

# Designing Clinical Addiction Research

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Fellow Immersion Training in Addiction Medicine  
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# Goals and Objectives

**Goal:** General principles of designing feasible clinical addiction research

## **Learning objectives**

1. Be able to specify and refine each component of a research question
2. Define community-based participatory research and implementation science
3. Review the top ten considerations for designing and implementing clinical research as a fellow
4. Share ways to incorporate addictions questions into other studies

# Quantitative clinical research question: PICOT

- Key for hypothesis testing

- **P = Population**

- Who are you studying? (e.g. people who use substances)

- **I/E = Intervention or exposure**

- Type of substance use, type of treatment?

- **C = Comparison or Control group**

- **O = Outcomes**

- Death, overdose, substance use, medical outcome, QOL?

- **T = Timing**

- Cross-sectional vs. longitudinal

# Clinical research question: PICOT Exercise

- Among a [Population], is an [Intervention/Exposure] compared to a [Comparison] associated with an [Outcome] when measured at [Time] intervals?
- Example from fellowship:
- Among **general medical service inpatients**, is having a **drug use disorder diagnosis** compared to not having a **drug use disorder diagnosis** associated with the **rate of acute care hospitalization** when measured at **30 days**?
- Answer: Medical patients with drug use disorder diagnoses have higher rates of recurrent acute care hospital utilization than those without drug use disorder diagnoses.

# Qualitative clinical research question: PICO

- Key for exploring meaning and understanding context

- **P = Population**

- Who are you studying? (e.g., people who inject drugs alone)

- **I = Phenomena of Interest**

- What is the main focus/experience? (e.g., reasons for injecting alone, decision-making)

- **C = Context**

- Where/when does this occur? (e.g., restrooms, at home alone)

# Qualitative Research: Exploring emerging phenomena

**Study Aim:** *The overall aim of this study is to explore experiences, beliefs, and attitudes of PWUIO who have attempted self-treatment with buprenorphine in an era of non-prescribed fentanyl and fentanyl analogue use.*

“Do you notice any differences in how well the Suboxone works for heroin versus how it works for fentanyl?”

A: Yes, for me it sends me into precipitated withdrawals every f\*ing time that I try to get off of fentanyl. Then I have these Sub doctors telling me that it's not real and it's like, go f\*ing ask the people that are buying it off the streets. It is real! I waited 80 hours. I was in a detox and after 80 hours they gave me a Suboxone and it still put me into precipitated.”

Silverstein SM, Daniulaityte R, Martins SS, Miller SC, Carlson RG.

"Everything is not right anymore": Buprenorphine experiences in an era of illicit fentanyl. *Int J Drug Policy*. 2019 Dec;74:76-83.

**Quantitative -Does injecting alone  
increase overdose risk?**

**Qualitative - What are people's experiences  
of and reasons for injecting alone?**

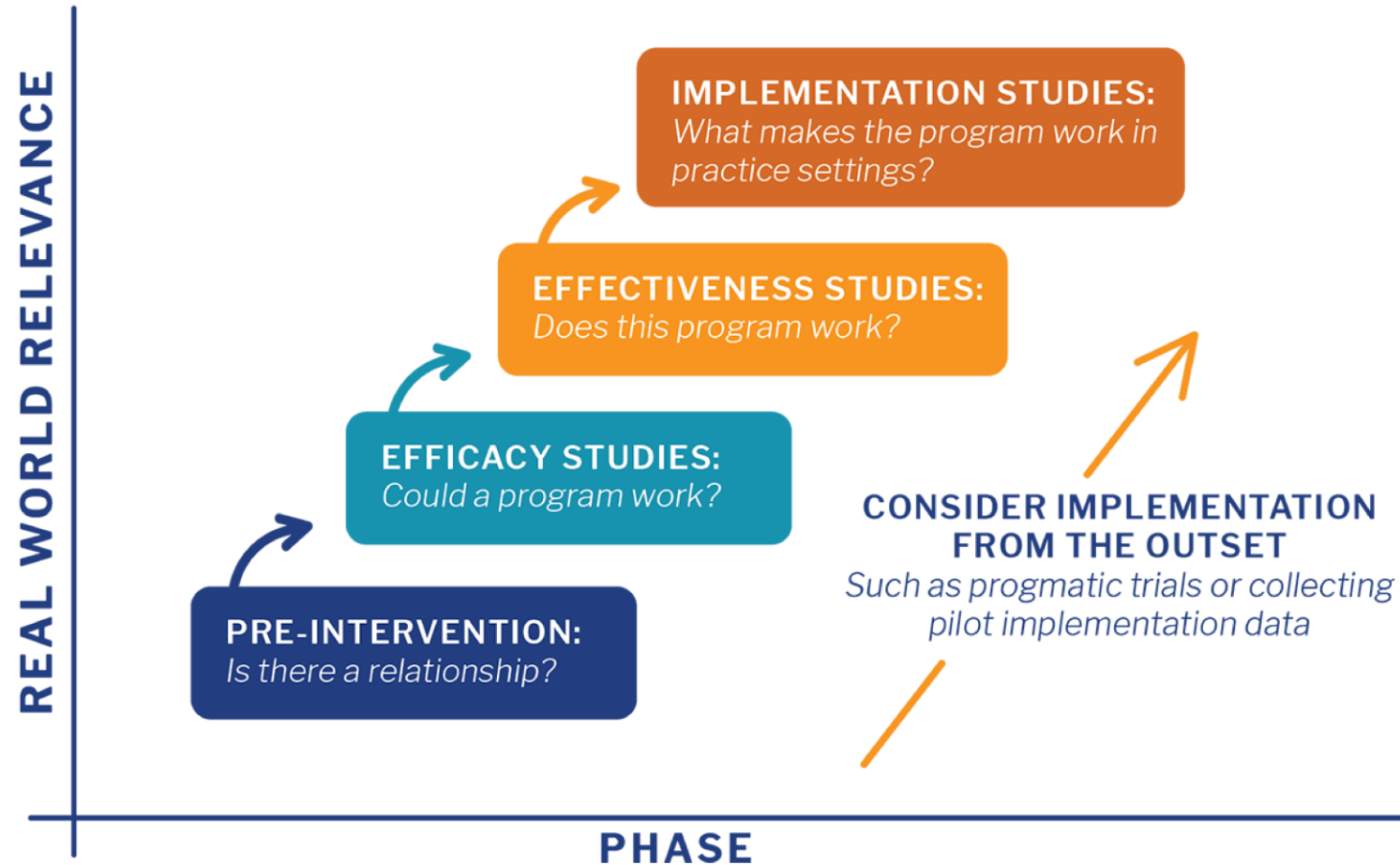
|                              |                                             |
|------------------------------|---------------------------------------------|
| Tests hypotheses             | Explores phenomena<br>Hypothesis generating |
| Measures relationships       | Describes experiences/meanings              |
| Seeks causation/association  | Seeks understanding/context                 |
| "Does it work?"              | "How does it work?" "What is it like?"      |
| Generalizable to populations | Rich detail in specific contexts            |
| Statistical significance     | Thematic saturation                         |

# Review OneDrive templates: Analytic Plan and Project Development Plan

# Additional Study Approaches and Frameworks

- **Prevalence, Case Study, Case Series, Program Descriptions**
  - Describe what you see defining the population, exposure/ intervention, outcome and timing, without a comparison group
- **Implementation Science**
- **Community-based participatory**
- **Community Driven**
- **Cost-effectiveness**

# Implementation Science



# Implementation Science - Frameworks

## RE-AIM FRAMEWORK

Elements of the RE-AIM Framework



## Consolidated Framework for Implementation Research (CFIR) 2.0

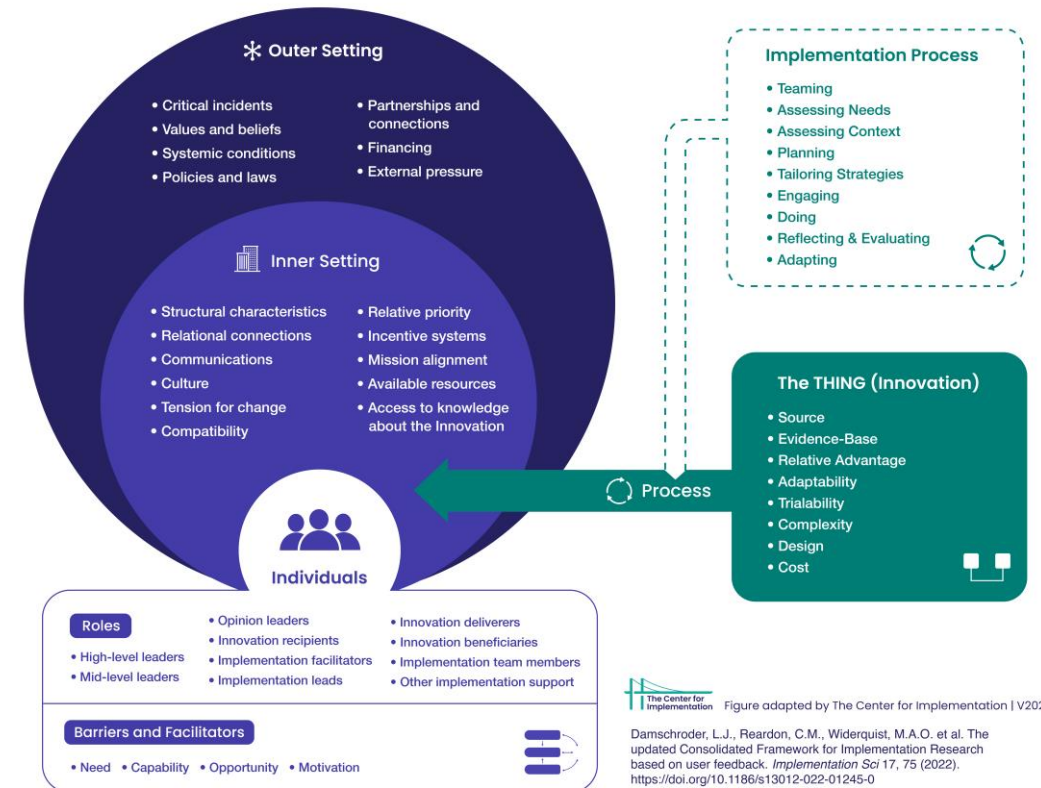
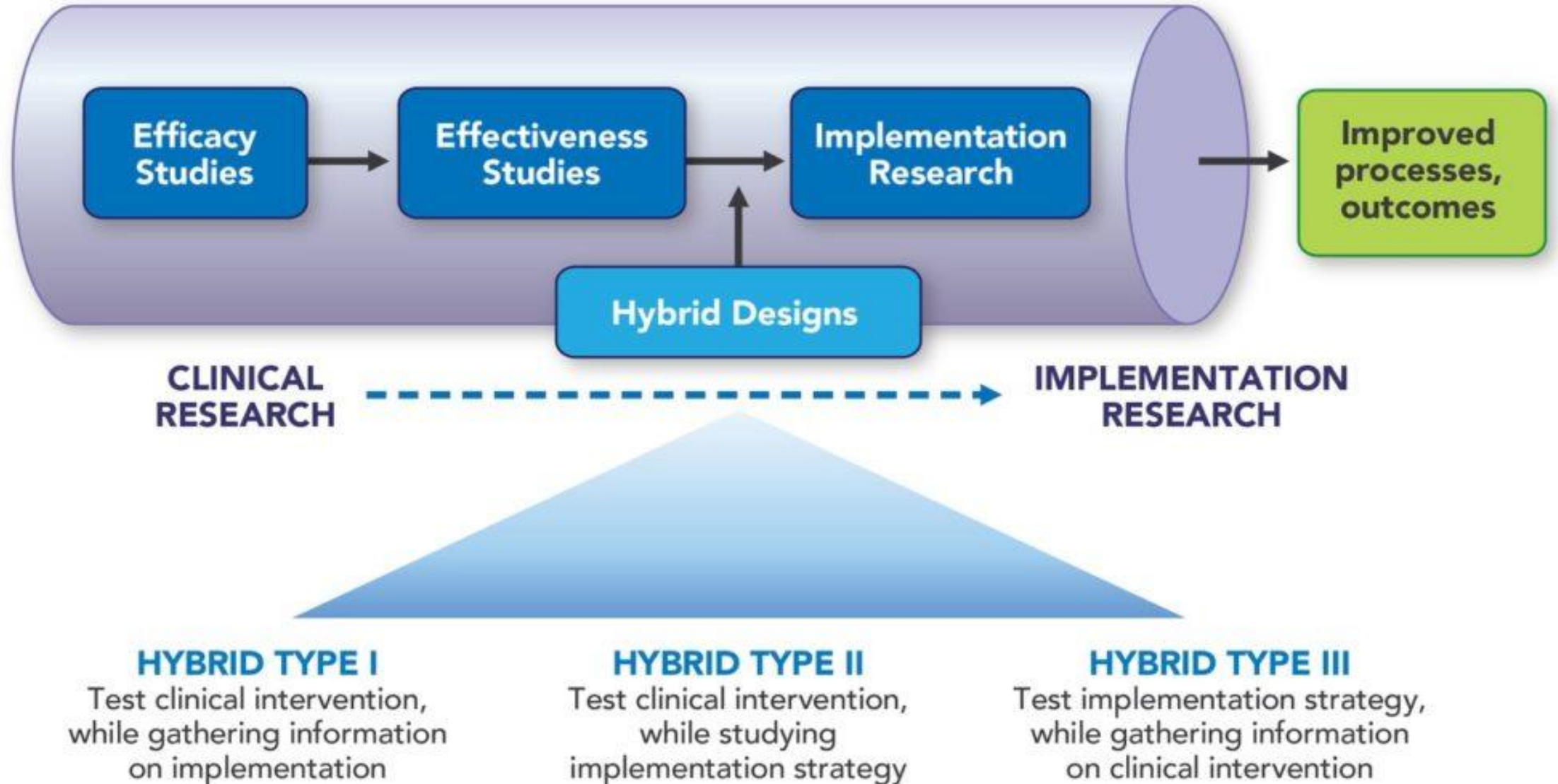
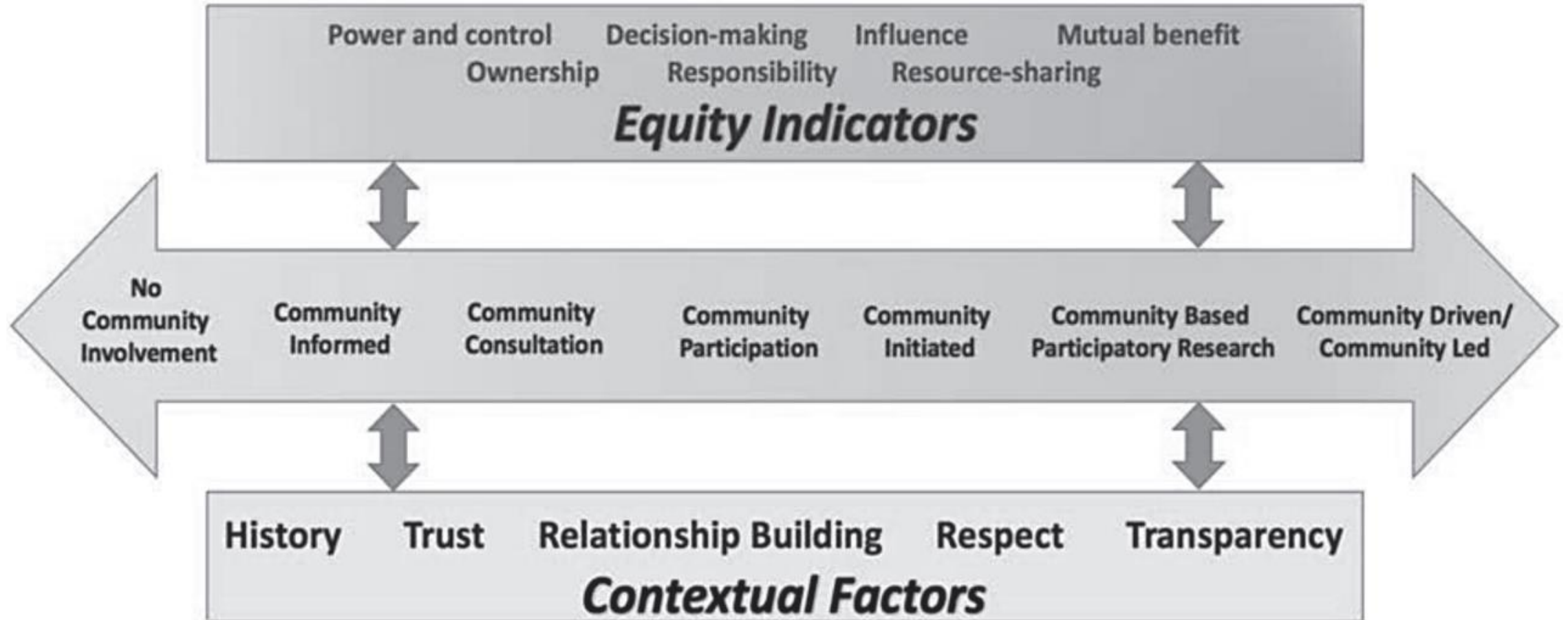


Figure adapted by The Center for Implementation | V2024.01  
 Damschroder, L.J., Reardon, C.M., Widerquist, M.A.O. et al. The updated Consolidated Framework for Implementation Research based on user feedback. *Implementation Sci* 17, 75 (2022). <https://doi.org/10.1186/s13012-022-01245-0>

# Implementation Science – Hybrid Designs



# Community-Based Participatory Research



# From Community-Based Participatory Research to Community-Driven Research

Commentary

## We are the researched, the researchers, and the discounted: The experiences of drug user activists as researchers

Caty Simon<sup>a b</sup>  , Sarah Brothers<sup>a c</sup>, Knina Strichartz<sup>a d</sup>, Abby Coulter<sup>a e</sup>, Nick Voyles<sup>a</sup>,  
Anna Herdlein<sup>a</sup>, Louise Vincent<sup>a d</sup>

We call for a shift from CBPR to Community Driven Research (CDR) in which the research supports our research questions, which are formulated in consultation with institutional researchers, rather than by institutional researchers. Academic researchers should act proactively to mediate the power imbalance between them and the directly impacted people who make up our organizations.

*Cherishresearch.org develops and disseminates health economic research to inform substance use disorder treatment policy and HCV and HIV care of people who use drugs*

# Inform real-world substance use interventions through health economic research

The Center for Health Economics of Treatment Interventions for Substance Use Disorder, HCV, and HIV (CHERISH) develops and disseminates health economic research to inform substance use disorder treatment policy and HCV and HIV care of people who use drugs.

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# Top Ten Considerations for Designing Clinical Research as a Fellow

10. Make a long list of possible research questions
9. Consider innovation (has the question been answered?)
8. Consider limitations. Avoid fatal flaws but don't get paralyzed
7. Consider a line of research
6. Consider your resources and feasibility. No one can do it alone. Get feedback  
    --**Mentor** (expertise+), biostats, data collection/management, coordination
5. Do a thorough literature review
4. Work with your IRB – a barrier and a resource
3. Implement at least two studies during a research fellowship, gain different skills
2. Find a model for your manuscript
1. Make sure you love it

# Incorporating substance use questions

- Add new measures to ongoing studies
  - E.g. Add questions about smoking fentanyl to an ongoing longitudinal cohort study
- Link substance use data to other studies
  - E.g. Link cohort to overdose death data
- Stratify or subset people who use substances
  - E.g. re-hospitalization among inpatients with and without substance use
- Address substance use impact on other medical condition outcomes
  - E.g. How does medication for opioid use disorder impact antibiotic completion?
- Study substance use in people with other medical conditions
  - E.g. Substance use among people with sleep apnea

# Validated substance use instruments

- [PhenX Toolkit – Substance and Addiction Collection](#)
- Include in your literature review a review of assessments and measures used in previous studies

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