NIAAA MOBC program guidance:
Moving the public health translational needle forward

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Outline of today's talk

I. Brief review of MOBC research and clinical accomplishments

II. Review some considerations for moving MOBC evidence base forward

III. Provide rationale and importance for intersecting MOBC science with clinical practice and Dissemination and Implementation (D & I) science

IV. Provide examples of intersecting MOBC science with theory

V. Review NIAAA MOBC portfolio and areas of interest

MOBC accomplishments: Enhancement of research methodology and statistics to study behavior change

- **Adoption and application of Kazdin and Nock criteria to assist in elevating a treatment mediator into a mechanism – focus on causality**
- **Implement specific types of experimental designs (e.g., dismantling studies) to evaluate MOBCs**
- **Modeling heterogeneity of behavior through the use of intensive person-centered repeated-measures data collection techniques**
- **Leveraging of translational research methods that examine MOBCs at multiple levels of analysis**
- **Understanding the importance of assessment reactivity and how assessment exposure within our clinical trials contribute to behavior change**

MOBC clinical accomplishments: Several candidate MOBCs are available for further dissemination and implementation!

Based on Stephen Maisto's talk, there are several candidate MOBCs ready for potential further translation, which need expert consensus:

1) **Protective Behavioral Strategies**
2) **Motivation to Change**
3) **AA practices**
4) **Depression symptoms**
5) **Craving**
6) **Change Talk**
7) **Social Support**
8) **Coping Skills**
9) **Self-efficacy**
10) **Impulsivity**

What evidence-based practices (active ingredients) that target specific potential MOBCs should we build consensus for too?

Some issues to consider in building evidence of MOBC science

- **Lots of questions about what the direct clinical public health impact actually is for MOBC science – <u>the evidence base needs further translation</u>**

- **Little is known about how MOBCs interact in real world settings and clinical practice – understanding helps build evidence of mechanisms**

- **MOBC science has not been as well integrated as it could be – can we develop any new theories of behavior change? How do we build evidence for what MOBCs and evidence-based practices to translate?**

- **Need to integrate existing behavior change theories a little better – how does behavior change theory explain MOBC evidence?**

Additional MOBC issues to consider

- **Focus has been more on initiation of individual behavior change – intersect the social-ecological theory with D & I science**

- **MOBC science has yet to debate on how translating the evidence makes the link between how a mechanism helps establish an evidence-based practice (e.g., coping skills training) – D & I science can help**

- **Need to develop a methodological approach (e.g., design considerations) for merging MOBC science with D & I science to understand more about how to study the implementation of evidence-based practices and how it drives MOBCs in the real world**

- **MOBC science evidence has been limited to understanding behavior change within the context of efficacy studies – need to understand how MOBC intersects with questions of effectiveness in clinical practice (builds more evidence of how well something is working)**

Why is it important to translate MOBC evidence into clinical practice?

- **An established MOBC is part of a causal process and directly influences behavior change – we have empirically supported MOBCs to further translate**

- **Moves MOBC science towards questions of effectiveness and provides understanding for how "well" the link between a potential evidence-based practice and MOBC deter alcohol use in a practice setting**

- **Substance abuse professionals are open to learning new treatment methods and agree research findings should be used in practice (Forman et al., 2001)**

- **Clinicians are more favorable to guidelines based on principles and procedures rather than session-by-session focus of a treatment manual - openness to understanding what works in and across treatments (Godley et al., 2001)**

Why is it important to intersect MOBC science with Dissemination and Implementation (D & I) Science?

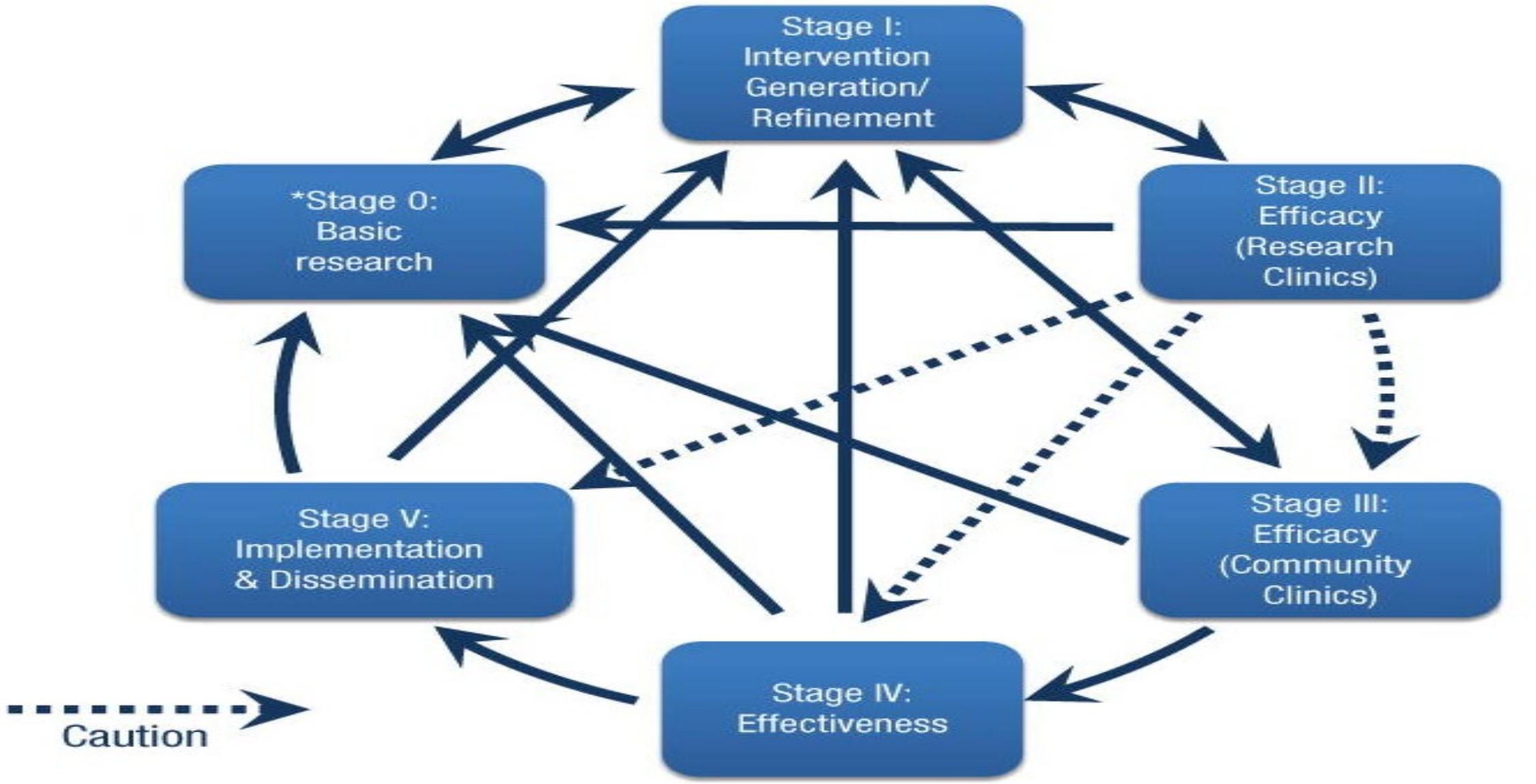
- **D & I science can provide further translation of MOBCs in real world settings – another methodological approach to build evidence**

- **Moves towards ensuring that we can develop an evidenced-based standard of care (i.e., coping skills training)**

- **Helps close the gap between what we *know* and what we *do* by identifying and addressing the barriers that slow or halt the uptake of proven AUD treatments and evidenced-based practices that target MOBCs**

- **Provides a methodological template and feedback for understanding how implementation strategies and mechanisms of implementation work**

Move AUD treatment research along the translational chain of evidence is our main priority!



Onken et al., 2016

Translating MOBC science into clinical practice requires an understanding of how knowledge is disseminated and needs to intersect public health communication theory!

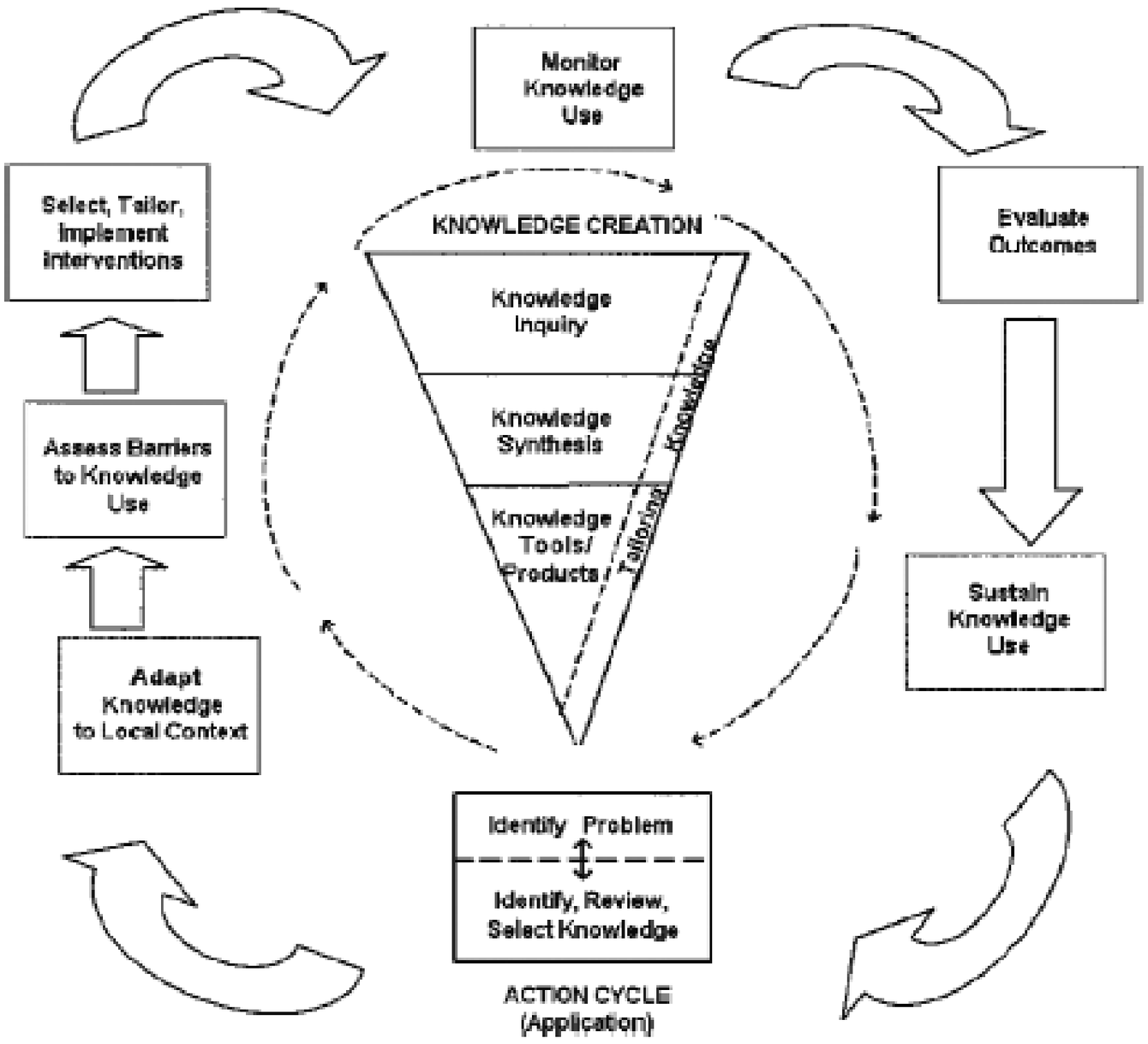
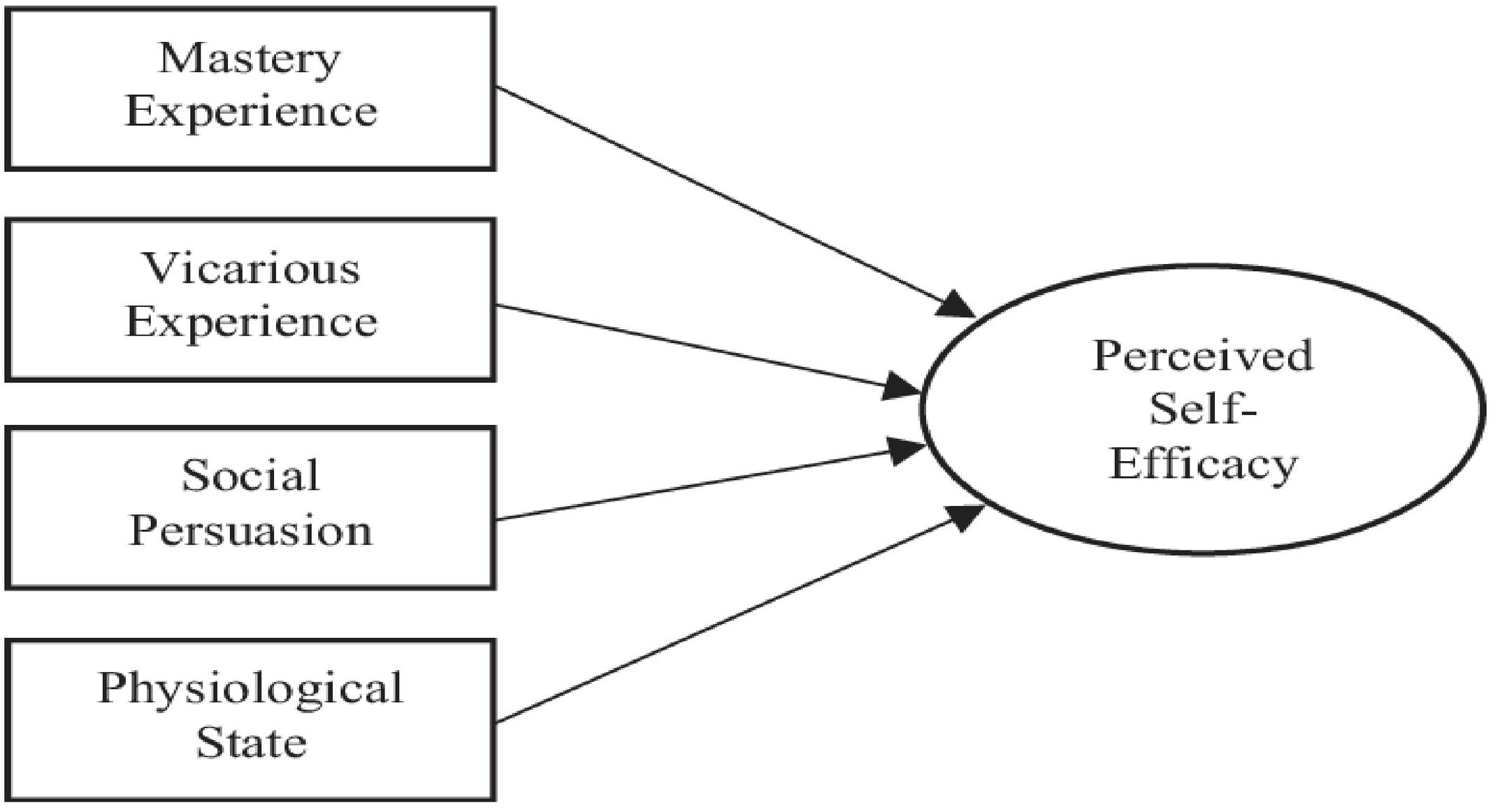


Figure 1 Knowledge-to-action cycle (Graham *et al*. 2006).

Broader behavior change theories will help us build our evidence for MOBCs ready for translation!



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

Time to move beyond a focus on individual change towards a social-ecological MOBC approach!

Should we be collecting information about determinants of health when developing or evaluating a treatment?

- **Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks**

- **SDOH may serve as moderators of the effectiveness of an AUD treatment or intervention**

- **Top Five Determinants of Health based on Healthy People 2030 are as follows:**

  1) Economic Stability
  2) Education Access and Quality
  3) Healthcare Access and Quality
  4) Neighborhood and Built Environment
  5) Social and Community Context

Carmela Alcántara, Sarah Valentina Diaz, Luciana Giorgio Cosenzo, Eric B.Loucks, Frank J. Penedo & Natasha J. Williams (2020) Social determinants as moderators of the effectiveness of health behavior change interventions: scientific gaps and opportunities, Health Psychology Review, 14:1, 132-144.

Defining MOBC science moving forward

- **An applied translational clinical public health focus (from basic science to D & I science) – use Onken model for guidance**

- **Primary goal is to enhance treatment efficacy and effectiveness and leads to treatment development (primary clinical goal of MOBC)**

- **Theory Driven and incorporates strong theoretical model development – hypothesis driven and integrates the evidence**

- **Focuses on translating the research evidence directly into clinical practice**

- **Has synergy with other Division of Treatment and Recovery portfolios (e.g., health services)**

NIAAA MOBC portfolio areas of interest

1) Translation of evidence-based practices and MOBCs directly into clinical practice

2) Merging MOBCs science with Dissemination and Implementation Science methods

3) Training and Supervision on MOBCs and evidence-based practices

4) Identifying MOBCs within the context of Maintenance of Behavior Change in Recovery

Initial research questions for translation of MOBC directly into clinical practice

- **What MOBCs and evidence-based practices are ready for further translation and implementation? How do we build consensus?**

- **What types of study designs and methodologies should be used to translate potential MOBC mediators directly into clinical practice? Should we start to focus on using real-world pragmatic clinical trials?**

- **Are micro-interventions useful in assessing the utility of MOBCs in clinical practice?**

- **What drives behavior change in clinical practice? Focus more on non-specific factors?**

Initial research questions for Merging MOBC methods with D & I science

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

- **How do you assess for MOBCs within an implementation science framework?**

- **What types of implementation mechanisms are going to be (e.g., clinician self-efficacy in delivering an evidence-based practice) important when understanding the context of a MOBC?**

- **Are pragmatic clinical trials going be the methodological standard to evaluate evidenced-based practices that target MOBCs within a D & I study?**

Initial research questions for training and supervision on MOBCs and evidence-based practices

- **What types of mediators enhance clinical training and supervision in the treatment of AUD?**

- **What kind of commons factor MOBC AUD treatment training module theory should be developed and tested?**

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

- **How does implementation science help us enhance clinical training and supervision?**

Initial research questions for identifying MOBCs within the context of maintenance of behavior change in recovery

- **Should any treatment specific MOBCs be considered in studying maintenance of behavior change in recovery? What about non-specific factors?**
- **What specific recovery-focused mediators should be evaluated as potential MOBCs when studying maintenance of behavior change in recovery?**
- **Are there specific MOBCs that predict both initiation of behavior change and maintenance of behavior change? What are the differences in characterizing these processes?**
- **Are there any useful theories to help identify potential mediators to evaluate in this context?**

Using Theory Better: Consider these theoretical constructs for studying maintenance of behavior change

- **1) Self-Regulation**
- **2) Motives for Drinking**
- **3) Psychological and Physical Resources**
- **4) Habits**
- **5) Environmental and Social Influences**
- **<u>6) What about structural racism?</u>**

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

Newly developed research NIAAA definition of recovery from DSM-5 AUD

National Institute on Alcohol Abuse and Alcoholism

50 YEARS SAVING LIVES THROUGH CUTTING-EDGE RESEARCH

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

"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 not meet any AUD criteria (excluding craving)"**

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

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

DTR focused PARs and PAs

National Institute on Alcohol Abuse and Alcoholism

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

50 YEARS SAVING LIVES THROUGH CUTTING-EDGE RESEARCH

Alcohol Treatment and Recovery Research PAR(s) (R01 and R34 Clinical Trial Required)

https://grants.nih.gov/grants/guide/pa-files/PAR-22-158.html (R01)

https://grants.nih.gov/grants/guide/pa-files/PAR-22-159.html (R34)

Alcohol Health Services Research PAR(s) (R01 and R34 Clinical Trial Optional)

https://grants.nih.gov/grants/guide/pa-files/PAR-22-156.html (R01)

https://grants.nih.gov/grants/guide/pa-files/PAR-22-157.html (R34)

Unsolicited Investigator Program Announcements

https://grants.nih.gov/grants/guide/pa-files/PA-20-185.html (R01 - Clinical Trial Not Allowed)

https://grants.nih.gov/grants/guide/pa-files/PA-20-183.html (R01- Clinical Trial Allowed)

https://grants.nih.gov/grants/guide/pa-files/PA-20-195.html (R21 - Clinical Trial Not Allowed)

https://grants.nih.gov/grants/guide/pa-files/PA-20-194.html (R21 - Clinical Trial Allowed)

Moving forward

- **A MOBC study moving forward needs to apply stringent criteria and focuses on translating mechanisms (guided by the research evidence) to enhance treatments**

- **Need to incorporate behavior change theories and do a better job linking with specific MOBCs**

- **Need to get behind an established set of validation criteria for leveraging a mediator into a mechanism**

- **Focus on the social-ecological theory of behavior change – collect information at each level of determinant**

- **Need to develop a methodological framework for merging MOBC science with Dissemination and Implementation (D & I) Science – develop overarching research questions of how to study MOBCs within this context**

Thank you!

One page concept papers outlining specific aims are encouraged!

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