





brewing ideas for research impact

Journal Club #2: HOW DO I KNOW WHEN THE TIME IS RIGHT? NEEDS ASSESSMENTS IN IMPLEMENTATION

Supported by

Nutrition & Health Innovation
Research Institute



Acknowledgment of Country





Edith Cowan University acknowledges and respects the Noongar people, who are the traditional custodians of the land upon which its campuses stand and its programs operate. In particular, ECU pays its respects to the Noongar Elders, past and present, and embraces their culture, wisdom and knowledge.

Session #1 Recap



1. Evolution of the field of implementation science

- Recognition that developing good evidence for health care was not in itself, any guarantee that it would be taken up by health care professionals
- Discipline created to improve people's health, strengthen health service delivery, empower communities, inform policy

2. Models, theories, frameworks

Help to structure implementation efforts to include all relevant factors

3. Important to decide whose is responsible for implementation

- Scientist who produces the research?
- Person who translates evidence into policy?
- End-user of the work?
- Or...?



The intervention/practice/innovation is THE THING

- Programs
- Practices
- Principles
- Procedures
- Pills
- Products
- Policies



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- Effectiveness research looks at whether THE THING works

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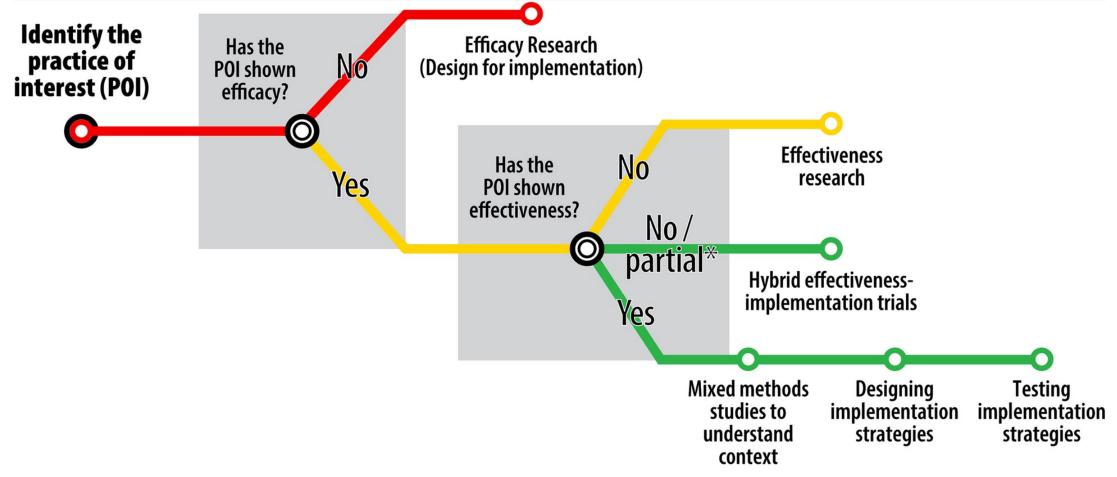


- The intervention/practice/innovation is THE THING
- Effectiveness research looks at whether THE THING works
- Implementation research looks at how best to help people/places DO THE THING
- Implementation strategies are the <u>stuff we do</u> to try to help people/places DO THE THING
- Main implementation outcomes are HOW MUCH and HOW WELL they DO THE THING

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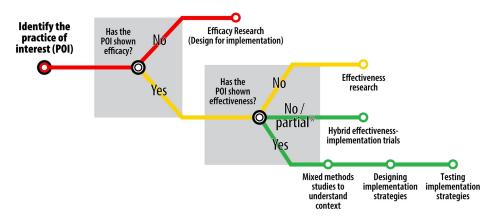
Locating yourself on the "subway line" of translational research





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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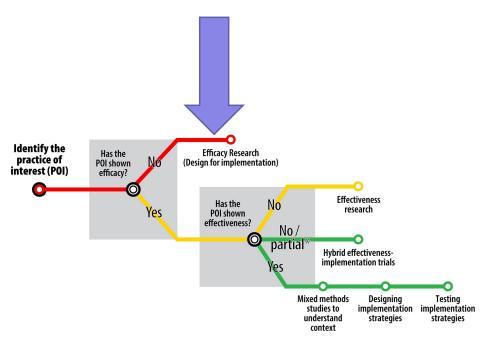
Research question 1

Does a new clinical protocol for sepsis improve patient outcomes?

The THING is the clinical protocol. It has been pilot tested in a <u>non-randomized</u> fashion with promising results.

^{*} 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).





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Research question 1

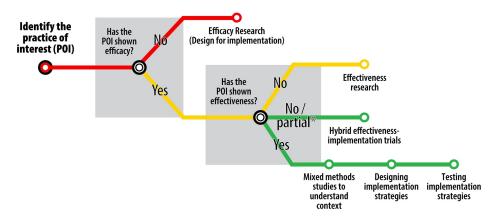
Does a new clinical protocol for sepsis improve patient outcomes?

The THING is the clinical protocol. It has been pilot tested in a <u>non-randomized</u> fashion with promising results.

Without randomized controlled trial data, we would say that evidence of efficacy is missing, so implementation studies are not yet warranted. The protocol should undergo efficacy testing, but the intervention developers should consider future implementation in the refinement and testing of the intervention (e.g., is it too complicated to work in routine clinical practice?).

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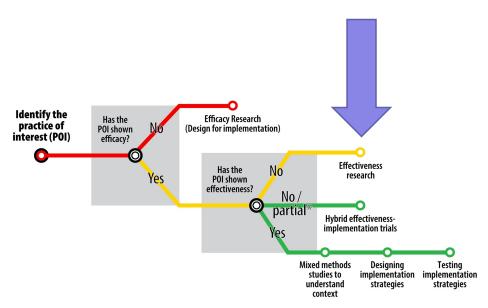
Research question 2

Multiple randomized clinical trials have shown that an exercise protocol improves bone strength in breast cancer patients.

Does this exercise protocol work in heterogeneous cancer patient populations? The THING is the exercise protocol.

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Research question 2

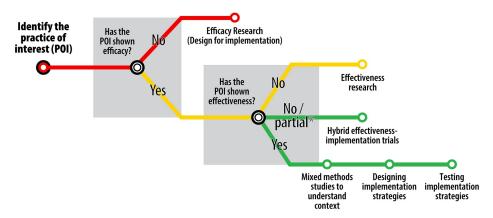
Multiple randomized clinical trials have shown that an exercise protocol improves bone strength in breast cancer patients.

Does this exercise protocol work in heterogeneous cancer patient populations? The THING is the exercise protocol.

Although there is evidence of efficacy, we do not yet know whether the exercise protocol works in routine clinical practice. Efficacious interventions can fall flat in the real world once the realities of dosing, side effects, and interactions with other conditions and medications are considered. The exercise protocol is not yet ready for studies of implementation, so effectiveness studies should occur next. However, effectiveness studies may yield observational data that will inform future implementation efforts.

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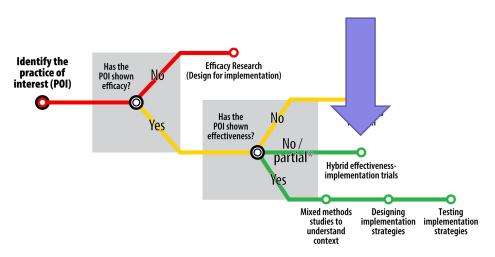
Research question 3

Care coordination pathway Y improves outcomes for heart failure patients in both efficacy and effectiveness studies. Will it work for patients with diabetes?

The THING is the care coordination pathway.

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Research question 3

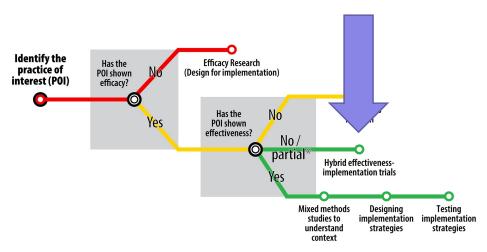
Care coordination pathway Y improves outcomes for heart failure patients in both efficacy and effectiveness studies. Will it work for patients with diabetes?

The THING is the care coordination pathway.

It would be reasonable to study Pathway Y in effectiveness studies focused on patients with diabetes. Alternatively, a hybrid Type 1 trial would maintain a focus on effectiveness while either prospectively or retrospectively collecting information to inform future implementation efforts.

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Research question 3

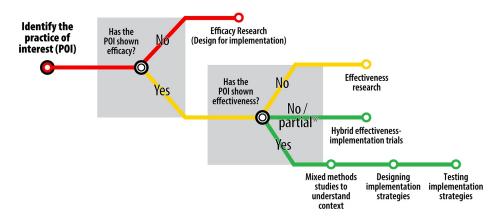
Relevant implementation outcomes for this early implementation evaluation include:

- Acceptability (i.e., how palatable or agreeable the THING is from the perspective of stakeholders)
- Appropriateness (i.e., the perceived fit of the THING for a given setting, clinician, or patient)
- Feasibility (i.e., the extent to which the THING can be successfully deployed in a given setting)
- Fidelity (i.e., the degree to which the THING is implemented as it was intended).

These implementation outcomes and their relationship to more studied clinical effectiveness outcomes are explained in detail in seminal papers by Proctor and colleagues in 2009 and 2011.

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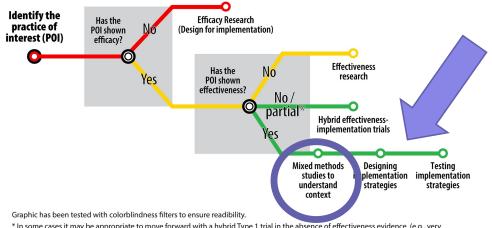
Research question 4

Colon cancer screening leads to earlier cancer detection and improved patient outcomes. What strategies can be used to increase colon cancer screening?

The THING is colon cancer screening.

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Research question 4

Colon cancer screening leads to earlier cancer detection and improved patient outcomes. What strategies can be used to increase colon cancer screening?

The THING is colon cancer screening.

This evidence-based practice is ripe for studies of implementation given the robust evidence base supporting it. Implementation studies are warranted. The focus of implementation studies will depend on what is known about the context to be studied.

Potential study designs range from observational contextual inquiry to randomized controlled trials of implementation strategies.

EXAMPLE: MIXED METHODS RESEARCH TO UNDERSTAND CONTEXT



International guidelines for the protection of athlete health

- Guidelines intended for use by international audience
- Understand <u>HOW</u> the guidelines are used in two distinct contexts: South Africa & Australia

Intended to:

- Inform dissemination of current and future guidelines
- Justify future guidelines
- Inform next step of research project





UNDERSTANDING THE CONTEXT



Inclusion and data collection

We identified two cases to be compared with consideration to:

- distinct health systems (low/high economic settings)
- location of research teams
- relationship with participants
- governance & ethics
- budget, timing,
- When two cases were established:
 - Organisations within those two countries
 - People in the organisations





UNDERSTANDING THE CONTEXT



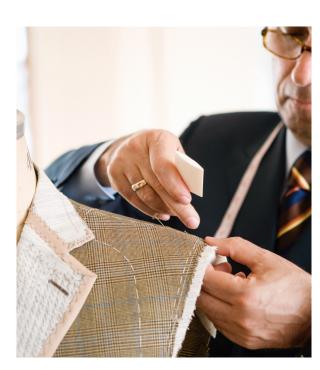
Choice and consideration of data sources & participants crucial

DATA SOURCES: CASE 1	Topic 1 Structure of the organisation	Topic 2 Country structure	Topic 3 Awareness of the guidelines
Participant interview Chief Medical Officer and committee chair			
Participant interview Physiotherapist committee member			
3. Field notes (two data collectors)			
4. Website Organisation main website			
5. Document (any reports or correspondence shared with us or identified in interview)			

Gale, N.K., Heath, G., Cameron, E. et al. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol 13, 117 (2013). https://doi.org/10.1186/1471-2288-13-117

How did context awareness set up the next steps?





Inform dissemination of current and future guidelines

Previously used the same strategies for everyone

Inform development of future guidelines

- Justified the cost and resources for future guideline development
- Identified the types of guidelines and formats that are most valued

Inform next step of study

Justification to conduct a global survey to extend findings
 Further understanding of challenges

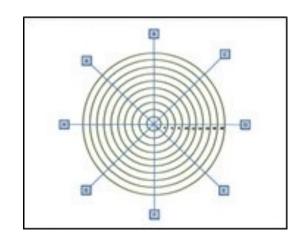
The guidelines are intended for use by international audience

Cannot (and should not) be changed, BUT strategies need to change

Checklist to Assess Organisational Readiness for Implementation ('CARI')



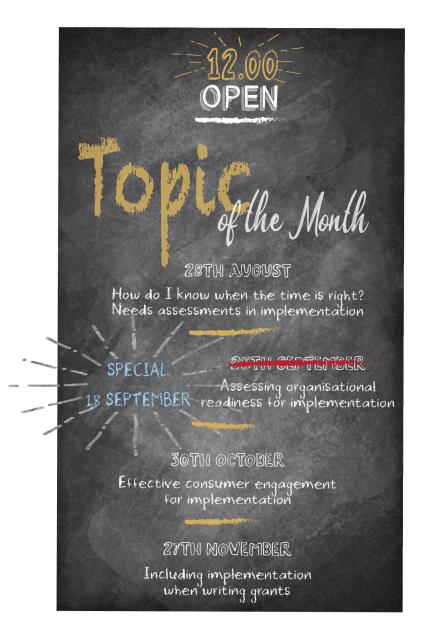
	ecklist to Assess Readiness for	Not even close	Some way to go	Nearly there	We're there
Implementation (CARI)		1	2	3	4
Α.	SYSTEM CAPACITY				
To w	hat extent do you think:				
A1.	The service funder (i.e., MCYS) recognizes the importance of EIP.				
A2.	The service funder accepts that implementation of EIPs will necessarily affect service provision (e.g., could increase waitlist for service).				
A3.	The service funder and/or administrator recognize that EIP implementation may require additional expenditures, requiring additional budget and/or shifting along budget lines.				
A4.	Technical assistance (e.g., EIP training, coaching, ongoing support) is available for the EIP(s) being implemented.				
A5.	All stakeholders having a role to play have been consulted about their views on the EIP implementation.				
	Sub-Totals:				
	Total for A:				



CARI - Checklist for Assessing Readiness for Implementation -BARWICK (melaniebarwick.com)

Completed by all in the **stakeholder group***

- * Is usually fluid, dynamic membership changes through the project
- * Some constants
- * KEY stakeholders can identify who should be present and when





Next session 18th September



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