

Perspectives in Practice

Evidence-Based Nutrition Practice Guidelines for Diabetes and Scope and Standards of Practice

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ABSTRACT

In the 1990s, the American Dietetic Association (ADA) began developing nutrition practice guidelines for registered dietitians (RDs) and evaluating how their use affected clinical outcomes. Clinical trials and outcomes research report that diabetes medical nutrition therapy, delivered using a variety of nutrition interventions and multiple encounters, is effective in improving glycemic and other metabolic outcomes. The process of developing nutrition practice guidelines has evolved into evidence-based nutrition practice guidelines, which are disease/condition-specific recommendations and toolkits. An expert work group identified important clinical questions related to diabetes nutrition therapy. Research studies were analyzed and evidence summaries and conclusion statements written and graded for strength of research design. Based on the research conclusions, evidence-based nutrition recommendations and guidelines for adults with type 1 and type 2 diabetes were formulated. The ADA evidence-based nutrition practice guidelines for diabetes are published in the Web-based evidence analysis library. The recommendations are similar to those of the American Diabetes Association, although developed using a different method. To define the RD's professional practice, the ADA has published the Scope of Dietetics Practice Framework, the Standards of Practice and Standards of Professional Performance, and specialized standards for the RD in diabetes nutrition care. The latter defines the knowledge, skills, and competencies required

by RDs to provide diabetes care at the generalist, specialist, and advanced practice level.

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In 1990, the American Dietetic Association (ADA) documented a need for both development of nutrition practice guidelines and studies evaluating how their use affects clinical outcomes (1). Nutrition practice guidelines were written for type 1, type 2, and gestational diabetes (2-4). These guidelines were implemented and showed that medical nutrition therapy (MNT) positively affects diabetes outcomes (5-7). Commentaries on evidence for effectiveness of diabetes MNT provided by registered dietitians (RDs) have been published (8,9). The role of the RD in contributing to improved outcomes—clinical as well as quality of life—are described in the Scope of Dietetics Practice Framework, Standards of Practice and Standards of Professional Performance (10,11). This article reviews diabetes MNT outcomes data, ADA's process for developing evidence-based nutrition practice guidelines, ADA's 2008 evidence-based nutrition recommendations for adults with type 1 and type 2 diabetes and recommendations from the American Diabetes Association, and defines professional practice for RDs.

EFFECTIVENESS OF DIABETES MNT INTERVENTIONS

Nutrition therapy for diabetes is effective. Randomized controlled trials and observational studies of MNT have documented decreases in hemoglobin A1c (HbA1c) of ~1% to 2% (range = -0.5% to -2.6%), depending on the type and duration of diabetes (8,9). Diabetes MNT has the greatest impact at initial diagnosis, and it continues to be effective at any time during the disease process. Outcomes resulting from nutrition interventions are generally known in 6 weeks to 3 months and evaluation should be done at these times. At 3 months, if no clinical improvement has been seen in glycemic control, the RD needs to recommend a change in medication(s). Type 2 diabetes is a progressive disease, and as β -cell function decreases, blood glucose—lowering medication(s) must be combined with MNT to achieve blood glucose goals (5).

Nutrition counseling must be sensitive to the personal needs and cultural preference of the individual and their willingness and ability to make changes (2,3,12). Research shows that there are many types of nutrition interventions that are effective (5,6,13-31). Central to these interventions are multiple encounters to provide education and counseling initially and on a continued basis. The Table summarizes the evidence, both for MNT and

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Table. Summary of evidence for effectiveness of medical nutrition therapy (MNT) in type 1 and type 2 diabetes

Type of study	Type of diabetes	Study length	No. of subjects	Nutrition intervention	No. of interventions	HCP ^a conducting intervention	Change in HbA1c ^b (%)
Randomized controlled trials							
MNT studies							
UK Prospective Diabetes Study Group, 1990 (13)	Type 2	3 mo	3,044	Decreased energy, 50% CHO ^c , 20% protein, 30% fat	3 (1-mo intervals)	Dietitian	↓ 1.9
Franz and colleagues, 1995 (5)	Type 2	6 mo	179	Individualized MNT	3 (within first 6 wks) 4-yr duration of diabetes 3 (within first 6 wks) newly diagnosed	RD ^d RD	↓ 0.9 ↓ 1.7
Kulkarni and colleagues, 1998 (6)	Type 1	3 mo	54	Type 1 nutrition practice guidelines	2-4 (108 min/3 mo)	RD	↓ 1.0
Miller and colleagues, 2002 (14)	Type 2	1 yr	98	Nutrition education, emphasis on food labeling	10 weekly sessions	RD	↓ 0.5
Goldhaber-Fiebert and colleagues, 2003 (15)	Type 2	12 wks	75	Portion control and healthy food choices	11 weekly nutrition classes (90 min)	Nutritionist	↓ 1.8
Ziemer and colleagues, 2003 (16)	Type 2	6 mo	648	Healthy food choices and exchange lists	4 (initial, 1, 2, 4 wks)	RD	↓ 1.9
MNT/DSMT^e studies							
Glasgow and colleagues, 1992 (17)	Type 2	6 mo	102	Decreased energy/fat, increased fiber	10 sessions (over 12-wk period)	RD, psychologist, exercise therapist	↓ 1.0
Sadur and colleagues, 1999 (18)	Type 2	6 mo	185	Healthy food choices	6 (monthly 2-hour cluster visit)	RD, RN ^f , psychologist, RPh ^g	↓ 1.3
DAFNE Study Group, 2002 (19)	Type 1	6 mo	169	Advanced CHO counting; insulin-to-CHO ratios	5-day course	RD, RN	↓ 1.0
Rickheim and colleagues, 2002 (20)	Type 2	6 mo	170	CHO counting, portion control, meal spacing	4 (initial, 2 wks, 3, 6 months)	RD, RN	↓ 2.0
Polonsky and colleagues, 2003 (21)	Type 1&2	6 mo	167	Usual care—standardized meal plan DSMT-individualized MNT	Usual care/qtr mailing 3.5-day program + 6-mo case management	RD, RN, MD ^h , exercise physiologist	↓ 1.7 ↓ 2.3
Observational studies							
MNT studies							
Delahanty and Halford, 1993 (22)	Type 1	9 yr	623	Intensive MNT; exchange lists; CHO counting	Quarterly visits during intensive therapy (averaged 4.1 years)	RD	↓ 0.9
Johnson and Thomas, 2001 (23)	Type 2	1 yr	162	Individualized MNT	Minimum of 2 visits	RD	↓ 2.1
Lemon and colleagues, 2006 (24)	Type 2	6 mo	244	Individualized MNT by RD; CHO counting and simplified meal plans	1-6; average of 2 times and 111 min	RD	↓ 1.7
Gaetke and colleagues, 2006 (25)	Type 2	3 mo	175	Individualized nutrition counseling session	1	RD	↓ 2.6
MNT/DSMT studies							
Pieber and colleagues, 1995 (26)	Type 1	3 yrs	210	CHO counting; insulin-to-CHO ratios	5 days (24 h total)	Dietitian, RN	↓ 1.2
Christensen and colleagues, 2000 (27)	Type 1 and 2	3 mo	102	MNT by RD-individualized goals	2 (2 weeks apart)	RD	↓ 1.6
Graber and colleagues, 2002 (28)	Type 2	3 mo	350	Individualized MNT	12 (weekly for 3 mo)	RD, RN	↓ 1.7
Bannister and colleagues, 2004 (29)	Type 2	1 yr	70	Basic nutrition; individualized meal plans	4-hour class; 1-2 individual RD consult; monthly groups	1 RD, 2 CDEs ⁱ	↓ 1.5
Bray and colleagues, 2005 (30)	Type 2	1 yr	160	9 Nutrition education classes + nurse case management	4 sessions in 6 mo	Nutritionist, RN, MD, RPh	↓ 1.1
Chima and colleagues, 2005 (31)	Type 2	90 days to 3 years	438	Individual MNT sessions, heart healthy foods	3-2 h group classes + 2-3 individual MNT sessions	RD, RN	↓ 1.6

^aHCP=health care provider.

^bHbA1c=hemoglobin A1c.

^cCHO=carbohydrate.

^dRD=registered dietitian.

^eDSMT=diabetes self-management training.

^fRN=registered nurse.

^gRPh=registered pharmacist.

^hMD=physician.

ⁱCDE=certified diabetes educator.

for MNT in combination with diabetes self-management training, and includes nutrition interventions utilized, number of encounters (sessions), and the health care providers involved in the care.

Studies in the Table were identified from the ADA's evidence analysis library (32) and studies identified in previously published articles (8,9). MNT studies report the outcomes of nutrition interventions provided by a dietitian (or food and nutrition professional). The MNT and diabetes self-management training studies also include a nutrition intervention, but the diabetes self-management training was provided by a multidisciplinary team, which included at least a minimum of an RD and registered nurse. Studies include randomized clinical trials, cross-sectional studies, nonrandomized single intervention outcome studies, chart reviews, and chart audits. Because it is consistently reported across all studies, HbA1c is the clinical outcome included in the Table. Although important, other outcomes such as blood pressure, lipids, change in weight, or in body mass index are not consistently reported and therefore are not included in the Table.

ADA'S FOUR-PHASE EVIDENCE-BASED NUTRITION PRACTICE GUIDELINES PROCESS

The ADA evidence-based nutrition practice guidelines are developed based on a four-phase systematic process for identifying, analyzing, and synthesizing scientific evidence. The results of this process are the evidence-based recommendations and treatment algorithms that guide RDs in providing therapy that produces optimum outcomes.

Phase one in the process is the selection of a topic and expert work group. Currently, the ADA has work groups for 24 topics, including diabetes. Expert work groups are appointed by the ADA's Evidence-Based Practice Committee. Phase two is the evidence analysis process, which includes selection of important practice questions, identification of research studies that meet predetermined criteria, analysis of the research, and grading of the research based on the strength of the evidence elements. The conclusion statement is graded using grade I, II, and III for good/strong, fair, and limited/weak, respectively; grade IV signifies expert opinion only, and grade V indicates a grade not assignable (32).

Phase three is the writing of the recommendations based on the research evidence for each question. Recommendations for a course of action for the RD are based on evidence as well as clinical experience, expert opinion, cost, and patient values. Links are provided from the recommendation page to the supporting evidence. Clinical algorithms (step-by-step flow charts) for treatment are then developed.

Phase four is the development and field testing of toolkits to support implementation of the recommendations and algorithms. They incorporate the Nutrition Care Process, including nutrition care standardized language (33,34).

The nutrition practice guidelines are reviewed by experts from many disciplines. Evidence is also updated on a regular basis to ensure they reflect current science and best practice. A literature search on each guideline topic is done on an annual basis and a determination is made

about whether the information could change the published recommendation or rating. If a revision is not warranted, the guideline will undergo a complete revision every 3 to 5 years.

APPLICATION OF EVIDENCE-BASED NUTRITION PRACTICE GUIDELINES PROCESS TO DIABETES

An expert work group was appointed to revise the ADA's Nutrition Practice Guidelines for Type 1 and Type 2 Diabetes Mellitus (35). In order to develop nutrition practice guidelines, the work group began by defining critical clinical questions related to diabetes nutrition therapy. The inclusion and exclusion criteria for research studies, search terms, and databases searched, articles identified through "hand searching," and the articles included and excluded with a reason for the exclusion can be found on the ADA Web site at www.eatright.org/adaevidencelibrary. A trained analyst critically appraised each article that met the inclusion criteria and summarized it using the review worksheet used for analysis by all evidence-based nutrition practice guidelines work groups. A summary of the evidence and a conclusion statement were written. The evidence summaries and conclusion statements were then used to develop the nutrition recommendations.

EVIDENCE-BASED NUTRITION PRACTICE GUIDELINES DIABETES CRITICAL QUESTIONS

The following are the identified questions and number of studies analyzed for each question. The studies analyzed are available in the ADA's evidence analysis library (32). The ADA evidence-based nutrition practice guidelines recommendations for adults with type 1 and type 2 diabetes are available at www.dce.org/links/jada/00448.htm.

1. How effective is the use of MNT implemented by RDs in diabetes management? Sixteen studies were reviewed to evaluate the effectiveness of MNT provided by an RD.
2. What is the relationship between carbohydrate intake, sucrose, glycemic index, fiber, and nonnutritive sweeteners and metabolic outcomes in people with type 1 and type 2 diabetes? Nine studies were evaluated related to carbohydrate intake; 15 studies for sucrose, 16 studies for glycemic index, 15 studies for dietary fiber, and 8 studies for nonnutritive sweeteners.
3. What is the relationship between protein intake and metabolic outcomes in people with type 1 and type 2 diabetes? Five studies in people with normal renal function and six studies on the effect of lower-protein diets in the management of diabetic nephropathy were evaluated.
4. What is the effect of weight management on metabolic outcomes? Twenty-two randomized clinical trials on weight management in people with diabetes with a minimum 1-year duration/follow-up were reviewed.
5. What is the effect of physical activity combined with MNT on metabolic outcomes? Fourteen studies involving physical activity in people with type 2 diabetes and four studies involving exercise in people with type 1 diabetes were analyzed.
6. What is the relationship between self-blood glucose monitoring and continuous glucose monitoring and

metabolic outcomes? With regard to self-blood glucose monitoring, 7 studies in people with type 1 diabetes and 18 studies in type 2 diabetes were reviewed. Seventeen studies on continuous glucose monitoring were reviewed.

7. What evidence supports nutrition interventions in the treatment and prevention of cardiovascular disease? Twenty-one treatment studies in people with diabetes and cardiovascular disease, using a variety of nutrition interventions over different time periods, were evaluated and 12 prevention studies for cardiovascular disease in people with diabetes were reviewed.

COMPARISON OF NUTRITION RECOMMENDATIONS FOR DIABETES

The American Diabetes Association also has published nutrition therapy recommendations and interventions, but uses a different process for their development (12,36). The American Diabetes Association's most recent nutrition recommendations are delineated in a nutrition position statement published in 2008 (12). Recommendations are based on a technical review (37) and key references published since the year 2000. A technical review is an analysis of literature related to a specific topic, including research studies, review articles, and conference proceedings. The American Diabetes Association uses an evidence-grading system that is different than ADA's—clinical practice recommendations are assigned ratings of A, B, or C, depending on the quality of the evidence (36).

The ADA and the American Diabetes Association nutrition-related recommendations for diabetes are available at www.dce.org/links/jada/00448.htm (12,32,38). It should be noted that the ADA recommendations first describe "what to do" and then state "why." The "why" summarizes the evidence used to make the recommendation. The recommendations are rated as Strong, Fair, Weak, Consensus, or Insufficient Evidence and as conditional or imperative statements. Conditional statements apply to specific situations, while imperative statements are broadly applicable to the target population.

SCOPE OF PRACTICE AND STANDARDS OF PRACTICE AND PROFESSIONAL PERFORMANCE

Evidence-based nutrition practice guidelines help the RD apply research to practice and improve the quality and outcomes of MNT delivered by the RD. They do not define scope of practice and do not include components of standards of practice, but are necessary in utilizing the nutrition care process and application of MNT. To help define scope of practice and other key terms, the ADA Board of Directors, in 2003, appointed the Practice Definitions Task Force to identify and differentiate the terms within dietetics practice that need clarification for members, and to examine the broad issues of scope of professional practice and standards for RDs and registered dietetic technicians.

In tandem, the Diabetes Care and Education Dietetic Practice Group appointed a task force to work with ADA to develop standards specific to diabetes care. The result of these task forces was the publication of the Scope of Dietetics Practice Framework (10), the Standards of

Practice and Standards of Professional Performance (11), and the Specialized Standards for the RD in Diabetes Nutrition Care (39). The Figure illustrates the relationships and provides definitions for scope, standards, and practice levels (10,11,39,40).

Scope of practice is based on education, training, credentials, level of experience, skill and proficiency, expertise, licensure or certification laws, state and federal laws and regulations, and more (10). The Scope of Dietetics Practice Framework Decision Analysis Tool can help an individual assess whether a function is within their scope (11). The diabetes-specific Standards of Practice can also help the practitioner determine if she/he is at a competent level of practice to perform a function (39).

Together, the Scope of Dietetics Practice Framework, the core nutrition care Standards of Practice and Standards of Professional Performance, and the Standards of Practice and Standards of Professional Performance for the RD practicing in diabetes care, along with the Code of Ethics (41), guide and direct practice (ie, competent level of practice) and professional performance (ie, competent level of behavior). All of these documents can be found on the ADA Web site at www.eatright.org/scope. The RD and registered dietetic technician should be familiar with these resources and should use them to guide, develop, and improve their competency and professional practice.

These standards have been formulated to be used for individual self-evaluation and development of practice guidelines, but not for institutional credentialing or for adverse or exclusionary decisions regarding privileging, employment opportunities or benefits, disciplinary actions, or determinations of negligence or misconduct. These standards do not constitute medical or other professional advice, and should not be taken as such. The information presented in these standards is not a substitute for the exercise of professional judgment by the health care professional. Use of the standards for any other purpose than that for which they were formulated must be undertaken within the sole authority and discretion of the user.

EXAMPLE OF DIABETES SCOPE AND STANDARDS

To demonstrate how these resources might be used, consider a common question in professional practice. "Can an RD in diabetes care teach and administer injectable medications used in diabetes management?" This is both a question related to scope and standards; scope of practice helps define what dietetic practitioners are authorized to do, and standards define a competent level of practice. While teaching and administering injectable medications may be within the RDs authorized scope of practice, each individual practitioner is accountable to assess their level of competence, and evaluate other factors (eg, state licensure laws) before teaching or administering injectable medications.

Within the standards, subindicator 3.5A2 under Standard 3: Nutrition Intervention identifies "selection and initiation of pharmacotherapy, including instructions on medication delivery systems" as a responsibility of a specialty or advanced-level RD. Thus, if you are a specialty or advanced level RD practicing in diabetes management and education and you satisfy the criteria of the Scope of Dietetics Practice Framework Decision Analysis Tool,

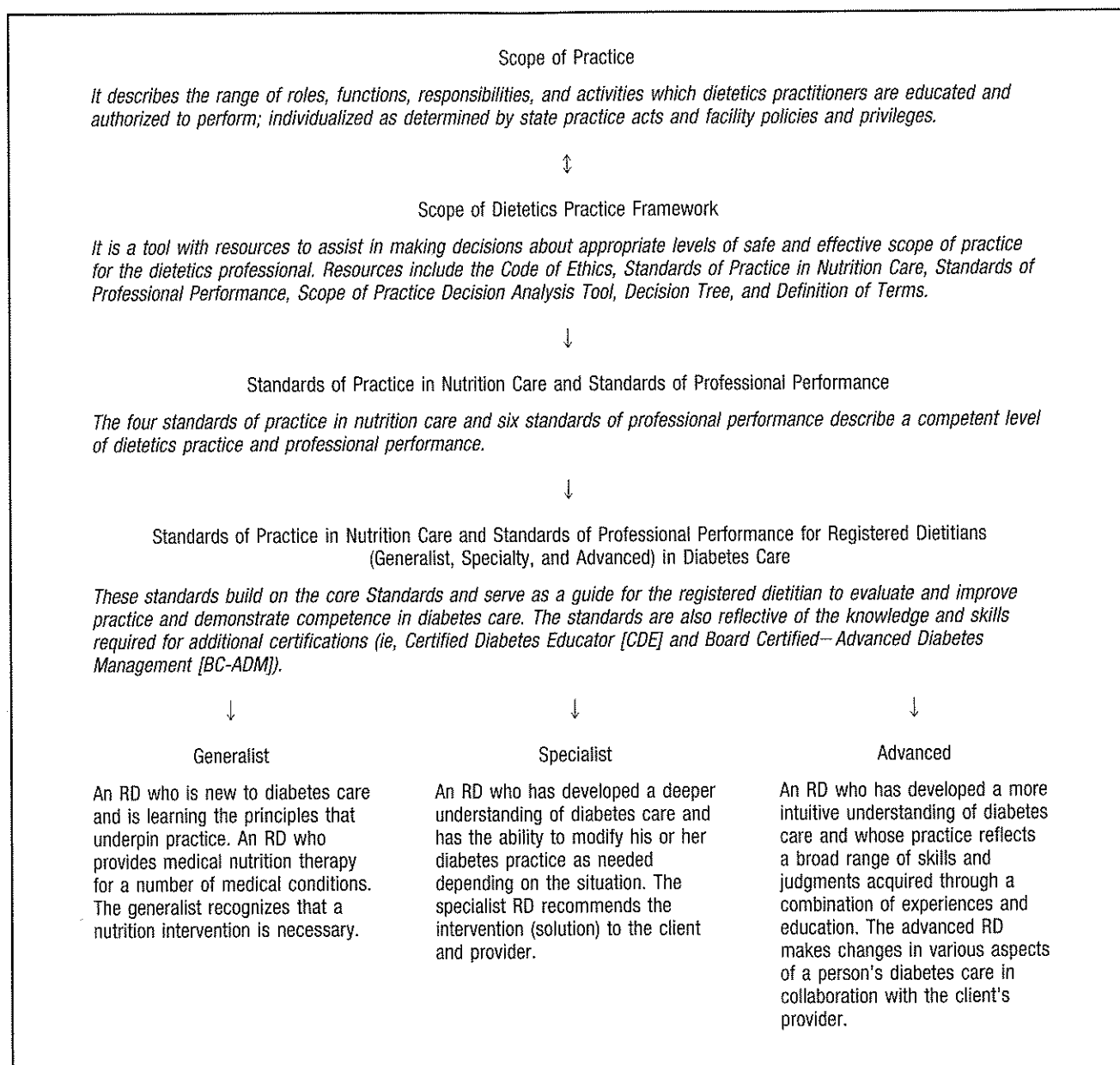


Figure. Understanding scope, standards, and the role of the registered dietitian (RD) (generalist, specialist, and advanced practice) in diabetes nutrition care. Sources: References 10,11,39,40.

you are competent to teach and administer medications (39). For additional information, the Diabetes Care and Education Dietetic Practice Group and the ADA have developed a statement on this topic (42).

SUMMARY

Clinical trials and outcome studies have demonstrated the effectiveness of diabetes MNT provided by RDs and, depending on the type and duration of diabetes, report reductions in HbA1c of ~1% to 2%. A variety of nutrition interventions and a number of initial and follow-up encounters

were implemented to obtain these clinically significant outcomes. It is essential that the RD select appropriate interventions for individual clients and evaluate outcomes to determine if changes in MNT and/or an addition of medication(s) are needed to reach desired outcomes.

Diabetes evidence-based nutrition practice guidelines for nutrition care have been developed by the ADA. The questions analyzed and conclusions are the basis for the nutrition recommendations and algorithms and toolkit. The ADA and the American Diabetes Association nutrition recommendations are very similar, despite use of differing development and grading methods.

Standards of Practice and Standards of Professional Performance are complementary core documents that describe a competent level of dietetics practice in nutrition care and professional performance common to all registered dietetics professionals. From these core standards, practice-specific standards have been developed to provide guidance for RDs related to diabetes nutrition care.

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