



# Nutrition Therapy for Adults With Diabetes or Prediabetes: A Consensus Report

*Diabetes Care* 2019;42:731–754 | <https://doi.org/10.2337/dci19-0014>

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This Consensus Report is intended to provide clinical professionals with evidence-based guidance about individualizing nutrition therapy for adults with diabetes or prediabetes. Strong evidence supports the efficacy and cost-effectiveness of nutrition therapy as a component of quality diabetes care, including its integration into the medical management of diabetes; therefore, it is important that all members of the health care team know and champion the benefits of nutrition therapy and key nutrition messages. Nutrition counseling that works toward improving or maintaining glycemic targets, achieving weight management goals, and improving cardiovascular risk factors (e.g., blood pressure, lipids, etc.) within individualized treatment goals is recommended for all adults with diabetes and prediabetes.

Though it might simplify messaging, a “one-size-fits-all” eating plan is not evident for the prevention or management of diabetes, and it is an unrealistic expectation given the broad spectrum of people affected by diabetes and prediabetes, their cultural backgrounds, personal preferences, co-occurring conditions (often referred to as comorbidities), and socioeconomic settings in which they live. Research provides clarity on many food choices and eating patterns that can help people achieve health goals and quality of life. The American Diabetes Association (ADA) emphasizes that medical nutrition therapy (MNT) is fundamental in the overall diabetes management plan, and the need for MNT should be reassessed frequently by health care providers in collaboration with people with diabetes across the life span, with special attention during times of changing health status and life stages (1–3).

This Consensus Report now includes information on prediabetes, and previous ADA nutrition position statements, the last of which was published in 2014 (4), did not. Unless otherwise noted, the research reviewed was limited to those studies conducted in adults diagnosed with prediabetes, type 1 diabetes, and/or type 2 diabetes. Nutrition therapy for children with diabetes or women with gestational diabetes mellitus is not addressed in this review but is covered in other ADA publications, specifically *Standards of Medical Care in Diabetes* (5,6).

## DATA SOURCES, SEARCHES, AND STUDY SELECTION

The authors of this report were chosen following a national call for experts to ensure diversity of the members both in professional interest and cultural background, including a person living with diabetes who served as a patient advocate. An outside market research company was used to conduct the literature search and was paid using ADA funds. The authors convened in person for one group meeting and actively participated in monthly teleconference calls between February and November 2018. Focused teleconference calls, email, and web-based collaboration were also used to reach consensus on final recommendations between November 2018 and January 2019. The 2014 position statement (4) was used as a starting point, and a search was conducted on PubMed for studies published in English between 1 January 2014 and 28 February 2018 to provide the updated evidence of nutrition therapy interventions in nonhospitalized adults with prediabetes and type 1 and type 2 diabetes. Details on the keywords and the search strategy are reported in the Supplementary Data, emphasizing randomized controlled trials (RCTs), systematic reviews, and meta-analyses of RCTs. An exception was made to the inclusion criteria for the use of meal studies for the insulin dosing section. In addition to the search results, in select cases the authors identified relevant research to include in reaching consensus. The

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This article contains Supplementary Data online at <http://care.diabetesjournals.org/lookup/suppl/doi:10.2337/dci19-0014/-/DC1>.

This article is part of a special article collection available at <http://care.diabetesjournals.org/evolution-nutritional-therapy>.

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consensus report was peer reviewed (see ACKNOWLEDGMENTS) and suggestions incorporated as deemed appropriate by the authors. Though evidence-based, the recommendations presented are the informed, expert opinions of the authors after consensus was reached through presentation and discussion of the evidence.

## EFFECTIVENESS OF DIABETES NUTRITION THERAPY

### Consensus recommendations

- Refer adults living with type 1 or type 2 diabetes to individualized, diabetes-focused MNT at diagnosis and as needed throughout the life span and during times of changing health status to achieve treatment goals. Coordinate and align the MNT plan with the overall management strategy, including use of medications, physical activity, etc., on an ongoing basis.
- Refer adults with diabetes to comprehensive diabetes self-management education and support (DSMES) services according to national standards.
- Diabetes-focused MNT is provided by a registered dietitian nutritionist/registered dietitian (RDN), preferably one who has comprehensive knowledge and experience in diabetes care.
- Refer people with prediabetes and overweight/obesity to an intensive lifestyle intervention program that includes individualized goal-setting components, such as the Diabetes Prevention Program (DPP) and/or to individualized MNT.
- Diabetes MNT is a covered Medicare benefit and should be adequately reimbursed by insurance and other payers or bundled in evolving value-based care and payment models.
- DPP-modeled intensive lifestyle interventions and individualized MNT for prediabetes should be covered by third-party payers or bundled in evolving value-based care and payment models.

### How is diabetes nutrition therapy defined and provided?

The National Academy of Medicine (formerly the Institute of Medicine) broadly defines nutrition therapy as the

treatment of a disease or condition through the modification of nutrient or whole-food intake (7). To complement diabetes nutrition therapy, members of the health care team can and should provide evidence-based guidance that allows people with diabetes to make healthy food choices that meet their individual needs and optimize their overall health. The Dietary Guidelines for Americans (DGA) 2015–2020 provide a basis for healthy eating for all Americans and recommend that people consume a healthy eating pattern that accounts for all foods and beverages within an appropriate calorie level (8). For people with diabetes, recommendations that differ from the DGA are highlighted in this report.

MNT is an evidence-based application of the nutrition care process provided by an RDN and is the legal definition of nutrition counseling by an RDN in the U.S. (9–12). Essential components of MNT are assessment, nutrition diagnosis, interventions (e.g., education and counseling), and monitoring with ongoing follow-up to support long-term lifestyle changes, evaluate outcomes, and modify interventions as needed (9,10). The goals of nutrition therapy are described in Table 1.

The unique academic preparation, training, skills, and expertise make the RDN the preferred member of the health care team to provide diabetes MNT and leadership in interprofessional team-based nutrition and diabetes care (1,9,13–18). Although certification (such as Certified Diabetes Educator, Board Certified-Advanced Diabetes Management) is not required, ideally the RDN will have comprehensive knowledge and experience in diabetes care and prevention (9,17). Detailed guidance for the RDN

to obtain the expert knowledge and experience can be found in the Academy of Nutrition and Dietetics Standards of Practice and Standards of Professional Performance (12). Health care professionals can use the education algorithm suggested by ADA, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics (1) that defines and describes the four critical times to assess, provide, and adjust care. The algorithm is intended for use by the RDN and the interprofessional team for determining how and when to deliver diabetes education and nutrition services. The number of encounters the person with diabetes might have with the RDN is described in Table 2 (9).

In addition to diabetes MNT, DSMES is important for people with diabetes to improve cardiometabolic and microvascular outcomes in a disease that is largely self-managed (1,19–23). DSMES includes the ongoing process that facilitates the knowledge, skills, and abilities necessary for diabetes self-care throughout the life span, with nutrition as one of the core curriculum topics taught in comprehensive programs (21).

### Is MNT effective in improving outcomes?

Reported hemoglobin A<sub>1c</sub> (A1C) reductions from MNT can be similar to or greater than what would be expected with treatment using currently available medication for type 2 diabetes (9). Strong evidence supports the effectiveness of MNT interventions provided by RDNs for improving A1C, with absolute decreases up to 2.0% (in type 2 diabetes) and up to 1.9% (in type 1 diabetes) at 3–6 months. Ongoing MNT support is helpful in maintaining glycemic improvements (9).

**Table 1—Goals of nutrition therapy**

- To promote and support healthful eating patterns, emphasizing a variety of nutrient-dense foods in appropriate portion sizes, in order to improve overall health and specifically to:
  - Improve A1C, blood pressure, and cholesterol levels (goals differ for individuals based on age, duration of diabetes, health history, and other present health conditions. Further recommendations for individualization of goals can be found in the ADA *Standards of Medical Care in Diabetes* [345])
  - Achieve and maintain body weight goals
  - Delay or prevent complications of diabetes
- To address individual nutrition needs based on personal and cultural preferences, health literacy and numeracy, access to healthful food choices, willingness and ability to make behavioral changes, as well as barriers to change
- To maintain the pleasure of eating by providing positive messages about food choices, while limiting food choices only when indicated by scientific evidence
- To provide the individual with diabetes with practical tools for day-to-day meal planning

**Table 2—Academy of Nutrition and Dietetics evidence-based nutrition practice guidelines—recommended structure for the implementation of MNT for adults with diabetes (9)**

**Initial series of MNT encounters:** The RDN should implement three to six MNT encounters during the first 6 months following diagnosis and determine if additional MNT encounters are needed based on an individualized assessment.

**MNT follow-up encounters:** The RDN should implement a minimum of one annual MNT follow-up encounter.

Cost-effectiveness of lifestyle interventions and MNT for the prevention and management of diabetes has been documented in multiple studies (12,17,24,25). The National Academy of Medicine recommends individualized MNT, provided by an RDN upon physician referral, as part of the multidisciplinary approach to diabetes care (7). Diabetes MNT is a covered Medicare benefit and should also be adequately reimbursed by insurance and other payers, or bundled in evolving value-based care and payment models, because it can result in improved outcomes such as reduced A1C and cost savings (12,17,25).

#### **What nutrition therapy interventions best help people with prediabetes prevent or delay the development of type 2 diabetes?**

The strongest evidence for type 2 diabetes prevention comes from several studies, including the DPP (26–28). The DPP demonstrated that an intensive lifestyle intervention resulting in weight loss could reduce the incidence of type 2 diabetes for adults with overweight/obesity and impaired glucose tolerance by 58% over 3 years (26). Follow-up of three large studies of lifestyle intervention for diabetes prevention has shown sustained reduction in the rate of conversion to type 2 diabetes: 43% reduction at 20 years in the Da Qing Diabetes Prevention Study (29); 43% reduction at 7 years in the Finnish Diabetes Prevention Study (DPS) (30); and 34% reduction at 10 years (28) and 27% reduction at 15 years extended follow-up of the DPP (31) in the U.S. Diabetes Prevention Program Outcomes Study (DPPOS). The follow-up of the Da Qing study also demonstrated a reduction in cardiovascular and all-cause mortality (32).

Substantial evidence indicates that individuals with prediabetes should be referred to an intensive behavioral lifestyle intervention program modeled on

the DPP and/or to individualized MNT typically provided by an RDN with the goals of improving eating habits, increasing moderate-intensity physical activity to at least 150 min per week, and achieving and maintaining 7–10% loss of initial body weight if needed (14,17,33,34). More intensive intervention programs are the most effective in decreasing diabetes incidence and improving cardiovascular disease (CVD) risk factors (35).

Both DPP-modeled intensive lifestyle interventions and individualized MNT for prediabetes have demonstrated cost-effectiveness (17,36) and therefore should be covered by third-party payers or bundled in evolving value-based care and payment models (25).

To make diabetes prevention programs more accessible, digital health tools are an area of increasing interest in the public and private sectors. Preliminary research studies support that the delivery of diabetes prevention lifestyle interventions through technology-enabled platforms and digital health tools can result in weight loss, improved glycemia, and reduced risk for diabetes and CVD, although more rigorous studies are needed (37–44).

#### **MACRONUTRIENTS**

##### *Consensus recommendations*

- Evidence suggests that there is not an ideal percentage of calories from carbohydrate, protein, and fat for all people with or at risk for diabetes; therefore, macronutrient distribution should be based on individualized assessment of current eating patterns, preferences, and metabolic goals.
- When counseling people with diabetes, a key strategy to achieve glycemic targets should include an assessment of current dietary intake followed by individualized guidance on self-monitoring carbo-

hydrate intake to optimize meal timing and food choices and to guide medication and physical activity recommendations.

- People with diabetes and those at risk for diabetes are encouraged to consume at least the amount of dietary fiber recommended for the general public; increasing fiber intake, preferably through food (vegetables, pulses [beans, peas, and lentils], fruits, and whole intact grains) or through dietary supplement, may help in modestly lowering A1C.

#### **Do macronutrient needs differ for people with diabetes compared with the general population?**

Although numerous studies have attempted to identify the optimal mix of macronutrients for the eating plans of people with diabetes, a systematic review (45) found that there is no ideal mix that applies broadly and that macronutrient proportions should be individualized. It has been observed that people with diabetes, on average, eat about the same proportions of macronutrients as the general public: ~45% of their calories from carbohydrate (see Table 3), ~36–40% of calories from fat, and the remainder (~16–18%) from protein (46–48). Regardless of the macronutrient mix, total energy intake should be appropriate to attain weight management goals. Further, individualization of the macronutrient composition will depend on the status of the individual, including metabolic goals (glycemia, lipid profile, etc.), physical activity, food preferences, and availability.

#### **Do carbohydrate needs differ for people with diabetes compared with the general population?**

Carbohydrate is a readily used source of energy and the primary dietary influence on postprandial blood glucose (8,49). Foods containing carbohydrate—with various proportions of sugars, starches, and fiber—have a wide range of effects on the glycemic response. Some result in an extended rise and slow fall of blood glucose concentrations, while others result in a rapid rise followed by a rapid fall (50). The quality of carbohydrate foods selected—ideally rich in dietary fiber, vitamins, and minerals and low in added sugars, fats, and sodium—should be addressed as part of an

individualized eating plan that includes all components necessary for optimal nutrition (4,9).

The amount of carbohydrate intake required for optimal health in humans is unknown. Although the recommended dietary allowance for carbohydrate for adults without diabetes (19 years and older) is 130 g/day and is determined in part by the brain's requirement for glucose, this energy requirement can be fulfilled by the body's metabolic processes, which include glycogenolysis, gluconeogenesis (via metabolism of the glycerol component of fat or gluconeogenic amino acids in protein), and/or ketogenesis in the setting of very low dietary carbohydrate intake (49).

#### **What are the dietary fiber needs of people with diabetes?**

The regular intake of sufficient dietary fiber is associated with lower all-cause mortality in people with diabetes (51,52). Therefore, people with diabetes should consume at least the amount of fiber recommended by the DGA 2015–2020 (minimum of 14 g of fiber per 1,000 kcal) with at least half of grain consumption being whole intact grains (8). Other sources of dietary fiber include non-starchy vegetables, avocados, fruits, and berries, as well as pulses such as beans, peas, and lentils.

A few studies have shown modest A1C reduction (−0.2% to −0.3%) (53, 54) with intake in excess of 50 g of fiber per day. However, such very high intake of fiber may cause flatulence, bloating, and diarrhea. Meeting the recommended fiber intake through foods that are naturally high in dietary fiber, as compared with supplementation, is encouraged for the additional benefits of coexisting micronutrients and phytochemicals (55).

#### **Does the use of glycemic index and glycemic load impact glycemia?**

The use of the glycemic index (GI) and glycemic load (GL) to rank carbohydrate foods according to their effects on glycemia continues to be of interest for people with diabetes and those at risk for diabetes. As defined by Brand-Miller et al. (56), “the GI provides a good summary of postprandial glycemia. It predicts the peak (or near peak) response, the maximum glucose fluctuation, and other attributes of the response

curve.” Two systematic reviews of the literature regarding GI and GL in individuals with diabetes and at risk for diabetes reported no significant impact on A1C and mixed results on fasting glucose (9,50). Further, studies have used varying definitions of low and high GI foods, leading to uncertainty in the utility of GI and GL in clinical care (45).

#### **What are the total protein needs of people with diabetes?**

There is limited research in people with diabetes or prediabetes without kidney disease on the impact of various amounts of protein consumed. Some comparisons of protein amounts have not demonstrated differences in diabetes-related outcomes (57–60). A 12-week study comparing 30% vs. 15% energy from protein noted improvements in weight, fasting glucose, and insulin requirements in the group that consumed 30% energy from protein (61). A meta-analysis from 2013 of studies ranging from 4–24 weeks in duration reported that high-protein eating plans (25–32% of total energy vs. 15–20%) resulted in 2 kg greater weight loss and 0.5% greater improvement in A1C but no statistically significant improvements in fasting serum glucose, serum lipid profiles, or blood pressure (62).

#### **What are the dietary fat and cholesterol goals for people with diabetes?**

The National Academy of Medicine has defined an acceptable macronutrient distribution for total fat for all adults to be 20–35% of total calorie intake (49). Eating patterns that replace certain carbohydrate foods with those higher in total fat, however, have demonstrated greater improvements in glycemia and certain CVD risk factors (serum HDL cholesterol [HDL-C] and triglycerides) compared with lower fat diets. The types or quality of fats in the eating plans may influence CVD outcomes beyond the total amount of fat (63). Foods containing synthetic sources of *trans* fats should be minimized to the greatest extent possible (8). Ruminant *trans* fats, occurring naturally in meat and dairy products, do not need to be eliminated because they are present in such small quantities (64).

The body makes enough cholesterol for physiological and structural functions such that people do not need to obtain cholesterol through foods. Although the

DGA concluded that available evidence does not support the recommendation to limit dietary cholesterol for the general population, exact recommendations for dietary cholesterol for other populations, such as people with diabetes, are not as clear (8). Whereas cholesterol intake has correlated with serum cholesterol levels, it has not correlated well with CVD events (65,66). More research is needed regarding the relationship among dietary cholesterol, blood cholesterol, and CVD events in people with diabetes.

#### **What is the role of fat in the prevention of type 2 diabetes?**

Large epidemiologic studies have found that consumption of polyunsaturated fat or biomarkers of polyunsaturated fatty acids are associated with lower risk of type 2 diabetes (67). Supplementation with omega-3 fatty acids in prediabetes has demonstrated some efficacy in surrogate outcomes beyond serum triglyceride levels. In a single-blinded RCT design in Asia, 107 subjects with newly diagnosed impaired glucose metabolism and coronary heart disease (CHD) supplemented with 1,800 mg/day of eicosapentaenoic acid (EPA) experienced improved postprandial triglycerides, glycemia, insulin secretion ability, and endothelial function over a 6-month period (68). Further, in a recent multisite RCT that included 57% of participants with diabetes, age 50 years or older, and with at least one additional CVD risk factor, plus elevated fasting triglycerides and low HDL-C, benefits were seen from adding 2 g of icosapent ethyl twice daily to statin therapy in terms of lower rates of a composite CVD outcome and CVD mortality, but there were also slightly higher rates of hospitalization for atrial fibrillation and serious bleeding (68a).

The intervention in the PREvención con Dieta MEDiterránea (PREDIMED) study, comparing a Mediterranean-style eating pattern supplemented either with extra-virgin olive oil or with nuts versus a control diet, reduced incidence of type 2 diabetes among people without diabetes at high cardiovascular risk at baseline (69). The Malmö Diet and Cancer cohort study examined specific food sources of saturated fat and found that intake of saturated fat from dairy products, coconut oil, and palm kernel oil were associated with lower diabetes risk (70), whereas saturated fat intake was associated with higher risk of diabetes in

**Table 3—Eating patterns reviewed for this report**

Type of eating pattern	Description	Potential benefits reported*
USDA Dietary Guidelines For Americans (DGA) (8)	Emphasizes a variety of vegetables from all of the subgroups; fruits, especially whole fruits; grains, at least half of which are whole intact grains; lower-fat dairy; a variety of protein foods; and oils. This eating pattern limits saturated fats and <i>trans</i> fats, added sugars, and sodium.	DGA added to the table for reference; not reviewed as part of this Consensus Report
Mediterranean-style (69,76,85–91)	Emphasizes plant-based food (vegetables, beans, nuts and seeds, fruits, and whole intact grains); fish and other seafood; olive oil as the principal source of dietary fat; dairy products (mainly yogurt and cheese) in low to moderate amounts; typically fewer than 4 eggs/week; red meat in low frequency and amounts; wine in low to moderate amounts; and concentrated sugars or honey rarely.	<ul style="list-style-type: none"> <li>• Reduced risk of diabetes</li> <li>• A1C reduction</li> <li>• Lowered triglycerides</li> <li>• Reduced risk of major cardiovascular events</li> </ul>
Vegetarian or vegan (77–80,92–99)	The two most common approaches found in the literature emphasize plant-based vegetarian eating devoid of all flesh foods but including egg (ovo) and/or dairy (lacto) products, or vegan eating devoid of all flesh foods and animal-derived products.	<ul style="list-style-type: none"> <li>• Reduced risk of diabetes</li> <li>• A1C reduction</li> <li>• Weight loss</li> <li>• Lowered LDL-C and non-HDL-C</li> </ul>
Low-fat (26,45,80,83,100–106)	Emphasizes vegetables, fruits, starches (e.g., breads/crackers, pasta, whole intact grains, starchy vegetables), lean protein sources (including beans), and low-fat dairy products. In this review, defined as total fat intake $\leq$ 30% of total calories and saturated fat intake $\leq$ 10%.	<ul style="list-style-type: none"> <li>• Reduced risk of diabetes</li> <li>• Weight loss</li> </ul>
Very low-fat (107–109)	Emphasizes fiber-rich vegetables, beans, fruits, whole intact grains, nonfat dairy, fish, and egg whites and comprises 70–77% carbohydrate (including 30–60 g fiber), 10% fat, 13–20% protein.	<ul style="list-style-type: none"> <li>• Weight loss</li> <li>• Lowered blood pressure</li> </ul>
Low-carbohydrate (110–112)	Emphasizes vegetables low in carbohydrate (such as salad greens, broccoli, cauliflower, cucumber, cabbage, and others); fat from animal foods, oils, butter, and avocado; and protein in the form of meat, poultry, fish, shellfish, eggs, cheese, nuts, and seeds. Some plans include fruit (e.g., berries) and a greater array of nonstarchy vegetables. Avoids starchy and sugary foods such as pasta, rice, potatoes, bread, and sweets. There is no consistent definition of “low” carbohydrate. In this review, a low-carbohydrate eating pattern is defined as reducing carbohydrates to 26–45% of total calories.	<ul style="list-style-type: none"> <li>• A1C reduction</li> <li>• Weight loss</li> <li>• Lowered blood pressure</li> <li>• Increased HDL-C and lowered triglycerides</li> </ul>
Very low-carbohydrate (VLC) (110–112)	Similar to low-carbohydrate pattern but further limits carbohydrate-containing foods, and meals typically derive more than half of calories from fat. Often has a goal of 20–50 g of nonfiber carbohydrate per day to induce nutritional ketosis. In this review a VLC eating pattern is defined as reducing carbohydrate to $<$ 26% of total calories.	<ul style="list-style-type: none"> <li>• A1C reduction</li> <li>• Weight loss</li> <li>• Lowered blood pressure</li> <li>• Increased HDL-C and lowered triglycerides</li> </ul>
Dietary Approaches to Stop Hypertension (DASH) (81,118,119)	Emphasizes vegetables, fruits, and low-fat dairy products; includes whole intact grains, poultry, fish, and nuts; reduced in saturated fat, red meat, sweets, and sugar-containing beverages. May also be reduced in sodium.	<ul style="list-style-type: none"> <li>• Reduced risk of diabetes</li> <li>• Weight loss</li> <li>• Lowered blood pressure</li> </ul>
Paleo (120–122)	Emphasizes foods theoretically eaten regularly during early human evolution, such as lean meat, fish, shellfish, vegetables, eggs, nuts, and berries. Avoids grains, dairy, salt, refined fats, and sugar.	<ul style="list-style-type: none"> <li>• Mixed results</li> <li>• Inconclusive evidence</li> </ul>

\*Source: RCTs, meta-analyses, observational studies, nonrandomized single-arm studies, cohort studies. USDA, U.S. Department of Agriculture.



the PREDIMED study (71). Other meta-analyses of observational studies have not shown an inverse relationship with full-fat dairy intake and diabetes risk (72,73). The inconsistent results in the above studies may be due to variations in food sources of fat (70) or the fact that some analyses have relied on self-reported dietary information, which can be limited by inaccuracy.

For more information on fat intake and CVD risk, see the section *ROLE OF NUTRITION THERAPY IN THE PREVENTION AND MANAGEMENT OF DIABETES COMPLICATIONS (CVD, DIABETIC KIDNEY DISEASE, AND GASTROPARESIS)*.

## EATING PATTERNS

### *Consensus recommendations*

- A variety of eating patterns (combinations of different foods or food groups) are acceptable for the management of diabetes.
- Until the evidence surrounding comparative benefits of different eating patterns in specific individuals strengthens, health care providers should focus on the key factors that are common among the patterns:
  - Emphasize nonstarchy vegetables.
  - Minimize added sugars and refined grains.
  - Choose whole foods over highly processed foods to the extent possible.
- Reducing overall carbohydrate intake for individuals with diabetes has demonstrated the most evidence for improving glycemia and may be applied in a variety of eating patterns that meet individual needs and preferences.
- For select adults with type 2 diabetes not meeting glycemic targets or where reducing anti-glycemic medications is a priority, reducing overall carbohydrate intake with low- or very low-carbohydrate eating plans is a viable approach.

An eating pattern represents the totality of all foods and beverages consumed (8) (Table 3). An eating plan is a guide to help individuals plan when, what, and how much to eat on a daily basis and applies to the foods emphasized in the individual's selected eating pattern.

This section emphasizes evidence from randomized trials of eating patterns in people with type 1 diabetes, type 2 diabetes, and prediabetes and was limited to those trials with at least 10 people in each dietary group and a retention rate of >50%. Overall, few long-term (2 years or longer) randomized trials have been conducted of any of the dietary patterns in any of the conditions examined.

### **What is the evidence for specific eating patterns to manage prediabetes and prevent type 2 diabetes?**

The most robust research available related to eating patterns for prediabetes or type 2 diabetes prevention are Mediterranean-style, low-fat, or low-carbohydrate eating plans (26,69,74,75). The PREDIMED trial, a large RCT, compared a Mediterranean-style to a low-fat eating pattern for prevention of type 2 diabetes onset, with the Mediterranean-style eating pattern resulting in a 30% lower relative risk (69). Epidemiologic studies correlate Mediterranean-style (76), vegetarian (77–80), and Dietary Approaches to Stop Hypertension (DASH) (76,81) eating patterns with a lower risk of developing type 2 diabetes, with no effect for low-carbohydrate eating patterns (82).

Several large type 2 diabetes prevention RCTs (26,74,83,84) used low-fat eating plans to achieve weight loss and improve glucose tolerance, and some demonstrated decreased incidence of diabetes (26,74,83). Given the limited evidence, it is unclear which of the eating patterns are optimal.

### **What is the evidence for specific eating patterns to manage type 2 diabetes?**

#### *Mediterranean-Style Eating Pattern*

The Mediterranean-style pattern has demonstrated a mixed effect on A1C, weight, and lipids in a number of RCTs (85–90). In the Dietary Intervention Randomized Controlled Trial (DIRECT), obese adults with type 2 diabetes were randomized to a calorie-restricted Mediterranean-style, a calorie-restricted lower-fat, or a low-carbohydrate eating pattern (28% of calories from carbohydrate) without emphasis on calorie restriction. A1C was lowest in the low-carbohydrate group after 2 years, whereas fasting plasma glucose was lower in the Mediterranean-style group than in the lower-fat group (90).

One of the largest and longest RCTs, the PREDIMED trial, compared a Mediterranean-style eating pattern with a low-fat eating pattern. After 4 years, glycemic management improved and the need for glucose-lowering medications was lower in the Mediterranean eating pattern group (89). In addition, the PREDIMED trial showed that a Mediterranean-style eating pattern intervention enriched with olive oil or nuts significantly reduced CVD incidence in both people with and without diabetes (91).

#### *Vegetarian or Vegan Eating Patterns*

Studies of vegetarian or vegan eating plans ranged in duration from 12 to 74 weeks and showed mixed results on glycemia and CVD risk factors. These eating plans often resulted in weight loss (92–97). Two meta-analyses of controlled trials (98,99) concluded that vegetarian and vegan eating plans can reduce A1C by an average of 0.3–0.4% in people with type 2 diabetes, and the larger meta-analysis (99) also reported that plant-based eating patterns reduced weight (weight reduction of 2 kg), waist circumference, LDL cholesterol (LDL-C), and non-HDL-C with no significant effect on fasting insulin, HDL-C, triglycerides, and blood pressure.

#### *Low-Fat Eating Pattern*

In the Look AHEAD (Action for Health in Diabetes) trial (100), individuals following a calorie-restricted low-fat eating pattern, in the context of a structured weight loss program using meal replacements, achieved moderate success compared with the control condition eating plan (101). However, lowering total fat intake did not consistently improve glycemia or CVD risk factors in people with type 2 diabetes based on a systematic review (45), several studies (102–105), and a meta-analysis (106). Benefit from a low-fat eating pattern appears to be mostly related to weight loss as opposed to the eating pattern itself (100,101). Additionally, low-fat eating patterns have commonly been used as the “control” intervention compared with other eating patterns.

#### *Very Low-Fat: Ornish or Pritikin Eating Patterns*

The Ornish and Pritikin lifestyle programs are two of the best known multicomponent very low-fat eating patterns. The Ornish program emphasizes a very low-fat, whole-foods, plant-based eating

plan (about 70% of calories from carbohydrate, 10% from fat, 20% from protein, and 60 g of fiber), predominantly from vegetables, beans, fruits, grains, nonfat dairy, and egg whites. The Pritikin intervention advises that people consume 77% of calories from carbohydrate, about 10% from fat, 13% from protein, and 30–40 g of fiber per 1,000 calories, with no calorie restriction during a 26-day stay in an in-patient treatment center. Three nonrandomized single-arm studies with 69 to 652 participants lasting between 3 weeks and 2–3 years show that these multicomponent lifestyle intervention programs may improve glucose levels, weight, blood pressure, and HDL-C, with a mixed effect on triglycerides (107–109).

#### **Low-Carbohydrate or Very Low-Carbohydrate Eating Patterns**

Low-carbohydrate eating patterns, especially very low-carbohydrate (VLC) eating patterns, have been shown to reduce A1C and the need for antihyperglycemic medications. These eating patterns are among the most studied eating patterns for type 2 diabetes. One meta-analysis of RCTs that compared low-carbohydrate eating patterns (defined as  $\leq 45\%$  of calories from carbohydrate) to high-carbohydrate eating patterns (defined as  $>45\%$  of calories from carbohydrate) found that A1C benefits were more pronounced in the VLC interventions (where  $<26\%$  of calories came from carbohydrate) at 3 and 6 months but not at 12 and 24 months (110).

Another meta-analysis of RCTs compared a low-carbohydrate eating pattern (defined as  $<40\%$  of calories from carbohydrate) to a low-fat eating pattern (defined as  $<30\%$  of calories from fat). In trials up to 6 months long, the low-carbohydrate eating pattern improved A1C more, and in trials of varying lengths, lowered triglycerides, raised HDL-C, lowered blood pressure, and resulted in greater reductions in diabetes medication (111). Finally, in another meta-analysis comparing low-carbohydrate to high-carbohydrate eating patterns, the larger the carbohydrate restriction, the greater the reduction in A1C, though A1C was similar at durations of 1 year and longer for both eating patterns (112). Table 4 provides a quick reference conversion of percentage of calories from carbohydrate to grams of

**Table 4—Quick reference conversion of percent calories from carbohydrate shown in grams per day as reported in the research reviewed for this report**

Calories	10%	20%	30%	40%	50%	60%	70%
1,200	30 g	60 g	90 g	120 g	150 g	180 g	210 g
1,500	38 g	75 g	113 g	150 g	188 g	225 g	263 g
2,000	50 g	100 g	150 g	200 g	250 g	300 g	350 g
2,500	63 g	125 g	188 g	250 g	313 g	375 g	438 g

carbohydrate based on number of calories consumed per day.

Because of theoretical concerns regarding use of VLC eating plans in people with chronic kidney disease, disordered eating patterns, and women who are pregnant, further research is needed before recommendations can be made for these subgroups. Adopting a VLC eating plan can cause diuresis and swiftly reduce blood glucose; therefore, consultation with a knowledgeable practitioner at the onset is necessary to prevent dehydration and reduce insulin and hypoglycemic medications to prevent hypoglycemia.

No randomized trials were found in people with type 2 diabetes that varied the saturated fat content of the low- or very low-carbohydrate eating patterns to examine effects on glycemia, CVD risk factors, or clinical events. Most of the trials using a carbohydrate-restricted eating pattern did not restrict saturated fat; from the current evidence, this eating pattern does not appear to increase overall cardiovascular risk, but long-term studies with clinical event outcomes are needed (113–117).

#### **DASH Eating Pattern**

One small, 8-week study comparing the DASH eating pattern with a control group in people with type 2 diabetes indicated improved A1C, blood pressure, and cholesterol levels and weight loss with the DASH eating pattern, with no difference in triglycerides (118). Another RCT compared the DASH eating pattern incorporating increased physical activity with a standard eating pattern without increased physical activity and found blood pressure was lower in the DASH and physical activity group, but A1C, weight, and lipids did not differ (119).

#### **Paleo Eating Pattern**

Research studies focused on a paleo eating pattern in adults with type 2 diabetes are small and few, ranging from

13–29 participants, lasting no longer than 3 months, and finding mixed effects on A1C, weight, and lipids (120–122).

#### **Intermittent Fasting**

While intermittent fasting is not an eating pattern by definition, it has been included in this discussion because of increased interest from the diabetes community. Fasting means to go without food, drink, or both for a period of time. People fast for reasons ranging from weight management to upcoming medical visits to religious and spiritual practice. Intermittent fasting is a way of eating that focuses more on when you eat (i.e., consuming all daily calories in set hours during the day) than what you eat. While it usually involves set times for eating and set times for fasting, people can approach intermittent fasting in many different ways.

Published intermittent fasting studies involving diabetes and diabetes prevention demonstrate a variety of approaches, including restricting food intake for 18 to 20 h per day, alternate-day fasting, and severe calorie restriction for up to 8 consecutive days or longer (123). Four fasting studies of participants with type 2 diabetes were small ( $\leq 63$  participants) and of short duration ( $\leq 20$  weeks). Three of the studies (124–126) demonstrated that intermittent fasting, either in consecutive days of restriction or by fasting 16 h per day or more, may result in weight loss; however, there was no improvement in A1C compared with a nonfasting eating plan. One of the studies (127) showed similar reductions in A1C, weight, and medication doses when 2 days of severe energy restriction were compared with chronic energy restriction. Another study looked at men with prediabetes and timing of food intake over a 24-h period, with the intervention group restricted to a 6-h schedule of eating (with final meal before 3 P.M.) compared with a control schedule where eating occurred over a 12-h period;

improved insulin sensitivity,  $\beta$ -cell responsiveness, blood pressure, oxidative stress, and appetite were shown in the intervention group (128). The safety of intermittent fasting in people with special health situations, including pregnancy and disordered eating, has not been studied.

#### What is the evidence to support specific eating patterns in the management of type 1 diabetes?

For adults with type 1 diabetes, no trials met the inclusion criteria for this Consensus Report related to Mediterranean-style, vegetarian or vegan, low-fat, low-carbohydrate, DASH, paleo, Ornish, or Pritikin eating patterns. We found limited evidence about the safety and/or effects of fasting on type 1 diabetes (129).

A few studies have examined the impact of a VLC eating pattern for adults with type 1 diabetes. One randomized crossover trial with 10 participants examined a VLC eating pattern aiming for 47 g carbohydrate per day without a focus on calorie restriction compared with a higher carbohydrate eating pattern aiming for 225 g carbohydrate per day for 1 week each. Participants following the VLC eating pattern had less glycemic variability, spent more time in euglycemia and less time in hypoglycemia, and required less insulin (130). A single-arm 48-person trial of a VLC eating pattern aimed at a goal of 75 g of carbohydrate or less per day found that weight, A1C, and triglycerides were reduced and HDL-C increased after 3 months, and after 4 years A1C was still lower and HDL-C was still higher than at baseline (131). This evidence suggests that a VLC eating pattern may have potential benefits for adults with type 1 diabetes, but clinical trials of sufficient size and duration are needed to confirm prior findings.

#### Does the current evidence support specific eating patterns for the management of diabetes?

Until the evidence surrounding comparative benefits of different eating patterns in specific individuals strengthens, health care providers should focus on the key factors that are common among the patterns: 1) emphasize nonstarchy vegetables, 2) minimize added sugars and refined grains, and 3) choose whole foods

over highly processed foods to the extent possible (132).

Multiple trials and meta-analyses have been published addressing the comparative effects of specific eating patterns for diabetes. Whereas no single eating pattern has emerged as being clearly superior to all others for all diabetes-related outcomes, evidence suggests certain eating patterns are better for specific outcomes. All eating patterns include a range of more-healthy versus less-healthy options: lentils and sugar-sweetened beverages are both considered part of a vegan eating pattern; fish and processed red meats are both considered part of a low-carbohydrate eating pattern; and removing the bun from a fast food burger might make it part of a paleo eating pattern but does not necessarily make it healthier. Further, studies comparing the same two or more eating patterns could easily differ in the investigators' definition of the patterns, the effectiveness of the research team in fostering pattern adherence among study participants, the accuracy of assessing pattern adherence, study duration, and participant population characteristics.

#### ENERGY BALANCE AND WEIGHT MANAGEMENT

##### Consensus recommendations

- To support weight loss and improve A1C, CVD risk factors, and quality of life in adults with overweight/obesity and prediabetes or diabetes, MNT and DSMES services should include an individualized eating plan in a format that results in an energy deficit in combination with enhanced physical activity.
- For adults with type 2 diabetes who are not taking insulin and who have limited health literacy or numeracy, or who are older and prone to hypoglycemia, a simple and effective approach to glycemia and weight management emphasizing appropriate portion sizes and healthy eating may be considered.
- In type 2 diabetes, 5% weight loss is recommended to achieve clinical benefit, and the benefits are progressive. The goal for optimal outcomes is 15% or more when needed and can be feasibly and safely accomplished. In prediabetes, the goal

is 7–10% for preventing progression to type 2 diabetes.

- In select individuals with type 2 diabetes, an overall healthy eating plan that results in energy deficit in conjunction with weight loss medications and/or metabolic surgery should be considered to help achieve weight loss and maintenance goals, lower A1C, and reduce CVD risk.
- In conjunction with lifestyle therapy, medication-assisted weight loss can be considered for people at risk for type 2 diabetes when needed to achieve and sustain 7–10% weight loss.
- People with prediabetes at a healthy weight should be considered for lifestyle intervention involving both aerobic and resistance exercise and a healthy eating plan such as a Mediterranean-style eating plan.
- People with diabetes and prediabetes should be screened and evaluated during DSMES and MNT encounters for disordered eating, and nutrition therapy should accommodate these disorders.

#### What is the role of weight loss therapy in people with prediabetes or diabetes with overweight or obesity?

There is substantial evidence indicating that weight loss is highly effective in preventing progression from prediabetes to type 2 diabetes and in managing cardiometabolic health in type 2 diabetes. Overweight and obesity are also increasingly prevalent in people with type 1 diabetes and present clinical challenges regarding diabetes treatment and CVD risk factors (133,134). Therefore, MNT and DSMES that include an overall healthy eating plan in a format that results in an energy deficit, as well as a collaborative effort to achieve weight loss in people with type 1 diabetes, type 2 diabetes, or prediabetes and overweight/obesity, are recommended.

Eating plans that create an energy deficit and are customized to fit the person's preferences and resources can help with long-term sustainment and are the cornerstone of weight loss therapy. Regular physical activity, which can contribute to both weight loss and prevention of weight regain, and



behavioral strategies are also important components of lifestyle therapy for weight management (26,74,83,135–137). Structured weight loss programs with regular visits and use of meal replacements have been shown to enhance weight loss in people with diabetes (138–140).

The combined data do not point to a threshold of weight loss for maximal clinical benefits in people with diabetes; rather, the greater the weight loss, the greater the benefits. Previous recommendations of weight loss of 5% or  $\geq 7\%$  for people with overweight or obesity are based on the threshold needed for therapeutic advantages; however, weight loss targeted at  $\geq 15\%$ , when such can feasibly and safely be accomplished, is associated with even better outcomes in type 2 diabetes (138,141).

The UK Prospective Diabetes Study (UKPDS) demonstrated that decreases in fasting glucose were correlated with degree of weight loss (142). A meta-analysis conducted by Franz et al. (137) found that lifestyle interventions producing  $< 5\%$  weight loss had less effect on A1C, lipids, or blood pressure compared with studies achieving weight loss of  $\geq 5\%$ . Other meta-analyses focusing on nonmedicine or medicine-assisted weight loss interventions in type 2 diabetes support this finding (143–145). More recently, the Look AHEAD trial (139,141) compared standard DSMES to a more intensive lifestyle intervention and reduced-calorie eating plan. The intensive lifestyle intervention resulted in 8.6% weight loss at 1 year, and the downstream therapeutic benefits were far-ranging even though benefits were not seen for the primary cardiovascular outcomes (100).

A systematic review of the effectiveness of MNT revealed mixed weight loss outcomes in participants with type 1 and 2 diabetes (9). Similarly, while DSMES is a fundamental component of diabetes care (1), it does not consistently produce sufficient weight loss to achieve optimal therapeutic benefits in people with diabetes (136,146,147). For these reasons, diabetes MNT and DSMES should emphasize a targeted and concerted plan for weight management.

The addition of metabolic surgery (148), weight loss medications (149), and glucose-lowering agents that promote weight loss (150) can also be used

as an adjunct to lifestyle interventions, resulting in greater weight loss that is maintained for a longer period of time. The data also support the position that weight loss therapy is effective at all phases of type 2 diabetes, both in individuals with recent-onset disease (1,149) and in people with longer durations of diabetes treated with multiple diabetes medications (136,149).

In the DPP, maximal prevention of diabetes over 4 years was observed at about 7–10% weight loss (151). This is consistent with the study using phentermine/topiramate ER, where weight loss of 10% reduced incident diabetes by 79% over 2 years and any further weight loss to  $\geq 15\%$  did not lead to additional prevention (152). For this reason, nutrition therapy to support a 7–10% weight loss is the appropriate goal in treating people with prediabetes, unless additional weight loss is desired for other purposes. Nutrition therapy can be a component of a lifestyle intervention program or used in conjunction with antiobesity medications and/or metabolic surgery (153,154) in people with prediabetes.

Regular physical activity by itself (155,156) or as part of a comprehensive lifestyle plan (26,74,83,151) can prevent progression to type 2 diabetes in high-risk individuals. Studies have demonstrated beneficial effects of both aerobic and resistance exercise and additive benefits when both forms of exercise are combined (157–159).

#### **What is the best weight loss plan for individuals with diabetes?**

For purposes of weight loss, the ability to sustain and maintain an eating plan that results in an energy deficit, irrespective of macronutrient composition or eating pattern, is critical for success (160–163). Studies investigating specific weight loss eating plans using a broad range of macronutrient composition in people with diabetes have shown mixed results regarding effects on weight, A1C, serum lipids, and blood pressure (102,103,106,164–171). As a result, the evidence does not identify one eating plan that is clearly superior to others and that can be generally recommended for weight loss for people with diabetes (172). Thus, an individualized plan for diabetes nutrition therapy is warranted, taking into

account dietary preferences together with the individual's health literacy, resources, food availability, meal preparation skills, and physical activity to maximize the ability to attain and maintain the eating plan (173,174). Individualized eating plans should support calorie reduction (e.g., employing use of appropriate portion sizes, meal replacements, and/or behavioral interventions) in the context of a lifestyle program, with appropriate modifications in the medication plan to minimize associated adverse effects such as weight gain, hypoglycemia, and hypotension.

Weight loss interventions can be implemented in usual care settings and alternately in telehealth programs (175,176). In general, the intervention intensity and degree of individual participation in the program are important factors for successful weight loss (161–163,175).

#### **What is the role of weight loss on potential for type 2 diabetes remission?**

The Look AHEAD trial (177) and the Diabetes Remission Clinical Trial (DiRECT) (138) highlight the potential for type 2 diabetes remission—defined as the maintenance of euglycemia (complete remission) or prediabetes level of glycemia (partial remission) with no diabetes medication for at least 1 year (177,178)—in people undergoing weight loss treatment. In the Look AHEAD trial, when compared with the control group, the intensive lifestyle arm resulted in at least partial diabetes remission in 11.5% of participants as compared with 2% in the control group (177). The DiRECT trial showed that at 1 year, weight loss associated with the lifestyle intervention resulted in diabetes remission in 46% of participants (138). Remission rates were related to magnitude of weight loss, rising progressively from 7% to 86% as weight loss at 1 year increased from  $< 5\%$  to  $\geq 15\%$  (138). Diet composition may also play a role; in an RCT by Esposito et al. (179), despite only a 2-kg difference in weight loss, the group following a low-carbohydrate Mediterranean-style eating pattern (see Table 3) experienced greater rates of at least partial diabetes remission, with rates of 14.7% at year 1 and 5% at year 6 compared with 4.7% and 0%, respectively, in the group following a low-fat eating plan.

### What is the role of eating plans that result in energy deficits and weight loss in type 1 diabetes?

Obesity prevalence among people with type 1 diabetes has been significantly increasing (180–182). Currently, over 50% of people with type 1 diabetes have overweight or obesity (180–182). A recent study suggested obesity may promote progression to overt type 1 diabetes in at-risk individuals (183), but further confirmatory studies are needed. In addition, in people with established type 1 diabetes, presence of obesity can worsen insulin resistance, glycemic variability, microvascular disease complications, and cardiovascular risk factors (184–188). Therefore, weight management has been recommended as an essential component of care for people with type 1 diabetes who have overweight or obesity (189–192).

There is a scarcity of evidence from RCTs evaluating weight loss interventions in type 1 diabetes. A retrospective nested-control study indicated that lifestyle-induced weight loss improved glycemia with a reduction in insulin doses compared with controls (193). Individuals with type 1 diabetes and obesity may benefit from eating plans that result in an energy deficit and that are lower in total carbohydrate and GI and higher in fiber and lean protein (194). Currently, adjunctive pharmacotherapy is not indicated for individuals with type 1 diabetes. However, there is preliminary evidence that in select individuals with type 1 diabetes and excess adiposity, newer pharmacotherapy (i.e., glucagon-like peptide 1 receptor agonists or sodium–glucose cotransporter 2 inhibitors) (195,196) can decrease body weight and improve glycemia, though they are currently not indicated. In addition, metabolic surgery in appropriate candidates can decrease body weight and improve glycemia (197,198).

### How does disordered eating factor into weight management?

When counseling individuals with diabetes and prediabetes about weight management, special attention also must be given to prevent, diagnose, and treat disordered eating. Disordered eating can make following an eating plan challenging (199). The prevalence of disordered eating varies, affecting 18% to 40% of people with diabetes (199–205).

Health care professionals should consider screening for disordered eating, refer to a mental health professional, and individualize nutrition therapy accordingly (206).

## SWEETENERS

### Consensus recommendations

- Replace sugar-sweetened beverages (SSBs) with water as often as possible.
- When sugar substitutes are used to reduce overall calorie and carbohydrate intake, people should be counseled to avoid compensating with intake of additional calories from other food sources.

### Does the consumption of SSBs impact risk of diabetes?

SSB consumption in the general population contributes to a significantly increased risk of type 2 diabetes, weight gain, heart disease, kidney disease, non-alcoholic liver disease, and tooth decay (207). For example, a meta-analysis reported that consumption of at least one serving of SSB per day increased risk of type 2 diabetes in adults with prediabetes by 26% (208). In a separate meta-analysis, consumption of regular soda increased type 2 diabetes risk by 13%, while consumption of diet soda increased type 2 diabetes risk by 8% (209). Conversely, the replacement of SSBs with an equal amount of water reduced the risk of type 2 diabetes by 7–8% (210).

### What is the impact of sugar substitutes?

The U.S. Food and Drug Administration (FDA) has reviewed several types of sugar substitutes for safety and approved them for consumption by the general public, including people with diabetes (211). In this report, the term sugar substitutes refers to high-intensity sweeteners, artificial sweeteners, nonnutritive sweeteners, and low-calorie sweeteners. These include saccharin, neotame, acesulfame-K, aspartame, sucralose, advantame, stevia, and luo han guo (or monk fruit). Replacing added sugars with sugar substitutes could decrease daily intake of carbohydrates and calories. These dietary changes could beneficially affect glycemic, weight, and cardiometabolic control. However, an American Heart Association science advisory on the

consumption of beverages containing sugar substitutes that was supported by the ADA concluded there is not enough evidence to determine whether sugar substitute use definitively leads to long-term reduction in body weight or cardiometabolic risk factors, including glycemia (212). Using sugar substitutes does not make an unhealthy choice healthy; rather, it makes such a choice less unhealthy. If sugar substitutes are used to replace caloric sweeteners, without caloric compensation, they may be useful in reducing caloric and carbohydrate intake (213), although further research is needed to confirm these concepts (214). Multiple mechanisms have been proposed for potential adverse effects of sugar substitutes, e.g., adversely altering feelings of hunger and fullness, substituting for healthier foods, or reducing awareness of calorie intake (215). As people aim to reduce their intake of SSBs, the use of other alternatives, with a focus on water, is encouraged (212).

Sugar alcohols represent a separate category of sweeteners. Like sugar substitutes, sugar alcohols have been approved by the FDA for consumption by the general public and people with diabetes. Whereas sugar alcohols have fewer calories per gram than sugars, they are not as sweet. Therefore, a higher amount is required to match the degree of sweetness of sugars, generally bringing the calorie content to a level similar to that of sugars (216). Use of sugar alcohols needs to be balanced with their potential to cause gastrointestinal effects in sensitive individuals. Currently, there is little research on the potential benefits of sugar alcohols for people with diabetes (217).

## ALCOHOL CONSUMPTION

### Consensus recommendations

- It is recommended that adults with diabetes or prediabetes who drink alcohol do so in moderation (one drink or less per day for adult women and two drinks or less per day for adult men).
- Educating people with diabetes about the signs, symptoms, and self-management of delayed hypoglycemia after drinking alcohol, especially when using insulin

or insulin secretagogues, is recommended. The importance of glucose monitoring after drinking alcohol beverages to reduce hypoglycemia risk should be emphasized.

### What are the effects of alcohol consumption on diabetes-related outcomes?

It is important that health care providers counsel people with diabetes about alcohol consumption and encourage moderate and sensible use for people choosing to consume alcohol. Moderate alcohol consumption has minimal acute and/or long-term detrimental effects on glycemia in people with type 1 or type 2 diabetes (218–221), with some epidemiologic data showing improved glycemia and improved insulin sensitivity with moderate intake. One alcohol-containing beverage is defined as 12-oz beer, 5-oz wine, or 1.5-oz distilled spirits, each containing approximately 15 g of alcohol (8). Excessive amounts of alcohol (>3 drinks per day or 21 drinks per week for men and >2 drinks per day or 14 drinks per week for women) consumed on a consistent basis may contribute to hyperglycemia (222). Starting with one drink per day, risk for reduced adherence to self-care and healthy lifestyle behaviors has been reported with increasing alcohol consumption (223).

### What are the effects of alcohol consumption on hypoglycemia risk in people with diabetes?

Despite the potential glycemic and cardiovascular benefits of moderate alcohol consumption, alcohol intake may place people with diabetes at increased risk for delayed hypoglycemia (221,224–226). This effect may be a result of inhibition of gluconeogenesis, reduced hypoglycemia awareness due to the cerebral effects of alcohol, and/or impaired counterregulatory responses to hypoglycemia (227). This is particularly relevant for those using insulin or insulin secretagogues who can experience delayed nocturnal or fasting hypoglycemia after evening alcohol consumption. Consuming alcohol with food can minimize the risk of nocturnal hypoglycemia (227,228). It is essential that people with diabetes receive education regarding the recognition and management of delayed hypoglycemia

and the potential need for more frequent glucose monitoring after consuming alcohol (227,229).

### How does alcohol consumption impact risk of developing type 2 diabetes?

Comprehensive reviews and meta-analyses suggest a protective effect of moderate alcohol intake on the risk of developing type 2 diabetes, with a higher rate of diabetes in alcohol abstainers and heavy consumers (222,230–232). Moderate alcohol intake ranging from 6–48 g/day (0.5–3.4 drinks) was associated with a 30–56% lower incidence of type 2 diabetes (9,222,230–232). Knott et al. (232) reported reduced risk of type 2 diabetes at all levels of alcohol intake <63 g per day with peak reduction at a daily alcohol intake of 10–14 g (approximately 1 drink) per day in women and non-Asian populations.

A meta-analysis and systematic review (233) that examined the effects of specific types of alcohol beverage consumption and the incidence of type 2 diabetes found that wine consumption was associated with significantly lower diabetes risk, as compared with a smaller reduction in risk with beer and spirits. A U-shaped relationship between alcohol dose and diabetes risk was found among all three types of alcohol, with lowest diabetes risk at 20–30 g of alcohol per day from wine and beer and 7–15 g of alcohol per day from spirits; the decrease in diabetes incidence was 20% for wine, 9% for beer, and 5% for spirits.

While epidemiologic evidence shows a correlation between alcohol consumption and risk of diabetes, the evidence does not suggest that providers should advise abstainers to start consuming alcohol. Ultimately, alcohol consumption is an individual's choice, but additional factors such as history of alcohol use, religion, genetic factors, and mental health, as well as medication interactions, should be considered when counseling on alcohol use.

### MICRONUTRIENTS, HERBAL SUPPLEMENTS, AND RISK OF MEDICATION-ASSOCIATED DEFICIENCY

#### Consensus recommendations

- Without underlying deficiency, the benefits of multivitamins or mineral supplements on glycemia for people

with diabetes or prediabetes have not been supported by evidence, and therefore routine use is not recommended.

- It is recommended that MNT for people taking metformin include an annual assessment of vitamin B12 status with guidance on supplementation options if deficiency is present.
- The routine use of chromium or vitamin D micronutrient supplements or any herbal supplements, including cinnamon, curcumin, or aloe vera, for improving glycemia in people with diabetes is not supported by evidence and is therefore not recommended.

### What is the effectiveness of micronutrients on diabetes-related outcomes?

Scientific evidence does not support the use of dietary supplements in the form of vitamins or minerals to meet glycemic targets or improve CVD risk factors in people with diabetes or prediabetes, in the absence of an underlying deficiency (234–236). People with diabetes not achieving glucose targets may have an increased risk of micronutrient deficiencies (237), so maintaining a balanced intake of food sources that provide at least the recommended daily allowance for nutrients and micronutrients is essential (234). For special populations, including women planning pregnancy, people with celiac disease, older adults, vegetarians, and people following an eating plan that restricts overall calories or one or more macronutrients, a multivitamin supplement may be justified (238).

A systematic review on the effect of chromium supplementation on glucose and lipid metabolism concluded that evidence is limited by poor study quality and heterogeneity in methodology and results (239,240). Evidence from clinical studies that evaluated magnesium (241,242) and vitamin D (243–253) supplementation to improve glycemia in people with diabetes is likewise conflicting. However, evidence is emerging that suggests that magnesium status may be related to diabetes risk in people with prediabetes (254).

### What is the role of herbal supplementation in the management of diabetes?

It is important to consider that nutritional supplements and herbal products are not standardized or regulated (255,256). Health care providers should ask about the use of supplements and herbal products, and providers and people with or at risk for diabetes should discuss the potential benefit of these products weighed against the cost and possible adverse effects and drug interactions. The variability of herbal and micronutrient supplements makes research in this area challenging and makes it difficult to conclude effectiveness. To date, there is limited evidence supporting the addition of herbal supplements to manage glycemia. Because of public interest and the lack of conclusive data, the National Center for Complementary and Integrative Health at the National Institutes of Health aims to answer important public health and scientific questions by funding and conducting research on complementary medicine.

### Does the use of metformin affect vitamin B12 status?

Metformin is associated with vitamin B12 deficiency, with a recent systematic review recommending that annual blood testing of vitamin B12 levels be considered in metformin-treated people, especially in those with anemia or peripheral neuropathy (257). This study found that even in the absence of anemia, B12 deficiency was prevalent. The exact cause of B12 deficiency in people taking metformin is not known, but some research points to malabsorption caused by metformin, with other studies suggesting improvements in B12 status with calcium supplementation (258–261). The standard of treatment has been B12 injections, but new research suggest that high-dose oral supplementation may be as effective (258,259). More research is needed in this area.

### MNT AND ANTIHYPERGLYCEMIC MEDICATIONS (INCLUDING INSULIN)

#### Consensus recommendations

- All RDNs providing MNT in diabetes care should assess and monitor medication changes in relation to the nutrition care plan.

- For individuals with type 1 diabetes, intensive insulin therapy using the carbohydrate counting approach can result in improved glycemia and is recommended.
- For adults using fixed daily insulin doses, consistent carbohydrate intake with respect to time and amount, while considering the insulin action time, can result in improved glycemia and reduce the risk for hypoglycemia.
- When consuming a mixed meal that contains carbohydrate and is high in fat and/or protein, insulin dosing should not be based solely on carbohydrate counting. A cautious approach to increasing mealtime insulin doses is suggested; continuous glucose monitoring (CGM) or self-monitoring of blood glucose (SMBG) should guide decision-making for administration of additional insulin.

### What is the role of the RDN in medication adjustment?

RDNs providing MNT in diabetes care should assess and monitor medication changes in relation to the nutrition care plan. Along with other diabetes care providers, RDNs who possess advanced practice training and clinical expertise should take an active role in facilitating and maintaining organization-approved diabetes medication protocols. Use of organization-approved protocols for insulin and other glucose-lowering medications can help reduce therapeutic inertia and/or reduce the risk of hypoglycemia and hyperglycemia (12,16–18,262,263).

### How should nutrition therapy vary based on type and intensity of insulin plan?

For people with type 1 diabetes using basal-bolus insulin therapy, a primary focus for MNT should include guidance on adjusting insulin based on anticipated dietary intake, particularly carbohydrate intake (9,264–270); recent or expected physical activity; and glucose data. Intensive insulin management education programs that include nutrition therapy have been shown to improve A1C (9,264,268,271–273) and quality of life (9,274). For people using fixed daily insulin doses, carbohydrate intake on a day-to-day basis should be consistent

with respect to time and amount per meal (9,275,276).

Results from recent high-fat and/or high-protein mixed meal studies continue to support previous findings that glucose response to mixed meals high in protein and/or fat along with carbohydrate differ among individuals; therefore, a cautious approach to increasing insulin doses for high-fat and/or high-protein mixed meals is recommended to address delayed hyperglycemia that may occur 3 h or more after eating (277–290). If using an insulin pump, a split bolus feature (part of the bolus delivered immediately, the remainder over a programmed duration of time) may provide better insulin coverage for high-fat and/or high-protein mixed meals (278,281). Checking glucose 3 h after eating may help to determine if additional insulin adjustments (i.e., increasing or stopping bolus) are required (278,290). Because these insulin dosing algorithms require determination of anticipated nutrient intake to calculate the mealtime dose, health literacy and numeracy should be evaluated. The effectiveness of insulin dosing decisions should be confirmed with a structured approach to SMBG or CGM to evaluate individual responses and guide insulin dose adjustments.

### ROLE OF NUTRITION THERAPY IN THE PREVENTION AND MANAGEMENT OF DIABETES COMPLICATIONS (CVD, DIABETIC KIDNEY DISEASE, AND GASTROPARESIS)

#### CVD

#### Consensus recommendations

- In general, replacing saturated fat with unsaturated fats reduces both total cholesterol and LDL-C and also benefits CVD risk.
- In type 2 diabetes, counseling people on eating patterns that replace foods high in carbohydrate with foods lower in carbohydrate and higher in fat may improve glycemia, triglycerides, and HDL-C; emphasizing foods higher in unsaturated fat instead of saturated fat may additionally improve LDL-C.
- People with diabetes and prediabetes are encouraged to consume less than 2,300 mg/day of sodium, the



same amount that is recommended for the general population.

- The recommendation for the general public to eat a serving of fish (particularly fatty fish) at least two times per week is also appropriate for people with diabetes.

### Does comprehensive diabetes nutrition therapy support cardiovascular risk factor reduction?

Nutrition therapy that includes the development of an eating plan designed to optimize blood glucose trends, blood pressure, and lipid profiles is important in the management of diabetes and can lower the risk of CVD, CHD, and stroke (9). Findings from clinical trials support the role of nutrition therapy for achieving glycemic targets and decreasing various markers of cardiovascular and hypertension risk (9,24,291–293).

### What are considerations for fat intake for people who are at risk for or have CVD and diabetes?

#### Total Fat

There has been increasing research examining the effects of high-fat, low-carbohydrate eating patterns on cardiometabolic risk factors, with two systematic reviews showing benefits of low-carbohydrate eating plans compared with low-fat eating plans on glycemic and CVD risk parameters in the treatment of type 2 diabetes (see the section LOW-CARBOHYDRATE OR VERY LOW-CARBOHYDRATE EATING PATTERNS) (106,111).

#### Saturated Fat

The 2015–2020 DGA recommend consuming less than 10% of calories from saturated fat by replacing it with monounsaturated and polyunsaturated fatty acids (8). The scientific rationale for decreasing saturated fat in the diet is based on the effect of saturated fat in raising LDL-C, a contributing factor in atherosclerosis (294).

In a Presidential Advisory on dietary fat and CVD, the American Heart Association concluded that lowering intake of saturated fat and replacing it with unsaturated fats, especially polyunsaturated fats, will lower the incidence of CVD (295). A meta-analysis of randomized trials not focused on people with diabetes showed a 17% reduction (hazard ratio 0.83 [95% CI 0.72–0.96]) in risk of CVD

events in studies that reduced saturated fat intake from about 17% to about 9% of energy, but reductions in stroke, cardiovascular mortality, or overall mortality were not found. Subgrouping of the studies suggested that benefit occurred by replacing saturated fat with polyunsaturated fat but not with carbohydrate or protein (296). In a systematic review of observational studies, saturated fats were not associated with all-cause mortality, CVD, CHD, ischemic stroke, or type 2 diabetes, but limitations common to observational studies were noted (297). Further, in a more recent large, prospective study including 7% of participants with self-reported diabetes, higher intake of saturated fat was associated with lower risk of total mortality (hazard ratio 0.86 [0.76–0.99], *P* for trend = 0.0088) (298). In the PREDIMED study, which included close to 50% of people with diabetes, intakes of monounsaturated and polyunsaturated fats were associated with a lower risk of CVD and death, whereas intakes of saturated fat and *trans* fat were associated with a higher risk of CVD. The replacement of saturated fat with monounsaturated or polyunsaturated fat in food or replacement of *trans* fat with monounsaturated fat in food was inversely associated with CVD (299).

In general, replacing saturated fat with unsaturated fats, especially polyunsaturated fat, significantly reduces both total cholesterol and LDL-C, and replacement with monounsaturated fat from plant sources, such as olive oil and nuts, reduces CVD risk. Replacing saturated fat with carbohydrate also reduces total cholesterol and LDL-C, but significantly increases triglycerides and reduces HDL-C (299,300).

#### Monounsaturated Fats

A recent meta-analysis of nine RCTs showed that, compared with control, the Mediterranean-style eating pattern, which is high in monounsaturated fats from plant sources such as olive oil and nuts, improved outcomes of glycemia, body weight, and cardiovascular risk factors in participants with type 2 diabetes (301). A systematic review and meta-analysis of 24 studies and including 1,460 participants compared the effect of eating plans high in monounsaturated fat with that of eating plans high in carbohydrates. The eating plans high

in monounsaturated fat showed significant reductions in fasting glucose, triglycerides, body weight, and systolic blood pressure along with significant increases in HDL-C. The systematic review and meta-analysis also reviewed four studies with a total of 44 participants comparing eating plans high in monounsaturated fat with those high in polyunsaturated fat. The eating plans high in monounsaturated fat led to a significant reduction in fasting plasma glucose (63).

#### Polyunsaturated Fats

As is recommended for the general public, an increase in foods containing the long-chain omega-3 fatty acids EPA and docosahexaenoic acid (DHA), such as are found in fatty fish, is recommended for individuals with diabetes because of their beneficial effects on lipoproteins, prevention of heart disease, and associations with positive health outcomes in observational studies (302,303). For people following a vegetarian or vegan eating pattern, omega-3  $\alpha$ -linoleic acid (ALA) found in plant foods such as flax, walnuts, and soy are reasonable replacements for foods high in saturated fat and may provide some CVD benefits, though the evidence is inconclusive.

Evidence does not conclusively support recommending omega-3 (EPA and DHA) supplements for all people with diabetes for the prevention or treatment of cardiovascular events. In the most recent ASCEND (A Study of Cardiovascular Events in Diabetes) trial, when compared with placebo, supplementation of omega-3 fatty acids at the dose of 1 g/day did not lead to cardiovascular benefit in people with diabetes without evidence of CVD (68a, 304–305). Omega-3 fatty acid supplements have not reduced CVD events or mortality in randomized trials but may have utility in people who require triglyceride reduction (304,306). The Vitamin D and Omega-3 Trial (VITAL), in which 13% of the participants had type 2 diabetes, supplementation with 1 g of omega-3 fatty acids did not result in a lower incidence of major cardiovascular events (305). However, in the Reduction of Cardiovascular Events With Icosapent Ethyl—Intervention Trial (REDUCE-IT), in which 57% of 823 participants had diabetes, 2 g of prescription icosapent ethyl twice daily (total daily dose, 4 g) significantly reduced

cardiovascular events by 25% when compared with placebo (68a).

#### Trans Fat

A meta-analysis of seven RCTs showed that increased *trans* fat intake did not result in changes in glucose, insulin, or triglyceride concentrations but led to an increase in total and LDL-C and a decrease in HDL-C concentrations (307). *Trans* fats also have been associated with all-cause mortality, total CHD, and CHD mortality (297).

#### Can lowering sodium intake reduce blood pressure and other cardiovascular risk factors in people with diabetes?

Many health groups acknowledge the current average intake of sodium, which is >3,500 mg daily (308), should be reduced (8,309–312) to prevent and manage hypertension. While reducing sodium to the general recommendation of <2,300 mg/day demonstrates beneficial effects on blood pressure (118), further reduction warrants caution. Some studies measuring urine sodium excretion in people with type 1 (313) and type 2 (314) diabetes have shown increased mortality associated with the lowest sodium intakes. A secondary analysis of data from the Ongoing Telmisartan Alone and in Combination With Ramipril Global Endpoint Trial (ONTARGET) suggests sodium excretions <3 g/day and >7 g/day were both associated with increased mortality in people with type 2 diabetes (315), leading to continued controversy over the potential benefits versus harms of lowering sodium intake below the general recommendation. In the absence of clear scientific evidence for benefit in people with combined diabetes and hypertension (313,314), sodium intake goals that are significantly lower than 2,300 mg/day should be considered only on an individual basis. When individualizing sodium intake recommendations, careful consideration must be given to issues such as food preference, palatability, availability, and additional cost of fresh or specialty low-sodium products (316).

#### Diabetic Kidney Disease

##### Consensus recommendation

- In individuals with diabetes and non-dialysis-dependent diabetic kidney disease (DKD), reducing

the amount of dietary protein below the recommended daily allowance (0.8 g/kg body weight/day) does not meaningfully alter glyce-mic measures, cardiovascular risk measures, or the course of glomerular filtration rate decline and may increase risk for malnutrition.

#### Are protein needs different for people with diabetes and kidney disease?

Historically, low-protein eating plans were advised to reduce albuminuria and progression of chronic kidney disease in people with DKD, typically with improvements in albuminuria but no clear effect on estimated glomerular filtration rate. In addition, there is some indication that a low-protein eating plan may lead to malnutrition in individuals with DKD (317–321). The average daily level of protein intake for people with diabetes without kidney disease is typically 1–1.5 g/kg body weight/day or 15–20% of total calories (45,146). Evidence does not suggest that people with DKD need to restrict protein intake to less than the average protein intake.

For people with DKD and macroalbuminuria, changing to a more soy-based source of protein may improve CVD risk factors but does not appear to alter proteinuria (322,323).

#### Gastroparesis

##### Consensus recommendations

- Selection of small-particle-size foods may improve symptoms of diabetes-related gastroparesis.
- Correcting hyperglycemia is one strategy for the management of gastroparesis, as acute hyperglycemia delays gastric emptying.
- Use of CGM and/or insulin pump therapy may aid the dosing and timing of insulin administration in people with type 1 or type 2 diabetes with gastroparesis.

#### How is diabetic gastroparesis best managed?

Consultation by an RDN knowledgeable in the management of gastroparesis is helpful in setting and maintaining treatment goals (324). Treatment goals include managing and reducing symptoms; correcting fluid, electrolyte, and nutritional deficiencies and glycemic

imbalances; and addressing the precipitating cause(s) with appropriate drug therapy (227). Correcting hyperglycemia is one strategy for the management of gastroparesis, as acute hyperglycemia delays gastric emptying (325,326). Modification of food and beverage intake is the primary management strategy, especially among individuals with mild symptoms.

People with gastroparesis may find it helpful to eat small, frequent meals. Replacing solid food with a greater proportion of liquid calories to meet individualized nutrition requirements may be helpful because consuming solid food in large volumes is associated with longer gastric emptying times (327,328). Large meals can also decrease the lower esophageal sphincter pressure, which may cause gastric reflux, providing further aggravation (327).

Results from an RCT demonstrated eating plans that emphasize small-particle-size (<2 mm) foods may reduce severity of gastrointestinal symptoms (329). Small-particle-size food is defined as “food easy to mash with a fork into small particle size.” High-fiber foods, such as whole intact grains and foods with seeds, husks, stringy fibers, and membranes, should be excluded from the eating plan. Many of the foods typically recommended for people with diabetes, such as leafy green salads, raw vegetables, beans, and fresh fruits, and other food like fatty or tough meat, can be some of the most difficult foods for the gastroparetic stomach to grind and empty (324,329). Notably, the majority of nutrition therapy interventions for gastroparesis are based on the knowledge of the pathophysiology and clinical judgment rather than empirical research (227).

The use of an insulin pump is another option for individuals with type 1 diabetes and insulin-requiring type 2 diabetes with gastroparesis (330). A small but positive 12-month trial reported a 1.8% reduction in A1C and decreased hospitalizations with insulin pump use (331). An insulin pump can be used to provide consistent basal insulin infusion, as well as the ability to modify mealtime insulin delivery doses as needed. The variable bolus feature allows the user to administer a portion of the meal bolus in an extended fashion over a longer period of time (227). Use of this feature

may help to decrease the risk of postprandial hyperglycemia as well as hypoglycemia.

### How is the risk of malnutrition in diabetic gastroparesis managed?

When an individual with gastroparesis falls below target weight, nutrition support in the form of oral (for acute exacerbation of symptoms), enteral, or parenteral nutrition should be considered (327). A 5% unintentional loss of usual body weight over 3 months or 10% loss over 6 months is indicative of severe malnutrition. Other nutritional risk parameters include weight <80% of ideal weight, BMI <20 kg/m<sup>2</sup>, or a loss of 5 lb or 2.5% of baseline weight in 1 month.

## PERSONALIZED NUTRITION

### Consensus recommendation

- Studies using personalized nutrition approaches to examine genetic, metabolomic, and microbiome variations have not yet identified specific factors that consistently improve outcomes in type 1 diabetes, type 2 diabetes, or prediabetes.

### Do genetic, metabolomic, or microbiome variants, or other types of personalized nutrition prescriptions, influence glycemic or other diabetes-related outcomes?

Currently, use of nutrition counseling approaches aimed at personalizing guidance based on genetic, metabolomic, and microbiome information is an area of intense research. Testing has become available commercially, with direct-to-consumer advertising. Some intriguing research has shown, for example, the wide interpersonal variability in blood glucose response to standardized meals that could be predicted by clinical and microbiome profiles (332). At this point, however, no clear conclusions can be drawn regarding their utility owing to wide variations in the markers used for predicting outcomes, in the populations and nutrients studied, and in the associations found.

Further, overall findings tend to support evidence from existing clinical trials and observational studies showing that people with markers indicating higher

risk for diabetes, prediabetes, or insulin resistance have lower risk when they reduce calorie, carbohydrate, or saturated fat intake and/or increase fiber or protein intake compared with their peers (333–337).

## CONCLUSIONS

Ideally, an eating plan should be developed in collaboration with the person with prediabetes or diabetes and an RDN through participation in diabetes self-management education when the diagnosis of prediabetes or diabetes is made. Nutrition therapy recommendations need to be adjusted regularly based on changes in an individual's life circumstances, preferences, and disease course (1). Regular follow-up with a diabetes health care provider is also critical to adjust other aspects of the treatment plan as indicated.

One of the most commonly asked questions upon receiving a diagnosis of diabetes is "What can I eat?" Despite widespread interest in evidence-based diabetes nutrition therapy interventions, large, well-conducted nutrition trials continue to lag far behind other areas of diabetes research. Unfortunately, national data indicate that most people with diabetes do not receive any nutrition therapy or formal diabetes education (4,9,16,20).

Strategies to improve access, clinical outcomes, and cost effectiveness include the following

- reducing barriers to referrals and allowing self-referrals to MNT and DSMES;
- providing in-person or technology-enabled diabetes nutrition therapy and education integrated with medical management (9,12,13,15,16,19,22, 291–293,338–342);
- engineering solutions that include two-way communication between the individual and his or her health care team to provide individualized feedback and tailored education based on the analyzed patient-generated health data (38,264,343);
- increasing the use of community health workers and peer coaches to provide culturally appropriate, ongoing support and clinically linked care coordination and improve the reach of MNT and DSMES (15,19,23,38, 343,344).

Evaluating nutrition evidence is complex given that multiple dietary factors influence glycemic management and CVD risk factors, and the influence of a combination of factors can be substantial. Based on a review of the evidence, it is clear that knowledge gaps continue to exist and further research on nutrition and eating patterns is needed in individuals with type 1 diabetes, type 2 diabetes, and prediabetes. Future studies should address

- the impact of different eating patterns compared with one another, controlling for supplementary advice (such as stress reduction, physical activity, or smoking cessation);
- the impact of weight loss on other outcomes (which eating plans are beneficial only with weight loss, which can show benefit regardless of weight loss);
- how cultural or personal preferences, psychological supports, co-occurring conditions, socioeconomic status, food insecurity, and other factors impact being consistent with an eating plan and its effectiveness;
- the need for increased length and size of studies, to better understand long-term impacts on clinically relevant outcomes;
- tailoring MNT and DSMES to different racial/ethnic groups and socioeconomic groups;
- comparisons of different delivery methods aided by technology (e.g., mobile technology, apps, social media, technology-enabled and internet-based tools); and
- ongoing cost-effectiveness studies that will further support coverage by third-party payers or bundling services into evolving value-based care and payment models.

**Acknowledgments.** The authors acknowledge Mindy Saraco (Managing Director, Medical Affairs, ADA) for her help with the development of the Consensus Report. The authors thank Margaret Powers for providing her expertise in reviewing and/or consulting with the authors, Melinda Maryniuk for serving as a liaison to the ADA Professional Practice Committee (PPC), and the PPC for providing valuable review and feedback. The authors acknowledge the invited peer reviewers who provided comments on an earlier draft of this report: Kelli Begay (Indian Health

Service, Rockville, MD), Guoxun Chen (University of Tennessee, Knoxville, TN), Frank Hu (Harvard T.H. Chan School of Public Health, Boston, MA), Melinda Maryniuk (Maryniuk & Associates Diabetes and Nutrition Consultants, Jamaica Plain, MA), Margaret Powers (HealthPartners Institute, Minneapolis, MN), Judith Wylie-Rosett (Albert Einstein College of Medicine, Bronx, NY), Alyce Thomas (St. Joseph's Health, Paterson, NJ), Emily Weatherup (Michigan Medicine, University of Michigan, Ann Arbor, MI), and Gretchen Youssef (MedStar Health, Washington, DC).

**Duality of Interest.** The authors disclosed all potential financial conflicts of interest with industry. These disclosures were discussed at the onset of the consensus statement development process. The ADA uses general revenues to fund development of its consensus reports and does not rely on industry support for these purposes. A.B.E. reports honorarium from the Academy of Nutrition and Dietetics and the ADA outside of the submitted work. W.T.G. reports personal fees from Novo Nordisk, Merck, Amgen, Gilead, BOYDSense, the American Medical Group Association, and Janssen and grants from Sanofi, Pfizer, Merck, and Novo Nordisk outside of the submitted work. K.H.K.L. reports personal fees from Sunstar Foundation outside of the submitted work. J.Mi. reports speaking fees from New England Dairy and Dairy Farmer, research support and consulting/speaking fees from the National Dairy Council, and research support from Kowa Company and the National Institutes of Health outside of the submitted work. K.R. was previously employed by the ADA. L.S. reports grants from the National Institutes of Health and internal University of Michigan grants. W.S.Y. reports a consulting relationship with dietdoctor.com, which began after the Consensus Report was submitted to *Diabetes Care*. No other potential conflicts of interest relevant to this article were reported.

**Author Contributions.** All authors were responsible for drafting the Consensus Report and revising it critically for important intellectual content. All authors approved the version to be published.

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