Which Dietary Reference Intake Is Best Suited to Serve as the Basis for Nutrition Labeling for Daily Values?[1,2]

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Abstract

The U.S. Food and Drug Administration is currently reviewing regulations on nutrition labeling to better address current health issues as well as updating nutrient daily values (DVs), most of which are still based on recommended dietary allowances (RDAs) established in 1968. In 2003 the Committee on Use of Dietary Reference Intakes in Nutrition Labeling of the Institute of Medicine recommended that the DVs be based on the estimated average requirement (EAR) rather than the RDA and that a population-weighted mean of EARs be used. The rationale given is that the EAR is the best statistical approximation of the nutrient requirement for any one individual in the population, and its use would result in a food appearing more nutritious, as it would provide a greater percentage of the DV if the DV were a smaller amount. Concerns about these recommendations focus on the appropriate role of the Nutrition Facts panel, 1 of the 3 major public nutrition education tools in the United States (along with MyPyramid and Dietary Guidelines for Americans). Providing a benchmark or standard that knowingly has only a 50% chance of meeting a consuming individual's requirement is not appropriate. The DV on a Nutrition Facts panel should provide useful guidance to the individual about how a serving will assist in meeting that person's goal for consumption, and thus it should be based on the RDA or adequate intake, rather than the EAR, and be derived from the highest recommended intake, as has been the practice since 1973. J. Nutr. 136: 2457–2462, 2006.

Introduction

In 1994, the Food and Nutrition Board (FNB)[4] of the Institute of Medicine (IOM), The National Academies, initiated the expansion of the recommended dietary allowances (RDAs) to include other reference values (1). Since 1997, periodic reports from the FNB have established multiple dietary reference intakes (DRIs) that include not only recommended intakes but also additional reference intake values for both the U.S. and Canada (2). While 2 reports from the FNB provided general guidance in how the various DRIs should be applied to dietary assessment and planning for individuals and groups (3,4), specific guidance with recommendations on how to apply the DRIs to food and dietary supplement labels were not included. In 2002 Health Canada and the U.S. Food and Drug Administration (FDA) requested specific guidance from the FNB on how to appropriately use the DRIs in nutrition labeling. In November 2003 the IOM/FNB Committee on Use of Dietary Reference Intakes in Nutrition Labeling issued its report (5).

The purpose of this article is to discuss 2 of the report's major recommendations, namely, which category of DRI should be used as the basis for nutrition labeling and should a population-weighted mean be used. To do this, a brief background on nutrition labeling is presented, followed by the recent IOM recommendations. (Although the DRIs were developed by both U.S. and Canadian scientists for use in both countries, legislation regarding nutrition labeling differs in Canada and the United States. This article is directed toward their use in nutrition labeling in the United States, recognizing that many of the issues identified remain the same regardless of the differing legislation.) The remainder of the article identifies concerns related to the recommendations and presents an alternative after reviewing information on the purpose of nutrition labeling. Others have commented recently on these recommendations as well (6).

Historical development of nutrition labeling in the United States

Over one-half of the U.S. population has grown up with nutrition labeling of food, dietary supplements, and specialized dietary products in some form or another. For over 30 y, information regarding the content of major nutrients as well as the percent a serving provides of a standard reference value based on the RDAs of the FNB of the National Academy of Sciences (7) has been displayed on food products in the United States.

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[2] A description of statute and U.S. Food and Drug Administration regulations regarding nutrition labeling and the role of the DV in food-based fortification is available with the online posting of this paper at jn.nutrition.org.

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[4] Abbreviations used: AI, adequate intake; CV, coefficient of variation; DRI, dietary reference intake; DRV, daily reference value; DV, daily value; EAR, estimated average requirement; FDA, U.S. Food and Drug Administration; FNB, Food and Nutrition Board; IOM, Institute of Medicine; NLEA, Nutrition Labeling and Education Act of 1990; RDA, recommended dietary allowance.

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At the inception of labeling in 1972 the FDA stated that the inclusion of a daily dietary intake standard was to enable consumers to determine the contribution a food would make to their daily intake of nutrients (8). Nutrition scientists at the time favored standards based on recommended intakes, recommending use of the adult male standard (7,8). The label values, the U.S. RDAs, were derived from nutrient recommendations in the 7th edition of the *Recommended Dietary Allowances* issued in 1968 (9). The final rule establishing this as a voluntary effort was published January 19, 1973 (7).

While a single set of values could not be considered reflective of the specific nutrient requirements of each consumer, the values could be considered useful for comparing relative nutrient contributions of items so labeled to the overall diet (10). The FDA, following the expert advice previously mentioned, proposed that the U.S. RDAs be based on the highest 1968 RDA value for each nutrient for nonpregnant, nonlactating persons ages 4 y and older (11). [This was true except for calcium and phosphorus, which were based on a level between that recommended for adults (800 mg/d) and that for adolescent boys (1400 mg/d) and girls (1300 mg/d).] As a result, the U.S. RDAs were in fact greater than the recommended intakes (RDAs) for some of the age and gender groups in the population for whom this voluntary labeling was intended (10).

Processed food labels thus carried nutrition labeling on a voluntary basis until February 1994 when, as a result of new authority granted by Congress to the FDA as part of the Nutrition Labeling and Education Act of 1990 (NLEA), it became mandatory for almost all processed foods to display the Nutrition Facts panel (11).

In implementing NLEA, the FDA issued regulations that established the daily value (DV); DVs continued to be based on the 1968 RDAs, while daily reference values (DRVs) were established and served as the basis for DVs for other nutrients and food components such as cholesterol (11). Thus, currently DVs on foods and dietary supplements in the U.S. are based on recommended intakes for many nutrients last reviewed in 1968, resulting in a significant need to update the DVs to reflect current science.

IOM recommendations

Current food and dietary supplement regulations related to nutrition labeling continue to be based on NLEA, and thus the 2003 recommendations from the IOM/FNB committee were provided to assist the U.S. FDA in revising current regulations to be in concert with the new DRIs.

The IOM committee recommended that the Nutrition Facts panel contain both the amount of a nutrient by weight and also as a percentage of a DV (%DV) (5). It also recommended 2 fundamental changes: 1) the %DV be based on the EAR, 1 of the new DRIs, rather than the RDA (which continues to be 1 of the categories of DRIs); and 2) that the EAR used should be a population-weighted mean of EARs, rather than selecting the highest value of an EAR for any age-and-gender group.

The rationale given for making these recommendations is quoted below:

"The best point of comparison for the nutrient contribution of a particular food is the individual's nutrient requirement. It is almost impossible to know the true requirement of any one individual, but a reasonable estimate can be found in the median of the distribution of requirements, or the EAR.... [T]he EAR represents the best current scientific estimate of a reference value for nutrient intake based on experimental and clinical studies that have defined nutrient deficiency, health promotion, and disease prevention requirements.... A level of intake above or below the EAR will have a greater likelihood of systematically over- or underestimating an individual's needs. The RDA is derived from the EAR and is defined to be 2 standard deviations above the EAR on the nutrient requirement distribution curve. Therefore the RDA is not the best estimate of an individual's requirement. For these reasons the committee recommends the use of a population-weighted EAR as the basis for the DV when an EAR has been set for a nutrient. This approach should provide the most accurate reference value for the majority of the population (5, p. 7)."

Of the 39 nutrients that have 1 or more of the categories of DRIs, 19 nutrients have EARs; for 15 other nutrients, no EAR could be established, and thus no RDA was set. For this group, another category of DRIs representing a recommended intake, the adequate intake (AI), is provided for use in dietary guidance until such time as an EAR (and consequently, an RDA) may be established. For these nutrients, the IOM report recommends that the AI be used until an EAR is developed in future revisions of the DRIs.

Concerns with the approaches recommended

The conclusions of the IOM/FNB committee that the EAR is the best reference value from which to derive the DV, and that it should be a population-weighted mean of EAR values, are of significant concern. When little is known about an individual's requirement, should it be deemed acceptable to provide a benchmark that would knowingly *not* be expected to meet the requirements of one-half of the individuals for whom it was intended? As explained below, the purpose of the DV on a Nutrition or Dietary Supplement Facts panel should be to provide guidance to the individual about how 1 serving will assist in meeting that person's daily *goal* for consumption.

Use of the EAR vs. the RDA

If the question is "what one number is the best estimate of the nutrient requirement for a given individual?" by definition within the DRI conceptual model (3), the EAR is that number. Approximately one-half of similar individuals will require more, one-half will require less, and thus it is the closest number, on average, to an individual's requirement. In this respect, the committee's conclusion regarding the EAR as the best available estimate of *requirement* for a given individual is correct.

However, if the question that is really most important in assisting the consumer is "what is the best (and lowest) estimate of an intake value that will meet the requirements of practically *all* who will be using the label in the population?" then the best available reference value for that number is the RDA. The primary issue of concern, then, is whether the EAR, as compared with the RDA, is the best choice for the purposes of NLEA.

EARs derived differently than past RDAs. Many of the issues identified as problematic disappear if the RDA were to be continued as the basis for nutrition labeling. In the context of the DRIs, the RDA is defined specifically as the recommended intake that meets the requirements of almost all those in the population subgroup for whom it is established. The AI, similarly, is a recommended intake for an individual, but because it is not based on data from an EAR, its derivation contains a greater degree of judgment.

Whereas most of the DVs currently in use are based on the RDAs from 1968 (9) and a few from 1989 (12) as required by regulation (13), there are now substantially more data on human

requirements for nutrients than existed 2–4 decades ago. The new RDAs for many nutrients are lower than those from 1968, reflecting the DRI approach to specifically setting them based on 2 standard deviations above the average requirement estimate, as opposed to methods used in 1968 where often the minimum amount required for all subjects tested was determined and a safety factor added (9).

Despite the significant advances in the understanding of human nutrient requirements, EARs are derived from data from relatively few subjects, because dose response data are required to establish a median or average requirement among individuals and such data are typically extremely limited (2).

Vitamin C as an example. The key data set used to develop the EAR for vitamin C (14) is from Levine et al. (15) in which 6 male subjects were evaluated at multiple levels of vitamin C intake while neutrophil ascorbate concentrations and urinary ascorbate excretion, among other indicators, were measured. The EAR corresponds to the level of intake tested at which one-half of the subjects (n = 3) had acceptable neutrophil ascorbate concentrations as well as urinary excretion (and thus, 3 did not). If such an EAR is chosen as the DV and becomes the comparison value to "evaluate the context of a serving in terms of an individual's diet," it will identify an amount that should be inadequate for one-half of the group of individuals in a similar subgroup who consume that level.

Safety factors no longer added. In earlier FNB nutrient recommendations that were used as the basis for the U.S. RDA, after the minimum amount required for all subjects was determined, a safety factor was added to the amount thought to be adequate to obtain the RDA (12). Thus, if all subjects had adequate leukocyte ascorbate concentrations at a given level, that level might be increased by 20 or 30 or even 50% to provide for the fact that others in a similar group might still require more. In the 1980 and 1989 RDAs the amount determined to provide for an adequate pool size of vitamin C was increased by 33% as a safety factor (12).

In the case of the current RDAs provided in the DRI reviews, no safety factor was added to an amount found to be minimally adequate for all; instead, the median requirement was determined (the EAR) and then 2 standard deviations, representing the expected variability in requirements, were added to obtain the RDA, an amount thus expected to meet the requirement for almost all in the specified population subgroup (actually 97–98%).

CV often based on default assumptions, not measured from requirement data. For all but 7 of the nutrients which have EARs, due to the few number of data points used to derive the EAR, a data-derived coefficient of variation (CV) could not be calculated, so a default CV of 10% based on the observed variation in energy requirements was assumed (2). The EAR was then increased by 20% (twice the CV) to provide for 2 standard deviations above the median requirement (the EAR) to obtain the RDA.

So, while the term RDA has been used in earlier recommendations as well as within the current DRI system, the method to obtain the RDA is much more specific in the DRI system and does not include a safety factor. The EAR upon which it is based is much more closely tied to a very limited dataset and more assumptions are included in deriving the RDA. This enhances the possibility that, although the EAR is our best estimate of the mean or median requirement for a group of individuals, it may actually underestimate the requirements of >50% of the group for whom it is established.

The resulting RDA also has the same potential problem, compounded by the default CV used, but because it is designated as an amount to meet the requirements of almost all individuals in the group, the number of individuals whose requirement will not be met is far less in the event of an underestimation of either the median requirement or the actual variation in requirements (CV) for the nutrient of interest.

Use of population weighting

The IOM report also recommends that the EAR or AI used as the DV be a mean of all of the EARs or AIs for a nutrient based on the relative population size in the U.S. of individuals ages 4 y through adulthood—a population-weighted mean (5). This is a fundamental change in the basis of the DV, which is currently based on the highest RDA for age and gender groups (with a few specific exceptions). Population-weighting results in the requirements of fewer individuals in the population being met by the DV than if the highest value had been chosen, regardless of whether it is based on the EAR or RDA. When the highest RDA is chosen (as has been past practice), the requirements of only 2–3% of one of the subgroups in the population (the one with the highest RDA) would not be met, thus covering the greatest number of individuals; however, if a population-weighted mean of RDAs is chosen, then more people in the population would not be covered, as the value would be less than if population weighting had not been applied (and if a population-weighted EAR is used, the requirements of a vastly larger group within the population would not be met).

DRI method to extrapolate to other age and gender groups. Concerns regarding use of population weighting further increase when one examines how DRIs are derived for subgroups for which data are not available to directly set DRIs. To obtain DRIs for other age and gender groups that were not studied directly and for whom no data were available, the RDA or AI obtained from an available dataset (usually, from young men) was typically extrapolated to these other subgroups. The extrapolation was based on valid scientific assumptions, such as known differences in body weight, energy expenditure, estimated growth needs, body water compartments, body composition, kidney function, etc. (2). This approach to fill in missing data was used in earlier RDA reports (12).

Such derived RDAs for other age and gender groups are thus not based on direct experimental evidence regarding the identified criterion of adequacy—for vitamin C, neutrophil ascorbate and urinary excretion (14)—and must be based on additional assumptions which may prove to be untenable in light of future research. This extrapolation adds additional uncertainty to the derived RDA, which may well be compounded when incorporated into a population-weighted value.

Resulting coverage of consumers. RDAs vary by age group and gender; population-weighted RDAs would thus be lower than the specific RDA for some age and gender groups. Many of the RDAs for pregnant women are greater than for young adult men; however, pregnant women are specifically excluded as a population group in the weighting methodology recommended by the IOM/FNB committee, as well as past practice (11). One of the most dramatic examples is iron; a DV based on a population-weighted RDA would fall below the requirements of a substantial proportion of women of child-bearing age. If based on the highest RDA (for

iron, the highest RDA is for women of child-bearing age), then this vulnerable group's higher requirements would be covered by the DV, and only 2–3% would be at risk of inadequacy. Another example is vitamin B-6: the elderly have higher requirements than do younger adults, so a population-weighted RDA would not ensure a low risk of inadequacy for this age group.

Purpose of nutrition labeling

In the authority given to FDA by statute, the intent of NLEA is not specific on the issue of whether guidance is to be based on a population estimate of the requirement versus based on providing a goal that can be used by an individual (see online supplemental data for a description of the sequence of Congressional and FDA statements relative to the purposes of nutrition labeling). In public debate, it was stated that the IOM study was to develop guidance for the population, not for the individual, referring to the preamble of the Federal Register notice of 1993 in which the FDA issued the final regulations implementing NLEA (11) (Experimental Biology 2005, "ASNS/ASCN Public Information Committee Symposium: The Food Label Debate: Dietary Reference Intake for Food Labeling", April 4, 2005, San Diego, CA).

This view of the purpose of NLEA, however, is countered by a number of examples, both in FDA public documents as well as the FDA's own description of Congressional intent (16), which point to the basis of nutrition labeling being the provision of *recommended* dietary information.

Since 1973 when voluntary labeling was initiated, the % U.S. RDA, and subsequently the %DV, have been based on recommended intakes and designed to meet the requirements of almost all by taking the highest RDA values (10). The intent to assist consumers is clear and was described in FDA regulations substituting RDAs for minimum daily requirements (17).

The statement introduced by NLEA in amending the Federal Food, Drug, and Cosmetic Act of 1938 is relevant to the determination of the purpose of nutrition labeling; it is "to assist consumers in maintaining healthy dietary practices" and must be "conveyed in a manner such that they can understand the relative significance [of the nutritional information and recommended intake] in the context of a total daily diet."

Neither the wording in NLEA nor the implementing regulations promulgated by the FDA is clear-cut regarding whether the statutory purpose of nutrition labeling is to provide information for use by the individual or as general guidance to a population, but in no case does it focus on average requirements, but rather on recommended intakes. Clearly, if the intent is to educate the consumer, it is to provide assistance to the individual.

Relevance of the label to the individual

In reviewing the sparse data on how consumers and health professionals use nutrition information on the Nutrition Facts panel, it becomes apparent that few studies conducted go beyond the general question "do you use the DV?" Most researchers in nutrition and consumer/marketing disciplines who have undertaken studies evaluating how consumers use the label nutrition information assume that the DV is a goal for the individual, based on the phrasing used in their studies. Examples abound of where the DV is evaluated as a maximum level of intake for the consumer respondent in the case of sodium, fat, etc. (18–21), or as a minimum, in the case of nutrients such as fiber or calcium (20,22,23).

A number of studies conducted by FDA researchers underscore the use by the consumer of the DV as a personal goal that applies specifically and directly to him or her. For example, in an FDA telephone survey on cancer prevention, responders were asked whether they could use %DV to select food as part of *their* overall diet (24); in an FDA mall intercept study (25), shoppers were asked "How many servings of this food would you need to get all of the carbohydrates that *you need* in a day?" In referring to the 1972 FDA proposal to establish nutrition labeling, federal nutrition researchers noted that "this feature was to enable consumers to determine the contribution of foods to *their* daily intakes of nutrients" (10).

The FDA itself has long seen the need to provide for differences among the nutrient requirements of diverse subsets of the population by proposing, in August 2, 1973, that nutrient reference standards be available for foods targeted to 3 additional groups: infants, children younger than 4 y, and pregnant or lactating women (26).

More recently, the FDA established an Obesity Work Group (27) to examine the FDA's role in addressing obesity. Their report in 2004 called for giving more prominence to calories on the food label to assist the consumer in recognizing the importance of energy intake from food. The recommendations focused on label messages aimed at individuals, thus emphasizing the use of the label, not for population estimates of the requirement for energy, but to meet an individual's goal for energy intake.

As an educational tool, the DV should be the best surrogate available for a more specific goal for intake based on an individual's physiological state and age, a goal to attain or be within range of in terms of daily intake, as providing more than a single set of DVs on food labels would increase the level of complexity for consumers who already report experiencing confusion when reading current labels (22,28,29).

Studies conducted internationally also treat the reference amount as a goal for the individual (30–32) and in fact specifically point to the U.S. system as an example of where there is *less* confusion for consumers, as it includes a recommended intake, found to be of considerable use to consumers (33).

Thus, even if the correct interpretation of the Congressional mandate of NLEA is that it is to provide nutrition labeling to serve as a general description of a healthy diet for the population, it has been utilized by both consumers and nutritionists alike as a goal for an individual.

Use of the nutrition label in client education

Changing the underlying basis for the DV to the EAR after over 30 y of labeling based on recommended intakes requires substantial evaluation. Before implementing major changes in the underpinning of the DV, it is important to consider the ramifications to consumer education and understanding. Changes in the DV and what it stands for will not be apparent to the knowledgeable consumer or client unless the name is changed from DV, which was specifically not recommended in the IOM report (5). Even if changed, the differences may be easily obscured.

Added confusion and misunderstanding will inevitably result from the use of average requirements rather than allowances, as well as that resulting from mixing DVs derived from EARs with those derived from AIs on the Nutrition or Dietary Supplement Facts panel; these are 2 very different reference values defined and derived from completely different perspectives and with different meanings.

If a population-weighted value is adopted as the DV, it would no longer be possible to advise clients or individuals that they should aim for (or limit intake to) 100% of the DV, as each nutrient would have to be discussed individually, comparing the client or consumer's recommended intake (either RDA or AI) to

the population-weighted EAR or AI. Having a number that does not correspond to at least the RDA for an individual in a subgroup that has a higher requirement is one more translation that nutrition and dietetics professionals will have to make, and it is not a constant difference that could be easily determined, such as, "get 20% more," and it will be different for each nutrient.

Studies of the use of the current %DV show that consumers have difficulty with percentages (24,25,28,34–36), which could be assumed to intensify when adding a new step in using the label information effectively for personal nutrition. Similarly, unless regulations are rewritten, the Dietary Supplement Facts panel will continue to use the %DV. The %DV column for vitamin and mineral supplements formulated to provide 100% of the RDA for various nutrients for a specific group (such as men or women or the elderly) but required to be labeled in terms of the percentage of the population-weighted EAR or RDA, will show a confusing array of percentages, and the entire concept of the formulation will be obscured. One can envision that a woman advised to choose a folate supplement that provided 400 μg/d would have a problem: some supplements might provide 100% DV, but if the DV were 250 or 330 μg (based on a population-weighted mean of the EAR or RDA), what should she do? Perhaps she would take 2 supplements each day? This level of consumer confusion would not be easy to overcome.

One of the advantages put forward by proponents of using the population-weighted EAR rather than the RDA for the DV is that a serving of food would now contribute a greater percentage of the DV in the Nutrition Facts panel due to the lower DV, thus improving the apparent nutrient profile of the food item. Is this an advantage? If regulations regarding nutrient content claims are not modified, more foods will be able to make content claims, despite no change in their composition or formulation (such as a fruit juice that previously could not claim to be a good source of vitamin C because it contained <10% of the DV but could now make that claim because the DV was lower; or a product which was a good source of vitamin B-12 could now be labeled as an excellent source).

Nutrition education programs in the U.S.

There are 3 main federal nutrition education programs for the public in the United States: the food guide (MyPyramid), dietary guidelines (*2005 Dietary Guidelines for Americans*), and the nutrition label. Two of these have recently been revised (37,38); their updates relied in great part on the DRI reports for the scientific basis of their recommendations (39,40). Both of these public educational efforts are oriented toward providing recommendations to the individual. It makes little sense to revise the label, the third leg of federal nutrition education efforts, to become a population-based estimate of an average requirement rather than a tool of use to that individual in planning his or her diet. As has been the practice since 1973, in order to cover the requirements of almost all individuals in the population, the DV should be based on the RDA and derived from the highest value for age and gender groups 4 y and above.

Current status of label changes

As of this writing, the FDA has issued 2 Advanced Notices of Public Rule Making and requested comments in response to questions about the prominence of caloric content declaration on labels (41) and portion sizes and labeling for whole packages versus 1 serving (42). It is expected that in the near future, questions will also be posed relative to the use of nutrient reference values on the label and how to approach voluntary fortification.[5]

If there is controversy regarding the authorizing language in NLEA, then guidance from Congress should be sought via close examination of early documents in House and Senate records relative to NLEA. Although the authorizing language does not require that nutrition labeling be directed toward an individual's goal, it does not prohibit such assistance. The overwhelming use by nutrition counselors and others of the DV (and the U.S. RDA prior to NLEA) emphasizes that it represents an amount thought to meet or exceed the requirements of practically all those within the population, and as such, it represents 1 of the 3 cornerstones of food and nutrition policy and education of the public.

[5] Letter dated June 10, 2005 from Barbara O. Schneeman, Ph.D., Food and Drug Administration, U.S. Delegate to the Codex Committee on Nutrition and Foods for Special Dietary Uses, to Mrs. Antoinette Booyzen, NRV Working Group Coordinator for the Codex Committee. The relation of the DV to voluntary fortification is available as Online Supporting Material.

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