National Institute on Alcohol Abuse and Alcoholism

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50 YEARS

SAVING LIVES THROUGH CUTTING-EDGE RESEARCH

Moving the Translation of Alcohol Behavioral Treatments Forward

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Brief Recap of Last Year's Meeting

- First of three satellite meetings that intersects dissemination and implementation (D & I) science and MOBC methodologies

- Provided an overview of specific MOBC(s) as potential candidates for D & I

- Presentations addressed how D & I science can enhance *Impact, Efficiency and Equity* of our empirically-supported treatments (focus on implementation mechanisms)

- Panel discussion on starting the conversation on the intersection of MOBC and D & I science

- NIAAA program guidance talk on MOBC science

Outline of today's talk

I. Channel today's discussion on hybrid effectiveness trials

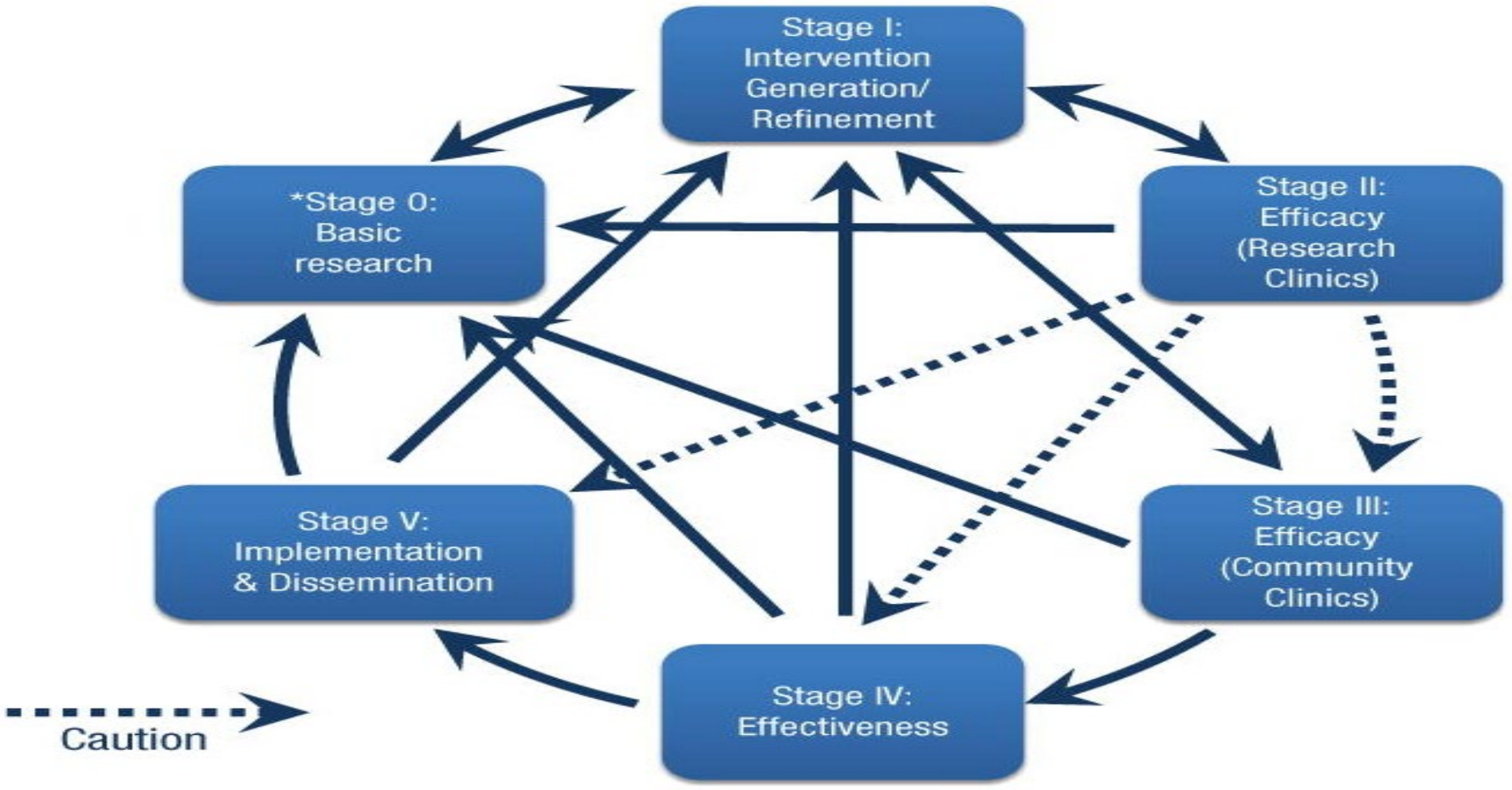
II. Review some public health considerations for translating our empirically-supported alcohol behavioral treatments

III. Review NIAAA program guidance on MOBC research initiatives

IV. Brief Q & A session with NIAAA (Brett Hagman and Laura Kwako)

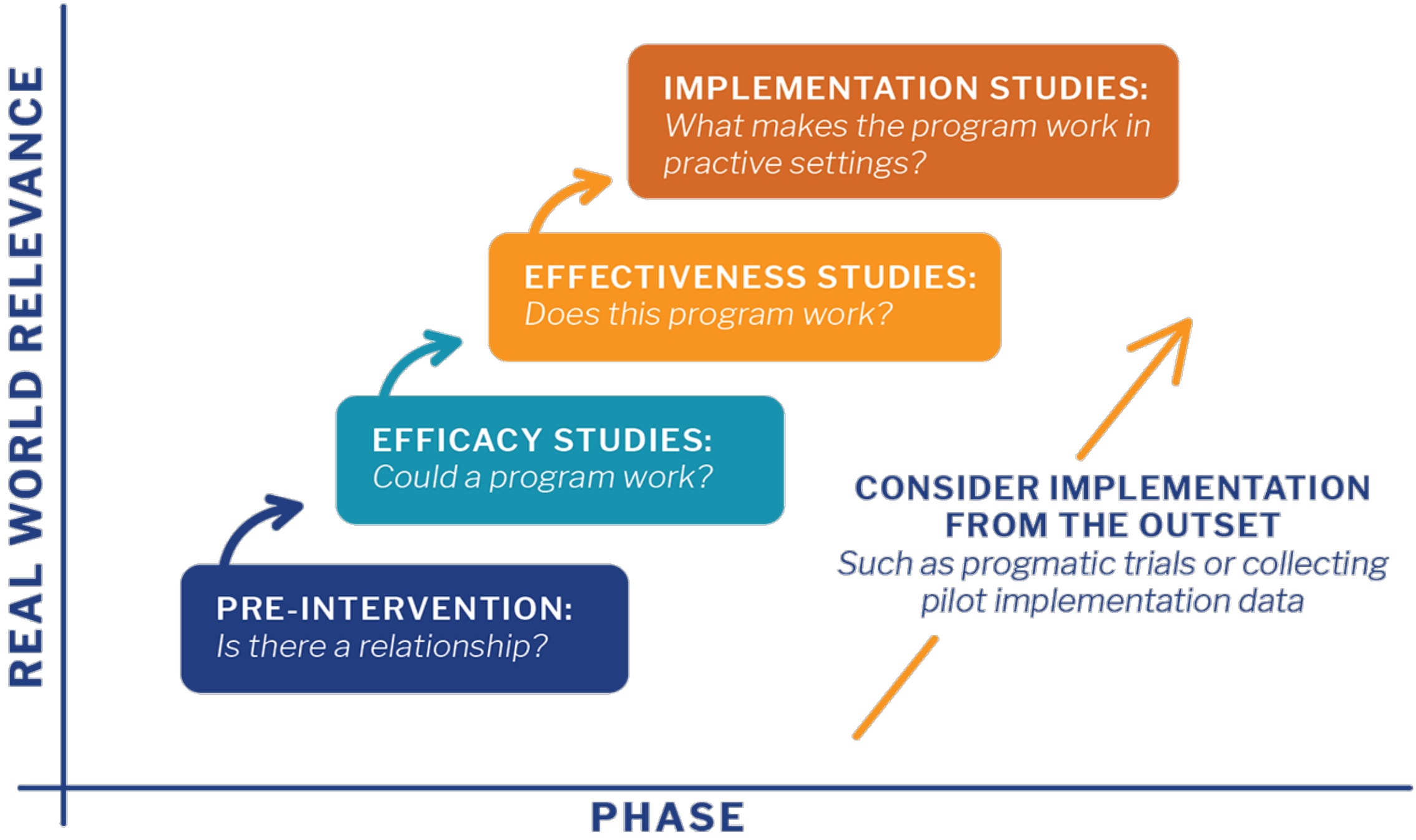
Part I: Channel today's discussion on hybrid effectiveness trials

Moving AUD behavioral treatments along the translational chain of evidence is a priority



Onken et al., 2016

Need to always consider implementation when evaluating a behavioral treatment



Why is research on treatment effectiveness important?

- Considered part of the evidence chain as it leverages translation into real world settings
- Shows us the benefit produced by a given treatment in day to-day clinical practice
- Aids key stakeholders in making clinical decisions about what improves health care (e.g., treatment of AUD)
- Enhances focus on external validity and representativeness
- We have several hybrid-effectiveness designs and frameworks at our disposal to use

Importance of Hybrid Effectiveness Trials

- Provide a unique combination and focus on effectiveness and implementation research
- Offers insight into how clinical outcomes are related to implementation outcomes (adoption and fidelity)
- Requires engagement early on with key stakeholders which provides input about implementation (barriers and facilitators)
- Permits study of implementation mechanisms and evaluating their mechanisms of action
- Leverages opportunities to translate and evaluate treatment-related health behavior change and MOBC(s) within hybrid designs

Do we need also a RCT design that leverages efficacy to effectiveness?

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<u>Effectiveness RCT may want to consider these concepts:</u>

- Incorporates real world features of hybrid effectiveness trial (e.g., sampling and analytical features)
- Includes some design features of efficacy studies (e.g., random assignment; different control groups)
- Reduction in the number of patient exclusion criteria
- Conducted in a range of clinical settings (not single centers)
- Reduced data collection structure
- Analysis done on an intent-to-treat basis

Part II: Review some public health considerations for translating our empirically-supported alcohol behavioral treatments

MOBC treatment efficacy and effectiveness research needs to intersect the social ecological approach!

MOBC treatment and effectiveness science needs to intersect the social determinants of health

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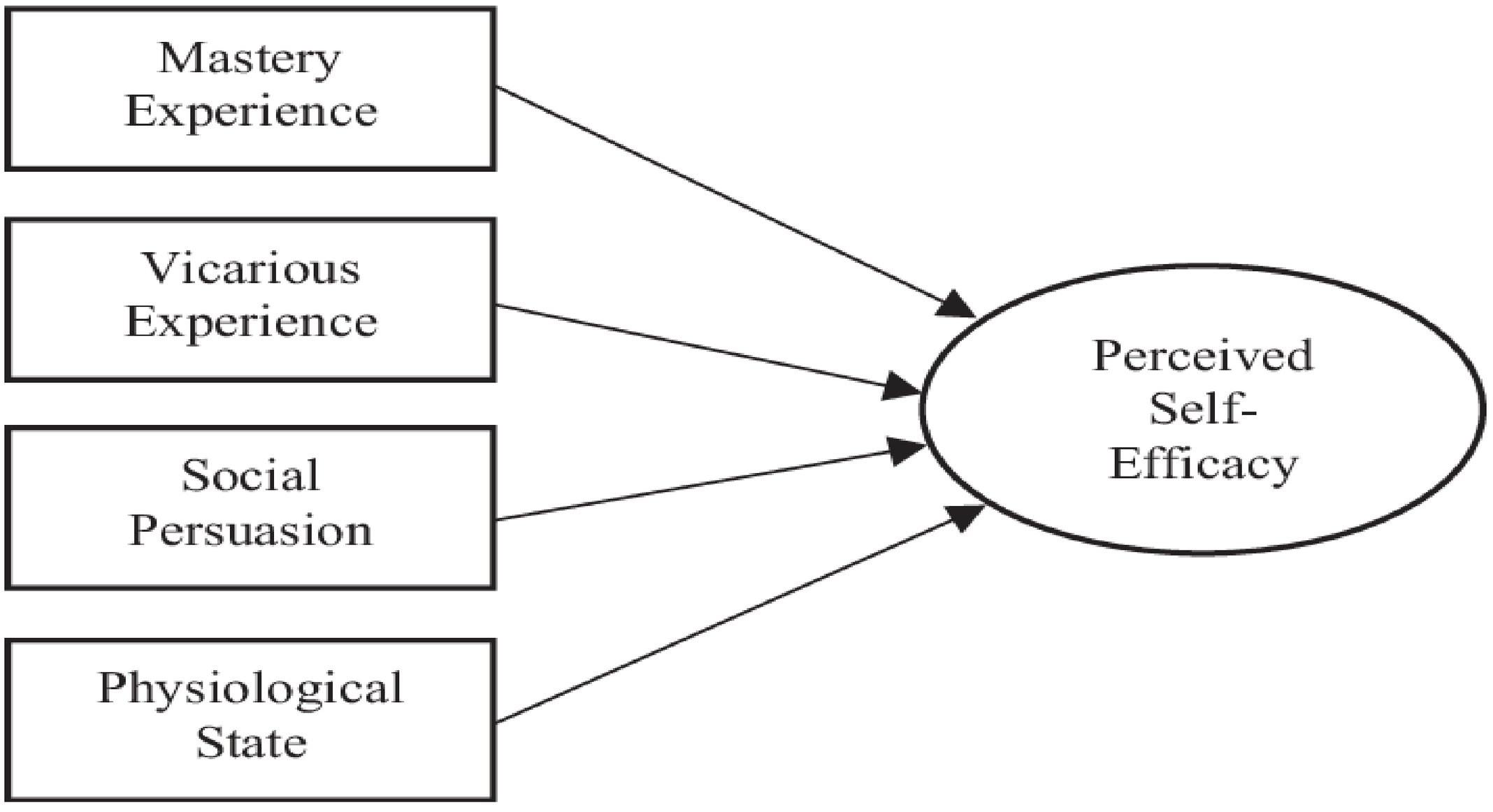
Intersecting health behavior change theories provides trans-theoretical behavioral constructs to study

- 1) Self-Regulation
- 2) Motives for Drinking
- 3) Psychological and Physical Resources
- 4) Habits
- 5) Environmental and Social Influences

Kwasnica, D., Dombrowski, SU., White, M. & Sniehotta. (2016). Theoretical explanations for maintenance of behavior: a systematic review of behavior theories. Health Psychology Review, 10(3): 277-296

Behavior change theories will help us understand why we have mediator(s) translated into MOBCs!



Graphical depiction of Albert Bandura's model of the four components of self-efficacy

Part III: Review NIAAA program guidance on MOBC research initiatives

NIAAA MOBC portfolio areas of interest

1) Translation of evidence-based treatments and MOBCs directly into clinical practice (treatment effectiveness)

2) Examining health behavior change science and behavioral treatments within D & I scientific methodologies

3) Training and supervision on evidence-based practices

4) Intersecting health behavior change science within the context of maintenance of behavior change in recovery

Translating MOBC(s) directly into clinical practice (treatment effectiveness)

- **What types of study designs and methodologies should be used to translate potential MOBC(s) directly into clinical practice?**

- **Should micro-interventions be used to test the effectiveness of MOBCs in clinical practice?**

- **What drives behavior change in clinical practice? Should we focus more on non-specific or etiological factors?**

- **What meta-analytic studies on specific behavioral treatments and processes would be useful? Comparative effectiveness studies?**

Examining health behavior change science and behavioral treatments within D & I scientific methodologies

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- What candidate mediators and MOBCs are ready for further implementation? What evidenced-based practices should be evaluated that target a mediator or MOBC?

- What D & I science frameworks will be the most useful for evaluating health behavior change?

- What types of implementation mechanisms are going to be important when understanding the context of a MOBC inside a behavioral treatment?

- How should hybrid-effectiveness/pragmatic clinical trials be used to evaluate an empirically-supported treatment that target MOBCs?

Training and supervision on MOBCs and evidence-based practices

- **What types of mediators and/or MOBC(s) enhance clinical training and supervision in the treatment of AUD?**

- **Which non-specific common factors should be of focus in training and supervision?**

- **What types of "e-training" protocols can be developed to enhance clinician training? What MOBCs should it assess for?**

- **What specific D & I science methodologies might help us enhance clinical training and supervision?**

Evaluating health behavior change within the context of maintenance of behavior change in recovery

- **Which specific treatment mediators/MOBCs should be translated in studying maintenance of behavior change in recovery? What about any common factors?**

- **What specific recovery-focused mediators should be evaluated as potential MOBCs when studying maintenance of behavior change in recovery?**

- **Are there specific mediators/MOBCs that predict both initiation of behavior change and maintenance of behavior change? What are the differences in characterizing these processes?**

- **Which behavior change science theories are the most useful to help identify potential mediators to evaluate in this context?**

NIAAA research definition of recovery from DSM-5 AUD

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"Recovery is a process through which an individual pursues both remission from AUD and cessation from heavy drinking.

An individual may be considered recovered if both remission from AUD and cessation from heavy drinking are achieved and maintained over time.

For those experiencing alcohol-related functional impairment and other adverse consequences, recovery is often marked by the fulfillment of basic needs, enhancements in social support and spirituality, and improvements in physical and mental health, quality of life, and other dimensions of well-being.

Continued improvement in these domains may, in turn, promote sustained recovery."

Hagman, B.T., Falk, D., Litten, R., & Koob, G. (published online). Defining Recovery in the Treatment of AUD: Development of an NIAAA Definition of Recovery. American Journal of Psychiatry. https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.21090963.

Two key processes of recovery from DSM-5 AUD

- ***Remission from DSM-5 AUD:*** **"Remission from alcohol use disorder (AUD), as defined by DSM-5 criteria, requires that the individual <u>not meet any AUD criteria (excluding craving)</u>"**

- ***Cessation from Heavy Drinking:*** **"Cessation from heavy drinking is defined as drinking <u>no more than 14 standard drinks per week or 4 drinks on a single day for men</u> and <u>no more than 7 drinks per week or 3 drinks on a single day for women</u>"**

- **Both are categorized based on <u>duration</u>: initial (up to 3 months), early (3 months to 1 year), sustained (1 to 5 years), and stable (greater than 5 years)**

DTR focused program announcements

Alcohol Treatment and Recovery Research PAR(s)

https://grants.nih.gov/grants/guide/pa-files/PAR-23-187.html PAR-23-187 (R01)

https://grants.nih.gov/grants/guide/pa-files/PAR-23-186.html PAR-23-186 (R34)

Alcohol Health Services Research PAR(s)

https://grants.nih.gov/grants/guide/pa-files/PAR-23-185.html PAR-23-185 (R01)

https://grants.nih.gov/grants/guide/pa-files/PAR-23-186.html PAR-23-186 (R34)

Thank you!

One page concept papers outlining specific aims are encouraged!

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