



**CTAF**  
CALIFORNIA TECHNOLOGY  
ASSESSMENT FORUM

# Diabetes Prevention Programs

Public Meeting  
June 24, 2016

# Welcome and Introduction

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

# ICER and CTAF Overview

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- ICER

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

- CTAF

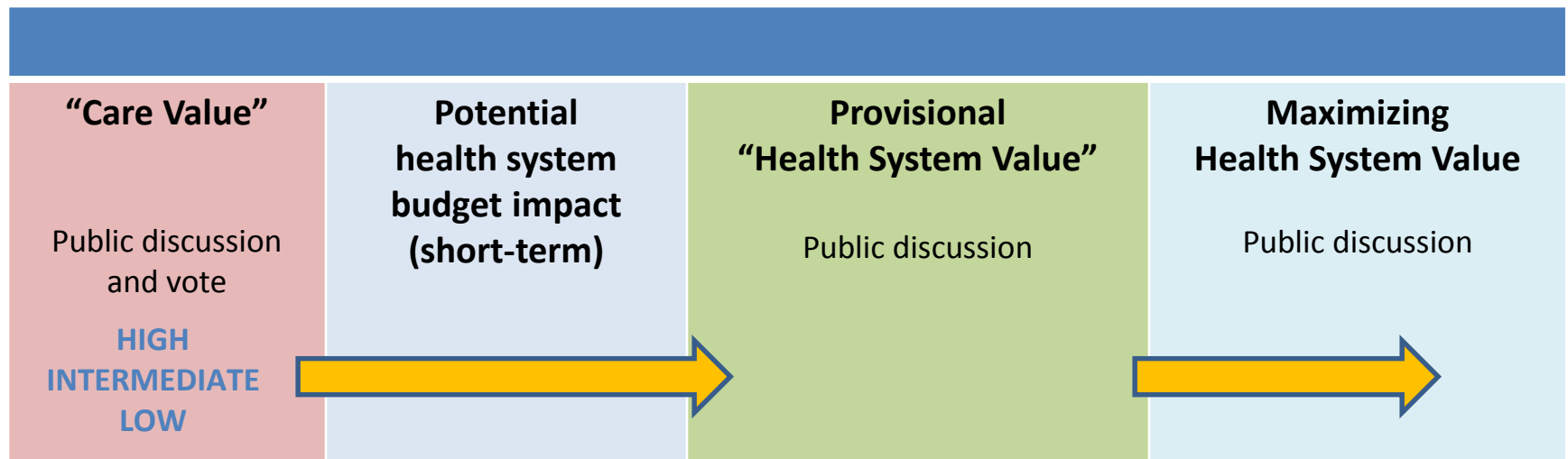
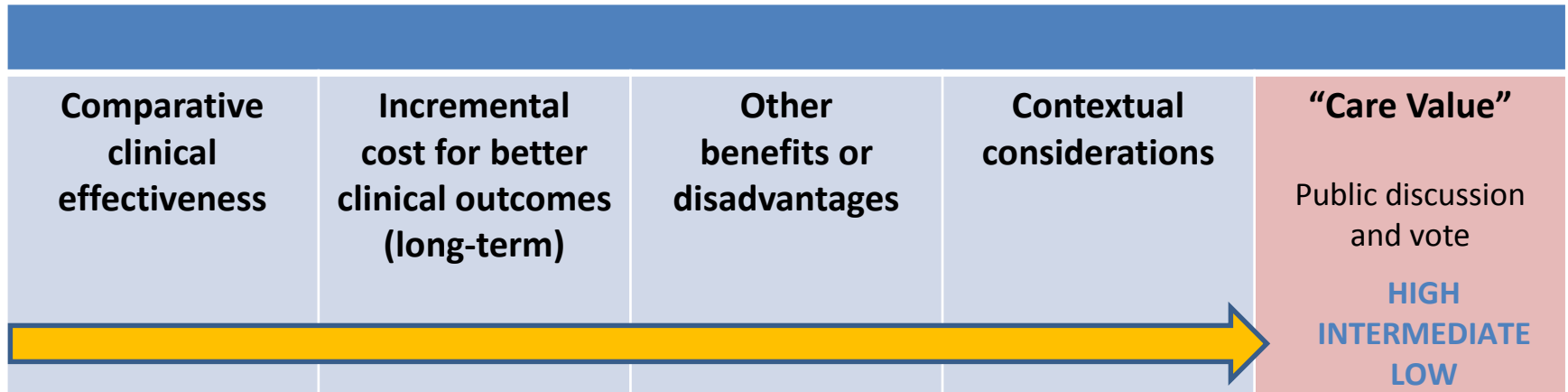
- Independent panel of experts in medicine, scientific evidence, patient experience and health policy
- Goal: Help patients, clinicians, insurers, and policymakers understand and apply evidence to improve the quality and value of health care
- Supported by grants from the Blue Shield of California Foundation,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

# Welcome and Introduction

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- How was the ICER report on diabetes prevention programs developed?
- How does the CTAF Panel consider evidence for voting?

# ICER Value Assessment Framework



# Welcome and Introduction

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- 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>

# Policy Landscape Analysis

**Karen K. Shore, PhD**

Partner

Transform Health



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- Disclosures

I have no conflicts of interest.

# Overview

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- 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

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- 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

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- 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

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

\* No group counseling, but participants can join optional virtual teams. The team size was 10 in the published trial.

# National Landscape

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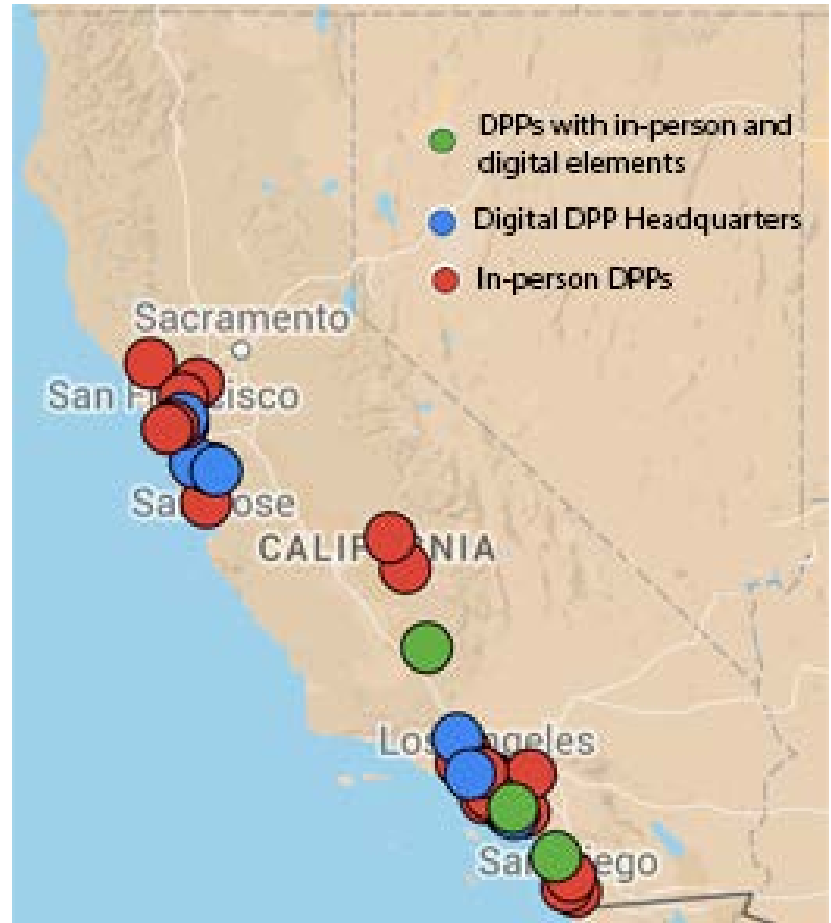
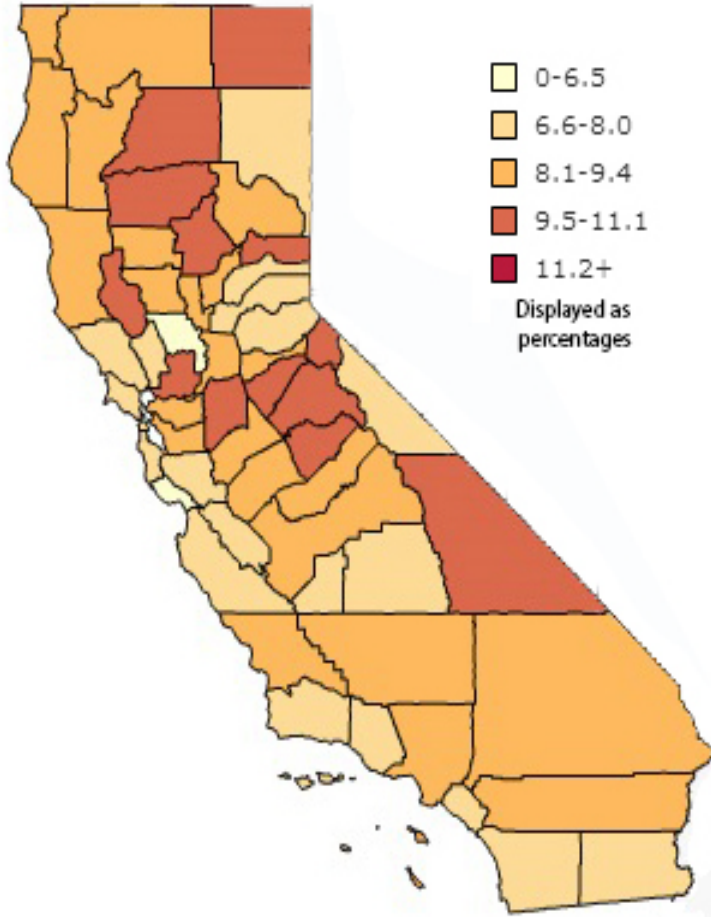
- National Diabetes Prevention Program (NDPP) focused on
  - Reducing prediabetes
  - Scalability
- New Prevent T2 curriculum released in March
  - One year, 26 module core curriculum (22 required for recognition by DPRP)
    - 16 modules in first 6 months, 6 modules (of 10) in next 6 months

# California Landscape

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- 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

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- 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

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- 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

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- 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

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- Disclosures

I have no conflicts of interest.

# Overview

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- 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

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- 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

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- 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 ( $\geq 14$  sessions) comprehensive lifestyle management program of at least 6 months duration



# Prior Systematic Reviews

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- 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

Balk et al, Ann Intern Med, 2015

# Methods

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- Systematic review of lifestyle intervention programs with full or pending recognition by the CDC's DPRP
- Randomized trials and observational studies

# Results – Study Description

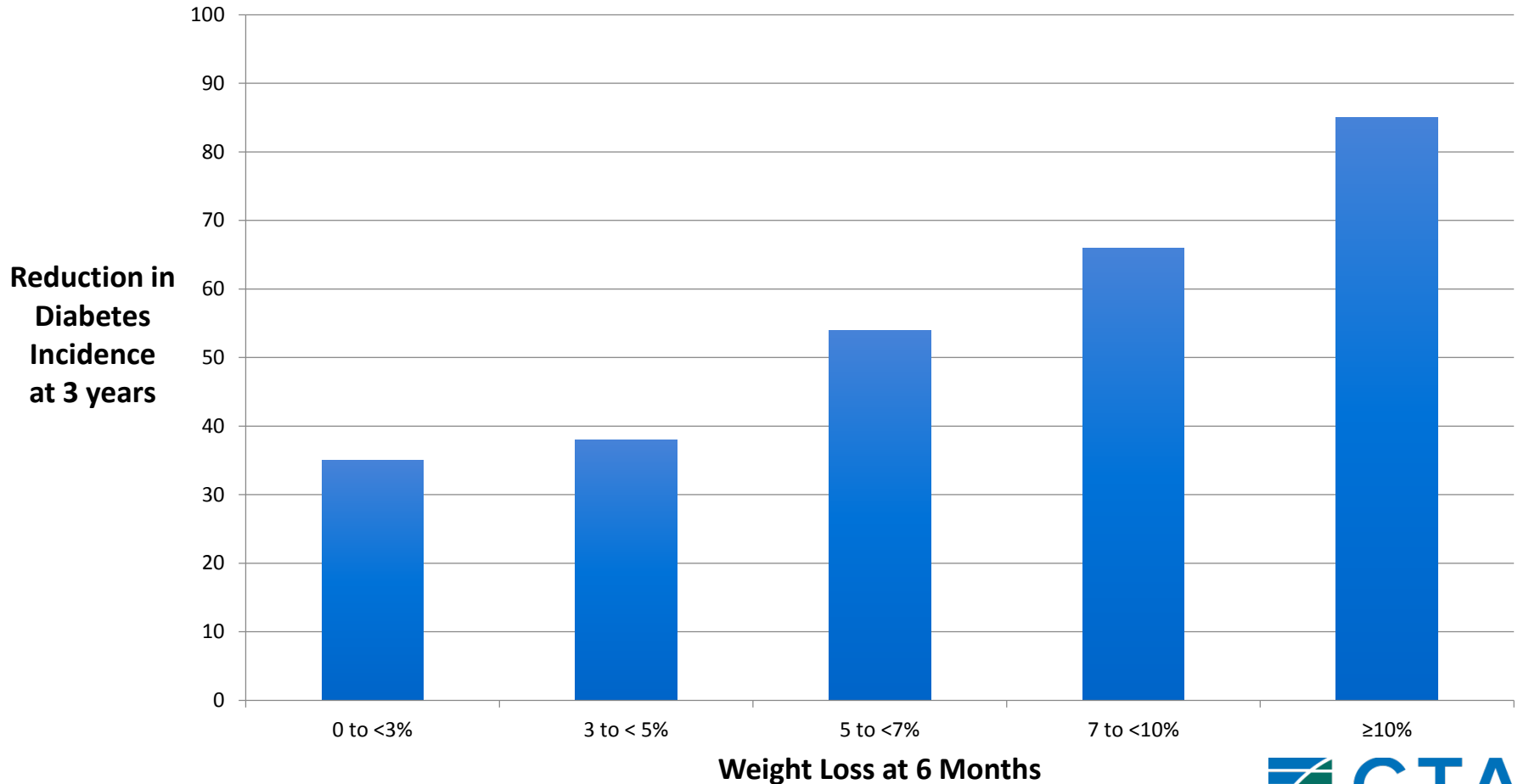
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- 10 studies: 5 RCTs and 5 observational trials
  - In-person, group coaching: 7 studies
    - Y, Weight Watchers, Montana DPH&HS, HELP PD
  - Digital, human coaching: 2 studies
    - Omada, VLM (Canary Health)
  - Digital, fully-automated: 1 study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

# Results – Study Quality

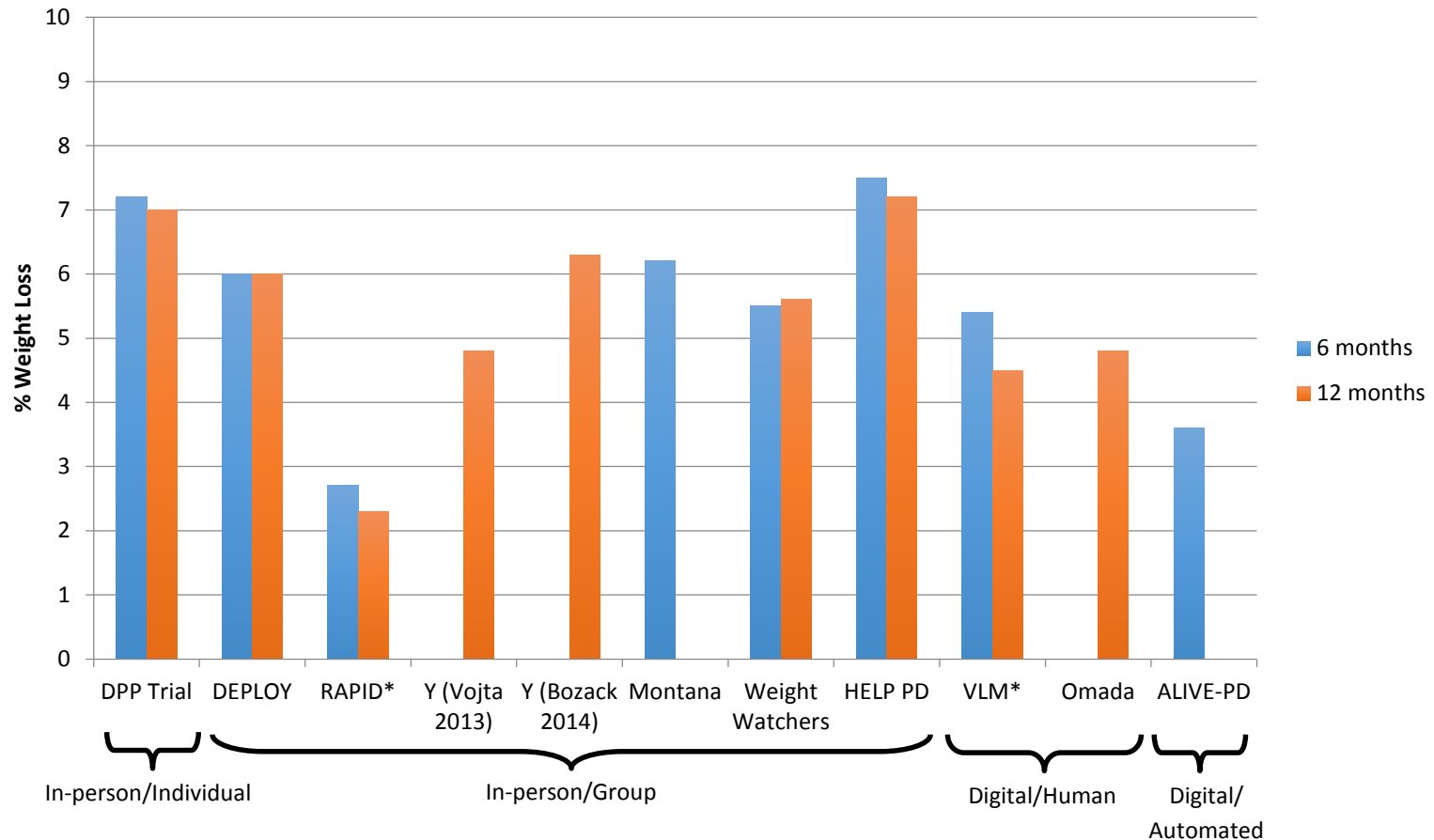
Program	Studies	N in lifestyle arm
<i>In-person, group coaching</i>		
Y	2 RCTs (1 good, 1 fair), 2 poor-quality pre-post	303 2623
Weight Watchers	1 fair-quality RCT	112
Montana DPH&HS	1 poor-quality pre-post	3804
HELP PD	1 good-quality RCT	151
<i>Digital, human coaching</i>		
Omada (Omada Health)	1 fair-quality pre-post	220
VLM (Canary Health)	1 poor-quality pre-post	50 (8 with pre-diabetes)
<i>Digital, fully-automated</i>		
Alive-PD (Turnaround Health)	1 good-quality RCT	163

# Weight Loss and Reduction in Diabetes Incidence (DPP Trial)



# Weight loss at 6 and 12 months

No implementation trials designed to evaluate diabetes incidence



# Change in HbA1c

	6 months	12 months
DPP Trial	-0.1%	-0.1%
Y	-0.1%	-0.1%
Weight Watchers		-0.3%
Omada		-0.4%
Turnaround Health Alive-PD	-0.3%	

# Harms

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- 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

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- 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

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- 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

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- 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

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- 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

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- 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

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- Disclosures

I have no conflicts of interest.

- Key review team members:

Dan Ollendorf, PhD

# Methods

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- 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

# CEAs of In-Person Individual Coaching (DPP Trial) (1)

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- 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

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- 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

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- 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

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- 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)

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

Note: No published or publicly-presented data were available for digital fully-automated programs

# Public Comments Received

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- 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



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# Questions for Deliberation

Diabetes Prevention Programs

# Comparative Clinical Effectiveness: Example Question

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

Yes

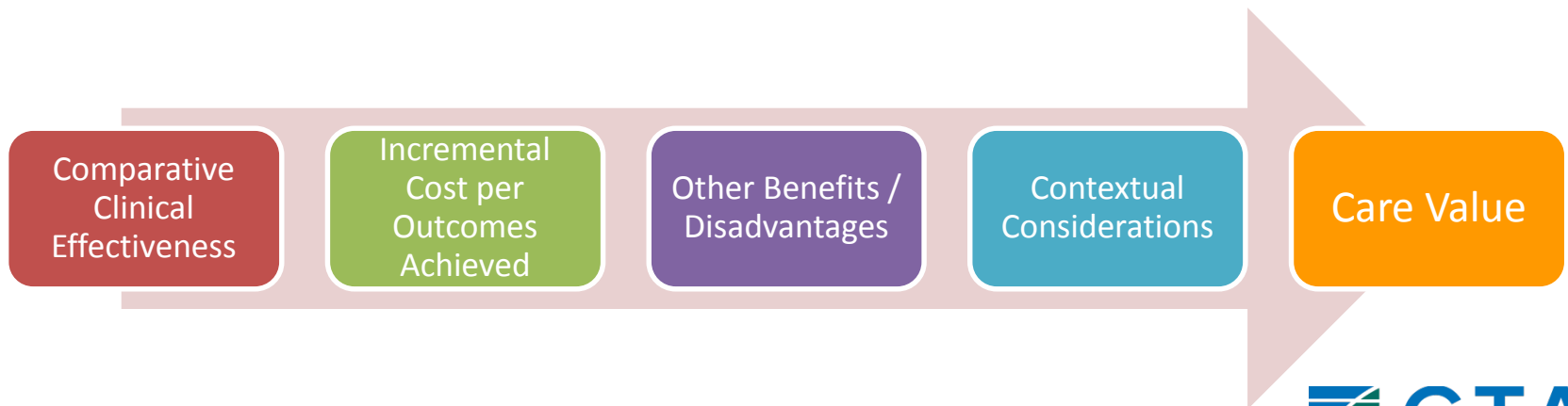
No



# Care Value Example Question

What is the care value of “intervention A” vs “comparator B”?

- a. Low
- b. Intermediate
- c. High



# Practice Question

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

- a. Chinatown (1974)
- b. Beverly Hills Cop (1984)
- c. L.A. Confidential (1997)

# Comparative Clinical Effectiveness: In-person DPP, Group Coaching

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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*?

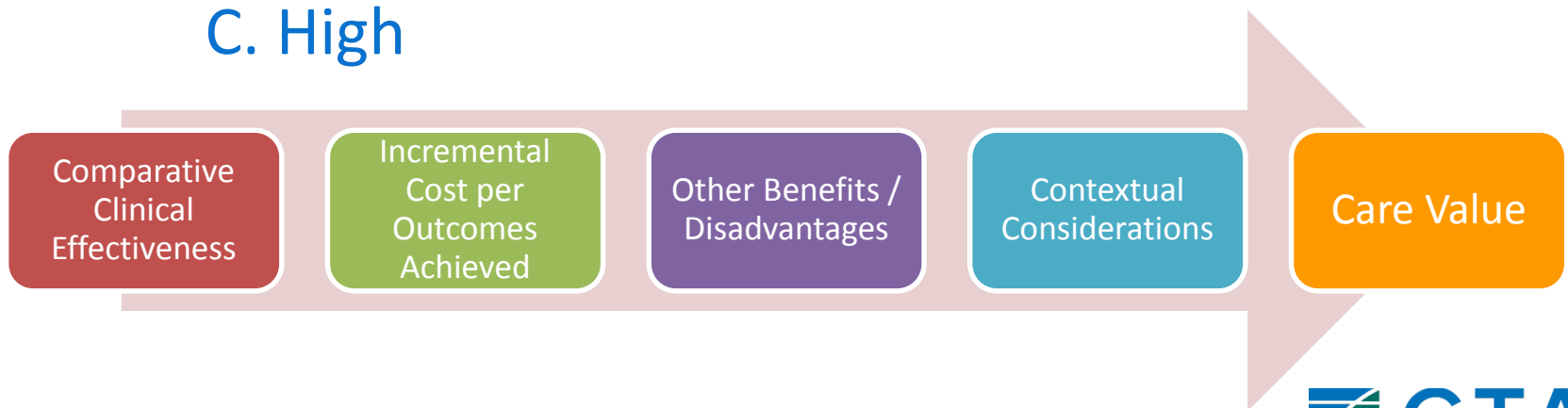
Yes

No

# Care Value: In-person DPP, Group Coaching

Q2. Given the available evidence for patients with prediabetes, what is the care value<sup>‡</sup> of participation in an *in-person DPP with group coaching vs. usual care*?

- A. Low
- B. Intermediate
- C. High



# Comparative Clinical Effectiveness: Digital DPP, Human Coach

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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***?

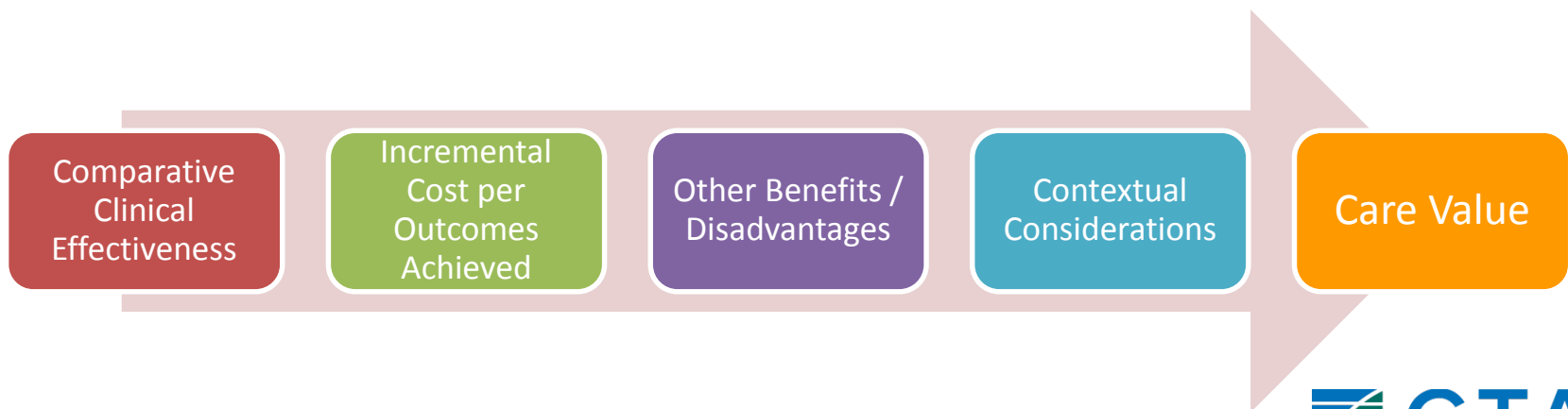
Yes

No

# Care Value: Digital DPP, Human Coaching:

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



# Comparative Clinical Effectiveness: Digital DPP, Automated Coaching

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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***?

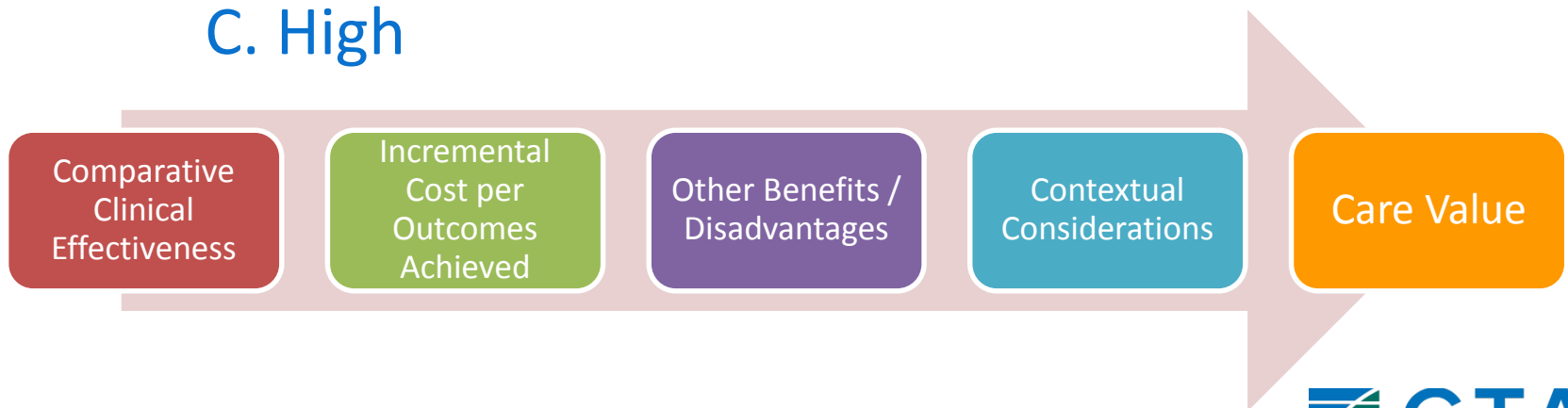
Yes

No

# Care Value: Digital DPP, Automated Coaching

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

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- 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/>