The NIH Stage Model (Updated, Draft)

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Various conceptualizations of research on intervention development share the notion of phases or stages of intervention development, and most stress the importance of translational research. The models generally agree that efficacy and effectiveness research vary along a continuum, from maximizing internal validity to maximizing generalizability. Models differ in what stages they include and in the way they number and name the stages. Models also differ in terms of the relevance, importance, and role of theory and basic research in intervention development; and in terms of the point at which they emphasize a focus on implementation.

The NIH Stage Model we use in the meeting is an iterative, recursive, bidirectional model of behavioral intervention development. This model asserts that the work is not complete until a treatment reaches its maximum level of potency and is implementable with a maximum number of patients in the population for which it was developed. In this model basic researchers, intervention developers, and community-oriented intervention and implementation researchers all have a significant role to play in every stage of developing potent and implementable interventions.

Stages of Intervention Development

- **Stage 0** involves basic science that occurs *prior to* intervention development, but is relevant (ultimately translatable) to intervention development. Another type of basic science research is an integral part of all other stages of intervention development: Research on mechanisms of problem maintenance and change that involves asking basic science questions about behavior maintenance and change *within the context of* intervention development studies.
- **Stage I** encompasses all activities related to the creation and preliminary testing of a new behavioral intervention. Stage I begins with the generation of new behavioral interventions as well as the modification, adaptation, or refinement of existing interventions (Stage IA), and it culminates in feasibility and pilot testing (Stage 1B). Finally, note that one can conduct Stage I studies in research settings, with research therapists (providers) and research subjects; or in community settings with community providers.
- **Stage II** ("Efficacy") research consists of experimental testing of promising behavioral interventions *in research settings, with research-based providers and patients.*
- **Stage III** ("Efficacy in Real World") research consists of experimental testing of promising behavioral interventions *in community settings, with community-based providers*, while maintaining a high level of control necessary to establish internal validity. Some refer to this as a hybrid (efficacy-effectiveness) stage.
- **Stage IV** ("Effectiveness") research examines empirically supported behavioral interventions in community settings, with community-based providers, while maximizing external validity.
- **Stage V** ("Implementation and Dissemination") research examines strategies of implementation and adoption of empirically supported interventions in community settings.

A Few Clarifications and Some Examples

1. This Stage Model is *not* prescriptive. Rather, it creates a common language for writing, discussing and reviewing behavioral intervention development research (e.g., grant applications, journal articles, etc.), ultimately leading to a more coherent, efficient, and progressive science.
2. As a non-prescriptive model, it does not require that research be done in any particular order, as long as investigators adequately justify the logic of their proposed sequence. For example, Stage I may lead to Stage II or may lead directly to Stage III (e.g., if the Stage I work was done in a community setting, with community providers). It is equally plausible that Stage II, III, or IV will lead to Stage I.
3. Some sequences, however, are more easily justifiable than others. For example, it is not always reasonable to expect that a positive Stage II efficacy study will automatically or even usually lead to a positive effectiveness study. There almost always is a need for work between traditional efficacy and effectiveness research. Before proceeding to an effectiveness study, an intervention needs to show efficacy in a community setting, in the hands of community providers (Stage III). And before proceeding to Stage III, the intervention needs to be ready for Stage III. If it was not initially developed for use in a community setting with community providers, it needs to be further developed in Stage I - where the intervention can be modified or "adapted " for use in community settings.
4. Basic science questions and basic science research paradigms are integral to the entire behavioral intervention development process.
5. Basic science questions and paradigms are *not limited* to research that occurs prior to intervention development. For example, research on mechanism of action (i.e., asking *how and why* a behavioral intervention works) is equivalent to asking basic science questions and using basic science paradigms within the context of applied behavioral intervention studies.
6. Understanding mechanism of action and the principles behind an intervention may involve basic science expertise, but can have pragmatic effects, such as helping to: (a) Boost the effects of interventions; (b) pare down interventions to what's essential, which can make the intervention more implementable and cut cost; and (c) simplify interventions for easier transportability.
7. Behavioral intervention development is incomplete until the intervention is implementable, which in most cases means that the intervention package includes materials describing how to ensure that community providers administer the intervention with *fidelity*. Therefore, methods for enhancing and maintaining the fidelity of intervention delivery (e.g., training and supervision materials) are an essential part of any therapist-delivered behavioral intervention, and should be developed in Stage I, even after an intervention has proven efficacious in Stage II.