

DESIGNING,
PREPARING
AND
DELIVERING
RESEARCH
DIETS



A TRAINING
WORKSHOP

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**Pennington Biomedical
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PLANNING STUDIES TO ANSWER SCIENTIFIC QUESTIONS

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Research studies as varied as cell culture studies and ecological studies contribute to a body of knowledge on issues of diet and human health. Human feeding studies are a unique line of research that contribute to establishing cause and effect relationships. Typically, a human feeding study is preceded by epidemiologic studies and animal studies that ask closely related research questions. Human feeding studies define a relationship between dietary intake and changes in an outcome, typically a risk factor for disease. Promising results from human feeding studies may be followed by clinical intervention trials. These trials may document that a change in dietary intake alters prevalence of a disease or disease endpoint. Together, various lines of research produce a body of knowledge that is tapped by imminent organizations to make dietary recommendations for the public.

Among human studies, the model producing the highest degree of control is the residential study, also known as the metabolic ward or in-patient study. In addition to strict dietary compliance, other variables, such as exercise, can be controlled. However, residential studies are expensive, and confinement to a metabolic ward is a major interference with the life-style of research subjects. When this degree of control is not critical, free-living subjects can be studied under controlled diet conditions. Participants continue their normal activities but eat only food provided within the context of the study. Food items are typically weighed in proportion to calorie needs, and subjects commonly eat a predetermined number of meals at the study facility.

Human feeding studies are typically planned by a team of researchers including the principal investigator, co-investigators and collaborators who have expertise concerning the research topic. These may include a study coordinator, dietitian and statistician. Depending on the complexity of the study, one or a series of planning meetings are held to clarify the research question, design the study and assign responsibilities to team members.

A research question or hypothesis dictates all aspects of study design. Therefore, the research question must be clearly stated and agreed upon by all team members before a study is designed. The research question identifies the subject population, nutrient of interest, endpoints to be measured and the confounding variables to be controlled. A good research question is specific, testable, biologically plausible and likely to produce an unequivocal answer. If a single study is designed to answer several research questions, the research questions should be prioritized.

The study design typically begins as a diagram that identifies the treatments and treatment order for each group of subjects. Common designs for human feeding studies are the crossover design, the parallel arm design and the longitudinal design. The statistician on the research team can provide valuable input on design as well as

procedures for randomizing subjects and for data management. In the crossover design, each subject receives all treatments in random order. This arrangement makes studies long and increases subject burden. However, the within-subject variability associated with subjects serving as their own controls is small, so fewer subjects are needed to detect statistical differences among treatments. In the parallel arm design, different groups of subjects receive different treatments. The sample size is large to compensate for a large among-subject variability, but the study duration is comparatively short. In the longitudinal design, each subject receives each treatment in a set order. A disadvantage of the longitudinal design is that outcome variables can be inadvertently influenced by uncontrolled changes that occur across time; for example, seasonal changes.

Once a design is agreed upon, a study protocol is written. The protocol documents the specific aims of the study and describes dietary treatments, the subject population, recruitment procedures, eligibility criteria, outcome variables, laboratory methods, statistical approaches and other pertinent issues for conducting the study including quality assurance. The protocol may identify individuals responsible for subject recruitment, data management and authorship for anticipated manuscripts. The protocol may include a budget, a description of the facility and CV's of investigators; in short, a mini grant proposal.

It is desirable to complete research studies with the minimum number of subjects needed to detect a true difference in the endpoint of interest. The number of subjects required in a study is best estimated by working with a statistician to conduct a power calculation. Sample size increases when 1) subject variability is high due to uncontrolled variables or design of the study, 2) measurement error is high due to lack of assay precision, 3) changes to be measured are small, or 4) changes in nutrient intake or bioavailability are small.

The length of feeding periods and the amount of the nutrient to be fed are dictated by the research question. Often, the research question seeks to establish consequences of a long-term change in a dietary variable. This necessitates feeding the nutrient in question long enough for the outcome variable of interest to stabilize. Feeding high levels of a nutrient, levels above those attainable through use of normal foods, can facilitate detecting small differences in an outcome variable, whereas smaller changes in nutrient intake can model realistic dietary changes in a population.

Cost, a major factor in conducting human feeding studies, is determined in part by the number of subjects to be fed and the length of feeding. The cost of operating feeding facilities varies greatly. Our non-residential studies currently cost about \$60 per subject per day, excluding expenses involved in sample collection and analysis. In estimating cost one must consider fixed costs (e.g., salaries, space charges, utilities, equipment expenses, medical coverage), funds for food and paper goods, temporary employees and, if applicable, subject payment.

Studies are often blinded to avoid bias. Blinding of participants prevents variation in compliance based on knowledge of the treatment. During information meetings, subjects

are told what the treatment variables are, and if the study is blinded, they are told that they will not know which diet they are eating. Diets can be coded by color, number or letter designations. It is common to have the statistician rather than the investigator assign subjects to dietary treatments to avoid selection bias. Blinding can be extended to the data collector to avoid bias in laboratory analysis; biological samples are sent to the lab without identifying subjects by name or treatment. As an added precaution, data can be sent directly from the data collector to the statistician without passing through a principal investigator who is not blinded.

Insightful and detailed planning of studies pays off by producing accurate, definitive data that contribute to the body of knowledge linking diet to disease prevention.

NOTES

CONSIDERING ETHICAL ISSUES IN STUDY PARTICIPANT MANAGEMENT

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Introduction

At first glance, delivering meals in a research setting seems to be a low risk, non-invasive intervention. But a surprising number of complex ethical issues can arise. Investigators must be prepared to deal ethically with events ranging from an employer's request for information about a study volunteer to managing an outbreak of food-borne illness.

Origin of Ethical Principles

In dealing with issues that arise from the diverse experiences surrounding research in feeding trials, it is helpful to refer to some general ethical principles. The principles guiding ethical human research derive chiefly from three documents. The 1948 Nuremberg Code evolved from the World War II crimes involving human research and was internationalized in the 1964 Helsinki Declaration. These two documents reinforce the principles that scientific rigor is an essential part of any human experimentation, reinforce the importance of truthfulness in the conduct of human research and underline the right of individuals to voluntarily participate or to withdraw from the research study at any time. Indeed, the Helsinki Declaration makes a strong point that the concern for the individual is paramount and prevails over the interests of science or society. The 1979 Belmont Report documents the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. That document stresses the following three ethical principles: 1) autonomy of the individual, 2) beneficence in intent, and 3) justice in sharing the burden and the benefit of research.

Responsibilities to Our Volunteers

Since there is some risk in any intervention, no matter how seemingly benign, each study must carry, as part of it, a component to do good. An ethical justification for volunteers receiving the "control" diet which the nutritionist may consider "less healthy," is that they would receive the benefit of health information acquired through screening procedures. This idea of beneficence of intent must extend to every individual volunteer. It is never appropriate to conduct sloppy or poorly thought out research just because the risk is low. Some degree of risk is **always** involved and scientific rigor and scientific precision are essential through all aspects of the study, from its design through its analysis.

A key component to the ethical treatment of our feeding trial volunteers is **respect**. Respect for volunteers must be practiced, not only by the Principal Investigator and study staff, but by every person who interacts with the research volunteers. Imparting this philosophy throughout an institution is key to successful recruitment and retention. It helps to start by replacing the word "subject" with "volunteer." Volunteers are individuals. They are autonomous. They have the right of free choice. A key element of

respect for these individuals is placed in the informed consent process. Research volunteers must be given sufficient information in a forthright and truthful manner. Volunteers have the right to withdraw from a study at any time. Coercion of compliance is not justifiable. Problem volunteers will be identified, but they are a minority. Treating volunteers courteously, being scrupulously truthful and keeping promises are the keys to compliance.

Another component that signifies respect for those who volunteer for our studies is the recognition of their right to privacy. A research volunteer's expressed permission is required before any information is released regarding that subject. Every member of the research team and every staff member at the research center must participate in the responsibility for maintaining our research volunteer's privacy. Staff must not respond to queries for telephone information from employees and all staff must know the importance of not repeating volunteer information.

Another responsibility to our research volunteers rests with study investigators. Investigators have the responsibility to make certain that the research burden and research benefits are shared by all. No one group should be singled out and no one group should be purposely omitted. It is especially important for women and minorities to be considered in the research design phase, since historically their inclusion in research has been problematic.

Compensating research subjects for their time and recognizing their valuable services to scientific research has traditionally been done by awarding modest fees. These fees do not, in and of themselves, provide sufficient motivation for people to volunteer and complete feeding trials. Volunteers are also motivated by desire for health knowledge and the altruistic impulse to advance biomedical knowledge. Recognizing these factors in addition to providing subject fees by providing T-shirts, coffee mugs and other symbols to show our appreciation for the efforts of our research volunteers are equally important. Since many volunteers are motivated by the desire for increased health knowledge, it is important to be aware that promises that are made regarding providing results of individual tests and overall trial results must be scrupulously kept. This is a difficult task, since once a study is completed, the number of personnel who are available to perform these duties may be limited. Promises should not be made unless they can be kept.

An important aspect of the ethical treatment of our research volunteers is how we behave when problems arise. They inevitably do. Institutions and individuals at those institutions must act responsibly when troubles pop up. Food-borne illnesses, adverse events, unforeseen life events which are unrelated to the research trials can all present ethical dilemmas. Accepting responsibility and truthfully conveying the salient aspects of any event which may be perceived by our research volunteers as a threat to their health or safety is squarely the responsibility of the medical monitor. Research volunteers should be told the truth and the medical monitor and the principal investigator should attempt to rectify any problems that can be remedied.

Other Aspects of Responsibility

The Principal Investigator bears the responsibility for seeking study approval from the Institutional Review Board prior to its initiation. Any adverse events that occur during the course of the study must be reported to the Institutional Review Board and sometimes to the other study participants. In addition, the institution and its investigators have a responsibility for continuous quality assurance and quality improvement in all aspects of research design and implementation. The overall safety of our subjects when they are in our institutions or on our premises is our responsibility.

Finally, investigators bear the moral responsibility for publishing the results of research investigations. Informing other scientists, and where appropriate the public, of the results of the investigation is an ethical imperative.

NOTES

FACILITY DESIGN AND STAFFING

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The unique design, equipment and staffing concerns of the research kitchen are identified in this session. Approaches and guidelines are presented for establishing a new facility or redesigning an existing layout.

Planning considerations include defining the project scope, facility requirements, equipment needs, space and budget guidelines. Future needs are considered during this “design phase” to allow for realistic growth and expansion.

Project Scope and Complexity

Mapping out the scope and complexity of the kitchen design or redesign project is the initial step in the planning process. Outlining specific parameters and resources is all-important at the onset.

Facility Requirements

The basis for facility requirements is forecasts for food production and menu requirements. Therefore, equipment needs are accurately identified.

Space Versus Function

Equipment placement and functionality are important aspects of designing floor plans that work well. (See work sheet for accurately estimating space requirements.) Actual space and configurations of workstations should be considered to save steps and optimize work flow.

Costs

Costs are predicted based on the aforementioned criteria. It is important to justify realistic expenses.

New Versus Remodeling Projects

A key step is to identify and revise existing design drawbacks. “Don’t make the same mistakes twice.” Space and cost efficiency will be maximized. Considering future expansion during the design or remodeling phase is advisable. “Flexible designs” can amount to a considerable cost savings in the future. Suggestions include incorporating movable equipment, table tops and modular furniture. Also, equipment contracts can include arrangements for future upgrades.

The complexity of the project and facility specific resources will dictate which design team members will participate in the proposed project. Potential design team members include the following:

Architect and General Contractors- Subcontractors may be advised for smaller projects. In addition to project planning and coordinating, may act as health department advocates.

Equipment Dealers- Lends the resources from parent companies, input regarding price competitive equipment options and realistic design considerations.

Health Inspector- Addresses health regulations and installation specifications.

Lead Nutrition Staff- Prepares needs assessment, identifies production and menu requirements, logistical problems and budget issues.

Advisory Board Member- Maintains awareness of current projects and resource utilization.

Criteria for kitchen layout include work flow, area specific function, floor, storage and counter space, and efficient arrangements. Space and function requirements of specific work stations dictate these priorities. Guidelines for planning the most efficient work station arrangements include 6 to 9 ft. of counter space for food preparation and 3 to 6 ft. in the cook area (per 5 to 10 participants). Additional space is required for “to go” meal preparation. Equipment space must be considered for the main kitchen areas. Ventilation, climate control, atmosphere and office space also need to be accommodated.

Work area configurations include straight line (best utilizes space and time), parallel (space efficient; provides ample work surfaces and two-sided access), U-shaped (provides a large surface area, but adds more steps for staff), L-shaped (uses limited space), and islands (6 x 9 foot are functional; enhances the efficiency of a work area).

Work areas need sufficient electrical access for major and minor equipment requirements. Multiple studies can be accommodated via two or more L- or U-shaped workstations. Each “bay” may be similar or specialized for the food preparation function.

“Research food” needs to be maintained separately from “regular food” to maintain the integrity of nutrient specific information per specific brands. Metabolic studies requiring batch food purchases can seriously impact food storage requirements.

Storage requirements for all aspects of food production are summarized in the work sheet for calculating capacity and space requirements. Other storage considerations include dry (mainly contingent on lot size and par values), refrigerator (raw ingredient and short-term food service dictate refrigerator storage), freezer (frozen food requirements hinge on lot size, advanced food preparation, prepared food and baked goods) and non-food (separate storage is required, away from food and perishables). Bulky items can be stored adjacent to the kitchen or “off-site.”

Space savers include deep pull-out drawers, tray cabinets, drawer dividers and lazy susans. Solutions for “tight space” situations include obtaining long-term storage for large lots from a local butcher or purveyor. Mobile locked cages can be utilized especially when space is shared.

Staffing Guidelines

Conducting a “staffing needs assessment” is a requirement to forecast full-time equivalents (FTE’s). A “Protocol Intensity Ranking Guide” helps to prioritize and synchronize multiple research protocols occurring simultaneously.

Worksheets for quantifying required effort for protocol design and methods, and for estimating nutrition staff requirements, are useful. These can be amended to gauge specific functions of an individual unit. Protocol requirements that impact staffing include research diet design, resident or non-resident study, number and length of study period, number of subjects, nutrients to be controlled, nutritional care to be provided, data collection instruments, and quality assurance procedures. Functional time analyses identify nutrition time requirements for differing aspects of new and on-going protocols.

A WORK SHEET FOR CALCULATING CAPACITY AND SPACE REQUIREMENTS

Capacity-

Number of Participants		X	_____
Projected meal requirements per day			_____
		Total	_____

Space Requirements for Kitchen Work Stations (1)

Storage Area- (1.0-2.0 sq. ft./meal)			
Dry: (.33 - 0.5 sq. ft./meal)			_____
Walk-in:			
• Refrig (0.5 - 1.0 sq. ft./meal)		+	_____
• Freezer (0.75-1.5 sq. ft./meal)		+	_____
Non-food: (.09 sq. ft./meal) <small>(may be increased for carry out containers and disposables)</small>		+	_____
Preparation (includes refrigeration) <small>(may be increased for multiple ovens and other large equipment)</small>			
1.1 - 1.5 sq. ft./meal		+	_____
Serving Area (2)			
.57 sq. ft./meal		+	_____
Dishwashing and Sanitation Areas (2)			
.58 sq. ft./meal		+	_____
Dining Area			
12-14 sq. ft./participant per seating		+	_____
		Total	_____

(1) Factors to estimate storage for a large research kitchen, those facilities feeding 25-100 participants, underestimate actual requirements.

(2) The figures for estimating serving and dishwashing areas may be inflated to calculate needs of large feeding programs. Less space is required when dishwashing and meal service is done in shifts.

Adapted from: VanEgmond-Pannell, D. 1081 School Foodservice, 2nd edition The AV1 Publishing Company, Inc. Connecticut.

NOTES

SPECIFYING AND PROCURING FOODS FOR RESEARCH DIETS

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Food Procurement and Specifications

The guiding philosophy of procuring foods for research diets is to meet the nutrient specifications of the experimental diets and to minimize nutrient variability, especially in target nutrients. Decisions about central or local procurement of food items are based on control of target nutrients. Developing well-defined food specifications and estimating amounts needed are also very important. Food specifications should include a complete description of the food items, size and type of packaging and amounts needed, as well as a delivery schedule. The amount of individual food items ordered should reflect actual needs plus losses and wastage. Contingency plans that are designed to deal with emergency situations are essential.

Local vs Central Procurement

Food items for well-controlled experimental diets can be procured either centrally or locally. In general, food items that contain significant amounts of the target nutrient(s) should be procured centrally to minimize nutrient variability. In the DELTA Study, since total fat, saturated fat and/or cholesterol were the dietary constituents of interest, all food sources of fat, saturated fat and/or cholesterol were procured centrally. As a general rule, food sources that are needed for the entire study should be procured all at once a few weeks prior to the beginning of the study (except where the shelf life of the food is shorter than the duration of the study). All foods that are not a significant source of the target nutrient(s) can be procured locally once food specifications have been defined.

After making a decision about what food items to procure centrally or locally, potential sources, vendors and brand names need to be identified. More than one potential source and brand for each centrally procured item should be identified. If the brand name for any locally procured item is not available, another brand name with the same nutritional profile may be used.

Food Specifications

A complete and accurate description of food items is the major criteria for developing good food specifications. Using catalogues from different food vendors and manufacturers could come in handy, especially when several variations of a single food item might be available. For example, there are at least 4 varieties of V-8 tomato juice. These include regular, picante, spicy and low salt. Also, white bread may be regular, low fat, fat free, high fiber, thin-sliced or extra-thin sliced. Describing meat, fish and poultry can be more challenging since most lay persons are not familiar with the standard terminology used to describe these products. It is advisable to work closely with a meat scientist, meat purveyor or at least cross check items with a nutrient database. An erroneous substitution could add a significant amount of fat to the experimental diet. For

meat items it is important to specify grade (prime, choice or select); the cut to be used; amount of fat, if any, that can be present; brand name; etc. (See table for specifications of meat items to be used for preparing experimental diets.) Other important food specification information includes specifying the type and size of the food packages (i.e., #10 can vs 4 oz. can of fruit; 10 lb block of cheese vs 10 1-lb shredded or sliced cheese in bags), the amounts needed and the exact dates of delivery.

Precise food specifications help prevent many problems related to receiving the wrong food items, returning them and trying to get the right ones. Thus, avoiding food substitutions will prevent compromising the integrity of the study (except in case of emergency in which case not feeding subject will have a greater adverse effect).

Estimating the Amount of Each Food Needed

The amount of each food item needed (AFN) for the entire study can be estimated by using the following formula:

$$\text{AFN} = \text{Amount of food needed for a participant on 2500 Kcal (average Kcal required)/menu cycle}^1 \times \text{potential number of participants} \times \text{number of menu cycles}$$

A "fudge factor" (FF) is added to the AFN to add a margin of safety that accounts for any waste and potential accidents leading to loss. The FF for most foods is shown below. The FF is usually higher for food items where substantial waste is expected such as untrimmed meat (see, for example, pork chops) and lower for food items where virtually no losses are anticipated such as portion control (PC) items. Purchasing large containers (i.e., #10 cans) of infrequently-used items may appear to be the way to save money. However, for infrequently-used items with limited shelf life, such as applesauce that is used in a cake recipe, the smaller cans may actually be more economical because of less waste.

Variability in Fudge Factor (FF)

FF	Food Item
1.5	4 oz Peach PC's
1.5	Jello-O-Free pudding PC's
2	Bread
2	Fats and oils
2	Pasta
2	Cod fillet
3	Pork Chops
3	Lettuce
3	# 10 cans of infrequently used items

¹ Menu cycle: the period of time within which a complete set of menus is served. For example, when an 8-day menu cycle is used, it might consist of one 6-day weekday cycle and one 2-day weekend cycle.

Logistics of Food Deliveries

Great care and planning are required to identify the logistics of food deliveries, especially for centrally procured foods. The first consideration is having appropriate and ample storage space. Appropriate storage space has to be cool and dry for the nonperishables, refrigerated items must be kept between 32 to 40°F and frozen items must be kept at 0°F or below. Shelves and pallets should be used so that nothing is stored on the floor or against the wall. Items must be rotated so that "first in is first out".

Ideally, deliveries should be made 2 to 4 weeks prior to the beginning of the study. It is important to specify exactly where the foods are to be delivered and when someone will be available to receive them. When accepting refrigerated or frozen items, the temperature and condition of the food upon arrival must be checked. Anything that has been temperature abused should be rejected. A contact person is also a necessity, especially to deal with problematic situations.

With centrally procured items (when participating in a multi-center study), packaging is very important. Most bulk food vendors and large food companies package food in units that are quite large making them very difficult to handle when they arrive. It is not uncommon to receive 30 lb boxes of pork loins or 200 lb barrels of oil. The size of the packages needs to be specified and sometimes negotiated. It is frequently easier and cheaper to obtain smaller units of certain foods that can be locally procured rather than accept the large units which have to be "broken" into smaller units and repackaged.

Other Considerations: Examples From DELTA

Portion Control Items (PC): The use of PC's for nonfat sources was very convenient, simplified food production efforts and minimized waste. However, PC's are more expensive than bulk packages and are not always appealing if served in the original container at a meal. As a compromise in the DELTA Study, PC's were used for take-out meals because they were convenient and minimized spillage. Weighed food items were used for on-site meals and served in regular dishes with meals. Portion control meat items may actually save money because although they are more expensive, there is less waste generated and less labor in preparation (trimming and/or cooking) and weighing.

Egg Products: Due to the variability in the cholesterol content of fresh eggs purchased from different farms and the impracticality of purchasing fresh eggs centrally, frozen whole eggs were obtained from a single source and lot. Egg yolk powder, used to increase dietary cholesterol, was also obtained from a single lot. Egg yolk powder was more convenient to use than fresh or frozen egg yolks because it could be easily incorporated in many different foods. In the DELTA Study recipes were developed for brownies, cookies and main-dish entrees that incorporated the egg yolk powder without compromising taste or quality.

Food Donations

In many feeding studies there may be an opportunity to use donated foods. While initially it may appear that donated foods could save money, the decision to solicit food

donations must be carefully considered. For example, the process of soliciting food donations is quite time consuming and costly as it involves many phone calls and faxes that are sometimes unsuccessful. Before seeking food donations, several issues need to be carefully considered to determine whether it is worthwhile to initiate this often elaborate process. First, the potential foods that might be donated must be identified and the costs of purchasing, shipping and storing them should be determined. With this information in hand the economical feasibility of requesting a donation can be assessed. Secondly, potential donors must be identified to determine whether they are willing to donate foods and if they have a mechanism in place to do so. It is also very helpful to have personal contacts with key individuals in these companies.

Emergency Situations

Having a backup plan for emergency situations is essential. For locally procured items, more than one vendor and brand name must be identified for each product. For centrally procured frozen and refrigerated food items, the temperature of the storage units needs to be monitored daily and the storage units need to have backup power supplies. If possible, each item should be divided among more than one storage unit so that if one unit fails, some of the food will be salvaged. This will allow enough time to replenish the lost food item(s) without interfering with the study.

Specifications of Meat Products For DELTA

Meat/Poultry/Fish	Specifications
Beef, top round (for chili)	beef, round, top round, USDA Select (do not substitute USDA choice), separable lean only, raw: trim all visible fat
Chicken, breast raw	chicken, broiler/fryer, breast meat only; preferred brands in order are Tyson, Perdue, Holly Farms (if these brands are not available, contact the coordinating center); remove all skin and loose fat (a small amount of visible fat should remain in the seams between the muscles)
Turkey, breast cooked	turkey, all classes, light meat, cooked/roasted; Butterball Skinless Turkey breast with broth, 99% fat free, subjected to one freeze/thaw cycle before using to insure consistent fluid purge, pat dry with paper towels before weighing; if Butterball is not available, contact the coordinating center to discuss the alternatives
Pork, center loin	pork, fresh loin, center loin, separable lean only, raw, boneless, IMPS #412B or 414; preferred brands in order are IBP, EXCEL, IPC, Hatfield (other national brands are acceptable as long as the loins are from “typical” market animals, i.e., the boneless center loin should not weigh more than 6 lbs); trimming instructions - all surface fat and “tail” should be removed leaving only the main muscle (longissimus), leave most surface connective tissue intact on the muscle, large end of the trimmed muscle can be cut into chops, smaller end into stir-fry strips after trimming all the fat
Pork, cured ham	pork, cured ham, boneless, extra lean, with water added, label claim 95% fat free; brand name is Wilson Corn King Lean, if this brand is not available, contact the coordinating center for alternatives
Breakfast sausage	brown & serve, sausage , pork links or bulk, pre-cooked; Hormel Little Sizzlers - 10 links/7 oz box, UPC code 3760043734 (bulk quantities can be obtained through food service divisions - these may be called “broil & serve”)
Shrimp	fish/shellfish, shrimp, mixed species cooked - moist heat, large salad, deveined, no tails, 100-200/pound; no brand name specified

NOTES

RECRUITING TECHNIQUES AND CONSIDERATIONS

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Introduction

Effective recruitment of study subjects is an important part of a successful feeding study. There are many activities that are integral in planning and implementing the recruitment effort. Ample planning is essential and adequate resources must be allocated to all recruitment activities to ensure that the goals of the study are achieved. In addition, methods for recruiting and selecting potential subjects must be carefully considered. The scope of these activities will be governed by the size and complexity of the study. Thus, all recruitment activities will reflect the inherent and unique characteristics of each study.

Recruitment Considerations

Successful recruitment of study subjects requires considerable planning. An effective recruitment effort must include a realistic timeline, development of all necessary screening forms, consideration of staffing needs, an adequate budget, appropriate equipment, facilities and resources, advertising strategies, a monitoring system, and a back-up plan ready to implement. A major goal of recruitment is to identify the required number of subjects necessary for the study within a projected timeline with the resources available. The amount of time that should be allocated to recruiting subjects depends on the type and complexity of the study as well as the eligibility criteria that have been defined.

Recruitment Plan

Before the initiation of recruitment of potential subjects, a recruitment plan should be developed. This should include short-term and long-term goals, carefully defined recruitment strategies, a realistic timeline, appropriate screening forms and adequate resources including: funding, staff, office space, equipment (phone lines, computer, office supplies, etc) and proven monitoring/tracking system. The eligibility criteria for participation in the study should be well-defined prior to initiating recruitment.

Timeline

The timeline for recruiting the required number of subjects has to be clearly defined. Recruitment efforts should be initiated well in advance of the study start date in order to complete all required screening activities. The time frame for the recruitment process will depend on the eligibility criteria and the characteristics of the study population that will be recruited. Recruiting normal healthy individuals is less time consuming and less challenging compared to recruiting individuals with specific metabolic disorders. For example, a demanding study with narrowly defined eligibility criteria will require more time, effort and resources than less intensive studies with broadly defined eligibility criteria. Additionally the number of subjects needed and the concentration of the target population in the community will also determine the length of recruitment. For example, recruiting 30 normal healthy males could take less than 2 months, whereas recruiting 30

individuals with NIDDM or specific lipid disorders takes approximately twice as long. Careful planning is therefore required to avoid a prolonged recruitment period since the extended period not only affects productivity of the staff and the recruitment efforts, but may also result in loss of interest by potential subjects.

Staffing

Depending on the study requirements the recruitment efforts may require a large (6 to 8 individuals) or small staff (2 to 3 individuals). The staff used for recruitment should be well trained, should have adequate background information about the study, and should be personable and friendly when interacting with potential subjects. It is essential to have a recruitment coordinator to oversee all aspects of the recruitment process. The support staff can be either part-time or full-time individuals depending on the recruitment efforts required. These individuals can be assigned different duties such as placing advertisements and flyers, preparing mailings, answering phones, conducting interviews. It is important that all staff involved in the recruitment efforts be well trained in all aspects of the process and be capable of taking on additional responsibilities. They must be dedicated and motivated individuals. At times during recruitment, considering the efforts of the staff will keep them motivated throughout the entire process. For example, offering them a small incentive such as a T-shirt, coffee mug, etc for referring potential eligible subjects to the study will give them a "boost" and encourage them to contribute in different ways to the study that is being launched.

Budget Considerations

The cost of recruitment depends on the study eligibility criteria, recruitment strategies used, staffing needs and equipment needs. Depending on the target population, different recruitment strategies should be used, which will vary in cost (see table). For example, newspaper advertisements can vary from \$45 to \$150 per ad depending on the size of the advertisement and its placement in the paper. On the other hand, flyers are less expensive (\$0.50 per flyer). Other recruitment costs include the cost of extra phone lines for interviews, copying costs, staff wages and fees for office space and supplies.

Summary

In summary, a successful recruitment effort requires careful planning and adequate resources. The scope of this effort will vary depending on the study objectives; for some studies, recruiting subjects may be straight-forward and relatively easy, whereas for other studies, this can be very challenging. Lastly, flexibility is of utmost importance in dealing with many unanticipated issues that arise when recruiting subjects into a well-controlled feeding study. With adequate attention to all aspects of recruiting subjects into a feeding study, recruitment goals will be achieved which will contribute significantly to the success of the study.

Recruitment Strategies for Well-Controlled Clinical Nutrition Studies

Strategy	Strengths	Limitations
Newspaper	Large display ads in specific sections reach a wide audience.	Can be costly, reaches a limited audience
Radio and Television	Generally as public service announcements; reaches a wide audience	Can be costly; stations not always willing to broadcast
Mailings	Very informative; can target specific population	Time intensive and can be costly; may not be read
Flyers/Posters	Inexpensive	Not effective when used alone; must be posted in high visibility areas
Physician/Dietitian Referrals	Increases study credibility and encourages participation of target groups	Slow rate of referrals
Word-of-Mouth/Networking	Presentations of clubs or professional organizations whose members are part of the target population; can tap into a source of reliable volunteers	Small yield; individuals may be forced to participate due to peer pressure
Recruitment Meetings	Personal contact and large audience sizes are reached; will attract only those who are really interested	Requires participant "effort"; time intensive for staff
Electronic Mail/Bulletin Board	Inexpensive and reaches a broad audience	May be discarded as junk mail; may not reach target population; limited to individuals with access to computers
Health Fair/Information Booth	Personalized contact allows promotion of the study to interested individuals and target population	Time intensive for staff; will attract all kinds of individuals
Databases from Previous Studies	Easily accessible, inexpensive; subject characteristics known	Must be updated; limited participant pool

NOTES

DETERMINING CALORIE LEVELS AND MONITORING WEIGHT FOR WEIGHT-MAINTENANCE STUDY

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Accurate estimation of energy requirements for individuals participating in a controlled feeding study is desirable. Such precise estimates lead to minimal weight fluctuation during the study assuming all other factors being equal (e.g. physical activity, hydration status) and thus produce minimal interference to the study outcome. In addition, the need to adjust food procurement and preparation procedures can be minimized.

Energy requirement:

Total energy requirement (or expenditure) usually consists of three components:

$$\boxed{\text{Total Energy Requirement}} = \boxed{\text{Basal Metabolic Rate (BMR)}} + \boxed{\text{Diet Induced Thermogenesis (DIT)}} + \boxed{\text{Physical Activity (PA)}}$$

BMR is usually the largest component of total energy expenditure. It stands for energy expended by an individual at rest under a neutral thermal condition. Lean body mass is the strongest predictor of BMR. It accounts for the higher BMR in men than in women and for the decrease in BMR with age.

DIT contributes to the total energy expenditure by a relatively small amount, usually around 5 to 10%, and it may be affected by the size and composition of the meal. However, DIT is difficult to detect due to day-to-day variation in energy expenditure.

Physical activity is the second largest component of total energy expenditure. To capture the usual pattern of activities, it is best to measure the activities over multiple days (weekdays, weekends and different seasons). Age, gender and BMI may affect the energy expended on any particular activity.

Estimation of calorie levels:

1. Calorimetry: Either direct or indirect calorimetry can measure total energy expenditure with high accuracy. However, both methods are expensive, time-consuming and rarely available.

2. Formula: Using a formula to estimate BMR and physical activity level is the simplest and most practical method to assess energy requirement. However, different formulae for BMR estimation in combination with various physical activity factor adjustments may result in a wide range of energy requirements. The table below demonstrates how the energy calculated using three BMR formulae and two PA assessments deviate from the true energy requirement.

Comparison of energy actually consumed by participants to the energy levels estimated by three BMR formulae and two physical activity factors.

(Values shown = estimated Kcal - consumed Kcal)

Pt ID	Wt range	Avg Kcal consumed	7-day physical activity factor			DASH modified physical factor		
			Bernstein et al., 1983	WHO	Harris Benedict	Bernstein et al., 1983	WHO	Harris Benedict
PEEJO	61.0-62.6	2222.22	-759	-475	-334	-737	-450	-307
CAMSU	68.7-70.5	2206.67	-711	-388	-295	-632	-292	-194
LLOGA	88.4-91.1	2764.44	-853	-401	-426	-919	-483	-506
HALJA	58.9-61.8	1875.56	-364	-59	17	-364	-59	17
GASJI	95.9-97.1	3204.44	-625	-48	-136	-692	-130	-216
FLOTO	68.2-70	3075.56	-1250	-711	-595	-1213	-663	-544
FISJE	55.1-56.4	1733.33	-298	-22	-51	-328	-58	-86
EURRA	68.1-70	3371.11	-473	379	819	-1285	-671	-355
DOWRO	93.4-96.8	3120	-1035	-510	-454	-957	-413	-355
COUKE	99.5-100.6	2960	-744	-140	-223	-877	-310	-388
SMIDA	110-111	4060	1	948	987	-909	-175	-144

Weight measurement:

Factors that may affect the accuracy of weight measurement include time of day, reliability of scale, accessories and clothing. Participants should be weighed daily to allow close monitoring and a better understanding of weight patterns.

Menu development:

1. Customized calorie level (for small study size only)
2. Fixed levels + unit foods

Weight monitoring and Energy adjustment:

Research menus for feeding studies are usually designed with small variations in energy intake from day to day. This does not always match the energy expenditure pattern of the study participants, and thus, some fluctuation in body weight from day to day is likely to be seen. Small weight fluctuations (≤ 2 lb) over a short term are likely to be fluid only. Energy adjustment is probably needed when a trend of weight change persists for more than 3 to 5 days. Other factors to consider when weight fluctuates include:

1. Consistent trend ≥ 3 days
2. Past weight pattern
3. Physical activity
4. Composition of meal
5. Hormonal changes
6. Illness (cold, flu, diarrhea, etc.)
7. Non-compliance with study foods

BMR formulae:

Bernstein et al., 1983: Women $7.48 (\text{kg}) - 0.42 (\text{cm}) - 3 (\text{yr}) + 844$
 Men $11 (\text{kg}) + 10.2 (\text{cm}) - 5.8 (\text{yr}) - 1032$

Harris Benedict, 1919: Women $655 + 9.5 (\text{kg}) + 1.9 (\text{cm}) - 4.7 (\text{yr})$
 Men $66 + 13.8 (\text{kg}) + 5 (\text{cm}) - 6.8 (\text{yr})$

WHO:

Gender	Age range	Equation
Men	18-30	$(15.3 \times \text{kg}) + 679$
	>30-60	$(11.6 \times \text{kg}) + 879$
	>60	$(13.6 \times \text{kg}) + 487$
Women	18-30	$(14.7 \times \text{kg}) + 496$
	>30-60	$(8.7 \times \text{kg}) + 829$
	>60	$(10.5 \times \text{kg}) + 596$

Guidelines for energy adjustment

	Weight patterns	Caloric adjustment
A	Weight fluctuates, (for example, goes up and down) but average weight of the week is within 1 kg of the target weight.	No action needed.
B	Weight fluctuates and the average weight of the week is 1 kg different from the target weight.	1. Increase/decrease unit foods first by 300-500 Kcal daily. 2. If weight stabilizes during the following week, move to the next higher/lower menu level if deemed appropriate.
C	Weight steadily goes up/down, and the change in weight at the end of the week is within 1 kg.	Increase/decrease unit foods by 100-200 Kcal.
D	Weight steadily goes up/down, and the average weight (or weight at the end of the week) deviates by more than 1 kg from the target weight.	Same as actions in section B.

NOTES

EVALUATION OF DIET COMPLIANCE

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Participant adherence to the research diet and guidelines is critical to the successful completion of the study. Monitoring and compliance expectations should be included in the recruitment phase when all requirements involved in the study participation are discussed with prospective participants. Adequate time must be taken during eligibility visits to thoroughly inform each individual of the study purpose, implementation and the crucial role of the study participant. Recruitment goals should be set generously enough to allow for careful subject selection.

Following selection of eligible and interested candidates, a “diet run-in” should be utilized to allow chosen individuals to experience the feeding center atmosphere, menus, limitations and expectations. Individuals completing the run-in phase should be evaluated regarding degree of commitment and adherence to feeding-center protocol. When participant selection and randomization has been completed, every effort should be made to promote cooperation and enhance commitment throughout the study feeding periods.

Participants should be provided with study limitations and adherence guidelines in written form not only during the recruitment visits but also subsequently for their continued reference throughout the study. Study guidelines and forms should be located in easy-to-access locations to allow availability of extra copies for review as needed. Such guidelines should clearly state information regarding limitations of any allowed self-selected food and/or beverages, restrictions on use of medications, policies for dining room attendance, instructions for emergency situations, activity level maintenance expectations, etc.

Participants of feeding studies must agree to eat all food provided by the feeding center and to not eat any food which has not been provided by the study. A designated number of meals each day are generally served at the feeding center, which allows for direct observation of participant attitudes toward compliance and also allows a tray inspection to be completed following each meal. Each meal tray set-up should include a name card to be certain that trays can be accurately assessed at the completion of each on-site meal. Waste containers should be removed from the dining area to prevent any omission of food or containers from the tray evaluation. Individual spatulas may be provided at each meal to facilitate the consumption of sauces, gravies, oils and remnants of food remaining on plates or in containers and to serve as a reminder of the need to consume all food served. Upon completion of an on-site meal, participant trays should be returned to designated tray racks for assessment purposes. Forgotten food or remaining remnants may be weighed and recorded to allow the exact portion amount to be returned at the following on-site meal. A tray check form can be used to 1) indicate the intake deviation that occurred; 2) alert kitchen staff regarding food replacement; and 3) provide a place to record how the particular deviation was resolved.

A food and beverage intake record should be completed daily by each participant to assure that an ongoing effort to record and track any deviation and enforce complete adherence is in place. The daily record can include information regarding the consumption of the experimental diet, as well as any food or beverage consumed in addition to the experimental diet. Information regarding possible use of caffeinated or alcoholic beverages, adjustment of calories by unit foods, use of medication, changes in or record of activity level or any other information pertinent to a particular study could be included on such a tracking form. Scoring of the tracking sheet can provide information on self-reported adherence daily, weekly, and throughout entire diet periods.

Body weight measurement can provide an ongoing assessment of caloric level adequacy as well as basic information which might suggest gross deviation from the experimental diet. Additionally, daily weight monitoring can provide for ongoing individualized participant contact and exchange of information. Ideally, the weight measurement scale should be located adjacent to the dining room, away from the direct comment and discussion of dining participants, thereby allowing private conversation. Communication regarding the day-to-day rigors of restricted eating can provide valuable insight into attitude and how the participants function in real-life situations demanding decisions affecting study adherence.

Further evaluation of compliance is dependent on participant contact with study staff. Ability to communicate with study staff for questions, problems or concerns both in and out of the dining room setting should be available. Use of telephone information cards can provide the participant with ongoing easy access to selected staff members. Frequent interaction between study staff and participants allows for valuable exchange of information regarding acceptance of study limitations and degree of difficulty with ongoing compliance concerns. Deviations from the protocol should be handled discreetly with a sincere interest in understanding the situation causing the deviation and counseling regarding alternative future adherence behavior. Care must be taken to secure accurate and complete information without shaming or embarrassing the participant, which could promote a cover-up of similar behavior in the future. Designated study staff should be readily available to answer questions, reinforce protocol issues, and solve problem situations. Use of trained staff for dining room monitoring during meal service hours is crucial as it allows continued observation of participants and can facilitate awareness of problem areas, diffuse negativism that may evolve as the result of limited food choices over time, steer conversations that could be possibly offensive to a more positive level and, in general, promote a beneficial research-oriented perspective.

NOTES

PREPARING AND DELIVERING RESEARCH DIETS

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The effective use of dietary control and its appropriate application is a vital component of the clinical research process in order to assure maximal patient compliance and accurate data collection.

Well controlled dietary studies are designed to study the metabolism or physiological effect of food constituents and/or specific nutrients or chemical elements. By controlling dietary intake, outcome variables can be more effectively measured, monitored, and evaluated.

Numerous types of methodologies are employed in controlled feeding studies. Which methods are used must be thought out very carefully in the initial study design in order to blend the need for accurate scientific data collection and outcome with patient compliance, food production and delivery, facilities and staffing, and cost.

A classification system for research diets was developed in 1973 by Sachiko de St. Jeor and published in the Journal of the American Dietetic Association. Accurate dietary intake can only be achieved when subjects are provided with all their foods, required to eat all the food provided, and not allowed to eat or drink anything else. Dietary methodology used in clinical feeding studies usually falls within the classification of the controlled nutrient diet, constant diet, and metabolic balance diet. This latter would also include formula diets. Some methods offer an advantage to the investigator because more reliable data are available, while others offer more flexible patterns of eating and more acceptable food choices for the subject. Each has its place, effectiveness and use as long as the inherent advantages and disadvantage of each are recognized and evaluated thoroughly.

Research diets are designed based on nutrient analysis of sophisticated databases usually using a combination of USDA data and manufacturer's data. When necessary, laboratory analyses of particular food items are conducted specifically for a study. Factors to consider in determining the methodology to use include an assessment of the following needs: constant food source and standardized food preparation techniques, individual or batch recipe preparation, use of fresh fruits and vegetables, distilled water vs. local water, single menu vs. rotation, number of subjects, duration of study, food storage and procurement, kitchen size and staffing, inpatient vs. outpatient, and cost.

Accuracy is the foundation for calculating the research diet and for its ultimate weighing, preparation, service, distribution, and monitoring. It is necessary that all procedures are defined, written out, and followed by the entire staff in exactly the same manner. Continuous monitoring and checking systems are important to minimize errors.

Food Preparation Techniques vary depending upon dietary methodology. For the most accurate solid food diets, all foods should be procured from the same supplier, used from the same lot for the duration of the study, and prepared individually for each subject. Fresh fruits and vegetables are frequently avoided due to variation in nutrient composition. However, if there is little effect on the nutrients being studied, they are a welcomed addition which adds to patient satisfaction. Distilled water may or may not be necessary depending upon elements being studied. All foods are weighed on electronic balances into the container in which they will be served or cooked. Meats are calculated and weighed raw so that changes in cooking time and weight will not add an additional variable. Guidelines for weighing vary; however, a common guideline is foods > 10 gm may have a variance of +/- 0.5 gm and foods < 10 gm a variance of +/- 0.1 gm.

The use of portion-controlled food items from the manufacturer may sometimes be incorporated. This helps to reduce labor and staffing. Also, batch recipes using weighed ingredients and standardized food preparation and cooking techniques can be developed and used in specified weighed amounts.

Unique Equipment Necessary For a Research Kitchen includes items such as electronic balances, a distilled water system, an automated packaging system, and an institutional blender.

Considerations for an electronic balance include capacity/weighing range necessary for weighing serving dishes plus the food item, food composites, TPN solutions, and formulas, readability to 0.1 gm, pan size and dimensions, stabilization time, ease of use, calibration, and price.

Distilled water systems can be incorporated into the kitchen water supply using undercabinet tanks. Systems can be purchased or rented and service contracts can be set up for routine regeneration.

Automated packaging systems such as an autobagger or heat sealer can facilitate food sealing and packaging for both dry goods and cooked foods.

An institutional blender with a minimum capacity may be necessary for preparing formula diets and foods aliquots.

Food Service To Inpatients is usually typical of conventional tray service. Name tags which identify the type of research diet or a simple command such as "FINISH" are helpful. Special individual dishes for food service are also usually required as well as small spatulas for subjects to use in cleaning their dishes.

Food Service For Outpatients can use all disposable containers and packaging, returnable food containers, or a combination. Containers for carrying the day's food home include brown shopping bags, large plastic bags with handles, or coolers with ice packs. Food safety is a necessary consideration. Availability of refrigerated or frozen food storage at home or at work must be assessed in addition to mode of transportation

and transport time. For subjects traveling a distance or having to store their food in a heated car, insulated coolers may be necessary. Temperature indicators are available to put on refrigerated foods to monitor food safety.

NOTES

DEVELOPING MENUS USING NUTRIENT DATABASE PROGRAMS

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Two important considerations when selecting nutrient database programs to calculate research diets are 1) the reliability of the database, and 2) the functionality of the program. Both aspects are important, but it would be hard to argue that anything would be more important than reliability of the data. No matter how easy a program is to use or how well the output from a program supports kitchen management, if the data is wrong, the research objective is not met.

Data from the USDA National Nutrient Databank forms the basis for most, if not all, dietary calculation packages used in the U.S. and has served researchers well. Therefore, it is important for the researcher to understand how USDA data is organized.

USDA provides nutrient data in a variety of formats. The printed version is called USDA Handbook 8, with 21 sections representing 21 food groups. There are also currently five provisional tables providing information about nutrients where valid data is available for only a limited number of foods.

Electronic versions of USDA data are primarily of two types: a “standard reference” which contains analytical values for 77 components, with fields left blank if no acceptable analytical values are available; and a “survey database” which contains analytical and imputed values for foods required for calculating the composition of food records and recalls from national surveys, each containing 30 components (with NO missing values). Each of these two general databases involve numerous supporting files.

Other sources of data used for research include Pennington and Church’s “Food Values of Portions Commonly Used,” data for specific products provided by the manufacturer, and data derived by individual investigators to support their own studies. For an example of the latter, at the University of Iowa we have calculated diets using carnitine and biotin data provided by local laboratories.

If desired nutrients are not included on the USDA database, developers must either search the literature for additional data or omit the nutrient from their database. When research centers need data not on the USDA tables, they often must manually add the needed nutrients to their database. This effort requires considerable time and knowledge of database development procedures to ensure the new data is appropriate. Attempts to keep pace with the addition of new foods in grocery stores and restaurants present another challenge to database development. This is a greater problem for population studies than it is for metabolic studies. For many database developers, keeping up with new products has meant that partial data is added to the database; for example, a manufacturer of a new product may only analyze for the nutrients required on the label, so only this information will be available when the food is added to the database. When

new foods with data for only a few nutrients is entered onto the database, we can call this an incomplete database, or a database with missing values. Information about the completeness of nutrient data on a database is often difficult to obtain, so the user must beware.

Calculating research diets and managing the production of the food and menus can be greatly facilitated by the appropriate computer software. There is not one single “best” computer application for this task. Many research centers have developed applications for their own operation. Few of these applications are packaged in a way to facilitate their distribution. For example, the USDA human study unit at Beltsville, MD uses SAS for manipulating the USDA nutrient data and for developing their own research diets. SAS is a common statistical package which facilitates sharing the data, but the application is not robust, and documentation is generally lacking.

A D-Base application developed at the University of California General Clinical Research Center (GCRC) uses the USDA Standard Reference Data and is packaged for limited distribution within the GCRC. A FOXPRO system is also being developed at the Pennington Biomedical Research Center with their own database that also has limited distribution.

Commercial software calculation systems are used in many research centers, and several of the programs offer features very helpful in research diet design. For example, the CBORD Diet Analyzer screen facilitates tracking the composition of a meal or a total menu as it is entered and altered to achieve a stated nutrient goal. Nutritionist III and IV provide a food selection screen which previews the composition of a food and gives the source of the data. ESHA’s Genesis program offers a recipe calculation system which facilitates adjustments to recipes to account for fat and moisture gain and loss during preparation. These features are very helpful to the research dietitian for selected uses.

While the above features facilitate research diet design, they fall short of providing the full potential of a computerized system designed specifically for research. For example, a project currently underway to design a comprehensive system for research diet design, service and reporting includes 8 major functions: 1) Diet creation and editing, with system manipulation of diet to meet target, 2) Study protocol design and tracking, 3) Investigator and subject records, 4) Kitchen management, 5) Data tracking and analysis, 6) Anthropometry, 7) Forms and reports, and 8) Tools. This system recognizes the significant management component involved in research diet design.

Typical tasks involved in diet design and calculation include developing the protocol, calculating the diet, selecting foods and recipes that are acceptable to the subject population and whose preparation make efficient use of study facilities and staff, scheduling meal service and delivery and documenting consumption. Advanced planning facilitates efficient use of human and equipment resources.

The first step to the actual design and calculation of research diets is developing the diet prescription. Typical diet prescriptions may involve 1) a “standard” diet identical for

all subjects, 2) a standard diet proportional to the calorie value of the diet or to the subject's body weight, or 3) a diet that varies with appetite or other variables unique to the study design. The actual prescription may consider the composition of the total diet, or the composition of each meal may be prescribed. If the total caloric level of the diet is flexible, but the proportional composition is set, units of the diet may be devised that match the overall composition to be eaten ad lib (sometimes called "unit foods").

During implementation of the diet, an important consideration is how much latitude should be allowed to accommodate a subject's food preferences. Modifying the diet does two things; first, the composition of the diet will change as foods are substituted that may not exactly match the original item, and second, making frequent dietary changes puts an additional burden on study personnel. It is important to balance the added workload involved in frequent diet changes with subject satisfaction and successful completion of the study.

After the diet has been completed and consumed, the computer is helpful for calculating the composition of the actual food consumed. Planning data collection and analysis strategies during this phase simplifies data summarization and analysis. If data is organized to permit direct import to a statistical package, summarization and analysis of the dietary data is greatly facilitated. A well-designed computer application can contribute significantly to this process.

NOTES

MEASURING FOOD COMPOSITION

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In the past, controlled or metabolic diets may have consisted of a solution of purified nutrients such as sugars, amino acids, various lipids, vitamins and minerals. Today research subjects participate in their normal daily activities while consuming a prescribed diet. An array of customary foods can be used to deliver a defined nutrient pattern to subjects. Since the daily intake of any component will be the sum of the contributions of different foods in the day's diet, the research staff is challenged to provide an acceptable, varied menu and yet maintain the prescribed nutrient intake over the course of the study.

Initially, a food composition database may be used to develop the menu plan for the study. However, the calculation of component levels should be supplemented by chemical analysis of representative samples of diet composites or individual foods to establish specific and accurate values for levels of major components consumed during the study period. Generally, a food component database contains estimates which represent the approximate nutrient content of a food sampled across a national or regional supply rather than of individual lots of locally obtained food supplies used in the feeding study. Use of a single lot or source of a food will minimize the variability in component intake due to different brands, production dates, formulations, etc. In contrast, the usual food composition database will not contain values for specific sources of foods.

The analysis of foods and diets to determine accurate estimates of their composition requires a thorough knowledge of the measurement process and includes the development and testing of protocols for sample selection and handling, as well as the validation of analytical methods. The process begins with the selection of the representative sample and ends with the acceptance of quantitative estimates. Other critical points in the process include homogenization and analytical quality control. Each step in the process must be defined, tested, and monitored to achieve accurate and representative results. In addition, the cost of analyses for specific components will affect the development of the plan of analyses to be conducted.

Daily diets for humans are generally composed of 15 to 25 foods per day and represent several different food groups. For any component, values for multiple individual units of a food product will exhibit a statistical distribution characterized by a mean and/or median value and variability about that value. For this reason it is important to obtain representative samples of each of the individual foods for analysis as a composite or as individual samples. Representative samples of the foods will be identical in weight and physical description to the food portions used to feed subjects. Foods should be taken from the same brands and lots as those portions used for feeding. Particular attention should be paid to cuts of meat and complicated mixtures (such as stews) to assure the selection of the portion which is similar to the others.

Diet samples should be homogenized according to predetermined and tested protocol to minimize nutrient loss and sample contamination. Improper homogenization can cause changes in the sample matrix which affect component levels or lead to difficulties in sampling the mixture. Homogenization protocols will vary from component to component and matrix to matrix. The analyst should participate in the development of the homogenization and storage protocols to assure the stability of the samples. Following homogenization proper storage of samples according to predetermined protocol is required to maintain the stability of components. Samples may be individual aliquots or composites of daily diets or individual meals. Compositing individual units of a product is efficient in terms of the number of analyses required, but diminishes the amount of information about variability of the component.

The choice of analytical methods for the measurement of component levels is determined by the study objectives, the required level of specificity, the availability of expertise and instrumentation, the number of analyses required, and budget. As scientific knowledge evolves, objectives focus on the metabolic effects of specific vitamins or component forms. As public health priorities change, new methods must be developed to determine these components of new interest. Investigators must be knowledgeable about analytical methodologies required, as well as the necessary quality assurance protocol to achieve accurate and representative food composition data. The validation of analytical methods before the analysis of food/diet samples occurs should be documented and reviewed by the investigator. Reports of analytical results must be accompanied by quality control results in order to guarantee the quality of the data. Use of food composition data with unknown accuracy or variability can lead to erroneous conclusions about the diet-response relationship and subsequent conclusions.

NOTES

ENCOURAGING COMPLIANCE AMONG PARTICIPANTS

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The strict dietary requirements of feeding studies are likely to create compliance challenges to the participants as well as the clinic staff. Sometimes simple communication techniques can mean the difference between contentment and frustration for participants and staff alike. The purpose of providing training in communication in the midst of a highly technical and procedure-oriented research study is twofold: 1) to help participants and staff find some sort of satisfaction, if not enjoyment, in the day-to-day routines of the study, and 2) to provide practical skills to assist staff in managing participants and the challenges that arise in working with them.

Obviously, enrolling the “perfect” participant would eliminate the challenges. And, certainly, careful screening *is* an essential factor in preventing some of the compliance problems that feeding studies present. Ideally, participants who may not be good candidates will exclude themselves *before* intervention begins when they realize that the expectations of the study exceed their willingness to commit, and the participants who are motivated and ready to commit will continue on with the intervention. However, regardless of how motivated participants may have been at the time of consent, most will feel a sense of ambivalence about their commitment at some point during the course of a research study. This ambivalence can be observed in missed meals, uneaten study foods, eating non-study foods, or a number of other behaviors. It’s at these times of noncompliance that the staff interaction with participants will be essential to the success of the study.

The study design does not allow for lengthy counseling sessions with participants when problems arise, nor is such counseling usually necessary in promoting compliance. Contact with participants will most often be brief but can be very productive if basic helping strategies are practiced. In essence, the staff’s use of these strategies in communicating with participants provides quality interactions that, in turn, will increase the likelihood of maintaining participant motivation and compliance. In addition, the communication style of staff may help in attaining accurate information from participants for data collection during the study. The following list includes some basic helping strategies and examples of how staff might use them in brief contacts with participants.

- **Non-verbal Communication**

Use body language to help express your interest in what the participant is saying. For example, slightly lean toward the participant and maintain eye contact.

- **Open-ended Questions**

Ask questions that require more than a simple “yes” or “no” answer. Use open-ended questions to encourage the participant to think and talk about concerns, as well as successes, in adherence to the diet. For example, “What have been the most difficult aspects of your participation so far?” “And what have been the easiest?”

- **Reflective Listening**

Let the participant know you are listening and understand them by re-stating what you heard the participant say. For example, “It sounds like you’ve had to deal with more special occasion eating situations than you originally anticipated.”

- **Summarizing Statements**

Use summarizing statements at transitional points or at the end of the conversation to pull together the gist of what has transpired. Re-cap the main issues the participant has raised with a summarizing statement such as, “Let me see if I understand what you’ve told me so far.”

Throughout the study, these brief but meaningful individual interactions will build rapport between staff and participants. The clinic staff style and manner of communicating play a key role in promoting trust between participants and staff. This style of communication can be summed up in the word “empathy,” that little something that makes a difference in results. And the manner is one of good, old-fashioned respect. Below are guidelines to assist staff in promoting motivation and compliance among participants while exuding this style and manner of empathy and respect:

- Try to understand the participant. Be warm, interested, and non-judgmental.
- Avoid confrontation and raising the participant’s resistance.
- Emphasize your confidence in the participant’s ability to adhere to the diet.
- Re-affirm the participant’s reasons for volunteering to be a part of the study.
- Emphasize the important contribution one participant can make to the study as a whole.
- Reinforce the study expectations in a gentle and encouraging manner.

Help the participant explore and resolve ambivalence about adherence to the diet.

A final word about communication techniques. Ideally, style and manner are outward expressions of an internal state. If you have the internal state--that is, if you are genuinely empathetic with the participant--most participants will be able to detect this. Conversely, most participants will be able to tell (and will respond unfavorably) if you are merely adopting a style as a means of conveying the *illusion* of empathy. Consequently, the above recommendations about manner (e.g., leaning towards the participant and maintaining eye contact) need to be taken with this in mind. The bottom line is: *be* genuinely empathetic and your manner will reflect this.

NOTES