NEW APPROACHES TO THE NUTRITIONAL ASSESSMENT OF POPULATION DIETARY DATA

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Background: A New National Academy of Sciences Report

For the last two years, a National Academy of Sciences Committee and its Subcommittee have been addressing the issues surrounding the design and interpretation of national surveys. The first report of the Committee was released last year (1). It addressed the broad issues of the need for both the NFCS and NHANES surveys and issues of improvement of compatability of the data bases arising from these two surveys. The second report, arising from the Subcommittee, is due to be released in July, 1985 (2). This report, "Food Consumption Surveys: Criteria For Assessing Dietary Adequacy", deals with matters that are very germane to this conference and should be of considerable interest to the audience of the present Conference. The present paper can do no more than provide a sampler of some of the material to be found in that report. It is hoped that this sampler will be enough to encourage the reader to acquire a copy of the full report and to consider its content in detail.

Four years ago, on the occasion of the opening of the USDA/ARS, Western Human Nutrition Research Center, I had the opportunity to present a paper describing the application of a probability approach to the assessment of observed dietary intake. This approach, which has since been presented elsewhere (3-6), accepts that human nutrient requirements vary between individuals. It emphasises, therefore, that there can be no single numerical criterion of adequacy applicable to all individuals in a class (e.g. adult men or women). Rather, the approach recognizes that as observed intake moves across the distribution of requirements, the likelihood or probability of inadequacy changes. That is, if observed intake lies in the upper tail of the requirement distribution, then there are very few individuals with requirements above that level of intake. It follows that the risk or probability that the intake is inadequate for a randomly selected individual is very low (7). By knowing the areas under the requirement distribution to the right and left of the observed intake, it is possible to make a probability statement with regard to adequacy of the particular intake. By making such assessments for each intake observed in a population study and summing the individual probabilities, one can generate an estimate of the prevalence of inadequate intakes in the population - one can estimate <u>how many</u> individuals are likely to have inadequate intakes but one cannot identify <u>which</u> individuals have inadequate intakes. The recent FAO/WHO/UNU report on Energy and Protein Requirements (7), released this summer, elaborates a number of statistical issues relating to the probability assessment of observed intake. This is the basic approach that has been developed in the NAS report. That report provides a greatly extended examination of issues and questions surrounding the application of the probability approach to population data.

During the past five or so years, a second major issue rose to considerable prominence in the nutrition community. That was the matter of day-to-day variation in intake and the implications for "reliability" of dietary data (8-20). It was recognized that for many applications, it was an estimate of the individual's usual intake, not intake on a particular day or in a particular week, that was needed. Commonly used quantitative dietary methods give a poor estimate of the usual intake of an individual. In data analyses, the error term in the estimate of usual intake can have profound effect on regression coefficients or correlation coefficients, potentially giving rise to false negative conclusions (8,14,16,17,19). There are issues also in relation to the interpretation of nutritional adequacy of population dietary data. The inclusion of day-to-day variation in population data leads to an overestimation of the variance of intakes in the population - a spuriously high proportion of very high and very low intakes (21). If this effect is not eliminated either by choice of method or by adjustment during data analysis, there will be an error in the estimation of the prevalence of inadequate (or excessive) intakes in the population.

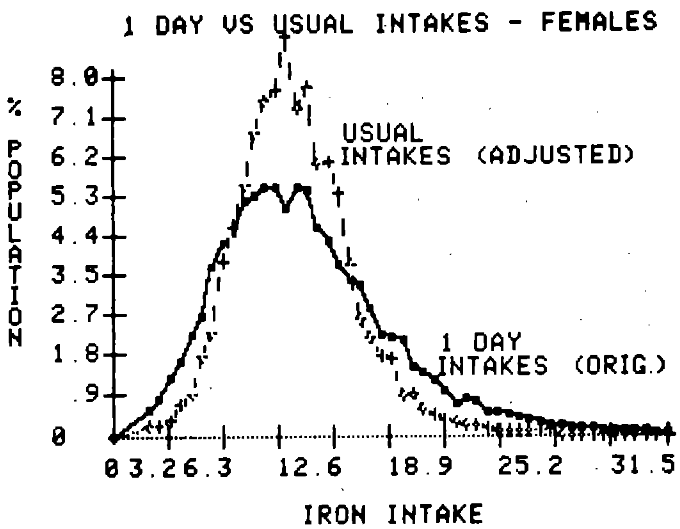
The Subcommittee considered this issue very carefully - indeed it was one of the first issues on the agenda. It was recognized that if the data set included a sufficient number of replicates, an analysis of variance (ANOVA) could be run and an estimate of the inter- and intra-individual variances could be obtained. With this information in hand, it would be possible to derive an estimate of the <u>distribution</u> of usual intakes in the population group - to adjust the observed distribution. The National Food Consumption Survey (NFCS) contains more than enough replications of intakes. From that data base it is quite feasible to generate adjusted distributions describing usual intakes. Unfortunately, the NHANES data bases of the past include no replications; no internal adjustments to those data can be made and they cannot be used in the manner described in this paper. It may be that future HANES studies will make provision for obtaining replicate observations for an appropriate sample of the population. The Subcommittee was able to work with data sets from the NFCS thanks to the work of staff of USDA who ran ANOVA's on logarithmically converted data required for the adjustment of the distributions and who also formatted the data sets into sequential files with 200 intervals each containing an equal number of individuals. These data were made available in log form, in untransformed form for all single days (as if they were independent) and for the 3 day means for young adult men and for young adult women. With these reduced data sets representing some 2400 women and 1700 men, it was quite feasible to mount the data in an Apple computer and to then write programs to conduct the analyses presented in the report and sampled in this paper. Thus, it was possible to demonstrate that the approaches both to adjustment of distribution and application of a probability approach were entirely feasible of implementation with population data.

The report, however, does not stop at presenting the approach. Rather, the Subcommittee attempted to address all of the possible sources of error in the estimation of prevalence of inadequate intakes by this method and then, through a process of sensitivity testing and statistical modelling, it assessed the potential impact of these individual sources of error. Availability of the data set on a microcomputer readily permitted the introduction of error terms in either requirement or intake distributions, shifting the locations of the distributions, and conducting other manipulations to see their impact on the prevalence estimate - to assess the sensitivity of the estimate to these variations and hence to ascertain which assumptions and inputs were really critical to the assessment.

The new NAS report, then, also makes major contribution to an understanding of "error terms" in population data sets and provides an approach to the assessment of these error terms - which have major import and which are of little significance for a defined use of the data set. The presentation of this approach to analysis of error terms - a "sensitivity analysis approach" - may be a more important contribution to our field than the specific proposals concerning the nutritional interpretaton of NFCS intake data. It is an approach that is applicable to the examination of other uses of dietary data.

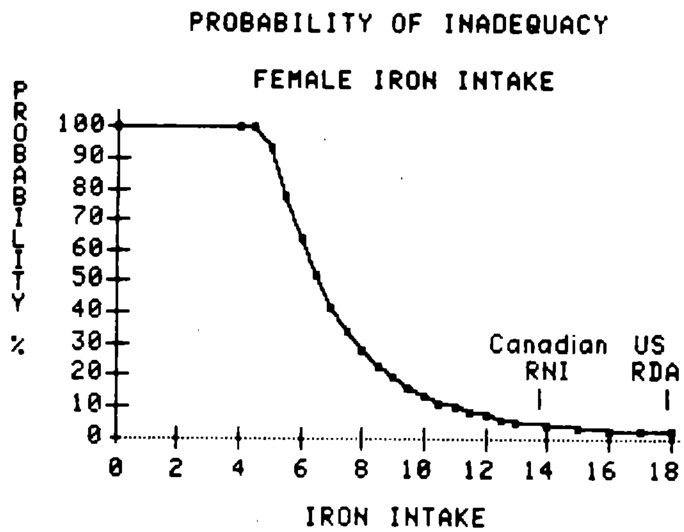
The Probability Approach to Assessment of Population Intake Data

The composite approach can be seen by examining one example - assessing the apparent adequacy of reported iron intakes among adult women. (Note that the NFCS data do not include intake from supplements. Thus total intake has been underestimated and prevalence of inadequate intake has been overestimated in the following examples.) Fig. 1 illustrates the distribution of single day intakes among the adult women and the distribution of "usual" intakes among these same women. To make this adjustment, the distributions were first normalized by logarithmic transformation (a more correct approach would be to use Box-Cox transformation appproaches (22)), the ANOVA was performed, the standard deviation of interindividual (between subject) variation was obtained and then mean intakes for each of the 200 intervals used in the reduced data sets were shifted toward the mean of the whole distribution by applying the following equation:

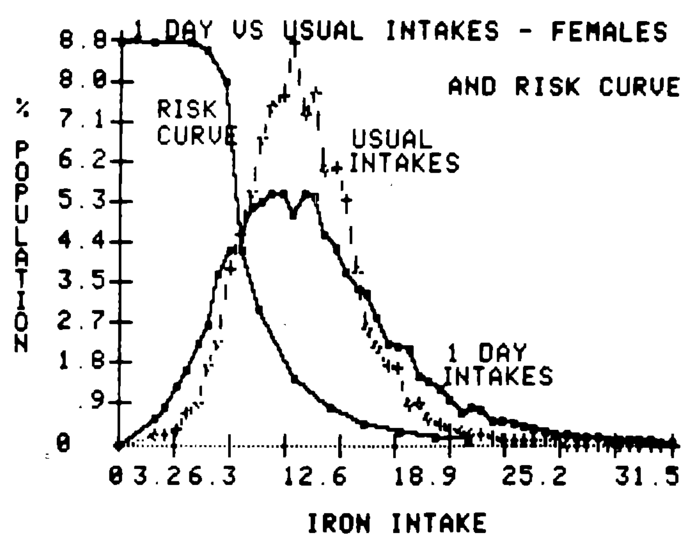


$$\text{Adjusted intake} = (\text{Mean Intake} - \text{Observed Intake}) \times SD_{inter}/SD_{observed}$$

The exponentials of the adjusted data were then computed to yield the new distribution shown in the figure. This procedure effectively removes the day-to-day variability of recorded intake. (As will be seen later, this variability includes true variation in intake by the same individual <u>and</u> random error terms in the data collection methodology.) By using a nonparametric approach it was possible to avoid an assumption of perfect fit of the converted distribution to the normal curve.



The next step requires a distribution of requirements. Fig. 2 portrays the cumulative distribution of iron requirements among menstruating women. This curve is based on measured menstrual losses plus an allowance for basal losses and assumes a constant upper limit for dietary iron bioavailability (23). When plotted in the manner shown, this curve portrays the probability that any given level of intake is inadequate to meet actual needs. Fortunately the distribution of menstrual iron losses approximates quite closely the log normal distribution. Following logarithmic conversion of data, it is quite possible to read from a table, or compute with available algorithms, the area under the normal distribution to the right of a given intake - the probability of inadequacy. This is what is portrayed in Fig. 2.



The final step involves application of this probability estimate to the adjusted distribution. This is portrayed graphically in Fig. 3. It was done with the computer for each of the 200 intervals of intake. Probabilities were then summed and an estimate of the population prevalence of inadequate intakes was derived.

The impact of this approach is vividly seen in Table 1 which compares assessments obtained by a common present approach with those obtained for the same population by the probablility approach.

Table 1. Comparison of Estimates of the Prevalence of Inadequate Iron Intakes - Menstruating Women

Approach to Assessment	Estimated Prevalence
Proportion with intake below the US RDA (18 mg/d)	98 %
Proportion with intake below the Canadian RNI (14 mg/d)	88 %
Predicted prevalence of inadequate intakes (probability approach)	23 %

Examination of Potential Sources of Error - Sensitivity Testing

The Subcommittee, in accepting this approach first satisified itself that the approach was statistically valid. It then satisfied itself that if indeed requirement were perfectly described and intake measurements were error free, the prevalence estimates derived in this manner would have acceptable confidence limits. Indeed, the limits are extremely tight - often the standard error of the prevalence estimate is in the order of ± 1-2%. This merely asserts that with large data sets, the ANOVA approach yields a statistically sound estimate of the interindividual distribution and that the error term in the final estimate of prevalence reflects this. After satisfying itself on these points the Subcommittee systematically identified and examined possible sources of error with regard to the potential magnitude of their effect. The sources of error considered are summarized graphically in Fig. 4 below.

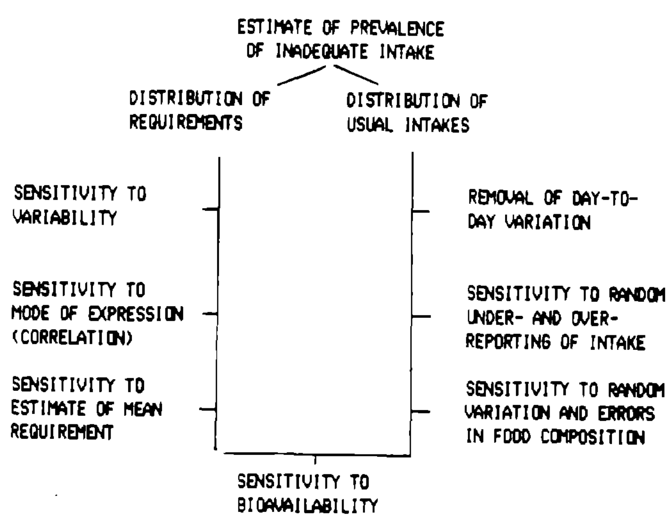


Fig. 4. A schematic portrayal of some potential sources of error

THE REQUIREMENT DISTRIBUTION

Sensitivity to Variability of Requirement

As portrayed earlier, the probability approach applied to individuals requires a knowledge of the distribution of requirements and a method of estimating the fractional areas under the distribution. It has been suggested by many authors that our present knowledge of the variability of human nutrient requirements among individuals within a relatively homogeneous class (e.g. young adult men or young adult women) is very limited. This criticism implies that a probability approach based on judgements about the distribution of requirements could be subject to major error. The NAS subcommittee examined this my making various assumptions about the magnitude of the variation of requirement and about the shape of the requirement distribution. For each of these assumptions, the prevalence of inadequate intakes was again estimated. Table 2 presents the results of two such sets of sensitivity trials.

Table 2. Sensitivity of the Prevalence Estimate to Variability of Nutrient Requirement

A. Protein in Young Adult Men

Mean Requirement g/d	Assumed CV of Requirement SD as % of Mean	Implied RDA* g/d	Prevalence Estimate** % of men
43	10	52	1.9
43	12.5	54	2.0
43	15	56	2.2
43	17.5	58	2.3
43	20	60	2.4

B. Ascorbic Acid in Young Adult Men

Mean Requirement mg/d	Assumed SD of Requirement mg/d	Implied RDA* mg/d	Prevalence Estimate** % of men
45	2	49	40.2
45	4	53	39.9
45	6	57	39.7
45	8	61	39.4
45	10	65	39.2

* Assuming the RDA had been set at mean + 2 SD to meet needs of all but 2.5% of individuals

** This is an estimate of the proportion of individuals expected to have intakes below their own requirements

Other analyses presented in the report examine the import of the shape of the requirement distribution. The main conclusion is that as long as there is reason to believe that requirements are distributed reasonably symmetrically about the mean the estimate of prevalence is relatively insensitive to the magnitude of the variability of requirement or to the shape of the distribution curve (normality is not a necessary assumption). Clearly these conditions are not met for iron requirements of menstruating women where the requirement distribution is known to be highly skewed. In the two examples presented above, the positions of the requirement distributions are quite different in relation to the intake distributions (see difference in prevalence estimates), nevertheless, the impact of variability of requirement is quite small in both. This was a surprising, but reassuring observation.

The analyses presented in Table 2 suggest also that it would be inappropriate to rely on the published RDA as the underpinning of a nutritional assessment of population data. What is needed is an estimate of the mean requirement and a knowledge of, or reasonable judgement about, the distribution of requirements (or a reasonable assurance that the distribution is not markedly skewed).

Sensitivity to Mode of Expression of Requirement - Correlation

A necessary assumption of the probability approach is that requirement and intake are not correlated (or that the correlation is known). It is necessary therefore to eliminate common variables that would lead to spurious correlation during analysis. Certain of these are obvious. The approach must be applied to reasonably homogeneous groups such as those conventionally described in dietary standards - specified age, sex and physiological state groupings. If young children and adults were included in the same analysis, it would be found that the children would have lower requirements and lower intakes than the adults simply because of major difference in body size; a spurious correlation between requirement and intake would be present in the data set snd the prevalence estimate would be wrong.

Other situations of correlation may be less obvious yet they too must be eliminated or analysed differently. A clear example is found in assessing thiamin intake in young adult men. Experimental evidence demonstrates that thiamin requirement per day is affected by the energy flux of the body and this in turn associates with energy intake (total food intake). Observational evidence clearly indicates that total thiamin intake associates with the level of total food intake. Thus, in population data a correlation between thiamin requirement per day and thiamin intake per day is to be expected. This can be eliminated if both requirement and intake are expressed in relation to the common variable, energy intake.

When these relationships are taken into account, the results are quite dramatic. Again using adjusted NFCS data, the prevalence of inadequate thiamin intakes is estimated to be about 37% when requirements and intakes are both expressed on a per day basis. However, when both are expressed on a per 1000 kcal basis, the estimate of prevalence of inadequate intakes falls to about 3.5%! (This latter estimate does not include provision for a "floor" of thiamin requirement below which need is said to be unrelated to energy flux. Such a floor could be built into the computations.) A moment's consideration will lead to the recognition that protein requirements and intakes should be expressed per kg per day, and that vitamin B_6 requirements and intakes should be expressed per gram protein intake per day, since these are recognized variables of requirement and associates of intake. The lesson that emerges is that for a correct assessment of intake, as many of the variables of requirement as possible should be incorporated.

For exactly the reasons described above, the probability approach cannot be applied to energy unless there is a direct estimate of the correlation between intake and requirement (7). There is <u>much</u> evidence to suggest that in free-living subjects consuming food without imposed restraint, energy intake and energy utilization (requirement) are strongly correlated. Application of the probability approach without taking this into account would be very misleading.

Sensitivity to Mean Requirement – Requirement for What?

Analyses of the type presented above served to demonstrate that the shape of the requirement distribution (unless skewed) has little impact on the prevalence estimate and that with care in mode of expression, the issue of correlation between intake and requirement can be avoided (except for energy). What then about the position of the requirement distribution. What is the impact of change in the estimate of mean or median requirement?

This can be portrayed in a particularly meaningful manner by considering the question "requirement for what?" The NAS Report places great emphasis on the need to address this question in any assessment of dietary data.

Consider ascorbic acid. Currently published requirement estimates in both Canada and United States base requirements on the intakes needed to maintain metabolic pools or metabolic turnover rates deemed to be desirable. For such a criterion of adequacy, mean requirements have been estimated at about 45 mg/d. In depletion studies, eye lessions were suggested at intakes of about 25 mg/d (not a clear estimate of a requirement level but used here as an example). The literature abounds with information to suggest that the average requirement for the prevention of clasical signs of scurvy is 10 mg/d or perhaps even lower. We then have three answers to the "requirement for what?" question. There is no reason why we cannot, and should not, provide three estimates of the prevalence of inadequate intakes:

Table 3. Prevalence of Inadequate Intakes of Ascorbic Acid in Men Defining Requirement on Differing Criteria of Nutriture

Criterion	Prevalence
A. inadequate to maintain metabolic pools	40%
B. inadequate to prevent eye lesions *	12%
C. inadequate to prevent scorbutic signs	2%

* a very uncertain criterion, used only for example

Similarly, for thiamin, expressed per 1000 kcal/d, the prevalence of intakes that would be inadequate to meet the criterion of maintenance of metabolic pools (and associated enzyme activities) was estimated to be about 3.5%. This falls to 0 when requirement is defined in terms of prevention of lesions suggestive of beriberi.

Clearly the prevalence estimate is sensitive to the estimate of the average requirement. It would be sensitive to any error (bias) in that estimate. Equally, or perhaps more, important, the prevalence estimate is very sensitive to the answer to the question "requirement for what?" In practical terms, the NAS Report opens the door to a multiple criteria assessment of observed dietary intake and points out that such an approach would add a great deal of information pertinent to understanding the situation of the population and to the formulation of policy. It would at least begin to make sense of the expected relationship between dietary assessments and biochemical and clinical assessments: one should not expect agreement unless all of the assessments accept the same underlying definition of adequacy - the same criterion of adequate nutriture!

THE INTAKE DISTRIBUTION

Sensitivity to Day-to-day Variation of Apparent Intake

Figure 2, portraying the adjustment of iron intake in adult women, illustrated the impact of removing day to day variation from the data set. The procedure of adjusting the distribution was described previously. Only two comments need be made here. First, as will be developed below, this step has other important advantages since it eliminates not only true variability in intake but also greatly reduces the impact of a number of sources or random error in the intake estimate. Second, the impact of day-to-day variation depends upon the nutrient (and probably also the population group and dietary methodology choice). The NAS report summarizes available information on the magnitude of this variation. Table 4 presents only a limited example drawn from one study (8,9). The point to note is that the ratio of variances changes with the nutrient. This is a measure of the relative error term in the estimate of usual intakes.

Table 4. An Example of the Ratio of Variances in Dietary Data

Nutrient (units)	Ratio of Intraindividual:Interindividual Variances	
	Adult Males	Adult Females
Energy (Kcal/d)	1.1	1.4
Protein (g/d)	1.5	1.5
Carbohydrate (g/d)	1.6	1.4
Starch (g/d)	2.9	1.4
Fat (g/d)	1.2	1.6
SFA (g/d)	1.1	1.4
PUFA (g/d)	2.8	4.0
Cholesterol (mg/d)	3.4	4.3
Vitamin A (IU/d)	- *	24.3 *
Vitamin C (mg/d)	3.5	2.0
Thiamin (mg/d)	2.5	4.4
Riboflavin (mg/d)	2.4	2.2
Niacin (NE/d)	1.6	4.0
Calcium (mg/d)	2.2	0.9
Iron (mg/d)	1.7	2.5

* The data of Beaton suggest an extremely high day-to-day variation for vitamin A. Other studies cited in the NAS report suggest much lower ratios, in the order of 3 to 11.

The available data suggest that, for adjustement of observed intake distributions, the partitioning of variance should be estimated from within the study data set. That is, it would be inappropriate to use the estimates presented in Table 4 as a basis for adjusting another data set. The implication is that the survey design must provide for the collection of a statistically appropriate sample of replicate intake estimates. This does not mean collection of a reliable estimate of usual intake for each individual - an objective that would require many replicates for each individual. The objective is the development of a reliable estimate of the distribution of usual intakes. This is much less demanding. (For example, the 1971-74 NFCS contained many more replicates that would be needed solely for this purpose. They may have been needed for other applications of the data.)

Sensitivity to Random Under- and Over-Reporting of Intake

If an individual randomly under- and over-reports intake across days, the error will appear as a part of the day-to-day variation discussed above and will be removed by the procedure of adjustment of the distribution. Therefore, it will have little or no impact on the prevalence estimate.

In contrast, if some individuals consistently under-report and other individuals consistently over-report intake, this will appear as a part of the interindividual variation and will not be removed by the adjustment procedures. The NAS Report presents an examination of the impact of this type of reporting error. It examined it on the assumption that such individuals were randomly distributed across the population (see later comments on bias associated with misreporting by a defined group).

To gain some perspective, consider the type of data that we have all seen presented in dietary validation studies - the distribution of the magnitude of misreporting (differences in reported intake between a reference and test method). In Table 5, this is presented from simulation modelling in relation to assumed random (between individual) reporting error.

Table 5. Impact of Random Reporting Error on the Distribution of Deviations Between Test and Reference Dietary Methods

Assumed Magnitude of Random Error CV (% of Mean)	Expected Distribution of Deviations Between a Test and Reference Method (Observed Intake vs. True Intake) Proportion of Population Showing Deviation of At Least					
	30%	25%	20%	15%	10%	5%
5	2.7	3.4	4.2	5.2	6.4	8.2
10	5.3	6.7	8.4	10.4	12.8	16.5
15	7.8	10.1	12.6	15.5	19.2	24.7
20	10.5	13.5	16.8	20.7	25.6	32.9
25	13.1	16.8	21.0	25.9	32.0	41.1
30	15.8	20.2	25.2	31.1	38.4	49.4

The above table is useful in deciding the outer limits of a reasonable assumption about potential error terms incorporated in a population data base. From the literature comparing methods, it appears that a realistic worst case situation would be that portrayed by the incorporation of a 20% random reporting error term. Table 6 then presents the impact of various magnitudes of this error term on the estimated prevalence of inadequate intakes. It is done for two nutrients (one with high prevalence estimates and one with low prevalence estimates) and the impact of both adding and removing a random error term is examined through simulation analyses. As would be expected the effect is greater when the prevalence estimate is low; here the tail of the intake distribution is more critical and adding or removing variance has substantial impact on the tails of the distribution. When the prevalence estimate approaches 50%, no matter what happens to the tails of the intake distribution, a similar proportion of the population will be estimated to have inadequate intakes. Considering the suggested worst case situation, removal of the error term would change the prevalence estimate for protein from 2.1% to 0.8% and for ascorbic acid from 41.0% to 39.8%.

<u>Table 6. Impact of Random Between Subject Reporting Error on the Estimate of the Prevalence of Inadequate Intakes</u>

Assumed Random Error CV (% of Mean)	Impact of Adding Error: Protein	Impact of Adding Error: Vitamin C	Impact of Removing Error: Protein	Impact of Removing Error: Vitamin C
0	2.1% *	41.0%	2.1%	41.0%
5	2.3%	41.1%	2.0%	41.0%
10	2.8%	41.3%	1.5%	40.8%
15	3.7%	41.6%	0.8%	40.4%
20	4.9%	42.1%	0.2%	39.8%
25	6.5%	42.6%	0%	39.1%
30	8.3%	43.1%	- **	38.0%

* Values are apparent prevalences of inadequate intakes computed by probability approach.

** Cannot be computed. The "error term" being removed is greater than the interindividual variation in the data set, an impossible situation.

These analyses suggest that a reasonable level of <u>random</u> under- and over- estimation of intake should not consitute a major concern <u>for this type of application</u>. While it will affect prevalence estimates, it will not affect the policy-relevant assessment that apparent prevalence of inadequate intakes is quite high or is very low. The issue for the designer and analyst to bear in mind is the needed precision of the estimate of prevalence. In turn this will establish the acceptable magnitude of random error in the reporting of intake.

The situation is very different if there is reason to believe that the error is systematic. The obvious example is a bias toward under- or over- reporting by the whole population. This can have major impact on the prevalence estimate just as did change in mean requirement estimates. It is clear, for example, that all prevalence estimates presented in this paper are too high for the simple reason that the NFCS data base does not include nutrient intake from pharmaceutical supplements. All that is being examined is nutrient intake estimated from food intake - a systematic underestimation of total nutrient intake. If it were established that certain segments of the population systematically misreported their intakes, and if these groups were a focus of interest, then obviously there would be errors in the estimates of prevalence of inadequate intakes among these groups!

The concern in design of surveys to be used in this type of analyses should focus upon the elimination of bias - consistent misreporting of intake - more than the elimination of random errors although these too should be minimized.

Sensitivity to the Variability of Food Composition

When one calculates nutrient intake using a food composition data base, at best one is assigning an average composition to the particular item of food consumed. We know that composition varies between foods falling into the same classification. Therefore, it follows that there is an unavoidable error in the estimation of nutrient intake even if the estimation of food intake is perfect! This error term does not appear within the data set. That is, we underestimate the true variability of nutrient intake because we assume the average composition rather than true composition. How large is this effect?

In Table 7 an estimate of the variability of composition of foods is presented. This has been generated from an examination of the new USDA food composition data base. For many foods, that data base provides an estimate of the standard error and the number of samples examined. From this the standard deviation of composition can be estimated. In turn, from this the coefficients of variation presented in Table 7 can be estimated. Empirically, it appears that the relative variability (CV) is higher at low concentrations of nutrient than at high concentrations. This may be a real biological phenomenon or it may be simply the result of methodologic errors (a constant error would be relatively greater at low concentration than at high concentration). For this reason, the table presents estimates of variability above and below the break point at which the CV appears to change for the particular nutrient. The variability terms appear to be very substantial. One might wonder whether, with this magnitude of "error", we can make any reliable interpretation of intake data.

Table 7. Apparent Variability of Food Composition
(Based on USDA Food Composition Data Base)

Nutrient Examined	Cut-off Point /100 g	Apparent Range of CV's Below Cut-off	Above Cut-off
Protein	2 g	5 - 50	5 - 15
Calcium	20 mg	5 - 50	5 - 15
Iron	1 mg	5 - 65	10 - 30
Magnesium	10 mg	5 - 50	10 - 30
Zinc	1 mg	5 - 65	10 - 30
Thiamin	.05 mg	5 - 50	10 - 30
Niacin	.5 mg	5 - 65	5 - 15
Vitamin C	7.5 mg	5 - 50	10 - 30
Folacin	20 mcg	5 - 65	10 - 30
Vitamin A	300 IU	5 - 65	10 - 30
Vitamin B_6	0.1 mg	5 - 65	10 - 30

To test the impact of this variation on a one day food intake estimate an actual record of intake was used. For each item of food a random member of the population of possible compositions for each nutrient was selected. To do this, either the data presented in the USDA tables were used as a descriptor of the population of compositions having mean and SD as described, or the population mean was taken as shown in the food composition table and the variability was inferred by selecting a random CV from the ranges shown in Table 7. In either case, a random member of a normal distribution having these characteristics was selected. The nutrient contents of the individual foods were then added to estimate the one day intake. The exercise was then repeated using new random members of the populations of possible compositions. This was repeated 1000 times and then the standard deviations and CV's of the computed one day nutrient intakes were computed. The results are presented in Table 8.

The table suggests that the error term in the one day intake estimate is appreciably less than might have been feared from an examination of the variability of composition of individual foods (Table 7). Statistical theory leads to the further conclusion that the more items of food included in the diet, the smaller will be the final relative error. This assumes that the individual error terms are indeed random and hence that while composition may be underestimated for one item, it may be overestimated for the next. If there is systematic error across all items, then of course the calculation would be misleading.

Table 8. Expected Variability of Composition of a One Day Diet Based on an Actual One Day Diet With 1000 Computations

Nutrient	Mean Content	Standard Deviation	Coefficient of Variation
Protein	105 g	6.2	5.9%
Calcium	1540 mg	80.8	5.2%
Iron	8.0 mg	1.2	14.9%
Magnesium	250 mg	15.7	6.3%
Zinc	11.6 mg	0.9	7.9%
Thiamin	2.1 mg	0.4	17.9%
Riboflavin	2.6 mg	0.2	7.9%
Niacin	15.9 mg	0.9	5.7%
Vitamin B_6	1.5 mg	0.13	9.4%
Vitamin C	153 mg	11.9	7.8%
Folacin	184 mcg	19.8	10.4%
Vitamin A	3800 IU	280	7.4%

Given the approach to adjustment of intake distributions to remove the impact of day-to-day variation, it should be recognized that part of the error remaining in Table 8 would be removed as a part of day-to-day variation. In the final distribution estimate, the contribution of variability of food composition would be quite small as long as there is reason to believe that it is random.

Conversely, it is also correct to recognize that the average compositions presented in the food composition data bases are not true averages - they are estimates of the true average composition. Each of these has an associated error represented in the USDA tables by the standard errors. In a manner analogous to that presented above, the standard error of the estimate of a one day intake may be calculated. Through statistical modelling the NAS Report examined the potential impa0t of this error on the prevalence estimate. For the nutrients examined, the standard error of the prevalence estimate ranged from ± 0.2 to ± 5%. This SE estimate included not only the error attributable to food composition but also the error terms assopciated with population sampling and intake reporting. These represent acceptably tight confidence intervals for the presumed purpose of the analyses.

In summary, then, the situation is not unlike that of random under- and over- reporting of intake. The random variation of food composition should not be a major concern for this application. Designers and users of data bases should be much more concerned about sources of systematic bias in the composition data than about random variation in food composition. An obvious example would be a methodologic error or an imputation error that consistently under- or over-estimates nutrient content for foods contributing a substantial part of the intake. Such an error is known to be present with regard to the iron content of meats used in the composition data base of the NFCS survey; it has been corrected in current USDA data bases and will appear in future food composition tables. A similar problem would arise if soil composition affects food composition and if all or most foods consumed were grown in the same region (e.g. selenium in wheat). It has been suggested that brand allegiance and differences in manufacturing practices might have similar impact although this should be subjected to sensitivity testing before any firm conclusion is drawn.

When there are very few analyses for a particular food item, or when the tabulated value in a food composition table has been imputed, there is obvious advantage in improving the reliability of the estimate of average composition. In either case, a priority among foods might be based on their relative contribution to total intake of the nutrient in question. The larger the contribution, the more important is the reliability of the food composition estimate.

Considerations of this type are very germane to this meeting. Sensitivity testing of the type portrayed offers an approach to considering the import, or non import, of reducing food composition data bases by lumping more foods into single descriptors. Such actions would alter both the reliability of the mean composition and the variability of possible compositions. The impact on prevalence estimates can be examined through simulation exercises and then a strong base for judgement about the appropriateness of the modification of the data base can be reached. A similar approach would hold for consideration of possible benefit of increased specificity in the description of ingested foods (in effect, an increase in the scope of the composition data base). As will be mentioned below, such considerations must take into account the intended purpose of data collection. Although the analyses presented herein suggest that the variability of food composition is a limited issue for the estimation of population prevalence of inadequate intakes, it remains a major source of error in the estimation of the composition of a particular individual's actual intake.

Mention should be made also of the impact of this variation in composition in validation studies involving the comparison of estimated food intake and direct chemical analysis of duplicate meals. One should not expect full agreement. One should not expect a regression slope of 1 in such comparisons. The so-called "flat slope syndrome" in comparison of dietary methodology may be explained, in part by the simple fact that the random error terms differ between methods of estimating intake (see Tables 10 and 11 for examples of effects that would be expected). The moral is that it is necessary to consider the nature and sources of variation in data sets before one can interpret them or before one can interpret validation studies.

BIOAVAILABILITY

Sensitivity to Nutrient Bioavailability in Ingested Diets

Dietary nutrient bioavailability can be considered as a variable affecting nutrient requirement or as a variable affecting effective intake. Either way the import is similar. It is illustrated in Table 9 for iron in young adult women. In this model, the upper limit of iron absorption is varied and the prevalence of inadequate intakes is estimated. This, in effect, generates a family of requirement curves each of which can be applied to the adjusted distribution of total iron intake. The same results would have been obtained were requirement described as the absorbed iron need and intake were discounted by taking into account the bioavailability limit.

Table 9. Impact of Change in the Estimate of Bioavailability on Apparent Prevalence of Inadequate Iron Intakes in Young Adult Women

Assumed Upper Limit of Iron Absorption	Estimated Prevalence of Inadequate Intakes
14%	50%
16%	39%
18%	30%
20%	23%
22%	18%
24%	14%
25%	13%

The effect shown in Table 9 is fully expected and has been the reason for major attention to the estimation of a bioavailability figure applicable to the population under consideration, i.e. to the nature of the usual diet.

Of considerable interest is the question of variability of bioavailability across the diets consumed by individuals. It is known that for iron at least, bioavailability is heavily influenced by the mixture of foods consumed at the same time. As the typical diet of individuals varies, so also would vary the appropriate bioavailability figure to apply to that diet. Thus, as a minimum, it is to be expected that there is a component of variation associated with bioavailability that is not taken into account in Table 9. If this is random across individuals, then its impact should be no more than that described for random under- and over- reporting or random variation in food composition. In this circumstance, a single bioavailability figure might be applied to the whole population without serious detriment to the prevalence estimate.

This would not be the case if relative bioavailability changed systematically with the level of total iron intake. That is, it is at least possible that diets that characteristically contribute a high level of total iron intake also characteristically have a high (or low)

% bioavilability and diets characteristically contributing a low level of total iron intake exhibit a relative bioavailability in the opposite direction. At present no studies examining this type of effect have been identified. One is underway in Toronto at present, hopefully again with the cooperation of USDA which has a data set that can address this issue.

While this may seem to be an esoteric question, it is really an issue that has considerable practical importance. There has been a major urging for expansion of food composition data bases and increase in precision of identification of foods ingested so that bioavailability algorithms can be applied on a meal by meal basis. To implement these recommendations is likely to mean a major expenditure of funds for food composition analyses, for data collection, and for computer analysis of collected data. Would such expenditures be justified? Would the acquisition of such increased precision be likely to change the final answers in material ways? This is the type of issue that can be addressed through sensitivity analyses. Undoubtedly the answer will depend upon the research question being asked. Nevertheless, the conduct of preliminary sensitivity analyses is going to be much cheaper than simply plunging into a commitment to the creation of new food composition data bases.

The Probability Approach to Estimation of the Prevalence of Inadequate Intakes: Data Requirements and Limitations

The foregoing discussion should have provided the reader with some assurance that the approach presented in the NAS Report is indeed viable. Many of the traditional concerns about nutritional interpretation of survey data have been set aside as having minimal import for this application. Some of these were surprising. For example, it was very surprising to this author that variability of requirement was not a major issue in actual practice. It is not surprising in hindsight!

A critical need that remains is the avail;ability of estimates of mean requirements of nutrients for the various age-sex groups and reasonable assurance that requirements are distributed in a generally symmetrical manner about these means (or an estimation of the actual distribution of requirements as in the case of iron in women). It is the position of the present author that for many if not most nutrients, we can generate reasonable estimates of these mean requirements and that the major issue we must address and declare is "requirement for what?" A recent FAO/WHO committee convened to address requirements for iron, folate, vitamin B_{12}, and vitamin A addressed this issue by defining two levels of requirement:

<u>Basal Requirement</u> The intake of a nutrient required to prevent any clinically demonstrable impairment of function. Individuals meeting this requirement will be well and will maintain normal growth and reproduction. They would not be expected to have any reserve of the nutrient.

<u>Normative Storage Requirement</u> This refers to the requirement of nutrient to maintain a reserve in body tissues. The reserve is seen as a supply of nutrient that can be mobilized without detectable impairment of function. The amount of such reserve deemed to be appropriate and desirable is a normative judgement.

I sincerely hope that this initiative of the FAO/WHO group is continued. It is consistent with the recommendation found in the NAS Report and will permit a multi-level assessment of observed nutrient intake in population data. Such assessments should be much more effective in facilitating consideration of the need or otherwise for interventions.

At the same time, it must be recognized that for some nutrients we really lack sufficient data to generate what we can all accept as reasonable estimates of average requirement. Calcium may be an example of this situation. It is extremely difficult, with existing methods, to estimate calcium requirement. This may or may not improve in the near future. Clearly if we cannot estimate requirements, or offer reasonable judgements about average requirement, we cannot apply the probability approach with confidence - nor can we apply any other assessment approach except one that gives assurance that all intakes above a stipulated level are adequate (i.e. a cut-point set above the highest suspected requirement). Thus, for example, one might suggest that if all intakes in a population fell above the RDA for a nutrient, there is no problem of inadequacy, one cannot say that if some intakes fall below the RDA there is a definable prevalence of inadequacy. On this rationale, it might be suggested that for some nutrients, and for public health purposes, the absence of requirement estimates is unimportant - intakes are known to be adequate thus no assessment is needed.

It is emphasized that this discussion focuses upon information about <u>requirements</u>. The published RDA's are not estimates of requirements although the text of the RDA reports may provide information about the underlying distribution of requirements. This is not a criticism of theh RDA report. Up until now it has not been a perceived mandate to the RDA committees to define average requirements or even to answer the question "requirement for what?" This may change in the future.

The NAS Report does emphasize, as should be apparent from the present paper, that there is no scientific justification for use of the RDA's, or some fixed proportion of the RDA"s, as a criterion of adequacy in assessing a population. There is no way in which RDA's or even a full knowledge of the requirement distribution can be used to classify the intake of a particular individual as either adequate or inadequate unless that intake falls outside of the range of requirements. At most a probability statement can be made.

The second major need for application of the probability approach, or any other approach to assessment of intake, is an unbiased estimate of the distribution of intakes. At present this may represent more a judged feeling of confidence, or non-confidence, about dietary data being collected than actual proof. If and when we detect bias in food intake data or in food composition data, the persons involved take steps to eliminate the source of bias. The judgement question arises from the fact that one cannot detect the absence of bias - one can only respond to the demonstration of bias.

Methodologic efforts must continue if we are to improve the estimation of nutrient intake; a major focus must be the detection and control of potential sources of bias. This is probably more important (for the present purpose) than eliminating all sources of variation although the two efforts will often move together.

A Warning: Always Remember the Purpose of Data Collection

The foregoing discussion and sensitivity testing presentations have addressed a defined purpose of data collection and analysis - the estimation of the prevalence of inadequate intakes in population data. For this purpose, a number of sources of variance, a number of "error" terms, have been demonstrated to have very limited impact.

This is not necessarily the case for other applications, other purposes of data collection.

It is critical that in the design of surveys, the ultimate purpose be borne in mind and the proposed analytical strategies be considered. It is only in this way that sound decisions can be made about which error terms must be reduced and which are acceptable.

To illustrate the importance of considering purpose and analytical strategy, let us consider a hypothetical example in which one wished to examine the relationship between usual ascorbic acid intake (independent variable) and white cell ascorbic acid (dependent variable). An analytic strategy might be the application of either regression analysis or correlation analysis. Several authors have pointed out that an error term in the independent variable will bias the regression coefficient toward 0 and error terms in either variable will attenuate the correlation coefficient. Tables 10 and 11 show the magnitude of these effects. (See reference 8 for equations to derive this table.)

Table 10. Bias of the Regression Coefficient Associated With Random Error in the Variables

Variance Ratio in Dependent Variable (Y)	Variance Ratio - Independent Variable (X) *							
	0	0.4	0.8	1.2	1.6	2.0	2.4	2.8
0	1.0 **	0.71	0.56	0.46	0.39	0.33	0.29	0.26
0.4	1.0	0.71	0.56	0.46	0.39	0.33	0.29	0.26
0.8	1.0	0.71	0.56	0.46	0.39	0.33	0.29	0.26
1.2	1.0	0.71	0.56	0.46	0.39	0.33	0.29	0.26
1.6	1.0	0.71	0.56	0.46	0.39	0.33	0.29	0.26
2.0	1.0	0.71	0.56	0.46	0.39	0.33	0.29	0.26
2.4	1.0	0.71	0.56	0.46	0.39	0.33	0.29	0.26
2.8	1.0	0.71	0.56	0.46	0.39	0.33	0.29	0.26

* Ratio of intraindividual variance/interindividual variance (See Table 4 for examples)

** The observed regression slope would be the true slope multiplied by the factor shown

Table 11. Attenuation of Correlation Coefficient by Random Error Terms in the Independent and Dependent Variables

Variance Ratio in Dependent Variable (Y)	Variance Ratio - Independent Variable (X) *							
	0	0.4	0.8	1.2	1.6	2.0	2.4	2.8
0	1.0 *	0.85	0.75	0.67	0.62	0.58	0.54	0.51
0.4	0.85	0.71	0.63	0.57	0.52	0.49	0.46	0.43
0.8	0.75	0.63	0.56	0.50	0.46	0.43	0.40	0.38
1.2	0.67	0.57	0.50	0.46	0.42	0.39	0.37	0.35
1.6	0.62	0.52	0.46	0.42	0.39	0.36	0.34	0.32
2.0	0.58	0.49	0.43	0.39	0.36	0.33	0.31	0.30
2.4	0.54	0.46	0.40	0.37	0.34	0.31	0.29	0.28
2.8	0.51	0.43	0.38	0.35	0.32	0.30	0.28	0.26

* Observed correlation coefficient would be the true correlation coefficient multiplied by factor shown

In the example chosen, the variance ratio for dietary ascorbic acid with one day data would be about 2.4 (a generalized estimate from Table 4). If one examined the relationship between dietary ascorbic acid and white cell ascorbate using one day data, the observed slope would be only 29% of the true slope; unless the relationship were very strong, this might not achieve statistical significance. As one increases the number of days of observation, the intraindividual variance would be decreased while the interindividual component would not change. With 3 days of data for each individual, the variance ratio would fall to 0.8 and the observed slope would rise to 56% of the true slope; after 6 days the variance ratio would be 0.4 and the observed slope would be about 70% of the true slope. Liu et al (16) calculated that if one wished to demonstrate statistical significance for the relationship between dietary cholesterol and serum cholesterol about three weeks of dietary data would be needed. Analogous calculations can be made for the correlation coefficient but here the error term in the dependent variable also contributes to the attenuation and would have to be taken into account. There are other statistical approaches, such as reversing the dependent and independent variables that can minimize some of these effects. Nevertheless, the point should be clear. In statistical analyses that use the individual's intake as a variable, the error terms assume a much greater importance than they do in the population assessments presented in this paper.

Actually the impact estimates presented above are conservative. Only measured day-to-day variability is taken into account. To the error term of the independent variable would have to be added the variability attributed to food composition and perhaps also the variability attributed to over- and under- reporting. As discussed previously, some of these error components would be factored out with increasing numbers of days while some (those attributed to interindividual variance in previous discussions) would remain as an error term in the independent variable.

In this situation, a viable alternative might be to select a dietary methodology that estimates usual intake rather than intake on a particular day - a food frequency or dietary history approach. This should minimize the error terms discussed above but these qualitative or semi-quantitative methods will tend to introduce imprecision in the estimate of intake (24).

The moral to be learned from this discussion is that there is no perfect dietary methodology. However, there are preferred methodologies for specified purposes. The secret then is to consider the purpose and analytical strategy before selecting the dietary methodology and conducting the survey or other dietary study.

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The members of the Subcommittee were:

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While acknowledging the contribution of all of the above persons, the present author accepts full responsibility for interpretations presented in the present paper. Readers are urged to examine the NAS Report for a full discussion of Subcommittee interpretations and recommendations.

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