Redefining the Vision for Clinical Science

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“Clinical science” is defined as a psychological science directed at the promotion of adaptive functioning; at the assessment, understanding, amelioration, and prevention of human problems in behavior, affect, cognition or health; and at the application of knowledge in ways consistent with scientific evidence.”
Clinical science is ultimately about the treatment and prevention of behavioral/ cognitive/ emotional/ mental health problems.
What’s the NIH Mission?

“NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.”

May 2012
Clinical science is ultimately about the treatment and prevention of behavioral/ cognitive/ emotional/ mental health problems. √

This is consistent with the NIH mission. √
How does clinical science foster these treatment and prevention goals?

Basic behavioral science + neuroscience ✓
Intervention generation + refinement ✓
Efficacy testing ✓
Effectiveness testing ✓
Dissemination + implementation science ✓

May 2012
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It all fits.
Thank you.
Is there any reason to re-envision what we do?
What are our accomplishments?

To name a few…

• Our understanding of basic behavioral and neurobiological processes is limited… but it is great, and growing.

• We’ve developed many efficacious interventions for behavioral problems… many previously believed to considered potentially intractable.

• Some of these interventions are being used to enhance health, lengthen life, and reduce the burdens of illness and disability.
Are there any problems?

- Basic behavioral science + neuroscience often does not inform intervention generation + refinement. ✓
- Intervention generation + refinement often stops before an intervention is put into a form conducive to implementation. ✓
- Efficacy testing often does not incorporate tests of mechanism. ✓
- Effectiveness testing of efficacious interventions often fails. ✓
- Implementation + dissemination of science-based interventions often does not occur ✓

May 2012
Given that clinical science is ultimately about treatment and prevention interventions, can a new vision of intervention development help to solve these problems?

Can this new vision inform clinical science, and hence, clinical science training?
What if there was a new definition of completion for intervention development where:

- interventions are not just maximally potent
- interventions are maximally implementable

It is acknowledged that implementation is not solely within the domain of services researchers, and that clinical scientists can:
- Develop interventions to fit in the system
- Further develop interventions that don’t fit

Training + fidelity are addressed during the intervention development process:
- Interventions are developed to be delivered with fidelity in the community
- Interventions that don’t retain fidelity are further developed

May 2012 …and …
Intervention Development Vision (continued)

There is a recognition that understanding the underlying principles (or change mechanisms) of an intervention can help to guide the development of maximally potent and implementable interventions. This means that:

- Basic science informs intervention development
- Intervention development informs basic science

*Use-inspired basic research is part of every stage of the intervention development process.*

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## Intervention Development Vision

<table>
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<tr>
<th>Maximally Potent</th>
<th>Maximally Implementable</th>
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<tr>
<td>Fits in system</td>
<td>Further development to fit</td>
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<tr>
<td>Training + fidelity Addressed</td>
<td>Further development for training + fidelity</td>
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<td>Basic is part of intervention development</td>
<td>Intervention development informs basic</td>
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How many clinical scientists does it take to develop an intervention to fit into the service delivery system?

One clinical scientist to develop the intervention…

May 2012
How many clinical scientists does it take to develop an intervention to fit into the service delivery system?

...One million people to reconfigure the service delivery system to accommodate the intervention.

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System
Intervention generation → Efficacy → Effectiveness

INTERVENTION → SYSTEM

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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

May 2012
Change the intervention to fit within the system
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

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Understanding mechanisms of behavior change is crucial to intervention development.

Asking questions about mechanisms of behavior change means asking *basic science questions*…
…within the context of *applied/clinical studies*.

That is, basic science is incorporated into the intervention development process.
Does this mean that basic science is related to intervention development?
Does this mean that basic science is related to implementation?
The NIH Stage Model of Intervention Development: A Bidirectional + Translational Conceptual Framework

Adapted from Rounsaville, Carroll, & Onken, 2001
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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Even if it is efficacious, work on an intervention is *not complete* 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)
The NIH Stage Model can provide a vision for clinical science, and hence, training
NIH Stage Model

Stage I
Intervention Generation/Refinement

Stage II
Efficacy (Research Ther + Clinics)

Stage III
Efficacy (Community Ther + Clinics)

Stage IV
Effectiveness

Stage V
Implementation & Dissemination

Basic research occurs in every Stage

Implementation of potent interventions is the ultimate goal

A step between Efficacy + Effectiveness is added

Basic research occurs in every Stage

Basic research occurs in every Stage
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.
Remarks about the Stage Model

- Intervention development doesn’t end with efficacy.
- Efficacy doesn’t lead directly to effectiveness.
- Changing the 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---before proceeding to effectiveness testing, the intervention needs to be tested for efficacy with community providers, in community settings (Stage III).
- Unless an intervention was generated for use in the community, researchers usually 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).
What does this mean for clinical science training?

• All clinical scientists must be trained to understand the need and urgency of conducting research that will have a positive impact upon the public health.

• Clinical scientists with a primary interest in understanding basic behavioral/cognitive/affective processes involved in psychopathology need to be trained to have an appreciation for intervention development, and an ability to collaborate in intervention generation, efficacy, effectiveness, and implementation research. They need to know how to conduct use-inspired basic research within the whole spectrum (all the Stages) of intervention development research.

• Clinical scientists with a primary interest in all other Stages of intervention development research need to be trained to have an appreciation for basic science, and need to recognize how answering questions about mechanism can help them fulfill the goal of developing maximally potent and implementable interventions.
Training needs to instill:

• An appreciation of the urgent need to solve public health problems.

• An understanding of how the pieces of the clinical science field can contribute to the whole, and can help improve the public health:
  
  Basic contributes to → Applied
  Applied contributes to → Basic
Solution = (Basic + Applied)
Public Health Problem
Good ID = Good D+I
Thank You
“It’s not the consumer’s job to know what they want.”

-Steve Jobs
30 smokers who were trying to quit watched 3 anti-smoking television commercials: they thought commercials “A” and “B” would be the best and “C” would be the worst.”

Experts in the anti-smoking field agreed that “A” and “B” were the best and “C” was the worst.”

All three commercials increased the number of phone calls to a quit line. Commercial “A” was associated with more than twice the expected calls, “B” was associated with more than ten times the number. “C” appeared to increase calls by a factor of 30.

Medial prefrontal cortex activity predicted which commercials were more effective in causing people to call the quit line better than the individuals’ own beliefs.