Building the Evidence

- It takes many years – is there a way to shorten the process?
- Funding (NIH) upholds a linear pipeline but does that fit for the interventions we want to develop for older adults? Is a linear pipeline necessary? Can we bypass or blend steps and if so which ones or how?
- Can we create a more dynamic, iterative model for building evidence for novel interventions and train a new generation in such an approach?
- Following a linear pipeline – we are severely limited by lack of available NIH $ for T2-T3 translation work or hybrid design models so how can we address this effectively?
Introducing a New Intervention

TRADITIONAL PIPELINE

- Should it work?
- Does it work?
- Does it work better than?

Medical Research Council, 2000
Phases of Randomized Controlled Trials (RCT)

Phase I (safety, feasibility, acceptability)

Phase II (preliminary effect size, side effects, dosing)

Phase III (efficacy of new treatment compared to standard)

Phase IV (effectiveness trial)

Phase V (translational/implementation trial)

Phase VI (sustainability)
Typology of RCT Phase III Trials

- **Pure top down or decontextualized**
  - Not service setting or profession specific
    - REACH II Multi-component

- **Hybrid**
  - Intervention elements potentially reimbursable under current guidelines
    - REACH I Skills 2 Care
    - ABLE/CAPABLE

- **Embedded**
  - Tested within adoption setting
    - Adult Day Service Plus (ADS Plus)
    - Beat the Blues
    - IMPACT
    - GRACE Model
# Translational Capacity of 3 Models

<table>
<thead>
<tr>
<th>Study</th>
<th>Research Design/Efficacy</th>
<th>Reach into Target Population (External validity)</th>
<th>Ecological validity (generalize research from artificial to natural settings)</th>
<th>Translatability – Adoption (willingness &amp; ability of natural settings to initiate program)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REACH II</td>
<td>High /High RCT</td>
<td>High (AA, White, Hispanic; Geographic diversity)</td>
<td>Low</td>
<td>-Unknown to Low&lt;br&gt;-Only components translatable</td>
</tr>
<tr>
<td>PURE TYPE</td>
<td>High/High RCT</td>
<td>Medium (AA, White, females do better)</td>
<td>High</td>
<td>-Medium to high&lt;br&gt;-For homecare setting and services with reimbursement capacity</td>
</tr>
<tr>
<td>REACH I-ESP</td>
<td>High/High RCT</td>
<td>Medium (AA, White, moderate income)</td>
<td>Very High</td>
<td>-Extremely high within tested setting&lt;br&gt;-Minimal cost and staff adjustments</td>
</tr>
<tr>
<td>HYBRED</td>
<td>Med/High Quasi-exper.</td>
<td>Medium (AA, White, moderate income)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADS Plus</td>
<td>Med/High Quasi-exper.</td>
<td>Medium (AA, White, moderate income)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Embedded</td>
<td>Med/High Quasi-exper.</td>
<td>Medium (AA, White, moderate income)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# of Translational steps

High  

Pure REACH II

Hybrid ESP

Embedded ADS Plus

Low

Benefits – more rapid translation, more effective implementation strategies, more useful information for policy, administrators, key stakeholders
Typology of Effectiveness-Implementation Models

- Testing effects of a clinical intervention and gathering implementation information
- Dual testing of clinical and implementation intervention strategies
- Testing an implementation strategy while observing intervention outcomes

- Curran et al., in press Effectiveness-implementation hybrid designs
Wilson et al., An Organizing Framework for Translation in Public Health: The Knowledge to Action Framework, 2011, Preventing Chronic Disease
Basic Science +
T1 Research
98.5% of NIH budget

T2, T3, and T4 Research
1.5% of NIH budget
“What a strange business this is: We stay in school forever. We have to battle the system with only a one in eight or one in ten chance of getting funded. We give up making a living until our forties. And we do it because we want to help the world. What kind of crazy person would go for that?”

Nancy Andrews, M.D., Ph.D.

Dean, Duke University Medical School

March 2008   A Broken Pipeline? Flat Funding of the NIH Puts a Generation of Science at Risk.
References

Normalisation process theory: a framework for developing, evaluation and implementing complex interventions BMC Medicine 8-63
www.biomedcentral/1741-7015/8/63

http://ajph.aphapublications.org

Effectiveness-Implementation Hybrid Designs: Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact (Medical Care 2 217-26  http://lww-medicalcare.com