4.0 INTRODUCTION TO THE DIET SEGMENT OF THE HHHQ

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4.1 PURPOSE AND CONSTRAINTS

In many epidemiological and clinical research situations, what is needed is a dietary assessment instrument which is both valid at the individual level and easy and relatively inexpensive to administer. The diet portion of the HHHQ was developed with the following purposes and constraints in mind:

A. Time limited to approximately 20-30 minutes for the diet section (if self-administered): In many epidemiologic studies or clinical trials, investigators are reluctant to impose additional burdens on their subjects or staff. One can get broad acceptance of the inclusion of a dietary component only if the instrument is brief.

B. Representative of an individual's usual intake: Only in this way can associations of dietary factors with clinical signs or health outcomes be fully and validly interpreted.

C. Capable of assessing nutrients as well as foods or food groups: Many research hypotheses involve nutrients, and the expansion and refinement of our understanding requires that we examine hypotheses at the nutrient level, in addition to examining foods and food groups.

D. Capable of assessing nutrients of future as well as current interest: The instrument must be broad enough to capture a wide range of nutrients of current interest. In this way it will serve the needs of investigations focusing on a single nutrient, while at the same time be capable of being analyzed for other potentially important nutrients. Furthermore, it is broad enough so that if, in ten years, nutrient x becomes of research interest, the data will provide the possibility of being analyzed for that nutrient.

E. Capable of assessing the diet of a wide range of (adult) population groups: An instrument which could be used in various population subgroups would allow for direct comparability between studies and comparison of such subgroups.

F. Capable of being self-administered: Some investigations will include a dietary component only if it does not impose significant additional burden on interviewers or on respondents' time in the clinic. An instrument which could validly assess an individual's diet in a self-administered way would promote the inclusion of dietary assessment in more investigations where it has heretofore been important but infeasible.

4.2 NUTRIENTS

4.2.1 Food List Coverage

Because of the nature of the development of the food list, it is anticipated that it will be adequate for the assessment of a wide range of nutrients consumed in the typical U.S. diet. This was achieved in two ways:

A. First, by ensuring that the food list includes foods representing at least 90 percent of the total U.S. consumption of each of 18 major nutrients; and

B. Second, by including in the list foods representing approximately 93 percent of total U.S. caloric consumption. In this way, the list is likely to include the major sources of nutrients other than the specific 18 mentioned above, if those nutrients are at all commonly consumed in the U.S. diet.

4.2.2 Dietary Assessment Program Nutrients

Nutrients in the DIETSYS Database

The following nutrients are currently on the database and thus, calculated by the program:

1. Total calories
2. Protein
3. Total Fat
4. Carbohydrate
5. Calcium
6. Phosphorus
7. Iron
8. Sodium
9. Potassium
10. Vitamin A (IU)
11. Vitamin A (RE)
12. Vitamin B1
13. Vitamin B2
14. Niacin
15. Vitamin C
16. Total saturated fat
17. Oleic acid
18. Linoleic acid
19. Total cholesterol
20. Dietary fiber
21. Folate[1]
22. Vitamin E[1]
23. Zinc[1]
24. Zinc from Animal Sources[1]
25. Vitamin B6
26. Magnesium
27. Alpha-Carotene[2]
28. Beta-Carotene[2]
29. Cryptoxanthin[2]
30. Lutein[2]
31. Lycopene[2]
32. Retinol
33. "Carotene" (Provitamin A carotenoids)

The database has a maximum capacity of 50 nutrients. Nutrients may be added to the database by editing the foods database via DIETSYS (Section 12).

1 Vitamin E has been added in this edition, through the generous collaboration of Dr. Suzanne Murphy at the University of California at Berkeley. Folate has been added with the assistance and collaboration of Denise Norris at the University of Alabama at Birmingham. The zinc values have been revised in collaboration with Dr. Julie Mares-Perlman at the University of Wisconsin.

2 Carotenoids are based on assayed or literature values or imputations based on Handbook 8, and have been updated somewhat since the prior version. These are not identical to recently developed USDA/NCI values (Mangels et al., J Am Diet Assoc 1993; 93:284-296), which are available on request. Ideally, correlations with plasma values should be examined. Nutrient 33, "carotene" has been shown to correlate well with plasma beta-carotene (Coates et al., 1992).

Estimates are also made of:

- Separate fiber estimates from: beans, grains, and fruits/vegetables;
- Percent of calories from fat
- Percent of calories from protein and carbohydrates
- Percent of calories from sweets
- Percent of calories from alcoholic beverages
- Weekly frequency of consumption of various specific foods and food groups.

4.2.3 Nutrients to be Added

It is anticipated that several other nutrients will be added to the database in the reasonably near future. Some investigators have developed or are developing database values for nitrites, glutathione (Flagg et al., 1993), methionine, polycyclic aromatic hydrocarbons, and other dietary factors. Other dietary factors of interest include copper and manganese. Anyone interested in participating in developing the database for these, or who has nutrient values they would be willing to share for this purpose, should contact Dr. Gladys Block.

4.2.4 Nutrient Calculation Algorithm

Nutrient estimates for the HHHQ dietary assessment are based on the NHANES II nutrient content database. This database is based on USDA food composition data tapes, as well as industry and other sources. All foods reported at least 20 times in NHANES II were updated in approximately 1980 with the latest USDA and industry information. Nutrient composition values for Vitamin A on the HHHQ database are based on Revised Handbook 8 values (8-1 through 8-21) which differed substantially from earlier values for several foods.

The Foods Database (see Section 12) includes portion sizes, in grams, for each food on the questionnaire as well as numerous additional foods. It also includes nutrients per 100 grams, developed as described in "A Data-based Approach to Diet Questionnaire Design and Testing" in Section 21, Appendix A. For each food, the program multiplies

$$\frac{(gram\ portion\ size * nutrient\ content\ in\ 100\ g * respondent's\ reported\ food\ frequency)}{100}$$

Nutrients are summed over all foods and expressed as average intake per day.

The above algorithm gives the basic structure, but in fact the program is much more complicated than that. For some foods the frequency is adjusted to accommodate the fact that they are eaten only in season. Milk on cereal may be added automatically by the program, or asked as a separate line item. Fats are adjusted in response to the answers on trimming meat, cooking fat, etc. The program also may add nutrients in response to the restaurant question. The questionnaire is intended to be used with the program and database developed for it. The algorithm for all adjustments are detailed in the descriptions of the analysis options (Section 16).

4.2.5 Derivation of Retinol, Carotene, and Retinol Equivalents

For vitamin A estimates, the NHANES II database does not provide nutrient composition values for carotene and retinol separately. Since current hypotheses require examination of the data separately by carotenoids and retinol, DIETSYS provides estimates of five specific carotenoids, as well as of retinol and a single "carotene" estimate. The specific carotenoids in the DIETSYS Foods Database are described in Section 4.2.7. In addition to these specific carotenoids, an estimate of provitamin A carotenoids (called, "carotene") is based solely on Revised Handbook 8 values. This "carotene" value has been found to correlate better with plasma beta-carotene than did any of the specific carotenoids (Coates et al., 1992; and Block, unpublished). The following section describes the calculation algorithms on which the estimates of retinol and "carotene" are based. These estimates derive from IU values from Revised Handbook 8, 1984.

A. All fruits and vegetables on the questionnaire are considered to derive essentially all of their vitamin A activity from carotenoids, as well as beef stew, vegetables soup, corn bread and pumpkin pie. In this revision of the software, tomatoes and tomato products once again have their full amount of beta-carotene corresponding to Handbook 8 values (in addition to substantial lycopene). In the previous editions of the software, tomatoes were given substantial lycopene but little beta-carotene.

   For fruits and vegetables, the calculation algorithm is

   Carotene = IU x .6
   Retinol = none
   RE = IU/10

   (See Section 4.2.6)

B. For the following foods, 90 percent of their vitamin A activity (expressed as IUs) is considered to come from carotenoids, and 10 percent from retinol:

   Chili con carne
   Chinese dishes
   Mexican dishes
   Seafood creole

   For these, the calculation algorithm is

   Carotene = (IU x .9) x .6
   Retinol = (IU x .1)/3.33
   RE = (IU x .9)/10 + (IU x .1)/3.33

   (See Section 4.2.6 for the source of all the proportions used here.)

C. For the following food, 75 percent of the vitamin A activity (expressed as IUs) is considered to come from carotenoids, and 25 percent from retinol:

   Spaghetti with tomato sauce

   For this, the calculation algorithm is

   Carotene = (IU x .75) x .6
   Retinol = (IU x .25)/3.33
   RE = (IU x .75)/10 + (IU x .25)/3.33

D. For the following food, 40 percent of the vitamin A activity (expressed as IUs) is considered to come from carotenoids, and 60 percent from retinol:

Pizza

For this, the calculation algorithm is

Carotene = (IU x .4) x .6
Retinol = (IU x .6)/3.33
RE = (IU x .4)/10 + (IU x .6)/3.33

E. For the following foods 27 percent of the vitamin A activity (expressed as IUs) is considered to come from carotenoids, and 73 percent from retinol:

(For Butter, see item 6)	Milkshake
Cheeses and cheese spreads	Ice cream
Mixed dishes with cheese	Yogurt
Whole milk (as beverage, in coffee or on cereal)	Sour cream,dips
	Other dairy product

For these, the calculation algorithm is
Carotene = (IU x .27) x .6
Retinol = (IU x .73)/3.33
RE = (IU x .27)/10 + (IU x .73)/3.33

F. For the following food, 11 percent of the vitamin A activity (expressed as IUs) is considered to come from carotenoids, and 89 percent from retinol:

2% milk (as beverage, in coffee or on cereal)
Butter (13% carotenoids, per Beecher 12/87)
Margarine (16% carotenoids, per Beecher 12/87)

For this, the calculation algorithm is

Carotene = (IU x .11) x .6
Retinol = (IU x .89)/3.33
RE = (IU x .11)/10 + (IU x .89)/3.33

G. For foods that are not from the vegetable kingdom and not among the mixed dishes mentioned above, essentially all of the vitamin A activity is considered to be derived from retinol.

For these, the calculation algorithm is

Carotene = none
Retinol = IU /3.33
RE = IU /3.33

4.2.6 Explanation of formulas used:

$$RE = \frac{IU\ from\ retinol}{3.33} + \frac{IU\ from\ b\text{-}carotene}{10}$$

$$ug\ retinol = IU_r\ x\ \frac{RE}{3.33 IU_r}\ x\ \frac{1\ ug\ retinol}{1\ RE} = \frac{IU_r}{3.33}$$

$$ug\ b\text{-}carotene = IU_c\ x\ \frac{RE}{10\ IU_c}\ x\ \frac{6\ ug\ b\text{-}carotene}{1\ RE} = IU_c\ x\ .6$$

Proportions of retinol and carotenoids can be derived from the following formulas which can be used when both IU and RE are given:

$$IU_r = \frac{10\ RE - total\ IU}{2}$$

$$IU_c = \frac{(3\ x\ total\ IU) - 10\ RE}{2}$$

Proportions were based on IU and RE values in Revised Handbook 8 or from recipe information provided by USDA.

4.2.7 Calculation of Specific Carotenoids

In addition to the estimation of provitamin A "carotene", described above, estimates are made for some specific carotenoids:

Alpha-carotene
Beta-carotene
Lutein
Lycopene
Cryptoxanthin

Values are based on recent assay data as well as literature values. When no such data were available, imputations were made based on Handbook 8 Vitamin A values. These specific carotenoids provided on the database (alpha-carotene, beta-carotene, cryptoxanthin, lutein and lycopene) are not the values recently developed by USDA/NCI (Mangels, et al., J Am Diet Assoc. 1993; 93:284-296). Those values are available on request. Ideally, correlations with plasma values, in nonsmokers, should be examined before deciding which database values to use.

4.3 THE FOOD LIST -- ITEMS AND GROUPS

The food list was selected as described in the attached methods paper (Section 21, Appendix A). By and large, food items are kept separate. However, in some cases several similar foods are asked in the same line. Generally, these are intended as prompts to the respondent rather than as items requiring multiple different nutrient contents. Nutrient content for group items are not calculated as weighted means, because often that would result in incorrect values for all users, rather than correct values for most users. In addition, weighted means are often inappropriate since a single portion size is used. Instead, usage-weighted medians are used, an approach that often falls on important modes for commonly-eaten foods. Some of these groupings are discussed below.

A. Pears with apples: Because they are eaten infrequently as reflected in the NHANES II data, pears would not warrant a line by themselves, and would be omitted altogether if we insisted on keeping them separate. Adding them to this line gives some nutrients to pear-eaters who would otherwise not get any credit for them. They are further justified on this line because they are similar in fiber & other nutrient content to apples, and probably substitute for each other in people's eating behavior.

B. Apricots with peaches: Again because they are eaten infrequently, apricots would not deserve a separate line, and would otherwise be omitted from the questionnaire, and apricot-eaters would get no credit for them. On the line with peaches, they get probably somewhat less carotene than they deserve, but still a substantial amount. Furthermore, although the carotene content of apricots per 100 grams is higher than that of peaches, the actual amount per serving is offset by their smaller portion size, so that the amount per serving is actually about right.

C. Other fruit: Fruits other than those listed are eaten too infrequently to warrant lines on the questionnaire. (The food list already represents 95% of the total Vitamin A and Vitamin C consumed in the U.S., for example.) This line is simply an opportunity to capture some additional nutrients. Because in self-selected diets these fruits are generally eaten either infrequently or in small quantities, we have shown that this line can actually be omitted altogether with absolutely no deleterious effect on correlations with reference data from multiple-day records (Block et al., 1990, J Clin Epidemiol).

D. Baked beans, pintos, etc. Not only would they not warrant separate lines, but they are probably thought of as interchangeable with one another, by respondents. (You would not have both baked beans and kidney beans at the same meal, for example.) And while they may differ slightly in their fiber content per 100 grams, all in this group are high in fiber. Eating any one of them with any frequency will put a respondent at the high end of the fiber distribution; further refinements of a few grams either way are of relatively little importance.

E. Similar comments could be made for mustard greens, turnip greens, etc.

F. Doughnuts, cookies, cakes, pastry. Although there may be some differences in nutrient content among these, the variation in nutrient content even within any one type can be great and many respondents interchange these desserts/snacks.

G. Cauliflower, brussel sprouts. Brussel sprouts were eaten extremely infrequently, would not warrant a separate line. On this line, brussel sprout eaters are given less Vitamin A and C than they deserve, but more than they would get if we left it out altogether.

H. Shellfish (shrimp, crab, oysters). These differ somewhat in cholesterol and other nutrients. However, in the NHANES II data the overwhelming majority of shellfish eaters ate shrimp. The scannable version of the questionnaire now includes a separate line for oysters, which are extremely high in zinc.

I. High fiber, bran or granola cereals, shredded wheat. Granolas actually have relatively little fiber, about 5g/100g compared with 30 for "All Bran". However, most of the public does not know that, thinks of it as a fiber cereal. What is given for this line item is 13g/100 grams -- most people ate something like "Raisin Bran", rather than "All Bran". If your study focuses specifically on fiber, you might wish to ask these as several separate items. Or, you might simply use the CodeCereal option, and ask the respondent which brand s/he eats most frequently; that will then give All Bran values to "All Bran", granola values to granola, etc.

For all combined items, there has been considerable thought regarding the effect on the length of the questionnaire and on the actual nutrient estimates. For some special purposes you may wish to omit a combined item and substitute two or more separate items. Consideration should be given, however, to the added length of the questionnaire and also the possible overestimates of nutrients such as A, C and fiber.

4.4 REDUCED VERSION OF THE QUESTIONNAIRE

A reduced 60-item questionnaire (BRIEF87) has been developed. Use of the full diet questionnaire is recommended unless truly precluded by time or burden considerations. (This recommendation applies specifically to the full **diet** questionnaire; the non-diet sections may be omitted or included as you choose.) However, in some situations a briefer questionnaire is essential, and consequently a reduced version has been developed. The diet section of the reduced version takes 17 minutes to interviewer-administer, and probably a somewhat shorter time if self-administered.

The reduced version has been shown to produce good correlations with the full-length version of the questionnaire and with reference data, although it produces lower absolute values of the nutrient estimates. The "brief" diet questionnaire consists of 60 line-item foods. The open-ended, restaurant and fat-added questions have been omitted.

The brief questionnaire was developed in a systematic way, using a large (approximately 1,000) dataset of full questionnaires. That dataset was split in half, and development was carried out in one half and tested in the other. Sections of the full questionnaire were omitted step by step, and nutrient analyses recalculated after each step. Correlations were then run between the nutrients estimated by the interim reduced version and the full questionnaire. Correlations with the full version were extremely high after dropping the open-ended, restaurant and fat-added questions. Foods were then deleted, from the bottom up with regard to their importance as nutrient sources (Block et al., 1985), and correlations recalculated.

Eventually it was concluded that the ancillary questions and all but approximately 60 food items could be omitted with little loss in the ability to rank individuals. Correlations between full and reduced versions were examined for all nutrients on the database. A few are reported below:

	r=		r=
• Calories	0.97	• Thiamin	0.98
• Protein	0.96	• Vitamin C	0.98
• Total fat	0.97	• Retinol Equivalents	0.99
• % cals from fat	0.94	• Dietary fiber	0.90

The dietary fiber correlation was the lowest seen. After examining U.S. dietary fiber sources (Block et al., 1987), chili with beans was added to both the full and brief questionnaires. Inclusion of the fat-added questions has a trivial beneficial effect on the correlations (0.94 --> 0.95), but causes a slight overestimate in the percent of calories from fat. The open-ended section has very trivial effects on the correlations, but there might be instances in which it could improve the assessment of populations with special diets. The restaurant question also appeared to have little effect on the correlations; however, those calculations were performed prior to some program improvements in the way the restaurant question adds nutrients. Thus, some may wish to include the restaurant question in the brief version. It is likely, however, that this would have a minor effect.

The brief version has been evaluated in several validation datasets, in which both the questionnaire and reference data (multiple 4-day or 7-day records) exist. The evaluation was conducted by examining correlations between the reference data and the 60-item subset of the FULL87 questionnaire (i.e., respondents completed the FULL87 version of the questionnaire and subsets of questions were subsequently analyzed).

A. A subset focused on calcium foods was validated against a 7-day record (Cummings et al., 1987) in elderly women. Whereas a 35-item version correlated with diet records at r=0.76, the list could be reduced to as few as 10 foods and still achieve a correlation of r=0.75.

B. Comparisons of correlations achieved by full and brief questionnaire with three 4-day records in one study, or two 7-day records in another, indicated that for some nutrients (notably Vitamin C and carotene) the correlations with the reference data are the same with the brief as with the full version. For most other nutrients there is a very small loss in correlation coefficient when the brief version is used, on the order of a change from r=0.60 --> r=0.57.

It should be noted that while correlations with reference data are nearly as good with the brief as with the full questionnaire, the <u>absolute value</u> of the nutrient estimates will of course be lower, since fewer foods are being asked. This is fairly unimportant for studies of diet-disease relationships, but could be a concern if the purpose were, for example, counseling patients or for comparing values of intake among different studies. Because of the extremely high correlations noted above between the full and reduced versions, prediction factors can make it possible to predict upwards from the reduced to the full-questionnaire estimates, (Harlan and Block, 1990). These are of use principally in counseling situations, and do not improve correlations with reference data.

Block et.al., 1990, Epidemiol describes the development of the brief questionnaire.

Vitamin supplement usage should be included in all questionnaires, including duration of supplement use. It is recommended that with either the full or the brief questionnaire, certain additional questions be asked, in order to interpret or analyze the diet data fully:

- Date, age, sex, height, weight
- Current cigarette smoking
- Use of skin on chicken, fat on meat, cooking fat, and table fat
- Overall number of vegetables per week, number of fruits per week, number of cereals per week.

A copy of the brief version of the diet questionnaire is included with the software, and is shown in Section 8. Like the full questionnaire, it may be modified and still be analyzed with the dietary analysis program.

4.5 RELIABILITY AND VALIDITY

4.5.1 Reliability

As used here, "reliability" means repeatability. A questionnaire is reliable if it produces the same results when repeated a second time (assuming that the actual truth, here the dietary intake, hasn't changed.) The reliability which is likely to be achieved by any instrument is influenced by the variability which it permits. For example, a questionnaire which does not permit variable portion size, or which uses categorical frequency responses (e.g., 2-3 times/week, 4-5 times/week, etc.), is likely to appear more reliable than one which allows for more variability in the responses. Thus, comparison of reliability of different questionnaires should be conducted with caution and with recognition of the different degrees of variability they may permit. Furthermore, reliability of the same instrument may be influenced by the method of administration, and particularly by the degree of error which the method of administration may foster. For example, in self-administration of the FULL87 or BRIEF87 questionnaire, respondents may accidentally put their food frequency response in the wrong column (e.g., "day" instead of "week"); this will introduce error in one but probably not an identical error in the other repeated administration. Since interviewers are somewhat less likely to commit this kind of error, interviewer administration is likely to appear more "reliable". Thus, while measures of reliability say <u>something</u> about respondents' ability to report their diets reliably, it should be remembered that other forces are also acting on repeatability estimates. It is also important to distinguish reliability from validity, how well it measures the truth as indicated by some reference method.

The diet questionnaire has been investigated for reliability in several studies, which will be summarized here.

A. Self-administration, season

In this study, conducted in collaboration with Dr. Winnie Chan of the Medical College of Virginia, the FULL87 questionnaire was self-administered by approximately 80 women. It was administered twice in a similar season (winter and early spring), approximately 6-8 weeks apart, and a third time in the summer, about 10 weeks later. Intraclass correlation coefficients among the three administrations were approximately 0.70 for most nutrients (Carotene, Vitamin C, and Iron were about 0.60). That is, the correlation between a first and second administration was about 0.70. The time unit referred to was "the past year or so"; season of administration did not appear to have a major effect on the overall nutrient estimates. (Hartman et al., National Cancer Institute, in preparation.)

B. Interviewer administration

In this study, conducted by Jessica Leighton at Columbia University, the FULL87 questionnaire was administered first by face-to-face interview and then by telephone interview (or in the reverse order for half the population.) Correlations between the two administrations were approximately 0.70 or better for all nutrients. Since differences may have been introduced by the different methods of administration, this presumably constitutes a lower bound on reliability which might be seen with interviewer administration using the same method. (Leighton et al., personal communication.)

Dr. Julie Mares-Perlman and colleagues at the University of Wisconsin have recently examined reproducibility among 214 participants (43-84 years of age) in the Beaver Dam Eye Study Nutrition Project. A modified version of the HHHQ, including oysters and some foods new to the market since the time of the original development, was interviewer administered to each subject two times, about three months apart. (First administration was between May, 1988 and December, 1990). Nutrient intake estimates between the first and second questionnaires, within age and sex categories, were not significantly different at the 0.05 alpha level. Median correlations for men and women were 0.8 and 0.7, respectively, ranging between 0.5 and 0.9.

4.5.2 Validity -- What constitutes good reference data?

A questionnaire is 'valid' if it measures what it is intended to measure. This HHHQ is intended to measure the usual, self-selected diets of individuals over an extended period of time, such as the past year. Its primary purpose is to rank or categorize individuals, although some data presented below suggest that it performs quite well at estimating absolute values and therefore group means, as well. Its ability to describe adequately distribution of intake is currently being studied through calibration (validation) studies (Freedman et al., 1991). That is, however, not its primary intention, nor is it mandatory, although desirable for studies of the relationship between diet and disease.

In validation studies of diet history questionnaires such as this one, some reference method is chosen which is defined, for that purpose at least, as the "gold standard" against which the questionnaire is to be compared. Thus, it is important to consider what constitutes an adequate reference method against which a questionnaire will be compared. Some possible reference methods, and their pros and cons, are discussed briefly below.

A. Using an earlier administration of the same questionnaire.

This is not validity, but repeatability (see Section 4.5.1 above.) A questionnaire could yield the same incorrect answers both times.

B. Using a more extensive diet history questionnaire or diet history interview.

It might, for example, be an interview conducted with careful probing and cross-checking, and/or with careful assessment of portion sizes using models, etc. This has some merit in that it is at least attempting to measure the same thing the questionnaire is attempting to measure, namely the long-term usual diet of an individual. An important reservation about this approach, however, is that respondents can make the same kinds of errors with both methods. For example, if a respondent thinks he eats more fruit than he really does, his Vitamin C estimate will be high on both methods and may correlate well, whereas in fact his true intake may be lower.

C. Using a 24-hour recall.

This is a completely inappropriate reference method for validating a diet history questionnaire. Because of day-to-day or intra-individual variability, 24-hour recalls do not represent the usual nutrient intakes of individuals very well, even for macronutrients. If carefully probed and quantitated, 24-hour recalls can produce reasonable group means. However, group means are not appropriate to use for validating a diet history questionnaire for two reasons:

1. For a questionnaire, group means are largely a function of what portion size assumptions are made by the investigator, and the length of the food list. Other things being equal, a long list will produce higher nutrient estimates than a short list. Thus, by manipulating the food list and quantitation, it is possible to make the group means come out approximately right for a given study group. That does not mean that it is valid, that it can correctly place individuals along the distribution of intake from low to high. We have shown in several studies that it is possible to have a food list which substantially underestimates group mean nutrient intake, but which correlates reasonably well with rigorous reference methods (see Section 4.4 on the development of the brief questionnaire). And conversely, we have shown that a questionnaire can produce group means essentially identical to those produced by multiple 7-day records, but whose correlation with those records at the individual level is literally no better than chance (Sobell et al., 1989).

2. The purpose of this questionnaire is not to produce correct absolute values of nutrient estimates, but to place individuals along the distribution of intake. That it appears to produce reasonable absolute values and group means in some instances is largely

fortuitous, and although desirable, not necessary to the study of the relationship between diet and disease. To study such relationships, it is necessary to relate an individual's health outcome to that individual's dietary intake. Comparison of group means constitutes a much weaker, less informative and more misinterpretation-prone approach (Lilienfeld, 1980).

D. Using multiple days of diet records or recalls.

If only a few days of diet information are used, they are not very representative of individuals' usual intake, and thus are less appropriate as reference data. The question then becomes, "How many days is enough?" There is no single answer to this. For the macronutrients (calories, total fat, saturated fat, protein and carbohydrate), a single four-day record itself correlates at about 0.65-0.70 with the "truth" as estimated from record-to-record intraindividual variability (Block, unpublished data). Thus, while a four-day record is not bad, it is also not a perfect reflection of usual intake for an individual. So while a four-day record constitutes somewhat reasonable reference data for the macronutrients, it should be recognized that at least some of the source of less than perfect correlations between questionnaire and reference data is due to the fact that the reference data themselves do not correlate perfectly with true long-term usual intake. It is not clear how many days are necessary. For macronutrients, perhaps 7-12 nonconsecutive days scattered over a year would constitute reasonable reference data. For micronutrients, or for linoleic acid and cholesterol, substantially more days are necessary, because of their greater day to day variability.

In addition, all estimates of required number of days assume independent -- i.e., nonconsecutive -- days. It is likely that four independent days provide more information about the diet than four consecutive days (Hartman et al., 1991). Ideally, the desired number of days would be scattered over the entire year, since it is usual diet over the year that is being assessed by the questionnaire. If record days are scattered over only a month, during the summer, for instance, they will provide reference data for usual intake during a summer month, which may not be representative of usual intake over an entire year.

It is difficult to obtain enough, and appropriately scattered, days of diet records to be strongly representative of individuals' usual diets. However, if this could be done it would constitute the most rigorous validation of a diet history questionnaire. Generally, fewer than the "ideal" number of days are used and correlations are adjusted for day-to-day variability in the reference method. This is because the types of errors which the two methods are subject to are different, so you don't get inflated correlations simply because the same errors were committed on both methods. For this reason, validations conducted against multiple days of diet records tend to produce lower correlations than validations conducted against another diet history interview.

E. Using investigator-administered diets.

Although this method has some appeal, because at least what was fed can be known with certainty, it is inappropriate as a validation method for any diet history questionnaire, especially this one. First, the food list was designed to reflect the most important foods in self-selected diets, as reflected in the NHANES II data. Unfortunately, these food choices do not usually correspond very well to what nutritionists would choose as a healthy balanced diet for study subjects. Similarly, the portion sizes fed may not correspond to what the subjects would normally choose in a free-living diet. Third, when the recall period is restricted to a very short period of time, such as the past one week or the past two weeks, subjects are thrown into a different response mode, that of actual recall; subjects actually try to remember eating events. Recall tends to produce underestimation, because of forgetting, while pattern-reporting tends to be less subject to this kind of error. Finally, this approach of using investigator-administered diets as the reference method often lends itself primarily to the calculation of group means. As discussed in 'C' above, group means are of little relevance to the validity of this questionnaire for the purpose for which it is intended.

F. Using physiologic measures

An advantage of using physiologic measures such as serum carotenoids or Vitamin C, urinary nitrogen or sodium is that they do not depend at all on the subject's reporting; and they should, for some nutrients, reflect actual intake. However, like dietary intake, physiologic measures are also subject to measure-to-measure variability. Thus, it is rarely the case that a single serum or urine measurement actually represents long-term usual intake; in almost all cases multiple measurements should be taken in order to represent long-term intake, although this has rarely if ever been done in validation studies. If a questionnaire addresses usual intake over the past year, and urinary nitrogen reflects intake over the past 24 hours, there is little point in examining their correlation. Physiologic measures are of course subject to numerous other problems of interpretation: effect of homeostasis, of interaction with energy intake or with other nutrients, effect of smoking, aspirin, other host behaviors, etc. All of these should be considered in conducting validation studies using physiologic measures. When comparing correlations obtained by different validation studies, it is important to examine the population characteristics carefully. Smoking lowers many plasma nutrients and results in poorer correlations with dietary intake among smokers. Vitamin supplement use raises plasma levels, and may result in inflated correlations if supplement intake is included in diet, or artificially low correlations if it is not. Study populations differ in the distribution of these characteristics, and are usually not directly comparable.

4.5.3 Validity -- Studies which have been performed.

A. Calcium study

Cummings et al., 1987 selected from this questionnaire the 34 food items which constituted the top 90% of calcium sources as seen in the NHANES II data (Block et al., 1985). They administered this subset of the FULL87 questionnaire to approximately 40 women in their 70's and 80's, and then had them keep a 7-day diet record. The correlation between the questionnaire and the diet records was 0.76. The mean calcium intake was 612 mg/day by diet records, and 637 mg/day by questionnaire.

B. Women's Health Trial Feasibility Study

A study was conducted in which about 100 women were maintained on their usual diet, and about 150 were trained and maintained on a diet consisting of approximately 20% of calories from fat. For reference data the control group had three four-day records, administered at baseline, six months and one year; the intervention group had three four-day records, administered at three months, six months and one year. At one year, both groups self-administered the FULL87 questionnaire, slightly modified, to assess their usual diets over the past year. Correlations for about 15 nutrients were approximately 0.5 to 0.6 (not calorie-adjusted), with a few correlations approaching 0.7. Correlations were similar in both the intervention and control groups. Mean values of nutrient intake in the two groups differed dramatically, and this was reflected extremely well by the questionnaire. For example: % fat in controls, 37.8 by records, 37.4 by questionnaire; % fat in intervention, 21.1 by records, 23.3 by questionnaire; polyunsaturated fat in controls, 13g by records, 12g by questionnaire; polyunsaturated fat in intervention, 5g by records, 5g by questionnaire (Block et al., 1991).

C. Retrospective dietary assessment

A study was conducted on approximately 250 middle-aged and older men. Reference data consisted of 2-4 seven-day records collected about two years apart, 12 to 15 years in the past. They were interviewed about their past diet using the FULL87 questionnaire. In the interview group, correlations for about 15 nutrients were approximately 0.5 to 0.6 (not calorie-adjusted), with a few correlations approaching 0.7. In the group which received the questionnaire by mail, however, and in which there was no personal instruction nor querying of unreasonable responses, correlations with reference data were substantially lower; in the case of a few nutrients, they did not even exceed that which would be expected by chance alone. In both the interviewed and mailed groups, the group means estimated by the questionnaire were very close to those estimated by diet records. (This illustrates the point mentioned above, that similarity (or dissimilarity) of group means, in the absence of good correlations, tells you nothing about the validity of a questionnaire for individual intakes.) In the interview group, the correlations are essentially as good as can be obtained for current diet using diet-record reference data. Poor results in the mailed group indicate that careful attention to data quality is crucial to obtaining valid data, and that the non-categorical form of the questionnaire used in FULL87 may not be appropriate for respondents who are not careful and committed to your study (Sobell et al., 1989).

D. Michigan study

A study was conducted in collaboration with researchers from the University of Michigan. The study population of 76 respondents included blacks and whites, males and females. Reference data consisted of 16 days of diet recalls and records collected over a one year period. For most nutrients the value of the questionnaire estimate was quite similar to that of the diet records. Most correlations were in the 0.5 - 0.6 range (Block et al., 1992).

E. Beaver Dam Eye Study Nutrition Project

In addition to the evaluation of reliability of a modified version of the HHHQ described in Section 4.5.1, this study also evaluated validity based on four sets of 2-day food records collected over a one year period of time starting a few weeks after the second administration of the questionnaire. Correlation coefficients between estimates from the questionnaire and food records were generally greater than 0.5 (Mares-Perlman et al., 1993).

F. Serum studies

A study was conducted in which approximately 40 men self-administered the diet questionnaire, and had their serum carotenoids analyzed. Preliminary analyses of these data indicated correlations between questionnaire and serum ranging from 0.4 to 0.55 for different carotenoids. This study is still in analysis, in collaboration with Dr. Phyllis Bowen.

A study among low-income Black women evaluated questionnaire estimates against plasma levels of carotenoids and Vitamin E, and found correlations comparable to those of other investigators (Coates et al., 1991).

Similarly, a study of 68 men (both white and non-white) found good correlations between dietary estimates and plasma levels of Vitamins C and E (Sinha et al., 1992, 1993).

G. Other validation studies have been conducted by other investigators. See Section 21 for bibliography.