Designing Clinical Addiction Research

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Fellow Immersion Training in Addiction Medicine
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Clinical Addiction Research & Education Unit
Grayken Center for Addiction
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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

Clinical research question: PICOT

- Key for hypothesis testing

- **P = Patient or problem**
  - Population that uses substances?
- **I/E = Intervention or exposure**
  - Type of substance use, type of treatment?
- **C = Comparison**
- **O = Outcomes**
  - Death, overdose, substance use, medical outcome, QOL?
- **T = Timing**
  - Cross-sectional vs. longitudinal

Clinical research question: PICOT Exercise

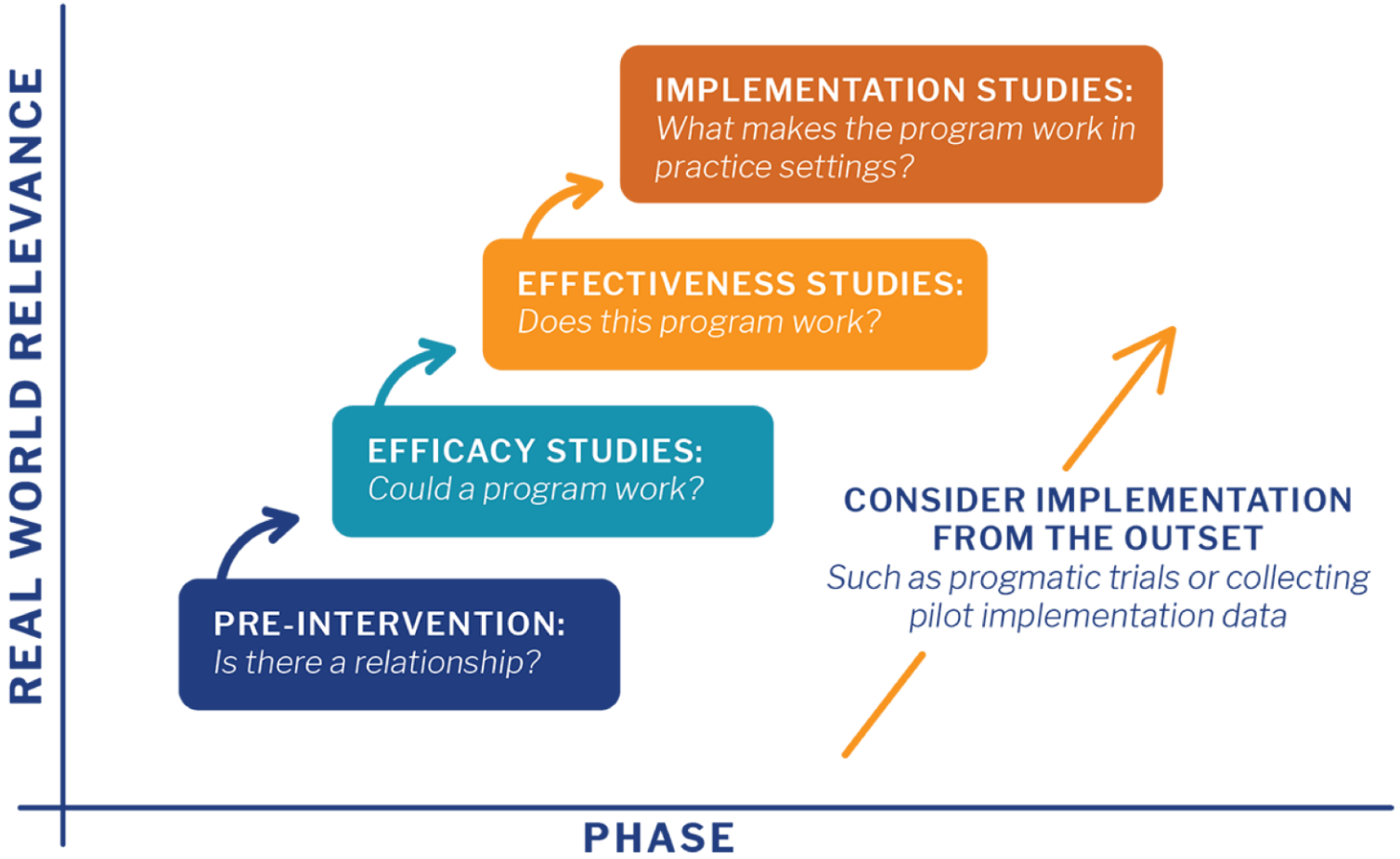
- Among a [Population], is an [Intervention/Exposure] compared to a [Comparison] associated with an [Outcome] when measured at [Time] intervals?
- Example from fellowship:
- Among **general medical service inpatients**, is having a **substance use disorder diagnosis** compared to not having **a substance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

Review OneDrive templates:
Analytic Plan and Project Development Plan

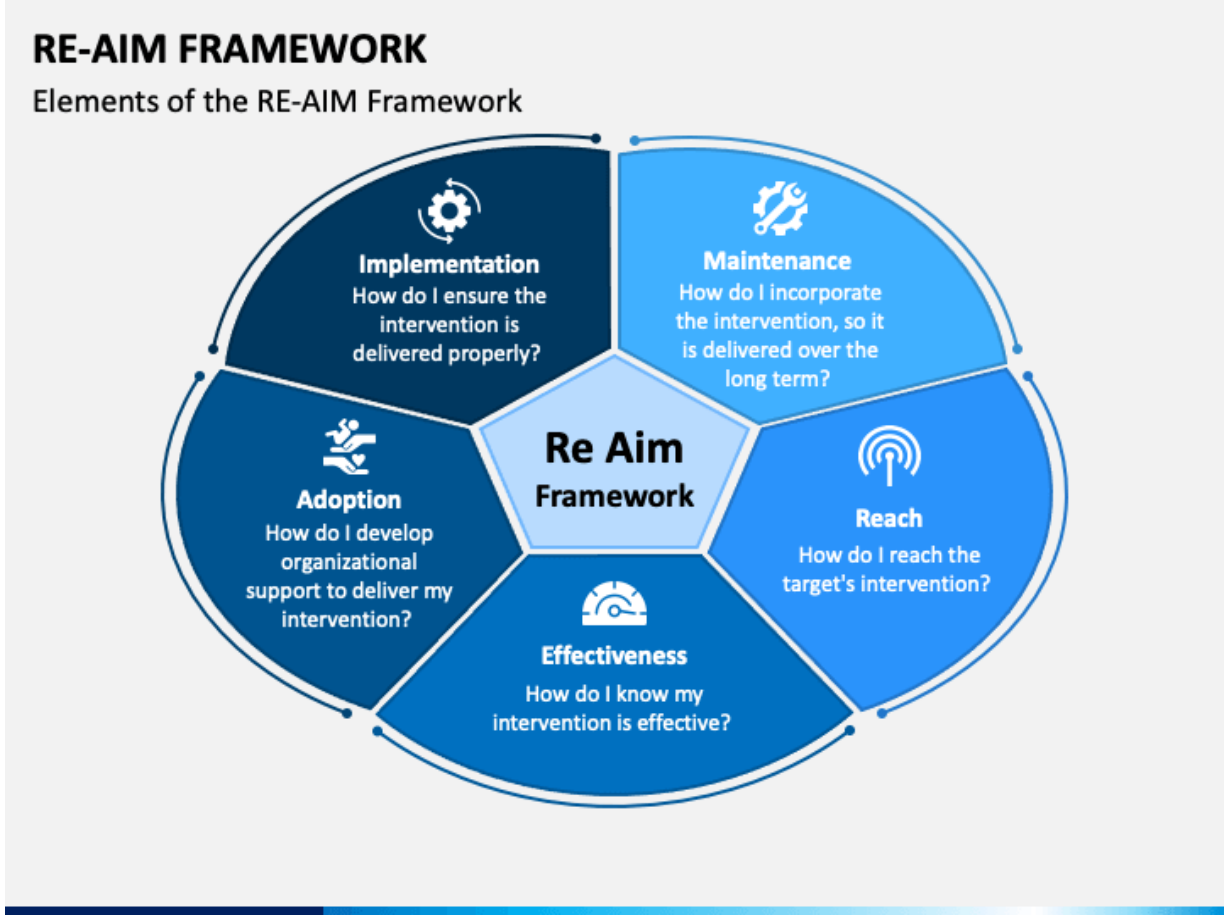
Additional Study Approaches

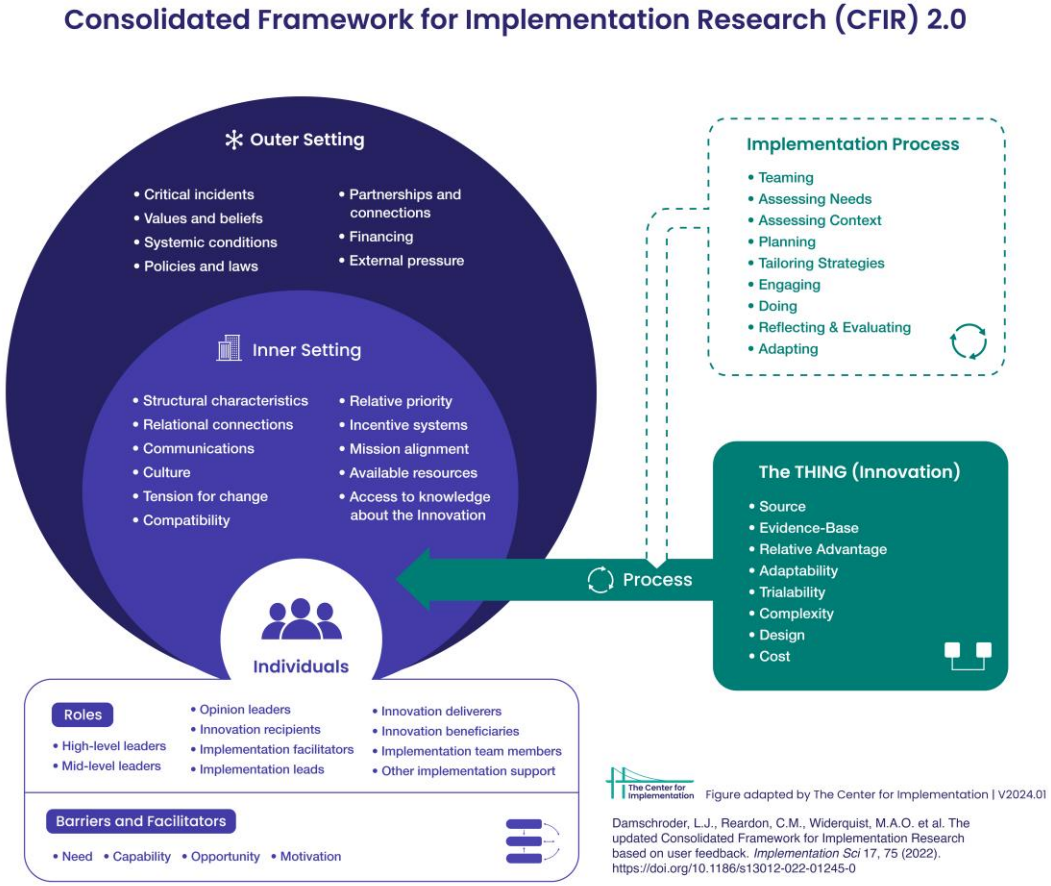
- **Qualitative Research** – Explore what should the population, exposure, exposure/intervention, comparison, or outcome be
  - -> Hypothesis generating; Intervention forming
- **Case Study, Case Series, Program Descriptions** – Describe what you see defining the population, exposure/intervention, outcome and timing, but may not have a comparison group
- **Prevalence** – How common is a condition?
- **Implementation Science**
- **Community-based participatory**
- **Community Driven**
- **Cost-effectiveness**

Implementation Science

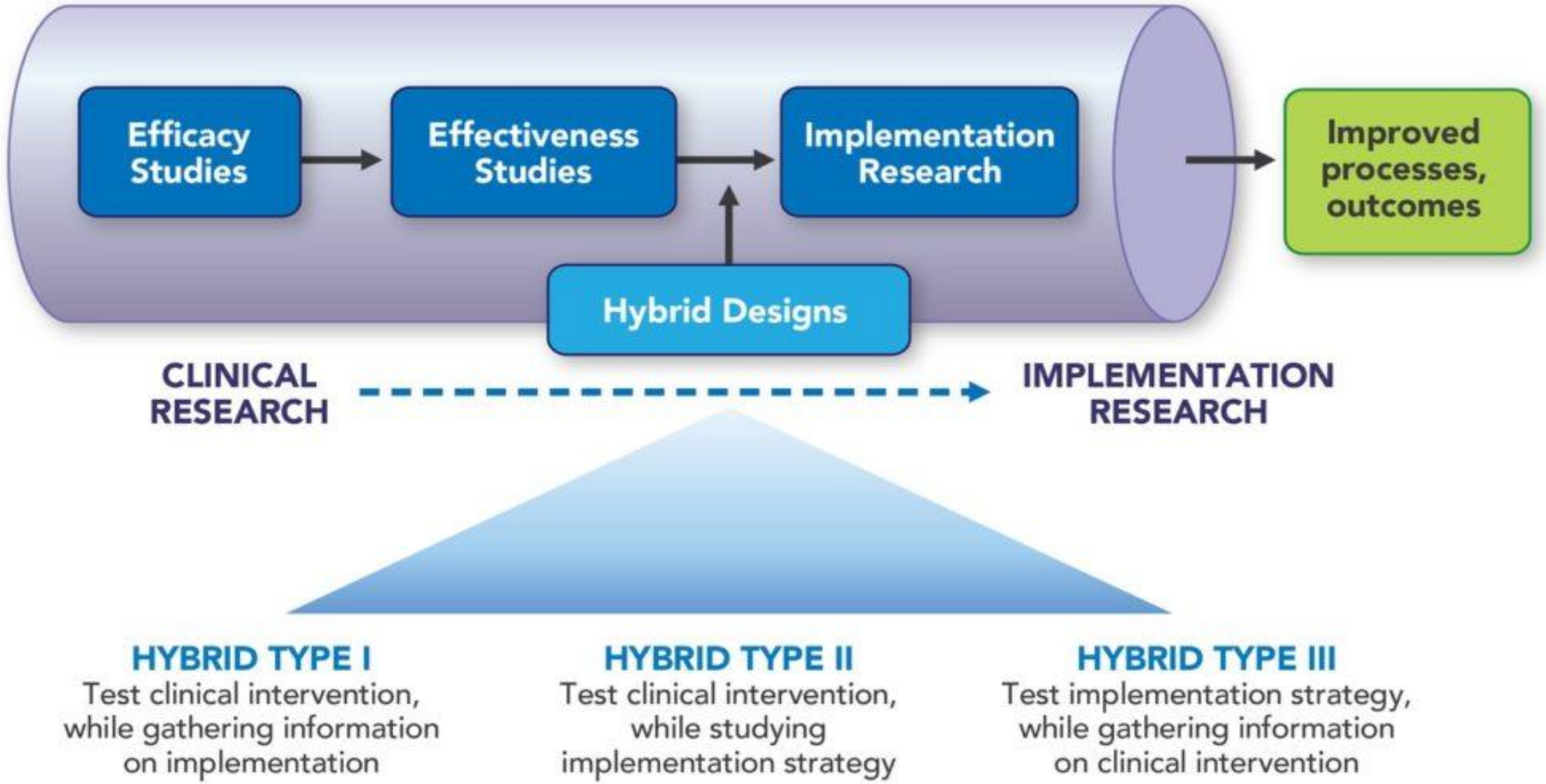


Implementation Science - Frameworks

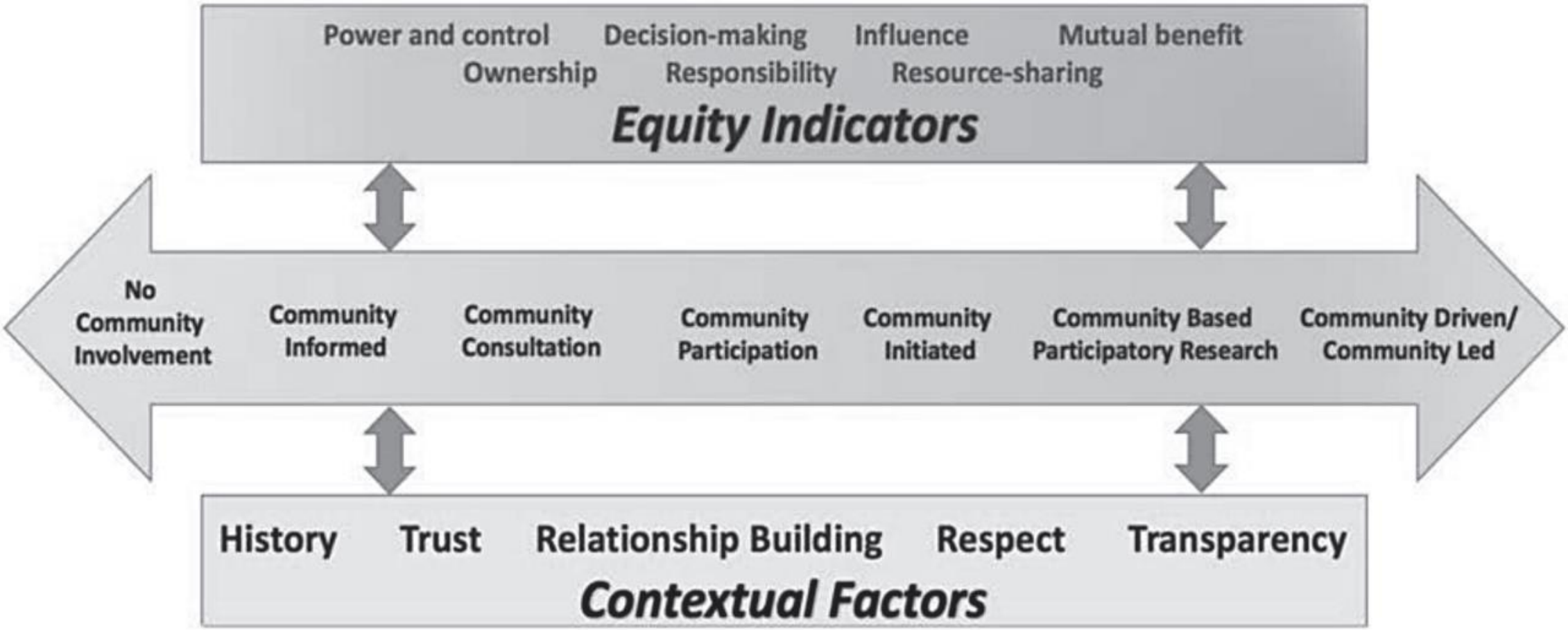




Implementation Science – Hybrid Designs



Community-Based Participatory Research



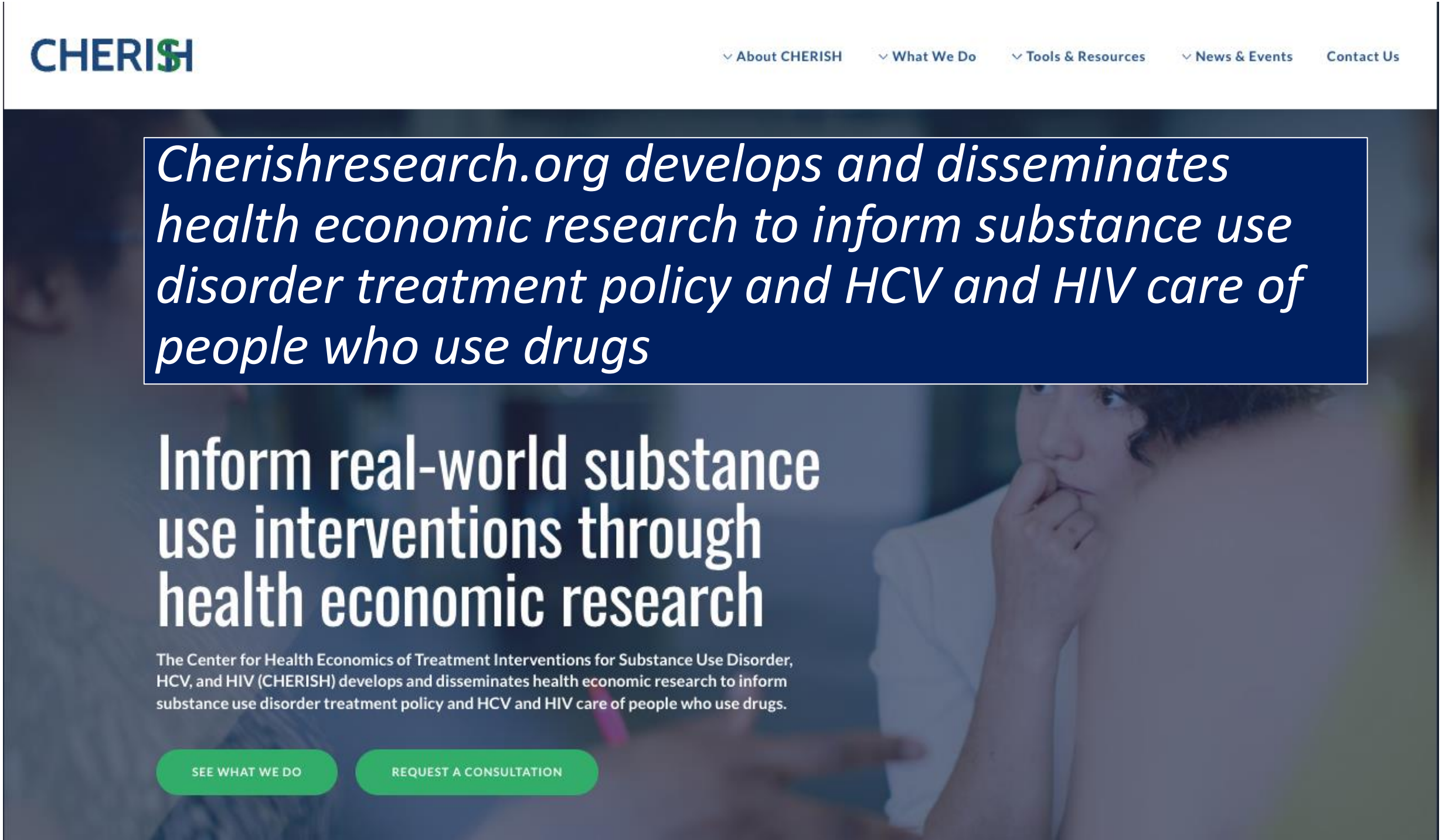
From Community-Based Participatory Research to Community-Driven Research

Commentary

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

Caty Simon [a b], Sarah Brothers [a c], Knina Strichartz [a d], Abby Coulter [a e], Nick Voyles [a], Anna Herdlein [a], Louise Vincent [a d]

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.


CHERISH
About CHERISH
What We Do
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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.
SEE WHAT WE DO
REQUEST A CONSULTATION

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, 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 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 substance use impact adherence to HIV medication?
- Study substance use in people with other medical conditions
  - E.g. Substance use among people treated for cancer
- Understand how substance use questions have been used in other studies – validated? Self-administered?
  - E.g. Timeline followback for self-reporting overdose

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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