

# **Evidence for Nutrition Therapy:**

## **Understanding the Science Behind the ADA's New Nutrition Therapy Recommendations for the Management of Adults with Diabetes and How to Incorporate Them Into Practice**

# Disclosure

Jackie Boucher has no conflicts of interest to disclose.



## Presentation Objectives

- Define the difference between medical nutrition therapy (MNT) and nutrition therapy.
- Explain the evidence supporting the American Diabetes Association's new nutrition guidelines.
- Translate the new ADA guidelines for practical application to patient care to help adults with type 1 and type 2 diabetes achieve nutrition therapy goals.

## Presentation Outline

- Background on the ADA evidence analysis process
- Review goals of nutrition therapy
- Defining MNT versus nutrition therapy
- Review of the recommendations
- Translation of recommendations for patients

## ADA Position Statements

- Typically based on a systematic review or other review of published literature.

Wheeler et al. Macronutrients, food groups, and eating patterns in the management of diabetes: a systematic review of the literature, 2010. *Diabetes Care*. 2012;35:434-445.

- An official point of view or belief of the ADA.
- Issued on scientific or medical issues related to diabetes – such as nutritional management.

# **Institute of Medicine Standards for Trustworthy Clinical Practice Guidelines (CPG)/Position Statements**

## **1. Establishing transparency**

- CPGs are funded from general revenues of the Association and not with any corporate support.

## **2. Management of conflict of interest (COI)**

- COI disclosure prior to confirmation of appointment to writing group

# **Institute of Medicine Standards for Trustworthy Clinical Practice Guidelines/Position Statements**

## **3. Group composition**

- The GDG should be multidisciplinary
- Patient and public involvement should be facilitated
- Strategies to increase effective participation of patient and consumer representatives

## **4. Clinical practice guideline–systematic review intersection**

# **Institute of Medicine Standards for Trustworthy Clinical Practice Guidelines/Position Statements**

- 5. Establishing evidence foundations for  
and rating strength of recommendations**
- 6. Articulation of recommendations**
- 7. External review**
- 8. Updating**



## **Systematic Review – “Macronutrients, Food Groups, and Eating Patterns of the Management of Diabetes”**

- Two critical components of nutrition therapy were not addressed
  - Energy balance
  - Healthful eating patterns

## **Systematic Review – “Macronutrients, Food Groups, and Eating Patterns of the Management of Diabetes”**

Following questions were addressed:

1. What aspects of macronutrient quantity and quality impact glycemic control and cardiovascular disease (CVD) risk in people with diabetes?
2. How do macronutrients combine in whole foods and eating patterns to affect health in people with diabetes?

## **Systematic Review – “Macronutrients, Food Groups, and Eating Patterns of the Management of Diabetes”**

3. Is there an optimal macronutrient ratio for glycemic management and CVD risk reduction in people with diabetes?
4. What findings and needs should direct future research?

## Inclusion Criteria

- **Date Range:**
  - For topics not included in the 2012 Macronutrient Systematic Review, PubMed data searches from January 2001 through April 2013
  - For topics included in Macronutrient Systematic Review – start after October 2010 to April 2013

\*ADA Systematic Review included studies with <80% retention rate; however, those studies were not included in the summaries

## **Inclusion Criteria – Current Review**

- **Age** – Adults
- **Setting** – Outpatient and ambulatory care
- **Nutrition Related Problem/Condition** – Diabetes Dx
- **Study Design Preferences:**
  - Systematic Review
  - Randomized controlled trial (RCT) or Clinical Controlled Studies
  - Prospective Observational Study
  - Cross-sectional Observational Study
  - Case-control Studies

## Inclusion Criteria

- **Size of study groups** > 10 individuals
- **Study Drop out rate\*** - Retention rate >80%
- **Language** – English

\*ADA Systematic Review included studies with <80% retention rate; however, those studies were not included in the summaries

## Exclusion Criteria

- **Age:** < 18 years
- **Setting** – Inpatient or acute care
- **Health Status:**
  - Diabetes Complications/poor health status
  - Critical illness or other disease conditions
  - Gestational Diabetes
  - Metabolic syndrome/risk of diabetes
- **Study Design** – Meal studies

## Multi-disciplinary Committee

- Co-chairs:  
Alison B. Evert, MS, RD, CDE  
Jackie Boucher, MS, RD, CDE
- Committee Members:  
Marjorie Cypress, PhD, C-ANP, CDE  
Elizabeth J. Mayer-Davis, PhD, RD  
Joshua Neumiller, PharmD, CDE, CGP, FASCP  
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William S. Yancy Jr, MD, MHSc.
- Staff Members:  
Stephanie Dunbar MPH, RD & Cassandra Rico MPH, RD



## Levels of Evidence

- Level A
  - Clear evidence from well-conducted, generalizable, RCTs that are adequately powered.
  - Supportive evidence from well-conducted RCTs that are adequately powered.
- Level B:
  - Supportive evidence from well-conducted cohort studies.
  - Supportive evidence from a well-conducted case-control study.

## Levels of Evidence

- Level C:
  - Supportive evidence from poorly controlled or uncontrolled studies.
  - Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Level E “Expert Consensus or Expert Opinion”
  - No evidence from clinical trials

## Goals of Nutrition Therapy for Adults with Diabetes

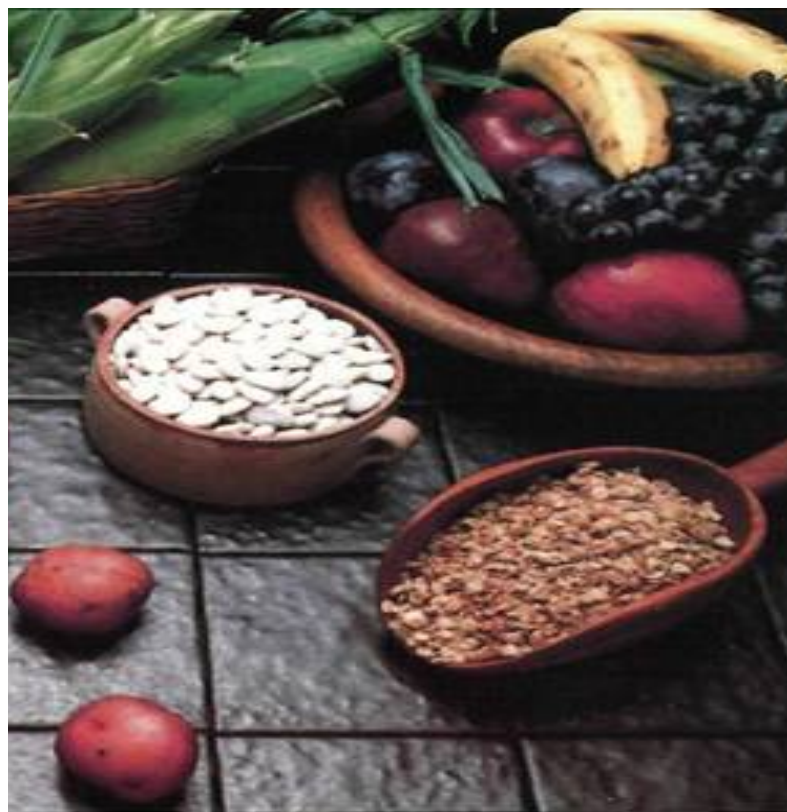
- To promote and support healthful eating patterns, emphasizing a variety of nutrient-dense foods in appropriate portion sizes, in order to improve overall health and to:
  - Attain glycemic (A1C <7%), blood pressure (<140/80 mmHg) and lipid goals (LDL <100 mg/dL; TG < 150 mg/dL; HDL >50 mg/dL men and >50 mg/dL for women)
  - Achieve body weight goals
  - Delay or prevent complications of diabetes

## **Goals of Nutrition Therapy for Adults with Diabetes** *(continued)*

- 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.

## Goals of Nutrition Therapy for Adults with Diabetes *(continued)*

- To provide the individual with diabetes with practical tools for day-to-day meal planning rather than focusing on individual macronutrients, micronutrients, or single foods



## Defining MNT

- In 1999, the IOM released a report concluding MNT can improve clinical outcomes and possibly decrease the costs to Medicare of managing diabetes.
- The IOM recommended that individualized MNT, provided by an RD upon physician referral be a covered Medicare benefit as part of the multidisciplinary approach to diabetes care.
- MNT is the legal definition of nutrition counseling by an RD in the U.S.

## Defining Nutrition Therapy

- Nutrition therapy is also defined by the IOM and has a broader definition than MNT.
- Nutrition therapy is the treatment of a disease or condition through the modification of nutrient or whole-food intake.
- The definition does not specify that nutrition therapy must be provided by an RD.

## **For MNT for adults with Diabetes, the Academy of Nutrition and Dietetics Recommends**

- A series of 3-4 encounters with an RD lasting from 45-90 minutes.
- The series of encounters should begin at diagnosis of diabetes or at first referral to an RD for MNT for diabetes and should be completed within 3-6 months.
- The RD should determine whether additional MNT encounters are needed.
- At least 1 follow-up encounter is recommended annually to reinforce lifestyle changes and to evaluate the need for changes in MNT or medication(s); an RD should determine whether additional MNT encounters are needed.



## **MNT and Nutrition Therapy Should Include:**

- Nutrition assessment
- Nutrition diagnosis
- Nutrition intervention (e.g., education and counseling)
- Nutrition monitoring and evaluation, with ongoing follow-up to support long-term lifestyle changes, evaluate outcomes, and modify interventions as needed.

# MNT and Nutrition Therapy are Effective

- Reported A1C reductions are similar to or greater to what would be expected with treatment with currently available pharmacologic treatments for diabetes.
- Documented decreases in A1C:
  - Studies with type 1 diabetes – demonstrate a -0.3 to -1% reduction
  - Studies with type 2 diabetes – demonstrate a -0.5% to -2% reduction

# Evidence on Nutrition Therapy Suggests

- Nutrition therapy be recommended for all adults with diabetes as a component of the overall treatment plan (A Level Evidence).
- Individuals with diabetes should receive individualized MNT as needed to achieve treatment goals; preferably with an RD familiar with the components of MNT (A Level Evidence)
  - Type 1: Participation in flexible insulin therapy education program using carbohydrate counting meal planning approach can result in improved glycemic control (A Level Evidence)
  - For individuals on fixed daily dose, consistent carbohydrate intake with respect to time and amount can result in improved glycemic control and reduce the risk for hypoglycemia (B Level Evidence)
  - A simple diabetes meal planning approach such as portion control or healthful food choices may be better suited to individuals with type 2 diabetes identified with health and numeracy literacy concerns. This may also be an effective meal planning strategy for older adults (C Level Evidence).

# Evidence on Nutrition Therapy Suggests

- People with diabetes should receive Diabetes Self-Management Education according to national standards and Diabetes Self-Management Support when their diabetes is diagnosed and as needed thereafter (B Level Evidence).
- Because diabetes nutrition therapy can result in cost savings (B Level Evidence) and improved outcomes (A Level Evidence), nutrition therapy should be adequately reimbursed (E Level Evidence).

## Energy Balance

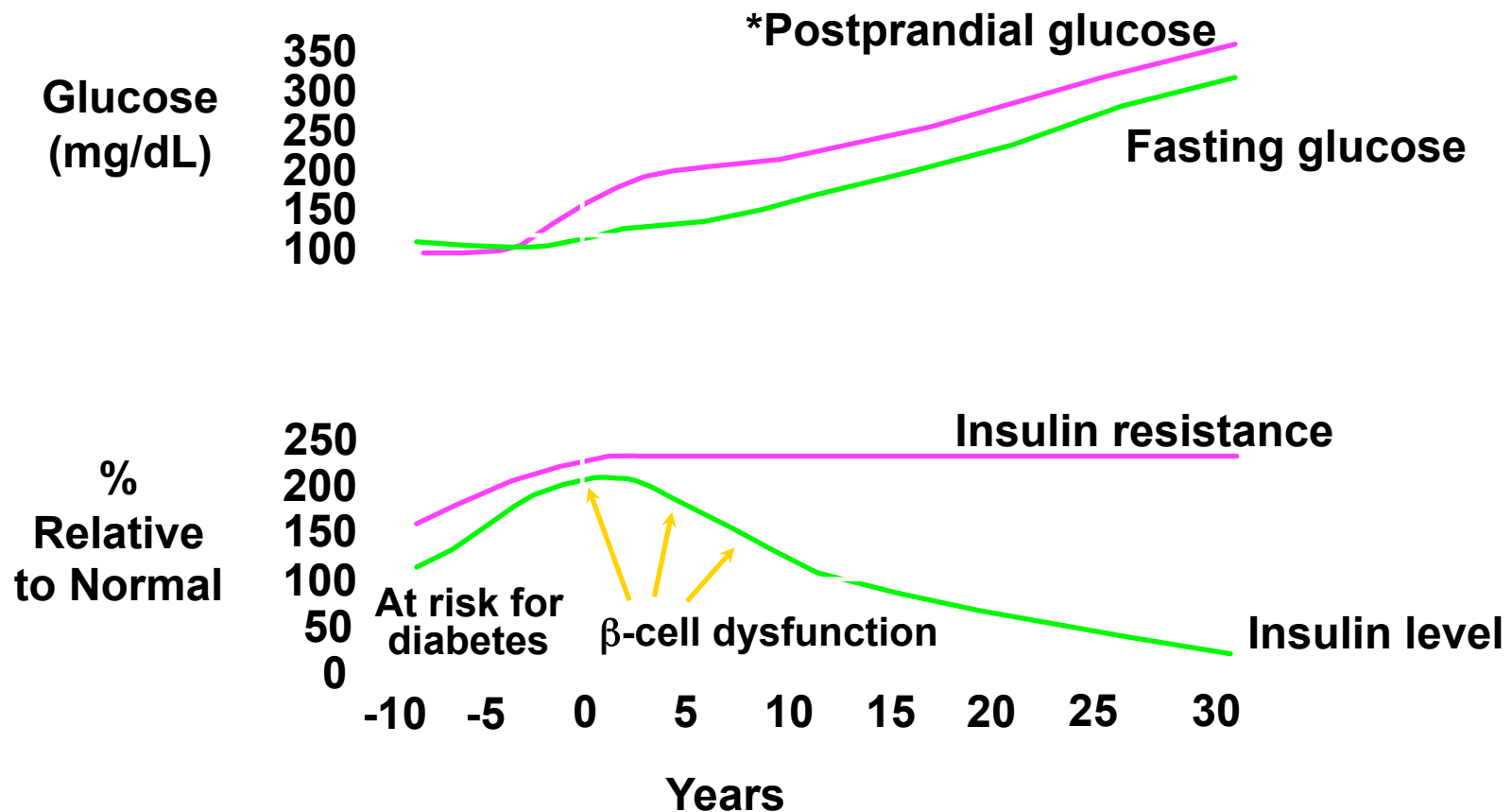
- We know more than 3 out of every 4 people with diabetes are at least overweight and nearly half of all individuals with diabetes are overweight.
- Often because of the relationship between body weight (i.e., adiposity) and insulin resistance weight loss has been recommended as a strategy for adults with diabetes.
- Yet we also know weight loss is challenging, and there is no optimal macronutrient intake to support reduction in excess body weight.



American Diabetes Association®

## Type 2 Diabetes: A Progressive Disease

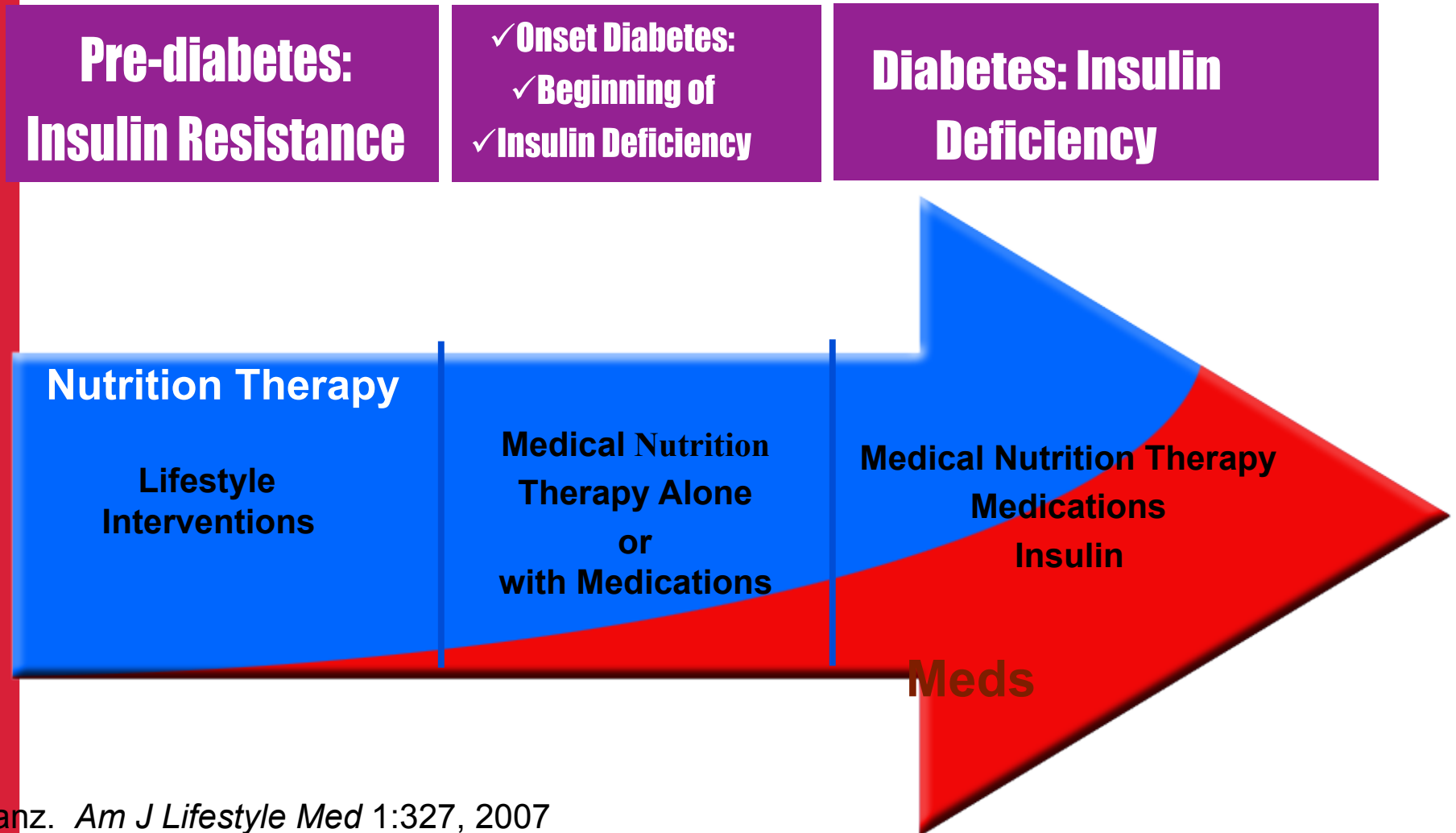
BG remains normal until insulin deficiency



\* Post Prandial = 1-2 h ppg

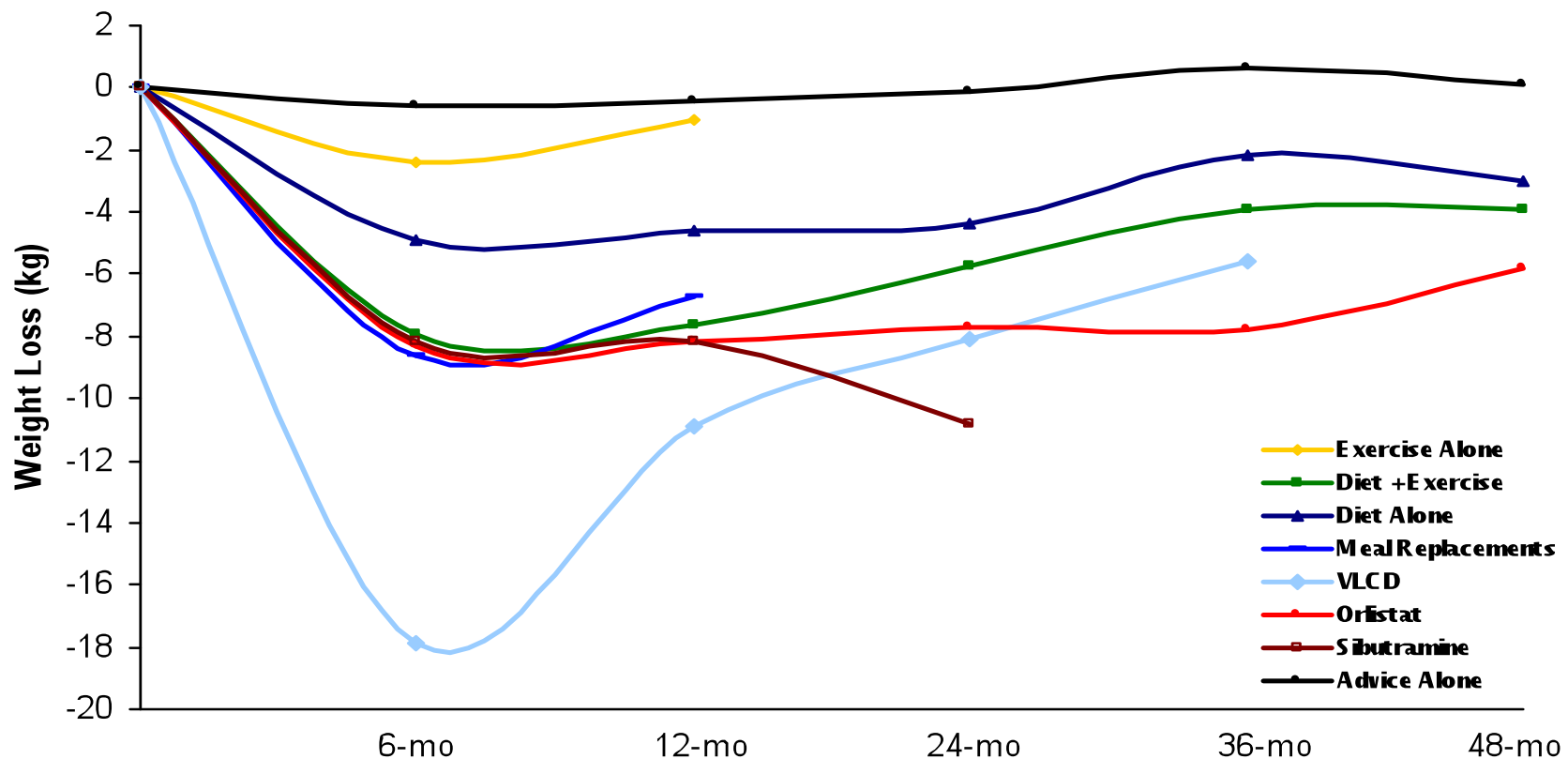
Bergenstal RM et al. *Management of Type 2 Diabetes in Endocrinology*. 4th Edition; Philadelphia, 2001

# Type 2 Diabetes: A Progressive



# Average Weight Loss Per Subject Completing a Minimum 1-Yr Intervention

80 studies; 26,455 subjects; 18,199 completers (69%)





# The Dilemma of Weight Loss in Diabetes

- “Diet” doesn’t fail—the beta cells of the pancreas fail
- Insulin resistance
  - amounts of weight loss (and physical activity) can prevent or delay type 2 diabetes
  - Weight loss may improve risk factors
- Insulin deficiency
  - Focus is on nutrition strategies for normalization of blood glucose levels, lipids and blood pressure
  - Results on glucose will be known by 6 weeks to 3 months

Feldstein et al. *Diabetes Care* 2008;31:1960;  
Franz et al. *J Am Diet Assoc* 1995;95:1015

## Energy Balance (continued)

- For overweight or obese adults with type 2 diabetes, reducing energy intake while maintaining a healthful eating pattern is recommended to promote weight loss (Level A Evidence)
- Modest weight loss may provide clinical benefits (improved glycemia, blood pressure, and/or lipids) in some individuals with diabetes, especially those early in the disease process. To achieve modest weight loss, intensive lifestyle interventions (counseling about nutrition therapy, physical activity and behavior change) with ongoing support are recommended (Level A Evidence).

## Energy Balance (continued)

- The literature does not support one nutrition therapy approach to reduce excess weight, but rather eating patterns that reduce energy intake.
- A weight loss of >6 kg (~7-8.5% loss of initial body weight), regular physical activity and frequent contact with RDs appear important for consistent beneficial effects of weight loss interventions.
- Strategies associated with successful weight loss included: weekly self-weighing, eating breakfast, reduced intake of fast foods, increasing physical activity, reducing portion sizes, using meal replacements and choosing healthful foods.

## Optimal Mix of Macronutrients

- Evidence suggests that there is not an ideal percentage of calories from carbohydrate protein, and fat for all people with diabetes (Level B Evidence); therefore, macronutrient distribution should be based on and an individualized assessment of current eating patterns, preferences and metabolic goals.

NOTE: Regardless of macronutrient mix, caloric intake should be appropriate to weight management goals.

# Eating Patterns

- Previous nutrition recommendations did not review evidence on eating patterns.
- Eating patterns, also called dietary patterns, is a term used to describe combinations of different food groups that characterize relationships between nutrition and health promotion and disease prevention.
- Eating patterns include patterns of intake among specific populations to eating patterns prescribed to improve health.
- Eating patterns studied in adults with diabetes were reviewed.

# The Mediterranean Style Eating Pattern

- Plant-based foods
  - High intake of fruits, vegetables, nuts, legumes, whole-grain cereals(Animal sources of protein are consumed relatively infrequently)
- Olive oil
  - Used almost exclusively over other fats, such as butter or other shortenings
- Omega-3 Fatty Acids
  - Includes fatty fish, flaxseed and walnuts



# Foods Encouraged in the Mediterranean Style of Eating

- **Eat Daily:**

- Whole grains
- Vegetables, specifically dark, leafy greens
- Seasonal fruit
- Flaxseeds and walnuts
- Extra virgin olive oil
- Legumes
- Red wine with meals
- Small portion of nuts
- Herbs and spices

- **Eat Weekly:**

- Fish (2 servings/week)
- Low-fat or fat-free dairy
- Poultry and eggs (once/week or less)
- Sweets (occasional)



# The Mediterranean Style Eating Pattern

- Improves cardiovascular risk factors
- Lowers combined end points for cardiovascular disease events and stroke when the eating pattern is supplemented with mixed nuts (including walnuts, almonds, hazelnuts) or olive oil.
- An energy-restricted Mediterranean style eating pattern also achieves improvements in glycemic control.
- More research needed to generalize to populations outside the U.S.



# Vegetarian/Vegan Eating Pattern



- Vegan: no animal-derived products
- Vegetarian: Includes eggs (ovo) and/or dairy (lacto)
- Higher in fruits, vegetables, whole grains, nuts, and soy products.
- Diets improve health outcomes when energy restricted

## Low-Fat Eating Pattern

- Emphasizes vegetables, fruits, grains, lean protein and low-fat dairy products. Defined as total fat intake <30% of total energy intake and saturated fat intake <10%.
- This pattern is one that has often been encouraged as a strategy to lose weight or to improve cardiovascular health.
- However, evidence does not suggest that lowering fat intake consistently improves glycemic control or cardiovascular risk factors. Most benefit is when it reduces energy intake.

## Low Carbohydrate Eating Patterns

- Focuses on eating foods higher (meat, poultry, fish, shellfish, eggs, cheese), fats (oils, butter, olives, avocado), and vegetables low in carbohydrate (salad greens, cucumbers, broccoli, summer squash).
- Limits sugar-containing foods and grain products.
- No consistent definition of “low” carbohydrate. In studies, very low carb (21-70 g/day), moderately low-carb (30 to <40% of calories from carb).
- Currently there is no ideal percentage of carbohydrates.

## DASH (Dietary Approaches to Stop Hypertension)

- Lower in sodium
- Includes more fruits, vegetables, low-fat dairy products, including whole grains, poultry, fish and nuts.
- Originally focused on lowering blood pressure, less studies in adults with diabetes



## Bottom Line on Eating Patterns

A variety of eating patterns (combinations of different foods or food groups) are acceptable for the management of diabetes.

Personal preferences (e.g., tradition, culture, religion, health beliefs, goals, economics) and metabolic goals should be considered when recommended one eating pattern over another.

(E Level Evidence)



Am I putting you to sleep yet?

# Carbohydrate

- Evidence is inconclusive for an ideal amount of carbohydrate intake for people with diabetes. Therefore, collaborative goals should be developed with the individual with diabetes (C Level Evidence).
- The amount of carbohydrates and available insulin may be the most important factors influencing glycemic response after eating and should be considered when developing the eating plan (A Level Evidence).

## **Carbohydrate** (continued)

- Monitoring carbohydrate intake, whether by carbohydrate counting or experience-based estimation remains a key strategy in achieving glycemic control (B Level Evidence).
- For good health, carbohydrate intake from vegetables, fruits, whole grains, legumes and dairy products should be advised over intake from other carbohydrate sources, especially those that contain added fats, sugars or sodium (B Level Evidence).

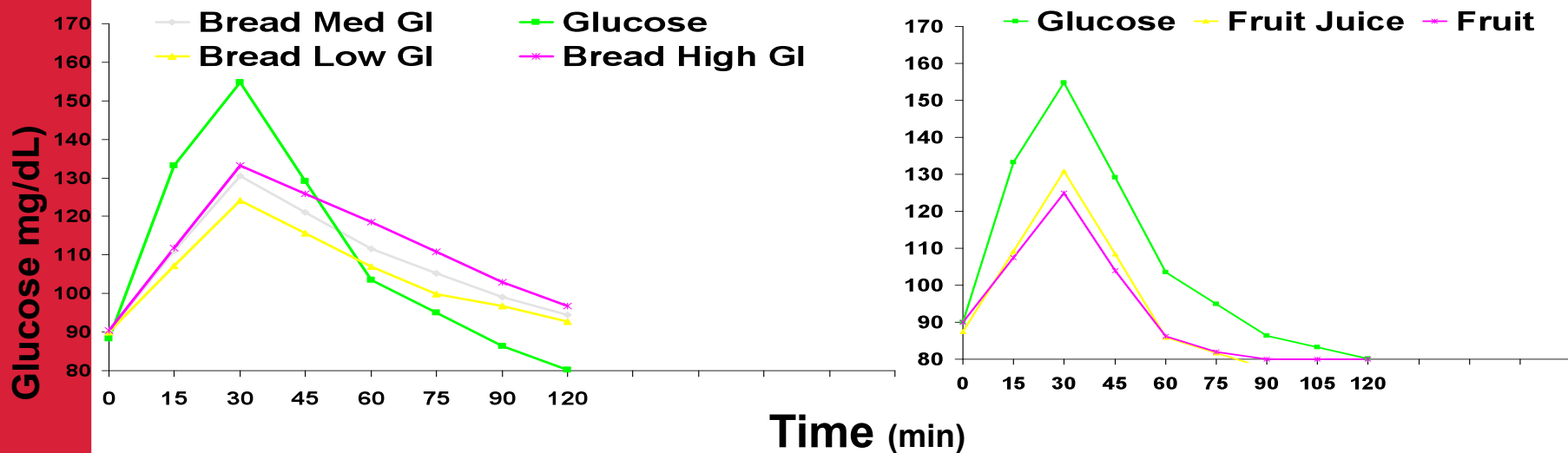


## Quality of Carbohydrates

- Substituting low-glycemic load foods for higher-glycemic load foods may modestly improve glycemic control (C Level Evidence).
- The literature regarding glycemic load and glycemic index is complex, and it is often difficult to discern the independent effects of fiber compared with that of glycemic index on glycemic control or other outcomes.

## Glycemic Index: The GI Does Not Measure How Rapidly BG Increases!

The GI is the relative area under the postprandial glucose curve (AUC) comparing 50 g of digestible carbohydrate from a test food to 50 g of carbohydrate of glucose



“No statistical difference in the glucose response curve from different foods...Low GI foods do not produce a slower rise in BG nor do they produce an extended, sustained glucose response.”

## Quality of Carbohydrates (continued)

- People with diabetes should consume at least the amount of fiber and whole grains recommended for the general public.
- Intake of dietary fiber is associated with lower all-cause mortality.
- Limited evidence fiber improves glycemic control.

## Other Carbohydrate Related Topics

- Sucrose: While substituting sucrose-containing foods for isocaloric amounts of other carbohydrates may have similar blood glucose effects, consumption should be minimized to avoid displacing nutrient dense food choices (A Level Evidence).
- Fructose:
  - Fructose consumed as “free lactose” (i.e., naturally occurring in foods such as fruit) may result in better glycemic control compared with isocaloric intake of sucrose or starch (B Level Evidence) and free fructose is not likely to have detrimental effects on triglycerides as long as intake is not >12% energy (C Level Evidence)
  - People with diabetes should limit sugar-sweetened beverages to reduce risk for weight gain and worsening cardiometabolic risk profile (B Level Evidence)

# **Nonnutritive sweeteners and hypocaloric sweeteners**

- Use of nonnutritive sweeteners has the potential to reduce overall caloric intake and carbohydrate intake if substituted for caloric sweeteners without compensation by intake of additional calories from other food sources (B Level Evidence).

# Carbohydrate: What's Important?

- In general, little difference in glucose control and CVD risk factors between low and high GI diets; confounded by fiber intake
- Different macronutrient distributions lead to improvement in glycemia and/or CVD risk factors
- Foods containing carbohydrate from fruits, vegetables, whole grains, legumes, and low-fat milk are important sources of vitamins and minerals and provide glucose for the brain
- Most individuals with diabetes do not eat a low or high CHO (or low CHO) diet; as CHO decreases, total and saturated fat increases
- Negotiate with patients; advise healthful CHO choices in appropriate amounts and portion sizes. Carbohydrate counting is useful for all individuals with diabetes. Emphasize the amount, not the source.

## Protein

- For people with diabetes and no evidence of diabetic kidney disease, evidence is inconclusive to recommend an ideal amount of protein intake for optimizing glycemic control or improving one or more CVD risk measures, therefore, goals should be individualized (C Level Evidence).
- For people with diabetes and diabetic kidney disease (either micro- or macro-albuminuria), reducing the amount of dietary protein below the usual intake is not recommended because it does not alter glycemic measures, cardiovascular risk measures, or the course of glomerular filtration rate (GFR) decline (A Level Evidence).

## Protein (continued)

- In individuals with type 2 diabetes, ingested protein appears to increase insulin response without increasing plasma glucose concentrations. Therefore, carbohydrate sources high in protein should not be used to treat or prevent hypoglycemia (B Level Evidence).



# Fat

**Total Fat:** Evidence is inconclusive for an ideal amount of total fat intake for people with diabetes; therefore goals should be individualized (C Level Evidence); fat quality appears to be more important than quantity (B Level Evidence).

**Monounsaturated/Polyunsaturated Fat:** In people with type 2 diabetes, a Med-style, MUFA eating pattern may benefit glycemic control and CVD risk factors and can be recommended as an alternative to a lower-fat, higher-carbohydrate eating pattern (B Level Evidence)

## Omega-3 Fatty Acids

- Evidence does not support recommending omega-3 (EPA and DHA) supplements for people with diabetes for the prevention and treatment of cardiovascular events (A Level Evidence).
- As recommended for the general public, an increase in foods containing long-chain omega-3 fatty acids (EPA and DHA) (from fatty fish) and omega-3 linolenic acid (ALA) is recommended for individuals with diabetes because of their beneficial effects on lipoproteins, prevention of heart disease, and other health outcomes (B Level Evidence)
- Encourage fatty fish at least two times (two servings) per week (B Level Evidence).

## Other Fat Topics

- The amount of dietary saturated fat, cholesterol and trans fat recommended for people with diabetes is the same as that recommended for the general public (C Level evidence).
- Individuals with diabetes and dyslipidemia may be able to modestly reduce total and LDL cholesterol by consuming 1.6-3 g/day of plant stanols or sterols typically found in enriched foods (C Level Evidence).

# Micronutrients and Herbal Supplements

There is no clear evidence of benefit from vitamin and mineral supplementation in people with diabetes who do not have underlying deficiencies (C Level Evidence).

- Routine supplementation with antioxidants, such as vitamins E and C and carotene is not advised because of lack of evidence of efficacy and concern related to long-term safety (A Level Evidence).
- There is insufficient evidence to support the routine use of micronutrients such as chromium, magnesium, and vitamin D to improve glycemic control in people with diabetes (C Level Evidence).

# Micronutrients and Herbal Supplements

- There is insufficient evidence to support the use of cinnamon or other herbs/supplements for the treatment of diabetes (C Level Evidence).
- It is recommended that individualized meal planning include optimization of food choices to meet recommended dietary allowance/dietary reference intake for all micronutrients (E Level Evidence).

# Alcohol

- If adults with diabetes choose to drink alcohol, they should be advised to do so in moderation (one drink per day or less for adult women and two drinks per day or less for adult men) (E Level Evidence).
- Alcohol consumption may place people with diabetes at increased risk for delayed hypoglycemia, especially if taking insulin or insulin secretagogues. Education and awareness regarding the recognition and management of delayed hypoglycemia is warranted.

# Sodium

- The recommendation for the general population to reduce sodium to less than 2,300 mg/day is also appropriate for people with diabetes (B Level Evidence).
- For individuals with both diabetes and hypertension, further reduction in sodium intake should be individualized (B Level Evidence).

## Areas of Future Research

Based on the evidence, it is clear that gaps in the literature exist and more research is needed. Future areas of study:

- The relationships between eating patterns and disease relationships in diverse populations.
- The basis for the beneficial effects of the Med-style eating pattern and approaches to translation of this eating pattern into diverse populations.
- The development of standardized definitions for high and low glycemic index diets and implementation of these definitions in long-term studies to further evaluate the impact of high and low GI diets on glycemic control.
- The impact of fiber supplements, long-term, on glycemic control and cardiovascular risk.
- The impact of key nutrients impact cardiovascular risk (e.g., sodium) in individuals with both type 1 and type 2 diabetes.



## Clinical Priorities

- A wide range of meal planning approaches or eating patterns are clinically effective. Examples include: carb counting, healthful food choices/simplified meal plans (i.e., Plate Method), and individualized meal planning methods based on macronutrients, exchange lists, glycemic index, and various eating patterns.
- There is not one ideal percentage of calories from carbohydrates, protein, or fat that is optimal for all persons with diabetes.
- Nutrition therapy goals should be developed collaboratively.

## **Prioritizing Nutrition Recommendations Key**

- Emphasize blood glucose, lipid, and blood pressure control.
- Reduce energy intake/carbohydrate portions and number of servings per meal.
- Encourage physical activity.
- Use food records with blood glucose monitoring data

# Using Food and Blood Glucose Records to Improve Control

- Eating plan is based on current food intake, and changes that would improve blood glucose and lipids
- Blood glucose monitoring used to evaluate outcomes of lifestyle changes on:
  - pre-meal glucose
  - 2 hour post-meal glucose, <160-180 mg/dL
- Determine if:
  - food and activity changes are needed
  - medication adjustments are required

## In An “Ideal” World

- All people with type 2 diabetes:
  - Lose 5% to 10% of baseline weight
  - Eat a nutrient dense eating pattern in appropriate portion sizes
  - Participate in 150 min/wk of regular physical activity
- All people with type 1 diabetes:
  - Count carbohydrates
  - Adjust insulin based on insulin-to-CHO ratios
  - Use correction factors

## In the “Real” World

- Facilitate behavior changes that individuals are willing and able to make based on proven lifestyle interventions
- A variety of nutrition and physical activity interventions can be implemented
- But nutrition therapy interventions for diabetes are effective!

## **Group Activity – At Your Table Answer the Following:**

1. What is the most challenging aspect of nutrition education and counseling?
2. What strategies can help address those challenges?
3. How can we work to individualize nutrition for each person with diabetes?
4. How do you work to prioritize nutrition strategies with individuals with diabetes?



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