

# Designing, Preparing and Delivering Research Diets



*Special Topics*



## A Training Workshop

June 8-11, 1997

*Sponsored by the National Heart, Lung, and Blood Institute*



Pennington Biomedical  
Research Center  
Baton Rouge, Louisiana

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## WORKSHOP SPEAKERS

**Pavinee Chinachoti, Ph.D.**, Associate Professor, Department of Food Science, University of Massachusetts, Amherst, MA.

Dr. Chinachoti's research focuses on the improvement of food product shelf-life stability with an emphasis on cereal and baked products. She will be the instructor for the food technology teaching modules.

**Beverly Clevidence, Ph.D., R.D.**, Beltsville Human Nutrition Research Center, USDA ARS, Beltsville, MD.

Dr. Clevidence, Research Nutritionist, has valuable experience in designing and implementing nutrition research studies. She will speak about study design aspects for the Outpatient Feeding Study Session.

**Wahida Karmally, M.S., R.D., C.D.E.**, Irving Center for Clinical Research, Columbia University, New York, NY.

As Director of Nutrition, Ms. Karmally oversees both inpatient and outpatient feeding studies. She is familiar with the food production needs for metabolic diet research and will speak during the Outpatient Feeding Study Session.

**Kelly Patrick**, Pennington Biomedical Research Center, Baton Rouge, LA.

Ms. Patrick is a nutritional chef at PBRC who has combined her culinary techniques with nutrition principles. She is the co-host of a public broadcasting cooking show and demonstrates low-fat cooking to various schools and organizations.

**Stephen Robichaux, M.B.A.**, Executive Education Department, College of Business Administration, Louisiana State University, Baton Rouge, LA.

Mr. Robichaux provides management and supervisory training and consultation for public employees. His areas of specialty include organizational behavior, conflict resolution, strategic planning, team building, and motivation. He will lead the teaching modules on solving problems and working effectively.

**Anita Sawyer, R.D.**, Metabolic Kitchen, Pennington Biomedical Research Center, Baton Rouge, LA.

Ms. Sawyer, as manager of the PBRC metabolic kitchen, has established procedures to assure quality that are unique to a research kitchen. She will share her knowledge during the Safety and Quality in Food Production session.

**Helen Seagle, M.S., R.D.**, Center for Human Nutrition, University of Colorado Health Sciences Center, Denver, CO.

Ms. Seagle, Research Dietitian, conducts research relating to energy expenditure and energy balance. Her expertise will be shared as instructor for the energy expenditure teaching modules.

**Cindy Seidman, M.S., R.D.**, The Rockefeller University Hospital, New York, NY.

Ms. Seidman, Director of Nutrition Research Services, has developed expertise in HACCP for the research kitchen, and has presented information regarding food safety to various research organizations. She will be a speaker for the Safety and Quality in Food Production session.

**Phyllis Stumbo, Ph.D., R.D.**, College of Medicine, Clinical Research Center Medical Research Facility, The University of Iowa, Iowa City, IA.

Dr. Stumbo, Head Research Nutritionist at the Clinical Research Center, has developed expertise in nutrient data bases, diet assessment tools, and computer programs. She will instruct the Computer/Nutrient Intakes teaching modules.

## STUDY DESIGN ASPECTS OF THE OUTPATIENT FEEDING STUDY

BEVERLY CLEVIDENCE, Ph.D., R.D.  
BELTSVILLE HUMAN NUTRITION RESEARCH CENTER, USDA

There has, in recent years, been a tendency to conduct more controlled feeding studies based on an outpatient (i.e., non-residential, free-living) basis. This trend has been driven, in large part, by the cost of residential studies, although science, not cost, must always be the deciding factor. Whereas some studies (e.g., micronutrient studies, studies using invasive procedures) may be inappropriate for non-residential settings, others can be conducted efficiently and effectively in non-residential settings with minimal interruption to subjects' lives. Subjects are more likely to volunteer for studies that allow them to live at home, thus increasing the opportunity to study specific populations (e.g., lactating mothers, people with specific diseases) that might otherwise be difficult to recruit for dietary studies.

Ultimate control is achieved in metabolic ward studies where virtually all aspects of a study are controlled. This degree of control cannot be reached (and in some cases is not desirable) in outpatient studies, but data from free-living subjects is more likely to be generalizable to the population at large. For free-living studies the investigator must determine the degree of control, both dietary and environmental, that is needed to assess the effect of the dietary variable on the outcome measurements of interest. The goal is to provide the degree of control required for a particular research question without spending additional resources where control is not required. Costs of human feeding studies vary by facility and design, but a well-controlled feeding study, conducted on an outpatient basis, can cost roughly 10% that of a comparable inpatient study.

The frequency and degree of dietary noncompliance in free-living, controlled diet studies is unknown and probably varies in association with the degree of involvement of investigators, the number of meals eaten away from the dietary facility, the palatability of the diet, and distribution of calories across the day. Dietary noncompliance has two aspects: subjects may eat foods other than those provided in the context of the study (unauthorized foods), or they may fail to eat all foods provided by the study. Noncompliance is often detected by tracking body weights of weight-stabilized subjects. Although there is no perfect dietary marker, several have been used successfully to assess dietary compliance, and this added level of documentation enhances the credibility of studies. Common markers of dietary compliance include urinary *p*-aminobenzoic acid (PABA), urinary osmolality, and urinary riboflavin. Each has distinctive advantages and disadvantages. Additionally, for some studies it is important to verify compliance with the study protocol concerning issues of smoking and drinking alcoholic beverages. Smoking status can be assessed by measuring cotinine, a metabolite of nicotine, but ruling out use of alcohol when it is not allowed is difficult in free-living subjects.

In free-living studies, a number of issues arise in conjunction with foods eaten away from the feeding facility. The most serious are issues of compliance and food safety. Subjects will typically want to eat more meals away from the facility than investigators find to be desirable. The number of take-out meals to be allowed must be established prior to the study, and each take-out meal must be documented. Check-off lists, commonly sent with take-out meals to encourage compliance, must be returned to the dietitian. Subjects should understand that the limitations on the take-out meals are not strictly an issue of trust; more importantly, they are one aspect by which the scientific community will judge the credibility of the study. Control by the dietary staff over food safety is largely lost when foods leave the facility, yet investigators may be held responsible for food borne illness arising from mistreated foods. Prospective subjects should be queried about food safety knowledge and provided appropriate information and routine reminders about safe storage and handling of foods. Subjects who cannot safely take care of take-out foods should not be included in feeding studies. A two-day supply of portioned food items will consume most of the space in a typical home refrigerator, so it should be determined on a case-by-case basis whether subjects have adequate refrigeration space. Foods for weekends and holidays are typically sent home in a cooler containing crushed ice.

Large numbers of subjects are often needed to detect statistically significant differences due to dietary treatment, and free-living studies can usually accommodate more subjects than can residential studies. On the other hand, slightly larger numbers of subjects may be needed in free-living studies to compensate for the loss of environmental control and (hopefully small) losses in dietary control. Subject size is minimized when subject variability is limited, subjects serve as their own controls, uncontrolled variables are limited, measurement errors are few, changes in endpoints are large, or changes in nutrient intake or bioavailability are large. To estimate the number of subjects needed (number completing the study) for detecting a true difference, a power calculation is conducted. To make this calculation, it is necessary to estimate the size of the effect expected as well as the variability expected; both are determined from previous studies.

Outpatient studies, used appropriately, can produce reliable data at minimal costs. In contrast to inpatient studies, where meals and collections can be regimented, more flexibility is required in outpatient studies to accommodate the routines of various subjects. Dietary markers are useful for documenting dietary compliance, but having subjects who are strongly motivated will best ensure compliance. Investigators who encourage subjects, listen to problems and respond in appropriate and supportive ways, and communicate the importance of the study to subjects are generally rewarded with motivated subjects who follow study protocol to their full capacities.

## NOTES

# TRANSFORMING THE RESEARCH KITCHEN FOR AN OUTPATIENT FEEDING STUDY

WAHIDA KARMALLY, M.S., R.D., C.D.E.  
COLUMBIA PRESBYTERIAN MEDICAL CENTER

There is a growing demand for outpatient resources, according to the General Clinical Research Centers' (GCRC) Survey conducted from 1980 to 1992 (*Evaluation of the NIH General Clinical Research Center Program, Final Report, 1996*). Although the survey shows that projects related to the heart and to nutrition and cancer decreased annually by 2% or less, research areas most cited for GCRC projects were metabolism (40%), drug therapeutic agents (39%), nutrition (13%), and immunology/allergy (12%). Sixteen percent of the endocrine systems' projects and 22% of metabolism/biochemical transport projects were nutrition related.

Two recently conducted multicenter trials funded by the NHLBI were DELTA (Dietary Effects on Lipoproteins and Thrombogenic Activity) and DASH (Dietary Approaches to Stop Hypertension). These trials gave the participating academic institutions opportunities to develop standardized methodology in conducting outpatient feeding studies.

Accuracy in the preparation and handling of outpatient research diets need not be compromised. In fact, additional effort is needed to achieve compliance when subjects are not closely monitored. This includes the screening of subjects, maintaining contact with subjects, providing good tasting food, and being available for subjects 24 hours a day in case of an emergency. There may be more paper processing with packing lists, compliance check sheets, and other forms.

In the planning of outpatient studies, the following information is important:

- 1) Nutrient control. Which nutrients must be controlled? This determines the intensity of the work load. Is it feasible to use portion-sized foods so that each food item will not have to be weighed and repackaged?

Menu design (variety of menus, foods and recipes used) also is determined by the extent of nutrient control. Which foods can be used without jeopardizing nutrient control? For example, if a study requires sodium control, considerations must be given to the source of water used. Will the subject be asked to carry distilled water? What about ice cubes?

For caffeine control, how will tea, coffee, and soda be handled?

- 2) Packed meals. Consider the number of meals eaten on site and the number of meals that need to be packed (weekdays and weekends). Is the food prepared and packed everyday? How is the food being transported? Can it be

packed in paper and plastic bags with freezer packs or in coolers? How long does the subject have to travel with the food? Will the subject be delayed some days for an evening class or for some other responsibility? Which meals have to be frozen? Do you and the subjects have enough freezer space? Do meals have to be sent by Federal Express?

- 3) Packaging materials and containers. Those used in the study are selected by the following factors:

Does the subject have a microwave or conventional oven for re-heating foods?

Do you want to serve food on china for on-site feeding? What if you decide to plate food on china, and the subject changes his/her mind about coming in? If you have to send the food to the subject, you will have to repackage the food. Consider nutrient losses in repackaging.

Do you want to use disposable containers, or do you have facilities for washing and sanitizing reusable containers?

- 4) Maintaining accuracy in food preparation and food packaging. Additional employee training, internal audits, and the use of food lists might be required.
- 5) Monitoring of patient compliance. This begins with careful screening of subjects. Subjects should be treated with dignity and sensitivity to their needs. Subjects must be instructed to complete daily compliance check sheets. In some studies, subjects are asked to return empty containers or are given spatulas to scrape out the food from containers. Considerations are also given to the availability and feasibility of using or testing markers of compliance, such as para-aminobenzoic acid (PABA) added to foods or 24-hour urine sodium.
- 6) Food safety issues need careful consideration.
- 7) Design and delivery of emergency meals. Plan for a possible mishap, such as an illness or even a winter storm.
- 8) On-site meals. For subjects who need to eat on site, a dining area which is comfortable, clean, and has pleasant surroundings is needed.

## NOTES

## THE APPLICATION OF HACCP PRINCIPLES IN A METABOLIC KITCHEN

CYNTHIA SEIDMAN, M.S., R.D.  
THE ROCKEFELLER UNIVERSITY

Food safety is a serious concern to the registered dietitian overseeing the production of a variety of research diet studies. Much can be learned from the actions taken by the food industry in their efforts to prevent food borne illness. The Hazard Analysis Critical Control Point (HACCP) concept can be applied in the research setting as a useful quality assurance measure.

HACCP is a two-part process. The *Hazard Analysis* portion of HACCP involves the evaluation of all the procedures concerned with the production and use of food products. *Critical Control Points (CCP's)* are those points that, if not properly controlled, can result in an unacceptable food safety risk, such as contamination, survival and growth of pathogens.

*Hazard analysis* identifies potentially hazardous foods, critical points in the food production process, and people control that must be monitored to assure product safety. When analyzing hazards, consider the following three factors: 1) potentially hazardous ingredients; 2) both biologic and physical hazards in processing; and 3) potential for consumer abuse.

A food capable of permitting the rapid growth of infectious microorganisms is considered *potentially hazardous*. There are intrinsic factors of potentially hazardous food that include 1) nutrient content (usually of animal origin), 2) high moisture content as measured by water activity ( $a_w$ ) $\geq$ 0.65, and 3) low acid foods (pH $\geq$ 4.6).

External factors of potentially hazardous foods are those foods that include:

- multiple preparation steps,
- major temperature changes (e.g., cook, cool, reheat),
- preparation several hours or days before service.

*CCP's* commonly fall into the following categories: microbiology, sanitation, employee cleanliness, and time-temperature.

The time-temperature relationship is an important aspect of training for all food service personnel. The 1995 Food Code recommends cooling foods to 41°F (5°C) or below, within 4 hours after cooking. The danger zone refers to the time it takes bacteria to grow at temperatures ranging from 41°F (5°C) to 140° F (60°C).

Important time-temperature control methods are as follows:

- cook foods to required temperatures,
- cool foods rapidly (to 41°F in 4 hours),
- reheat foods to 165°F,
- hold hot foods at 140°F.

There are seven steps involved in the implementation of a HACCP system:

- Assess hazards at each step of the food flow and develop procedures to lower risks.
- Identify critical control points (*CCP's*) in food preparation.
- Establish critical limits for preventative measures.
- Establish procedures to monitor *CCP's*.
- Establish the corrective action to be taken when monitoring shows that a critical limit has been exceeded.
- Establish effective record-keeping systems that document the HACCP process.
- Establish procedures to verify that the HACCP system is working.

Some examples of monitoring and verifying control points are:

- checking food temperatures frequently and at each process step,
- checking for conditions leading to contamination,
- changing procedures as needed,
- training employees.

The basic concepts of HACCP dovetail with those of Total Quality Management (TQM) or Continuous Quality Improvement (CQI).

CQI is a process that seeks to continually improve procedures to meet the needs of those served through development, design, redesign, and refinement. CQI uses a systems approach, statistical analysis, and flow diagrams as tools.

The foci of CQI are:

- customer satisfaction,
- continuous improvement,
- service strategies,
- teamwork,
- systems approach,
- education and training.

HACCP exemplifies CQI methodology and plays a critical role in assuring food safety in the metabolic research kitchen.

## NOTES

# ESTABLISHING QUALITY ASSURANCE PROCEDURES

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PENNINGTON BIOMEDICAL RESEARCH CENTER

The word “quality” is difficult to define because it may have different meanings for different individuals. The American Society for Quality Control defines quality as the sum of the features and characteristics of a product or service that affects the satisfaction of a customer’s needs. Quality may also be measured in terms of conformance to specifications, the relative absence of defects, and the degree of customer satisfaction with a product’s characteristics and features.

A customer is someone who uses products or receives services. Study participants, who consume the meals we provide, are external customers. Internal customers include those individuals who depend on our accuracy and consistency in meeting study-specific criteria.

Quality assurance, QA, is “a procedure that defines and ensures maintenance of standards with prescribed tolerances for a product or service” (1).

“The quality assurance program is a continuous process of assessment and evaluation according to predetermined criteria, feedback, and correction” (2).

Quality assurance consists of the documentation of continuous monitoring of processes and products, and the evaluation of results. Feedback is necessary to determine the need for changes required to meet goals and to verify that needed changes have led to the achievement of these goals (3).

“Quality control is one aspect of the management function of controlling, which is a continuous process of checking to determine if standards are being followed and of taking corrective action if they are not” (3).

The control element in a management system has the following four components:

- goals and objectives,
- quality standards,
- policies and procedures for quality control,
- quality assurance program.

Goals and objectives, derived from the mission statement of the organization, provide the basis for defining quality standards, that is, the characteristics by which quality is to be judged.

For example, the mission statement of the Pennington Biomedical Research Center is “to promote healthier lives through research and education in nutrition and preventative medicine.” The mission of the Pennington Center’s metabolic kitchen is

“to support research by designing, preparing and serving meals with safety, accuracy and consistency that meet study-specific criteria and produce valid scientific results.”

Policies and procedures for quality control are derived from the established quality standards. To control the variables that might affect the results, written procedures addressing the necessary duties are designed, and recipes, including necessary and clear instructions, are developed. Staff training is planned to address the following areas: kitchen sanitation and safety; use and care of equipment; food preparation techniques; scale check and recalibration; temperature checks of refrigerators, freezers, and dishmachines; and cleaning and sanitation of equipment, tools, and tableware. The implementation of these procedures and the documentation of adherence to them throughout all processes establishes a system of quality control.

TQM, or total quality management, is a “management philosophy directed at improving customer satisfaction while promoting positive change and an effective cultural environment for continuous improvement of all organizational aspects” (4). Total quality management strives to establish systems which ensure desired objectives.

Formalized quality control programs in the foodservice industry first became widely used in the healthcare segment through standards published in 1979 by the Joint Commission on Accreditation of Hospitals (JCAH). The importance of defining quality standards and monitoring operations to ensure adherence to these standards has resulted in a shift of emphasis from evaluation of results to control of processes. Now, in the 1990’s, we are striving for the assuring and improving of quality.

Kenneth Heymann, vice president of The Hospitality Group, a consulting company in Denver, Co., has stated that the “key difference between quality control and quality management is that quality control is a reactive process and quality management is a proactive process. Quality control is predicated on follow-up and inspection and finding error after the fact. Quality management is devoted to organizing and delivering service in a way that allows you to ensure that you don’t make an error.”

CQI, or continuous quality improvement, is “a focused management philosophy for providing leadership, structure, training, and an environment to continuously improve all organizational processes” (5).

The following are examples of QA forms currently being used by the metabolic kitchen staff at the Pennington Center. The present forms have resulted from our continuous process of designing, implementing, evaluating, and revising the quality control process.

- Quality Assurance Procedures
- Production Control Form
- Daily Tray Check Form
- Weekly Random Tray Check Form
- Problem/Action Form
- Scale Calibration Form
- Refrigerator and Freezer Temperature Form
- Quality Management Record
- Dishwashing Machine Temperature Form
- Sanitation Self-Inspection Check List

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## NOTES

## **CREATING APPETIZING AND APPEALING METABOLIC MEALS**

KELLY PATRICK, CHEF  
PENNINGTON BIOMEDICAL RESEARCH CENTER

When designing research diets and trying to reach specific nutritional guidelines, minerals, nutrients and calories are put into a continuous shuffle. This job is difficult, because a small amount of one ingredient can completely change the game. Unfortunately, the flavor and appeal of the foods often come second. It is usually the regulation of fat or sodium that causes flavor to suffer. However, herbs and spices usually contain very little nutrient value. With an understanding of basic culinary techniques, you will be able to maintain full flavors in foods, while the diets still adhere to strict nutritional standards.

All prepared foods can be classified into five cooking method categories. These are roast (or bake), braise, sauté, steam, or fry. All foods, at some point in cooking, fall into one of these categories. Fat can be lowered and calories regulated in all of the cooking methods without sacrificing flavor. The only cooking method that poses problems is frying. Proper culinary skills required for each of these cooking methods can be applied to specific menus.

The preparation and serving of research foods usually utilize industrial cooking techniques, rather than commercial techniques. Commercial techniques are those used by restaurants or private catering, where foods are prepared to order and freshness rarely suffers. In industrial cooking, many foods must be cooked and re-warmed. Steam tables or warmers are used for holding foods. The holding time of foods is very important to maintain quality and differs for all foods. Furthermore, in industrial cooking, foods may be prepared with frozen or preserved ingredients. The flavor and texture of foods must be regulated to maintain good quality.

Understanding the beauty of seasoning and the wonderful marriages of spices and herbs can be the ultimate factor in acceptability of foods. The endless list of herbs and spices can be overwhelming. But, by learning which spices and herbs go together, and when to add spices and herbs, you can maximize flavors.

Finally, every food, whether cooked at home, commercially, or with industrial techniques, must be “finished”. I am not talking about whether the chicken breast was cooked through or if the pork roast reached a certain temperature on the thermometer! The finishing touches to all foods, even if this only refers to a plate presentation, can turn a meal’s appeal to the positive direction.

## NOTES

## **INCORPORATING FOOD TECHNOLOGY IN THE RESEARCH KITCHEN**

PAVINEE CHINACHOTI, Ph.D.  
UNIVERSITY OF MASSACHUSETTS

Consumer perception toward food has changed rapidly in recent years. Designing new food to meet nutritional, sensory, and safety requirements is more challenging than ever before. From ingredient, processing, and packaging, to product evaluation and scaling up, assembling the necessary information requires a multidisciplinary approach to consider important factors responsible for product quality.

Every food technologist knows that a product will be accepted or not depending largely on the sensory quality of the food. Usually, a new food product is preferred over others when it appears, tastes, and smells like a traditional product. For instance, replacing sugar with an artificial sweetener potentially results in a loss of viscous texture or mouth-feel and this causes a deviation from the traditional product. Basic knowledge of the physicochemical properties of a variety of food ingredients is, therefore, one of the important requirements for product development.

Food processing and packaging play a very critical role in preserving such quality. Not only does a food product have to be safe, but it must also maintain its nutritional, physical, and other qualities during processing and storage. Operating parameters, such as heating, cooling, time, dehydration, freezing, and other physical treatments, all contribute to the final product quality. The relationships between these parameters and the final quality is what food processing technologists try to understand in order to further optimize the ingredients and each processing step. Selecting appropriate packaging materials and conditions (e.g., with or without vacuum, or in modified atmosphere) is key to the shelf-life stability of the nutrients. Finally, but importantly, storage conditions may influence the product quality as well.

Incorporating new ingredients to replace traditional ingredients is not an easy task. Other ingredients may need to be modified or replaced entirely to achieve the desired quality. Additionally, processing conditions and packaging also must be reconsidered, since the chemical, microbial, and other degradation kinetics may change considerably, possibly leading to an unpredictable result upon exposure to heat or other physical changes.

Ultimately, the sensory attributes must be monitored closely in order to assure acceptance by the consumers. Sensory analysis is a scientific investigation of defined sensory attributes under scientifically controlled conditions. In order to collect useful information, the panels and method used must be appropriate to the target group. Methods include the triangle test, pairwise testing, and hedonic scaling. Additionally, physical conditions and the order of testing can significantly influence

the results. Finally, statistically sound experiments are necessary to avoid faulty conclusions.

## NOTES

## **DETERMINING NUTRIENT INTAKES USING COMPUTERIZED PROGRAMS**

PHYLLIS J. STUMBO, Ph.D., R.D., L.D.  
UNIVERSITY OF IOWA

Two important reasons to assess dietary intake in a metabolic ward are 1) to assist in planning for a metabolic study or in screening subjects to determine study eligibility, and 2) to assess adherence to dietary protocol following a treatment or intervention.

### **Planning and Screening**

An important consideration in the planning phase of a metabolic study is past intake, which can influence current nutrition and the way the body handles nutrients. Thus, it is advisable to determine previous intake before embarking on a new research procedure. For example, calcium balance studies require either a long period of adjustment to the new calcium level of a research diet or a match of the research diet to habitual calcium intake (1). The same is true for other nutrients, although the time to reach equilibrium is usually shorter. For example, studies of insulin resistance are more reliable when subjects consume adequate carbohydrate for several days before the study. Sodium and protein require several days to achieve equilibrium at a new dietary level.

Another reason for obtaining a food record or recall from potential research subjects is to gather data about meal pattern and food preferences that aid in designing research diets. Assessments may also be used in the screening phase of a study to determine eligibility of subjects for a study protocol. For example, if investigators want to determine whether reducing fat intake of children will lower their blood lipids, they may wish to recruit subjects consuming a relatively high fat diet so the intervention (a low fat diet) has an opportunity to show an effect.

Several techniques are used to assess habitual intake, including a dietary “history,” food record, food recall, and food frequency (2). These assessments can be divided into two types: 1) meal-based methods; and 2) list-based methods. Food records and recalls tend to be meal-based because subjects record meals and snacks in the order eaten. Typical probes for 24-hour recalls refer to meals or time periods when food is consumed, thus suggesting a “meal.” Food frequencies tend to be list-based, where subjects are asked how often they drink milk or eat eggs or other foods from a list of foods. These methods usually produce different results.

## **How do you summarize and report dietary intake data?**

The usefulness of any intake data requires a meaningful summary. Summarization can be informal, by comparing the intake with general rules such as a food group assessment, or it may be more complex, by using food tables to determine composition in terms of nutrients and/or other components.

For both meal-based and list-based methods, nutrient summaries are the most common. Both require nutrient databases which differ in important ways. The dietary record or recall database contains all the foods the population eats, whereas the food frequency database is driven by what epidemiologists are studying and by how the food list is compiled. For example, for dairy foods, if protein, calcium, and vitamin D intake are of interest, the food list may group all milks together. However, if fat intake is also of interest, 2% fat, 1% fat, and skim milk all may be listed separately. It may be difficult to use data from a list devised for one outcome to study another outcome. For example, suppose an investigator is interested in assessing intake of the food additive carageenan, which is largely present in chocolate milk. If chocolate milk is not listed separately on the list, one cannot determine carageenan intake from data provided by the questionnaire.

## **What nutrient database or software should you use?**

Published data from USDA is available in a series of publications called *Handbook 8* (which includes 22 sections from “Dairy” to “Mixed Dishes”) (3) and in a consumer booklet, *Home and Garden Bulletin #72. Bowes and Church’s Food Values of Foods Commonly Used*, written by Jean Pennington (4), is a frequently updated food composition book containing USDA information as well as information about a wide variety of brand name products. USDA also provides data from *Handbook 8* in electronic form, called “Standard Reference,” which is available in a file that can be downloaded or searched on-line through the National Library of Agriculture’s web site ([http://www.nal.usda.gov/fnic/cgi-bin/nut\\_search.pl](http://www.nal.usda.gov/fnic/cgi-bin/nut_search.pl)). Numerous computer programs are available for calculating the composition of a food record or recall. These programs provide USDA nutrient data and most also include data about manufactured products. The utility of a computer program depends first on the usefulness of the database, and secondly on the appropriateness of the output. Three applications commonly used in research are: 1) The University of Minnesota Nutrient Data System (NDS); 2) University of Texas Food Intake Analysis System (FIAS) for food records and recalls; and 3) the NCI’s Dietsys for analyzing food frequencies.

Likewise, food frequency questionnaires have databases for calculating nutrient intake and computer programs for evaluating questionnaires. Gladys Block has worked on development of food frequency questionnaires for many years, beginning with the NHANES II data collection activities, followed by development work while

with the National Cancer Institute, and currently at the University of California at Berkeley (see [www.nutritionquest.com](http://www.nutritionquest.com)). The computer program to analyze the Block questionnaire is distributed by the NCI and is provided at no charge to the research community. The analysis system for this questionnaire is called "Dietsys" and is available from the NCI web site (<http://www-seer.ims.nci.gov/ScientificSystems/DIETSYS>).

Walter Willett at Harvard School of Public Health in Boston also has worked with food frequency questionnaires over many years. Dr. Willett's work with the food frequency has been primarily at Harvard, but he has collaborated with numerous investigators around the world. Calculation of the nutrient composition of data gathered with his questionnaire relies on a main-frame program, but a PC-based analysis system is being developed. Thus, two validated food frequency instruments are available to investigators.

Analysis and summarization of nutrient intake is facilitated by computer applications. Careful study design and selection of appropriate tools can facilitate the task of collecting and analyzing research data. Data collection and analysis tools must be validated for the setting and protocol in which they are used. Many researchers have described their methods and validations to facilitate the appropriate use of dietary methodology by other investigators (5).

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## Further Reading

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## NOTES

# SOLVING PROBLEMS AND WORKING EFFECTIVELY

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Organization members must understand and practice the behaviors and skills that contribute to effective group problem solving and decision making. Individuals should learn how certain behaviors can positively or negatively affect the performance of a group working to solve a common problem.

## Synergistic Decision Making

In problem-solving situations:

- Why do some groups perform better than others?
- What accounts for such differences in the way groups function?
- How do these differences affect group outcomes?

Effective decision making is the product of the *quality* of the decision, multiplied by the degree to which the decision is *accepted* by those who must implement it. In other words:

$$\text{Effective Decision} = \text{Quality} \times \text{Acceptance}$$

For example, let's assume that the thinking behind a particular decision is rational and creative, and that the objective quality of the decision is high ( $Q=10$ ). If, however, the people who must implement the decision don't accept it ( $A=0$ ), the decision may not be implemented properly. Therefore, the overall effectiveness of the decision is low ( $10 \times 0 = 0$ ).

The reverse can also be true. Irrational thinking may lead to an inappropriate decision that, nonetheless, is acceptable to those who must implement it. In this case, a poor decision may be effectively executed ( $0 \times 10 = 0$ ).

“Quality” and “acceptance” can be brought about through *synergistic decision making*.

Synergistic decision making is based on the premise that when people are supportive of one another and follow a rational sequence of activities in dealing with a problem, they can perform beyond the sum of their individual resources. The old adage “two heads are better than one” captures this meaning.

Synergistic decision making requires participation in effective *interpersonal* and *rational* processes.

## **The Interpersonal Process**

The *interpersonal process* involves various skills we use when working with others. These skills are:

- Listening to others.
- Supporting their efforts to do well.
- Differing with others when necessary in a manner that is constructive rather than defensive.
- Participating equally in group discussion.

## **The Rational Process**

The *rational process* involves the skills we use in thinking a problem through to a solution. These skills are:

- Analyzing the situation.
- Identifying objectives (i.e., aims or goals).
- Considering alternative strategies.
- Discussing adverse consequences.

## **Reaching a Consensus Decision**

In businesses and other organizations, members are less likely to implement a decision if they don't accept it - yet, the coordinated and cooperative efforts of *all* members are necessary for effective implementation.

Reaching a consensus is the hallmark of "acceptance" in the effective decision equation.

## NOTES

# ESTIMATING ENERGY EXPENDITURE AND CALORIC REQUIREMENTS

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## Importance

Many studies require that participants remain weight stable during the course of a study to avoid weight fluctuation from becoming a confounding variable. It is critical, therefore, that caloric requirements are calculated appropriately.

## Components of Energy Expenditure

Daily energy expenditure has three major components: 1) the resting metabolic rate (RMR); 2) the thermic effect of food; and 3) the caloric cost of physical activity. In most sedentary adults, RMR accounts for about 60-70% of daily caloric expenditure; thermic effect of food accounts for about 10%; and physical activity accounts for the remainder. Physical activity is the most variable component of energy expenditure.

## Estimating Caloric Requirements

### 1) Resting Metabolic Rate

- a) can be measured with a metabolic cart, or
- b) can be estimated from equations based on
  - i) body weight;
  - ii) age, sex, and body weight;
  - iii) fat-free mass as measured by underwater weighing, dual-energy x-ray absorptiometry, bioelectrical impedance, or skinfolds.

After RMR has been determined, additional calories must be added to account for the caloric cost of activity.

### 2) Determining the caloric cost of physical activity:

- a) physical activity recalls - review usual activity over a period of days
- b) use of activity factors - usually range between 1.4 and 2.2 (multiples of RMR)

3) Usual food intake records. Self-reports of usual food intake are *not* good predictors of caloric requirements. However, important qualitative information can be obtained, such as meal patterning, or variability from day to day. This

information could be useful, for example, in deciding energy distribution across meals for the study diet.

## **Special Issues**

### *Subject's perception of intake:*

Subjects may perceive that they are being under- or over-fed. This may depend on an individual subject's concern about his/her own body weight, diet composition or energy density (particularly relative to a subject's own usual diet), or the number of unfamiliar foods in the study diet. It is important to discuss the goal of weight maintenance with all subjects, that is, how it is being measured and what to expect.

### *Food modules:*

For short term studies, it is useful to use food modules. A food module is a discrete combination of the overall study diet. For example, for our protocols, two 200 kcal food modules are added to each subject's food for each day. The subject may choose to eat one or both of the modules if he/she feels hungry. Subjects are instructed to consume the entire module if they choose to eat that food module. Food modules enable the subject to have control over his/her intake particularly if physical activity varies greatly from day to day, or if caloric requirements have been underestimated. Food modules are also useful if a subject's caloric intake needs to be adjusted at the last minute (after the diet calculation and food preparation has taken place).

### *Translating caloric requirements into food:*

Depending on a study's constraints, diets may be designed in different ways. Menus may be individually tailored to each subject's caloric needs. Alternatively, menus and calorie levels may be set *a priori*. Each subject would then be given the calorie level closest to his/her predicted needs. Food modules or "unit foods" can be used to modify the study calorie level to meet a subject's individual caloric requirement.

### *Monitoring weight stability:*

The ultimate goal for predicting caloric requirements is to achieve weight stability. A procedure should be established for determining when and how to adjust caloric intake to accommodate weight fluctuations. Most protocols call for caloric adjustment after detecting a *trend* of weight change over a period of days. Usually a change +/-2 lb. or +/-1% of initial body weight, persisting over more than 3 days, is cause for altering calorie levels. Be familiar with the study procedures for obtaining body weights. Always consider variables that may affect daily weights before making changes in a subject's caloric intake. These variables may include inconsistency in standard weighing procedure (e.g., subject is wearing heavier clothing or is weighed after a meal), illness, premenstrual weight fluctuation, change in fluid status, or an increase in physical activity.

## **Summary**

Caloric requirements can be predicted with a variable amount of accuracy using a variety of prediction tools. The key to success is monitoring weight stability and adjusting caloric intake appropriately. Regardless of which prediction tool is used, it is important to monitor the success rate in achieving weight maintenance in your study population. You may wish to consider developing your own prediction formula that is appropriate for your study population and constraints of the study.

## NOTES