DASH2 Diet MOP

Table of Contents

Summary of Edits

31. Screening

Overview

In order to be randomized, participants must complete a series of screening visits and a run-in period. Each screening visit includes questions and procedures designed to determine eligibility for the trial. At each visit there are both clinical and dietary questionnaires and procedures. The flow of the visit will differ at each site. The dietitian's role will be one part of a visit that will need to be coordinated with the clinical staff. See the DASH2 Clinical MOP (Chapters 5-8) for a description of all the clinical screening procedures.

Prescreening Visit (PSV)

The PSV is a fast way to identify ineligible participants. It may take place at the clinical center, via telephone, or offsite. It is generally conducted by the recruitment staff. It may also be conducted at the same time as SV1. The information about the potential participant is recorded on the Prescreen Eligibility Form (#1).

The following materials are needed to complete diet-related segments of the visit:

Prescreen Eligibility Form (#1)

Dietitian's Role

Review Prescreen Eligibility Form (#1)

There is a question on the form about special diets and foods that a participant will not eat. If the recruitment staff have questions about the response, it will be flagged and brought to the nutrition staff to determine if the participant is still eligible for participation.

Screening Visit 1 (SV1)

The purpose of SV1 is to continue screening prospective participants for eligibility based on blood pressure and their responses to the General Dietary Information Questionnaire (Form #100). The SV1 may take place at the clinical center or at a location in the community convenient to the population being recruited. If conducted offsite, the SV1 will usually be conducted in conjunction with the PSV. Persons who are eligible at PSV may immediately receive an SV1 or they may be scheduled for an SV1 at a later time.

The following materials are needed to complete diet-related segments of the visit:

1. General Dietary Information Questionnaire (Form #100)
2. SV1 Visit Form (#3)

Dietitian's Role

Review General Dietary Information Questionnaire (Form #100)

The review can be done either during or after the participant's visit. The decision about eligibility is made, and recorded on the SV1 Visit Form (#3). The General Dietary Information Questionnaire is a short form designed to identify people who have food allergies, medical conditions, or strong personal preferences that limit the types of foods they can consume and thus could interfere with their participation in DASH2. If there are questions about specific items, discuss them with the participant. Persons who cannot consume the food items listed on the form are not eligible to participate.

Screening Visit 2 (SV2)

The purpose of SV2 is to continue to identify eligible participants based on medical information, clinical data, and dietary history. The SV2 and all subsequent DASH2 visits take place at the clinical center. Questionnaires will be administered/reviewed in a setting that permits privacy for the participant.

The following materials are needed to complete diet-related segments of the visit:

1. Food Frequency Questionnaire (Form #9)
2. SV2 Visit Form (#5)

Dietitian's Role

Distribute the Food Frequency Questionnaire (Form #9)

Review the instructions for completing the Food Frequency Questionnaire (FFQ) with the participant. Instruct the participant to bring the completed form to the SV3 visit. Make sure that the participant's label is on the upper right corner of the form, in the orange box. Do not separate the pages of the form, even to photocopy the form. After the FFQ is given to the participant, the dietitian should check the appropriate "Done?" box on the SV2 Visit Form. See the DASH2 Forms Manual for additional instructions on the FFQ administration.

Some participants will request/need assistance with filling out the form. See the form instructions for how to do this.

Screening Visit 3 (SV3)

The purpose of SV3 is to continue screening prospective participants for eligibility based on blood pressure and to collect data on physical activity, weight, and waist circumference. The

visit is also used to review the Food Frequency Questionnaire (#9), collect specimens and samples as needed, and review in detail the study foods and menus with the participant. If the participant remains eligible, the start of the first dietary feeding period will be scheduled. The SV3 takes place at the clinical center. Questionnaires need to be administered/reviewed in a setting that permits privacy for the participant.

The following materials are needed to complete diet-related segments of the visit:

1. Study Foods Checklist (Form #101)
2. Study Menus (Form #102)
3. Food Frequency Questionnaire (Form #9)
4. SV3 Visit Form (#8)

Dietitian's Role

Review Study Foods Checklist (Form # 101)

The purpose of this review is to make sure that the participant is fully aware of the foods/menus included in the study and is willing to eat these foods. It is important that the participant be willing to comply with two dietary patterns. We do not want to randomize participants in the hope that they will, for example, be assigned to one of the two dietary patterns that they are willing to tolerate. It is much better, from the study's perspective, to exclude participants prior to randomization than to have them drop out of the study or be very noncompliant post randomization. If the participant is not eligible based on the Study Foods Checklist, mark the "Done?" box on the SV3 Visit Form, indicate that the participant is ineligible, and stop the visit.

Review Food Frequency Questionnaire (Form #9)

The participant should have brought in the completed Food Frequency Questionnaire. If so, review it for completeness, resolve any unanswered questions or invalid responses, and check the "Done?" box on the SV3 Visit Form. The FFQ will be sent to the Coordinating Center for batch scanning and processing and will become part of the central database.

Any participant who has not returned a completed FFQ should be given a new one, reinstructed on its use, and asked to return it, either by mail or by bringing it in. Do not mark the "Done?" box on the SV3 Visit Form. Whether or not the FFQ is completed does not affect continued eligibility.

If the participant is unable or refuses to complete the FFQ, record this on the SV3 Visit Form(#8).

Review DASH2 Study Menus (Form #102) with Participant

The SV1 included a brief review of common food items in the DASH diets to make sure the participant could eat them. During the SV3 a member of the clinic's nutrition staff should carefully review with the participant all of the foods included in the study diets and the menus to be used in both intervention groups. The Study Foods Checklist completed by the participant is an eligibility test. The review of menus serves as an orientation tool as well as an eligibility screen.

This review, along with a review of the Food Frequency Questionnaire (see above), should take approximately 20 minutes. At the end of the review the DASH2 staff person reviewing the foods should classify the participant as eligible or ineligible to continue, based on the review. This should then be noted on the SV3 Visit Form.

Other Screening Activities

The dietitians at a particular site may be called upon to participate in other screening activities, including administering the Physical Activity Questionnaire or weighing the participant. It is important to be familiar with Chapters 5-8 of the DASH2 Clinical Manual of Procedures, which contain the screening visit information.

Summary of Edits

New changes in Version 1.1

- Information regarding the new handout for participants on the importance of salt
- Section on Orientation QA process added
- Section on medications and vitamins added
- Section on activity level added
- Section on weight maintenance added
- Section on optional site specific activities added

Formatted: Bullets and Numbering

32. Participant Orientation to Study

Purpose of Orientation

There are four major reasons for formally orienting participants to the DASH2 protocol:

1. to teach DASH2 participants how to follow the protocol

2. to minimize dropouts from the study after randomization by making the expectations clear prior to entry into the study

3. to assure that the intervention protocol is followed the same way among diet arms and among clinical centers, by instructing participants at each center on the same exact procedures for following the diet

4. to clarify the participants' expectations

When to Orient Participants

The orientation visit should occur prior to run-in feeding and, ideally, should be scheduled as a separate visit, for two reasons:

1. There may not be enough participants if it is done in conjunction with a screening visit.

2. Participants may be pressed for time if it is combined with a screening visit.

Materials for Orientation

Orientation Packet for Participants

- Orientation Form (Form #104)
- Salt and the DASH2 Diet (Form #129)
- Guidelines For Beverages and Seasonings (Form #106)
- Safe Foods TO GO (Form #107)
- Clinical Measurements (Form #114)
- Participant Instructions for Daily Diary (Form #115)
- Site-specific schedule of DASH2 events and measurements
- Allowed Medications (Form #116)
- The Kitchen Connection
- Site-specific information

Formatted: Bullets and Numbering

Audiovisual Materials

The DASH2 video covers the importance of the subject's role in the study and reviews each of the points addressed above. Each center has a few copies of the video so that subjects can take turns borrowing it to watch at home with their families if they have a VCR. This serves to reinforce the importance of the study to the subjects and their families, as well as to remind all subjects of the study guidelines and procedures.

Who Conducts Orientation

We recommend that the principal investigator or co-investigator open the orientation with a greeting to participants, review of the importance of hypertension as a health problem, impact of diet on blood pressure, importance of following the study protocol, and importance of blinding, and introduction of study staff. The coordinator then briefly reviews the study schedule, procedures, blood pressure measurement, and any ancillary visits, if time. A dietitian or nutrition/food service representative then conducts most of the orientation since the orientation is focused on dietary issues.

Format for Orientation

Orientation should begin with an introduction of study staff and other participants, and viewing of the DASH2 video, if time. It is suggested that each center serve a combination, low-sodium meal or samples of various DASH2 menu items during the orientation visit. This allows each participant to try the most potentially problematic menu prior to randomization. The precise format for orientation varies by site, but a suggested format follows:

- Introduce investigator…….. 5 minutes
- View DASH2 video …….. 10 minutes (optional)
- Coordinator…….. 10 minutes
- Dietitian…… 25 minutes
- Provide written material……... 5 minutes
- Question and answer period……. 5 minutes
- Meal or food tasting..... ad lib

Some sites use stations to present the information by displaying some of the allowed beverages, spices, clinical measurement equipment such as urine containers and blood pressure equipment, and food packaging materials.

Quality Assurance

The Participant Orientation Checklist (Form #94) is completed for every orientation session, either group or individual, that is done. The completed forms are kept with other site QA documents and reviewed on site visits. See the instructions for Form #94 and the Diet MOP Chapter 42, Quality Assurance, for more details.

Information to Cover during Orientation

DASH2 Study Protocol

The study protocol ideally is reviewed by the principal investigator to increase PI visibility at the site. The timeline of run-in and intervention periods, including site-specific breaks, is reviewed. Participants can be provided with calendars at this time.

Blinding

1. Explain that the diet cannot be discussed with blood pressure measurement staff and that blood pressure issues should not be discussed with diet staff.

2. Explain that we are not able to provide them with their blood pressure results until the end of the study but will let them know if their blood pressure rises above a certain level.

Site-Specific Schedule of DASH2 Measurements and Events

A calendar that gives site-specific information regarding dates of feeding, breaks, and measurements is distributed to the participants. It is also important to cover any site-related information such as parking.

Participant Expectations

Help participants explore the reasons why they are participating by asking them open-ended questions, such as:

1. Why do you want to participate in a research study?
2. What are your some of your expectations?
3. What are some of your concerns?

Where, When, and Frequency of Visits to the Center

The frequency of visits is unique for each site and can be reviewed by the coordinator or the dietitian. Discuss times to arrive at meals, as well as location of meals, blood pressure measurements, weight measurements, and meal pick-up. Participants may be provided with a personalized schedule. Reinforce the importance of being on time, and of calling if there will be a delay.

Note: The minimum allowable number of visits is one meal per day, five days per week. Study sites can be flexible regarding which meal is fed to participants; however, lunch or dinner is the preferred meal.

Clinical Measurements

A series of clinical measurements is taken during each feeding period, including run-in. Form #114 describes those measures. Refer to this handout when explaining the measures during orientation.

Blood Pressure

Blood pressure is usually measured once per week, with more frequent measurements at the end of each intervention period. Describe the ambulatory blood pressure measurement (ABPM), with the monitor and cuff displayed (optional). ABPM occurs at the end of each intervention period (total of three times). Blood pressure is always measured prior to eating the on-site meal. Ask subjects to wear loose-fitting clothes on blood pressure days.

Weight Measurements

It is important to emphasize that this is not a weight-loss study. Participants should know that they will be weighed each time they come in for a meal, prior to eating the meal. Explain that shoes, wallets, keys, and jackets should be removed for this measurement. Weight patterns are carefully monitored, and if weight increases or decreases by more that 2% of initial weight, calories will be adjusted. This is done because weight changes can affect blood pressure. Participants who are hungry or too full may speak to the dietitian. We may be able to adjust calories.

~~**Note: Activity patterns should stay constant throughout the study. This is because changes in activity can affect blood pressure and changes in activity can affect weight.**~~

Other Measurements

Blood tests, 24-hour urine collections, questionnaires, and other site-specific ancillary studies can be **briefly** reviewed at this time.

Medications/Vitamins

Review the Allowed Medications (Form #116) with the participants. Explain the importance of discontinuing any vitamins and over-the-counter medications that are not allowed prior to run-in. Explain the request that participants not make changes in dosages of allowed medications during feeding. Indicate that they will be asked about medication use at the end of each feeding period and asked to record any supplements, vitamins, or over-the-counter products daily.

Activity Level

Activity patterns need to stay constant throughout the study. This is because changes in activity can affect both blood pressure and weight.

Formatted
Formatted
Formatted
Formatted
Formatted

Weight Maintenance

One of the main issues to stress with participants is that DASH2 is not a weight-loss program. To answer our very important research question, we need participants to maintain their current weight.

~~*Food Consumption Guidelines*~~

Finishing All Foods/No Additional Foods

~~**Note: Participants should discontinue all nutritional supplements now if they haven't done so already.**~~

Explain the importance of adhering closely to the research diet. Suggested script:

"We design and prepare all meals at our facility, to meet specific nutritional goals for the study. Many foods are weighed precisely on a scale, and special recipe formulations are followed. We've calculated how many calories you need to maintain your weight. It is, therefore, important that you eat all of the food we give to you, and that you don't eat foods that are not part of the diet." (See pamphlet "The Kitchen Connection" by Pennington Biomedical Research Center.)

Participants are expected to eat the edible portions of all foods provided, both on-site and off-site. They should consume potato peels and skins of vegetables and other fruits (e.g., apple). When participants are unsure of what is "edible," they should call the center for clarification. They should clean up leftover gravies and sauces with a piece of bread or potato, and can use a rubber spatula when transferring foods from one container to another. ~~Since salt consumption is integral to the study, it is especially important that participants follow the rules for salt consumption.~~ Salad dressings, salt packets, butter pats, and other small packaged items should be emptied completely.

Aside from "allowed beverages," participants should not consume any foods or fluids other than what we provide. They should be encouraged to speak with a dietitian prior to an event (e.g., wedding) or party for advice on how to avoid temptations to consume other foods. Suggestions include: eating prior to an event, bringing study foods to the event, and consuming allowed beverages at the event. No food or beverage substitutions should be made unless directed by a DASH2 dietary staff member.

The Importance of Salt

Explain the importance of salt to the study and how to make sure you get it all. Suggested script from Form #129:

"The amount of salt you eat in your diet has been carefully calculated by the DASH2 dietitians. It differs among all of the three 4-week feeding periods. You may notice the difference in the taste of the foods, and they may seem more or less salty than you are used to. It is important to remember that the diet with the most salt represents less than the typical salt intake of many Americans. Most people find that after a few days they adjust to the level of saltiness.

Salt in our diet comes from three main sources: 1) as a natural part of the food, 2) added to foods during processing, and 3) added to food from a salt shaker.

In order to get the specific amount of salt in your food which DASH2 requires, we

1. Use foods that have minimal processing;

2. Add weighed salt to your food;

3. Serve salted broth (bouillon) as part of your diet;

Leftover meat juices, gravies, sauces and broth are an important source of salt and other nutrients. This is why we ask that you use bread or a roll to mop up all leftover liquids and to finish all of the broth."

Energy Foods

Describe how energy foods are used to help keep weight stable and to prevent hunger. They are considered a part of the diet, and the participant is encouraged to eat all the food provided, including the energy foods. Provide samples of each for tasting.

Emergency Energy Foods

Subjects are provided with energy foods to keep in their freezer. These may be used when the participant is unusually hungry, provided his or her weight is in the appropriate range.

Allowed Beverages and Seasonings

Show a display on a table of samples of the allowed beverages and other items.

~~1.~~ Coffee, Tea, Soda, and Crystal Light

Review that participants are allowed to consume a total of three servings, in any combination, of coffee, tea, diet soda, or Crystal Light (Iced Tea Flavor, citrus blend, fruit punch, lemon lime, pink grapefruit, or lemonade flavor only) each day—in the quantities outlined on The Guideline for Beverages and Seasoning (Form #106). Any brand of coffee or tea is allowed, but only add items to these beverages that are already contained in the diet. For example, add milk to coffee if

provided in diet, but do not add additional half-and-half or coffee whitener. An exception is that Equal may be added to coffee or tea. Brands of diet soda must be chosen from the list provided.

2. Alcoholic Beverages

Prepare a display of the allowed alcoholic beverages (Form #106). Up to two servings of alcohol are allowed per day. A serving is considered a:

- 12 oz Lite beer
- 12 oz regular beer (no dark beers)
- 5 oz white wine (no red wine)
- 1.5 oz spirits

Hard liquor may be consumed either straight or mixed with an allowed beverage. For example, the participant may not have orange juice and vodka unless the orange juice is juice the study provided. O'Doul's non-alcoholic beer is permitted as a substitute beer.

3. Non-restricted Beverages

The following beverages are unrestricted:

- Water
- Poland Springs carbonated water with essence of fruit flavoring (not fruit juice)
- Crystal Light (Raspberry Ice, Pineapple-Orange, and Strawberry-Kiwi flavors only)

4. Miscellaneous Items

Review brands of chewing gum, over-the-counter medications, and free spices with the items displayed on a table.

Food Safety

Review the Safe Foods To Go (Form #107) and "The Kitchen Connection," prepared by the Pennington Biomedical Research Center for participants. Carefully instruct participants on proper food handling and storage techniques for foods they take home. Review the importance of keeping foods in a cooler if travel time will be greater than an hour.

Completeness of Menus Checks

Subjects will be provided with written menus of their meal plan, in a manner that may vary by site. Show participants a sample form (Weekly Detailed Menu, Form #105). They are to use these forms to cross-check the foods given to them in their take-home bags to ensure that they are not missing any items. If they are missing items, they should call the clinic. Participants should not make substitutions on their own. Give explicit instructions, which may be different at each site. At Baton Rouge, for example, if the discovery of missing items occurs before 7:00 PM

on a weekday, the participant calls the kitchen; if it occurs after 7 PM or on a weekend, participants call a paging service which then contacts the on-call dietitian on the study.

Meal Passes

Meal passes excuse a participant from consuming a meal on-site and are reserved for emergency situations. We recommend that the matter of meal passes be reviewed only if someone asks during orientation. If participants are sick, or foresee that they will be late, they should alert the center immediately so that the staff can work out a meal shipment, pick-up, or replacement plan with the participant. Keep this to no more than two meal passes per participant for the entire study.

Emergency Meals

During run-in and each intervention period, each participant will be provided with one day's worth of frozen meals in case of an emergency (e.g., inclement weather). Participants are not to consume this food unless instructed to do so.

Daily Diary

Procedures for filling out the Daily Diary (Form #24) are reviewed using an overhead projector and handouts. The Participant Instructions for the Daily Diary (Form #115) will be in the packet. Explain that diaries need to be filled out daily and will reflect the previous day. On Mondays, participants will bring in or fill out diaries for the weekend. Each item on the diary should be reviewed. Recording of allowed beverages and alcohol should be reviewed in detail.

Under "was anything left?" or "was anything additional eaten?" remind participants that it is very important for the study that they eat all of the food provided and nothing else. If something happens to their food, or if they consume foods or beverages not included on the diet, it is important that they provide us with that information in as much detail as possible (e.g., record exact foods and quantities). Explain that the diary also provides a way to relay other concerns the participant has to the study staff.

Communication with Staff

Provide participants with all relevant telephone numbers and contact names for questions or emergencies. Some centers provide wallet-sized cards for participants, and some have a "DASH2 Buddy System" (primary contact), where a participant reports to a particular staff member. Whatever the site-specific policy, be sure that the participant is clear on whom to contact for what.

Optional Site-Specific Activities

Each site may have specific materials to cover during orientation. In addition, the site may want to serve a sample meal, talk about perks and prizes, give a tour of the facility, or have DASH participants talk to the group.

Summary of Edits

New changes in version 1.1

- Addition of administration of the Diet Acceptability Questionnaire

33. Run-In and Randomization

Overview

All participants who are eligible based on the three screening visits undergo a run-in period on the control diet (alternatively described as the "A" diet in the Diet MOP) prior to randomization. The run-in phase has two main objectives:

1. To identify and exclude individuals who do not comply with the trial's eating and data collection requirements, and
2. To determine, for each participant, the appropriate energy level needed to maintain weight.

Run-in feeding must begin within 150 days of SV1, and all laboratory eligibility criteria must be met prior to the start of run-in. In addition, if the Eligibility Questionnaire (Form #6) is completed more than one month before run-in begins, the Eligibility Review (Form #13) must be completed within one month of the start of run-in. During the run-in period, participants receive all of their food from the clinic and are required to attend the clinic for at least one meal per day, five days per week, preferably lunch or dinner. For logistical reasons, the clinics conduct the feeding in four successive cohorts over a period of two years. In order to allow for dropouts and exclusions during the run-in phase, the run-in cohorts include between 28-30 participants per site.

Run-in feedings are scheduled to start on the same day for all participants in a given feeding cohort in a given clinic. However, participants may be allowed to start run-in feeding up to two days late if the clinic determines that the delay is due to exceptional circumstances not likely to affect future compliance. In this latter case, the length of run-in feeding for those participants is shortened so that all subjects are scheduled to finish run-in feeding on the same day.

The duration of run-in feeding may vary between 12 and 14 days, is determined locally, and may vary from cohort to cohort. To provide consistent terminology, we shall refer to these as run-in days 0 through 14, and shall use the notation RI-0...RI-14. Thus a participant who starts run-in feeding two days late is said to start on run-in day 2 (RI-2).

Because feeding does not begin with the breakfast meal, the first and last days of run-in feeding represent partial feeding days. For example, if feeding begins with dinner, then only dinner is fed on run-in day 0 and only breakfast and lunch are fed on run-in day 14. All data gathered on run-in day 14 is assigned to that day, even if this coincides with the initial day of intervention feeding. In order for study measurements to reflect the effect of the diets, no study measurements are taken on run-in day 0 or, if a participant starts late, on the initial day of feeding.

In order for the clinics to assemble and prepare the necessary foods for the start of intervention feeding, randomization occurs midway through the second week of run-in feeding rather than at

the end of the run-in period. Neither the participants nor the staff conducting measurements are told the randomization assignment. Only staff involved in meal preparation are unblinded to treatment allocation. There is an optional break of up to three days (nine meals) between the end of run-in and the beginning of the initial intervention feeding period. Subsequent intervention feeding periods may be separated by breaks of up to five days in duration. These breaks are not mandatory, and their duration may vary within a cohort, from site-to-site, and from cohort-to-cohort. During the breaks between feeding periods, subjects are not provided any food and are allowed to return to their original diets.

Preparing for Run-In

The primary task for nutrition staff in preparation for run-in is the procurement of the foods necessary to feed the participants. Many food items may also be prepared ahead of time to ease the meal-preparation burden during run-in. Instructions for procuring and preparing the food are found in the DASH2 Diet MOP Chapter 40. The DASH2 food procurement program may be used to project the amounts of food to purchase or order. The calorie levels of the run-in eligible participants are entered into the food procurement system to estimate the amounts of foods needed. The Run-In Energy Level Report from the unblinded area of the data management system provides the calorie levels of all run-in eligible participants. In addition, check the Food Donation Tracking System (Form #117) for information on procuring donated food items.

The nutrition staff is also responsible for training the kitchen staff in all aspects of preparation and safety prior to run-in.

Materials Needed During Run-In

- DASH2 food procurement program
- Master Menus (Form #111)
- Production Menus (Form #112)
- Tray Assembly Forms (#113)
- Recipes (Form #108)
- Run-In Calorie Level Report
- Scale
- Daily Diary (Form # 24)
- Diet Acceptability Form (#35)
- Case Conference Form (# 33)
- Study charts for scheduled participants

Run-In Activities

Table 33.1 lists the various activities that take place during run-in. The activities that involve nutrition staff are listed below.

Table 33.1 DASH2 Activity Sequence: Run-in Feeding Period

------ Day of Run-in ------

DASH2 Activity Sequence: Run-in Feeding Period

------- Day of Run-in --------

Run-in Event	0	1	2	3	4	5	6	7	8	9	10	11	12	13*	14
RZ Blood Pressure (2 sets only)	<====== One set per week =====>								<==== One set per week ====>						
Weight		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Run-in Feeding Activities	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Patient History Questionnaire	<========== Any time during Run-In ==========>														
Measure Waist Circumference	<========== Any time during Run-In ==========>														
Medication Questionnaire									<========== X ==========>						
Diet Acceptability Form									<========== X ==========>						
Symptoms Form									<========== X ==========>						
Case Conference									<==== X ===>						
Resolution of Data Issues									<==== X ===>						
Randomization												X			
Compliance Monitoring		X	X	X	X	X	X	X	X	X	X	X	X	X	

* optional, may vary from site-to-site and from cohort-to-cohort within a site.

Procure Necessary Food Items

The DASH2 food procurement program is designed to aid sites in building a shopping list for all foods needed for a particular week. The staff enters the participants and their energy levels into the system, which in turn produces the shopping list. This is done as soon as the participants entering run-in are known. In addition, many foods are acquired through a centralized process. Most of these are donated and are tracked with the Food Donation Tracking Form (#117). Each site keeps a notebook containing records of all food acquired regardless of the mechanism of acquisition.

Prepare Daily Meals

DASH2 kitchens prepare all the meals for participants. The details on the preparation of all DASH2 foods are found either in the DASH2 Recipes (Form #108) or in Chapter 40 of the DASH2 Diet MOP, Food Procurement, Safety, and Preparation. Quality assurance procedures are also found in Chapter 35 of the Diet MOP and are followed by each clinic site. Because each site operates differently, all sites are required to have procedures in place to ensure that participants receive the correct meals.

Distribute Meals to be Eaten Off-site

Each participant is required to eat one meal at the study site each weekday. All other meals are prepared at the site and distributed to the participant to consume elsewhere. It is critical that each site follow standard guidelines for ensuring the safety and palatability of the food. Safety guidelines are found in the DASH2 Diet MOP, Chapter 40. Participants are given instructions on keeping the foods safe (Safe Foods To Go, Form #107). In addition, the sites provide participants with adequate containers for the storage and transfer of the food.

Administer, Review, and Code the Daily Diary

The nutritionist's responsibility is to administer and review the Daily Diary (Form #24). The purpose of the form is to collect information related to the participant adherence to the diet. The Participant Instructions for the Daily Diary (Form #115) is used for explanation of the form at any time. Four areas are evaluated:

- The type and amount of discretionary or "allowed" foods the participant eats, including alcohol.
- The kind and amount of study foods not eaten, and non-study foods eaten, including supplements and over the counter medications.
- Menstruation information from female participants.
- Feedback from participants regarding concerns they have about participating in the study.

The nutritionist is responsible for making sure the data are correct and clear, and that all fields on the Daily Diary are complete. Please see the instructions for Form #24 for detailed information on the coding and review of the Daily Diary.

Monitor Weight and Adjust Energy Level

Participants are weighed at each clinic visit during the run-in and intervention phases of the trial. All participants whose weight changes by five percent or more between SV3 and the first full day of run-in (RI-1) are excluded from the trial at that point.

The average of the SV3 weight measurement and the first two run-in weights (those taken on

RI-1 and RI-2) defines the participant's target weight and is used as the baseline against which to measure weight change during run-in feeding. As noted in DASH2 Diet MOP, Chapter 41, Participant Management and Compliance, weight is to remain constant during the study. These daily weight measurements are used to monitor weight changes, and the overall caloric content of the participant's meals is adjusted as needed in order to ensure that the participant's weight remains stable throughout the study. The weight is recorded on the Daily Diary (Form #24). The Daily Diaries are entered daily so that the Weight Tracking Reports generated from the data management system can be reviewed daily.

Complete Diet Acceptability Questionnaire

All participants complete the Diet Acceptability Questionnaire (Form # 35) during the last week of run-in. It is best to complete it as late as possible in run-in while still feeding. Dietary staff administer the questionnaire and review returned questionnaires for completeness. The forms are entered on-site within 7 days.

Conduct Case Conference

In addition to the exclusionary criteria applied during the screening visits, participants may be excluded during run-in for unusually large weight swings or for noncompliance with the diet. Several measurements are used by the dietitians to assess compliance with the feeding protocol during run-in. Participants keep Daily Diaries (Form #24) and can be excluded for missed meals, poor clinic attendance, and over- or under-consumption of food. Clinic staff subjectively evaluate each participant's overall compliance and attitude just prior to randomization, and may exclude participants on the basis of this assessment as well. This is referred to as a case conference, and the Case Conference Form (#33) is completed. A more detailed discussion of compliance assessment is provided in the DASH2 Diet MOP, Chapter 41, Participant Management and Compliance. If the participant is excluded by the case conference, the Participant Close-out Form (#18) is completed.

Randomize Participant

Details of the randomization process are found in the DASH2 Clinical MOP, Chapter 9, Run-In and Randomization. For the nutrition staff, the case conference and all associated forms must be completed and entered prior to randomization. The randomization must happen 3 days prior to the start of Intervention Feeding Period 1 in order that the kitchen staff may be prepared.

Following randomization, participants remain on the run-in diet until the run-in period ends. Participants are not told to which group they have been assigned. Clinic personnel are also blinded to intervention assignment. Blinding is discussed further in DASH2 Clinical MOP Chapter 14, Quality Control and Data Management. The nutrition staff print out the Treatment Assignment Report from the unblinded area of the data management system. This lists the

treatment assignment and calorie level for each individual randomized. This allows the kitchen staff to prepare for intervention feeding.

End Run-In

Remind subjects of dates and procedures for starting Intervention Feeding Period 1, and dismiss them for the break period, if applicable.

Summary of Edits

New Changes in Version 1.1

- Change instructions for the Diet Acceptability Questionnaire
- Change definition of baseline weight
- Change instructions for Participation Survey
- Clarify information on Exit Interview

New Changes in Version 1.2

- Change in window for final two RZ measurements each feeding period

34. Intervention

Overview

The three-month intervention feeding period begins 0-3 days after the end of run-in (12-17 days after the start of run-in feeding). During this period participants continue to receive all of their food from the clinic, and eat at least one meal per day on-site, five days a week. As with the run-in feeding, the on-site meal should be a lunch or dinner if possible. Intervention feeding is divided into three separate one-month (30-day) feeding periods, each at a different level of sodium intake. Feeding periods 1 & 2, and 2 & 3, may be separated by breaks up to five days, during which subjects return to their usual home diets.

To provide consistent terminology, we shall refer to the three months of intervention feeding as **intervention feeding periods I, II, and III.** Within each intervention feeding period, days are numbered 0 - 30. Thus, intervention feeding period I, day 10 can be written as IFP/I-10, and intervention feeding period III, day 30 can be written as IFP/III-30.

Because feeding does not begin with the breakfast meal, the first and last days of each feeding period represent partial feeding days. For example, if feeding begins with dinner, then only dinner is fed on day 0 and only breakfast and lunch are fed on day 30. Thus the feeding periods cover 31 calendar days but only 30 metabolic days. In order for study measurements to reflect the effect of the diets, no study measurements are taken on feeding day 0.

Weight is recorded at each clinic visit and blood pressure is assessed weekly during the first three weeks of each intervention feeding period. In addition, 24-hour urine and fasting blood samples are collected. See the DASH2 Clinical MOP, Chapter 13, Other Clinical Measurements, for more information.

During the **final 7 days** of each intervention period the following procedures are also performed:

1. Formal assessment of side effects
2. Monitoring of medication use
3. A brief assessment of physical activity
4. Completion of the Anonymous Survey (Form #25)
5. Assessment of Diet Acceptability (Form #35)

At the end of each feeding period, participants are given the Anonymous Survey (Form #25) and asked to indicate aspects of the study with which they did not comply. Because the questionnaire is anonymous, it is used along with measures of compliance to assess overall compliance to study diets in a retrospective fashion.

At the conclusion of each feeding cohort (i.e., at the end of IFP/III), study participants receive a summary of their study blood pressures and dietary counseling for heart disease prevention.

They also complete a Participation Survey (Form # 26) at this time. Details are provided in the DASH2 Diet MOP, Chapter 37, Participant Close-out and Counseling.

Preparing for Intervention

The primary task for nutrition staff in preparation for intervention is the procurement of the foods necessary to feed the participants. Many food items are prepared ahead of time to ease the burden during feeding. Instructions for procuring and preparing the food are found in the DASH2 Diet MOP Chapter 40. The DASH2 food procurement program may be used to project the amounts of food to purchase or order. The participants are randomized on approximately day 11 of run-in. Once this has occurred, the Diet Assignment Report from the unblinded area of the data management system is printed to provide information that will allow the most accurate estimations of food items needed. In addition, check the Food Donation Tracking System (Form #117) for information on procuring food items that are donated.

Materials Needed During Intervention

A variety of materials are needed for the clinical measurements conducted during intervention. A detailed list can be found in the DASH2 Clinical MOP, Chapter 10, Intervention. The materials needed to support the tasks done by the dietitian are:

- DASH2 food procurement program
- Master Menus (Form #111)
- Production Menus (Form #112)
- Tray Assembly Forms (#113)
- Recipes (Form #108)
- Diet Assignment Report
- Scale
- Daily Diary (Form #24)
- Intervention Flow Form (#20)
- Anonymous Survey (Form #25)
- Diet Acceptability Survey (Form #35)
- Participation Survey (Form #26) (IFPIII only)~~) (See Diet MOP, Chapter 37, Participant Close-Out and Counseling)~~
- Study charts for scheduling participants
- ~~(See Diet MOP, Chapter 37, Participant Close-out and Counseling)~~

- ~~Intervention Activities Occurring During Each Intervention Feeding Period~~

Table 34.1 lists the various activities that take place during each intervention feeding period. The activities that involve nutrition staff are listed below.

Table 34.1 DASH2 Activity Sequence: Intervention Feeding Period

DASH2 Activity Sequence

Intervention Feeding Period

Event	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
RZ BP^		<=======X=======>							<=======X=======>							<=======X=======>							<==X==X==X==>					<==X==X==>				
Weight	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
24-HR urine																							<==========X==========>							
ABPM																							<==========X==========>							
Fasting Blood Draw																							<==========X==========>							
Medication Questionnaire																									<========X=======>					
Symptoms Questionnaire																									<========X=======>					
Anonymous Survey																									<========X=======>					
Brief Physical Activity																									<========X=======>					
Diet Acceptability Questionnaire								<==X==>																				<===X===>			
Intervention Feeding	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Compliance Monitoring		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Participation Survey*																									<========X=======>					
Exit Interview and Counseling																															X

^ once per week during days 1-21; five times during the final 9 days, including at least twice during days 27-30 of each feeding period.

* done at the end of the third intervention period (IFP-III) only

~~**Intervention**~~

~~Event~~	~~1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30~~
~~RZ BP ^~~	~~<-------X-------> <-------X--------> <---------X--------> <---X---X---X---><-X-X->~~
~~Weight~~	~~X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X~~
~~24 HR Urine~~	~~<----------X----------></~~
~~ABPM~~	~~<----------X----------></~~

Fasting Blood Draw	<------------X----------->
Medication Questionnaire	<--------X------->
Symptoms Questionnaire	<--------X------->
Anonymous Survey	<--------X------->
Brief Physical Activity Questionnaire	<--------X------->
Diet Acceptability Questionnaire	<---X---> <---X--->
Intervention Feeding	X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X
Compliance Monitoring	X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X
Participation Survey*	<--------X------->
Exit Interview and Counseling*	X

^ once per week during days 1-21; five times during the final 9 days including at least twice during days 28-30 of each feeding period.

* done at the end of the third intervention period (IFPIII) only.

Procure Necessary Food Items

Each site plans in advance the food needed to ensure that all the necessary foods are on hand. The DASH2 food procurement program is designed to aid sites in building a shopping list for all foods needed for a particular week. The staff enters the individuals and their energy levels into the system at randomization, which in turn produces the shopping list. The participant's randomization assignment is found in the Diet Assignment Report, which is printed from the unblinded area of the data management system.

Many foods are acquired through donations. Foods donated are recorded and tracked with the Food Donation Tracking Form (#117). Each site keeps a notebook containing records of all food acquired, regardless of the mechanism of acquisition. See the Diet MOP, Chapter 40, Food Procurement, Safety, and Production.

Conduct Inventory

All foods are stored and kept in a locked area. It is important to see that an adequate supply of food is available to not interfere with the feeding period. See Diet MOP Chapter 40, Food Procurement, Safety, and Production.

Prepare Daily Meals

DASH2 kitchens prepare all the meals for participants. The details on the preparation of all DASH2 foods are found either in the DASH2 Recipes (Form #108) or in Chapter 40 of the DASH2 Diet MOP, Food Procurement, Safety, and Preparation. Quality assurance procedures are also found in Chapter 35 of the Diet MOP and are to be followed at each clinical site.

Distribute Meals to be Eaten Off-site

Each participant is required to eat one meal at the study site each weekday. All other meals are prepared at the site and distributed to the participant to consume elsewhere. It is critical that each site follow standard guidelines for ensuring the safety and palatability of the food. Safety guidelines are found in the DASH2 Diet MOP, Chapter 40. Participants are to be given instructions on keeping the foods safe (Safe Foods To Go, Form #107). In addition, the sites need to provide participants with adequate containers for the storage and transfer of the food. Because each site operates differently, all sites are required to have procedures in place for ensuring that all participants receive the correct meals.

Measure and Monitor Weight at Each Clinic Visit

All participants are weighed at each clinic visit (except day 0 of each intervention period) during the intervention phase of the trial using the protocol outlined in DASH2 Clinical MOP, Chapter 13. The average of all weight measurements recorded during run-in feeding plus the weight

taken at SV3 defines the participant's **baseline weight** and is used as the baseline against which to measure weight change during intervention feeding. The daily weight measurements recorded during intervention are used to monitor for weight changes, and the overall energy content of each participant's meals is adjusted as needed to ensure that weight remains stable throughout the study. The daily weight is recorded on the Daily Diary (Form #24). Entries to The Daily Diary are entered each day by the data entry person. The Weight Tracking Report is then produced by the data management system. This report should be reviewed daily for possible compliance counseling or calorie adjustment. Please see DASH2 Diet MOP Chapters 41 and 36, respectively.

Administer, Review, and Code the Daily Diary

The nutritionist's responsibility is to administer and review the Daily Diary (Form #24). The purpose of the form is to collect information related to the participant adherence to the diet. The Participant Instructions for the Daily Diary (Form #115) can be used for explanation of the form at any time. Four areas are evaluated:

- The type and amount of discretionary or "allowed" foods the participant eats, including alcohol.
- The kind and amount of study foods not eaten, and non-study foods eaten, including supplements and over the counter medications.
- Menstruation information from female participants.
- Feedback from participants regarding concerns they have about participating in the study.

The nutritionist is responsible for making sure the data are correct and clear, and that all fields are complete on a daily basis. Please see the instructions for Form #24 for detailed information on the coding and review of the Daily Diary.

The Compliance Report, generated from the unblinded area of the data management system, contains summarized compliance data from the Daily Diary. The nutritionists should review this on a daily basis in order to identify problems with compliance early. If problems occur, the nutritionist counsels the participant. Details of identifying problems and counseling are found in the DASH2 Diet MOP Chapter 41, Participant Management and Compliance.

Complete Dietary Forms

There are many forms completed by the participants during each intervention feeding period. The dietary forms are listed below. The nutrition staff may or may not be involved in the administration and collection of the surveys.

Anonymous Survey

All participants complete the Anonymous Survey (Form #25) between days 24 and 30 of each intervention feeding period describing their compliance during that period. The survey is to be handed out by the staff but has no identifying information on it. The participants are instructed to return it to a specific place or in a sealed envelope to ensure their anonymity. Check the appropriate box on the Intervention Flow Form (#20) when the form has been distributed to the participant. The completed forms are entered on-site.

Diet Acceptability Survey

Participants complete the Diet Acceptability Survey (Form #35) twice during each feeding period, once between days 7 and 9 and again between days 27 and 30. The Diet Acceptability Questionnaire is administered and reviewed by the dietary staff. Check the appropriate box on the Intervention Flow Form (#20) when the form has been completed. The competed forms are entered on-site.

Intervention Activities Occurring Only Once During the Cohort

Complete the Participation Survey

During days 24-30 of the third intervention feeding period, the participant is asked to complete the Participation Survey (Form #26.) Check the appropriate box on the Intervention Flow Form (#20) when the form has been completed. The competed forms are entered on-site.

Exit Interview and Counseling

After all intervention feeding is concluded, participants receive a personalized Health Risk Assessment and nutritional counseling ~~and a summary of their data~~. This activity can happen in a group or individually. It does not need to coincide with the final day of feeding but may be incorporated into a celebration event. See Diet MOP Chapter 37 for more details.

Early Termination of Feeding

Inevitably, some participants will complete all required data collection, except for daily compliance monitoring, prior to the scheduled end of intervention feeding. Such subjects may be excused from further intervention feeding. This does not affect the timeline for data collection, however. Since final blood pressures must be taken on two of the final three days, intervention feeding cannot terminate prior to day 29. Participants who have not completed all required data collection **cannot** be excused early from feeding. Missed meals in such subjects count as noncompliance with the dietary requirements of the trial.

Premature Termination from Study

If for any reason a participant chooses to terminate participation in DASH2 prior to the end of the cohort, complete the Premature Study Termination Form (#22). Collect as many of the study data as possible prior to the termination. See Clinic MOP Chapter 19, Participant Closeout and Counseling, for details of closeout activities.

35. DIET TRAINING 2

35. Diet Training

Introduction

Procedures for training DASH2 dietary staff are outlined in this chapter. The training programs are divided into sections or modules. The sections are:

Dietary Screening
Food Acquisition
Participant Orientation
Compliance Assessment
Food Safety and Preparation
Exit Interview

Each section contains the overview of the training, performance objectives, materials, curriculum and reference to forms to use as observation checklists, certification forms, tests, and answers to the test.

Certification Forms and Training Checklists

To be certified a staff member completes each item on the certification form. This includes all the activities necessary for certification. For some of the sections, quality assurance observation checklists are also used in the certification process. Each module describes the process and references the correct form. Completed certification forms are sent to the Coordinating Center, as are some tests. The Coordinating Center has the answer key for the tests.

Training Options

Most initial training and certification takes place centrally. After each cohort, the Diet Committee reviews and evaluates the dietary activities. Additional training is developed and delivered as needed. If new staff is hired during the course of the study, training and certification for any appropriate activity occurs. Members of the Diet Committee who have been trained centrally conduct this training.

Dietary Screening

Overview

Procedures for screening DASH2 participants are outlined in chapters 5-8 of the DASH2 Clinical Manual of Operations. The goal of dietary screening is to ensure that participants at each of the clinical sites can tolerate study foods, be able to store take-home meals safely, and be able to meet the requirement of daily meal attendance. Though not a screening tool, the Food Frequency Questionnaire (FFQ) is administered during screening to assess participant incoming food consumption patterns.

Training Activities

The trainer at each site follows procedures outlined in this module to orient staff who conducts screening. In addition, at the end of each cohort, the Diet Committee reviews the screening process and develops additional training as necessary. Specifically, this includes reviewing problems with the FFQ data.

1. Review performance objectives below with trainee.
2. Ask trainee to review the MOP chapters outlined in "Training Materials" below.
3. Conduct training in the sequence identified under "Training Curriculum" below.
4. Assess the performance of each trainee using the Dietary Screening Checklist (Form #81).
5. Complete a Dietary Screening Certification (Form #80) for each trainee. Store a copy of the form at the clinical site for audit purposes. Send the original to the Coordinating Center.

Performance Objectives

<u>Overall Objective</u>

At the completion of this module, the DASH2 staff person is able to explain the uses of the four dietary screening forms, can administer them to participants, and conduct all required editing of the forms

Specific Objectives

1. State the primary uses of the General Dietary Information Questionnaire (Form # 100) and the Study Food Checklist (Form #101).
2. Explain the purpose of each of the sections in Forms #100 and #101.
3. State the primary uses of the Food Frequency Questionnaire (FFQ) (Form #9).
4. Explain the purpose of each of the four sections of the FFQ.
5. Distribute the FFQ and other forms to participants according to procedures specified in the DASH2 Manual of Operations. The specific procedures are found in the instructions to Form #9 "Instructions for processing the FFQ."
6. Conduct a pre-mailing review of the FFQ in accordance with procedures specified in the DASH2 Manual of Operations. The specific procedures are found in the instructions to Instructions for Processing the FFQ (Form #9).
7. Learn how to conduct a post-coding FFQ interview with participants using non-leading questions and answer participant questions as outlined in the DASH2 Manual of Operations. The specific procedures are found in the instructions to Form #9 "Instructions for processing the FFQ."
8. Explain how the Dietary Screening Quality Assurance Checklist (Form #81) is used to monitor quality assurance of dietary assessment throughout the trial.

Training Materials and Curriculum

Training Materials

1. DASH2 Clinical MOP Chapter 5
2. DASH2 Clinical MOP Chapter 6
3. DASH2 Clinical MOP Chapter 7
4. DASH2 Clinical MOP Chapter 8
5. DASH2 Diet MOP Chapter 2
6. Food Frequency Questionnaire and instructions (Form #09)
7. Dietary Assessment Certification (Form #80)
8. Dietary Screening Quality Assurance Checklist (Form #81)
9. General Dietary Information Questionnaire and instructions (Form #100)
10. Study Food Checklist and Instructions (Form #101)
11. Lay menus (Form #102)
12. Participant instructions, how to complete the FFQ (Form #103)

Training Curriculum

Sequen	Training Curriculum	Estimated Time
1.	Screening overview	10
2.	Prescreening Overview	10
3.	Screening Visit 1 overview and primary uses of the General Dietary Information form (#100)	10
4.	Screening Visit 2 overview and uses of the Study Food Checklist (Form #101)and the study menus (form #102)	10
5.	Complete the Food Frequency Questionnaire	25
6.	Discuss the uses, criteria for development, and schedule for completing the FFQ	10
7.	Review Structure of the FFQ • Face page • Vitamin Intake section (page 2) • Individual food sections (page 3 to7) • Restaurant eating (page 7, bottom) • Summary questions (page 8)	15
8.	Review procedures for distributing the FFQ (Page 2 to 5 of Form 9 instructions)	15
9.	Screening Visit 3 overview. Review procedures for checking returned FFQs • Cursory Review • Pre-mailing Review	15
10.	FFQ Error Reports Review situations that generate error reports Review procedures for noting: • Multiple mark errors • Missing data • Missing food items • Missing frequencies • Missing portion sizes • Missing responses to summary questions	20
11.	Post-coding interviews with participants (asking non-leading questions)	15
12.	Review the Dietary Screening Quality Assurance Checklist (Form #81) and how it is used to monitor quality at each site.	30
	Review the Dietary Screening Certification form (Form #80). The trainee completes the evaluation form separately.	
	Total Time	3.0 hours

Food Procurement

Overview

The goal of this function is to standardize study food procurement.

An electronic program, DASH2 Food Procurement System, developed at the DASH2 Coordinating Center is available at each site. This system predicts the amount of food to order after the site's participant census is entered. Use this program to plan shopping lists.

Training Activities

1. Review the overall, and specific objectives of the training below.
2. Use the materials list and curriculum below to conduct the training.
3. Observe the trainee and complete the Food Procurement Checklist (Form #98).
4. Complete the Food Procurement Certification (Form #97) and return to the original to the Coordinating Center.

Performance Objectives

Overall Objectives

At the completion of this section the DASH2 staff person is familiar with the DASH2 food brands, can use the Food Procurement System, order DASH2 donated and purchased foods, use the process to make a food substitution and is aware of the site's local food procurement procedures.

Specific Objectives

The DASH2 food procurement staff is able to:

1. Use the DASH2 Food Procurement System
2. Use the DASH2 Donation Tracking Forms
3. Make an emergency food substitution
4. Request a permanent food substitution
5. Be aware of the site's local food inventory procedures
6. Order donated food

Training Materials and Curriculum

Materials

1. DASH2 Food Procurement System
2. DASH2 Diet MOP, Chapter 40
3. Food Substitution Record (Form #109)
4. Food Donation Tracking Form (Form #117)
5. Food Substitution Fax Cover Sheet (Form #121)
6. Food Procurement Checklist (Form #98)
7. Food Procurement Certification (Form #97)

Curriculum

Sequence	Training Curriculum	Estimated Time
1.	Prior to training have staff person read DASH2 Diet MOP, Chapter 40.	
2.	Review the reasons specific food brands is selected for DASH2.	10
3.	Review the food sources, donated and purchased, used in DASH2.	15
4.	Review the companies that have agreed to donate food for DASH2 and the process used to order donated food using the Donation Tracking Form (Form #117).	10
5.	Review the site's local procedures to purchase foods from either a distributor or a retail grocery.	15
6.	Show the staff person how to enter participant data and use the DASH2 Food Procurement System.	10
7.	Show the staff person how to convert the information collected from the Food Procurement System to determine food quantities.	10
8.	Review the process to select an emergency food.	10
9.	Review the process to request a food become a permanent food substitution.	10
10.	Review the site's local inventory procedures and documentation process.	15
11	Complete the Food Acquisition Checklist (Form #98).	
12.	Complete the Food Acquisition Certification (Form 97) and send the original to the Coordinating Center.	

Participant Orientation

Overview

Procedures for conducting the Participant Orientation session are outlined in the DASH2 Diet MOP, Participant Orientation, and Chapter 32.

Training Activities

1. Review orientation performance objectives with trainee.
2. Conduct the training activities using the material and curriculum below.
3. Administer the Participant Orientation Test (Form #95).
4. Complete the Participant Orientation Certification (Form #82).
   Store with other quality assurance documents at your site, and mail the original to the coordinating center.

Performance Objectives

Overall Objectives

At the completion of this module, each trainee is able to explain to participants their day-to-day obligations to the study, what participants can expect to happen each day, and procedures to follow for emergencies.

Specific Objectives

Staff trained to do participant orientation is able to:

1. teach participants how to follow the protocol
2. know techniques to reduce participant dropout
3. help participants to have a clear understanding of the expectations of participation
4. support study protocol by understanding the value of following procedures in both arms and all sites
5. identify when in the study participant orientation occurs
6. identify the materials used in the Participant Orientation packet
7. know the content of the Participant Orientation video

8 know the flow of the Participant Orientation visit

8. know the content of the Participant Orientation visit

Training Materials and Curriculum

Materials

1. DASH2 Diet MOP Chapter 32, Participant Orientation
2. DASH2 Orientation Video
3. Participant Orientation Packet
   Orientation Form (Form #104)
   Guidelines for Beverages and Seasonings (Form #106)
   Safe Foods TO GO (Form #107)
   Clinical Measurements (Form #114)
   Participant instructions for Daily Diary, Daily Diary Information (Form #115 a and b)
   Allowed Medications (Form #116)
4. Site specific schedule of DASH2 events and measurements
5. Site-specific information
6. Participant Orientation Certification (Form #82)
7. Participant Orientation Test (Form #95)
8. Participant Orientation Test Answer Key (Form #97). Available to the trainer from the Coordinating Center.
9. Participant Orientation Checklist (Form #94)

Curriculum

Sequence	Training Curriculum	Estimated Time
1.	Review Participant Orientation protocol.	
2.	Review participant expectations.	
3.	Review the purpose and value of following the same protocol and procedures in both diet arms and between sites.	
4.	Review the participant frequency of the visits to the site.	
5.	Review the blinding needs and their purpose.	
6.	Review the clinical measurements that occur at a participant visit.	
7.	Review the purpose of the energy cookies, emergency foods and allowed beverages and seasonings.	
8.	Review the need for the participant to be aware of food safety and completeness of menus.	
9.	Review the Daily Diary (Form #115) protocol and procedures to code.	
10.	Discuss the time frame to orient participants.	
11.	Review the Participant Orientation packet.	
12.	See the DASH2 video.	
13.	Review the format and curriculum of the Participant Orientation session.	
14.	Take Participant Orientation Test (Form #95).	
15.	Complete Participant Orientation Certification Form (Form # 82) and send to the Coordinating Center.	

Participant Management and Daily Diary Certification

Overview

Procedures for promoting compliance are outlined in the DASH2 Diet Manual of Operations Chapter 41, Compliance Assessment. The goal of compliance assessment is to promote participant compliance in the feeding intervention and standardize the method used to score the Daily Diary between sites.

Training Activities

The trainer at each site follows the procedures outlined in this section to orient new staff who assesses participant compliance. Also use the module to certify staff.

1. Review performance objectives below with the trainee.
2. Have the trainee read and review the DASH2 Diet MOP
   Run-in and Randomization, Chapter 33
   Intervention, Chapter 34
   Energy Assignment and Adjustment, Chapter 36
   Participant Management and Compliance, Chapter 41
   DASH2 Clinical MOP, Chapter 9, Run-in and Randomization
   DASH2 Clinical MOP, Chapter 10, Intervention
3. Conduct the training according to the curriculum below.
4. Complete the Participant Management and Daily Diary Certification (Form #83) and mail it to the coordinating center. Keep a copy at your site for audit purposes.

Performance Objectives

<u>Overall Objectives</u>

At the completion of this module, the DASH2 staff person is:
1. able to explain the main uses of the Daily Diary (Form #24)
2. able to generate and interpret the Compliance and Weight Tracking Reports
3. able to interpret the audit reports generated by the data management system
4. understands the energy assignment process and how and when to adjust calorie level
5. understand good communication skills and roadblocks to listening
6. able to deal with compliance deviations

Specific Objectives

State the primary uses and purpose for each of the following:
1. Daily Dairy (Form #24)
2. Weight Tracking Record
3. Compliance Report
4. Guidelines for Beverages and Seasonings (Form #106)
5. Review the Participant Instructions for the Daily Diary (Form #115) and practice explaining the diary to a participant.
6. Accurately complete the coding and review of the practice Daily Diaries.
7. Review the use of compliance assessment during run-in.
8. Review the purpose of the case conference and the accompanying form, Case Conference form (Form #33).
9. Review the randomization procedure.
10. State the purpose of the unblinded area of the data management system.
11. Review the process for printing reports from the system.
12. Review the process for assigning calorie levels and making adjustments using the Weight Tracking Record.
13. Understand the fundamental approach to motivating compliance. Be able to use the tools and strategies suggested in counseling participants.
14. Value of the Anonymous Questionnaire (Form #25) and process to administer
15. Value of the Diet Acceptability Questionnaire (Form #35)

Training Materials and Curriculum

Materials

1. DASH2 Diet MOP Chapter 33, Run-in
2. DASH2 Diet MOP Chapter 41, Participant Management and Compliance
3. DASH2 Diet MOP Chapter 36, Energy Assignment
4. DASH2 Clinical MOP, Chapter 9, Run-in and Randomization
5. DASH2 Clinical MOP, Chapter 10, Intervention
6. Guidelines for Beverages and Seasonings (Form #106)
7. Daily Diary (Form #24) and instructions
8. Run-in Flow Form (Form 16)
9. Participant Management and Daily Diary Certification (Form #83)
10. Case Conference Form (Form #33)
11. Weight Tracking Report
12. Compliance Report
13. Diet Assignment Report
14. Run-in Calorie Report
15. Participant instructions for the Daily Diary, Daily Diary Information (Form #115a and #115b)

16. Flower Form - Confidential (Form #118)
17. Data Management Manual related to randomization
18. Packet on Motivational Skills and Strategies (available from the CC)

Training Curriculum

Sequence	Training Curriculum	Estimated Time
1.	Review purpose of compliance assessment.	5 minutes
2.	Review purpose of Daily Diary (Form #24)	10
3.	Review the energy assignment process and discuss when to adjust the participant calorie level.	5
4.	Demonstrate process to generate Compliance and Weight Tracking Reports	5
5.	Demonstrate the process to generate an audit report.	5
6.	Review process to interpret audit reports generated from the Data Management System.	5
7.	Review the Weight Tracking Report	5
8.	Review the Compliance Report	5
9.	Review Run-In Calorie Report	5
10.	Review Diet Assignment Report	5
11.	Review the Guidelines for Beverages and Seasonings (Form #106)	5
12.	Review t Daily Diary Information forms (Form #115 a and b)	5
13.	Review the Flower Form – Confidential (Form #118) and discuss form confidentiality issues.	5
14.	Arrange to have the central trainer for motivational interviewing review the good communication skills and roadblocks to listening and conduct an evaluation.	5
	Total	75 minutes

Food Safety and Preparation

Overview

Procedures for food preparation and distribution are outlined in DASH2 Diet Manual of Operations, Chapter 40, Food Procurement, Safety and Preparation. The goal of this training is to ensure that study meals are provided to participants in a safe and accurate manner.

Training Activities

The lead trainer follows the sequence below to orient all new kitchen staff and conduct annual certification.

1. Review the overall, and specific performance objectives of the training below.
2. Use the curriculum provided below to conduct the training.
3. Complete the Food Preparation Checklist (Form #128).
   Keep a copy at the site and mail original to the CC for each newly trained or newly certified staff member.
4. Complete the Food Preparation Certification (Form #84).
   Keep a copy at the site and mail original to the coordinating center for each newly trained or newly certified staff member.
5. Administer the Food Preparation and Distribution Test (Form # 92).
   Keep a copy at the site and mail original to the CC for each newly trained or newly certified staff member.

Performance Objectives

Overall Objective

At the completion of this module, the DASH2 food preparation staff is able to produce and package DASH2 meals as written on the DASH2 menus, production sheets, and recipes in accordance with food safety and sanitation guidelines.

Specific Objectives

The DASH2 food preparation staff is able to:

1. Read Production Sheets (including Forms # 111 and #112)
2. Correctly identify product brands, weights of product, and number of servings needed for food production.
3. Read Tray Assembly Forms (Form # 113) and assemble and/or package the correct product and amount.

4. Read DASH2 Recipes (Form #108), correctly identify the product and its amount, the number of servings or batch size, and demonstrate the ability to produce a recipe in accordance with the recipe instructions.
5. Demonstrate appropriate use of scales and correctly identify allowed measurement.
6. Identify appropriate packaging materials for take-home foods.
7. Identify the location of food preparation instructions, including recipes and cooking instructions.
8. Demonstrate sanitary and safe practices in handling food.
9. Identify appropriate staff who is authorized to answer questions, concerns, or comments regarding DASH2 food products and/or production.

Training Materials and Curriculum

Materials

1. DASH2 Diet MOP Chapter 40-Food Procurement, Safety and Preparation
2. Food Production Forms (Form #112)
3. DASH2 Recipes (Form #108)
4. Tray Assembly Form (Form #113)
5. Food Service Sanitary Inspection Checklist (Form # 91)
6. Spot Checking of DASH2 Recipes, Meals, and Food Items (Form # 87)
7. Kitchen Quality Assurance Schedule (Form # 90 to # 93)
8. Food Preparation Certification (Form # 84)
9. DASH2 Food Preparation and Distribution Test (Form # 92)
10. Food Preparation Test Answer Sheet. Available from the Coordinating Center.
11. Food Preparation Checklist (Form #128)
12. Scale, powder-free gloves, hair net or hat, apron
13. DASH2 food for one selected recipe
14. DASH2 packaging, tray materials and label materials

Curriculum

Sequence	Training Curriculum	Estimated Time
1.	Discuss organizational structure including identification of the DASH2 staff person whom each kitchen staff should to report to for comments, problems, concerns, or questions regarding DASH2 food production.	5 minutes
2.	Review DASH2 production sheets (including Forms # 111 and 112) and instructions on the following: • how to identify which diet and day of the week the production form is to be used for food preparation • how to identify the food items for each meal (breakfast, lunch, dinner or snack) • how to correctly identify food item and/or product • how to identify the weight of a food or unit (PC) to use for each food item and calorie level. • how to identify when a DASH2 recipe is to be used • where to find the production forms	1 hour
3.	Review DASH2 Recipes (Form #108). Include explanations for the following: • how to identify correct recipe name and diet to use from the item listed "Recipe: "on production sheet • how to calculate the number of servings needed for each calorie level or batch • how to read the recipe to determine the weight of each item specific to calorie level • review cooking procedures for recipes • location of up-to-date DASH2 recipes	30 minutes
4.	Review food preparation procedures. Emphasize the following: • meats; fish; vegetables; fruits; pasta; cereal; grains; bread products; milk and dairy products; fats and oils; spices • food preparation methods and times • location of most up to date MOP cooking instructions • Demonstrate how to portion food items to be edible and presentable. (For example, slice bread into pieces for sandwich without using small scraps to make correct weight).	30 minutes
5.	Review DASH 2 MOP guidelines to weigh food and proper use of scales • All foods are weighed to the $\pm$ 0.5 grams, except fats and oils when < 10 grams needed and all spices are weighed to +- 0.1 grams. • Demonstrate how to properly zero scales between weighings • Demonstrate proper weighing technique. • Show how to use Kitchen Scale (s): Weekly Accuracy Check (Form #90)	15 minutes

6.	Review and demonstrate proper food packaging/tray assembly (Form # 113). Include the following: • proper materials used for each type of food item, i.e. liquids, cereals, salads, meats • how to label a meal so it can be identified correctly for distribution	15 minutes
7.	Review food safety and sanitation in food preparation and storage. Include the following: • Review DASH2 Diet MOP food sanitation procedures • Review Food Service Sanitary Inspection Checklist (Form #91)	30 minutes
8.	Review quality assurance forms. • Kitchen Quality Control Schedule (Form #93) • Checking Recipes, Meals, and Food Items	10 minutes
9.	Administer Food Preparation and Distribution Test (Form #92).	10 minutes
10.	Administer the Food Preparation Checklist (Form #?). File with quality assurance forms for audit purposes.	
11.	Complete Food Preparation Certification Form (Form #84) independent of the training for each trainee. Keep a copy for audit purposes and send the original to the Coordinating Center.	
	Total time approximately	3 hours 25 minutes

Exit Interview

Overview

Procedures for conducting the Exit Interview are outlined in Chapter 37 of the DASH2 Diet Manual of Operations, Participant Closeout and Counseling. The exit interview may be conducted in-group or individual format. Its purpose is to provide the participant with specific feedback regarding their risk factors, generic health and nutrition information as it relates to heart disease, and individual counseling if the participant would like to develop an action plan.

Training Activities

The initial training for the exit interview was delivered to the entire Diet Committee. Certified staffs conduct the interview. Certification is recorded on the Exit Interview Certification (Form #86). Each staff must practice and be observed explaining the Health Risk Assessment and conducting the individual counseling session to be certified.

After each cohort the Diet Committee reviews and evaluates the exit interview activities. Additional training is developed and delivered as needed. If new staff is hired during the course of the study, training and certification for any appropriate activity occurs. Members of the Diet Committee who have been trained centrally complete this training.

Performance Objectives

Overall Objectives

The overall objective is to assure participants receive consistent feedback at the close of the trial about their blood pressure and other study-related information.

Specific Objectives

1. Each staff person understands that the participant intervention status and individual blood pressure measurements remain blinded.
2. The staff person understands the individualized Health Risk Assessment and can explain it to participants.
3. The staff person is able to conduct an individual counseling session according to the Exit Interview Flow.
4. The staff person is familiar with and can use the education materials available.

Training Materials and Curriculum

Training Materials

1. DASH2 MOP Chapter 37- Participant Closeout and Counseling
2. Health Risk Assessment, sent by the Coordinating Center
3. Health Risk Assessment cover letter (Form #126)
4. Exit Interview Height/Weight Table (Form #124)
5. Action Planning Worksheet (Form #122)
6. Exit Interview Flow (Form #123)
7. Participants study charts
8. Education materials
   Healthy Snacking with Fresh Fruits
   Fruits and Vegetables: It's Easy to Take the "5 A Day Challenge"
   Facts about Sodium and Healthy Blood Pressure
   The Lean'n Easy Way to Enjoy Meat
   Milk Gets a Makeover:
   New Labels Help Make Shopping a Snap
   The ABCs of Fats, Oils, and Cholesterol
   Health and Fitness Come in All Sizes
   Healthy Weight – It's About Balance
   Cholesterol and Your Health
   About High Blood Pressure
   Just Move
   Clearing the Air
   Moderate Drinking

Curriculum

Sequence	Training Curriculum	Estimated Time
1.	Review the format, purpose, timing, and blinded nature of the exit interview. Summarize activities of the interview. •	15 minutes
2.	Review the Health Risk Assessment, Exit Interview Flow, Height/Weight table, and Action Planning.	15 minutes
3.	Review the educational materials that are distributed at the exit interview.	15 minutes
4.	Review the process for distributing the Health Risk Assessment and education materials if the participant was not present.	5 minutes
5.	Have staff practice explaining the Health Risk Assessment and conducting an individual counseling session.	20 minutes
6.	Complete Exit Interview Certification (Form #86) independent of the training for each trainee. Send a copy to the Coordinating Center.	
Total time		1 hour 10 minutes

Summary of Edits

New changes in version 1.1

- New definition of baseline weight
- New definition of acceptable weight fluctuation during run-in and intervention

36. Energy Assignment and Adjustment

Energy Assignment

The daily energy requirement of each subject will be calculated using the basal metabolic rate adjusted for physical activity levels. Basal metabolic rate will be calculated by the WHO formula (Table 36.1), using the weight taken at SV3. Physical activity levels will be estimated by a 7-day Physical Activity Recall Interview administered at SV3. See the DASH2 Clinical MOP, Chapter 9, Run-In and Randomization Procedures. The physical activity questionnaire overestimates energy needs for participants where energy needs are above 3500 kcal. To offset this bias, the activity factor for all participants estimated by the exercise questionnaire should be adjusted using information shown in Table 36.2.

Table 36.1 Equations for Predicting Resting Energy Expenditure from Body Weight[a]

Sex	Age Range	Equation to Derive REE in Kcal/day	R[b]	SD[b]
Male	18-30	(15.3 x wt[c]) + 679	0.65	151
	>30-60	(11.6 x wt) + 879	0.60	164
	>60	(13.6 x wt) + 487	0.79	148
Female	18-30	(14.7 x wt) + 496	0.72	121
	>30-60	(8.7 x wt) + 829	0.70	108
	>60	(10.5 x wt) + 596	0.74	108

[a]From WHO (1985). Technical Report Series 724.
[b]Correlation coefficient (R) of reported BMRs and predicted values, and standard deviation (SD) of the differences between actual and computed values.
[c]Weight of person in kilograms.

Table 36.2 Adjustment Factors for Setting Initial Energy Needs

Activity Factor Calculated from the Exercise Questionnaire	Adjustment Factor[d]
≤ 1.45	1.4
1.46-1.50	1.5
1.51-1.69	1.6
≥ 1.70	1.8

[d]Based on traditional factors used to adjust energy needs for physical activity (Source: National Research Council, Food and Nutrition Board, Subcommittee on the Tenth Edition of the RDAs: Chapter 3. Energy, *Recommended Dietary Allowances*, Washington, DC National Academy Press, 1989, pp 24-39).

The above WHO formulae are programmed into the computerized data entry system, as is the calculation of physical activity factor. Thus, once the SV3 weight and physical activity data are entered into the computer, daily energy requirement will be calculated automatically.

Once the daily energy requirement is calculated from the above methods, each subject is assigned to one of the five energy levels that were used for menu development (1600, 2100, 2600, 3100, and 3600). Table 36.3 depicts the guideline for energy assignment.

Table 36.3 Guideline for Energy Assignment

Calculated Energy Requirement (Kcal)	Assigned Menu Energy	Supplement of Energy Foods
Kcal ≤ 2000	1600 Kcal	as needed up to 400 Kcal
2000 <Kcal ≤ 2500	2100 Kcal	as needed up to 400 Kcal
2500 <Kcal ≤ 3000	2600 Kcal	as needed up to 400 Kcal
3000 <Kcal ≤ 3500	3100 Kcal	as needed up to 500 Kcal
3500<Kcal	3600 Kcal	as needed

For example, if the calculated energy requirement is 1980 Kcal, the participant is assigned to the 1600 Kcal level with the supplementation of 400 Kcal provided by energy foods. Since energy foods are 100 Kcal each, the supplemental energy will be rounded to the next greater number (using the above example, 400 Kcal instead of 380 Kcal).

Although each subject will be assigned to a specific caloric level with or without supplemental energy foods, an additional 200 Kcal of energy foods will be provided to each subject as discretionary food during the first week of run-in to assist weight stabilization.

Energy Adjustment

In general, subjects are to be weighed daily during the week, and a weekly average weight will be computed for each subject. Evaluation of weight status and necessary caloric adjustment will be performed weekly unless abrupt changes in weight are observed.

The goal of energy adjustment is to maintain the weight within 2% of the target weights. However, when a participant is on the 50 mmol sodium diet, the tolerance weights will be +2% and -3% of their target weight. The target weight for the run-in period (target weight) is defined as the average of weights taken at SV3 and the first two days of run-in. The target weight for the intervention period (baseline weight), however, is defined as the average of all run-in weights plus the SV3 weight.

Adjustments in the energy level may be made during the run-in period based on two criteria: 1) subject's perception of whether the amount of food is too much or too little, and 2) body weight. Thereafter, adjustments will be made based on body weight. Since participants will be placed on different sodium levels, which may cause body weight to fluctuate, energy adjustment should not be made during days 0-3 of each sodium period.

Weight gain in premenopausal women is evaluated in relation to the menstrual period. If weight gain occurs before and during the menstrual period, reduction in energy intake should be made only if the weight gain persists one week after the menstrual period.

If a subject's weight starts to fluctuate after being stable for a couple of weeks, changes in physical activity pattern may be one of the causes. Subject should be reminded to maintain his/her usual pattern throughout the study if possible. If the physical activity pattern needs to be changed significantly, the subject should notify the nutrition staff prior to the changes so that energy adjustment can be made in a timely fashion.

In order to achieve the goal of maintaining weight (± 3% of the target weight during run-in or baseline weight during intervention), energy adjustment will be made using Table 36.4 as a guideline. This chart depicts possible changes in weight status and suggested actions on a weekly basis. Different time reference may be used and different actions may be required in individual cases.

Table 36.4 Guideline for Energy Adjustment

	Patterns of Weights	**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 (for example, goes up and down), and the average weight of the week is 1 kg different from the target weight.	1. Increase/decrease energy 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 energy 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 the actions in section B.

Summary of Edits

New changes in version 1.1

- Edits associated with adding individualized Health Risk Assessment to the exit interview.
- Recommendations given for all the health behaviors and the list of materials used.
- Removes Participation Survey from exit interview as it is to be administered during intervention.

37. Participant Close-out and Counseling

Purpose

This chapter contains instructions for providing feedback to participants at the end of the trial about their blood pressure and about other issues relevant to their health. At the conclusion of each cohort, study participants receive a summary of their blood pressure and other clinical measurements, some behavioral indicators, and dietary feedback. They are offered information on heart disease prevention, with an opportunity for nutritional counseling. Recommendations are given on all indicators. At the conclusion of the full trial, study participants are unblinded to their treatment assignment, receive a record of their average individual blood pressure responses to each intervention, and are informed about the overall findings of the trial.

Unblinding

Once data collection on any given participant is complete, the unblinding of treatment assignment and blood pressure results cannot affect that person's data. However, the staff person presenting the data would also become unblinded to that person's results and over time might develop subjective opinions about the efficacy of the various interventions. This in turn could influence the manner in which this individual interacts with other study participants. Also, participants may be recruited from the same pool and may know one another. Thus, a participant who is unblinded to his treatment assignment may develop subjective opinions about the efficacy of the interventions and could influence other study participants who are currently enrolled in the trial.

DASH2 participants are not informed of their intervention group status and individual blood pressure measurements until the end of the entire study. Nonetheless, participants may often know their diet assignment because their food will differ from that of other participants and change after run-in. Still, participants and unblinded staff should not discuss diet assignment.

Timing and Context of Close-out Activities

Close-out activities take place in the context of either an individual exit interview or a group counseling session. Both types of events are scheduled after all feeding has ceased for the cohort. While the structure and content of these close-out activities is left largely up to the individual sites, the following must occur:

- Provide personalized feedback with the Health Risk Assessment
- Offer a variety of educational materials
- Provide individual counseling if desired

The counseling is conducted by someone qualified to provide counseling on heart disease prevention (e.g., dietitian, nurse, health educator, etc.) and trained and certified on the Exit Interview.

Preparing for Close-out

Materials

The following materials are needed to conduct the close-out activities:

1. Health Risk Assessment, sent by the CC
2. Health Risk Assessment cover letter (Form #126)
3. Exit Interview Height/Weight Table (Form #124)
4. Action Planning Worksheet (Form #122)
5. Exit Interview Flow (Form #123)
6. Participant's study chart, if desired by the study physician
7. Education materials:

Healthy Snacking with Fresh Fruits
Fruits and Vegetables: It's Easy to Take the "5 A Day Challenge"
Facts About Sodium and Healthy Blood Pressure
The Lean'n Easy Way to Enjoy Meat
Milk Gets a Makeover: New Labels Help Make Shopping a Snap
The ABCs of Fats, Oils, and Cholesterol
Health and Fitness Come In All Sizes
Healthy Weight – It's About Balance
Cholesterol and Your Health
About High Blood Pressure
Just Move
Clearing the Air
Moderate Drinking

Completing Close-out

Counseling Session

To thank them for participating, all participants are offered health and nutrition education on reducing cardiovascular disease risk at the end of the cohort. The purpose of the session is to give participants information on the risk factors for cardiovascular disease and on how to follow a healthy diet for its prevention.

Exit Interview Flow (Form #123)

The counseling can take place either in a group session or in an individual visit. The Exit Interview Flow (Form #123) provides a flow for the session, a script to introduce the Health Risk Assessment, and guidelines on offering advice to participants, if they ask.

Health Risk Assessment Report

Prior to the close-out visit(s), a personalized two-page Health Risk Assessment for each participant is sent to the clinical centers from the Coordinating Center. This includes the participant's name, feedback from the Food Frequency Questionnaire, height, average weight, SV3 blood cholesterol, the average of all blood pressure measurements (SBP and DBP) taken since SV1, physical activity, smoking status, and alcohol consumption. The report contains the recommendations tailored to that participant. The participant is encouraged to share the information with his or her primary care provider.

The report is reviewed with the participant either in the group session or individually. The assessment is based on the information provided by the participant during the study. The first page is the dietary feedback based on the Food Frequency Questionnaire completed by the participant during screening. The recommendations are based on the DASH diet. There are four graphs at the top of the assessment. The shaded area indicates the recommended range and the star represents where the participant is. The top five high-fat and high-sodium foods are also noted. At the bottom of the first page of the Health Risk Assessment is the participant's height and averaged weight.

The second page of the assessment contains the additional information collected during screening (and intervention for blood pressure): the participant's blood cholesterol, blood pressure, physical activity, smoking status and alcohol consumption. The blood pressure values are the average of the participant's blood pressure measurements. The recommendations are based on this average. It is important to point out to the participant that the blood pressure may have varied during the feeding periods, but at this time of the study the actual blood pressures cannot be provided. The participant receives all the blood pressure information and diet assignment at the end of the study. See the specific recommendations below for more detail.

Exit Interview Height/Weight Table (Form #124)

Distribute the Exit Interview Height/Weight Table (Form #124) with the Health Risk Assessment Report. At the bottom of the first page of the Health Risk Assessment is the participant's height and averaged weight. The participant can use the Exit Interview Height/Weight Table (Form #124) to determine his or her optimal weight for height. It is important to note the recommendations for the optimal weight for height are based on the general population and are not specific for gender or race. If the Health Risk Assessment report is mailed to the participant, include this form.

Action Planning Worksheet (Form #122)

Use the Action Planning Worksheet (Form #122) if the participant is interested in making a behavior change. The form is a guide to help the participant make a reasonable, concrete goal that is achievable. Have the participant complete the form at the interview. This allows the

counselor to help the participant make a feasible goal and identify barriers that can interfere with achieving the goal.

Educational Materials

Educational materials are used during the Exit Interview and distributed centrally by the Coordinating Center. A clinical center can choose to provide additional health educational materials at this session or mail to the participant if he or she doesn't attend the group Exit Interview.

Health Risk Assessment Cover Letter (Form #126)

Although attendance at the group session is not mandatory, staff will make every effort to get participants to attend. When participants are unable to attend a group or individual Exit Interview, mail the two-page Health Risk Assessment report with the Health Risk Assessment cover letter (Form #126). If possible, followup with the participant to see that the report is received and to find out if the participant has questions and is interested in making a behavior change.

Recommendations for Heart Disease Risk Reduction

The dietary recommendations for cardiovascular risk reduction are based on the DASH diet. Other recommendations come from appropriate organizations. They are individualized for the participant and printed on their Health Risk Assessment. These recommendations are below. The text in italics are the statements that appear in the Health Risk Assessment based on the participant's risk factors.

Blood Cholesterol Recommendations

If blood cholesterol is $\geq$ 200 mg/dl:

"The desirable cholesterol level is: less than 200 mg/dl. For most people, lowering blood cholesterol level will reduce the risk of heart disease. We encourage you to see your physician to have your cholesterol checked. Also consider making lifestyle changes such as reducing saturated fat, losing weight, or increasing physical activity as a way of reducing your cholesterol level and risk of heart disease.

If blood cholesterol is <200 mg/dl:

"The desirable cholesterol level is: less than 200 mg/dl. Good work! For most people, keeping the cholesterol below this level will reduce the risk of heart disease. Lifestyle patterns such as reducing saturated fat, maintaining or losing weight, and increasing physical activity will help you keep your risk down."

Blood Pressure Recommendation

If blood pressure is <120 (systolic) and <80 (diastolic):

"Your blood pressure values place you in the optimal category (systolic less than 120 and diastolic less than 80). This is great news for your health. Some things you can do to keep it in the optimal range are to get daily physical activity, limit alcohol consumption, eat the DASH way (see first page of this assessment), reduce sodium intake, and lose weight if you are overweight."

If blood pressure is <130 (systolic) and <85 (diastolic):

"Your blood pressure values place you in the normal category (systolic less than 130 and diastolic less than 85). This is good news for your health. Some things you can do to keep it in the normal range are to get daily physical activity, limit alcohol consumption, eat the DASH way (see first page of this assessment), reduce sodium intake, and lose weight if you are overweight."

If blood pressure is 130-139 (systolic) and 85-89 (diastolic):

"Your blood pressure values place you in the high normal category (systolic 130-139 or diastolic 85-89). We encourage you to consider making some lifestyle changes such as increasing physical activity, reducing alcohol consumption, eating the DASH way (see first page of this assessment), reducing sodium intake, and/or losing weight if you are overweight. Any of these changes may reduce your blood pressure."

If blood pressure is ≥140 (systolic) and ≥ 90 (diastolic):

"Your blood pressure values place you in the hypertensive category (systolic greater than or equal to 140 and diastolic greater than or equal to 90). We strongly recommend that you visit your physician to discuss your blood pressure. We also encourage you to consider making some lifestyle changes such as increasing physical activity, reducing alcohol consumption, eating the DASH way (see first page of this assessment), reducing sodium intake, and/or losing weight if you are overweight. Any of these changes may reduce your blood pressure."

Physical Activity Recommendation

If physical activity is ≥ 2.5 hours per week:

"Positive health benefits are gained with 2.5 hours per week of moderate-to-vigorous physical activity (at least as strenuous as a brisk walk). You are doing a good job! Keep it up. Continued activity will provide continued benefits."

If physical activity is <2.5 hours per week:

"Positive health benefits are gained with 2.5 hours per week of moderate-to-vigorous physical activity (at least as strenuous as a brisk walk). We encourage you to find a way to increase your physical activity. Walking, dancing, mowing the lawn, gardening, heavy housework – all these activities count!"

Recommendations Regarding Smoking

If the participant is not a current smoker:

"Good choice! Not smoking is one of the best things you can do for your health. It is also important to note that minimizing your exposure to second-hand smoke will have a positive impact on your health."

If the participant is a current smoker:

"As you might guess, we encourage you to quit smoking. It is one of the most important things you can do for your health. Many people have been able to quit, and when you are ready, we're confident you can too. It may be difficult, but there are many options available to help you."

Recommendations on Alcohol Consumption

"It is recommended that a person drink no more than 2 standard drinks (12 oz of beer, 5 oz of wine, 1 1/2 oz liquor) a day. We encourage you to continue doing that."

Recommendations Regarding Weight

The actual recommendation regarding weight is not written on the Health Risk Assessment. It is written on the Exit Interview Height/Weight Table (Form #124), which has the height/weight table and the recommendations. The text of this is below.

"At the bottom of the first page of your personalized health risk assessment is your average weight during the duration of DASH2 and your height. We encourage you to look at the table below for the recommendation for optimal weight for you. This information is based on the general population but will give you a good range to work with.

If your weight is within the optimal range that is great news. Staying physically active and limiting the fat in your diet can help you stay within that range.

If your weight is either below or above the optimal range, we encourage you to consider making some lifestyle changes that will help you get to the optimal range. There are many options for doing that and we would be happy to discuss those with you."

End of Trial Close-out

At the conclusion of the entire trial, the clinical centers provide additional information to participants beyond that provided at the end of cohort feeding. Such information can be provided in the context of a meeting or mailing. In both instances, include a summary of trial results and information specific to the individual. A general description of the diet in lay terms is provided. At this time, participants also receive a listing of their individual blood pressure responses to each intervention.

Premature Study Termination

Participants who suffer a morbid event with a lasting effect on blood pressure (e.g., myocardial infarction, stroke), who start on blood pressure medications, or who die during the study are considered terminated as of the date of the morbid/mortal event or start of medications. Where possible, these individuals and any other participants who are unable to complete the study for any reason should receive an end-of-study briefing similar to that described above. This briefing should occur as soon after the terminating event as the participant's condition permits. It need not be done as a face-to-face meeting, however; the information may be sent by mail.

As with other participants, these individuals should be told their average blood pressure since SV1 and be counseled about ways to reduce cardiovascular disease risk.

Note also that for anyone who drops out of the study prematurely, for whatever reason, DASH2 personnel should try to obtain a complete set of end-of-study measurements. If this is not possible, first priority should be given to collecting the five end-of-study blood pressure measurements.

39. CHEMICAL ANALYSES OF DIET 2

39. CHEMICAL ANALYSES OF DIET

Pre-Feeding Menu Validation

Target nutrient concentrations are chemically analyzed in the eight menus developed for each of the six dietary treatments (Control and Combination diets, each at "lower," "intermediate," and higher sodium levels. See Table 39-1**.** These data are used to validate nutrient concentrations in the prepared daily menus and select to the subset of seven menus to be used for intervention feeding.

Sampling Design

The eight menus for each diet (Control and Combination) and sodium level (lower, intermediate, and higher) at the 2100 and 3100 kcal energy levels and the eight menus for the 1600 kcal level of each diet at the lower sodium level are prepared for validation prior to intervention. Each set of eight menus is prepared in duplicate, with the two sets being generated at separate centers, according to the schedule summarized in Table 39-1. Thus, a total of 224 menus are sampled for validation.

Menu Preparation, Collection, Shipment, and Analysis

The menus are prepared according to the food specifications summarized in the DASH2 Diet MOP, Chapter 40, Food Procurement, Safety and Preparation. Each menu is collected and frozen individually, then shipped frozen to the Food Analysis Laboratory Coordinating Center (FALCC) according to FALCC Standard Operating Procedure (SOP) #1035, located at the end of this chapter. At the FALCC, menus are homogenized individually and assayed for total fat, moisture, protein, ash, sodium, potassium, magnesium, and calcium; total carbohydrates and total energy are calculated values. Assay methods are described in the Chemical Analysis of Menu and Diet Samples section of this chapter. Selected menus indicated in Table 39-1 are also assayed for fatty acids (total saturated, total monounsaturated, and total polyunsaturated) and cholesterol, but these data are not used for menu selection.

Menu Selection

Menus in which nutrient concentrations fall outside any of the targeted ranges for calcium, magnesium, potassium, sodium, and total fat in the assayed samples are omitted or re-formulated and re-assayed until the nutrient concentrations are acceptable. Food costs, product availability, labor costs and production time, as well as results of taste-testing studies, are considered in selecting the final 7-day menu cycle for intervention from among the menus meeting nutrient specifications.

Table 39-1. Sampling and Analysis Plan for Menu Validation

Diet	Na Level	Kcal Level	# of Menus	Moisture	Protein	Ash	Total Fat	Fatty Acids (SFA,MUFA, PUFA)	Chol	Na	K	Mg	Ca	Ctr 1	Ctr 2
Control	Lower	1600	8	X	X	X	X	X	X	X	X	X	X	PBRC	JHU
Control	Lower	2100	8	X	X	X	X			X	X	X	X	PBRC	JHU
Control	Lower	2600													
Control	Lower	3100	8	X	X	X	X	X	X	X	X	X	X	DUKE	BWH
Control	Lower	3600													
Control	Intermediate	1600													
Control	Intermediate	2100	8	X	X	X	X	X	X	X	X	X	X	DUKE	BWH
Control	Intermediate	2600													
Control	Intermediate	3100	8	X	X	X	X			X	X	X	X	PBRC	JHU
Control	Intermediate	3600													
Control	Higher	1600													
Control	Higher	2100	8	X	X	X	X			X	X	X	X	PBRC	JHU
Control	Higher	2600													
Control	Higher	3100	8	X	X	X	X			X	X	X	X	DUKE	BWH
Control	Higher	3600													
Combination	Lower	1600	8	X	X	X	X	X	X	X	X	X	X	DUKE	BWH
Combination	Lower	2100	8	X	X	X	X			X	X	X	X	DUKE	BWH
Combination	Lower	2600													
Combination	Lower	3100	8	X	X	X	X	X	X	X	X	X	X	PBRC	JHU
Combination	Lower	3600													
Combination	Intermediate	1600													
Combination	Intermediate	2100	8	X	X	X	X	X	X	X	X	X	X	DUKE	BWH
Combination	Intermediate	2600													
Combination	Intermediate	3100	8	X	X	X	X			X	X	X	X	PBRC	JHU
Combination	Intermediate	3600													
Combination	Higher	1600													
Combination	Higher	2100	8	X	X	X	X		X	X	X	X	X	DUKE	BWH
Combination	Higher	2600													
Combination	Higher	3100	8	X	X	X	X		X	X	X	X	X	PBRC	JHU
Combination	Higher	3600													

Re-validation

Approximately 23% of the 228 composites prepared for menu validation deviated from target sodium levels by 15% or more. A plan was prepared to re-align the aberrant menus with the DASH2 sodium goals and address the volatility of sodium content in processed food within the validation budget. The plan was as follows:

1. Aberrant menus were identified as follows:
   - lower sodium menus that deviated from target sodium by 30%
   - medium sodium menus that deviated from target sodium by 20%
   - higher sodium menus that deviated from target sodium by 15%

This exercise focused on problem foods within the aberrant menus and identified potential quality control problems at individual sites. Nine menus (18 composites) were identified for which both sites that prepared the food for validation were off target.

2. Discrepant menus were reviewed for potential culprit foods that contribute to the sodium deviation.

3. To control variance and error in sodium levels, normal sodium foods, such as bouillon, pretzels, nuts and pickles, were replaced with their salt-free counterparts, and the lost sodium was replaced with known amounts of salt on all menus. This was done not just for the aberrant menus, but all the study menus.

4. Four of the discrepant menus were reformulated by comparing sodium from food labels to the study database sodium values, and adjusting the sodium content of the menus to fit the food label estimates.

5. The four menus were assayed, both in their original version and reformulated version. This included replacing normal sodium foods with their salt-free counterpart, as outlined in Step 3 above.

6. A revised FALCC standard operating procedure (SOP) was created that included the re-validation plan. SOP 1038 replaced the 1035 version.

7. Because the reformulation seemed to work well (the reformulation menus were close to target sodium levels), the food label reformulation was applied to all menus.

8. A quality assurance protocol is now in place to tighten the range of food brands, standardize food preparation and production, and monitor food labels for changes in product formulation that affect key nutrient levels (e.g.; Na).

Table 39-2 is the sampling plan used for re-validation of the sub-set of menus for sodium. The menus were prepared and analyzed for sodium and moisture. Two of the menus were prepared in both their original and revised version for quality control.

In summary, based on the results of the initial validation analyses, a sub-set of menus was re-formulated and re-assayed for sodium content. Additionally, all menus were reformulated with a revised design strategy to minimize deviations from target and across centers. See Steps 3 through 7.

Table 39-2. Sampling Plan for Menu Re-validation

Diet	Sodium Level	kcal Level	Menu number	Version	Preparation for Validation		
					Center 1	Center 2	Center 3
Control	Higher	3100	8 (EXTRA)	Revised	BWH	JHU	
Control	Higher	3100	4 (WED)	Revised	BWH	JHU	
Control	Higher	3100	4 (WED)	Original	BWH	JHU	
Combination	Higher	3100	5 (THURS)	Revised	JHU	DUKE	PBRC
Combination	Lower	3100	2 (MON)	Revised	BWH	JHU	
Combination	Lower	3100	2 (MON)	Original	BWH	JHU	
Control	Lower	1600	1 (SUN)	Revised	PBRC		

Energy Cookie Validation

The nutrient composition of the energy cookies for each of the six dietary treatments is validated prior to intervention. For each energy cookie, two batches are prepared, one replicate from each of two clinical centers. The cookie samples are frozen and shipped to the FALCC for chemical analysis. Table 39-3 summarizes the sampling plan for energy cookie validation. Each energy cookie batch is homogenized and assayed for total fat, moisture, protein, ash, sodium, potassium, magnesium, and calcium. For purpose of documentation, the intermediate sodium level energy cookie for each diet is also assayed for fatty acids and cholesterol. Analytical methods are described in Table 39-3. Any energy cookie not meeting target nutrient criteria is re-formulated and re-assayed until the nutrient composition is acceptable.

Table 39-3. Sampling and Analysis Plan for Energy Cookie Validation

Diet	Na Level	Kcal Level	# of Menus	Moist	Protein	Ash	Total Fat	Fatty Acid (SFA,MUFA, PUFA)	Chol	Na	K	Mg	Ca	Ctr 1	Ctr 2
Control	Lower	N/A	N/A	X	X	X	X		X	X	X	X	X	DUKE	JHU
Control	Inter-mediate	N/A	N/A	X	X	X	X	X	X	X	X	X	X	BWH	PBRC
Control	Higher	N/A	N/A	X	X	X	X		X	X	X	X	X	DUKE	JHU
Combination	Lower	N/A	N/A	X	X	X	X		X	X	X	X	X	BWH	PBRC
Combination	Inter-mediate	N/A	N/A	X	X	X	X	X	X	X	X	X	X	DUKE	BWH
Combination	Higher	N/A	N/A	X	X	X	X		X	X	X	X	X	BWH	PBRC

Diet Monitoring during Intervention

Because nutrient levels may vary over time, both as a result of variation in foods available and as a consequence of local preparation practices, the diets are monitored on a regular basis during the intervention phase of the trial to document the nutrient levels delivered throughout the study.

Cohort 1 Sampling Design

An ideal sampling plan samples each DASH2 diet at least once. However, budget constraints do not allow such intensive sampling. The monitoring plan shown in Tables 39-4 and 39-5 samples each of the three energy levels consumed by 85% of the DASH2 participants in a manner that attempts to balance the number of times each of the sodium level diet arms, energy levels and clinical sites are sampled.

Table 39-4. Cohort 1 Control Diet Monitoring Schedule Design

	2100 kcal			2600 kcal			3100 kcal		
Cohort	**Lo Na**	**Md Na**	**Hi Na**	**Lo Na**	**Md Na**	**Hi Na**	**Lo Na**	**Md Na**	**Hi Na**
1	ab	ab	ab	cd	cd	cd			
2				cd	cd	cd	ab	ab	ab
3	bd	bd	bd				ac	ac	ac
4	c	c	c	ab	ab	ab	d	d	d

Site a = Baltimore
Site b = Baton Rouge
Site c = Boston
Site d = Duke

Lo = lower sodium
Md = intermediate sodium
Hi = higher sodium

Table 39-5. Cohort 1 Combination Diet Monitoring Schedule Design

	2100 kcal			2600 kcal			3100 kcal		
Cohort	**Lo Na**	**Md Na**	**Hi Na**	**Lo Na**	**Md Na**	**Hi Na**	**Lo Na**	**Md Na**	**Hi Na**
1	cd	cd	cd	ab	ab	ab			
2				bd	bd	bd	ac	ac	ac
3	ab	ab	ab				cd	cd	cd
4	d	d	d	ac	ac	ac	b	b	b

Site a = Baltimore
Site b = Baton Rouge
Site c = Boston
Site d = Duke

Lo = lower sodium
Md = intermediate sodium
Hi = higher sodium

Each dietary treatment is sampled once per cohort at each site, according to the site-specific schedule summarized in Table 39-6, 39-7, 39-8, and 39-9. A total of 24 diet samples per cohort are collected. Each sample comprises one full diet cycle (7 daily menus). The sampling design is balanced across energy levels within each dietary treatment, and the 6 samples per center per cohort are divided equally across the three feeding periods within a cohort.

Table 39-6. Diet Monitoring Schedule Cohort 1- Baltimore (JHU)

Cohort	Feeding Period	Week	Diet	Na^+ Level	kcal Level
1	1	2	Control	Lo	2100
1	1	3	Combination	Lo	2600
1	2	2	Control	Md	2100
1	2	3	Combination	Inter	2600
1	3	2	Control	Hi	2100
1	3	3	Combination	Hi	2600

Na+ Level : Lo = Lower sodium level
Inter = Intermediate sodium level
Hi = Higher sodium level

Table 39-7. Diet Monitoring Schedule Cohort 1- Baton Rouge (PBRC)

Cohort	Feeding Period	Week	Diet	Na^+ Level	kcal Level
1	1	2	Control	Lo	2100
1	1	3	Combination	Lo	2600
1	2	2	Control	Inter	2100
1	2	3	Combination	Inter	2600
1	3	2	Control	Hi	2100
1	3	3	Combination	Hi	2600

Na+ Level : Lo = Lower sodium level
Inter = Intermediate sodium level
Hi = Higher sodium level

Table 39-8. Diet Monitoring Schedule Cohort 1 -Boston (BWH)

Cohort	Feeding Period	Week	Diet	Na^+ Level	kcal Level
1	1	2	Control	Lo	2600
1	1	3	Combination	Lo	2100
1	2	2	Control	Inter	2600
1	2	3	Combination	Inter	2100
1	3	2	Control	Hi	2600
1	3	3	Combination	Hi	2100

Na+ Level : Lo = Lower sodium level
Inter = Intermediate sodium level
Hi = Higher sodium level

Table 39-9. Diet Monitoring Schedule Cohort 1- Durham (DUKE)

Cohort	Feeding Period	Week	Diet	Na^+ Level	kcal Level
1	1	2	Control	Lo	2600
1	1	3	Combination	Lo	2100
1	2	2	Control	Inter	2600
1	2	3	Combination	Inter	2100
1	3	2	Control	Hi	2600
1	3	3	Combination	Hi	2100

Na+ Level : Lo = Lower sodium level
Inter = Intermediate sodium level
Hi = Higher sodium level

Cohort 2 Sampling Design

The original menu monitoring plan for DASH2 was designed to collect enough composited samples for laboratory analysis to demonstrate, at the end of the trial, that good separation had been achieved with regard to the targeted sodium levels in the lower, intermediate, and higher sodium groups. Original funding permitted only 24 samples per cohort to be processed. However, the results from Cohort 1 prompted the Steering Committee to request additional funds to double the number of samples analyzed in Cohort 2. The Cohort 2 Monitoring Design and justification is outlined in Appendix A. See Table 39-10 through 39-13 for each site's specific monitoring schedule.

Table 39-10. Diet Monitoring Schedule Cohort 2 –Baltimore (JHU)

Cohort	Feeding Period	Week	Diet	Na+ Level	kcal Level
2	1	1	Combination	Lo	2100
2	1	2	Control	Lo	3100
2	1	3	Combination	Lo	3100
2	1	4	Control	Lo	2100
2	2	1	Combination	Inter	2100
2	2	2	Control	Inter	3100
2	2	3	Combination	Inter	3100
2	2	4	Control	Inter	2100
2	3	1	Combination	Hi	2100
2	3	2	Control	Hi	3100
2	3	3	Combination	Hi	3100
2	3	4	Control	Hi	2100
3	1	1	Combination	Lo	2600
3	1	2	Control	Lo	3100
3	1	3	Combination	Lo	2100
3	1	4	Control	Lo	2600
3	2	1	Combination	Inter	2600
3	2	2	Control	Inter	3100
3	2	3	Combination	Inter	2100
3	2	4	Control	Inter	2600
3	3	1	Combination	Hi	2600
3	3	2	Control	Hi	3100
3	3	3	Combination	Hi	2100
3	3	4	Control	Hi	2600
4	1	1	Combination	Lo	1600
4	1	2	Control	Lo	2600
4	1	3	Combination	Lo	2600
4	1	4	Control	Lo	1600
4	2	1	Combination	Inter	1600
4	2	2	Control	Inter	2600
4	2	3	Combination	Inter	2600
4	2	4	Control	Inter	1600
4	3	1	Combination	Hi	1600
4	3	2	Control	Hi	2600
4	3	3	Combination	Hi	2600
4	3	4	Control	Hi	1600

Table 39-11 Diet Monitoring Schedule Cohort 2 - Baton Rouge (PBRC)

Cohort	Feeding Period	Week	Diet	Na+ Level	kcal Level
2	1	1	Combination	Lo	2100
2	1	2	Control	Lo	3100
2	1	3	Combination	Lo	2600
2	1	4	Control	Lo	1600
2	2	1	Combination	Inter	2100
2	2	2	Control	Inter	3100
2	2	3	Combination	Inter	2600
2	2	4	Control	Inter	1600
2	3	1	Combination	Hi	2100
2	3	2	Control	Hi	3100
2	3	3	Combination	Hi	2600
2	3	4	Control	Hi	1600
3	1	1	Combination	Lo	1600
3	1	2	Control	Lo	2100
3	1	3	Combination	Lo	2100
3	1	4	Control	Lo	2600
3	2	1	Combination	Inter	1600
3	2	2	Control	Inter	2100
3	2	3	Combination	Inter	2100
3	2	4	Control	Inter	2600
3	3	1	Combination	Hi	1600
3	3	2	Control	Hi	2100
3	3	3	Combination	Hi	2100
3	3	4	Control	Hi	2600
4	1	1	Combination	Lo	1600
4	1	2	Control	Lo	2600
4	1	3	Combination	Lo	3100
4	1	4	Control	Lo	1600
4	2	1	Combination	Inter	1600
4	2	2	Control	Inter	2600
4	2	3	Combination	Inter	3100
4	2	4	Control	Inter	1600
4	3	1	Combination	Hi	1600
4	3	2	Control	Hi	2600
4	3	3	Combination	Hi	3100
4	3	4	Control	Hi	1600

Table 39-12 Diet Monitoring Schedule Cohort 2 - Boston (BWH)

Cohort	Feeding Period	Week	Diet	Na+ Level	kcal Level
2	1	1	Combination	Lo	1600
2	1	2	Control	Lo	2100
2	1	3	Combination	Lo	3100
2	1	4	Control	Lo	2600
2	2	1	Combination	Inter	1600
2	2	2	Control	Inter	2100
2	2	3	Combination	Inter	3100
2	2	4	Control	Inter	2600
2	3	1	Combination	Hi	1600
2	3	2	Control	Hi	2600
2	3	3	Combination	Hi	3100
2	3	4	Control	Hi	2100
3	1	1	Combination	Lo	2600
3	1	2	Control	Lo	3100
3	1	3	Combination	Lo	3100
3	1	4	Control	Lo	1600
3	2	1	Combination	Inter	2600
3	2	2	Control	Inter	3100
3	2	3	Combination	Inter	3100
3	2	4	Control	Inter	1600
3	3	1	Combination	Hi	2600
3	3	2	Control	Hi	3100
3	3	3	Combination	Hi	3100
3	3	4	Control	Hi	1600
4	1	1	Control	Lo	3100
4	1	2	Control	Lo	2100
4	1	3	Combination	Lo	2600
4	1	4	Combination	Lo	2100
4	2	1	Control	Inter	3100
4	2	2	Control	Inter	2100
4	2	3	Combination	Inter	2600
4	2	4	Combination	Inter	2100
4	3	1	Control	Hi	3100
4	3	2	Control	Hi	2100
4	3	3	Combination	Hi	2600
4	3	4	Combination	Hi	2100

Table 39-13. Diet Monitoring Schedule Cohort 2 - Durham (Duke)

Cohort	Feeding Period	Week	Diet	Na+ Level	kcal Level
2	1	1	Combination	Lo	1600
2	1	2	Control	Lo	2600
2	1	3	Combination	Lo	2600
2	1	4	Control	Lo	1600
2	2	1	Combination	Inter	1600
2	2	2	Control	Inter	2600
2	2	3	Combination	Inter	2600
2	2	4	Control	Inter	1600
2	3	1	Combination	Hi	1600
2	3	2	Control	Hi	2600
2	3	3	Combination	Hi	2600
2	3	4	Control	Hi	1600
3	1	1	Combination	Lo	1600
3	1	2	Control	Lo	2100
3	1	3	Combination	Lo	3100
3	1	4	Control	Lo	1600
3	2	1	Combination	Inter	1600
3	2	2	Control	Inter	2100
3	2	3	Combination	Inter	3100
3	2	4	Control	Inter	1600
3	3	1	Combination	Hi	1600
3	3	2	Control	Hi	2100
3	3	3	Combination	Hi	3100
3	3	4	Control	Hi	1600
4	1	1	Combination	Lo	2100
4	1	2	Control	Lo	3100
4	1	3	Control	Lo	2100
4	1	4	Combination	Lo	3100
4	2	1	Combination	Inter	2100
4	2	2	Control	Inter	3100
4	2	3	Control	Inter	2100
4	2	4	Combination	Inter	3100
4	3	1	Combination	Hi	2100
4	3	2	Control	Hi	3100
4	3	3	Control	Hi	2100
4	3	4	Combination	Hi	3100

Menu Preparation, Collection, Shipment, and Analysis

Menus for diet monitoring are prepared exactly like those for participants' consumption, and collected according to the FALCC Standard Operating Procedure 1038 (included at the end of this chapter). Each daily menu is frozen individually, and the 7-day menu set constituting each diet cycle sample is shipped frozen to the FALCC for analysis. For Cohort 1 the FALCC homogenizes the menus into 7-day diet cycle composites, which are assayed for total fat, moisture, protein, ash, sodium, potassium, magnesium, and calcium. Total carbohydrates and total energy are calculated values. In Cohort 2 the additional samples collected in Weeks 1 and 4 are assayed for total weight, moisture, sodium, potassium, magnesium and calcium. Analytical methods are described below.

Energy Cookie Monitoring

Energy cookies are sampled throughout intervention to document the average composition by diet and sodium level.

Sampling Design

During each cohort, for each diet-sodium level, each center randomly samples one energy cookie from each of two batches. Thus, each site collects a total of two cookies per diet-sodium level per cohort. At each site, the cookie samples for a diet-sodium level are collected into a single airtight, zip-lock freezer storage bag and held frozen (-20^{o}C or lower) until the end of Cohort 4, when they are shipped frozen to the FALCC for compositing and chemical analysis. Each site maintains a log for each diet-sodium level indicating the dates and number of cookies added to the collection bag. A copy of each log sheet is shipped to the FALCC with the samples.

Compositing and Analysis

At the FALCC, the energy cookies are composited by diet-sodium level. The result is a total of six composites, each composed of 32 cookies (eight from each center). Each composite is assayed for total fat, moisture, protein, ash, sodium, potassium, magnesium and calcium. Total carbohydrates and total energy are calculated values. Analytical methods are described below.

Chemical Analysis of Menu and Diet Samples

Units of reporting assayed and calculated nutrient contents are summarized in Table 39-14. All procedures used in the chemical analysis of diet samples are fully documented by Standard Operating Procedures (SOPs) at the FALCC. Relevant FALCC SOPs are listed in Table 39-15. Only copies of the procedures used by the clinics are included at the end of this chapter.

Table 39-14. Assayed and Calculated Unit Values

ASSAYED COMPONENT	UNITS
Na, K, Ca, Mg	mg/100g dry weight
Total Fat	g/100g dry weight
Total SFA	g/100g dry weight (triacylglycerols)
Total MUFA	g/100g dry weight (triacylglycerols)
Total PUFA	g/100g dry weight, (triacylglycerols)
Cholesterol	mg/100g dry weight
Protein	g/100g dry weight
Ash	g/100 g dry weight
Moisture	g/100g
Total Weight	grams
CALCULATED COMPONENT	**UNITS**
Na, K, Ca, Mg	mg/menu
Cholesterol	mg/menu
Total Carbohydrate	g/100g dry weight, % of total kcal
Total Energy	kcal
Total Fat	% of total kcal
SFA	% of total kcal
MUFA	% of total kcal
PUFA	% of total kcal

Compositing and Homogenization

A menu is an entire day's food (breakfast, lunch, dinner, snacks). For diet validation, each menu is homogenized individually. Energy cookie samples are composited by diet/sodium level/center. For diet monitoring during intervention, the 7-day diet cycle of menus sampled for a given diet-kcal level at a given center (see Diet Monitoring section above) is composited and homogenized. Homogenization and subsampling procedures are designed to provide uniform subsamples for each of the assays and are detailed by FALCC SOPs #5005, #5029, #5038, #5028, #5048 (see SOP list at end of chapter).

Sample Storage

Before homogenization, menus are stored at -20^{o}C. Homogenized food samples are stored at -60^{o}C.

Archive Samples

Five (5) 20-25g samples of each diet homogenate are archived for the duration of the DASH2 study and for two years after the close of the study. The archive samples are stored at -60^{o}C in a secure location designated by the FALCC principal investigator. The archive samples are the property of the DASH2 principal investigators, and the dispensation of archive samples requires approval of the DASH2 Steering Committee.

Assay Samples

Assay samples are those designated for the nutrient assays specified in subsequent sections.

Reserve Samples

Reserve samples are extra samples taken from each composite to accommodate any necessary repeat assays, additional analysis of ancillary nutrients, method development and validation assays, etc. A minimum of eight (8) reserve samples is taken from each homogenate. Reserve samples are used at the discretion of the FALCC principal investigator without approval of the Steering Committee.

Assay Methods and Validation

Minerals (Na, K, Ca, Mg)

Method

Sodium, potassium, calcium, and magnesium are determined in wet-ashed diet composites using inductively coupled plasma spectroscopy (ICP) (FALCC SOP #5035). Two aliquots of each composite are assayed. The ICP analysis of digested samples is subcontracted to the Department of Crop and Soil Environmental Science at VPI & SU. The FALCC includes blinded standards and control material(s) in each assay batch.

Validation

Validation of the method is based on analyses of a standard mixed diet reference material (NIST SRM #1548) and infant formula (NIST SRM #1846), yielding results for Na, K, Ca, and Mg which are within the certified range of uncertainty. Note: In initial analysis of SRM #1548, Ca mean was high by 0.5%. Recovery of each of the above minerals spiked into mixed diet composites including two DASH pilot menu composites (Control and Combination) were >98% for each element. Additionally, five selected diet composites (including those with higher and lower lipid content) were independently analyzed by an expert outside lab, USDA Food Composition Laboratory (FCL). FALCC values were 100.5% of FCL values for Na, 105% for Ca, 101% for Mg, and 114% for K for each sample assayed.

Total Fat

Method

Total fat is determined gravimetrically as total lipid extracted by chloroform/methanol using a modification of Association of Official Analytical Chemists' method 983.23 (FALCC SOP #5024). Each composite is assayed in duplicate.

Validation

Validation of the method is described in the publication by Phillips et al. [J. Amer. Oil Chem. Soc. 74:137-42 (1997)].

Moisture

Method

Moisture in diet composites is determined using a microwave moisture/solids analyzer (CEM Labwave 9000, CEM Corp.) (FALCC SOP #5007). Moisture in energy cookie composites is determined by vacuum oven drying (FALCC SOP #5002). Moisture is measured in triplicate aliquots of each composite. The mean assayed moisture content is used to calculate all assay results for the composite on a dry weight basis.

Validation

Validation is based upon agreement within 0.5% of results by microwave drying (FALCC SOP #5007). Validation is also based on agreement from conventional vacuum oven drying (e.g., AOAC 934.01, modified; FALCC SOP #5002), and agreement within 2% of independently determined moisture values for a reference sample (#Q93-FR-4495) supplied by the USDA Food Composition Laboratory (FCL). Homogeneity and stability of moisture content in diet composite samples prepared and stored according to FALCC SOPs has been tested and documented as well.

Protein

Method

Protein is determined as Kjeldahl nitrogen multiplied by 6.25 (FALCC SOP #5023, or sub-contract to Covance, Madison, WI). If the assay is subcontracted, a blinded control sample is included in each assay batch.

Validation

Validation of the method is based on results obtained for NIST SRM #1548 being within the certified range, and results for a reference material within 5% of the value determined independently by the USDA FCL.

Ash

Method

Ash is determined as residual weight after incineration of duplicate aliquots of each homogenate at 550^{o}C overnight in a muffle furnace (FALCC SOP #5011).

Validation

Validation is based upon results for NIST SRM #1548 (total diet reference material) within the certified range, and within 5% for the ash content of a reference sample analyzed independently by the USDA FCL.

Cholesterol

Method

Cholesterol is assayed in duplicate aliquots of each composite, using the total lipid extract in which total fat was quantified gravimetrically (see above). Cholesterol is determined after saponification of the total lipid extract and derivatization of sterols to the trimethylsilyl ethers, using gas-liquid chromatography with dihydrocholesterol as an internal standard [modification of the method of Thompson and Merola, J Assoc Off Anal Chem Intl 76:1057-68 (1993); FALCC SOP #5026].

Validation

Validation of the method is based on >95% recovery of cholesterol spiked into mixed diet composites, results for standard reference material (fortified coconut oil, NIST SRM #1563-2) within the certified range, agreement of results within 5% with those obtained by FCL for selected diet samples.

Fatty Acids (Saturated, Monounsaturated, Polyunsaturated)

Method

Fatty acids are assayed in duplicate aliquots of each composite, using the total lipid extract from which total fat was quantified gravimetrically (see above). Fatty acids are determined as methyl esters (FAME) after saponification of the total lipid extract and derivatization with BF_3/methanol using gas-liquid chromatography with C19:0 as an internal standard [modification of AOCS method Ce-1b; FALCC SOP #5055]. FAME are reported as triacylglycerol equivalents, normalized to the total fat content (determined as described above), and summed as follows to yield total saturated fatty acids (SFA): C10:0, C11:0, C12:0, C13:0, C14:0, C15:0, C16:0, C17:0, C18:0, C20:0, C22:0, C24:0; total monounsaturated fatty acids (MUFA): C14:1, C16:1, C17:1, C18:1, C19:1, C20:1, C22:1; and l polyunsaturated fatty acids (PUFA): C18:2, C18:3n-3, C20:2, C20:3, C20:4, C20:5n-3, C22:6,
C22:6n-3.

Validation

Validation is based on >90% recovery of fatty acids from canola oil, menhaden oil, and coconut oil spiked into diet composites. Calibration of the gas chromatograph is validated with every batch of samples, by assaying a solution of a commercially available reference standard (#GLC-85, from Nuchek Prep, Elysian, MN) and obtaining results within 2% of known values for each FAME quantified by the method.

Quality Control/Quality Assurance

Quality Control Material and Quality Control Charts

For each assay, an appropriate blinded control sample(s) (mixed diet composite) is included in every batch of samples or every 20 samples, whichever is less. A quality control (QC) chart for this material is established for each assay: Prior to running samples, a minimum of 15 samples of the control material are assayed, according to the assay SOP. The mean and +/-2SD and +/-3SD of these data are calculated and used to generate a QC chart (assayed control sample value vs. assay date). Subsequently, the value for the control material in each assay batch is plotted on the QC chart. If the control value falls outside the +/-3SD limits, all data from that assay batch are rejected and samples are re-assayed. Assay results are also rejected if the relative standard deviation of results for within-composite replicates is unacceptable (>5% in general). The QC chart is also used by the QA/QC officer and PI to evaluate assay stability. If notable drift is detected, then sample assays are stopped until the assay system has been checked and any problems have been corrected.

Blinded Samples

Analysts are blinded to the identity of samples. Samples are labeled only with sequential numbers, which are linked to identifying information in the FALCC sample database.

Standard Operating Procedures (SOP)

The FALCC documents each procedure with a detailed SOP. Each SOP is approved and signed by the FALCC project director or designated senior lab personnel. Originals are kept in a central notebook in a fire-safe cabinet. Disk copies of SOPs are also maintained. Non-current SOPs are archived. See SOP list at the end of this chapter.

Other Quality Assurance Procedures

In addition to validation and full documentation of each analytical method and control and replicate analyses as described above, a number of other QA/QC measures are taken. These include periodic blinded re-runs, independent review of all calculations and numeric transcriptions, complete documentation of sample handling and analysis in laboratory bench books by individual analysts, weekly instrument and equipment calibration, and daily monitoring of the temperature of refrigerators and freezers (Monday-Saturday). A freezer back-up protocol is in place to prevent sample loss in the event of freezer failure.

An audit trail is maintained between samples as-received and data reported. A custom database is used to assign a unique number to each sample and maintain a link between any given whole food sample received for analysis and its composited subsamples and associated analytical data. Assay data are linked to samples via an assay batch number reported with each value.

Electronic data are stored on hard drive and/or floppy disks. A minimum of two copies of each file are maintained. Computers are backed up weekly on tape. Disk copies and/or hard copies of all data are archived in fire-safe cabinets.

Table 39-15. Relevant FALCC SOP Numbers and Titles as of June 16, 1997

SOP Number	SOP Title
1003a	Programming and Calibration of Hamilton Microlab 910
1003b	Use of Hamilton Microlab 910
1006	Maintenance Protocol for Balance Calibration
1008	Using the Sartorius Basic Analytical Balance
1010	Using the Sartorium Model R200D Semi-Microbalance (M1-31-3)
1012	Maintenance Protocol for Balance and Refrigeration Calibration
1016	Gas Chromatograph Injection Port Liner Siliconization
1021	Computer Back-up
1022	25L Robot Coupe Batch Processor: Assembly, Operation, and Clean-Up
1025	Procedure for Collection and Shipping of Menus - DELTA Protocol 2
1026	Acid Washing of Glassware
1027	Procedure for Collection and Shipping of Menus -DELTA Protocol 2
5002	Determination of Moisture in Diet Composites by Vacuum Oven Drying
5007	Determination of Moisture in Composited Mixed Diets by Microwave Drying
5008	Siliconizing of Labware
5010	Fatty Acid Methylation
5011	Determination of Ash in Diet Composites
5015	Extraction of Lipids from Foods with Cholorform-Methanol
5016	Preparation of Fatty Acid Methyl Ester Standards
5017	Preparation of Cholesterol Calibration Standards
5018	Internal Standard Spikes for Fatty Acid Methyl Ester Quantitation
5020	Saponification and Derivitization for Cholesterol Analysis
5022	GC Method for Cholesterol Analysis
5023	Kjeldahl Determination of Protein in Diet Composites
5024	Gravimetric Determination of Total Lipid in Foods
5026	Cholesterol Determination in Mixed Diets
5028	Use and Handling of Food Composite Samples
5029	Preparation of Diet Cycle Composites
5030	Wet-Ash Sample Preparation for Elemental Analysis
5034	Preparation of Standards for ICP Analysis
5035	Trace Element Analysis in Mixed Diet Composites ICP
5054	Calibration Factor Calculation for FAME Method and FAME Quantification
5055	Quantification of Fatty Acids in Food Composites, Fats, and Oils
5056	GC Method for Fatty Acid Methyl Ester Analysis Using Calibration Factors

PROCEDURE FOR COLLECTING AND SHIPPING MENUS

DASH2

Diet Validation

Food Analysis Laboratory Control Center SOP (1035)

SOP #1035-2

06-NOV-97

Department of Biochemistry
Virginia Tech
Blacksburg, VA 24061-0308

DASH2 Diet Manual of Procedures

Scope

This procedure applies to menu collection for DASH2 diet validation study, 1997.

Purpose

To describe the procedure for collecting and shipping prepared menus to the FALCC.

Overview

Menus for the two diets, Control and Combination, will be prepared at the kcal levels and sodium levels indicated below, at the centers shown. Each center will prepare all 8 menus for the assigned diets according to the schedule below. The prepared menus will be shipped frozen on dry ice via overnight delivery to FALCC for compositing.

Table 39-16. DASH2 Diet Validation Plan[1,2]

Diet	Sodium Level	kcal Level	# of Menus	Prep for Validation	
				Center 1	Center 2
Control	Lower	1600	8	PBRC	JHU
Control	Lower	2100	8	PBRC	JHU
Control	Lower	3100	8	DUKE	BWH
Control	Intermediate	2100	8	DUKE	BWH
Control	Intermediate	3100	8	PBRC	JHU
Control	Higher	2100	8	PBRC	JHU
Control	Higher	3100	8	DUKE	BWH
Combination	Lower	1600	8	DUKE	BWH
Combination	Lower	2100	8	DUKE	BWH
Combination	Lower	3100	8	PBRC	JHU
Combination	Intermediate	2100	8	DUKE	BWH
Combination	Intermediate	3100	8	PBRC	JHU
Combination	Higher	2100	8	DUKE	BWH
Combination	Higher	3100	8	PBRC	JHU

[1]Accepted by Diet Subcommittee at 3/24/97 meeting.
[2]Number of menus/diet changed to 8 for validation on 5/21/97 conference call.

Table 39-17. Sampling Plan for Re-Validation of Selected Menus (11/97)

Diet	Sodium Level	kcal Level	Menu number	Version	Preparation for Validation		
					Center 1	Center 2	Center 3
Control	Higher	3100	8 (EXTRA)	revised	BWH	JHU	
Control	Higher	3100	4 (WED)	revised	BWH	JHU	
Control	Higher	3100	4 (WED)	original	BWH	JHU	
Combination	Higher	3100	5 (THURS)	revised	JHU	DUKE	PBRC
Combination	Lower	3100	2 (MON)	revised	BWH	JHU	
Combination	Lower	3100	2 (MON)	original	BWH	JHU	
Control	Lower	1600	1 (SUN)	revised	PBRC		

READ THROUGH THIS ENTIRE PROCEDURE PRIOR TO FOOD COLLECTION.

If you have any questions, contact the FALCC at (540) 231-4361, or e-mail at falcc1@vt.edu.

Materials

At Field Center

1. Prepared foods from menus (See attached instructions)
2. Refrigerator (0-4^{o}C)
3. Freezer (-20^{o}C or lower)
4. Heavy paper (e.g. brown paper or newspaper)
5. Dry ice (ca. 5 lbs per cooler)

Food Collection and Shipping Materials Supplied by FALCC

1. Rubbermaid™ containers (8 per diet), with Cryogenic label
2. Stainless steel spatula(s)
3. Cryogenic marker
4. Disposable, fat-free, powder-free gloves
5. Form #F001 (sample transfer)
6. Form #F002 (deviation from SOP)
7. Shipping cooler(s)
8. Packing tape
9. Federal Express dry ice identification stickers
10. Pre-addressed Federal Express shipping labels (1 per cooler)
11. Pre-addressed envelope for returning forms to the FALCC

Note: The following procedures must be followed exactly. If a deviation occurs, fill out form #F002 and include it with the food shipment.

Procedures

Receipt of Shipping Materials

Make sure you received all items listed above. If there is a discrepancy or if you should need replenishment of supplies, immediately notify the FALCC at (540) 231-4361 or FAX (540) 231-9070 or electronic mail falcc1@vt.edu.

Total Menu Food Collections

READ THROUGH THIS ENTIRE PROCEDURE AND ATTACHED INSTRUCTIONS FOR FOOD PREPARATION PRIOR TO FOOD COLLECTION.

PERFORM THE FOLLOWING STEPS FOR EACH MENU OF FOODS TO BE COLLECTED.

Breakfast

1. Assemble all foods from the breakfast menu. **Include** milk and juices, but **not** ad lib beverages (e.g., coffee, tea, water, and diet soft drinks).

2. Retrieve a Rubbermaid™ container prelabeled with the appropriate diet identification and menu identification for the menu you are collecting; enter the date and your initials on the label using the cryogenic marker supplied.

3. While wearing fat-free powder-free gloves and using a clean stainless steel spatula (included in shipping kit), scrape all of the food into the container. If bread or a muffin is a part of the meal being collected, set it aside and use it to scrape plate, then add to collection container.

Note: It is critical that all food residues are collected, or else analytical values will not reflect the composition of the menu.

4. Completely seal the container, and using the cryogenic permanent marker record the menu ID. **(Important: Use codes on attached list for diet and menu identification.)** Record the date and your initials on the sample label on the container.

5. Place the container in the refrigerator (0-4^{o}C) until collection of total menu is complete ($\leq$24 hours).

READ THROUGH THIS ENTIRE PROCEDURE AND ATTACHED INSTRUCTIONS FOR FOOD PREPARATION PRIOR TO FOOD COLLECTION.

PERFORM THE FOLLOWING STEPS FOR EACH MENU OF FOODS TO BE COLLECTED.

Lunch

1. Assemble all foods from the lunch menu. Include milk and juices, but not ad lib beverages (e.g., coffee, tea, water and diet soft drinks).

2. Retrieve the container containing breakfast foods from the same menu from the refrigerator. **Check the label and make sure you have the correct container for the menu you are collecting.**

3. While wearing fat-free powder-free gloves, scrape all of the lunch food into the container (use a clean stainless steel spatula to obtain all food residues; if bread or a muffin is a part of the meal being collected, set it aside and use it to scrape plate, then add to collection container).

It is **critical** that all food residues are collected, or else analytical values will not reflect the composition of the menu.

4. Completely seal the container, and place it in the refrigerator (0-4^{o}C) until collection of total menu is complete ($\leq$24 hrs).

READ THROUGH THIS ENTIRE PROCEDURE AND ATTACHED INSTRUCTIONS FOR FOOD PREPARATION PRIOR TO FOOD COLLECTION.

PERFORM THE FOLLOWING STEPS FOR EACH MENU OF FOODS TO BE COLLECTED.

Dinner

1. Assemble all foods from the dinner menu. Include milk and juices, but not ad lib beverages (e.g., coffee, tea, water and diet soft drinks).

2. Retrieve the container containing breakfast and lunch foods from the same menu from the refrigerator. **Check the label and make sure you have the correct container for the menu you are collecting**.

3. While wearing fat-free, powder-free gloves, scrape all of the dinner food into the container (use a clean stainless steel spatula to obtain all food residues; if bread or a muffin is a part of the meal being collected, set it aside and use it to scrape plate, then add to collection container).

It is critical that all food residues are collected, or else analytical values will not reflect the composition of the menu.

4. Completely seal the container, and place it in the refrigerator (0-4^{o}C) until collection of total menu is complete ($\leq$24 hrs).

READ THROUGH THIS ENTIRE PROCEDURE AND ATTACHED INSTRUCTIONS FOR FOOD PREPARATION PRIOR TO FOOD COLLECTION.

PERFORM THE FOLLOWING STEPS FOR EACH MENU OF FOODS TO BE COLLECTED.

Snacks

1. Assemble all snacks from the menu. Include milk and juices, but not ad lib beverages (e.g., coffee, tea, water and diet soft drinks).

2. Retrieve the container for the corresponding breakfast, lunch, and dinner menu items. **Check the label and make sure you have the correct container for the menu you are collecting**.

3. While wearing fat-free, powder-free gloves, scrape all of the snack food into the container (use a clean stainless steel spatula to obtain all food residues; if bread or a muffin is a part of the meal being collected, set it aside and use it to scrape plate, then add to collection container).

Note: It is critical that all food residues are collected, or else analytical values will not reflect the composition of the menu.

4. Completely seal the container and place it in the freezer ($\leq 20^{o}C$). All foods from the menu should now be in the container.

5. The food must be frozen at $\leq 20^{o}C$ at least overnight prior to shipment.

Shipping

NOTE: Do not ship on Friday. Call FALCC before shipping. Do not let packed coolers sit at ambient temperature for an extended time period prior to federal express pick-up.

1. Assemble containers of food to be shipped: **frozen** solid (at least **overnight** at $\leq$-20^{o}C) prior to shipment.

2. Ensure that each container is completely sealed.

3. Fill out a sample transfer form (#F001) for each cooler. Include all required information (see sample form included). Make a copy for your records.

4. **Wrap EACH container of food in several layers of brown paper, newspaper, or other cushioning wrap. This is necessary in order to prevent container breakage during transit.**

5. Place wrapped containers in the cooler, then pack wads of brown paper, newspaper or other cushioning material around each container.

6. Place a layer of brown paper, newspaper, or other cushioning material on top of containers, then add a minimum of 5 pounds of dry ice. **Use caution when handling dry ice; wear appropriate protective apparel and insulated gloves.**

7. Pack wads of newspaper or brown paper to fill out cooler and prevent movement.

8. Place completed **sample transfer form (#F001), and any Deviations from SOP forms (#F002)** in a sealed zip-lock bag (to protect from moisture), and place in cooler, on top.

9. Tightly seal the lid of the cooler with packing tape.

10. Fill out all information on the dry ice stickers (included in shipping kit) required for Federal Express shipping: Make sure to include your complete address and make sure that the dry ice weight agrees on all stickers for the same cooler.

11. Affix a pre-addressed, pre-paid Federal Express shipping label to the box, and send via Federal Express overnight delivery to FALCC:

    Attn: Katherine Phillips
    FALCC - Dept. of Biochemistry
    304 Engel Hall
    Blacksburg, VA 24061-0308

12. Notify the FALCC of shipment

    Telephone (540) 231-4361
    FAX: (540) 231-9070
    E-mail: falcc1@vt.edu

Instructions for Food Preparation

The purpose of the diet validation is to evaluate by chemical analysis, prior to feeding, whether the prepared menus contain the key nutrients at the levels targeted for the intervention.

The primary concerns in food collection for diet validation are to ensure that the food collection assayed strictly replicates the food as it will be consumed by subjects, and to ensure that no nutrient loss or degradation occurs after collection.

Follow the standard procedure for DASH2 diet validation menu collection and shipping (FALCC SOP #1035), along with the following instructions.

1. Procure the foods from the same sources and prepare, handle, and heat the foods exactly as specified by the menu/recipes for participants' consumption. For example, reconstitute dehydrated foods (e.g., mashed potatoes) and prepare and cook composite foods (e.g., casseroles) and other cooked items (e.g., meats) according to the recipe/menu.

2. Reconstitute beverage mixes specified by the menu (i.e., not discretionary) according to menu instructions (i.e., as if the drink were to be consumed) before adding to the food collection.

3. Remove inedible portions (e.g., apple cores, chicken bones, wrappers) when food is collected for analysis.

4. Do not include discretionary/ad lib beverages (e.g., water, coffee, tea, diet sodas) in the menu samples for assay.

5. For portion control items, weigh the exact amount specified by the menu and add to the menu collected for diet validation.

6. Protect samples from contact with extraneous materials, and maintain a clean environment.

7. Use carefully cleaned and dried containers and utensils and wear powder-free gloves (as provided by FALCC) to handle and collect foods.

8. Include all traces of prepared/weighed foods specified by the menu in the menu collection (since the goal at the diet validation is to verify calculated nutrient levels).

9. Record and report any known deviations from the menu preparation protocol (use the standard form supplied with the food collection materials from FALCC). Deviations include ingredient substitutions, weight differences, preparation differences, brand name differences, etc. (This information will be used to evaluate any discrepancies between assayed and calculated nutrient levels.)

10. Make sure that each diet sample container is clearly labeled with sample identification information, using a cryogenic marker.

Diet and Menu Names for Diet Validation

When labeling the menu containers for diet validation, use the following codes, corresponding to the diet and menu descriptions shown below.

NOTE: Since FALCC will be logging, tracking, and managing a large number of menus and associated data, it is very important that these consistent designations be used for sample identification.

Table 39-18. Menu Containers Identification Codes

For Diet Code Use:	For Diet Name	For Sodium Level
Ctrl/Lo	Control	Lower
Ctrl/Inter	Control	Intermediate
Ctrl/Hi	Control	Higher
Comb/Lo	Combination	Lower
Comb/Inter	Combination	Intermediate
Comb/Hi	Combination	Higher

Label

Project: DASH2 **Study:** DIETVAL
Diet: Combin/Med **Menu #:** Thursday
Kcal level: 2100 **Week #:** N/A
Sample Description: Total Menu
Date Collected: 6/9/97
Initials: _____ **Center**: Duke

Table 39-19. Menu Day Container Identification Codes[1]

For "Menu" on Container Label Code Use:	For Menu Day	Menu#
SAT	Saturday	7
SUN	Sunday	1
MON	Monday	2
TUES	Tuesday	3
WED	Wednesday	4
THURS	Thursday	5
FRI	Friday	6
EXTRA	Extra	8

[1]Example: For Combination diet, intermediate sodium level, Thursday menu at 2100 kcal level collected 6/9/97 at Duke:

Form #F002-2
Original Date: 16-FEB-93
Revised: 14-JAN-97

Food Analysis Laboratory Control Center (FALCC)

NOTIFICATION OF MENU DEVIATION

FROM:_____

Tech
_____

_____

TO: Dr. Katherine Phillips
Dept. of Biochemistry - Virginia

Room 304 Engel Hall
Blacksburg, VA 24061-0308

Study:_____ Date of Deviation:_____

Sample Affected: Center_____ Diet_____ Kcal_____Menu_____Cycle_____

Name of Operator:_____

Description of Deviation:

PROCEDURE FOR COLLECTION AND SHIPPING OF MENUS FOR DIET MONITORING

DASH2

Food Analysis Laboratory Control Center SOP (1038-2) Standard Operating Procedure (SOP)

SOP #1038-2
Revision: 2

30 Sept-98

Department of Biochemistry
Virginia Tech
Blacksburg, VA 24061-0308

PLEASE READ THIS PROCEDURE COMPLETELY PRIOR TO FOOD COLLECTION.

DASH2 Diet Manual of Procedures

Scope

This procedure applies to menu collection for diet monitoring during DASH-2 intervention.

Purpose

To describe the procedure for collecting prepared menus and shipping them to the FALCC for chemical analysis to monitor the composition of the experimental diets during intervention.

Rationale for revision

To support the revised monitoring plan for weeks 1 and 4 for Cohort 2

Overview

Menus are collected according to the sampling plan in the Manual of Operations and distributed by the Coordinating Center and sent to the FALCC to be assayed. Each sample consists of the collection of 7 daily menus constituting the complete diet cycle.

IMPORTANT: Samples collected for FALCC are prepared without staff knowledge that those meals are analyzed, and not consumed.

Table 39-20. Summary of DASH2 Diet Monitoring Plan

Cohort 1

Feeding Period	Week	Diet	Na^+ Level	kcal Level	Preparation Centers	
1	2	Control	Lower	2100	JHU	PBRC
1	2	Control	Lower	2600	BWH	DUKE
1	3	Combination	Lower	2100	BWH	DUKE
1	3	Combination	Lower	2600	JHU	PBRC
2	2	Control	Intermediate	2100	JHU	PBRC
2	2	Control	Intermediate	2600	BWH	DUKE
2	3	Combination	Intermediate	2100	BWH	DUKE
2	3	Combination	Intermediate	2600	JHU	PBRC
3	2	Control	Higher	2100	JHU	PBRC
3	2	Control	Higher	2600	BWH	DUKE
3	3	Combination	Higher	2100	BWH	DUKE
3	3	Combination	Higher	2600	JHU	PBRC

Cohort 2

Feeding Period	Week	Diet	Na^+ Level	kcal Level	Preparation Centers	
1	1	Combination	Lower	1600	BWH	DUKE
1	1	Combination	Lower	2100	JHU	PBRC
1	2	Control	Lower	2100	BWH	
1	2	Control	Lower	2600	DUKE	
1	2	Control	Lower	3100	JHU	PBRC
1	3	Combination	Lower	2600	DUKE	PBRC
1	3	Combination	Lower	3100	BWH	JHU
1	4	Control	Lower	1600	DUKE	PBRC
1	4	Control	Lower	2100	JHU	
1	4	Control	Lower	2600	BWH	

*Samples from weeks 1 and 4 are stored at the preparation centers at –20□C until notified to send to FALCC.

Materials at Feeding Site

Prepared foods from menus **(See attached instructions)**
Refrigerator (0-4°C)[1]
Freezer (0°C or lower)
Heavy paper (e.g., brown paper or newspaper)
Dry ice (5 lbs per cooler)

Food Collection and Shipping Materials Supplied by FALCC

Rubbermaid™ containers (7 per diet cycle) with cryogenic labels
Stainless steel spatula(s)
Cryogenic marker
Powder-free disposable gloves
Form #F001 (sample transfer)
Form #F002 (menu deviation)
Shipping cooler(s)
Packing tape[2]
Federal Express dry ice identification stickers
Pre-addressed Federal Express shipping labels (1 per cooler)

Procedures

NOTE: Follow these procedures exactly. If a deviation occurs in preparation, packaging, ingredients, shipping, etc., fill out Form #F002 and include it with the food shipment. If the freezer is > -0°C, complete a menu deviation Form (Foo2).

Receipt of Shipping Materials

Make sure you received all items listed above. If there is a discrepancy or if you should need replenishment of supplies, immediately notify the FALCC at (540) 231-4361 or e-mail falcc1@vt.edu[1].

[1] See Table 30-24 Site freezer termperatures

[2] The FALCC will supply each site with a reasonable amount of packing tape for shipping foods to the FALCC - please reserve the tape for this use only.

Collection of each Total Menu

NOTE: **Each container has been pre-labeled at the FALCC with the study, diet, week #, a kcal level, description, and center name. Each center will fill in the menu #, date collected, and initials.**

READ THROUGH THIS ENTIRE PROCEDURE PRIOR TO FOOD COLLECTION

PERFORM THE FOLLOWING STEPS FOR EACH MENU OF FOODS TO BE COLLECTED. TREAT FOODS SHIPPED TO FALCC JUST LIKE ANOTHER "PARTICIPANT."

Breakfast

1. Assemble all foods from the breakfast menu. **Include** milk and juices, but **NOT** *ad lib* beverages (e.g., coffee, tea, water, diet soft drinks).

2. Retrieve one of the Rubbermaid™ containers prelabeled with the diet, week #, and center identification for the menu you are collecting. **Enter the menu number, date and your initials** on the label using the supplied **cryogenic marker**. **Double check all label information for accuracy.**

3. While wearing powder-free gloves and using a clean stainless steel spatula (included in shipping kit), scrape **all** of the food into the container. If bread or a muffin is a part of the meal being collected, set it aside and use it to scrape plate, then add to collection container.

NOTE: **It is as CRITICAL that all food residues are collected as it is that each subject eats all of the food**; if not, analytical values will not reflect the composition of the diet.

4. Completely seal the container, and place the container in the refrigerator until collection of total menu is complete (≤ 24 hrs).

NOTE: **Collection of total menu must be completed within the same time frame as it would be consumed by participants.**

READ THROUGH THIS ENTIRE PROCEDURE PRIOR TO FOOD COLLECTION

PERFORM THE FOLLOWING STEPS FOR EACH MENU OF FOODS TO BE COLLECTED

Lunch

1. Assemble all foods from the lunch menu. **Include** milk and juices, but **not** *ad lib* beverages (e.g coffee, tea, water, diet soft drinks).

2. Retrieve the container containing breakfast foods from the same menu from the refrigerator. **CHECK THE LABEL AND MAKE SURE YOU HAVE THE CORRECT CONTAINER FOR THE MENU YOU ARE COLLECTING.**

3. While wearing powder-free gloves, scrape **all** of the lunch food into the container (use a clean stainless steel spatula to obtain **all** food residues; if bread or a muffin is a part of the meal being collected, set it aside and use it to scrape plate, then add to collection container).

NOTE: **It is CRITICAL that all food residues are collected**, or else analytical values will not reflect the composition of the menu.

4. Completely seal the container, and place it in the refrigerator until collection of total menu is complete (≤ 24 hrs).

READ THROUGH THIS ENTIRE PROCEDURE PRIOR TO FOOD COLLECTION

PERFORM THE FOLLOWING STEPS FOR EACH MENU OF FOODS TO BE COLLECTED

Dinner

1. Assemble all foods from the dinner menu. **Include** milk and juices, but **not** *ad lib* beverages (e.g coffee, tea, water, diet soft drinks).

2. Retrieve the container containing breakfast and lunch foods from the same menu from the refrigerator. **CHECK THE LABEL AND MAKE SURE YOU HAVE THE CORRECT CONTAINER FOR THE MENU YOU ARE COLLECTING.**

3. While wearing powder-free gloves, scrape **all** of the dinner food into the container (use a clean stainless steel spatula to obtain **all** food residues; if bread or a muffin is a part of the meal being collected, set it aside and use it to scrape plate, then add to collection container).

NOTE: **It is CRITICAL that all food residues are collected**, or else analytical values will not reflect the composition of the menu.

4. Completely seal the container, and place it in the refrigerator until collection of total menu is complete (≤ 24 hrs).

READ THROUGH THIS ENTIRE PROCEDURE PRIOR TO FOOD COLLECTION

PERFORM THE FOLLOWING STEPS FOR EACH MENU OF FOODS TO BE COLLECTED

Snacks

1. Assemble all snacks from the menu. **Include** milk and juices, but **not** *ad lib* beverages (e.g coffee, tea, water, diet soft drinks).

2. Retrieve the container for the corresponding breakfast, lunch, and dinner menu items. **CHECK THE LABEL AND MAKE SURE YOU HAVE THE CORRECT CONTAINER FOR THE MENU YOU ARE COLLECTING.**

3. While wearing powder-free gloves, scrape **all** of the snack food into the container (use a clean stainless steel spatula to obtain **all** food residues; if bread or a muffin is a part of the meal being collected, set it aside and use it to scrape plate, then add to collection container).

NOTE: **It is CRITICAL that all food residues are collected**, or else analytical values will not reflect the composition of the menu.

4. Insure that the lid is completely sealed to the container (it is not necessary to tape around the edges of container) and place it in the **FREEZER (-0^{o}C or lower)**. All foods from the menu should now be in the container.

5. The food must be frozen at 0^{o}C or lower at least overnight prior to shipment.

Shipping

NOTE: Do not ship on Friday! Contact FALCC before preparing coolers for shipping. During times of potential severe storms, which may interfere with usual Fed Ex schedules, it may be prudent to delay shipment to avoid potential loss of samples.

DO NOT LET PACKED COOLERS SIT AT AMBIENT TEMPERATURE FOR AN EXTENDED TIME PERIOD PRIOR TO FED EX PICK-UP!

1. Assemble containers of food to be shipped: **FROZEN solid (at least OVERNIGHT at -20°C or lower) prior to shipment**.

2. Ensure that each container is completely sealed.

3. Fill out a sample transfer form (#F001) for each cooler. Include all required information (see sample form included). Make a copy for your records.

4. **Wrap EACH container of food in several layers of brown paper, newspaper, or other cushioning wrap. This is necessary in order to prevent container breakage during transit.**

5. Place wrapped containers in the cooler, then pack wads of brown paper, newspaper or other cushioning material around each container.

6. Place a layer of brown paper, newspaper, or other cushioning material on top of containers, then add a minimum of 5 pounds of dry ice. **USE CAUTION WHEN HANDLING DRY ICE; WEAR APPROPRIATE PROTECTIVE APPAREL AND INSULATED GLOVES.**

7. Pack wads of newspaper or brown paper to fill out cooler and prevent movement.

8. Place completed Sample Transfer Form (#F001), Menu Deviation (#F002), if any, for each menu, the cryogenic marker, and spatula in a sealed zip-lock bag (to protect from moisture), and place in cooler, on top of containers.

9. Tightly seal around the seam of the cooler and lid with packing tape.

10. Fill out all information on the dry ice stickers (included in shipping kit) required for Federal Express shipping: Make sure to include your complete address and make sure that the dry ice weight agrees on all stickers for the same cooler.

11. Affix a pre-addressed pre-paid FedEx shipping label to the box, and send via Federal Express overnight delivery to FALCC:

12.

    Dr. K. Phillips, Dept. of Biochemistry, 304 Engel Hall, Virginia Tech, Blacksburg, VA 24061-0308

12. **Notify FALCC of shipment:** Phone: (540) 231-4361 **or** e-mail: falcc1@vt.edu

Food Preparation Instructions

The purpose of diet monitoring is to evaluate by chemical analysis the composition of the diets **as consumed by subjects**.

The primary concerns in food collection for diet monitoring are to ensure that the foods collected replicate the foods as consumed by subjects, and to ensure that no nutrient loss or degradation occurs after collection.

Guidelines

Prepare, handle, heat, and plate/package all foods exactly as delivered to participants for consumption. Food preparer should be blinded to the identity of the collected sample as a "lab" sample; menus should be prepared as though delivered to an actual subject.

Remove food from plate/packages, etc. into collection container according to instructions given to participants for consumption.

Remove inedible portions (e.g. apple cores, chicken bones, wrappers) when food is collected for analysis, in the same way a subject would do so.

Do not include discretionary/*ad lib* beverages (e.g. water, coffee, tea, diet sodas) in the menu samples for assay.

Protect samples from contact with extraneous materials, and maintain a clean environment.

Use carefully cleaned and dried containers and utensils and wear powder-free gloves (both provided by FALCC) to collect foods.

Record and report any known deviations from the menu preparation protocol (use the standard form supplied with the food collection materials from FALCC) and enclose copy of all deviation forms with the shipment to FALCC. Deviations include ingredient substitutions, weight differences, preparation differences, brand name differences, deviations from food collection and shipping SOP etc. (This information will be used to evaluate any discrepancies between assayed and calculated nutrient levels.)

IMPORTANT: Make sure that each diet sample container is clearly labeled with the correct sample identification information, using a cryogenic marker.

FOR CONSISTENCY (AND ACCURATE IDENTIFICATION) USE THE DESCRIPTIVE CODES ON THE FOLLOWING PAGE

Diet and Menu Names for Food Collection Labels

When labeling the menu containers for diet monitoring, use the following codes, corresponding to the diet and menu descriptions shown below.

NOTE: **Since FALCC will be logging, tracking, and managing a large number of menus and associated data, it is VERY IMPORTANT that these consistent designations be used for sample identification.**

Table 39-21 For "Diet" on Container Label Use

Diet Code	For Diet name	At Sodium level:
CONTROL-LO	Control	Lower
CONTROL-INTER	Control	Intermediate
CONTROL-HI	Control	Higher
COMBIN-LO	Combination	Lower
COMBIN-INTER	Combination	Intermediate
COMBIN-HI	Combination	Higher

Table 39-22 For "Menu" on Container Label Use

Menu Code	For Daily Menu	Menu #
SAT	Saturday	Menu 7
SUN	Sunday	Menu 1
MON	Monday	Menu 2
TUES	Tuesday	Menu 3
WED	Wednesday	Menu 4
THURS	Thursday	Menu 5
FRI	Friday	Menu 6
EXTRA	Extra	Menu 8

Example: For Combination diet, intermediate sodium level, Thursday menu at 2100 kcal level, week 2, collected on 6/9/97 by Jane Doe at Duke:

(see sample label on next page)

Sample Label

Project: DASH2 **Study:** DIETVAL
Diet: Combin/Med **Menu #:** Thursday
Kcal level: 2100 **Week #:** N/A
Sample Description: Total Menu
Date Collected: 6/9/97
Initials: _____ **Center**: Duke

Table 39-24 Site Freezer Temperatures

Center	Temperature
BWH	-22C
Duke	-15 to -20C
JHU	-22C
PBRC	-18 to -23C

APPENDIX A: Request for Supplemental Funding of Menu Monitoring

Dietary Approaches To Stop Hypertension 2 (Dash2) Study

July 28, 1998

Request for Supplemental Funding of Menu Monitoring

Aim

To ensure that the DASH2 trial has adequate, chemically verified information about the sodium contents of the meals provided to participants, in order to protect the interpretation of the presence or absence of sodium effects on SBP at the end of the trial.

Rationale

The original menu monitoring plan for DASH2 was designed to collect enough composited samples for laboratory analysis to demonstrate, at the end of the trial, that good separation had been achieved with regard to the targeted sodium levels in the lower, intermediate, and higher sodium groups. Over the entire trial, there will be 480 possible instances in which composited samples could be obtained (4 sites x 4 cohorts x 3 sodium levels x 2 diets x 5 energy levels). Funding permitted 96 (20%) of these to be processed. In order to decide which instances to sample, the Dietary Monitoring Committee elected to (a) not implement a balanced sample for each cohort, but rather to ensure a balanced sampling of all factors over the entire trial, (b) not sample the 1600 and 3600 kcal levels, and (c) pair certain sites to permit direct comparisons. It was not the intention to use the menu monitoring data for the purpose of making mid-study corrections in the actual sodium levels in the meals, because it was felt that based on the DASH experience, the targeted levels would be achieved relatively easily.

The results from cohort 1 have prompted some re-thinking of some of the assumptions that went into the monitoring design.

(1) The urinary sodium excretions suggested that the dietary sodium levels might be correct for the lower sodium period, but that there was lower excretion than expected during the intermediate and higher sodium periods. This prompted a decision to raise the sodium levels in the diets by 10% in the intermediate and higher period meals.
(2) Comparison of the relationship between the DASH menu monitoring data and the corresponding urinary sodium excretions suggest that virtually 100% of sodium is recovered at the 1600 kcal level; 90% is recovered at the 2100 kcal level, and 80% is recovered at the 2600 and 3100 kcal levels. Varying recovery rates by energy intake level have not been reported in the literature.

(3) When the intake/recovery relationships found in DASH are applied to the DASH2 urinary sodium excretion values to estimate sodium intake, and then the estimates are compared to the sodium targets, the results are as follows:

Table 1. Average & SDE Target Ratios by Sodium and Diet Arms

(Sodium: na coded 0=low, 1=med, 2=high. Comb: 0=Control, 1=Combination)

MEAN comb	na 0	1	2	Total
0	1.20	0.95	0.94	1.03
1	1.11	0.93	0.87	0.97
Total	1.15	0.94	0.91	1.00

SDE comb	na 0	1	2	Total
0	0.06	0.03	0.03	0.04
1	0.05	0.05	0.03	0.05
Total	0.06	0.04	0.03	0.04

Here, the "target ratio" is the ratio of sodium intake (estimated by urinary excretion) to that targeted by the study design, taking energy level into account. The SDE is the standard deviation of the estimate. These results suggest that during the lowest sodium period the sodium intakes may exceed the target (15% overshoot, 2.5 SD units), that they may fall short during the intermediate period (6% undershoot, 1.5 SD units), and that they may also fall short during the higher period (9% undershoot, 2.25 SD units).

(4) As noted at the July 1998 DSMB meeting, the urinary sodium excretion data show rather large variability. One consequence of this is that the estimated sodium intakes do not uniformly show the pattern that would be indicated by the design. That is, the estimated sodium intake can rise as an individual proceeds from a higher to lower dietary sodium feeding period, and conversely the estimated sodium intake can fall as the individual proceeds from a lower to a higher dietary sodium feeding period. These patterns are, in fact, seen in the DASH2 data. One explanation for this phenomenon is that the sodium delivered is not that which is targeted. Another is that there may be variations in adherence.

These results suggest that in order to understand and report the results relating sodium intake to SBP, it is necessary to conduct a more comprehensive analysis of the sodium content of the meals across all cohorts and for all the calorie levels consumed by the DASH2 participants. In addition, the modifications of the sodium targets introduced at cohort 2 make it even more important to assess the dietary sodium more closely. The original scheme of 96 composites for the entire study will likely be inadequate for this purpose.

Plan

The original and proposed supplemental monitoring is shown in the following two tables (modified from the MOP). The lower-case letters indicate sites in the original design, whereas capitals indicate the proposed supplemental measurements. The total number of additional composites is 72, exactly doubling the 72 originally designed composites (cohorts 2-4).

Table 39-4. Control Diet Monitoring Schedule Design (modified)

	1600 kcal			2100 kcal			2600 kcal			3100 kcal		
Coh	**Lo**	**Md**	**Hi**	**Lo**	**Md**	**Hi**	**Lo**	**Md**	**Hi**	**Lo**	**Md**	**Hi**
1				ab	ab	ab	Cd	cd	cd			
2	BD	BD	BD	AC	AC	AC	Cd	cd	cd	ab	ab	ab
3	CD	CD	CD	bd	bd	bd	AB	AB	AB	ac	ac	ac
4	AB	AB	AB	cD	cD	cD	Ab	ab	ab	Cd	Cd	Cd

Table 39-5. Combination Diet Monitoring Schedule Design (modified)

	1600 kcal			2100 kcal			2600 kcal			3100 kcal		
Coh	**Lo**	**Md**	**Hi**	**Lo**	**Md**	**Hi**	**Lo**	**Md**	**Hi**	**Lo**	**Md**	**Hi**
1				cd	cd	cd	Ab	ab	ab			
2	CD	CD	CD	AB	AB	AB	Bd	bd	bd	ac	ac	ac
3	BD	BD	BD	ab	ab	ab	AC	AC	AC	cd	cd	cd
4	AB	AB	AB	Cd	Cd	Cd	Ac	ac	ac	bD	bD	bD

Site a = Baltimore
Site b = Baton Rouge
Site c = Boston
Site d = Duke

Lo = lower sodium
Md = intermediate sodium
Hi = higher sodium

Cells in which changes or additions to the original schedule were made are shaded.

40. FOOD PROCUREMENT, SAFETY AND PREPARATION 3

Summary of Edits

Updated the food substitution process.
Updated Table 40-3 food product information
Added frozen vegetable steaming instructions.
Added salt addition process
Updated food donation process to reflect process for Cohort 1 and Cohort 2.

40. Food Procurement, Safety and Preparation

Food Procurement

The purpose of this section is threefold:

1) To facilitate and document food procurement procedures at each center,
2) To provide a sample model for organizing food procurement,
3) To ensure sites use food brands with similar nutrients levels
4) To standardize ordering procedures for donated items
3) To standardize the process to use for food substitutions

Food Sources

Foods served to participants are as similar as possible at all feeding sites. Therefore, selected brands are identified. Since DASH2 is conducted in four separate geographical areas, that some brands will inevitably be different (e.g., fresh produce, milk, and miscellaneous items such as yams). Each site will maintain a document including this information.

Foods are procured from three primary sources:

1) donated items (mostly central procurement),
2) local distributors, and
3) retail food stores.

Donated Items

Companies agreed to donate foods for DASH2. Donating companies prefer to make as few shipments as possible. For most foods, shipment is pre-arranged. For others, sites are responsible for initiating shipment. The donation information is compiled on the Donation Tracking Forms (Form #117)**,** and housed in a notebook for each site. See the section on Ordering and Shipping Schedules, Donated Items, in this chapter, and the Donation Tracking Forms (Form #117) for more detail.

Local Distributors

Purchased items and some donated items may be procured through local distributors (e.g., Kraft, Sysco). In selecting a distributor, attention was given to the number of food items carried, cost, and willingness to provide donated items free of charge.

Retail Food Stores

Some retail grocers have a shopping and delivery service. For a minimal charge, the store may shop for items and deliver to preparation site. If the store finds the project too large, try to negotiate a price for the service.

Guidelines for shopping for foods are discussed in detail with the shopper, so that substitutions do not occur. Each site may want to develop a shopping list with correct food items, brands, and package sizes and provide this to the shopper. The list can be can be sent by FAX or called to the store in advance of the shopping. The store may have its own order form.

Deliveries are checked by study dietary personnel to verify full receipt of the order, with special attention to brand and sodium level of products.

To minimize burden to staff, buy "difficult-to-obtain" items in bulk or order directly from the company.

Food Substitutions

Specific brands of food are selected during the menu-planning process. National brands are chosen over local brands. This is done to standardize food sources and ensure continuous supplies throughout the study. However, frequently foods become unavailable at a site during the feeding period.

Emergency Food Substitutions

There are two forms of substitutions, emergency and permanent. An emergency food substitution is made when a food is suddenly not available to the site. This can occur when a food is unavailable in the local market, a donation does not arrive in time; the food arrives not in a condition to use, or is not edible due to spoilage or other reason. If a participant can not tolerate a food due to an allergy or other reason, an emergency a food substitution can be made. When an emergency food substitution occurs, the nutritionist at the site evaluates the food substitution for appropriateness and records the food on the Food Substitution Record (Form # 109). Send the form to the Coordinating Center once per cohort.

Permanent Food Substitution

A permanent substitution occurs when a brand becomes permanently unavailable during the feeding period. To make a food substitute the nutritionist compares the product nutrient profile on the product label with the DASH2 nutrient database in Moore's Extended Nutrient Database (MENu), version 3, which contains the USDA standard reference data and is updated according to the USDA schedule.

If the product is an appropriate substitute send a copy of the product food label with the justification for the decision to the entire Diet Committee. Use the Food Substitution Facsimile

Transmission Cover Sheet and form (Form #121). The Diet Committee, with Dr. Champagne's input, discusses and approves the food substitute on the next Diet Committee conference call if the nutrient profiles are comparable.

Food substitutes are evaluated and made with the highest priority going to the micronutrients and minerals without disturbing the macronutrients. If the substitution is an appropriate substitute Ms. Craddick records the food on the DASH2 Permanent Food Substitution List (Form #120), on the DASH2 Food List and Recipe Ingredient (Form #127), and in Table 40.

Table 40.1 Food Substitution List

Site	Original Product	Substitution
Baltimore	Hollywood Canola Oil	?
	Sysco Cranapple juice	?
	Lactaid	?
	Decaffeinated coffee	Postum - ?
	Marvel Turkey Pastrami	All white or all dark meat. Please clarify.
	Creamy French Dressing	Kraft French Dressing - ? Who else is using French instead of Creamy French?
Baton Rouge	Marvel Turkey Pastrami	Louis Rich Premium Deli Meat, 96% Fat Free. Add 0.3 gm salt/serving to replace sodium.
	Arnold's Bread	Pepperidge Farm, Light, Mild Flavor Sandwich White, Sliced, Enriched Bread Pepperidge Farm, Whole Grain, Natural, 100% Stoneground Whole Wheat Bread
Boston	Breakstone Cottage Cheese	Stop and Shop - need specific product name
	Duncan Hines Cream Cheese Frosting	Duncan Hines Vanilla Frosting
	Barbecue sauce	Heinz Catsup – Is this the correct brand?
Duke	10 GM dried apricot	33 GM banana (for one participant only)

Each food is reviewed and evaluated independently. The impact foods have on the nutrient database vary. Foods with different nutrient profiles may have a small impact, because they are used in small quantities. Foods with similar nutrient profiles can be used in larger quantities. It is important to select foods that match the database as close as possible.

Record Keeping for Donated Items

Food procured via donations is arranged centrally. The items are listed on the Donation Tracking Forms (Form #117), which are housed in a notebook prepared for each site. Information on the form is proprietary, therefore, confidential. Please see the Donation Tracking Form (Form #117) before contacting the company. Some donating company's request that the study use the company's order forms (e.g. Curtis Foods for vegetables they are donating).

It is recommended that each site house the order and delivery information for donated foods in one notebook, possibly the same notebook is which purchased food information is kept. Organization of the donation notebook can be by frequency of delivery, e.g., yearly, per cohort, and as needed. Under each of these sections, file the information for purchased, donated, and locally acquired foods.

Maintaining Inventory

All foods are locked. We recommend that you keep a one-week's supply of food, except for perishable foods. All foods, including donated items, are inventoried monthly to ensure that supplies are adequate for the cohort, and that no food is lost. Storage of foods varies from site to site, and inventory likewise. The exact method to use to inventory food items is optional. Inventory may be designed either by storage area (e.g., inventory the storage closet) or by procurement source (e.g., inventory all Sysco items).

Forecasting Food Needs

Forecasting of food items is done using the product estimation procurement application developed at the DASH2 Coordinating Center, with the input of Duke University. A copy of the program is shipped to each site and installed on any IBM-compatible personal computer running Windows. It is not to be installed on the DASH2 File Server. Directions and documentation accompany the program. The program does not estimate the ingredients needed to prepare the energy cookies, since the number of cookies per participant varies.

The application can produce two pieces of information-a shopping list and a food preparation worksheet. The two pieces of information are produced after the diet, sodium sequence, and calorie level is entered for each participant.

Ordering and Shipping Schedules

Donated Items for Cohort 1

Donating companies prefer an easy, streamlined process for direct shipments. They prefer to make as few shipments as possible. If small additional quantities are needed, consider purchasing the item to avoid burdening the contact with too many calls.

There is a donation representative at each site who is aware of the donation ordering procedures. These representatives are Phyllis McCarron, Baltimore; Kim Hoben, Duke; Staci Crawford, Baton Rouge; and Marji McCullough or Susan Redican, Boston.

Food items are donated via two principle routes:

- directly shipped per cohort, or per year, according to a pre-arranged scheduled coordinated by Marji McCullough, or

- ordered as needed by each site.

Donated Food Items for Cohort 2

The same companies who donated food for Cohort 1 are donating for Cohort 2. Most companies ship food once per cohort prior to the feeding period to a representative at each site. This representative is the contact for most of the companies. Ms. McCullough arranges the initial shipment of food with follow-up contacts by the site representative. Representatives are Donna Rhodes, Baltimore, Staci Crawford, Baton Rouge, Susan Redican, Boston, and Fran Rukenbrod, Duke. The representative uses the Donation Tracking Form to estimate the quantity of food the site needs and sends this Ms. McCullough.

Direct-Shipped Donated Items

Cohort 1

As foods arrive, a designated staff person uses the Donation Tracking Form (Form #117) to check to see that the correct product, unit size and complete order arrives. This person records the date the shipment arrives, initials the form, and makes necessary comments. See the form for complete instructions. Contact Ms. McCullough by electronic mail for any discrepancies.

Cohort 2

As foods arrive, a designated staff person uses the Donation Tracking Form (Form #117) to check to see that the correct product, unit size and complete order arrives. This person records the date the shipment arrives, initials the form, and makes necessary comments. See the form for complete instructions. Contact the company if there is a discrepancy.

Order-As-Needed Donated Items

Some companies, especially those providing perishable items, have agreed to have each site request foods as needed. The Donation Tracking Form (Form #117) outlines the process for making these requests. To maintain positive relations, it is important to adhere to lead times requested by the companies

Other Routes of Procurement of Donated Items

In some cases, donated items are procured via distributors or grocery stores. In this instance, the distributor or grocer may need to bill the donating company. All efforts will be made to avoid having companies reimburse the study for paying full retail price for items they manufacture.

Purchased Items

The process for shipping and receiving with local food sources is worked out individually.

Billing Procedures

Donated Items

Donating companies who ship directly to the sites do not send bills. **(The process to be developed).**

Purchased Items

Most sites have center-specific methods for billing. It is ideal to a have a pre-arranged cost code for major sources (e.g., major retailer, distributor) who can be paid on an ongoing basis or at a defined number of times per cohort.

Food Safety

Food safety is a serious concern in every feeding study. It is particularly important for DASH2, because subjects receive virtually all of their food from the field centers.

All feeding and food -production sites adhere to the US Food and Drug Administration (FDA) "Model Food Service Sanitation Ordinance." Each site is in accordance with their state Health Department guidelines.

Each center is responsible for implementing appropriate procedures and training personnel to protect subjects from any food-borne illness. Critical control points are areas in the flow of food production, from raw materials to finished products, where loss of control can result in an unacceptable food-safety risk. Critical areas to be addressed include treatment of foods, personal hygiene and health of the food handlers, and participants' handling of foods once taken off-site.

Safe Food Storage

Once the procurement of fresh and wholesome foods, that meet the DASH2 menu specifications, has taken place the next step is to ensure proper storage. The following principles apply to the storage of all types of foods:

- Follow the First-in-First-Out rule (FIFO). Date new deliveries and place them behind existing products to help guarantee the use of the oldest product first.
- Keep foods that spoil rapidly below 45 ^{o} Fahrenheit.
- Use only designated areas for food storage space. Keep storage areas clean and dry.
- Store only food packages and wrappers that are clean and free from spills.

Dry Food Storage

Store dry food goods in an area that is well ventilated, dry, clean, well lighted, and free from pests and excessive heat. The ideal temperature for extended shelf life of dry storage is 50^{o} F. Most dry products will remain safe at temperatures of 60^{o} to 70^{o} F with a relative humidity of 50 - 60 percent. All food items should be stored off of the floor.

Refrigeration Storage

To prevent food-borne illness outbreaks, store cold food items at 36^{o} to 40^{o} F. Properly cool hot food items that need to be refrigerated in an ice bath prior to refrigeration storage. To avoid cross-contamination, store raw foods below cooked foods and foods that will receive no further cooking. Also, cover all foods in the refrigerator. To ensure proper holding temperatures and air circulation, refrigerators should not be overloaded. Monitor refrigeration temperatures daily in each unit used on-site.

Freezer Storage

Freezer temperature must be maintained at or below 0^{o} F. Storage between minus 10^{o} and 0^{o} F is strongly recommended to ensure high food quality. Only frozen or pre-chilled items should be placed in freezer units. Adequate space in the freezer is necessary to provide proper air circulation. Monitor freezer temperatures daily.

Safe Food Handling

The food handler's good personal hygiene is a protective measure against food-borne illness. Therefore, policies for procedure, enforcement, and monitoring need to be established. All food handlers and kitchen staff need to be certified and monitored according to the schedule outlined in DASH2 Diet MOP Chapter 35, Module 5. Use the Food Service Sanitation Checklist (Form #91) for monitoring food handlers.

Hand Washing

Frequent and thorough hand washing is the most critical aspect of per`sonal hygiene. Instruct food handlers on proper hand washing techniques and the importance of washing hands frequently.

Gloves

Gloves can provide an additional barrier to contamination when used properly. Gloves are as susceptible to cross-contamination as hands. Therefore, care should be taken to throw away gloves, wash hands, and replace with new gloves when any action is taken that may cause contamination (for example, after handling raw meat).

Fingernails

To keep hands sanitary, fingernails need to be trimmed, unpolished, and clean.

Health

Food handlers who have visible symptoms of illness (sore throat, cough, sinus pains, or diarrhea) are a risk to food safety and should not engage in food production until symptoms are cleared.

Uniform

Food service handlers should have clean uniforms (or wear aprons when uniforms are not provided). Hair restraints should be worn at all times. These can include hair nets, headbands, barrettes, hats, or caps. The restraint should cover all hair.

Food Safety During Preparation

Food contamination can also occur during cooking. Table 40.1 provides guidelines for cooking and reheating foods.

Safe Food Preparation and Serving

Since many foods are cooked, cooled, weighed, and later reheated, it is critical to maintain high standards of safety at each point in production. When foods are being prepared, be sure the working surface area, scales, and utensils are clean and sanitized. When thawing frozen foods, the ideal way is to defrost frozen foods under refrigeration. When pulling cold food items for preparation or packing, it is essential to check expiration dates and freshness. Remember FIFO food rotation. When preparing foods for the weekend, keep the extended length of time in mind and check expiration dates and product freshness. Never use a food item when freshness and/or safety is in question: “When in doubt, throw it out.”

Meats and fresh produce should be washed thoroughly before use. Separate cutting boards are recommended for meats and produce. A color-code system-green for poultry, blue for fish, red for meat, and white for everything else-works well.

Perishable foods such as meats, milk, cheese, yogurt, gravy, sauces, butter, margarine, mayonnaise, and fish should be refrigerated or frozen immediately after preparation and weighing. A maximum time of 20 minutes should elapse between the time of tray assembly and delivery to a participant or refrigeration storage.

To reduce the risk of bacterial survival, foods should be cooked to an internal temperature that will ensure the safety of the food (Table 40.1).

Common symptoms of food-borne diseases caused by bacteria are nausea, cramps, diarrhea, vomiting, and headache. See Table 40.4 for a more detailed listing of symptoms and typical food carriers.

Table 40.2 Principles of Time/Temperature Control of Potentially Hazardous Foods[1]

Cook Food to a Minimum Temperature:

- 165° Poultry and stuffing
- 150° Pork
- 140° Other entrees and casseroles

Reheat Foods to a 165° minimum

Cool foods rapidly to 45° in four hours using one or more of the following methods:

- Shallow pans (2-3" depth)
- Ice bath
- Agitation
- Loose fitting covers
- No stacking
- Place food in coldest part of cooling unit

Equipment Maintenance

- Refrigeration units 35° F - 45° F
- Freezer units 0° F or below
- Provide thermometers to check temperatures

[1] *Adapted from a publication in process by Elaine Ayers, MS, RD, LD, Metabolic Diet Studies in Humans: A Practical Guide to Design and Management, P.15.*

Off-site Food Safety

Feeding Sites' Responsibilities for "To Go" Foods

All feeding sites provide safe and fresh food in "To Go" meals. Feeding sites instruct participants on the importance of timely refrigeration or freezing of the "To Go" foods once they leave the site. Sites provide participant with ice packs to put in coolers for extended transport of food over 1 hour along with a copy of Safe Foods To Go (Form #107**).**

Participants' Responsibilities for "To Go" Foods

Participants are required to have adequate facilities to hold foods at proper temperature. Participants are required to have access to adequate heating methods to cook or reheat foods provided on the menus.

Participants are encouraged to bring coolers to transport foods for extended periods of time. Any questions about holding temperatures or heating temperatures should be directed to the clinic staff.

Participants are asked to contact their feeding site whenever the freshness or safety of a food item is questionable.

Table 40.3 Common Food-borne Diseases Caused by Bacteria

Disease (causative agent)	**Principal Symptoms**	**Typical Foods**
(Bacillus cereus) food poisoning, diarrhea	Diarrhea, cramps, occasional vomiting	Meat products, soups, sauces, vegetables
(Bacillus cereus) food poisoning, emetic	Nausea, vomiting, sometimes diarrhea and cramps	Cooked rice and pasta
Botulism; food poisoning (heat-labile toxin of *Clostridium botulinum)*	Fatigue, weakness, double vision, slurred speech, respiratory failure, sometimes death	Types A&B: vegetables, fruits, meat, fish, and poultry products; condiments; Type E: fish and fish products
Botulism: food poisoning infant infection	Constipation, weakness, respiratory failure, sometimes death	Honey, soil, and home-canned products
Campylobacteriosis (*Camplyobacter jejuni*)	Diarrhea, abdominal pain, fever, nausea, vomiting	Infected food-source animals
Cholera (*Vibrio cholerae*)	Profuse, watery stools; sometimes vomiting, dehydration, often fatal if untreated	Raw or undercooked seafood
(*Clostridium perfringens*) food poisoning	Diarrhea, cramps, rarely nausea and vomiting	Cooked meat and poultry
(*Escherichia coli*) food-borne infections enterohemorrhagic	Watery, bloody diarrhea	Raw or undercooked beef, raw milk
(*Escherichia coli*) food-borne infections entroinvasive	Cramps, diarrhea, fever, dysentery	Raw foods **(all kinds?)**
(*Escherichia coli*) food-borne infection enterotoxigenic	Profuse watery diarrhea; sometimes cramps, vomiting	Raw foods **(all kinds?)**
Listeriosis (*Listeria monocytogenes*)	Meningoencephalitis; stillbirths, septicemia, or meningitis in newborns	Raw milk, cheese, and vegetables
Salmonellosis (*Salmonella species*)	Diarrhea, abdominal pain, chills, fever, vomiting, dehydration	Raw, undercooked eggs; raw milk, meat and poultry

Disease (causative agent)	**Principal Symptoms**	**Typical Foods**
Shigellosis (*Shigella species*)	Diarrhea, fever, nausea; sometimes vomiting, cramps	Raw foods
Staphylococcal food poisoning (heat-stable enterotoxin of *Staphylococcus aureus*)	Nausea, vomiting, diarrhea, cramps	Ham, meat, poultry products, cream-filled pastries, whipped butter, cheese
Streptococcal food-borne infection (*Streptococcus pyogenes)*	Various, including sore throat, crysipelas, scarlet fever	Raw milk, deviled eggs
(Vibrio parahaemolyticus) foodborne infection	Diarrhea, cramps; sometimes nausea, vomiting, fever, headache	Fish and seafood
(Vibrio vulnificus) foodborne infection	Chills, fever, prostration, often death	Raw oysters and clams
Yersiniosis (*Yersinia enterocolitica*)	Diarrhea, pains mimicking appendicitis, fever, vomiting, etc.	Raw or undercooked pork and beef, tofu packed in spring water

Food Preparation

Weighing

In order to minimize variability contributed by weighing of food portions in individual centers, Nutrient Composition Laboratory (NCL) has provided identical sets of weights to each center, including the FALCC. These weights have been calibrated against an NIST weight set (Class P Certified). Please provide the simple instructions to your staff members for their daily use. If you have any questions please call NCL at 301-504-8356.

Bi-Weekly Calibration of Food Scales

Wear fat-free powder-free gloves.
Clean balance plan.
Level balance if necessary.
Zero balance.
Use gloves and forceps when handling weights.

Weigh 1 gram, 10 gram, and 100 gram and 1 kg weights and record their weights on a calibration
For the 100 gram weight be sure to use both hands and forceps (one pair for each side).

Specific Food Preparation Procedures

Salt Addition

The amount of salt served in the meals is to be as close to the target sodium level as possible. Foods with added salt are not used, but their salt-free counter part is, such as salt-free broth, pretzels, nuts, etc. To bring the meal sodium level to the target sodium level the calculated added salt is spread over the meal all at one time. One exception is the hamburger patty. Salt is mixed with the meat before cooking.

Salt packets are used (average salt packet weighs 0.4 GM) to add salt, however, when the sodium target can not be reached with a packet, the additional salt is weighed. See Table 40.3 for the amount of salt to add to each meal to bring the day's salt to the calculated target.

Salt packets vary in weight, therefore, weigh many packets and average their weight to determine the amount of salt in a packet. As long as the correct amount of salt is added, sites select the method. See the specific site procedure below. For quality control only one staff person distributes the salt over the food. Up to 5 salt packets are added to a menu per day per participant. Alliance is the selected brand of salt.

Broth is used also as a vehicle to serve salt to bring the menu to the calculated sodium value. Up to 2.4 GMS of salt is added to the meal before broth is used. See the Broth recipes (Form #108). To make the broth weigh the water, boil and add the broth flavoring and salt, than weigh the recipe at the completion of the preparation. Both the beef and chicken broth recipes are 100-ml increments. Chicken broth is prepared to be 3 GMS of salt per 8 ounces, and beef is 4 GMS of salt per 8 ounces. Sites can serve scallions at meals to help season the broth.

Table 40.4 Salt Addition Table

Day	Diet	Na+	Meal	Food	1600 kcal	2100 kcal	2600 kcal	3100 kcal	3600 kcal
Mon	B/Comb	Low	Dinner	Spaghetti Sauce	0.3 g	1 pkt + 0.3 g	2 pkt + 0.3 g	2 pkt + 0.2 g	3 pkt
Mon	B/Comb	Inter	Dinner	Spaghetti Sauce	0.3 g	4 pkt + 0.2 g	0.3 g		
Mon	B/Comb	High	Dinner	Spaghetti Sauce	6 pkt + 0.3 g	9 pkt + 0.2 g	9 pkt	8 pkt	12 pkt
Mon	B/Control	Low	Dinner	Spaghetti Sauce				0.2 g	
Mon	B/Control	Inter	Dinner	Spaghetti Sauce		2 pkt + 0.2 g	0.2 g	0.3 g	
Mon	B/Control	High	Dinner	Spaghetti Sauce	1 pkt	3 pkt + 0.3 g	0.2 g		0.2 g
Tues	B/Combo	Low	Dinner	None					
Tues	B/Combo	Inter	Dinner	Rice		0.3 g		0.2 g	1 pkt

									+ 0.2 g
Tues	B/Combo	High	Dinner	Rice	3 pkt	2 pkt	2 pkt	3 pkt	3 pkt
Tues	B/Combo	High	Dinner	Spinach	3 pkt	1 pkt	2 pkt	2 pkt + 0.3 g	3 pkt
Tues	B/Control	Low		None					
Tues	B/Control	Inter	Lunch	Salad		1 pkt	2 pkt	2 pkt	1 pkt
Tues	B/Control	Inter	Dinner	Potato Salad	2 pkt + 0.2 g	2 pkt	2 pkt	2 pkt	2 pkt
Tues	B/Control	Inter	Dinner	Burger		1 pkt	1 pkt	1 pkt	2 pkt
Tues	B/Control	High	Lunch	Salad			2 pkt	1 pkt	2 pkt
Tues	B/Control	High	Dinner	Potato Salad	1 pkt	2 pkt + 0.3 g	2 pkt	2 pkt + 0.2 g	2 pkt
Tues	B/Control	High	Dinner	Burger		1 pkt	1 pkt	1 pkt	2 pkt
Wed	B/Combo	Low		None					
Wed	B/Combo	Inter	Dinner	Spanish Rice/ Chicken	0.3 g				
Wed	B/Combo	High	Dinner	Spanish Rice/ Chicken	1 pkt + 0.3 g	3 pkt	1 pkt + 0.2 g	2 pkt	4 pkt
Wed	B/Control	Low		None					
Wed	B/Control	Inter	Dinner	Spanish Rice/ Chicken	2 pkt	2 pkt + 0.2 g	2 pkt	3 pkt	4 pkt
Wed	B/Control	High	Dinner	Spanish Rice/ Chicken	4 pkt	2 pkt + 0.2 g	3 pkt	2 pkt	4 pkt
Thur	B/Comb	Low	Dinner	Turkey Meatloaf	0.3 g				
Thur	B/Comb	Inter	Lunch	Tuna Salad				1 pkt	1 pkt
Thur	B/Comb	Inter	Dinner	Turkey Meatloaf	2 pkt	2 pkt	2 pkt + 0.2 g	2 pkt	2 pkt
Thur	B/Comb	Inter	Dinner	Collards	2 pkt	2 pkt	2 pkt	2 pkt	2 pkt
Thur	B/Comb	High	Lunch	Tuna Salad	1 pkt		2 pkt	2 pkt	2 pkt
Thur	B/Comb	High	Dinner	Turkey Meatloaf	2 pkt	2 pkt	2 pkt	2 pkt + 0.3g	3pkt + 0.3g
Thur	B/Comb	High	Dinner	Collards	2 pkt	1 pkt	2 pkt	2 pkt	3 pkt
Thur	B/Control	Low		None					
Thur	B/Control	Inter	Lunch	Tuna Salad	1 pkt		1 pkt	1 pkt	1 pkt
Thur	B/Control	Inter	Dinner	Meatloaf	1 pkt	1 pkt	1 pkt	1 pkt + 0.2 g	1 pkt
Thur	B/Control	High	Lunch	Tuna	1 pkt	2 pkt	2 pkt	2 pkt	2 pkt

				Salad					
Thur	B/Control	High	Dinner	Meatloaf	2 pkt	2 pkt	2 pkt	2 pkt	2 pkt + 0.2 g
Thur	B/Control	High	Dinner	Green beans			0.3 g	1 pkt	1 pkt
Fri	B/Comb	Low	Dinner	Spicy Seafood	0.2 g	1 pkt			
Fri	B/Comb	Inter	Dinner	Spicy Seafood	1 pkt	1 pkt	1 pkt	1 pkt	1 pkt
Fri	B/Comb	Inter	Dinner	Spinach	1 pkt	1 pkt	1 pkt	1 pkt	1 pkt
Fri	B/Comb	High	Dinner	Spicy Seafood	1 pkt	1 pkt + 0.2 g	0.2 g	1 pkt	2 pkt
Fri	B/Comb	High	Dinner	Spinach	0.3 g				1 pkt + 0.2 g
Fri	B/Control	Low		None					
Fri	B/Control	Inter	Dinner	Spicy Seafood	1 pkt	1 pkt + 0.2 g	1 pkt + 0.2 g	1 pkt + 0.3 g	3 pkt
Fri	B/Control	Inter	Dinner	Carrots	1 pkt	1 pkt	1 pkt	1 pkt	1 pkt
Fri	B/Control	High	Dinner	Spicy Seafood	0.3 g	1 pkt	3 pkt	1 pkt t	1 pkt
Fri	B/Control	High	Dinner	Carrots		1 pkt	1 pkt		
Sat	B/Comb	Low	Dinner	Spinach		0.2 g	1 pkt		
Sat	B/Comb	Inter	Dinner	Spinach				1 pkt	1pkt
Sat	B/Comb	High	Dinner	Spinach	2 pkt		3 pkt	3 pkt	3 pkt
Sat	B/Comb	High	Dinner	Stewed Tomatoes			1 pkt	1 pkt	2 pkt
Sat	A/Control	Low		None					
Sat	A/Control	Inter	Dinner	Green Beans			0.3 g	1 pkt	
Sat	A/Control	High	Dinner	Rice	3 pkt		2 pkt		2 pkt
Sat	A/Control	High	Dinner	Green Beans	2 pkt	3 pkt	3 pkt	2 pkt	2 pkt
Sun	B/Comb	Low	Dinner	Green Beans	0.3 g	1 pkt	1 pkt + 0.3 g	1 pkt + 0.3 g	2 pkt + 0.2 g
Sun	B/Comb	Inter	Lunch	Chicken Salad	1 pkt	2 pkt	2 pkt	2 pkt	2 pkt
Sun	B/Comb	Inter	Dinner	Green Beans	3 pkt	3 pkt	3 pkt	2 pkt + 0.2 g	3 pkt
Sun	B/Comb	High	Lunch	Chicken Salad	1 pkt	2 pkt	3 pkt		2 pkt
Sun	B/Comb	High	Dinner	Green Beans	1 pkt	3 pkt	3 pkt + 0.2 g	2 pkt	2 pkt + 0.2 g
Sun	B/Control	Low	Dinner	Gravy			1 pkt	1 pkt +	

								0.3 g	
Sun	B/Control	Inter	Dinner	Low Na Gravy	0.2 g			1 pkt	
Sun	B/Control	High	Dinner	Gravy	0.3 g			3 pkt	

Each site's salt addition process is below:

1. Baltimore

Salt is weighed (1 packet = 0.4 GM of salt) and added directly to the food at the production site as specified in the Salt Addition Table. For the Monday through Friday dinner meal salt is weighed into soufflé cups and is sent to the distribution site. For the Saturday and Sunday control and Sunday combination meals the salt is weighed and sprinkled over the entire plated meal rather than over individual food items.

2. Boston

Using the salt addition tables, the dietitian or diet technician determines the weight or number of salt packets to add to a meal. Salt packets are used when no salt packets are weighed. If the salt needs to be weighed the entire amount of salt for the meal is weighed and no salt packets are used. The weights and number of packets are recorded on the food container labels. The diet technician than checks the entrée labels against the production sheets and participant roster quality control.

At the beginning of each shift the metabolic technician puts the labels on the lids of containers. The lids guide the food preparation. After the foods are weighed into the containers, the metabolic technician sprinkles the salt on designated salt on the food. The technician than checks the colored dot on the label. (For what purpose?) Food labels are checked three times, by the dietitian, diet technician and food server to assure the correct food, amount of salt is served the participant.

3. Baton Rouge

A research associate adds all salt at the dinner meal. The salt is weighed into a small container and sprinkled evenly on the dinner plate.

4. Duke

The salt-addition table is housed in a notebook divided by "Diet" and "Day of the Week". The kitchen staff uses the notebook to determine the amount of salt to weigh the day's meals. "S" indicates salt is added, and "NS" means no salt is added. During the meal quality control process the meal delivery staff check to see the correct amount of salt, or no salt, is added.

Food Preparation Procedures

Table 40.4 outlines food preparation procedures for 13 classes of foods used in DASH2. Please follow these procedures closely to ensure standardized food preparation procedures across sites.

Table 40.5 Food Preparation Procedures

1. Beef

Weighing **Defrosting** **Sanitation**	• Weigh all individual meat portions to + or -0.5 grams. • Defrost frozen meat in the refrigerator at a temperature not to exceed 50^{o}F. • Do not defrost in water or at room temperature. Meat products are ideal for the growth of bacteria and food poisoning organisms. Handle raw meats carefully to avoid contamination of other food products. • Use separate cutting boards for cutting raw meats. • Wash and sanitize utensils, cutting boards, and counter tops that might come in contact with uncooked meats.
Beef, Eye of round	• Wrap unused beef securely, date, label, and refrigerate immediately. Do not keep cooked roast beef longer than 3 days. • May be frozen. • Cook from raw. Bake roast at 300^{o} F. to internal temperature of 145^{o}F using a meat thermometer, 25 to 27 minutes per pound. • To prevent overcooking, remove roast when the meat thermometer shows several degrees lower than the final internal temperature desired, as roasts continue to cook after being removed from the oven. Allow to cool. Slice. • Weigh into individual portions.
Beef, ground, raw 80 to 85% lean	• Weigh into individual servings. • Cook according to individual recipe instructions. Serve with juice and grease. • Wrap unused ground beef securely, dated, label, and refrigerate. Do not keep longer than 3 days under refrigeration. • May be frozen.
Beef, ground, frozen, patties	• Defrost in refrigerator (3 to 4 hours per pound). Cook in individual serving dishes. • Pour juice and grease in the dish over the burger and bun.

2. Poultry

Weighing **Defrosting** **Sanitation**	• Weigh all individual meat portions to + or -0.5 grams. • Defrost frozen meat in the refrigerator at a temperature not to exceed 50°F. Do not defrost in water or at room temperature. • Meat products, particularly poultry, are ideal for the growth of bacteria and food poisoning organisms. Handle raw meats carefully to avoid contamination of other food products. • Provide separate cutting boards for raw meats. • Wash and sanitize utensils, cutting boards, and counter tops that might have come in contact with uncooked meats.
Chicken, raw breasts	• Rinse raw breasts under cold water and pat dry. • Trim off all residual fat and membrane. Weigh portion as directed into individual casserole dish. • Bake individual breasts 20 minutes at 350° F.
Chicken, baked breasts	• Rinse raw breasts under cold water and pat dry. • Trim off all residual fat and membrane. • Bake breasts 20 minutes at 350° F. Weigh portion as directed into individual servings.
Chicken, Sysco, diced (includes white and dark meat); frozen cooked	• Defrost in refrigerator overnight. • Use in recipe as directed. • Do not refreeze unused chicken.
Luncheon meats: Turkey, Jennie-O deli style, cooked breast, smoked, Oscar Meyer, 96% FF Ham, Low Sodium, Hormel Pastrami, Marvel	• Slice turkey into approximate 1 ounce slices. Weigh into individual portions. • Unopened package can be kept refrigerated until expiration date on package. • Pull for use and remove first slice. Turkey already sliced should be wrapped securely, labeled, dated, and refrigerated immediately. Keep sliced turkey only 3 days.

3. Pork

Weighing **Defrosting** **Sanitation**	• Weigh all individual meat portions to + or -0.5 grams. • Defrost frozen meat in the refrigerator at a temperature not to exceed 50^{O}F. Do not defrost in water or at room temperature. • Meat products are ideal for the growth of bacteria and food poisoning organisms. Handle raw meats carefully to avoid contamination of other food products. • Provide separate cutting boards for raw meats. • Wash and sanitize utensils, cutting boards, and counter tops that might have come in contact with uncooked meats.
Pork Sausage, Hormel Little Sizzler, cooked	• Weigh individual portions.

4. Fish

Weighing **Defrosting** **Sanitation**	• Weigh individual portions to + or - 0.5 gm. • Defrost in refrigerator (1 pound/3 to 4 hours). Do not freeze. • Handle raw fish carefully to avoid contamination of other food products. • Provide separate cutting boards for fish. • Wash and sanitize any utensils, cutting boards, and counter tops that might have come in contact with uncooked fish. • Defrost frozen meat in the refrigerator at a temperature not to exceed 50^{O}F. Do not defrost in water or at room temperature.
Cod, frozen (to be baked)	• Defrost in refrigerator. • Pat dry with paper towel. • Weigh portion into individual casserole dish. • Follow recipe cooking instructions • Cook at 375^{o} F for 8 to 12 minutes. • Weigh.
Cod, frozen (for Spicy Seafood recipe)	• Follow recipe cooking instructions.
Tuna, canned, Starkist (light in oil) **Low Sodium (white in water)**	• Drain 5 minutes in colander. • Weigh.

5. Vegetables

Weighing	Weigh to + or - 0.5 gm.
Storage	• Refrigerate when not being prepared.
Sanitation	
Fresh	• Wash thoroughly in tap water. • Keep refrigerated.
Ready-to use	• Salad ingredients may be used directly from the packaging. Do not wash again. • Weigh into individual portions.

Fresh Vegetables

Dole Mixed Salad	• Weigh into individual portions.
Lettuce, fresh, Iceberg	• Remove outer leaves, wash, pat dry. • Weigh into individual servings.
Tomatoes Baby carrots Celery Cucumber Green onions Peppers Zucchini	• Wash, pat dry • Weigh into individual servings as directed in recipe.
Potatoes, baked, flesh and skin	• Scrub individual potatoes. • Bake 60 minutes at 400^{o} F. Remove from oven; pierce with fork. Cool 15 minutes. • Weigh into individual portions.

5. Vegetables

Fresh Vegetables

Potatoes, baked flesh only	• Scrub individual potatoes. • Bake 60 minutes at 400° F. Remove from oven; pierce with fork. Cool 15 minutes. • Remove skin. • Weigh into individual portions.
Potatoes, boiled	• See recipe Baltimore Potato Salad recipie
Potatoes, red, steamed	• Steam whole potatoes 20 to 30 minutes. See instructions in recipe.
Red peppers	• Follow recipe guidelines for Vegetarian Spaghetti sauce.

Canned Vegetables

Tomatoes, stewed, whole, no salt added	• Wash top of can before opening. • Drain vegetables in colander for 5 minutes. • Weigh directly into individual dishes or incorporate into recipe. • Refrigerate unused portions.
Sweet potatoes, Sysco Sweet Classic	• Wash top of can before opening. • Weigh directly into individual dishes. • Refrigerate unused portions.

5. Vegetables

Frozen Vegetables

Steaming	• Frozen vegetables are steamed, according to guidelines listed below unless otherwise noted in recipe. • Tap vegetables to break up solid block and cook in their frozen state. • Five-pound lots are the most that should be cooked at a time.
To cook in steamer:	• Place vegetables in steamer pans. Pans should be non-perforated shallow cafeteria pans (12 x 20 x 12 1/2 inches) or flat, narrow steam cooker pans. • Material is available from equipment manufacturers giving recommended steaming times for their own equipment. • Each site has standardized steaming procedure.
To cook in conventional steamer, or covered pot with steamer rack	• Bring approximately 1 cup water to a boil in pot with a steamer rack, steam according to directions. Remove vegetables from stove, drain 5 minutes in colander. • Weigh into individual portions. • Refrigerate unused portions.

Frozen Vegetables

Steam Times

Vegetable	Baltimore	Baton Rouge	Boston	Duke
Beans, snap, green, or wax	25 minutes in a crab pot	4 bags/4 minutes	5 minutes	8 minutes
Cauliflower	15minutes in a crab pot	4 bags/4 minutes	4 minutes	8 minutes

Carrots	15 minutes in a crab pot	4 bags/4 minutes	4 minutes	8 minutes

5. Vegetables

Steam Times

Collards	70 minutes in a crab pot	8 – 9 bags/26 minutes	10 minutes	10 minutes
Peppers, green	• Follow recipe for Spanish Rice and Pork Stir-Fry.			
Peas, green	30 minutes in a crab pot	4 bags/ 2 1/2 minutes	5 minutes	8 minutes
Onion	• Follow recipe for Spanish Rice; Vegetarian Spaghetti Sauce • Weigh frozen.			
Spinach	30 minutes in a crab pot	8 to 9 bags/25 minutes	5 minutes	10 minutes
Turnip Greens	55 minutes in a crab pot	8 – 9 bags/26 minutes	10 minutes	10 minutes
Yellow Squash	8 minutes, in a crab pot	2 boxes/6 minutes	12 minutes	8 to 10 minutes
Zucchini	14 minutes in a crab pot	1 deep steamer pan for 4 minutes, than follow recipe for Vegetarian Spaghetti Sauce	Uses fresh and adds directly to Vegetarian Spaghetti Sauce uncooked	8 to 10 minutes

6. Fruits

Weighing **Storage**	• Weigh to + or - 0.5 gm. • All fruits, except bananas, are refrigerated when not being prepared.

Frozen

Strawberries, unsweetened	• Defrost in refrigerator enough to break up. • Weigh into serving dish.

Fresh

Weighing **Sanitation**	• Use proper size. • Rinse.
Apples	• Keep refrigerated. • Wash and dry thoroughly. • Do not weigh. Use one whole, size 113 count (138 gm).
Banana, fresh	• 32% refuse factor is reflected in the portion weight. (Example, 100 gm banana = 132 gm banana with skin. • Weigh with skin. Cut from the stem end. • Dip end in lemon juice. Wrap end in plastic wrap. • Use green banana to have not over ripe when served. • Weigh bananas to the target weight. When bananas are inadvertently cut to weigh below the target weight, weigh them within $\pm$ 10 GMS of the target weight.
Cantaloupe	• Rinse outside of melon. Remove skin and cut into chunks. • Weigh into individual portions.
Orange, fresh navel	• Keep refrigerated. • Do not weigh. Use one whole, size 138 count (140 gm).

6. Fruits (cont'd)

Dried

Raisins, Sunmaid	• Use PC portions.
Apricots, Sunmaid Fruit Bits	• Weigh individual portions.

Canned

Applesauce, sweetened, Motts Peaches, DelMonte Fruit cocktail, DelMonte	• Use PC portion.
Pineapple, tidbits or chunks	• Drain 5 minutes • Weigh juice and solids individual portions.
Applesauce, unsweetened, Motts	Weigh for energy cookies.

7. Pastas, Cereals, Grains

<table>
<tr><td>Weighing
Storage</td><td colspan="4">• Weigh to nearest + or - 0.5 gm.
• Store at room temperature.</td></tr>
<tr><td>Rice, white, cooked</td><td colspan="4">• Weigh uncooked rice according to amount needed and recipe portion. Bring water to boil. Add weighed rice. Reduce heat to low, cover pan, simmer 20 minutes. Remove from heat. Stir. Let cool 5 minutes with cover on. Stir again.
• Cool completely.
• Weigh into individual servings.
• 100 gm uncooked white rice + 250 ml water = 295.7 gm cooked rice (average of 297.5, 294, 295.6).</td></tr>
<tr><td></td><td>Baltimore</td><td>Baton Rouge</td><td>Boston</td><td>Duke</td></tr>
<tr><td></td><td>Rice cooked according to above directions.</td><td>Fill one transport pan with 996 gm rice and 2385 gm water. Steam 30 minutes with lid on.</td><td>Follow site specific Steamed White Rice recipe. Steam for 22 minutes.</td><td></td></tr>
<tr><td>Rice, brown, cooked Steaming option specific to individual sites.</td><td colspan="4">• Weigh uncooked rice according to amount needed and recipe proportion. Bring water to boil. Add weighed rice. Reduce heat to low, cover pan, simmer 25 minutes. Stir once after 15 minutes. Remove from heat. Stir. Cover pan and cool 5 minutes. Stir again.
• Cool completely.
• Weigh into individual servings.
• 100 gm uncooked brown rice + 250 ml water = 288 gm cooked rice (average 260.4, 294.3; 310.4).
• Each site has standardized steaming procedures.</td></tr>
<tr><td></td><td>Baltimore</td><td>Baton Rouge</td><td>Boston</td><td>Duke</td></tr>
<tr><td></td><td>Rice cooked according to above instructions</td><td>Fill one transport pan with 996 gm rice and 2385 gm water. Steam 30 minutes with lid on.</td><td>Follows DASH2 Brown Rice recipe.</td><td></td></tr>
</table>

7. Pastas, Cereals, Grains

Spaghetti, cooked, Ronzoni	• Weigh uncooked spaghetti according to amount needed and recipe proportion. Bring 500 gm dry/3 L H_2O) water to boil. Add dry, weighed spaghetti. Stir. Return to boil and boil uncovered 10 minutes. • Drain in colander. Rinse 2 minutes with cold water. Drain 3 minutes. • Weigh individual portions. • 100 gm uncooked spaghetti = 256.8 gm cooked spaghetti (average of 258.4, 253.8, 258.2).
Cereals (cold and hot) Multi Bran Chex, Cream of Wheat, Grits, quick	• Weigh portion into individual servings. • Weighed cereals should be stored in tightly sealed containers to avoid getting stale or soggy.
Corn Flakes, LS; Bran Flakes Oatmeal, instant Cornflakes, Kellogg's Frosted Mini-Wheats, Grits, instant	• Use portioned controlled box as directed.
Granola bar	• Weigh

8. Bread Products (Bread, Bagels, Pita, Hamburger Buns, Sandwich Rolls, Dinner Rolls, and French Bread)

Weighing Storage	• Weigh to + or - 0.5 gm • Bread products may be prepared and weighed ahead and frozen based on acceptability.
Precooked Bread Rolls	• Weigh to individual serving. • Package and seal.
Bread, sliced 100% Whole wheat (LS and regular) White; regular White, low sodium, Super G or Stop and Shop	• Look carefully for low-sodium vs. regular-sodium products, especially with sliced bread. • Trim bread for sandwiches together (e.g., stack 2 slices), so that they will fit together for sandwich. • Trim off from one end to include crust and bread.

9. Milk and Dairy Products

Weighing **Storage**	• Weigh to + or - 0.5 gm. • Refrigerate and cover at all times. • Label opened containers with date opened. Discard after 5 days.
Cheese, Cheddar American Alpine Lace Cabot cheddar Cream cheese Cottage cheese Breakstone or lowest sodium brand available	• Weigh and package. • Keep refrigerated.
Cheese, Parmesan	• Use PC when available. • Weigh and package if PC not available.
Milk 1% Whole Skim	• Weigh directly into individual glass or container. • Keep refrigerated until served.
Sour Cream Regular Fat-free	• Use PC when available. • Weigh directly into individual containers.
Yogurt Low-fat fruit on the bottom Blended fat-free Dannon	• Use as portion controlled as indicated.

10. Mixed Dishes

Weighing **Storage**	• **?** • Freeze until needed. Defrost in the refrigerator.
Pizza, Stouffer's Lean Cuisine Cheese French bread	• PC = 170 gm. • Weigh and package as needed. • Include cooking instructions for participant.
Lasagna with meat Sauce, Stouffer's Lean Cuisine Meat Sauce	• PC = 297 gm

11. Snacks and Sweets

Cookies, chocolate chip, Chips Ahoy, blue package Shortbread cookies, Walker's Orange slices Farley's	• Do not weigh • PC = 1 cookie = 10. 7 gm each • PC = 1 slice candy = 15 gm • • Do not weigh. PC = 1 each
Crackers Saltines Graham Animal crackers, Nabisco Barnum's Animal Gelatin, Jello sweetened unsweeted M & M's Milky Way candy bar Kit Kat Wafer bar	• PC. • .PC = 56.8 gm • PC = 99 gm sweetened • PC = 99 gm • PC = 92 gm • PC = 48 gm ? • PC = 24 gm GM ? • PC = 21 gm = 1, 2-stick package
Crackers Triscuits, whole wheat Triscuits, whole wheat, low sodium Ritz Ritz, low sodium	• PC = 4 gm = 1 each • PC = 4 gm = 1 each • PC = 3 gm = 1 each • PC = 3 gm = 1 each
Sour balls, Brachs	• PC = 5 gm = 1 ball. • Do not weigh, count balls.
Pound cake, Sara	• Weigh and package individual portions.

Lee Frosting, Cream cheese flavored, Duncan Hines Frosting, vanilla, Duncan Hines	
Cake, Duncan Hines Vanilla	• Follow recipe instructions.
Pretzels, unsalted Mini, Snyder's of Hanover	• Weigh and package if PC not available **(?)**

11. Snack and Sweets

Nuts, unsalted Almonds, Blue Diamond Peanuts, w/o salt, Planters cocktail Mixed nuts, w/o salt, Planters 50% less peanuts **Pecans - ?**	• Weigh into individual portions.
Cookies, Energy Combination, low, medium and high Control, low, medium and high	• See recipe.
Cookies, lemon colored	•
Cookies, lime colored	•
Cookies, cherry colored	•

12. Fats and Oils

Weighing **Storage**	• Weigh quantities > 10 gm weigh to 0.5 gm. • Weigh quantities < 10 gm weigh to 0.1 gm. • Refrigerate all open containers.
Fats, Oils and Spreads Canola oil, Hollywood or Mazola Corn oil Safflower, Hollywood Olive, Pompeiian Butter with and without salt	• Weigh into individual portions or as recipe indicates.
Butter, margarine, mayonnaise, and salad dressing with fat Butter w/o salt, Cabot, 5 gm pc Sysco Creamy Italian salad dressing Kraft Creamy French dressing	• Use portion-controlled packaging (PCs) do not weigh

13. Spices and Condiments

Weighing **Storage**	• Weigh to nearest 0.1 gm. • Add to recipe. • Store spices at room temperature in dry area. • Refrigerate condiments after opening.
Salt, Alliance	PC = 0.4 gm.
Cinnamon, McCormick Salt, Alliant Broth, beef, salt-free Custom Broth, chicken, salt-free, Custom Lemon juice Kraft Jelly Gravy, beef Menu Magic Franco American Gravy, turkey Franco American Mustard Kraft Catsup, Heinz Hunts, no added salt Sugar	• Use portion-controlled packaging (PCs). • Weigh as needed

14. Beverages

Grape juice Orange juice Apricot nectar Apple juice Cranberry juice Fruit punch Prune juice	• Use PC portion.
Kool-Aid, powder dry	• Weigh into individual portions. • Needs ___ gm water with ___ gm of powder.

Summary of Edits

41. Participant Management and Compliance

Overview

The strict dietary requirements of the study are likely to create compliance challenges to the participants as well as the clinic staff. The goal of participant management activities is to promote compliance in this feeding intervention.

Study staff will have the opportunity to clarify overall expectations of adherence to the experimental protocol and diets during orientation. During run-in, participants found to be at high risk of dropping out should be excluded from the study. Ideally, participants will exclude themselves when they realize the expectations of the study exceed their willingness or ability to commit to the time requirements of the study. **Because DASH2 has an "intent-to-treat" design, participants cannot be asked to leave the study once they are randomized. Study staff must therefore work with randomized participants to ensure maximum compliance with the study protocol.**

Measuring and Monitoring Compliance

The study uses several measures to assess compliance with the feeding protocol, both prior to randomization (during run-in) for purposes of exclusion and following randomization (during intervention) for purposes of monitoring and encouraging compliance. These measures, and the corresponding actions they require, are summarized below.

Compliance Assessment during Run-In

Participants are evaluated for compliance on days 2 through 8 of run-in. Participants are evaluated on: missed study foods, non-study foods eaten, and attendance. Staff may conduct case conferences to review each participant's compliance performance, and to decide which participants will move on to randomization.

<u>Missed Study Foods or Non-Study Foods Eaten</u>

Participants complete the Daily Diary (Form #24) during run-in. Missed study foods and non-study foods eaten are recorded on this form. For the first occurrence of missed study food, or non-study foods eaten, participants are counseled by the clinic staff on the importance of compliance with the study diet. A daily compliance composite score is determined for each participant. See Subjective Compliance Assessment Tools below.

To review the participants' compliance ratings during run-in days 2 through 8, print the Run-In Compliance Report from the unblinded area of the file server. Participants are excluded from further participation when:

1. they receive two compliance scores of a "2,"
2. they receive four compliance scores of a "1," or
3. they miss two or more meals and do not have an acceptable reason. for missing the meals

Participants having good reasons for missing meals may be counseled or excluded at local discretion. Exceptions based on extraordinary circumstances may be appealed to the coordinating center.

Meal Attendance

Participants who miss a scheduled clinic meal and do not call in to provide a valid explanation shall be excluded (this constitutes three missed meals, since they would have failed to pick up their other meals for that day). Exceptions based on extraordinary circumstances may be appealed to the coordinating center. Participants who do not eat a scheduled meal at the clinic and do call in to explain may be kept in the study provided they make arrangements to pick up their meals.

Case Conference

At the end of the second week of run-in and prior to randomization, the clinic staff reviews each participant's overall compliance history and decides whether the participant is a good candidate for the trial or whether they should be excluded. This conference should consider all aspects of a participant's participation in the trial to date, including tardiness, attitude, need for special staff effort, and variance from the diet. That the case conference occurred is reported on the Run-In Flow Form (#16). Case conference results (to randomize or not randomize each participant) are recorded on the Case Conference Form (#33). This form must be entered prior to randomization.

Compliance Assessment during Intervention Period

During the intervention period participants are monitored for their adherence to the feeding protocol. If compliance issues arise, dietary staff should counsel participants (see Promoting Participant Compliance and Motivation on page 41-7).

Tools for Monitoring Compliance

Both objective and subjective measures of compliance are used to assess each individual subject's adherence to the protocol and study diets.

Subjective Compliance Assessment Tools

1. Daily Diary

During run-in and intervention all participants are expected to maintain a Daily Diary (Form #24), summarizing study foods and beverages that were not consumed and non-study foods that

were consumed. Participants also complete questions each day summarizing problems or illnesses that may interfere with their compliance. This information is reviewed by the intervention staff at each of the daily feedings and summarized in a "for office use only" column on the Daily Diary for purposes of data entry and analysis. Instructions for reviewing and coding the Daily Diary are attached to the electronic version of the form.

Two overall daily compliance scores are determined for each participant, based on the Daily Diary (Form #24) data, the Run-In Compliance Score and the Sum Score.

The "Run-In Compliance Score" provides a categorical rating indicating compliance and two levels of non-compliance. The daily Run-In Compliance Score is computed from the Daily Diary compliance ratings using the following guidelines:

- If any "2" rating, then the Run-In Compliance Score would be a 2.
- If no "2" but any "1," the Run-In Compliance Score is 1.
- If all "0," the Run-In Compliance Score is 0.

In general, the Run-In Compliance Score denotes non-attendance, study foods not eaten, non-study foods eaten, and deviation from beverage allowances, as follows. A score of:

- "0" indicates no deviation from the feeding protocol,
- "1" indicates non-attendance, one full serving, three or fewer partial servings, and/or one or two additional beverages, and
- "2" indicates two or more full servings, four or more partial servings, one or more full meals, or more than two additional beverages.

The Run-In Compliance Report generated from the unblinded area of the data management system shows daily Run-In Compliance Scores for days 2-8.

The "Sum Score" is calculated as the summation of the compliance ratings on questions #1, 2, 3, 5, and 6 on the Daily Diary. The scores may range from 0 to 9. A score of 0 indicates perfect attendance and compliance with the feeding protocol, while a score of 9 is maximum non-compliance. The Compliance Report generated from the unblinded area of the data management system shows daily Sum Scores for the time period selected.

2. Case Management and Meal Monitoring

A staff person, referred to here as the "case manager," manages the progress of participants throughout the intervention. The duties of the case manager include ongoing chart review, assessment of the participants' progress, planning, follow-up, and case conferencing, if necessary. The case manager communicates with each participant regularly, providing counsel as needed. The case manager is required to arrange for a back-up manager to follow participants in her absence. The case management schedule includes the following:

- A minimum of one contact with each participant during weeks 1 and 2 of run-in
- A minimum of one contact with each participant during the first week of intervention
- A minimum of one contact with each participant during the first week of subsequent intervention feeding periods
- Individual counseling with any participant who is non-compliant in any aspect of the intervention
- Brief progress notes describing the case manager's subjective evaluation of each participant's progress

Sites are required to have staff monitor each meal. Participant problems identified are referred to the case manager.

3. Anonymous Questionnaire

At the end of each feeding period, subjects are given an anonymous questionnaire (Anonymous Survey, Form # 25) and asked to indicate aspects of the study with which they did not comply. Because the questionnaire is anonymous, it is used along with other measures of compliance to assess overall compliance to study diets in a retrospective fashion. Each site has a plan to administer and collect the majority of the surveys during the intervention period (not during closeout).

Objective Compliance

Two separate measures are used to objectively assess compliance. These are attendance at meals and body weight.

1. Attendance

Meal attendance is monitored and recorded for each subject. Participants are required to consume at least one meal, (lunch or dinner,) on site, five days per week. This daily visit ensures that study personnel have a chance to observe approximately 1/5 of the research diet being consumed. The daily visit is also a way for study personnel to evaluate a given subject's attitude. This information is used to formulate subjective staff judgment of compliance.

2. Weight

When food intake is constant and weight has stabilized at a given energy level, fluctuations in weight may be a reflection of noncompliance. It is anticipated that body weight will stabilize within the first week of the run-in diet and that the second week of the run-in can be used to assess compliance to study diets. Thus, body weight will be measured daily (5 days per week) throughout each feeding period and is tracked using the Daily Diary (Form # 24). The Weight Tracking Report is used to identify potential compliance problems with weight.

Promoting Participant Compliance and Motivation

Participant and Staff Relations

A key element of successful intervention is the participant-staff relationship. The ability of clinic staff to practice both professionalism and empathy will help in establishing an environment of trust. In turn, this will increase the likelihood of maintaining participant compliance as well as attaining accurate information from participants during the study.

Participant Management

Setting Expectations

Each center is expected to incorporate an orientation visit, most often in a group setting of potential participants, conduct during the screening phase. The primary purpose of this visit is to set the expectations of adherence to the experimental routine and diets. Briefly summarized, the key expectations are:

1. The participant comes to the center every weekday to eat one meal and pick up packaged meals to be eaten off-site.
2. The participant picks up weekend meals and consumes those meals (and only those meals) off-site.
3. The participant eats only food provided by the study and nothing else.
4. The participant consumes all provided food in its entirety.
5. The participant is willing to provide periodic urine samples, blood samples, and blood pressure measurements.

The orientation visit also gives participants a chance to ask questions and to meet the intervention team and the other participants. The conduct and content of the orientation visit is detailed in Diet MOP, Chapter 32, Participant Orientation to Study.

To assist the participant in organizing his or her time for the various commitments of the study, each center is encouraged to produce a meal attendance schedule, which may also include other events or clinic visits the participant is expected to attend. The meal attendance schedule should be flexible enough that a participant can attend an alternate meal should he miss the scheduled meal on any given day. In addition, each center is to adopt procedures designed to provide the participants easy access to its research facility and staff.

Reinforcing Expectations

Information provided during orientation will introduce the study expectations to the participants. It will be necessary to remind participants of their primary responsibilities throughout the course

of the study. This reinforcement should begin in the first week of run-in and continue until the last clinic measurement is recorded.

Establishing Rapport and Trust

The building of rapport with participants through brief but meaningful individual interaction is invaluable in promoting compliance. The clinic staff style and manner of communicating with participants play a key role in promoting trust between participants and staff. Key elements of quality interactions that promote rapport and trust with participants are:

1. Try to understand the participant. Be warm, interested, and non-judgmental.
2. Avoid confrontation and raising the participant's resistance.
3. Emphasize your confidence in the participant's ability to adhere to the diet.
4. Re-affirm the participant's reasons for volunteering to be a part of the study.
5. Emphasize the important contribution one participant can make to the study as a whole.
6. Reinforce the study expectations in a gentle and encouraging manner.
7. Help the participant explore and resolve ambivalence about adherence to the diet.
8. Provide easy access to participants, i.e., convenient and flexible meal times, answered phones, and beeper access to key staff for off-hour problems.

Participant and Staff Contact

Although participants have agreed to participate in the study, they may still have some ambivalence about the strict dietary compliance required. Clinic staff who have direct contact with participants will have the greatest opportunity to address the participants issues and concerns. The greater the quality of contact and quantity of time the clinic staff has with each participant, the better the overall participant compliance will be. However, clinic staff have limited resources and must set realistic goals for themselves as to how much time they can spend and what they can accomplish with each participant.

There are two levels of contact: 1) the day-to-day contact when participants come to the center for their on site meals, and 2) the case-by-case contact and follow-up conducted in a case-management format.

Day-to-Day Contact

Each center should arrange to have a staff member present at each on-site meal to attend to a wide range of participant needs. This staff person will be referred to here as the “manager on duty.” The best person for this role is one who is not serving meals or performing other activities related to the on-site visit (e.g., weighing, blood pressure measurement). The sole purpose of this manager on duty is to interact with the participant, either one-on-one or in small conversation groups. Manager on duty fields participant questions and concerns, document interactions, and plan follow-up courses of action.

The managers on duty must be well informed in study protocol and dietary procedures. The manager on duty position may work best if rotated among staff. Care must be taken to keep any staff who take clinic measurements blinded to participants' treatment status.

Brief Contact Strategies

Contact with the participant either day-to-day during on site meals or case-by-case with individuals will usually be brief. The study design does not allow for lengthy sessions with participants nor is it usually necessary in promoting compliance. Brief intervention with participants can be very productive if basic helping strategies are practiced. The following helping strategies will increase the likelihood the participant will comply:

1. Nonverbal 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.

2. Open-ended questions

Ask questions which 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?" "What have been the easiest?"

3. 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."

4. Summarizing statements

Use summarizing statements at transitional points or at the end of a conversation to pull together the gist of what has transpired. Recap 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...." Brief interventions have been shown to be effective in motivating people to make and maintain lifestyle changes. Although participants in this study are not making major lifestyle changes, they are maintaining a specific diet (the study diet) that they have consented to follow. The clinic staff, by practicing a motivational style of communication with participants, can promote this "maintenance" or compliance with the study routine and diets.

Relapse Prevention

After participants have adjusted to the project diet, close adherence can be expected for at least a few weeks. However, over the course of intervention participants are likely to exhibit an increasing tendency to deviate from the study diet. These adherence slips can be seen as relapses in which the participants return to some or all of their former dietary habits. These relapse events can be seen as participant responses to situation triggers, such "triggers" being birthday parties, business travel, or houseguests, for example. The majority of the time, participants can identify these situations in advance. This relapse-prevention model is based on that premise.

The most opportune times to address possible relapse situations with the participant would be during day-to-day contact at on site meals or during an individual case-management contact. Steps in conducting a relapse-prevention treatment are:

1. Ask the participant to identify several situations specific to him which are highly likely to cause deviations from the study diet.
2. From the list of situations, ask the participant to choose one or two which are likely to come up in the near future and are highly problematic.
3. Help the participant develop active coping strategies for those particular situations. Ask them to generate a plan which includes realistic solutions. (One key to success in this process is finding an active substitute for the trigger situation.)
4. Ask the participant to add details to the plan. (Key questions to answer are "What will the participant do?" "When will they do it?" and "How will they remember to follow through?")
5. Follow up with the participant in a timely manner. Find out how the plan worked for them.

<u>Incentives</u>

Each center is expected to use whatever incentives they have used in the past to promote compliance. Examples are: gift certificates, raffles (e.g., movie tickets), door prizes (e.g., flowers, key chains, tote bags). Aside from the payment for completing study requirements, at no other time should cash be used as an incentive. Most important is that the incentives should be motivating to the participants. Clinic staff may choose to ask participants what would be most helpful to them in meeting the goals of intervention. To maximize the reinforcement value incentives, should be dispersed intermittently. In other words, do not have a drawing for a door prize every weekday during intervention. Alternate methods and modes of rewards. Consider including special events such as birthday or holiday celebrations that enhance the participant's sense of value as a study subject.

At the close of intervention, a group dinner with self-selected foods is recommended. This may give the participant additional incentive in completing the study and provides a concrete reward for doing so. It also makes for a very positive closing event. Participants may share their experiences with friends or family which, in turn, can have an influence on persons screened for future cohorts.

Procedures for Dealing with Potential Compliance Deviations

Overview

Missed meals are either excused or not excused. Non-excused meals are a participant being absent from an on-site meal without a valid reason during run-in, and are grounds for dismissal from the study. Excused meals constitute a participant being absent from an on-site meal with a valid reason. If the subject did not eat any non-study food during the absence, a replacement meal will be provided to be eaten during the remainder of the day.

Excused Missed Meals

Illness

Illnesses that interfere with the dietary compliance should be reported immediately to the study director, who will determine appropriate action.

Emergency Meals

Emergency meals are used in the event of inclement weather, such as hurricanes and snowstorms, or other emergencies, when participants cannot get to the site to eat their scheduled meal. Each site designates one 50 mmol sodium level menu, prepares it, and sends it home with the participant to be kept in their freezer during the intervention. Participants are told how many salt packets to use depending on their sodium level at the time of the emergency.

Meal Passes

Meal passes excuse a participant from consuming a meal on-site and are reserved for emergency situations. The purpose of meal passes is to give a participant permission to miss consuming a meal on-site when unanticipated real-life events occur. This gives the participant the choice of determining whether or not an event that precludes eating at the site is an actual emergency. The participant must still pick up the meal but can consume the meal off-site. The participant must notify the kitchen staff of their need to use the pass and must get the approval of the staff to eat their meal off-site.

Uneaten Foods

Uneaten portions

If the subject is still at the feeding site, any food that is left should be returned to the subject to eat. If the subject cannot eat all of the meal, it may be packaged for later consumption or it may be added to the next meal. Foods that cannot be safely or aesthetically saved for another meal

should be discarded and a replacement provided. If the participant refuses to eat the leftover meal, the missed foods are documented and the appropriate compliance score is recorded.

Missing, Lost, or Spoiled food

If food is missing, lost, or found to be spoiled during an on-site meal, a replacement item will be provided at that time. If the mishap occurs during an off-site meal, the participant is instructed to telephone the staff on-call. The staff on-call will contact the dietitian or provide guidance directly to the participant on appropriate substitutions. Wherever possible, DASH2 study foods will be provided. Emergency meals are allowed to be consumed by participants in this situation. If so, the clinic prepares a replacement emergency meal in a timely manner. The participant is to document any substitutions in their Daily Diary (Form #24).

Participants Who Withdraw

Randomized participants who withdraw during the feeding program are asked to re-enter their assigned intervention feeding period when and if it seems feasible to make such a request. The underlying goals shall be to maximize the amount of study foods consumed during the intervention period, minimize the amount of non-study foods consumed, and collect outcome data on as many randomized participants as possible.

Summary of Edits

42. Diet Quality Assurance

Introduction

This chapter outlines the DASH2 quality assurance procedures for the nutrition and dietary staff. The purposes of the procedures are to build quality into the dietary screening, food procurement and preparation, participant orientation, and counseling areas of the study by doing ongoing checks of processes. Quality assurance methods include training staff, observing procedures, monitoring data for completeness and accuracy, evaluating processes, giving feedback, and documenting that tasks are done according to protocol. After a brief discussion of the quality assurance methods, the chapter is divided into sections that outline the quality assurance techniques used for the following areas.

- Dietary Screening
- Food Procurement
- Participant Orientation
- Participant Management and Daily Diary
- Food Safety and Preparation
- Exit Interview

Methods

Training

Initial training occurs for each procedure. Initial certification and regular re-certification ensure that staff have a general understanding of the study procedures, have acceptable performance standards, and maintain their skills. Staff responsible for collecting data and procuring and preparing food are initially trained and certified for the specific tasks. Retraining frequency depends on the procedure.

Observations

Observations of staff performing activities ensure that staff have received adequate training and perform tasks using standardized study procedures. Observations help identify procedures that are not clearly understood or need improvement, as well as areas where additional training is needed. Lead staff, certified peers, and Coordinating Center staff are responsible for observing routine activities. Observations occur during initial training, scheduled certification periods, and routine quality assurance monitoring. The Coordinating Center observations occur at central training and at site visits.

Monitoring Equipment

Equipment checks and routine maintenance identify short- and long-term problems with equipment performance. Each site is responsible for the appropriate functioning and maintenance of equipment used in the study. Clinical sites use logs to record equipment checks and maintenance following both the manufacturer and study requirements.

Site-Specific Quality Assurance Procedures

Each DASH2 clinical site has quality assurance procedures specific to the site. The sites are encouraged to develop an internal procedure manual and have it available as a resource to all staff. Important topics to include are:

1. Site-specific policies, procedures, and forms
2. Emergency procedures
3. Documentation and update procedures
4. Site-specific quality assurance plans that includes training, certification, standards of performance, monitoring and documentation of the quality assurance activities
5. Equipment monitoring procedures

Sites regularly monitor the processes and systems they have and make corrections as necessary. In addition, each site puts in place the process to have accessible participant study records, the steps to monitor the content of the records, their management and kept confidential.

Site Visits

Site visits occur regularly and are used to monitor quality. The visit is a team effort that includes a mix of staff from the project office, the DASH2 Coordinating Center, and peers from clinical sites. It offers an opportunity to gather ideas to make the work more efficient, share information between sites, and provide feedback. Site visits occur at the clinical sites during feeding periods. The dates are set based on availability of staff and the mix of activities at the sites. The amount of time spent at a site depends on the activities to observe.

The visit looks at site processes and systems and may identify areas that need to be strengthened. The visit activities include a review of quality assurance activities and documentation.

The Coordinating Center, with input from the other site visitors, prepares a checklist that is used during the site visit. After the visit the Coordinating Center prepares a report of the findings with input from the cross-site visitors. This report is sent to the site principal investigator and a copy to the project office and includes an overview of the visit, a summary, action items, and recommendations. Each site prepares a written response to the report.

Dietary Screening

Overview

The goal of dietary screening is to ensure that participants at each of the clinical sites can tolerate study foods, are able to store take-home meals safely, and meet the daily meal-attendance requirements. Though not a screening tool, the Food Questionnaire (also referred to as the Food Frequency Questionnaire, FFQ) is administered to assess participant food-consumption patterns.

Purpose

The purpose of the dietary screening quality assurance activities is to ensure that participants are properly screened and staff are routinely evaluated to make sure standardized methods are used to collect data and screen participants.

Quality Assurance Activities

1. The Coordinating Center gives feedback on errors observed on the Food Questionnaire.

2. On conference calls, the Diet Committee discusses screening activities and modifies processes as the need occurs.

3. The Diet Committee documents in the minutes decisions or actions based on the committee discussion.

4. The Diet Committee reviews screening activities and modifies necessary processes at the end of each cohort.

During the screening process and at the end of each cohort the Diet Committee on conference calls reviews the dietary screening activities and determines if modifications need to occur to the process. If screening activities are modified, the trainer retrains and observes staff, following the steps outlined in the DASH2 Diet MOP, Chapter 35, Training.

Food Procurement

Overview

The goal of this section is to ensure that proper study food is acquired and prepared. It is necessary in a controlled feeding study to prepare and serve foods with the same or similar nutrient content.

Purpose

This section describes the processes in place to monitor the food procurement for the study. The process ensures that standardized procuring methods are used and correct foods are acquired. In addition, quality assurance methods see that an adequate supply of food is stored at each site to prevent the possibility of a short supply during the feeding period.

Quality Assurance Activities

1. The Diet Committee reviews suitability of food product procurement processes on regular conference calls and at the end of each cohort.

   During the feeding periods and at the end of each cohort the Diet Committee reviews the food procurement processes, develops additional tools, and trains, if necessary. Sub-groups are organized to prepare a plan and bring it back to the Diet Committee. If necessary, processes, systems, and/or forms are modified. Any modifications that occur are documented in the Diet Committee minutes. For example, a sub-group at the end of each cohort reviews the study production forms to make sure they contain the appropriate foods and amounts of food. The group reports back to the Diet Committee.

2. Each clinical site develops specific procedures used to monitor food purchases and inventory.

   These systems are reviewed at site visits.

3. The CC distributes food procurement software that contains an updated list of approved food products so the site nutritionists can predict the amount of food needed for each cohort based on the participant census.

   The food information in the Food Procurement database system is driven by the information on the production forms. When the Diet Committee determines that modifications need to be made, the Coordinating Center updates both the production form database and the Food Procurement system and distributes an updated version.

4. The Diet Committee reviews the study product nutrient content to determine if the formulas fit the study nutrient calculations.

Both donated and purchased study food labels are reviewed by the Diet Committee members during the feeding periods and at the end of each cohort to make sure the nutrient content of the product is consistent with the study database. The food labels are collected by the Coordinating Center and kept for documentation.

Participant Orientation

Overview

The goal of participant orientation is to ensure that all participants understand the requirements of the study prior to the start of run-in.

Purpose

To retain participants in the study it is imperative that they have a clear understanding of the study expectations, and are prepared, comfortable, and ready to follow the study diets during the duration. Because of this, each site performs the same activities during orientation and monitors and documents the process.

Quality Assurance Activities

1. The assigned person at each site completes the Participant Orientation Checklist (Form #94) for each orientation session.

   Generally, sites provide group orientation sessions for participants before being randomized into the study. However, participant orientation can occur individually if necessary. For each orientation session, the nutritionist completes the Participant Orientation Checklist (Form #94). Any concerns about the orientation, problems identified, or points omitted are noted on the form. Each site attaches to the form a list of study identification numbers for participants attending the orientation. In addition, the study identification numbers of the staff who conduct the orientation are noted on the form. The completed forms are stored at the site with other quality assurance documents. The documents are reviewed at site visits.

2. The Diet Committee reviews orientation activities, processes and systems on conference calls and at the end of each cohort.

   During the feeding periods and at the end of each cohort the Diet Committee reviews the orientation activities, develops additional tools, and trains, if necessary. Sub-groups are organized to prepare a plan and bring it back to the Diet Committee. Processes, systems, and/or forms are modified, if necessary. Any modifications that occur are documented in the Diet Committee minutes.

.

Quality Assurance Materials

Participant Orientation Checklist (Form #94)

Participant Management and Daily Diary Review

Overview

The goal of participant management quality assurance is to use the same process to promote and monitor participant retention and compliance between sites. Strict dietary requirements of the study are likely to create compliance challenges for the participants. Because DASH2 has an "intent-to-treat" design, participants cannot leave the study once they are randomized. Study staff must, therefore, work with randomized participants to ensure maximum compliance with study protocol.

Purpose

The purpose of the participant management and compliance quality assurance is to monitor and evaluate participant management activities to make sure they are performed uniformly at each site and documented.

Quality Assurance Activities

1. The Diet Committee reviews and evaluates participant management activities at the end of each cohort and modifies, if needed.

2. A second dietitian codes 10% of the Daily Diaries (Form #24).

Daily Diary Quality Control Process

Check 10% of the Daily Diaries during each feeding week to make sure they are coded accurately. For example, if the cohort size is 30, check at least three participants' Daily Diaries. This converts to 21 total diaries (7 diaries per week X 3 participants = 21 diaries).

The process is:

1. During each week of feeding, alphabetize the cohort, than select 10% of the participants to code a second time. Do this by selecting the first 10% in Week 1, the second 10% in Week 2, etc.

2. Record on the Cohort Attendance Roster, the each participant's Daily Diary score is coded by a second person.

   The goal is to code each participant's week of Daily Diaries twice, using a second person within two weeks of the date of the original diary.

3. Copy the 10% sample of Daily Diaries on colored paper before the first coding is done. Leave the coding area blank for the second person to conduct the quality control. An

alternative is to cover the coded area with a template to allow the second person to code without seeing the original answers.

4. Divide the selected participants between the nutritionists conducting the coding each week. The original coder does not do the quality control for the same participant. Each nutritionist participates in the quality control process.

5. Flag the questions that are coded differently by the two people. Discuss the coding differences. Date and record the outcome of the discussion on the colored paper for audit purposes.

   Use the Daily Diary Coding Instructions found at the back of the Daily Diary to correct the original Diary. Send the modified Daily Diary to the Coordinating Center by FAX after removing the participant's name from the form.

6. Calculate the error rate per week. This is done using the following formula and premise (15 fields per diary X 21 diaries per week = Total of 315 fields per Week)

   # Errors/315 fields = % Error

7. If the error rate is $\leq$ 2%, follow the process in Step 5.

8. If the error rate is $\geq$ 2% check another 10% of the participants, and follow the process in Step 5.

9. Discuss all coding questions on the Diet Committee conference call.

Food Safety and Preparation

Overview

The goal of this section is to ensure that the study meals are provided to participants in a safe and accurate manner. The frequency of monitoring quality is described below and documentation is kept at each site and reviewed at site visits.

During all DASH2 cohorts, each site puts in place mechanisms to ensure that:

- Proper food preparation techniques are used
- Complete meals are trayed and packaged
- Foods are weighed accurately
- Correct food product brands are used
- Correct diets, calorie levels, type and number of unit foods are delivered to participants
- Safe and sanitary food preparation techniques are used
- Cold food is stored safely
- Food scales are accurate
- Correct recipes are used and prepared according to the study directions

Purpose

This section describes the processes in place to monitor the accuracy and safety of the DASH2 meals. Quality control follows a schedule listed on the Quality Assurance Schedule (Form #93), and documentation is kept at each site.

Quality Assurance Activities

1. Each site uses the Quality Assurance Schedule (Form #93) to administer the following:

   Food Service Sanitary Inspection Checklist (Form #91)
   Spot Checking Recipes, Meals, and Food Items (Form #87)

2. Staff from the CC and clinical sites conduct site visits.

3. Each site prepares systems to monitor and document food preparation and safety.

4. The Diet Committee reviews the study food preparation and safety procedures on conference calls to determine if modifications need to be made to any of the processes or systems.

Quality Assurance Schedule

The frequency of monitoring the food production follows a schedule. Documentation is stored at each site. The schedule is summarized in the Kitchen Quality Control Schedule (Form #93). The A diet is monitored and documented during the first two weeks of run-in, and the B diet the first two weeks of intervention. The schedule is:

Once per Cohort

Check each recipe at least once per cohort or during pre-preparation. This assures foods are properly prepared according to standardized recipes. Use Checking Recipes, Meals and Food Items (Form #87). Each site monitors staff for:

- Correct type and brand of ingredient
- Accurate ingredient weighing
- Correct food preparation methods, including mixing, cooking, baking times, temperature, and portion size
- Proper food labeling
- Proper preparation for storage

Every Two Weeks

To ensure that foods are prepared under safe and sanitary conditions, inspect the DASH2 research kitchens, equipment, and employees every two weeks. Inspect and monitor employees preparing the food to see that they are using safe and sanitary food preparation techniques. Use Food Service Sanitary Inspection Checklist and Action Plan (Form #91) to check for:

- appropriate staff dress and cleanliness
- proper food handling
- clean equipment
- proper food storage practices
- correct dishwashing techniques
- clean kitchen area

Twice per Week

Twice a week during run-in and intervention randomly select weighed foods and weigh again. Check that corrects brands are being used. For two randomly selected foods, weigh three

samples of the same food twice. Continue this process for foods from each diet, calorie level, menu, recipe, and sodium level. Check appropriate raw and cooked weights. Use Checking Recipes, Meals and Food Items (Form #87).

Weekly

Calibrate food scales using Kitchen Scale (s): Weekly Accuracy Check (Form #90)

Daily

Check on-site meals daily to make sure they are properly prepared and assembled for each participant. Match plated foods with the menu and participant diet assignment. Use Checking of Recipes, Meals and Food Items (Form #87). Record one meal per diet per sodium level, six total. Select meals so that during the cohort each calorie level is monitored. Monitor for correct:

- type of food
- brand of food
- weight and/or amount of food
- number of energy cookies
- calorie level
- sodium level
- diet

Check take-out meals to make sure they are properly prepared and packed. Match the foods with the menu and the participant diet assignment. Use Checking Recipes, Meals and Food Items (Form #87). Monitor for correct:

- type of food
- brand of food
- amount of food
- number of energy cookies
- assigned calorie level
- assigned sodium level
- assigned diet

Inspect refrigerators and freezers for proper temperatures. Record the information on a site-specific refrigerator/freezer log.

Check meal delivery to make sure each participant receives the correct meal. Monitor for correct.

- diet
- calorie level

- label for energy cookies
- meal

Quality Assurance Materials

Checking Recipes, Meals and Food Items (Form #87)
Kitchen Scale (s): Weekly Accuracy Check (Form #90)
Food Service Sanitary Inspection Checklist and Action Plan (Form #91)
Kitchen Quality Control Schedule (Form #93)

Exit Interview

Overview

The dietary aspects of the exit interview are conducted in a group or individual format. The purpose of the exit interview is to provide participants with personal feedback about their health status from information collected during the trial. The goal of the exit interview quality assurance activities is to maintain continuity and consistency between sites in the process used to conduct the interview and in the information and feedback they give to participants at the end of the trial.

Purpose

The purpose of the closeout quality assurance activities is to ensure that participants are appropriately closed out of the study and that standardized methods are used between sites.

Quality Assurance Activities

1. The assigned person at each site completes the Exit Interview Observation Checklist (Form #85).

2. Via ongoing conference calls the Diet Committee discusses participant closeout and counseling processes and modifies as the need occurs.

3. The Diet Committee documents in the minutes any decisions on actions taken.

The Exit Interview Observation Checklist (Form #85) is completed once for each cohort and tracks the activities of the process. For each activity on the form a staff person indicates if the activity was done or not. If the activity was unable to be done, a comment is made. The form is than stored with other quality assurance forms at the site and reviewed during site visits.

During the exit interview process, and at the end of each cohort, the Diet Committee on conference calls reviews the participant closeout activities and determines if modifications need to occur to the process or materials. If modifications are necessary, the site trainer trains and observes staff following the steps outlined in the DASH2 Diet MOP, Chapter 35, Training.

Quality Assurance Materials

Exit Interview Observation Checklist (Form #85)