CHAPTER 11

# DESIGNING RESEARCH DIETS

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## DESIGN GOALS, NUTRIENT INTAKE, AND DIETARY GUIDELINES

Research diets are first designed, calculated, and analyzed to ensure that study design goals are met and that intake is adequate for all nutrients other than those being investigated. Each nutrient value in the diet should then be compared against a population goal or standard. The Recommended Dietary Allowances (RDA) (1, 2) are often used as the basis for determining whether intake of nutrients other than the study variable(s) is adequate. RDA are standards for nutrient intake designed to meet the nutrient needs of virtually all healthy individuals in the United States. With the exception of energy, the RDA are established at two standard deviations above the mean requirement of the population and are, therefore, believed to meet or exceed the requirements of about 95% of the population. Most people who consume less than the RDA for a specific nutrient will nevertheless meet their own personal nutrient requirement. However, for practical purposes, a cutoff point, such as two-thirds or three-fourths of the RDA, could be used to judge whether intake for a specific nutrient is adequate.

The Food Nutrition Board, National Academy of Sciences, has developed the Dietary Reference Intakes (DRI) with the intention of providing a comprehensive set of parameters for evaluating dietary adequacy. These parameters include, among others, the RDA. This discussion will refer to the RDA as the basis for assessing adequacy of intake.

When a research diet is deliberately designed to be deficient or low in one or more nutrients, other nutrients in the diet are also likely to be inadequate. Likewise, if a very high-fat or low-energy diet is fed, many nutrients in the diet may fall below 70% RDA. In some cases, it may be difficult to feed a nutrient at the RDA level specified for one sex group. For example, the current RDA for iron is 15 mg/day for adult women (1), a level that is often difficult to meet with foods

eat right. American Dietetic Association

Source: "Well-Controlled Diet Studies in Humans, A Practical Guide to Design and Management", American Dietetic Association, © 1999.

alone, especially at low calorie levels. To meet the RDA in these situations, either a commercial vitamin or mineral supplement may be fed, or the lacking nutrient can be added directly to the diet. Direct addition is preferable to avoid "overbalance" for intakes of other nutrients. Folate, iron, magnesium, vitamin B-6, and calcium are nutrients particularly likely to need special attention.

Whereas the RDA are useful for assessing adequacy of nutrients in research diets, other types of population dietary goals have been developed to target nutrients of excess. The National Cholesterol Education Program (NCEP) Guidelines (3) are commonly used for comparing fat type and amount to dietary goals (Table 11-1). NCEP nutrition publications for patients and professionals are described at the National Heart, Lung, and Blood Institute Web site (www.nhlbi.nih.gov/nhlbi/nhlbi.htm).

It also can be useful to relate nutrient levels in research diets to the current nutrient intakes of the US population. The Continuing Survey of Food Intakes by Individuals (4), published by the USDA Survey Research Laboratory, reports mean intakes of various nutrients by gender and age and compares current intake levels to the RDA. This publication also has useful information about the percent of individuals consuming foods from various food groups, weight status of the population, frequency of physical activity, and perceived importance of dietary guidance. The Food Survey Research Laboratory home page (www.barc.usda.gov/bhnrc/foodsurvey/home.htm) provides information on new releases of survey data, highlights from the surveys, information about the Survey Discussion Group, and links to other USDA Internet sites related to food and nutrition.

The National Health and Nutrition Examination Surveys (NHANES) also provide population-based estimates of nutrient intake, as well as data about physical characteristics and indicators of health and nutritional status (5). The NHANES surveys are conducted by the National Center for Health Statistics. Reports detailing survey results as well as methodology are available in print and electronic format (6). Three study cycles have been completed (NHANES I-III); the fourth (NHANES IV) began its pilot testing phase in 1998.

## DETERMINING NUTRIENT INTAKE

### Calories

Energy is provided by fat, carbohydrate, protein, and alcohol. The carbon and hydrogen components of these compounds can be oxidized to carbon dioxide and water. The nitrogen component of protein is not oxidized but is, for the most part, excreted from the body as urea. Gross energy of foods can be measured from the heat released by oxidation of foods in a bomb calorimeter (the heat of combustion). An adjustment to this measure is made for apparent digestibility of foods because some nitrogenous materials, fibers, and other organic matter are lost in the feces. From these measurements, calorie factors have been derived for energy sources for individual and complex foods.

The calorie factors that databases use for protein, fat, and carbohydrate are food-specific, meaning they are adaptations of the traditional Atwater factors commonly used for calculating energy in mixed diets (ie, 4, 9, and 4 kcal/g for protein, fat, and carbohydrate, respectively). The Atwater factors used in the current USDA Nutrient Data Base for Standard Reference (Release 12) (9) (see Exhibit 11-1) and also in the print versions of Agricultural Handbook 8 (10)

**TABLE 11-1**

**Intake of Dietary Components: Recommended and Current Levels**

| | Recommended Intake[1] | Current Intake[2] |
|---|---|---|
| Carbohydrate | 50-60 en% | 50 en% |
| Protein | 10-20 en% | 16 en% |
| Total fat | $<$30 en% | 33 en% |
| Saturated fat | $<$10 en% | 11 en% |
| Polyunsaturated fat | $\leq$10 en% | 7 en% |
| Monounsaturated fat | 10-15 en% | 13 en% |
| Cholesterol | $<$300 mg | 212 mg (women)<br>334 mg (men) |
| Dietary fiber | 20-30 g | 14 g (women)<br>19 g (men) |
| Reference age group | Over age 2 years | Adults |

[1]Recommended intakes of fat, carbohydrate, and protein are from Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction, National Cholesterol Education Program. US Department of Health and Human Services, NIH publication 90-3046, 1990 (3). Recommended intake of dietary fiber is from Butrum et al, 1988 (4).
[2]Source: 1994 Continuing Survey of Food Intakes by Individuals and 1994 Diet and Health Knowledge Survey. Agricultural Research Service, US Department of Agriculture, 1996 (5).

## EXHIBIT 11-1

**USDA Nutrient Database for Standard Reference, Release 12**
available at www.nal.usda.gov/fnic/foodcomp

### WHAT IS SR12?

The USDA Nutrient Database for Standard Reference, Release 12 (SR12), is prepared by the Nutrient Data Laboratory of USDA's Agricultural Research Service. It is the major compilation of food composition data in the United States and provides the foundation for most public- and private-sector databases. SR12 contains data about 5,976 food items. Data lists up to 81 nutrients when a complete profile is available for a food item. SR12 supercedes the previously published food composition data in printed sections of Agriculture Handbook No. 8 and SR11-1.

### FORMAT

The database is being provided in the two relational formats, ASCII and DBF. There are four principal files: Food Description, Nutrient Data, Gram Weight, and Footnotes. Four support files include: Nutrient Definition, Measure Description, Food Group Description, and Source Code. New information (first provided in SR11) about all foods includes scientific name (where appropriate); factors for calculating protein from nitrogen and calories from protein, fat, and carbohydrate; INFOODS tagnames to identify food components internationally; a source code to indicate whether the value is based on analytical data or is an imputed value; and additional measures for many foods. A series of update files is provided for users who have obtained a copy of SR11-1 and who wish to perform their own updates. An abbreviated flat-file format featuring fewer nutrients is also included; this feature was available previously. Also provided are reports on each food item.

### NUTRIENTS

| | | |
|---|---|---|
| Water | Ash | Vitamin A (IU & RE) |
| Food energy (kcal and KJ) | Amino acids | Ascorbic acid |
| Protein | Calcium | Thiamin |
| Total fat | Iron | Riboflavin |
| Total saturated fatty acids | Magnesium | Niacin |
| Total monounsaturated fatty acids | Phosphorus | Pantothenic acid |
| Total polyunsaturated fatty acids | Potassium | Vitamin B-6 |
| Individual fatty acids | Sodium | Folate |
| Cholesterol | Zinc | Vitamin B-12 |
| Total dietary fiber | Copper | $\alpha$-tocopherol |
| Caffeine | Manganese | Alcohol |
| Theobromine | Selenium | |

### CHANGES IN THIS RELEASE

Items that are no longer on the market, such as most beef cuts trimmed to ½-inch fat, have been deleted. Several hundred new items have been added and a number of other items have been updated. Two major changes to nutrients in this release concern folate values and selenium. The revised folate values for enriched grain products and foods containing these products reflect the change in FDA regulations that required the addition of folic acid to selected foods effective January 1, 1998. The nutrient data for selenium for most foods in the database was added in this release.

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are specific to two decimal places. Because this database forms the core of most other food databases, specific Atwater factors are used in most nutrient calculations. These factors, derived from heat of combustion, are adjusted for available energy (11). Thus, the Atwater factor for carbohydrate for a food containing highly digestible carbohydrate forms is higher than for a food with an equivalent amount of which a large proportion is indigestible.

Energy calculations for recipes (and sometimes menus) can differ substantially when general factors rather than specific factors are applied. Consider, for example, that "energy for whole-grain wheat flour is calculated using the specific factors of 3.59 kilocalories per gram of protein, 8.37 kilocalories per gram of fat, and 3.78 kilocalories per gram of carbohydrate. The result is 339 total kilocalories. Using the general factors of 4, 9, and 4, the estimate would be 362 kilocalories" (12). It is a common experience for novice dietitians to be dismayed to discover that hand-calculated values for a recipe, based on general Atwater factors, do not exactly agree with the values calculated using a food database. This problem is greater for individual foods or when a small number of foods are involved than when averages are for many foods. When general Atwater factors are applied to mixed diets as opposed to individual foods, the differences are generally small, (approximately 1%).

## Protein and Nitrogen-to-Protein Conversion Factors

Protein values in databases are derived by assessing the nitrogen content of foods and applying a conversion factor reflecting the mass proportion of nitrogen in the protein molecule. Just as there are general and specific values for caloric values of carbohydrate, protein, and fat, there are also general and specific values for nitrogen-to-protein conversion factors. Although the general conversion factor of 6.25 (based on the assumption that protein contains 16% nitrogen by weight) is appropriate for many research diets, some protocols, such as nitrogen balance studies, should use specific factors. In formula diets where the predominant source of protein comes from eggs, the conversion factor will be 6.25, but when milk is the predominant source of protein, the conversion factor used will be 6.38. The nitrogen-to-protein conversion factors used in current food tables are based largely on data published by Jones (13).

Dietary needs for protein exceed the need for a set amount of nitrogen because there are specific requirements for essential amino acids. The literature on protein quality and on estimating nitrogen and amino acid requirements of humans is extensive and includes a collection of papers by the Committee on Amino Acids, National Academy of Sciences (14). Although typical American diets provide ample high-quality protein, research diets low in total protein content or low in animal protein content should be reviewed for adequate protein quality, particularly if the study participants are growing children, adolescents, or pregnant women.

## Fiber

Methodological problems are obstacles to the accurate assessment of food fiber (15). Different chemical methods measure different classes of fiber components. Some databases may contain values for fiber analyzed by an array of methods that are not directly comparable (Table 11-2). Values for crude fiber, which have been reported in food tables in the past, should not be used. Analytical values for total dietary fiber in the current USDA Nutrient Data Base for Standard Reference, Release 12, were determined by the Association of Official Analytical Chemists (AOAC) (Gaithersburg, Md) enzymatic-gravimetric method (9, 16). Although soluble and insoluble fiber values may be more informative for nutritionists, these fiber fractions present particularly difficult analytical barriers and their values differ according to method of analysis. Values for total dietary fiber, soluble fiber, and insoluble fiber have been published for a number of foods (17, 18). Several methods have been approved by AOAC International as the official methods for dietary fiber analysis (16).

Recommendations for fiber intake have been expressed in quantitative values and in qualitative terms, based on servings of fiber-rich foods. The dietary guidelines of the National Cancer Institute recommend that fiber intake in the United States be increased to 20 g/day to 30 g/day from a variety of food sources with an upper limit of 35 g/day (8) (Table 11-1). Guidelines based on food selection advocate the consumption of at least five servings of fruits and vegetables per day and at least six servings of grains and legumes (19).

## Alcohol

Alcohol is a source of calories for a substantial proportion of adults. Alcohol yields 7.07 kcal/g when combusted in a bomb calorimeter (11) and 6.93 kcal/g when adjusted for a 98% coefficient of digestibility. For protein, fat, and carbohydrate, the values generated by bomb calorimetry, and adjusted for digestibility, are directly applicable to biological use. That is, replacing one nutrient for another at an equivalent calorie level will produce equivalent effects on body weight. However, alcohol appears to contribute to the body's energy balance in a different manner (20–22). Using alcohol to replace carbohydrate calories may fail to maintain body mass in some individuals (20); and alcohol added to a maintenance diet may not produce the anticipated weight gain (21, 23). Other investigators, however, have found that energy balance is maintained by isoenergetic diets that substitute moderate amounts of alcohol for carbohydrate (23).

## Vitamins and Minerals

When investigators formulate research diets for vitamin and mineral content, particular attention must be paid to the possibility of inadequate intake. Cooking losses or gains must be accounted for,[1] and diets must be checked carefully to ensure that intakes will be adequate. For example, smoking increases the need for vitamin C; intake of this vitamin should be 140 mg/day or more if the participants of a research study are smokers (24, 25). Also, it may be difficult to meet the RDA for calcium and iron for women and elderly

[1]The Provisional Table on Retention of Nutrients in Food Preparation (April 1984) is available from the Nutrient Data Laboratory of the USDA Beltsville Human Nutrition Research Center and can be downloaded from the Nutrient Data Laboratory home page (http://www.nal.usda.gov/fnic/foodcomp) or bulletin board (301) 734-5078. These retention values are based on the True Retention method:

$$\% \text{ True retention} = (\text{Nutrient content per g cooked food} \times \text{g food after cooking}) \div (\text{Nutrient content per g raw food} \times \text{g food before cooking}) \times 100$$

(This equation can be found in Murphy EW, Criner PE, Gray BC. Comparisons of methods for calculating retentions of nutrients in cooked foods. *J Agric Food Chem.* 1975;23:1153-1157.)

**TABLE 11-2**

**Total Dietary Fiber Content of a Diet Reference Material Analyzed by Six Different Methods[1]**

| Method | Total Dietary Fiber (g/100 g dry weight) |
|---|---|
| Crude fiber | 1.4 |
| Neutral detergent fiber | 1.8 |
| Englyst[2] | 3.6 |
| Theander | 5.1 |
| AOAC | 5.3 |
| Li | 5.6 |

[1]Diet Reference Material 8431, National Institute of Standards and Technology, Gaithersburg, MD. Table adapted from Li (15).
[2]Differences among the Englyst value and those of Theander, AOAC, and Li are caused mainly by the exclusion of lignin.

people, especially at lower calorie levels (26). Although calcium can be obtained from some vegetables, large quantities would be required to meet the RDA. Dairy products are generally required unless calcium supplements are used. Iron supplements may also be required.

Folate, B-12, B-6, and riboflavin intakes may need to be increased if female participants are taking oral contraceptives (27). Folate nutrition is a problem for elderly subjects also; among this group anemia and subnormal erythrocyte levels are common problems (28, 29). The Food and Drug Administration amended the Standards of Identity for enriched grain products to require the addition of folic acid effective January 1, 1998 (30). This fortification policy has made it easier to design low-energy diets that are adequate in folate.

Another factor hampering the design of diets with specific vitamin content is the inadequacy of nutrient databases. For example, little is known about carotene content of foods, particularly the individual carotenoids. Because of the historical view of carotenoids as mainly precursors of vitamin A, most food composition tables provide vitamin A activity or provitamin A carotenoid content of foods (31, 32) rather than total carotenoid content. For data on individual carotenoid content of foods as well as total carotenoid content, research dietitians can refer to the USDA/NCI Carotenoids Food Composition Database (33) (Version 2, 1998), which can be downloaded from the Nutrient Data Laboratory home page or bulletin board.

It is likely that there will be increased emphasis on the tocopherol and ascorbate content of research diets because these antioxidants appear to protect cells from oxidative damage and because the requirement for vitamin E may depend partly on the dietary vitamin C intake. In preparing for studies that investigate both vitamins C and E, it is essential to have nutrient information on these vitamins for all foods. Values for vitamin E in milligram $\alpha$-tocopherol equivalents are available for only about 60% of the items in Release 12 of the USDA Nutrient Data Base for Standard Reference (9). The vitamin C information in nutrient databases is relatively complete, but comparability to actual vitamin C values of foods in research diets will be questionable, in large part because of variation in such factors as storage time and cooking conditions for food items.

Improved nutrient database values are also badly needed for trace elements. This problem is highlighted in the case of selenium. Because little is known about the biological function of selenium in humans, more investigations are being conducted in selenium metabolism. Topics of interest include the effects of dietary selenium on selenium metabolism and immune status, selenium dependent metabolic and physiological processes, and utilization of different chemical forms of selenium. The current USDA Standard References database (SR-12) (9) has selenium content for the foods that are the major contributors of selenium in the US diet.[2] Because the selenium content of foods varies significantly throughout the United States depending on soil content, when purchasing food for a study of selenium, it is important to specify clearly the regions where wheat (34) and beef products (where selenium content reflects grain—wheat—intake) will be procured.

Absorption of selenium and other trace elements may be affected by the level of major minerals and other trace minerals in the diet and by the presence of other potentially interfering substances such as phytate and other chelating agents. Final review of the overall diet design and calculated nutrient content will help in identifying these food and nutrient interactions.

## Commentary: Quality of Nutrient Data

Although critical to the planning of research diets, accurately analyzed data do not exist for all nutrients and all foods. (See Using a Computer to Design Research Diets and Chapter 3, ‘‘Computer Applications in Controlled Diet

[2]Provisional tables for sugars (HERR-48, 1987), vitamin D (HNIS/PT-108, 1991), selenium (HNIS/PT-109, 1992), and vitamin K (HNIS/PT-104, 1994) are available from the Nutrient Data laboratory, USDA, 4700 River Road, Riverdale, MD 20737. They can be downloaded from the Nutrient Data Laboratory home page (http://www.nal.usda.gov/fnic/foodcomp) and the Nutrient Data Laboratory bulletin board (301) 734-5078.

Studies.'') Also, in developing its nutrient databases, the USDA generally has sought to provide data that can be used to represent national average values. Thus, although estimates for nutrient values have been indispensable for evaluating survey data, they may give a false sense of security concerning the preciseness of data for the purposes of feeding studies.

Both the quality and quantity of available data vary depending on the nutrient component of interest. For many foods, values are imputed or missing for folate, pantothenic acid, and vitamins A and E. Similarly, data may be limited for certain categories of foods. The USDA often publishes these smaller databases in provisional form. Although there is a large body of food composition data for commodities, there are fewer data for manufactured or processed foods. Even for commodity foods with adequate analytical data, the standard error often indicates large variation in the nutrient content.

The seasoned research dietitian is aware of these problems and avoids using food items that have missing values or large standard deviations for nutrients of interest. It is standard practice to print the nutrient breakdown for each food in a menu or recipe and check for missing values (many computer programs flag foods that have missing values for nutrients). Each nutrient database handles this problem differently; in some instances nutrient values are imputed from values of similar foods, but other databases will leave a data cell blank rather than supply an estimated value. Missing data can cause calculated values to be falsely low. Chemical validation of research diets thus is highly desirable. (See Chapter 22, ''Validating Diet Composition by Chemical Analysis.'')

## Selecting the Foods

When developing menus, the research dietitian must translate nutrient goals into specific food items and palatable menus that can be prepared at the study facility and that will be appealing to research participants. This section addresses issues to consider in selecting food items for research studies.

### Study Goals and Key Foods

Food items are selected for use in diet studies based, in large part, on the nutrient variables to be studied. In formulating diets, it is helpful to have one list of foods containing minimal amounts of the nutrient of interest and another list of foods containing substantial amounts. Typically, key foods are used as vehicles to deliver nutrients of interest. The ideal key food will allow incorporation of the dietary variable in varying amounts, will facilitate masking of dietary treatments, and will provide optimal palatability. For these reasons, baked products are standard vehicles for dietary fats, although fats can also be added to some entrees and side dishes.

### Caloric Distribution and Serving Sizes

During menu planning, it is important to examine the caloric distribution of the diet throughout the day. Compliance is thought to be best when approximately 70% to 80% of the day's calories are distributed among the breakfast, lunch, and dinner meals, and the remaining 20% to 30% is disbursed between the afternoon and evening snacks. However, this caloric distribution may not be practical in research units with limited staff to deliver and monitor food intake several times a day.

Compliance in feeding studies also is enhanced when serving sizes have relatively normal appearance on the plate or tray. When investigators develop the research menu these ''household measure'' servings must be translated into gram amounts. The USDA Nutrient Data Base for Standard Reference (9, Exhibit 11-1) and most other food tables provide nutrient values based on amounts expressed in two forms: as 100-g edible portions (with information on standard error and number of samples) and as one or more common household measures. Practical information on serving sizes, such as approximate measure and weight, also is given. For example, one small loaf of pita bread (4-in diameter) is equivalent to 28 g; one large pita (6½-in diameter) weighs about 64 g.

Information about typical portion sizes of more than 100 foods is available from a government publication entitled *Foods Commonly Eaten in the United States: Quantities Consumed Per Eating Occasion and in a Day, 1989–91* (35). These data were collected from a survey conducted by the US Department of Agriculture (Continuing Survey of Food Intakes by Individuals). Data for each food item are displayed as both means and percentiles and are tabulated for individuals by gender and age.

It is customary in controlled diet studies to portion each food item according to the caloric needs of the participants. In the most conservative approach to this direct proportional allocation of foods, the quantities are ''scaled'' for calorie level; each food item is weighed to the nearest gram. This practice sometimes yields awkward portions of foods because gram amounts seldom coincide with whole units of foods such as crackers, muffins, or cookies. For example, a participant assigned exactly 30 g of whole wheat bread might receive one whole slice of bread and an additional small piece of bread. This degree of detail is not always necessary. In many studies it is acceptable to serve bread in units of half or quarter slices. When consistent with study objectives, apples and oranges also may be served in units of half or quarter slices; raw vegetables such as carrot sticks and lettuce can be served as pieces. This allows portioning in normal units and is more aesthetically pleasing to participants.

It is necessary to assess in advance how such changes affect a research diet. Nutrient values should be calculated for any prospective liberalized change at all calorie levels and then compared to nutrient values calculated using the more precise measures.

When investigators plan menus, careful consideration must be given to serving sizes and numbers of food items: quantities must first be estimated for intermediate or average calorie levels, but then the menus must be checked to see what happens at the extremes. As discussed in Chapter 10, ''Planning Diet Studies,'' serving sizes often become distorted from typical sizes as food items are scaled for very high- and low-calorie levels. This becomes particularly apparent in studies with both men and women whose energy requirements may range from 1,600 kcal to 4,400 kcal. In order that men at the highest calorie levels do not receive unreasonably large servings, the number of food items must be increased. For example, instead of a single vegetable at dinner, two or three different vegetables may be required. In a direct proportional allocation system, women at the lowest calorie levels then receive two or three very small servings.

## Food Preferences of Participants

When designing menus for a study, the research dietitian must consider common food preferences, intolerances, and allergies. It is essential to screen participants carefully before entry to the study in order to evaluate dietary habits as well as to obtain vital information about whether the participant can and will eat the diet study foods.

Although diets can be designed to closely match nutrient goals, this is of little value if participants will not eat the meals. Food aversions are widespread. (See Chapter 13, ''Delivering Research Diets.'') It is critical to make clear to potential participants what exceptions can and cannot be made to suit their personal preferences. If this is not done, compliance will suffer. A single intolerance for a food, such as applesauce, often can be accommodated by substituting another pureed fruit. An allergy or intolerance to chocolate, however, would be a strong reason to disqualify a potential participant from entering a study that uses chocolate to provide particular fatty acids. If a food item or recipe is widely disliked in the course of a diet study by a large proportion (over one-fifth) of participants, alternate recipes or uses of the key ingredients should be considered.

In many research facilities it is not feasible to offer food choices, so diets are planned using widely acceptable food items. The disadvantage to this approach is that such meals can be bland. Although few people prefer bland foods, there is no common agreement on how to season foods. Onion, garlic, and green peppers are staple seasonings for many people, but these foods are offensive or cause indigestion for others. Similarly, a product may be too salty for some, yet not salted enough for others. Of the 300 potential participants interviewed for a recent study (36), about one-third reported a strong dislike for certain foods. Among those potential subjects, the most disliked foods in decreasing order were: liver and other organ meats, brussels sprouts, milk, cheese, oatmeal, fish, green pepper, onion, and pork.

A prestudy ''buffet'' featuring different potential diet study recipes and foods is a convenient and helpful forum in which to realistically assess participants' food preferences. Prospective participants should be encouraged to evaluate and comment about the study foods. Following up on comments and suggestions is a small but important way for the staff to build rapport with the participants and to demonstrate receptiveness to their needs. Recipe testing and meal assessment is traditionally conducted using staff members, but a different perspective is gained from having potential participants evaluate food products and menus.

## Special Populations and Ethnic Food Patterns

If younger people such as college or graduate school students are participants, it is important to include daily snacks for consumption during evening study hours. Exam and school vacation schedules must be accommodated as well. Students or others who play team sports may have drastic changes in caloric needs and exercise level during certain seasons (eg, baseball players in spring). Providing calculated, portion-controlled snack packages is an option that students are usually grateful to receive. A useful snack item can be a ''unit'' snack, which is a muffin, cookie, or other food or combination of foods that have a composition that is identical to the composition of the diet. (See recipes for unit foods in Chapter 18, ''Documentation, Record Keeping, and Recipes.'') With the exception of the unit snack, it is advisable *not* to include essential diet items in snack packages. For example, in a diet study that focuses on fats, it is better to provide low-fat snacks.

For elderly participants, foods that are ''kinder'' to artificial dentition, such as applesauce or baked apples instead of raw fruit, are recommended. Also, with the elderly, decreased lactose tolerance may necessitate pretreatment of some foods with the enzyme lactase. (See Chapter 13, ''Delivering Research Diets,'' for a discussion of lactose maldigestion.)

When subjects are children, a more repetitive menu cycle may be indicated in order to ensure compliance. Thus, whereas in an adult study a pasta entree may be served once or twice a week, if it is a well-consumed favorite of child participants, it can be served more often if the study design permits. (Also see Chapter 9, ''Children as Participants in Feeding Studies.'')

Recruitment of ethnically diverse study populations is an increasingly important feature of human studies. Developing menus acceptable to diverse tastes while meeting study design goals presents a particular challenge. This issue actually has several components: population groups, food patterns and choices, and nutrient data. Investigators must assess exactly which demographic groups are likely to contribute individuals to the participant pool. Sometimes this is related to key hypothesis-testing aspects of the protocol. For example, investigators may wish to study whether response to diet differs significantly between Hispanics and Asians; in this case specific numbers of subjects must be recruited to fill predefined statistical ''cells.'' At other times, recruitment strategies will seek participants in proportion to their numbers in the overall US population; in this case a large array of racial or ethnic subgroups may be represented.

Once the likely demographic composition of the study population is known, food patterns must be considered. They can be another challenge because food preferences may be affected by degree of acculturation (eg, food patterns differ greatly between first-, second-, and third-generation immigrants); yet finer demographic distinctions (eg, there are many Asian countries, and food patterns vary among them), and religious practices within ethnic groups (eg, Moslems and Hindus from India have different dietary habits) exist. However, individuals willing to submit to the rigors of a feeding study may also be willing to subjugate food preferences for the duration of the protocol. Appropriate screening procedures will seek out individuals whose food preferences are sufficiently flexible to accommodate most menu plans.

Researchers designing diets to accommodate ethnic food patterns may be interested in exploring these publications:

- Sanjur D. *Hispanic Food Ways, Nutrition and Health.* Needham Heights, Mass: Allyn and Bacon, Publishers; 1995.
- *The American Dietetic Association Ethnic and Regional Food Practice Series.* Chicago, Ill: American Dietetic Association; Hmong, 1992; Filipino, 1994; Soul & Traditional Southern, 1995; Cajun & Creole, 1996; Indian & Pakistani, 1996; Chinese American, Mexican American, Jewish, Navajo, and Alaska Native, 1998. Northern Plains Indians is being developed.
- Achterberg C, Eissenstat B, Peterson S. Intervention strategies for special groups. In: Kris-Etherton PM, Burns J, eds. *Cardiovascular Nutrition: Strategies for Disease Management and Prevention.* Chicago, Ill: American Dietetic Association; 1997.

Finally, foods chosen to accommodate ethnic preferences must meet the same standards for characterization and consistency in appearance, taste, physical properties, and nutrient content that are applied to all other foods used in assembling a research menu. This consistency may be hard to guarantee in imported foods or those manufactured by small specialty producers. Satisfactory data about nutrient content also is needed, but the great demand for nutrient information for ethnic or foreign foods has exceeded the ability of US databases to provide reliable data on these foods. Users may find data from foreign sources to be helpful. A list of composition tables for foreign foods (37) can be obtained from the International Network of Food Data Systems (INFOODS) (e-mail address: http://www.crop.cri.nz/crop/infoods/infoods.html). INFOODS also supports an Internet discussion group about food composition activities around the world (Food-Comp@Infoods.unu.edu). Subscription requests can be sent to Food-Comp-Request@Infoods.unu.edu. A food description system, Langual, is useful for linking food items in international databases (38).

## Food Substitutions

For the most strictly controlled feeding studies, participants rarely have a choice in food selection. When participants are required to eat only the provided foods, individuals who repeatedly fail to consume a particular food typically are dismissed. Other studies allow limited exchange of food items that are similar in composition (eg, sugar for hard candy) or limited addition of items not carrying nutrients of interest (eg, carrots or celery in a study of dietary fat). This flexibility allows participants some degree of control over their diets without compromising the study.

Some investigators will exclude potential participants who strongly dislike a food to be used in a study (eg, cheese); others will accept the participant and make appropriate substitutions (eg, whole milk to achieve equivalent intakes of type and amount of fat). In some controlled feeding studies, it is common to make allowances for ''free meals'' or ''days off'' (39). At these times, substitutions or tradeoffs can be used to ensure that nutrient intake does not stray too far from controlled intakes.

A more liberalized approach to food substitution is often appropriate for long-term intervention studies. For example, one intervention study's goal was not only to study outcome parameters but also to permanently change the eating patterns of the study participants. This might be done, for example, to lower fat intake as a potential protection against breast cancer in an intervention study that spans many years. Participants in such studies might be free-living women who prepare their own food and document food intake through diet records; dietary goals would be tailored to food preferences of the participants to add variety, maintain motivation, improve compliance, and retain participants.

If substitutes are deemed acceptable, the dietitian's role is to ensure correct application of substitutions to achieve the study goals. Exhibits 11-2, 11-3, and 11-4 are examples of substitutions or tradeoffs that have been used in an intervention study (40) to reduce fat intake. Participants are provided with a list of tradeoffs and are responsible for implementing appropriate food substitutes, a strategy that promotes more involvement of participants in the research process. Using tradeoffs adds variety and flexibility for participants without the time-consuming effort of recalculating research menus.

The tradeoffs in Exhibits 11-2 and 11-3 are isocaloric substitutes for nonfat foods containing carbohydrates. (It should be noted that in some studies these specific tradeoffs would not be appropriate because of changes in fiber and antioxidant contents of the tradeoff pairs.) Milk products can be substituted for other dairy combinations containing similar fatty acid compositions (Exhibit 11-4). These substitutions are helpful in alleviating varying degrees of lactose—or, more specifically, milk—intolerance, especially

## EXHIBIT 11-2

### Carbohydrate Equivalents Used in a Study of Dietary Fats[1,2]

| | |
|---|---|
| 1 packet jam (0.5 oz) = ½ small banana | 1 cup orange juice = 3 packets jam |
| 1 slice white bread = ½ white bagel | 1 cup cranberry juice = 4 packets jam |
| 1 slice wheat bread = ½ wheat bagel | 1 cup apple juice = 3 packets jam |
| 5 oz cola = 4 oz orange juice | 12 oz cola = 4 packets jam |
| 4.5 oz root beer = 4 oz orange juice | 10 oz Mystic® or fruit-flavored soda = 4 packets jam |
| 2 tsp Coffeemate® = 1 packet jam (less than 1 g fat) | 12 oz ginger ale = 3 packets jam |
| 2.5 oz cranberry juice = 4 oz orange juice | 3 slices of rye or wheat bread = 70 g pita bread |
| 2.5 oz grape juice = 4 oz orange juice | 2 packets of jam = 1 cup cantaloupe, watermelon, or papaya |
| 3.5 oz apple juice = 4 oz orange juice | 70 g french bread = 70 g pita bread |
| ¼ cup candy corn = 5 packets jam | 2 tsp of white or brown sugar, or honey = 1 packet of jam |
| 1 oz gumdrops = 3 packets jam | 1 Matzoh cracker = 3 packets of jam |
| 1 oz hard candy = 3 packets jam | |

[1]A variety of substitutions should be encouraged. Tradeoffs are isocaloric but may differ in vitamin C content. Orange juice, in particular, should not be consistently substituted for vitamin C-poor foods in studies where this antioxidant might affect outcome variables.
[2]Quantities of food typically reflect single-serving allotments.

## EXHIBIT 11-3

### Tradeoffs for Popcorn Used in a Study of Dietary Fats[1,2]

Alternatives for 8 cups of Nonfat Popcorn (choose one):

| | |
|---|---|
| 3 fresh, medium apples (with skin), 2¾″ diameter | 7 fresh, medium peaches |
| 4 fresh, medium oranges, 2⅝″ diameter | 7 fresh, medium plums (2⅛″ diameter) |
| 2 oz hard pretzels (< 2 g fat/oz) | 10 cups of raw broccoli or cauliflower |
| 2.5 fresh, medium pears, 2½″ diameter | 1.5 cups cooked, drained, cooled macaroni |
| 2.5 fresh, medium, ripe bananas (8¾″) | 2 medium baked potatoes with skin (2¼″ to 3″ diameter) |
| 4 cups frozen strawberries, unsweetened | 4 slices wheat bread (4 × 4 × ½″) |

[1]The substitutes for popcorn provide the same calories. However, some popcorn tradeoffs provide more fiber than others. Therefore, it is important to choose different substitutes each week for variety and to distribute fiber intake. In particular, do not choose broccoli and cauliflower exclusively.
[2]Quantities of food typically reflect allotments for 1 week.

when lactase-containing products or supplements fail to alleviate gastrointestinal symptoms. (Also see Chapter 13, ‘‘Delivering Research Diets.’’) Egg whites or egg substitutes and foods high in sugar content are combined to balance the amounts of protein and carbohydrate and to maintain calorie levels.

It is more difficult to make tradeoffs among complex foods while maintaining a precise distribution of fatty acids in the diet. A useful approach for maintaining a fatty acid profile is to replace a fat-containing food with a fat source that closely matches the fatty acid pattern of the replaced food. Some examples are: substituting soybean or safflower oil for the polyunsaturated fat content of bean curd (tofu); substituting olive oil for the monounsaturated fat content of almonds or olives; and substituting a selected vegetable oil for nuts or seeds containing the same primary unsaturated fat (eg, walnut oil replacing walnuts). In each case, an oil replaces an equivalent amount of fat in the disliked food.

Making any kind of substitutions for research foods requires instructing participants thoroughly on how to trade off amounts of equivalent items. In addition, follow-up measures to ensure compliance must be performed. Measures may include frequent review of food records by dietitians, telephone interviews with participants, and home visits by nutritionists.

Food substitutions have been used to achieve a high degree of compliance, to encourage meal completion, to heighten awareness of diet requirements, and to educate participants about implementing intervention diets. However, meeting participants' individual food choices is challenging within the strict requirements of research diet studies and, in some research settings, making substitutions is not feasible or practical. In those instances, it is advisable to serve universally acceptable foods.

## Staff and Facilities

Menus should be designed to be consistent with the capabilities of the staff and the operation of the facility. Ideally, staffing is scheduled to meet the needs of the protocol. In instances where research facilities overlap with larger, insti-

## EXHIBIT 11-4

**Milk and Dairy Equivalents Used in a Study of Dietary Fats[1,2]**

7.5 cups 1% milk = 4 oz part skim mozzarella cheese
and 8 oz Egg Beaters
and 3 cups orange juice

7.5 cups 1% milk = 2½ cups vanilla yogurt
(3%–4% milk fat: 8 g fat/cup)
and 3 packets jam (0.5 oz ea)
and 12 oz Egg Beaters

7.5 cups 1% milk = 19 oz Egg Beaters
and 1¾ cups orange juice
and 1⅓ cups Breyers® Vanilla Ice Cream
omit 1 packet jam

10 cups 1% milk = 4 oz whole-milk mozzarella cheese
and 18 oz Egg Beaters
and 4 cups orange juice

10 cups of 1% milk = 1¾ cups Breyers Vanilla Ice Cream
and 25 oz Egg Beaters
and 2¼ cups orange juice
omit 1 packet jam

10 cups of 1% milk = 3¼ cups vanilla yogurt
(3%–4% milk fat: 8 g fat/cup)
and 17 oz Egg Beaters
omit 4 packets jam

1 qt 2% milk = 2⅓ cups vanilla yogurt
(3%–4% milk fat: 8 g fat/cup)
and 5 oz Egg Beaters
omit 2¼ cups orange juice

1 qt 2% milk = 2 oz cheddar cheese
and 6 oz Egg Beaters
and 1¾ cups orange juice

1 qt 2% milk = 1⅓ cup Breyers Vanilla Ice Cream
and 10 oz Egg Beaters

2 cups (1 pint) whole milk = 2 oz cheddar cheese
and 2 oz Egg Beaters
and 5½ tsp sugar

2 cups whole milk = ½ cup Haagen Daz® Vanilla Ice Cream
and 5 oz Egg Beaters
and ¾ tsp sugar

11.5 cups whole milk = 2 tsp sugar
and 28 oz Egg Beaters
and 3 cups Haagen Daz Vanilla Ice Cream

11.5 cups whole milk = 10 oz cheddar cheese
and 6 oz Egg Beaters
and 4¾ cups orange juice

1 cup skim milk = 1 cup nonfat frozen yogurt
omit 2 packets jam (0.5 oz ea)

9 oz cheddar cheese = 12 oz whole-milk mozzarella cheese

6 oz cheddar cheese = 8 oz whole-milk mozzarella cheese

6.5 oz cheddar cheese = 9 oz whole-milk mozzarella cheese

[1]Tradeoffs are balanced for calories and total fat, including saturated, polyunsaturated, and monounsaturated fats. Units are in household measures to facilitate implementation by study participants. Tradeoffs can be calculated in weight equivalents, but accuracy should be verified prior to use.
[2]Quantities of food typically reflect allotments for 1 week.

tutional facilities (eg, university feeding facilities), it may be necessary to plan the most critical aspects of feeding participants to coincide with optimal staffing times. For example, if lunch is the best staffed and best monitored meal, incorporation of key dietary material should take place at this time to enhance accuracy in meal preparation, consumption, and compliance.

## Details Can Make a Difference

The examples given here are intended to draw attention to the importance of vigilance in planning diet studies, whether by eliminating extraneous sources of nutrients or carefully making food choices that enhance the match between the menu and the study goals.

- Calcium chloride is added to low-sodium canned tomatoes.
- The sodium content of "quick-cooking" Cream of Wheat® is higher than in the "instant" or regular-cooking Cream of Wheat.
- Some brands of low-sodium cheese actually have sodium chloride added; therefore, direct, chemical analysis is vital.
- When aluminum containers are used for frozen constant/metabolic diets, the aluminum content of the diet may be increased.
- Low-sodium baking powder used in pancakes or baked products for constant/metabolic diets can increase the aluminum content of those diets.
- In studies in which urinary pH changes are important (eg, whether the acidifying effect of exercise on urine contributes to renal stone formation), it is necessary that the diet have at least 10 mEq acid ash content. An alkaline ash diet can negate the results by alkalinizing the urine. The ash content of the diet is determined by adding the milliequivalent values for calcium, sodium, potassium, and magnesium (alkaline ash) and comparing them to the milliequivalent values for phosphorus, chloride, and sulfur (acid ash). A source of food composition information for chloride and sulfur has been published (41).
- If the crust on low-sodium bread seems to be significantly darker and heavier than the rest of the bread, the sodium content of the crust should be analyzed separately. Some bakeries brush the top of bread with raw egg white prior to baking to hasten the browning process. This practice

slightly increases the sodium content of the crust. If this small variation in sodium content from slice to slice is not acceptable for constant or metabolic diets, crusts can be trimmed off before the bread is weighed.

- Very-low-sodium diets are often low in calcium as well, because most dairy products are typically omitted from these diets. For studies (eg, hypertension studies) that involve changing subjects from a very-low- to a high-sodium diet, the sodium content of the diet should not be increased by increasing the content of dairy products. This may alter calcium intake which, in turn, may influence blood pressure.
- At low calorie levels, it is often difficult to meet the RDA for calcium. In these cases, vegetable sources of calcium may be useful for meeting the RDA (eg, tofu, broccoli, and spinach). Orange juice enriched with calcium is another option.
- Drink mixes such as Kool-Aid® are commonly used in research diets, often to increase calorie intake. The major nutrients of Kool-Aid are vitamin C, calcium, phosphorus, and sugar. A serving supplies about 10% of the RDA for vitamin C. Although the calcium and phosphorus contents of these beverages are low compared to the RDA, these quantities may be important in studies of minerals, particularly when participants receive multiple servings of these drinks (Table 11-3).
- Many cereals are fortified with iron and thus will not be appropriate for low-iron studies. These cereals are useful, however, for meeting the RDA for iron for premenopausal women.
- Dietary supplements (eg, NaCl, $KHCO_3$, KCl, PEG) can be mixed in water to a specified concentration and weighed amounts served to study participants. This eliminates possible errors of loss that can occur if supplements are administered in powdered form.
- The increasing popularity of baking soda toothpaste warrants a strong warning to dietitians and other investigators who study sodium intake. Baking soda toothpastes often have much higher sodium content than regular formulations, but there also is considerable variation among brands. For protocols requiring strict control of sodium intake, it may be advisable to poll the participants about their preferred brand of toothpaste, analyze these brands for sodium content, and choose the brands that best complement the protocol. Another option is to ask a research pharmacist to compound a dentrifice specifically for use in the study. (See Table 13-1.)

Toothpaste manufacturers' data for 6 brands indicated 19 mg to 87 mg sodium is ingested per episode of brushing. (Swain J. Sodium in toothpaste. Practice Note. *The Digest.* Chicago, Ill: American Dietetic Association; Spring 1993.)

## USING A COMPUTER TO DESIGN RESEARCH DIETS

### General Considerations for Selecting Database Software

The use of printed food composition tables has been superseded in recent years by microcomputer nutrient database programs. Software vendors provide a variety of programs that calculate nutrient intake. For many of these packages, however, the food composition data will not meet the stringent quality control that is required for research diets.

Although a large number of user-friendly software packages are available, no one software package is ideal for all applications. Too often a nutrient calculation package is chosen on the basis of convenience of use rather than the quality of the data. Research nutritionists should carefully evaluate and test the quality of a nutrient analysis system before applying it to diet studies. The evaluation process should include a dem-

**TABLE 11-3**

**Nutrient Content of Three Flavors of Kool-Aid® Soft Drink Mix[1]**

| | | Grape | | Cherry | | Lemon-Lime | |
|---|---|---|---|---|---|---|---|
| Nutrient | Unit | Per 100 g[2] | Per Serving[3] | Per 100 g[2] | Per Serving[3] | Per 100 g[2] | Per Serving[3] |
| Energy[4] | kcal | 211 | 98 | 210 | 98 | 215 | 98 |
| Sugars (total) | g | 0.5 | 25 | <0.5 | 25 | 3.0 | 25 |
| Vitamin C[5] | mg | 1,089 | 6 | 1,095 | 6 | 1,097 | 6 |
| Calcium[6] | mg | 1,963 | 11 | 1,119 | 6 | 1,077 | 6 |
| Phosphorus[6] | mg | 870 | 5 | 512 | 3 | 493 | 3 |

[1]Manufacturer's data compiled by Janis Swain, MS, RD, Brigham and Women's Hospital, Boston, Mass.
[2]Dry soft drink mix without sugar.
[3]8 fluid oz of reconstituted beverage as prepared (0.140 oz package, 1 cup sugar, and cold water to make 2 quarts).
[4]The main sources of energy in unsweetened Kool-Aid® powder are citric acid and maltodextrin, carbohydrates that are not classified as sugars. (R. Cutrufelli, USDA Nutrient Data Laboratory, personal communication).
[5]The ascorbic acid content of soft drink powders can vary by twofold or more due to storage, manufacturing changes and other factors. Researchers who must control vitamin C intake should assay each batch directly. (R. Cutrufelli, USDA Nutrient Data Laboratory, personal communication).
[6]May be higher if local sources of water rather than deionized water are used.

onstration of the software facilities by the vendor and use of a demonstration disk or system for a trial period. The algorithms used for calculating the research diet must be clearly documented. In addition, the quality of the nutrient composition database used to calculate the diet must be evaluated. Some database factors worth considering are:

- The origin and nutrient completeness of the database.
- The accuracy of the nutrient information.
- The frequency with which nutrient composition data are updated.
- The number of food items included.
- The strategies used to estimate or impute missing nutrient data.
- The ability to add food items and nutrient values.
- The use of manufacturer's data in the database.
- The ability to create recipes with the existing food composition database files.
- The ability to add a recipe as a new record onto the food composition database.

Other factors to evaluate in a nutritional software package include program flexibility, performance speed, user interface, clarity of support material, completeness of nutrient reports, availability of technical support, and appearance and readability of printouts.

## Databases with Software

Since 1976, annual National Nutrient Databank (NND) conferences have been held to address issues surrounding the use of nutrient databases. The organizers of the NND conference also produce a Nutrient Databank Directory (42) describing current commercial database systems. Although the features and contents of more than 50 software and database systems are listed in this directory, the directory makes no attempt to evaluate individual systems. Likewise, this manual makes no attempt to evaluate or endorse individual database programs.

Some programs that are widely used to calculate research diets are:

- CBORD Diet Analyzer (The CBORD Group, 61 Brown Road, Ithaca, NY 14850).
- Minnesota Nutrition Data System (NDS) (University of Minnesota, Nutrition Coordinating Center (NCC), 2221 University Avenue, SE, Ste 310, Minneapolis, MN 55414).
- Food Intake Analysis System (FIAS) (University of Texas, School of Public Health, PO Box 20186, Room W606, Houston, TX 77225).
- MENu Database Planning Software (Pennington Biomedical Research Center, Baton Rouge, LA 70808).
- Nutritionist IV (First Databank, The Hearst Corporation, San Bruno, CA 94066).
- Food Processor (ESHA Research, Salem, OR 97302).
- ProNutra Nutrient Analysis System for Metabolic Studies (Princeton Multimedia Technologies, Princeton, NJ).

For more information about database programs, refer to Chapter 3, "Computer Applications in Controlled Diet Studies." Also, professional journals often publish comparative database studies (43–48) that can provide guidelines in selecting an analysis system suitable for designing research diets.

## Developing Computer Programs to Analyze Menus

Many metabolic units have found commercial database programs limiting or too costly to purchase. Thus, some research centers have elected to custom design a computer program to analyze research menus. Several steps are involved in this process before a system is available to calculate research diets.

### *Selecting a Database Management Program*

First, the designer must decide what database management system (DBMS) will be used to store the food composition database. The system should be user friendly so that the nutritionist need not depend on a programmer to maintain the database or produce the programs to calculate the diet menu. Some database management packages that have been successfully used to store a food composition database and to create diet calculation programs are dBASE IV Plus®, Microsoft Access®, and SAS® (Statistical Analysis System).

Features to consider in selecting a DBMS include: What version of DOS (desktop operating system) or Microsoft Windows® is needed to operate this system? Is this a relational database management system (RDMS)? Will the system be able to handle meta-data (data about data)? Is the system interactive? Does it have pull-down menus? Is there a file linking capability? Are there entry windows? How many fields can one record contain? How many records can a file hold? Is there an automatic validation of field entry against a look-up file? Can the system provide graphical reports?

### *Selecting a Food Composition Database*

Besides selecting a DBMS, one must select an appropriate food composition database to be the primary file in the calculation program. Most research facilities and database developers use the USDA Nutrient Data Base for Standard Reference in their microcomputer diet calculation programs (9, Exhibit 11-1). This continually updated database incorporates all revisions to Agriculture Handbook No. 8 and now supersedes the earlier print versions (10). Like Handbook 8, the data on this database are expressed per 100 grams of the edible portion of the food item. Included in the Standard Reference is a file that provides a description of the field arrangements for items on the records and a list of food descriptions and item numbers. The food descriptions and item numbers may serve as an online coding source or can be used to generate a paper copy for an in-house coding manual.

The database files for Standard Reference can be downloaded from the Nutrient Data Laboratory of the Beltsville Human Nutrition Research Center, US Department of Agriculture (http://www.nal.usda.gov/fnic/foodcomp). The complete version of Standard Reference is now available only in relational format (a change initiated with Release 11).

### Checking Hardware Support Capabilities

After selecting a DBMS and an appropriate food composition database, the designer must calculate the amount of computer memory needed to support the DBMS and the food composition database files. Enough memory must be allotted for data processing and for file storage. In addition, older microcomputers should have math coprocessors to facilitate mathematical calculations. In some cases, hardware will need to be upgraded to support the DBMS and the food composition database. (For details on hardware and computer memory refer to Chapter 3, ‘‘Computer Applications in Controlled Diet Studies.’’)

### Converting Food Composition Information into a DBMS File

Generally, in order to associate the food composition information file with the selected DBMS, the food composition files must be converted into files recognizable by the DBMS program. This conversion can be done by importing the food composition information into the DBMS, then saving the food composition information as a file or files with the configurations given by the DBMS.

### Creating a Menu

Developing a menu for diet calculation can be done in two ways: a semiautomated method or an online automated method.

In the semiautomated method, the research nutritionist must first create a handwritten food list (Exhibit 11-5). Next, using a coding manual, the nutritionist selects the appropriate food code numbers for each of the menu item on the food list. Then, after a diet file is created, the following information is manually entered into a database management file: food description, food code number, meal sequence, menu day, and food amount. The file is saved after the last item on the food list is entered.

Although some research nutritionists prefer to design a diet by first listing on paper the foods to serve in a menu, it is more convenient to use an online automated method. The menu list is created by directly selecting foods for the menu from an online coding file. To do this, the designer must create a ‘‘diet list’’ file containing variable names such as food description and code number. Then, the designer must have ready a ‘‘coding’’ file that contains a complete list of food descriptions and code numbers for the foods stored in the ‘‘food composition’’ file. Next, using a file linking or multisegment approach, the diet list file and the coding file in the DBMS are simultaneously opened. To select foods from the coding file, the user scans through the foods in the coding file, selects the foods to be included into the diet list file by highlighting or flagging each food record needed, then duplicating the selected food items found in the coding file for the diet list file (Figure 11-1). Once the diet list is created, it can be modified to include information such as intake amounts for each food, meal sequence, and menu day.

### Calculating Nutrient Composition

To calculate the nutrient composition of the proposed diet, the diet list file and the food composition file must be merged. The food code numbers on the diet list file are used to link each food to its corresponding nutrients in the food composition file. A diet calculation program can be written such that each code number in the diet list file is matched with the same code number in the food composition file (Figure 11-2). This type of match-up process is referred to as a *relational system.* For quality assurance, after the match-up process, the matched foods must be checked for entry and match-up accuracy.

When all the foods on the menu are linked with their corresponding nutrients, the computer can be programmed to perform an array of calculations. To generate a specific nutrient value for a specific amount of food fed, the proposed food amount from the diet list file must be multiplied with the nutrient values of that food (Table 11-4). To present nutrient intake information as a whole day's intake, the computer can be programmed to sum the values of one nutrient from all foods in the whole day's menu (Table 11-5). Depending on the needs, the calculation program can be written to give information that describes the nutritional values of the menu in a variety of formats. For example, a nutrient summary report can provide nutrient information on a per food item (Table 11-4), per day (Table 11-5), or per meal (Table 11-6) basis. The nutrient summary report also can provide intake statistics (Table 11-7), a review of nutrient deficiencies or excesses (as percent RDA), and an accounting of the frequency of missing nutrient values in a diet (Table 11-8).

Recipes used in research diets can be calculated and stored as records in the food composition file. As new studies are planned, one may adapt these existing recipes, which is more efficient than developing new recipes. Unlike the nutrient summation program, calculating a recipe may involve linking three or more files because of cooking losses/yields and nutrient retention problems (Figure 11-3). For example, if there are three files involved in a recipe calculation program, one of the files is a primary food composition file, whereas the other files are a ‘‘nutrient retention’’ file and a ‘‘moisture/fat gain/loss’’ file. A nutrient retention file should contain factors used to calculate the nutrient retention of vitamins and minerals after cooking. The CD-ROMs for the 1994 and 1996 Continuing Surveys of Food Intakes for In-

## EXHIBIT 11-5

**Food List for Computer Entry**

Description of Diet: ____________________ Study Number: __________

| Food Code | Food Description | Portion Size | Mealtime | Menu Day |
|---|---|---|---|---|
| | | | | |
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dividuals contain a relational file based on an electronic version of the Provisional Table on Retention of Nutrients.

In a recipe, the amounts of vitamins and minerals retained in cooking will vary depending on the method of cooking, the length of cooking time, and the kind of preparation and treatment given to the food before cooking (49). It would be erroneous to calculate a recipe without applying a nutrient retention method in the calculation program. Data describing percentage of moisture or fat gain/loss are also important in recipe calculations. Most ingredients in a recipe are uncooked items that become part of a mixed dish. Without applying moisture and fat gain/loss factors, the actual dish served may be more or less nutrient-dense than the calculated recipe. Depending on the amount served, there may be great differences between calculated nutrient levels and true intake levels.

### *Comparison with Target Goals*

Although the computer can facilitate the mathematical calculation of a research diet, producing a diet that provides nutrients at specified levels is no easy task. Even with the computer performing most of the calculations, planning a research diet is largely a trial-and-error process. After menu items are transformed into nutrient information via nutrient calculation and summary programs, nutrient levels of each menu must be compared with the target goals. Generally, it takes several diet modifications and computer runs before a satisfactory menu is produced. For more complex diet designs, the diet manipulation and calculation process can take days of work.

Although there is no easy way to make the comparison between the calculated results and the target goals, the com-

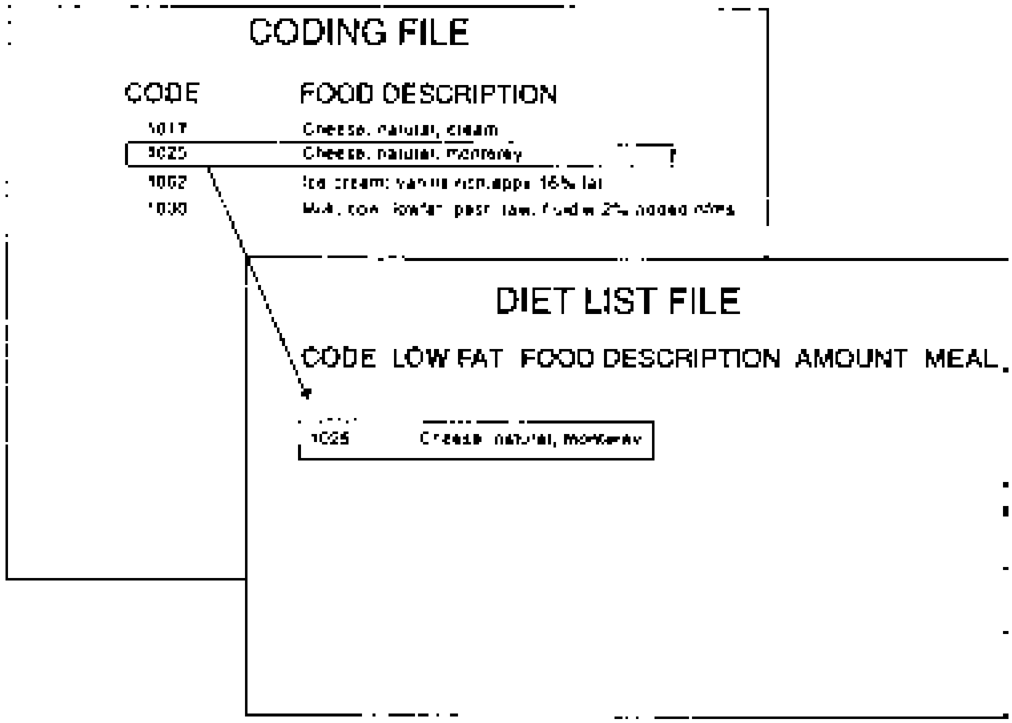


**FIGURE 11-1.** Selecting foods from coding file to create the diet list file.

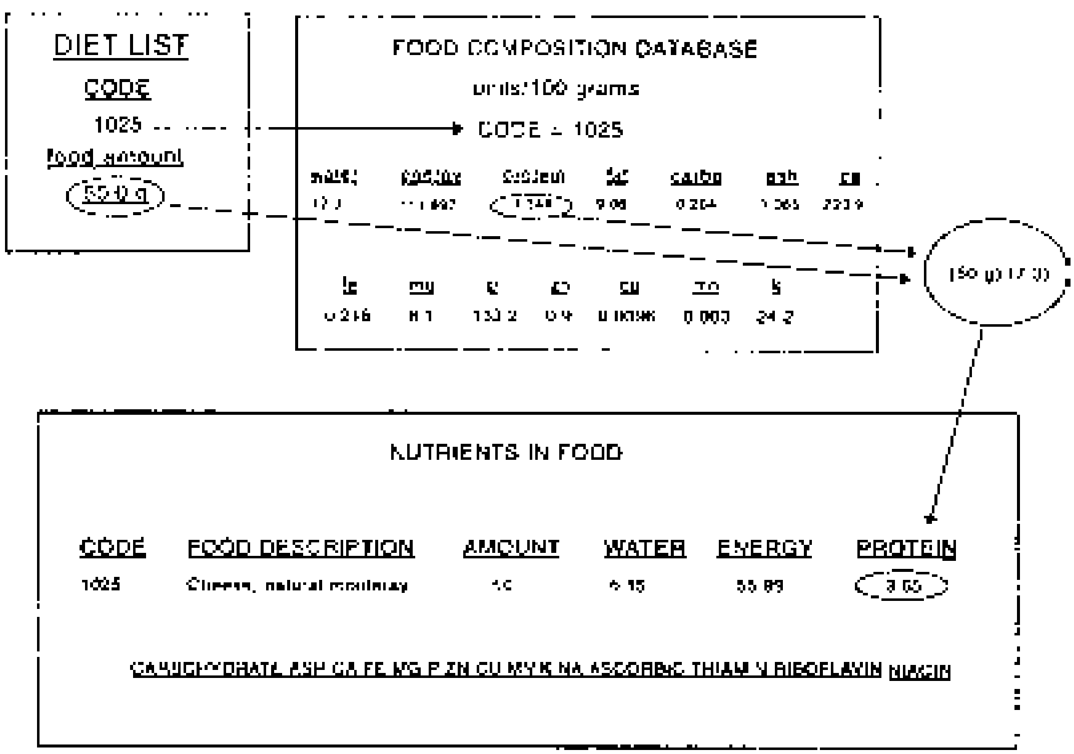


**FIGURE 11-2.** The diet calculation program matches code numbers from the diet list file with the food composition file.

**TABLE 11-4**

**Nutrient Content of Foods for Lunch: Menu Day 7**

| Meal | Food Item | Amount (g) | Energy (kcal) | Protein (g) | Fat (g) | Carbohydrate | Code |
|---|---|---|---|---|---|---|---|
| L | Bread, pita | 50 | 142.00 | 4.55 | 1.50 | 27.00 | 3542.1 |
| L | Turkey breast, rst slice | 60 | 94.20 | 17.94 | 1.93 | 0.00 | 5186.0 |
| L | Cheese, jack, sliced | 30 | 112.00 | 7.34 | 9.08 | 0.204 | 1025.0 |
| L | Cake, chocolate | 94 | 337.50 | 4.23 | 14.60 | 52.10 | 526.4 |
| L | Milk, low-fat | 170 | 86.65 | 5.92 | 3.26 | 8.45 | 1080.0 |

**TABLE 11-5**

**Nutrient Content of Menu Day 7**

| Variable | Amount |
|---|---|
| Food Amount (g) | 1711.00 |
| Water from Food (g) | 1259.00 |
| Energy (kcal) | 2098.90 |
| Protein (g) | 77.50 |
| Total Fat (g) | 78.26 |
| Carbohydrate (g) | 283.71 |
| Protein (% Energy) | 14.77 |
| Fat (% Energy)[1] | 33.56 |
| Carbohydrate (% Energy) | 54.07 |
| Saturated Fat (% Energy) | 14.20 |
| Total Monounsaturated Fat (% Energy) | 10.10 |
| Total Polyunsaturated Fat (% Energy) | 10.90 |
| P:S Ratio | 0.4 |
| Calcium (mg) | 717.70 |
| Calcium (% RDA) | 59.75 |

[1]The sum of saturated, monounsaturated and polyunsaturated fat usually is less than the total fat content (ie, about 90%). Total fat values include not only saturated, monounsaturated, and polyunsaturated fatty acids but also mono- and diglycerides, phospholipids, and short chain and branched chain fatty acids.

**TABLE 11-6**

**Macronutrient Distribution of a 2,200-kcal Diet by Meal**

| Meal | Energy (kcal) | Protein (g) | Fat (g) | Carbohydrate (g) |
|---|---|---|---|---|
| Breakfast | 517 | 10.99 | 22.86 | 76.11 |
| Lunch | 721 | 13.73 | 41.35 | 47.12 |
| Dinner | 645 | 18.68 | 40.08 | 42.05 |
| PM snack | 298 | 4.72 | 18.05 | 79.30 |

**TABLE 11-7**

**Statistics Report: Mean and Standard Deviation of Selected Nutrients (7-day Menu)**

| Variable | Unit | Days (N) | Minimum | Maximum | Mean | Std Deviation |
|---|---|---|---|---|---|---|
| Food Amount | g | 7 | 1,547 | 1,715 | 1,647 | 81 |
| Water | g | 7 | 1,120 | 1,259 | 1,196 | 68 |
| Energy | kcal | 7 | 2,067 | 2,099 | 2,098 | 1 |
| Protein | g | 7 | 70 | 78 | 75 | 4 |
| Fat | g | 7 | 58 | 89 | 76 | 13 |
| Carbohydrate | g | 7 | 257 | 320 | 290 | 26 |

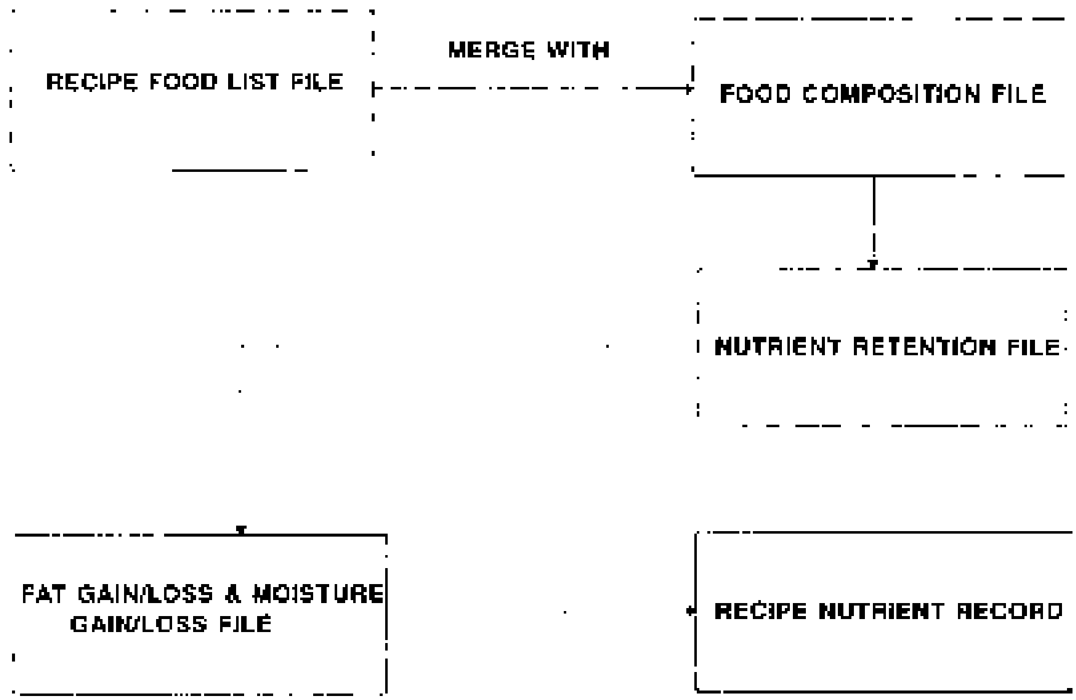


**FIGURE 11-3.** Linking files to calculate a recipe.

puter can be used to report percentage of goal (that is, the fraction each calculated nutrient level is above or below its target). Sometimes, to achieve the target goal, the nutritionist may need to modify the menu by adding new foods, substituting foods, increasing amounts of foods, or eliminating foods from a menu. To do this on the computer, food intake amounts in the diet list file may need to be manually modified before another computer nutrient analysis is performed.

For some research studies, no matter how many times a diet is manipulated and recalculated, the target nutrient levels will never be achieved until a specialty item is used. For example, to feed a large amount of saturated fatty acids in a low-fat diet, a highly saturated margarine may need to be added to the menu. Most likely, this margarine will need to be specially prepared by a manufacturer for the study. Another example is a protocol that specifies study participants are to be fed three diets differing only in selenium content. Except for the selenium level of the diets, nutrient content and food quantities in all three diets must remain the same. To achieve these specifications, specially grown high-selenium-content wheat and low-selenium-content wheat must be included in the diets. (Also see the discussion of modified and experimental foods in Chapter 12, ‘‘Producing Research Diets.’’)

Sometimes, in order to meet nutrient target levels, an investigator might use nutrient loss or retention information to create the control necessary for a research diet. Consider, for example, a study conducted to assess the effect of animal or plant protein sources on the vitamin B-6 requirement of young women (50, 51). Strictly controlled, conventional food, 3-day cycle diets with protein from animal or from plant sources were fed during four repletion periods. Both repletion diets were calculated to provide a 0.5 mg per day of vitamin B-6, and a multiple vitamin and mineral supplement devoid of vitamin B-6 was fed daily to the volunteers. The difficulty in designing this diet was that when protein intake levels were met, vitamin B-6 intake exceeded the target level. Through the use of nutrient retention information, special cooking procedures were devised to lower the vitamin B-6 content of the foods. All poultry, beans, and

**TABLE 11-8**

**Missing Nutrient Values in Menu Day 7**

| Nutrient | Percent of Foods with Missing Value |
|---|---|
| Carbohydrate | 0 |
| Fat | 0 |
| Protein | 0 |
| Vitamin A (IU) | 6 |
| Vitamin A (RE) | 24 |
| Vitamin E | 67 |

vegetables were boiled and drained three times before serving. Poultry was skinned and boiled prior to the three cooking treatments. Microbiological assay confirmed that the boiling procedure was effective in reducing the vitamin B-6 content in the foods tested.

### Developing the Purchasing List

Once a diet is calculated and accepted for a research study, a purchasing list must be developed. It is critical that foods purchased for a research study are exact matches with the food items coded for the nutrient calculations. The simplest way to create this exact match list is to append and merge foods from all menus in the study into one file. The purchasing list in this file should identify each food used in a menu cycle, along with the food code, a full food composition description of the food, and the food amount to be served to one participant. A simple program can be written to help tabulate, by food code, the amount of each food needed on a weekly basis for the entire study. In addition, this tabulation program can be written to show the number of times each food is served during a menu cycle or the amount of food required at each calorie level. Furthermore, the purchasing list can be converted into an inventory list for use throughout the study or a work flow planner for the dietary staff.

## Using Food Subsets to Develop Menus

From experience, the most efficient way to use a computer to design a research diet that will meet study specifications is to create two subsets of foods for each day's menu. One subset should consist of *core foods,* which are served on all diets and contain relatively small amounts of the nutrients under investigation. The other subset should contain *modifiable foods,* which are rich in the nutrients under study, and whose quantities and composition can be manipulated to accommodate most of the required variability in the experimental diets. The foods comprising these subsets, and the quantities needed, are determined through a series of iterations that bring the calculated diet successively closer and closer to the design targets.

*Example:* Following is background information for a test diet high in saturated fat. Consider a study requiring two double-blinded dietary treatments that differ in fat content. For a 2-week (14-day) menu cycle, the average energy distribution of both diets should be: 36% of calories from fat, 15% from protein, and 48% from carbohydrate. The average cholesterol content should be 400 mg/day. For the Saturated Fat Diet, the energy distribution (%kcal) of saturated (S), monounsaturated (M), and polyunsaturated (P) fatty acids should be: S 19%: M 11%: P 6%. For the Monounsaturated Fat Diet, the energy distribution from fatty acids is S 11%: M 19%: P 6%. Oleic acid (18:1) is the predominant monounsaturated fatty acid in the diet, and linoleic acid (18:2) is the predominant polyunsaturated fatty acid. The design target for the Saturated Fat Diet specifies that 3% of energy should be provided by stearic acid (18:0); there is no target value for the other saturated fatty acids.

### Preliminary Activities

Menu designers should verify that the available food composition databases and software packages contain appropriate information for all potential study foods. The database should also include the composition of any foods prepared from special study recipes.

The designer chooses one energy level for calculating the sample diet; this typically is the most common calorie level, or the one that forms the best basis for adjusting the other energy levels. (The sample menus provided here are based on 3,000 kcal/day).

### Separating the Foods for Each Menu into Core Food and Modifiable Food Subsets

The menu designer first identifies the foods that are candidates for use in each subset, then estimates likely portion sizes for each food.

In this example (see Table 11-9), the core foods contain relatively small amounts of fat, or their fat content cannot easily be adjusted through recipe changes. The modifiable foods subset contains foods such as baked goods, table spreads, and salad dressings, because these are excellent vehicles for presenting the special test fats (special margarines, oils, and shortenings) that are used to achieve the required fatty acid distribution.

The modifiable foods subset should provide most of the test nutrient needed to achieve the design target. In the example below, the modifiable foods subset is expected to provide about three fourths of total dietary fat, or approximately 90 g (810 kcal).

### First Iteration: Quantities of Foods from Each Subset

The first iteration comprises the following steps:

1. Start with the core foods subset. Using the likely portion sizes as estimated above, calculate their nutrient content. (The core foods for the Saturated Fat Diet and their fat content are shown in Table 11-10.)
2. Repeat this process for the modifiable foods subset. (Fat-rich modifiable foods are shown in Table 11-11.) This first iteration yielded 83 g of fat, slightly below the target of 90 g.
3. Next, evaluate the results of the first iteration by adding the contributions from the two food subsets and compare the results with the target values.

In the example shown here (see Table 11-12), total fat was higher than desired (because the core foods subset contained slightly more total fat than originally expected), whereas saturated fat was lower than desired (because the modifiable foods subset contained less saturated fat than originally expected).

**TABLE 11-9**

**Food Subsets for the Design of Fat-Modified Menus**

| Core Foods Subset | Modifiable Foods Subset[1] |
|---|---|
| Meats | Baked goods |
| Vegetables | Spreads |
| Grains | Salad dressings |
| Fruits | Snacks |
| Dairy products, low-fat | Dairy products, high fat |
| Eggs[1] | Eggs[2] |

[1]In this example, the modifiable foods subset includes foods that have a high content of fat as well as foods whose fat composition or content is relatively easy to alter.
[2]Eggs (as whole eggs, yolks, and/or whites) can be used as needed in either subset to meet design specifications.

**TABLE 11-10**

**Core Foods Subset for Saturated Fat Diet (3,000-kcal/day); Fat Content, First Iteration for Menu Day 3**

| Fat (g) | Portion (g) | Food Description[1] |
|---|---|---|
| 0.061 | 103 | Orange juice; added calcium, frozen concentrate, diluted 1:3 |
| 10.594 | 34 | Sausage; pork, links or bulk, cooked |
| 0.028 | 28 | Jelly; other than guava |
| 9.446 | 492 | Milk; cow; pasteurized, fluid, 2% fat |
| 9.513 | 90 | Pork products; ham, cured, boneless, regular (approx. 11% fat) |
| 0.550 | 50 | Bread; rye, made with nonhydrogenated soybean oil |
| 0.047 | 25 | Lettuce; iceberg (includes crisp head types), raw |
| 0.148 | 45 | Tomatoes; red, ripe, raw, year-round average |
| 5.355 | 150 | Chicken; broilers or fryers, breast, meat only, cooked, roasted |
| 4.052 | 20 | Gravy, turkey; made with moderate oleic acid content mayonnaise (Test Fat) |
| 0.250 | 250 | Potatoes; baked, flesh and skin, without salt |
| 0.066 | 60 | Broccoli; frozen, spears, cooked, boiled, drained, without salt |
| 0.104 | 55 | Lettuce; iceberg (includes crisp head types), raw |
| 0.148 | 45 | Tomatoes; red, ripe, raw, year-round average |
| 1.543 | 5 | Eggs; chicken, yolk, raw, fresh |
| 0.550 | 25 | Bread, cracked wheat, made with nonhydrogenated soybean oil |
| 4.723 | 246 | Milk; cow, pasteurized, fluid, 2% fat |
| 0.000 | 12 | Sugar; beet or cane, granulated |
| 0.597 | 166 | Apples; raw, with skin |
| 47.775 | — | Total, all items |

[1]Foods listed several times are served at different meals.

**TABLE 11-11**

**Modifiable Foods Subset for Saturated Fat Diet (3,000-kcal/day); Fat Content, First Iteration for Menu Day 3**

| Fat (g) | Portion (g) | Food Description[1] |
|---|---|---|
| 13.018 | 165 | Blueberry muffins, made with coconut oil (Test Fat) |
| 15.960 | 20 | Margarine, high-saturated-fat (Test Fat) |
| 9.448 | 14 | Mustard spread, made with high-saturated-fat margarine (Test Fat) |
| 20.557 | 75 | Oatmeal cookies, made with high-saturated-fat margarine (Test Fat) |
| 3.087 | 10 | Eggs; chicken, yolk, raw |
| 5.442 | 30 | Chocolate mayonnaise cake, made with high-oleic-acid mayonnaise (Test Fat) |
| 15.960 | 20 | Margarine, high-saturated-fat (Test Fat) |
| 83.472 | — | Total, all items |

[1]Foods listed several times are served at different meals.

**TABLE 11-12**

**Core Foods + Modifiable Foods Subsets (Total Diet) for Saturated Fat Diet (3,000-kcal/day); Fat and Energy Content, First Iteration for Menu Day 3[1]**

| | Energy Distribution (% kcal) | | Nutrient Content (g/3,000 kcal) | |
|---|---|---|---|---|
| | Target | Calculated | Target | Calculated |
| Calories | 3,000 | 3,036 | — | — |
| Fat, total | 36 | 38.5 | 118 | 130 |
| Fat, saturated | 19 | 14.8 | 63 | 50 |
| **Fatty Acids** | | | | |
| Stearic | 3 | 2.7 | 9 | 9 |
| Oleic | 11 | 13.1 | 36 | 44 |
| Linoleic | 6 | 6.9 | 19 | 23 |
| Other[2] | 16 | 13.6 | 54 | 46 |

[1]Values may not add to 100% because of rounding.
[2]Other fatty acids: exclusive of 18:0 (stearic), 18:1 (oleic), 18:2 (linoleic).

### *Subsequent Iterations: Adjust Items and Quantities of Subset Foods*

Later iterations fine-tune the food amounts and measure calculated and target values for the diet:

1. Revise the type and amounts of foods in both subsets if the nutrient values of highest interest (in this case, total fat and saturated fat) do not meet target levels.
2. In later iterations, focus on the quantities and composition of the items in the Modifiable Foods Subset (see Table 11-13).
3. After each iteration, compare the calculated and target values for the entire diet (comprising both the core foods and modifiable foods subsets) to assess whether the goals have been reached.

In this example, several modifications were made to the foods comprising the subset: the high oleic acid mayonnaise chocolate cake was deleted; a portion of coconut oil was added; portion sizes of high-saturated-fat margarine were reduced; coconut oil-based salad dressing was added; and the quantity of egg yolk was reduced to adjust the cholesterol content. (Note: To construct a corresponding Monounsaturated Fat Diet, test fats rich in oleic acid would be used.) The results of these changes are shown in Table 11-14: after multiple iterations, the calculated composition of the entire sample menu, based on the contribution of all food subsets, is close to the target values. Note, for later discussion on chemical analysis of diets, the discrepancy between target and calculated values for total fat.

In actual practice, after the modifiable foods are ad-

**TABLE 11-13**

**Modifiable Foods Subset for Saturated Fat Diet (3,000-kcal/day); Fat Content, Final Iteration for Menu Day 3**

| Fat (g) | Portion (g) | Food Description[1] |
|---|---|---|
| 13.018 | 165 | Blueberry muffins, made with coconut oil (Test Fat) |
| 11.172 | 14 | Margarine, high-saturated-fat (Test Fat)[2] |
| 9.448 | 14 | Mustard spread, made with high-saturated-fat margarine (Test Fat) |
| 20.557 | 75 | Oatmeal cookies, made with high-saturated-fat margarine (Test Fat) |
| 1.543 | 5 | Eggs; chicken, yolk, raw[2,3] |
| 10.041 | 30 | Salad dressing or dip, made with coconut oil (Test Fat)[2] |
| 10.000 | 10 | Coconut oil (Test Fat)[2] |
| 11.97 | 15 | Margarine, high-saturated-fat (Test Fat)[2] |
| 87.749 | — | Total, all items |

[1]Foods listed several times are served at different meals.
[2]Amount changed or new food added. In this example, compare with food list in Table 11-11 and note: deletion of chocolate cake made with high-oleic-acid mayonnaise; addition of coconut oil test fat in several forms; decrease in portion size for high-saturated-fat margarine; and decrease in portion size of egg yolk (see footnote 3).
[3]Egg yolk decreased from 10 g to 5 g to effect a decrease in cholesterol content from 454 mg/day to 386 mg/day. (In this example, the design target for cholesterol is 400 mg/day.)

**TABLE 11-14**

**Core Foods + Modifiable Foods Subsets (Total Diet) of Saturated Fat Diet (3,000-kcal/day) for Fat and Energy Content[1], Final Iteration for Menu Day 3[1]**

| | Energy Distribution (% kcal) | | Nutrient Content (g/3,000 kcal) | |
|---|---|---|---|---|
| | Target | Calculated | Target | Calculated |
| Calories | 3000 | 3019 | — | — |
| Total Fat | 36 | 39.9 | 118 | 134 |
| Saturated Fat | 19 | 18.2 | 63 | 61 |
| **Fatty Acids** | | | | |
| Stearic | 3 | 2.7 | 9 | 9 |
| Oleic | 11 | 11.2 | 36 | 38 |
| Linoleic | 6 | 6.3 | 19 | 21 |
| Other[2] | 16 | 17.6 | 54 | 59 |

[1]Values may not add to 100% because of rounding.
[2]Other fatty acids: exclusive of 18:0 (stearic), 18:1 (oleic), 18:2 (linoleic).

justed the dietary levels of all relevant nutrients must be evaluated; further iterations may be necessary if any do not meet target values. The example shown in Tables 11-9 through 11-14 has been simplified for didactic purposes and focuses on dietary fat composition and content, but the protein and carbohydrate levels also are components of the overall dietary design and also must ultimately meet the requirements of the study design.

The complexity (ie, difficulty and cost) of the iterative calculation process varies with the dietary software packages and other computer support available. It often is advisable to first use simpler ways to estimate or otherwise ‘‘try out’’ contemplated changes in the core foods and modifiable foods subsets. One approach is to use a calculator. Also, if the user is familiar with linear programming, a linear equation can be written to calculate the amounts of food needed to meet target variable levels; this technique has the potential to reduce the needed number of computer iterations. (Also see the discussion of computer-assisted menu planning in Chapter 3, ‘‘Computer Applications in Controlled Diet Studies.’’)

### *Reviewing the Menu Cycle and Verifying Composition through Chemical Assay*

The review process encompasses the following:

1. Summarize the calculated (estimated) nutrient content of the entire menu cycle, and calculate descriptive statistics such as mean, median, and range.
2. Verify nutrient content through direct chemical analysis.
3. Determine which menus fall within acceptable limits. Menus not meeting necessary design or production standards should be discarded or adjusted (reformulated or recalculated).
4. Calculate the menus for the other calorie levels that are needed to meet participants’ energy requirements. Using menus that have been determined to be acceptable, scale the portions as needed (ie, make proportional adjustments in the serving sizes for each food item).

The ultimate goal of this process is an entire cycle of menus whose average composition (determined by chemical assay) closely approximates the design target (see Table 11-15). It is not unusual to observe some variation between the calculated values and the assayed composition. Often this reflects the difference between the average values in the nutrient database used to calculate the diets compared with the composition of the specific foods used to construct the diets. (In Table 11-15, the assayed fat content is lower than the calculated fat content.) Using the foods subset approach provides a convenient means of creating such an appropriately designed cycle menu for each dietary treatment. Thus, on any given day of the study described in the example, all diets will have the same meats, vegetables, salads, and breads, but each treatment will provide baked goods, sauces, salad dressings, spreads, and dessert toppings with differing composition.

The painstaking process of estimation and refinement must be carried out separately for each study menu (this example only shows the iterations for Menu Day 3). Numerous (five or more) successive iterations may be necessary until the design targets are reached. So many factors can constrain the design of appealing diets that it is highly recommended that extra menus be designed; it is likely that several will not be usable. Not only must the calculations result in a satisfactory nutrient composition but the recipes and portion sizes must also be palatable as well as practical for delivering to the study participants.

## Linear Programming Approaches

Research diets traditionally are formulated by first defining a list of foods to use in a diet and then calculating the nutrient composition of the proposed diet. As described earlier, if the

**TABLE 11-15**

**Core Foods + Modifiable Foods Subsets (Total Diet) of Saturated Fat Diet (3,000-kcal/day), Average Composition of 14-day Menu Cycle[1]**

| | Energy Distribution (% kcal) | | | Nutrient Content (g/3,000 kcal) | | |
|---|---|---|---|---|---|---|
| | Target | Calculated | Assayed | Target | Calculated | Assayed |
| Protein | 15 | 15.1 | 15.2 | 112 | 113 | 114 |
| Carbohydrate | 48 | 46.0 | 48.7 | 352 | 345 | 365 |
| Total Fat | 36 | 39.9 | 36.1 | 118 | 134 | 120 |
| Saturated Fat | 19 | 18.2 | 17.2 | 63 | 61 | 57.5 |
| **Fatty Acids** | | | | | | |
| Stearic | 3 | 2.7 | 2.7 | 9 | 9 | 9.1 |
| Oleic | 11 | 11.2 | 10.6 | 36 | 38 | 35.5 |
| Linoleic | 6 | 6.3 | 5.8 | 19 | 21 | 19.2 |
| Other[2] | 16 | 17.6 | 16.5 | 54 | 59 | 54.9 |

[1]Values may not add to 100% because of rounding.
[2]Other fatty acids: exclusive of 18:0 (stearic), 18:1 (oleic), 18:2 (linoleic).

total nutrient values exceed or fall below required values, food quantities are altered or exchanged and the diet recalculated. Calculations are repeated as often as necessary until a suitable diet meeting all nutrient levels is obtained. One way to simplify this tedious task is to allow the computer to calculate the research diet, a process called *linear programming.* (Also see the discussion of computer-assisted menu planning in Chapter 3, ‘‘Computer Applications in Controlled Diet Studies.’’)

Although linear programming techniques have been used successfully to calculate formula diets (51), using linear programming to formulate conventional food diets is a much more complicated task. In calculating a formula diet, the function of the linear program is to find estimates by fitting the linear equations with various iterations until all given conditions are satisfied. In formulating a conventional food diet, a linear program is first written to eliminate or select foods based on set nutrient criteria. Then, linear equations must be set for each target nutrient variable. A logical definition for frequency of use of foods and serving limits must also be set. A subset of foods must then be developed to be used in the linear equation to help adjust the nutrient requirements.

Once a diet is produced by linear programming, sample meals must be prepared and evaluated for portion size and palatability. For formula diets, it would be wise to generate several combinations of different ratios of chemical salts to produce several different formulas. From these formulas, the most palatable formula should be selected based on a taste test. (Also see Chapter 14, ‘‘Planning and Producing Formula Diets.’’)

## Conclusion

This chapter has addressed various aspects of nutrient data and the use of computers to design research diets. Food databases provide data for an ever-increasing array of nutrients and for an ever-increasing number of food items. Nutritionists must have a full understanding of the degree of accuracy of these data, as well as the computer skills to form this basic information into carefully defined research diets. A skillful blend of science and art underlies the exercise of designing a simple yet tasteful research diet that creatively meets the scientific requirements of the protocol.

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