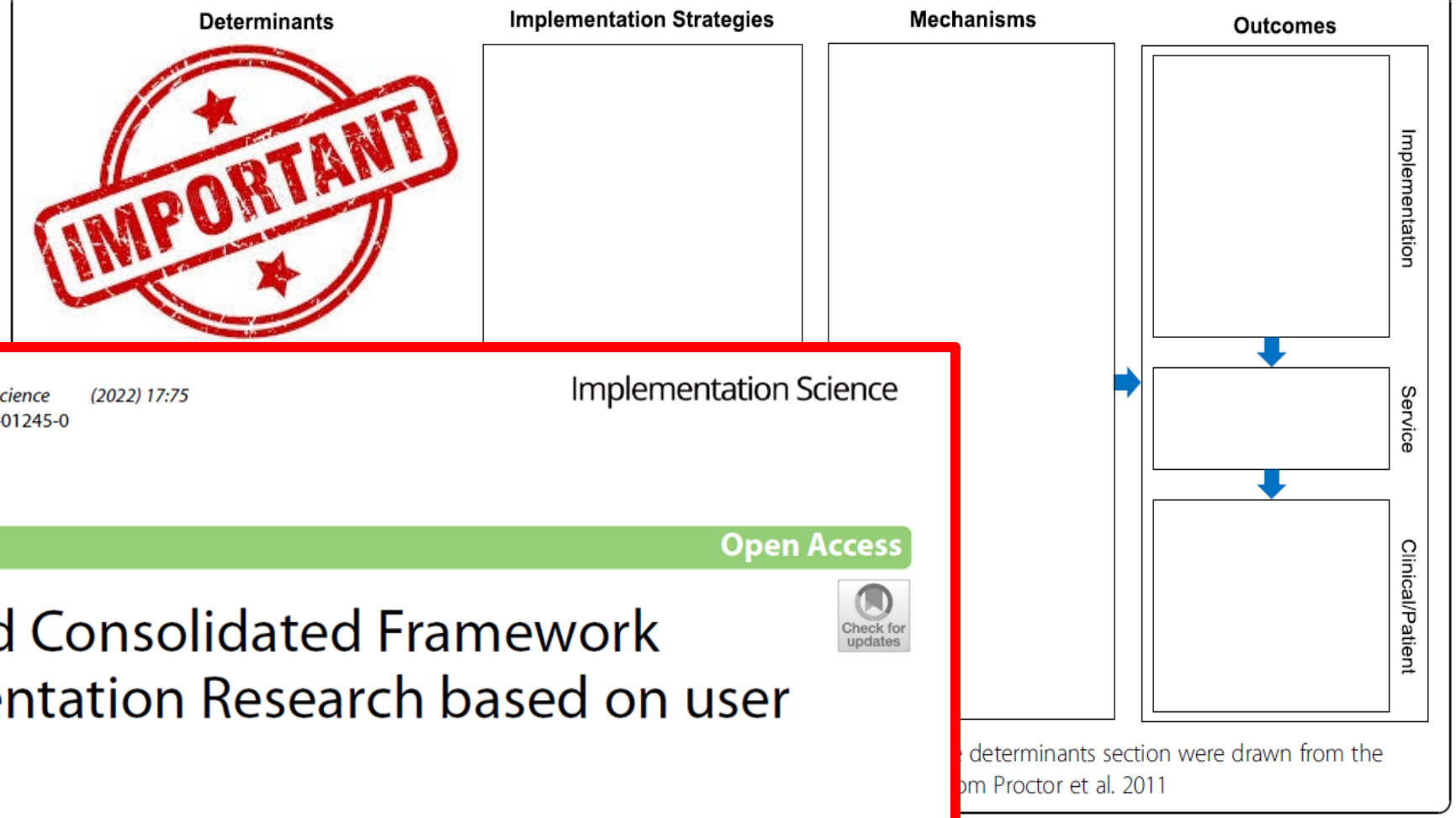

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The updated Consolidated Framework for Implementation Research based on user feedback

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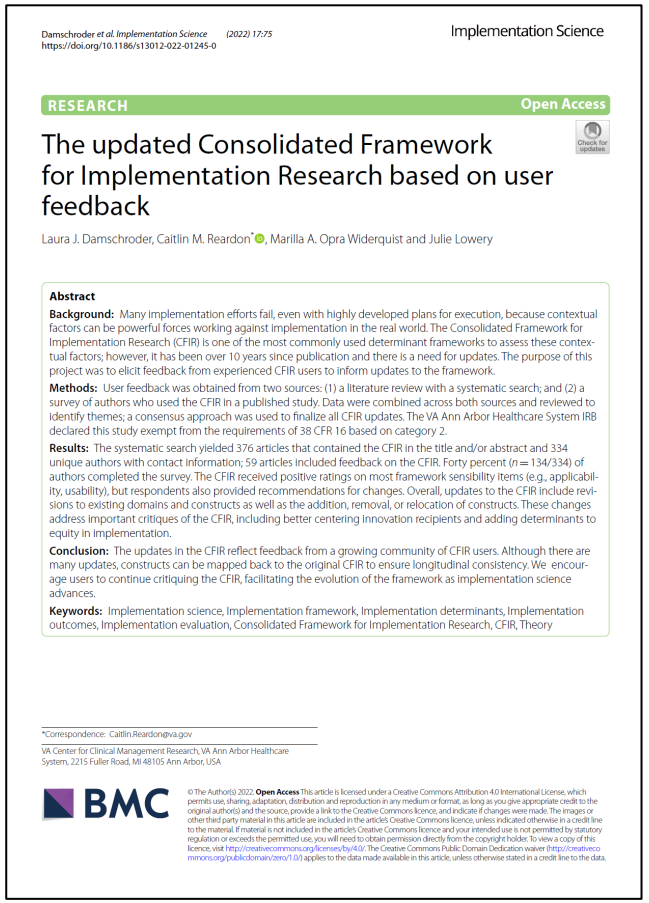

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Abstract

Background: Many implementation efforts fail, even with highly developed plans for execution, because contextual factors can be powerful forces working against implementation in the real world. The Consolidated Framework for Implementation Research (CFIR) is one of the most commonly used determinant frameworks to assess these contextual factors; however, it has been over 10 years since publication and there is a need for updates. The purpose of this project was to elicit feedback from experienced CFIR users to inform updates to the framework.

Methods: User feedback was obtained from two sources: (1) a literature review with a systematic search; and (2) a survey of authors who used the CFIR in a published study. Data were combined across both sources and reviewed to identify themes; a consensus approach was used to finalize all CFIR updates. The VA Ann Arbor Healthcare System IRB declared this study exempt from the requirements of 38 CFR 16 based on category 2.

Results: The systematic search yielded 376 articles that contained the CFIR in the title and/or abstract and 334 unique authors with contact information; 59 articles included feedback on the CFIR. Forty percent ($n = 134/334$) of authors completed the survey. The CFIR received positive ratings on most framework sensibility items (e.g., applicability, usability), but respondents also provided recommendations for changes. Overall, updates to the CFIR include revisions to existing domains and constructs as well as the addition, removal, or relocation of constructs. These changes address important critiques of the CFIR, including better centering innovation recipients and adding determinants to equity in implementation.

Conclusion: The updates in the CFIR reflect feedback from a growing community of CFIR users. Although there are many updates, constructs can be mapped back to the original CFIR to ensure longitudinal consistency. We encourage users to continue critiquing the CFIR, facilitating the evolution of the framework as implementation science advances.

Keywords: Implementation science, Implementation framework, Implementation determinants, Implementation outcomes, Implementation evaluation, Consolidated Framework for Implementation Research, CFIR, Theory

*Correspondence: Caitlin.Reardon@va.gov

VA Center for Clinical Management Research, VA Ann Arbor Healthcare System, 2215 Fuller Road, MI 48105 Ann Arbor, USA

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Additional File 4: Original CFIR (2009) to Updated CFIR (2022): Construct Mapping

This additional file maps the original CFIR (published in 2009) constructs to the updated CFIR (published in 2022) constructs.

Original CFIR *No specific guidance provided at the framework-level in the original CFIR*		**Updated CFIR** ***Framework Guidance:*** The CFIR is intended to be used to collect data from individuals who have power and/or influence over implementation outcomes. See the CFIR Outcomes Addendum for guidance on identifying these individuals and selecting outcomes [1]. The CFIR must be fully operationalized prior to use in a project: 1) Define the subject of each domain for the project (see guidance for each domain below). 2) Replace broad construct language with project-specific language if needed. 3) Add constructs to capture salient themes not included in the updated CFIR.	
I. INTERVENTION CHARACTERISTICS DOMAIN *No specific guidance provided at the domain-level in the original CFIR.*		**I. INNOVATION DOMAIN** ***Innovation:*** The "thing" being implemented [2], e.g., a new clinical treatment, educational program, or city service. ***Project Innovation***: [Document the innovation being implemented, e.g., innovation type, innovation core vs. adaptable components, using a published reporting guideline [3–6]. Distinguish the innovation (the "thing" that continues when implementation is complete) [2,7] from the implementation process and strategies used to implement the innovation [8,9] (activities that end after implementation is complete) [10].]	
Old Construct Name	**Old Construct Definition**	**Construct Name**	**Construct Definition** *The degree to which:*
Intervention Source	Perception of key stakeholders about whether the intervention is externally or internally developed.	A. Innovation Source	The group that developed and/or visibly sponsored use of the innovation is reputable, credible, and/or trustable.
Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.	B. Innovation Evidence-Base	The innovation has robust evidence supporting its effectiveness.

The Positive Health Check (PHC) Project: A type 1 hybrid trial

IMPLEMENTATION SCIENCE

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Effectiveness of an Interactive, Highly Tailored "Video Doctor" Intervention to Suppress Viral Load and Retain Patients With HIV in Clinical Care: A Randomized Clinical Trial

Megan A. Lewis, PhD,[a] Camilla Harshbarger, PhD,[b] Carla Bann, PhD,[a] Vincent C. Marconi, MD,[c] Charurut Somboonwit, MD,[d] Michelle Dalla Piazza, MD,[e] Shobha Swaminathan, MD,[e] Olivia Burrus, MPH,[a] Carla Galindo, MPH,[b] Craig B. Borkowf, PhD,[b] Gary Marks, PhD,[b] Shawn Karns, BA,[a] Brittany Zulkiewicz, MPH,[a] Alexa Ortiz, MSN, RN,[a] Iddrisu Abdallah, MPH,[f] Bryan R. Garner, PhD,[a] and Cari Courtenay-Quirk, PhD,[b] for the Positive Health Check Study Team

Background: To determine whether Positive Health Check, a highly tailored video doctor intervention, can improve viral suppression and retention in care.

Setting: Four clinics that deliver HIV primary care.

Methods: A hybrid type 1 effectiveness-implementation randomized trial design was used to test study hypotheses. Participants (N = 799) who were not virally suppressed, were new to care, or had fallen out of care were randomly assigned to receive Positive Health Check or the standard of care alone. The primary endpoint was viral load suppression, and the secondary endpoint was retention in care, both assessed at 12 months, using an intention-to-treat approach. A priori subgroup analyses based on sex assigned at birth and race were examined as well.

Results: There were no statistically significant differences between Positive Health Check (N = 397) and standard of care (N = 402) for either endpoint. However, statistically significant group differences were identified from a priori subgroup analyses. Male participants receiving Positive Health Check were more likely to achieve suppression at 12 months than male participants receiving standard of care adjusted risk ratio [aRR] [95% confidence interval (CI)] = 1.14 (1.00 to 1.29), $P = 0.046$}. For retention in care, there was a statistically significant lower risk for a 6-month visit gap in the Positive Health Check arm for the youngest participants, 18–29 years old [aRR (95% CI) = 0.55 (0.33 to 0.92), $P = 0.024$] and the oldest participants, 60–81 years old [aRR (95% CI) = 0.49 (0.30 to 0.81), $P = 0.006$].

Conclusions: Positive Health Check may help male participants with HIV achieve viral suppression, and younger and older patients consistently attend HIV care.

Registry Name: Positive Health Check Evaluation Trial. Trial ID: 1U18PS004967-01. URL: https://clinicaltrials.gov/ct2/show/NCT03292913.

Key Words: video doctor intervention, viral suppression, retention in care

(*J Acquir Immune Defic Syndr* 2022;91:58–67)

INTRODUCTION

HIV transmission remains an urgent public health challenge. The Centers for Disease Control and Prevention (CDC) estimates that 1.2 million persons in the United States have HIV, with 34,800 new infections occurring in 2019.[1] Because of advances in antiretroviral therapy (ART), which suppresses the plasma HIV-1 RNA viral load (VL), more people are managing HIV as a chronic health condition. Early initiation of and adherence to ART and retention in care (RIC) are critical prevention strategies, because people with HIV (PWH) who are adherent to ART and are virally suppressed

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From the [a]RTI International; [b]Division of HIV Prevention, Centers for Disease Control and Prevention, Atlanta, GA; [c]Division of Infectious Diseases, Emory University School of Medicine, Emory Vaccine Center, and Rollins School of Public Health, Atlanta, Georgia; VA Medical Center, Decatur, GA; [d]University of South Florida, Morsani College of Medicine, Tampa, FL; [e]Rutgers New Jersey Medical School, Newark, NJ; and [f]SeKON, Atlanta, GA.

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The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Correspondence to: Megan A. Lewis, PhD, RTI International, 3040 East Cornwallis Road, PO Box 12194, Research Triangle Park, NC 27709-2194 (e-mail: melewis@rti.org).

Lewis MA, Harshbarger C, Bann C, Marconi VC, Somboonwit C, Dalla Piazza M, Swaminathan S, Burrus O, Galindo C, Borkowf CB, Marks G. Effectiveness of an interactive, highly tailored "video doctor" intervention to suppress viral load and retain patients with HIV in clinical care: a randomized clinical trial. Journal of acquired immune deficiency syndromes (1999). 2022 Sep 9;91(1):58.

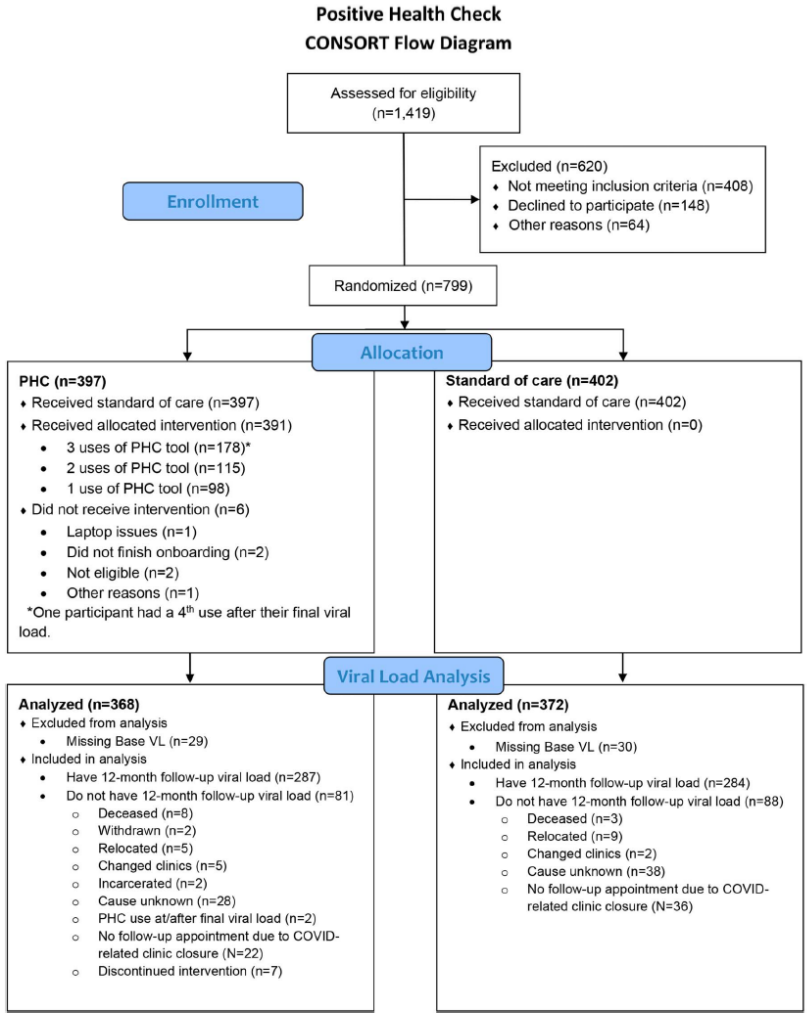

Figure 1. Positive health check trial consort diagram. full color online

The Positive Health Check (PHC) Project: A type 1 hybrid trial

IMPLEMENTATION SCIENCE

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A Longitudinal Mixed-Methods Examination of Positive Health Check: Implementation Results From a Type 1 Effectiveness-Implementation Hybrid Trial

Bryan R. Garner, PhD,[a] Olivia Burrus, MPH,[a] Alexa Ortiz, MSN,[a] Stephen J. Tueller, PhD,[a] Susana Peinado, PhD,[a] Haley Hedrick, BA,[a] Camilla Harshbarger, PhD,[b] Carla Galindo, MPH,[b] Cari Courtenay-Quirk, PhD,[b] and Megan A. Lewis, PhD[a]

Background: Positive Health Check is an evidence-based video doctor intervention developed for improving the medication adherence, retention in care, and viral load suppression of people with HIV receiving clinical care.

Setting: Four HIV primary care clinics within the United States.

Methods: As part of a type 1 hybrid trial, a mixed-methods approach was used to longitudinally assess the following 3 key implementation constructs over a 23-month period: innovation-values fit (ie, the extent to which staff perceive innovation use will foster the fulfillment of their values), organizational readiness for change (ie, the extent to which organizational members are psychologically and behaviorally prepared to implement organizational change), and implementation climate (ie, the extent to which implementation is expected, supported, and rewarded). Quantitative mixed-effects regression analyses were conducted to assess changes over time in these constructs. Qualitative analyses were integrated to help provide validation and understanding.

Results: Innovation-values fit and organizational readiness for change were found to be high and relatively stable. However, significant curvilinear change over time was found for implementation climate. Based on the qualitative data, implementation climate declined toward the end of implementation because of decreased engagement from clinic champions and differences in priorities between research and clinic staff.

Conclusions: The Positive Health Check intervention was found to fit within HIV primary care service settings, but there were some logistical challenges that needed to be addressed. Additionally, even within the context of an effectiveness trial, significant and nonlinear change in implementation climate should be expected over time.

Key Words: HIV, implementation effectiveness, web-based interventions, computer-based interventions, video interventions, medication adherence

(*J Acquir Immune Defic Syndr* 2022;91:47–57)

INTRODUCTION

After the results of several studies supporting treatment as prevention,[1–4] HIV treatment has become a key HIV prevention priority. Nonetheless, the number of new HIV diagnoses in the United States has remained relatively stable at about 38,000 new diagnoses annually. Contributing to the number of new HIV infections each year is the number of people with HIV (PWH) who are not virally suppressed. Viral suppression rates have improved over time, yet about 420,000 PWH aged 13 years or older are not virally suppressed.[5] Suboptimal adherence to the prescribed HIV treatment regimen is a key factor in why viral suppression rates are not higher.[6] Research has focused on developing effective interventions to improve HIV medication adherence, including interventions that are computer based.[7,8] Web-based HIV adherence promotion interventions may be more cost-effective and sustainable than person-delivered interventions.

In 2015, Claborn et al conducted a systematic review of computer-based HIV adherence promotion interventions.[9] Of the 10 studies identified, only 3 were fully powered randomized controlled trials (RCTs).[10–12] Concluding there was not yet sufficient evidence to support the efficacy of computer-delivered HIV adherence interventions, the authors noted more RCTs were needed and "Future studies should be designed with regard to evaluation of implementation and sustainability of the intervention within the clinic setting." In 2018, Kemp and Velloza reviewed research conducted since 2015 that focused on implementing electronic health interventions designed to improve outcomes along the HIV care continuum.[13] Of the 17 studies identified, more than half (n = 9; 53%) included a focus on improving HIV medication adherence,[14–22] only 2 were RCTs, and the most of the studies (n = 15; 88%) focused on

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From the [a]RTI International, Research Triangle Park, NC; and [b]Centers for Disease Control and Prevention, Division of HIV Prevention, Atlanta, GA.
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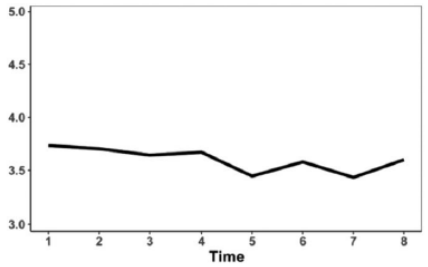
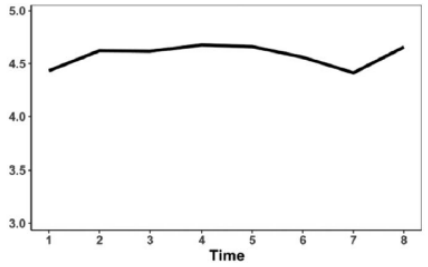
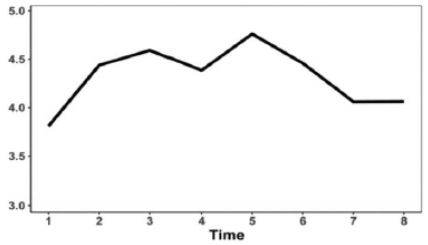
The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Correspondence to: Bryan R. Garner, PhD, The Ohio State University, Columbus, OH 43210 (e-mail: bryan.garner@osumc.edu).

Garner BR, Burrus O, Ortiz A, Tueller SJ, Peinado S, Hedrick H, Harshbarger C, Galindo C, Courtenay-Quirk C, Lewis MA. A longitudinal mixed-methods examination of Positive Health Check: Implementation results from a type 1 effectiveness-implementation hybrid trial. Journal of Acquired Immune Deficiency Syndromes. 2022 May 18.

TABLE 1. Overall Trajectories for Innovation-Values Fit, Organizational Readiness for Change, and Implementation Climate

	Cross-clinic Trajectories	Beta	PHC Staff Experiences
Innovation-values fit		Intercept: 4.18* Time: −0.25 Time^2: 0.03	Three of the 4 clinics reported few major ongoing barriers with integrating PHC into the clinic workflow. Communication and collaboration with front office staff and the PHC staff's physical location within the clinic emerged as key factors for integrating PHC into the clinic workflow. Addressing internet connectivity issues and printer access at 2 clinics and space concerns at 1 clinic align with the slight increase in perceived fit at T4 (Table 2).
Organizational readiness for change		Intercept: 4.42* Time: 0.11 Time^2: −0.02	Three of the 4 clinics noted a slight decrease in organizational readiness at T7 because of clinic providers misunderstanding PHC requirements (clinic B), a nondirect chain of communication clinic C, and staff turnover clinic D.
Implementation climate		Intercept: 3.95* Time: 0.55* Time^2: −0.09*	Clinics had not started implementing the intervention at T1. The initial trend upward may be because of ramp-up time. The most common leadership method used to support PHC was advocating for the study in clinical site meetings. All 4 clinics noted receiving support from site health care providers. Implementation climate dipped in the end for many reasons, including decreased engagement from champions and difference in priorities between research and clinic staff.

Time refers to measurement time point, T1 to T8. The Time variable indicates how fast the outcome is increasing over time. The Time^2 variable indicates how fast the outcome starts moving back to values from earlier in the study. The combination of these 2 effects describes the upside-down "u" shape of the trajectory over time.
*$P < 0.05$ indicates a significant change over time.

Effectiveness-Implementation Hybrid ~~Designs~~ Studies

ANNALS OF HSR

Effectiveness-implementation Hybrid Designs

Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

Geoffrey M. Curran, PhD, Mark Bauer, MD,† Brian Mittman, PhD,‡ Jeffrey M. Pyne, MD,* and Cheryl Stetler, PhD,‡*

Objectives: This study proposes methods for blending design components of clinical effectiveness and implementation research. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains, more effective implementation strategies, and more useful information for decision makers. This study proposes a "hybrid effectiveness-implementation" typology, describes a rationale for their use, outlines the design decisions that must be faced, and provides several real-world examples.

Results: An effectiveness-implementation hybrid design is one that takes a dual focus a priori in assessing clinical effectiveness and implementation. We propose 3 hybrid types: (1) testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation; (2) dual testing of clinical and implementation interventions/strategies; and (3) testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

Conclusions: The hybrid typology proposed herein must be considered a construct still in evolution. Although traditional clinical effectiveness and implementation trials are likely to remain the most common approach to moving a clinical intervention through from efficacy research to public health impact, judicious use of the proposed hybrid designs could speed the translation of research findings into routine practice.

Key Words: diffusion of innovation, implementation science, clinical trials, pragmatic designs

(*Med Care* 2012;50: 217–226)

From the *Central Arkansas Veterans Healthcare System, and Department of Psychiatry, University of Arkansas for Medical Sciences, Little Rock, AR; †VA Boston Healthcare System, Harvard Medical School, Boston, MA; and ‡Center for Implementation Practice and Research Support (CIPRS), VA Greater Los Angeles Healthcare System, Los Angeles, CA.

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The authors declare no conflict of interest.

Reprints: Geoffrey M. Curran, PhD, Department of Psychiatry, Division of Health Services Research, University of Arkansas for Medical Sciences, 4301 W. Markham St. #755, Little Rock, AR 72205. E-mail: currangeoffreym@uams.edu.

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Much has been written about the nature of health care science-to-service gaps both in general[1–3] and relative specifically to health promotion[4] and numerous medical specialties.[5–9] Thus far, the literature indicates that gaps between research and practice can result from multiple factors, including educational/knowledge deficiencies and/or disagreements,[10,11] time constraints for practitioners,[12,13] lack of decision support tools and feedback mechanisms,[13] poorly aligned incentives,[14] and a host of other organizational climate and cultural factors.[2,15,16]

In addition to these provider-level and systems-level barriers to rapid translation, Glasgow et al[4] and others[17–20] argue that the time lag between research discovery and routine uptake is also inflated by the dominant developmental approach; that is, one that encourages delimited, step-wise progressions of research through clinical efficacy research, then clinical effectiveness research, and finally implementation research. In addition, it has been suggested that current conceptions of research designs fail to "maximize clinical utility for practicing clinicians and other decision makers"[18]; for example, through a failure to focus on external validity or implementation-related barriers and facilitators to routine use and sustainability of "effective" practices.[4,21,22]

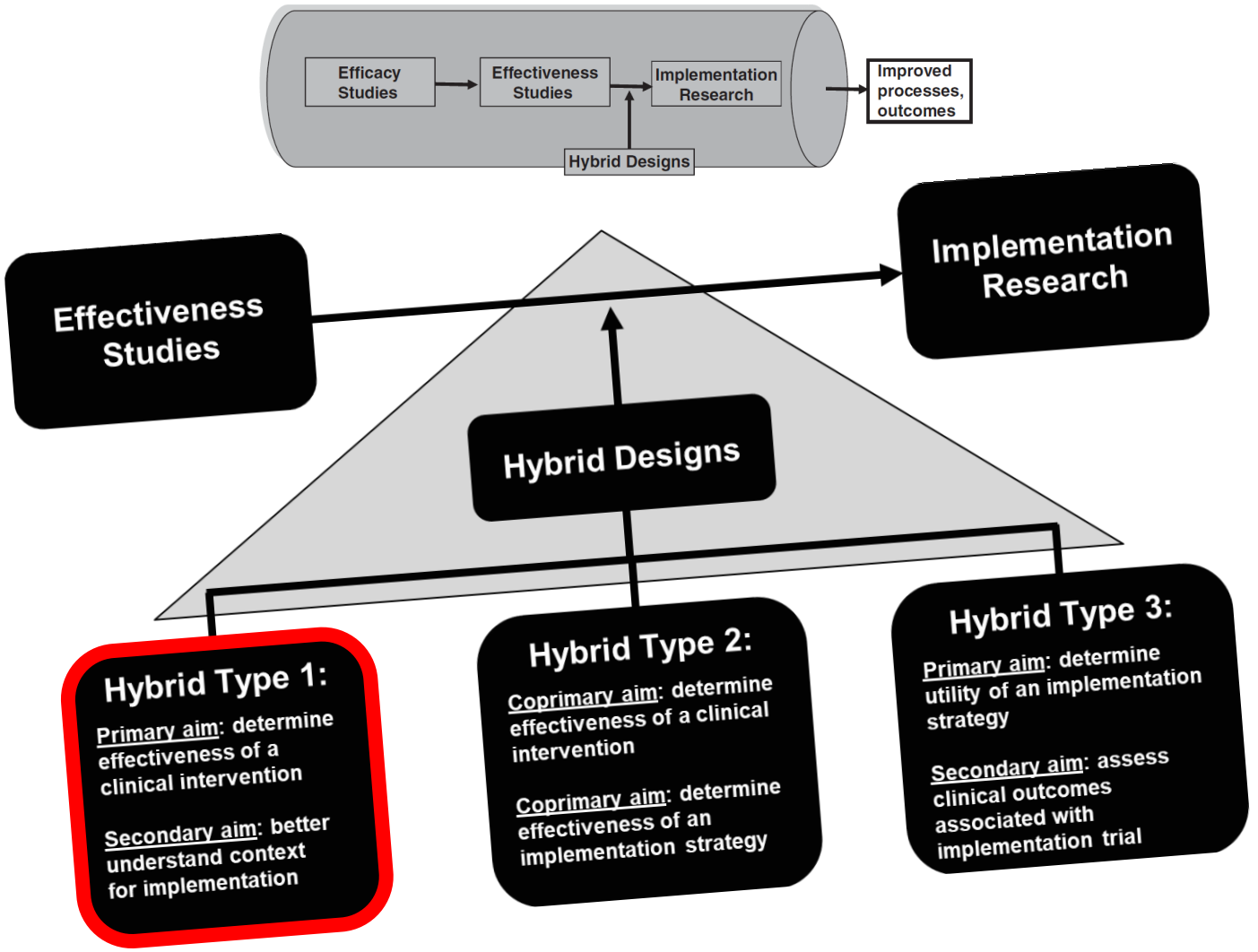
Wells[19] and Glasgow et al[4] suggested that a blending of the efficacy and effectiveness stages of intervention development could improve the speed of knowledge creation and increase the usefulness and policy relevance of clinical research. We propose that a blending of the design components of clinical effectiveness trials and implementation trials also is feasible and desirable. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains in clinical intervention uptake, more effective implementation strategies, and more useful information for researchers and decision makers. This study describes the elements of such "effectiveness-implementation hybrid designs," discusses the indications for such approaches, outlines the design decisions that must be faced in developing such protocols, and provides several examples of funded hybrid studies to illustrate the concepts.

DEFINING TERMINOLOGY

Terminology in this study has been informed by a glossary provided by the Department of Veterans Affairs Quality Enhancement Research Initiative (VA QUERI)[22];

Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*, *50*(3), 217.

FIGURE 1. Research pipeline.



Effectiveness-Implementation Hybrid ~~Designs~~ Studies

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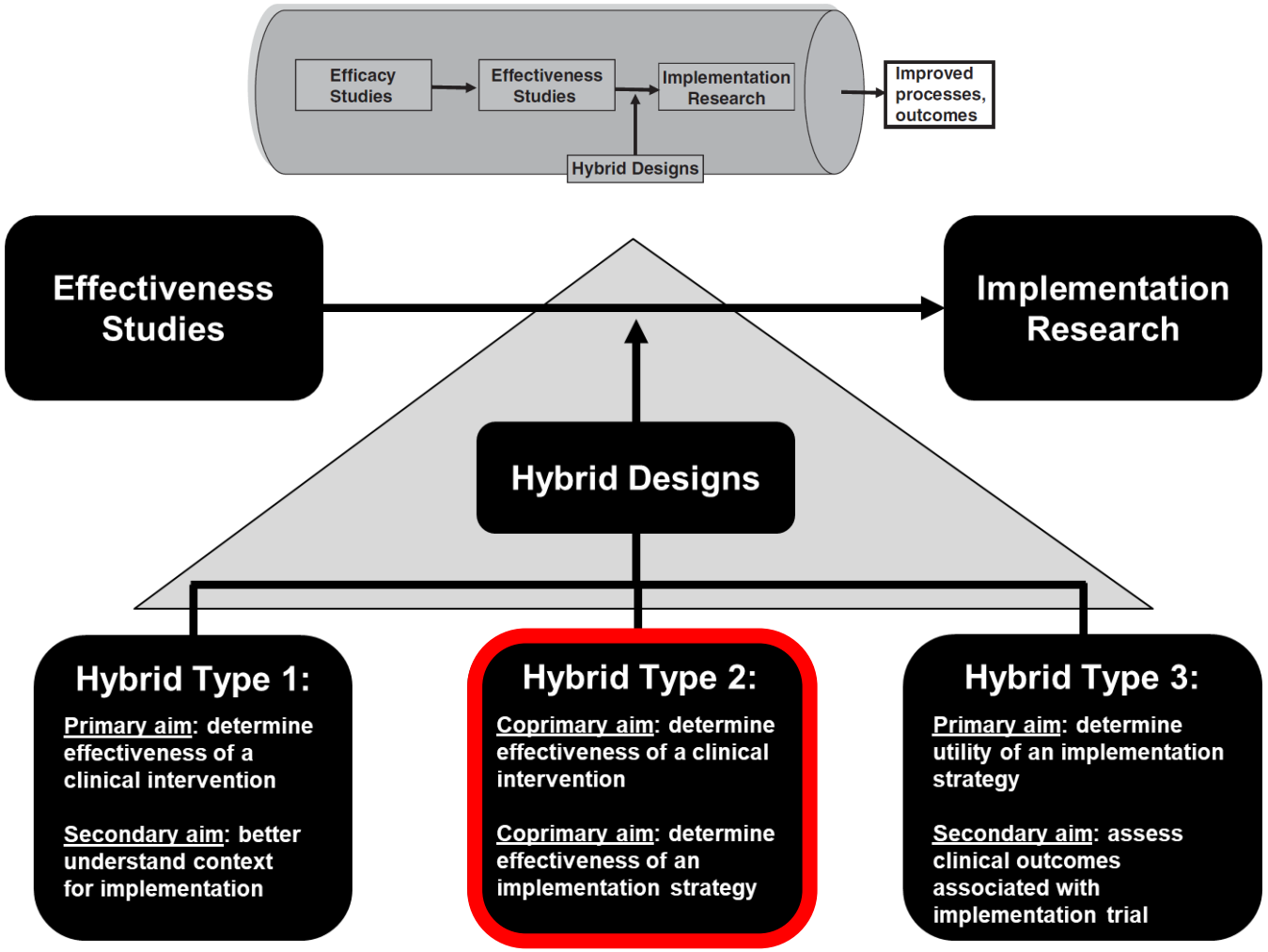
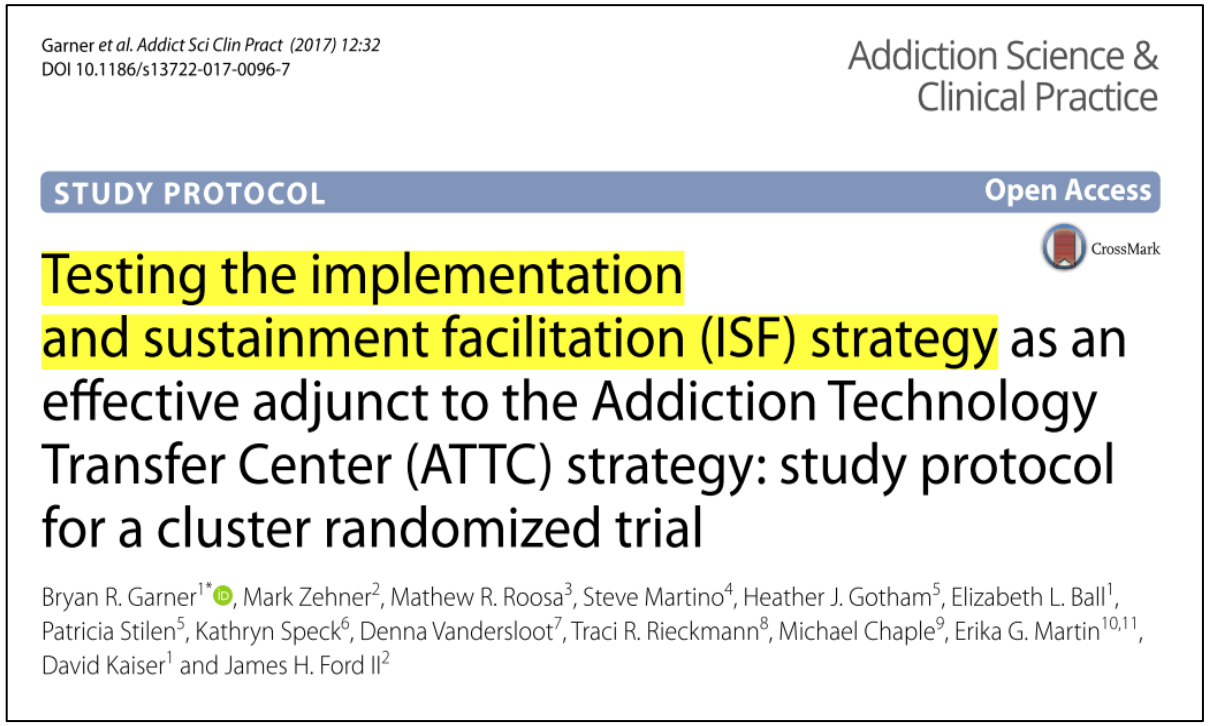


The Substance Abuse Treatment to HIV Care (SAT2HIV) Project:
A *dual-randomized* type 2 hybrid trial



Garner *et al. Addict Sci Clin Pract* (2017) 12:32
DOI 10.1186/s13722-017-0096-7

Addiction Science & Clinical Practice

STUDY PROTOCOL Open Access

CrossMark

Testing the implementation and sustainment facilitation (ISF) strategy as an effective adjunct to the Addiction Technology Transfer Center (ATTC) strategy: study protocol for a cluster randomized trial

Bryan R. Garner[1*], Mark Zehner[2], Mathew R. Roosa[3], Steve Martino[4], Heather J. Gotham[5], Elizabeth L. Ball[1], Patricia Stilen[5], Kathryn Speck[6], Denna Vandersloot[7], Traci R. Rieckmann[8], Michael Chaple[9], Erika G. Martin[10,11], David Kaiser[1] and James H. Ford II[2]

Garner, B. R., Zehner, M., Roosa, M. R., Martino, S., Gotham, H. J., Ball, E. L., ... Ford, J. H. (2017). Testing the implementation and sustainment facilitation (ISF) strategy as an effective adjunct to the Addiction Technology Transfer Center (ATTC) strategy: Study protocol for a cluster randomized trial. Addiction Science & Clinical Practice, 12(1), 32.

Garner *et al. Addict Sci Clin Pract* (2017) 12:31
DOI 10.1186/s13722-017-0095-8

Addiction Science & Clinical Practice

STUDY PROTOCOL Open Access

CrossMark

Testing the effectiveness of a motivational interviewing-based brief intervention for substance use as an adjunct to usual care in community-based AIDS service organizations: study protocol for a multisite randomized controlled trial

Bryan R. Garner[1*], Heather J. Gotham[2], Stephen J. Tueller[1], Elizabeth L. Ball[1], David Kaiser[1], Patricia Stilen[2], Kathryn Speck[3], Denna Vandersloot[4], Traci R. Rieckmann[5], Michael Chaple[6], Erika G. Martin[7,8] and Steve Martino[9]

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The Substance Abuse Treatment to HIV Care (SAT2HIV) Project:
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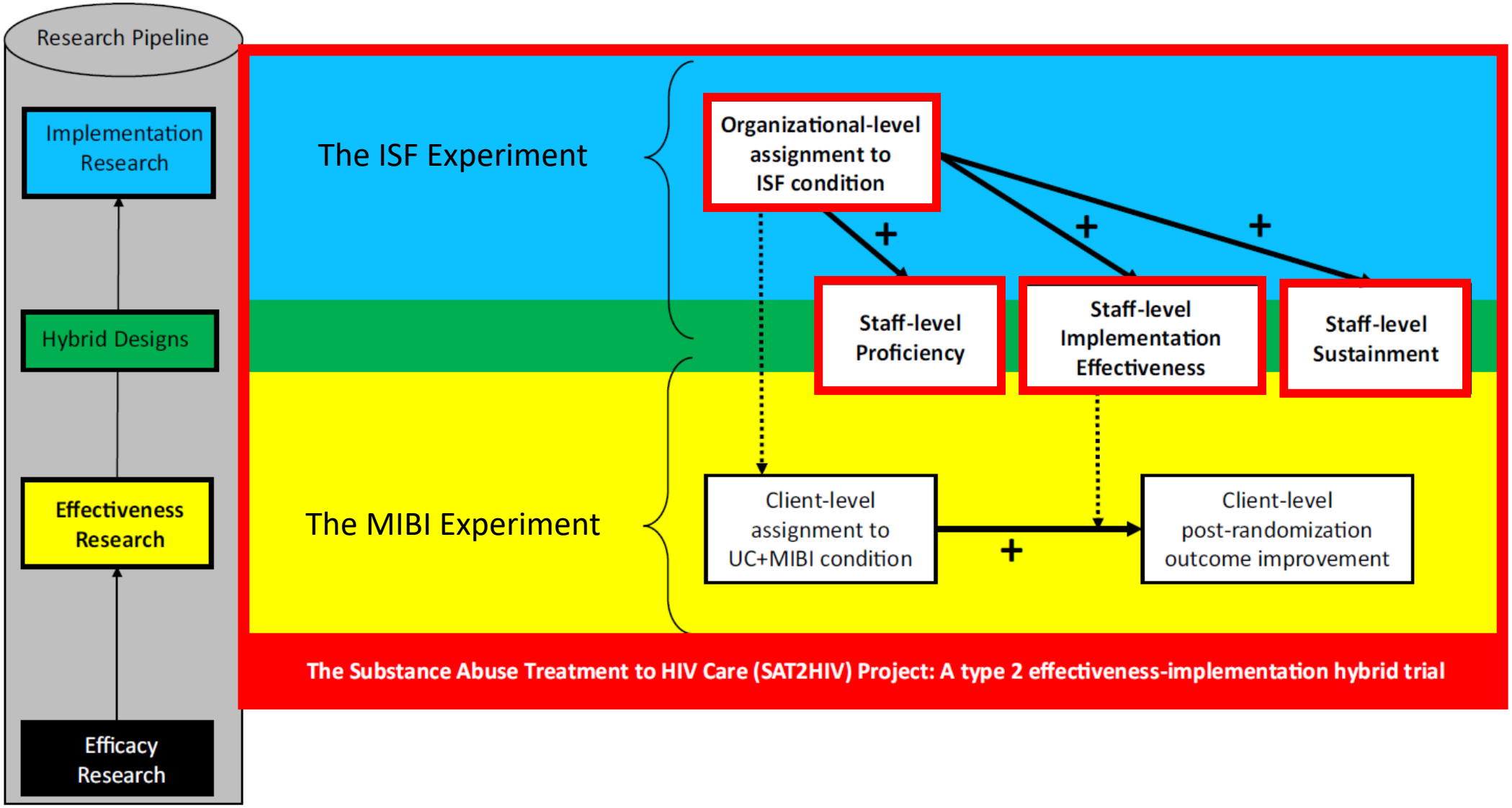

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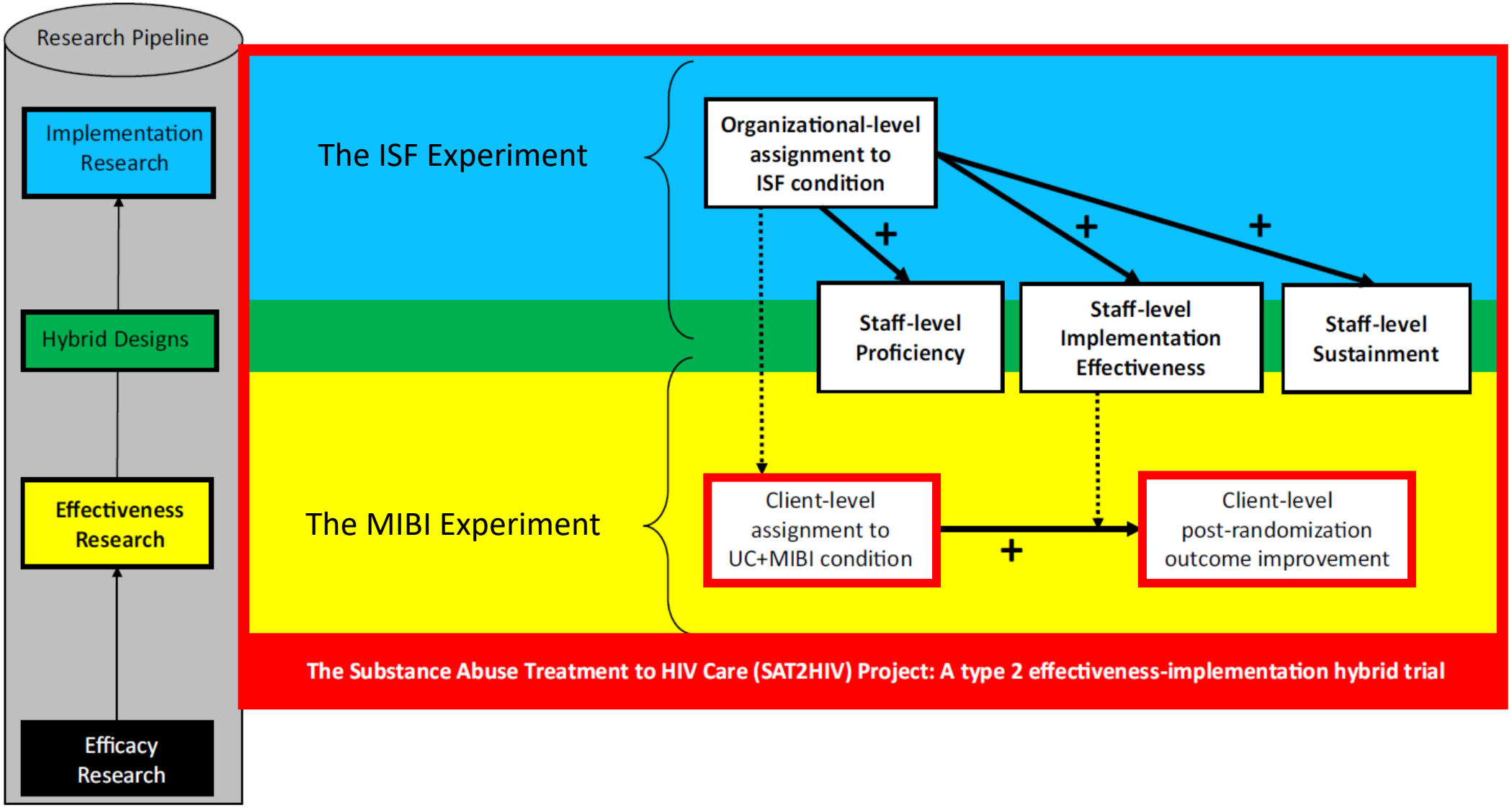

The Substance Abuse Treatment to HIV Care (SAT2HIV) Project:
A *dual-randomized* type 2 hybrid trial

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Implementation Research & Practice

Original Empirical Research

The implementation and sustainment facilitation strategy improved implementation effectiveness and intervention effectiveness: Results from a cluster-randomized, type 2 hybrid trial

Implementation Research and Practice
Volume 1: Jan-Dec 2020 1–23

DOI: 10.1177/2633489520948073
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Bryan R Garner[1], Heather J Gotham[2], Michael Chaple[3], Steve Martino[4], James H Ford II[5], Mathew R Roosa[6], Kathryn J Speck[7], Denna Vandersloot[8], Michael Bradshaw[1], Elizabeth L Ball[1], Alyssa K Toro[1], Christopher Griggs[1] and Stephen J Tueller[1]

Abstract

Background: Substance use disorders (SUDs) among people with HIV are both prevalent and problematic. The Substance Abuse Treatment to HIV care project was funded to test the Implementation and Sustainment Facilitation (ISF) strategy as an adjunct to the Addiction Technology Transfer Center (ATTC) strategy for integrating a motivational interviewing-based brief intervention (MIBI) for SUDs within HIV community-based organizations.

Methods: Using a cluster-randomized, type 2 hybrid trial design, 39 HIV organizations were randomized to either (1) ATTC ($n=19$) or (2) ATTC + ISF ($n=20$). Each HIV organization identified two staff members to be prepared to implement the MIBI ($N=78$). Subsequently, during the implementation phase, HIV organizations in each condition randomized client participants ($N=824$) to one of the two intervention conditions: usual care (UC; $n=415$) or UC + MIBI ($n=409$). Both staff-level outcomes and client-level outcomes were examined.

Results: The ISF strategy had a significant impact on the implementation effectiveness (i.e., the consistency and the quality of implementation; $\beta=.65$, $p=.01$) but not on time-to-proficiency ($\beta=-.02$) or level-of-sustainment ($\beta=.09$). In addition, the ISF strategy was found to have a significant impact on the intervention effectiveness (the effectiveness of the MIBI), at least in terms of significantly decreasing the odds (odds ratio = 0.11, $p=.02$) of clients using their primary substance daily during follow-up.

Conclusion: The ISF strategy was found to be an effective adjunct to the ATTC strategy in terms of implementation effectiveness and intervention effectiveness. It is recommended that future efforts to integrate the project's MIBI for SUD within HIV organizations use the ATTC + ISF strategy. However, given the ISF strategy did not have a significant impact on level-of-sustainment, implementation research testing the extent to which the ATTC + ISF strategy can be significantly enhanced through effective sustainment strategies is warranted.

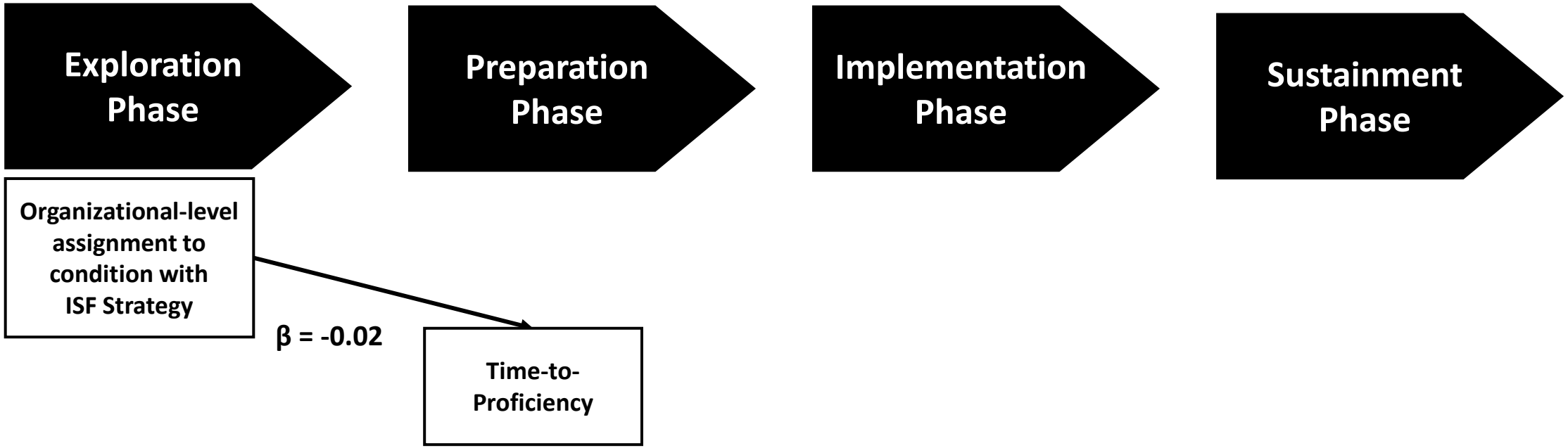
[1]RTI International, Research Triangle Park, NC, USA
[2]School of Medicine, Stanford University, Palo Alto, CA, USA
[3]Division on Substance Use Disorders, New York State Psychiatric Institute, Columbia University, New York, NY, USA
[4]Department of Psychiatry, VA Connecticut Healthcare System, Yale University, West Haven, CT, USA
[5]School of Pharmacy, University of Wisconsin–Madison, Madison, WI, USA
[6]Roosa Consulting, Syracuse, NY, USA
[7]University of Nebraska Public Policy Center, Lincoln, NE, USA
[8]Vandersloot Training & Consulting, Portland, OR, USA

Corresponding author:
Bryan R Garner, RTI International, P.O. Box 12194, Research Triangle Park, NC 27709-2194, USA.
Email: bgarner@rti.org

Garner, B. R., Gotham, H. J., Chaple, M., Martino, S., Ford, J. H., Roosa, M. R., ... & Tueller, S. J. (2020). The implementation and sustainment facilitation strategy improved implementation effectiveness and intervention effectiveness: results from a cluster-randomized, type 2 hybrid trial. Implementation Research and Practice, 1, 2633489520948073.

- **A dual-randomized type 2 hybrid trial with 39 HIV service organizations, 78 staff, and 824 clients.**
  - Tested the effectiveness of the team-focused Implementation and Sustainment Facilitation (ISF) Strategy as an adjunct to the staff-focused Addiction Technology Transfer Center (ATTC) strategy.
  - Tested the effectiveness of a motivational interviewing-based brief intervention (MIBI) for substance use disorders as an adjunct to usual care within HIV service organizations.
- **Main Findings**
  - The ISF Strategy significantly improved *implementation effectiveness*, which is the consistency and quality of implementation by the organization's trained staff.
  - The ISF strategy significantly improved *intervention effectiveness*, which is the effectiveness of the motivational interviewing-based brief intervention for reducing client's days of primary substance use.

The ISF Strategy's Empirical Support from the SAT2HIV Project: Effectiveness results



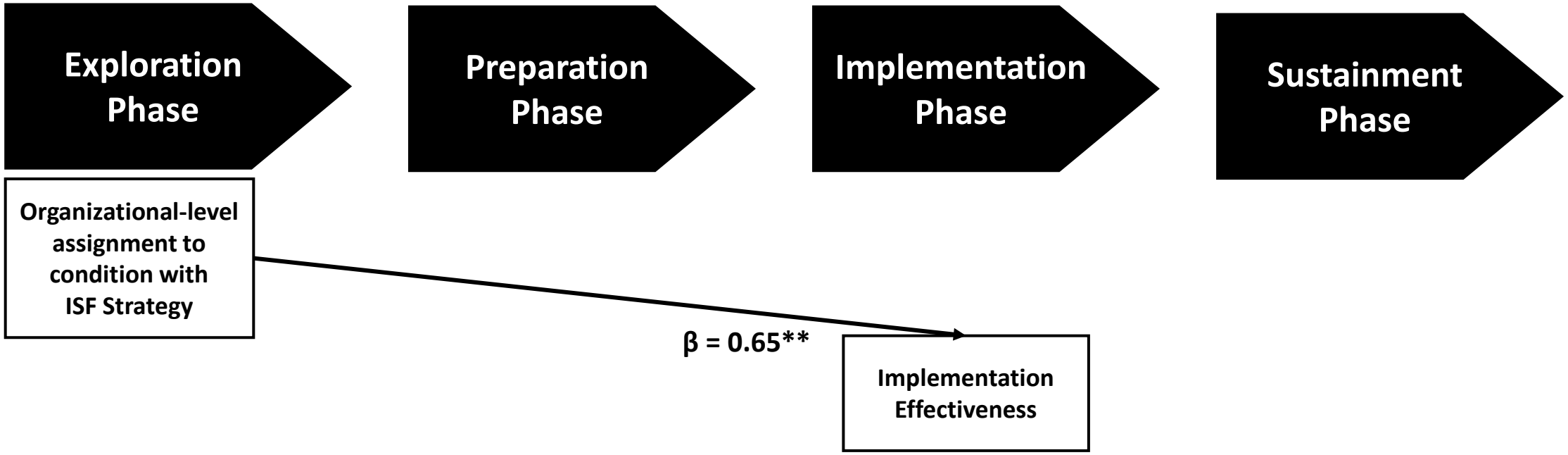
ATTC Strategy
Average of 12.35 days

ATTC+ISF Strategy
Average of 11.44 days (7% decrease)

78 of 78 Staff (100%) trained to proficiency

* $p < .05$; ** $p < .01$

The ISF Strategy's Empirical Support from the SAT2HIV Project: Effectiveness results



ATTC Strategy

Consistency Sum (i.e., penetration) = Average of 3.3 brief interventions

Quality Sum (i.e., fidelity) = Average of 560 quality score

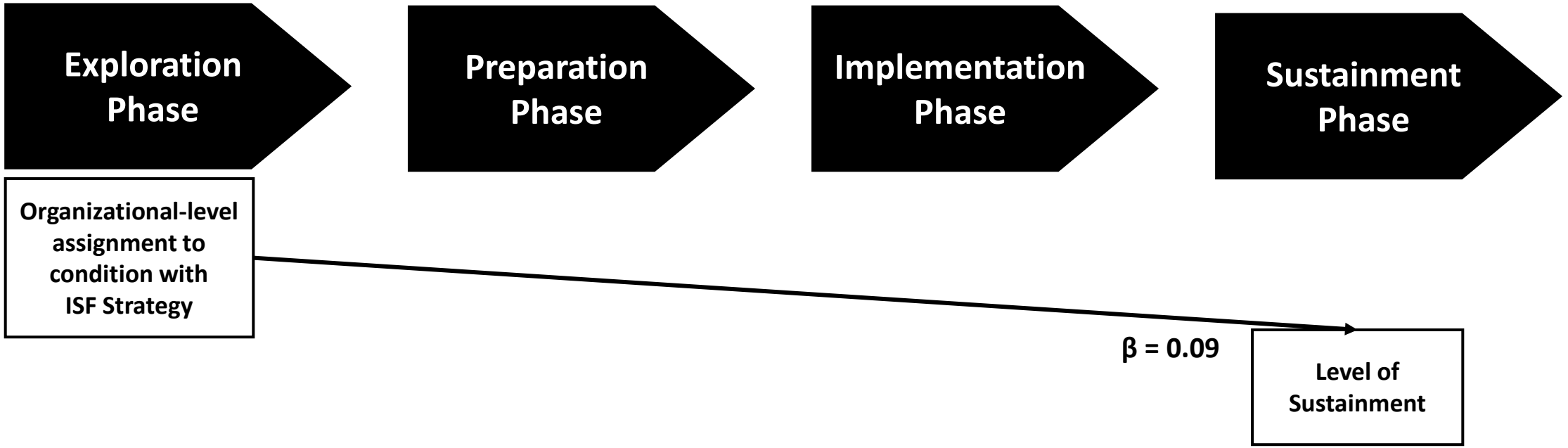
ATTC+ISF Strategy

Consistency Sum (i.e., penetration) = Average of 6.9 brief interventions (109% increase)

Quality Sum (i.e., fidelity) = Average of 1,324 quality score (136% increase)

* $p < .05$; ** $p < .01$

The ISF Strategy's Empirical Support from the SAT2HIV Project: Effectiveness results

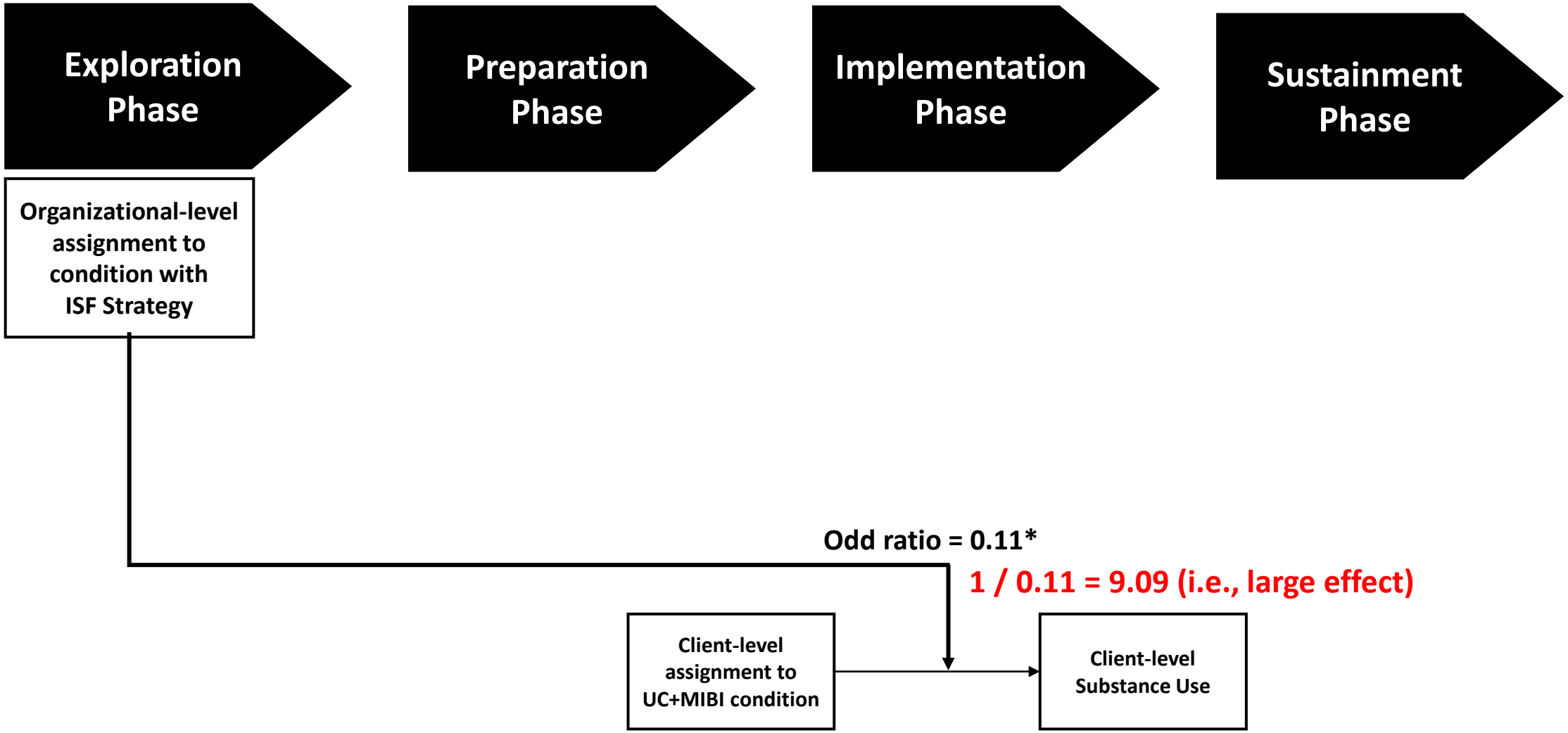


ATTC Strategy
Average of 3.2 brief interventions

ATTC+ISF Strategy
Average of 3.4 brief interventions (6% increase)

* $p < .05$; ** $p < .01$

The ISF Strategy's Empirical Support from the SAT2HIV Project: Effectiveness results

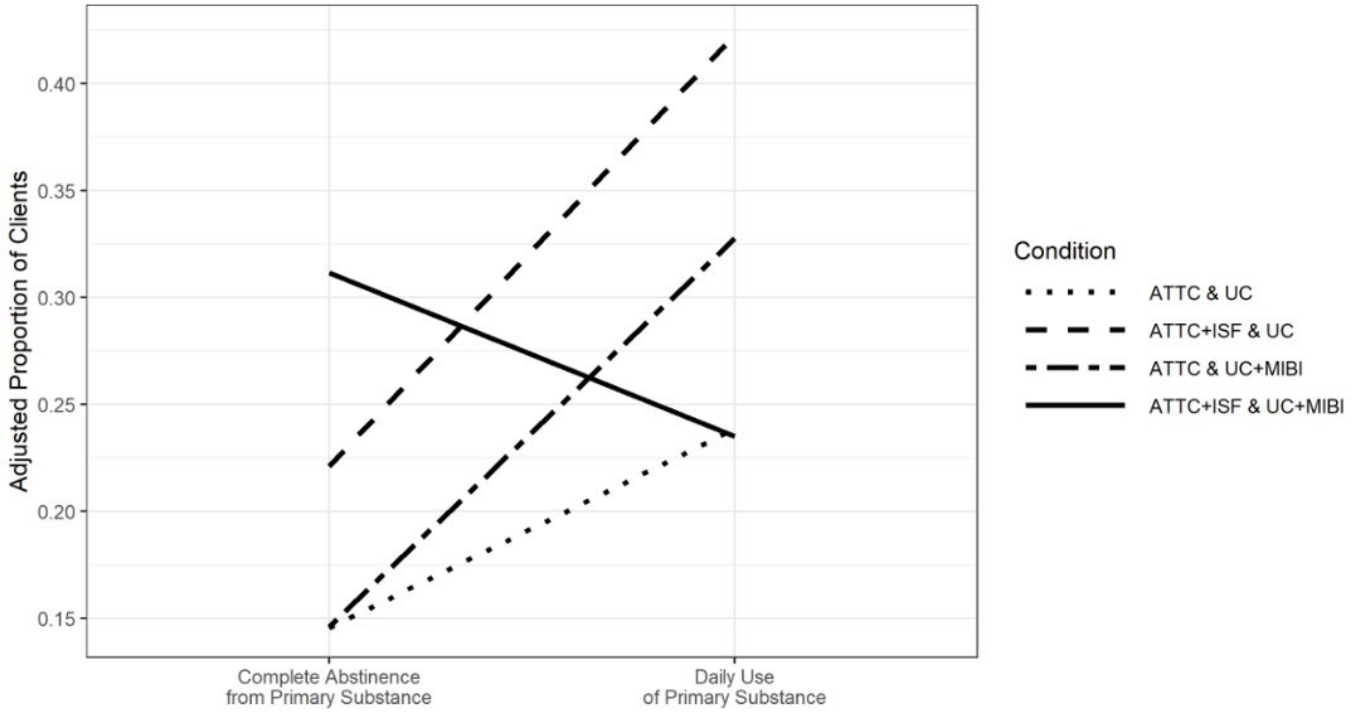


* $p < .05$; ** $p < .01$

The ISF Strategy's Empirical Support from the SAT2HIV Project: Effectiveness results

Exploration Phase → **Preparation Phase** → **Implementation Phase** → **Sustainment Phase**

Organizational-level assignment to condition with ISF Strategy



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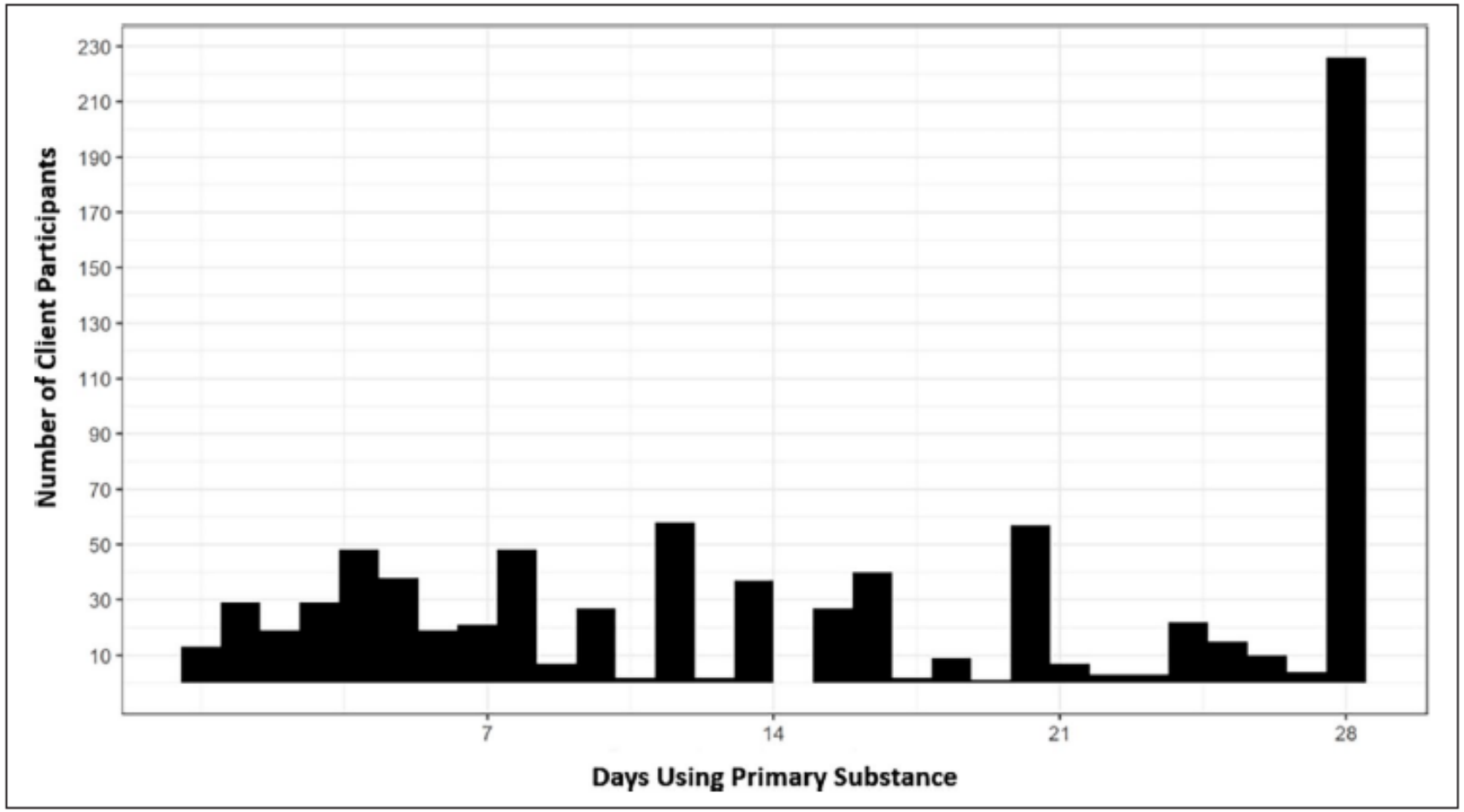


Figure 3. Baseline distribution for client's days of primary substance use.

The ISF Strategy's Empirical Support from the SAT2HIV Project: Effectiveness results

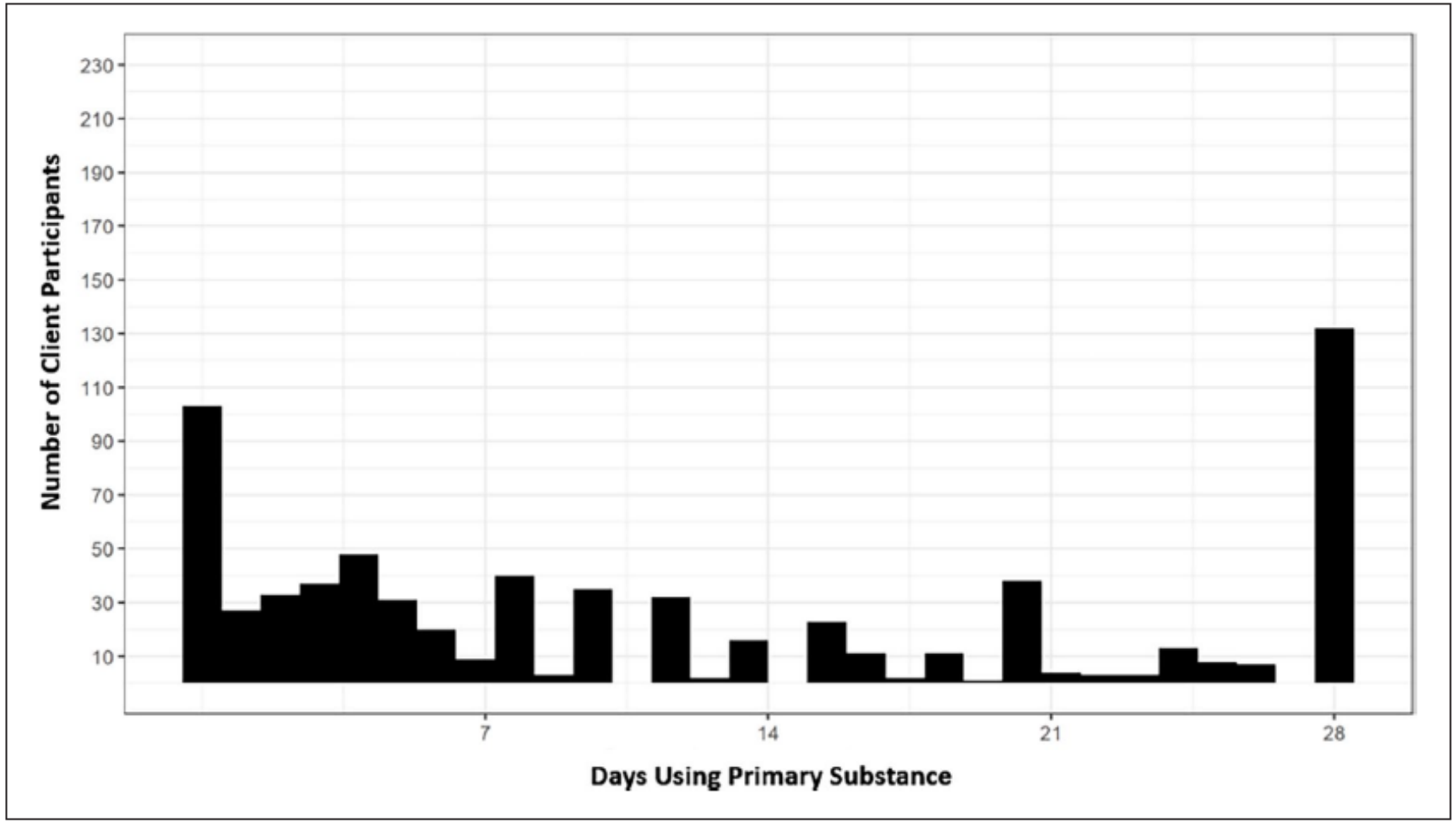
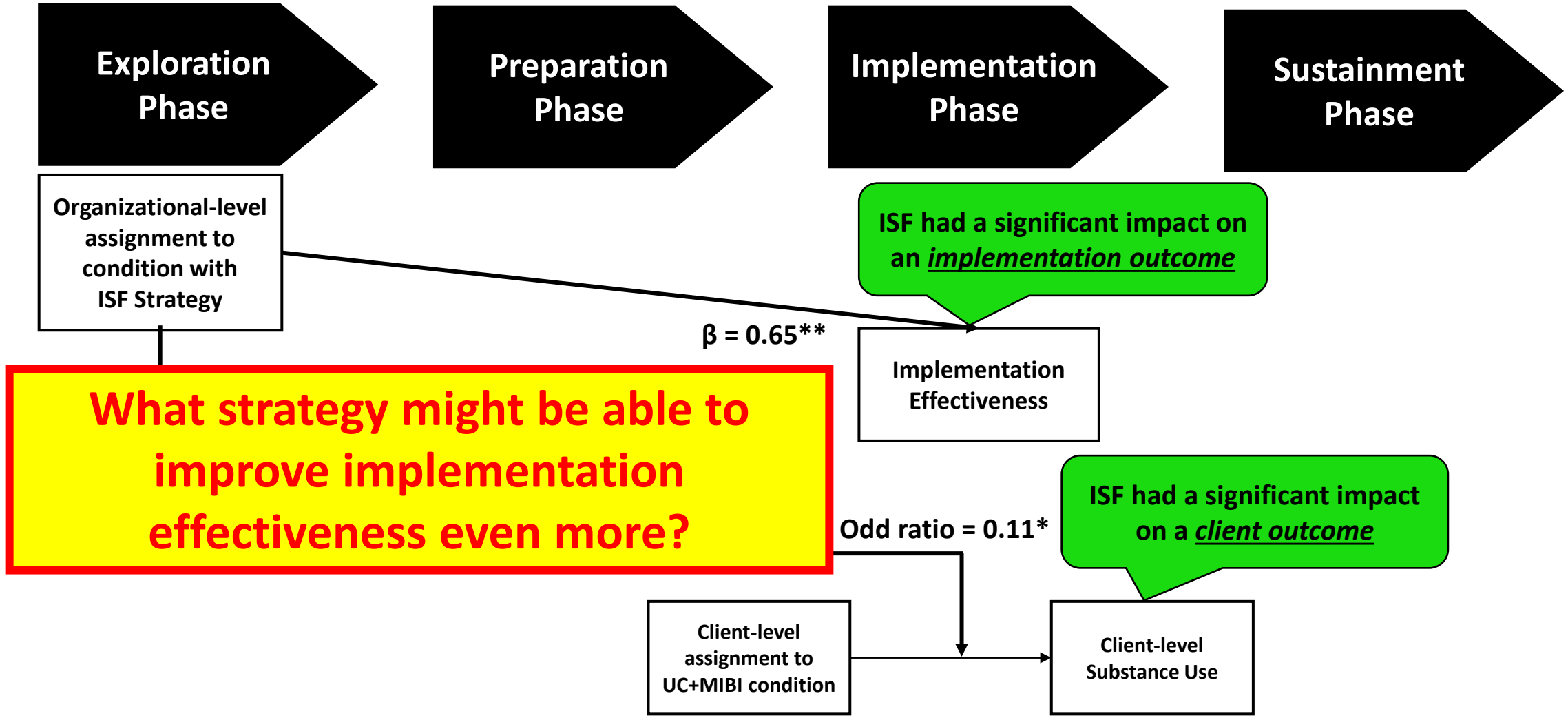


Figure 4. Follow-up distribution for client's days of primary substance use.

The ISF Strategy's Empirical Support from the SAT2HIV Project: Effectiveness results



* $p < .05$; ** $p < .01$

Effectiveness-Implementation Hybrid ~~Designs~~ Studies

ANNALS OF HSR

Effectiveness-implementation Hybrid Designs

Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

Geoffrey M. Curran, PhD, Mark Bauer, MD,† Brian Mittman, PhD,‡ Jeffrey M. Pyne, MD,* and Cheryl Stetler, PhD,‡*

Objectives: This study proposes methods for blending design components of clinical effectiveness and implementation research. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains, more effective implementation strategies, and more useful information for decision makers. This study proposes a "hybrid effectiveness-implementation" typology, describes a rationale for their use, outlines the design decisions that must be faced, and provides several real-world examples.

Results: An effectiveness-implementation hybrid design is one that takes a dual focus a priori in assessing clinical effectiveness and implementation. We propose 3 hybrid types: (1) testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation; (2) dual testing of clinical and implementation interventions/strategies; and (3) testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

Conclusions: The hybrid typology proposed herein must be considered a construct still in evolution. Although traditional clinical effectiveness and implementation trials are likely to remain the most common approach to moving a clinical intervention through from efficacy research to public health impact, judicious use of the proposed hybrid designs could speed the translation of research findings into routine practice.

Key Words: diffusion of innovation, implementation science, clinical trials, pragmatic designs

(*Med Care* 2012;50: 217–226)

From the *Central Arkansas Veterans Healthcare System, and Department of Psychiatry, University of Arkansas for Medical Sciences, Little Rock, AR; †VA Boston Healthcare System, Harvard Medical School, Boston, MA; and ‡Center for Implementation Practice and Research Support (CIPRS), VA Greater Los Angeles Healthcare System, Los Angeles, CA.

Supported by a research grant for the Department of Veterans Affairs, Health Services Research and Development Service: MNT-05-152 (Pyne, PI) and also funded by a research grant from the National Institute on Drug Abuse: K01 DA15102 (Curran, PI).

The authors declare no conflict of interest.

Reprints: Geoffrey M. Curran, PhD, Department of Psychiatry, Division of Health Services Research, University of Arkansas for Medical Sciences, 4301 W. Markham St. #755, Little Rock, AR 72205. E-mail: currangeoffreym@uams.edu.

ISSN: 0025-7079/12/5003-0217

Much has been written about the nature of health care science-to-service gaps both in general[1–3] and relative specifically to health promotion[4] and numerous medical specialties.[5–9] Thus far, the literature indicates that gaps between research and practice can result from multiple factors, including educational/knowledge deficiencies and/or disagreements,[10,11] time constraints for practitioners,[12,13] lack of decision support tools and feedback mechanisms,[13] poorly aligned incentives,[14] and a host of other organizational climate and cultural factors.[2,15,16]

In addition to these provider-level and systems-level barriers to rapid translation, Glasgow et al[4] and others[17–20] argue that the time lag between research discovery and routine uptake is also inflated by the dominant developmental approach; that is, one that encourages delimited, step-wise progressions of research through clinical efficacy research, then clinical effectiveness research, and finally implementation research. In addition, it has been suggested that current conceptions of research designs fail to "maximize clinical utility for practicing clinicians and other decision makers"[18]; for example, through a failure to focus on external validity or implementation-related barriers and facilitators to routine use and sustainability of "effective" practices.[4,21,22]

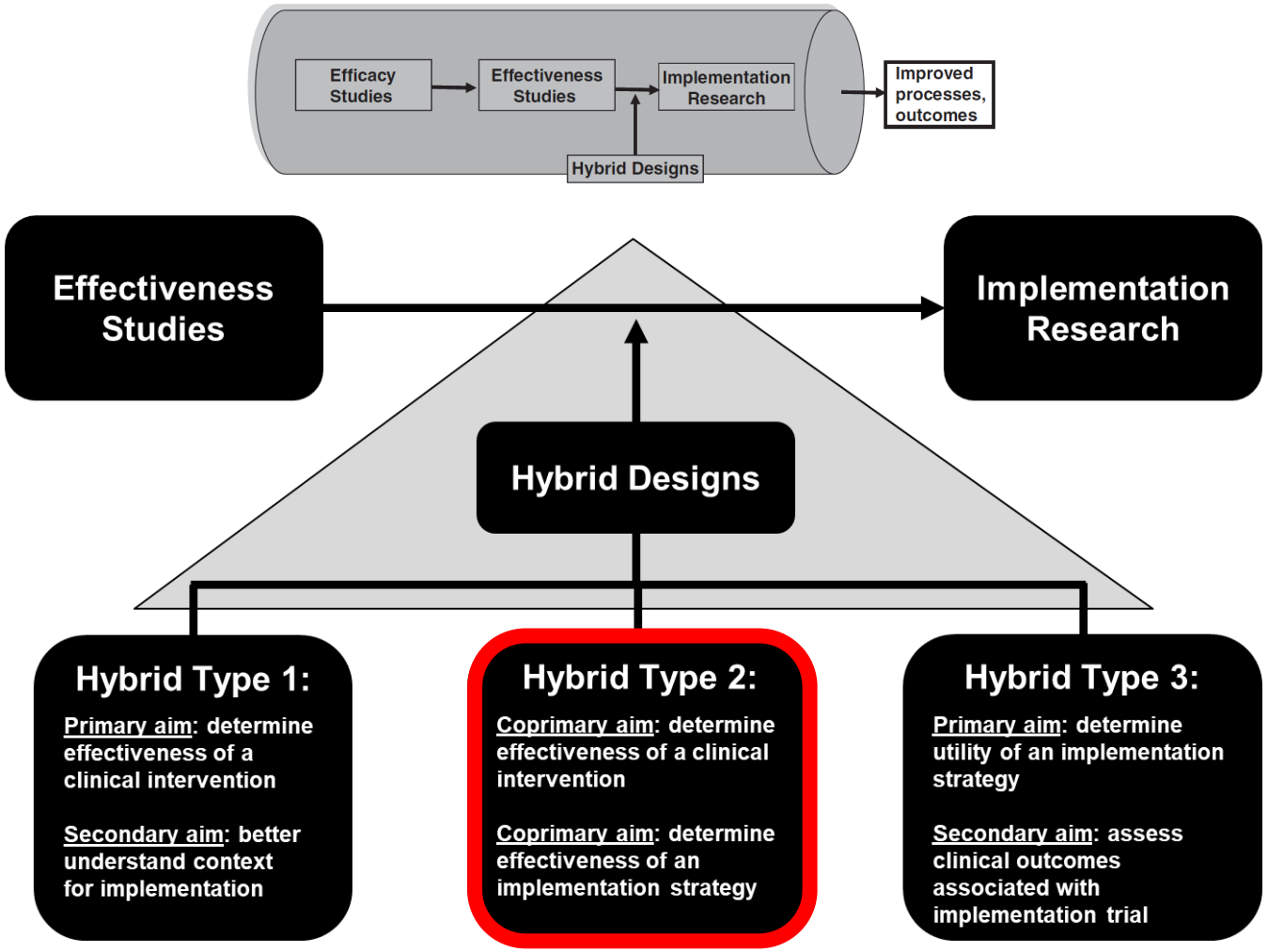
Wells[19] and Glasgow et al[4] suggested that a blending of the efficacy and effectiveness stages of intervention development could improve the speed of knowledge creation and increase the usefulness and policy relevance of clinical research. We propose that a blending of the design components of clinical effectiveness trials and implementation trials also is feasible and desirable. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains in clinical intervention uptake, more effective implementation strategies, and more useful information for researchers and decision makers. This study describes the elements of such "effectiveness-implementation hybrid designs," discusses the indications for such approaches, outlines the design decisions that must be faced in developing such protocols, and provides several examples of funded hybrid studies to illustrate the concepts.

DEFINING TERMINOLOGY

Terminology in this study has been informed by a glossary provided by the Department of Veterans Affairs Quality Enhancement Research Initiative (VA QUERI)[22];

Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*, *50*(3), 217.

FIGURE 1. Research pipeline.



Effectiveness-Implementation Hybrid ~~Designs~~ Studies

ANNALS OF HSR

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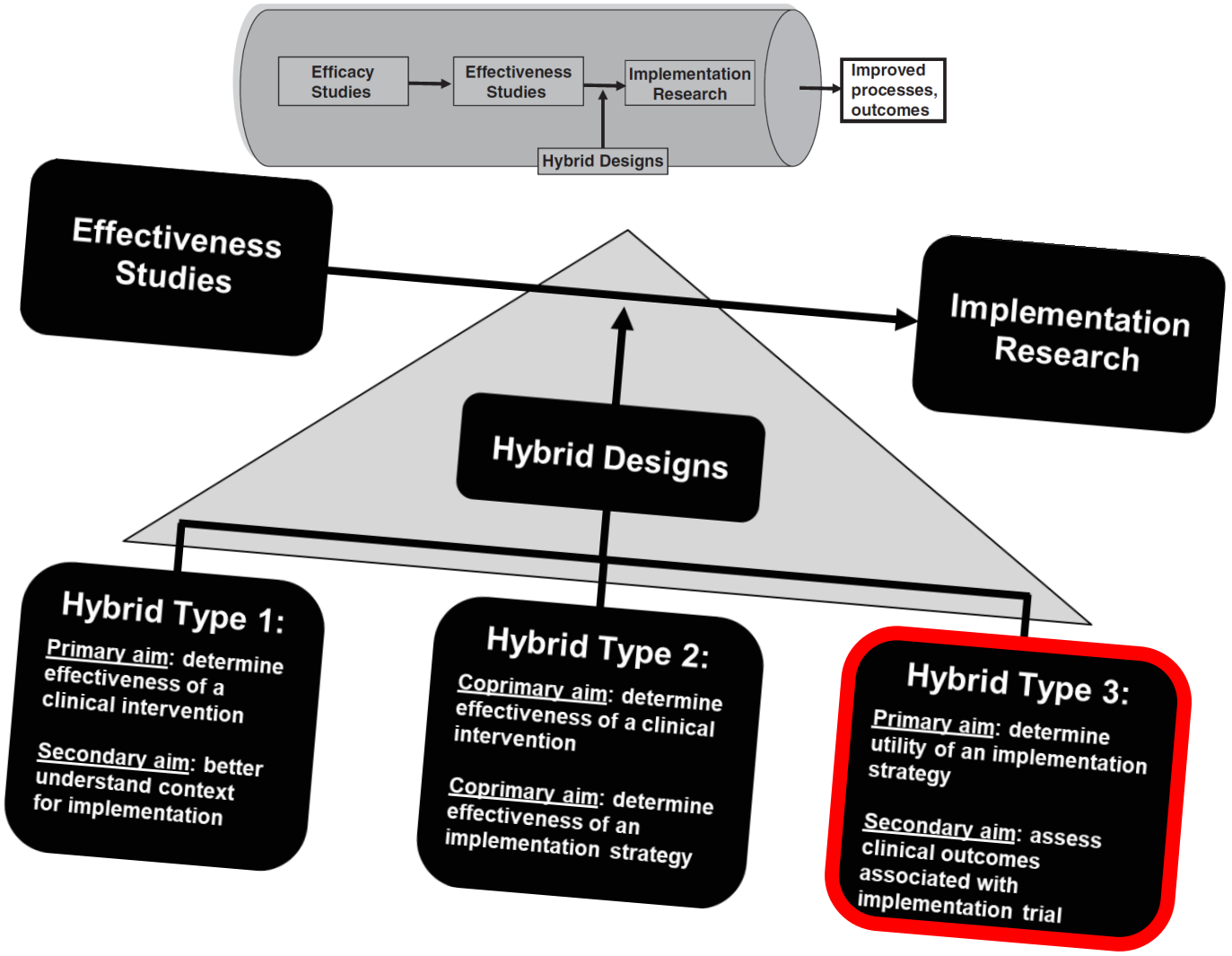


The Implementation Research Logic Model

Smith et al. Implementation Science (2020) 15:84
https://doi.org/10.1186/s13012-020-01041-8

Implementation Science

RESEARCH Open Access

The Implementation Research Logic Model: a method for planning, executing, reporting, and synthesizing implementation projects

Justin D. Smith[1,2*], Dennis H. Li[3] and Miriam R. Rafferty[4]

Abstract

Background: Numerous models, frameworks, and theories exist for specific aspects of implementation research, including for determinants, strategies, and outcomes. However, implementation research projects often fail to provide a coherent rationale or justification for how these aspects are selected and tested in relation to one another. Despite this need to better specify the conceptual linkages between the core elements involved in projects, few tools or methods have been developed to aid in this task. The Implementation Research Logic Model (IRLM) was created for this purpose and to enhance the rigor and transparency of describing the often-complex processes of improving the adoption of evidence-based interventions in healthcare delivery systems.

Methods: The IRLM structure and guiding principles were developed through a series of preliminary activities with multiple investigators representing diverse implementation research projects in terms of contexts, research designs, and implementation strategies being evaluated. The utility of the IRLM was evaluated in the course of a 2-day training to over 130 implementation researchers and healthcare delivery system partners.

Results: Preliminary work with the IRLM produced a core structure and multiple variations for common implementation research designs and situations, as well as guiding principles and suggestions for use. Results of the survey indicated a high utility of the IRLM for multiple purposes, such as improving rigor and reproducibility of projects; serving as a "roadmap" for how the project is to be carried out; clearly reporting and specifying how the project is to be conducted; and understanding the connections between determinants, strategies, mechanisms, and outcomes for their project.

(Continued on next page)

* Correspondence: jd.smith@hsc.utah.edu; jd.smith@northwestern.edu
[1]Department of Population Health Sciences, University of Utah School of Medicine, Salt Lake City, Utah, USA
[2]Center for Prevention Implementation Methodology for Drug Abuse and HIV, Department of Psychiatry and Behavioral Sciences, Department of Preventive Medicine, Department of Medical Social Sciences, and Department of Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA
Full list of author information is available at the end of the article

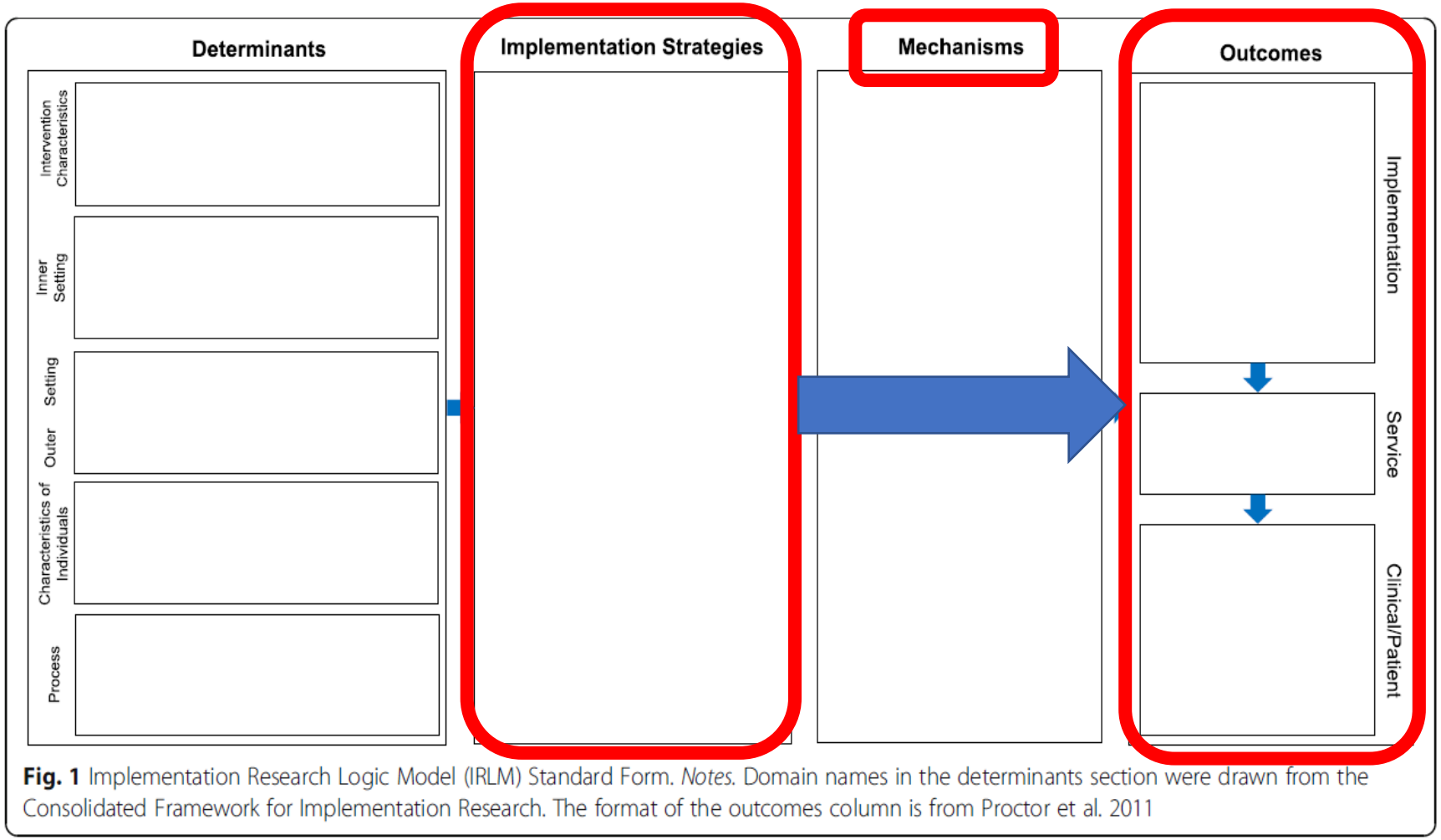


Fig. 1 Implementation Research Logic Model (IRLM) Standard Form. *Notes.* Domain names in the determinants section were drawn from the Consolidated Framework for Implementation Research. The format of the outcomes column is from Proctor et al. 2011

Smith JD, Li DH, Rafferty MR. The implementation research logic model: a method for planning, executing, reporting, and synthesizing implementation projects. Implementation Science. 2020 Dec;15(1):1-2.

A Conceptual Model of Implementation Research

Adm Policy Ment Health (2009) 36:24–34
DOI 10.1007/s10488-008-0197-4

ORIGINAL PAPER

Implementation Research in Mental Health Services: an Emerging Science with Conceptual, Methodological, and Training challenges

Enola K. Proctor · John Landsverk · Gregory Aarons · David Chambers · Charles Glisson · Brian Mittman

Published online: 23 December 2008

Abstract One of the most critical issues in mental health services research is the gap between what is known about effective treatment and what is provided to consumers in routine care. Concerted efforts are required to advance implementation science and produce skilled implementation researchers. This paper seeks to advance implementation science in mental health services by overview ing the emergence of implementation as an issue for research, by addressing key issues of language and conceptualization, by presenting a heuristic skeleton model for the study of implementation processes, and by identifying the implications for research and training in this emerging field.

Keywords Implementation · Evidence-based practice · Mental health services · Translation two research

An earlier version of this paper was presented at the NIMH Services Research Conference, July 23, 2007.

E. K. Proctor (✉) · J. Landsverk
George Warren Brown School of Social Work, Washington University, 1 Brookings Drive Campus Box 1196, St Louis, MO 63130, USA
e-mail: ekp@wustl.edu

J. Landsverk
Child and Adolescent Services Research Center, San Diego Children's Hospital Work, San Deigo, CA, USA

G. Aarons
Department of Psychiatry, University of California, San Diego, CA, USA

D. Chambers
Dissemination and Implementation Research Program
Division of Services and Intervention Research,
National Institute of Mental Health, Bethesda, MD, USA

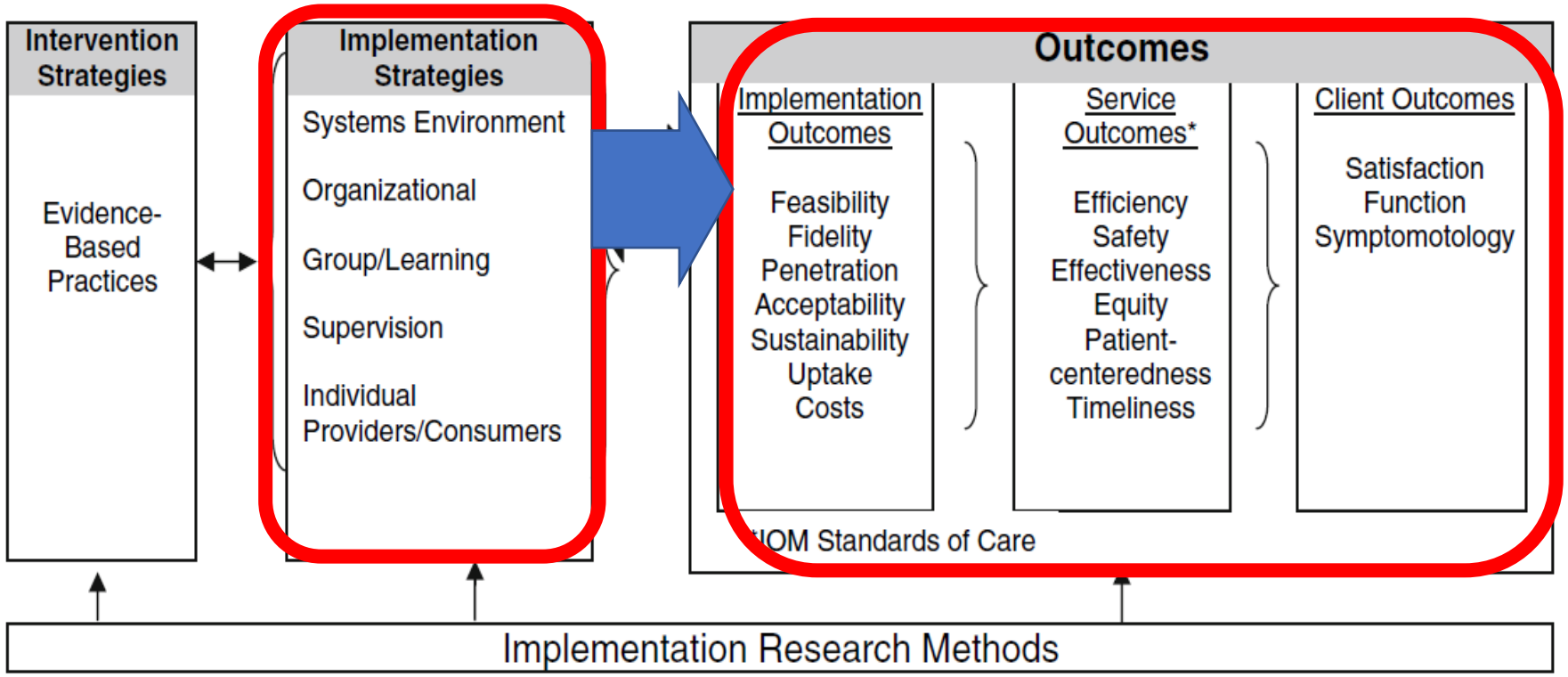
C. Glisson
Children's Mental Health Services Research Center,
University of Tennessee, Knoxville, TN, USA

B. Mittman
Department of Veterans Affairs, VA Center for Implementation Research & Improvement Science, Greater Los Angeles Healthcare System, Los Angeles, CA, USA

Springer

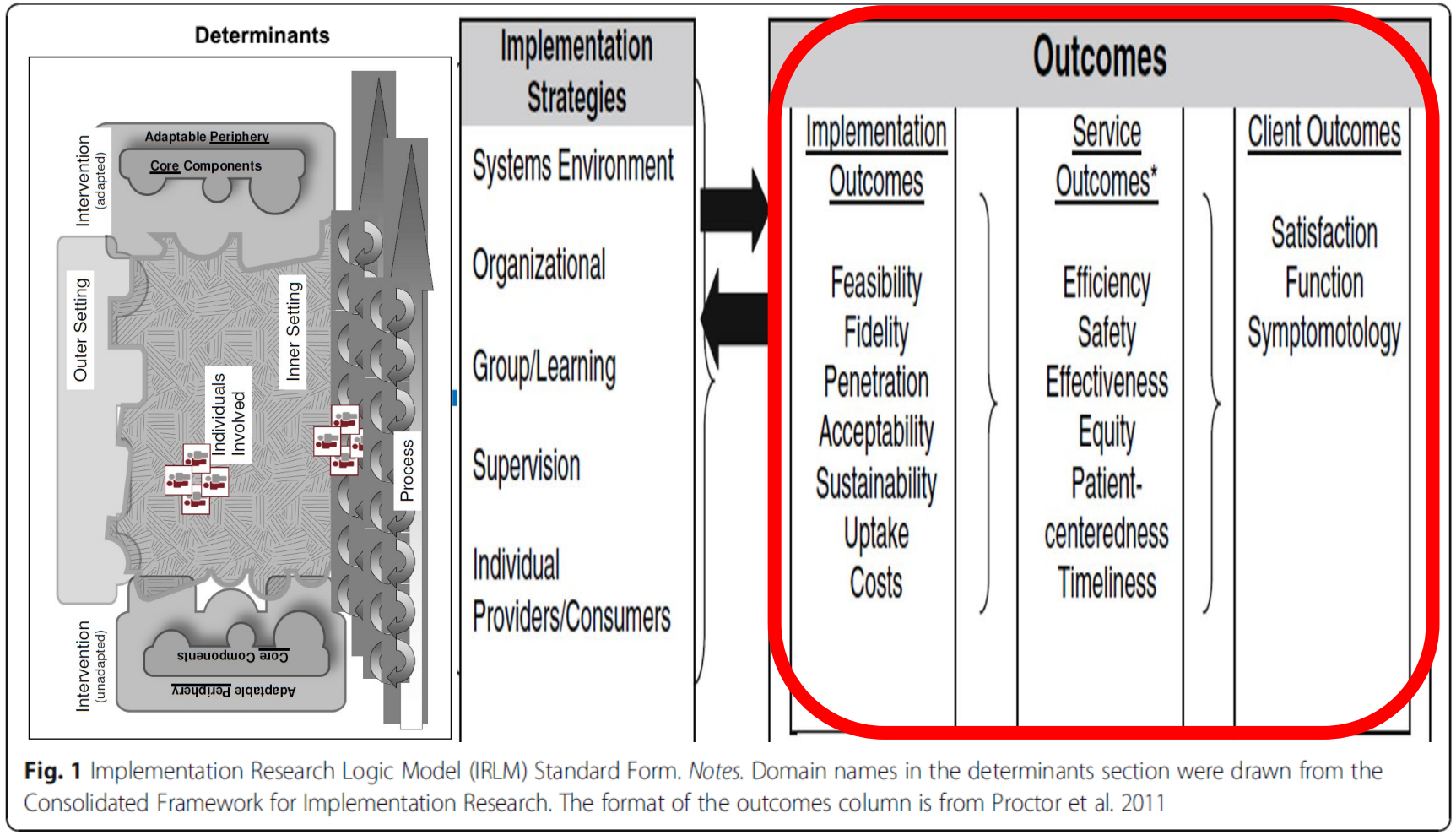
One of the most critical issues in mental health services research is the gap between what is known about effective treatment and what is provided to and experienced by consumers in routine care in community practice settings. While university-based controlled studies yield a growing supply of evidence-based treatments and while payers increasingly demand evidence-based care, there is little evidence that such treatments are either adopted or successfully implemented in community settings in a timely way (Bernfeld et al. 2001; Institute of Medicine 2001; National Advisory Mental Health Council 2001; President's New Freedom Commission on Mental Health 2003; U.S. Department of Health and Human Services 1999, 2001, 2006). Indeed new interventions are estimated to "languish" for 15–20 years before they are incorporated into usual care (Boren and Balas 1999). The implementation gap prevents our nation from reaping the benefit of billions of US tax dollars spent on research and, more important, prolongs the suffering of millions of Americans who live with mental disorders (President's New Freedom Commission on Mental Health 2003). Ensuring that effective interventions are implemented in diverse settings and populations has been identified as a priority by NIMH Director Thomas Insel (2007).

Fig. 1 Conceptual model of implementation research



Proctor EK, Landsverk J, Aarons G, Chambers D, Glisson C, Mittman B. Implementation research in mental health services: an emerging science with conceptual, methodological, and training challenges. Administration and Policy in Mental Health and Mental Health Services Research. 2009 Jan;36(1):24-34.

The CFIR and Proctor Model within IRLM



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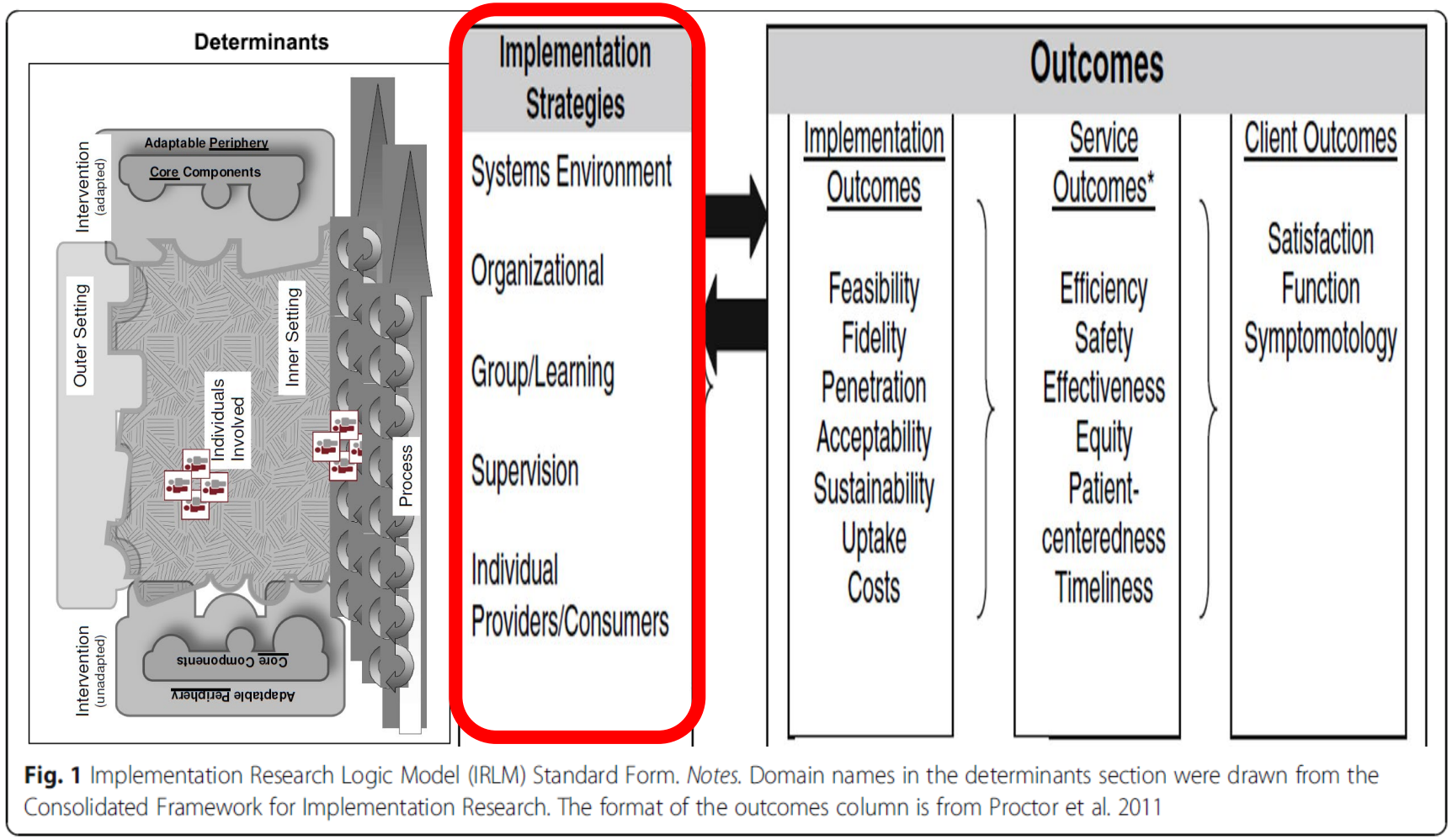

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A Compilation and Refined Compilation of Implementation Strategies

Review

Medical Care Research and Review
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http://mcr.sagepub.com
SAGE

A Compilation of Strategies for Implementing Clinical Innovations in Health and Mental Health

Byron J. Powell[1], J. Curtis McMillen[2], Enola K. Proctor[1], Christopher R. Carpenter[3], Richard T. Griffey[3], Alicia C. Bunger[4], Joseph E. Glass[1], and Jennifer L. York[3]

Abstract

Efforts to identify, develop, refine, and test strategies to disseminate and implement evidence-based treatments have been prioritized in order to improve the quality of health and mental health care delivery. However, this task is complicated by an implementation science literature characterized by inconsistent language use and inadequate descriptions of implementation strategies. This article brings more depth and clarity to implementation research and practice by presenting a consolidated compilation of discrete implementation strategies, based on a review of 205 sources published between 1995 and 2011. The resulting compilation includes 68 implementation strategies and definitions, which are grouped according to six key implementation processes: planning, educating, financing, restructuring, managing quality, and attending to the policy context. This consolidated compilation can serve as a reference to stakeholders who wish to implement clinical innovations in health and mental health care and can facilitate the development of multifaceted, multilevel implementation plans that are tailored to local contexts.

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[1]Washington University in St. Louis, St. Louis, MO, USA
[2]The University of Chicago, Chicago, IL, USA
[3]Washington University School of Medicine, St. Louis, MO, USA
[4]The University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Corresponding Author:
Byron J. Powell, George Warren Brown School of Social Work, Washington University in St. Louis, Campus Box 1196, One Brookings Drive, St. Louis, MO 63130, USA
Email: bjpowell@wustl.edu

Powell BJ, McMillen JC, Proctor EK, Carpenter CR, Griffey RT, Bunger AC, Glass JE, York JL. A compilation of strategies for implementing clinical innovations in health and mental health. Medical care research and review. 2012 Apr;69(2):123-57.

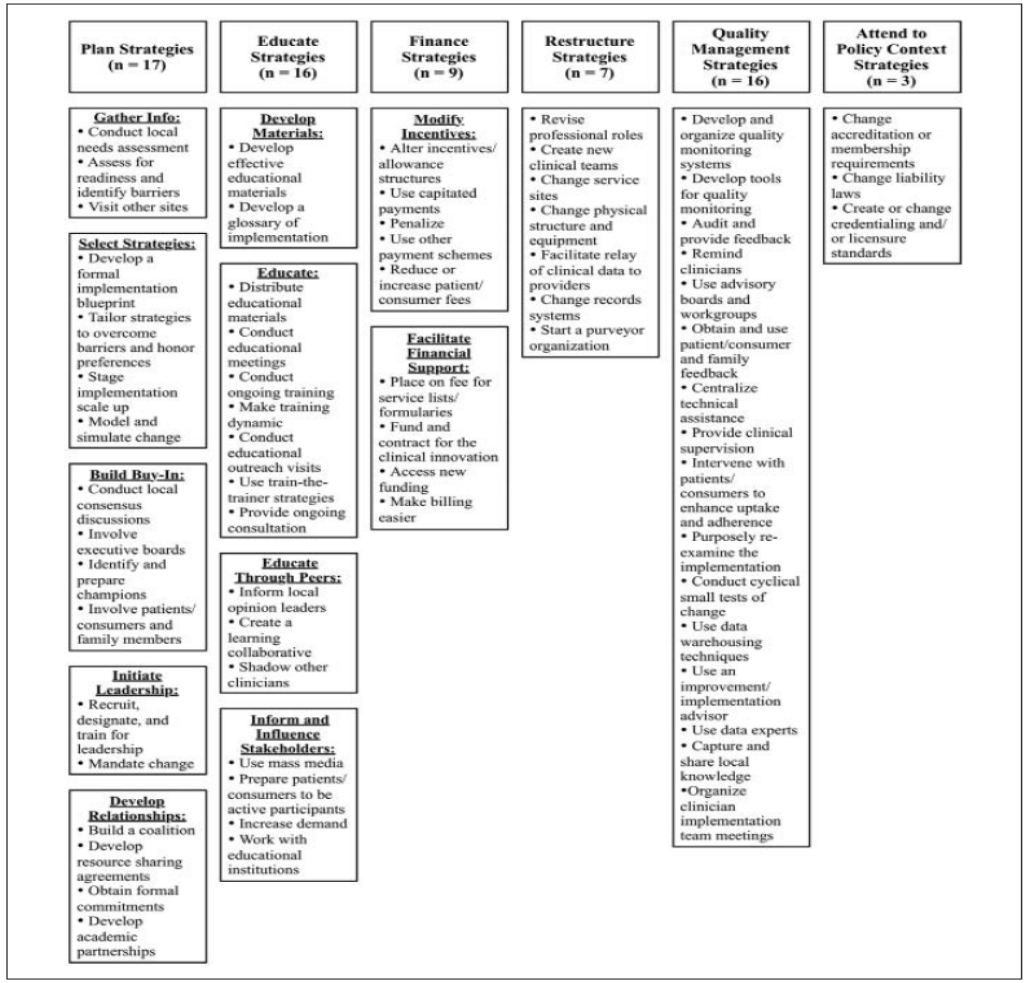

Figure 2. "Quick view" of the compilation of discrete implementation strategies

Powell *et al. Implementation Science* (2015) 10:21
DOI 10.1186/s13012-015-0209-1

IMPLEMENTATION SCIENCE

RESEARCH Open Access

A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project

Byron J Powell[1*], Thomas J Waltz[2], Matthew J Chinman[3,4], Laura J Damschroder[5], Jeffrey L Smith[6], Monica M Matthieu[6,7], Enola K Proctor[8] and JoAnn E Kirchner[4,9]

Abstract

Background: Identifying, developing, and testing implementation strategies are important goals of implementation science. However, these efforts have been complicated by the use of inconsistent language and inadequate descriptions of implementation strategies in the literature. The Expert Recommendations for Implementing Change (ERIC) study aimed to refine a published compilation of implementation strategy terms and definitions by systematically gathering input from a wide range of stakeholders with expertise in implementation science and clinical practice.

Methods: Purposive sampling was used to recruit a panel of experts in implementation and clinical practice who engaged in three rounds of a modified Delphi process to generate consensus on implementation strategies and definitions. The first and second rounds involved Web-based surveys soliciting comments on implementation strategy terms and definitions. After each round, iterative refinements were made based upon participant feedback. The third round involved a live polling and consensus process via a Web-based platform and conference call.

Results: Participants identified substantial concerns with 31% of the terms and/or definitions and suggested five additional strategies. Seventy-five percent of definitions from the originally published compilation of strategies were retained after voting. Ultimately, the expert panel reached consensus on a final compilation of 73 implementation strategies.

Conclusions: This research advances the field by improving the conceptual clarity, relevance, and comprehensiveness of implementation strategies that can be used in isolation or combination in implementation research and practice. Future phases of ERIC will focus on developing conceptually distinct categories of strategies as well as ratings for each strategy's importance and feasibility. Next, the expert panel will recommend multifaceted strategies for hypothetical yet real-world scenarios that vary by sites' endorsement of evidence-based programs and practices and the strength of contextual supports that surround the effort.

Keywords: Implementation research, Implementation strategies, Knowledge translation strategies, Mental health, US Department of Veterans Affairs

* Correspondence: byronp@upenn.edu
[1]Center for Mental Health Policy and Services Research, Department of Psychiatry, Perelman School of Medicine, University of Pennsylvania, 3535 Market Street, 3rd Floor, Philadelphia, PA 19104, USA
Full list of author information is available at the end of the article

Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, Proctor EK, Kirchner JE. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. Implementation Science. 2015 Dec;10(1):1-4.

Mechanisms

Smith et al. Implementation Science (2020) 15:84
https://doi.org/10.1186/s13012-020-01041-8

Implementation Science

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Background: Numerous models, frameworks, and theories exist for specific aspects of implementation research, including for determinants, strategies, and outcomes. However, implementation research projects often fail to provide a coherent rationale or justification for how these aspects are selected and tested in relation to one another. Despite this need to better specify the conceptual linkages between the core elements involved in projects, few tools or methods have been developed to aid in this task. The Implementation Research Logic Model (IRLM) was created for this purpose and to enhance the rigor and transparency of describing the often-complex processes of improving the adoption of evidence-based interventions in healthcare delivery systems.

Methods: The IRLM structure and guiding principles were developed through a series of preliminary activities with multiple investigators representing diverse implementation research projects in terms of contexts, research designs, and implementation strategies being evaluated. The utility of the IRLM was evaluated in the course of a 2-day training to over 130 implementation researchers and healthcare delivery system partners.

Results: Preliminary work with the IRLM produced a core structure and multiple variations for common implementation research designs and situations, as well as guiding principles and suggestions for use. Results of the survey indicated a high utility of the IRLM for multiple purposes, such as improving rigor and reproducibility of projects; serving as a "roadmap" for how the project is to be carried out; clearly reporting and specifying how the project is to be conducted; and understanding the connections between determinants, strategies, mechanisms, and outcomes for their project.

(Continued on next page)

* Correspondence: jd.smith@hsc.utah.edu; jd.smith@northwestern.edu
[1]Department of Population Health Sciences, University of Utah School of Medicine, Salt Lake City, Utah, USA
[2]Center for Prevention Implementation Methodology for Drug Abuse and HIV, Department of Psychiatry and Behavioral Sciences, Department of Preventive Medicine, Department of Medical Social Sciences, and Department of Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA
Full list of author information is available at the end of the article

Smith JD, Li DH, Rafferty MR. The implementation research logic model: a method for planning, executing, reporting, and synthesizing implementation projects. Implementation Science. 2020 Dec;15(1):1-2.

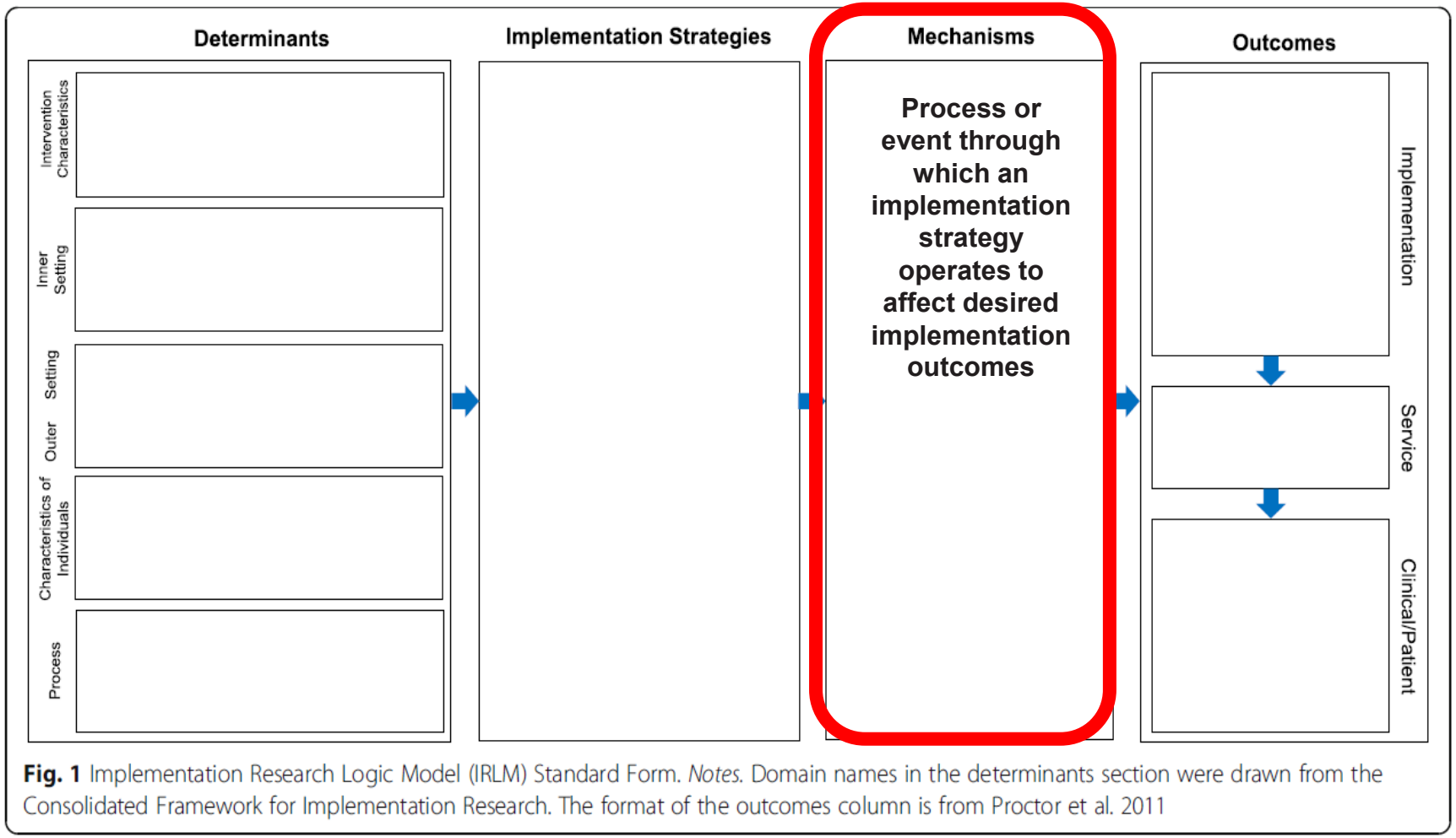


Fig. 1 Implementation Research Logic Model (IRLM) Standard Form. *Notes.* Domain names in the determinants section were drawn from the Consolidated Framework for Implementation Research. The format of the outcomes column is from Proctor et al. 2011

THE Mechanism of Change, according to the Theory of Implementation Effectiveness

Journal of Applied Psychology
2001, Vol. 86, No. 5, 811–824

0021-9010/01/$5.00 DOI: 10.1037//0021-9010.86.5.811

Implementing Computerized Technology: An Organizational Analysis

Katherine J. Klein, Amy Buhl Conn, and Joann Speer Sorra
University of Maryland

Why do some organizations succeed and others fail in implementing the innovations they adopt? To begin to answer this question, the authors studied the implementation of manufacturing resource planning, an advanced computerized manufacturing technology, in 39 manufacturing plants (number of individual respondents = 1,219). The results of the plant-level analyses suggest that financial resource availability and management support for technology implementation engender high-quality implementation policies and practices and a strong climate for implementation, which in turn foster implementation effectiveness—that is, consistent and skilled technology use. Further research is needed to replicate and extend the findings.

During the past decade, analysts have admonished organizations to innovate their work practices, products, and services in order to survive and thrive in today's global marketplace (e.g., Barrett, 1995; Jick, 1995; Slocum, McGill, & Lei, 1995). And yet, many organizations adopt innovations—for example, total quality management, statistical process control, and manufacturing resource planning—with disappointing results. Recent analyses suggest that the reason is not innovation failure but implementation failure (Bushe, 1988; Pfeffer, 1994; Reger, Gustafson, DeMarie, & Mullane, 1994). That is, many organizations fail to fully implement the innovations they adopt; they fail to gain employees' skilled, consistent, and committed innovation use. In the absence of effective implementation, however, innovation adoption is more likely to yield waste and cynicism than performance improvement.

Unfortunately, research on innovation implementation is very limited (Beyer & Trice, 1978; Nord & Tucker, 1987; Tornatzky & Klein, 1982). Thus, relatively little is known about the organizational characteristics and practices that may explain between-organizational differences in implementation effectiveness: Why do some organizations succeed and others fail in implementing the innovations they adopt? To begin to answer this question, we studied the implementation of manufacturing resource planning (MRP II), a software system designed to streamline and integrate production, purchasing, scheduling, inventory control, and cost accounting, in a sample of manufacturing plants and companies. Below, we define key terms and present our hypotheses, method, and results.

Katherine J. Klein, Amy Buhl Conn, and Joann Speer Sorra, Department of Psychology, University of Maryland.

Amy Buhl Conn is now at Personnel Decisions International, Boston, Massachusetts. Joann Speer Sorra is now at Westat, Rockville, Maryland.

This research was supported by a grant to Katherine J. Klein from the National Science Foundation.

We thank Michelle Paul for her contributions during the early stages of the research project. We thank Michele Gelfand, Paul Hanges, David Hofmann, Rob Ployhart, Ben Schneider, and Neal Schmitt for their helpful comments and suggestions on earlier versions of this article.

Correspondence concerning this article should be addressed to Katherine J. Klein, Department of Psychology, University of Maryland, College Park, Maryland 20742. Electronic mail may be sent to klein@psyc.umd.edu.

Innovation Stages, Implementation Effectiveness, and Innovation Effectiveness

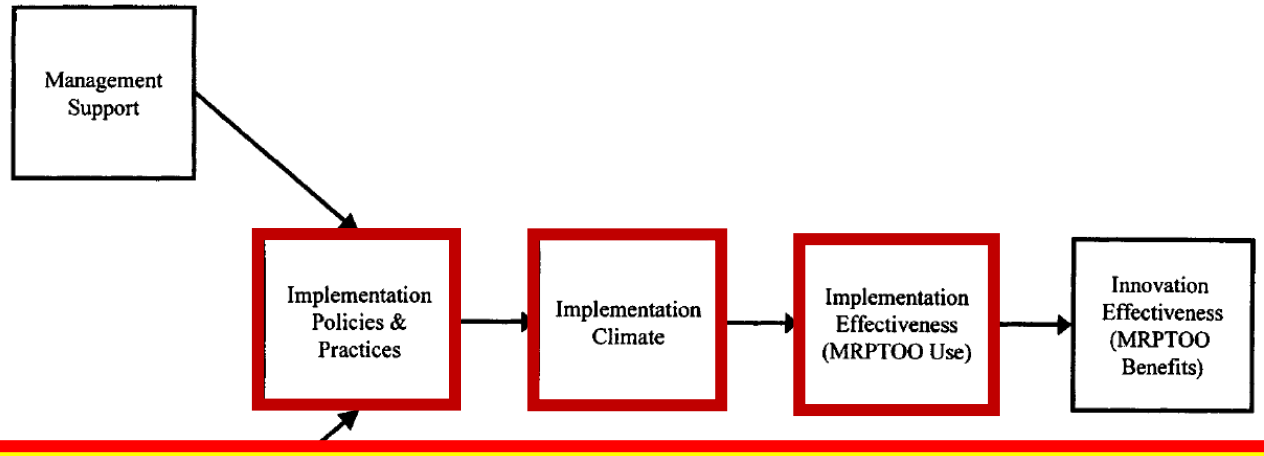
Innovation scholars use stage models to describe the many steps of the innovation process. Source-based stage models trace the innovation process from the gestation of the idea to the marketing of the final product (e.g., research, development, testing, manufacturing, dissemination; Amabile, 1988; Tornatzky & Fleischer, 1990). Within these models, an *innovation* is a new product or service that an organization has created for market. Building on source-based stage models, researchers explore the correlates of the development of innovative products and services (see, e.g., Dougherty & Heller, 1994).

User-based stage models, in contrast, trace the stages of innovation from the user's awareness of a need or opportunity to change to the incorporation of the innovation in the user's behavioral repertoire (e.g., awareness, selection, adoption, implementation; Nord & Tucker, 1987; Tornatzky & Fleischer, 1990). Within these models and within our research, an *innovation* is a technology or practice that an organization is using for the first time, regardless of whether other organizations have previously used the technology or practice (Nord & Tucker, 1987). Innovation *adoption* refers to an organization's decision to install an innovation within the organization. Adoption is a decision point, a plan, or a purchase. *Implementation* follows adoption and is "the transition period during which targeted organizational members ideally become increasingly skillful, consistent, and committed in their use of an innovation" (Klein & Sorra, 1996, p. 1057).

Innovation adoption has been the focus of considerable research. Thus, for example, numerous studies have examined the innovation characteristics (e.g., innovation complexity, innovation trialability) that make an innovation particularly likely to be adopted by individual or organizational users (e.g., Tornatzky & Klein, 1982). Furthermore, many studies have examined the characteristics that distinguish innovative organizations (Damanpour, 1991).

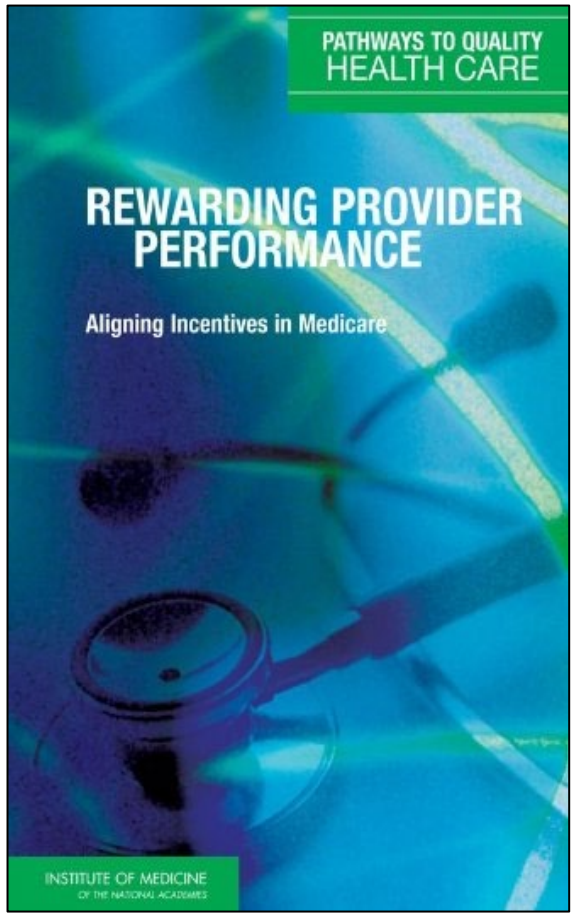
Unfortunately, innovation implementation has been the focus of very little research. In this study, we examined manufacturing plants in the process of implementing the same technology. Innovation adoption was thus a constant in this study. All of the plants had formally adopted MRP II; they had bought the same software system. The plants differed, however, in their *implementation*

Klein, K. J., Conn, A. B., & Sorra, J. S. (2001). Implementing computerized technology: an organizational analysis. Journal of applied Psychology, 86(5), 811.



Implementation Climate **is defined as the extent to which implementation is expected, supported, and rewarded**

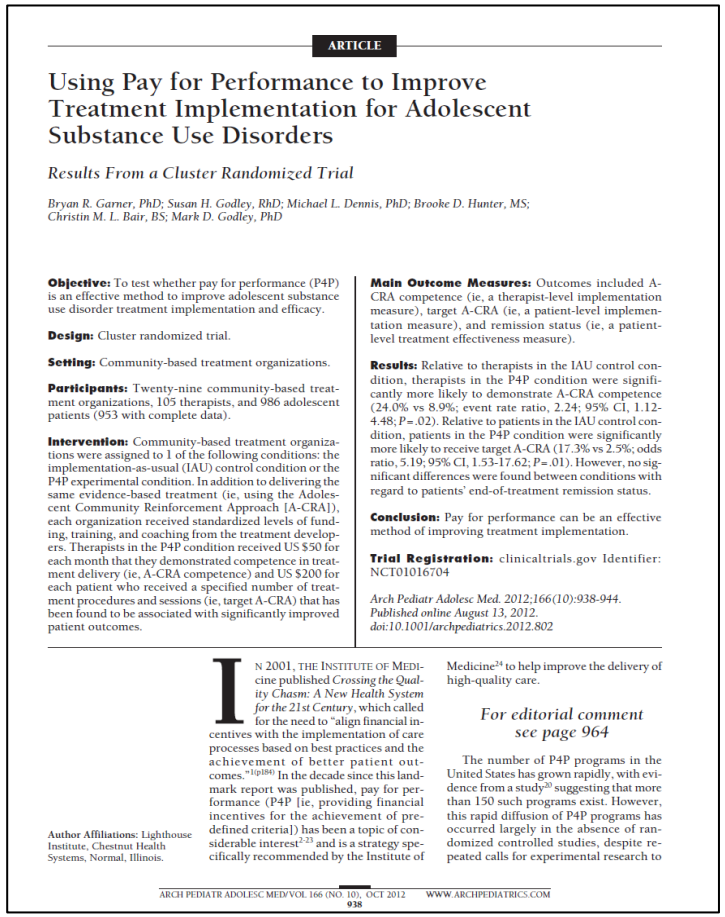
Rewarding Provider Performance via Pay-for-Performance (P4P)



English, W. J. (2008). Rewarding provider performance: aligning incentives in Medicare.

Recommended pay-for-performance as a strategy to improve the quality of health care

The Reinforcing Therapist Performance (RTP) Project: A type 3 hybrid trial



ARTICLE

Using Pay for Performance to Improve Treatment Implementation for Adolescent Substance Use Disorders

Results From a Cluster Randomized Trial

Bryan R. Garner, PhD; Susan H. Godley, RhD; Michael L. Dennis, PhD; Brooke D. Hunter, MS; Christin M. L. Bair, BS; Mark D. Godley, PhD

Objective: To test whether pay for performance (P4P) is an effective method to improve adolescent substance use disorder treatment implementation and efficacy.

Design: Cluster randomized trial.

Setting: Community-based treatment organizations.

Participants: Twenty-nine community-based treatment organizations, 105 therapists, and 986 adolescent patients (953 with complete data).

Intervention: Community-based treatment organizations were assigned to 1 of the following conditions: the implementation-as-usual (IAU) control condition or the P4P experimental condition. In addition to delivering the same evidence-based treatment (ie, using the Adolescent Community Reinforcement Approach [A-CRA]), each organization received standardized levels of funding, training, and coaching from the treatment developers. Therapists in the P4P condition received US $50 for each month that they demonstrated competence in treatment delivery (ie, A-CRA competence) and US $200 for each patient who received a specified number of treatment procedures and sessions (ie, target A-CRA) that has been found to be associated with significantly improved patient outcomes.

Main Outcome Measures: Outcomes included A-CRA competence (ie, a therapist-level implementation measure), target A-CRA (ie, a patient-level implementation measure), and remission status (ie, a patient-level treatment effectiveness measure).

Results: Relative to therapists in the IAU control condition, therapists in the P4P condition were significantly more likely to demonstrate A-CRA competence (24.0% vs 8.9%; event rate ratio, 2.24; 95% CI, 1.12-4.48; *P*=.02). Relative to patients in the IAU control condition, patients in the P4P condition were significantly more likely to receive target A-CRA (17.3% vs 2.5%; odds ratio, 5.19; 95% CI, 1.53-17.62; *P*=.01). However, no significant differences were found between conditions with regard to patients' end-of-treatment remission status.

Conclusion: Pay for performance can be an effective method of improving treatment implementation.

Trial Registration: clinicaltrials.gov Identifier: NCT01016704

Arch Pediatr Adolesc Med. 2012;166(10):938-944. Published online August 13, 2012. doi:10.1001/archpediatrics.2012.802

Author Affiliations: Lighthouse Institute, Chestnut Health Systems, Normal, Illinois.

In 2001, the Institute of Medicine published *Crossing the Quality Chasm: A New Health System for the 21st Century*, which called for the need to "align financial incentives with the implementation of care processes based on best practices and the achievement of better patient outcomes."[1(p186)] In the decade since this landmark report was published, pay for performance (P4P [ie, providing financial incentives for the achievement of predefined criteria]) has been a topic of considerable interest[2,23] and is a strategy specifically recommended by the Institute of Medicine[24] to help improve the delivery of high-quality care.

For editorial comment see page 964

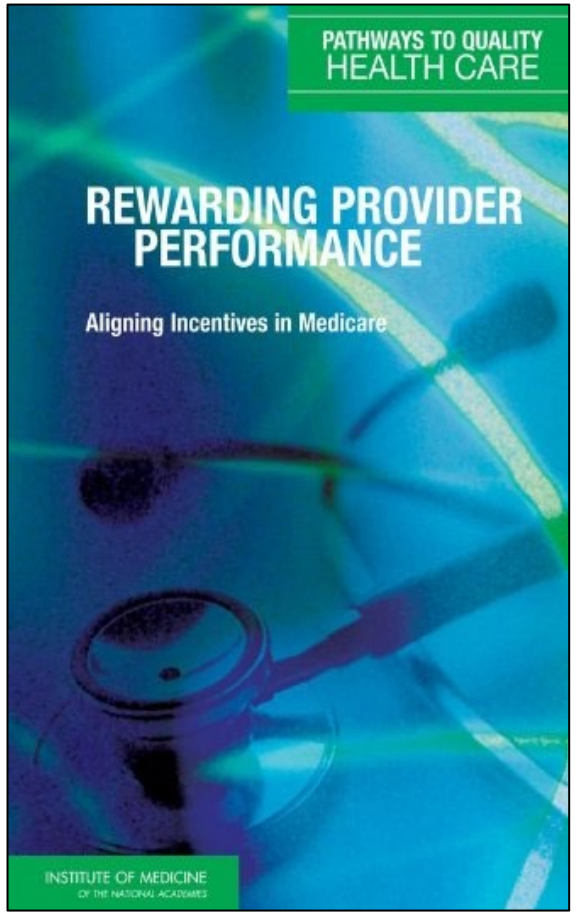
The number of P4P programs in the United States has grown rapidly, with evidence from a study[20] suggesting that more than 150 such programs exist. However, this rapid diffusion of P4P programs has occurred largely in the absence of randomized controlled studies, despite repeated calls for experimental research to

Garner, B. R., Godley, S. H., Dennis, M. L., Hunter, B. D., Bair, C. M., & Godley, M. D. (2012). Using pay for performance to improve treatment implementation for adolescent substance use disorders: results from a cluster randomized trial. Archives of pediatrics & adolescent medicine, 166(10), 938-944.

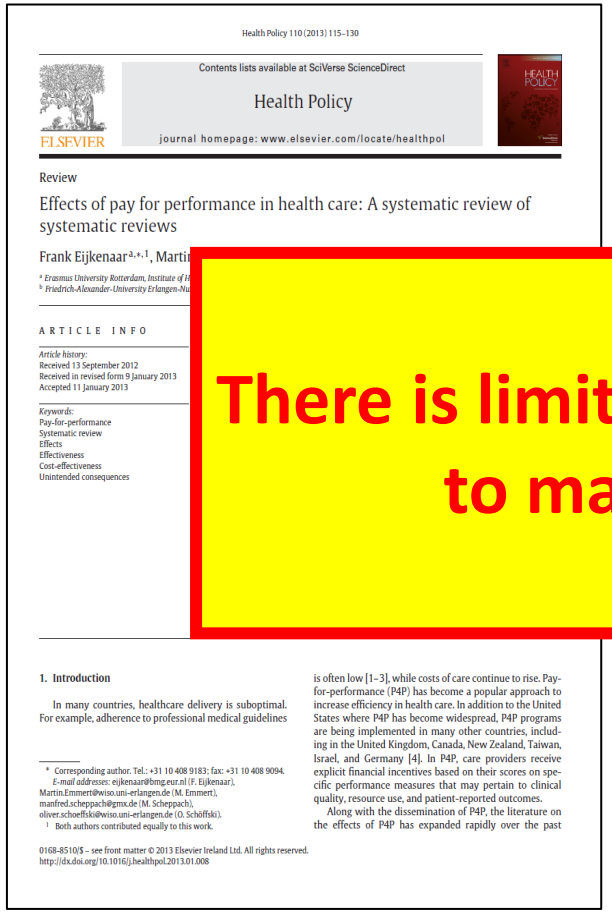
- **A type 3 hybrid trial with 29 substance use disorder treatment organizations, 105 staff, and 986 clients.**
  - Tested the effectiveness of pay-for-performance (P4P) as an adjunct to implementation-as-usual (i.e., training, feedback, and consultation) on implementation outcomes and client outcomes.
    - Staff earned a $50 incentive per month that a randomly selected session recording met or exceeded the fidelity benchmark.
    - Staff earned a $200 incentive per client that received the benchmark treatment adherence benchmark.

- **Main Findings**
  - The P4P strategy has a direct effect on improving staff fidelity and client's receiving sufficient dosage of treatment, as well as an indirect effect on improving client's days of abstinence at follow-up.
  - The P4P strategy was highly cost-effective (see Garner et al., 2018)
    - 5% increase in cost led to 116% increase in months of staff fidelity demonstrated and 325% increase in clients receiving sufficient dosage of treatment.

Rewarding Provider Performance via Pay-for-Performance (P4P)



English, W. J. (2008). Rewarding provider performance: aligning incentives in Medicare.


Health Policy 110 (2013) 115–130

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Review

Effects of pay for performance in health care: A systematic review of systematic reviews

Frank Eijkenaar[a,*,1], Marti

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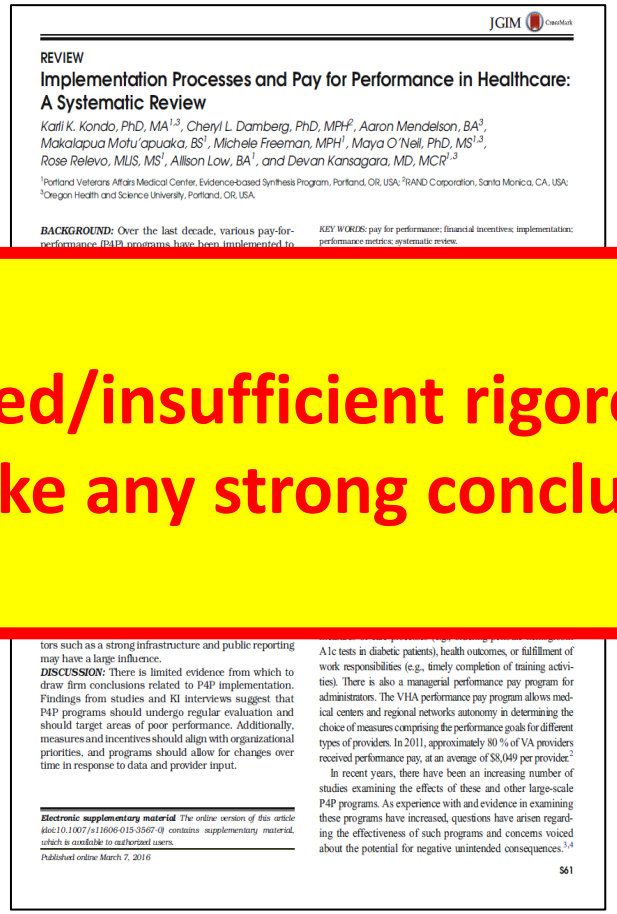
1. Introduction

In many countries, healthcare delivery is suboptimal. For example, adherence to professional medical guidelines is often low [1–3], while costs of care continue to rise. Pay-for-performance (P4P) has become a popular approach to increase efficiency in health care. In addition to the United States where P4P has become widespread, P4P programs are being implemented in many other countries, including in the United Kingdom, Canada, New Zealand, Taiwan, Israel, and Germany [4]. In P4P, care providers receive explicit financial incentives based on their scores on specific performance measures that may pertain to clinical quality, resource use, and patient-reported outcomes.

Along with the dissemination of P4P, the literature on the effects of P4P has expanded rapidly over the past

Eijkenaar, F., Emmert, M., Scheppach, M., & Schöffski, O. (2013). Effects of pay for performance in health care: a systematic review of systematic reviews. Health policy, 110(2-3), 115-130.


JGIM

REVIEW

Implementation Processes and Pay for Performance in Healthcare: A Systematic Review

Karli K. Kondo, PhD, MA[1,3], Cheryl L. Damberg, PhD, MPH[2], Aaron Mendelson, BA[3], Makalapua Motu'apuaka, BS[1], Michele Freeman, MPH[1], Maya O'Neil, PhD, MS[1,3], Rose Relevo, MLIS, MS[1], Allison Low, BA[1], and Devan Kansagara, MD, MCR[1,3]

[1]Portland Veterans Affairs Medical Center, Evidence-based Synthesis Program, Portland, OR, USA; [2]RAND Corporation, Santa Monica, CA, USA; [3]Oregon Health and Science University, Portland, OR, USA.

BACKGROUND: Over the last decade, various pay-for-

KEY WORDS: pay for performance; financial incentives; implementation; performance metrics; systematic review.

tors such as a strong infrastructure and public reporting may have a large influence.

DISCUSSION: There is limited evidence from which to draw firm conclusions related to P4P implementation. Findings from studies and KI interviews suggest that P4P programs should undergo regular evaluation and should target areas of poor performance. Additionally, measures and incentives should align with organizational priorities, and programs should allow for changes over time in response to data and provider input.

A1c tests in diabetic patients), health outcomes, or fulfillment of work responsibilities (e.g., timely completion of training activities). There is also a managerial performance pay program for administrators. The VHA performance pay program allows medical centers and regional networks autonomy in determining the choice of measures comprising the performance goals for different types of providers. In 2011, approximately 80 % of VA providers received performance pay, at an average of $8,049 per provider.[2]

In recent years, there have been an increasing number of studies examining the effects of these and other large-scale P4P programs. As experience with and evidence in examining these programs have increased, questions have arisen regarding the effectiveness of such programs and concerns voiced about the potential for negative unintended consequences.[3,4]

Electronic supplementary material The online version of this article (doi:10.1007/s11606-015-3567-0) contains supplementary material, which is available to authorized users.

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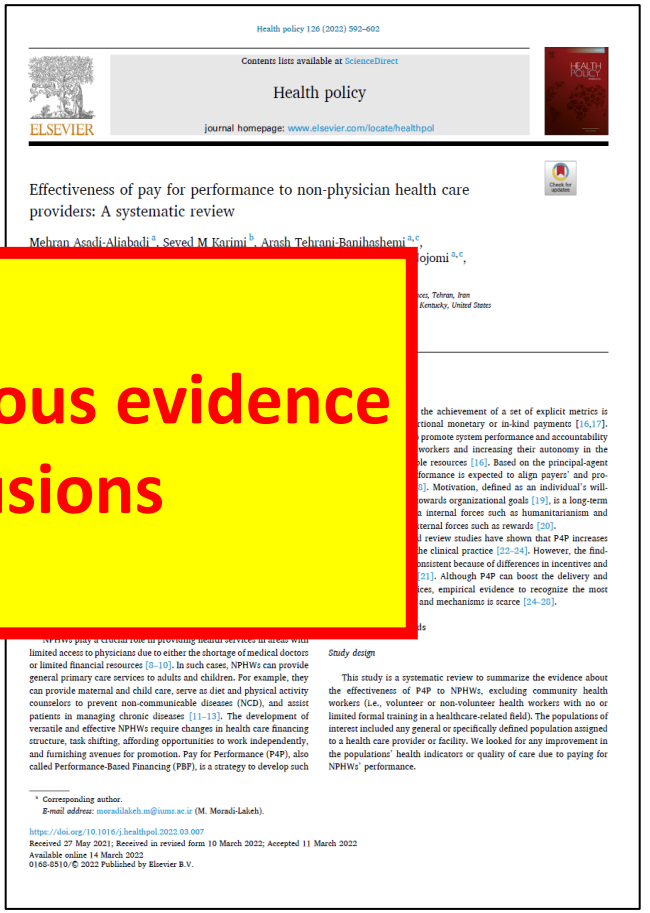
S61

Kondo, K. K., Damberg, C. L., Mendelson, A., Motu'apuaka, M., Freeman, M., O'Neil, M., ... & Kansagara, D. (2016). Implementation processes and pay for performance in healthcare: a systematic review. Journal of general internal medicine, 31(1), 61-69.


Health policy 126 (2022) 592–602

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Health policy

journal homepage: www.elsevier.com/locate/healthpol

Effectiveness of pay for performance to non-physician health care providers: A systematic review

Mehran Asadi-Aliabadi[a], Seyed M Karimi[b], Arash Tehrani-Banihashemi[a,c], ojoni[a,c],

ees, Tehran, Iran
Kentucky, United States

the achievement of a set of explicit metrics is ctional monetary or in-kind payments [16,17]. promote system performance and accountability workers and increasing their autonomy in the le resources [16]. Based on the principal-agent formance is expected to align payers' and pro- 8]. Motivation, defined as an individual's will- owards organizational goals [19], is a long-term internal forces such as humanitarianism and ternal forces such as rewards [20].
d review studies have shown that P4P increases he clinical practice [22–24]. However, the find- onsistent because of differences in incentives and 21]. Although P4P can boost the delivery and ces, empirical evidence to recognize the most and mechanisms is scarce [24–28].

NPHWs play a crucial role in providing health services in areas with limited access to physicians due to either the shortage of medical doctors or limited financial resources [8–10]. In such cases, NPHWs can provide general primary care services to adults and children. For example, they can provide maternal and child care, serve as diet and physical activity counselors to prevent non-communicable diseases (NCD), and assist patients in managing chronic diseases [11–13]. The development of versatile and effective NPHWs require changes in health care financing structure, task shifting, affording opportunities to work independently, and furnishing avenues for promotion. Pay for Performance (P4P), also called Performance-Based Financing (PBF), is a strategy to develop such

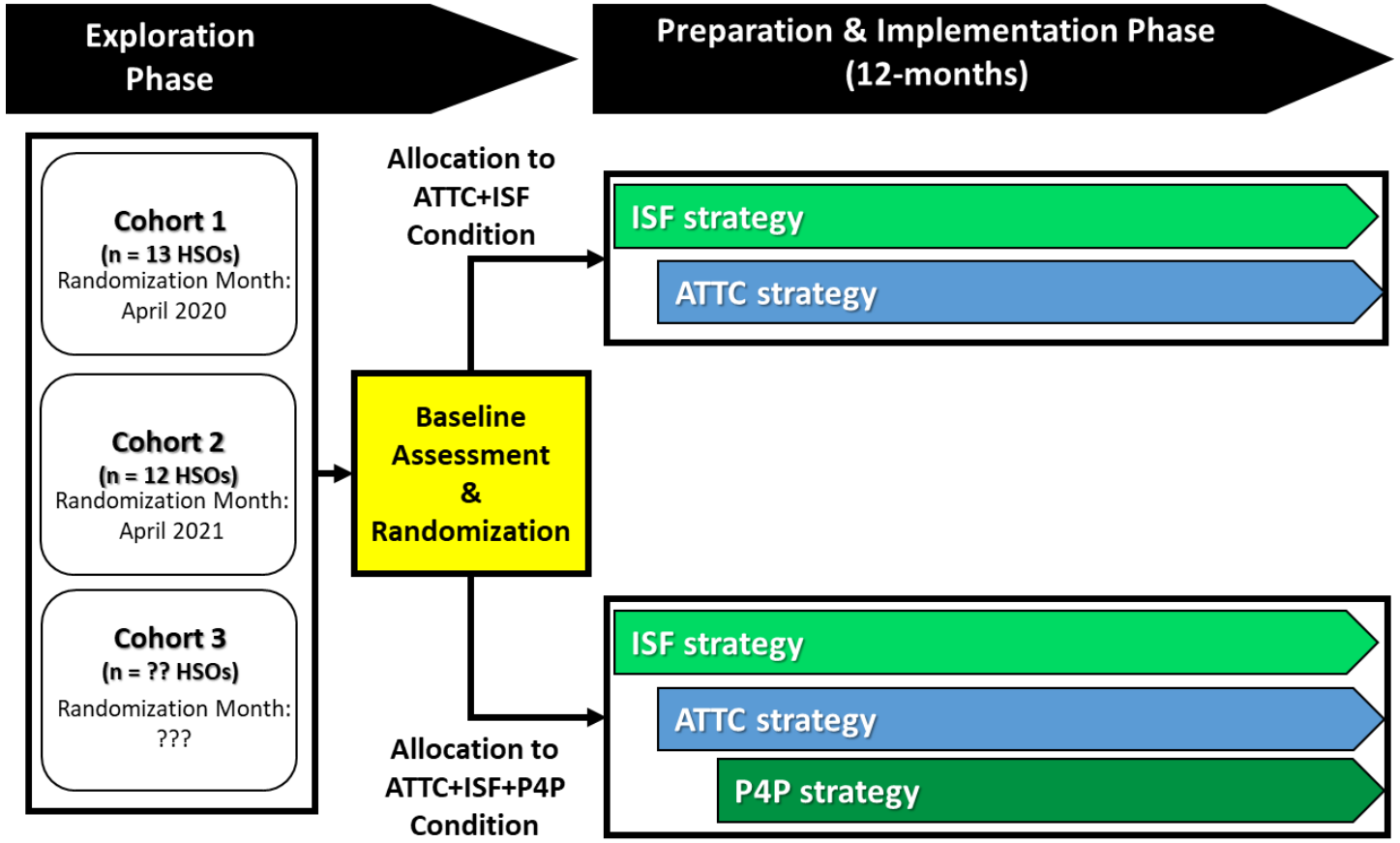
Study design

This study is a systematic review to summarize the evidence about the effectiveness of P4P to NPHWs, excluding community health workers (i.e., volunteer or non-volunteer health workers with no or limited formal training in a healthcare-related field). The populations of interest included any general or specifically defined population assigned to a health care provider or facility. We looked for any improvement in the populations' health indicators or quality of care due to paying for NPHWs' performance.

Asadi-Aliabadi, M., Karimi, S. M., Tehrani-Banihashemi, A., Mirbaha-Hashemi, F., Janani, L., Babaee, E., ... & Moradi-Lakeh, M. (2022). Effectiveness of pay for performance to non-physician health care providers: A systematic review. Health Policy.

There is limited/insufficient rigorous evidence to make any strong conclusions

The SAT2HIV-II Project:
A type 3 hybrid trial



Flow of participating organizations

Note: HSO = HIV Service Organization; ATTC = Addiction Technology Transfer Center; ISF = Implementation & Sustainment Facilitation; P4P = Pay-for-Performance.

- **A 25-site cluster-randomized type 3 hybrid trial**
  - Testing a staff-focused pay-for-performance (P4P) strategy as an adjunct to the ATTC+ISF Strategy.
    - Staff earn $10 per motivational interviewing-based brief intervention (MIBI) session implemented with a client participant, AND $10 per MIBI session that is rated at a benchmark level of fidelity/quality (assessed by an artificial intelligence fidelity rating platform from Lyssn Inc).

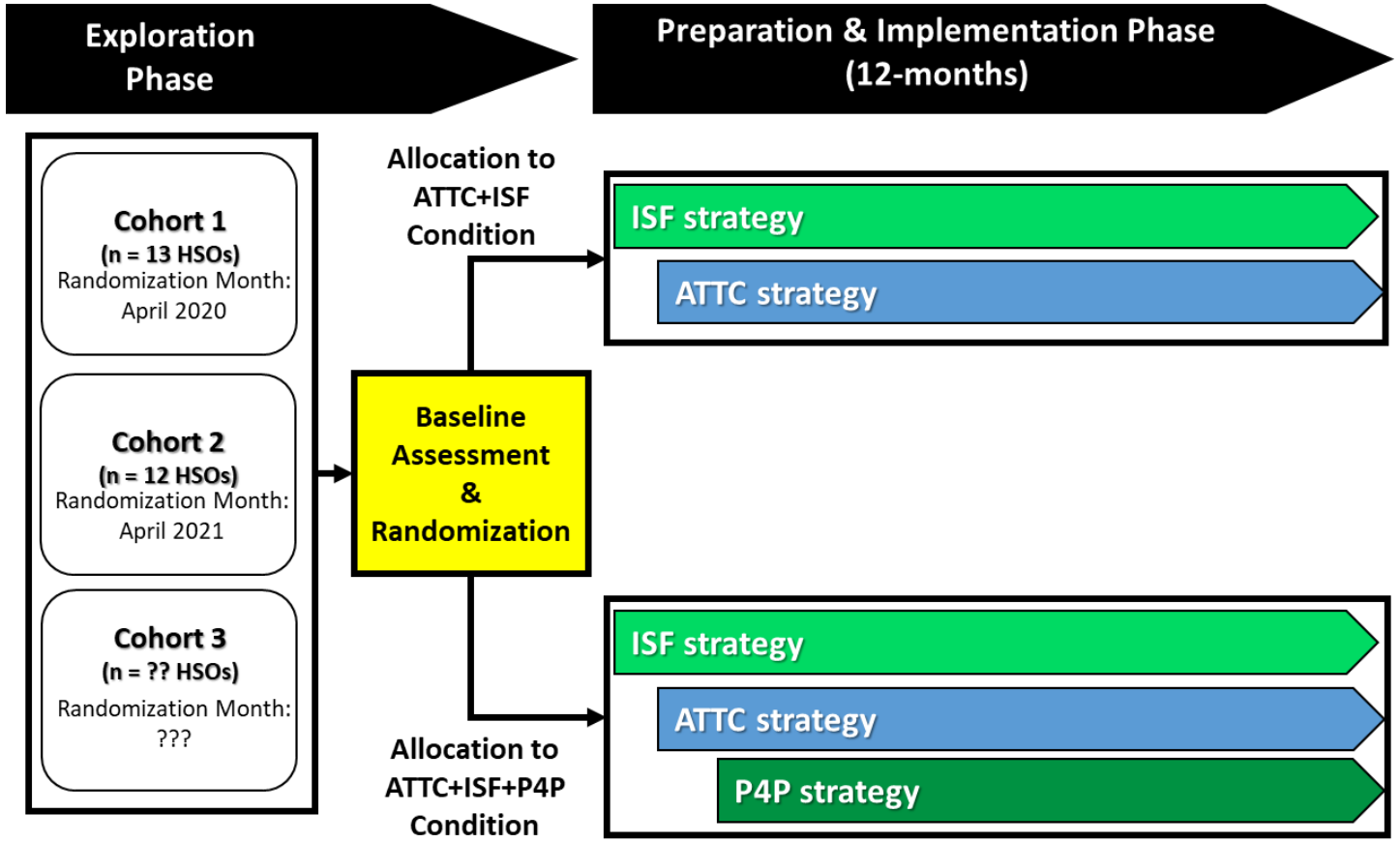
Results:

Baseline characteristics of staff participants

	Overall (N=86)		ISF + ATTC (N=43)		ISF + ATTC + P4P (N=43)	
	N	%	N	%	N	%
Age						
18-24	4	4.7	2	4.7	2	4.7
25-34	35	40.7	23	53.5	12	27.9
35-44	16	18.6	6	14.0	10	23.3
45-54	13	15.1	5	11.6	8	18.6
55-64	15	17.4	7	16.3	8	18.6
65 and older	3	3.5	0	0.0	3	7.0
Female	57	66.3	30	69.8	27	62.8
Hispanic	27	31.4	17	39.5	10	23.3
White	39	45.4	23	53.5	16	37.2
Graduate degree or higher	33	38.4	21	48.8	12	27.9
Experience at current organization						
12 months or less	29	33.7	15	34.9	14	32.6
13-24 months	6	7.0	2	4.7	4	9.3
25-60 months	31	36.1	18	41.9	13	30.2
61-120 months	9	10.5	6	14.0	3	7.0
121+ months	11	12.8	2	4.7	9	20.9
Tenure at current position						
12 months or less	32	37.2	16	37.2	16	37.2
13-24 months	13	15.1	6	14.0	7	16.3
25-60 months	30	34.9	18	41.9	12	27.9
61-120 months	4	4.7	2	4.7	2	4.7
121+ months	6	7.0	0	0.0	6	14.0

Results:

Staff preparation by condition: Completed the MIBI training



30/43 (79%)

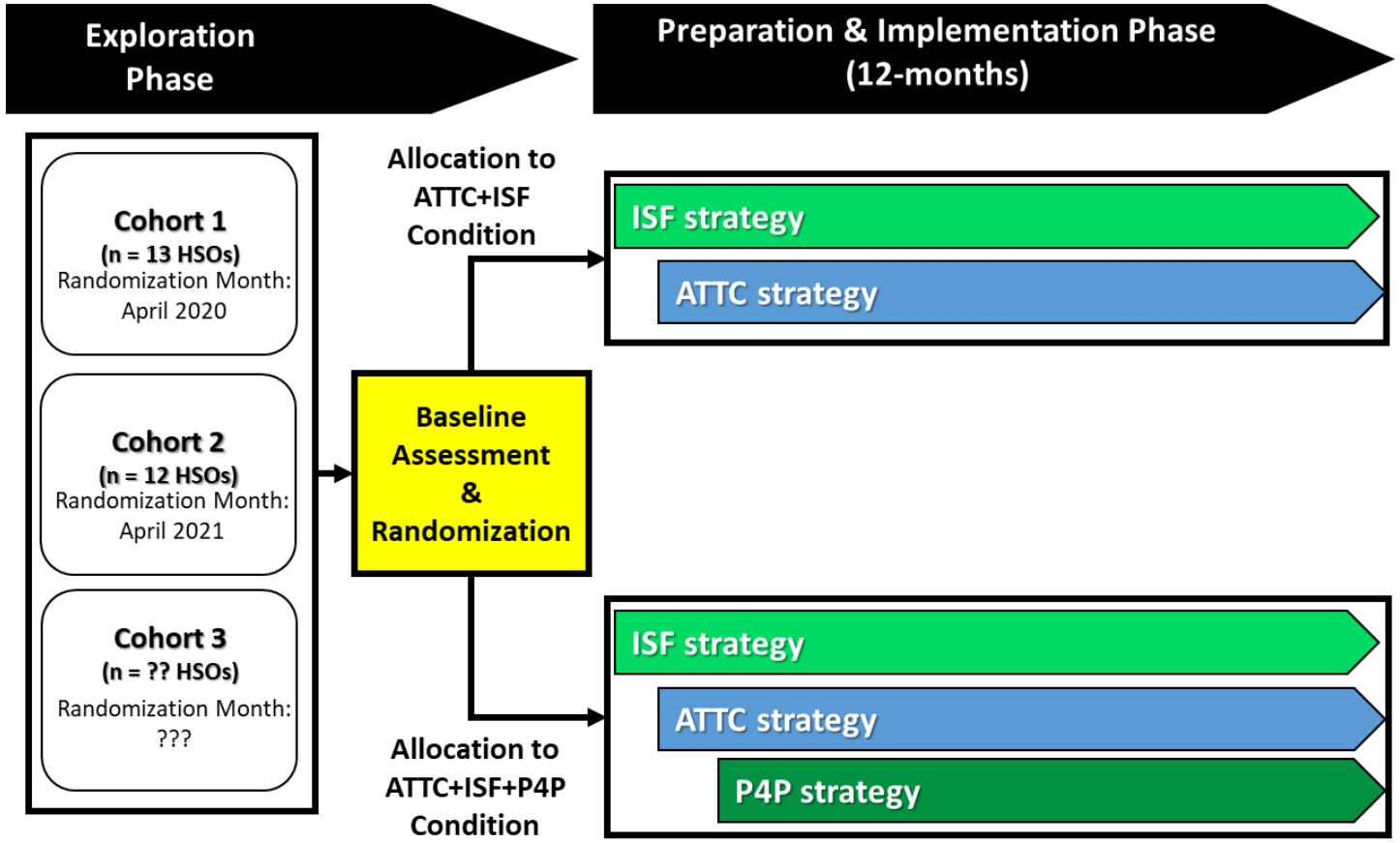
30/43 (79%)

Flow of participating organizations

Note: HSO = HIV Service Organization; ATTC = Addiction Technology Transfer Center; ISF = Implementation & Sustainment Facilitation; P4P = Pay-for-Performance.

Results:

Staff implementation by condition: Implemented the MIBI with 1+ client participant



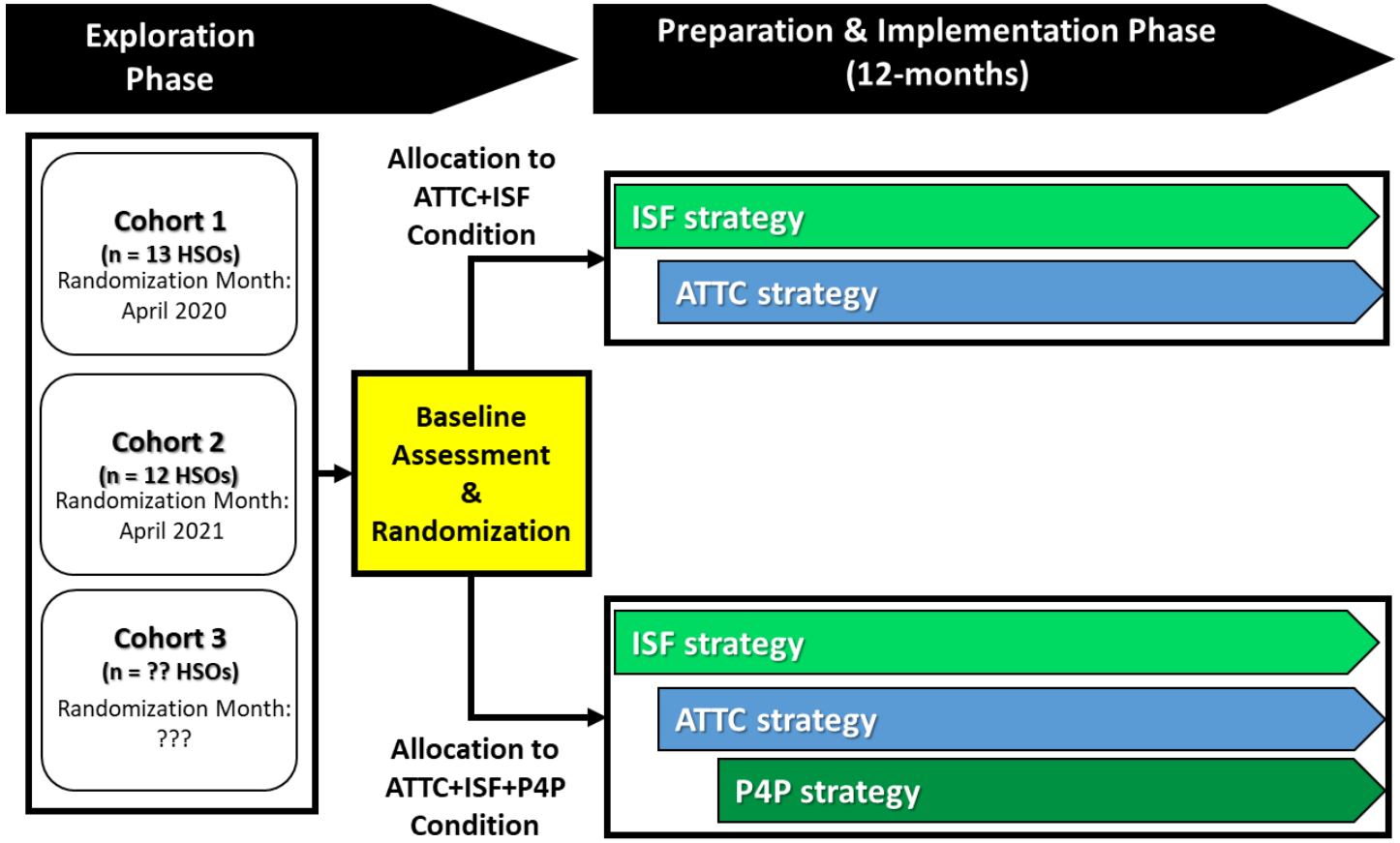
Of All Targeted: 14/43 (33%)
Of Training Completers: 14/30 (47%)

Of All Targeted: 18/43 (42%)
Of Training Completers: 18/30 (60%)

Flow of participating organizations

Note: HSO = HIV Service Organization; ATTC = Addiction Technology Transfer Center; ISF = Implementation & Sustainment Facilitation; P4P = Pay-for-Performance.

Results:
Staff implementation by condition: implementation consistency



Flow of participating organizations

Note: HSO = HIV Service Organization; ATTC = Addiction Technology Transfer Center; ISF = Implementation & Sustainment Facilitation; P4P = Pay-for-Performance.

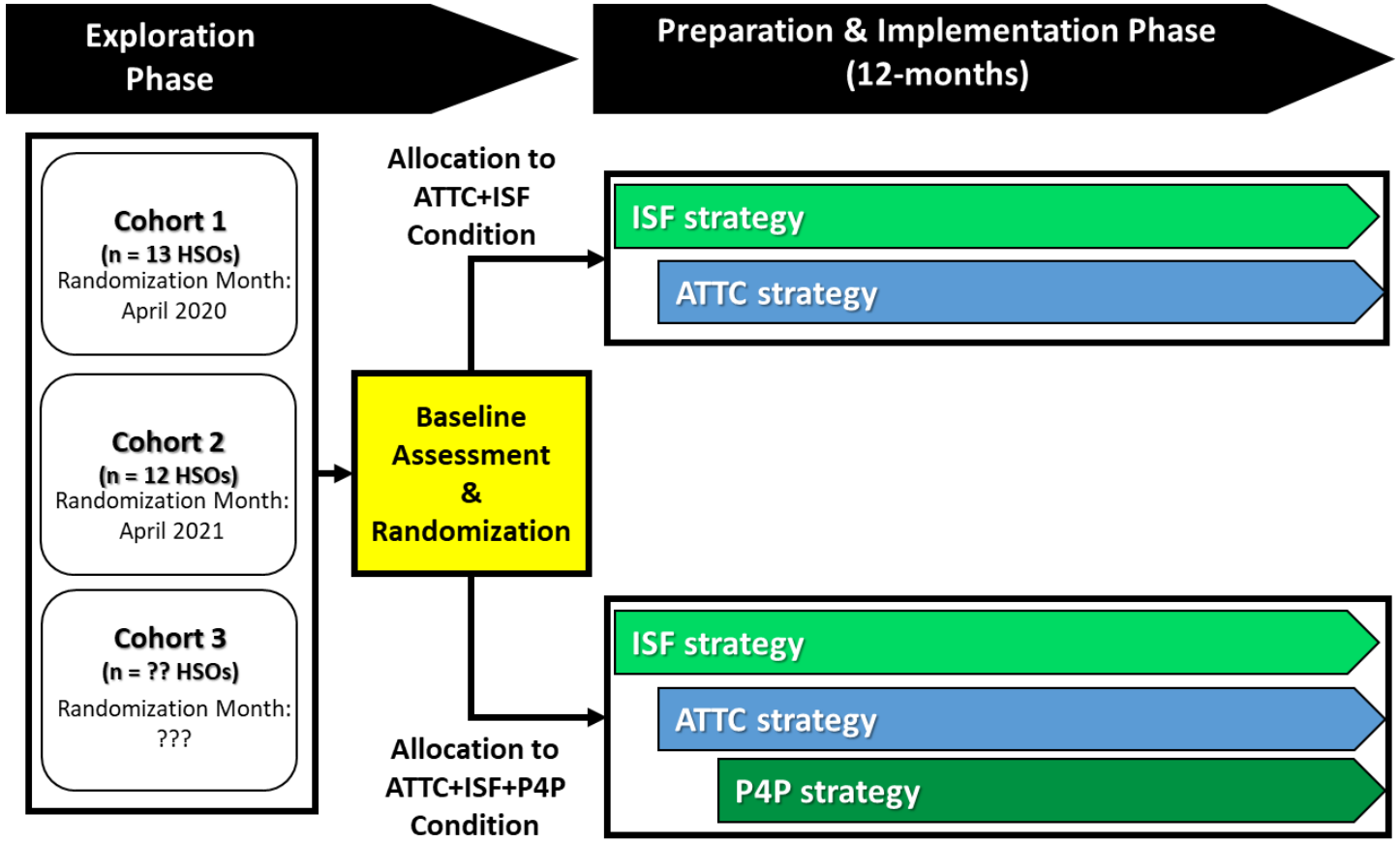
Ranged from 0 to 8 per staff

The average number of MIBIs implemented per staff was **0.81** (SD = 1.56)

Ranged from 0 to 12 per staff

The average number of MIBIs implemented per staff was **2.51** (SD = 2.67)

Results:
MIBIs implemented by condition



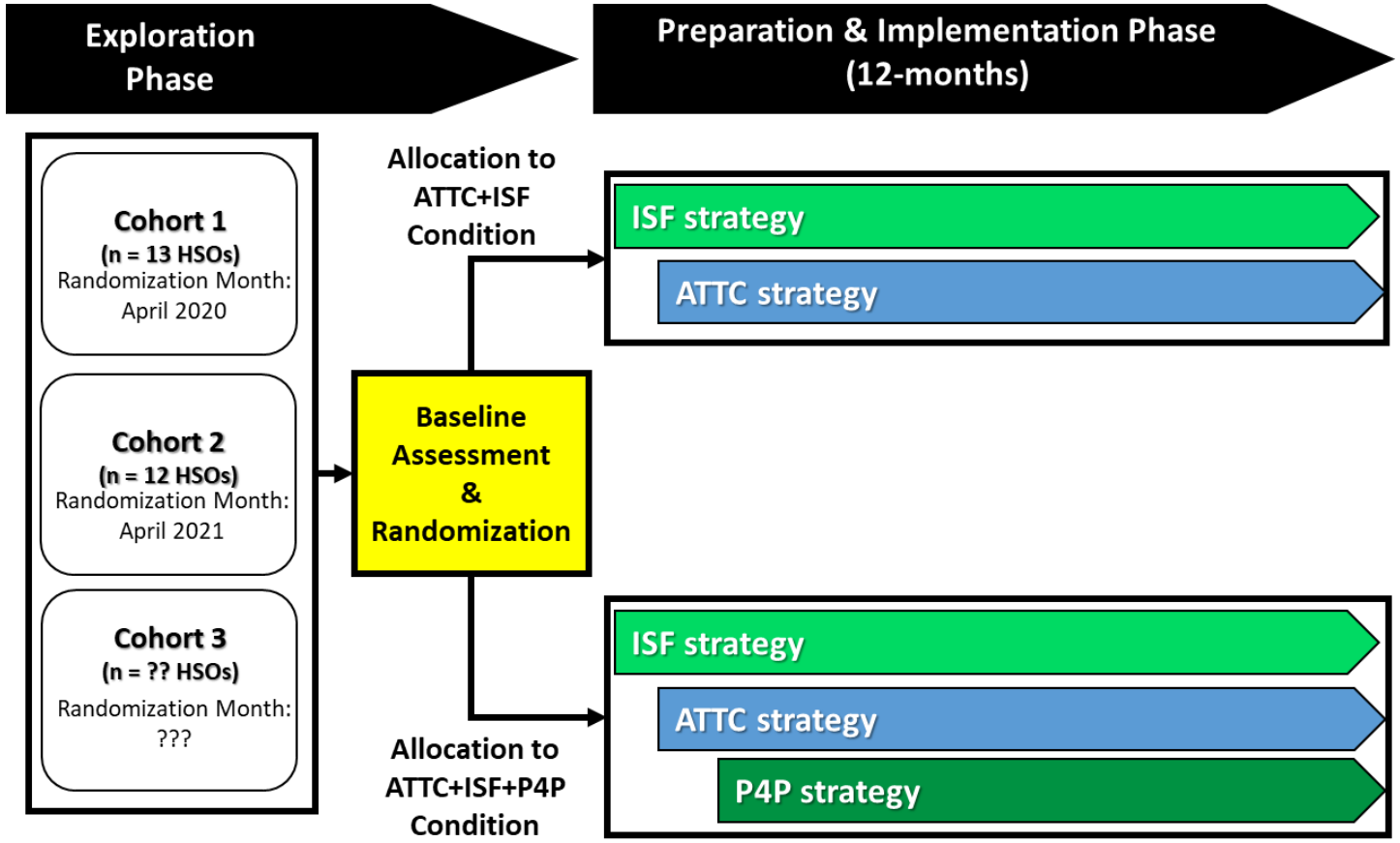
35 MIBIs

108 MIBIs

Flow of participating organizations

Note: HSO = HIV Service Organization; ATTC = Addiction Technology Transfer Center; ISF = Implementation & Sustainment Facilitation; P4P = Pay-for-Performance.

Results:
Staff implementation by condition: implementation quality



Flow of participating organizations

Note: HSO = HIV Service Organization; ATTC = Addiction Technology Transfer Center; ISF = Implementation & Sustainment Facilitation; P4P = Pay-for-Performance.

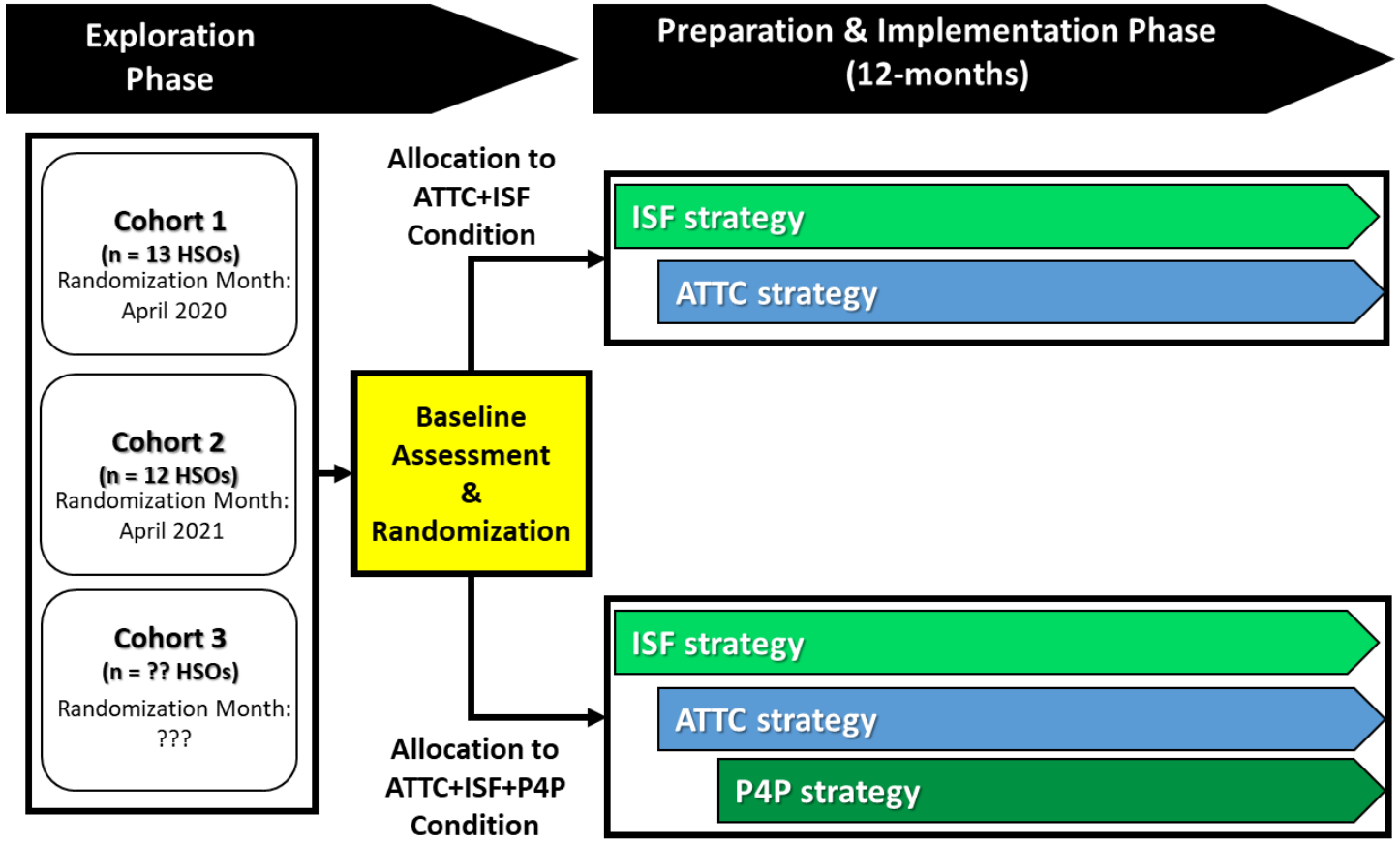
Ranged from 0 to 44 per staff

The average overall level of MIBI quality demonstrated per staff was **4.72** (SD = 9.96)

Ranged from 0 to 77 per staff

The average overall level of MIBI quality demonstrated per staff was **12.39** (SD = 20.57)

Results:
Staff implementation by condition: implementation effectiveness



Flow of participating organizations

Note: HSO = HIV Service Organization; ATTC = Addiction Technology Transfer Center; ISF = Implementation & Sustainment Facilitation; P4P = Pay-for-Performance.

Ranged from -.52 to 2.24 per staff

The average standardized implementation effectiveness score per staff was **-.25** (SD = .57)

Adjusted effect size difference of .47 (*p* = .001)

Ranged from -.52 to 3.91 per staff

The average standardized implementation effectiveness score per staff was **.26** (SD = 1.25)

Effectiveness-Implementation Hybrid ~~Designs~~ Studies

ANNALS OF HSR

Effectiveness-implementation Hybrid Designs

Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

Geoffrey M. Curran, PhD, Mark Bauer, MD,† Brian Mittman, PhD,‡ Jeffrey M. Pyne, MD,* and Cheryl Stetler, PhD,‡*

Objectives: This study proposes methods for blending design components of clinical effectiveness and implementation research. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains, more effective implementation strategies, and more useful information for decision makers. This study proposes a "hybrid effectiveness-implementation" typology, describes a rationale for their use, outlines the design decisions that must be faced, and provides several real-world examples.

Results: An effectiveness-implementation hybrid design is one that takes a dual focus a priori in assessing clinical effectiveness and implementation. We propose 3 hybrid types: (1) testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation; (2) dual testing of clinical and implementation interventions/strategies; and (3) testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

Conclusions: The hybrid typology proposed herein must be considered a construct still in evolution. Although traditional clinical effectiveness and implementation trials are likely to remain the most common approach to moving a clinical intervention through from efficacy research to public health impact, judicious use of the proposed hybrid designs could speed the translation of research findings into routine practice.

Key Words: diffusion of innovation, implementation science, clinical trials, pragmatic designs

(*Med Care* 2012;50: 217–226)

From the *Central Arkansas Veterans Healthcare System, and Department of Psychiatry, University of Arkansas for Medical Sciences, Little Rock, AR; †VA Boston Healthcare System, Harvard Medical School, Boston, MA; and ‡Center for Implementation Practice and Research Support (CIPRS), VA Greater Los Angeles Healthcare System, Los Angeles, CA.

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The authors declare no conflict of interest.

Reprints: Geoffrey M. Curran, PhD, Department of Psychiatry, Division of Health Services Research, University of Arkansas for Medical Sciences, 4301 W. Markham St. #755, Little Rock, AR 72205. E-mail: currangeoffreym@uams.edu.

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Much has been written about the nature of health care science-to-service gaps both in general[1–3] and relative specifically to health promotion[4] and numerous medical specialties.[5–9] Thus far, the literature indicates that gaps between research and practice can result from multiple factors, including educational/knowledge deficiencies and/or disagreements,[10,11] time constraints for practitioners,[12,13] lack of decision support tools and feedback mechanisms,[13] poorly aligned incentives,[14] and a host of other organizational climate and cultural factors.[2,15,16]

In addition to these provider-level and systems-level barriers to rapid translation, Glasgow et al[4] and others[17–20] argue that the time lag between research discovery and routine uptake is also inflated by the dominant developmental approach; that is, one that encourages delimited, step-wise progressions of research through clinical efficacy research, then clinical effectiveness research, and finally implementation research. In addition, it has been suggested that current conceptions of research designs fail to "maximize clinical utility for practicing clinicians and other decision makers"[18]; for example, through a failure to focus on external validity or implementation-related barriers and facilitators to routine use and sustainability of "effective" practices.[4,21,22]

Wells[19] and Glasgow et al[4] suggested that a blending of the efficacy and effectiveness stages of intervention development could improve the speed of knowledge creation and increase the usefulness and policy relevance of clinical research. We propose that a blending of the design components of clinical effectiveness trials and implementation trials also is feasible and desirable. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains in clinical intervention uptake, more effective implementation strategies, and more useful information for researchers and decision makers. This study describes the elements of such "effectiveness-implementation hybrid designs," discusses the indications for such approaches, outlines the design decisions that must be faced in developing such protocols, and provides several examples of funded hybrid studies to illustrate the concepts.

DEFINING TERMINOLOGY

Terminology in this study has been informed by a glossary provided by the Department of Veterans Affairs Quality Enhancement Research Initiative (VA QUERI)[22];

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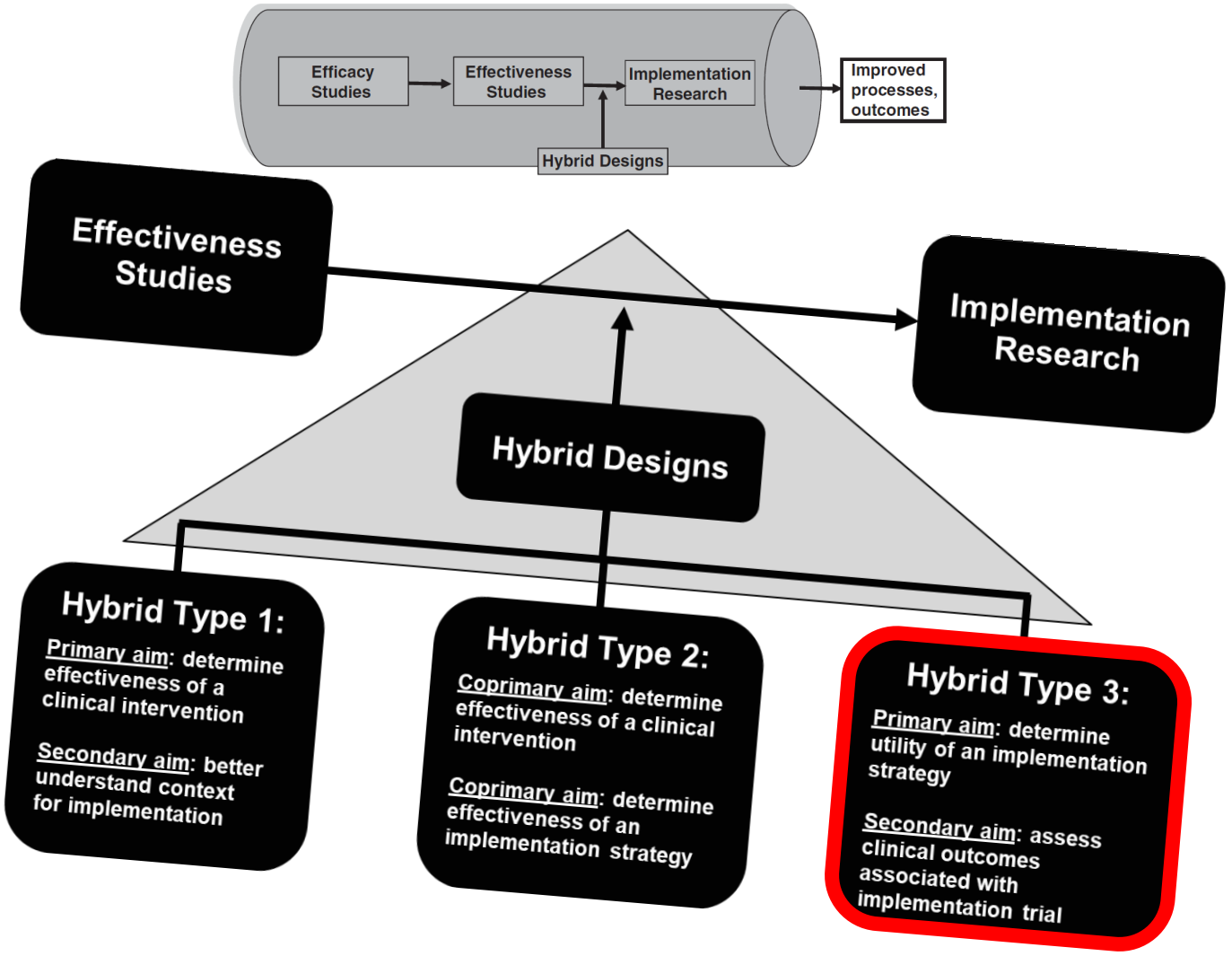
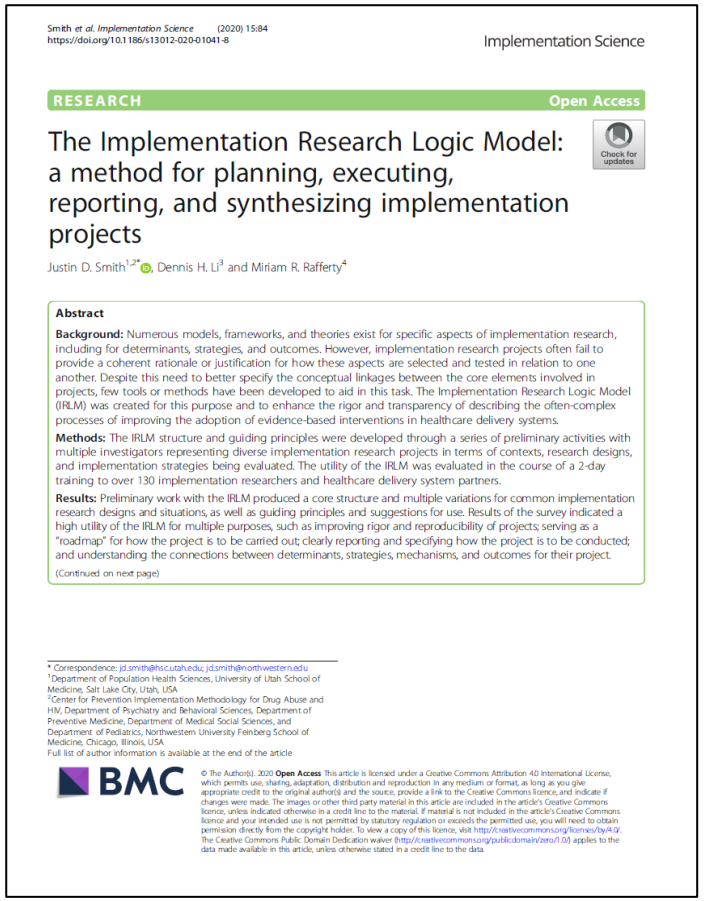
FIGURE 1. Research pipeline.



Mechanisms?



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Implementation Science

RESEARCH Open Access

The Implementation Research Logic Model: a method for planning, executing, reporting, and synthesizing implementation projects

Justin D. Smith[1,2*], Dennis H. Li[3] and Miriam R. Rafferty[4]

Abstract

Background: Numerous models, frameworks, and theories exist for specific aspects of implementation research, including for determinants, strategies, and outcomes. However, implementation research projects often fail to provide a coherent rationale or justification for how these aspects are selected and tested in relation to one another. Despite this need to better specify the conceptual linkages between the core elements involved in projects, few tools or methods have been developed to aid in this task. The Implementation Research Logic Model (IRLM) was created for this purpose and to enhance the rigor and transparency of describing the often-complex processes of improving the adoption of evidence-based interventions in healthcare delivery systems.

Methods: The IRLM structure and guiding principles were developed through a series of preliminary activities with multiple investigators representing diverse implementation research projects in terms of contexts, research designs, and implementation strategies being evaluated. The utility of the IRLM was evaluated in the course of a 2-day training to over 130 implementation researchers and healthcare delivery system partners.

Results: Preliminary work with the IRLM produced a core structure and multiple variations for common implementation research designs and situations, as well as guiding principles and suggestions for use. Results of the survey indicated a high utility of the IRLM for multiple purposes, such as improving rigor and reproducibility of projects; serving as a "roadmap" for how the project is to be carried out; clearly reporting and specifying how the project is to be conducted; and understanding the connections between determinants, strategies, mechanisms, and outcomes for their project.

(Continued on next page)

* Correspondence: jd.smith@hsc.utah.edu; jd.smith@northwestern.edu
[1]Department of Population Health Sciences, University of Utah School of Medicine, Salt Lake City, Utah, USA
[2]Center for Prevention Implementation Methodology for Drug Abuse and HIV, Department of Psychiatry and Behavioral Sciences, Department of Preventive Medicine, Department of Medical Social Sciences, and Department of Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA
Full list of author information is available at the end of the article

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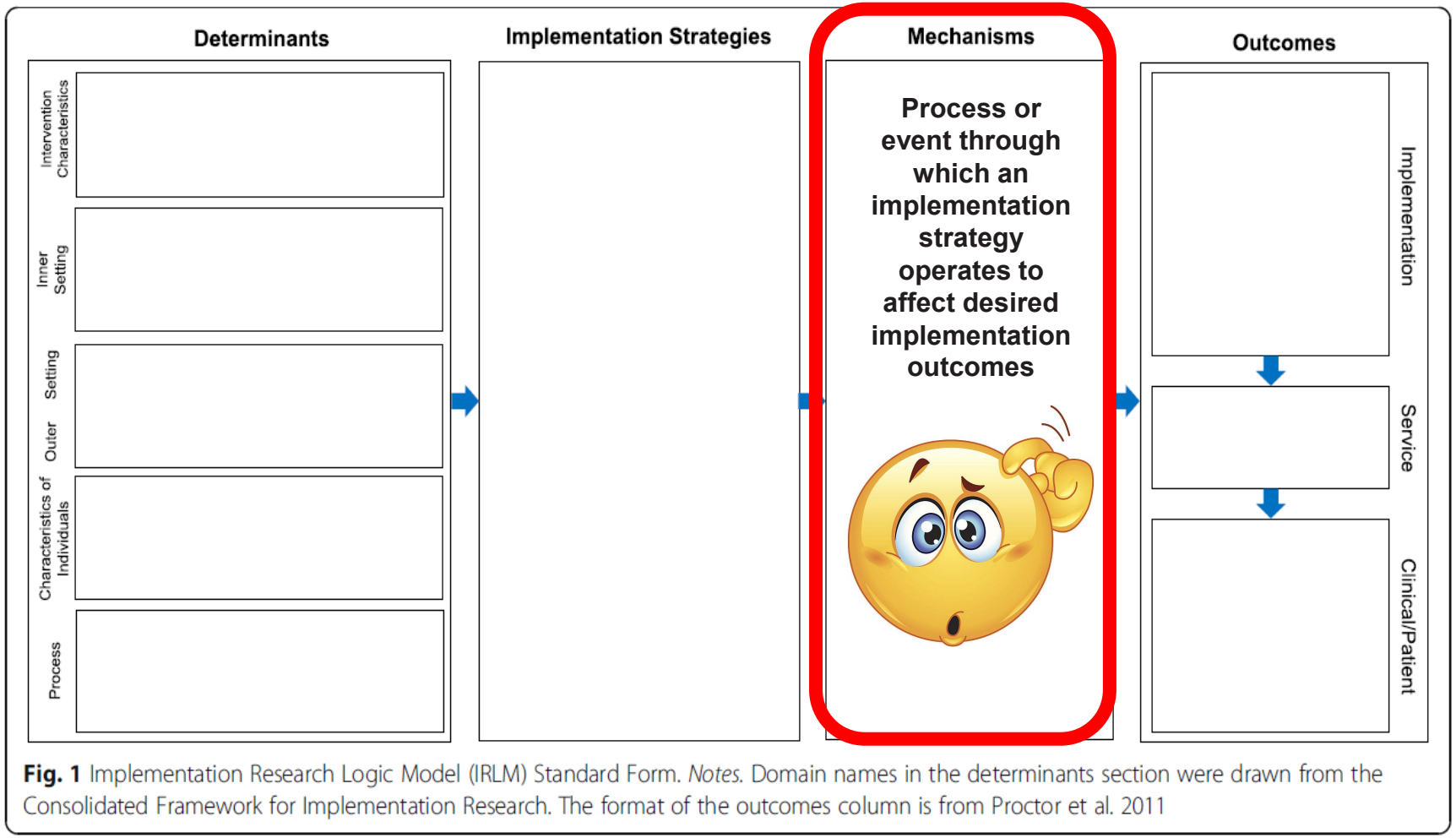
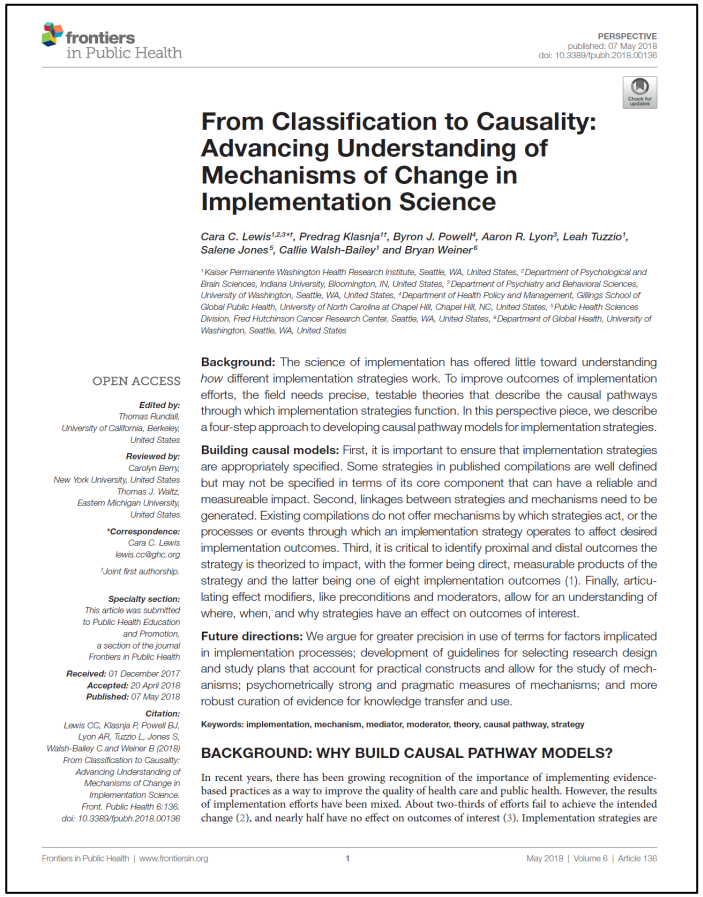


Fig. 1 Implementation Research Logic Model (IRLM) Standard Form. *Notes.* Domain names in the determinants section were drawn from the Consolidated Framework for Implementation Research. The format of the outcomes column is from Proctor et al. 2011

Mechanisms of Change in Implementation Science



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PERSPECTIVE
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From Classification to Causality: Advancing Understanding of Mechanisms of Change in Implementation Science

Cara C. Lewis[1,2,3†], Predrag Klasnja[1†], Byron J. Powell[4], Aaron R. Lyon[3], Leah Tuzzio[1], Salene Jones[5], Callie Walsh-Bailey[1] and Bryan Weiner[6]*

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Background: The science of implementation has offered little toward understanding *how* different implementation strategies work. To improve outcomes of implementation efforts, the field needs precise, testable theories that describe the causal pathways through which implementation strategies function. In this perspective piece, we describe a four-step approach to developing causal pathway models for implementation strategies.

Building causal models: First, it is important to ensure that implementation strategies are appropriately specified. Some strategies in published compilations are well defined but may not be specified in terms of its core component that can have a reliable and measureable impact. Second, linkages between strategies and mechanisms need to be generated. Existing compilations do not offer mechanisms by which strategies act, or the processes or events through which an implementation strategy operates to affect desired implementation outcomes. Third, it is critical to identify proximal and distal outcomes the strategy is theorized to impact, with the former being direct, measurable products of the strategy and the latter being one of eight implementation outcomes (1). Finally, articulating effect modifiers, like preconditions and moderators, allow for an understanding of where, when, and why strategies have an effect on outcomes of interest.

Future directions: We argue for greater precision in use of terms for factors implicated in implementation processes; development of guidelines for selecting research design and study plans that account for practical constructs and allow for the study of mechanisms; psychometrically strong and pragmatic measures of mechanisms; and more robust curation of evidence for knowledge transfer and use.

Keywords: implementation, mechanism, mediator, moderator, theory, causal pathway, strategy

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***Correspondence:**
Cara C. Lewis
lewis.cc@ghc.org

†*Joint first authorship.*

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BACKGROUND: WHY BUILD CAUSAL PATHWAY MODELS?

In recent years, there has been growing recognition of the importance of implementing evidence-based practices as a way to improve the quality of health care and public health. However, the results of implementation efforts have been mixed. About two-thirds of efforts fail to achieve the intended change (2), and nearly half have no effect on outcomes of interest (3). Implementation strategies are

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Step 1: Specify Implementation Strategies

Step 2: Generate Strategy-Mechanism Linkages

Step 3: Identify Proximal and Distal Outcomes

Step 4: Articulate Effect Modifiers

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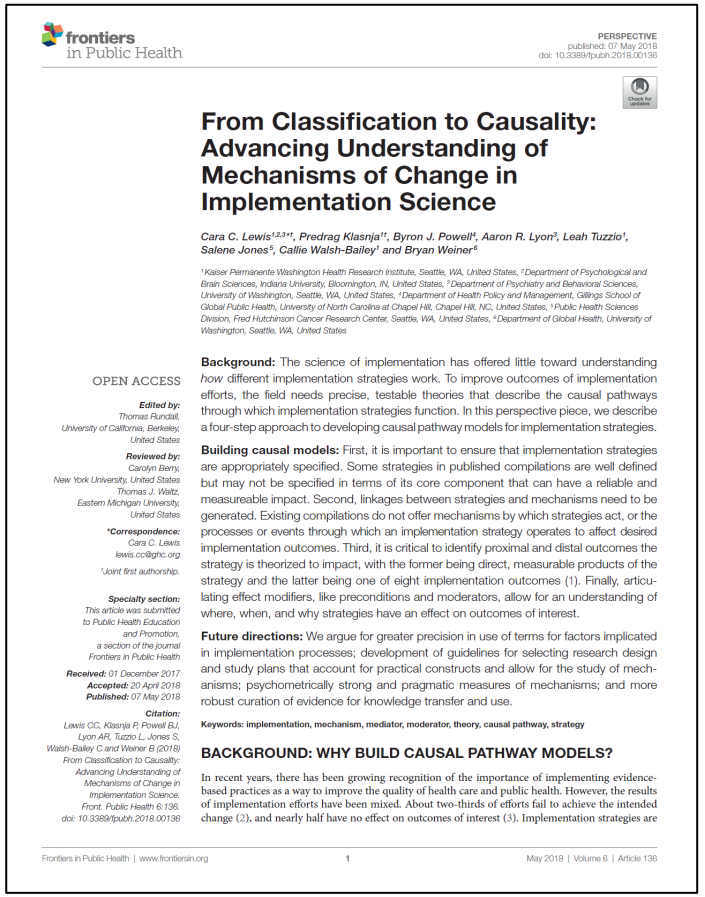

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**Correspondence:*
Cara C. Lewis
lewis.cc@ghc.org

[†]Joint first authorship.

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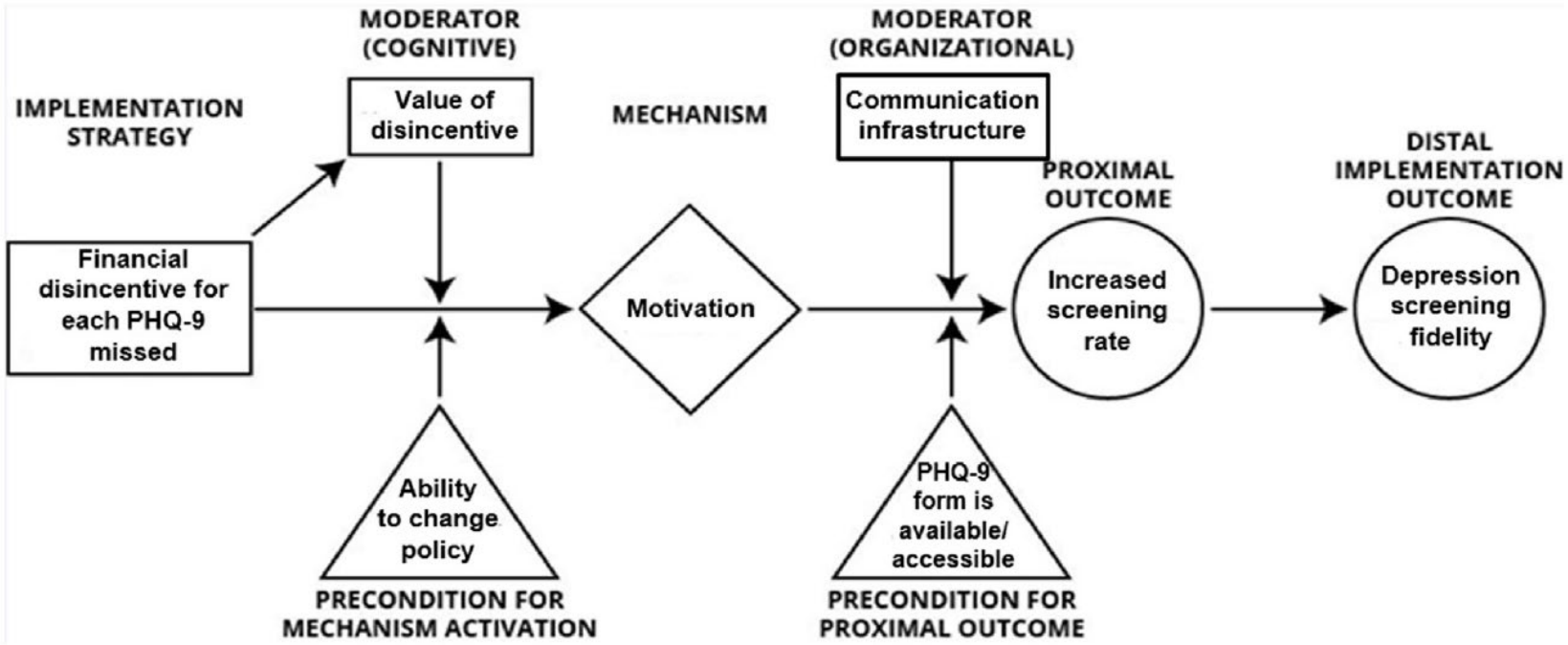

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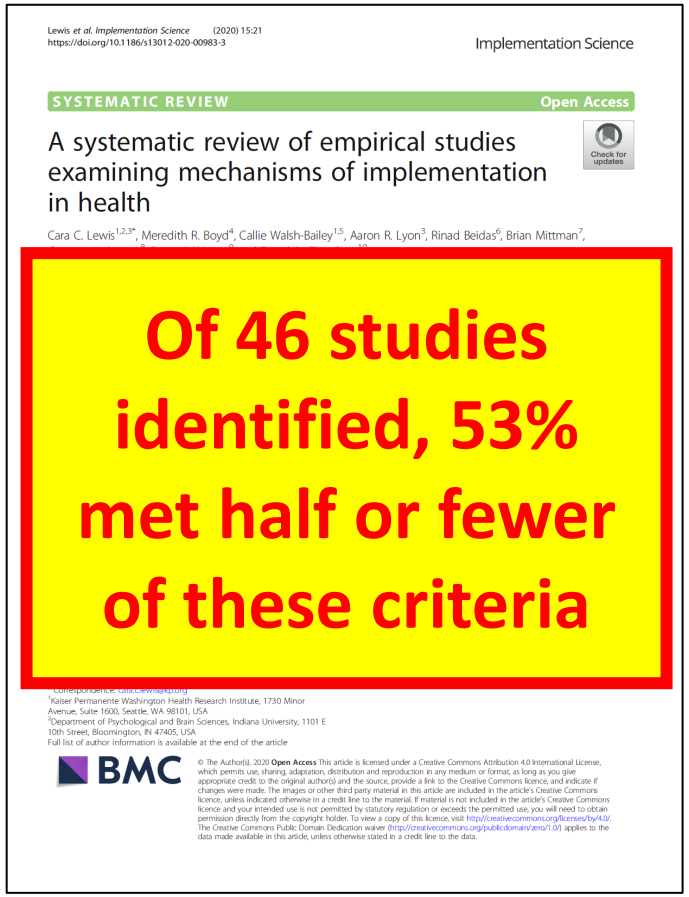

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Implementation Science

SYSTEMATIC REVIEW Open Access

A systematic review of empirical studies examining mechanisms of implementation in health

Cara C. Lewis[1,2,3*], Meredith R. Boyd[4], Callie Walsh-Bailey[1,5], Aaron R. Lyon[3], Rinad Beidas[6], Brian Mittman[7],

Of 46 studies identified, 53% met half or fewer of these criteria

[1]Kaiser Permanente Washington Health Research Institute, 1730 Minor Avenue, Suite 1600, Seattle, WA 98101, USA
[2]Department of Psychological and Brain Sciences, Indiana University, 1101 E 10th Street, Bloomington, IN 47405, USA
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BMC

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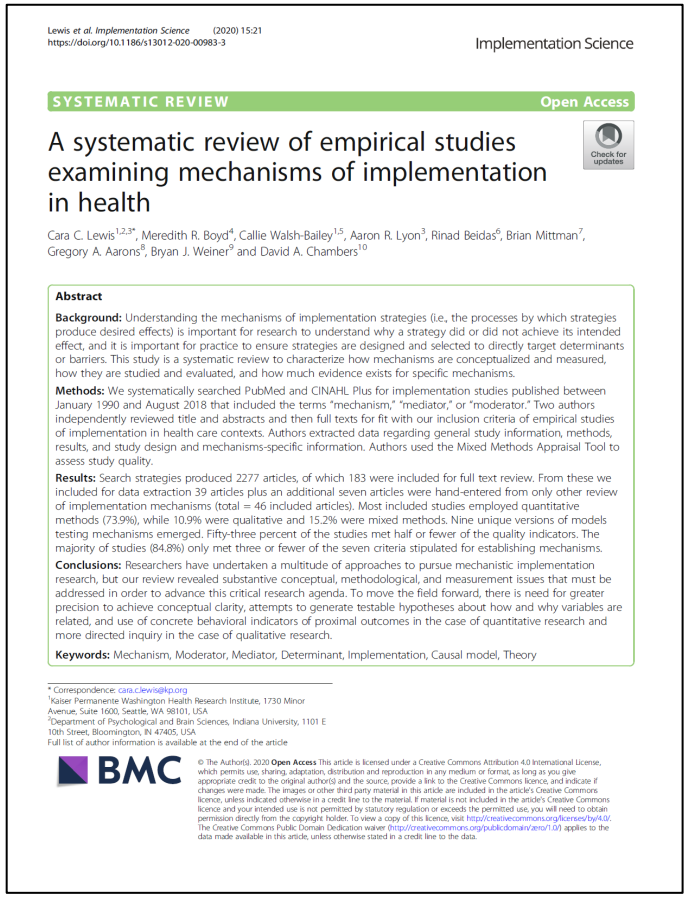
Table 2 Kazdin's criteria for establishing a mechanism

Term	Definition
Strong association	Association between implementation strategy and mechanism AND between mechanism and behavior change.
Specificity	One plausible construct accounts for behavior change.
Consistency	Replication of observed results across studies, samples, and conditions.
Experimental manipulation	Direct manipulation of implementation strategy or proposed mediator or mechanism shows impact on outcomes.
Timeline	Causes and mediators temporally precede effects and outcomes.
Gradient	Dose response relationship between mediator and outcome.
Plausibility or coherence	Explanation invokes other info and steps in a process-outcome relation that are reasonable or supported by other research.

Emergent Mechanism Models (Model 1)



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Abstract

Background: Understanding the mechanisms of implementation strategies (i.e., the processes by which strategies produce desired effects) is important for research to understand why a strategy did or did not achieve its intended effect, and it is important for practice to ensure strategies are designed and selected to directly target determinants or barriers. This study is a systematic review to characterize how mechanisms are conceptualized and measured, how they are studied and evaluated, and how much evidence exists for specific mechanisms.

Methods: We systematically searched PubMed and CINAHL Plus for implementation studies published between January 1990 and August 2018 that included the terms "mechanism," "mediator," or "moderator." Two authors independently reviewed title and abstracts and then full texts for fit with our inclusion criteria of empirical studies of implementation in health care contexts. Authors extracted data regarding general study information, methods, results, and study design and mechanisms-specific information. Authors used the Mixed Methods Appraisal Tool to assess study quality.

Results: Search strategies produced 2277 articles, of which 183 were included for full text review. From these we included for data extraction 39 articles plus an additional seven articles were hand-entered from only other review of implementation mechanisms (total = 46 included articles). Most included studies employed quantitative methods (73.9%), while 10.9% were qualitative and 15.2% were mixed methods. Nine unique versions of models testing mechanisms emerged. Fifty-three percent of the studies met half or fewer of the quality indicators. The majority of studies (84.8%) only met three or fewer of the seven criteria stipulated for establishing mechanisms.

Conclusions: Researchers have undertaken a multitude of approaches to pursue mechanistic implementation research, but our review revealed substantive conceptual, methodological, and measurement issues that must be addressed in order to advance this critical research agenda. To move the field forward, there is need for greater precision to achieve conceptual clarity, attempts to generate testable hypotheses about how and why variables are related, and use of concrete behavioral indicators of proximal outcomes in the case of quantitative research and more directed inquiry in the case of qualitative research.

Keywords: Mechanism, Moderator, Mediator, Determinant, Implementation, Causal model, Theory

* Correspondence: cara.clewis@kp.org
[1]Kaiser Permanente Washington Health Research Institute, 1730 Minor Avenue, Suite 1600, Seattle, WA 98101, USA
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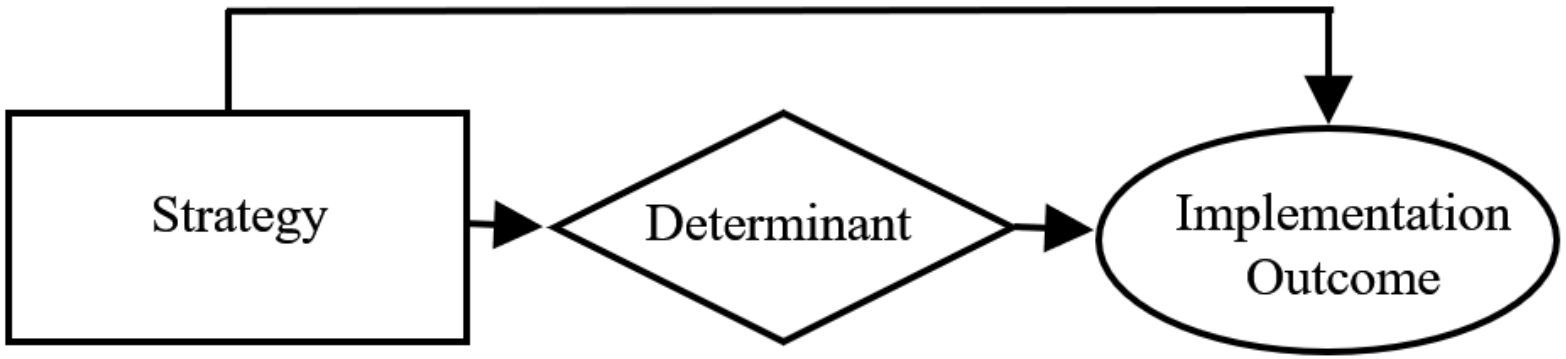

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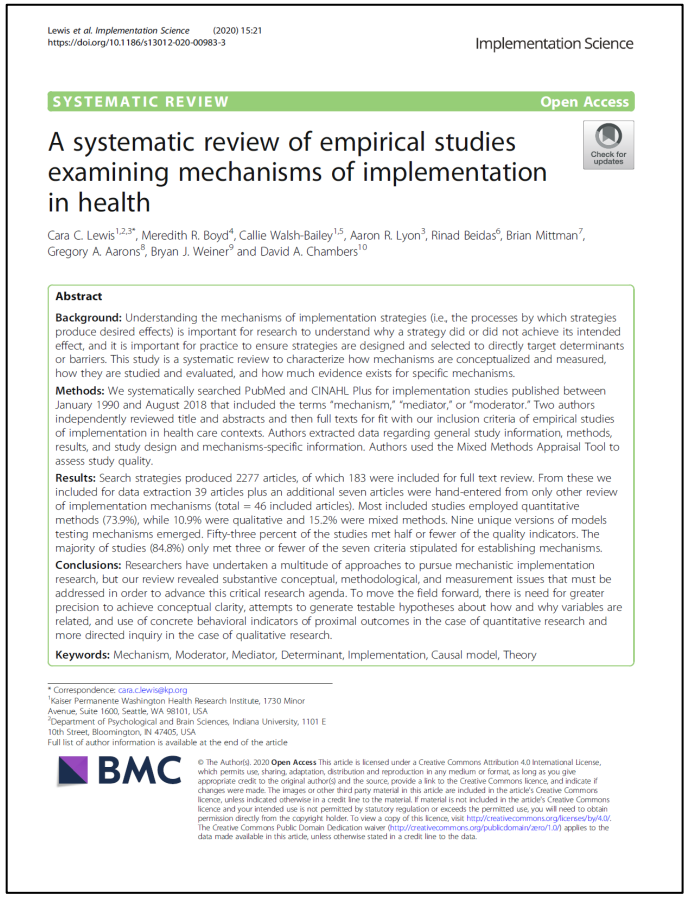
Emergent Mechanism Models (Model 2)



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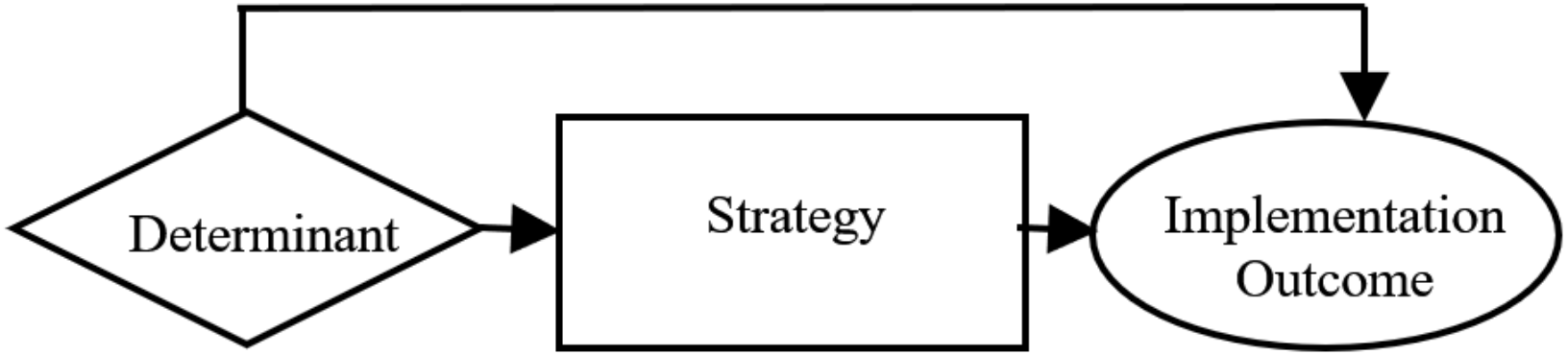

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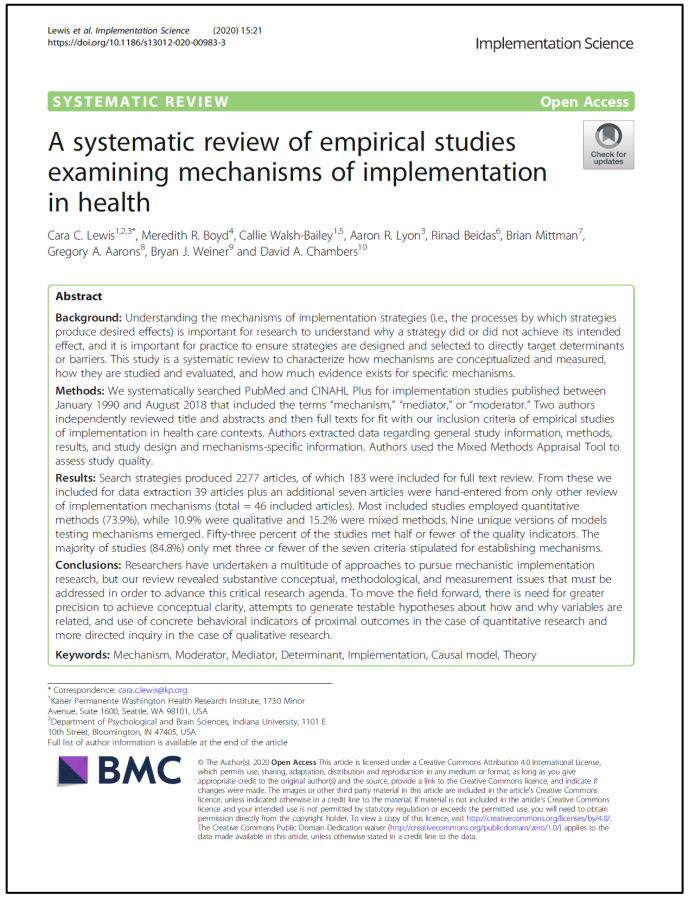
Emergent Mechanism Models (Model 3)



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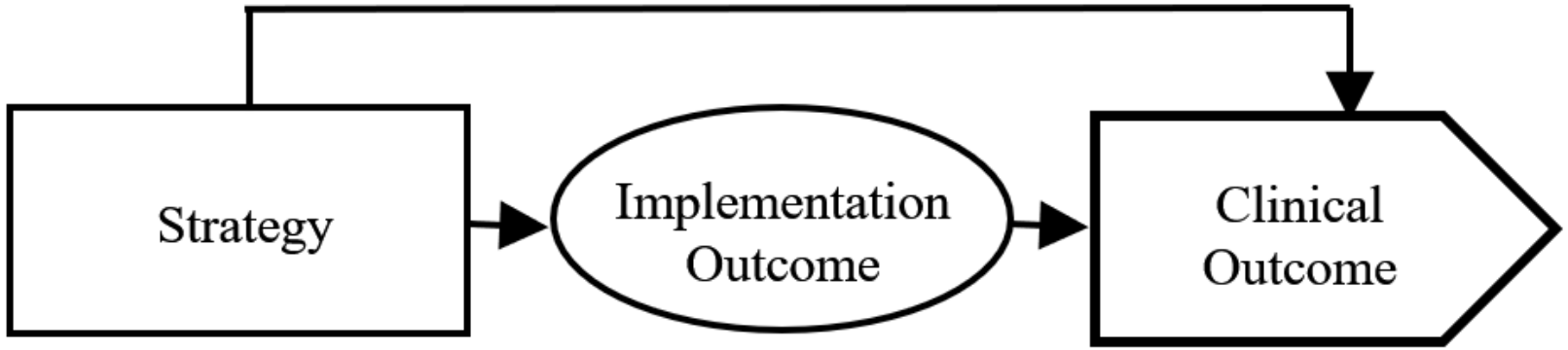

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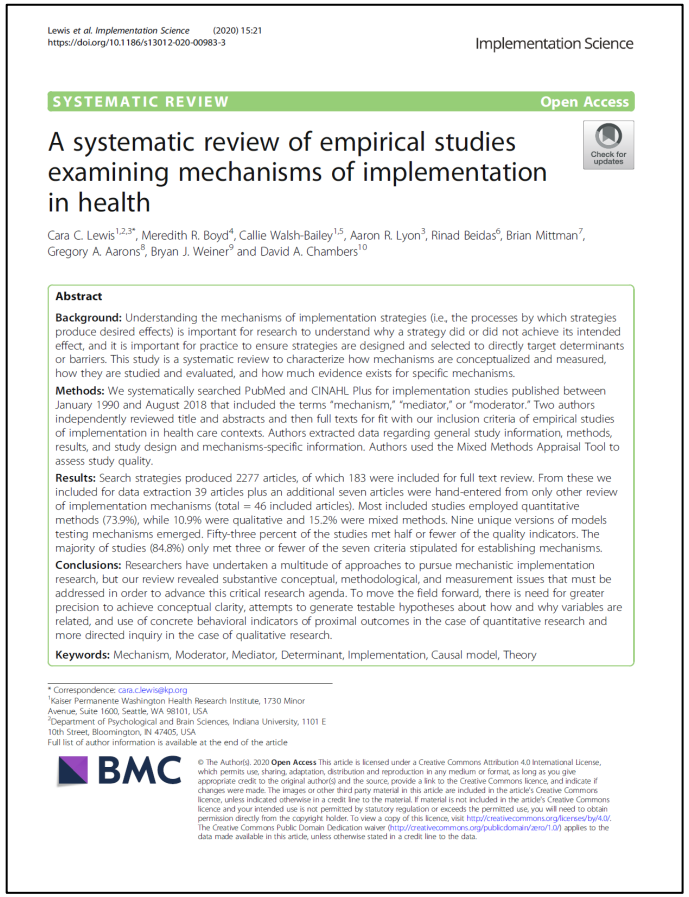
Emergent Mechanism Models (Model 4)



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Implementation Science

SYSTEMATIC REVIEW Open Access

A systematic review of empirical studies examining mechanisms of implementation in health

Cara C. Lewis[1,2,3*], Meredith R. Boyd[4], Callie Walsh-Bailey[1,5], Aaron R. Lyon[3], Rinad Beidas[6], Brian Mittman[7], Gregory A. Aarons[8], Bryan J. Weiner[9] and David A. Chambers[10]

Abstract

Background: Understanding the mechanisms of implementation strategies (i.e., the processes by which strategies produce desired effects) is important for research to understand why a strategy did or did not achieve its intended effect, and it is important for practice to ensure strategies are designed and selected to directly target determinants or barriers. This study is a systematic review to characterize how mechanisms are conceptualized and measured, how they are studied and evaluated, and how much evidence exists for specific mechanisms.

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Results: Search strategies produced 2277 articles, of which 183 were included for full text review. From these we included for data extraction 39 articles plus an additional seven articles were hand-entered from only other review of implementation mechanisms (total = 46 included articles). Most included studies employed quantitative methods (73.9%), while 10.9% were qualitative and 15.2% were mixed methods. Nine unique versions of models testing mechanisms emerged. Fifty-three percent of the studies met half or fewer of the quality indicators. The majority of studies (84.8%) only met three or fewer of the seven criteria stipulated for establishing mechanisms.

Conclusions: Researchers have undertaken a multitude of approaches to pursue mechanistic implementation research, but our review revealed substantive conceptual, methodological, and measurement issues that must be addressed in order to advance this critical research agenda. To move the field forward, there is need for greater precision to achieve conceptual clarity, attempts to generate testable hypotheses about how and why variables are related, and use of concrete behavioral indicators of proximal outcomes in the case of quantitative research and more directed inquiry in the case of qualitative research.

Keywords: Mechanism, Moderator, Mediator, Determinant, Implementation, Causal model, Theory

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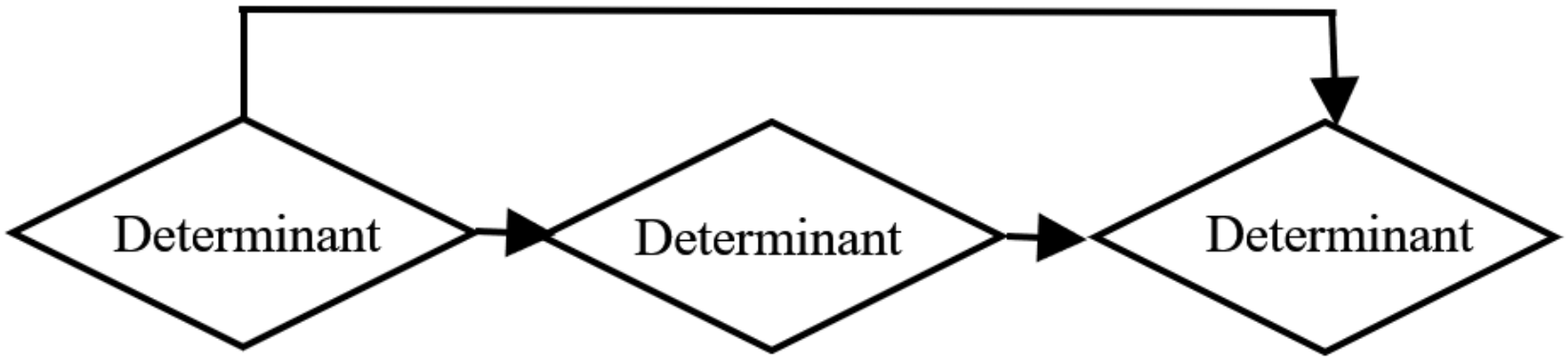

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Emergent Mechanism Models (Model 5)

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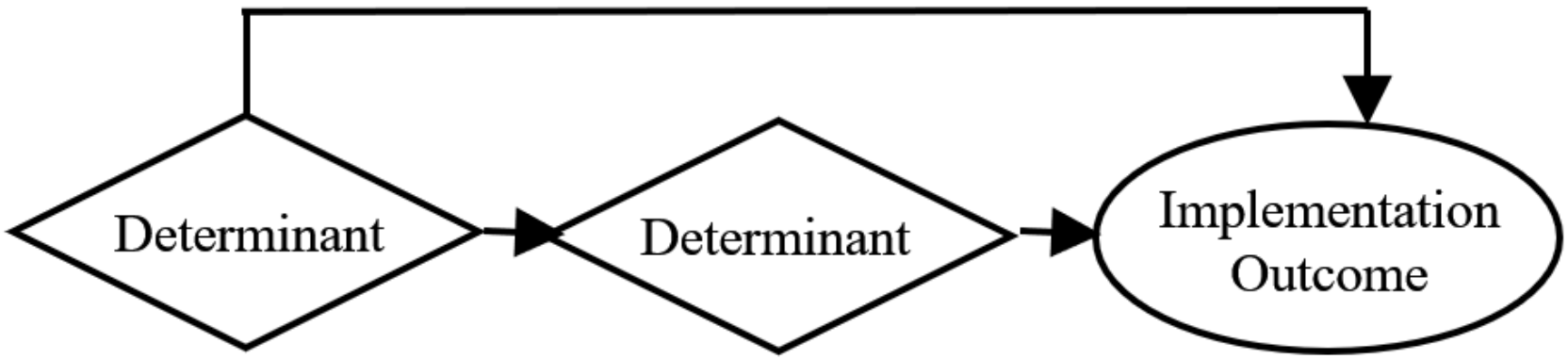

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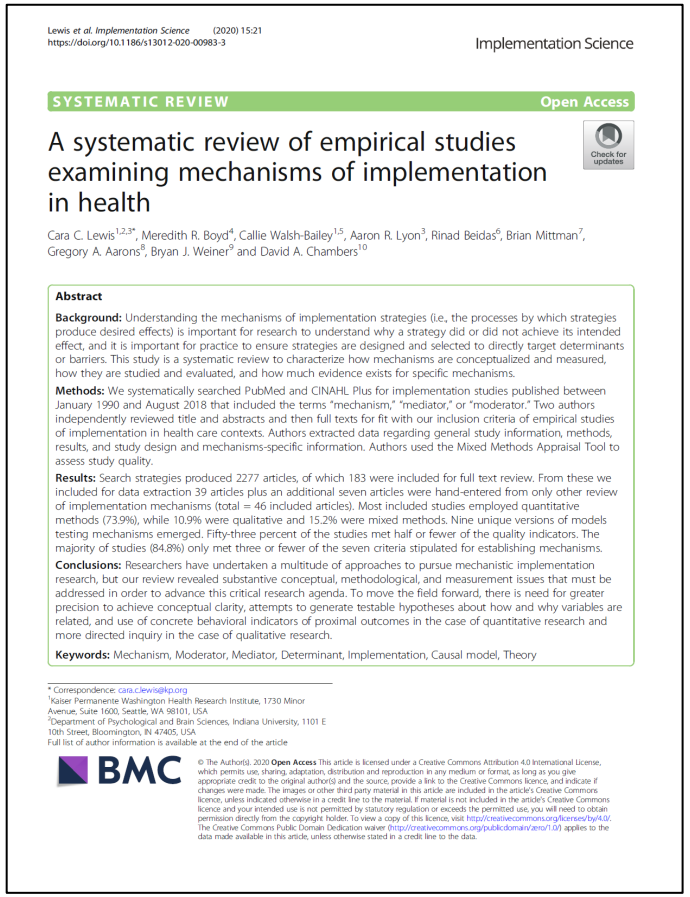
Emergent Mechanism Models (Model 6)



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Implementation Science

SYSTEMATIC REVIEW Open Access

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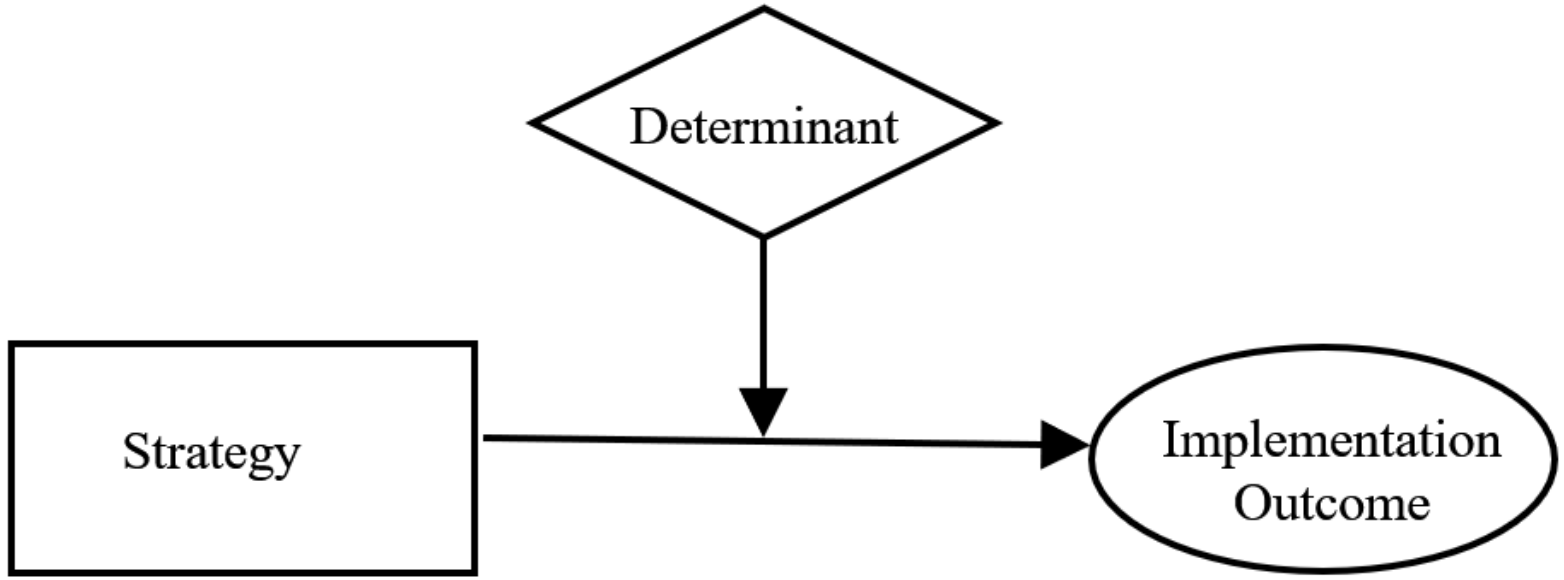

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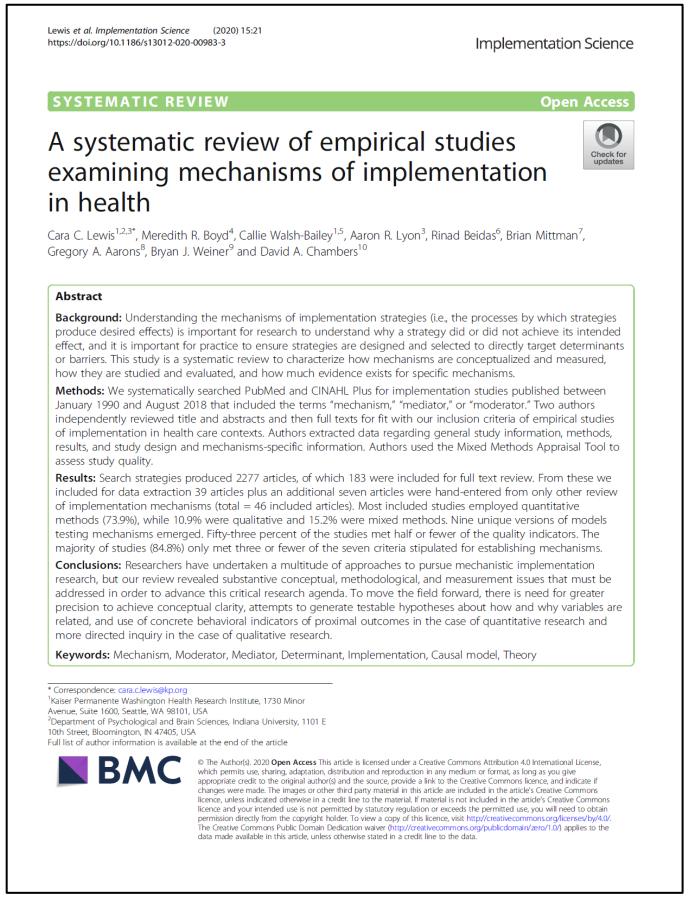
Emergent Mechanism Models (Model 7)



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Implementation Science

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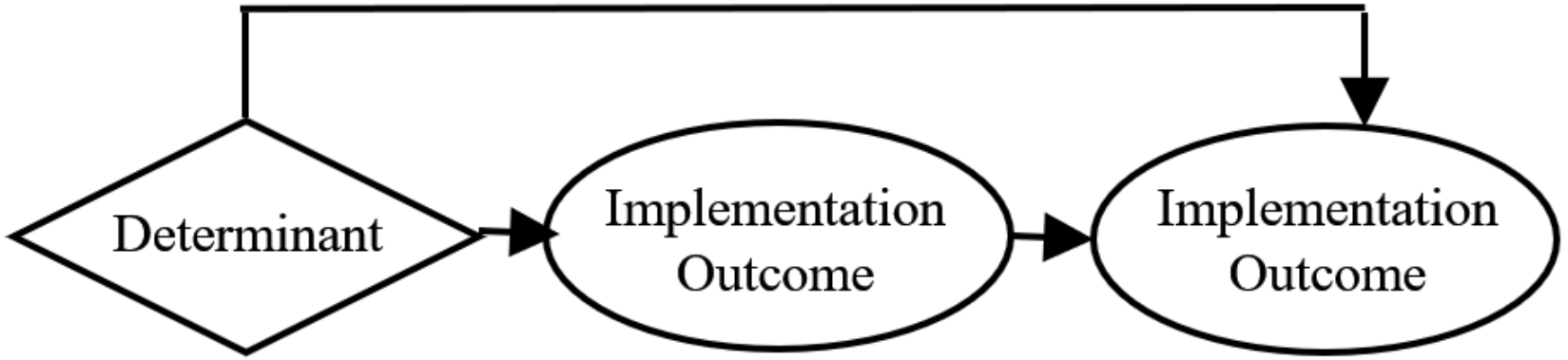

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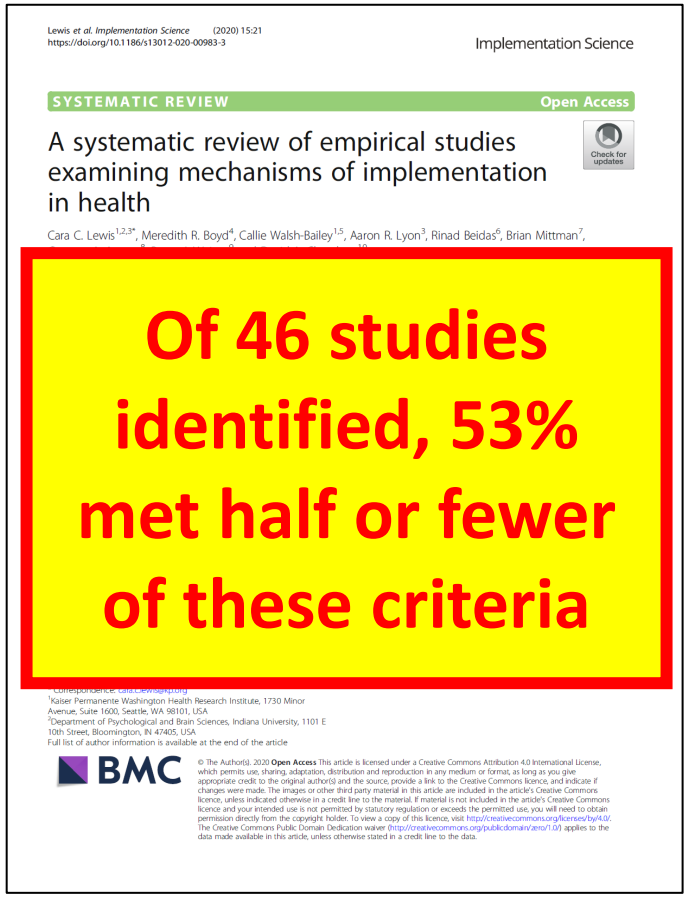
Mechanisms of Change in Implementation Science



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Of 46 studies identified, 53% met half or fewer of these criteria

[1]Kaiser Permanente Washington Health Research Institute, 1730 Minor Avenue, Suite 1600, Seattle, WA 98101, USA
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Table 2 Kazdin's criteria for establishing a mechanism

Term	Definition
Strong association	Association between implementation strategy and mechanism AND between mechanism and behavior change.
Specificity	One plausible construct accounts for behavior change.
Consistency	Replication of observed results across studies, samples, and conditions.
Experimental manipulation	Direct manipulation of implementation strategy or proposed mediator or mechanism shows impact on outcomes.
Timeline	Causes and mediators temporally precede effects and outcomes.
Gradient	Dose response relationship between mediator and outcome.
Plausibility or coherence	Explanation invokes other info and steps in a process-outcome relation that are reasonable or supported by other research.

Effectiveness-Implementation Hybrid ~~Designs~~ Studies

ANNALS OF HSR

Effectiveness-implementation Hybrid Designs

Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

Geoffrey M. Curran, PhD, Mark Bauer, MD,† Brian Mittman, PhD,‡ Jeffrey M. Pyne, MD,* and Cheryl Stetler, PhD,‡*

Objectives: This study proposes methods for blending design components of clinical effectiveness and implementation research. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains, more effective implementation strategies, and more useful information for decision makers. This study proposes a "hybrid effectiveness-implementation" typology, describes a rationale for their use, outlines the design decisions that must be faced, and provides several real-world examples.

Results: An effectiveness-implementation hybrid design is one that takes a dual focus a priori in assessing clinical effectiveness and implementation. We propose 3 hybrid types: (1) testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation; (2) dual testing of clinical and implementation interventions/strategies; and (3) testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

Conclusions: The hybrid typology proposed herein must be considered a construct still in evolution. Although traditional clinical effectiveness and implementation trials are likely to remain the most common approach to moving a clinical intervention through from efficacy research to public health impact, judicious use of the proposed hybrid designs could speed the translation of research findings into routine practice.

Key Words: diffusion of innovation, implementation science, clinical trials, pragmatic designs

(*Med Care* 2012;50: 217–226)

From the *Central Arkansas Veterans Healthcare System, and Department of Psychiatry, University of Arkansas for Medical Sciences, Little Rock, AR; †VA Boston Healthcare System, Harvard Medical School, Boston, MA; and ‡Center for Implementation Practice and Research Support (CIPRS), VA Greater Los Angeles Healthcare System, Los Angeles, CA.

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The authors declare no conflict of interest.

Reprints: Geoffrey M. Curran, PhD, Department of Psychiatry, Division of Health Services Research, University of Arkansas for Medical Sciences, 4301 W. Markham St. #755, Little Rock, AR 72205. E-mail: currangeoffreym@uams.edu.

ISSN: 0025-7079/12/5003-0217

Much has been written about the nature of health care science-to-service gaps both in general[1–3] and relative specifically to health promotion[4] and numerous medical specialties.[5–9] Thus far, the literature indicates that gaps between research and practice can result from multiple factors, including educational/knowledge deficiencies and/or disagreements,[10,11] time constraints for practitioners,[12,13] lack of decision support tools and feedback mechanisms,[13] poorly aligned incentives,[14] and a host of other organizational climate and cultural factors.[2,15,16]

In addition to these provider-level and systems-level barriers to rapid translation, Glasgow et al[4] and others[17–20] argue that the time lag between research discovery and routine uptake is also inflated by the dominant developmental approach; that is, one that encourages delimited, step-wise progressions of research through clinical efficacy research, then clinical effectiveness research, and finally implementation research. In addition, it has been suggested that current conceptions of research designs fail to "maximize clinical utility for practicing clinicians and other decision makers"[18]; for example, through a failure to focus on external validity or implementation-related barriers and facilitators to routine use and sustainability of "effective" practices.[4,21,22]

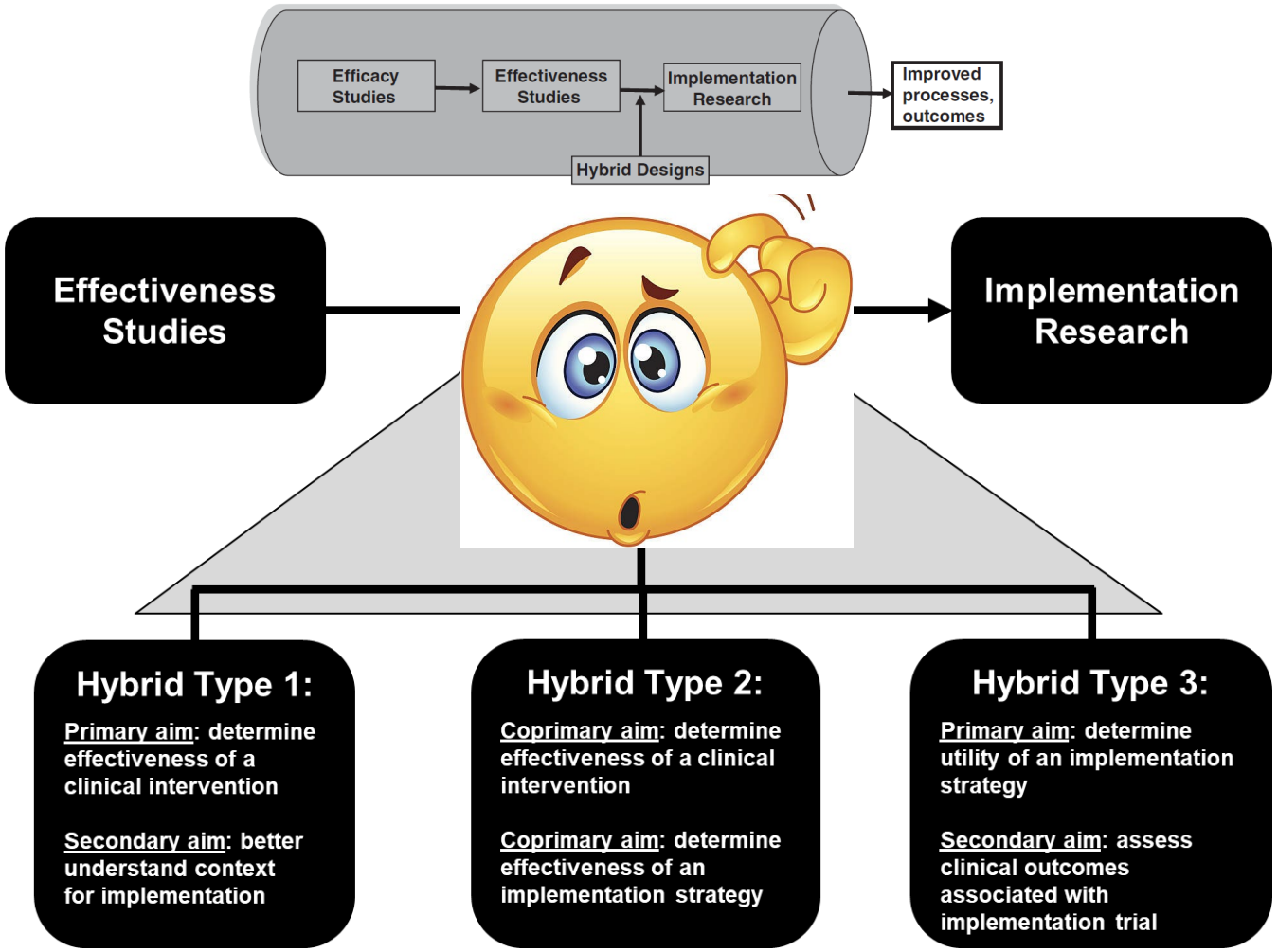
Wells[19] and Glasgow et al[4] suggested that a blending of the efficacy and effectiveness stages of intervention development could improve the speed of knowledge creation and increase the usefulness and policy relevance of clinical research. We propose that a blending of the design components of clinical effectiveness trials and implementation trials also is feasible and desirable. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains in clinical intervention uptake, more effective implementation strategies, and more useful information for researchers and decision makers. This study describes the elements of such "effectiveness-implementation hybrid designs," discusses the indications for such approaches, outlines the design decisions that must be faced in developing such protocols, and provides several examples of funded hybrid studies to illustrate the concepts.

DEFINING TERMINOLOGY

Terminology in this study has been informed by a glossary provided by the Department of Veterans Affairs Quality Enhancement Research Initiative (VA QUERI)[22];

Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*, *50*(3), 217.

FIGURE 1. Research pipeline.



Reflections on 10 years of effectiveness-implementation hybrid ~~designs~~ studies

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Ann Catrine Eldh,
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REVIEWED BY
Lauren Clack,
University of Zurich, Switzerland
Lars Wallin,
Dalarna University, Sweden

*CORRESPONDENCE
Sara J. Landes
sjlandes@uams.edu

†These authors share first authorship

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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]

[1]Department of Pharmacy Practice, University of Arkansas for Medical Sciences, Little Rock, AR, United States, [2]Center for Mental Health Outcomes Research, Central Arkansas Veterans Healthcare System, North Little Rock, AR, United States, [3]Behavioral Health Quality Enhancement Research Initiative (QUERI), Central Arkansas Veterans Healthcare System, Little Rock, AR, United States, [4]Department of Psychiatry, University of Arkansas for Medical Sciences, Little Rock, AR, United States, [5]Department of Population Health Sciences, Spencer Fox Eccles School of Medicine at the University of Utah, Salt Lake City, UT, United States, [6]Center for Health Promotion and Prevention Research, University of Texas, Houston, TX, United States, [7]Division of Cancer Control and Population Sciences, National Cancer Institute, Rockville, MD, United States, [8]Department of Research and Evaluation, Kaiser Permanente Southern California, Los Angeles, CA, United States

This article provides new reflections and recommendations from authors of the initial effectiveness-implementation hybrid study manuscript and additional experts in their conceptualization and application. Given the widespread and continued use of hybrid studies, critical appraisals are necessary. The article offers reflections across five conceptual and methodological areas. It begins with the recommendation to replace the term "design" in favor of "study." The use of the term "design" and the explicit focus on trial methodology in the original paper created confusion. The essence of hybrid studies is combining research questions concerning intervention effectiveness and implementation within the same study, and this can and should be achieved by applying a full range of research designs. Supporting this recommendation, the article then offers guidance on selecting a hybrid study type based on evidentiary and contextual information and stakeholder concerns/preferences. A series of questions are presented that have been designed to help investigators select the most appropriate hybrid type for their study situation. The article also provides a critique on the hybrid 1-2-3 typology and offers reflections on when and how to use the typology moving forward. Further, the article offers recommendations on research designs that align with each hybrid study type. Lastly, the article offers thoughts on how to integrate costs analyses into hybrid studies.

KEYWORDS
implementation science, hybrid studies, research design, cost analysis, health services research, effectiveness-implementation hybrid

Introduction

In 2012, Curran and colleagues (1) proposed hybrid effectiveness-implementation research designs that encouraged combining, in the same study, questions concerning the effectiveness of an intervention with questions about how best to implement it. In addition to the perceived benefit of more rapidly moving toward widespread

Frontiers in Health Services 01 frontiersin.org

Curran, G. M., Landes, S. J., Mcbain, S. A., Pyne, J. M., Smith, J., Fernandez, M. E., ... & Mittman, B. S. (2022) Reflections on 10 Years of Effectiveness-Implementation Hybrid Studies. *Frontiers in Health Services*, 125.

- **The essence of hybrid studies is combining research questions concerning intervention effectiveness and implementation in the same study,**
- **and this can and should be achieved by applying a full range of designs (e.g., experimental, quasi-experimental, observational)**

Effectiveness-Implementation Hybrid ~~Designs~~ Studies

Hybrid Type 1:

Primary aim: determine effectiveness of a clinical intervention

Secondary aim: better understand context for implementation

Hybrid Type 2:

Coprimary aim: determine effectiveness of a clinical intervention

Coprimary aim: determine effectiveness of an implementation strategy

Hybrid Type 3:

Primary aim: determine utility of an implementation strategy

Secondary aim: assess clinical outcomes associated with implementation trial

Types of Research Questions

1. Will the clinical intervention work in this setting and/or with this population?
2. What are the barriers and facilitators to implementation of the clinical intervention?
3. How (if at all) does the implementation context change over time?

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Primary aim: determine utility of an implementation strategy

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Types of Research Questions

1. Which implementation strategy is most effective?
2. Are the patient/client outcomes acceptable?
3. Did the implementation strategy have a direct or indirect impact on the patient/client outcome(s)?

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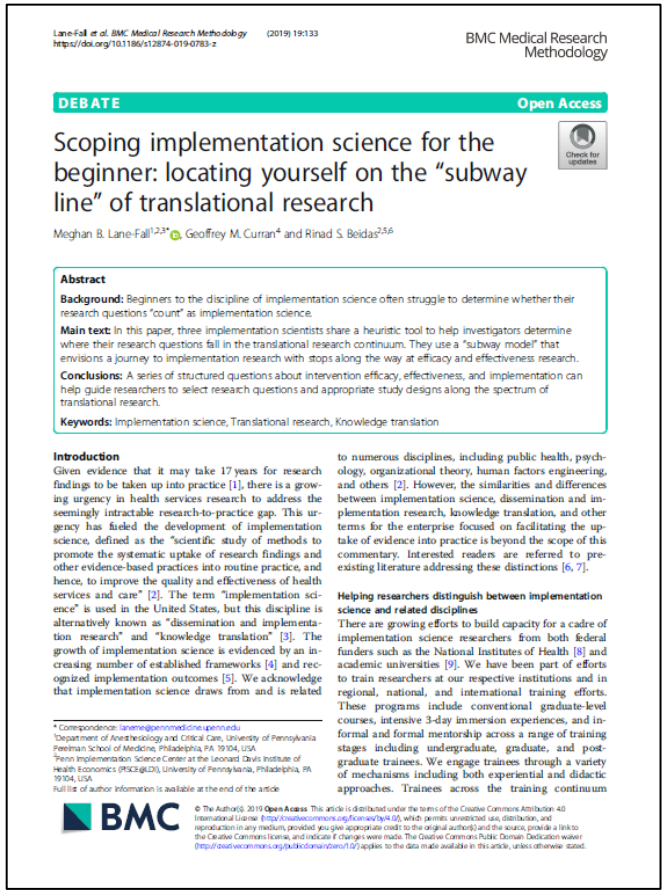
Secondary aim: assess clinical outcomes associated with implementation trial

Types of Research Questions

1. Which implementation strategy is most effective?
2. Are the patient/client outcomes acceptable?
3. How effective is the clinical intervention?
4. What impact does the implementation strategy have on the effectiveness of the clinical intervention?

Locating where your innovation of interest (THE THING) is along the translational research spectrum



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https://doi.org/10.1186/s12874-019-0783-z

BMC Medical Research Methodology

DEBATE Open Access

Scoping implementation science for the beginner: locating yourself on the "subway line" of translational research

Meghan B. Lane-Fall[1,2,3*], Geoffrey M. Curran[4] and Rinad S. Beidas[2,5,6]

Abstract

Background: Beginners to the discipline of implementation science often struggle to determine whether their research questions "count" as implementation science.

Main text: In this paper, three implementation scientists share a heuristic tool to help investigators determine where their research questions fall in the translational research continuum. They use a "subway model" that envisions a journey to implementation research with stops along the way at efficacy and effectiveness research.

Conclusions: A series of structured questions about intervention efficacy, effectiveness, and implementation can help guide researchers to select research questions and appropriate study designs along the spectrum of translational research.

Keywords: Implementation science, Translational research, Knowledge translation

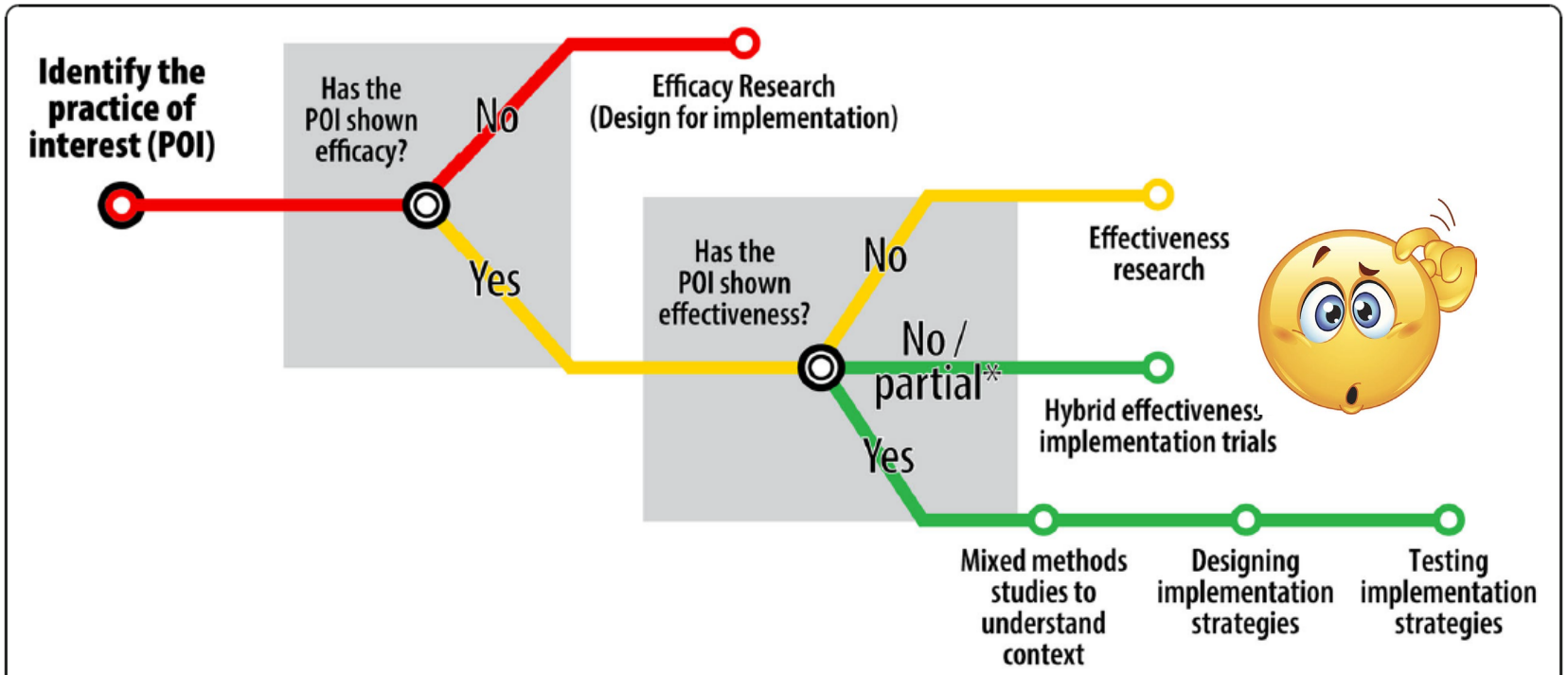
Introduction

Given evidence that it may take 17 years for research findings to be taken up into practice [1], there is a growing urgency in health services research to address the seemingly intractable research-to-practice gap. This urgency has fueled the development of implementation science, defined as 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 and care" [2]. The term "implementation science" is used in the United States, but this discipline is alternatively known as "dissemination and implementation research" and "knowledge translation" [3]. The growth of implementation science is evidenced by an increasing number of established frameworks [4] and recognized implementation outcomes [5]. We acknowledge that implementation science draws from and is related to numerous disciplines, including public health, psychology, organizational theory, human factors engineering, and others [2]. However, the similarities and differences between implementation science, dissemination and implementation research, knowledge translation, and other terms for the enterprise focused on facilitating the uptake of evidence into practice is beyond the scope of this commentary. Interested readers are referred to pre-existing literature addressing these distinctions [6, 7].

Helping researchers distinguish between implementation science and related disciplines

There are growing efforts to build capacity for a cadre of implementation science researchers from both federal funders such as the National Institutes of Health [8] and academic universities [9]. We have been part of efforts to train researchers at our respective institutions and in regional, national, and international training efforts. These programs include conventional graduate-level courses, intensive 3-day immersion experiences, and informal and formal mentorship across a range of training stages including undergraduate, graduate, and post-graduate trainees. We engage trainees through a variety of mechanisms including both experiential and didactic approaches. Trainees across the training continuum

* Correspondence: lanemeg@pennmedicine.upenn.edu
[1]Department of Anesthesiology and Critical Care, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA 19104, USA
[2]Penn Implementation Science Center at the Leonard Davis Institute of Health Economics (PISCE@LDI), University of Pennsylvania, Philadelphia, PA 19104, USA
Full list of author information is available at the end of the article



Graphic has been tested with colorblindness filters to ensure readibility.

* In some cases it may be appropriate to move forward with a hybrid Type 1 trial in the absence of effectiveness evidence (e.g., very strong efficacy, indirect evidence supportive of potential effectiveness in context of interest, and/or strong momentum supporting implementation in a health care context).

Fig. 1 "Subway" schematic to guide researchers contemplating implementation studies of evidence-based interventions

Lane-Fall MB, Curran GM, Beidas RS. Scoping implementation science for the beginner: locating yourself on the "subway line" of translational research. BMC medical research methodology. 2019 Dec;19(1):1-5.

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Linköping University, Sweden

REVIEWED BY
Lauren Clack,
University of Zurich, Switzerland
Lars Wallin,
Dalarna University, Sweden

*CORRESPONDENCE
Sara J. Landes
sjlandes@uams.edu

†These authors share first authorship

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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]

[1]Department of Pharmacy Practice, University of Arkansas for Medical Sciences, Little Rock, AR, United States, [2]Center for Mental Health Outcomes Research, Central Arkansas Veterans Healthcare System, North Little Rock, AR, United States, [3]Behavioral Health Quality Enhancement Research Initiative (QUERI), Central Arkansas Veterans Healthcare System, Little Rock, AR, United States, [4]Department of Psychiatry, University of Arkansas for Medical Sciences, Little Rock, AR, United States, [5]Department of Population Health Sciences, Spencer Fox Eccles School of Medicine at the University of Utah, Salt Lake City, UT, United States, [6]Center for Health Promotion and Prevention Research, University of Texas, Houston, TX, United States, [7]Division of Cancer Control and Population Sciences, National Cancer Institute, Rockville, MD, United States, [8]Department of Research and Evaluation, Kaiser Permanente Southern California, Los Angeles, CA, United States

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KEYWORDS
implementation science, hybrid studies, research design, cost analysis, health services research, effectiveness-implementation hybrid

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1. **What is the nature of the effectiveness data on your intervention of interest?**
2. **How much do you expect the intervention will need to be adapted for where you want to study/use it?**
3. **How much do you already know about implementation determinants for the intervention in your context of interest?**
4. **How ready are you to evaluate a "real world" implementation strategy or package of strategies?**

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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).

   - **Mixed results or missing strong effectiveness data**
     - Consider types 1 or 2

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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 type 3
- **A lot**
  - Consider type 1 or type 2

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3. **How much do you already know about implementation determinants for the intervention in your context of interest?**

- **Not much, and you also need to focus on effectiveness data**
  - Consider a type 1

- **If the effectiveness data are strong, and you know enough already to develop/select a strategy**
  - Consider a type 2 or 3

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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
- **Ready and your effectiveness data are strong**
  - A type 3 is indicated
- **Ready and you need to focus as well on effectiveness of the intervention**
  - A type 2 is indicated

Effectiveness-Implementation Hybrid ~~Designs~~ Studies

ANNALS OF HSR

Effectiveness-implementation Hybrid Designs

Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

Geoffrey M. Curran, PhD, Mark Bauer, MD,† Brian Mittman, PhD,‡ Jeffrey M. Pyne, MD,* and Cheryl Stetler, PhD,‡*

Objectives: This study proposes methods for blending design components of clinical effectiveness and implementation research. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains, more effective implementation strategies, and more useful information for decision makers. This study proposes a "hybrid effectiveness-implementation" typology, describes a rationale for their use, outlines the design decisions that must be faced, and provides several real-world examples.

Results: An effectiveness-implementation hybrid design is one that takes a dual focus a priori in assessing clinical effectiveness and implementation. We propose 3 hybrid types: (1) testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation; (2) dual testing of clinical and implementation interventions/strategies; and (3) testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

Conclusions: The hybrid typology proposed herein must be considered a construct still in evolution. Although traditional clinical effectiveness and implementation trials are likely to remain the most common approach to moving a clinical intervention through from efficacy research to public health impact, judicious use of the proposed hybrid designs could speed the translation of research findings into routine practice.

Key Words: diffusion of innovation, implementation science, clinical trials, pragmatic designs

(*Med Care* 2012;50: 217–226)

From the *Central Arkansas Veterans Healthcare System, and Department of Psychiatry, University of Arkansas for Medical Sciences, Little Rock, AR; †VA Boston Healthcare System, Harvard Medical School, Boston, MA; and ‡Center for Implementation Practice and Research Support (CIPRS), VA Greater Los Angeles Healthcare System, Los Angeles, CA.

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Reprints: Geoffrey M. Curran, PhD, Department of Psychiatry, Division of Health Services Research, University of Arkansas for Medical Sciences, 4301 W. Markham St. #755, Little Rock, AR 72205. E-mail: currangeoffreym@uams.edu.

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Much has been written about the nature of health care science-to-service gaps both in general[1–3] and relative specifically to health promotion[4] and numerous medical specialties.[5–9] Thus far, the literature indicates that gaps between research and practice can result from multiple factors, including educational/knowledge deficiencies and/or disagreements,[10,11] time constraints for practitioners,[12,13] lack of decision support tools and feedback mechanisms,[13] poorly aligned incentives,[14] and a host of other organizational climate and cultural factors.[2,15,16]

In addition to these provider-level and systems-level barriers to rapid translation, Glasgow et al[4] and others[17–20] argue that the time lag between research discovery and routine uptake is also inflated by the dominant developmental approach; that is, one that encourages delimited, step-wise progressions of research through clinical efficacy research, then clinical effectiveness research, and finally implementation research. In addition, it has been suggested that current conceptions of research designs fail to "maximize clinical utility for practicing clinicians and other decision makers"[18]; for example, through a failure to focus on external validity or implementation-related barriers and facilitators to routine use and sustainability of "effective" practices.[4,21,22]

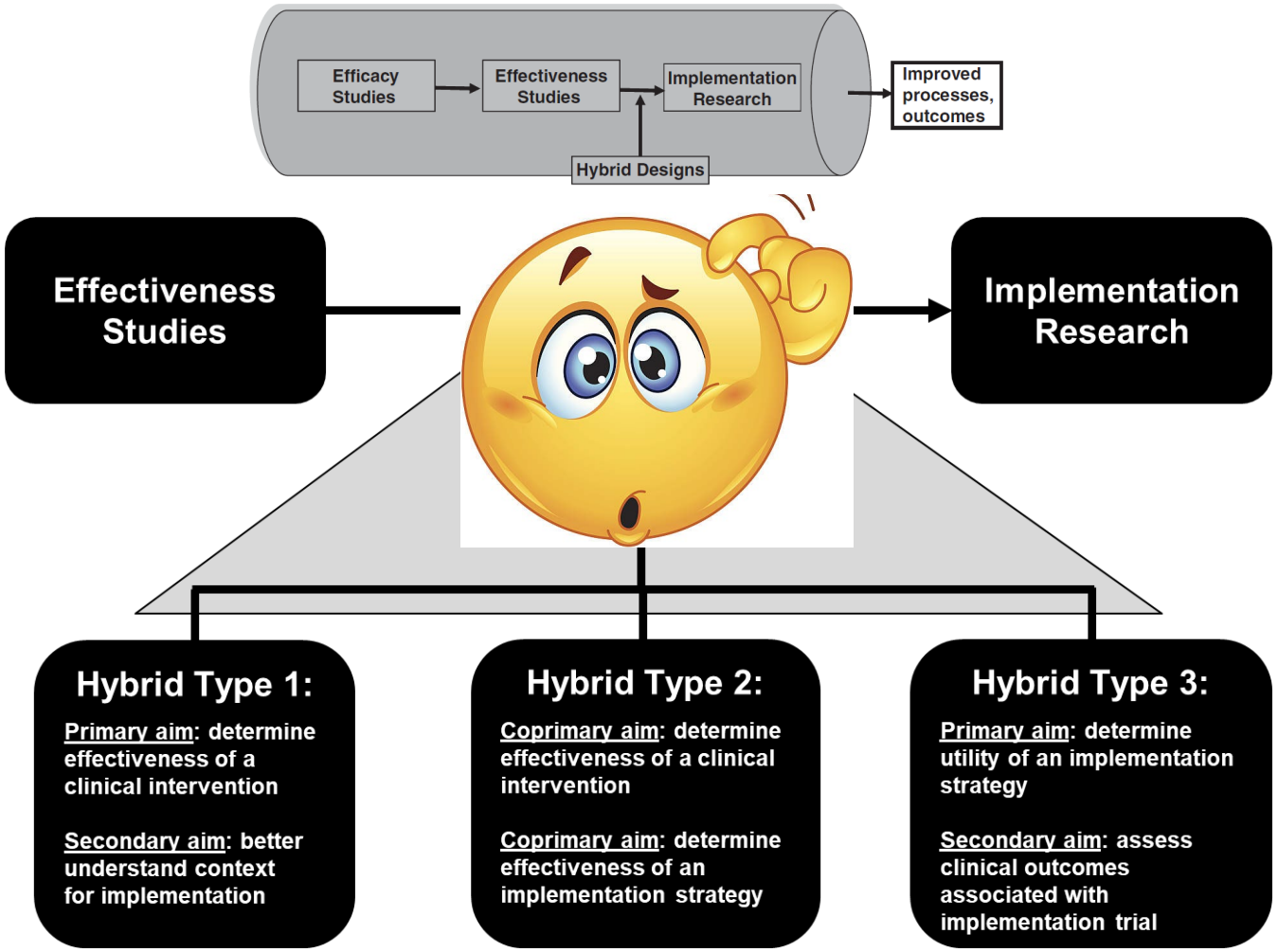
Wells[19] and Glasgow et al[4] suggested that a blending of the efficacy and effectiveness stages of intervention development could improve the speed of knowledge creation and increase the usefulness and policy relevance of clinical research. We propose that a blending of the design components of clinical effectiveness trials and implementation trials also is feasible and desirable. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains in clinical intervention uptake, more effective implementation strategies, and more useful information for researchers and decision makers. This study describes the elements of such "effectiveness-implementation hybrid designs," discusses the indications for such approaches, outlines the design decisions that must be faced in developing such protocols, and provides several examples of funded hybrid studies to illustrate the concepts.

DEFINING TERMINOLOGY

Terminology in this study has been informed by a glossary provided by the Department of Veterans Affairs Quality Enhancement Research Initiative (VA QUERI)[22];

Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*, *50*(3), 217.

FIGURE 1. Research pipeline.



Effectiveness-Implementation Hybrid ~~Designs~~ Studies

ANNALS OF HSR

Effectiveness-implementation Hybrid Designs

Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

Geoffrey M. Curran, PhD, Mark Bauer, MD,† Brian Mittman, PhD,‡ Jeffrey M. Pyne, MD,* and Cheryl Stetler, PhD,‡*

Objectives: This study proposes methods for blending design components of clinical effectiveness and implementation research. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains, more effective implementation strategies, and more useful information for decision makers. This study proposes a "hybrid effectiveness-implementation" typology, describes a rationale for their use, outlines the design decisions that must be faced, and provides several real-world examples.

Results: An effectiveness-implementation hybrid design is one that takes a dual focus a priori in assessing clinical effectiveness and implementation. We propose 3 hybrid types: (1) testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation; (2) dual testing of clinical and implementation interventions/strategies; and (3) testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

Conclusions: The hybrid typology proposed herein must be considered a construct still in evolution. Although traditional clinical effectiveness and implementation trials are likely to remain the most common approach to moving a clinical intervention through from efficacy research to public health impact, judicious use of the proposed hybrid designs could speed the translation of research findings into routine practice.

Key Words: diffusion of innovation, implementation science, clinical trials, pragmatic designs

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From the *Central Arkansas Veterans Healthcare System, and Department of Psychiatry, University of Arkansas for Medical Sciences, Little Rock, AR; †VA Boston Healthcare System, Harvard Medical School, Boston, MA; and ‡Center for Implementation Practice and Research Support (CIPRS), VA Greater Los Angeles Healthcare System, Los Angeles, CA.

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Reprints: Geoffrey M. Curran, PhD, Department of Psychiatry, Division of Health Services Research, University of Arkansas for Medical Sciences, 4301 W. Markham St. #755, Little Rock, AR 72205. E-mail: currangeoffreym@uams.edu.

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Much has been written about the nature of health care science-to-service gaps both in general[1–3] and relative specifically to health promotion[4] and numerous medical specialties.[5–9] Thus far, the literature indicates that gaps between research and practice can result from multiple factors, including educational/knowledge deficiencies and/or disagreements,[10,11] time constraints for practitioners,[12,13] lack of decision support tools and feedback mechanisms,[13] poorly aligned incentives,[14] and a host of other organizational climate and cultural factors.[2,15,16]

In addition to these provider-level and systems-level barriers to rapid translation, Glasgow et al[4] and others[17–20] argue that the time lag between research discovery and routine uptake is also inflated by the dominant developmental approach; that is, one that encourages delimited, step-wise progressions of research through clinical efficacy research, then clinical effectiveness research, and finally implementation research. In addition, it has been suggested that current conceptions of research designs fail to "maximize clinical utility for practicing clinicians and other decision makers"[18]; for example, through a failure to focus on external validity or implementation-related barriers and facilitators to routine use and sustainability of "effective" practices.[4,21,22]

Wells[19] and Glasgow et al[4] suggested that a blending of the efficacy and effectiveness stages of intervention development could improve the speed of knowledge creation and increase the usefulness and policy relevance of clinical research. We propose that a blending of the design components of clinical effectiveness trials and implementation trials also is feasible and desirable. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains in clinical intervention uptake, more effective implementation strategies, and more useful information for researchers and decision makers. This study describes the elements of such "effectiveness-implementation hybrid designs," discusses the indications for such approaches, outlines the design decisions that must be faced in developing such protocols, and provides several examples of funded hybrid studies to illustrate the concepts.

DEFINING TERMINOLOGY

Terminology in this study has been informed by a glossary provided by the Department of Veterans Affairs Quality Enhancement Research Initiative (VA QUERI)[22];

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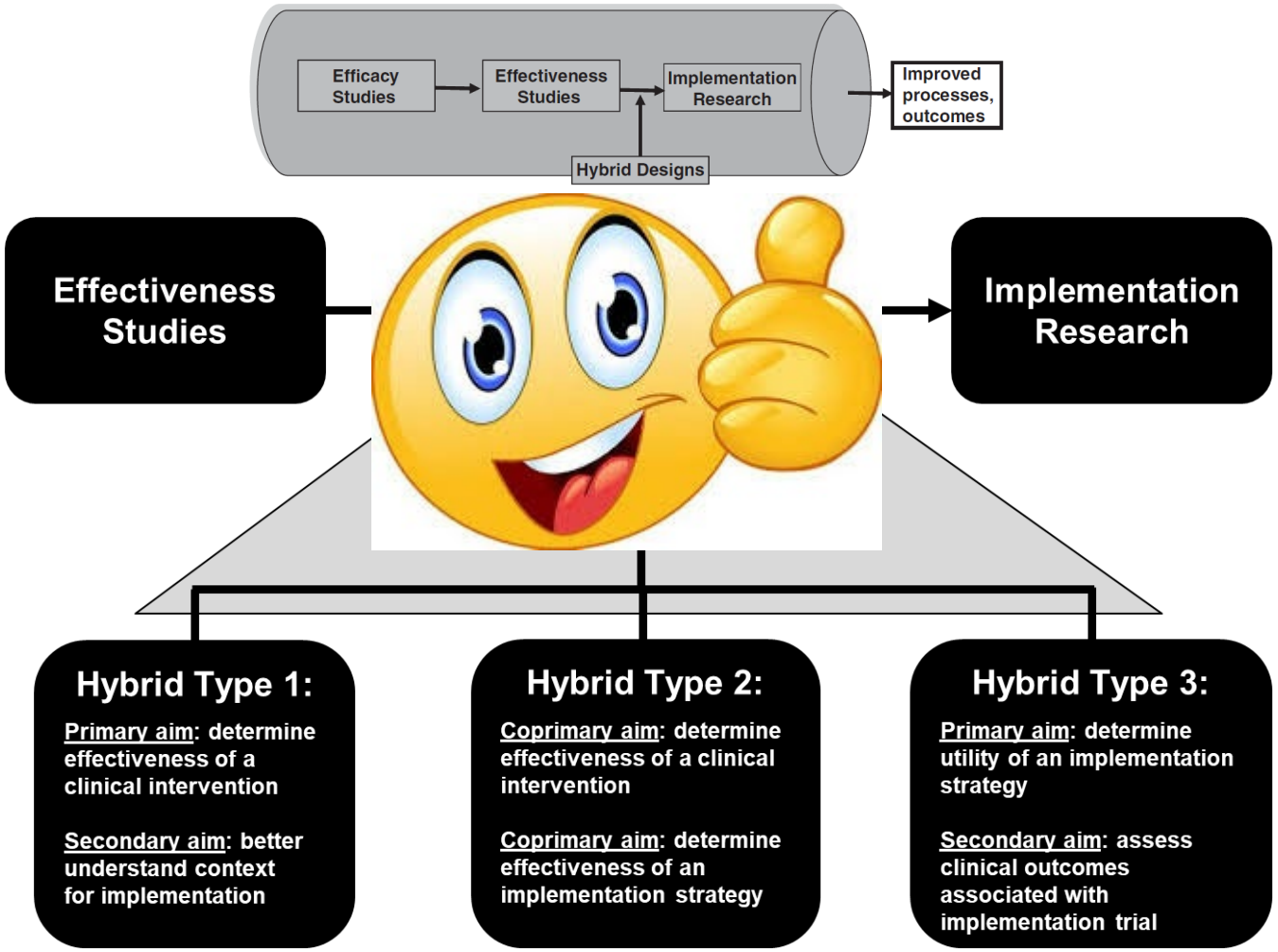

A methods primer on hybrid effectiveness-implementation studies

Bryan R. Garner, PhD
Professor and Director of Dissemination & Implementation Science
The Ohio State University (OSU) College of Medicine (COM) and
Center for the Advancement of Team Science,
Analytics, and Systems Thinking in Health Services and
Implementation Science Research (CATALYST)

THE OHIO STATE UNIVERSITY

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