The Role of Medical Foods in Clinical Programs

Medical Foods in Clinical Care

**FOODS, FUNCTIONAL FOODS, AND MEDICAL FOODS**
The United States population faces greater health challenges with the rise in obesity and chronic diseases; and as the aging population grows larger, identification of safe and effective solutions for management of diseases has become a high priority for the medical community.\(^1\)\(^2\) Pharmaceutical companies focus primarily on providing solutions for select and homogeneous populations; therefore, patients are looking to their physicians for a more comprehensive approach to patient care.\(^3\)

Increasingly, a healthy lifestyle is recognized as a cornerstone for maintaining a long and active life, and also as a fundamental approach for the management of disease.\(^4\) Lifestyle medicine, comprised of structured interventions such as modified diet, exercise plan, and behavioral counseling, has become the recommended first line of therapy due to numerous clinical studies that underscore the effectiveness of a healthy lifestyle in preventing or managing a wide range of diseases.\(^5\)\(^6\) The inherent safety and economy of lifestyle medicine allows it to be accessible to most patient populations.

Research on natural products has recently experienced tremendous growth, making available a variety of options for the consumer, and a veritable trove of resources for the physician seeking to improve patients’ lives. The concept of nutrition has shifted from the United States Department of Agriculture’s food pyramid to a rapidly evolving science describing specific foods and nutrients that support healthy lifestyles and help manage diseases. Clinicians and medical organizations recommend a range of different types of food plans, functional foods, medical foods, and dietary supplements.

**Functional Food Definition.** A clear distinction exists between functional foods and medical foods. A functional food is not defined by the FDA and usually refers to a food that has biologically active compounds added to enhance the health benefit of the food.\(^9\) Some examples of functional foods include salad dressing with added phytosterols and yogurt that contains live cultures. Health claims are limited to specific nutrients in specific amounts based on widely accepted benefits supported by publicly available scientific evidence. Functional foods are a growing industry with an increasing demand from health-conscious consumers. Regulation under the Food and Drug Association (FDA) is the same as for other foods and requires nutrition labeling.\(^10\)

**Medical Food Definition.** In contrast, a medical food, according to section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is defined as "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."\(^11\)

The following criteria that clarify the statutory definition of a medical food can be found in FDA regulations at 21 CFR 101.9(j) (8).\(^11\)

- **a.** 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 by tube;
- **b.** 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;
- **c.** 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; 
d. It is intended to be used under medical supervision; and 
e. 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.

Although a prescription from a medical practitioner is not required, a medical food is intended to be used under ongoing medical supervision. Medical foods have to comply with all regulations pertaining to the manufacture of food. According to FDA regulations for foods, ingredients must be approved food additives or Generally Regarded as Safe (GRAS). Medical foods can be manufactured for enteral or parenteral use, and are available in many formats, ranging from powdered beverage mixes and ready-to-drink formulas to tablets and bars.

Medical foods are not the same as dietary supplements, which are consumer products intended for healthy individuals. Dietary supplements are products containing dietary substances such as vitamins, minerals, amino acids or botanical extracts that are taken by mouth to supplement the diet.12

Medical foods provide an opportunity for a healthcare practitioner to manage a patient’s clinical condition through recognition of their nutritional needs. Practitioners should perform a complete medical evaluation to determine a patient’s nutritional needs.

**Medical Foods in Clinical Practice.** Medical foods are used for the nutritional management of a specific disease or condition. Medical foods may help support a patient presenting with early signs or symptoms prior to advanced disease onset, before pharmaceuticals are recommended. Clinicians may recommend a medical food for nutritional support in the management of specific acute medical conditions—for example, as part of inpatient care—including chronic illnesses.

Other applications may include use of a medical food in conjunction with prescription drugs. Furthermore, some medical conditions or drug treatments may reduce the physiological capacity to absorb or metabolize specific nutrients, creating a deficiency, and thus a specially formulated medical food can be beneficial.13 While a drug acts to target the disease mechanism, a medical food provides specialized nutritional support for the patient to help with the appropriate functioning of body systems.

One of the first commercially available medical foods provided a primary source of nutrition for phenylketonuria (PKU), an inherited disease that prevents metabolism of phenylalanine, which is important for melanin production. When phenylalanine builds up in the body, brain damage and other deleterious symptoms occur. Conventional treatment for patients includes avoidance of phenylalanine-containing foods. A medical food formulated with a protein source that is extremely low in phenylalanine and contains other essential amino acids and fatty acids can provide a dietary solution to support normal growth and development in PKU patients. This specific dietary management would not be possible by simply modifying a diet of conventional foods.14

Physician-supervised dietary management with medical foods may be effective for resolving some of the symptoms present in chronic illnesses. Other conditions for which medical foods have been developed for nutritional support include metabolic syndrome, Alzheimer’s disease, osteoarthritis, inflammatory bowel disease, hypercholesterolemia, type 2 diabetes, chronic fatigue syndrome, fibromyalgia, premenstrual syndrome, leaky gut syndrome, and pre- and post-operative bariatric surgery. A medical food should be supported by solid scientific evidence that demonstrates it is an effective nutritional management approach for the intended population, usually with clinical trials demonstrating safety and efficacy. Peer-reviewed, published clinical research is a valuable element in determining whether the combination of ingredients in a medical food is safe and effective.

**CONCLUSION**

Medical foods belong to a special category designated by FDA. It is an important component of therapeutic nutritional management of specific illnesses for which distinct nutritional requirements need to be addressed. Many different medical food products are commercially available for a variety of medical conditions and diseases, and selecting a quality medical food is important for ensuring safety and effectiveness. Especially with vulnerable populations, evaluation of the science and quality measures taken by the manufacturer is necessary.
The greatest opportunity for clinical use of medical foods is for slowing the progression of chronic diseases. Even when a patient’s medical condition requires a pharmaceutical regimen, medical foods are sometimes helpful to meet the distinctive nutritional requirements of the patient, and the right medical food will support improved physiological functioning for disease management from the nutritional perspective. Although not mandated, well-designed clinical studies provide evidence that the product benefits the intended population. Extensive testing and clinical research on medical food products demonstrates a commitment to patient success.

Nutritional therapy should be used to optimize the nutritional status of hospital patients, as well as outpatients to speed their recovery and to slow disease progression. Medical foods complement lifestyle medicine approaches and can often be used with pharmaceuticals. Overall, this product category is increasingly used by the medical community as an overall strategy to nutritionally manage specific chronic diseases, as evidence suggests that nutritional therapy improves clinical outcomes and lowers the economic burden of disease.

REFERENCES