

Nutrition for the Full Spectrum of Disease

Differentiating Medical Foods and FSDU

Jena Rostorfer, Abbott Nutrition

Alex Biella, Nestlé Health Science

MEDICAL FOODS WORKSHOP:
**Science, Regulation
and Practical Aspects**

AUGUST 13-14, 2019 WASHINGTON, DC

What does dietary management of a disease mean to the patient?



Nutritional Support Needs

- Determined by either physiological manifestations or physical impairments
- Classical nutrients, other substances of biological value, and total dietary management

Changes to Lifestyle

- Complexity of dietary adaptation to meet nutritional needs
- Oral and/or tube feeding

Identifying practical, safe, and effective choices for Dietary Management

- Modification of the diet
- Commercially available products

Maintaining health and
reducing the risk of disease

Diseases or conditions that
result in a special dietary need

Acute or Chronic disease that
requires dietary management



Nutrition Across the Continuum of Care

**Conventional Food,
The mainstay of the diet**

**Dietary Supplements,
To supplement the diet**

FDA has clearly defined labeling
regulations for foods (NLEA) and dietary
supplements (DSHEA)

Foods for Special Dietary Use

**Meets a special dietary
need**

Must also follow FDA food labeling
regulations (NLEA).

Additional labeling related to the
special dietary usefulness in disease
is not explicitly defined or clarified
today.

Medical Foods

**Dietary management of a
disease**

Exempt from NLEA labeling to
enable labeling tailored to the needs
of the medical community. Labeling
related to the dietary management
of the disease is permitted.

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Disease Management AND Disease Compatibility

How do we help people with disease not only live, but live BETTER?

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Potential Path Forward in Distinguishing Therapeutic Foods?

Disease Management

Medical Foods

For the dietary management of a disease or condition.
Must be used under medical supervision.

“Distinctive Nutritional Requirements”, or “DNR”, based on recognized scientific principles, established by medical evaluation

Disease Compatible

Sub category of Foods for Special Dietary Use (FSDU)

For the particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases
For the everyday health of a person living with disease.

Special Dietary Need

Modified nutrition (i.e., fulfilling a special dietary need) would provide benefits to a person’s nutritional status, health outcomes or quality of life as part of living with disease

A Modern Approach to “DNR”

Putting the patient’s nutritional needs and quality of life at the forefront

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Healthcare Nutrition Council's take on "DNR"

Healthcare Nutrition Council

529 14th Street, NW • Suite 750 • Washington, DC 20045

Definition of Distinctive Nutritional Requirement

"Distinctive nutritional requirement" refers to the clinical need for a specific nutritional intake (compared to the intake of healthy populations) which may exist by reason of abnormal physiological manifestation or physical impairment associated with a disease or condition, the dietary management of which results in clinically meaningful improvements, including but not limited to nutritional status, health outcomes, or quality of life.*

**"Abnormal physiological manifestation or physical impairment" includes the following conditions associated with acute and chronic diseases or health conditions:*

- (I) a limited, impaired or disturbed capacity to ingest, digest, absorb, metabolize or excrete ordinary food or certain nutrients or metabolites, or*
- (II) other medically-determined requirements for nutrients/other food substances of biological value.*

Four Key Pillars to ensure a patient-centric approach to the Medical Foods category:

- 1) **Focus on patients' complete nutritional requirements, beyond just nutrient levels:** Our proposed definition of "distinctive nutritional requirement", as indicated above, appropriately narrows the category of Medical Foods to products formulated with a high standard of scientific rigor and quality, while also providing sufficient flexibility to address overall patient needs, and supporting innovations in nutrition science. While necessary adjustments to the intake of essential nutrients is an example of a distinctive nutritional requirement, it should not be the *only* accepted criteria for the classification of a product as a Medical Food. This restrictive interpretation creates a scenario where other products, like standard enteral tube feedings, are excluded from the same regulatory category despite their critical role in the dietary management of the disease or medical condition and their benefit to patients (see below for proposed types of distinctive nutritional requirements).
- 2) This definition of "Distinctive nutritional requirement" is intended to be taken in a context in which it is impossible, impractical, unsafe or nutritionally or clinically disadvantageous for patients to meet their nutritional needs through the exclusive consumption of foods other than Medical Foods.
- 3) **Keep positive health outcomes for patients as the core goal:** The definition should inform the development of Medical Foods that are specifically formulated to meet the "distinctive nutritional requirements" of patients in order to maintain/improve nutritional status and overall health status, clinical outcomes and quality of life. The definition should also inform the development of Medical Foods when it is impossible, impractical or unsafe for these patients to meet their "distinctive nutritional requirements" exclusively through the normal diet and/or the patients would have a nutritional or clinical disadvantage from consuming the normal diet alone rather than Medical Foods. In other words, the definition

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Four Key Pillars to this Interpretation

Focus on Patients' complete nutritional requirements, beyond just nutrient levels

DNR should encompass more than adjustments to essential nutrient DRIs.

- 1) Mode of delivery
 - 2) Conditionally essential (no DRI)
 - 3) Other food substances of high biological value
- Etc.

Patient feasibility must be considered

Is it impossible, impractical, unsafe, or nutritionally or clinically disadvantageous to meet needs through diet alone?

Keep positive health outcomes for patients as the core goal

DNR should be public-health promoting: consider benefit to patients' nutrition status, clinical outcomes, and quality of life (rather than just necessity).

All of these will translate to benefits to the healthcare system as well, such as reductions in cost of care or reductions in readmissions.

Recognize disease severity can amplify a patient's need for a Medical Food

Patients presenting with higher severity and multiple co-morbidities also necessitating nutritional changes need access to Medical Foods even if the "healthiest" patient can successfully modify diet

and Practical Aspects

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