Diabetes Prevention Programs

Public Meeting
June 24, 2016
Welcome and Introduction

- Why are we here today?
- What are ICER and CTAF?
ICER and CTAF Overview

- **ICER**
  - Independent non-profit research institute that evaluates evidence on effectiveness and value of medical tests, treatments, and delivery system innovations

- **CTAF**
  - Independent panel of experts in medicine, scientific evidence, patient experience and health policy
  - Goal: Help patients, clinicians, insurers, and policymakers understand and apply evidence to improve the quality and value of health care
  - Supported by grants from the Blue Shield of California Foundation, the California Health Care Foundation, and the Laura and John Arnold Foundation
Welcome and Introduction

• How was the ICER report on diabetes prevention programs developed?

• How does the CTAF Panel consider evidence for voting?
## ICER Value Assessment Framework

<table>
<thead>
<tr>
<th>Comparative clinical effectiveness</th>
<th>Incremental cost for better clinical outcomes (long-term)</th>
<th>Other benefits or disadvantages</th>
<th>Contextual considerations</th>
<th>“Care Value”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Public discussion and vote</td>
<td>HIGH INTERMEDIATE LOW</td>
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</table>

<table>
<thead>
<tr>
<th>“Care Value”</th>
<th>Potential health system budget impact (short-term)</th>
<th>Provisional “Health System Value”</th>
<th>Maximizing Health System Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public discussion and vote</td>
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<td>Public discussion</td>
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<td>HIGH INTERMEDIATE LOW</td>
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</table>
Welcome and Introduction

• What is the agenda for the day?
Agenda

- **Public Meeting Convened, Topic Overview** | 10:00 am
- **Presentation of the Policy, Evidence, and Economic Analyses** | 10:05 – 11:20 am (Dr. Karen Shore, Dr. Jeff Tice, Dr. Rick Chapman)
- **Public Comments** | 11:20 – 11:50 am
- **Public Comments from DPP Vendors** | 11:50 am – 12:15 pm
- **Lunch** | 12:15 – 12:30 pm
- **CTAF Deliberation and Vote** | 12:45 – 1:30 pm
- **Break** | 1:30 – 1:45 pm
- **Policy Roundtable Discussion** | 1:45 – 3:25 pm
- **Reflections from CTAF Panel** | 3:25 – 3:40 pm
- **Summary, Closing Remarks** | 3:40 – 3:45 pm
  - WiFi SSID: meeting | password: 62016
  - Download meeting materials: [http://tinyurl.com/dpp0624](http://tinyurl.com/dpp0624)
Policy Landscape Analysis

Karen K. Shore, PhD
Partner
Transform Health
• **Disclosures**

  I have no conflicts of interest.
86 million American adults (37%) have prediabetes: blood glucose levels higher than normal but not high enough to be diagnosed with diabetes
  - 90% do not know they have it

13 million adults in CA (~46% of the adult population) have prediabetes or undiagnosed diabetes
  - Prevalence higher among Pacific Islanders (55%), American Indians (51%), African Americans (50%) vs. Asians (42%)
DPP Trial Findings

• Diabetes Prevention Program Trial (DPP Trial): diabetes incidence can be reduced using intensive diet and lifestyle counseling for individuals at high risk for developing diabetes and:
  – Improve individual health/quality of life
  – Save medical costs
CDC Recognition of DPPs

- Available through the Diabetes Prevention Recognition Program (DPRP) for organizations delivering a DPP with:
  - A CDC-approved curriculum that promotes 5-7% weight loss and increased physical activity
  - A lifestyle coach
  - A peer support group of program participants
# Key Features of DPPs

<table>
<thead>
<tr>
<th>Format</th>
<th>Scalability</th>
<th>Cost</th>
<th>Typical Group Size</th>
<th>Key Resources</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-person, individual coaching</td>
<td>Lowest</td>
<td>Highest</td>
<td>1</td>
<td>Humans, facilities</td>
<td>DPP Trial</td>
</tr>
<tr>
<td>In-person, group coaching</td>
<td>Medium</td>
<td>Medium</td>
<td>8-15</td>
<td>Humans, facilities</td>
<td>Weight Watchers for Prediabetes Y</td>
</tr>
<tr>
<td>Digital, human coaching (virtual interaction)</td>
<td>High</td>
<td>Medium</td>
<td>1-24</td>
<td>Humans, technology</td>
<td>Omada® (Omada Health, Inc.) Virtual Lifestyle Management (VLM™, Canary Health, Inc.)</td>
</tr>
<tr>
<td>Digital, fully-automated coaching (based on algorithms)</td>
<td>Highest</td>
<td>Lowest</td>
<td>1+*</td>
<td>Technology</td>
<td>Alive-PD™ (Turnaround Health)</td>
</tr>
</tbody>
</table>

* No group counseling, but participants can join optional virtual teams. The team size was 10 in the published trial.
National Diabetes Prevention Program (NDPP) focused on
  – Reducing prediabetes
  – Scalability

New Prevent T2 curriculum released in March
  – One year, 26 module core curriculum (22 required for recognition by DPRP)
    ▪ 16 modules in first 6 months, 6 modules (of 10) in next 6 months
California Landscape

• CDPH received two CDC grants to increase:
  – Awareness of prediabetes
  – Number and use of DPPs

• Prevent Diabetes STAT program—partnering with CDC and AMA

• Development of statewide action plan to address prediabetes
Prevalence of Diagnosed Diabetes, Location of DPPs in CA
DPP Implementation Considerations

- Increasing awareness of prediabetes (providers and patients)
- Scalability
  - Lifestyle program coach identification, training, retention
- Sustainability
- Culturally-appropriate curricula and strategies to reach underserved communities with populations at high risk
Coverage of DPPs

• Medicare: March 2016 announcement of proposal to expand coverage to all beneficiaries at high risk of developing diabetes

• Medicaid: only Montana covers currently; identification of additional 2-3 states for pilot project

• Private plans: varies but may be increasing based on two relevant USPSTF recommendations

• Employer coverage: 8 states for their employees, variable otherwise
Public Comments

• Language suggestions about DPP heterogeneity, impact, and scalability

• Include a person with diabetes and/or prediabetes as a participant at the public meeting
Evidence Review

Jeffrey A. Tice, MD
Division of General Internal Medicine
Department of Medicine
University of California San Francisco
• **Disclosures**
  
  I have no conflicts of interest.
Overview

• 86 million in US with prediabetes

• The DPP Trial
  – Randomized 3,234 individuals with prediabetes
  – Followed for > 15 years
  – Average 7.2% weight loss at one year
  – 58% reduction in diabetes at 3 years
  – 27% reduction at 15 years
  – 55% diagnosed with DM at 15 years (2-3 year delay in diagnosis)
DPP Trial Intervention

• 16 core lessons
  – Weekly 1 on 1 sessions with lifestyle coach
  – Diet, exercise, goal setting

• 8 post-core sessions
  – Monthly 1 on 1 with lifestyle coach
  – Problem solving, adherence, reinforcement

• 3 goals
  – 7% weight loss; 150 minutes/week exercise; reduce dietary fat to <25% total calories
Guidelines

• USPSTF (Grade B)
  – Individuals who screen positive for prediabetes should be referred to a behavioral counseling program to improve diet and physical activity

• AHA / ACC
  – Obese / overweight individuals with hyperglycemia should be referred to high intensity (≥14 sessions) comprehensive lifestyle management program of at least 6 months duration
Prior Systematic Reviews

- 53 studies describing 66 diet and physical activity programs
- Mean body weight reduction: 2.2%
- Mean diabetes incidence reduction: 41%
- More intensive programs like the DPP Trial intervention were more effective

Methods

• Systematic review of lifestyle intervention programs with full or pending recognition by the CDC’s DPRP

• Randomized trials and observational studies
Results – Study Description

• 10 studies: 5 RCTs and 5 observational trials
  – In-person, group coaching: 7 studies
    ▪ Y, Weight Watchers, Montana DPH&HS, HELP PD
  – Digital, human coaching: 2 studies
    ▪ Omada, VLM (Canary Health)
  – Digital, fully-automated: 1 study
    ▪ Turnaround Health Alive-PD
## Results – Study Quality

<table>
<thead>
<tr>
<th>Program</th>
<th>Studies</th>
<th>N in lifestyle arm</th>
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<tbody>
<tr>
<td><strong>In-person, group coaching</strong></td>
<td></td>
<td></td>
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<tr>
<td>Y</td>
<td>2 RCTs (1 good, 1 fair), 2 poor-quality pre-post</td>
<td>303 2623</td>
</tr>
<tr>
<td>Weight Watchers</td>
<td>1 fair-quality RCT</td>
<td>112</td>
</tr>
<tr>
<td>Montana DPH&amp;HS</td>
<td>1 poor-quality pre-post</td>
<td>3804</td>
</tr>
<tr>
<td>HELP PD</td>
<td>1 good-quality RCT</td>
<td>151</td>
</tr>
<tr>
<td><strong>Digital, human coaching</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Omada (Omada Health)</td>
<td>1 fair-quality pre-post</td>
<td>220</td>
</tr>
<tr>
<td>VLM (Canary Health)</td>
<td>1 poor-quality pre-post</td>
<td>50 (8 with pre-diabetes)</td>
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<tr>
<td><strong>Digital, fully-automated</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alive-PD (Turnaround Health)</td>
<td>1 good-quality RCT</td>
<td>163</td>
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</table>
Weight Loss and Reduction in Diabetes Incidence (DPP Trial)

Reduction in Diabetes Incidence at 3 years

Weight Loss at 6 Months

- 0 to <3%
- 3 to <5%
- 5 to <7%
- 7 to <10%
- ≥10%
Weight loss at 6 and 12 months

No implementation trials designed to evaluate diabetes incidence

% Weight Loss

In-person/Individual
In-person/Group
Digital/Human
Digital/Automated

DPP Trial DEPLOY RAPID* Y (Vojta 2013) Y (Bozack 2014) Montana Weight Watchers HELP PD VLM* Omada ALIVE-PD

6 months
12 months
## Change in HbA1c

<table>
<thead>
<tr>
<th></th>
<th>6 months</th>
<th>12 months</th>
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<tbody>
<tr>
<td>DPP Trial</td>
<td>-0.1%</td>
<td>-0.1%</td>
</tr>
<tr>
<td>Y</td>
<td>-0.1%</td>
<td>-0.1%</td>
</tr>
<tr>
<td>Weight Watchers</td>
<td></td>
<td>-0.3%</td>
</tr>
<tr>
<td>Omada</td>
<td></td>
<td>-0.4%</td>
</tr>
<tr>
<td>Turnaround Health Alive-PD</td>
<td>-0.3%</td>
<td></td>
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Harms

• No excess of adverse events or serious adverse events in lifestyle group compared with placebo or usual care group in randomized trials

• No significant increases in myalgia, arthralgia, fracture, or other musculoskeletal injuries
Controversies / Uncertainties

• Implementation trials are short (1 year)
  – Long-term benefits uncertain

• Definition of prediabetes
  – OGTT was used in DPP Trial
  – Fasting glucose 100-109 is controversial

• Labeling effects of “prediabetes”
Other Potential Benefits or Disadvantages

- Public health benefits of decreased obesity and increased physical activity of the population.
  - Reductions in diabetes and CVD described earlier
  - Reductions in arthritis, sleep apnea, and esophageal reflux disease
  - Improvements in mental health and quality of life
  - Decreased long-term disability
Contextual Considerations

• Prediabetes prevalence is increasing and is linked to the obesity epidemic in the United States

• Culturally appropriate interventions may decrease disparities in prediabetes and diabetes prevalence noted earlier
  – Higher prevalence in lower SES groups
  – Higher prevalence in Pacific Islanders, American Indians, and African Americans
Summary of the Evidence

• In-person, group counseling
  – B+: Incremental or better net health benefit compared to usual care

• Digital, human coach
  – B+: Incremental or better net health benefit compared to usual care

• Digital, fully-automated
  – C+: Comparable or better net health benefit compared to usual care

• Insufficient evidence to distinguish among the 3 approaches
Public Comments Received

- The uncertainty due to the lack of data on the incidence of diabetes in the implementation trials was not highlighted enough.
- The backgrounds of the health coaches are heterogeneous (lay persons to trained health professionals) and that may impact outcomes.
- The DPP Trial demonstrated a delay in diagnosis rather than prevention of type 2 DM.
- The epidemiologic associations between BMI and both prediabetes and diabetes were not included.
- Criticisms on controversies: describing prediabetes as a risk factor for a risk factor downplays the health impact of type 2 diabetes.
Review of Evidence on Cost-Effectiveness

Rick Chapman, PhD, MS
Director of Health Economics
Institute for Clinical and Economic Review
• **Disclosures**
  I have no conflicts of interest.

• **Key review team members:**
  Dan Ollendorf, PhD
Methods

• Reviewed published literature for analyses of economic impact of DPPs in the US with full or pending recognition from CDC

• Included studies of cost of DPPs, analyses of costs potentially offset through use of such programs (e.g., reduced downstream medical costs), and cost-effectiveness analyses (CEAs)
Cost-Effectiveness Analyses

- Li et al. conducted systematic review of economic analyses of “diet and physical activity promotion programs… delivered to persons at increased risk for type 2 DM”
- In 8 US-based studies (of 22 total), median cost per quality-adjusted life-year (QALY) was $9,824, with interquartile range of $1,930 to $41,982 per QALY gained
- Few studies included information on recruitment costs, or cost to implement and scale programs

Li et al, Diabetes Care, 2015
CEAs of In-Person Individual Coaching (DPP Trial) (1)

- DPP Research Group conducted multiple analyses based on DPP Trial, finding that cost per QALY decreased as time horizon increased:
  - $32,000/QALY at 3 years
  - $13,000/QALY at 10 years
  - $1,100/QALY at lifetime horizon
CEAs of In-Person Individual Coaching (DPP Trial) (2)

• In contrast, Archimedes model estimated DPP Trial intervention would cost $143,000 per QALY gained over 30-year time horizon

• Primary differences:
  – Assumed clinical benefits of DPP would diminish over time
  – Participant turnover
  – Lower rate of glycemic progression (i.e., slower progression from prediabetes to diabetes, and from diabetes diagnosis to complications)
CEAs of In-Person DPPs with Group Coaching

- **DPP Trial:** DPP Research Group evaluated DPP as a group intervention rather than individual, assuming lower costs but equal effectiveness
  - $9,000/QALY at 3 years
  - $1,500/QALY at 10 years
  - Cost-saving at lifetime horizon
  - $27,000/QALY at 30 years (Archimedes model)

- **Y-USA DPP:**
  - Cost-saving at 2 years (claims analysis)
  - Cost-saving at lifetime horizon (Medicare budget)
CEAs of Digital DPPs

• Digital, Human Coaching
  – Omada ROI analysis: Cost-saving over 10 years
  – Canary Health VLM: $7,800/QALY at 10 years

• Digital, Fully-automated
  – No published CEAs were found
Summary of DPP Cost-Effectiveness

• Economic analyses estimate that DPPs are cost-effective or cost-saving, especially when provided in a group setting or as digital program with human coaching
  – All estimates <$50,000/QALY, except 1 (<$150,000/QALY)
• Evidence is more robust for in-person DPPs
• Fewer studies of shorter duration for digital, human-coached programs
• No published economic analyses of digital, fully-automated programs
Public Comments Received

• Not consistent with prior reports because summarized literature on cost-effectiveness of DPP programs rather than developing our own model

• Request to add a direct question about cost-effectiveness to the voting questions

• Suggestion to include a study on cost-effectiveness of intensive, individual coaching published in *Journal of the Academy of Nutrition and Dietetics* in 2012
Potential Budget Impact Analysis

Rick Chapman, PhD, MS
Director of Health Economics
Institute for Clinical and Economic Review
Potential Budget Impact: Methods

- Explored the potential health system budget impact of DPPs over 5-year time horizon
- Used published or publicly-available information on program costs, any cost offsets, and potential population eligible for such services
- Total net cost: incremental health care costs of DPPs minus any health care costs that were offset in enrolled participants
Potential Budget Impact: Population

• Estimated entire candidate populations for treatment
  – Adults ages 18 and older with prediabetes
  – Impaired fasting glucose (IFG) threshold of 100 mg/dL: 93.7 million

• Assumed uptake: 10% over 5 years
  – 2% per year

• Year 5 treated estimates:
  – 100 mg/dL: 9.4 million
## Potential Budget Impact at 5 Years (100 mg/dL)

<table>
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<tr>
<th>DPP Type</th>
<th>5-year Analytic Horizon</th>
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<tbody>
<tr>
<td></td>
<td>Number Enrolled (millions)</td>
<td>Weighted BI per Participant ($)*</td>
<td>Average BI per year (billions)</td>
</tr>
<tr>
<td>In-person, Individual Coaching</td>
<td>9.37</td>
<td>$2,793</td>
<td>$5.23</td>
</tr>
<tr>
<td>In-person, Group Coaching</td>
<td>9.37</td>
<td>-$1,146</td>
<td>-$2.15</td>
</tr>
<tr>
<td>Digital, Human Coaching</td>
<td>9.37</td>
<td>-$618</td>
<td>-$1.16</td>
</tr>
</tbody>
</table>

*Note: No published or publicly-presented data were available for digital fully-automated programs.*
Public Comments Received

- Primary cost analysis for digital automated DPP program was based on unpublished HbA1c results from only one program; suggestion to add results based on (unpublished) change in fasting blood glucose, along with those for HbA1c
Public Comments
Lunch

Meeting will resume at 12:45 pm PT
Questions for Deliberation

Diabetes Prevention Programs
Is the evidence “adequate” to demonstrate that “intervention A” is superior to “comparator B” for patients with “condition X”?

Yes

No
What is the care value of “intervention A” vs “comparator B”?

a. Low  
b. Intermediate  
c. High
Practice Question

Which classic movie did not include scenes filmed at the Millennium Biltmore Hotel Los Angeles?

c. L.A. Confidential (1997)
Q1. For patients with prediabetes, is the evidence adequate to demonstrate that the net health benefit of participation in an *in-person diabetes prevention program (DPP) with group coaching* is superior to that of *usual care*?

Yes

No
Q2. Given the available evidence for patients with prediabetes, what is the care value‡ of participation in an in-person DPP with group coaching vs. usual care?

A. Low
B. Intermediate
C. High
Q3. For patients with prediabetes, is the evidence adequate to demonstrate that the net health benefit of participation in a digital DPP with human coaching is superior to that of usual care?

Yes
No
Q4. Given the available evidence for patients with prediabetes, what is the care value of participation in a digital DPP with human coaching vs. usual care?

A. Low

B. Intermediate

C. High
Q5. For patients with prediabetes, is the evidence adequate to demonstrate that the net health benefit of participation in a digital DPP with fully-automated coaching is superior to that of usual care?

Yes

No
Q6. Given the available evidence for patients with prediabetes, what is the care value of participation in a digital DPP with fully-automated coaching vs. usual care?

A. Low
B. Intermediate
C. High
Break

Meeting will reconvene at 1:45 pm PT
Policy Roundtable Participants

- **Ann Albright, PhD, RD**, Director, Division of Diabetes Translation, Centers for Disease Control and Prevention
- **Tony Kuo, MD, MSHS**, Acting Director, Division of Chronic Disease and Injury Prevention and Director, Office of Senior Health, Los Angeles County Department of Public Health
- **Andrew Kuykendall, MSSW**, DPP Participant
- **Elizabeth Murphy, MD, DPhil**, Chief, Endocrinology and Metabolism Division and Director of Diabetes Center for High Risk Populations, San Francisco General Hospital; Professor of Clinical Medicine, UCSF
- **Arthur Southam, MD, MBA, MPH**, Executive Vice President, Health Plan Operations, Kaiser Permanente
- **Tony Van Goor, MD, MMM, CPE, FACP**, Senior Director, Medical Affairs and Medical Director for Policy and Health Technology Assessment, Blue Shield of California
Summary and Closing Remarks
Reflections from CTAF Panel
Meeting Adjourned
Next Steps

- Final report and accompanying materials expected on July 25, 2016
- Meeting materials and outputs:
  http://icer-review.org/meeting/diabetes-prevention-programs/

For more information, please visit
http://icer-review.org/programs/ctaf/