**Supplemental Table S1.** Summary of additional studies on DASH diet worthy of consideration

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Study # | Citation | Study Type | Description | Subjects | Duration | Findings for DASH Diet | Comments (support or not of each eating pattern overall) |
| 1 | Blumenthal J, 2010 | RCT (ENCORE study) | Compared DASH; DASH + exercise + calorie restriction; usual care | **n= 45** for patients with prediabetes or T2D | 4 months | Post hoc analysis of prediabetes and diabetes who improved in at least 1 category:  DASH with exercise/energy restriction – 72%  DASH alone - 54%  UC – 42%  Worsening diabetes status:  DASH with exercise/energy restriction – 2%  DASH – 16%  UC – 11% | **Limited support for claims.** Diabetes status worsened in DASH only arm. |
| 2 | Paula TP, 2015 | RCT | Compared DASH diet with ADA recommended diet in T2D with uncontrolled hypertension. The intervention group was encouraged to walk more using a pedometer. Calorie intake was higher in the control group compared to the intervention group | **n=40** persons with T2D and high blood pressure | 4 weeks | BP: DASH arm significantly improved  Glycemic control: nSS | **Limited support for claims.** Short study and no advantage in glycemic control for DASH |

**Supplemental Table S2.** Summary of additional studies on Mediterranean diet worthy of consideration

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Study # | Citation | Study Type | Description | Subjects | Duration | Findings for Med Diet | Comments  (support or not of each eating pattern overall) |
| 1 | Toobert D, 2003 | RCT | Med diet vs. control diet (usual care). No calorie restriction. Included exercise and intensive behavioral support.  Main outcomes included HbA1c, lipids, BMI, blood pressure. | **n=279** postmenopausal women with T2D | 6 months | **♦ HbA1c** ↓4.8% **BG SS** **♦ BMI ↓**1.0% **BG SS**  **Lipids, blood pressure** **nSS** | **Supports claims.** |
| 2 | Ajala O, 2013 | Systematic review and meta-analysis | Assessed the effect of diet types on glycemic control, lipids, and weight loss.  Based on search to Aug 2011 for RCTs of ≥ 6 mo. Includes 3 studies on Med diet. | Persons with T2D |  | Found the Med diet superior to other diets for glycemic control (HbA1c) and weight loss; improved TRIG, HDL, need for diabetes medication. | **Supports claims.** |
| 3 | Huo R, 2015 | Systematic review and meta-analysis | Meta-analysis of RCTs to explore the effects of the Med diet, compared to control diets, on glycemic control, weight loss and CVD risk factors in persons with T2D. Included 9 studies. Based on search of literature to Feb 2014. | Persons with T2D |  | Med diet resulted in greater improvement in HbA1c, FBG, weight loss, HDL and TRIG than control diets. | **Supports claims.** |
| 4 | Shai I, 2008 | RCT | Compared Med, low-carb, and low-fat diets. | **n = 46** with T2D | 2 years | **FBG** better in Mediterranean  **HOMAIR** better in Mediterranean  **HbA1c**:  Low fat decrease 0.4  Mediterranean decrease 0.5  Low carb decrease 0.9 | **Supports claims.** |

**Supplemental Table S3.** Summary of additional studies on plant-based diets worthy of consideration

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Study # | Citation | Study Type | Intervention | Subjects | Duration | Findings | Comments  (support or not of each eating pattern overall) |
| 1 | Barnard N, 2018 | RCT | Tested efficacy of low-fat vegan diet vs. control diet in clinical setting. E-restricted only in control diet. | **n=45** obese, T2D | 20 weeks | **♦ HbA1c ↓**7.5% **WG SS, BG nSS** **♦ Weight loss ↓**6.4% **WG SS, BG nSS**  **♦ TRG 12% increase** | **Limited support for claims** not better than control.  Triglycerides increased Published after 2018 SOC. |
| 2 | Kahleova H, 2014 | FU to RCT | Compared E-restricted vegetarian and conventional diabetic diets on body fat, IS, oxidative stress. | **n=45** obese, T2D | 6 months after end of 24-week RCT | from baseline **♦ HbA1c** ↓.1 **BG nSS, WG nSS** **♦ Weight loss** ↓4.5% **BG SS** | **Limited support for claims** glycemic control not better than control but weight was better. |
| 3 | Lee Y, 2016 | RCT | Compared vegan diet to Korean Diabetes Assn. diet. | **n=93**, T2D | 12 weeks | **♦ HbA1c** ↓6.5% **WG SS, BG SS** **♦ Weight loss** ↓2.1% **WG SS, BG nSS**  **♦ TRG increased significantly in the vegan arm** | **Limited support for claims.** Triglycerides increased in vegan arm |
| 4 | Berman MA, 2018 | Single arm demonstration | Effect sustainable shift to PBD; test efficacy of digital therapeutic in glycemic control and medication use | **n=118**, T2D | 12 weeks | **♦ HbA1c** ↓9.9% **SS** | **Supports claim.**  Note: HbA1c were patient- reported. |
| 5 | Yokoyama Y, 2014 | Systematic review and meta-analysis | Lit search 1900 through Dec 9 2013 for trials on PBD in adults with T2D ≥ 4 weeks and reporting HbA1c and FBG. Six studies included: 3 RCTs and two clinical trials. | **Total n=255** (17 lacto-ovo-vegetarian and 238 vegan)   All participants had T2D | 4-22 weeks | **HbA1c** Mean absolute difference between test and control diets  was .39. | **Supports claim**  A follow up study was excluded which may have impacted findings |
| 6 | Ajala O, 2013 | Systematic review and meta-analysis | Lit search to August 2011 of RCTs ≥ 6 mo comparing various diet types. Included 2 RCTs on PB diets (Barnard, 2009 and Kahleova, 2011) |  |  | "...there is a suggestion that vegan and vegetarian diets might be beneﬁcial in improving glycemic control and inducing weight loss. However, there is a need for more studies to support the wider use of these diets in people with diabetes." | **Limited support for claim** |
| 7 | Mishra, 2013 | RCT | Worksite program comparing no diet change to low-fat vegan diet for weight, lipids, blood pressure and HbA1c | **n=35**, with T2D | 18 weeks | **♦ HbA1c** ↓9% **WG** **SS, BG SS** | **Limited support for claim** Only glycemic control reported separately for participants with diabetes.  Triglycerides worsened in the intervention arm for whole study population |
| 8 | Ferdowsian, 2010 | Non-randomized | To determine whether a multicomponent intervention program at a corporate site in its effectiveness in reducing body weight and improving cardiovascular risk factors in overweight individuals. | **n=19**, with diabetes |  | **♦ HbA1c** ↓4.1% **WG** n**SS, BG nSS** | **Limited support for claim** Medication adjustment discussed but not reported |
| 9 | De Natale, 2009 | Randomized, cross-over | Compared high fiber and high (52%E carb, 30%E fat, low GI); fiber mainly from plants, fruits, legumes and cereal vs high-fat diet (45%E carb, 37%E fat, high GI) | **n=14,** with diabetes |  | **Higher carbohydrate and low GI resulted in SS lower glucose and plasma insulin 2-3 hrs after meal** | **Limited support for claim**  Control diet was high GI |

**Supplemental Table S4.** Summary of additional studies on the low-carbohydrate diet worthy of consideration

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Study # | Citation | Study Type | Description | Subject s | Duration | Findings for the Low-Carb Diet | Comments |
| Randomized Controlled Trials | | | | | | | |
| 1 | Saslow L, 2017 | RCT | Compared low-carb, ketogenic diet vs. moderate-carb, lower-fat, calorie-restricted diet | **n=34** adults with T2D; 29 (85.3%) completed. | 1 year | **♦ HbA1c** ↓7.6% **BG SS**  **♦ Weight Loss** 7.9% **BG SS**  **♦ Fasting insulin** ↑4.6% **BG nSS**  **♦ HOMA2IR** 0.0% **BG nSS**  **♦ HDL, TRG, LDL BG nSS  ♦ TRG:HDL ratio** ↓22.7% **BG SS**  **♦ Diabetes Medications**  Sulfonylureas or dipeptidyl peptidase-4 inhibitors: all 6 in low-carb diet group discontinued the meds by 12 months. **BG SS**  **♦** Metformin: reductions in low-carb group greater. **BG nSS** | **Supports claims** |
| 2 | Yamada Y, 2014 | RCT | Examined the effects of a non-calorie-restricted, low-carbohydrate diet vs. a calorie-restricted diet. | **n=24** adults with diabetes; 24 (100%) completed. | 6 months | **♦ HbA1c ↓8.6% BG SS  FBG BG nSS**  **♦ Weight Loss** ↓3.9% **BG nSS**  **LDL, HDL, SBP, DBP BG nSS   ♦ TRG ↓**41.7% **WG SS BG nSS**  **Safety and Adverse Effects**  "...no changes in the markers of the renal function (i.e., urinary nitrogen, Cr, eGFR and albumin-to-creatinine ratio) … in either group. A marker of the liver function, the alanine aminotransferase level, tended to improve in the low-carbohydrate group ..." | **Supports claims** |
| 3 | Jonasson, 2014 | Secondary analysis from RCT (Guldbrand, 2012) | Investigated effects on inflammation of a low-carb diet vs. a low-fat diet. | **n=61** adults with T2D; 100% completed. | 6 months | **♦ HbA1c**  ↓5.3% **WG SS BG nSS**  **♦ BMI** ↓6.3% **WG SS BG nSS**  **♦ IL-IRa and IL-6** **BG SS**  **Lipids BG nSS** | **Limited support for claims**  Between groups nSS but inflammation reduction in low-carbohydrate arm |
| 4 | Guldbrand, 2012 | RCT | Compared the effects on HbA1c and weight loss of a low-fat diet vs. a low-carb diet. | **n=61** adults with T2D; 7 did not take part, but their outcomes data were included; 100% included in analysis. | 2 years | **♦ HbA1c** 6 mo ↓5.3%  12 mo ↓2.3%  24 mo ↓0%  **BG nSS** over all time points.  **♦ Weight ↓**2.2% **WG SS BG nSS**  **♦ SBP WG SS**, **BG nSS**  **♦ HDL BG SS**  **♦ LDL BG nSS**  **♦ Diabetes Medications**  Insulin doses **↓** **BG SS** | **Limited support for claims.**  Between groups nSS but more medication reduction in low-carbohydrate arm. |
| 5 | Yancy WS, 2010 | RCT | Compares effects of low-carbohydrate ketogenic diet vs. low-fat plus Orlistat supplement diet on body weight, blood pressure, lipids, and glycemic control in adults with T2D. | **n=146** overweight or obese adults; 122 (83.6%) completed. | 48 weeks | **♦ HbA1c ↓**6.0% **BG nSS**  **♦ Weight ↓**9.5% **WG SS BG nSS**  **♦ Fasting insulin WG SS** **BG nSS**  **♦ SBP, DBP** ↓ **BG SS**  **HDL, TRG WG nSS BG nSS  LDL BG nSS**  **♦ Diabetes Medications**  16 patients: 1 (6%) **↑** 13 (81%) **↓  Adverse Events**  **Symptomatic effects more common in low-carb group**: constipation, increased urinary frequency, halitosis, leg muscle cramps.  **Serious adverse events that may have been related to the intervention:**1 LCKD participant was hospitalized for syncope attributed to excessive anti-hypertension medication. | **Limited support for claims.**  Between groups nSS but more medication reduction in low-carbohydrate arm. |
| 6 | Westman EC, 2008 | RCT | Tested the hypothesis that a diet lower in carbohydrate would lead to greater improvement in glycemic control in patients with obesity and T2D. Compared a very low-carbohydrate, ketogenic diet vs. a calorie-restricted low-glycemic index diet. | **n=84** obese adults with T2D; 49 (58.3%) completed. | 24 weeks | **♦ HbA1c** ↓18.1% **BG SS  ♦ FBG ↓**11.2% **WG SS BG nSS**  **♦ Weight** ↓10.6% **BG SS**  **♦ Fasting insulin** ↓29.4% **WG SS** **BG nSS**  **♦ HDL** ↑**BG SS**  **♦ Diabetes Medications**  92.5% subjects reduced or eliminated meds. **BG SS**  **Adverse events:** symptomatic; most common - headache, constipation, diarrhea, insomnia, and back pain **BG nSS for all.** | **Supports claims** |
| 7 | Haimoto H, 2008 | RCT | Compared low-carb diet vs. conventional diet. Results at 1 and 2 years. | **n=135** adults with T2D; 102 (75.6%) completed. | 2 years | **♦ HbA1c**  **↓**9.5% **BG SS**  **♦ BMI ↓**5.2% **BG SS**  **♦ LDL ↓**4.3% **BG SS  ♦ Total cholesterol ↓**2.4% **BG SS**  **♦ Diabetes Medications**  Significant reductions.  . | **Supports claims** |
| 8 | Samaha FF, 2003 | RCT | To study the effects of a low-carb diet vs. a calorie-restricted, low-fat diet in severely obese individuals. | **n=132** severely obese subjects most having diabetes or MetSyn; 79 (59.9%) completed the study. T2D sub-analysis conducted for FBG only. | 6 months | **♦ FBG** ↓15.4% **BG SS** | **Supports claims** |
| 9 | Tay J 2018 \*\*earlier data cited in 2018 ADA | RCT | Compared a very low-carbohydrate, high-unsaturated/low-saturated fat diet vs. a high-unrefined carb, low-fat diet on glycemic control and CVD risk in T2D.  Both groups were calorie restricted. | **n=115** obese adults with T2D (53% retention) | 2 years | **HbA1c**  Decrease 0.7% average in both groups **BGnSS**  **Glucose variability**  Improved more in LC group  **Weight** maintained almost 7% weight loss in both groups for 2 years **BG nSS**  **Trig** decreased 6% in the low carb arm **BG SS**  **Diabetes Medication**  Reduced more in low carb arm | **Limited support for claims**  Between groups nSS but more medication reduction, decreased triglycerides and decreased glucose variability in low-carbohydrate group |
| Crossover trials | | | | | | | |
| 10 | Boden G, 2005 | Crossover trial | Compared effects first of a usual care diet (hospital food + food from "outside") followed by strict low-carb diet. | **n=10** obese adults with T2D, 100% completed. | 7 days on usual care diet; 14 days on low-carb diet | **HbA1c** ↓6.8% **SS**  **FBG ↓**16.3% **SS**  **Weight** ↓1.8% **SS** even when water loss was calculated diet  **Insulin sensitivity**  Serum insulin ↓ **SS**  Rate of insulin-stimulated glucose disappearance ↑200% **SS**  **TRG** ↓35% **SS  LDL** **nSS HDL nSS**  **Total C ↓**10% **SS** | **Supports claims** |
| 11 | Gannon MC, 2004 | Crossover RCT | Investigated the effect on glycemic control of a non-ketogenic low-carbohydrate, high-protein diet in individuals with T2D. The test diet was the formulated low-biologically-available-glucose (LoBAG) diet. Weight loss was not a goal of this study. Control diet was based on recommendations of the American Heart Association. | **n=8** overweight men with T2D; 100% completed. | 5 weeks on each diet with a 5-week washout between the two diets | **♦ FBG** ↓28.7% **SS**  **Fasting Insulin nSS**  **♦ Mean 24-h integrated net glucose area response** ↓77% **SS**  **♦ Total 24-h integrated glucose area** **response** **SS** | **Supports claims** |
| Non-randomized trials | | | | | | | |
| 12 | Hallberg SJ, 2018 | Non-randomized, controlled parallel-arm trial | Outcomes (see McKenzie 2017) for ongoing trial assessing the effectiveness and safety of a remote, continuous care intervention combined with a very low-carbohydrate ketogenic diet for T2D management. Compared to usual care. | **n=349** overweight and obese adults with T2D; 218 (83%) in test diet group completed. | 1 year | **♦ HbA1c ↓**18.4% **BG SS  ♦ FBG ↓**23.3% **BG SS**  **♦ Weight** ↓12.3% **BG SS**  **♦** **HOMA-IR ↓**55% **BG SS**  **♦ TRG ↓**24.4% **BG SS ♦** **HDL ↑**18.1% **BG SS ♦ LDL ↑**9.9% **BG SS ♦ SBP ↓**4.8% **BG SS ♦ DBP ↓**4.3% **BG SS**  **♦ Diabetes Medications** Insulin therapy was reduced or eliminated in 94% of users; sulfonylureas were entirely eliminated.  **No adverse events** attributed to intervention. | **Supports claims** |
| 13 | Krebs JD, 2013 | Single-arm trial | Tested intervention based on the Atkins diet; with 3 phases and gradual increase of carb intake over time. | **n=14** obese adults with T2D; 12 (85.7%) completed. | 24 weeks | **HbA1c** At week 24 **↓**17.6% **SS**  **FBG** At week 12 **↓**21.6% **SS** At week 24 ↓17.5 **nSS**  **Weight** At week 24↓8.1% **SS**  **HOMA** At week 12 **SS improved** At week 24 **nSS**  At week24 **HDL SS improved, LDL SS worsened, TRG** ↓15.5% **nSS   SBP, DBP nSS** | **Supports claims** |
| 14 | Hussain TA, 2012 | Non-randomized, 2-arm trial | Compared very low carbohydrate, ketogenic diet vs. low-calorie diet. Participants allowed to select diet. | **n=102** overweight and obese adults with T2D; 102 (100%) completed. | 24 weeks | **♦ HbA1c ↓**~19.2% **BG SS**  **♦ Weight ↓**12.0% **BG SS**  **♦ HDL, total C, TRG, LDL SS**  **Adverse effects**. Urea levels increased SS. The uric acid and creatinine levels decreased. | **Supports claims** |
| 15 | Sasakabe T, 2012 | Single-arm trial | Investigated impacts on reduction of CVD risk and abdominal fat of a moderately low-carb diet in adults with T2D.  Two arms were given different instructions based on participants' HbA1c levels. Those below <9.0% were asked to eliminate carbohydrate-rich foods from their dinner; patients with an HbA1c level ≥ 9.0% were asked to eliminate carbohydrates  from breakfast and dinner. | **n=63** overweight and obese adults with T2D; 52 (82.5%) completed. | 6 months | **HbA1c Men ↓**22.6% **SS Women ↓**18.6% **SS  FBG Men ↓**13.5% **SS Women ↓**12.2% **nSS**  **Weight**  **Men** ↓2.8% **SS** **Women** ↓3.0% **SS**  **Fasting insulin nSS**  **TRG nSS  LDL** Men **nSS** Women ↓15.3% **SS  DBP, SBP nSS** | **Supports claims** |
| 16 | Nielsen JV, 2008 | Follow-up to a 2-arm trial | Compared the effects on glycemic control and weight of a low-carb diet vs. a high-carb diet at 3, 6, 22, and 44 months. | **n in analysis at 44 mo.=23.** | Original trial was 6 months; follow-up at 44 months | Only outcomes for low-carb were reported  **HbA1c ↓15.0% SS**  **Weight**  ↓7.4% **SS**  **HDL, TRG, TG:HDL** improved **SS**  **Diabetes Medications**  11 used insulin at start of study. At end of study, 10 of the 11 used insulin. | **Supports claims** |
| 17 | Dashti HM, 2007 | non-randomized trial | Explored effects of low-carbohydrate, ketogenic diet on obese adults with normal blood glucose and obese adults with T2D. | Total n=64; with T2D **n=31**; 100% completed. T2D sub-analysis conducted. | 56 weeks | **FBG** ↓53.4% **SS**  **Weight** ↓22.7% **SS**  **HDL ↑**53.5% **SS**   **LDL ↓**34.5% **SS  TRG ↓**78.5% **SS**  **Adverse Effects.** Urea decreased SS. "No significant alteration was noticed in renal function test." | **Supports claims** |
| 18 | Yancy WS, 2005 | single-arm trial | Tested the effectiveness of a low-carbohydrate, ketogenic diet for improving glycemic control in individuals with T2D | **n=28** overweight and obese adults with T2D;  21 (75%) completed the study. | 16 weeks | **HbA1c ↓**16.0% **SS FBG** ↓16.6% **SS**  **Weight** ↓6.6% **SS**  **HDL ↑**7.6% **SS TRG ↓**41.6% **SS LDL nSS  BP nSS**  **Diabetes Medications.** Reduced or discontinued for most subjects.  **Adverse Effects**  Urea, creatinine **nSS.**  **Adverse Events.** None related to the diet. | **Supports claims** |
| 19 | Dashti HM, 2004 | single-arm trial | To determine effects of ketogenic diet on glucose, weight, and lipids | **n=83** obese adults with high FBG (>125). | 24 weeks | **FBG ↓**22.6% **SS**  **Weight** ↓14.2% **SS**  **HDL** ↑ **SS** **LDL** ↓ **SS** **TRG** ↓ **SS**  ↓ Urea and ↑ creatinine **nSS** | **Supports claims** |
| Systematic Reviews and Systematic Review/Meta-analyses | | | | | |
| 20 | Huntriss R, 2017 | Systematic review and meta-analysis | Evaluated the effects on HbA1c and weight loss of a low-carb diet in T2D. Reviewed 18 RCTs; 7 studies in quantitative meta-analysis. | Pooled n=2204 adults with T2D | 3 months-4 years | **HBA1c** Low-carb diet ↓HbA1c 0.02-1.2; -0.28 mean difference.  **Weight**  At 1 year improved **BG SS** in 3 of 10 trials.  Weight loss range: 0.9% to 7.5%. Pooled analysis: **BG nSS.**  **♦ HDL, TRG** SS improved **BG SS**  **LDL, total C** improved **BG nSS**  **Diabetes Medications**  In 9 of 14 studies with data, reduction was SS greater with low-carb (insulin, hypoglycemic agents or combined meds score).  **Compliance**: Concluded that dietary adherence was a problem in most studies reviewed and that <50g carb/day was unrealistic and that <130g carb/day was more achievable. | **Supports claims** |
| 21 | Ajala O, 2013 | Systematic review and meta-analysis | Assessed the effect of diet types on glycemic control, lipids, and weight loss. 20 RCTs included. 16 studies included in meta-analysis.  Compared low-carbohydrate; vegetarian; vegan; low-glycemic index (GI); high-ﬁber; Mediterranean; high-protein diets vs. control diets (low-fat; high-GI; ADA; European Association for the Study of Diabetes; and low-protein diets). | n in analyses= 3073 adults T2D | 6 mos-4 years | **♦ HbA1c** ↓**SS** compared to control.  WMD\*=-0.12%  **Weight** ↓**nSS** compared to control.  **♦ HDL** ↑**SS** compared to control. WMD=+0.08mmol/L  **♦ TRG** ↓SS compared to control. WMD=-0.04mmol/L.   **♦ LDL** ↓ nSS compared to control. | **Supports claims** |
| 22 | Castañeda-González LM, 2011 | Systematic review | Reviewed 8 trials (2000-2010) ≥ 12 weeks duration, to evaluate longer-term effects of low-carb diet compared to low-fat, low-carb Mediterranean diet, usual care diet, healthy eating diet, or low-glycemic index diet. | Adults with T2D | Range: 3-48 months | **HbA1c** 6 studies showed greater reduction with low-carb, 2 BG SS.  **Weight** 5 studies showed greater loss with low-carb, 1 BG SS. The longest trial did not show a difference in weight change.  **IR** Improved in 1 study.  **Lipids**: mixed results compared to control. Improved in several studies | **Limited support for claims** |

**Abbreviations list for Supplementary tables 1-4**:

**T2D**, type 2 diabetes; **BG**, between group; **WG**, within group; **FBG**, fasting blood glucose; **SS**, statistically significant; **nSS**, not statistically significant; **DBP**, diastolic blood pressure; **SBP**, systolic blood pressure; **HDL**, high-density lipoprotein; **TRG**, triglyceride; **DGA**, dietary guidelines for American; **RCT**, randomized controlled trial; **UC**, usual care; **low-carb**, low carbohydrate; **CHO**, carbohydrate; **Med**, Mediterranean; **LDL**, low-density lipoprotein; **BMI**, body mass index; **HOMA-IR**, homeostasis model assessment of insulin resistance; **CVD**, cardiovascular disease; **PBD**, plant based diet; **FU**, follow-up; **VLDL**, very low-density lipoprotein; **LFV**, low-fat vegan; **E**, energy; **GI**, glycemic index; **total C**, total cholesterol; **OB**, obese; **VLCK**, very low calorie ketogenic; **IL-IRa**, interleukin 1-receptor antagonist,: **IL-6**, interleukin-6 **Supplemental Table S5** Standards for reviewing scientific evidence for clinical guidelines

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| System | Link | Year Published | Description | Summary | Focus |  |  |
| GRADE | <http://gdt.guidelinedevelopment.org/app/handbook/handbook.html> | 2016 | "Process of rating the quality of the best available evidence and developing health care recommendations following the approach proposed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group" | "a transparent and structured process for developing and presenting evidence summaries and for carrying out the steps involved in developing recommendations" | Evidence based summaries |  |  |
| AGREE II | <https://www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf> |  | "1. Assess the quality of guidelines; 2. Provide a methodological strategy for the development of guidelines; 3. Inform what information and how information ought to be reported in guidelines." | "developed to address the issue of variability in guideline quality" | Guidelines |  |  |
| Guidelines International Network | <http://annals.org/aim/fullarticle/1103747/guidelines-international-network-toward-international-standards-clinical-practice-guidelines> |  | "key components address panel composition, decision-making process, conflicts of interest, guideline objective, development methods, evidence review, basis of recommendations, ratings of evidence and recommendations, guideline review, updating processes, and funding" | "proposed set of key components for guideline development." | Guidelines |  |  |
| Institute of Medicine | <http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx> | 2013 | "proposed standards cover a number of elements essential to developing sound practice guidelines, including transparency; conflict of interest; guideline development group composition; CPG– SR intersection; establishing evidence foundations for and strength of recommendations; articulation of recommendations; external review; and updating" | The product of study to "develop a set of standards for developing rigorous, trustworthy clinical practice guidelines." | Clinical Practice Guidelines |

**Supplemental Table S6** Assessment and recommendations for improvement of the ADA guidelines using the National Academies of Sciences, Engineering and Medicine’s *Clinical Practice We Can Trust* evaluation method

|  |  |  |  |
| --- | --- | --- | --- |
| NAM Standard | ADA Report | ADA Critique | Recommendations |
| Standard 1 - Establishing Transparency | "The ADA adheres to the  . " | Adherence to National Academy of Medicine Standards not explicitly defined. | Provide a table to ensure National Academy of Medicine Standards 1-7 are adhered to. |
| "The processes by which a CPG is developed and funded should be detailed explicitly and publicly accessible. | "Appointment to the PPC is based on excellence in clinical practice and research." | Process not explicitly described. Unknown how the Committee is selected. | Explicitly describe the process of selection. Publish all nominations and selected committee members before guidelines are published. |
|  | "The ADA funds development of the Standards of Care out of its general revenues and does not use industry support for this purpose." | Funding not explicitly stated. Unknown funding supporting guidelines development | Specify where "general funds" originated and how influence from industry support to ADA activities is minimized. |
| "Strategies for managing potential COI range from exclusion of conflicted members from direct panel participation or restriction of roles, to formal or informal consultation, to participation in certain exclusive recommendations, to simple disclosure of COI." | "All members of the PPC are required to disclose potential conflicts of interest with industry and/or other relevant organizations" | Most members of PPC were conflicted: Only 3/14 on SOC committee had no COI, and only 5/11 on Nutrition Therapy Panel had no COI | Describe how conflicts amongst members of the review are managed  Nam recommends that not more than a minority of members should have a COI so this standard should be upheld  Ensure that no funders have COI roles and make this information available |
| Standard 2 - Management of conflict of interest |  |  |  |
| 2.1 Individuals being considered for membership should declare all interests and activities potentially resulting in COI | "All members of the PPC are required to disclose potential conflicts of interest with industry and/or other relevant organizations. " | Patient and public not obviously involved | Consider COI for membership. State policy |
| 2.2 COI disclosure and discussion | "Members of the committee, their employers, and their disclosed conflicts of interest are listed in the “Professional Practice Committee Disclosures” table" | COI not explicitly considered prior to membership composition | Patient representation from both type1 and type 2 community |
| 2.3 Divestment | None | Divestment policy not stated | Whenever possible guideline development group members should not have COI |
| 2.4 Exclusions | None | Exclusion policy not stated |  |
| Standard 3 - Guideline development group composition |  |  | Compose multidisciplinary & balanced guideline development group, with each component explicitly defined |
| 3.1 Multidisciplinary & Balanced | “The PPC is a multidisciplinary expert committee comprised of physicians, diabetes educators, registered dietitians, and others who have expertise in a range of areas, including adult and pediatric endocrinology, epidemiology, public health, lipid research, hypertension, preconception planning, and pregnancy care.” | Not uniformly applied | Ensure patient (Type 1 and Type 2)and public involvement by recruiting additional members to the guideline development group. |
| 3.2 Patient & Public Involvement | Unknown | None | "Selection criteria should be applied to choose a consumer representative who can consider the evidence objectively, and make recommendations departing from preconceived views of self or interests" ADA might invite patients or other laypersons to review draft documents or attend a meeting to share perspectives. |
| 3.3 Strategies to increase participation by patient & public |  |  |  |
| Standard 4 - Clinical Practice Guideline–Systematic Review Intersection |  |  |  |
| 4.1. Use systematic reviews that meet IOM standards | Unknown | Unknown |  |
| 4.1. Systematic reviews should coordinate with Guideline Development Review Team | "PPC members systematically searched MEDLINE for human studies related to each section" | No search criteria identified |  |
| 5. Establishing Evidence Foundations for and Rating Strength of Recommendations |  |  |  |
| 5.1. Components: For each recommendation, the following should be provided |  |  |  |
| -- Underlying reasoning | Variable | Not uniformly applied | Define harms/benefits |
| -- Potential Harms/Benefits | Variable | Not uniformly applied | Define relevant available evidence |
| -- Summarize Relevant Available Evidence | Variable | Not uniformly applied | Define quality |
| -- Description of Quality | Variable | Not uniformly applied | Define quantity and consistency |
| -- Description of Quantity and consistency | Variable | Not uniformly applied | Define part played by values, opinion, theory, and clinical experience |
| -- Explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation. | None | Not performed | Uniformly apply rating to level of confidence |
| -- A rating of the level of confidence in (certainty regarding) the evidence underpinning the recommendation | Variable | Not uniformly applied |  |
| 6. Articulation of Recommendations |  |  | Implement standard reporting tools |
| 6.1 Standard reporting: Recommendations should be articulated in a standardized form detailing precisely what the recommended action is, and under what circumstances it should be performed | None | Form not standardized | Define recommendations precisely |
| 6.2 Precise recommendations: Strong recommendations should be worded so that compliance with the recommendation(s) can be evaluated. | None | Recommendations not clearly articulated | Implement formal external review |
| 7. External Review | Unknown. A process to submit comments has been established (“Readers who wish to comment on the 2018 Standards of Medical Care in Diabetes are encouraged to do so. All suggestions will be reviewed by the Association and the Professional Practice Committee.”) | External review not stated | Recruit external reviewers with a full diversity of experiences |
| 7.1 Diversity of experiences: External reviewers should comprise a full spectrum of relevant stakeholders, | None |  | Develop systems to ensure confidentiality of external reviews |
| 7.2 Confidentiality: The authorship of external reviews submitted by individuals and/or organizations should be kept confidential | None | Confidentiality of comments is not explicitly assured |  |

**Supplemental Appendix. Description of Eating Patterns**

**DASH Diet**

The DASH or Dietary Approach to Stop Hypertension eating plan requires no special foods and instead provides daily and weekly nutritional goals. This plan recommends:

* Eating vegetables, fruits, and whole grains
* Including fat-free or low-fat dairy products, fish, poultry, beans, nuts, and vegetable oils
* Limiting foods that are high in saturated fat, such as fatty meats, full-fat dairy products, and tropical oils such as coconut, palm kernel, and palm oils
* Limiting sugar-sweetened beverages and sweets.

<https://www.nhlbi.nih.gov/health-topics/dash-eating-plan>

**Mediterranean Diet**

The common Mediterranean dietary pattern has these characteristics:

* High consumption of fruits, vegetables, bread and other cereals, potatoes, beans, nuts and seeds
* Olive oil is an important monounsaturated fat source
* Dairy products, fish and poultry are consumed in low to moderate amounts, and little red meat is eaten
* Eggs are consumed zero to four times a week
* Wine is consumed in low to moderate amounts

<http://www.heart.org/HEARTORG/HealthyLiving/HealthyEating/Mediterranean-Diet_UCM_306004_Article.jsp#.WzZlqC2ZNAY>

**Plant-based Diet**

A plant-based diet consists of all minimally processed fruits, vegetables, whole grains, legumes, nuts and seeds, herbs, and spices and excludes all animal products, including red meat, poultry, fish, eggs, and dairy products.

Ostfeld RJ. Definition of a plant-based diet and overview of this special issue. *Journal of Geriatric Cardiology : JGC*. 2017;14(5):315. doi:10.11909/j.issn.1671-5411.2017.05.008.

**Very low carbohydrate Diet**

We chose to define as < 50gr total carbs per day

**Low-carbohydrate Diet**

We chose to define as 51 - 100gr total carbs per day