Take Home Points

• Partnerships and existing infrastructure accelerate uptake and enhance scalability and sustainability

• Know your audience
  – Consider multiple stakeholders
  – Balance between engagement and “trust me”

• Carefully consider the trade-offs between tailoring and generalizability
Prevalence of Diagnosed Diabetes among U.S. Adults

Source: 2003-2004 National Health Interview Survey (NHIS) and 2004 Indian Health Service outpatient database.
Prevalence* of Diabetes in 2011
Adults, Ages 20-79

Comparative prevalence, percent

- **61.3 M** in 2011
- **101.2 M** Projected in 2030
- **23.7 M** in 2011
- **29.6 M** Projected in 2030
- **92 Million... in 2008**

Data sources: International Diabetes Federation
**Scope, Consequences, and Cost**

**Obesity**
- Approx. 2/3 of U.S. adults overweight or obese
- Approx. 1/3 of U.S. adults obese
- Increasing in the young
- Annual cost: $147B

**Type 2 Diabetes**
- Approx. 25.8 million U.S. cases (8.3% of population)
- Projected to ~50 million by 2050
  - Annual cost: $245B
  - ↑ 41% since 2007

**Chronic Kidney Disease**
- Approx. 23 million U.S. cases of CKD
- Major causes: diabetes, hypertension
- ESRD annual cost: $27B
What next?
What we did....

• NIDDK’s translation program (R34/R18) was initiated in 2003 to accelerate progress in translating interventions with well-established efficacy (e.g.; DPP and DCCT) to “real world” settings/populations

• Goals:
  – Accelerate the translation of interventions with well-established efficacy to “real world” settings and diverse populations—emphasis on high risk pops
  – Test practical, scalable, generalizable, sustainable, and cost efficient prevention and treatment approaches
  – Emphasis approaches with the potential to be widely disseminated to clinical practice and individuals and communities at high risk
DPP Lifestyle Intervention Delivered in the YMCA

• Study Design
  – Comparative effectiveness trial
  – Group-based DPP at YMCA vs. brief education only
  – 92 participants at risk for diabetes

• Study Questions
  – Can the YMCA deliver group-based DPP?
  – Could it achieve similar weight loss to DPP?
  – Would it be less costly?

Results: Weight Loss & Maintenance

Percent Weight Loss

- **16 weekly visits**
  - p<0.001
- **6 monthly visits**
  - p=0.008
- **NO VISITS!**
- **12 visits in 8 mos**
  - Same intervention now offered to both groups

* p-values comparing Group DPP to Brief Advice

Costs and Cost-effectiveness

<table>
<thead>
<tr>
<th>PRE Diabetes Treatment</th>
<th>Cost per year</th>
<th>$US /QALY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensive Lifestyle</td>
<td>$1,500 / $700</td>
<td>$11,000*</td>
</tr>
<tr>
<td>Group Lifestyle at YMCA</td>
<td>$240†</td>
<td>Cost Saving‡</td>
</tr>
</tbody>
</table>

* https://research.tufts-nemc.org/cear/ratio0.aspx
‡ Herman, et al. 2005 Diabetes Care
Public Health Impact

• 2011: Congressional legislation established the CDC-led National Diabetes Prevention Program
  – Establish local evidence-based lifestyle change programs for people at high risk for type 2 diabetes
    • Train workforce to implement cost effectively
    • Recognition Program: Assure quality and (hopefully) lead to reimbursement
    • Develop intervention sites
    • Marketing to support program uptake
  – Inaugural partners (YMCA and United Health Group)
  – Already provided services to thousands of patients
HELP-PD: Community Health Worker Delivery of DPP Intervention

• Capitalized on a partnership with an existing community-based diabetes education program

• Randomized trial of a community-based DPP
  – 301 overweight or obese persons with pre-diabetes

• Group behavioral lifestyle intervention vs. UC

• Delivered by trained Community Health Workers
  (Patients with DM who had completed DM education, made lifestyle change and judged to have the personality/competency to lead groups

PMID: 19758580.
Percent Weight Loss: 24 month change

Baseline to 12 month change:
LWL: -7.3%
UCC: -1.4%
p<0.001

Baseline to 24 month change:
LWL: -5.1%
UCC: -0.6%
p<0.001

Katula et al. (2013). American Journal of Preventive Medicine
Fasting Blood Glucose: 24 month change

Baseline to 12 month change:
LWL: -4.2 mg/dl
UCC: -0.3 mg/dl
p = 0.002

Baseline to 24 month change:
LWL: -2.2 mg/dl
UCC: 2.1 mg/dl
p = 0.002

Katula et al. (2013). American Journal of Preventive Medicine
HELP PD Costs

- Direct Medical Costs
  - CHW, RD, staff time
  - Materials, overhead

<table>
<thead>
<tr>
<th>Costs</th>
<th>DPP</th>
<th>HELP PD</th>
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</thead>
<tbody>
<tr>
<td>Total Cost (Year 1)</td>
<td>$1771</td>
<td>$569</td>
</tr>
<tr>
<td>Total Cost (Year 2)</td>
<td>$860</td>
<td>$284</td>
</tr>
<tr>
<td>Total Cost (Years 1 &amp; 2)</td>
<td>$2631</td>
<td>$853</td>
</tr>
</tbody>
</table>

Group Discussion

• Public health benefit—what are the pros and cons of each study?
“If you build it they will come.”
Lessons Learned

• Research is rewarding but challenging and high risk
  • Recruitment and retention in high risk groups is often difficult
  • Generalizability limits traditional R & R methods
  • Time consuming: many need 2 yrs of no cost extension
Lessons Learned

• Partnerships with existing organizations and infrastructure are critical for sustainability, scalability, and public health impact

• Consider cost and resources from the beginning

• Community engagement should be considered with ALL stakeholders

• Tension: tailored versus public health/generalizable
Common Issues from Investigators

• What is an adequate comparison condition?

• Is behavior change an acceptable outcome?

• Is this innovative enough?

• My answer: IT DEPENDS!
NIDDK Future Directions

• Continued focus:
  – High risk populations/ reducing health disparities
  – Generalizability and scalability to “real world” context and practice
  – Potential for sustainability outside of research period
  – Cost relative to benefit

• New focus:
  – Evaluation of Natural Experiments
  – Pragmatic
Evaluation of Natural Experiments in Obesity

• PAR 12-257: Time Sensitive Obesity Policy and Program Evaluation (R01)
  – Trans-NIH initiative released August 2012
  – Partners: NCI, NICHD, NIA, and OBSSR
  – Accelerated review/award process
  – No resubmission

• Non-time sensitive “companion” FOAs:
  – PA-13-110, Obesity Policy Evaluation Research (R01)
  – PA-13-100, School Nutrition and Physical Activity Policies, Obesogenic Behaviors and Weight Outcomes (R01)
    • PA13-098 (R21) and PA13-099 (R03
Evaluation of Natural Experiments in Diabetes

- Escalating rates of diabetes and healthcare costs
- A time of dynamic change for healthcare in the U.S.
- Often there is limited evidence about how well these changes in healthcare work

Need research to:
- Support rigorous evaluation of “natural experiments” in healthcare
- Identify what works for whom in clinical practice with diverse populations, and/or patients with multiple co-morbidities
- Provide data to more rapidly inform patients, caregivers, clinicians, healthcare systems, employer/purchasers, and policy makers
Pragmatic Research in Healthcare

- Pragmatic research designs—research that maximizes the applicability and relevance of the trial’s results to routine care/community conditions
  - Test novel, practical, and cost efficient healthcare based strategies to improve health outcomes

- Considerations:
  - Integrated into existing healthcare settings
  - Leveraging existing resources within these practices
Take Home Points

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  – Consider multiple stakeholders
  – Balance between engagement and “trust me”

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Discussion/Questions?
Centers for Diabetes Translation Research (P30)

**Purpose:** enhance the efficiency, productivity, effectiveness and multidisciplinary nature of diabetes translation research.
National Collaborative on Childhood Obesity Research

Public-private partnership: Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Robert Wood Johnson Foundation (RWJF), and the U.S. Department of Agriculture (USDA)

Mission: To improve the efficiency, effectiveness, and application of childhood obesity research, and to halt – and reverse childhood obesity through enhanced coordination and collaboration

Many resources for researchers:  
http://nccor.org