

Public Comments Received on “Diabetes Prevention Programs: Effectiveness and Value” by May 23, 2016

- **John Morton, MD, MPH, FACS, FASMBS**, Chief, Bariatric and Minimally Invasive Surgery, Stanford School of Medicine / Immediate Past President, American Society for Metabolic and Bariatric Surgery, Stanford, CA
- **Leslie Kolb, MBA, BSN, RN**, Vice President of Science and Practice, American Association of Diabetes Educators, Chicago, IL
- **Todd Hobbs, MD**, Diabetes & Obesity Chief Medical Officer, Novo Nordisk, Plainsboro, NJ
- **Bruce Wolfe, MD**, Professor of Surgery and Vice Chair of Research, Department of Surgery; Division of Bariatrics, Oregon Health & Science University, Portland, OR
- **Karin Gillespie, MBA**, Senior Manager, Government Affairs and Public Policy, Novo Nordisk / Diabetes Advocacy Alliance (DAA) Co-chair; **Meghan Riley, BA**, Vice President, Federal Government Affairs, American Diabetes Association, Washington, DC / DAA Co-chair; **Henry Rodriguez, MD**, Chair, Public Policy Council, Pediatric Endocrine Society / DAA Co-chair
- **Gary Foster, PhD**, Chief Scientific Officer, Weight Watchers, Philadelphia, PA
- **Heather Hodge, MEd**, Director, Chronic Disease Prevention Programs, YMCA of the USA, Chicago, IL
- **Gladys Block, PhD**, Scientific Director, Turnaround Health / Professor Emerita, University of California, Berkeley, Berkeley, CA
- **Stefanie Winston Rinehart, Esq**, Director of HHS Legislation and Policy, Academy of Nutrition and Dietetics, Washington, DC

From: John M Morton <morton@stanford.edu>
Date: May 14, 2016 at 8:39:44 PM EDT
To: "publiccomments@icer-review.org" <publiccomments@icer-review.org>
Cc: "Raul J. Rosenthal MD" <rosentr@ccf.org>, "Georgeann Mallory (mallorygn@asmbs.org)" <mallorygn@asmbs.org>
Subject: **Bariatric Surgery's Role in Diabetes Prevention**

To Whom It May Concern:

We read your Draft Evidence Report regarding Diabetes Prevention with great interest. As you are aware, bariatric surgery provides significant relief from the burden of diabetes. As noted in the systematic review by Buchwald JAMA 2006, diabetes remission is >60% at one year following bariatric surgery. The remission of diabetes following sleeve gastrectomy and gastric bypass is further demonstrated through randomized trials with intensive medical therapy such as the STAMPEDE trial in NEJM 2014 wherein gastric bypass patients had a seven fold reduction in diabetes in comparison to medical therapy. Even longer term data regarding the prevention of future diabetes is shown in the SOS trial (JAMA 2014) with a 72.3 remission of diabetes vs. 16.4% for controls at 15 years . In addition, Adams in NEJM 2007 showed that bariatric surgery reduced diabetes associated mortality by 92% in comparison to controls at five years. It is clear and apparent that bariatric surgery can play a significant role in preventing diabetes or its further progression. Bariatric surgery should be included as a primary, secondary and tertiary means of diabetes prevention. On behalf of the American Society for Bariatric and Metabolic Surgery, I am also requesting a speaking opportunity at your June 24, 2016 meeting.

With very best wishes,

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**American Association of Diabetes Educators (AADE) Public Comments on
the ICER Draft Evidence Report on Diabetes Prevention Programs**

The *ICER Draft Evidence Report on Diabetes Prevention Programs* (DPPs) should indicate that there is considerable heterogeneity among in-person DPP delivery models and that these differences are not factored in by their evidence review in the *Draft Evidence Report*. (Please see reference 16 of the *Draft Evidence Report* for a listing of these differences). The report should note that a key difference among in-person DPP delivery models are the eligibility criteria for the implementation staff. For example, the American Association of Diabetes Educators (AADE) DPP model requires that the DPP be delivered by an organization that is accredited by AADE or recognized by the American Diabetes Association (ADA) to deliver diabetes self-management education and support (DSMES). As a result, most AADE DPP staff are health care professionals and all AADE DPP programs have oversight by a Diabetes Educator who is a nurse, a pharmacist, or a dietitian. The AADE DPP network is part of the National DPP (NDPP) and includes 10 DPP Sites that are Fully Recognized by DPRP. The AADE DPP model contrasts with some other DPP models that do not require any staffing by healthcare professionals. While it is understood that ICER chose not to include the AADE DPP model in its evidence review because there are no publications on the model at this time, the AADE DPP model has served over 2,590 persons at risk for diabetes in the US since the inception of the AADE network of DPP Sites in 2012 and is the second largest in-person DPP delivery network in the nation. The existence of the AADE DPP model merits acknowledgment and description in the *ICER Draft Evidence Report* on that basis.

The statement “*Several systematic reviews found that these programs decrease body weight, decrease fasting plasma glucose, improve blood pressure and cholesterol levels, and prevent the onset of type 2 DM.11-16*” on page ES4 of the *ICER Draft Evidence Report* should be revised to reflect the fact that the timeframe for diabetes prevention has not been defined, so that the word *prevent* should be replaced by the phrase *prevent or delay*. This type of correction should be made throughout the report. For example, on page 5 of the *ICER Draft Evidence Report* it is stated, “*Studies have shown that 5-7% weight loss can prevent the development of diabetes in people with elevated levels of blood sugar consistent with prediabetes*”.

May 20, 2016,

Dear representatives of the Institute for Clinical and Economic Review,

Novo Nordisk Inc. (“Novo Nordisk”) appreciates the opportunity to comment on the Draft Evidence Report, titled Diabetes Prevention Programs: Effectiveness and Value prepared by The Institute for Clinical and Economic Review (ICER).

Headquartered in Denmark, and with over 6,000 U.S. employees, Novo Nordisk is a global health care company with 90 years of innovation and leadership in diabetes, obesity, hemophilia and growth hormone disorders. Novo Nordisk is committed to the goal of ensuring patients have access to high-quality, affordable health care, and we welcome the opportunity to work with ICER to achieve this objective.

Prevention of diabetes is a priority for Novo Nordisk and we support the recent certification of the expansion of the Diabetes Prevention Program (DPP) by the Office of the Actuary in the Centers for Medicare & Medicaid Services (CMS) as announced by Secretary Sylvia M. Burwell on March 23, 2016.¹ We are pleased with the findings in ICER’s draft report, namely, that DPPs with in-person group based or digital, human coaching platforms appear to be cost saving, based on a budget impact analysis.

However, Novo Nordisk is concerned with the lack of consistency within ICER’s approach to economic modelling across its evidence assessments. ICER recently reviewed insulin degludec and, within that evaluation, conducted a thorough, independent cost-effectiveness analysis of insulin degludec compared to insulin glargine. However, Novo Nordisk notes that ICER did not conduct such analyses in this assessment. Rather, ICER only evaluated the cost-effectiveness evidence in the scientific literature. Novo Nordisk believes that all assessments conducted by ICER should be treated equally and with the same application of methodological rigor in order to maintain a fair and balanced approach to assessments. We urge ICER to consider this comment for not only this, but also future assessments.

Finally, we strongly suggest that ICER include a person with diabetes and/or pre-diabetes as active participants in the public hearings of its assessments that involve diabetes-related interventions. Such inclusion ensures that voting members on the panel are directly considering the patient perspective in their decision-making rather than taking an indirect approach by filtering the patient perspective through a clinician’s viewpoint. We acknowledge that the CTAF Panel includes a representative with experience in patient advocacy. However, we do not feel this is sufficient since this representative may lack the disease-specific experience that someone diagnosed with the disease can offer.

Sincerely,

Todd Hobbs, M.D.
Diabetes & Obesity Chief Medical Officer
Novo Nordisk

References

1. Independent experts confirm that diabetes prevention model supported by the Affordable Care Act saves money and improves health. HHS Press Office.
<http://www.hhs.gov/about/news/2016/03/23/independent-experts-confirm-diabetes-prevention-model-supported-affordable-care-act-saves-money.html#>. Accessed May 18, 2016.

From: Bruce Wolfe <wolfeb@ohsu.edu>

Date: May 20, 2016 at 6:43:33 PM EDT

To: "publiccomments@icer-review.org" <publiccomments@icer-review.org>

Cc: Raul Rosenthal <R.Rosenthal@asmbsfoundation.org>, John M Morton <morton@stanford.edu>, Georgeann Mallory <mallorygn@asmbs.org>

Subject: The Role of Bariatric Surgery in Diabetes Prevention

To Whom It May Concern:

I am writing in response to your request for public comments regarding Draft Evidence Report regarding Diabetes Prevention. A randomized clinical trial comparing usual or non-operative care to bariatric/metabolic surgery with adequate power and duration to assess the impact of surgery on the incidence of type 2 diabetes (T2DM) has not been reported. Nevertheless, the Swedish Obese Subjects (SOS) study provides important outcomes which should be considered. This observational trial of bariatric surgery versus usual care includes a well-matched comparator group of over 2,000 subjects followed for as long as 15 years. The SOS investigators reported an approximate 80% reduction in the incidence of T2DM (1). The extent of impact on the incidence of diabetes was directly correlated with weight loss (2). The efficacy of nonsurgical weight loss in reducing the incidence of progression of pre-diabetes to diabetes is demonstrated by the DPP. These data indicate that greater weight loss as achieved by surgery has a greater impact on the incidence of type 2 diabetes.

Multiple RCTs comparing surgical to non-surgical intervention for T2DM, summarized by Schauer, et al., demonstrate superior diabetes outcomes (3). The remission of T2DM following gastric bypass is a function of both weight loss and endocrine effects (4). In sum, this body of literature indicates there is a definite role for bariatric/metabolic surgery in the prevention of the progression of pre-diabetes to T2DM in people with obesity. I encourage you to accept the request of Dr. John Morton to speak at the June 24 2016 meeting and consider this information carefully.

Sincerely,

Bruce M. Wolfe, MD

1. Carlsson LM, Peltonen M, Ahlin S, Anveden Å, Bouchard C, Carlsson B, Jacobson P, Lönroth H, Maglio C, Näslund I, Pirazzi C. Bariatric surgery and prevention of type 2 diabetes in Swedish obese subjects. *New England Journal of Medicine*. 2012;367(8):695-704.
2. Sjöholm K, Pajunen P, Jacobson P, Karason K, Sjöström CD, Torgerson J, Carlsson LM, Sjöström L, Peltonen M. Incidence and remission of type 2 diabetes in relation to degree of obesity at baseline and 2 year weight change: the Swedish Obese Subjects (SOS) study. *Diabetologia*. 2015;58(7):1448-53.
3. Schauer PR, Mingrone G, Ikramuddin S, Wolfe BM. Clinical Outcomes of Metabolic Surgery: Efficacy of Glycemic Control, Weight Loss, and Remission of Diabetes. *Diabetes Care*. 2016;39:1-10. doi:10.2337/dc16-0382.
4. Purnell JQ, Selzer F, Wahed A, Pender J, Pories W, Pomp A, Dakin G, Mitchell J, Garcia L, Staten MA, McCloskey C, Cummings DE, Flum DR, Courcoulas AP, Wolfe BM. Type 2 diabetes remission

rates following laparoscopic gastric bypass and gastric banding: Results of the Longitudinal Assessment of Bariatric Surgery Study. Diabetes Care, In Press.

Bruce M. Wolfe, MD

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To The Institute for Clinical and Economic Review:

The Diabetes Advocacy Alliance (DAA), a coalition of 21 diverse members, appreciates the opportunity to provide comments related to the **Diabetes Prevention Programs: Effectiveness and Value** draft evidence report and draft questions for deliberation.

Overall, we support the Institute for Clinical and Economic Review's (ICER) review of diabetes prevention programs (DPPs) and its findings that DPPs are effective at preventing or delaying the onset of type 2 diabetes. We also support ICER's findings that DPPs, particularly in-person group and digital human-coached programs, are cost-effective and cost-savings over time.

The DAA provides the following suggestions for ICER to consider as it finalizes the Diabetes Prevention Program report:

Characterization of Prediabetes and Diabetes

The DAA is extremely concerned about ICER's characterization of prediabetes and diabetes and strongly urges ICER to revise this mischaracterization in the final report. Specifically, the DAA is opposed to ICER stating "*...critics of the term 'prediabetes' have raised concerns about the adverse effects of labeling patients given that prediabetes is simply a group at high risk for diabetes, which in itself is primarily a risk factor for conditions that matter to patients: strokes, heart attacks, blindness, kidney failure and death (ES8).*" For the nearly 30 million Americans living with diabetes, the disease is not simply a "risk factor for other conditions." Diabetes is, in fact, a serious and life-threatening condition that impacts the daily lives of people with diabetes, as well as the lives of their loved ones. Diabetes is a very complex, chronic disease that requires daily decisions about how to manage one's glucose levels. Without proper management, diabetes can lead to devastating and costly complications including, but not limited to, the conditions ICER mentions in the above statement.

In downplaying the seriousness of diabetes and the diabetes epidemic, ICER does a huge disservice to public health efforts to better prevent, manage and treat this devastating disease. In addition to the tens of millions of people who already have diabetes—and live with and manage their disease every day—there are 86 million Americans with prediabetes who are at risk for developing the disease without intervention. The diabetes epidemic, which includes diabetes and prediabetes, costs our nation \$322 billion per year. In the draft report, ICER refers to critics who have raised concerns about labeling patients with prediabetes. The DAA would like to point out, as referred to in the draft report, the Center for Medicare and Medicaid Innovation (CMMI) found improved health outcomes and significant cost savings accrued when individuals with prediabetes participated in a DPP through the YMCA of the USA. It's difficult to understand what kind of "adverse effects" result from targeting individuals with prediabetes and enrolling them in DPPs when the outcomes are improved health and reduced health spending. Further, new guidelines for screening for abnormal blood glucose and type 2 diabetes released by the United States Preventive Services Task Force (USPSTF) in October 2015 found no long-term psychological harms associated with measuring blood glucose and also that the harms of lifestyle intervention (DPP) to reduce the incidence of diabetes are small to none.

Potential Budget Impact

The DAA is requesting a clarification within the “Potential Budget Impact” section of the Draft Report. (pages ES11-ES13 and Sec 6.3 in the Main Report and Appendix I). Specifically, the DAA observes that the first year cost-offset and budget impact numbers for in-person group coaching appear far greater than the other program approaches. Because digital plus human coaching is designed to be scalable and efficient, and because ICER establishes in this report that both approaches are equally clinically effective (B+), it is not intuitive that digital plus human coaching would be dramatically less cost-effective at any point in time relative group in-person coaching. Therefore, we are recommending that ICER include possible explanations and limitations for the dramatic difference in year one savings among in person group coaching. The reason this point is important is because, commercial payers, who have high turn-over among their membership and relatively short payback periods could seize upon these differences to limit their policies to in-person group coaching. The DAA – and the CDC through its Recognition Program – believe that both in-person group coaching and digital plus human coaching are viable alternatives. Furthermore, the DAA believes that the cost-effectiveness literature associated with both modalities is too nascent to clearly establish the short-term cost-effectiveness of one versus the other at this point in time.

Draft Voting Questions

The DAA recommends ICER add an additional voting question related to the cost-effectiveness of DPPs. The draft report includes an in-depth analysis and discussion of the potential budget impact of DPPs and, overall, finds evidence supporting the cost-effectiveness and cost-savings of DPPs. Because payers and employers will be interested in ICER’s findings related to the impact DPPs may have on their budget and health spending, ICER should include a direct question on the cost-effectiveness of DPPs as opposed to referring to “value” in some of the draft questions which is not clearly defined. A potential draft question could be: “Given the available evidence, in-person DPP with group coaching/digital DPP with human coaching is cost-effective/cost-saving?”

Other

We’d like to clarify that Omada Health, a DAA member, has renamed its “Prevent Program” to “The Omada Program”. To avoid confusion, we recommend ICER refer to it as such throughout the report.

Thank you for considering our suggestions. We look forward to the final report and June public meeting. Please feel free to contact Amy Wotring at awot@novonordisk.com with any questions.

Sincerely,

Karin Gillespie
Novo Nordisk
DAA Co-chair

Meghan Riley
American Diabetes Association
DAA Co-chair

Henry Rodriguez, MD
Pediatric Endocrine Society
DAA Co-chair

May 23, 2016

Institute for Clinical and Economic Review
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Re: Draft Evidence Report, “Diabetes Prevention Programs: Effectiveness and Value”

Transmitted by Email to: publiccomments@icer-review.org

On behalf of Weight Watchers International, I appreciate the opportunity to review the Draft Evidence Report titled “Diabetes Prevention Programs: Effectiveness and Value”. Your work to review and synthesize the available evidence on effective diabetes prevention is an invaluable contribution to transform our nation’s health coverage and appropriately balance prevention, wellness, and disease treatment in health care delivery. As the report aptly notes in the background section, “interventions to prevent diabetes have potential to improve individual health and quality of life”.

I commend your report for providing an accurate and succinct overview of the evidence on DPP efficacy and value. Overall, we had two comments that you will see repeatedly in our specific comments organized by report section, they are:

- ❖ We think it would be useful and strengthen the report to directly note and reference the relationship between weight and pre-diabetes and diabetes, including the most up to date professional guidelines on this topic.
- ❖ We request that the discussion of scalability in the report include and address the solutions and innovations that Weight Watchers brings to the NDPP: 1) 16,000 weekly in-person group counseling sessions at 3,000 locations per week; 2) a curriculum and meeting structure that allows people to initiate DPP at any time and attend meetings in various locations or times that are convenient to their schedule; and 3) a supply of 14,000 trained healthy lifestyle coaches.

I offer the following specific comments on the report, organized by section of the report:

- ✓ Background - Executive Summary and Full Report:
Add to the background section – it would be useful to provide the link and data on the strong relationship between weight and prediabetes and diabetes. NHANES found that of the Americans (aged 12 years and older) with prediabetes, 64.9% had overweight or obesity (BMI 25.0 and higher).¹ Only 8% of those with healthy weight have diabetes compared to 15% in with overweight, and 23-43% in those with obesity (dependent on class of obesity).² In addition, weight loss is clearly shown to be the primary method to prevent diabetes³ and an extremely effective way to improve glycemic control in those with diabetes.⁴

weightwatchers

Add to the background section - the American Association of Clinical Endocrinologists, American College of Endocrinology, and USPSTF recommend behavioral counseling for healthy lifestyle, the primary component of DPP, as a first line therapy for those with prediabetes ^{5, 6}.

- ✓ Topic in Context - Executive Summary and Full Report:
Recommend citing the broader range of weight loss (3% to 5%) leading to reduction in risk of diabetes, following the AHA/ACC/TOS guidelines for the management of overweight and obesity in adults. "lifestyle changes that produce even modest, sustained weight loss of 3%-5% produce clinically meaningful health benefits, and greater weight losses produces greater benefits. Sustained weight loss of 3%-5% is likely to result in clinically meaningful reductions in triglycerides, blood glucose, HbA1c, and the risk of developing type 2 diabetes." ⁷
- ✓ The Topic in Context: Full Report, CDC Initiatives – Please make note in Table 2 that Weight Watchers, with meetings held at over 3,000 locations each week, is counted as 1 provider in this chart. You note this anomaly in the California landscape.
- ✓ The Topic in Context: Full Report, California Landscape: Please note that Weight Watchers operates in 136 sites in California that are capable of reporting to NDPP, this is a conservative number that is growing on a daily basis. Also of note, Weight Watchers participates in the California STAT campaign.
- ✓ Barriers and Opportunities: Executive Summary and Full Report:
Add to scalability section - To gain scalability – While there have been barriers as noted by the report, the addition of Weight Watchers significantly enhance the availability of DPP throughout the nation. Specifically, Weight Watchers offers over 16,000 meetings each week at over 3,000 locations throughout the U.S. and the ability for those to begin the program when they are ready to take action (i.e. they do not have to wait for a cohort to form or for the beginning of a class series).

Note on Additional DPP Implementation Considerations:

Coach Workforce Identification Training, and Retention (factor 4) has been substantially addressed with the addition of Weight Watchers to the NDPP– **Weight Watchers has over 14,000 trained lifestyle coaches**, all of whom have successfully lost weight, receive both initial training, and continuing training on behavioral lifestyle counseling for weight management. Please note this significant addition to NDPP for 2016 substantially addresses this issue.

✓ Barriers and Opportunities Full Report: In Scalability Section:

1. Recommend noting, in the paragraph in which The Y's locations are cited (last paragraph on page 9), the availability of Weight Watchers which, as a nationally available provider, was a significant step in addressing scalability. Weight Watchers holds over 16,000 meeting each week, at over 3,000 locations that are run by 14,000 trained lifestyle coaches who have all successfully lost weight.
2. Recommend providing clarity in paragraph at top of page 11 – the addition of Weight Watchers to the NDPP expanded the in-person group meeting options and offers initiation of DPP whenever a person is ready to take action, i.e. they do not need to wait for the start of a class series.

✓ Quality of the Studies – Executive Summary and Full Report:

On the quality of the Weight Watchers RCT, while we understand that the higher loss to follow up in the control arm (but not the intervention arm) is the reason ICER cited for rating the RCT “fair”, the analysis provided to ICER showed that loss to follow up did not impact results. We ask that ICER consider this and, if it retains the rating of fair then more robustly explain that the loss to follow up was in the control arm and data provided showed that this loss to follow up did not impact the findings.

✓ Summary and Comment: The rating of the evidence is excellent and we thank ICER for its careful and thorough review.

Thank you for your leadership and work to advance policy and programs to prevent diabetes, one of the nation's most significant and costly public health issues. Please contact me if you have any questions or would like any additional information. I can be reached at Gary.Foster@weightwatchers.com.

Sincerely,



Gary Foster, Ph.D.
Chief Scientific Officer

¹ McKeever Bullard K et al. Secular changes in U.S. prediabetes prevalence defined by hemoglobin A1c and fasting plasma glucose. *Diabetes Care* 2013;36:2286-2293.

² Nguyen NT, Nguyen XT, Lane J. Relationship between obesity and diabetes in the US adult population: findings from the national health and nutrition examination survey, 1999-2006. *Obes Surg* 2011;21:351-355

³ Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002;346:393-403.

⁴ The Look AHEAD Research Group. Eight-year weight losses with an intensive lifestyle intervention; the Look AHEAD Study. *Obesity* 2014;22:5-13.

⁵ Garber AJ et al. on behalf of the American Association of Clinical Endocrinologists and American College of Endocrinology. (2016). Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm- 2016 executive summary. *Endocrine Practice*

⁶ Siu AL on behalf of the U.S. Preventive Services Task Force. Screening for abnormal blood glucose and type 2 diabetes mellitus: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern*

⁷ Jensen MD et al. (2013) 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. *Circulation*.

May 23, 2016

To The Institute for Clinical and Economic Review:

YMCA of the USA (Y-USA) has reviewed the Draft Evidence Report – Diabetes Prevention Programs and would like to thank ICER for the thorough analysis presented within the report. Based on our review, there are only two items of clarification we'd like the panel to address. Please consider the following suggestions.

2. The Topic In Context

ICER refers to in-person DPPs in California at the organization level (32) and mapped the organizations according to the DPRP listing. One item of clarification is that the organization level information in the DPRP does not constitute the actual number of program locations across those organizations. We kindly request, ICER include a parenthetical reference on page 9 near Figure 2 which indicates that DPP in-person organizations may have several program locations which CDC does not list on the registry.

6. Comparative Value, In-person, Group Coaching

ICER refers to Diabetes Education & Prevention with a Lifestyle Intervention Offered at the Y (DEPLOY) as the section header on page 38 but the content of the section is actually on the CMS actuarial analysis conducted on the Y-USA's Health Care Innovation Award funded under Grant Number 1C1CMS330965 from the Department of Health and Human Services, Centers for Medicare & Medicaid Services, not the DEPLOY study. We kindly request an update to this section header.

Additionally, on page 39 of this section, the payment per beneficiary modeled in the text does not reflect what was published in the CMS actuarial report. The second sentence in the paragraph reflects a payment model per beneficiary that does not clearly align with what was modeled in the CMS actuarial analysis on the potential of two years of payments based on continued program participation. We kindly request a clarification on the data point in the second sentence if the payment amounts might be realized beyond the second year of program participation.

Thank you for considering the above suggestions. We look forward to the final report. Please feel free to contact me with any questions.

Sincerely,

A handwritten signature in black ink that reads "Heather Hodge". The signature is written in a cursive style with a large, stylized 'H' and 'H'.

Heather Hodge, M.Ed.
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Comments on ICER draft report on Diabetes Prevention Programs

Congratulations on a most excellent report -- very comprehensive and well-done.

Our major concern is the use of HbA1c instead of FPG in the estimate of "costs that are potentially offset". We had provided both HbA1c and FPG, but it was an oversight on our part to have answered your question about "costs potentially offset" using only HbA1c. Instead we should have used the FPG results, but at the time we didn't appreciate that fasting glucose is the more routinely-used criterion. It is FPG that was used by Katula et al (2013) in reporting their one-year and 2-year incidence for the HELP PD study.

We request that you use this incidence rate for the cost offset, instead of the incidence based on HbA1c.

Below is a table of incidence at 12 months by FPG (FPG \geq 126), using a last-observation-carried-forward approach (LOCF). We first removed those diabetic by FPG at baseline (8 in Intervention, 4 in Control), leaving 155 in Intervention and 172 in Control.

Table A. Diabetes incidence by Fasting Plasma Glucose.

	FPG Status at 12 months (LOCF)			
	Normal	Prediabetic	Diabetic	Total
Intervention (n, row %)	38 24.52%	107 69.03	10 6.45%	155
Control (n, row %)	34 19.77%	117 68.02	21 12.21%	172
	72	224	31	327

In Intervention, 10 of 155 (6.45%) were diabetic at 12 months using LOCF.

In Control, 21 of 172 (12.21%) were diabetic at 12 months using LOCF.

The difference in incidence rates is 12.21-6.45 or 5.76%. This (5.76 prevented per 100) is parallel to the "2/176" you used from our previous answer based on HbA1c.

The new cost offset would be \$7900 x .0576 = \$455.

As further justification for use of the FPG results, note that our mean FPG at baseline was 109.9 mg/dl, definitely in the prediabetic range and much closer to the baseline levels seen in the DPP, 106 mg/dl. In contrast, our baseline HbA1c, 5.6%, wasn't even in the prediabetic range but rather was in the Normal range. In addition, using incidence by FPG would make our results directly comparable to Katula et al., one of the other "good" studies.

We've also looked at our data a number of different ways (available on request), all of which suggest substantially greater impact than the 1.1% (2 of 176) data that you used for cost offsets based on HbA1c. For example, using the classic 16% diabetes risk reduction per kg lost results in a 32% risk reduction at 12 months from LOCF. Similar or greater risk reductions are supported by analyses of the joint distribution of HbA1c & BMI, the proportion who lowered fasting glucose, and the proportion who moved to Normal fasting glucose.

Some specific points:

Table ES1 and Table 3. Typical Group Size could perhaps be changed to "1 to N". Alive-PD does have a team or group system, which is "virtual". In the PAMF trial, teams were 10 persons each, but the team system can be set to team size of any number.

p.ES7 and page 30, Diabetes Incidence: Perhaps you could mention Alive-PD's results here. HELP PD (Katula) reported diabetes incidence, based on FPG ≥ 126 . Our 1-year results for FPG, as mentioned above, are 6.45% in Intervention and 12.21% in Control. By intention-to-treat.

p.ES8, last full paragraph, and page 32 last paragraph: I wonder if you might consider increasing the grade somewhat for "fully automated programs". We recognize that with only a single paper there has to be greater uncertainty. But the study is Good, unlike the studies of the other virtual programs (rated only as Fair or Poor) that you gave a B+. And we have actual glycemic effects, showing an actual reduction in diabetes incidence based on FPG, unlike studies that are based solely on imputing from weight loss. In terms of Effect Size, Alive-PD's results are as good as or better than many others.

p.ES11, cost-effectiveness analysis for fully-automated: A cost-effectiveness analysis is planned.

Table ES2, page ES12, and Table 5, page 42. Hopefully you will be willing to change this table after reconsideration of the estimates about cost offsets, above. Changing the cost-offset from \$90 to \$455 ($.0576 \times \$7900$) would change the annual BI at 1 year from \$-24 to \$-389. I'm not suggesting what the figure should be for the 5-year horizon, as I don't understand how it was derived.

Figure ES3, Figure 8, Figure 11. Similarly, this figure would have to change.

p.6, End of top paragraph: Perhaps point out that our figure of 3.5% is for an ITT analysis.

p.22, last sentence of first full paragraph: "no group experience" is not quite correct for Alive-PD. Participants are assigned to 'virtual' teams, and within- and between-team messaging is incentivized with points and facilitated with a messaging system.

p.27, top paragraph. The first two sentences don't begin to describe the Alive-PD program, which is a lot more than "just" goal-setting. A more accurate summary might be "...an automated program using email, individualized web resources, smartphone and Interactive Voice Response, which support weekly goal-setting and reminders, tracking, a virtual team system and

gamification using a points system. There are no in-person group sessions and no personal contact...." We also have quizzes, a messaging system to promote peer support, as well as weekly health information and infographics, should you want to add any of that.

p. 27, second paragraph. Perhaps add "with NIH funding" to first sentence.

p.43, Table 6. I see that you didn't have estimates from any of the studies on what the offsets would be if only those over 110 are enrolled. A higher proportion would develop diabetes. So for your information: Using difference between intervention and control in percent who moved to glucose by FPG: In those with FPG ≥ 110 at baseline, ITT results are as follows, for Alive-PD: Intervention, developed diabetes: 9/69, 13.04%. Control, developed diabetes: 17/73, 23.29%

p.87, digital fully automated: Perhaps change "Group=No" to "Virtual"

p.97,98, Tables I2, I3, I4: As noted, the cost offsets for "Digital fully automated" should be changed to \$455 (.0576 x \$7900), reflecting incidence reduction in the same way that Katula did. Then, the (\$24) in Table I3 would change to (\$389) (\$66-\$455).

Comments of general nature (we can send, on request, further separate suggestions on text unrelated to the fully-automated approach).

P ES3. Perhaps, for the footnote to Table ES1, you meant to refer to Table I2 rather than I1, for costs and cost offsets. Also, it would be helpful if the table included a range of costs cited, instead of or in addition to "Highest, Medium, Lowest".

p.ES5, under Weight loss, first sentence. For clarity, I would insert "incidence" after "35%" and "85%".

p 6, under CDC Initiatives. Sentence beginning "To achieve recognition..." is not quite correct. There is no requirement to provide data on preventing or delaying T2DM, only to provide data on weight change and aspects of data collection (Table 1 of Standards document). The fact that there is no requirement to provide data on actually preventing or delaying T2DM seems to me quite remarkable, and worth calling attention to.

P 31. Controversies and Uncertainties. The lack of reporting of effects on glycemic markers seems a critical uncertainty and worthy of being discussed. To rely on weight change without confirmation of a prevention of diabetes, given the uncertainty about the durability of weight loss, seems an important shortcoming that should be remedied in future studies.

P.63. The title for Table C3 should add "for those using the DPP curriculum", as other curricula (including Alive-PD's) can be considered by CDC/DPRP and approved.

Thank you for the opportunity to review and comment on your draft report. And please let us know if you'd like any clarification.

Gladys Block, Scientific Director



May 23, 2016

re: Comments to the Institute for Clinical and Economic Review on the Diabetes Prevention Programs: Effectiveness and Value

The Academy of Nutrition and Dietetics (the “Academy”) applauds the Institute for Clinical and Economic Review (ICER) for the comprehensive review of the effectiveness and value of Diabetes Prevention Programs, and we appreciate the opportunity to comment on the Draft Evidence Report and the Draft Questions for Deliberation. Representing over 100,000 registered dietitian nutritionists (RDNs),ⁱ nutrition dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals in the United States committed to improving the nation’s health through food and nutrition across the lifecycle. Academy members provide professional services such as medical nutrition therapy (MNT)ⁱⁱ and were involved in the development, implementation, and provision of the National Diabetes Prevention Program (NDPP) from the very beginning. The Diabetes Care and Education Dietetic Practice Group (DCE DPG) is comprised of Academy members that are experts in diabetes prevention and care, and provided valuable input on the Draft Evidence Report.

The Academy offers the following suggestions to be highlighted in the Draft Evidence Report.

1. The Draft Evidence Report highlighted the improved benefits from more intensive interventions, particularly the original DPP Trial, which utilized in-person DPP with individual coaching. The Diabetes Prevention Programs Outcomes Study (DPPOS) also highlights the importance of long-term outcomes, and focuses on these outcomes in relation to cardiovascular disease. The Academy recommends that the importance of these more intensive interventions, particularly with long-term outcomes, be highlighted in the final Evidence Report.
2. The Academy suggests including the importance of culturally appropriate curricula for DPP programs, particularly as it relates to diet. RDNs remain the most cost-effective, qualified healthcare professional to provide nutrition based lifestyle interventions, including MNT and evidence-based nutrition counseling and weight-loss management services. RDNs have demonstrated competencies and outcomes that differently and less qualified providers of non-medical nutrition services have been yet unable to demonstrate. RDNs are trained to provide motivational interviewing, and have expertise in counseling pregnant women. RDNs are also able to connect patients to community resources, which may be especially helpful for first-time mothers. RDNs’ evidence-based national practice guidelines and Evidence Analysis Library are leading, respected tools for effecting positive health outcomes. The Institute of Medicine (IOM) found that “the registered dietitian is currently the single identifiable group of health-care professionals with standardized education, clinical training, continuing education and national credentialing requirements necessary to be directly reimbursed as a provider of nutrition therapy.”ⁱⁱⁱ

3. As noted on page 14 of the Draft Evidence report, it is important that coaches for the DPP programs be well-trained and competent to provide the program to the community targeted by the DPP. Dietetic technicians, registered (DTRs) are educated and trained at the technical level of nutrition and dietetics practice for the delivery of safe, culturally competent, quality food and nutrition services. DTRs already work in many community settings, helping to educate clients about the connection between food, fitness and improved health outcomes.^{iv} The Academy recommends including DTRs as examples of skilled lifestyle program coaches.
4. The Academy suggests adding a study on the cost-effectiveness of intensive, individual coaching, which was published in the Journal of the Academy of Nutrition and Dietetics in 2012.^v The aims of this study were to determine the thresholds of diabetes cases that need to be averted by prediabetes lifestyle interventions in order to be cost saving and/or cost-effective to a single health care insurance payer, such as Medicare; and to compare those thresholds with published intervention data to determine the feasibility of cost savings and/or cost-effectiveness. The study concluded that prediabetes lifestyle interventions for people aged 65 years or older are highly cost-effective and possibly cost saving to a health care insurance payer such as Medicare. It is likely that medical nutrition therapy could be even more cost saving and/or cost-effective than intensive lifestyle interventions. These results suggest that Medicare would receive financial benefit from providing coverage for these services.

The Academy also offers the following recommendations on the Draft Questions for Deliberation.

1. The Academy suggests including a question that asks if the evidence is adequate to demonstrate that the net health benefit of participation in an in-person diabetes prevention program with individual counseling is superior to that of usual care.
2. The Academy also suggests including a question that assesses the adequacy of evidence for valuing cost-effectiveness across the different DPP delivery methods.

ⁱ The Academy recently approved the optional use of the credential “registered dietitian nutritionist (RDN)” by “registered dietitians (RDs)” to more accurately convey who they are and what they do as the nation’s food and nutrition experts. The RD and RDN credentials have identical meanings and legal trademark definitions.

ⁱⁱ Medical nutrition therapy (MNT) is an evidence-based application of the Nutrition Care Process focused on prevention, delay or management of diseases and conditions, and involves an in-depth assessment, periodic re-assessment and intervention. [Academy of Nutrition and Dietetics' Definition of Terms list, <http://www.eatright.org/scope/>, accessed 2 April 2014.] The term MNT is sometimes used interchangeably with, but is sometimes considered different from, nutrition counseling in health insurance plans.

ⁱⁱⁱ Committee on Nutrition Services for Medicare Beneficiaries. "The Role of Nutrition in Maintaining Health in the Nation's Elderly: Evaluating Coverage of Nutrition Services for the Medicare Population." Washington, DC: Food and Nutrition Board, Institute of Medicine; January 1, 2000 (published).

^{iv} What is a Dietetic Technician, Registered? <http://www.eatrightpro.org/resources/about-us/what-is-an-rdn-and-dtr/what-is-a-dietetic-technician-registered>.

^v Anderson, Jennifer M. Achievable Cost Saving and Cost-Effective Thresholds for Diabetes Prevention Lifestyle Interventions in People Aged 65 Years and Older: A Single-Payer Perspective, *Journal of the Academy of Nutrition and Dietetics* , Volume 112 , Issue 11 , 1747 – 1754.