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Developing Public Health Messages for Non-essential Food Components

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ABSTRACT

Foods contain a variety of essential and non-essential components. Emerging evidence suggests that both the traditional essential and some non-essential portions of foods provide health benefits. For example, vitamin A and C must be provided in the diet to prevent deficiency diseases, but what about non-vitamin A producing carotenoids, polyphenols, isothiocyanates, allyl sulfides, etc.? The weight of experimental evidence suggests that these and other dietary bioactives contribute to healthfulness. Most countries have "quantitative" Recommended Dietary Allowances (RDAs) to help guide health professionals to avoid deficiency diseases in their populations. The United States has the Dietary Reference Intakes that includes RDAs, Adequate Intakes and Upper Levels. In addition, many countries provide "qualitative" advice, such as the Dietary Guidelines for Americans, which focus more on recommendations for food pattern consumption. The amount of clinical evidence necessary for establishing an RDA is substantial. While it is possible to conduct a randomized placebo-controlled trial to establish an RDA for vitamin C, there are inherent difficulties in constructing human trials for food extracts or for dietary bioactives. Thus, the amount of evidence that can be collected for non-essential food components may be less than what is expected for the essentials. Some suggest that the "totality of the evidence" should be sufficient to drive public health messages about non-essentials. Here we address potential mechanisms for "accreditation" of bioactive food components and will address issues regarding design of studies, lack of biomarkers, challenges in funding needed research, and the consequences in inaction.

Key words: Public Health, Nutrition, DRIs, RDAs, Dietary Bioactive

INTRODUCTION

In the United States, the Nutrient and Diet Recommendations include Dietary Reference Intakes (DRIs), Dietary Guidelines and MyPyramid/MyPlate. DRIs are developed by the Institute of Medicine (IOM) to provide quantitative advice to health professionals about amounts of nutrients or food components found to be of benefit. On the other hand, Dietary Guidelines and MyPyramid/MyPlate are developed by the U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS) to provide qualitative advice to the general public about diet (foods) and chronic disease prevention and maintaining health. Two phases of science translation are involved: Phase I is to translate the science (DRIs) into recommendations (Dietary Guidelines), and the Phase II is to translate the recommendations (Dietary Guidelines) into actions (MyPyramid/MyPlate).

Why were DRIs developed? Back in 1941, the National Research Council issued the first set of Recommended Dietary Allowances (RDAs) for vitamins, minerals, protein, and energy. Since then, the RDAs have served as the basis for almost all U.S. federal and state food and nutrition programs and policies. By 1989, the RDAs (10th edition) had been revised nine times and expanded from a coverage of 8 original nutrients to 27 nutrients. Beginning in 1994, the Food and Nutrition Board (FNB) of the IOM set out to develop and implement a new paradigm to establish recommended nutrient intakes that combined the traditional approach of reduction of deficiency diseases with the emerging concerns of reduction of chronic disease risk.

A family of reference values collectively known as the Dietary Reference Intakes (DRIs) was then developed during 1997 - 2005 and subsequently published in a series of reports. In contrast to the old RDAs, which involved single values for each nutrient, adjusted for age, sex, and physiological condition, the DRIs framework features four reference values.The DRIs are based on scientifically grounded relationships between nutrient intakes and indicators of adequacy, as well as the prevention of chronic diseases, in apparently healthy populations. In addition, the potential adverse effects of nutrients when consumed at high levels, was considered.

THE DRI FRAMEWORK

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The DRIs in the United States include four nutrient-based reference values: Estimated Average Requirement (EAR), Recommended Dietary Allowance (RDA), Adequate Intake (AI), and Tolerable Upper Intake Level (UL). Estimated Average Requirement (EAR) is the average daily nutrient intake level that is estimated to meet the requirements of half of the healthy individuals in a particular life stage and gender group. Based on the EAR, the Recommended Dietary Allowance (RDA), which is the average daily dietary nutrient intake level that is sufficient to meet the nutrient requirements of nearly all (97 - 98%) healthy individuals in a particular life stage and gender group, can be calculated (RDA = EAR + 2SD). However, when an RDA can't be determined, the Adequate Intake (AI) is used, which is defined as the recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups of healthy people) that are assumed to be adequate. The Tolerable Upper Intake Level (UL) is the highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase.

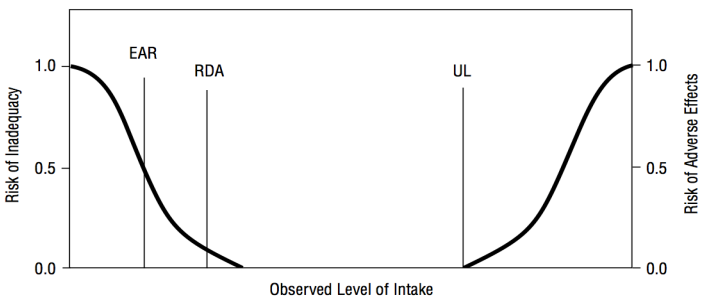

Figure 1. Relationship between Dietary Reference Intakes. [Otten *et al.*[1]]

WHAT ARE ESSENTIAL NUTRIENTS?

How does one define an essential nutrient? A FNB subcommittee in about 1992 decided not to define the term. One of the reasons is because it is difficult to define, just like the term "organic". This subcommittee did not want to "limit" the boundaries of the upcoming DRI process, since the DRI process was designed to consider both alleviation of chronic disease and reduction of chronic disease risk as potential end points. Take vitamin C as an example, all will agree that vitamin C is essential to prevent scurvy in humans. Vitamin C has been depleted in human volunteers with observed deficiency symptoms and was replenished to alleviate them. This is a classical test of essentiality. Would other clinical endpoints related to vitamin C such as providing a general antioxidant function be considered essential? Even though there are other anti-oxidative enzymes and compounds in tissues, and there is no doubt that a general antioxidant function can be provided by the vitamin C, this function may or may not be considered as essential by a panel of experts.

Among the 42 DRI nutrients, are all of them considered essential? At least some, like fiber, fluoride and even choline may not be classically essential, since the deficiencies of these nutrients are not lethal to humans. However, fiber assists in gastrointestinal tract function; fluoride helps prevent teeth cavities; choline contributes to one carbon metabolism. All these non-classically essential nutrients enhance human's wellbeing and have DRI status. Similar stories can be found in the cases of pantothenic acid, biotin, and manganese. Interestingly, RDAs for these nutrients could not be established, and AIs were established instead. Beyond these DRI nutrients, would other food components, like tea catechins or grape resveratrol that enhance health, be considered as essential? Probably not, but those may enhance health nevertheless, just like fiber or fluoride. As we consider DRIs for these components in the future, the level of scientific evidence will play an important role in establishing a food component's essentiality.

LEVEL OF EVIDENCE: TYPES, AMOUNT, AND THE END POINTS

What types of evidence are needed to set dietary recommendations? Blumberg *et al.*[2] stated, "Because of limitations inherent in randomized controlled trials, particularly of nutrients, it is suggested that nutrient policy decisions will have to be made using the totality of available evidence. This may mean action at a level of certainty that is different from what would be needed in the evaluation of drug efficacy. Similarly, it is judged that the level of confidence needed in defining nutrient requirements or dietary recommendations to prevent disease can be different from that needed to make recommendations to treat disease."

What amount of evidence is needed? The amount of evidence necessary should depend upon the risk versus benefit of consuming the substance (risk/benefit ratio). If the substance is of high risk and lower benefit, more evidence will be needed. An example would be a food component with higher potential for adverse side effects with marginal benefits, like selenium supplements for cancer prevention. In contrast, a food component with few side effects but high benefit should require less evidence.For examples, lutein consumption and reduction of risk for age-related macular degeneration (AMD).

It is also critical to define the clinical end points of interest. For example, Blumberg *et al.*[2] pointed out that the amount of dietary folate necessary to reduce the risk of neural tube defects is greater than that needed to prevent macrocytic anemia and probably less than that needed to reduce risk of coronary heart disease. Similarly, iron needs for maintaining hemoglobin at 11 g/dl is higher than needed for maintaining biochemical

functions (as a co-factor for enzymes).

It should be pointed out that the standards of evidence should not change whether one is considering drugs, essential nutrients or other food components. However, the amount of evidence necessary depends upon the risk/benefit ratio of consuming the substance.

CHALLENGES FOR ACCREDITATION OF NON-ESSENTIAL FOOD COMPONENTS

For non-essential food components, it is important to ensure the integrity of the component and specificity of action. Whether the bioactivity comes from the whole food (chocolate or tea) or purified bioactives (a cocoa polyphenol or EGCG), it is important to authenticate the sources, document the manufacturing processes, and perform quality control procedures to ensure the quantity and quality of bioactives. Upon the dietary consumption, validated biomarkers will also need to be used to assess the health impact of the substance. This is a challenge and is a broader challenge than just with non-essential food components. Even for nutrients with established RDAs like vitamin D, the establishment of validated biomarkers are still in progress.

Collecting thorough information is also challenging. For any accreditation from a public health body, it is necessary to have baseline information including a validated analytical technique, food composition database, population intake patterns, pharmacokinetics of the substance, a no observable adverse effect level (NOAEL), and consideration of safety issues. Other information such as epidemiological support, biological plausibility, specificity, which are parts of "Hill's Criteria", are also needed. At times some foods or food extracts could be the difficult to blind in human trials. For example, due to their strong odors, testing of broccoli sprouts or garlic extracts present a challenge.

The lack of double-blind, randomized, placebo-controlled trials (RTCs) has always been the biggest challenge. The lack of RTCs leads to the insufficient data for systematic evidence-based reviews, which are highly valued by public health administrators. However, the costs of human intervention trials would be enormous considering the "small effects" expected from food components compared to drugs. Also, long intervention times may be needed to demonstrate efficacy, and a huge population size may be needed to complete such a trial with a bioactive food component. With the current budget deficit, the U.S. federal government is unlikely to support large-scale clinical trials on dietary bioactives. Private sectors are also unlikely to sponsor this type of trial, unless the trials are directly associated with exclusive product protection. Thus, the lack of RTCs is expected to continue.

One may ask why should we care about "accreditation" of bioactive food components? We would like to point out that most food bioactives are components of plant-based foods, and despite decades of promotion of 5-a-day programs, consumers have not increased their consumption of fruits and vegetables. Accreditation of bioactive food components can be part of a new message to promote mindful and healthful eating, which could decrease risks of many chronic diseases, including obesity, metabolic syndromes, and cancer. Moreover, consumers are more likely to respond to a positive health message about a benefit of consumption of a food containing a bioactive than to be continued to be told what not to eat.

WHAT ARE THE NEXT STEPS?

"A paradigm for assessing the effects of bioactives is needed. Whether these are studied as nutrients or drugs must be established to properly inform future regulatory and policy decisions."[3,4], using classes of polyphenols as examples, suggested that the daily intake recommendations (or AI) of bioactives might be based upon amounts delivered by 5-a-day patterns that are associated with healthy endpoints. Other potential food components to consider could include: carotenoids, classes of dietary fiber, bioactive peptides, isothiocyanates, allyl sulfides, and etc.

Are there consequences of inaction? Inaction could suppress critical research to close gaps in knowledge and provide the "open range" for supplement claims. Inaction may further confuse consumers and continue the state of current food consumption patterns, for example, poor consumption of fruits, vegetables and whole grains.

CONCLUSIONS

Actions are needed to assist in developing public health messages for non-essential food components. The current DRI framework may limit scholarly evaluation and potential "accreditation" of the contributions of bioactive substances in foods to overall healthfulness. Development of RDA's for bioactives are not likely to occur. It is suggested that the AI might be an approach where accredited food bioactives might receive approval from health policy groups. The AI, as defined by the Food and Nutrition Board of the Institute of Medicine, appears to be appropriate. We urge continued international discussion regarding health effects of non-essential food bioactives and eventual communication of these benefits to consumers.

REFERENCES

1. Blumberg, J., Heaney, R. P., Huncharek, M., Scholl, T., Stampfer, M., Vieth, R., Weaver, C. M. and Zeiselm S. H. 2010. Evidence-based criteria in the nutritional context. Nutr. Rev. 68: 478-84.
2. Otten, J. J., Hellwig, J. P. and Meyers, L. D. 2006. Dietary reference intakes: the essential guide to nutrient requirements. National Academies Press. Washington, DC.
3. Shao, A. and Mackay, D. 2010. A Commentary on

the Nutrient-Chronic Disease Relationship and the New Paradigm of Evidence-Based Nutrition. Nat. Med. J. http://naturalmedicinejournal.com/article_content.asp?article=117.

4. Williamson, G. and Holst, B. 2008. Dietary reference intake (DRI) value for dietary polyphenols: are we heading in the right direction? Br. J. Nutr. 99: S55-S58.