

The NIH Stage Model of Intervention Development: A Bidirectional + Translational Conceptual Framework

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Stage Model Framework
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Goal of the NIH Stage Model

To produce the best interventions possible...

Goal of the NIH Stage Model

To produce the best, *most implementable* interventions possible...

There are many efficacious behavioral interventions-
-many of them for disorders once believed to be intractable.

Some of these interventions have enduring effects.

Not all efficacious intervention are effective.

Too few are successfully implemented.

“Improving the Quality of Health Care for Mental and Substance-Use Conditions” (IOM 2006)

...the efficacy of specific treatments under rigorously controlled conditions has been accompanied by almost no research identifying how to make these same treatments effective when delivered in usual settings of care ...”

Intervention Development: Expectation

Develop



Efficacy



Effectiveness

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Intervention Development: Reality



What stops efficacious interventions from being effective?



What would need to change for efficacious interventions to be effective?

Develop

→ Efficacy

~~→~~ Effectiveness

INTERVENTION

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SYSTEM

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A close-up photograph of a wooden handle, likely from a musical instrument or tool. The handle is light-colored wood with a visible grain. It features a metal ferrule (a ring of metal) near the top, which is secured with several thin, dark threads. Below the ferrule is a rounded, light-colored wooden head. The background is a dark, textured surface, possibly wood or fabric. The image is framed by a blue gradient bar on the left and right sides.

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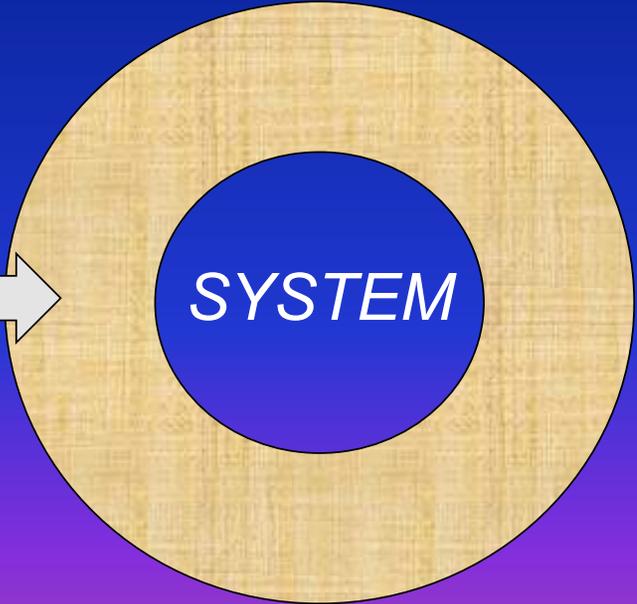


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Development
Effectiveness

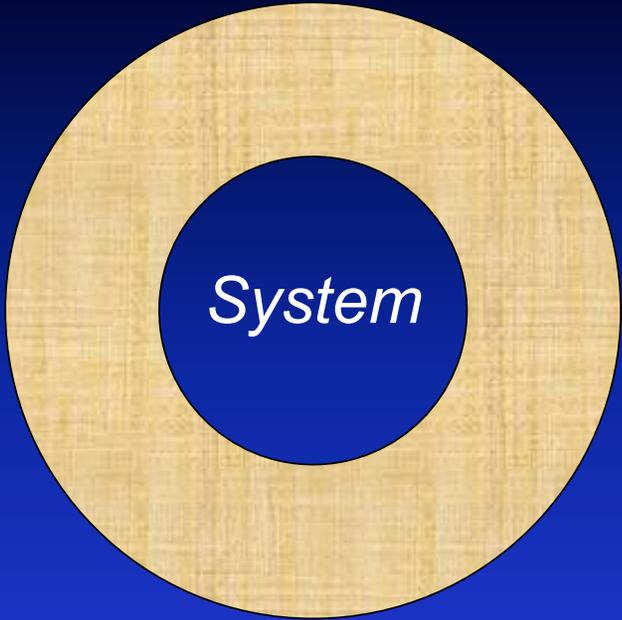


Efficacy

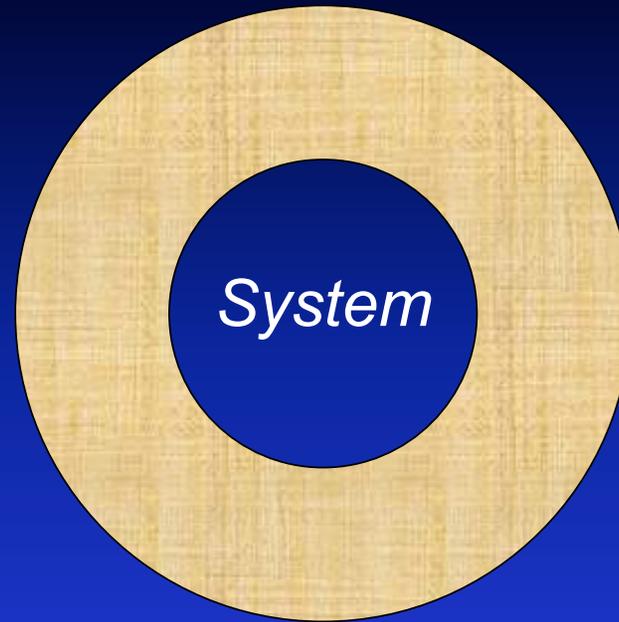


What needs to change?

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Change the system to accommodate the intervention.

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Change the Service Delivery System

The community would need the same resources as in research:

- Sufficient funding
- Adequate time allotted per patient
- Adjunct services available
- Well-educated providers (same as in research)
- Well-trained providers
- Providers' motivation and goals would = those of research therapists
- Any other barriers to implementation would need to be overcome

Change

Intervention

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Change



Intervention

Change the intervention to fit within the system

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Intervention

If it doesn't fit...?

- Decrease the time required to administer the intervention
- Pare down intervention to its essential elements
- Simplify administration of the intervention
- Develop materials, *as part of the intervention*, to train community practitioners to administer it easily and correctly.
- Develop methods, *as part of the intervention*, to ensure fidelity of delivery in community
....While increasing effects (or at least not decreasing them).

Changing an intervention
could lead to loss of potency

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Strategies?

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Understand Mechanism of Action (MOA),

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Why Mechanism?

Knowing how and why an intervention works can guide efforts to pare down or otherwise simplify an intervention, without losing potency.

Knowing guiding principles can help to train practitioners.

Knowing MOA can help make an intervention more implementable.

Are questions about mechanism basic or applied science?

Asking questions about mechanisms of behavior change
means asking *basic science questions*.

These basic science questions can be asked within the context
of *applied/clinical studies*.

Does this mean that basic science is related to intervention development?

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YES

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Does this mean that basic science
is related to implementation?

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YES

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Are there other strategies to develop potent + implementable Interventions?

- Determine mechanism of action, mediators + moderators
- **Determine essential elements**

Elements of Efficacious Intervention X

*Seems important,
Does nothing*

**Critical.
Won't work
without this**

**Does almost
nothing**

*Does almost
nothing alone, but
helps boost effects
of other elements*

**Only works
with purple**

**Does
nothing**

**Only works
with green**

*Seems
unimportant.
Contributes
greatly*

**Contributes
a small
amount**

Anything else?

- Determine mechanism of action, mediators + moderators
- Determine essential elements
- **Develop methods to ensure fidelity**

Anything else?

- Determine mechanism of action, mediators + moderators
- Determine essential elements
- Develop methods to ensure fidelity
- **Develop methods for training community providers**

Can technology help?

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Can technology help?

Partially computerize interventions

(↑ fidelity, help training, ↑ potency, ↓ cost,)

Mobile technologies

(↑ reach, ↓ cost)

Remote patient monitoring + feedback

(↑ ability to determine MOA, ↑ potency, ↑ assessment)

Is it necessary to involve service providers when developing implementable interventions?

Some would argue yes.

“It’s not the consumer’s job to know what they want.”

-Steve Jobs

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The NIH Stage Model of Intervention Development: A Bidirectional + Translational Conceptual Framework

Adapted from Rounsaville, Carroll, & Onken, 2001

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Similarities of Models of Intervention Development

- Many models share the notion of *phases or stages* of intervention development
- Most underscore bidirectionality \leftrightarrow
- Most stress the importance of *translational research*.
- General agreement that efficacy & effectiveness research vary along a continuum, *from maximizing internal validity to maximizing external validity* and generalizability.

Differences among Models of Intervention Development

- What stages to include; Numbers + names of stages.
- Stage(s) between efficacy + effectiveness
- Inclusion of training + fidelity as part of intervention development (prior to effectiveness research)
- Relevance, importance, and role of theory + basic research in intervention development
- The point at which to focus on implementation.
- The points where intervention development begins + ends

The NIH Stage Model

Iterative, recursive, + bidirectional
Translational

Keeps implementation + potency as the ultimate goal

Emphasizes theory and the role of basic science

Emphasizes importance of understanding processes of behavior change

Non-prescriptive

The NIH Stage Model

The model asserts that the work is not complete with efficacy.

Intervention development is not complete until the intervention reaches its maximum level of potency and is *implementable* with a maximum number of people-- in the people for whom it was developed.

Even if it is efficacious, work is not complete on an intervention if...

...it is not known for whom it is (and isn't) efficacious

...it is not maximally efficacious

...it is not effective.

...it is not implementable.

...methods to ensure fidelity are not available.

...methods to train providers are not available (and it requires training to administer it properly)

Stage 0

**Basic
research**

Basic research may precede and may produce findings that form the basis for Stage I intervention generation studies.

Stage 0

**Basic
research**

Questions on mechanisms, mediators, & moderators of behavior change are basic science questions and are part of *all stages* of intervention development.

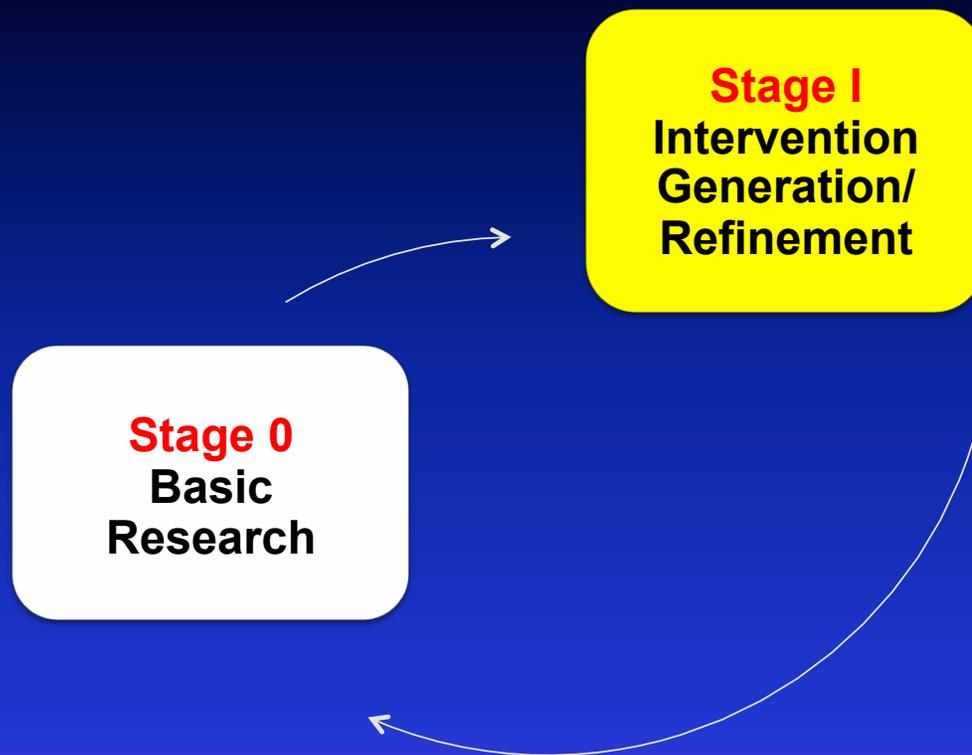
Therefore, basic science questions are asked within the context of applied research on interventions.

Stage 0
Basic
Research



Stage I
Intervention
Generation/
Refinement





Stage I is when something new is created, or something that exists is refined, modified, or adapted.

*Research clinics
or
Community settings*

Stage I-A: Intervention generation or refinement.
Stage I-B: Feasibility + pilot testing

Stage 0
Basic
Research



Stage I
Intervention
Generation/
Refinement

Stage I includes
generation + refinement
of
*Therapist Training
Materials*



Stage I includes generation + refinement of
Methods to ensure Fidelity in the community.

Stage I

**Intervention Generation/
Refinement**



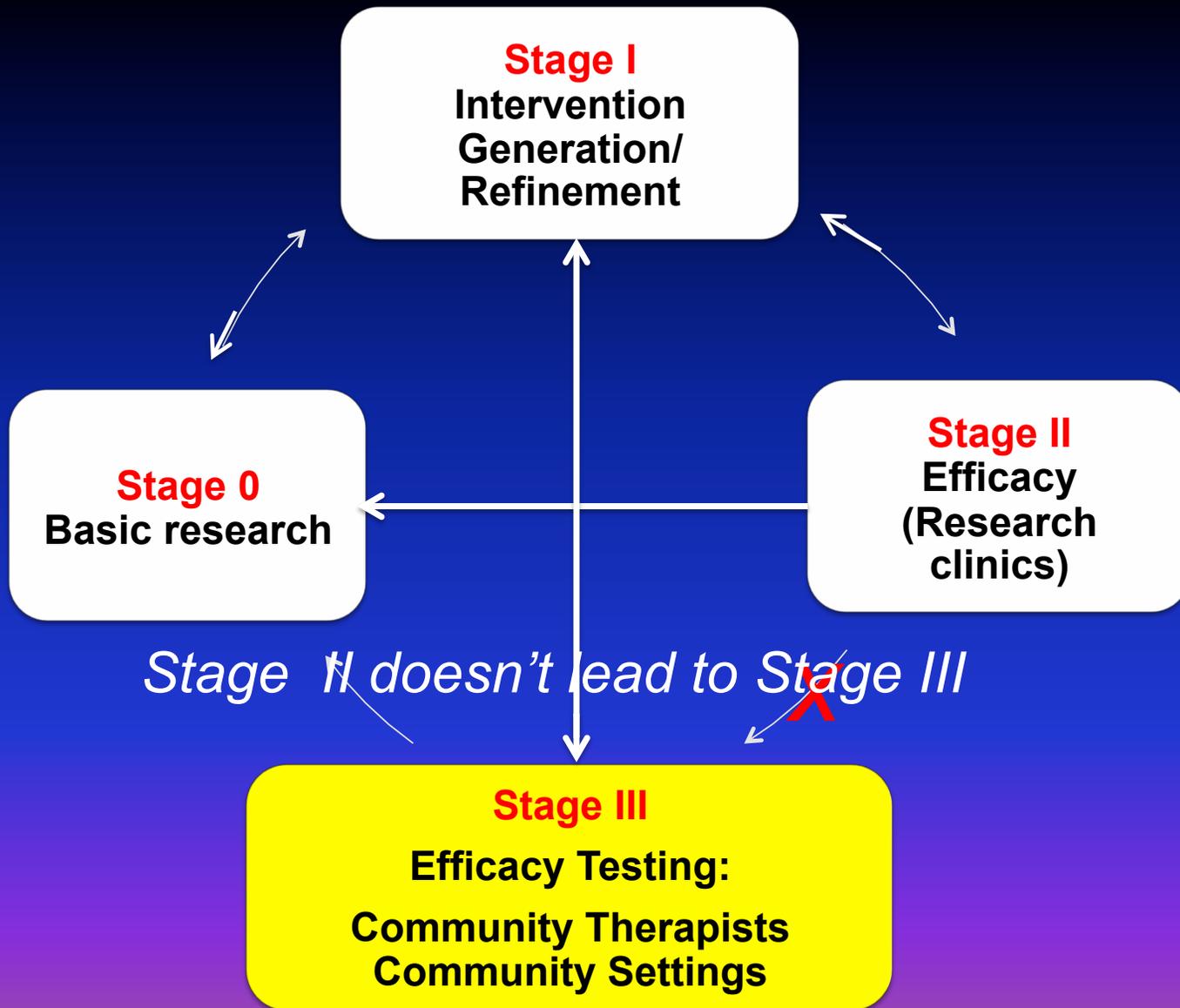
Stage 0

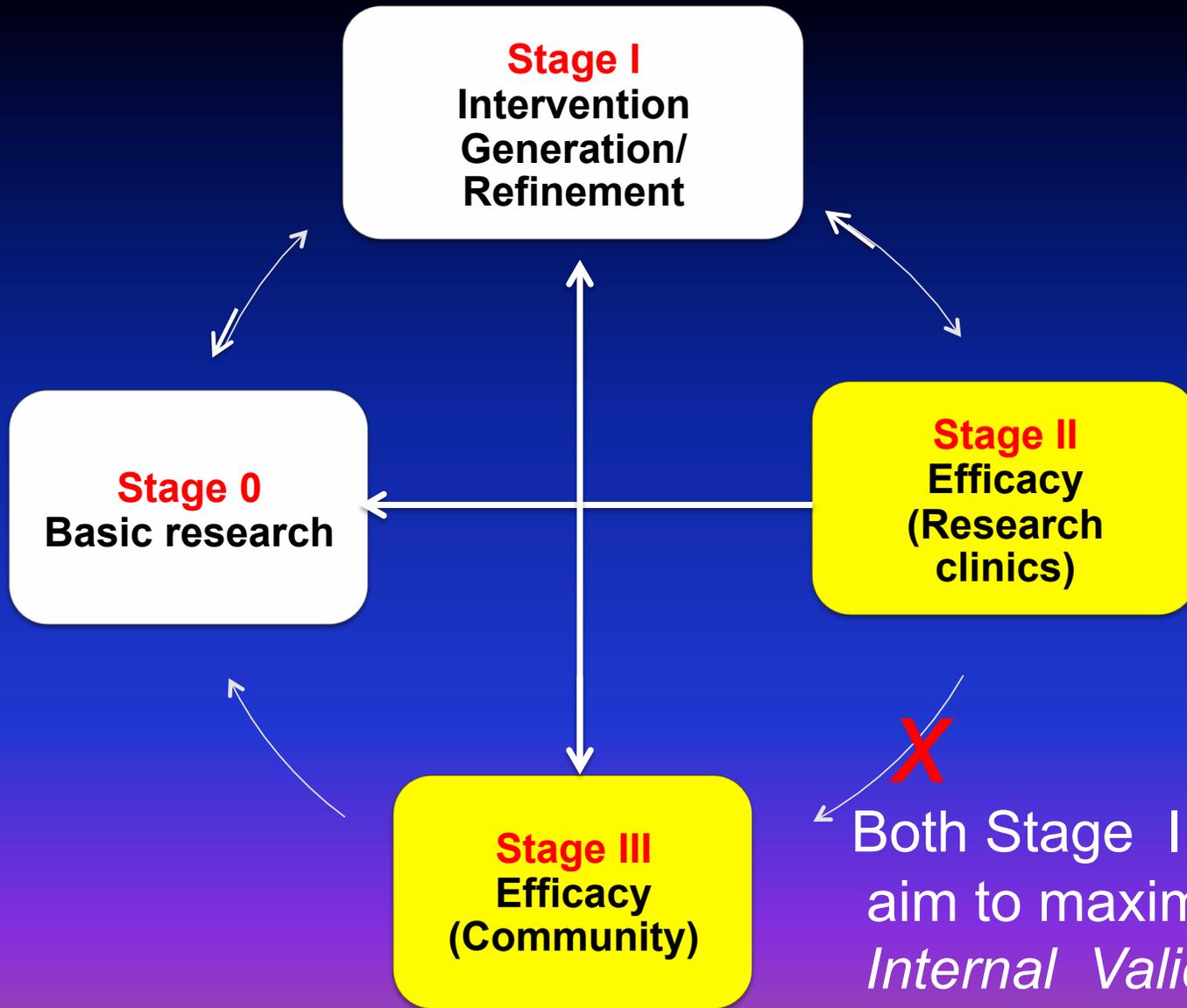
Basic research

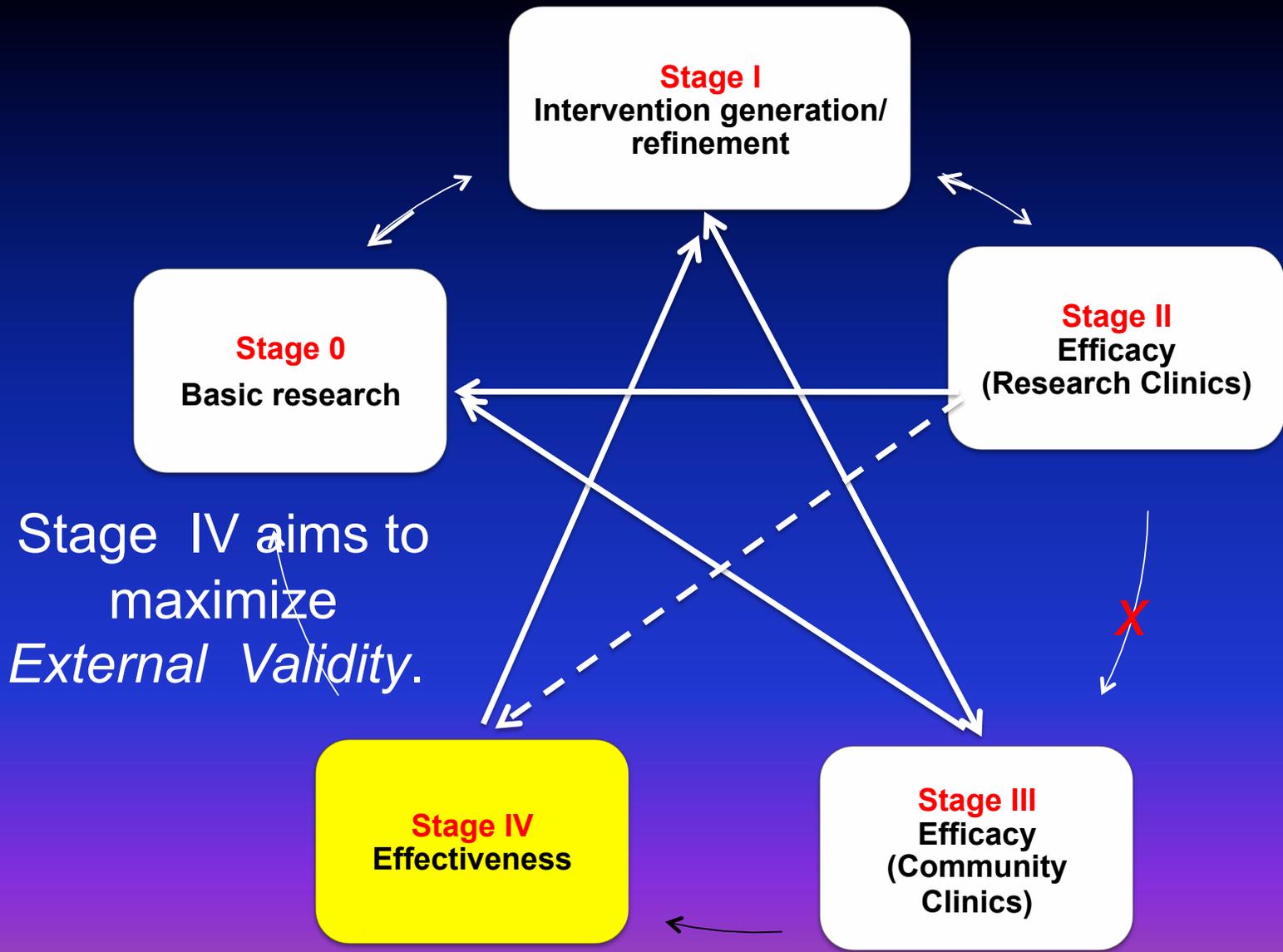
Stage II

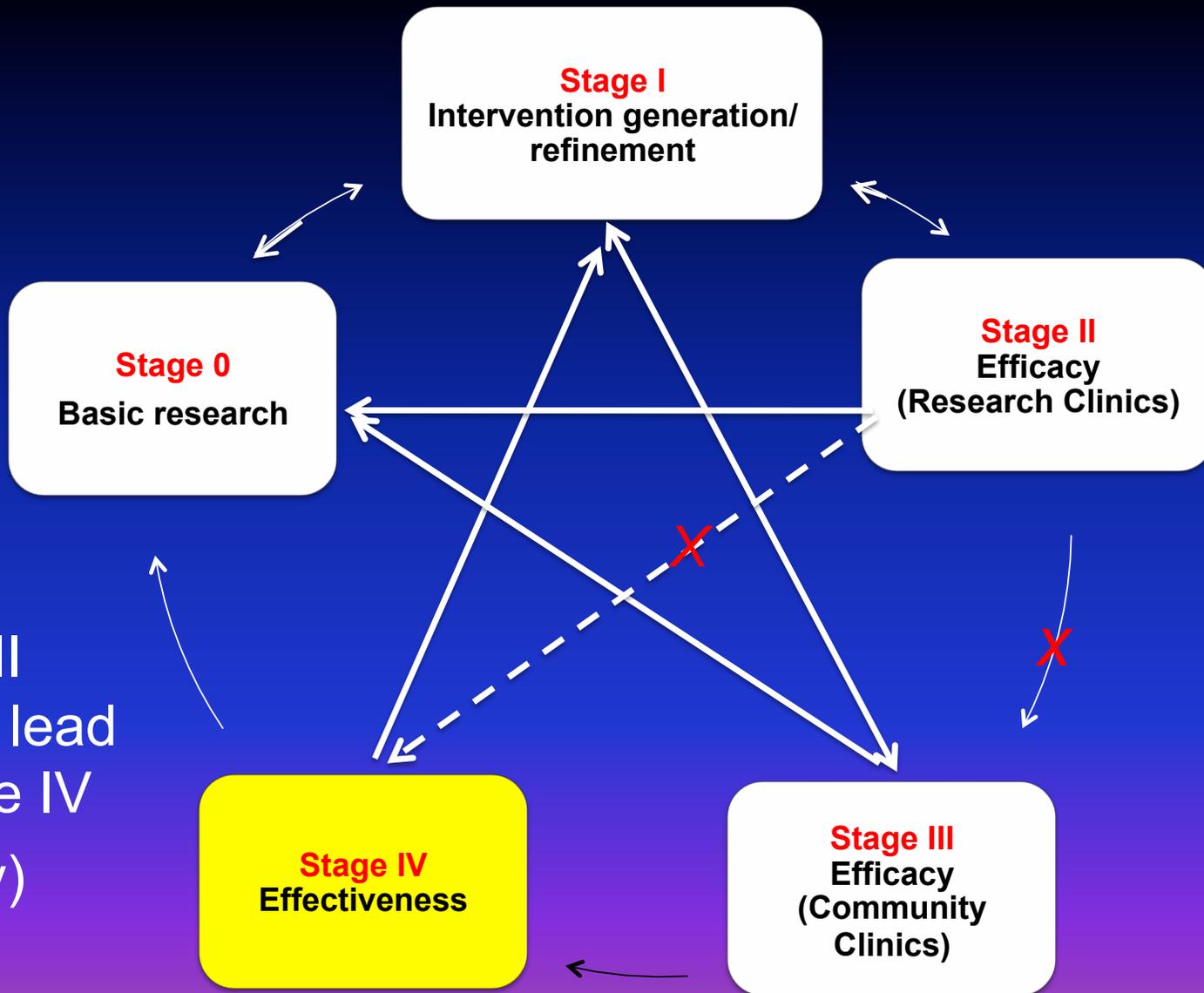
**Efficacy Testing:
Research Therapists
in
Research Clinics**





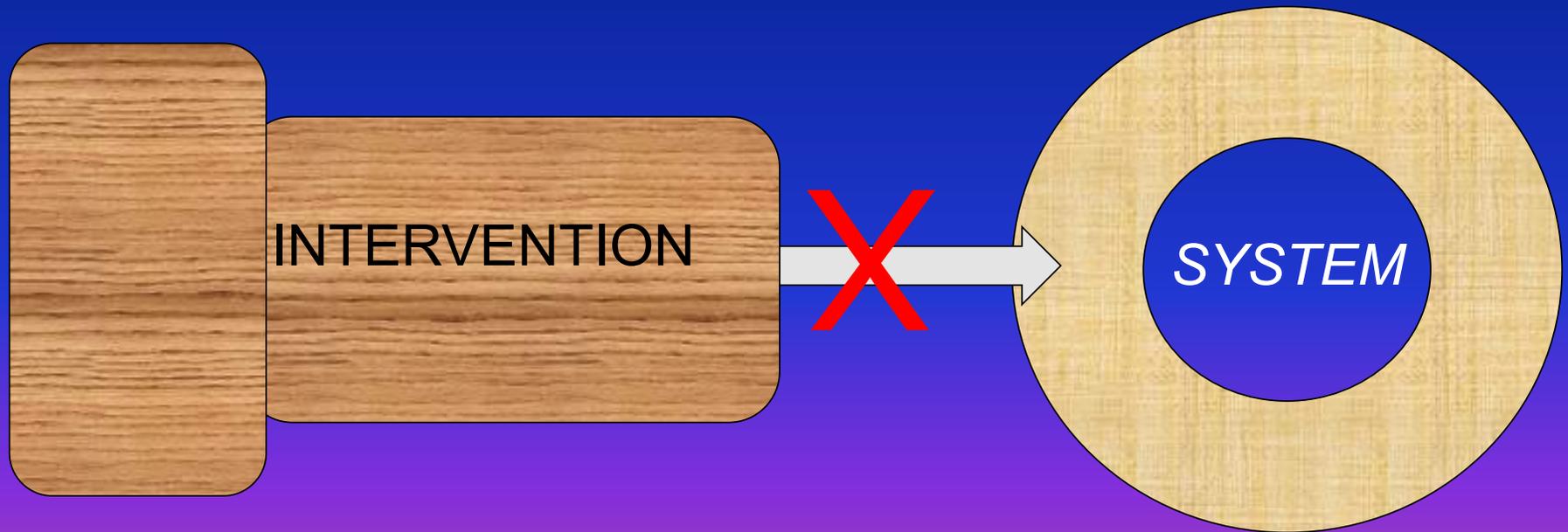




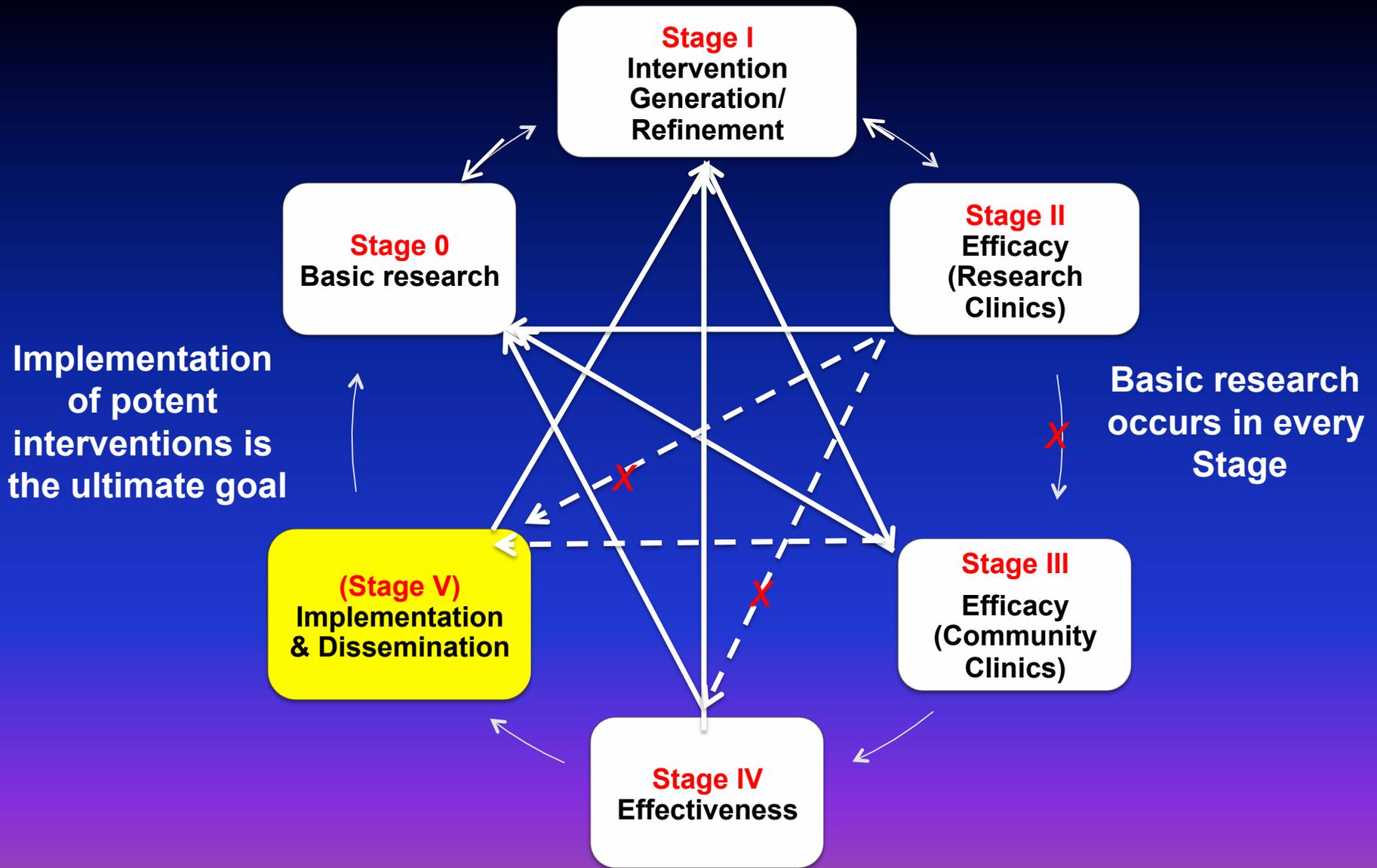


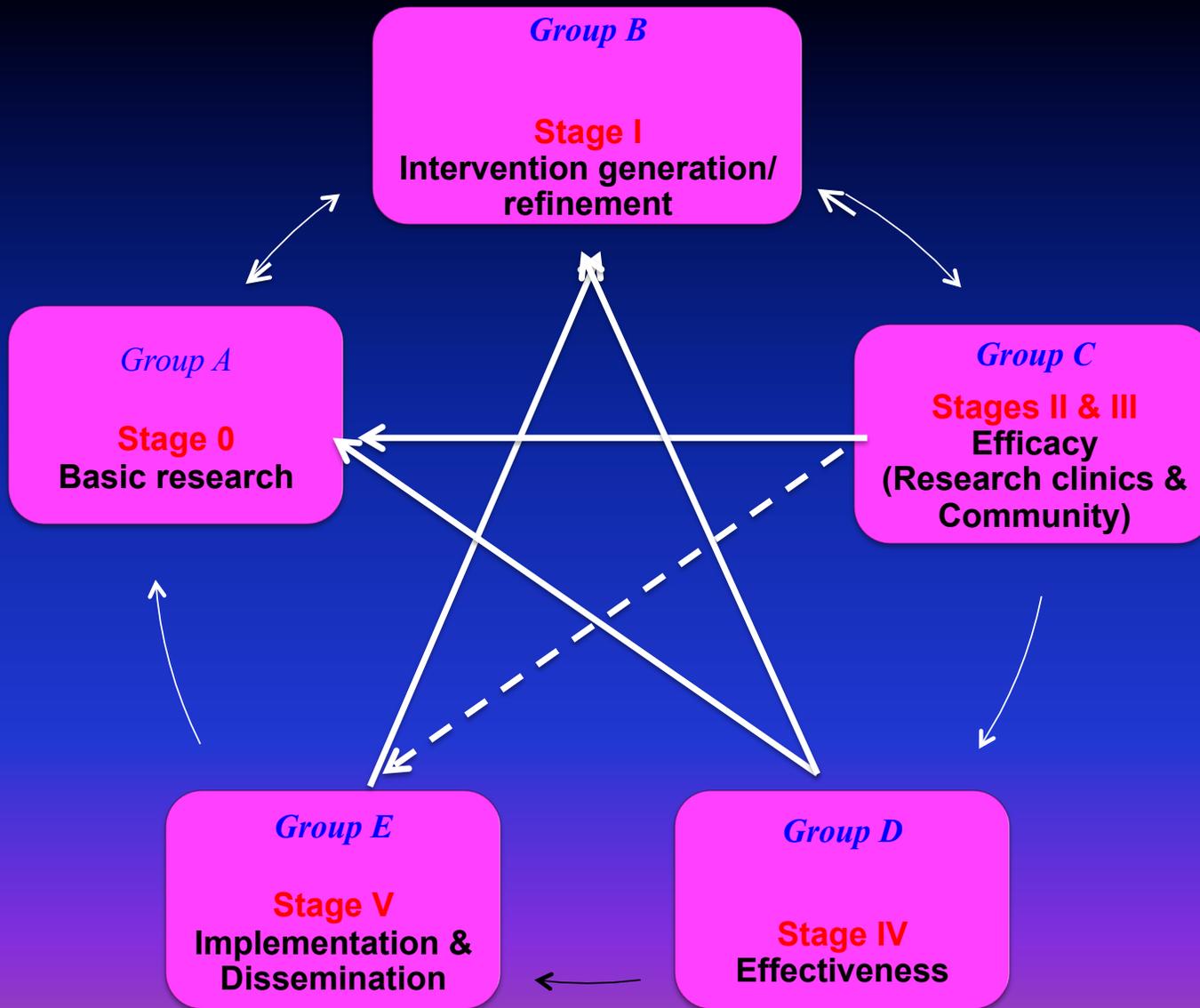
Stage II
doesn't lead
to Stage IV
(usually)

Stage I → Stage II Efficacy ~~→~~ Effectiveness



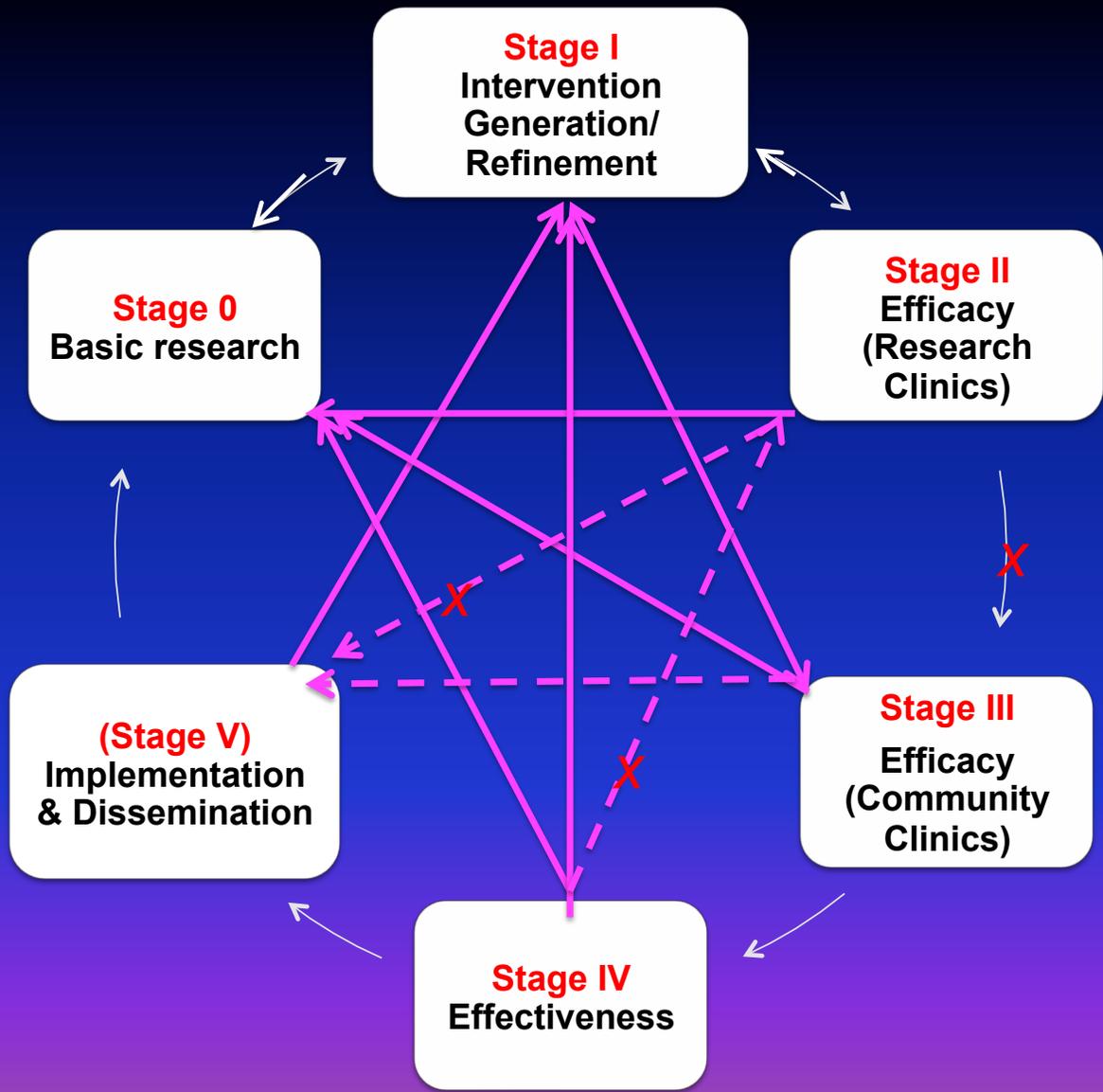
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Remarks

- Intervention development doesn't end with efficacy.
- Efficacy doesn't lead directly to effectiveness.
- Changing the service delivery system isn't the only way to make efficacious interventions effective + implementable.
- The interventions themselves can be changed.
- To maximize the probability that an efficacious intervention will be effective, it needs to be known that the intervention is efficacious with community providers, in community settings (Stage III).
- Unless an intervention was generated in the community, researchers will need to go back to Stage I to conduct successful Stage III research.
- We're not done until an intervention is maximally potent and implementable with maximal fidelity.
- Successful intervention development requires ALL of the expertise of clinical science (+ often other disciplines).



NIH Stage Model

