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 …”

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Intervention Development:

Expectation

Develop → Efficacy → Effectiveness
Intervention Development: Reality

Develop → Efficacy → Effectiveness
What stops efficacious interventions from being effective?
What would need to change for efficacious interventions to be effective?

Develop → Efficacy → Effectiveness

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Development
Effectiveness

→

Efficacy

SYSTEM

INTERVENTION

→

SYSTEM

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What needs to change?
Change the system to accommodate the intervention.
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

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Change

Intervention

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Change

Change the intervention to fit within the system
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
Strategies?
Understand Mechanism of Action (MOA),
Why Mechanism?

Knowing how and why and 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*.

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

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Does this mean that basic science is related to implementation?
Are there other strategies to develop potent and 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
- Only works with green
- Seems unimportant. Contributes greatly
- Does nothing
- 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

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Can technology help?
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
The NIH Stage Model of Intervention Development: A Bidirectional + Translational Conceptual Framework

Adapted from Rounsaville, Carroll, & Onken, 2001
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

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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.

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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.

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.

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

Stage 0
Basic Research

Research clinics
or
Community settings
Stage I includes generation + refinement of Therapist Training Materials.
Stage I
Intervention Generation/Refinement

Stage 0
Basic research

Stage II
Efficacy Testing: Research Therapists in Research Clinics
Stage I
Intervention Generation/Refinement

Stage 0
Basic research

Stage II
Efficacy (Research clinics)

Stage III
Efficacy Testing:
Community Therapists
Community Settings

Stage II doesn’t lead to Stage III
Stage 0
Basic research

Stage I
Intervention
Generation/Refinement

Stage II
Efficacy (Research clinics)

Stage III
Efficacy (Community)

Both Stage II + III aim to maximize Internal Validity.
Stage IV aims to maximize *External Validity.*
Stage I
Intervention generation/refinement

Stage II
Efficacy
(Research Clinics)

Stage III
Efficacy
(Community Clinics)

Stage IV
Effectiveness

Stage II doesn’t lead to Stage IV (usually)
Stage I                           Stage II Efficacy  Effectiveness

INTERVENTION                      SYSTEM

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Stage I
Intervention Generation/Refinement

Stage II
Efficacy (Research Clinics)

Stage III
Efficacy (Community Clinics)

Stage IV
Effectiveness

Stage V
Implementation & Dissemination

Basic research occurs in every Stage

Implementation of potent interventions is the ultimate goal
Group B
Stage I
Intervention generation/ refinement

Group C
Stages II & III
Efficacy (Research clinics & Community)

Group D
Stage IV
Effectiveness

Group E
Stage V
Implementation & Dissemination

Group A
Stage 0
Basic research
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).

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Stage I
Intervention Generation/Refinement

Stage 0
Basic research

(Stage V)
Implementation & Dissemination

Stage IV
Effectiveness

Stage II
Efficacy (Research Clinics)

Stage III
Efficacy (Community Clinics)
NIH Stage Model

Stage I
Intervention Generation/Refinement

Stage II
Efficacy (Research Clinics)

Stage III
Efficacy (Community Clinics)

Stage IV
Effectiveness

Stage V
Implementation & Dissemination

Basic research occurs in every Stage

Implementation of potent interventions is the ultimate goal

Basic research occurs in every Stage