1 Does nutrition have a role in disease management?

By Barbara O. Schneeman, PhD

Introduction

The current regulatory approach, with respect to food and nutrition, tends to categorize individuals as consumers or patients and yet these states often occur simultaneously and must be managed by the individual and his or her healthcare provider on an ongoing basis as a part of the daily routine. In addition, research in medicine and health is increasingly moving toward options that personalize healthcare and have the potential to engage individuals more directly in monitoring and managing their health and medical conditions. For example, one perspective noted the multiple personal variables, such as age, sex, microbiome, physical activity, lifestyle that will impact the ability of diets to maintain normal postprandial blood glucose response.[1] Techniques in areas such as genomics, metabolomics, diagnostics can personalize awareness of health and disease status and provide the ability to better manage status. A recent report from the National Academies of Sciences, Engineering, and Medicine (NASEM) indicated that the Dietary Guidelines for Americans (DGA) should address the food and nutrition needs of those in the general population who can benefit from improving their diet, and thus would include those with chronic disease or at risk for such disorders.[2] NASEM also has published a report outlining principles for establishing Dietary Reference Intakes (DRIs) for Chronic Diseases.[3] This report highlights that DRIs for chronic disease differ from DRIs for nutrient adequacy, that chronic disease DRIs can apply to nutrients and other food substances, and that a process is needed to integrate these principles into the DRI framework. The Academy of Nutrition and Dietetics (AND) have developed a Nutrition Care Process (NCP) that provides a systematic approach to quality nutrition care. NCP relies on an interactive model of nutrition assessment, diagnosis, intervention, and monitoring/evaluation to assess the needs of a patient or client and make decisions that are evidence-based. Progress with NCP has illustrated that food and nutrition has an important role in managing certain diseases.

Managing disease states and medical conditions has been recognized as the purpose of Medical Foods (MF) and Foods for Special Dietary Uses (FSDU), in the Federal Food, Drug, and Cosmetic Act as well as regulations promulgated in the Code of Federal Regulations. However,

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clarifying when managing a disease or medical conditions causes a product to be considered a MF, FSDU, drug, or biologic can be challenging to discern in the current regulatory environment. The lack of clarity raises the question of whether the current regulatory framework is sufficient for this emerging area in healthcare. I do not have answers to this challenge but view the discussion and recognition of the issues as critically important to understand to recognize the value of nutrition in managing disease and health-related conditions.[4]

Conventional foods and dietary supplements have had a framework for conveying nutrition information based on two landmark amendments to the Federal Food, Drug, and Cosmetic Act, the Nutrition Labeling and Education Act of 1990 (NLEA) and the Dietary Supplement Health and Education Act of 1994 (DSHEA). A fundamental principle of the framework created by NLEA and DSHEA is that nutrient requirements for adequate nutrient intake can be established for the general population and that scientific evidence can be evaluated to determine when food or food components can reduce the risk of chronic diseases that are prevalent in the general population. In addition, the most recent DGA are based on the evaluation of scientific evidence on dietary patterns associated with meeting nutrient requirements and reducing risk of chronic disease for the general population.[5] One of the dietary patterns included in the DGA, is the Dietary Approaches to Stop Hypertension (DASH), which is a dietary approach specifically designed to manage a medical condition, hypertension. Because nutrition labeling for conventional foods and dietary supplements focuses on meeting nutritional needs of the general population, MFs, which are for individuals with distinctive nutrient requirements, are excluded from the nutrition labeling requirements under NLEA. The category of FSDU was revised to exclude products based on nutrient content claims (e.g., low sodium) or health claims (e.g., sugar alcohols and dental caries), but still exists for individuals with normal nutrient requirements, but with special needs for utilizing the foods (e.g., difficulty swallowing). These categories within foods (i.e., MF, FSDU, conventional foods plus dietary supplements) characterize a spectrum of products that can be used to meet nutritional needs based on metabolic, physiologic and nutritional status of individuals.

A Federal Register Notice published in 1996 by FDA provided insight into the agency's thinking about MF and FSDU; the notice was withdrawn in 2004 because of lack of resources to analyze comments and move forward. However, in the withdrawal notice, the agency suggested the principles articulated in the 1996 Notice were consistent with current thinking and these principles recognized that MF and FSDU are intended to help in the dietary management of diseases or medical conditions.[6] More recently, the final guidance on MF published in 2016 appears to narrowly define MF in a manner most focused on inborn errors of metabolism.[7]

The MF market has grown steadily in the US and various factors may contribute to ongoing growth, including the interest in personalized healthcare, but is complicated by regulatory action from FDA that often appears minimal.[6,8] In the absence of a process for FDA recognition of status as a MF or FSDU, manufacturers may learn of a product's status through regulatory action, e.g., if FDA sends a warning letter that it does not agree with the manufacturer's determination that the product meets criteria as a MF. Without a consistent framework that clearly defines parameters for MF and FSDU, some manufacturers may be reluctant to develop products due to uncertainty about the market plus concern of regulatory action, and unfortunately, other manufacturers may take advantage of the lack of clarity in the regulatory framework to mislead consumers and

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patients about products and their ability to manage disease or medical conditions. A review of the mechanisms of action of various medical foods in gastrointestinal disorders suggests that various products can be valuable in managing certain medical conditions.[8] However, such an analysis raises the question of what standards have been agreed upon for the scientific evaluation of a MF product and specifically what evidence is necessary to establish that a medical condition has a distinctive nutrient requirement that requires special formulation and processing to meet these special needs. An additional question raised is to understand the difference between managing a disease or medical condition and an intervention that mitigates or treats symptom, an effect which makes a product more drug-like in scope. A key concern from a regulatory perspective is protection of public health and having a level playing field for the standards that must be met for a product to meet the criteria of a MF or FSDU; consumers, patients, and healthcare providers must have confidence in the efficacy of such products.[1]

The European Commission has recently revised its regulations and created a category of Foods for Special Groups (FSG), which includes Foods for Special Medical Purposes (FSMP). The FSG category includes other categories such as foods for infants and young children, meal replacement for weight control, and gluten-free and lactose-free foods but these are not within the scope of FSMP.[9] Thus a characteristic of products within the FSMP category reflect the degree to which the "medically determined nutrient requirements…cannot reasonably or realistically [be] satisfied by modifying the normal diet, i.e., the extent to which it is impossible, impractical or un-safe… and/or the extent to which patients would have a nutritional or clinical disadvantage from consuming foodstuffs…that are not FSMPs."[10] To facilitate this approach EFSA, has published scientific and technical guidance that focuses on the key characteristics of a FSMP, including characteristics of the food product, characterization of the disease, disorder, or medical condition, characteristics of the patients use of the product and its role in their dietary management. The establishment of criteria for determination of whether a product is a FSMP will facilitate the ability of food manufacturers to develop products that fit the FSMP category and enable the EC to decide if a product falls with the scope of the regulation and where it belongs within the scope.[10] Understanding the EU approach in creating the FSG category and the criteria for approving products, can be useful in developing a way forward.

The value of diet and nutrition in prevention of disease is often highlighted and yet as Harvey Fineberg has pointed out, disease prevention is "celebrated in principle, resisted in practice."[11] Being able to manage certain disease states or medical conditions using dietary approaches can help manage quality of life for individuals living with such conditions and help manage healthcare costs.[4,11] RAPS has opened and sustained an important dialogue about the role of MF and FSDU in managing health and disease. This dialogue and discussion are important for addressing questions about the contribution of food and nutrition to manage disease and medical conditions. To move forward the discussion needs to identify and address the question of the scientific and regulatory frameworks necessary to evaluate products to determine the validity of claims made about their role in managing disease or medical conditions so that individuals and healthcare providers can have confidence in the use of such products.

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2 Codex Alimentarius Commission: The World's Food Safety and Quality Parliament

By Tom Heilandt

Introduction

Food has been traded for millennia and consequently some forms of food standards and measurement have developed for a similar long time. As agriculture, food trade, and sales to consumers changed from local to global, these standards were set in national, bilateral, regional, and multilateral settings.

The texts are an evolution of many earlier attempts to create a food code and were developed by the Codex Alimentarius Commission (the Commission)—an international body with delegates representing more than 99% of the worlds' population—working as a "world food safety and quality parliament" with core values, common vision, mission, and strategy. The Commission was established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) in 1963 as the central pillar of the FAO/WHO Food Standards Programme to develop food safety and quality standards to protect the health of consumers and ensure fair practices in the food trade. It also is tasked with promoting the coordination of all food standards work undertaken by international governmental and non-governmental organizations. The Commission's work is complemented by the pillars of FAO/WHO food safety scientific advice and capacity building programs.

Codex texts cover all aspects of food production and trade from the producer to the final consumer. The texts have been recognized specifically as benchmarks for food safety in the World Trade Organization (WTO) agreement on sanitary and phyto-sanitary measures (SPS) and also are considered in the WTO agreement on technical barriers to trade (TBT).

The collection of Codex texts (standards, guidelines, codes of practice, maximum residue limits [MRLs], and other texts) developed by the Commission is also known as the Codex Alimentarius.

Codex Past, Present, and Future

As the Commission nears its 60th anniversary in 2023, it has gone through many changes—the most striking being becoming a reference in WTO-SPS in 1995 and the subsequent systematic integration of the principles of scientific risk

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