

Hybrid Designs Webinar

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Reprint of: An introduction to effectiveness-implementation hybrid designs[☆]

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Terminology

Terms	Definitions
Implementation science	is commonly defined as the study of methods and strategies to promote the uptake and integration of interventions that have proven effective into routine practice or policy, with the aim of improving health.
Implementation strategies	Methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice
Implementation outcomes	The effects of deliberate and purposive actions to <i>implement</i> new treatments, practices, and services.
Implementation trial	Tests the effects of implementation strategies on implementation outcomes



How do implementation trials differ from conventional clinical trials?

CONVENTIONAL CLINICAL TRIALS

Efficacy of the intervention is not known

Assesses impact of intervention e.g.,

- A therapy, surgical procedure, medication, public health program

Outcomes e.g.,

- Patient measures
- Disease measures
- etc

IMPLEMENTATION TRIALS

Efficacy of the intervention is known

Effectiveness of implementation strategy is not known

Assesses impact of implementation strategies e.g

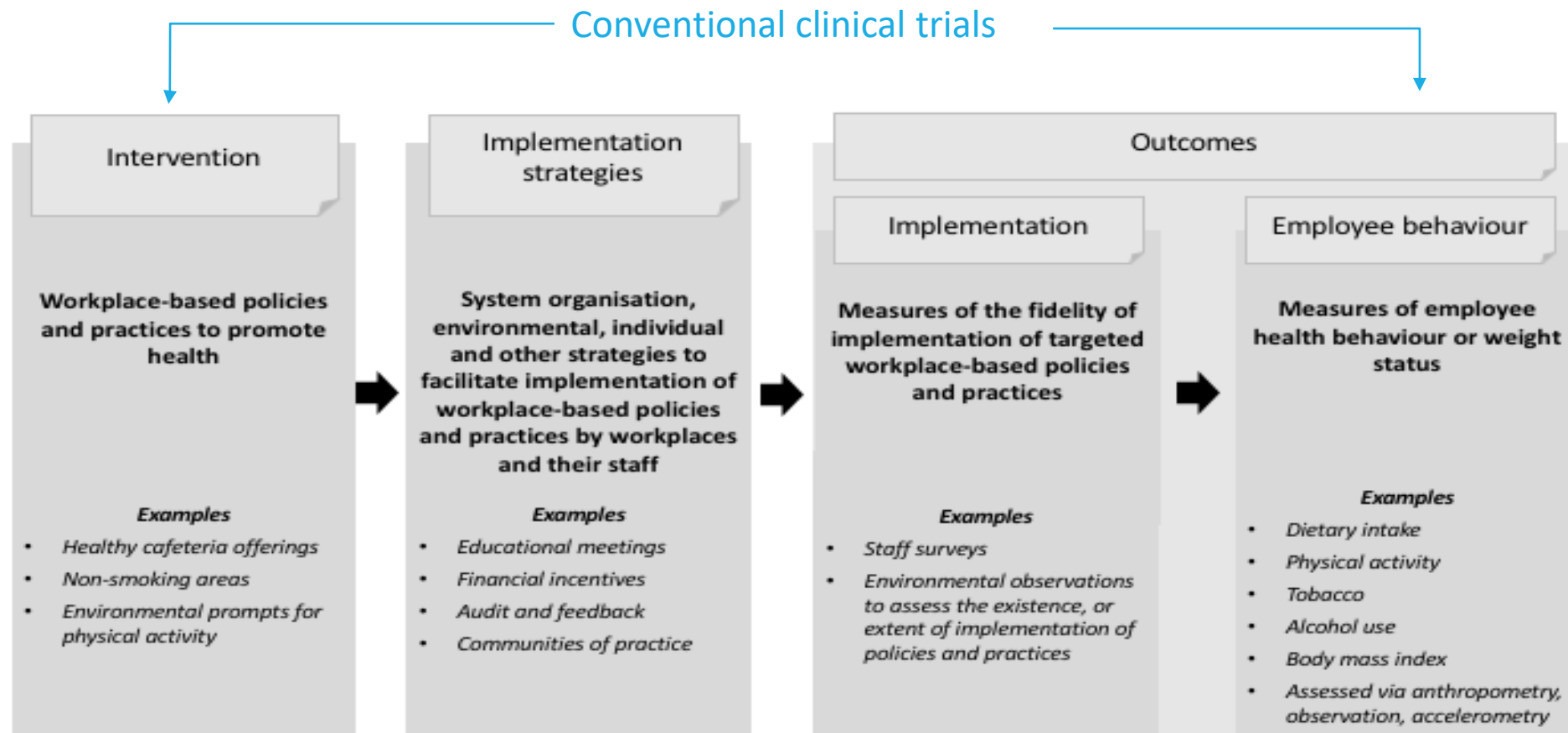
- audit and feedback, training, reminders

Outcomes e.g.,

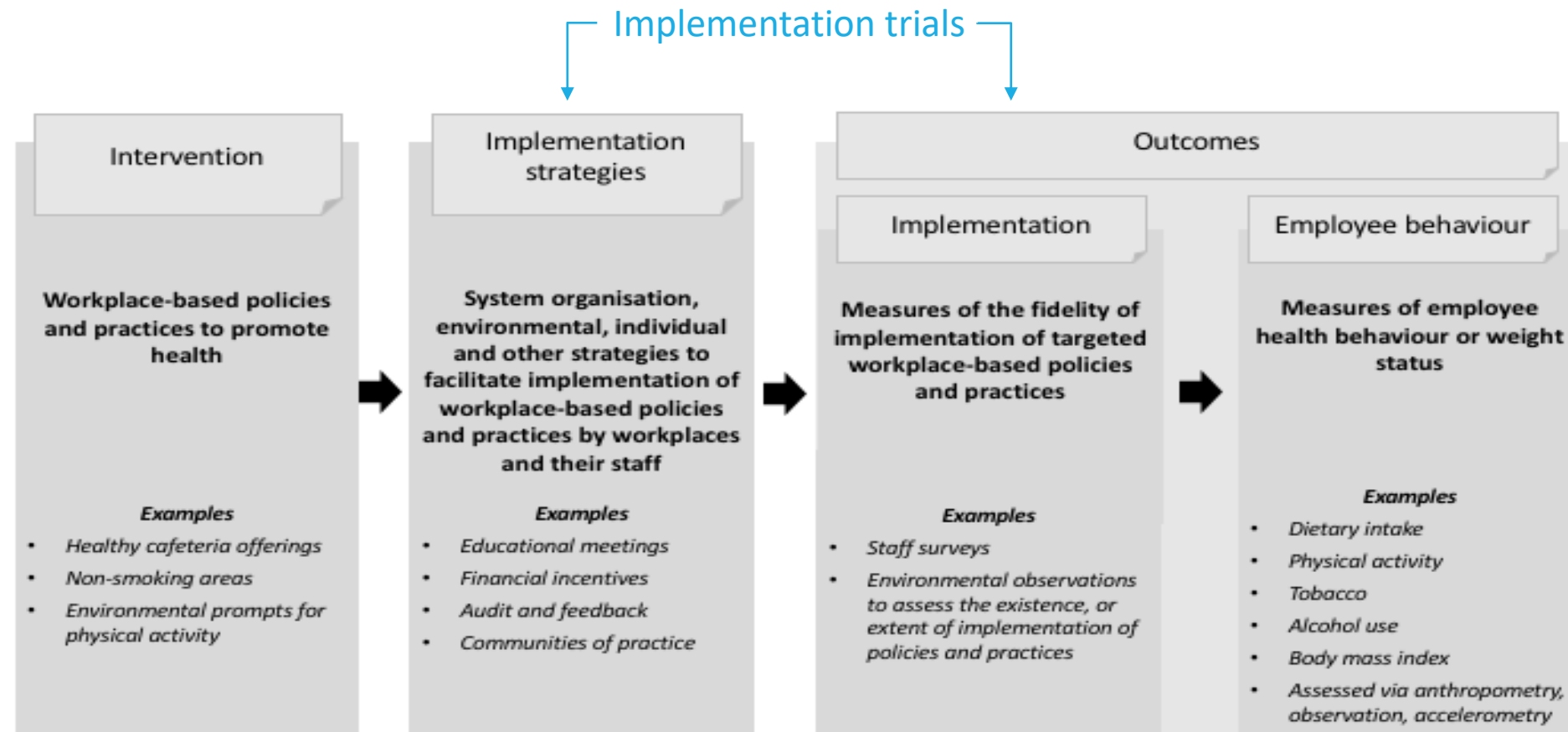
- Quality of health care
- Use of clinical practice guidelines
- etc



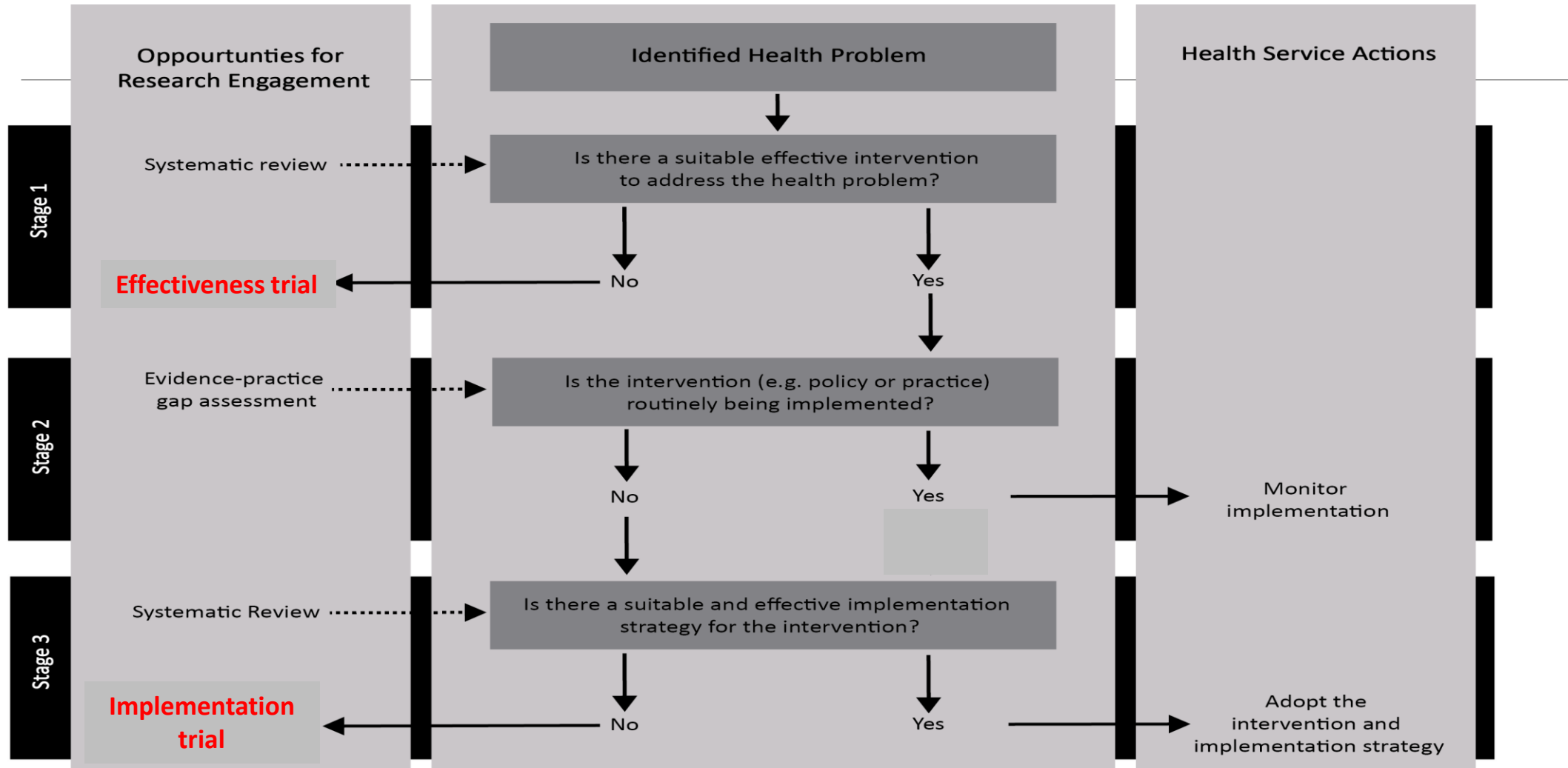
How do implementation trials differ from conventional clinical trials?



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When is an implementation trial warranted?

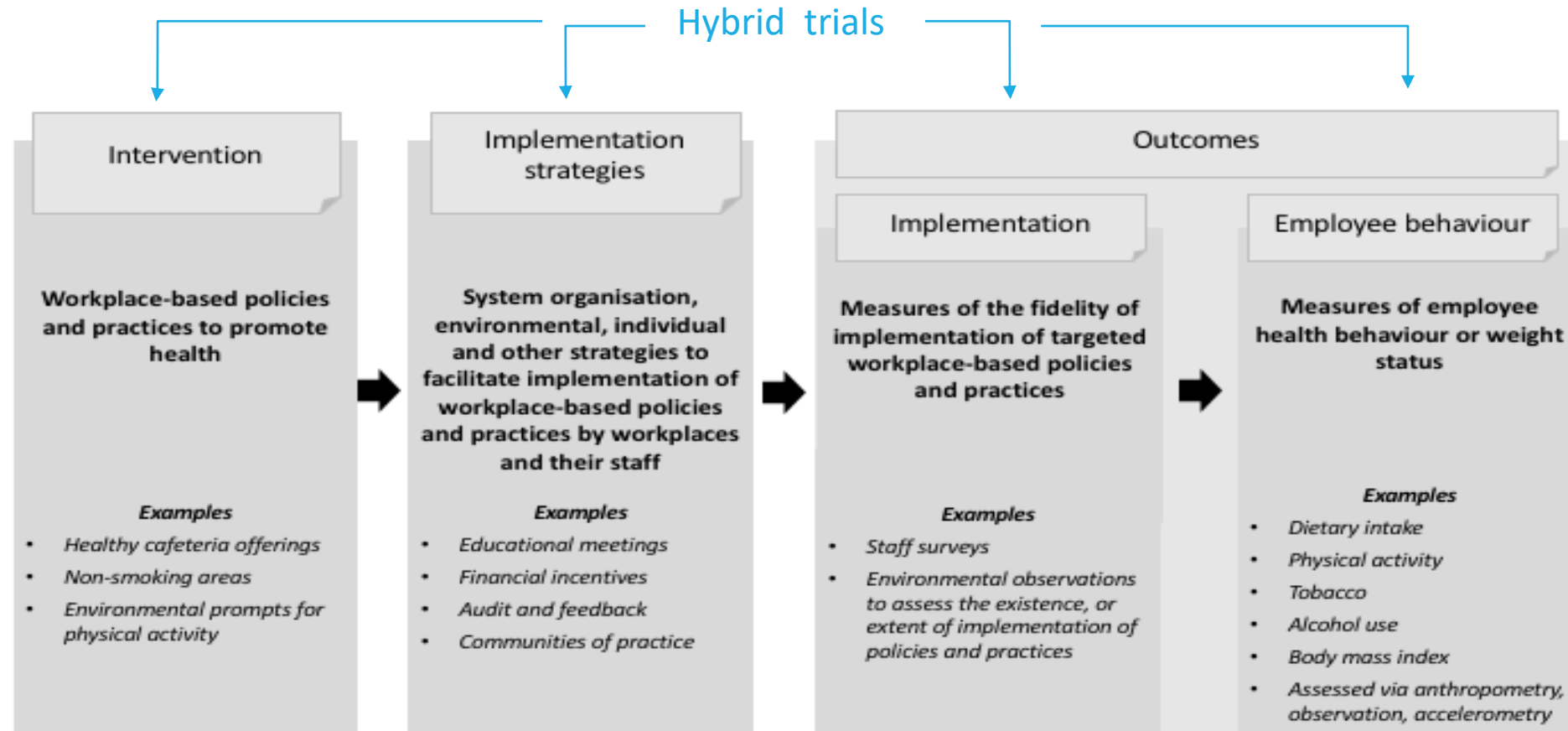


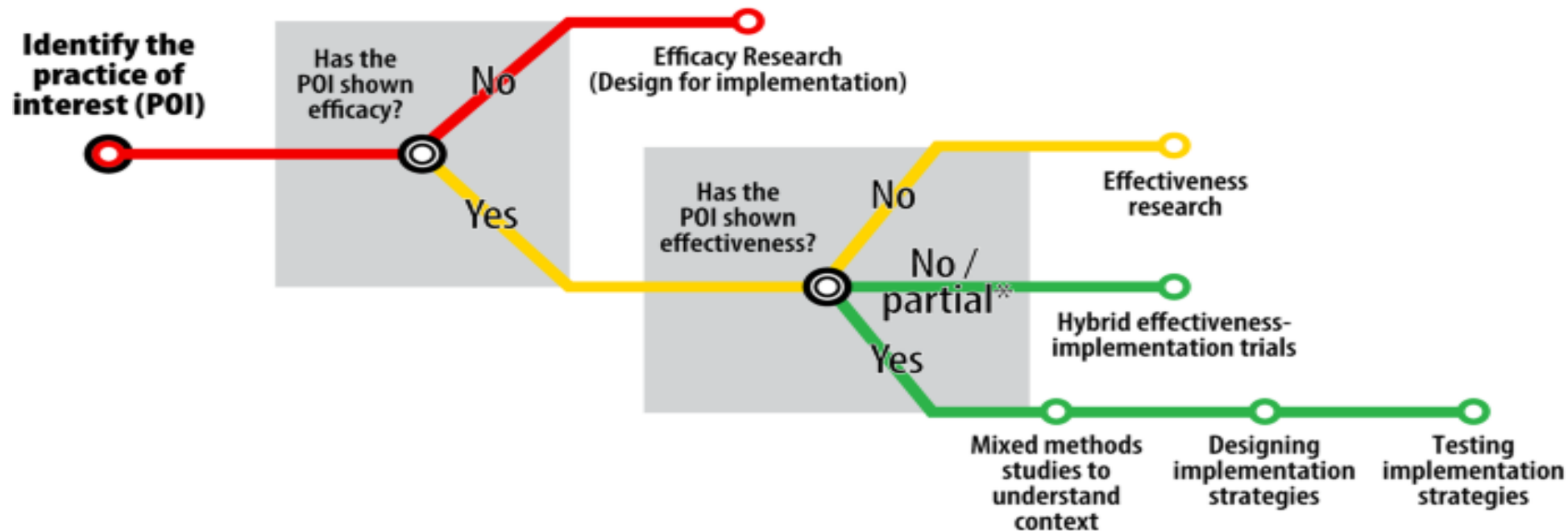
Effectiveness-implementation hybrid designs

- Examine both effectiveness and implementation aspects within a single study or trial
- Break or blend the conventional separate and sequential phases of research
- May accelerate the translation of research by allowing early harvesting of evidence on implementation
 - 3% of physical activity interventions test dissemination or implementation strategies (Milat)
 - Interventions frequently rolled out without dissemination/implementation trial



How do implementation trials differ from conventional clinical trials?

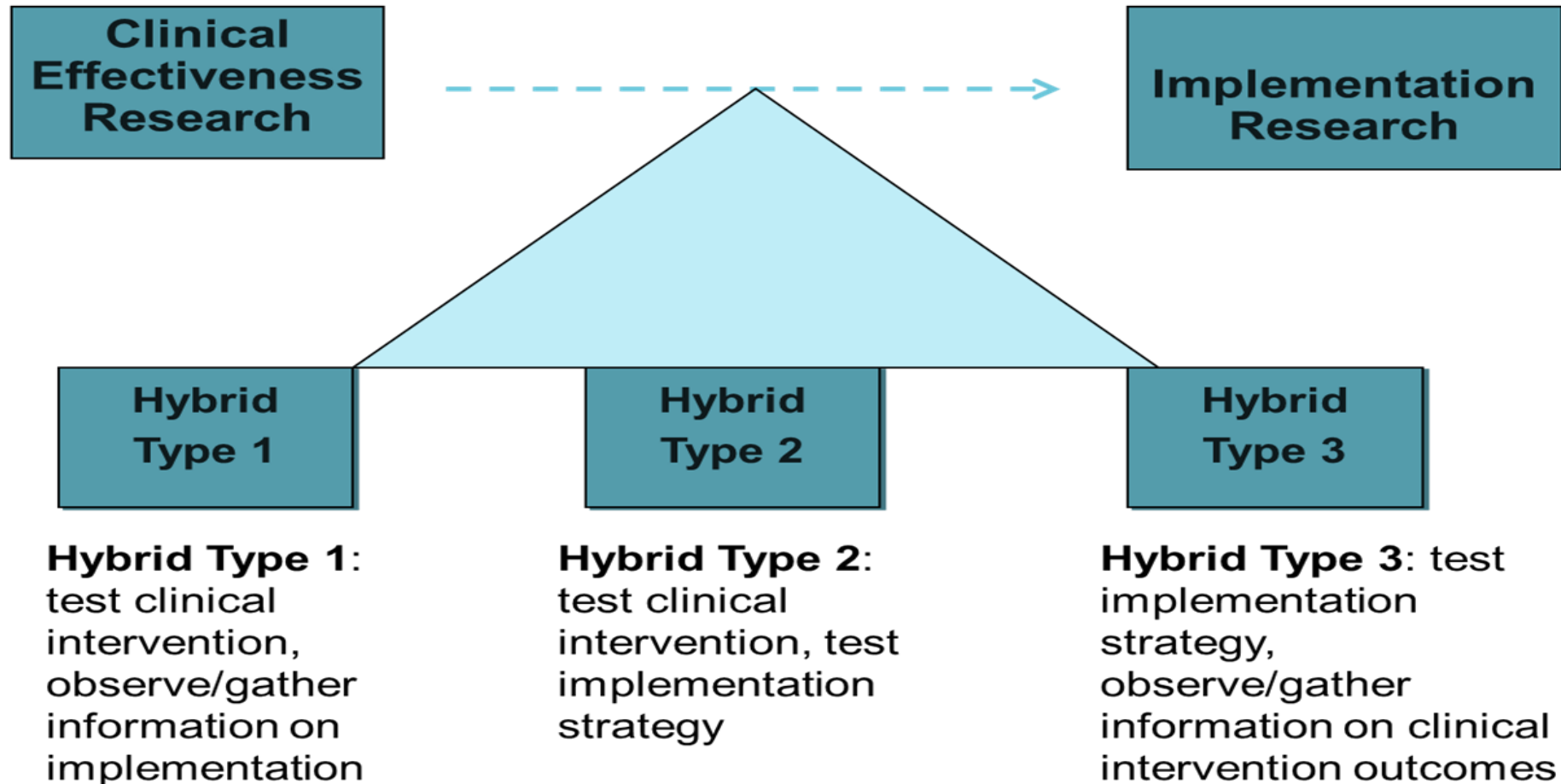




Graphic has been tested with colorblindness filters to ensure readability.

* 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).

Hybrid trials



	Hybrid T1	Hybrid T2	Hybrid T3
Research aim	Primary. Therapeutic effectiveness of an intervention Secondary: Better understand context for implementation to aid in the design of implementation strategies	Co-Primary: Therapeutic effectiveness of an intervention AND assess the effects of an implementation strategy on an implementation outcome	Primary” To assess the effects of an implementation strategy on implementation outcomes Secondary: To describe health outcomes
Population	Patients, populations	Patients, populations AND clinicians, policy makers, service providers	clinicians, policy makers, service providers
Effects of intervention	Is being tested	Is being tested	Is known to be effective
Effects of implementation strategy	Is not being tested	Is being tested	Is being tested
Primary trial outcome measures	Clinical conditions, symptoms health behaviours	Clinical conditions, symptoms health behaviours AND professional practice improvement, clinical standards, quality of care	Professional practice improvement, clinical standards, quality of care

Conducting effectiveness-implementation hybrid trials and securing funding



Statement of trial aim

Aims - a precise statement of which includes information about the population, implementation strategy, comparison and outcome under investigation

Hybrids must distinguish clearly between the aims of the intervention and implementation strategy



Statement of trial aim

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Hybrids must distinguish clearly between the aims of the intervention and implementation strategy

Example of a Type 2 Hybrid:

“The primary aims of the study were to:



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Example of a Type 2 Hybrid:

“The primary aims of the study were to: i) assess the effectiveness of audit and feedback (*implementation strategy*), relative to usual practice (*implementation comparison*)



Statement of trial aim

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Hybrids must distinguish clearly between the aims of the intervention and implementation strategy

Example of a Type 2 Hybrid:

“The primary aims of the study were to: i) assess the effectiveness of audit and feedback (*implementation strategy*), relative to usual practice (*implementation comparison*) for improving clinician (*implementation population*) provision (*implementation outcome, and target of the implementation strategy*)



Statement of trial aim

Aims - a precise statement of which includes information about the population, intervention/implementation strategy, comparison and outcome under investigation

Hybrids must distinguish clearly between the aims of the intervention and implementation strategy

Example of a Type 2 Hybrid:

“The primary aims of the study were to: i) assess the effectiveness of audit and feedback (*implementation strategy*), relative to usual practice (*implementation comparison*) for improving clinician (*implementation population*) provision (*implementation outcome, and target of the implementation strategy*) of nicotine replacement therapy (*clinical intervention*);



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and ii)



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and ii) to assess the effectiveness of nicotine replacement therapy (*clinical intervention*)



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and ii) to assess the effectiveness of nicotine replacement therapy (*clinical intervention*), relative to usual care (*clinical comparison*),



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and ii) to assess the effectiveness of nicotine replacement therapy (*clinical intervention*), relative to usual care (*clinical comparison*), in improving smoking cessation (*therapeutic outcome and therapeutic intent of the clinical intervention*)



Statement of trial aim

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Example of a type 2 Hybrid:

“The primary aims of the study were to: i) assess the effectiveness of audit and feedback (*implementation strategy*), relative to usual practice (*implementation comparison*) for improving clinician (*implementation population*) provision (*implementation outcome, and target of the implementation strategy*) of nicotine replacement therapy (*clinical intervention*);

and ii) to assess the effectiveness of nicotine replacement therapy (*clinical intervention*), relative to usual care (*clinical comparison*), in improving smoking cessation (*therapeutic outcome and therapeutic intent of the clinical intervention*) among cardiac inpatients (*therapeutic population*).



Hybrid trial recruitment and retention

Recruitment and retention strategies are important to ensure sufficient sample, minimise risk of bias, and maximise external validity

Hybrid trials often require participation at multiple levels

- Participating organisation
- Staff (e.g., clinicians or school teachers)
- Patients

Motivations and capacity are different for different participant groups

- Managers of these organisations vs patients

We know a-lot about patient recruitment and retention but little about clinician or health service participation and retention strategies

- Engage potential trial organisational 'sites' through co-production processes



Strategies to improve trial participation or reduce participant attrition

IMPROVING TRIAL PARTICIPATION

- Disseminating study information using methods allowing direct (e.g face to face) contact with potential participants
- Quotes of the experiences of previous participants
- Enclosing a questionnaire covering issues relevant to trial with the invitation to participate
- Framing treatment as more effective
- Financial incentives for participation
- Use of trained recruiters with characteristics similar to population group
- Telephone reminders to non-responders

REDUCING PARTICIPANT ATTRITION

- Collection of comprehensive participants contact information (e.g. alternate contact numbers or persons) to enabling tracking
- Use of pre-notification and reminder contacts for data collection activities
- Schedule data collection activities at times and using methods convenient for participants
- Financial incentives for completion of research activities
- Acknowledge, and reinforce completion of research activities
- Use of a dedicated co-ordinator to plan and monitor strategies to reduce participant drop-out



Using theory and frameworks in trial design

Hybrid trials should use an explicit programme theory in the development of the intervention/implementation strategy

Programme theory should detail the rationale and assumptions about the mechanisms linking the intervention and implementation strategy, processes and inputs to trial outcomes.

- Informal theory - understandings of the problem and its determinants through experience/ tacit knowledge.
- Formal behavioural or implementation theories or frameworks

Program theory is the skeleton for trial evaluation and measures selection



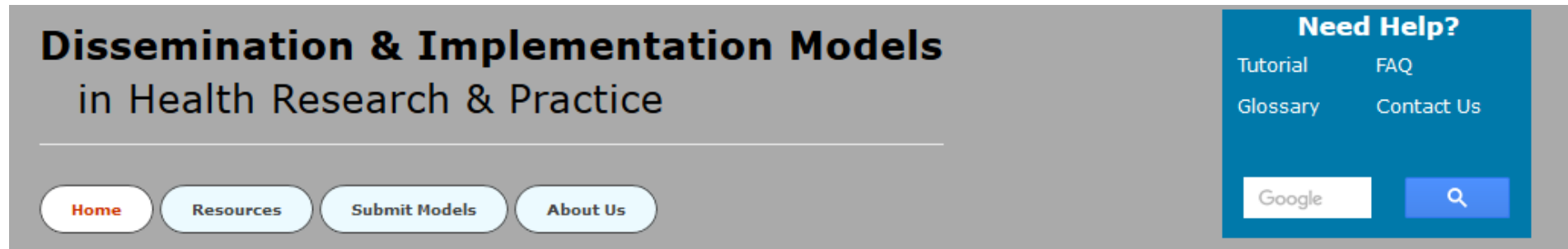
Using theory and frameworks

Theory / framework type	Description	Application
Classic (e.g Theory of planned behaviour) or implementation theories (Normalization Process Theory).	Originate from related disciplines (e.g psychology) to help understand or explain behaviour including that related to implementation	Classic and implementation theories describe precise mechanisms of change.
Determinants frameworks (e.g Consolidated Framework for Implementation Research, Theoretical Domains Framework)	Often developed through the consolidation of a range of theories,	Do not describe mechanisms for change. However, they can help identify factors thought to be associated with implementation, and implementation strategies that can be employed to address these, for which programme theory can be developed.

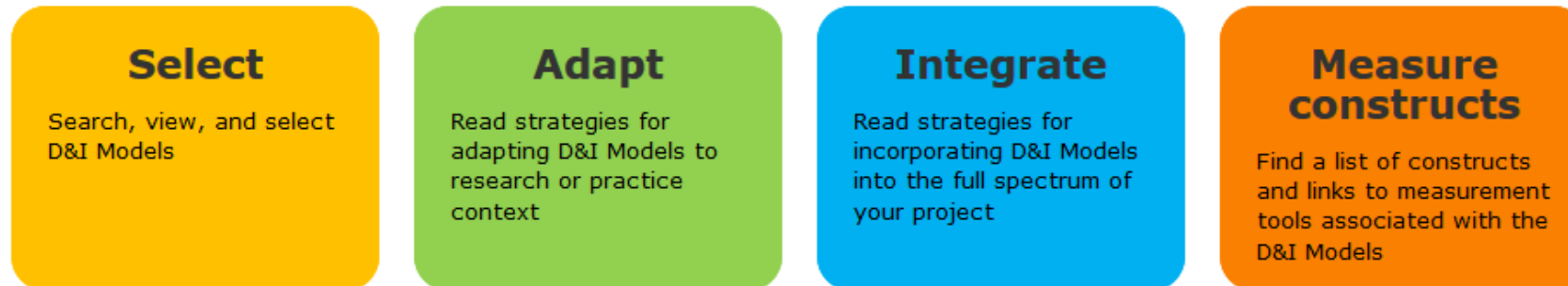


Other resources to help select and apply theory / frameworks

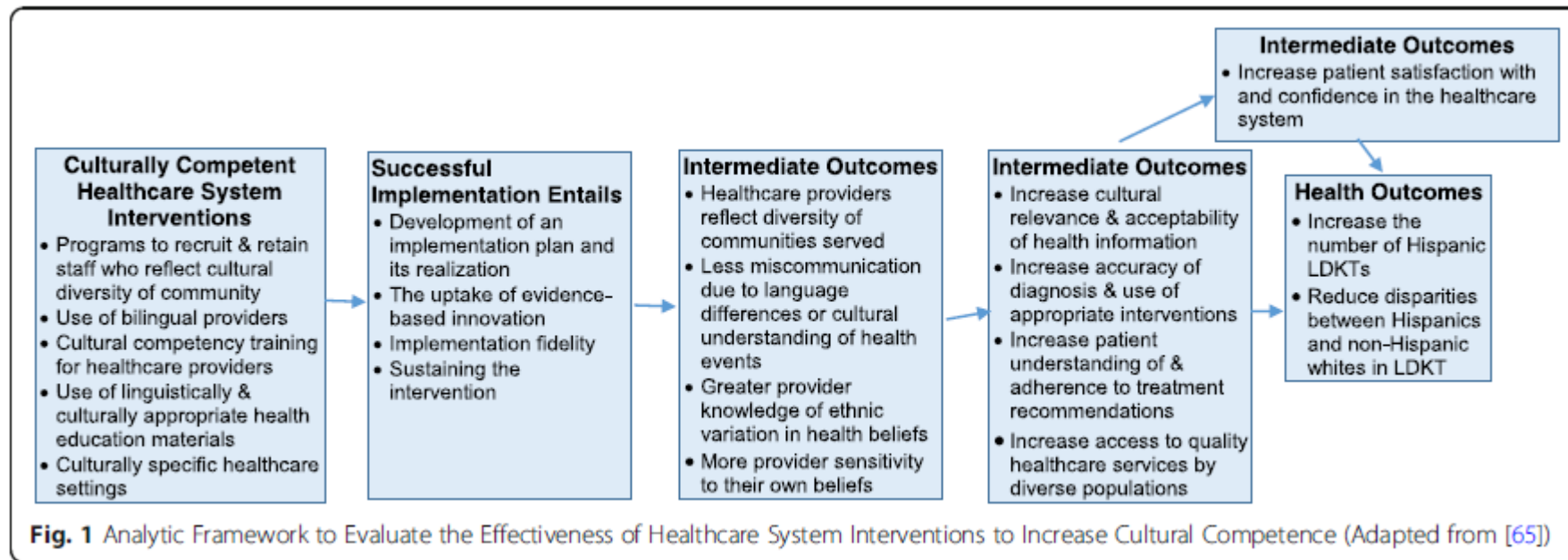
Interactive web resources



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



Example hybrid logic model



Outcomes measures

Should be directly linked to the trial primary and secondary aims

Hybrid trial measures need to be included to assess implementation outcomes and clinical level health outcomes

Trial outcomes should:

- Be valid
- Be sufficiently sensitive for use in an RCT



Common measures in implementation trials

Terms	Proctor et al.'s 8 implementation measures
Acceptability	is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory.
Adoption	is defined as the intention, initial decision, or action to try or employ an innovation or evidence-based practice
Appropriateness	is the perceived fit, relevance, or compatibility of the innovation or evidence based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem
Costs	is defined as the cost impact of an implementation effort. Implementation costs vary according to three components.
Feasibility	is defined as the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting
Fidelity	is defined as the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers
Penetration	is defined as the integration of a practice within a service setting and its subsystems
Sustainability	is defined as the extent to which a newly implemented treatment is maintained or institutionalized within a service setting's ongoing, stable operations

Implementation context (Type 1)

3. Implementation context

Refer to external factors that may influence the effects of an implementation strategy

Provide information to enable assessment of applicability

May include measures of the social, political or economic environment that may influence implementation

- leadership, workforce capacity, readiness to change, existing implementation infrastructure and other organizational or patient characteristic
- Other macro-level factors including policy change, financing

Typically descriptive not analytically presented

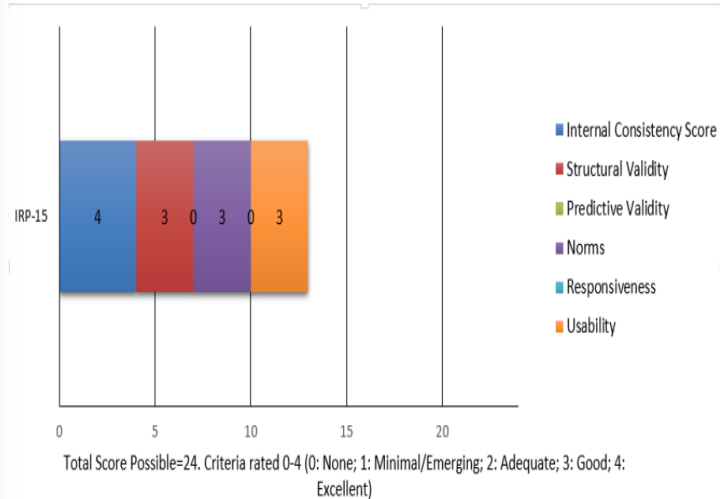


Abbreviated Acceptability Rating Profile (AARP)

[Home](#)

[CFIR](#) >> [Acceptability Instruments](#) >> [Abbreviated](#)

The Abbreviated Acceptability Rating Profile is an 8-item instrument used to
Evidence-Based Assessment Rating Profile



SYSTEMATIC REVIEW

Open Access



Psychometric properties of implementation measures for public health and community settings and mapping of constructs against the Consolidated Framework for Implementation Research: a systematic review

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Abstract

Background: Recent reviews have synthesised the psychometric properties of measures developed to examine implementation science constructs in healthcare and mental health settings. However, no reviews have focussed primarily on the properties of measures developed to assess innovations in public health and community settings. This review identified quantitative measures developed in public health and community settings, examined their psychometric properties, and described how the domains of each measure align with the five domains and 37 constructs of the Consolidated Framework for Implementation Research (CFIR).

Methods: MEDLINE, PsycINFO, EMBASE, and CINAHL were searched to identify publications describing the development of measures to assess implementation science constructs in public health and community settings. The psychometric properties of each measure were assessed against recommended criteria for validity (face/content, construct, criterion), reliability (internal consistency, test-retest), responsiveness, acceptability, feasibility, and revalidation and cross-cultural adaptation. Relevant domains were mapped against implementation constructs defined by the CFIR.

(Continued on next page)



Sample size calculation

Conducted prior to enrolment as part of study planning process

Sample size estimates are important to enrol the required number of participants to detect significant important effects

Sample size calculations should be performed on the primary outcomes in hybrid trials

- Health outcomes - clinical meaningfulness
- Implementation outcome needs to be **considered from a health system perspective** (rather than biological individual participant level).



Reporting guidelines

Standards for reporting implementation studies (STaRI) guidelines

CONSORT reporting guideline (and extension) specific to the RCT type

The Enhancing the Quality and Transparency of Health Research Network (Equator) houses a range of reporting guidelines



Table 1| Standards for Reporting Implementation Studies: the StaRI Checklist of items to be reported

Checklist item		Implementation strategy	Intervention†
Title	1	Identification as an implementation study, and description of the methodology in the title and/or keywords	
Abstract	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes	
Introduction	3	Description of the problem, challenge, or deficiency in healthcare or public health that the intervention being implemented aims to address	
	4	The scientific background and rationale for the implementation strategy (including any underpinning theory, framework, or model, how it is expected to achieve its effects, and any pilot work)	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects)
Aims and objectives	5	The aims of the study, differentiating between implementation objectives and any intervention objectives	
Methods: description	6	The design and key features of the evaluation (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons	
	7	The context in which the intervention was implemented (consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere)	
	8	The characteristics of the targeted "site(s)" (locations, personnel, resources, etc) for implementation and any eligibility criteria	The population targeted by the intervention and any eligibility criteria
	9	A description of the implementation strategy	A description of the intervention
	10	Any subgroups recruited for additional research tasks, and/or nested studies are described	
Methods: evaluation	11	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed.	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed.
		Document any pre-determined targets	Document any pre-determined targets



Tips for securing funding



Funding

Demonstrated consideration of research translation will improve funding application competitiveness

Hybrid trial MAY help with this

Greater acceptance of Hybrid trials in the U.S and funding schemes targeting these types of studies - PICORI

In Australia NHMRC partnership scheme precludes the inclusion of 'effectiveness' outcomes

- We have had considerable success with 'implementation' trials
- Could included nested studies to assess effectiveness outcomes

Some concern that Hybrid designs may require design concessions



End of presentation
