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Medical Foods: Their Role in Therapeutic Nutrition

March 2, 2021

Sponsored by the Healthcare Nutrition Council

Disclosures

AFFILIATION/FINANCIAL INTERESTS (prior 12 months)	ENTITIES
Grants/Research Support	
Scientific Advisory Board/Consultant/Board of Directors	
Speakers Bureau	
Stock Shareholder	
Employee	American Society for Nutrition
Other	

Original Workshop and Published Proceedings

Access both at:
https://healthcarenutrition.org/medical-foods-workshop-2019/

Learning Objectives

At the end of this webinar, learners will be able to:

1. Define medical foods and describe their role in nutrition therapy and how they are different from foods for special dietary uses (FSDU).

2. Identify research gaps and other opportunities to get involved in the scientific and regulatory aspects of medical foods.

3. Describe highlights and next steps from the HNC-ASN Medical Foods Workshop.

Speakers

- **Jessica O'Connell**, **JD,** Covington & Burling LLP
  A 101 on medical foods

- **Barbara Schneeman, PhD,** University of California, Davis
  Themes from the 2020 Dietary Guidelines Advisory Committee

- **Patrick Stover, PhD,** Texas A&M University
  Research considerations for medical foods

- **Tim Morck, PhD,** Spectrum Nutrition LLC
  Proposed next steps

CPE Credit

- ASN designates this educational activity for a maximum of 1 CPEUs. Dietitians and Dietetic Technicians, Registered should only claim credit commensurate with the extent of their participation in the activity.

- To claim credit, please take the post webinar evaluation provided after the webinar.

Asking Questions

- Please use the “questions” box on your “Go To Meetings” screen to submit questions to our presenters.

- Please submit your questions at any time during today’s webinar.

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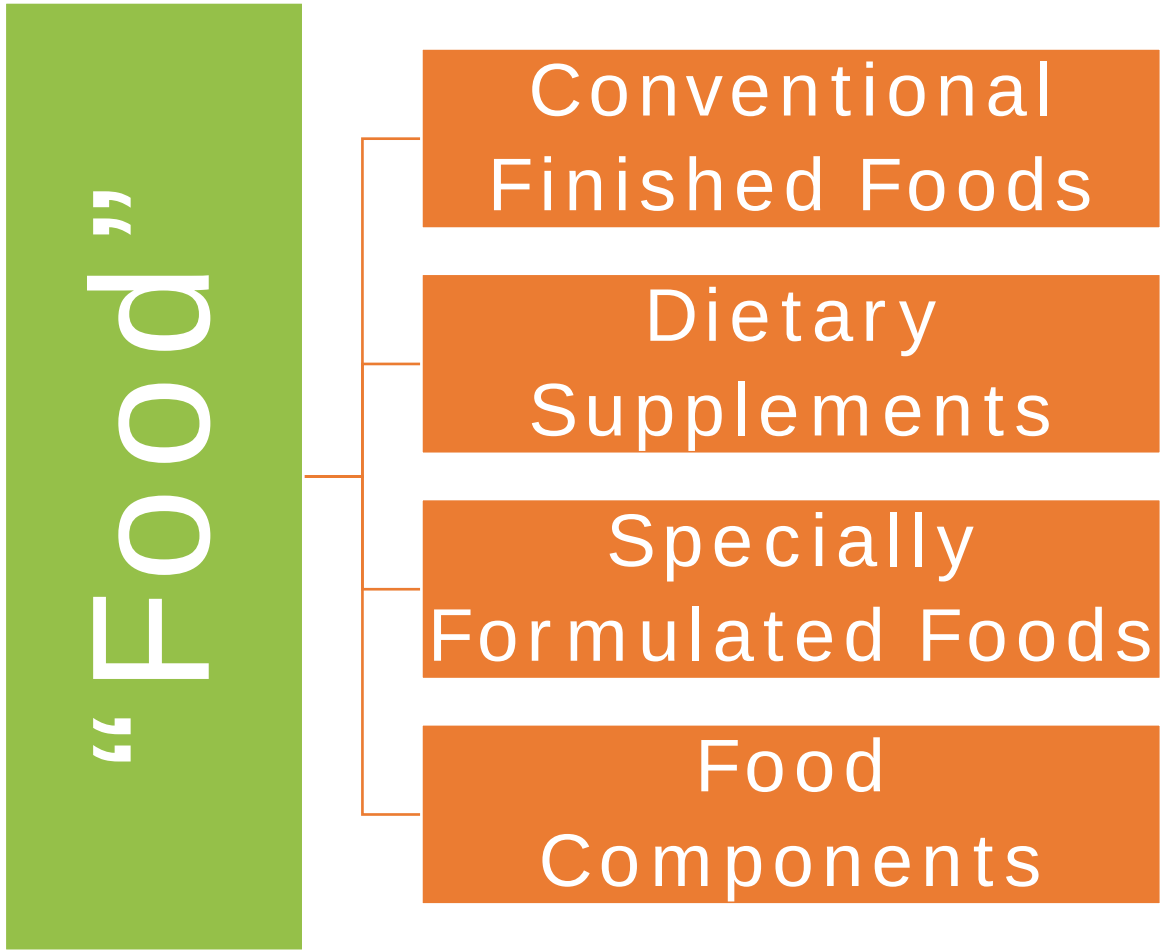
Medical Foods 101: Regulatory Framework and Key Considerations

Jessica P. O'Connell, JD, MPH

Partner, Covington & Burling LLP

Food: Range of Possibilities



Food: Range of Possibilities

Food

- articles **used for** food or drink for man or other animals
- chewing gum
- articles **used for** components of any such article

Dietary Supplement

- **intended to** supplement the diet that contains a dietary ingredient
- **intended for** ingestion
- not **represented for use** as a conventional food

Food: Range of Possibilities

Food for Special Dietary Use

- Uses for supplying **particular dietary needs** due to a **physical, physiological, pathological or other condition**, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;
- Uses for supplying particular dietary needs due to age;
- Uses for **supplementing or fortifying the ordinary or usual diet** with any vitamin, mineral, or other dietary property

Medical Food

- a food which is formulated
  - to be consumed or administered enterally
  - under the **supervision of a physician**
- and which is **intended for** the specific dietary management of a disease or condition for which **distinctive nutritional requirements**, based on recognized scientific principles, are established by medical evaluation

Brief Definitional History

- “Medical Food” defined in 1988 amendments to Orphan Drug Act
  - a food which is formulated
    - to be consumed or administered enterally
    - under the supervision of a physician
  - and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation

- Nutrition Labeling and Education Act (1990)
  - exempted medical foods from nutrition labeling, nutrient content claim, and health claim requirements

Brief Definitional History

1993 FDA rulemaking to implement NLEA exemption

21 CFR 101.9(j)(8) - Food is subject to exemption only if:

- It is a specially formulated and processed product for the partial or exclusive enteral feeding of a patient;
- It is intended for the dietary management of a patient who has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved through dietary modification alone;
- It provides nutritional support specifically modified for the management of unique nutrient needs that result from the specific disease or condition;
- It is intended to be used under medical supervision; and
- It is intended only for a patient receiving active and ongoing medical supervision

Notable Differences

Statute

- Dietary management of disease or condition
- "Distinctive Nutritional Requirement" established by medical evaluation
- No mention of dietary modification

Regulation

- Dietary management of patient with limited capacity to …
- "Unique Nutrient Needs" that result from disease or condition
- Dietary management cannot be achieved through dietary modification alone

FDA's Guidance – FAQ About Medical Foods
Final Guidance issued May 2016

- FDA generally would not consider pregnancy or diabetes to be diseases/conditions for which medical foods should be marketed
  - No distinctive nutritional requirements for either condition *because* needs can be met through dietary modification alone

- IEMs that medical foods could be used to manage involve amino acid/protein, organic acid, or fatty acid metabolism
- *Note*: FDA has never defined "distinctive nutritional requirement"

FDA's Final IND Guidance
issued September 2013

- Generally, human research studies must be conducted under an investigational new drug application (IND) if the research involves a drug.
- This requirement **applies to human research studies intended to evaluate the effect of a food (including medical foods) on a disease.**
- If medical food is being fed to subjects for nutritional purposes during a study examining the effects of another intervention, the use of the medical food in the study would not trigger the need for an IND.

  **FDA stayed certain parts of this guidance in 2015; however, the above principles remain in effect

  ** Proposed Rule in 2018-2020 Unified Agendas: "Investigational New Drug Applications Requirements for **Conventional Foods, Dietary Supplements, and Cosmetics**"

2017 IND-Related Warning Letter

- March 29, 2017 Warning Letter from CDER – Targeted Medical Pharma, Inc.
- Result of FDA inspection of clinical research site as part of FDA's BIMO Program

- **Charge**: "Failure to submit an IND for the conduct of clinical investigations with an investigational new drug"
  - Company 483 response: Research was of "Medical Food used to treat the nutritional deficiencies associated with pain and inflammation"
  - FDA:
    - No distinctive nutritional requirements
    - Clinical endpoint was comparison to a drug
    - Because studying effects of product on disease, product being evaluated as a drug and IND required

Looking to Future: Key Questions

"Distinctive nutritional requirement" – what does it mean?	• Ongoing stakeholder engagement
What substantiation is required for medical foods? What are IND implications?	• Potential for FDA rulemaking on IND requirements for foods
What is role of FSDU? Dietary Supplements? Other specially formulated foods?	• Will FDA provide guidance on other categories?
How can we distinguish between disease *treatment* or *mitigation* and disease *management?*	• Key consideration for developing claims within FDA's current framework

What can we learn from the Dietary Guidelines process?

Barbara Schneeman, PhD

Disclosures

AFFILIATION/FINANCIAL INTERESTS (prior 12 months)	ENTITIES
Grants/Research Support	None
Scientific Advisory Board/Consultant/Board of Directors	McCormick Science Institute; International Food Information Council Trustee; International Advisory Board for Saudi Arabia National Nutrition Committee
Speakers Bureau	None
Stock Shareholder	Mutual funds or managed accounts
Employee	N/A-Retired from UC Davis and Federal government
Other	2020 Dietary Guidelines Advisory committee, chair WHO NUGAG Diet and Health subcommittee WHO NUGAG Policy Actions subcommittee NASEM: Food and Nutrition Board Speaker at Healthcare Nutrition Council Workshop

Main Question

- What can we learn from the *Dietary Guidelines for Americans* process?
- Topics
  - Populations addressed by the *Dietary Guidelines for Americans*
  - Evidence considered in the scientific report for the Dietary Guidelines Advisory Committee

Dietary Guidelines for Americans

- Published every 5 years since 1980 by USDA and HHS and reflects the ‘preponderance of scientific evidence’
- Serves as the cornerstone of Federal nutrition programs and policies
- Provides food-based recommendations to reduce risk for diet-related chronic diseases and promote overall health.
- Used by government as well as non-government organizations to support policies and programs

USDA

DGA Dietary Guidelines for Americans 2020 - 2025

Make Every Bite Count With the *Dietary Guidelines*

Dietary Guidelines for Americans: What It Is, What It Is Not*

- Quantitative Guidance on Foods, Not Nutrient Requirements
  - Dietary Reference Intakes for nutrients and food components are established by the National Academy of Sciences, Engineering, and Medicine
  - The DGA translates nutrient requirements into food and beverage recommendations.

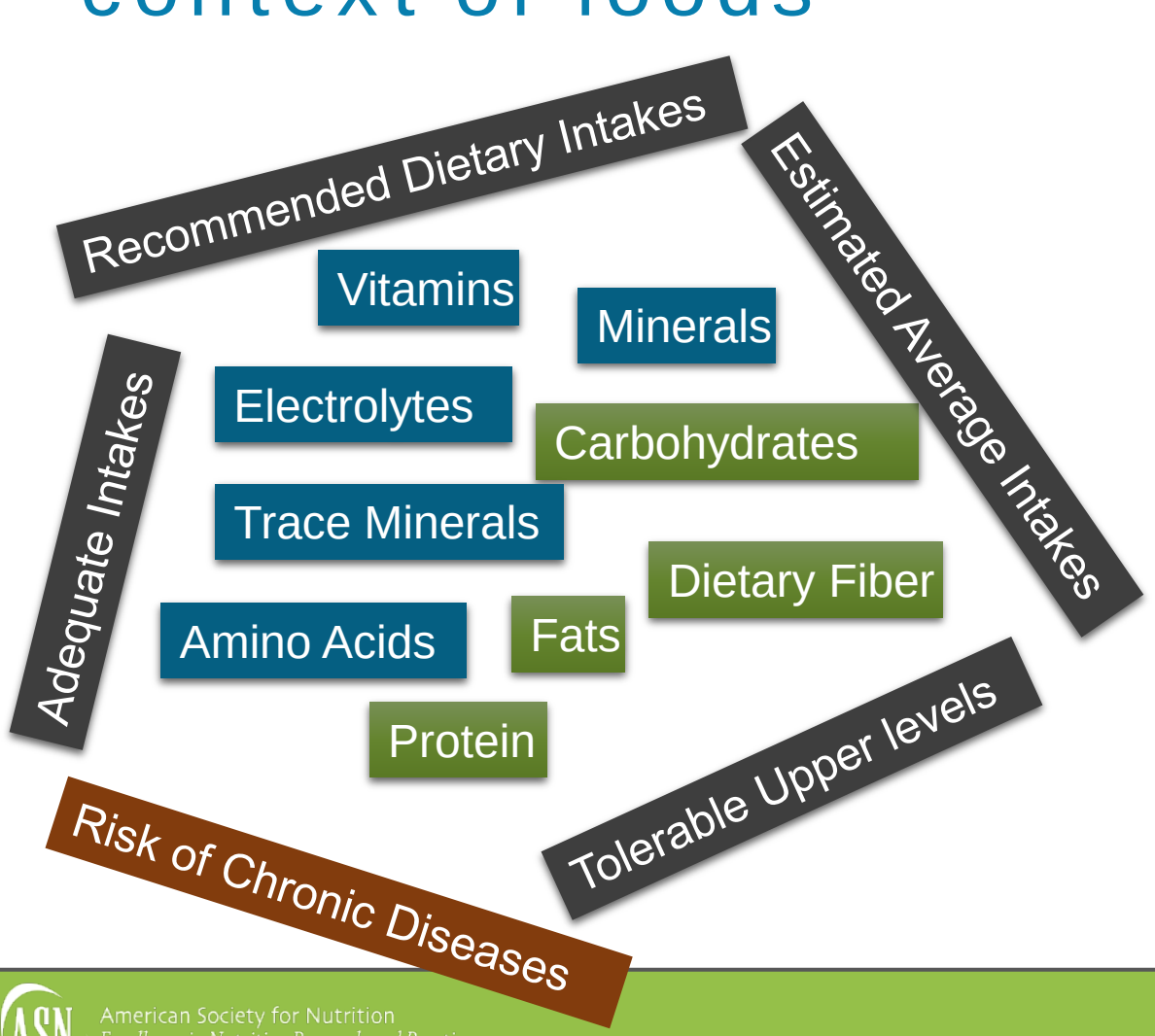
*From the *2020-2025 Dietary Guidelines for Americans*

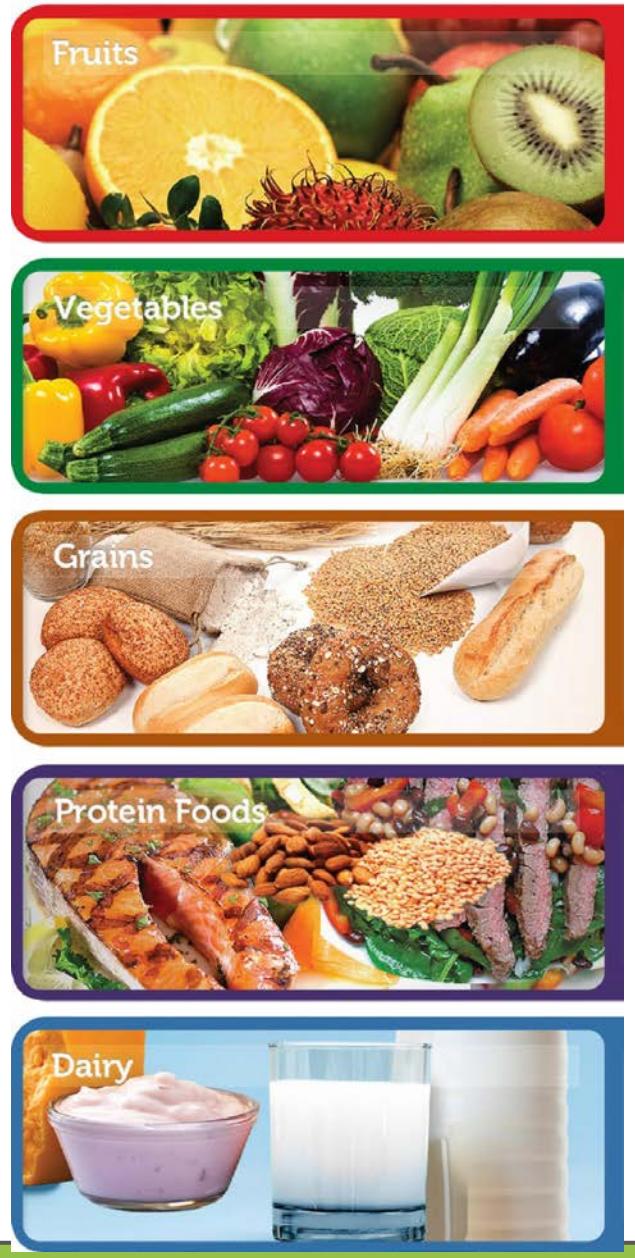
Dietary Guidelines for Americans: What It Is, What It Is Not*

- Health Promotion, Not Disease Treatment
  - Participants in the scientific evidence evaluated includes healthy individuals, people at risk of diet-related chronic conditions and diseases, and people living with diet-related chronic illness.
  - Not intended as clinical guidelines for treating chronic diseases
  - Health professionals may adapt the *Dietary Guidelines* to meet the specific needs of their patients.

*From the *2020-2025 Dietary Guidelines for Americans*

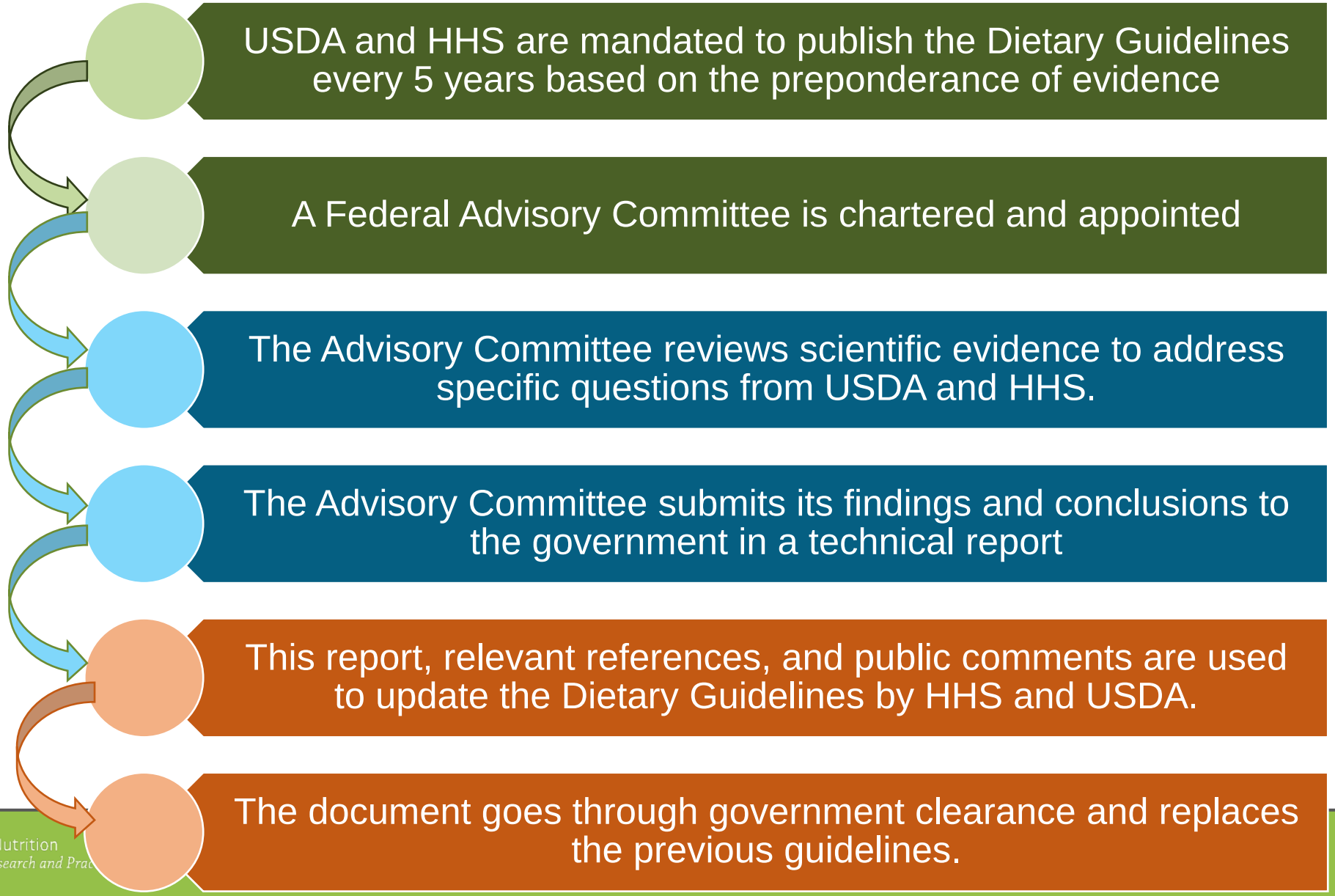
Food-Based Dietary Guidelines: Understanding nutrition in the context of foods



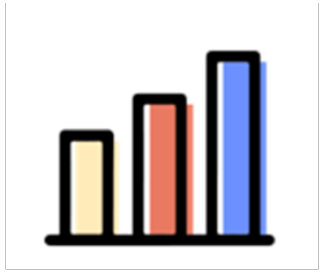


How are they developed?

Dietary Guidelines for Americans



Approaches to Examine the Evidence



Data Analysis

Food Pattern Modeling

NESR* Systematic Reviews

- The Committee answered questions on diet and health using one of three approaches.
- Each of these approaches has its own rigorous, protocol-driven methodology, and plays a unique, complementary role in examining the science.

*NESR refers to the Nutrition Evidence Systematic Review Team

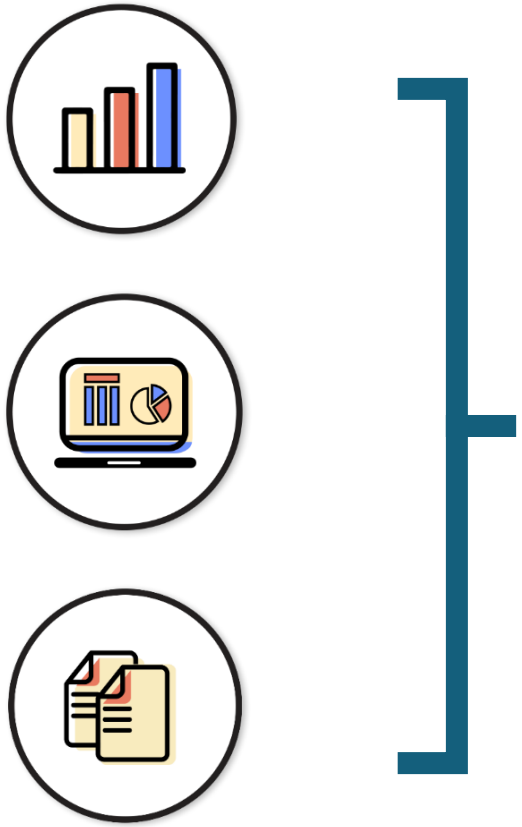
Approaches to Examine the Evidence

Data Analysis
A collection of analyses that uses national data sets to help us understand the current health and dietary intakes of Americans. These data help make our advice practical, relevant, and achievable.

Food Pattern Modeling
Analysis that helps us understand how changes to the amounts or types of foods and beverages in a pattern might impact meeting nutrient needs across the U.S. population.

NESR Systematic Review
Research project that answers a question on diet and health by searching for, evaluating, and synthesizing all relevant, peer-reviewed studies.

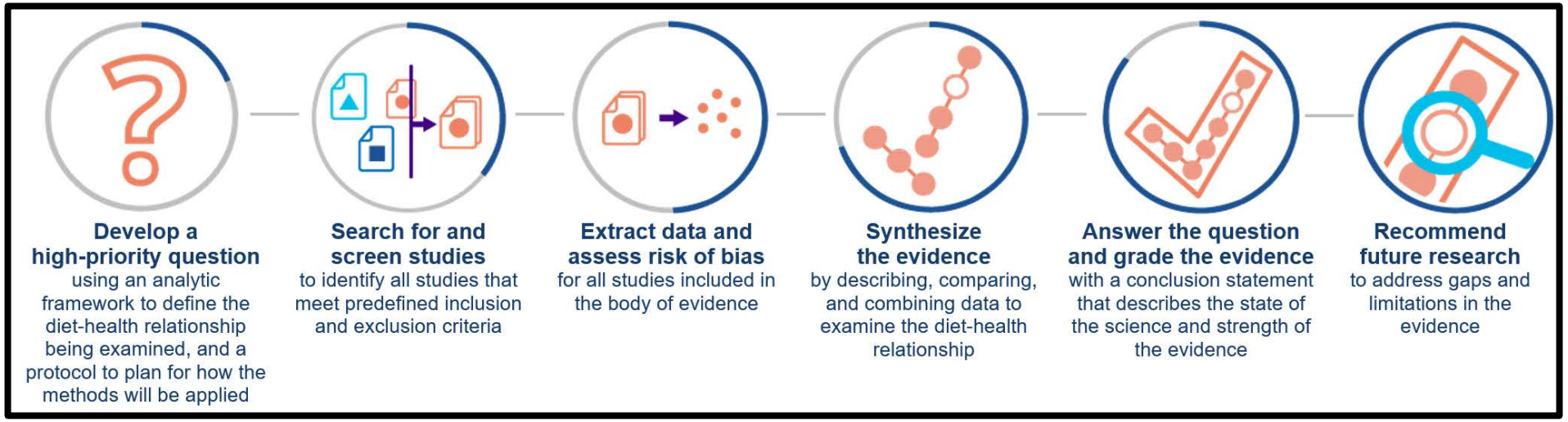
From Conclusion Statements to Advice



The Committee looked across *all* of the conclusion statements – the totality of our scientific review – to develop overarching advice for USDA and HHS to consider as the Departments develop the *2020-2025 Dietary Guidelines*

The NESR systematic review methodology

NESR Systematic Review
Research project that answers a question on diet and health by searching for, evaluating, and synthesizing all relevant, peer-reviewed studies.



Information available at the NESR website: https://nesr.usda.gov

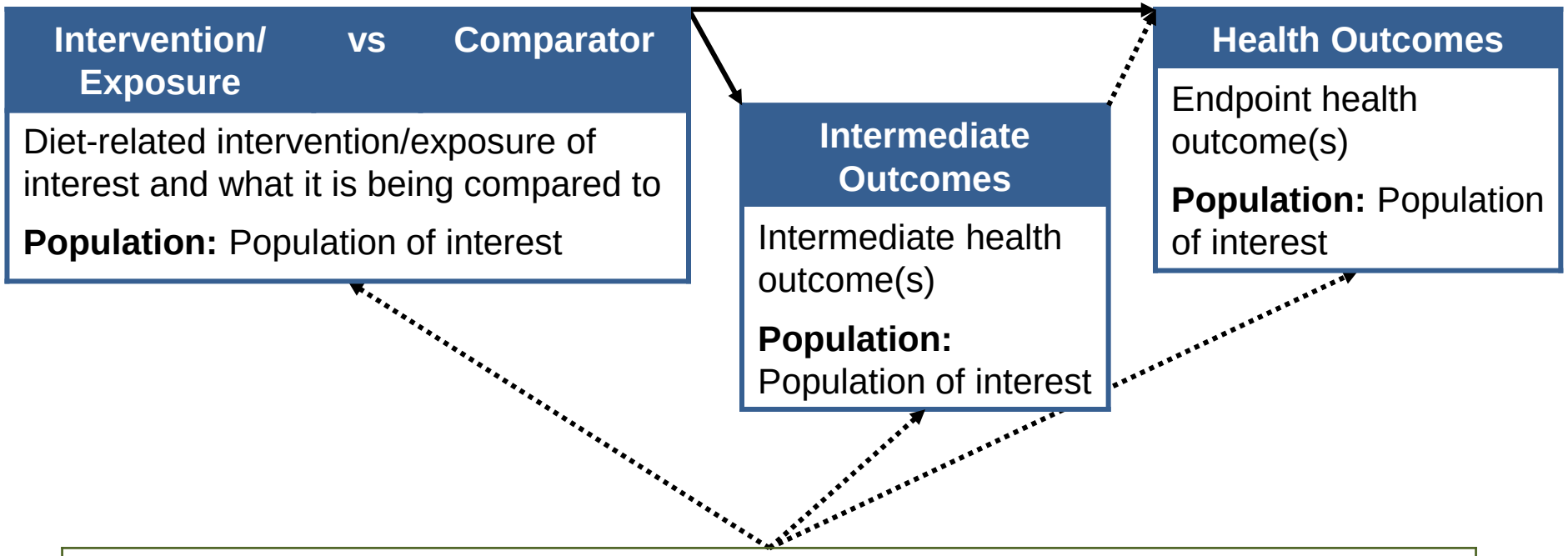
The Advisory Committee developed a protocol for each scientific question they answered

NESR systematic review protocols include:

- Analytic framework
- Inclusion and exclusion criteria
- Literature search strategy
- Literature search and screening results
- Lists of included and excluded articles

Note: Protocols and conclusions were posted at www.dietaryguidelines.gov.

Components of the NESR Analytic Framework



Key definitions

[Term] – [definition]
[Term] – [definition]
[Term] – [definition]

Legend

The relationship of interest in the systematic review
Factors that may impact the relationship of interest in the systematic review

NESR Inclusion and Exclusion Criteria

- Established up front to provide an objective, consistent, and transparent framework for identifying articles to include in each review
- Framed around relevancy to U.S. Federal policy
- Standard criteria have been applied to the extent possible
- Some criteria are tailored to the specific review, such as:
  - Diet-related intervention/exposure of interest
  - Health outcomes, endpoint and/or intermediate
  - Date of publication
  - Size of study groups
  - Study duration
  - Age of study participants

Standard NESR Inclusion and Exclusion Criteria

Category	Inclusion Criteria	Exclusion Criteria
Study design	• Randomized controlled trials • Non-randomized controlled trials, including quasi-experimental and controlled before-and-after studies • Prospective cohort studies • Retrospective cohort studies • Nested case-control studies	• Uncontrolled trials • Case-control studies • Cross-sectional studies • Uncontrolled before-and-after studies
Publication status	Peer-reviewed articles	Non-peer-reviewed articles (e.g., unpublished data, manuscripts, pre-prints, reports, abstracts, and conference proceedings)
Language of publication	English	Languages other than English
Country	Very High or High Human Development (based on the year the study was conducted)	Medium or lower Human Development
Study participants	Humans, males and females	Non-human participants (e.g., animal or in-vitro models)

Standard NESR Inclusion and Exclusion Criteria

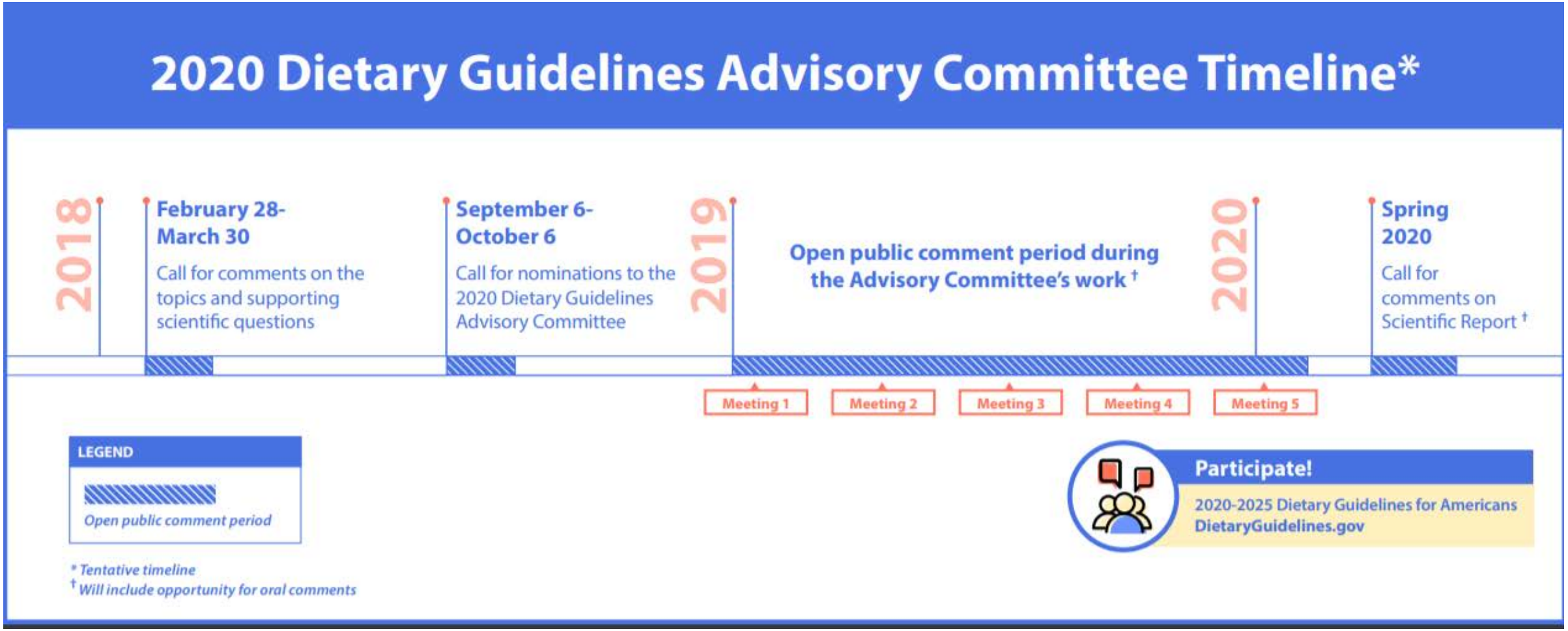
Category	Inclusion Criteria	Exclusion Criteria
Health status of study participants*	Studies that enroll: • participants who are healthy and/or at risk for chronic disease, *including those with obesity* • ***some*** participants diagnosed with a disease or with the health outcome of interest • infants born full-term (≥37 weeks and 0/7 days gestational age), low birth weight (<2500g), and/or small for gestational age	Studies that ***exclusively*** enroll: • participants diagnosed with a disease, or hospitalized with an illness or injury (For this criterion, studies that exclusively enroll participants with obesity will *not* be excluded) • participants with the outcome of interest (i.e., studies that aim to treat participants who have already been diagnosed with the outcome of interest) • infants born preterm, low birth weight (<2500g), and/or small for gestational age

**In each protocol, this criterion has been tailored specifically for the outcomes being examined*

Note: Medical Foods vs Conventional Foods (and dietary supplements)

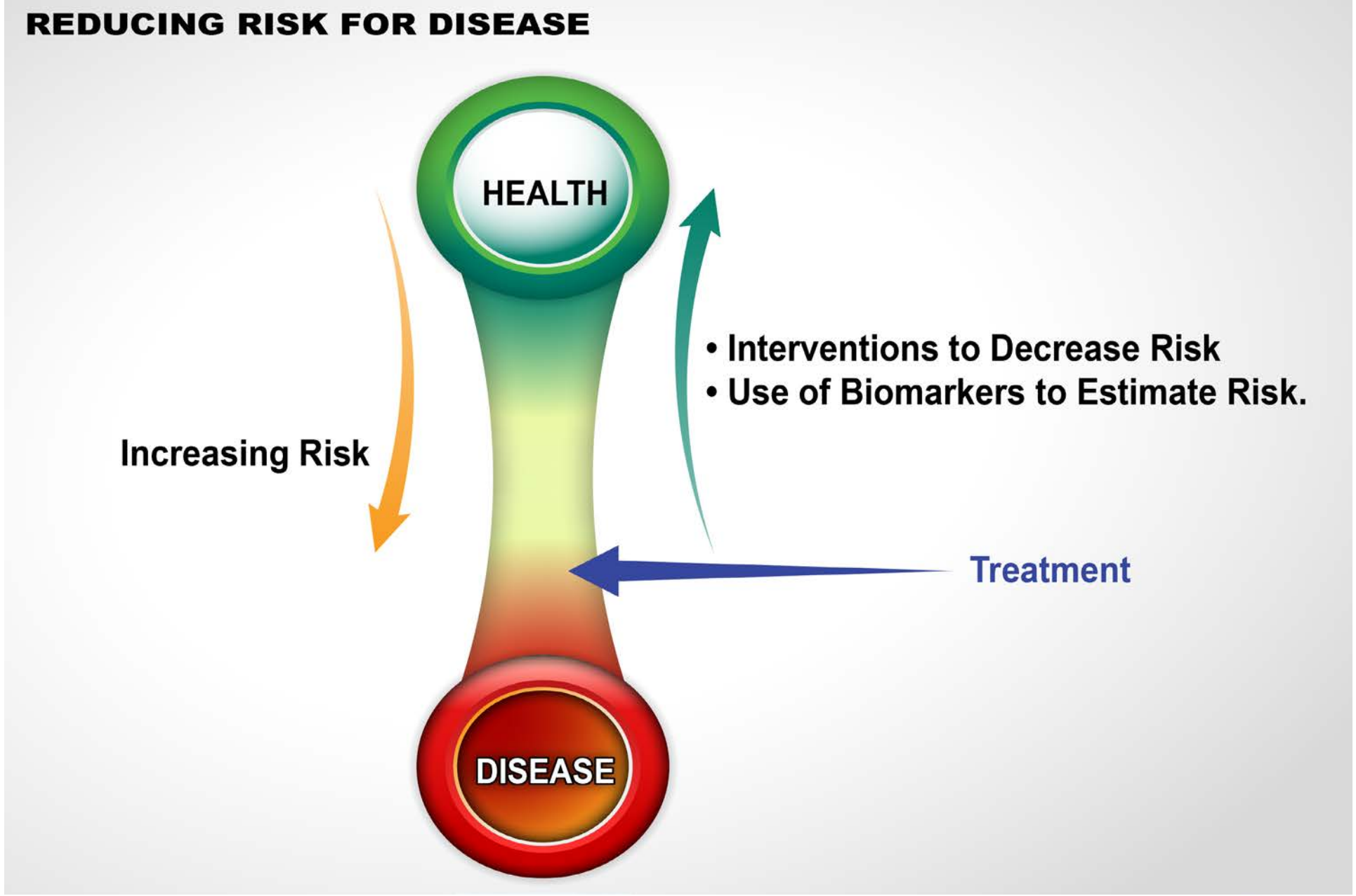
- Regulations for the 1990 Nutrition Labeling and Education Act defined medical foods and excluded them from certain nutrition labeling requirements.
- Nature of nutrition-related claims for conventional foods and dietary supplements
  - Nutrient Content Claims
  - Health claims (Disease risk reduction)
  - Structure/function claims

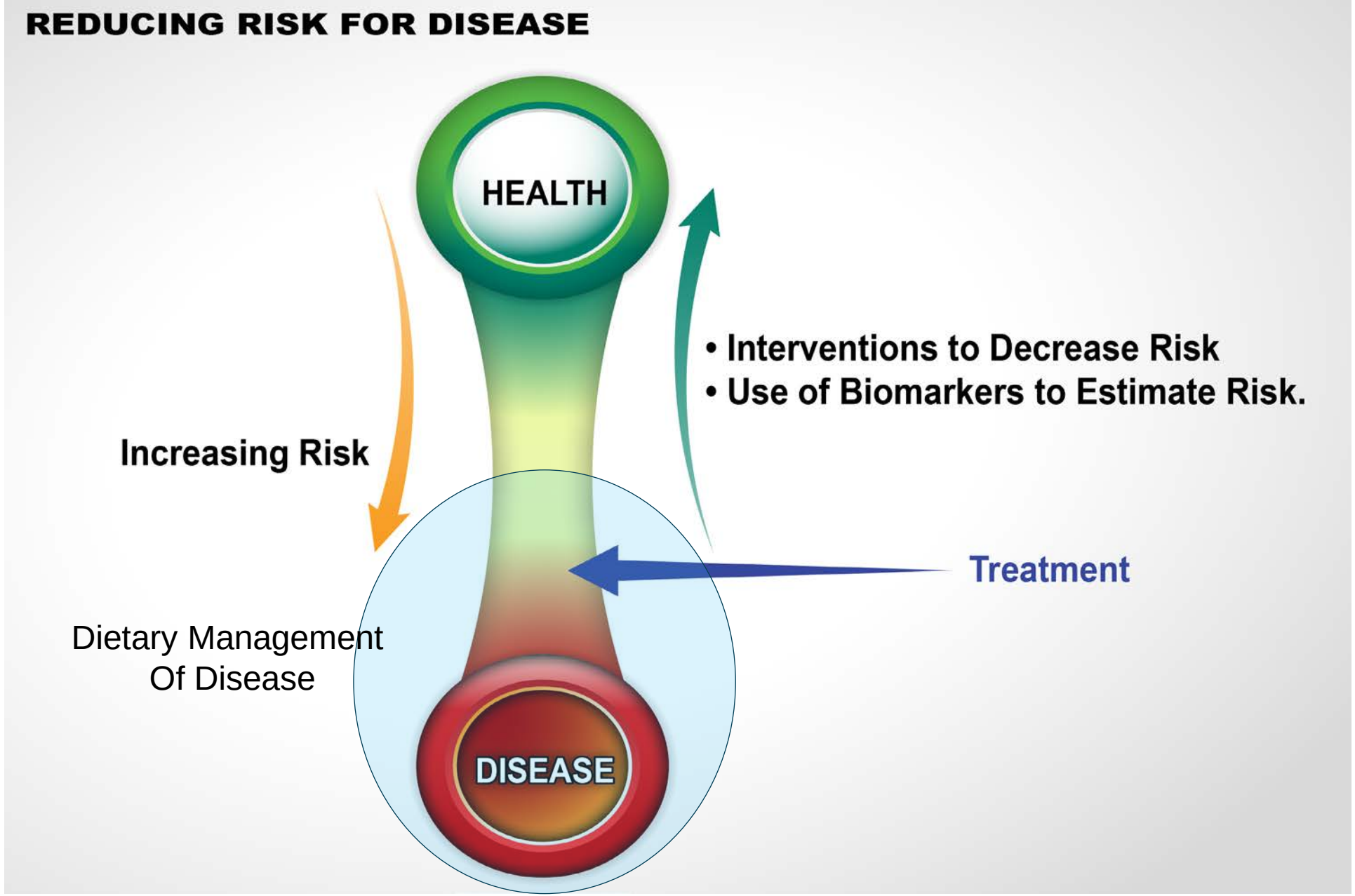
Advisory Committee Process



Future Directions in the DGAC Scientific Report

- “Identify collaborative efforts across the Federal government… [for] consideration of dietary patterns, in treating and managing diet-related conditions and disorders, such as type 2 diabetes, obesity, and cardiovascular disease (CVD).”
  - Identified based on public comments on the need for such guidelines
  - Included the need for weight loss strategies
- “Examine the relationship between nutrition and immune function”
- “Consider the role of genetics and epigenetics in future guidelines (e.g., single nucleotide polymorphisms (SNPs) for fatty acid metabolism; folate metabolism).”


REDUCING RISK FOR DISEASE
HEALTH
DISEASE
Increasing Risk
• Interventions to Decrease Risk
• Use of Biomarkers to Estimate Risk.
Treatment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Dietary Management
Of Disease
DISEASE

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Texas A&M AgriLife

Research considerations for medical foods

Patrick J. Stover, Ph.D.

Vice Chancellor, Texas A&M AgriLife

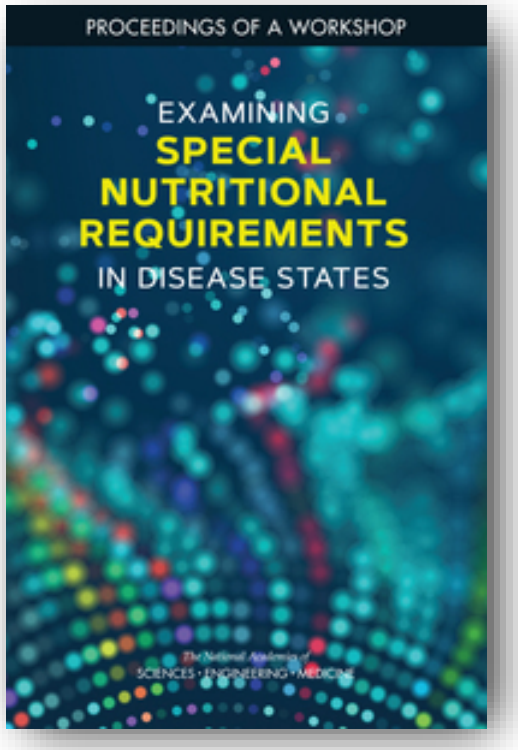
Dean, Texas A&M College of Agriculture and Life Sciences

Director, Texas A&M AgriLife Research

Disclosures

AFFILIATION/FINANCIAL INTERESTS (prior 12 months)	ORGANIZATION
Grants/Research Support:	NIH: T32-DK007158 R37DK58144; ODS Supplement HD059120
Scientific Advisory Board/Memberships:	Marabou Foundation, National Academy of Sciences, American Society for Nutrition, ICAAS Scientific Advisory Board; NIH Nutrition Strategic Plan Thought Leader Panel: Chair
Speakers Bureau:	None
Stock Shareholder:	TIAA

Special Nutrient Needs:
Disease can modify nutrient requirements



2018

- As of 2014, 60% of adult Americans had a least one chronic condition, and 40% had more than one. Rand, 2017
- Reviewed evidence for special nutritional requirements in disease states and medical conditions that cannot be met with a normal diet
- The workshop explored how these requirements may apply to the management of chronic or acute conditions or diseases: inborn errors of metabolism, burns or surgical trauma, cancer, inflammatory bowel disease, traumatic brain injury, and other non-communicable diseases or medical conditions.

Disease influences whole-body nutrient status and/or specific tissue nutrient status

Disease-Related Etiology

- Inflammation
- Genetic predisposition
- Autoimmunity
- Mitochondrial dysfunction
- Pharmaceuticals
- Trauma

Physiological Impact on Nutrients & Function

- Gut absorption
- Brain/Nerve Barriers
- Degradation/turnover
- Excretion
- Metabolism
- Redistribution

Impact on Human Nutrition

- Whole-body deficiencies
- Tissue-specific deficiencies
- Conditionally essential nutrients
- Nutrient toxicities

Impact on Biomarkers

- ***Function & Status***
- **Whole-body (serum)**
- **Tissue-specific (CSF, tissue)**
- ***Predictive Biomarkers***
- **Cells & Stem cells**

Inspired by: *Aust N Z J Med* **2**, 69-77 (1972).

Considerations for Distinctive Nutritional Requirements

Examples of factors that affect nutrient status and/or biomarkers of status:

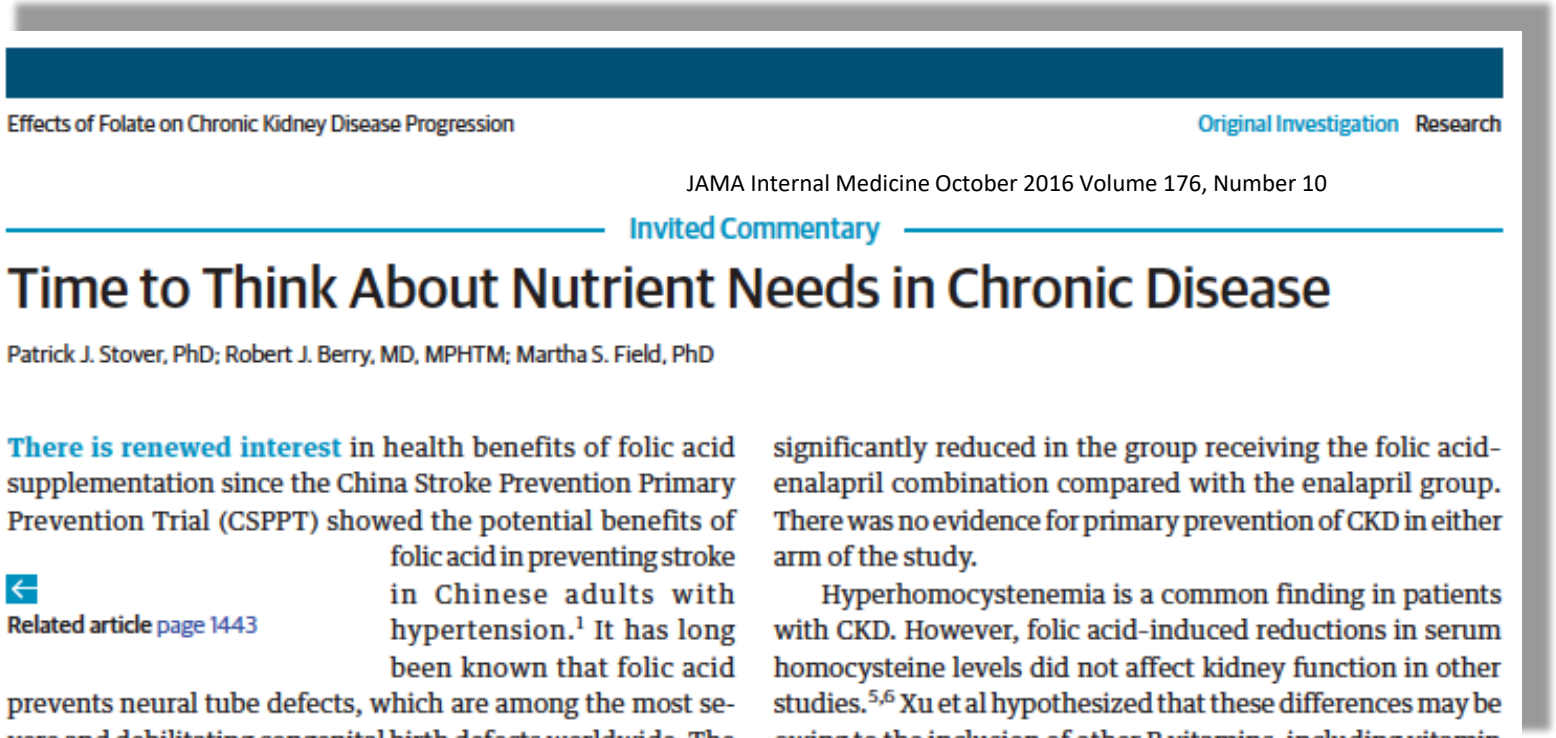
- **Increased rates of nutrient catabolism**
  - *Acquired Arginine Deficiency Syndrome*
    - Arginase is elevated in many diseases and cancers and in trauma/surgery Nutr Clin Pract. 2017, 32:30S-47S
  - *Inflammation (vitamin B6, vitamin D, others)* *Mol Aspects Med 53, 10, 2016; AJCN; 2011 93(5):1006*

- **Tissue redistribution and/or excretion**
  - *Infection* (iron) *Semin Cell Dev Biol. 2015 39:35*
  - *Inflammation* (vitamin B6, vitamin D) *Mol Aspects Med 53, 10, 2016; J Clin Pathol. 2013 66(7):620.*

- **Decreased rates of uptake across barriers (gut and blood-brain barrier transport)**
  - Genetics, Inflammation, Drug use, Autoimmunity, others

- **Stem cell-specific nutrient requirements –> Tissue Regeneration**
  - Serine auxotrophy in myoblasts *BBRC 70: 1085, 1976*

Drugs Can Alter Nutrition Needs but are Outside the Scope of DNR



Effects of Folate on Chronic Kidney Disease Progression

Original Investigation Research

JAMA Internal Medicine October 2016 Volume 176, Number 10

Invited Commentary

Time to Think About Nutrient Needs in Chronic Disease

Patrick J. Stover, PhD; Robert J. Berry, MD, MPHTM; Martha S. Field, PhD

There is renewed interest in health benefits of folic acid supplementation since the China Stroke Prevention Primary Prevention Trial (CSPPT) showed the potential benefits of folic acid in preventing stroke in Chinese adults with hypertension.[1] It has long been known that folic acid prevents neural tube defects, which are among the most severe and debilitating congenital birth defects worldwide. The significantly reduced in the group receiving the folic acid-enalapril combination compared with the enalapril group. There was no evidence for primary prevention of CKD in either arm of the study.

Hyperhomocystenemia is a common finding in patients with CKD. However, folic acid-induced reductions in serum homocysteine levels did not affect kidney function in other studies.[5,6] Xu et al hypothesized that these differences may be owing to the inclusion of other B vitamins, including vitamin

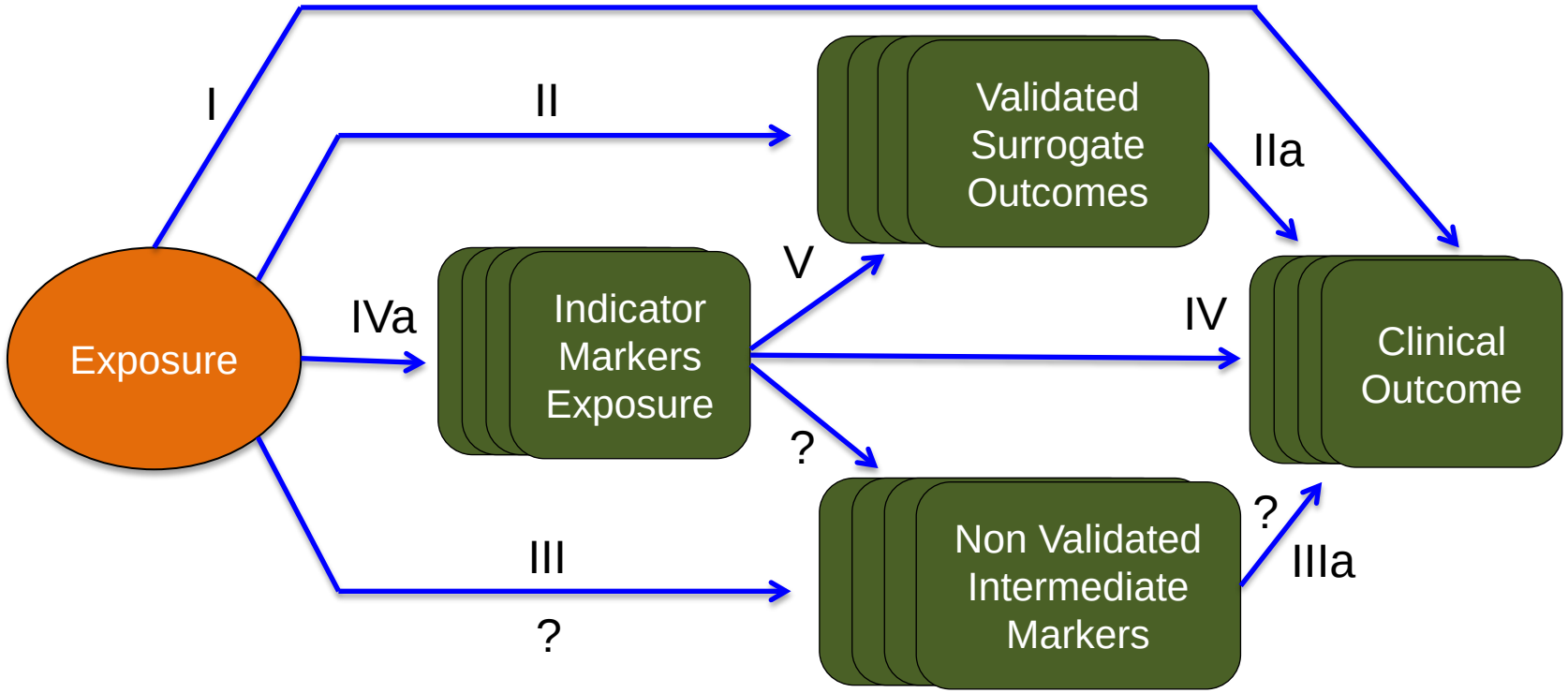
Related article page 1443

A folic acid–enalapril combination was more effective than enalapril alone in the secondary prevention of renal function decline among Chinese adults with hypertension across a spectrum of mild to moderate chronic kidney disease (CKD).

JAMA Intern Med. 2016 Oct 1;176(10):1443-1450.

Enalapril treatment alone in the absence of supplemental folic acid increased serum folate by 5.1 ng/mL, with a modest decrease in serum homocysteine (0.2 µM).

How do we establish DNRs??
Analytic framework applicable to assessment of nutrients



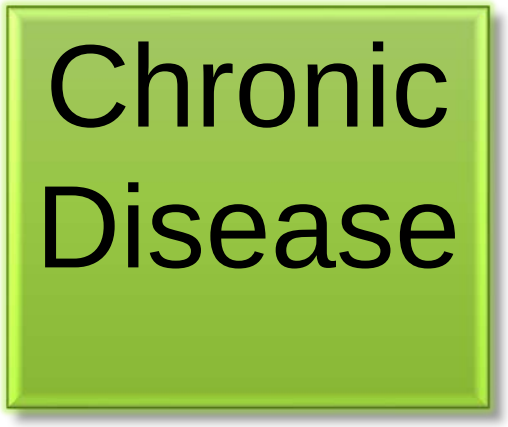
I. Association of exposure with clinical outcomes of interest
II. Association of exposure with validated surrogate outcomes of interest (functional biomarker)
III. Association of exposure with intermediate biomarker of interest (to clinical outcome)
IV. Association of exposure indicators to clinical outcomes of interest
V. Association of exposure indicator to surrogate outcome of interest

Russell et al. 2009 Am J Clin Nutr

Inborn Errors of Metabolism (IEM) inform Distinctive Nutritional Requirements in Disease

Medical Foods Address Nutrient Requirements that originate from a Loss of Function

Nutrition Compensating for Functional Deficits Caused by Genetics



Nutrition Compensating for Functional Deficits Caused by Disease

Diet-related interventions and IND applications

Perspective: US Documentation and Regulation of Human Nutrition Randomized Controlled Trials

Connie M Weaver,[1] Naomi K Fukagawa,[2] DeAnn Liska,[3] Richard D Mattes,[4] Gregory Matuszek,[5] Jeri W Nieves,[6] Sue A Shapses,[7,8] and Linda G Snetselaar[9]

[1]Weaver and Associates Consulting LLC, West Lafayette, IN, USA; [2]USDA–Agricultural Research Service Beltsville Human Nutrition Research Center, Beltsville, MD, USA; [3]Texas A&M AgriLife, College of Agriculture and Life Science, College Station, TX, USA; [4]Department of Nutrition Science, Purdue University, West Lafayette, IN, USA; [5]Biostatistics and Data Management Core Unit, Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University, Boston, MA, USA; [6]Mailman School of Public Health and Institute of Human Nutrition, Columbia University, New York, NY, USA; [7]Department of Nutritional Sciences, Rutgers University, New Brunswick, NJ, USA; [8]Department of Medicine, Rutgers RWJ Medical School, New Brunswick, NJ, USA; and [9]Department of Epidemiology, College of Public Health, University of Iowa, Iowa City, IA, USA

ABSTRACT

Training to ensure good documentation practices and adherence to regulatory requirements in human nutrition randomized controlled trials has not been given sufficient attention. Furthermore, it is difficult to find this information conveniently organized or in a form relevant to nutrition protocols. Current gaps in training and research surveillance exist in clinical nutrition research because training modules emphasize drugs and devices, promote reliance on monitoring boards, and lack nutrition expertise on human nutrition research teams. Additionally, because eating is essential, ongoing, and highly individualized, it is difficult to distinguish risks associated with interventions from eating under free-living conditions. Controlled-feeding trials provide an option to gain more experimental control over food consumed, but at a price of less external validity, and may pose human behavior issues that are unrelated to the intervention. This paper covers many of the expected practices for documentation and regulation that may be encountered in planning and conducting nutrition intervention trials with examples and references that should be useful to clinical nutrition researchers, funders of research, and research institutions. Included are definitions and guidance on clinical nutrition research oversight (institutional review boards, data safety and monitoring boards, US FDA); participant safety; standard operating procedures; training of investigators, staff, and students; and local culture and reporting requirements relevant to diet-related clinical research conduct and documentation.
Adv Nutr 2021;12:21–45.

Keywords: nutrition, diet, randomized controlled trials, documentation, regulation, scientific integrity, standard operating procedures, investigational new drugs, institutional review boards, data safety and monitoring boards

Adv. Nutr. 2021 12: 21-45

Any study that assesses the effect of a food or nutrient on the diagnosis, cure, mitigation, treatment, or prevention of disease requires an IND or an appropriate waiver from the US FDA.

Foods and nutrients used to prevent or treat a nutrient deficiency are exempt

Diet-related interventions and IND applications

IND is not required for the following studies:

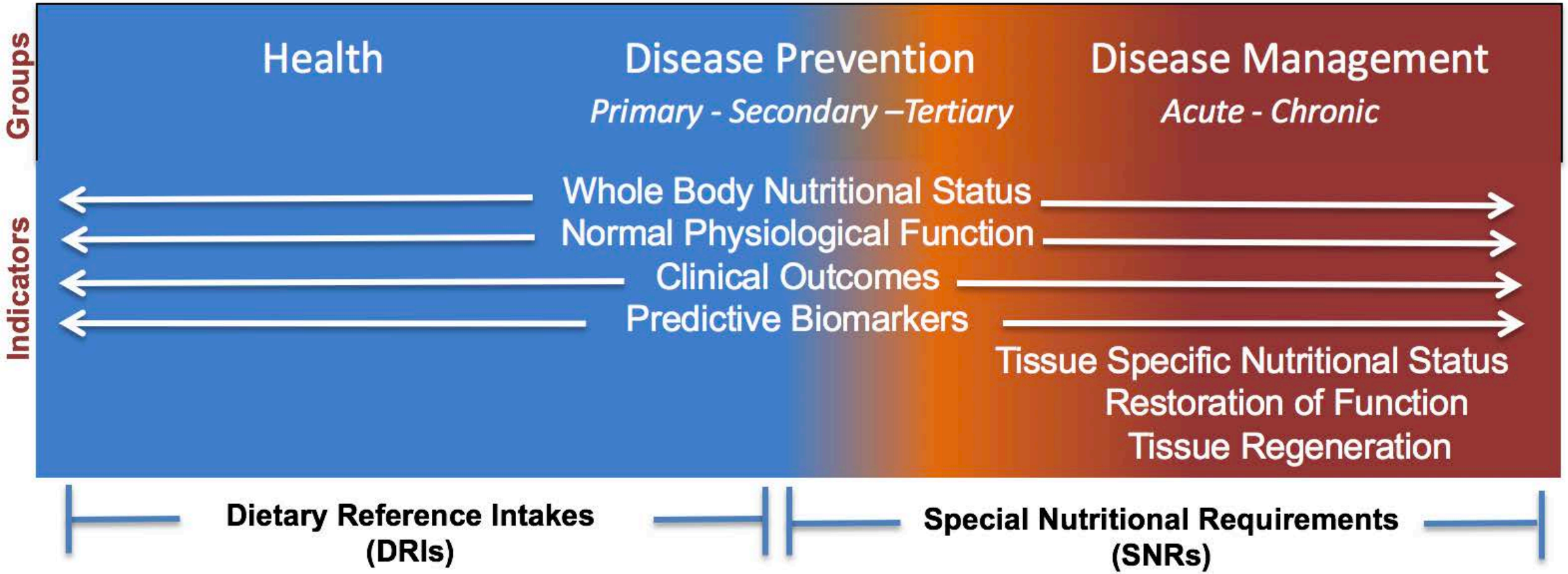
- Food or dietary supplement to reduce the risk of a disease, intended to support a new or expanded health claim, and conducted in a population that does not include individuals <12 mo old, those with altered immune systems, or those with serious or life-threatening medical conditions.

- Clinical studies designed to evaluate a nutritional structure/function effect of a conventional food or dietary supplement. (e.g. effect of iron on hemoglobin concentrations)

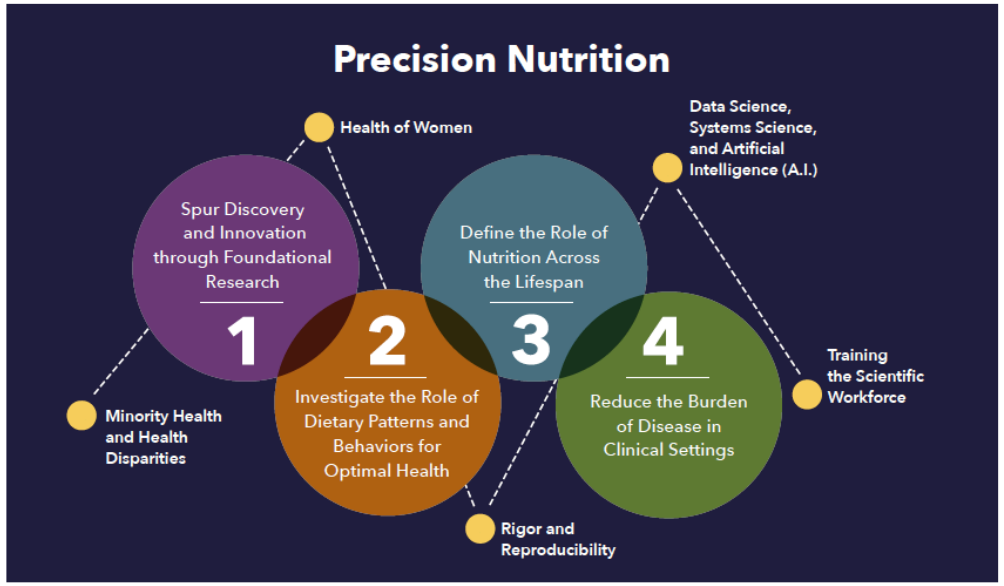
- A clinical study to evaluate the safety or tolerability of a food or ingredient generally does not require an IND provided the target outcome is not indicative of a treatment or mitigation of a disease or condition.

Adv. Nutr. 2021 12: 21-45

Classifying and Evaluating Human Nutrient Needs in Disease



NIH 2020 USDA



This Plan is organized around a central unifying vision of Precision Nutrition research. Progress in each of the four Strategic Goals, as well as the five Cross-Cutting Research Areas, are essential to achieve this vision.

USDA SCIENCE BLUEPRINT
A ROADMAP FOR USDA SCIENCE FROM 2020 TO 2025

Food and Nutrition Translation

USDA plays a pivotal role in providing Americans with safe, nutritious, and wholesome foods. This means supplying foods, both fresh and processed, that are of the highest quality and that provide adequate nutrition supporting the entire population life span. This task must address challenges to reduce foodborne illnesses; understand the drivers of poor diets and nutritional choices; provide better access to nutritious foods in low-income households; and reduce the overall cost of foods through more efficient processing, packaging, and repurposing to minimize food waste.

Proposed next steps

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Disclosures

AFFILIATION/FINANCIAL INTERESTS (prior 12 months)	ENTITIES
Grants/Research Support	
Scientific Advisory Board/Consultant/Board of Directors	EAS Consulting Group (Independent Consultant) Hoy Health, Blue Nalu (Scientific Advisor)
Speakers Bureau	
Stock Shareholder	
Employee	
Other	

Workshop Closing Session: Proposed Next Steps

- Panelists and audience contributed to an extensive list of next steps to address some of the hurdles associated with the medical food regulatory landscape (see Table 2 of the proceedings document)
- Key elements include:
  - Need to clarify key definitions of terms that qualify a product as a medical food
    - “Distinctive nutritional requirements” for various disease conditions
    - Modification of the ordinary diet alone
    - Intended for use under medical supervision
  - Updating an understanding of “dietary management of disease” and how nutrition can improve nutritional status and health outcomes, add to quality of life, and may reduce overall healthcare costs, for certain patient groups
  - Exploring paths to open dialogue around these scientific subjects, with those responsible for establishing policy and regulations having the goal to improve patient care through innovation and research

Need to clarify key definitions in Medical Food regulations

21 C.F.R. 101.9(j)(8)

i. It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding tube;

ii. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has **other special medically determined nutrient requirements**, the dietary management of which cannot be achieved by the **modification of the normal diet alone**;

iii. It provides nutritional support specifically modified for the management of the **unique nutrient needs** that result from the specific disease or condition, as determined by medical evaluation;

iv. It is intended to be **used under medical supervision**; and

v. It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

(Highlighting added)

Keep the patient at the center of regulatory policy

- Safety - preeminent in FDA's regulations - remains the focus
- Consider updating the medical food definition
  - Specially formulated food using GRAS ingredients
  - Promotes improvements for patients including, but not limited to, nutritional status, health outcomes, and quality of life
  - Not treating the disease pathology, but supporting the body's metabolic and physiological systems
- Can safe, cost-effective, food products that provide metabolic and physiological support, "normalize metabolic function" impaired by disease, and/or clinically meaningful improvements be allowed to be marketed as "medical food" to benefit patients?
  - Shouldn't sole source nutrition, given by feeding tube (medical device), be firmly established as a medical food?
- How broadly will "nutritional support" or "nutritional management" be defined?

Suggested ways forward

- Keeping the health, safety, welfare, and quality of life benefits of patients at the heart of any discussion is key
- Collaboration between scientific groups (eg. ASN) and trade associations (eg. HNC)
  - To promote research and publication of responsible, up to date, scientific evidence for the value of nutrition in optimal care of patients with defined conditions
  - Contribute to definitions about “distinctive” and “unique” nutrient needs of patients
- Engagement with FDA staff
  - Share and discuss most current, peer-reviewed, research findings to support patient-centered regulatory policy
  - Helps equip them to promulgate the best regulations
- Legislative Channels
  - Key bills have been introduced to Congress attempting to obtain financial assistance for nutritional support of patients
    - Medical Nutrition Equity Act of 2019-2020 (H.R. 2501)
    - Medical Nutrition Therapy Act of 2019-2020 (H.R. 6971)

What Can I do?

- Read the workshop proceedings publication in *"Current Developments of Nutrition"* to get the full perspective of the 1.5 day workshop, complexity of the issues, and ideas for moving forward (see next slide)
- Become knowledgeable about medical foods, their benefits, and limitations, in order to promote their true value for patients
- Consider engaging with groups dedicated to improving the lives of patients with diseases and conditions, that could benefit from improved nutritional support provided by targeted medical foods

Original Workshop and Published Proceedings

Access both at:
https://healthcarenutrition.org/medical-foods-workshop-2019/

Special thanks to:

HEALTHCARE
NUTRITION
COUNCIL