Understanding Tolerable Upper Intake Levels

Evaluation of Dietary Intake Data Using the Tolerable Upper Intake Levels

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ABSTRACT We discuss the problem of assessing nutrient intake relative to the tolerable upper intake levels (UL) for the nutrient proposed by the Institute of Medicine and focus on 2 important topics: the estimation of usual nutrient intake distributions and the extent to which intakes above the UL can be considered risky. With the information that is currently available for most nutrients, it is not possible to estimate the proportion of individuals in a group with intakes that place them at risk. This is because the shape of the dose-response curve needed to carry out a risk assessment is unknown for most nutrients. Thus, intakes above UL cannot be declared to be unsafe. Intakes below the UL, however, are likely to pose no risk to individuals in the group. Because determining the proportion of individuals with intakes below the UL requires estimation of an upper-tail percentile of the intake distribution, the use of 1-d intake data or otherwise unadjusted intake data are likely to lead to severely biased estimates. It is important to remove within-individual variance in intakes from daily intakes so that the tails of the usual intake distribution are accurately estimated. Underreporting of the amount of nutrients consumed will tend to shift the estimated usual nutrient intake distribution downwards. In this case, the true proportion of individuals with intakes below the UL is likely to be overestimated. J. Nutr. 136: 507S–513S, 2006.

KEY WORDS: • upper level intakes • usual intake distributions • total nutrient intake • day-to-day variability in intake • under-reporting of calories

The United States government has regularly collected dietary intake data for >60 y. Over time, the design of nationwide food consumption surveys has changed significantly, as have the uses of the survey information and the methods for analyses of the data. Today, many of the consumers of the information provided by nationwide food consumption surveys are interested in public health issues and, in particular, in the links between diet and health. Many health outcomes are the result of exposure to foodborne pathogens (e.g., Salmonella enterica serovar Enteritidis), and such exposures are manifest as acute and deleterious effects on health. Although we are not minimizing the effects of those acute exposures on health, we focus here on the problem of assessing chronic exposure to nutrients and other components in food. That is, we consider the problem of estimating the distribution of the usual intake of nutrients and other food components and of evaluating that distribution relative to the new dietary reference intakes (DRIs) (1). In particular, we discuss approaches for evaluating usual intakes relative to the tolerable upper intake levels (ULs) and discuss the appropriate interpretation of the results of such analyses. We distinguish between daily intake and usual intake in the next section.

At the national level, collection of dietary intake data has been the purview of two departments. The United States Department of Agriculture (USDA) has been responsible for implementing the Continuing Survey of Food Intakes by Individuals (CSFII), whereas the United States Department of Health and Human Services (DHHS) has been in charge of the National Health and Nutrition Examination Survey (NHANES). The CSFII surveys have focused exclusively on food consumption, whereas the NHANES surveys have also focused on health and have included a comprehensive questionnaire on health and well-being, as well as a complete medical examination of all survey respondents at a mobile examination center. Because of the significant differences in the designs of the surveys, the use of combinations of data from both surveys for statistical analyses has been impractical. Late in the 1990s, CSFII was discontinued, and today only NHANES is conducted. To address the effects of the discontinuation of CSFII on the quality of information about food intake that is available to policy makers, researchers, and other practitioners, the design of NHANES was revised to include several of the design features of CSFII. In particular, the design of the new NHANES surveys calls for the collection of replicated observations for a randomly chosen subset of all respondents, a feature that was not present in the earlier NHANES surveys. In addition, DHHS also adopted the USDA five-pass method to collect dietary intake data during NHANES.
Nationwide food consumption surveys are designed as complex probability samples that often oversample socioeconomic groups of special interest, such as children, elderly individuals, low-income individuals, and members of ethnic minority groups. Regardless of the methods used to reach sample individuals, a certain proportion of nonresponse is expected. Because the nonresponse mechanism cannot be assumed to be unimportant (that is, nonresponse is often not random and can be influenced by factors such as income, gender, age, and ethnicity), individual weights that attempt to correct for the original oversampling and for the lack of individual responses are constructed and must be used in analyses.

In the remainder of this article, we discuss the issue of assessing the usual intake of nutrients relative to the ULs. In particular, we discuss the challenges that arise when nationwide food consumption survey data are used to estimate the proportion of individuals in a group whose usual nutrient intake (either from food sources alone or from food and supplement sources) is below the UL for the nutrient. We briefly revisit the concept of ULs, distinguish between daily and usual intakes, and introduce the concept of a distribution of usual intakes for a group. We also describe various approaches that are available for estimating usual intake distributions of nutrients and note the differences that arise when intake is recorded only from food sources or from food and supplement sources. In addition, we discuss the use of ULs to assess nutrient intake and focus on the correct interpretation of the results of such analyses and provide an example for illustration. Finally, a short discussion is presented.

**Daily nutrient intake measurement errors**

In the United States and Canada, dietary intake data in nationwide food consumption surveys are collected via 24-h recall questionnaires. An individual who completes a 24-h recall questionnaire is asked to list every food and beverage that he or she consumed during the previous 24 h. To translate food consumption information into daily nutrient intake, it is necessary to use large food composition databases that map foods and beverages into their components. One such database is created and maintained by the USDA, which contains ~6,000 “recipes.” We briefly discuss the impact of the accuracy of food composition databases on the assessment of nutrient adequacy in the final section of this article.

At least two serious shortcomings of the methods used at present to obtain information on daily nutrient intake continue to be actively discussed in the literature. First, it has been hypothesized that the food intake information collected using survey instruments, such as 24-h recall questionnaires, tends to underestimate the true daily consumption of some nutrients. The degree to which true intake is underestimated may depend not only on individual attributes, such as body weight and gender, but also on food items: individuals appear to underreport the consumption of foods that are high in fat and calories and overreport intake of socially acceptable foods such as fruits and vegetables. The results of several studies have been reported in the literature, and in general, it is accepted that energy consumption tends to be underreported (2–8). Results from a recent study conducted by scientists at the National Cancer Institute (NCI) suggest that, at least for the population considered, energy consumption is underreported by both men and women, but protein consumption is not underreported by women and is only slightly underreported by men. It is not clear, however, how the under- and overreporting of the consumption of selected foods may affect the information available on micronutrients, such as vitamins and minerals. Underreporting of food energy does not necessarily lead to underreporting of, for example, vitamin C intake if the foods that are omitted from the response to the questionnaire are not rich in vitamin C (2).

A second challenge in the assessment of daily nutrient intakes for individuals is the fact that food composition databases are difficult to keep up-to-date. With the proliferation of new designer foods and ethnic dishes, and with the constant introduction of fortified, low-calorie, low-fat, low-sodium, or otherwise modified foods, it is no surprise to find food composition databases falling behind. It is thus an enormous challenge for USDA to keep abreast of this bewildering assortment of new foods and beverages presented to consumers on an almost daily basis; and yet, an incomplete food composition database can have serious consequences on dietary assessments. When a single piece of hard candy can contain 100% of the daily value of vitamin C for an adult, it becomes clear that granularity in the food composition databases currently available is not fine enough to permit an accurate translation of foods into nutrients (9).

Inaccuracies in the food composition databases may also arise when nutrient content information is based on amounts reported on the product label. In the United States, and in particular in the case of fortified foods, manufacturers are required to report the minimum amount of the nutrient that can be expected in any unit of the food available to consumers over the shelf life of the product. Thus, the actual nutrient content in any one unit is likely to be significantly higher than the label suggests, which implies that food composition databases probably underestimate the real nutrient content in some products.

Inaccurate reporting of food and beverage intakes by individuals and incomplete food composition databases are but two of the sources of measurement error incurred during the collection of daily nutrient intake data. The effects of inaccurate reporting and of incomplete food composition information cannot be easily corrected by using statistical methods, at least with the information that is currently available. Recent work (5,8,10,11) suggests that biomarkers may be useful for calibrating energy and protein consumption information. Yet, the collection of biomarker data for a large sample of individuals is still prohibitively expensive and, furthermore, would lead to better information only in the case of energy, protein, and a very reduced set of additional nutrients for which biomarkers are available. An alternate approach to adjusting 24-h recalls for inaccurate reporting would consist of modeling the under- or overreporting as a function of individual socioeconomic attributes and then attempting to adjust recorded intakes by using model predictions and the appropriate statistical methodology (12–14). As is the case with biomarkers, the statistical adjustment route might alleviate the inaccuracies in the reporting of macronutrient intakes but is of limited usefulness for the reporting of intakes of micronutrients and other food components for which little is known about the extent of over- or underreporting.

In most applications, however, it is the usual intake rather than the daily intake that is of interest. Daily intake is an indicator of usual intake that is subject to a different kind of measurement error that can be alleviated by using the appropriate statistical tools. The factors that contribute to the measurement error include the effect of intake on a weekday versus intake on a weekend day, the day-to-day variability, and the impact of the interview method on the accuracy with which intake data can be collected. All of these factors can have non-negligible effects on the quality of the data collected, but these effects can largely be minimized if the appropriate survey design and statistical analyses methods are used.
Some fundamental ideas

Survey instruments such as 24-h recall questionnaires attempt to capture the daily intake of a nutrient or other food component by an individual. We use \( Y_{ij} \) to denote the intake of a nutrient or other food component by individual \( i \) on day \( j \). We assume in the remainder of this paper that the sources of systematic error in recorded daily intake are negligible (that is, that daily intakes measured by survey instruments such as 24-h recall questionnaires are not affected by under- or overreporting, the day of the week, or other such factors). As discussed earlier, this is an untestable assumption for most micronutrients so results of analyses must be interpreted with caution.

From a statistical point of view, daily intakes are subject to two sources of variability: within-individual variability and between-individual variability. The day-to-day (or within-individual) variability arises simply because individuals tend to consume different amounts and types of foods each day. The individual-to-individual (or between-individual) variability reflects differences in nutrient intakes among the members of the group (15–18).

On some scale in which measurement error can be assumed to be additive, the usual intake of a nutrient is often defined as the long-term average intake of the nutrient by an individual. Usual intakes cannot be observed directly, but in principle, they can be estimated as the mean of a large number of daily intakes for each individual in the sample. We use \( \gamma_i \) to denote the usual intake of the nutrient by individual \( i \) and define it formally as

\[
\gamma_i = E(Y_{i|})
\]

where \( E \) denotes expectation. Note that the usual intake of a nutrient is subject to only one source of variability: the individual-to-individual variability, which reflects the differences among the individuals in a group. The distribution of usual intakes in the group is called the usual nutrient intake distribution and has the following properties: 1) its mean is equal to the mean of observed daily intakes (perhaps on a transformed scale), and 2) its variance reflects the between-individual variability in intakes in the group and is, by definition, smaller than the variance of the distribution of observed daily intakes. This is because the observed daily intakes are also subject to the within-individual variability.

A very simple model that arises from the concepts just presented was proposed by the National Research Council (16). The model states that observed daily intake for an individual on any day can be expressed as a deviation from that individual’s usual intake. That is,

\[
Y_{ij} = \gamma_i + \epsilon_{ij},
\]

where \( \epsilon_{ij} \) is the random additive-measurement error often assumed to be normally distributed with mean of zero and variance equal to the within-individual variability. This simple additive model may not hold in the scale of measurement, but it is assumed to hold in a transformed scale (such as a logarithmic scale). If usual intakes are assumed to be independent of the measurement errors, then the model in Equation 1 implies that

\[
\text{Var}(Y_{ij}) = \sigma^2_1 + \sigma^2_2/d,
\]

where \( Y_i \) is the mean of the observed daily intakes over \( d \) days for individual \( i \), and \( \sigma^2_1 \) and \( \sigma^2_2 \) denote the between- and within-individual variabilities, respectively. If \( \sigma^2_2 \) is large relative to \( \sigma^2_1 \), then estimation of the distribution of usual intake as the distribution of observed means leads to inaccurate inferences. This is because the nuisance component of variance, \( \sigma^2_2/d \), does not become negligible unless \( d \) is very large. In most food consumption surveys, \( d \) tends to be no \( > 2 \) or 3, and therefore, the variance of the observed mean daily intake can significantly overestimate the variance of usual intakes and may thus result in a distribution with an excessive spread. Because estimation of the distribution of usual intakes as the distribution of observed intake means is not practical, statistical approaches that result in estimated distributions with the desired characteristics must be implemented. In the next section we briefly discuss two methods for estimating usual nutrient intake distributions that have been proposed and compare their advantages and disadvantages.

Estimating usual nutrient intake distributions using food intake data

Researchers and practitioners often obtain an estimate of the distribution of the usual intakes \( (\gamma_i) \) in a group, using information on individual daily nutrient intakes. A simple approach for estimating usual nutrient intake distributions consists in using the distribution of the observed individual mean intakes \( Y_{ij} \) as the estimate of the distribution of usual intakes. Although this approach is easy to implement, it results in an estimated usual nutrient intake distribution with a variance that reflects more than just the individual-to-individual variabilities in intakes. As a consequence, estimates of quantities such as the proportion of the population with intakes below or above a given threshold will be biased, and sometimes severely so.

At least in terms of usage, the two most popular approaches used to estimate usual nutrient intake distributions today are the method proposed by the National Research Council (NRC) (16) and the Iowa State University (ISU) method (18), which is also described in greater detail elsewhere (1,19–21). Both of these approaches are based on the simple measurement error model described in Equation 1, and both attempt to estimate a usual nutrient intake distribution with the correct variability. Both methods consider estimators of individual usual intakes whose variance equals the between-individual variance in intakes and that are computed by shrinking the observed means for \( d \) days toward the group mean intake.

The NRC method, proposed in 1986, consists of several steps. First, observed intake data are transformed by using a simple power transformation into a scale in which daily intakes can be assumed to be approximately normally distributed. In this scale, daily intakes are considered unbiased estimators of usual intake, and the measurement error is additive. Individual usual intakes are computed by shrinking individual means toward the group mean. The estimator of individual usual intake proposed by NRC is denoted \( \hat{\gamma}_i \), and is given by

\[
\hat{\gamma}_i = \bar{Y}_{iT} + \frac{\sigma_b}{(\sigma^2_b + \sigma^2_e/d)^{1/2}} (Y_i - \bar{Y}_{iT}),
\]

where \( \bar{Y}_{iT} \) is the group mean intake and where \( Y_i, \sigma^2_b, \) and \( \sigma^2_e \) are the individual mean intake, the between-individual variance in intake, and the within-individual variance in intake, respectively. This estimator of usual intake can also be written in the form of a weighted average by rewriting the expression in Equation 3 as follows:

\[
\hat{\gamma}_i = \frac{\sigma_b}{(\sigma^2_b + \sigma^2_e/d)^{1/2}} Y_i + \left[ \frac{\sigma_b}{(\sigma^2_b + \sigma^2_e/d)^{1/2}} \right] \bar{Y}_{iT}.
\]

Note that the estimate of usual intake for an individual in the transformed scale will tend toward the individual’s observed mean intake whenever the ratio of the variance components tends toward 1. That happens either when the within-individual variance \( (\sigma^2_e) \) is small relative to the between-individual variance \( (\sigma^2_b) \) or when the number of days \( d \) of daily individual-to-individual measurements is very large. In most food consumption surveys, \( d \) is not very large. In most food consumption surveys, \( d \) tends to be no > 2 or 3, and therefore, the variance of the observed mean daily intake can significantly overestimate the variance of usual intakes and may thus result in a distribution with an excessive spread. Because estimation of the distribution of usual intakes as the distribution of observed intake means is not practical, statistical approaches that result in estimated distributions with the desired characteristics must be implemented. In the next section we briefly discuss two methods for estimating usual nutrient intake distributions that have been proposed and compare their advantages and disadvantages.
Intakes available for individual \( i \) is large. When the term \( \sigma_i^2/d \) is relatively large, the estimated usual intake for the individual approaches the group mean intake. The estimator of individual usual intake for the individual in the transformed scale has good statistical properties; under some assumptions, the estimator \( \hat{y} \) is a linear function of the observations and is unbiased. However, it is not an optimal predictor in the minimum prediction error variance sense. The best linear unbiased predictor (BLUP) of an individual’s usual intake can also be obtained by shrinkage, but in that case, the shrinkage factor is given by \( \sigma_i^2/(\sigma_i^2 + \sigma_e^2/d) \). The distribution of the BLUPs, however, does not have variance equal to the between-individual variance.

Typically, practitioners back-transform the estimated usual intakes into the original scale simply by applying an inverse transformation. One unfortunate feature of the NRC approach for estimating usual nutrient intake distributions is that in the original scale, the naive back-transformation produces a distribution of usual nutrient intakes whose mean is different from the mean of the observed daily intakes for the group. Although this is a consequence of the approach itself and not an error, it can be disconcerting; why, in the process of adjusting variability, is the mean of the distribution also shifted?

A second approach to estimating usual nutrient intake distributions is the ISU method (18). The ISU method is closely related to the NRC approach in that it is based on the same simple measurement error model, which is assumed to hold in some transformed scale. The ISU approach includes a more sophisticated semiparametric transformation into the normal scale and does not require computation of the individual usual intakes \( \hat{y}_i \) in the transformed scale. As proposed by Nesser et al. (18), the measurement error model in the normal scale allows investigators to test whether the within-individual variance can be considered homogeneous across individuals. Furthermore, the back-transformation is estimated so that in the original scale of measurement, estimated usual nutrient intake distributions have a mean equal to the observed group mean and a variance that reflects only the between-individual variability in usual intakes. Thus, after the transformation of daily intakes into the normal scale and removal of the nuisance daytime variability in intakes, practitioners return to a distribution with a smaller variance but with the same original mean. The ISU method results in estimates of usual nutrient intake distributions with good statistical properties, and performs well even when sample sizes are relatively small and when the proportion of replicated daily intakes in the group is low (as long as the number of replicated observations still allows the reliable estimation of the within-individual variability) (22). Recent results obtained in a large study using biomarkers suggest that it is possible to use urinary nitrogen to correct the bias in the estimate of usual intake distribution of energy and protein that arises from underreporting of food consumption in 24-h recalls (23).

Total nutrient intake

For some nutrients, such as vitamin C and calcium, the proportion of intake from supplement sources has increased in the past few years (24). During the third NHANES survey (NHANES III), \( \sim 33 \% \) of Caucasian women aged 19–50 y reported that they consumed supplements (25). Among African-American and Hispanic women, the proportions who reported that they consumed supplements were 23 and 18\%, respectively. These proportions, based on a survey that is more than a decade old, are likely to be even higher today. Therefore, collection of the data and development of the methods that permit usual total nutrient intake distributions to be estimated might be of interest to practitioners and policy makers. Taking into account the consumption of a nutrient from all sources is particularly important when the objective of the analysis is to assess the proportion of individuals in a group whose intake of the nutrient is high enough to perhaps put them at risk of adverse effects for those nutrients for which the UL is defined.

Scarc data are available on a national scale for characterizing supplement intake patterns in the United States. In nationwide food consumption surveys, participants have been administered a question on the frequency of supplement use that is meant to capture usual supplement consumption. These data are difficult to combine with daily nutrient intake data from food sources to obtain estimates of total usual daily intake that can then be adjusted as described above. In the absence of information beyond that provided by the question on the frequency of supplement intake, it is necessary to make strong (and untestable) assumptions when food and supplement intake data are combined to estimate total nutrient intake. One possible approach is proposed in a recent Institute of Medicine report (1) and is further discussed and presented in greater detail elsewhere (25). This approach is unsatisfactory because, owing to data limitations, it must assume that respondents accurately recall their usual daily nutrient intake from supplement sources. Because this is unlikely to be the case and because the data do not permit estimation of the within-individual variance in supplement intakes, the variance of the estimated usual total nutrient intake distribution may not accurately reflect the individual-to-individual variability in total usual intake. This may result in biased estimates of the quantities consumed, or of summaries such as the prevalence of nutrient inadequacy or the proportion of individuals consuming amounts exceeding the UL.

Carriquiry (21) discussed the data that would be needed to obtain reliable estimates of the distributions of total usual nutrient intake. In addition to the frequency question that participants are already being asked, Carriquiry proposed that this information be supplemented with replicate 24-h recalls to obtain usual nutrient intake from supplement sources. Given these two sources of information, it would then be possible to more accurately estimate the distributions of total usual nutrient intake in the group. Researchers at NCI have proposed a similar approach to estimate the usual intake distribution of infrequently consumed items such as green leafy vegetables (unpublished research). The NCI approach consists of combining intake data collected via 24-h recalls and a propensity questionnaire using a statistical method similar to the one proposed by Tooze and collaborators (26).

Using the supplement consumption data available and, sometimes, information from smaller food consumption surveys, several researchers have found that individuals who already consume adequate amounts of nutrients and who lead healthy lifestyles also tend to consume more supplements (24,27). This suggests that a comparison of estimated usual nutrient intake distributions obtained by using food intake alone or both food and supplement intakes would exhibit a larger tail to the right, and thus, a smaller proportion of individuals would be found to have intakes below the ULs when supplements are taken into account. In fact, Arab et al. (25), using NHANES III food and supplement consumption data for vitamin C and vitamin E by women aged 19–50 y, found that the estimated total usual intake distribution has a long tail to the right, as individuals who already show relatively high levels of nutrient consumption from foods are also the ones who tend to consume supplements. As a consequence, the proportion of individuals whose intakes exceed the UL for the nutrient may also be larger.
Assessing intakes relative to the ULs

The UL for a nutrient is one of four DRIs that have been defined for most nutrients and other food components (28). The concept of the UL is new and reflects for the first time the need to monitor not only inadequate intakes of a nutrient but also excessive intakes of a nutrient. In the United States, the UL of a nutrient by gender and life-stage group is defined as the highest level of usual intake of the nutrient that is likely to pose no risks of adverse health effects for most individuals in the group. The UL is not a recommended level of intake for an individual; instead, it should be interpreted as the level of intake below which adverse health effects are very unlikely. Note that this implies that usual daily intakes above the UL cannot be considered unsafe. To determine the health risks associated with nutrient intakes above the UL, it would be necessary to know with some degree of accuracy the dose-response relation of nutrient intake and the clinical endpoint of interest. These dose-response curves have not been estimated for most nutrients or gender and life-stage groups, and thus, it is difficult today to formally quantify the risks associated with the consumption of nutrients and other food components.

The lack of information about the dose-response curve for nutrient intake places a very real constraint on the type of inferences that can be drawn from statistical analyses that involve ULs. In particular, it is simply incorrect to conclude that intakes above the UL are excessive. Consider, for example, the hypothetical cases presented in Figure 1. In Figure 1A, the dose-response relation for nutrient consumption and the probability of an adverse effect is very flat, meaning that usual intake would need to exceed the UL by a large amount before the individual is at a non-negligible risk. Figure 1B shows the estimated usual intake distributions of vitamin B-6, for which a slight increase in the level of consumption over the UL results in a significant risk of adverse health effects.

Because data that can be used to determine the shape of the dose-response curves for each nutrient and for each gender and life-stage group are not available, estimation of the proportion of individuals in a group with usual intakes that pose a risk is not possible. Instead, policy makers, researchers, and other practitioners must limit themselves to referring to the proportion of individuals in the group whose intakes are below the UL and thus are very likely not excessive.

To estimate the proportion of individuals whose usual intakes are below the UL (and that can thus be considered not excessive), it is important to adjust intake distributions as described earlier. This is because the adjustment of intake distributions has an important effect on the sizes of the tails of the distribution. As an example, consider the two estimated usual intake distributions shown in Figure 2. Figure 2 shows the usual intake of vitamin B-6 for women ages 19–50 years, estimated by using daily intake data from the 1994–1996 CSFII.

The distribution with longer tails was estimated as the distribution of first-day intakes, with no adjustment. The distribution with shorter tails is the estimate obtained by the ISU method. Suppose that we are interested in estimating the proportion of individuals with usual intakes below the threshold represented by the vertical line in the plot. The resulting proportions in this hypothetical example are ~89 and 98% when the 1-d and the ISU estimates of usual intake distributions, respectively, are used. Using daily intake data from NHANES III, we estimated the proportion of women ages 51–70 years whose usual intakes of zinc are <40 mg, the UL for the group. When intake data are adjusted by the ISU method, the proportion of individuals whose intakes are below the UL is estimated to be 100%. However, when unadjusted 1-d data are used in the analysis, the proportion of intakes below the UL is 98%. This difference, which is not statistically significant, still serves to illustrate the consequences of not properly adjusting intake distributions.

The ULs are set at rather high intake levels for most nutrients. Therefore, the problem of estimating the proportion of individuals with nonexcessive usual intakes is equivalent to the problem of estimating an upper-tail percentile in a distribution. Indeed, the percentiles that must be estimated are in the very extreme upper tail. From a statistical point of view, the reliable estimation of lower- or upper-tail percentiles is not easy; in the case of usual nutrient intake distributions, a relatively small change in the estimates of the within-individual and the between-individual variances can lead to significant changes in the estimates of tail percentiles. Thus, it is important to interpret estimates obtained from analyses with these limitations in mind, in particular when working with moderately small sample sizes or with groups in which the proportion of individuals for which replicate observations are available is not high.

Typically, results from the analyses of nationwide food consumption surveys suggest that for most micronutrients, an overwhelmingly large proportion of individuals in most gender and life-stage groups have usual intakes below the ULs. For example, using data from the NHANES III, the proportion of women ages 31–50 years whose total usual vitamin C intakes are below the UL for vitamin C (1800 mg/d for that gender and life-stage group) is essentially 100%, even though the level of consumption of vitamin C from supplement sources is relatively high in the population. One notable exception is the case of...
children ages 1–3 y. By using zinc consumption data collected in the 1994–1998 CSFII, the estimated proportion of children whose usual intakes of zinc is below the UL for the age group is approximately 40%. This estimate was obtained without including zinc intakes from supplement sources; thus, it is possible that the proportion of young children whose total usual zinc intakes are below the UL is in fact 40%. Because no clinical data on health problems in children associated to excessive zinc consumption are available, these results would tend to suggest that the UL for zinc for children aged 1–3 might warrant revisiting.

**DISCUSSION**

We have discussed the problem of estimating the proportion of individuals in a group whose usual intakes of a nutrient are below the UL for the nutrient and the group. We have also discussed, at some length, how to correctly interpret the results of the assessment of usual intakes relative to the UL. Perhaps the two most important concepts in this paper are the following:

With the information that is currently available for most nutrients, it is not possible to estimate the proportion of individuals in a group with excessive intakes. This is because the shape of the dose-response curve needed to carry out a risk assessment is unknown for most nutrients. Thus, when we estimate that, for example, 75% of usual intakes in a group are below the UL and are therefore safe, it is incorrect to then conclude that the remaining 25% of usual intakes must be unsafe. Although it is true that 25% of usual intakes in this hypothetical example are above the UL, it is not possible to declare them unsafe unless the dose-response curve for the nutrient is known.

Estimation of the proportion of individuals in a group with usual intakes below the UL by the use of 1-d intake data or otherwise unadjusted intake data are likely to lead to severely biased estimates. As was argued in the preceding section, moving the effects of the day-to-day variability in intakes from daily intakes has a deep impact on the sizes of the tails of the estimated usual intake distribution. Because estimation of the proportion of usual intakes below the UL is tantamount to estimation of an upper-tail percentile, the results will be sensitive to the adjustment.

If respondents underreport the amount of the nutrient consumed, the estimated usual nutrient intake distribution may be shifted downwards even if it has the correct shape. In this case, the true proportion of individuals with intakes below the UL is likely to be overestimated.

We have focused on methods that are applicable to micronutrients and minerals. For some macronutrients (such as energy and fat), assessment of intake relative to the DRIs presents other challenges that have not been discussed here (29).

Methods that can be used to obtain reliable estimates of usual intake distributions for most nutrients are available; and the use of such methods results in estimated distributions with good statistical properties, as long as a replicate 24-h recall is available for at least a subsample of the individuals in a group. Under- and overreporting of food intake problems notwithstanding, the dietary intake data collected from nationwide food consumption surveys provide valuable information. What is lacking, however, are reliable data on nutrient intakes from supplements and other nonfood sources. Also lacking is precise information on the nutrient content of foods in food composition databases.

The data currently available on nutrient consumption from nonfood sources consist of self-reported data based on long-term habitual consumption. These data do not allow estimation of within-individual variance, nor are they appropriate for combination with daily intake data from food sources into a total intake estimate. Several studies (24) indicate that supplement consumption is more prevalent among individuals who already consume adequate amounts of nutrients. Thus, when the upper-tail percentiles in the usual intake distribution are estimated, it is important that the distribution be based on total daily nutrient intake rather than just on nutrient intake from food sources.

At this time, the estimates of total usual nutrient intake distributions that can be obtained are not justified from a statistical point of view and may have questionable properties.

**LITERATURE CITED**


