Eight characteristics of rigorous multilevel implementation research: a step-by-step guide

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Our overarching premise:

Given the multilevel nature of healthcare and public health service delivery, **we propose that implementation researchers should always *start* with the default assumption that their research design will need to address multilevel context** and related methodological issues, *moving away* from this assumption only after confirming that all the methodological decisions made place the study design completely in "single-level" research territory.

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Eight characteristics of rigorous multilevel implementation research: a step-by-step guide

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Abstract

Background Although healthcare is delivered in inherently multilevel contexts, implementation science has no widely endorsed methodological standards defining the characteristics of rigorous, multilevel implementation research. We identify and describe eight characteristics of high-quality, multilevel implementation research to encourage discussion, spur debate, and guide decision-making around study design and methodological issues.

Recommendations Implementation researchers who conduct rigorous multilevel implementation research demonstrate the following eight characteristics. First, they map and operationalize the specific multilevel context for defined populations and settings. Second, they define and state the level of each construct under study. Third, they describe how constructs relate to each other within and across levels. Fourth, they specify the temporal scope of each phenomenon at each relevant level. Fifth, they align measurement choices and construction of analytic variables with the levels of theories selected (and hypotheses generated, if applicable). Sixth, they use a sampling strategy consistent with the selected theories or research objectives and sufficiently large and variable to examine relationships at requisite levels. Seventh, they align analytic approaches with the chosen theories (and hypotheses, if applicable), ensuring that they account for measurement dependencies and nested data structures. Eighth, they ensure inferences are made at the appropriate level. To guide implementation researchers and encourage debate, we present the rationale for each characteristic, actionable recommendations for operationalizing the characteristics in implementation research, a range of examples, and references to make the characteristics more usable. Our recommendations apply to all types of multilevel implementation study designs and approaches, including randomized trials, quantitative and qualitative observational studies, and mixed methods.

Conclusion These eight characteristics provide benchmarks for evaluating the quality and replicability of multilevel implementation research and promote a common language and reference points. This, in turn, facilitates knowledge generation across diverse multilevel settings and ensures that implementation research is consistent with (and appropriately leverages) what has already been learned in allied multilevel sciences. When a shared and integrated description of what constitutes rigor is defined and broadly communicated, implementation science is better positioned to innovate both methodologically and theoretically.

Keywords Multilevel, Research methods, Research reporting, Guideline, Research best practices

†Rebecca Lengnick-Hall and Nathaniel J. Williams contributed equally to this work.

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The predicament of the implementation scientist interested in conducting multilevel research

Goals for our presentation

1. Introduce you to this paper and how it came about
2. Provide a high-level review of the eight characteristics
3. Hurt your brain (just a little)
4. Whet your appetite and help you feel supported in pursuing more

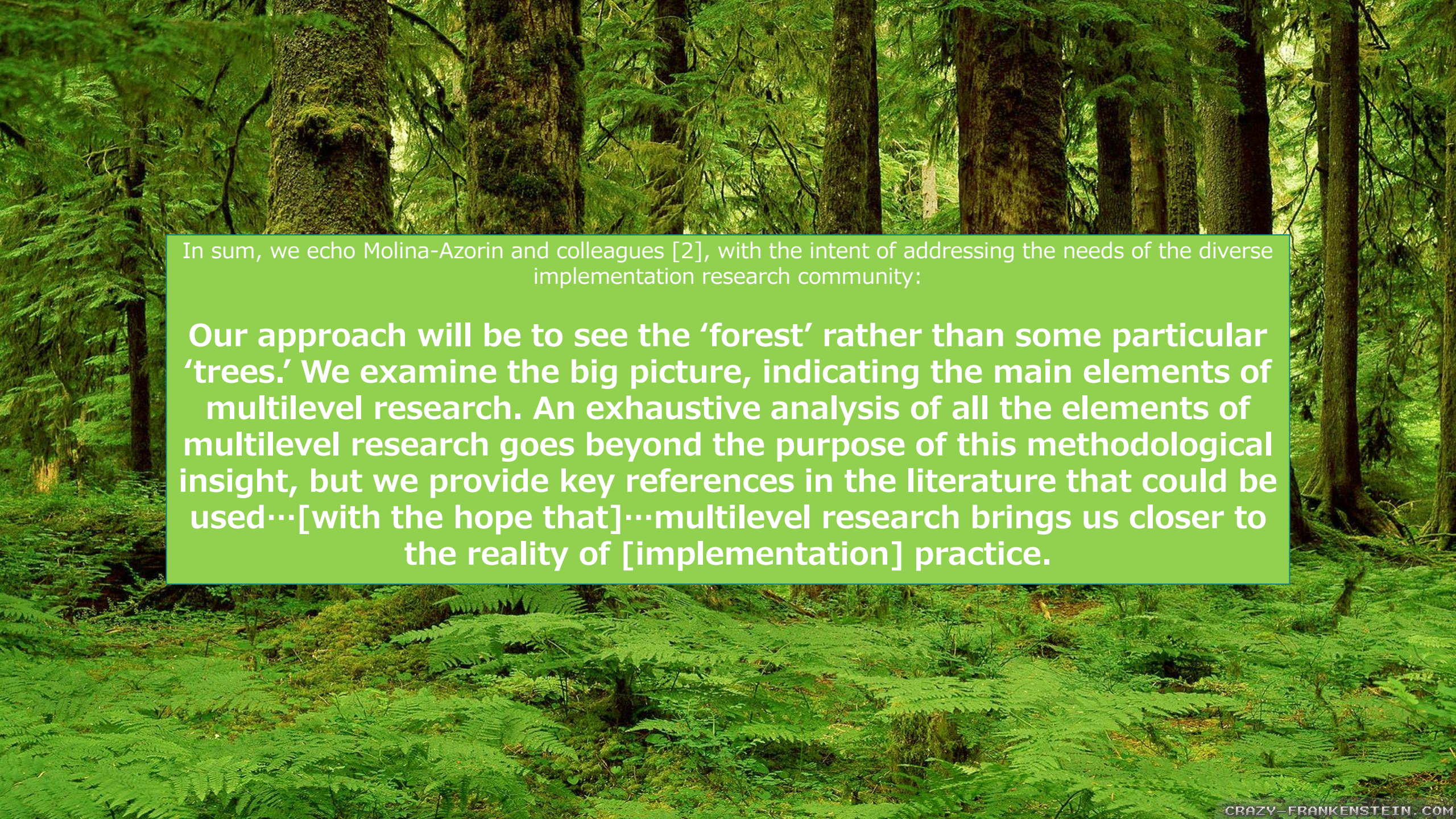
Eight characteristics of rigorous multilevel implementation research: a step-by-step guide

WHAT THIS PAPER CAN DO

- Raise your awareness about the complexities (and fun?) of conducting multilevel implementation research
- Give you some core building blocks (the 8 characteristics) that you can pursue more deeply
- Get you thinking about both quantitative and qualitative considerations
- Translate existing literature with imp sci-specific examples and applications

WHAT THIS PAPER CAN'T DO

- Discuss and summarize every important issue you will encounter when you do multilevel implementation research
- Give detailed technical quantitative or qualitative methodological guidance on any specific topic
- Tell you what levels or constructs are most important for your project

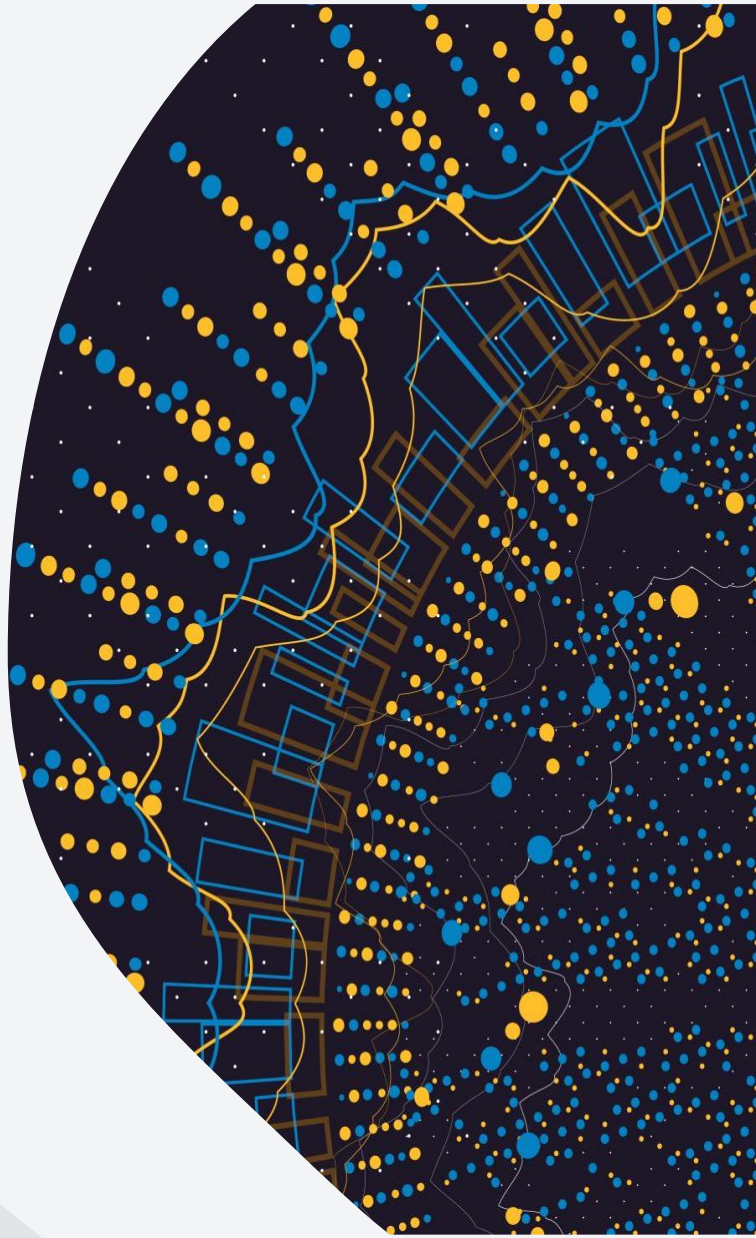


In sum, we echo Molina-Azorin and colleagues [2], with the intent of addressing the needs of the diverse implementation research community:

Our approach will be to see the ‘forest’ rather than some particular ‘trees.’ We examine the big picture, indicating the main elements of multilevel research. An exhaustive analysis of all the elements of multilevel research goes beyond the purpose of this methodological insight, but we provide key references in the literature that could be used…[with the hope that]…multilevel research brings us closer to the reality of [implementation] practice.

To conduct rigorous, high-quality multilevel implementation research…

1. Map and operationalize the specific multilevel context for defined populations and settings.
2. Define and state the level of each construct under study.
3. Describe how constructs relate to each other within and across levels.
4. Specify the temporal scope of each phenomenon at each relevant level.
5. Align measurement choices and construction of analytic variables with the levels of theories selected (and hypotheses generated, if applicable).
6. Use a sampling strategy consistent with the selected theories or research objectives and sufficiently large and variable to examine relationships at requisite levels.
7. Align analytic approaches with the chosen theories (and hypotheses, if applicable), ensuring that they account for measurement dependencies and nested data structures.
8. Ensure inferences are made at the appropriate level.



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How we organized the material in this paper

In the text, we provide:

- Brief rationale for why we decided this characteristic was important and necessary
- Concrete action steps (“our recommendation for implementation researchers” section)

Each characteristic also has an Additional File with:

- Implementation research-specific examples that apply the high-level concepts we introduce in the text
- Practical considerations
- Prompts to use to spur discussion with your research team as you work through this material
- Additional selected references specific to the issues discussed in that characteristic
- Considerations for both quantitative and qualitative methods

We also provide:

- A glossary of terms
- A summary table of our characteristics that can be used for both planning and evaluating multilevel implementation projects
- A real example that illustrates all 8 characteristics (ASPIRE trial in Additional File 9)

Map and operationalize the specific multilevel context for defined populations and settings

Characteristic 1

Characteristic 1: Map and operationalize the specific multilevel context for defined populations and settings

---

What do we mean in plain language?

Comprehensively think about: (1) what layers of context are important for your implementation research question (2) what they look like in your study.

Why is it important?

Not thinking through and acknowledging relevant levels can lead to blind spots in your analysis and interpretation of results.

Where can you start?

Visually map out the contextual levels you are thinking about (frameworks like CFIR & EPIS can help!). See Table 2 in the paper.

Comprehensively think about: (1) what layers of context are important for your implementation research question (2) what they look like in your study.

Phase: Early implementation

EPIS domain – Outer Context Level: State	**EPIS Construct**	**What it looks like in my study**
	Service Environment	State-level Office of Mental Health, statewide implementation processes
	Funding	Managed Care Plans
	Interorganizational environment	Academic partner + EBP developer + agencies implementing a particular EBP
		Office of Mental Health + payor (managed care plans) + implementing agencies
Level: Agency **EPIS domain – Inner Context** Level: Individual clinicians and leaders	**EPIS Construct**	**What it looks like in my study**
	Organizational characteristics	Infrastructure to support EBP trainings
	Leadership	Agency leadership – communication and diffusion of information re: EBP and implementation activities
	Provider characteristics	Fit of EBP with clinician characteristics
EPIS domain- Innovation Factors	**EPIS Construct**	**What it looks like in my study**
	EBP developers	Entities involved in EBP development, training, certification – expectations for and formalization re: data collection, fidelity monitoring
	EBP characteristics	How structured/manualized EBP is; infrastructure requirements for training and implementation
EPIS domain- Bridging factors	**EPIS Construct**	**What it looks like in my study**
		Academic partnership *(relational type of bridging factor)*
		Contract to pay for EBP training across agencies in the state *(formal arrangement type of bridging factor)*

Additional File teaser!
Prompts to use with your research team to make a map of contextual levels

Prompts to consider when creating your own map of contextual levels:

When identifying and justifying which levels and units (external to the organization) could be relevant to the study:

□ Will environmental influences affect lower-level units (e.g., within the organization)? How will we account for these influences in our analysis and inferences?

□ What sources of theory and evidence support our prioritization of outer context levels and units? How will we report this information?

When identifying and justifying which hierarchically nested intra-organizational levels and units to include in the study:

□ What theoretical or practical basis is there for specifying the intra-organizational levels and units in our study?

□ Who in the organization should we consult to identify the most appropriate and relevant levels and units?

□ Are there any organizational records (e.g., organizational charts) we could draw upon?

□ Do we need to address the presence of informal structures (e.g., informal social groups) in the organization that may affect our implementation research questions? If so, how will we identify those structures and address their influence?

Define and state the level of each construct under study

Characteristic 2

Characteristic 2: Define and state the level of each construct under study

---

What do we mean in plain language?

Figure out: (1) what levels you are going to deal with in your study, (2) what constructs you are going to consider for each level, (3) how you are going to define each construct for your study.

Why is it important?

It provides the basis for the accurate: construction of measures (Characteristic 5), treatment of analytic variables (Characteristic 7), appropriate interpretation of results (Characteristic 8).

Where can you start?

For each construct you are considering: (1) Define it (2) Identify the level (3)Provide an explanation or “mini theory” for the level.

Construct: Organizational culture

- Define its substantive meaning

"A pattern of shared basic assumptions learned by a group as it solved its problems of external adaptation and internal integration, which has worked well enough to be considered valid and, therefore, to be taught to new members as the correct way to perceive, think, and feel in relation to those problems" (Schein pg. 18).

- Identify the level at which it resides in my study

Hospital level (organizational culture is a characteristics of the hospital)

- Provide an explanation or "mini theory" that clarifies why organizational culture is assigned to the hospital level

[Drawing upon Schein's theorizing…] Medical providers work together, observe each other, and learn from each other. They see how people react to their own behavior and the behavior of their colleagues. They notice what policies, goals, and organizational processes are formalized and enforced.

Through this, medical providers develop a shared understanding of what the norms and values of working at this hospital are.

Culture at the hospital level 'emerges' from these individual provider level experiences and behaviors.

Additional File teaser!

ASPIRE trial example

Table A2. Construct definitions and levels in the ASPIRE trial.

Construct	Substantive Definition	Level/ Population Unit	Theoretical rationale for level
Implementation strategy condition	This is the study's primary antecedent variable. It is defined and operationalized as covariate constrained random assignment to *Nudge* (electronic health record intervention) vs. *Nudge+* (electronic health record intervention + external facilitation).	Primary care practice	This variable occurs at the level of primary care practices because (a) randomization occurred at the level of primary care practices, and (b) the implementation strategies (modification of electronic health record and facilitation) target entire primary care practices for change.
Practice adaptive reserve	This is the study's primary (only) quantitative mediator for the analysis of mechanisms. It is defined as the collective capacity within the practice to make and sustain change in support of implementing newly introduced clinical interventions. Measured using the Practice Adaptive Reserve Scale [2], a staff-reported measure that assesses relationship infrastructure, facilitative leadership, sense-making, teamwork, work environment, and culture of learning.	Primary care practice	This variable occurs at the level of primary care practices because theory on adaptive reserve indicates it is a collective (i.e., shared) characteristic of practices, not of individual clinicians within the practices.
Reach of *S.A.F.E. Firearm*	This is the study's primary implementation outcome. It is defined and operationalized as youth-caregiver dyad's receipt or nonreceipt of *S.A.F.E. Firearm* as documented in the electronic health record.	Youth-caregiver dyad	This variable occurs at the youth-caregiver dyad because *S.A.F.E. Firearm* is designed to be delivered to individual youth and their caregivers during primary care clinical encounters.

Describe how constructs relate to each other within and across levels

Characteristic 3

Characteristic 3: Describe how constructs relate to each other within and across levels

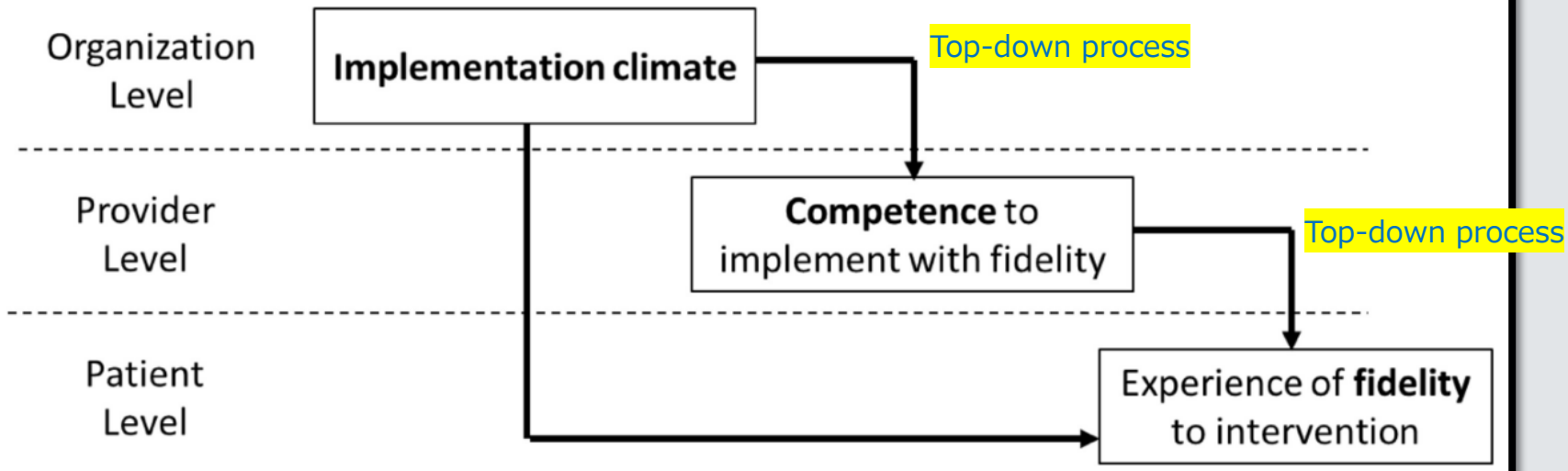
---

What do we mean in plain language?

Identify and describe top-down and bottom-up processes that explain how the levels in your study are connected to and influence each other.

Fig. 1

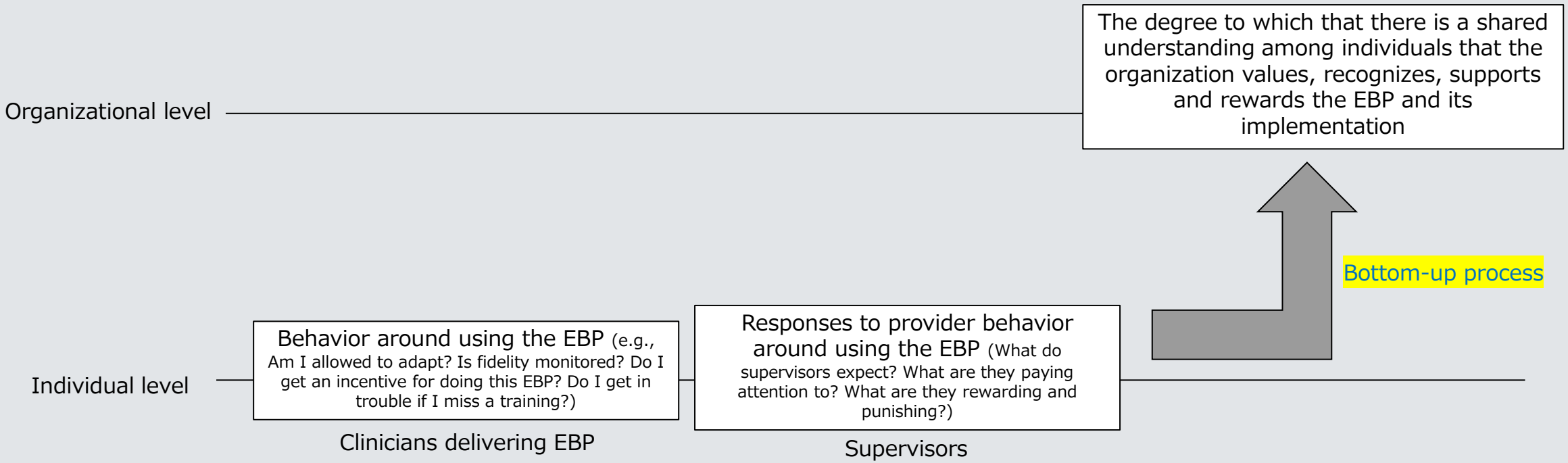
From: Eight characteristics of rigorous multilevel implementation research: a step-by-step guide



Example multilevel theoretical model.

Note: In this example, the study tests the relationships between three constructs which occur at different levels of the implementation context. The researchers hypothesize that variation in implementation climate across organizations will explain variation in provider competence to implement a focal intervention with fidelity which in turn will explain variation in the extent to which patients experience fidelity to the focal intervention during the course of treatment

Another implementation climate-focused example multilevel theoretical model



Ehrhart MG, Aarons GA, Farahnak LR. Assessing the organizational context for EBP implementation: the development and validity testing of the Implementation Climate Scale (ICS). Implement Sci. 2014 Oct 23;9:157. doi: 10.1186/s13012-014-0157-1.

Weiner BJ, Belden CM, Bergmire DM, Johnston M. The meaning and measurement of implementation climate. Implement Sci. 2011 Jul 22;6:78. doi: 10.1186/1748-5908-6-78.

Characteristic 3: Describe how constructs relate to each other within and across levels

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What do we mean in plain language?

Identify and describe top-down and bottom-up processes that explain how the levels in your study are connected to and influence each other.

Why is it important?

This is an essential step for planning your data collection and analysis.

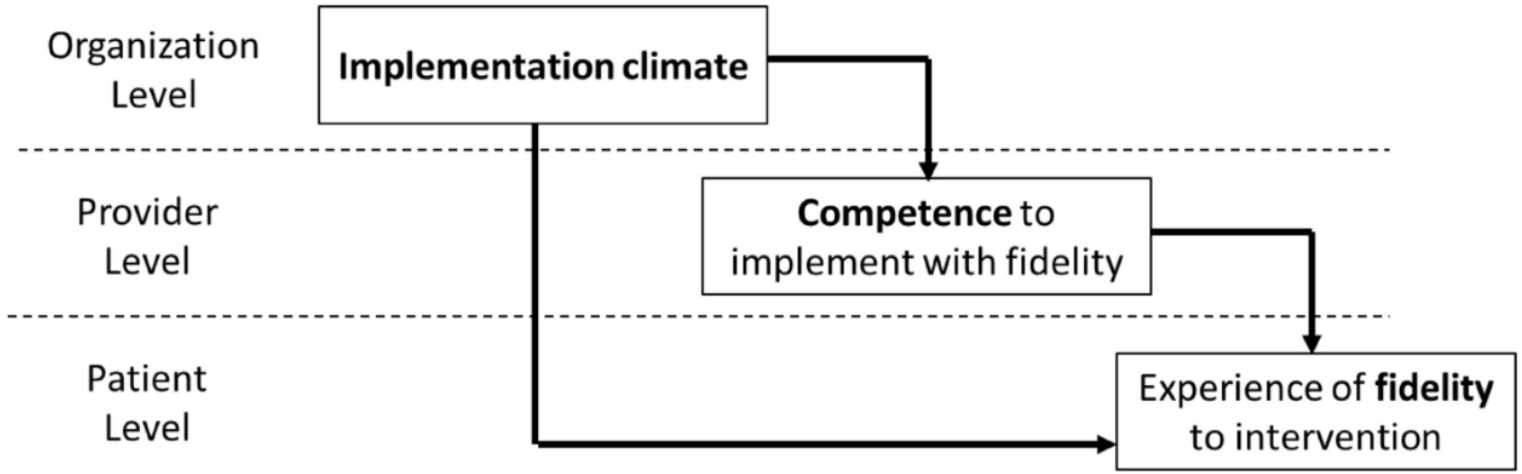
Helps you isolate testable relationships and test your assumptions about how things work.

Where can you start?

Draw out your theorizing like I just showed you!

Fig. 1

From: Eight characteristics of rigorous multilevel implementation research: a step-by-step guide



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As you visualize:

- Depict each level and what's going on at that level (constructs).
- Draw those top-down, bottom-up relationships.
- Write out what the cross-level relationships mean (articulate hypotheses if relevant).
- Use theory to explain why you chose these specific levels and cross-level relationships.

Resource reminder…we made a Glossary too!

Characteristic #3: Describe how constructs relate to each other within and across levels.

Bottom-up processes – A sequence or series of events, or actions taken, in a specific order toward a specific outcome, which begin at a lower level and terminate at a higher level. An example is increased motivation among individual clinicians within a team to use a screening tool may lead to increased leader advocacy for funding for use of the tool (in response to the groundswell of support from clinicians), which may lead to increased funding available for the tool and greater reach of the tool to more patients within the organization.

Top-down processes – A sequence or series of events, or actions taken, in a specific order toward a specific outcome, which begin at a higher level and terminate at a lower level. An example is focused organizational implementation climate increasing individual clinicians' self-efficacy to deliver an intervention with fidelity resulting in patients experiencing high-fidelity to the intervention during service interactions.

Specify the temporal scope of each phenomenon at each relevant level

Characteristic 4

Characteristic 4: Specify the temporal scope of each phenomenon at each relevant level

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What do we mean in plain language?

For each level in your study, ask yourself: How quickly can I expect to see change?

Characteristic 4: Specify the temporal scope of each phenomenon at each relevant level

- At each level… how long do I need to wait before I first measure change? How often do I need to measure things to pick up on these changes?
- How is change at this level going to match up with change at the other levels I care about? (e.g., seeing changes sooner in one level and accounting for that in measurement plan)
- Is there something expected (e.g., planned major leadership change) or unexpected (e.g., global pandemic) going on that could affect the timing and pace of change at the different levels?

Characteristic 4: Specify the temporal scope of each phenomenon at each relevant level

---

Why is it important?

People, teams, organizations and systems change at different rates. Rule of thumb in org behavior literature: lower level (e.g., individual) likely to change more quickly than higher level (e.g., organization).

Where can you start?

Look at Additional File 4 for prompts to consider when deciding and explaining the frequency and timing of measurements at different levels.

Additional File teaser!

Checklist of what to report in your research plan to help you specify the temporal scope of phenomena at different levels

Checklist of what to report in your research plan:

□ When do you expect to observe change in each relevant outcome at each relevant level (e.g., of system- or organization-level implementation strategies)?

□ How frequently and when will you measure constructs to capture these changes?

□ How will changes in outcomes at different levels align with each other in the research design? For example, how long might it take for a leadership strategy to change supervisor's behavior and what implications would that have for when we should see change in providers' fidelity and ultimately in patient outcomes?

□ What are the theoretical rationales for these choices (formal 'big T' theories or informal 'little t' theories)?

Halfway through: Let’s take a quick cuteness break!!

Align measurement choices and construction of analytic variables with the levels of theories selected (and hypotheses generated, if applicable)

Characteristic 5

Characteristic 5: Align measurement choices and construction of analytic variables with the levels of theories selected (and hypotheses generated, if applicable)

What do we mean in plain language?

Be sure that the measures and how they will be collected are consistent with the levels and theories of interest. Measurement must align with the level of theory!

Why is it important?

How questions are asked impacts how participants respond and the validity of those responses. It is hard to disentangle measurement issues from substantive findings after the fact.

Characteristic 5: Align measurement choices and construction of analytic variables with the levels of theories selected (and hypotheses generated, if applicable)

Where can you start?

For each construct in the model, review items or questions and ensure that:

- **The referent is consistent with the level of theory**
- **Participants can report on the construct**
- **You can actually aggregate individual-level data to the unit level if appropriate (and with evidence)**

3 types of unit-level constructs that come up in multilevel research

1. Global constructs
2. Shared constructs
3. Configural constructs (too nerdy to get into today)

Global constructs: originate at the unit level and represent objective, easily observable characteristics of the unit

- You do not have to rely on individuals' perceptions, experiences, attitudes, behaviors to measure global constructs
- Global constructs are a property of the unit as a whole
- There isn't within-unit variation (you can ask everyone about a global construct, and you will/should get the same answer)
- Examples: # of employees, # of clients served in x program, # of subunits in the organization, annual revenue

***Shared constructs*:** originate at the individual level but are shared across unit members

- You do have to rely on individuals' perceptions, experiences, attitudes, behaviors to measure shared
- Shared constructs describe characteristics that are common to –shared by—the members of a unit
- You have to take into account the degree to which the individuals giving you data for a shared property actually agree with each other (is it really shared or not?)
- Examples: culture, climate, organizational citizenship behavior, psychological safety

Implementation climate scale:

6 dimensions

- focus on EBP
- educational support for EBP
- recognition for EBP
- rewards for EBP
- selection for EBP
- selection for openness.

5-point scale: 0 (‘not at all’) to 4 (‘to a very great extent’)

Ehrhart, M.G., Aarons, G.A. & Farahnak, L.R. Assessing the organizational context for EBP implementation: the development and validity testing of the Implementation Climate Scale (ICS). *Implementation Sci* 9, 157 (2014). https://doi.org/10.1186/s13012-014-0157-1

Org average: 3.7

Individual mean scores for implementation climate in yellow

What do you notice?

- Are the scores hanging together? (Yes! And the are on the positive end.)

- Because of the lack of variation among these individual scores, we can infer that there is in fact a shared experience going on here.

- Generally, this individuals in this organization are experiencing a positive implementation climate.

Org average: 1.3

Individual mean scores for implementation climate in yellow

What do you notice?

- Are the scores hanging together? (Yes! And the are on the negative end.)

- Because of the lack of variation among these individual scores, we can infer that there is in fact a shared experience going on here.

- Generally, this individuals in this organization are experiencing a negative implementation climate.

Org average: 2.5

Individual mean scores for implementation climate in yellow

What do you notice?

- Are the scores hanging together? (No!)

- Because of the variation among these individual scores, we cannot infer that there is in fact a shared experience going on here.

- Generally, individuals in this team are all over the place. There isn't really a organization level implementation climate, positive or negative.

Why does this matter for implementation research and practice?

People agree…
implementation climate in this org stinks

People are all over the place about what the organization expects, rewards, etc.

Two very different problems and potential implementation strategy solutions!

Characteristic 5: Align measurement choices and construction of analytic variables with the levels of theories selected (and hypotheses generated, if applicable)

Avoid misalignment!

- If your theoretical set-up involves characteristics at a team level, for example, make sure you are measuring team level constructs and referencing team level actors in your instruments (not just saying or measuring ‘climate’ or ‘leader’ broadly).
- Avoid using individually referenced items to measure a theoretically shared organizational characteristic (rather than “I am expected” → “Clinicians in this hospital are expected”)
- Do not treat shared constructs like global constructs (ex: asking one dude to report on implementation climate for the whole organization).

Can these individuals even speak to a shared property of the (org, team, group)?

Do they actually work together?

Are they actually around each other and interacting during EBP implementation?

Are there other ways of grouping people that are more meaningful in this setting?

Again, this matters for identifying the best target for our implementation strategies/ not employing strategies that aren’t addressing the real problem!

Use a sampling strategy consistent with the selected theories or research objectives and sufficiently large and variable to examine relationships at requisite levels

Characteristic 6

Characteristic 6: Use a sampling strategy consistent with the selected theories or research objectives and sufficiently large and variable to examine relationships at requisite levels

---

What do we mean in plain language?

Need to make sure that the sample for the study is an adequate size at all levels of interest. Need to also pay attention to issues of variability and representativeness (*quant) at each level.

Why is it important?

Implementation research often considers interventions and outcomes that cut across levels. Poorly planned sampling strategies can have disastrous results for research findings.

Characteristic 6: Use a sampling strategy consistent with the selected theories or research objectives and sufficiently large and variable to examine relationships at requisite levels

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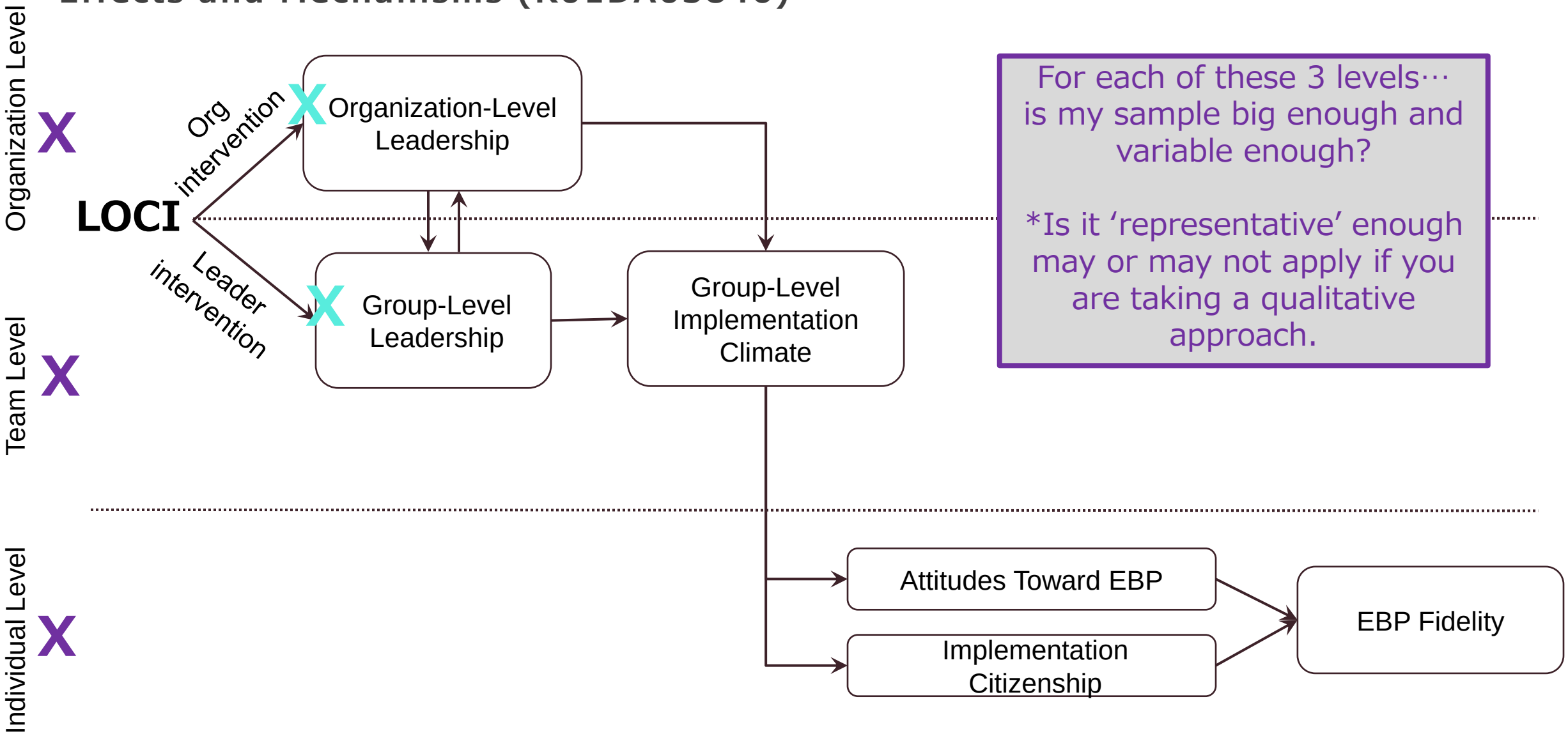
Where can you start?

Build on other characteristics and ensure that sampling choices align with the constructs and relationships being studied, as well as the measurement choices.

See Addition File 6 for prompts to consider when designing your multilevel study and checklist for reporting sampling plan.

Leadership and Organizational Change for Implementation (LOCI) Proposed Effects and Mechanisms (R01DA03846)



Aarons, G. A., Ehrhart, M. G., Moullin, J. C., Torres, E. M., & Green, A. E. (2017). Testing the leadership and organizational change for implementation (LOCI) intervention in substance abuse treatment: a cluster randomized trial study protocol. *Implementation Science*, *12:*29.

Align analytic approaches with the chosen theories (and hypotheses, if applicable), ensuring that they account for measurement dependencies and nested data structures

Characteristic 7

Characteristic 7: Align analytic approaches with the chosen theories (and hypotheses, if applicable), ensuring that they account for measurement dependencies and nested data structures

---

What do we mean in plain language?

There is no single best way to analyze data from multilevel implementation studies. An anchor point to ask yourself is does my analytic approach fit all of the things I figured out and set up in the previous characteristics?

Why is it important?

A lack of alignment between proposed theories or hypotheses and how the data are analyzed can lead to erroneous conclusions.

Characteristic 7: Align analytic approaches with the chosen theories (and hypotheses, if applicable), ensuring that they account for measurement dependencies and nested data structures

---

Where can you start?

Clarity on levels of theory, constructs, and measurement should make analyses more straightforward.

Select analyses that account for the dependencies in hierarchically sampled observations (or make a strong case they aren't necessary).

Be clear in write-up on what decisions were made and why.

What do you mean by ‘nested’?

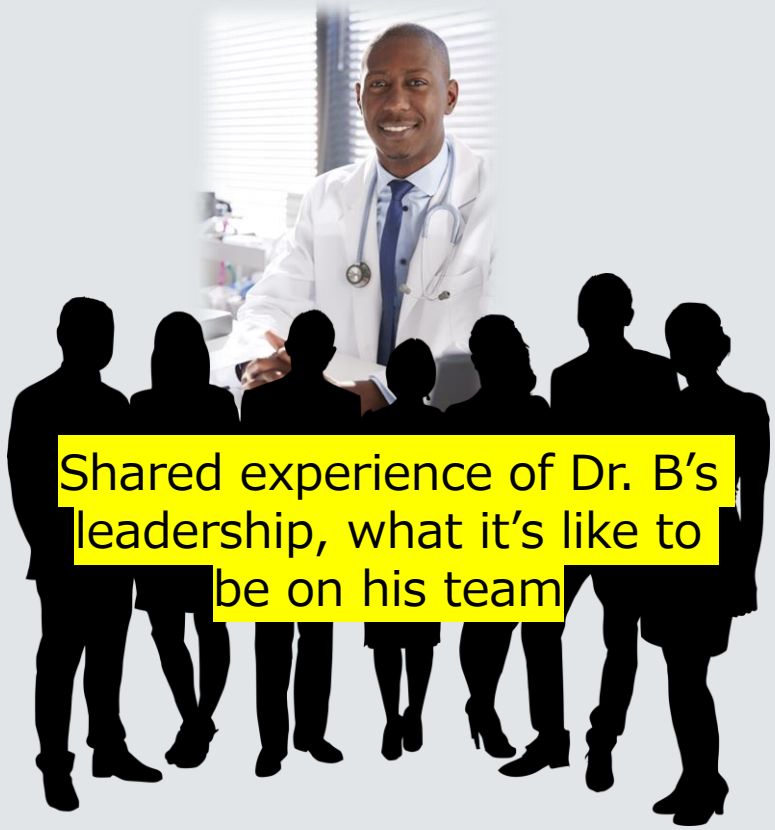
Hospital unit

Surgical Oncology Department

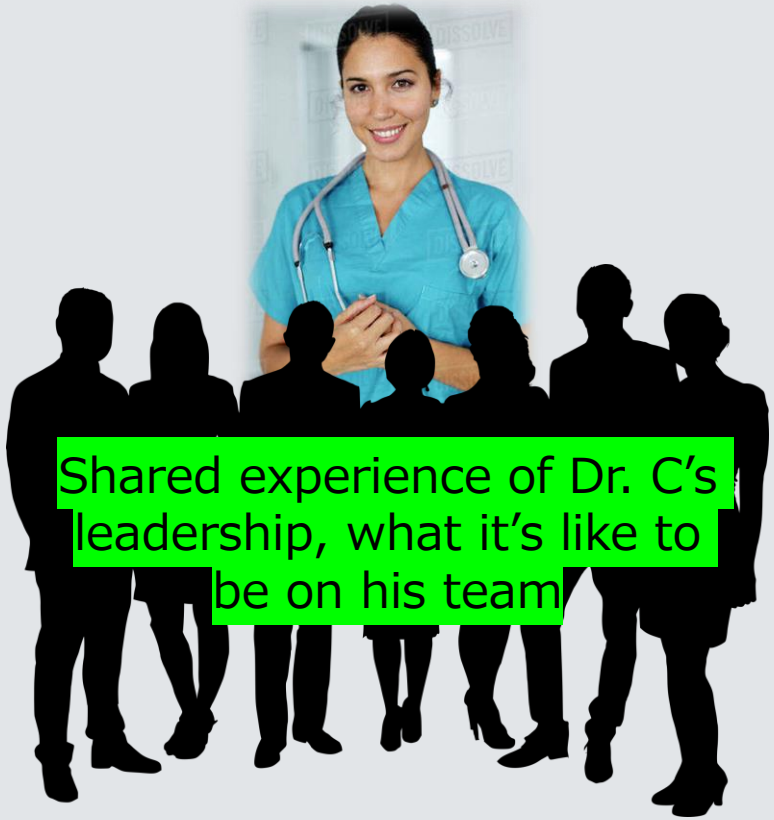
Providers

Patients

What do you mean by ‘measurement dependencies’?



‘Dependence among the observation and measurements’ that you have to account for when there is nesting



Ensure inferences are made at the appropriate level

Characteristic 8

Characteristic 8: Ensure inferences are made at the appropriate level

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What do we mean in plain language?

Ultimately, we want to reach conclusions about our findings and address their implications for practice – we need to make sure those implications reflect what we actually found.

Why is it important?

If we infer effects at the wrong level, we can inadvertently limit or misdirect the advancement of implementation science, as well as create bad policies, use implementation strategies sloppily, and waste resources.

Characteristic 8: Ensure inferences are made at the appropriate level

---

Where can you start?

Follow the suggestions from the first seven characteristics! Doing so should make the level of the inferences we make clear.

Take care in writing up the results to ensure that readers understand what our findings mean and how to properly interpret them.

Atomistic fallacy: You have cool & promising individual-level data and think that you can then apply it to the team, org or some higher level.

Ex: Financial incentives given to clinicians improved EBP use.
I want to increase adoption at the agency-level, let's just give the agency money!

Ecological fallacy: You have cool & promising team/org (or some higher) level data and think that you can then apply it to individuals.

Ex: Our organization is high in readiness (operationalized as having the resources and infrastructure in place to implement) – this is positively related to feasibility at the organizational level.

My individual clinicians indicate high individual-level readiness…this must mean that EBP implementation is totally feasible for them too!

Low hanging fruit for the field

Be precise in language and descriptions!

- Imprecise: “Higher readiness for change was associated higher fidelity”
- Precise: “Higher clinic-level readiness for change was associated with higher provider-level fidelity”

Wrap-Up

Take Away points

- **Multilevel implementation research is deceptively hard.**
- **You can’t measure and deal with everything in a single study, so you have to have good reasons for the levels and relationships you choose to focus on.**
- **Specifying and reporting this reasoning (what levels and why) is critical to the rigor of implementation research.**
- **Conducting rigorous multilevel research is an important area for growth in the field in terms of how we are trained, who is on our research teams, and what existing literature and thinking we draw upon when conceptualizing and executing our multilevel studies.**

Thank you!

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