Clinical care delivery and implementation research

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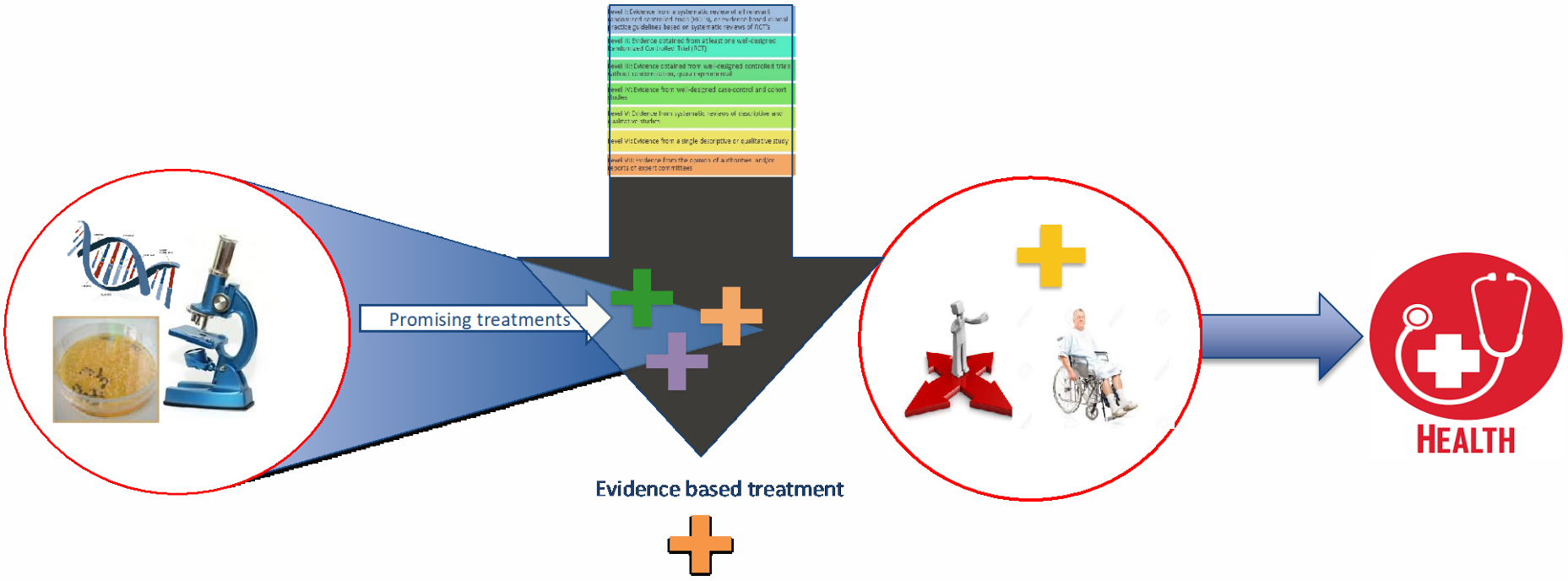
What is implementation science?

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

Eccles MP, Mittman BS. (2006) Welcome to implementation science. Implementation Science, 1(1).

Part of the translational science spectrum



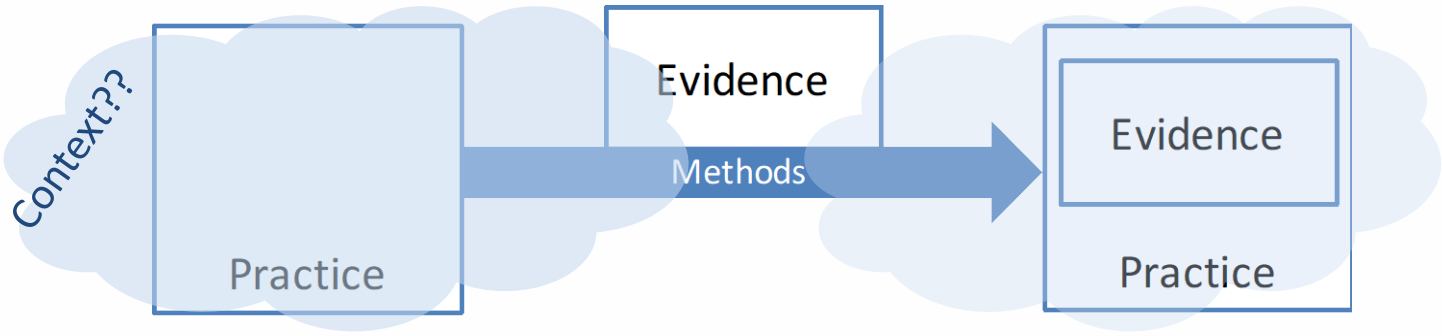
Basic Research	Pre-Clinical Research	Clinical Research	Clinical Implementation	Public Health
Explore fundamental mechanisms of biology, disease or behavior	Examine fundamental biological innovations	Testing for effectiveness	General adoption of EBP into practice	Outcomes research

Why is it needed?

- Previously, assumed ”if we build it, they will come”
- Reality: it takes 17 years for evidence to be routinized into practice
- Funders are asking for it
  - IS addresses the lack of research impact

Concepts and Assumptions

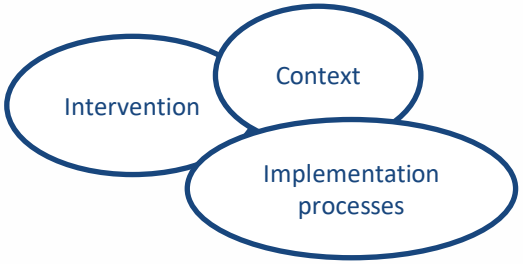
- Evidence
  - The *what* of implementation: a robust solution
- Implementation 'methods'
  - The *how* of implementation: mechanism of action
- Practice, which entails Context
  - Practice: the *where/who* of implementation
  - Context not so easily localized, and heterogeneously conceptualized
    - Culture, resources, leadership, infrastructure, economic climate, etc.



Concepts embedded into Models

Intervention/evidence, **implementation**, and **context,** are overarching concepts in many implementation science models/frameworks

Harvey & Kitson, 2016
iPARIHS



May, Johnson & Finch, 2016
Normalization Process Theory

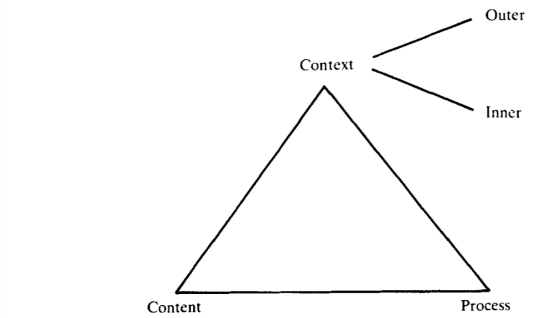
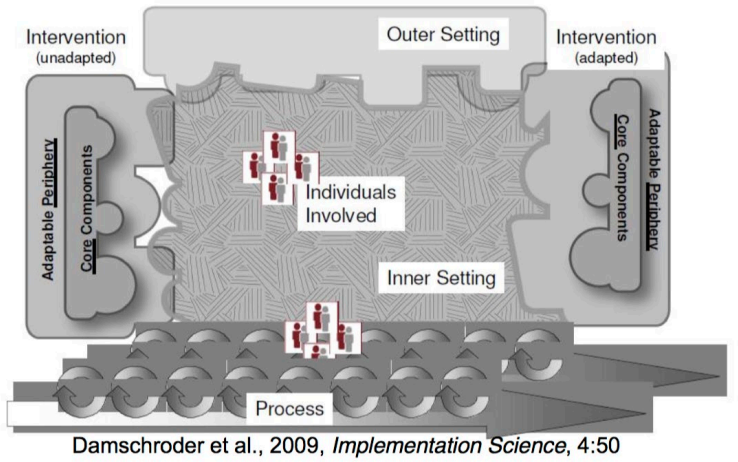


Figure 1. The broad framework guiding the research

Pettigrew 1987



Damschroder et al., 2009, *Implementation Science*, 4:50

CFIR

Other factors important to IS

Fundamentals of **Implementation Research**

IR Characteristic	Application for use
Systematic	• The systematic study of how a specific set of activities integrate an evidence-based public health intervention within specific settings and how health outcomes vary across communities • Balances relevance with rigor, strictly adhering to norms of scientific inquiry
Multidisciplinary	• Analysis of biological, social, economic, political, system, and environmental factors that impact implementation • Interdisciplinary collaborations between behavioral and social scientists, clinicians, epidemiologists, statisticians, engineers, business analysts, policy makers, and stakeholders
Contextual	• It is relevant to local specifics and need • Generates generalizable knowledge that can be applied across contexts • Culture, community
Complex	• Dynamic and adaptive • Multi-scale: occurs at multiple levels of health care systems and community practices • Analyzes multi-component programs and policies • Non-linear, iterative, evolving

Bridging Research and Practice
Models for Dissemination and Implementation Research

Rachel G. Tabak, PhD, Elaine C. Khoong, BS, David A. Chambers, DPhil, Ross C. Brownson, PhD

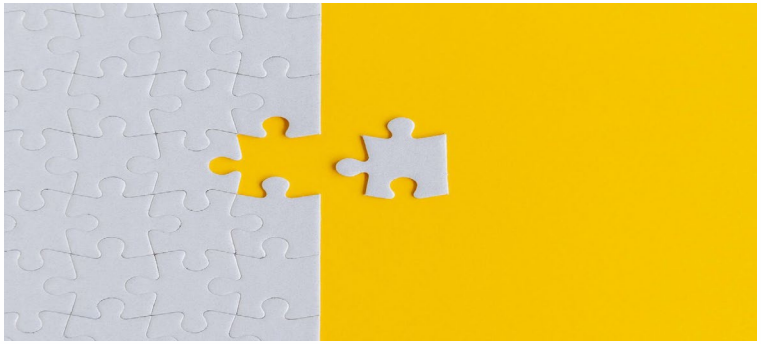
Table 2. Categorization of D&I models for use in research studies

Model	Dissemination and/or implementation	Construct flexibility: broad to operational	Socioecologic Level					References
			System	Community	Organization	Individual	Policy	
Diffusion of Innovation	D-only	1		x	x	x		21
RAND Model of Persuasive Communication and Diffusion of Medical Innovation	D-only	1		x	x	x		22
Effective Dissemination Strategies	D-only	2		x	x	x		23
Model for Locally Based Research Transfer Development	D-only	2		x	x			24
Streams of Policy Process	D-only	2	x	x	x		x	25, 26
A Conceptual Model of Knowledge Utilization	D-only	3	x	x			x	27
Conceptual Framework for Research Knowledge Transfer and Utilization	D-only	3			x			28
Conceptualizing Dissemination Research and Activity: Canadian Heart Health Initiative	D-only	3		x	x			29, 30
Policy Framework for Increasing Diffusion of Evidence-Based Physical Activity Interventions	D-only	3	x	x	x		x	31
Blueprint for Dissemination	D-only	4		x	x			32
Framework for Knowledge Translation	D-only	5		x	x	x		33
A Framework for Analyzing Adoption of Complex Health Innovations	D > I	2	x	x	x	x		34, 35

Plenty of models to choose from, yet challenging to how know which one is the right one

What to do?

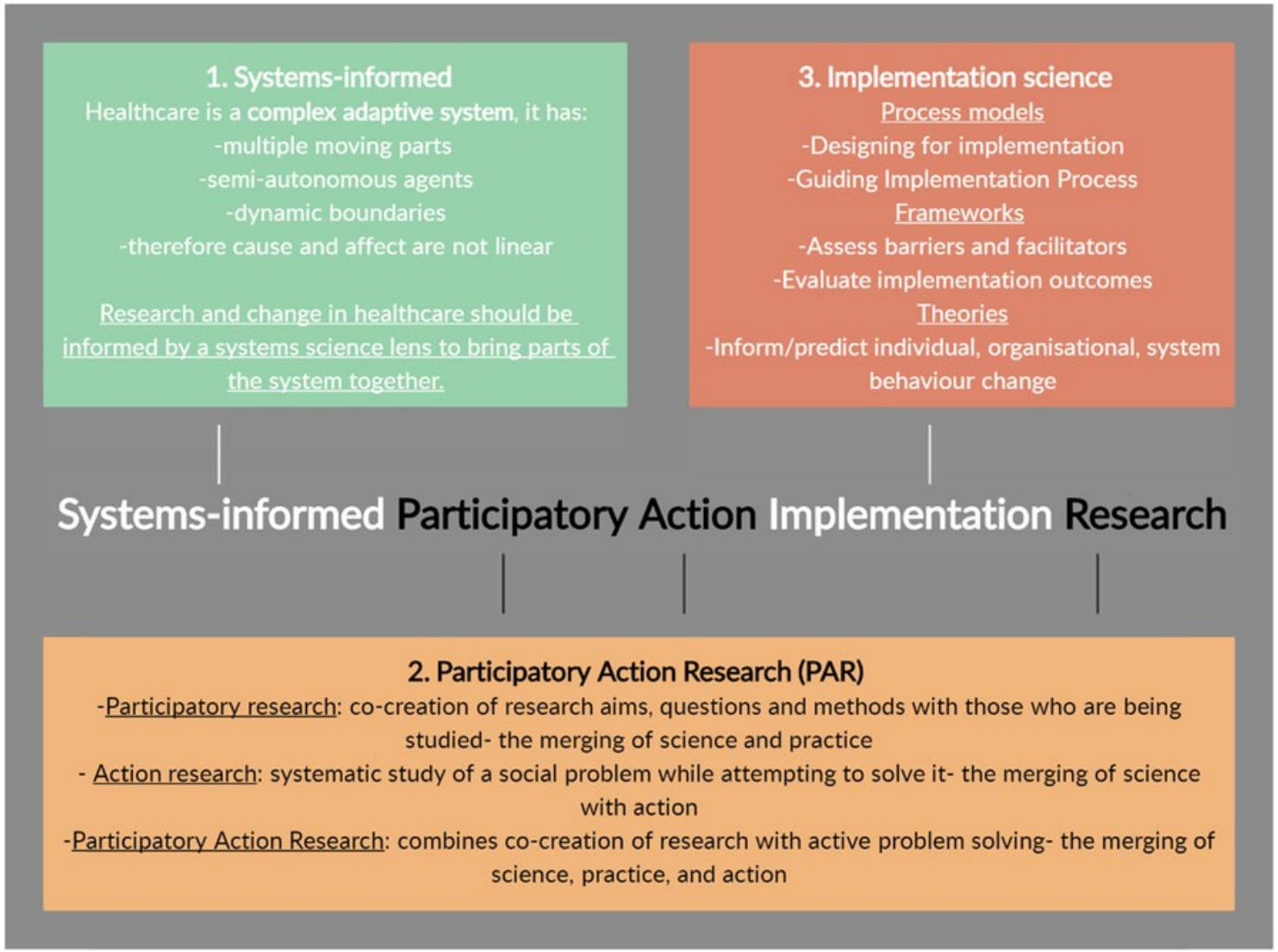
- Pick and choose appropriate models



- Use a participatory approach

- Adaptation; it happens so make it work for you!

Participatory/community engaged efforts



https://implementationscience.biomedcentral.com/articles/10.1186/s13012-020-01062-3

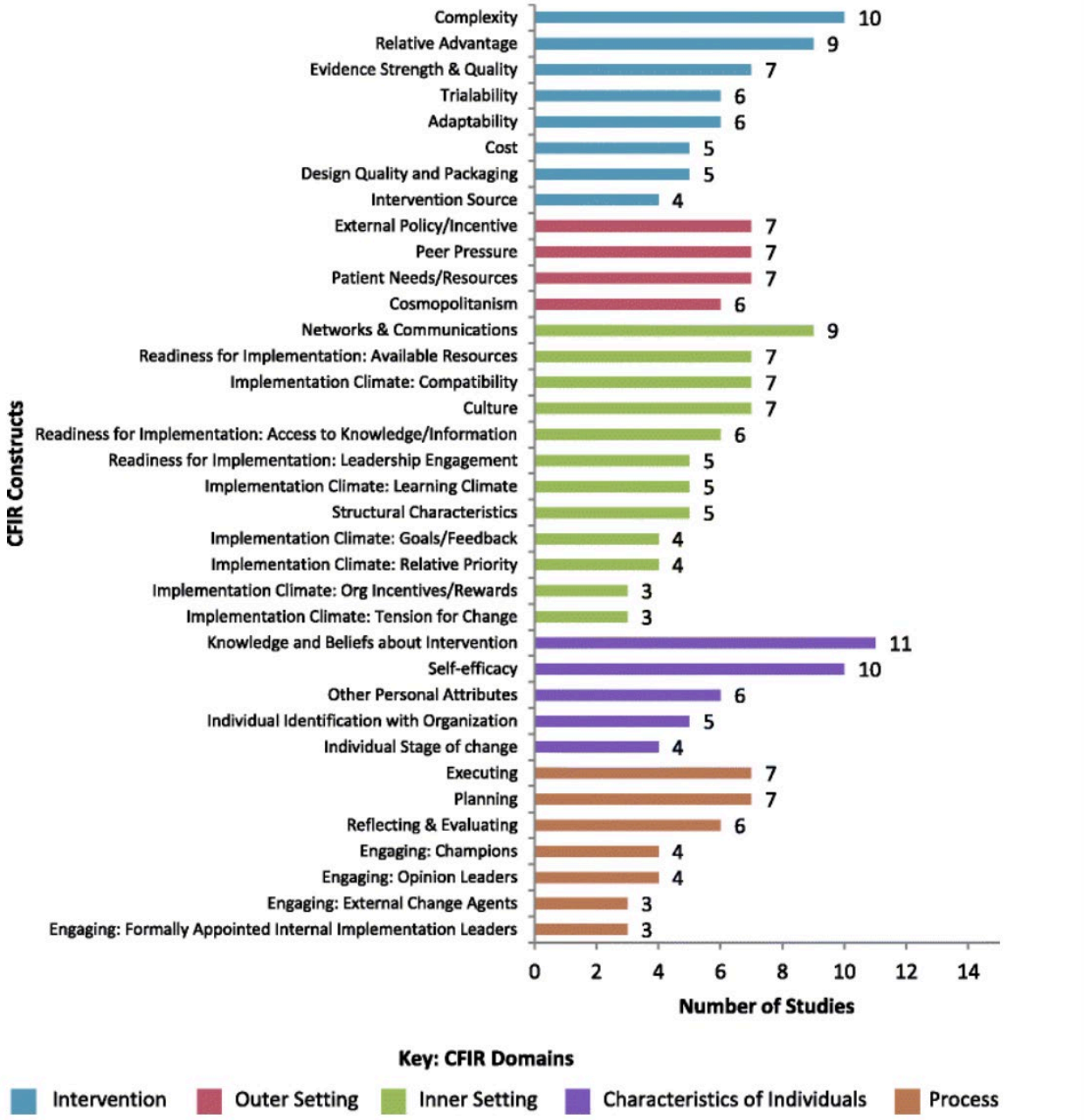
Models: Look at what's important

Consolidated framework for implementation research

Intervention characteristics	Outer setting	Inner setting	Characteristics of Individuals	Process of implementation

- Intervention source
- *Evidence Strength & Quality*
- **Relative advantage**
- **Adaptability**
- *Trialability*
- **Complexity**
- *Design Quality & Packaging*
- **Cost**
	- Patient Needs & Resources
	- *Cosmopolitanism*
	- Peer pressure
	- *External Policy & incentives*
		- **Structural Characteristics**
		- Networks & Communications
		- Culture
		- Implementation Climate
		  - **Tension for Change**
		  - **Compatibility**
		  - Relative Priority
		  - **Organizational Incentives & Rewards**
		  - *Goals & Feedback*
		  - Learning Climate
		- Readiness for Implementation
		  - **Leadership Engagement**
		  - **Available Resources**
		  - Access to Knowledge & Information
			- *Knowledge & Beliefs about the Intervention*
			- *Self-Efficacy*
			- **Individual Stage of Change**
			- Individual Identification with Organization
			- Other Personal Attributes
				- *Planning*
				- **Engaging**
				  - Opinion Leaders
				  - Formally Appointed Internal Implementation Leaders
				  - **Champions**
				  - External Change Agents
				- Executing
				- *Reflecting & Evaluating*

CFIR constructs used in research



Kirk, M. A., Kelley, C., Yankey, N., Birken, S. A., Abadie, B., & Damschroder, L. (2015). A systematic review of the use of the consolidated framework for implementation research. *Implementation Science*, *11*(1), 1-13.

RE-AIM: Measure what you implement

RE-AIM Dimension	Key pragmatic questions to consider and answer
Reach (Individual level)	WHO is (was) intended to benefit and who actually participates or is exposed to the intervention? *(**Participation rate and representativeness**)*
Effectiveness (Individual level)	WHAT is (was) the most important benefits you are trying to achieve and what is (was) the likelihood of negative outcomes? *(**Main and subgroup (equity) effects on multiple outcomes and unintended consequences**)*
Adoption (Setting and Staff levels)	WHERE is (was) the program or policy applied and WHO applied it? *(**Beginning participation rate and representativeness of settings and staff**)*
Implementation (Setting and Staff levels)	HOW consistently is (was) the program or policy delivered, HOW will (was) it be adapted, HOW HOW much will (did) it cost, and WHY will (did) the results come about? *(****this one is loaded, lots of things to measure!**)*
Maintenance (Individual and Setting levels)	WHEN will (was) the initiative become operational; how long will (was) it be sustained (Setting level); and how long are the results sustained (Individual level)? (***Tracking and follow-ups over time at the relevant level***)

https://www.re-aim.org/resources-and-tools/figures-and-tables/

How researchers have operationalized RE-AIM

Gaglio et al. 2013

TABLE 1—Inclusion of RE-AIM Elements Across All Articles Included in Review by Dimension and Evaluation Criteria: 1999–2010

RE-AIM Dimension and Evaluation Criteria Reported	Average Inclusion, %
Reach (n = 65) all 4 criteria reported	0.0
Exclusion criteria (% excluded or characteristics)	61.5
Percentage of individuals who participate, based on valid denominator	83.1
Characteristics of participants compared with nonparticipants; to local sample	58.5
Use of qualitative methods to understand recruitment	12.3
Effectiveness (n = 55) all 6 criteria reported	1.9
Measure of primary outcome	89.1
Measure of primary outcome relative to public health goal	76.4
Measure of broader outcomes or use of multiple criteria (e.g., measure of quality of life or potential negative outcome)	56.4
Measure of robustness across subgroups (e.g., moderation analyses)	48.2
Measure of short-term attrition (%) and differential rates by patient characteristics or treatment group	43.6
Use of qualitative methods/data to understand outcomes	7.3
Adoption–setting level (n = 58) all 4 criteria reported	0.0
Setting exclusions (% or reasons or both)	39.7
Percentage of settings approached that participate (valid denominator)	56.9
Characteristics of settings participating (both comparison and intervention) compared with either (1) nonparticipants or (2) some relevant resource data	37.9
Use of qualitative methods to understand setting level adoption	3.5
Adoption–staff level (n = 53) all 4 criteria reported	0.0
Staff exclusions (% or reasons or both)	11.3
Percent of staff offered that participate	35.9
Characteristics of staff participants vs nonparticipating staff or typical staff	17.0
Use of qualitative methods to understand staff participation/staff level adoption	9.4
Implementation (n = 64) all 6 criteria reported	1.6
Percent of perfect delivery or calls completed (e.g., fidelity)	76.6
Adaptations made to intervention during study (not fidelity)	14.1
Cost of intervention–time	14.1
Cost of intervention–money	23.4
Consistency of implementation across staff/time/settings/subgroups (not about differential outcomes, but process)	35.9
Use of qualitative methods to understand implementation	15.6
Maintenance–individual level (n = 46) all 6 criteria reported	2.2
Measure of primary outcome (with comparison with a public health goal) at ≥ 6 mo follow-up after final treatment contact	63.0
Measure of primary outcome ≥ 6 mo follow-up after final treatment contact	56.5
Measure of broader outcomes (e.g., measure of quality of life or potential negative outcome) or use of multiple criteria at follow-up	32.6
Robustness data–something about subgroup effects over the long-term	26.1
Measure of long-term attrition (%) and differential rates by patient characteristics or treatment condition	28.3
Use of qualitative methods data to understand long-term effects	4.4
Maintenance–setting level (n = 51) all 4 criteria reported	0.0
If program is still ongoing at ≥ 6 mo posttreatment follow-up	41.2
If and how program was adapted long-term (which elements retained after program completed)	7.8
Some measure/discussion of alignment to organization mission or sustainability of business model	15.7
Use of qualitative methods data to understand setting level institutionalization	5.9

Note. RE-AIM = Reach, Effectiveness, Adoption, Implementation, and Maintenance.

Adaptation: its not good or bad, it just happens…

Adaptation as inherent – perhaps crucial – to the implementation process

Regarding local adaptations, cultural adaptation, and other efforts to improve fit as flaws in implementation fidelity is ***at best a missed opportunity, and at worst, a recipe for implementation failure***

Baumann, A. A., Cabassa, L. J., & Stirman, S. W. (2017). Adaptation in dissemination and implementation science. *Dissemination and implementation research in health: translating science to practice*, *2*, 286-300.
Baumann, A., Mejia, A., Lachman, J., Parra-Cardona, R., Lopez-Zeron, G., Amador Buenabad, N. G., ... & Domenech Rodrigeuz, M. M. (2018). Parenting programs for underserved populations: Issues of scientific integrity and social justice. *Global Social Welfare*.
Parra-Cardona, R., Leijten, P., Lachman, J. M., Mejía, A., Baumann, A. A., Buenabad, N. G. A., ... & Ward, C. L. (2018). Strengthening a culture of prevention in low-and middle-income countries: Balancing scientific expectations and contextual realities. *Prevention Science*, 1-11.

From Rabin, 2021 NCI IS workshop (used with permission)

- This scoping study identified and summarized adaptation frameworks in published reports and grey literature
- Step by step process for successful adaptation

Step name	Step descriptions
1.Assess community	• Identify behavioral determinants and risk behaviors of the new target population using focus groups, interviews, needs assessments, and logic models • Assess organizational capacity to implement the program
2.Understand the intervention	• Identify and review relevant EBPs and their program materials • Understand the theory behind the programs and their core elements
3.Select intervention	• Select the program that best matches the new population and context
4.Consult with experts	• Consult content experts, including original program developers, as needed • Incorporate expert advice into program
5.Consult with stakeholders	• Seek input from advisory boards and community planning groups where program implementation takes place • Identify stakeholder partners who can champion program adoption in new setting and ensure program fidelity
6.Decide what needs adaptation	• Decide whether to adapt or implement original program • Theater test selected EBP using new target population and other stakeholders to generate adaptations • Determine how original and new target population/setting differ in terms of risk and protective factors • Identify areas where EBP needs to be adapted and include possible changes in program structure, content, provider, or delivery methods • Retain fidelity to core elements • Systematically reduce mismatches between the program and the new context
7.Adapt the original program	• Develop adaptation plan • Adapt the original program contents through collaborative efforts • Make cultural adaptations continuously through pilot testing • Core components responsible for change should not be modified
8.Train staff	• Select and train staff to ensure quality implementation
9.Test the adapted materials	• Pretest adapted materials with stakeholder groups • Conduct readability tests • Pilot test adapted EBP in new target population • Modify EBP further if necessary
10.Implement	• Develop implementation plan based on results generated in previous steps • Identify implementers, behaviors, and outcomes • Develop scope, sequence, and instructions • Execute adapted EBP
11.Evaluate	• Document the adaptation process and evaluate the process and outcomes of the adapted intervention as implemented • Write evaluation questions; choose indicators, measures, and the evaluation design; plan data collection, analysis, and reporting • Employ empowerment evaluation approach framework to improve program implementation

Escoffery, C., Lebow-Skelley, E., Udelson, H., Böing, E. A., Wood, R., Fernandez, M. E., & Mullen, P. D. (2019). A scoping study of frameworks for adapting public health evidence-based interventions. *Translational behavioral medicine*, *9*(1), 1-10.

IS and Quality Improvement

TABLE 1 | Summary of similarities and differences between implementation science and improvement science across six thematic aspects.

Aspect	Similarities	Differences
Influences	Both fields ultimately concern practice change Both fields acknowledge the relevance of psychology for understanding how desired change might be achieved	The fields have different origins and draw on mostly different sources of knowledge
Ontology, epistemology, and methodology	The research characteristics of the two fields are largely similar, primarily belonging to the positivist tradition, but with some interpretivist features	
	Both fields are highly applied in nature, with aspirations to inform practice	
Problem identification	Both fields describe a gap or chasm between current and optimal care and/or service delivery	For improvement science, the problem is related to the efficiency, safety, and/or quality of current practice; in implementation science the problem relates to delays in getting effective practices (clinical interventions, programmes, services, etc.) applied systematically in practice
Potential solutions	The two fields share multiple common strategies, although they use partially different terminology to describe them	Improvement science posits that quality improvement follows from successful change in the health care system and its processes. Implementation science assumes that implementation of evidence-based practices will reduce or eliminate the problem. The scope of change is broader in improvement science than in implementation science, because a QI initiative is not necessarily limited to application of scientifically supported evidence, but can also involve operations, service quality and efficiency
Analytical tools	Both fields use analytical tools to analyse problems and to identify possible solutions	Improvement science uses a range of QI tools, typically adapted for use in health care from the manufacturing industry and management, whereas implementation science emphasises the use of theories, models and frameworks as analytical tools
Knowledge production and use	Both fields produce knowledge that is both applicable for improved practice and sufficiently generalizable to contribute to scientific knowledge accumulation Both fields focus on studies in health care but also encompass research carried out in the broader health and welfare services	Health care practitioners and organisational developers are more likely to have QI and/or improvement science knowledge than implementation science knowledge

Nilsen P, Thor J, **Bender M**, Leeman J, Andersson-Gäre, Sevdalis N. (2022). Bridging the silos: A comparative analysis of implementation science and improvement science. *Frontiers in Health Services. 1:817750.*

Some additional IS resources

- Models for dissemination and implementation research (Tabak et al., 2012
- Theoretical domains framework (Michie et al., 2005)
- Measurement resources for D&I research (Rabin et al., 2016; Chaudoir et al., 2013)
- Implementation strategies (Leeman et al., 2017)
- Outcomes for IS; review of instruments (Lewis et al., 2015)
- https://libguides.llu.edu/implementation/speakers
- https://dissemination-implementation.org/index.aspx
- https://www.gem-measures.org/Login.aspx

Context Matters

Context matters, but we don't have a good conceptual handle on what it 'is' or 'does'

Nilsen and Bernhardsson *BMC Health Services Research* (2019) 19:189
https://doi.org/10.1186/s12913-019-4015-3

BMC Health Services Research

RESEARCH ARTICLE Open Access

Context matters in implementation science: a scoping review of determinant frameworks that describe contextual determinants for implementation outcomes

Per Nilsen[1] and Susanne Bernhardsson[2,3*]

"there is considerable variation with regard to … how context is defined and conceptualized, and which contextual determinants are accounted for in frameworks used in implementation science"

Context shows up everywhere

Mielke *et al. BMC Medical Research Methodology* (2022) 22:320

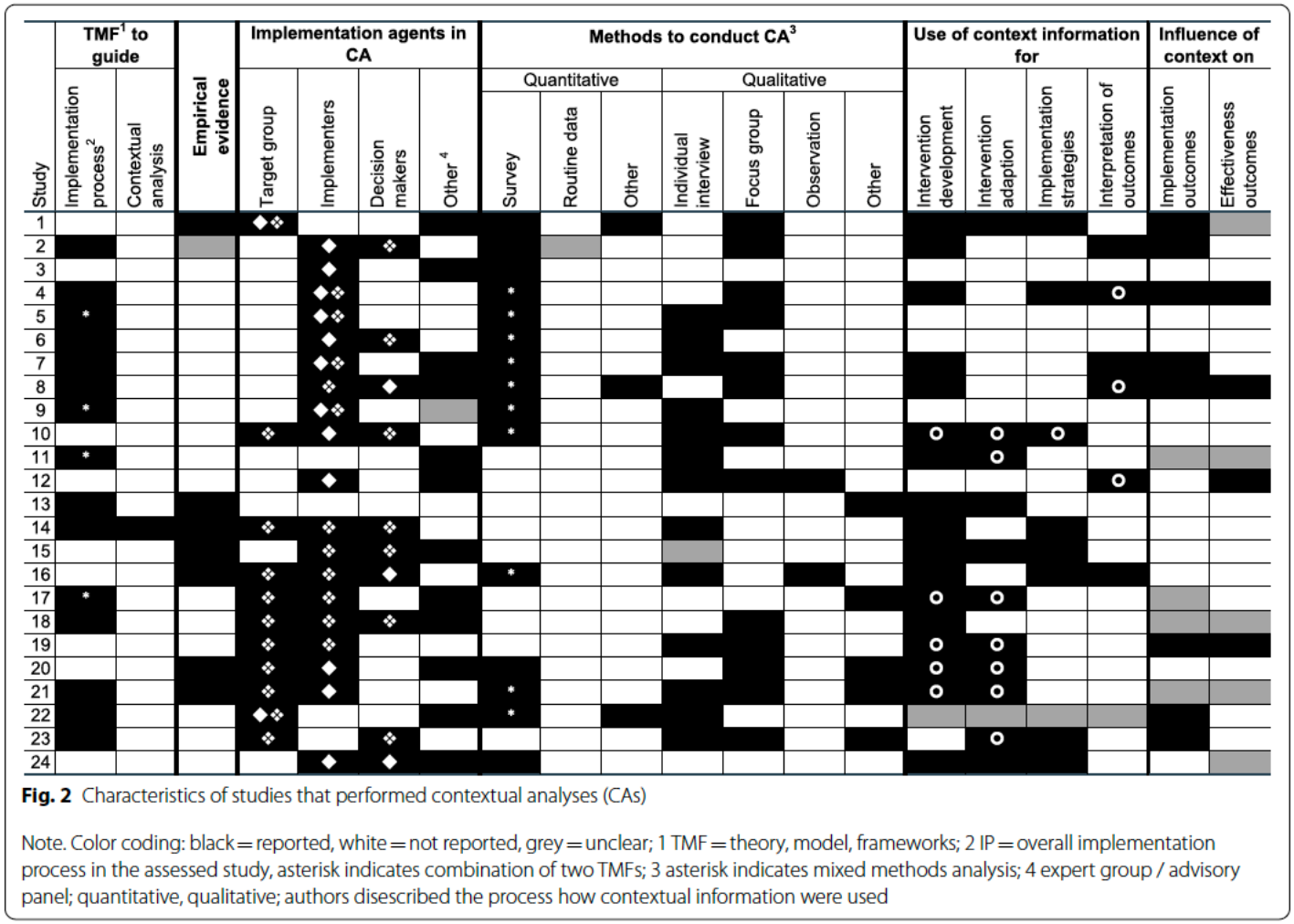


Fig. 2 Characteristics of studies that performed contextual analyses (CAs)

Note. Color coding: black = reported, white = not reported, grey = unclear; 1 TMF = theory, model, frameworks; 2 IP = overall implementation process in the assessed study, asterisk indicates combination of two TMFs; 3 asterisk indicates mixed methods analysis; 4 expert group / advisory panel; quantitative, qualitative; authors disescribed the process how contextual information were used

Creates challenges for research

- What contextual element(s) is/are important in any particular IS program of research?
- How decide which IS framework to use?
  - Which context descriptions are best?
- What about what's NOT in the frameworks?

Research to address challenge

- Implementation-effectiveness study design
- Examined the role of context in a complex nursing care delivery intervention delivered in 11 hospitals across 5 states
  - Interviews were conducted 2016-2019 with clinicians and administrators (n=399) along with 2-22 hours of observation of the implementation process per hospital
- Used deductive AND inductive qualitative analytic approaches to identify what context 'was' in terms of what influenced implementation success
  - CFIR and CNL Practice Model used for deductive analysis
  - Qualitative content analytic approach for inductive analysis

Key Finding

- One of the most consistent contextual components influencing implementation across settings was the clinical routine
  - Pre-existing before intervention implementation

- Some routines we found:
  - Interdisciplinary rounding
  - Patient admission and discharge
  - Handoffs between patients/units/clinicians
  - Medication administration
  - Attending MD and resident communication

Bender M, Lefkowitz D. (2020). Clinical routines as an under-explored yet critical component of context in implementation science. *Implementation science, 15*(Suppl 1):26, p. 12. https://doi.org/10.1186/s13012-020-00985-1

What exactly is a clinical routine?

- Could NOT find a definition of 'clinical routine' in Pubmed
- Searched "clinical routine" in IS journal
  - 7 articles, 6 mention clinical routine only in passing, superficially
  - Potthoff et al., 2017: Routine as "habit" of a person, "once a behavior has become routine"

- Routines considered individual behavioral habits in IS, not clinical practices
  - Nilsen et al. 2017: "handle a certain task in a routinized way"
  - Michie et al. 2005: clinician behavior as a routine

Potthoff, S., Presseau, J., Sniehotta, F. F., Johnston, M., Elovainio, M., & Avery, L. (2017). Planning to be routine: habit as a mediator of the planning-behaviour relationship in healthcare professionals, 1–10. http://doi.org/10.1186/s13012-017-0551-6
Nilsen, P., Neher, M., Ellström, P.-E., & Gardner, B. (2017). Implementation of Evidence-Based Practice From a Learning Perspective. *Worldviews on Evidence-Based Nursing*, *14*(3), 192–199. http://doi.org/10.1111/wvn.12212
Michie, S., Johnston, M., Abraham, C., Lawton, R., Parker, D., Walker, A., "Psychological Theory" Group. (2005). Making psychological theory useful for implementing evidence based practice: a consensus approach. *Quality and Safety in Health Care*, *14*(1), 26–33. http://doi.org/10.1136/qshc.2004.011155

That wasn't what we found

- Influential routines were practices, not behaviors
  - The routines identified spanned multiple disciplines and teams with shared goals and occurred over time, many times across multiple spaces
  - PEOPLE moved in and out of the routine while the routine itself stayed observably recognizable
    - Residents coming on board or leaving for new settings
    - Different nurses handing off different patients to different units

- DID Find a relevant definition in the Organization Science literature
  - "an organizational routine is a repetitive, recognizable pattern of interdependent actions, involving multiple actors"

Feldman, M. S., & Pentland, B. T. (2003). Reconceptualizing organizational routines as a source of flexibility and change. *Administrative Science Quarterly*, *48*(1), 94–118.

Routines influenced implementation

- Nursing intervention may or may not 'touch' pre-existing routines when implemented
  - If they 'touched,' the nursing intervention might be:
    - Added to the routine
    - Inhibited by the routine
    - Modified to better align with existing routines
    - Enhance existing routines

- The routines 'pushed back'
  - Effective pre-existing routines were prioritized over intervention
  - Intervention could be implemented only to the extent effective pre-existing routines could stay effective

The Causality of Context

- Findings suggest a complex causality between interventions and contexts that manifests via unanticipated intersections among existing multi-professional clinical routines

- However, clinical routines are not listed (let alone defined) as a component in existing context determinant frameworks

- Further investigation is needed to advance knowledge about the causal significance of clinical routines when implementing healthcare interventions

Summary

- IS research is about how what you want to develop and test can be routinized into practice
  - Hint, it won't happen by itself
- The earlier this addressed, the more chances for ultimate adoption
- Can be as simple as asking people their opinions
  - If we can develop X, what are your thoughts about it? What makes you excited or nervous about it? What would be the barriers to adoption?

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