

# 4

## A Brief Review of the History and Concepts of the Dietary Reference Intakes<sup>1</sup>

The Dietary Reference Intakes (DRIs) are a set of reference values for specific nutrients, each category of which has special uses. The development of the DRIs replaces the reports on Recommended Dietary Allowances (RDAs), issued periodically from 1941 to 1989 by the National Academy of Sciences, and Recommended Nutrient Intakes (RNIs), published by the Canadian government (Canada, 1990). Seven reports have resulted from the comprehensive effort undertaken by the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes (DRI Standing Committee) of the Food and Nutrition Board (FNB), Institute of Medicine, the National Academies, and its panels and subcommittees (IOM, 1997, 1998, 2000a, 2000b, 2001, 2002a, 2003). This report on nutrition labeling and discretionary fortification is a derivative report that is separate from the DRI committee oversight process, yet is based entirely in the science and outcomes of the DRI reports. This chapter provides a brief description of the overall origin of the DRIs, the basic DRI concepts, and several issues from the DRI reports that are particularly relevant to nutrition labeling.

### ORIGIN

The DRI initiative began in June 1993, when FNB organized a symposium and public hearing entitled “Should the Recommended

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<sup>1</sup>This chapter is derived from the description of the DRIs in the macronutrient report (IOM, 2002a).

Dietary Allowances Be Revised?” Shortly thereafter, to continue its collaboration with the larger nutrition community on the future of the Recommended Dietary Allowances (RDAs), FNB prepared, published, and disseminated the concept paper “How Should the Recommended Dietary Allowances Be Revised?” (IOM, 1994), which invited comments regarding the proposed concept, and it held several symposia at nutrition-focused professional meetings to discuss its tentative plans and to receive responses to the concept paper. Many aspects of the conceptual framework of the DRIs came from the United Kingdom’s report *Dietary Reference Values for Food Energy and Nutrients in the United Kingdom* (COMA, 1991).

The five general conclusions presented in FNB’s concept paper were:

1. Sufficient new information has accumulated to support a reassessment of the RDAs.
2. Where sufficient data for efficacy and safety exist, reduction in the risk of chronic degenerative diseases is a concept that should be included in the formulation of future recommendations.
3. Upper levels of intake should be established where data exist regarding risk of toxicity.
4. Components of food that may benefit health, although not meeting the traditional concept of a nutrient, should be reviewed, and if adequate data exist, reference intakes should be established for them.
5. Serious consideration must be given to developing a new format for presenting future recommendations.

Subsequent to the symposium and the release of the concept paper, FNB held workshops at which invited experts discussed many issues related to the development of nutrient-based reference values. In addition, FNB gave attention to the international uses of the earlier RDAs and the expectation that the scientific review of nutrient requirements should be similar for comparable populations.

Concurrently, Health Canada and Canadian scientists were reviewing the need for revision of the RNIs (Canada, 1990). Consensus following a symposium for Canadian scientists, cosponsored by the Canadian National Institute of Nutrition and Health Canada in April 1995, was that the Canadian government should pursue the extent to which involvement with the developing FNB process would benefit both Canada and the United States by leading toward harmonization.

Based on extensive input and deliberations, FNB initiated action to provide a framework for the development and possible inter-

national harmonization of nutrient-based recommendations that would serve, where warranted, for all of North America. To this end, in December 1995, FNB began a close collaboration with the government of Canada and took action to establish the DRI Standing Committee.

### RATIONALE FOR THE FRAMEWORK

The 1993 symposium and subsequent activities provided substantial evidence that a comprehensive, coordinated approach to developing DRIs was needed for diet planning, nutritional assessment, and nutrition policy development. The current framework is based on the following four assumptions:

1. Since the publication of the tenth edition of *Recommended Dietary Allowances* (NRC, 1989b) in the United States and the RNIs in Canada (Canada, 1990), there has been a significant expansion and evolution of the research base toward defining functional endpoints that are relevant to the understanding of nutrient requirements and food constituents and their relationship to a number of aspects of human health.

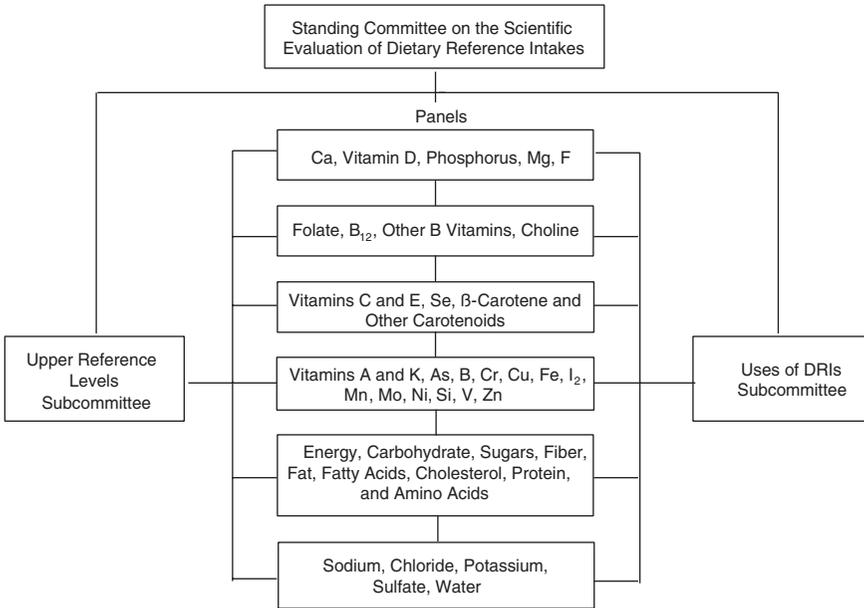
2. These advances allow the refinement of the conceptual framework for quantitatively defining nutrient requirements, as well as a clearer determination of the legitimate uses of nutrient requirement estimates and their derivatives in the interpretation and use of dietary intake data. Such uses might broadly be categorized according to whether they are: (a) prescriptive or planning applications, where suitable levels of nutrient intake by individuals and population groups are established, or (b) diagnostic or assessment applications, where determinations are made about the likely nutritional adequacy of the observed intake when considered in relation to appropriate nutrient requirement data. Major differences in the types of information required about nutrient needs and relevant nutrient intake data are fundamental to appropriately focusing on the individual or on a defined population group (Beaton, 1994).

3. Neither the RDAs nor the RNIs have been applied appropriately in many settings. The availability of only a single type of reference value in the face of various needs has led to inappropriate applications. Moreover, inconsistent methods and criteria for deriving certain RDAs and RNIs and insufficient documentation of methods and criteria have also contributed to inappropriate applications.

4. In these times of extensive international collaboration, agricultural and food exchange, and global nutrition-related health prob-

lems, harmonization of nutrient-based dietary standards between Canada and the United States is viewed as a first step, with the expectation that Mexico will be able to join in the future. Such harmonization within the North American continent would further global development of similar efforts. Although the same general approaches have been used by most countries in developing recommended nutrient intakes (e.g., RDAs in the United States, RNIs in Canada, and Dietary Reference Values in Great Britain), and physiological requirements for nutrients are expected to be similar across healthy population groups, many of the quantitative values that have emerged from the different national expert groups are quite divergent, largely reflecting differences in the interpretation and use of scientific data and often based on different food habits and indigenous diets. A mechanism is needed to determine the commonality of the bases on which recommendations are made and to use scientific data to indicate differences in requirements among apparently similar population groups in different geographic locations.

In 1995 the DRI Standing Committee was appointed to oversee and conduct the establishment of DRIs. It devised a plan involving the work of seven or more expert nutrient-group panels and two overarching subcommittees (Figure 4-1). The nutrient-group panels, composed of experts on those nutrients, were responsible for: (1) reviewing the scientific literature concerning specific nutrients under study for each stage of the lifespan, (2) considering the roles of nutrients in decreasing the risk of chronic and other diseases and conditions, and (3) interpreting the current data on nutrient intakes of North American population groups. The panels were charged with analyzing the literature, evaluating possible criteria or indicators of adequacy, and providing substantive rationales for their choices of each criterion. Using the criterion or criteria chosen for each stage of the lifespan, the panels estimated the average requirement for each nutrient or food component reviewed, assuming that adequate data were available. As the panel members reviewed data on requirements, they also interacted with two subcommittees regarding their group of nutrients. The Subcommittee on Upper Reference Levels was charged with reviewing possible risk assessment models for estimating levels of nutrients that may increase risk of toxicity or adverse effects and then assisting the panel to apply the model to each nutrient or food component reviewed. Similarly, the Subcommittee on the Interpretation and Uses of DRIs assisted the panels and the DRI Standing Committee in developing practi-

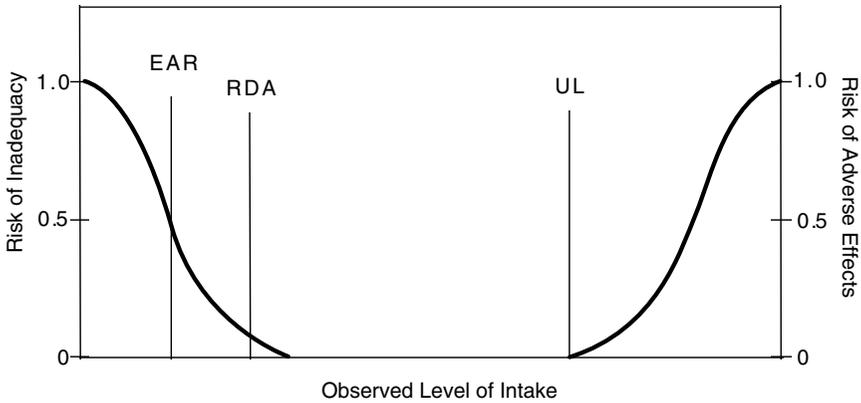


**FIGURE 4-1** Dietary Reference Intakes Standing Committee, Subcommittee, and Panel Structure.

cal information and guidance on using DRIs appropriately. Based on interaction with and information provided by the panels and subcommittees, the DRI Standing Committee determined the DRI values to be included in the reports (IOM, 1997).

### WHAT ARE DIETARY REFERENCE INTAKES?

The DRIs include the Estimated Average Requirement (EAR), the RDA, the Adequate Intake (AI), and the Tolerable Upper Intake Level (UL). Establishment of these reference values requires that a criterion be carefully chosen for each nutrient and that the population for whom these values apply be carefully defined. For the DRIs a requirement is defined as the lowest continuing intake level of a nutrient that, for a specific indicator of adequacy, will maintain a defined level of nutriture in an individual (IOM, 1997). The chosen criterion or indicator of nutritional adequacy upon which the EARs and AIs are based is identified for each nutrient. The criterion may differ for individuals at different life stages. Particular attention is



**FIGURE 4-2** Dietary reference intakes. This figure shows that the Estimated Average Requirement (EAR) is the intake at which the risk of inadequacy is estimated to be 0.5 (50 percent) to an individual. The Recommended Dietary Allowance (RDA) is the intake at which the risk of inadequacy would be very small—only 0.02 to 0.03 (2 to 3 percent). At intakes between the RDA and the Tolerable Upper Intake Level (UL), the risks of inadequacy and of excess are both estimated to be close to 0. At intakes above the UL, the potential risk of adverse effects may increase. SOURCE: IOM (2002a).

given in each DRI report to the choice and justification of the criterion used to establish requirement values and the intake levels beyond which the potential for increased risk of adverse effects may occur.

## CATEGORIES OF DIETARY REFERENCE INTAKES

### *Estimated Average Requirement*

The *Estimated Average Requirement*<sup>2</sup> (EAR) is the daily intake value that is estimated to meet the requirement, as defined by the specified indicator or criterion of adequacy, in half of the apparently healthy individuals in a life stage or gender group (see Figure 4-2).

<sup>2</sup>The definition of the EAR implies a median as opposed to a mean, or average. The median and average would be the same if the distribution of requirements followed a symmetrical distribution and would diverge as a distribution became skewed.

(A normal or symmetrical distribution [median and mean are similar] is usually assumed for nutrient requirements.) This use follows the precedent set by others that have used the term “Estimated Average Requirement” for reference values similarly derived, but meant to be applied to population intakes (COMA, 1991).

The EAR’s usefulness as a predictor of an individual’s requirement depends on the appropriateness of the choice of the nutritional status indicator or criterion and the type and amount of data available. The general method used to set the EAR is the same for all nutrients. The specific approaches differ since each nutrient has its own indicator(s) of adequacy, and different amounts and types of data are available for each. Thus, coupled with an estimate of the variance in requirements, the EAR has served three major functions: as the basis for the RDA, as the primary reference point for assessing the adequacy of estimated nutrient intakes of groups (IOM, 2000a), and, together with estimates of the variance of intake, in planning for the intake of groups (IOM, 2003).

### *Recommended Dietary Allowance*

The *Recommended Dietary Allowance* (RDA) is an estimate of the minimum daily average dietary intake level that meets the nutrient requirements of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group (see Figure 4-2). The RDA is intended to be used as a goal for daily intake by individuals as this value estimates an intake level that has a high probability of meeting the requirement of a randomly chosen individual (about 97.5 percent). However the RDA is not an appropriate value to use to assess the adequacy of intakes. The process for setting the RDA is described below; it depends on being able to set an EAR and estimating the variance of the requirement itself. Note that if an EAR cannot be set due to limitations of the data available, no RDA will be set.

This approach differs somewhat from that used by the World Health Organization, Food and Agriculture Organization of the United Nations, and International Atomic Energy Agency (WHO/FAO/IAEA) Expert Consultation on *Trace Elements in Human Nutrition and Health* (WHO, 1996). That publication uses the term basal requirement to indicate the level of intake needed to prevent pathologically relevant and clinically detectable signs of dietary inadequacy. The term normative requirement indicates the level of intake suffi-

cient to maintain a desirable body store or reserve. In developing an RDA (and AI, see below), emphasis is placed instead on the reasons underlying the choice of the criterion of nutritional adequacy used to establish the requirement. It is not designated as basal or normative.

*Method for Setting the RDA When Nutrient Requirements Are Normally Distributed*

When the distribution of a requirement for a nutrient among individuals in a group can be assumed to be approximately normal (or symmetrical) and a standard deviation (SD) of requirement ( $SD_{\text{requirement}}$ ) can be determined, the EAR can be used to set the RDA as follows:

$$RDA = EAR + 2 \times SD_{\text{requirement}}$$

If data about variability in requirements are insufficient to calculate an  $SD_{\text{requirement}}$  for that specific nutrient in that population group, but normality or symmetry can be assumed, then a coefficient of variation (CV) of 10 percent is assumed and the calculation becomes:

$$RDA = EAR + 2 (0.1 \times EAR) = 1.2 \times EAR$$

The assumption of a 10 percent CV is based on extensive data on the variation in basal metabolic rate (FAO/WHO/UNA, 1985; Garby and Lammert, 1984) and the CV of 12.5 percent estimated for the protein requirements in adults (FAO/WHO/UNA, 1985). If there is evidence of greater variation, a larger CV is used. In all cases, the method used to derive the RDA from the EAR is stated in the DRI reports.

Since it is derived from the EAR, the RDA's usefulness as a goal depends on the choice of nutritional status indicator or criterion and the type and amount of data available. Its applicability also depends on the accuracy of the form of the requirement distribution and the estimate of the variance of requirements for the nutrient in the population subgroup for which it is developed. For many of the nutrients there are few direct data on the requirements of children and the elderly. In the case of children, EARs and RDAs are based on extrapolations from adult values.

*Method for Setting the RDA When Nutrient Requirements Are Not Normally Distributed*

For most of the nutrients for which EARs have been established, the required assumption of distribution of requirements is that of symmetry about the mean. In the case of iron, a nutrient of concern in many subgroups in the population in the United States, Canada, and other areas, requirements are known to follow a non-normal distribution. Thus a different method was needed to determine the intake of iron at which half of the individuals would be expected to be inadequate in the criterion used to establish adequacy (the EAR) and also to construct an intake level at which only a small percentage of the population would be inadequate (the RDA).

If the requirement of a nutrient is not normally distributed but can be transformed to normality, its EAR and RDA can be estimated by transforming the data, calculating the 50th and 97.5th percentiles, and transforming these percentiles back into the original units. In this case the difference between the EAR and the RDA cannot be used to obtain an estimate of the SD of the CV because skewing is usually present.

When factorial modeling is used to estimate the distribution of requirement from the distributions of the individual components of requirement, as was done in the case of iron recommendations (IOM, 2001) and for the maintenance and growth components of the recommendations for children for protein and amino acids (IOM, 2002a), it is necessary to add the individual distributions (convolutions). This is easy to do given that the average requirement is simply the sum of the averages of the individual component distributions, and an SD of the combined distribution can be estimated by standard statistical techniques. The 97.5th percentile can then be estimated.<sup>3</sup> If normality cannot be assumed for all of the components of requirement, then Monte Carlo simulation is used for the summation of the components. This approach models the distributions of the individual distributions and randomly assigns values to a large simulated population. The total requirement is then calculated for each individual and the median and the 97.5th percentile are calculated directly. As was the case for iron (IOM, 2001), the underlying joint distribution is approximated and a large

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<sup>3</sup>For further elaboration of this method, see Chapter 9 and Appendix I of *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc* (IOM, 2001).

number of individuals (100,000) are randomly generated. Information about the distribution of values for the requirement components is modeled on the basis of known physiology. Monte Carlo approaches may be used in the simulation of the distribution of components; where large data sets exist for similar populations (e.g., growth rates in infants), estimates of relative variability may be transferred to the component in the simulated population (Gentle, 1998). At each step the goal is to achieve distribution values for the component that not only reflect known physiology or known direct observations, but also can be transformed into a distribution that can be modeled and used in selecting random members to contribute to the final requirement distribution. When the final distribution representing the convolution of components has been derived, then the median and 97.5th percentiles of the distribution can be directly estimated. It is recognized that in its simplest form the Monte Carlo approach ignores possible correlation among components. In the case of iron, however, expected correlation is built into the modeling of requirement where components are linked to a common variable (e.g., growth rate) so that not all sources of correlation are neglected.

### *Adequate Intake*

If sufficient scientific evidence is not available to calculate an EAR, a reference intake called an *Adequate Intake* (AI) is provided instead of an RDA. The AI is a value based on experimentally determined approximations or estimates of observed median nutrient intakes by a group (or groups) of healthy people. In the judgment of the DRI Standing Committee, the AI is expected to meet or exceed the amount needed to maintain a defined nutritional state or criterion of adequacy in essentially all members of a specific, apparently healthy population. Examples of defined nutritional states include normal growth, maintenance of normal circulating nutrient values, or other aspects of nutritional well-being or general health.

For young infants for whom human milk is the recommended sole source of food for most nutrients for the first 4 to 6 months of life, the AI is based on the daily mean nutrient intake supplied by human milk for healthy, full-term infants who are exclusively fed human milk. The goal may be different for infants consuming infant formula for which the bioavailability of a nutrient may be different from that in human milk. For adults the AI may be based on data from a single experiment, on estimated dietary intakes in apparently healthy population groups, or on a review of data from different

approaches that, when considered alone, do not permit a reasonably confident estimate of an EAR.

### *Comparison of Recommended Dietary Allowances and Adequate Intakes*

There is much less certainty about an AI value than about an RDA value. Because AIs depend on a greater degree of judgment than is applied in estimating an EAR and subsequently an RDA, an AI may deviate significantly from, and be numerically higher than, an RDA. For this reason AIs must be used with greater care than is the case for RDAs. Also, an RDA is usually calculated from an EAR by using a formula that takes into account the expected variation in the requirement for the nutrient.

Both the AI and the RDA are to be used as goals for individual intake. In general the values are intended to cover the needs of nearly all apparently healthy persons in a life stage group. (For infants the AI is the mean intake when infants in the age group are consuming human milk. Larger infants may have greater needs, which they meet by consuming more milk.) The AI for a nutrient is expected to exceed the RDA for that nutrient, and thus it should cover the needs of more than 97 to 98 percent of individuals in the life stage group. The degree to which the AI exceeds the RDA is likely to differ among nutrients and population groups. As with RDAs, AIs for children and adolescents may be extrapolated from adult values if no other usable data are available.

For people who have diseases that increase specific nutrient requirements or who have other special health needs, the RDA and AI each may serve as the basis for adjusting individual recommendations. Qualified health professionals should adapt the recommended intake to cover higher or lower needs.

### *Tolerable Upper Intake Level*

The *Tolerable Upper Intake Level* (UL) is the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects for almost all individuals in the specified life stage group (see Figure 4-2). As intake increases above the UL, there is the potential for an increased risk of adverse effects. The term *tolerable* was chosen to avoid implying a possible beneficial effect. Instead the term is intended to connote a level of intake that can, with high probability, be tolerated biologically. The UL is not intended to be a recommended level of intake as there is no established benefit for healthy

individuals if they consume a nutrient in amounts exceeding the recommended intake (the RDA or AI).

The UL is based on an evaluation conducted by using the methodology for the risk assessment of nutrients. The need for ULs has arisen because high consumption levels of some nutrients have resulted from the increased nutrient fortification of conventional foods and the increasing use of dietary supplements. The UL applies to chronic daily use and is usually based on the total intake of a nutrient from food, water, and supplements if adverse effects have been associated with total intake. However, if adverse effects have been associated with intake from supplements or food fortificants only, the UL is based on nutrient intake from one or both of those sources only rather than on total intake. As in the case of applying AIs, professionals should avoid very rigid application of the ULs and should first assess the characteristics of the individual or group of concern (e.g., the source of nutrient, the physiological state of the individual, and the length of sustained high intakes).

For some nutrients data may not be sufficient to develop a UL. This indicates the need for caution in consuming amounts greater than the recommended intake; it does not mean that high intake poses no potential for risk of adverse effects.

The safety of routine, long-term intake above the UL is not well documented. Although the general population should be advised not to routinely exceed the UL, intake above the UL may be appropriate for investigation within well-controlled clinical trials. Clinical trials of doses above the UL should not be discouraged as long as participants have signed informed consent documents regarding possible toxicity and they are appropriately monitored. Because the DRI concept is relatively new, there are few published reports that have examined population-based intake levels in the context of the UL. Recent dietary intake studies, which take into account nutrients from conventional food and dietary supplements, have demonstrated total intake levels that regularly approach and sometimes exceed the ULs (Allen and Haskell, 2002; O'Brien et al., 2001). Long-term intake of nutrients at levels above the UL places individuals at risk for adverse effects, but only continued longitudinal research will be able to demonstrate the level of potential harm.

### *Life Stage Groups*

The life stage groups described below were chosen as part of the initial DRI process (IOM, 1997) while keeping in mind all the nutrients to be reviewed. If data were too sparse to distinguish differences

in requirements by life stage or gender group, the analysis provided in establishing the DRI for any given nutrient may have been presented for a larger grouping.

### *Infancy*

Infancy covers the period from birth through 12 months of age and is divided into two 6-month intervals. Except for energy in the macronutrient report, the first 6-month interval was not subdivided further because intake is relatively constant during this time. That is, as infants grow, they ingest more food; however, on a body-weight basis, their intake remains nearly the same. Growth velocity slows during the second 6 months of life, and thus daily nutrient needs on a body-weight basis may be less than needs during the first 6 months of life.

The average intake of nutrients by full-term infants who are born to healthy, well-nourished mothers and who are exclusively fed human milk has been adopted as the primary basis for deriving the AI during the first 6 months of life. The DRI values established are thus not EARs. The extent to which the intake of human milk may result in exceeding the actual requirements of the infant is not known, and ethics of human experimentation preclude testing the levels known to be potentially inadequate. Therefore, the AIs, while determined from the average composition of an average volume of milk consumed by this age group, are not EARs in which only half of the group would be expected to have their needs met.

Using the infant fed human milk as a model is in keeping with the basis for estimating nutrient allowances of infants developed in the last revisions of the RDA (NRC, 1989b) and the RNI (Canada, 1990) reports. It also supports the recommendation that exclusive breastfeeding is the preferred method of feeding for normal, full-term infants for the first 4 to 6 months of life. This recommendation has also been made by the Canadian Paediatric Society (Canada, 1990), the American Academy of Pediatrics (AAP, 1997), and in the FNB report *Nutrition During Lactation* (IOM, 1991).

In general special consideration was not given to possible variations in physiological need during the first month after birth or to the variations in intake of nutrients from human milk that result from differences in milk volume and nutrient concentration during early lactation. Specific DRIs to meet the needs of formula-fed infants have not been proposed in the DRI reports. The previously published RDAs and RNIs for infants have led to much misinterpretation.

tation of the adequacy of human milk because of a lack of understanding about their derivation for young infants. Although they were based on human-milk composition and volume of intake, the previous RDA and RNI values allowed for the lower bioavailability of nutrients from nonhuman milk. However, where warranted, information on specific changes in the bioavailability or the source of nutrients for use in developing formulations is included in the DRI reports.

*Ages 0 through 6 Months.* To determine the AI value for infants ages 0 through 6 months, the mean intake of a nutrient was calculated by multiplying the average concentration of the nutrient in human milk produced during the second through sixth month of lactation (derived from consensus values from several reported studies [Atkinson et al., 1995]) by the average volume of milk intake of 0.78 L/day (as reported from studies of full-term infants by test weighing [Butte et al., 1984; Chandra, 1984; Hofvander et al., 1982; Neville et al., 1988]). Because there is variation in both of these measures, the computed value represents the mean. It was assumed that infants have adequate access to human milk and that they consume increased volumes as needed to meet their requirements for maintenance and growth.

*Ages 7 through 12 Months.* EARs were developed for these older infants for iron, zinc, and protein (IOM, 2001, 2002a). The reference body-weight method was used in the DRI reports to extrapolate the AI for infants 0 through 6 months of age to an AI for older infants in the absence of direct data on older infants (IOM, 1997). The extrapolation method was not deemed appropriate for dietary fats or carbohydrate in the macronutrient report (IOM, 2002a). This is because the amount of energy required on a body-weight basis is significantly lower during the second 6 months of life, due largely to the slower rate of weight gain per kilogram of body weight. Therefore the basis of the AI values derived for this age category for dietary fats and carbohydrate was the sum of the specific nutrients provided by 0.6 L/day of human milk (the average intake of infants in this age group [Heinig et al., 1993]) and that which was provided by their usual intake of complementary weaning foods (Specker et al., 1997). This approach is in keeping with the recommendations of the Canadian Paediatric Society (Canada, 1990), the American Academy of Pediatrics (AAP, 1997), and *Nutrition During Lactation* (IOM, 1991) for continued feeding of human milk to infants through 9 to 12 months of age with the appropriate introduction of solid foods.

*Toddlers: Ages 1 through 3 Years*

Two points were primary in dividing early childhood into two groups. First, the greater velocity of growth in height for children ages 1 through 3 years of age compared with those 4 through 5 years of age provides a biological basis for dividing this period of life. Second, because children in the United States and Canada begin to enter the public school system starting at age 4 years, ending this life stage prior to age 4 years seemed appropriate so that food and nutrition policy planners have appropriate targets and cutoffs for use in program planning.

Data are sparse for indicators of nutrient adequacy on which to derive DRIs for these early years of life. In these cases, extrapolation from data on 0- to 6-month-old infants has been employed (IOM, 1997, 1998, 2000b, 2001, 2002a).

*Early Childhood: Ages 4 through 8 Years*

Major biological changes in the velocity of growth and changing endocrine status occur in children 4 through 8 or 9 years of age (the latter depending on onset of puberty in each gender); therefore, the category of 4 through 8 years is appropriate. For many nutrients, a reasonable amount of data is available on nutrient intake and on various criteria for adequacy (e.g., nutrient balance measured in children 5 through 7 years of age) that can be used as the basis for the EARs and AIs for this life stage group.

*Puberty/Adolescence: Ages 9 through 13 Years and 14 through 18 Years*

Because current data support younger ages for pubertal development, it was determined that the adolescent age group should begin at 9 years. The mean age of onset of breast development (Tanner Stage 2) for white girls in the United States is  $10.0 \pm 1.8$  years (SD); this is a physical marker for the beginning of increased estrogen secretion (Herman-Giddens et al., 1997). In African-American girls, the onset of breast development is earlier (mean  $8.9 \pm 1.9$  years). The reason for the observed racial differences in the age at which girls enter puberty is unknown. The onset of the growth spurt in girls begins before the onset of breast development (Tanner, 1990); the age group of 9 through 13 years allows for the early growth spurt of African-American girls.

For boys the mean age of initiation of testicular development is 10.5 to 11 years, and their growth spurt begins 2 years later (Tanner,

1990). Thus, to begin the second age category at 14 years and to have different EARs and AIs for girls and boys for some nutrients at this age seems biologically appropriate. All children continue to grow to some extent until as late as age 20 years; therefore, having these two age categories span the period 9 through 18 years of age seems justified.

*Young Adulthood and Middle Ages: Ages 19 through 30 Years and 31 through 50 Years*

The recognition of the possible value of higher nutrient intakes during early adulthood on achieving optimal genetic potential for peak bone mass was the reason for dividing adulthood into ages 19 through 30 years and 31 through 50 years. Moreover, mean energy expenditure decreases during this 30-year period, and needs for nutrients related to energy metabolism may also decrease. For some nutrients, the DRIs may be the same for the two age groups. However, for other nutrients, especially those related to energy metabolism, EARs (and RDAs) are likely to differ for these two groups.

*Adulthood and Older Adults: Ages 51 through 70 Years and Over 70 Years*

The age period of 51 through 70 years spans the active work years for most adults. After age 70, people of the same age increasingly display variability in physiological functioning and physical activity. A comparison of people over age 70 who are the same chronological age may demonstrate as much as a 15- to 20-year age-related difference in their level of reserve capacity and functioning. This is demonstrated by age-related declines in nutrient absorption and renal function. Because of the high variability in the functional capacity of older adults, the EARs and AIs for this age group may reflect a greater variability in requirements for the older age categories. This variability may be most applicable to nutrients for which requirements are related to energy expenditure.

*Pregnancy and Lactation*

Recommendations for pregnancy and lactation may be subdivided because of the many physiological changes and changes in nutrient need that occur during these life stages. In setting EARs and AIs for these life stages however, consideration was given to adaptations to increased nutrient demand, such as the increased absorption and

greater conservation of many nutrients. Moreover, nutrients may undergo net losses due to physiological mechanisms regardless of the nutrient intake. Thus, for some nutrients there may not be a basis for EAR values that are different from those for nonpregnant or nonlactating women of comparable age.

### *Reference Heights and Weights*

#### *Use of Reference Heights and Weights*

Reference heights and weights are useful when more specificity about body size and nutrient requirements are needed than that provided by life stage categories. For example, while the EAR may be developed for the 4- to 8-year-old age group, a small 4-year-old child may be assumed to require less than the EAR for that age group, whereas a large 8-year-old child may require more than the EAR. Based on the model for establishing RDAs however, the RDA (and for that matter, an AI) should meet the needs of both.

In cases where data regarding nutrient requirements are reported on a body-weight basis, it is necessary to have reference heights and weights to transform the data for comparison purposes. Frequently, where data regarding adult requirements represent the only available data (e.g., on adverse effects of chronic high intakes for establishing ULs), extrapolating on the basis of body weight or size becomes a possible option to estimate ULs for other age groups. Thus when data are not available, the EAR or UL for children or pregnant women may be established by extrapolation from adult values on the basis of body weight.

#### *Reference Heights and Weights Used in the Early DRI Reports*

The most up-to-date data providing heights and weights of individuals in the United States and Canada when the DRI process was initiated in 1995 were limited to anthropometric data from the 1988–1994 Third National Health and Nutrition Examination Survey (NHANES III) in the United States and older data from Canada. Reference values derived from the NHANES III data and used in early DRI reports are given in Table 4-1.

These earlier values were obtained as follows: the median heights for the life stage and gender groups through age 30 years were identified, and the median weights for these heights were based on reported median body mass indexes (BMIs) for the same individuals. Since there is no evidence that weight should change as adults age

**TABLE 4-1** Reference Heights and Weights for Children and Adults in the United States Used in the Vitamin and Element Dietary Reference Intake Reports

Sex	Age	Median Body Mass Index, kg/m <sup>2</sup>	Reference Height, cm (in)	Reference Weight <sup>a</sup> , kg (lb)
Male, female	2-6 mo	—	64 (25)	7 (16)
	7-12 mo	—	72 (28)	9 (20)
	1-3 y	—	91 (36)	13 (29)
Male	4-8 y	15.8	118 (46)	22 (48)
	9-13 y	18.5	147 (58)	40 (88)
	14-18 y	21.3	174 (68)	64 (142)
Female	19-30 y	24.4	176 (69)	76 (166)
	9-13 y	18.3	148 (58)	40 (88)
	14-18 y	21.3	163 (64)	57 (125)
	19-30 y	22.8	163 (64)	61 (133)

<sup>a</sup> Calculated from body mass index and height for ages 4 through 8 years and older.

SOURCE: IOM (1997, 1998, 2000a, 2000b, 2001). Adapted from the Third National Health and Nutrition Examination Survey, 1988-1994.

if activity is maintained, the reference weights for adults ages 19 through 30 years were applied to all adult age groups.

The most recent nationally representative data available for Canadians at the time (from the 1970-1972 Nutrition Canada Survey [Demirjian, 1980]) were also reviewed. In general median heights of children from 1 year of age in the United States were greater by 3 to 8 cm (1 to 2.5 in) than those of children of the same age in Canada measured two decades earlier (Demirjian, 1980). This difference could be partly explained by approximations necessary to compare the two data sets, but more likely by a continuation of the secular trend of increased heights for age noted in the Nutrition Canada Survey when it compared data from the 1970-1972 survey with a 1953 national Canadian survey (Pett and Ogilvie, 1956).

Similarly, median weights beyond age 1 year derived from the then most recent survey in the United States (NHANES III, 1988-1994) were also greater than those obtained from the older Canadian survey (Demirjian, 1980). Differences were greatest during adolescence, ranging from 10 to 17 percent higher. The differences probably reflect the secular trend of earlier onset of puberty (Herman-Giddens et al., 1997) rather than differences in populations. Calculations of BMI for young adults (e.g., a median of 22.6 for

Canadian women compared with 22.8 for U.S. women) resulted in similar values, thus indicating greater concordance between the two surveys by adulthood. The reference weights used in the earlier DRI reports (IOM, 1997, 1998, 2000a, 2000b, 2001) were thus based on the most recent data set available from either country, with recognition that earlier surveys conducted in Canada indicated shorter stature and lower weights during adolescence than did surveys conducted in the United States.

### *New Reference Heights and Weights*

Given the increasing prevalence of overweight and obesity in both adults and children, the use of population data, as was done with the earlier DRI reports, is of concern. With the recent publication of new U.S.-based growth charts for infants and children and the introduction of BMI recommendations for adults (Kuczmarski et al., 2000), reference heights and weights for children and adults have been updated. These data have allowed the development of new reference heights and weights for the most recent DRI report, the macronutrient report (IOM, 2002a). Besides being more current, these new reference heights and weights are more representative of the U.S. population, which should more closely approximate ideal weights based on low risk of chronic disease and adequate growth for children. However, while these data are the best available data, it is recognized that information on older individuals is still seriously lacking. Table 4-2 provides the updated values.

## DIETARY REFERENCE INTAKE ISSUES ESPECIALLY RELEVANT TO NUTRITION LABELING AND DISCRETIONARY FORTIFICATION

### *Determination of Adequacy*

In the derivation of EARs or AIs, close attention has been paid to the determination of the most appropriate indicators of adequacy. A key question is, Adequate for what? In many cases a continuum of benefits may be ascribed to various levels of intake of the same nutrient. One criterion may be deemed the most appropriate to determine the risk that an individual will become deficient in the nutrient, whereas another may relate to reducing the risk of a chronic degenerative disease, such as certain neurodegenerative diseases, cardiovascular disease, cancer, diabetes mellitus, or age-related macular degeneration.

**TABLE 4-2** New Reference Heights and Weights for Children and Adults in the United States

Sex	Age	Previous Median Body Mass Index <sup>a</sup> , kg/m <sup>2</sup>	New Median Body Mass Index <sup>b</sup> , kg/m <sup>2</sup>	New Median Reference Height <sup>b</sup> , cm (in)	New Reference Weight <sup>c</sup> , kg (lb)
Male, female	2–6 mo	—	—	62 (24)	6 (13)
	7–12 mo	—	—	71 (28)	9 (20)
Male	1–3 y	—	—	86 (34)	12 (27)
	4–8 y	15.8	15.3	115 (45)	20 (44)
	9–13 y	18.5	17.2	144 (57)	36 (79)
	14–18 y	21.3	20.5	174 (68)	61 (134)
Female	19–30 y	24.4	22.5	177 (70)	70 (154)
	9–13 y	18.3	17.4	144 (57)	37 (81)
	14–18 y	21.3	20.4	163 (64)	54 (119)
	19–30 y	22.8	21.5	163 (64)	57 (126)

<sup>a</sup>Taken from male and female median body mass index and height-for-age data from the Third National Health and Nutrition Examination Survey, 1988–1994; used in earlier Dietary Reference Intake reports (IOM, 1997, 1998, 2000a, 2000b, 2001).

<sup>b</sup>Taken from new data on male and female median body mass index and height-for-age data from the Centers for Disease Control and Prevention/National Center for Health Statistics (CDC/NCHS) Growth Charts (Kuczmarski et al., 2000).

<sup>c</sup>Calculated from CDC/NCHS Growth Charts (Kuczmarski et al., 2000), median body mass index, and median height for ages 4 through 19 years.

Each EAR and AI in the DRI report series is described in terms of the selected criterion or indicator of adequacy. The potential role of the nutrients in the reduction of disease risk was considered in developing the EARs. With the acquisition of additional data relating intake more directly to chronic disease or disability, more sensitive and reliable indicators or criteria may be validated and thus the criterion for setting the EAR may change.

The DRI process is iterative in nature; with each set of nutrients the DRI concept evolves slightly, but with future science the DRI concept may change significantly. In terms of nutrition labeling, when the Food and Drug Administration devised the U.S. Recommended Daily Allowances in the early 1970s there was national concern about the quality of the food supply and the RDAs were set as reference values to prevent deficiency disease. In the DRIs a requirement is defined as the lowest continuing intake level of a nutrient that will maintain a defined level of nutriture in an individual. This

intake level is dependent on the specific indicator of adequacy identified in the DRI report for that nutrient. Depending on the nutrient, the indicator of adequacy may incorporate not only research on deficiency diseases, but also evidence for risk reduction for chronic diseases and amounts to maintain health. Scientific data have not identified an optimum level for any nutrient for any life stage or gender group, and the DRIs are not presented as such. Therefore for this study, key elements that the committee considered were the various criteria for adequacy and how these were related to developing a reference value for nutrition labeling and discretionary fortification

### *Special Issues for Macronutrients*

Unlike other nutrients, energy-yielding macronutrients can be used somewhat interchangeably (up to a point) to meet energy requirements of an individual. In the DRI report on macronutrients (IOM, 2002a) EARs or AIs were provided for specific macronutrients or components of the classes of macronutrients where the data were adequate to establish a causal relationship between intake and a specific function or chosen criterion of adequacy. However, for the general classes of nutrients and some of their subunits, this was not always possible; the data did not support a single number, but rather trends between intake and chronic disease identified a range. Given that energy needs vary with individuals, a specific number was not deemed appropriate to serve as the basis for developing diets that would be considered to decrease risk of disease, including chronic diseases, to the fullest extent possible. Thus Acceptable Macronutrient Distribution Ranges (AMDRs) were established for macronutrients and components as percentages of total energy intake. These are ranges of macronutrient intakes that are associated with reduced risk of chronic disease while providing recommended intakes of other essential nutrients.

Because much of this evidence is based on clinical endpoints (e.g., coronary heart disease, diabetes, cancer, obesity) that point to trends rather than distinct endpoints, and because there may be factors other than diet that may contribute to chronic disease, it is not possible to determine a defined level of intake at which chronic disease may be prevented or may develop. Therefore, an AMDR is not considered to be a DRI that provides a defined intake level. An AMDR is provided to give guidance in dietary planning by taking into account the trends related to decreased risk of disease identified in epidemiological and clinical studies.

AMDRs are expressed as percentages of total energy intake because their requirements, in a classical sense, are *not* independent of each other or of the total energy requirement of the individual. Each must be expressed in terms relative to the others. A key feature of each AMDR is that it has a lower and upper boundary, some of which are determined mainly by the lowest or highest value judged to have an expected impact on health. Above or below these boundaries, there is a potential for increasing the risk of chronic diseases.

### *Nutrient Intakes*

Each type of DRI refers to the average daily nutrient intake of individuals over time. The amount consumed may vary substantially from day to day without ill effect in most cases. Moreover, unless otherwise stated, all values given for EARs, RDAs, AIs, and AMDRs represent the quantity of the nutrient or food component to be supplied by foods from diets similar to those consumed in the United States and Canada. Healthy subgroups of the population often have different requirements, so special attention has been given to the differences due to gender and age, and often separate reference intakes are estimated for specified subgroups.

For some nutrients (e.g., trace elements) a higher intake may be needed for healthy people if the degree of absorption of the nutrient is unusually low on a chronic basis (e.g., because of very high fiber intake). If the primary source of a nutrient is a supplement, a higher or lower percentage of the nutrient may be absorbed, so a smaller or greater intake may be required. In addition, an adverse effect may be demonstrated at a lower level of intake when the source of the nutrient is from a supplement rather than from a food. When issues such as these arise, they are discussed in each DRI report.

The DRIs apply to the apparently healthy population and while the RDAs and AIs are levels of intake recommended for individuals, meeting these levels would not necessarily be sufficient for individuals who are already malnourished. People with diseases that result in malabsorption syndrome or who are undergoing certain treatments, such as hemo- or peritoneal dialysis, may have increased requirements for some nutrients. Special guidance should be provided for those with greatly increased or decreased needs (e.g., decreased energy due to disability or decreased mobility). Although the RDA or AI may serve as the basis for such guidance, qualified health care personnel should make necessary adaptations for specific situations.

## GENERAL ISSUES FOR NUTRITION LABELING AND DISCRETIONARY FORTIFICATION

The new DRIs are more complex and differ considerably from the earlier RDAs and RNIs. They also represent a much broader conceptual approach from the earlier RDAs and RNIs, and they employ very specific modeling and statistical designs:

Where specific data on safety and a role in health exist, reduction in the risk of chronic degenerative disease or developmental abnormality, rather than just the absence of signs of deficiency, is included in the formulation of recommendations. The concepts of probability and risk underpin the determination of the EAR, RDA, and UL, and inform their application in assessment and planning. (IOM, 2003, p. 17)

An important change in DRIs from a public health perspective is the inclusion of the UL. As intake increases above the UL, there is the potential for an increased risk of adverse effects. This is the first time a reference value that deals with toxicity has been ascribed to nutrients. The DRI Standing Committee cited the potential for the overconsumption of specific nutrients due to high levels of discretionary fortification (sometimes over 100 percent of the Daily Value), coupled with the widespread use of dietary supplements, as rationales for developing the UL (IOM, 1997). In the DRIs, the ULs for children for some nutrients overlap with new recommended intakes for adults (for children ages 1–3 years: vitamin A, zinc, manganese, folate, and niacin; for children ages 4–8 years: vitamin A, niacin, and folate). The committee was charged with considering the best way to use the UL in developing reference values for nutrition labeling given this overlap and the resulting implications for discretionary food fortification. The challenge of these changes in the context of appropriate values for nutrition labeling is addressed in the next two chapters.