Disclosure to Participants

- Notice of Requirements For Successful Completion
  - Please refer to learning goals and objectives
  - Learners must attend the full activity and complete the evaluation in order to claim continuing education credit/hours

- Conflict of Interest (COI) and Financial Relationship Disclosures:
  - Patti Urbanski – Consultant, Abbott Diabetes Care; Spouse – Medtronic Diabetes Stockholder
  - Christopher Gardner –

- Non-Endorsement of Products:
  - Accredited status does not imply endorsement by AADE, ANCC, ACPE or COR of any commercial products displayed in conjunction with this educational activity

- Off-Label Use:
  - Participants will be notified by speakers if any product used for a purpose other than for which it was approved by the Food and Drug Administration.
Session Objectives

Attendees will be able to:
• Differentiate between the major types of research studies included in the ADA consensus statement
• Describe how to evaluate nutrition research publications for application in clinical practice
• Define a consensus report and explain the process involved in developing a consensus report

Definition of an ADA Consensus Report

• Comprehensive examination by an expert panel (i.e., consensus panel) of a scientific or medical issue related to diabetes
• A consensus report is not an ADA position and represents expert opinion only
• Required 80% consensus of committee members to include in this report

If I know what the ADA Nutrition Consensus Statement says, why do I need to worry about nutrition research studies?
Objectives

1. Study Design Framework
2. Study Design (How do we know what we know?)
   
   Observational Studies
   - Less expensive and time-consuming
   - Case-Control
   - More expensive and time-consuming
   - Cohort
   - Other (Biological Plausibility)
   - Animal studies, cell culture, etc.

   Intervention Studies
   - Randomized Controlled Trial (RCT)
   - Meta-Analyses
   - Systematic Reviews

Factors Affecting Level of Evidence Contributed

<table>
<thead>
<tr>
<th>Nutrition Data</th>
<th>Country or Population Level Data</th>
<th>Individual Person Level Data</th>
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<tbody>
<tr>
<td>Health Outcome Data</td>
<td>Cross-Sectional</td>
<td>Prospective</td>
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<tr>
<td>Observational</td>
<td>Risk Factors</td>
<td>Outcome Predictors</td>
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<td>Interventional</td>
<td>Primary (prevention)</td>
<td>Secondary (treatment)</td>
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</table>
### Nutrients, Foods, and Culture

<table>
<thead>
<tr>
<th></th>
<th>Acute Onset Disease</th>
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### Strength of Available Evidence

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### Added layer of complexity

**Observational Studies (Associations)**

**vs.**

**Intervention Studies (Cause and Effect)**

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Nutrients
Foods
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**Chronic Disease Risk Factors vs. Chronic Disease**

Assuming: A powerful drug that lowers HbA1c among adults with prediabetes is shown to be preventive of incident type 2 diabetes.

Assuming: A Low-Carb diet lowers HbA1c.
Assuming: A powerful drug that lowers HbA1c among adults with prediabetes is shown to be preventive of incident type 2 diabetes.

Assuming: A Low-Carb diet lowers HbA1c

Is it therefore considered proven, indirectly, that going on a low-carb diet will prevent diabetes?

Is it possible that going on a low-carb diet will actually increase diabetes onset?
Assuming: A powerful drug that lowers HbA1c among adults with prediabetes is shown to be preventive of incident type 2 diabetes.

Assuming: A Low-Carb diet lowers HbA1c.

Is it therefore considered proven, indirectly, that going on a low-carb diet will prevent diabetes?

Is it possible that going on a low-carb diet will actually increase diabetes onset?

Studying Risk Factors vs. Disease Outcomes

Major limitation of studies with "risk factors" as study outcomes.
Objectives

1. Study Design Framework

2. Study Design (How do we know what we know?)
   - Observational Studies
     - Case-Control
     - Cohort
     - Other (Biological Plausibility)
     - Animal studies, cell culture, etc
   - Intervention Studies
     - Randomized Controlled Trial (RCT)

Case-Series Studies
Cross-sectional

Case-Control Studies
Cross-sectional
Tofu and Risk of Breast Cancer in Asian-Americans

Chinese-, Japanese- and Filipino-American women in Los Angeles, San Francisco/Oakland, Oahu

Wu et al., Canc Epid BioMark Prev, 1996:5:901-906

Controls (n=966)

Frequency of Tofu Intake (per year)

%

≤12 13 - 42 43 - 54 ≥55

Cases (n=597)

Controls (n=966)

Frequency of Tofu Intake (per year)

%

≤12 13 - 42 43 - 54 ≥55

Wu et al., Canc Epid BioMark Prev, 1996:5:901-906

Odds Ratio

1.0

0.8

0.6

0.4

0.2

0

≤12 13 - 42 43 - 54 ≥55

Wu et al., Canc Epid BioMark Prev, 1996:5:901-906

Tofu and Risk of Breast Cancer in Asian-Americans

Chinese-, Japanese- and Filipino-American women in Los Angeles, San Francisco/Oakland, Oahu

Wu et al., Canc Epid BioMark Prev, 1996:5:901-906
Frequency of Tofu Intake (per year)

Wu et al., Canc Epid BioMark Prev, 1996:5:901-906

- Breast cancer rates were 33% lower among those consuming tofu at least 55 times/year compared to those consuming less than 12 times/year.

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<th>Frequency of Tofu Intake (per year)</th>
<th>Odds Ratio</th>
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<td>13 - 42</td>
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<td>43 - 54</td>
<td>0.84</td>
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<tr>
<td>≥55</td>
<td>0.67</td>
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Nutrients

- **Observation Or Intervention?**
- **Acute Onset Disease**
- **Chronic Disease Risk Factors**
- **Chronic Disease**

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Association

- **Observation Or Association**
- **Acute Onset Disease**
- **Chronic Disease Risk Factors**
- **Chronic Disease**

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Case-Control Study

**Major limitation(s):**
- Many alternate hypotheses
- Can’t tell if dietary habit preceded, or followed the onset of disease (temporal relationship unclear)

(i.e., finding out about your disease may have caused you to change your diet, or may bias your memory of your diet [RECALL BIAS])

**Major advantage(s):**
- Relatively quick and inexpensive
- Particularly appropriate for RARE diseases!
  (e.g., study of folic acid & birth defects)

---

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Prospective / Longitudinal

**Cohort Studies**

Note: The majority of newspaper headlines linking diet to health come from cohort studies
RESEARCH ARTICLE

Plant-Based Dietary Patterns and Incidence of Type 2 Diabetes in US Men and Women: Results from Three Prospective Cohort Studies

Ambika Satija1,2,*, Shilpa N. Bhusanthinji1, Eric B. Rimm1,2,3, Donna Spiegelman1,2,4,5, Stephanie E. Chiuve6,*, Lea Borglum7, Walter C. Willett8,9, JoAnn E. Manson4,9, Qi Sun1,2, Frank B. Hu1,2,9

15
Cohort Study

Major limitation(s):
- Many alternate hypotheses can explain the same observation
- Expensive, and long durations

Major advantage(s):
- Establishes prospective nature of relationship (e.g., temporal sequence) between diet and health
- Examines achievable range of diet variability (e.g., comparing lowest to highest intake)
Plausibility/Mechanism

1. Observational (convenience)
   - Case reports

2. Observational (more intensive) plus diet data collected from individuals
   - Case-Control studies - humans
   - Cohort studies – humans

3. Biological Plausibility
   - Animal and cell studies

Animal & Cell Studies

Mechanism

Biological plausibility
Animal/Cell Studies

**Major limitation(s):**
Extrapolating to human health

**Major advantage(s):**
Establishes biological plausibility (i.e., mechanisms)

---

Meal Studies

---

Cell Metabolism

Clinical and Translational Report

**Ultra-Processed Diets Cause Excess Calorie Intake and Weight Gain: An Inpatient Randomized Controlled Trial of Ad Libitum Food Intake**

Kevin D. Hall,1,2 Alexa Ayyavuz,1 Robert Brynhild,1 Jiayi Cai,1 Thomas Cessmate,2 Kong Y. Chen,1 Stephanie E. Chung,1 Elisa Costa,2 Amber Cravahn,1 Yilong Dai,1 Luong A. Fitcher,2 Gabriel D. Fortin,3 Ahmed M. Gharbi,1 Juan Guo,1 Rebecca Howard,1 Paula V. Joseph,1 Suzanne McGhee,1 Robert Osweber,1 Xiaoliou Kian,1 Irene Ruggier,1 Michael Stojkovic,1 Mary Walker,1 Peter J. Walker,1 Shansun Yang,1 and Megan Zhou1
Oral Glucose Tolerance Test

In Brief
Hall et al. investigated 20 inpatient adults who were exposed to ultra-processed versus unprocessed diets for 14 days each, in random order. The ultra-processed diet caused increased ad Libum energy intake and weight gain despite being matched to the unprocessed diet for presented calories, sugar, fat, sodium, fiber, and micronutrients.

Figure 4. Glucose Tolerance and Continuous Glucose Monitoring
A) Glucose concentrations following a 75 g oral glucose tolerance test (OGTT) were not significantly different between the diets. Data are expressed as mean ± SE.
B) Insulin concentrations following the OGTT were not significantly different between the diets. Data are expressed as mean ± SE.
The Gold Standard

1. Observational (convenience)
   - Ecological studies
   - Case reports

2. Observational (more intensive) plus diet data collected from individuals
   - Case-Control studies - humans
   - Cohort studies – humans

3. Biological Plausibility
   - Animal and cell studies

4. Clinical Trials

The “Gold Standard” of “Evidence-Based” Science

- Ecological Studies
- Case-control Studies
- Cohort Studies
- Molecular & cell biology
- Animal models
- Clinical Trials

= Observational
The GOLD standard of science: The double-blind, Placebo-controlled, Randomized, Clinical trial

If we feed “X” vs. a Placebo to a group of “ABC’s” at a dose of “D” for a duration of “T” there will be more/less of “IT”.

The New England Journal of Medicine

REDUCTION IN THE INCIDENCE OF TYPE 2 DIABETES WITH LIFESTYLE INTERVENTION OR METFORMIN

Diabetes Prevention Program Research Group*
Fig. 1. Number of people seen at each of the screening steps during exclusion at step 1 and after step 2. Reasons for exclusion were not recorded; reasons for exclusion after step 2 were given as: the main reason for exclusion was the need for reasons for exclusion were possible. (Only 2.9% of persons reached.)

Exclusion reasons at Step 1:
- Participant interest: 28,653
- Fingerstick glucose: 27,092
- BMI: 16,387
- Medical conditions: 10,950
- Diabetes: 6,053
- Other: 16,159
- No reason given: 51,467

Exclusion reasons after Step 2:
- 2-h glucose: 20,790
- Diabetes: 3,808

~160,000 screened
~4,000 randomized
~40:1

1,713 Persons were assessed for eligibility
Hazard ratio for diabetes, 0.88 (95% CI, 0.75-1.04) P=0.12

Gold Standard to establish cause and effect

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<td>Culture</td>
<td>7 8 9</td>
<td></td>
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</table>
Typical “Scientific” approach to diet complexity

Reductionist/Isolationist approach
Example: Low Carb Diet and HbA1c
HbA1c and Diabetes

Overall health is goal, but there could be benefits for one outcome and increased risk for another

Isoflavones
Estrogen-like molecules in soy

Lipids
CVD
Breast Cancer
Menopausal symptoms
Clinical Nutrition Trials:
Advantages

• **Cause and effect established**
• **Human relevance clear**
  (conducted with humans)
• **End points clinically relevant**

Clinical Nutrition Trials:
Limitations (Issues)

• **Generalizability** (often limited, due to...)
• **Population** (often specific)
• **Dose** (usually just one at a time)
• **Duration** (often relatively short)
• **Effect attributable to what was eaten or what was replaced?**
• **Risk factor benefits may not lead to improved health outcomes**
• **Usually focuses on one health outcome, not overall health**
• **Result reproducible?**

One specific answer to one specific question

---

Systematic Review & Meta-Analysis
Systematic review and meta-analysis of dietary carbohydrate restriction in patients with type 2 diabetes

Ole Snorgaard,1 Gitte M Poulsen,2 Henning K Andersen1, Aine Astrup2

2017 Feb 23;5(1):e000354

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Figure 4: The excess effect of 3 or 6 months low to moderate carbohydrate diet compared with high carbohydrate baseline diet on HbA1c (Δ%) versus mean dietary intake (Δ%) of carbohydrate in the low to moderate carbohydrate groups in eight randomized trials.

Excess reduction in HbA1c (Δ%) versus carbohydrate intake (Δ%), 8 RCTs
The ideal amount of carbohydrates in the diet in the management of type 2 diabetes is unclear. The current meta-analysis conducted according to the GRADE system of using quality of evidence shows that low to moderate carbohydrate diets have greater glucose-lowering effect compared with high-carbohydrate diets. The greater the carbohydrate restriction, the greater glucose lowering. Apart from improvements in HbA1c over the short term, there is no superiority of low-carbohydrate diets in terms of glycemic control, weight, or LDL cholesterol.

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**Optimal**

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Inclusion criteria for ADA consensus report

- Subjects 18 years of age or older
- Outpatient/ambulatory care, community, metabolic/clinical research unit settings
- Non-hospitalized, no acute illness
- Diabetes or prediabetes diagnosis!
- Sample size of 10 subjects per study group
- 50% retention rate

Inclusion criteria for ADA consensus report, continued

- English language
- Study design preferences
  - RCT or clinical controlled studies
  - Single-arm clinical study
  - Prospective observational study
  - Cross-sectional observational study
  - Case-control studies
Process of coming to consensus on controversial topics

- Monthly telephone conference calls and email discussions led by committee co-chairs, February 2018 through January 2019
- Evidence presented and discussed
- Bullet-point statements suggested and discussed
- 80% consensus needed to include major statements in paper

Committee member search and selection process

- National call for expert committee applications
- Diversity sought in professional interest and cultural background
- Each topic team included both researchers and MNT clinicians

The challenge of clinical nutrition research trials

- Sample size
- Funding challenges
- Study length
- Adherence and retention confusion
Nutrition

Diet Patterns
- Mediterranean
- Vegetarian
- Vegan
- Paleo
- Low-Carb
- Ketogenic
- Middle Eastern
- Latin American
- Japanese
- Chinese
- Scandinavian
- And more...

Diet Patterns
- Mediterranean
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- Japanese
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- Scandinavian
- And more...

Health Outcomes
- Morbidity / Mortality
- Heart Disease
- Stroke
- Cancer
- Diabetes
- Osteoporosis

Food Groups
- Vegetables
  - Broccoli
  - Peppers
  - Tomatoes
  - Kale
- Beans/Peas
  - Garbanzo
  - Lentils
  - Kidney
  - Soy
- Grains
  - Oats
  - Wheat
  - Barley
  - Amaranth
- Fruits
  - Mango
  - Raspberries
  - Banana
  - Apple
  - Orange
- Dairy
  - Milk
  - Yogurt
  - Ice Cream
- Meat/Fish
  - Beef
  - Pork
  - Chicken
  - Salmon
- Eggs
- Alcohol
  - Wine
  - Beer
  - Liquor
- Coffee
- Fast Food
  - French fries
  - Milkshakes
  - Candy
- And More...
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Nutrition studies are COMPLEX.