

MANUAL OF OPERATIONS

for

DASH

Dietary Approaches to Stop
Hypertension Study

September 18, 1998

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DASH Manual of Operations

DASH Study Manual

Table of Contents

1	Trial Administration and Personnel.....	<i>Version 4.1</i>
2.	Trial Policies.....	<i>Version 4.3</i>
3.	Human Subjects.....	<i>Version 4.0</i>
4.	Recruitment.....	<i>Version 4.1</i>
5.	Prescreening Visit (PSV).....	<i>Version 4.1</i>
6.	Drug Withdrawal.....	<i>Version 4.1</i>
7.	Screening Visit 1 (SV1).....	<i>Version 4.1</i>
8.	Screening Visit 2 (SV2).....	<i>Version 4.1</i>
9.	Screening Visit 3 (SV3).....	<i>Version 4.1</i>
10.	Participant Orientation to Study.....	<i>Version 4.0</i>
11.	Run-in and Randomization.....	<i>Version 4.1</i>
12.	Intervention.....	<i>Version 4.1</i>
13.	Study Menus.....	<i>Version 4.0</i>
14.	Menu Validation and Monitoring.....	<i>Version 4.1</i>
15.	Food Procurement, Safety and Preparation.....	<i>Version 4.1</i>
16.	Energy Assignment.....	<i>Version 4.1</i>
17.	Diet Training and Quality Assurance.....	<i>Version 4.1</i>
18.	Participant Management and Compliance.....	<i>Version 4.1</i>

DASH Manual of Operations

19.	Blood Pressure Assessment.....	<i>Version 4.1</i>
20.	Central Laboratory Procedures.....	<i>Version 4.0</i>
21.	Other Clinical Measurements.....	<i>Version 4.0</i>
22.	Forms and Questionnaire Data.....	<i>Version 4.0</i>
23.	Data Management.....	<i>Version 4.1</i>
24.	Data Analysis.....	<i>Version 4.1</i>
25.	Trial Monitoring Reports.....	<i>Version 4.1</i>
26.	Trial Communications.....	<i>Version 4.1</i>
27.	Safety Monitoring.....	<i>Version 4.1</i>
28.	Participant Close-out and Counseling.....	<i>Version 4.1</i>
29.	Ambulatory Blood Pressure Monitoring.....	<i>Version 4.2</i>

DASH Manual of Procedures

1. Trial Administration and Personnel

Steering Committee	4
Membership	4
Functions and Responsibilities	4
Clinic Coordinators	5
Membership	5
Functions and Responsibilities	5
Design and Analysis Committee	5
Membership	5
Functions and Responsibilities	5
Measurement and Quality Control Committee	6
Membership	6
Functions and Responsibilities	6
Diet Committee	6
Membership	6
Functions and Responsibilities	7
Recruitment Committee	7
Membership	7
Functions and Responsibilities	7
Publications and Ancillary Studies Committee	7
Membership	7
Functions and Responsibilities	7
Data, Safety, and Monitoring Board	8
Membership	8
Ex-Officio Members: Eva Obarzanek, PhD, RD	8
Functions and Responsibilities	8
Project Office Personnel	9
Coordinating Center	11
Central Laboratories	13
Baltimore Clinical Center	15
Baton Rouge Clinical Center	18
Boston Clinical Center	20
Durham Clinical Center	22

Summary of Edits

New changes in version 2.0

- personnel change at Baton Rouge (Macchiavelli for Wozniak)
- personnel change at coord ctr (Squires for Craddick; Pearson)

New changes in version 2.1

- updated committee rosters
- added section for clinic coordinators' committee
- added separate sections for central laboratory staff
- expanded last para under "Steering Committee
- phone number for Duke University

New changes in version 2.2

- changes in personnel

New changes in version 2.3

- changes in personnel (Ihrig for Culbert as clinic coordinator @ Pennington)
- add Jessie Rice, Coord. Center to clinic coordinators members and to CC roster
- changed clinic coordinators to contact person except Baton Rouge

New changes in version 2.4

- change for Duke Clinical's mailing address
- change in personnel
- removed personnel from some committees - Vani Williams, Patricia Wozniack

New changes in version 2.5

- added Staci Crawford to Baton Rouge's personnel
- no RN after Sharon Cappelli's name
- new address, fax and phone numbers for Project office, effective May 8, 1995
- change in prefix for phone numbers @ Baton Rouge, effective now

New changes in version 4.0

- Rosalind Bullard is no longer working @ Duke. Patrice Reams is the new Recruitment Coordinator and added Staff ID Numbers

DASH Manual of Procedures

New changes in version 4.1

- The coordinating center's secretary is no longer Nancy Adams and is now Jeanne Taylor.
- Area code of FALCC change from 703 to 540.
- New phone number for Brenda Harnish
- Janis Swain - new address
- Address for Dr. Lin @ Stedman Center
- Name change error corrected for Linda Gaffe to Linda Jaffe
- Name change for Luanna Squires to Luanna Diller Internet - dillerlu@chr.mts.kpnw.org
- Larry Appel change of internet address
- Benjamin Caballero change of internet address
- Pat Coleman change of internet address
- Temp address for Priscilla Steele
- Maureen MacDonald has replaced Yolanda Courtney at Boston
- Changed references to DSMB to "Data, Safety, and Monitoring Board."

DASH Manual of Procedures

DASH is a cooperative agreement in which the NHLBI Project Office, participating clinical centers, and the coordinating center act together to design a common protocol and administer the trial. The Steering Committee is the primary decision making body for the trial. Standing subcommittees include: design and analysis, recruitment, measurement and quality control, diet, and publications and ancillary studies. An independent Data, Safety, and Monitoring Board (DSMB) also serves the study. The functions of these committees and of the DSMB are given in the protocol and summarized below. Membership rosters are also given.

Steering Committee

Membership

Members: Principal and co-investigators at the coordinating center and at each clinical center and the members of the Project Office

Chair: Tom Moore, MD

Vice Chair: Larry Appel, MD

Voting: One vote for each of: Project Office, coordinating center, and each clinical center

Functions and Responsibilities

Assure clear delineation of roles and responsibilities among participating institutions.

Review and approve all policies, protocols, and trial-wide procedures.

Monitor performance of DASH overall and of each clinical center, including recruitment, adherence, data collection, quality control, and data analysis.

Consider and approve any ancillary studies and access to study data.

The Steering Committee meets face-to-face at least semiannually, with conference calls or additional meetings as needed and with regular sharing of information. Meetings are open to all study personnel. Conference calls should include at least the PI (or designee) from each site, project officer, and chairs of Diet and Clinic Coordinator committees.

DASH Manual of Procedures

Clinic Coordinators

Membership

Members: Sharon Cappelli, (Chair)
Eva Obarzanek, PhD
Pierre La Chance, BS
Jean Charleston, RN
Eleanor Meador
Maureen MacDonald
Kathy Aicher
Jessie Rice, BS

Functions and Responsibilities

Serves as primary liaison at sites when communicating with C.C. on issues of Data Management and Quality Assurance.

Design and Analysis Committee

Membership

Members: Frank Sacks, MD (chair)
Larry Appel, MD
Jeff Cutler, MD
Shiriki Kumanyika, PhD
Eva Obarzanek, PhD
Michael Proschan, PhD
Laura Svetkey, MD
Tom Vogt, MD
Bill Vollmer, PhD

Functions and Responsibilities

Recommend to the Steering Committee the basic design components of the trial, and recommend changes in and additions to the protocol during implementation as appropriate.

DASH Manual of Procedures

Measurement and Quality Control Committee

Membership

Members: Laura Svetkey, MD (chair)
 Ben Caballero, MD
 Jeanne Charleston, RN
 David Harsha, PhD
 Bill Vollmer, PhD
 Pierre La Chance, BA
 Tom Moore, MD
 Larry Appel, MD, MPH
 Deborah Schaffhauser, RN
 Denise Simons-Morton, MD

Functions and Responsibilities

Recommend to the Steering Committee measures, processes and procedures.

Recommend processes and procedures for assuring quality control of the trial, including training, certification, quality control measures and procedures, and other activities directed at assuring that the data are valid and reliable.

Diet Committee

Membership

Members: Marlene Windhauser, PhD RD (chair)
 Catherine Champagne, PhD RD
 Njeri Karanja, PhD RD
 Pao-Hwa Lin, PhD
 Marjorie McCullough, MS RD
 Bernestine McGee, PhD
 Eva Obarzanek, PhD MPH RD
 Marguerite Evans, MS RD
 Priscilla Steele, RD
 Kent Stewart, PhD
 Janis Swain, MS RD
 Kim Hoben, MPH RD LDN

DASH Manual of Procedures

Functions and Responsibilities

Recommend to the Steering Committee policies, practices, and procedures relating to development, assay, analysis, preparation, delivery, consumption, and assessment of intake of the various diets.

Recruitment Committee

Membership

Members: Larry Appel, MD (chair)
 Betty Kennedy, MPA
 Bill Vollmer, PhD
 Jean Charleston, RN MSN
 Eva Obarzanek, PhD
 Patrice Reams

Functions and Responsibilities

The Recruitment Committee will facilitate the successful recruitment of study subjects, monitor and report on progress to the Steering Committee, and recommend actions to be taken to correct poor recruitment.

Publications and Ancillary Studies Committee

Membership

Members: George Bray, MD (chair)
 Eva Obarzanek, PhD
 Connie Bales, PhD
 Njeri Karanja, PhD
 Tom Moore, MD
 Tom Vogt, MD
 Larry Appel, MD
 Laura Svetkey, MD

Functions and Responsibilities

The Publications and Ancillary Studies Committee will develop and recommend to the Steering Committee policies on publications and presentations and will oversee the implementation of these policies. This committee will also recommend policies for the conduct of ancillary studies and will review and recommend ancillary study proposals.

DASH Manual of Procedures

Data, Safety, and Monitoring Board

Membership

Members: Jeremiah Stamler, MD (chair)
 Jerome Cohen, MD
 Patricia Elmer, PhD
 James Neaton, PhD
 Phyllis Stumbo, PhD, RD
 Jackson Wright, Jr., MD, PhD

Ex-Officio Members: Eva Obarzanek, PhD, RD
 Tom Moore, MD
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 Marguerite Evans, MS, RD

Functions and Responsibilities

An independent Protocol Review Committee (PRC), appointed by the NHLBI director, reviewed the protocol prior to implementation. The PRC provided advice to the Institute regarding the scientific merit of the protocol and made recommendations to improve the protocol and its implementation.

Subsequent to the review of the protocol, a Data, Safety, and Monitoring Board (DSMB), composed primarily of members of the PRC, is established. The purpose of the DSMB is to serve in an advisory capacity to the Institute in order to monitor, review, and assess the progress of the study. The DSMB has access to unblinded outcome data during the trial and, in order that participants are not exposed to unreasonable or unnecessary research risks, recommends early termination of one or more arms of the trial (1) if the data suggest significant adverse risk to participants in the trial or (2) if the question posed by the trial appears to have been answered. The DSMB also reviews the timeliness of recruitment and the timeliness and quality of the data, based on data monitoring reports and other materials submitted by the coordinating center, and suggests analyses to be included in data monitoring reports.

The DSMB meets at least annually throughout the trial once the protocol has been developed. In addition to the PRC or DSMB members, meetings are attended by representatives from the coordinating center, the Steering Committee (including the chair and vice chair), and the NHLBI. Only the PRC or DSMB members may vote.

DASH Manual of Procedures

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DASH Manual of Procedures

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DASH Manual of Procedures

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208

DASH Manual of Procedures

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DASH Manual of Procedures

Alphabetical Listing of all DASH Personnel

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DASH Manual of Procedures

Alphabetical Listing of all DASH Personnel, (cont'd)

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DASH Manual of Procedures

Alphabetical Listing of all DASH Personnel, (cont'd)

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Coord. Center

Larson, Sandra Data Entry

Coord. Center

Laws, Reesa BS

Coord. Center

Lin, Pao-Hwa PhD

Durham Clinical Center

Macchiavelli, Raul PhD

Baton Rouge Clinical Center

MacDonald, Maureen BA

Boston Clinical Center

Marsh, Carol

Central Laboratories

DASH Manual of Procedures

Alphabetical Listing of all DASH Personnel, (cont'd)

McCarron, David MD

Central Laboratories

McCullough, Marjorie MS RD

Boston Clinical Center

McGee, Bernestine PhD

Baton Rouge Clinical Center

Meador, Eleanor,

Baton Rouge Clinical Center

Miller, Pete MD

Baltimore Clinical Center

Moore, Thomas MD

Boston Clinical Center

Nauth, Karin,

Boston Clinical Center

Nilan, Kate

Central Laboratories

Obarzanek, Eva PhD MPH RD

Project Office

Palmisano, Carmella Secretary

Boston Clinical Center

Pearson, Kathy BA

Coord. Center

Phillips, Katherine Biochemist

Central Laboratories

Plaisted, Claudia Ms RD

Durham Clinical Center

DASH Manual of Procedures

Alphabetical Listing of all DASH Personnel, (cont'd)

Proschan, Michael PhD

Project Office

Rice, Jessie BS

Coord. Center

Reams, Patrice

Durham Clinic Center

Rosofsky, Wendie MS RD

Baltimore Clinical Center

Roulet, Jean-Baptiste

Central Laboratories

Ryan, Donna MD

Baton Rouge Clinical Center

Sacks, Frank MD

Boston Clinical Center

Schaffhauser, Deborah RN

Baltimore Clinical Center

Shah, Lopa

Boston Clinical Center

Simons-Morton, Denise MD PhD

Project Office

Steele, Priscilla RD

Baltimore Clinical Center

Stewart, Kent PhD

Central Laboratories

Svetkey, Laura MD

Durham Clinical Center

DASH Manual of Procedures

Alphabetical Listing of all DASH Personnel, (cont'd)

Swain, Janis RD

Boston Clinical Center

Taylor, Jeanne Secretary

Coord. Center

Vogt, Tom MD PhD

Coord. Center

Vollmer, Bill PhD

Coord. Center

Walsh, Kristen

Boston Clinical Center

Whelton, Paul MD MSc

Baltimore Clinical Center

Windhauser, Marlene PhD RD

Baton Rouge Clinical Center

2. Trial Policies

Protocol	3
Manual of Procedures	3
Institutional Review Board (IRB)	3
Provision of Medical Care to Participants	3
Disclosure of Study Results	4
Publicity	4
Publications	4
Scope Of The Guidelines	4
Approval of Analysis Proposals and Formation of Writing Groups	6
Submission of Analysis Requests	6
Approval of Papers and Abstracts	8
Authorship	8
Ancillary Studies	9
Availability And Analysis Of Data	10
Prioritization	10
Data Tapes	10
Use of DASH Computing Equipment	10
Access to Stored Laboratory Specimens	11
Summary of Process for DASH Paper Proposal, Approval, And Analysis	12
SPECIAL REPORT “Uniform Requirements for Manuscripts Submitted to Biomedical Journals,” from <i>The New England Journal of Medicine</i>	15

Summary of Edits

New changes in version 2.0

- form numbers added to text

New changes in version 2.1

- Formatting and added “Hard copies of” to Data slides on page 7
- Page 8, 1st par, 1st sentence, deleted “a Project”, “Request” and inserted an “Analysis”
- Page 6, Deleted Publications, etc..
- Page 10 Deleted “(POLICY TO BE DEVELOPED)”
- Misc. technical edits
- Third para under *Approval of Papers and Abstracts* modified to indicate that “hard copies” of slides and handouts will be distributed.
- Figure 2.1 modified at end
- Policy for *Access to Stored Laboratory Specimens* has been added

New changes in version 4.0

- Forms 55, 56, 57, and 58 moved from Chapter 2 to DASH Forms Manual
- Paragraph added regarding notifying the PASC of acceptances of papers or presentations.

New changes in version 4.1

- Second paragraph under *Disclosure of Study Results* amended to reflect that participants are not unblinded to treatment status until the end of the trial.
- Phase “still needs SC approval” struck from paragraph on *Access to Stored Laboratory Specimens*.

New changes in version 4.2

- Added appendix *Summary of Process for DASH Paper Proposal, Approval, and Analysis*
- Changed Form 55 and 56 names to reflect current names throughout chapter
- Revised section *Approval of Analysis Proposals and Formation of Writing Groups* and Figure 2.1 to reflect use of new Form 88

DASH Manual of Procedures

This section records policies that have been approved by the Steering Committee.

Protocol

The protocol is a document that presents the scientific background, design, and governing policies of the study. Changes to the protocol may be proposed by any member of the Steering Committee. Proposed modifications must be approved by the Steering Committee, the Data, Safety and Monitoring Board, and appropriate offices at the NHLBI in the order listed. Voting on changes is done at regularly scheduled meetings and conference calls of the Steering Committee or the Data, Safety and Monitoring Board. A majority vote of approval is required for each committee before forwarding to the next level. Protocol changes that affect participant eligibility or management must be submitted by each clinical center to its Institutional Review Board (IRB) according to local IRB guidelines. Changes must be approved by the IRB before being instituted at any site.

Manual of Procedures

The manual of procedures (MOP) is a working document that translates the protocol into working procedures. Its goal is to describe the procedures with sufficient clarity to ensure that all clinical centers use the same examination procedures, participant management, intervention schedules, definitions, and, as far as possible, the same equipment.

The Coordinating Center is responsible for minor revisions of the MOP. Substantive changes require approval of the Steering Committee. A majority vote of approval by the Steering Committee is required for adoption of a substantive modification. A mail ballot may be used as necessary. Changes to the MOP and relevant forms are made as soon as practical and, unless otherwise noted, become effective on receipt of the revised procedures at the clinical centers.

Once accepted, the policies in the protocol and the procedures described in the MOP must be followed fastidiously by each clinical center. The Coordinating Center monitors adherence to the MOP and prepares regular reports summarizing trial adherence to the Steering Committee.

Institutional Review Board (IRB)

The Coordinating Center and each clinical center must obtain permission from its local IRB to conduct the study before beginning recruitment. As noted above, all changes to the protocol must also be submitted for IRB review and approval according to local IRB guidelines.

Provision of Medical Care to Participants

DASH Manual of Procedures

In the course of screening participants and conducting interventions, medical problems will occasionally be identified among participants. The responsibility of clinical centers in following up such problems will vary from site to site according to generally accepted medical guidelines, individual IRB requirements, and the resources available to provide referral and follow-up services. In no instances, however, should resources essential to the proper implementation of the protocol be utilized to provide medical care services.

Disclosure of Study Results

Participants are blinded to their study blood pressure data during the intervention phase of the study. Participants are alerted, however, if their blood pressure goes above a predetermined escape level. Clinical centers are allowed to unblind participants if the participants' physicians demand to see the data for reasons of medical management. This option is not disclosed to participants in advance. Clinics will notify the Coordinating Center of any participant who is unblinded to their blood pressure values during the intervention period.

At the conclusion of each feeding wave, study participants receive a summary record of their study blood pressures and are given individualized counseling for reducing coronary heart disease risk. Participants who were withdrawn from antihypertensive medications are also advised that they should consult their physicians about resuming their medications. At the conclusion of the full trial, study participants are unblinded to their treatment assignment, receive a record of their individual study blood pressures, and are informed about the overall findings of the trial.

Laboratory results collected as part of the central study database are not routinely provided to participants. However, clinical centers may, at their own discretion, provide participants with the results of the local laboratory tests used to determine eligibility.

Publicity

Results derived from DASH data may not be discussed with the news media without authorization of the Steering Committee. DASH investigators may discuss design and recruitment issues with the media, but should inform the Steering Committee of any DASH related information scheduled for release in the national media. Any written statements about DASH that are shared with national media should be approved by the Steering Committee before release. No approval is required for interviews or discussions with media, either local or national.

Publications

Scope Of The Guidelines

This policy covers papers, abstracts, and oral presentations that involve unpublished data collected as a part of the DASH study. These policies will remain in force until July 31,

DASH Manual of Procedures

2002, or until the Publications and Ancillary Studies Committee (PASC) is formally dissolved.

DASH Manual of Procedures

Approval of Analysis Proposals and Formation of Writing Groups

Initiation of analysis for a writing project can begin in one of two ways.

1. A member of the DASH project may complete a Proposal for a DASH paper (Form #55 - see DASH Forms Manual or the DASH Analysis Guide), which specifies the research question(s) and the primary variables to be used in the analysis. The individual who completes this form is termed the “convener.” The convener FAXes copies of the form to the Coordinating Center and the PASC chair. The CC circulates the Form 55, along with a Form 88 (PASC Review Form for a DASH Publication Proposal) to the members of the PASC for approval. Once the project is approved, the PASC chair informs the proposer and the CC. Persons interested in participating in the analysis should then notify the convener.
2. The second method of beginning the analysis of data for publication is through the formation of a writing group appointed by the Publications and Ancillary Studies Committee to develop the data for a specific publication.

Writing project proposals submitted to the PASC must be reviewed promptly. Committee members shall respond in writing within 2 weeks to the Chair of the Publications and Ancillary Studies Committee, who will notify the convener directly of the approval (or disapproval) of the Analysis Proposal. After approval, the convener will, within a reasonable amount of time, arrange for the group of persons who express interest in participating in the project to meet and then plan the analysis. The CC will distribute an updated list of approved papers regularly.

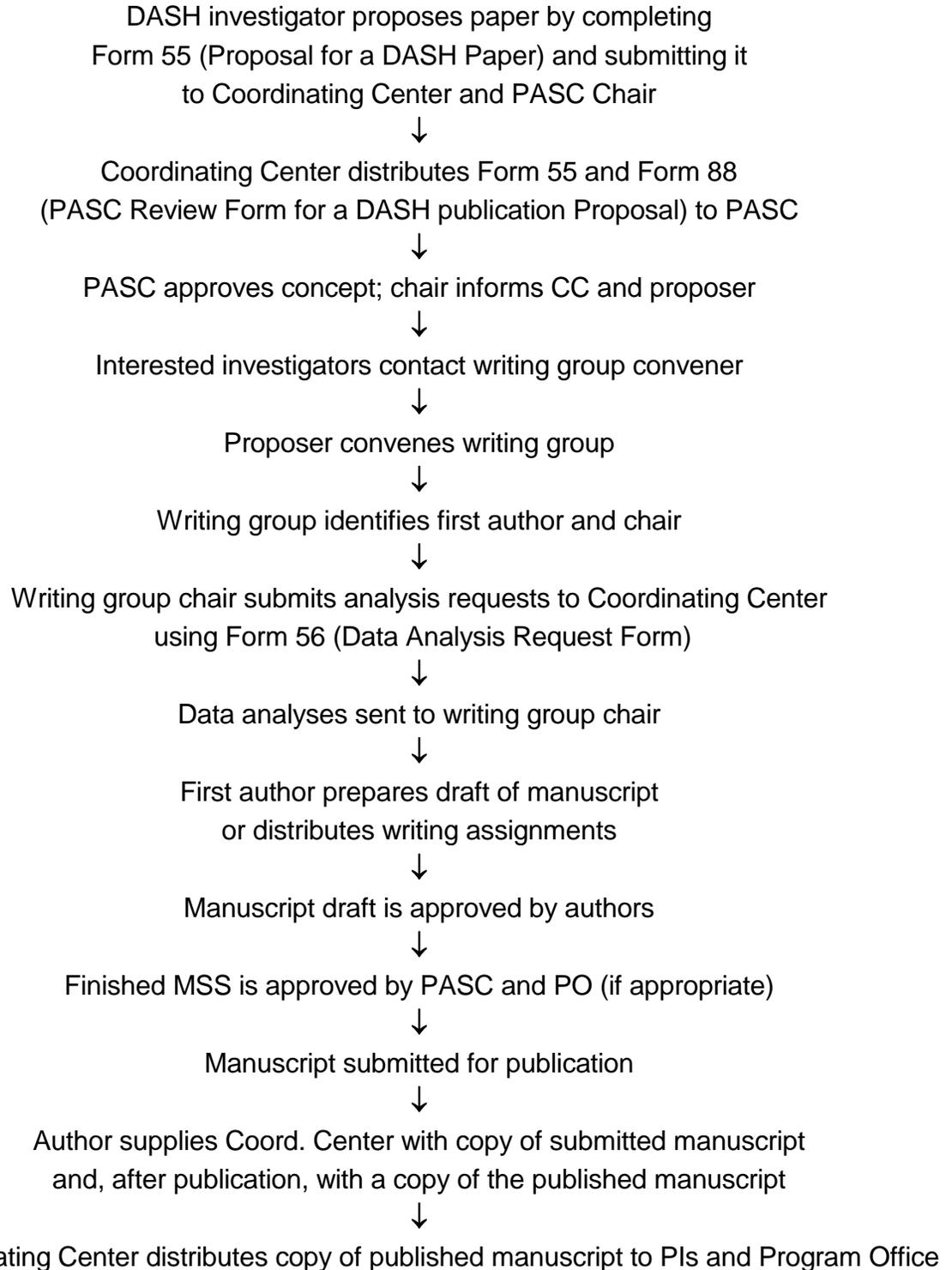
See Appendix at the end of this chapter for an outline of this process.

Submission of Analysis Requests

Once an analysis proposal has been approved, the chair of the writing group may request specific analyses by completing the for Data Analysis Request Form (Form #56-see DASH Forms Manual or DASH Analysis Guide). The request should identify the title of the proposal and the proposal number as originally listed on the Form 55. A member of the Coordinating Center RA Department will work with the requester to provide the needed analyses. After a data request is received by the CC, the analyst assigned to that request will confirm the request by FAX. Each request is assigned a data request number, and this number should be used on all communications related to the request. The number should be left on all tables and figures until the final manuscript submission.

Figure 2.1 summarizes the process.

Figure 2.1: Outline of DASH Process for Proposing Paper, Assembling Writing Group and Identifying First Author



DASH Manual of Procedures

Approval of Papers and Abstracts

Abstracts for presentation to scientific meetings and manuscripts of DASH results should be sent directly to members of the PASC for approval prior to submission. Abstracts must be in the hands of Publications and Ancillary Studies Committee members at least 5 working days prior to submission. Members of the Publications and Ancillary Studies Committee must respond within 4 working days.

Three copies of each manuscript should be sent to the NHLBI Project Officer and one copy to each member of the PASC. The members of the PASC must respond in writing to the PASC chair within 30 working days unless they are unavailable and have so notified the Chair. A cover sheet will accompany each abstract and manuscript (Manuscript and Abstract Review Form, Form #57 in DASH Forms Manual) and should be returned to the Chair of the PASC, who will relay comments to the chairperson of the writing group. Non-response by a Publications and Ancillary Studies Committee member will be assumed to be an approval.

Hard copies of data slides and handouts to be presented to national meetings should be circulated to the PASC for distribution to other DASH investigators. The Publications and Ancillary Studies Committee may, by majority vote, withdraw any abstract or manuscript after it has been submitted and before it is published.

It is the responsibility of the senior (first) author of any manuscript, abstract, or presentation to notify the Publications and Ancillary Studies Committee of the acceptance of this paper, abstract, or presentation and the citation of an abstract or publication and to send a preprint along with the citation of any accepted manuscript to the Publications and Ancillary Studies Committee and to the Coordinating Center.

Authorship

This section applies to the main studies and papers, but not ancillary studies carried out at only one or two sites. Authors who participate in the writing of a manuscript from the DASH project do so in accordance with the International Committee of Medical Journal Editors guidelines (N Engl J Med 1991;324:424-8)(see attached). First authors are expected to delete names from the final list of authors if those individuals have not participated in the writing and/or analysis of the paper in accordance with those guidelines. All papers, excluding ancillary studies, should include the word "DASH" or "Dietary Approaches to Stop Hypertension Research Group" in the authorship line. All papers should also include an "Acknowledgments" section that lists the DASH investigators and key staff at the Clinical and Coordinating Centers unless journal policy prohibits publication of such a list. In general, at least one investigator from the Coordinating Center should be included as an author on papers using study-wide DASH data.

DASH Manual of Procedures

First authors will usually be DASH investigators. Fellows and other scientists may serve as first authors if:

1. the opportunity of first authorship on a project has been offered to all DASH investigators and none requested to serve as first author,
2. at least one other DASH investigator serves as a co-author and "sponsor" of the project, and
3. the fellow or scientist has played a major role in the data analysis and writing for the paper.

First authorship will be decided by the writing group that is convened by the individual who first submitted an Analysis Proposal Form. The first author will generally serve as chair of the writing group. Conflicts about first authorship should be resolved, if at all possible, by members of the writing group. In case the writing group is unable to resolve a conflict, the Publications and Ancillary Studies Committee will adjudicate and may assign first authorship. Disputes about first authorship, if not settled by the writing group, will be referred to the Publications and Ancillary Studies Committee and thence to the Steering Committee.

If progress on a given writing project is unduly slow, the Publications and Ancillary Studies Committee may request an explanation from the chair of the writing group. If timely progress is not likely to occur in the near future, the Publications and Ancillary Studies Committee may, at its discretion, assign a new Chair to the writing group. Such an assignment may be appealed to the Steering Committee.

The order of *co-authorship* on a paper should be determined by the first author. In general, authors will appear in order of contribution to the writing and analysis of the paper. When contributions to writing and analysis have been similar, priority should be given to:

1. DASH investigators from Clinical Centers,
2. more junior authors, and
3. those who have contributed to a greater degree to management and data collection for the study, and to DASH investigators who have had fewer opportunities to author DASH papers.

If conflicts regarding the order of authorship cannot be resolved by the writing group, the Publications and Ancillary Studies Committee will adjudicate and may assign order.

Ancillary Studies

All studies of subjects enrolled in the DASH project that are not part of the main protocol must be approved by the Publications and Ancillary Studies Committee prior to enrolling subjects. In order to obtain approval, complete and submit the Ancillary Study Request

DASH Manual of Procedures

Form (Form #59-see DASH Forms Manual) to the Publications and Ancillary Studies Committee. If a proposal is subsequently submitted to your IRB, you must send a copy of the final approved proposal to the PASC.

The Publications and Ancillary Studies Committee will review the proposal within 2 weeks and, if necessary, make suggestions for modification in order to assure that inclusion of subjects from the DASH study for ancillary protocols will not impede the basic data collection essential for the primary end points. The Publications and Ancillary Studies Committee may refuse to approve ancillary projects that appear to interfere with conduct of the main trial.

For papers resulting from ancillary studies, the following language should be inserted in the Methods section of the paper.

"This was a study ancillary to the Dietary Approaches to Stop Hypertension (DASH) study, and as such was designed, conducted, and analyzed only by the co-authors."

All ancillary studies must be approved by the Steering Committee. A copy of all accepted manuscripts of the ancillary study (and published papers when available) should be sent to the Coordinating Center.

Availability And Analysis Of Data

Prioritization

Requests for DASH data and their analyses will be submitted to the Coordinating Center after approval by the Publications and Ancillary Studies Committee. The Coordinating Center will notify the Publications and Ancillary Studies Committee if resource limitations do not permit a timely completion of an analysis request, and the Publications and Ancillary Studies Committee will assign priority rankings to projects so that the highest priority projects are completed first.

Data Tapes

It is the intention of the Coordinating Center to supply clean data tapes to the clinical centers and to the Project Office at the end of the trial so that additional analyses can proceed after the termination of the Coordinating Center's grant award. So long as the Publications and Ancillary Studies Committee remains active, it must continue to approve all analysis proposals and review all manuscripts and abstracts, even if the analyses are done locally.

Use of DASH Computing Equipment

Kaiser Permanente Center for Health Research (CHR), as DASH Coordinating Center, is supplying the following equipment for use by DASH Study intervention sites:

DASH Manual of Procedures

- 1 DELL 466LV Desktop Server system
- 3 Compaq LTE Lite 4/25E Laptop systems (4 at Baltimore)
- 1 Hewlett Packard DeskJet 500 printer
- 1 Compaq Desktop Expansion Base
- All Required peripherals, batteries, cables, and connectors

CHR retains rights of ownership for this equipment and all installed software. The equipment and software are provided for the sole purpose of conducting DASH activities as specified in the DASH Manual of Procedures (MOP). These activities include, but are not limited to, study communications, data entry, data transfer, report swapping, data edits, and data repairs. This equipment will be returned to the CHR upon demand.

Additional uses or modifications of the equipment, software, and/or configuration, are not authorized, except as approved by the Coordinating Center Project Administrator, and are considered a violation of study procedures. Non-authorized use or modification include but are not limited to: personal use of equipment or software, making and/or distributing unlicensed copies of DASH study software, installing additional softwares, making configuration changes to equipment or existing software, or connection to non-study networks.

Any request for exceptions to this policy must be authorized by the DASH Coordinating Center Project Administrator prior to action.

Access to Stored Laboratory Specimens

Dash will store a variety of frozen blood and urine samples from DASH participants. Proposals to use these samples should be submitted to the DASH Steering Committee in writing. These proposals should include the type of study/test proposed, the amount of each sample required to conduct it, the rationale for the test, the study questions and hypotheses to be addressed, the plans for publication of the data, the approximate cost of the proposed test(s), and the source of funds to conduct them. Study investigators not involved in the initial proposal may request to be included in the work group conducting the additional studies.

The discussion of whether to permit use of the store samples should include attention to possible alternative uses of limited materials. That is, the Steering Committee will attempt to plan for optimal uses of the stored samples rather than simply to grant requests for their use on the basis of which were submitted first.

Summary of Process for DASH Paper Proposal, Approval, And Analysis

A. To Propose a Paper

1. Complete DASH Form 55 (*Proposal for a DASH Paper*) and fax one copy each to:
 - George Bray, Pennington (fax # 504-763-0935)
 - Jeanne Taylor, Coordinating Center (fax # 503-335-2428)
2. The CC will circulate the Form 55 and a DASH Form 88 (*PASC Review Form for a DASH Publication Proposal*) to members of the PASC.

B. Approval of a Paper

1. PASC members sign the Form 88 by the due date (14 days after the form is distributed) and fax one copy each to George Bray and Jeanne Taylor.
2. *If no negative votes or concerns are raised* on the Form 88, Dr. Bray will inform the proposer and the Coordinating Center of the paper's approval.
3. *If PASC reviewers raise questions or concerns* on the Form 88, Dr. Bray will pass these on to the paper's proposer. The proposer will respond to Dr. Bray with a revised request (repeating the process outlined in Part A above) or with a written response to the concerns. Dr. Bray will approve the proposal if, in his judgment, the response satisfies the concerns, or he may defer approval until the PASC can discuss the issues in a call or meeting.
4. The person who completes the Form 55 will serve as convener for the first conference call/meeting of the writing committee. The committee will select a chair at this first call/meeting and notify George Bray and Jeanne Taylor of this selection.
5. The CC will distribute the list of approved papers each month. Each approved paper will be assigned a number which should be used on all correspondence related to the paper.
6. DASH investigators interested in participating in an approved writing project should contact the convener or chair of the writing committee to request being added to the paper.

C. Analysis Requests

1. The writing committee will develop and submit analysis requests on DASH Form 56 (*Data Analysis Request Form*) directly to Reesa Laws at the Coordinating Center. All requests should come directly from the writing committee chair to Reesa (i.e., only one person on the committee should submit requests, to avoid duplication, overlap, and discrepant instructions).

DASH Manual of Procedures

2. After Reesa receives your data request, she assigns an analyst to the request; the analyst will send you a confirmation fax summarizing what we believe you want. *We will not begin working on your request until you confirm that we have correctly interpreted your request.*
3. Each request will come back to you with a data request number. *Use the data request number whenever you communicate with the analyst assigned to your request.* We often work on multiple, similar requests, and we keep these straight with the data request number.
4. Reesa Laws at the CC will assign a research analyst to each data request. Multiple analysts may serve on one paper.
5. ***Please leave the data request number on all tables and figures we generate until the final manuscript submission.*** If you refer in the text to data or statistics which aren't linked directly to a table in the text, please include the data request number in parentheses directly after the data; any tables or figures we send you will already have the request number on it. (For example, a mention in the Methods section to the numbers of participants included in an analysis would need a data request number so we know where that number came from.) This number allows us to efficiently return to the original output to verify the numbers in a table. Failure to keep this data request number on the table may add substantially to the verification time and diminish the pleasure of personal interactions with your analyst. ***Call Reesa Laws with any questions about this.***

D. Paper Production Process (These steps are included in the DASH Paper Milestone Report.)

1. *Topic Approved* - Form 55 (Proposal for a DASH Paper) has been submitted to the PASC, and the PASC has approved the paper.
2. *Group Convened* - The writing committee has had its first conference call or meeting.
3. *Work Started* - Reesa Laws has received a data request on Form 56 (Data Analysis Request Form) from the writing committee chair.
4. *Work in Queue* - The assigned analyst has confirmed the data request with the requester. Work remains "in the queue" until code, statistical and documentation reviews are complete.
5. *Work Complete* - Main author has notified the CC that work is complete (no more data requests will be submitted).
6. *Paper Complete* - Main author has notified the CC that the paper is complete (final draft written).
7. *Approved Pub/NHLBI* - The paper has been approved by the authors. In addition, if someone from the Project Office is an author on the paper, the PO must approve the paper before it is submitted for publication. If no one from the PO is an author, a copy of the paper should be sent to Eva, but prior PO approval is not required.

DASH Manual of Procedures

8. *Final Revision* - Main author has notified the CC that the final revisions have been made.
9. *Numbers Verified* - Main author has sent the CC a copy of the final manuscript including tables (with data request numbers attached to all data). All programs have been re-run and numbers verified. Reesa has notified the main author that all numbers have been verified.
10. *Sub to Journal* - Main author has notified the CC that the paper has been submitted.
11. *Paper Published* - Main author has notified the CC that the paper has been published.

DASH Manual of Procedures

Attach a copy of the SPECIAL REPORT “Uniform Requirements for Manuscripts Submitted to Biomedical Journals,” from The New England Journal of Medicine.

3. Human Subjects

Principles of Informed Consent	3
Process of Obtaining Informed Consent	4
Confidentiality	5
Site Specific Consent Procedures	5
Baltimore Appendix 3-1	5
Pennington Appendix 3-2	5
Boston Appendix 3-3	5
Baton Rouge Appendix 3-4	5

Summary of Edits

New changes in version 2.1

- Section on *Confidentiality* totally revised
- *Site Specific Consent Procedures* newly written. Hard copies of consent forms are included as appendices. These are NOT included in electronic versions of MOP that are stored on your systems.

New changes in version 4.0

- None

DASH Manual of Procedures

All DASH participants must provide written, informed consent for screening visits, DEV visits (if applicable), run-in and intervention. The number and timing of these consents is determined by the local IRBs and thus varies across the clinical centers. A listing of local procedures and copies of consent forms are included at the end of this section.

Information leading to informed consent must be provided in a language that is understandable to the participant. Even when extensive printed information is provided, the investigator or interviewer must verify that the participants understand what they have read and heard. The participants must be given the opportunity to ask questions, and the interviewer should ask questions to determine the participant's level of understanding.

Principles of Informed Consent

In seeking informed consent, the following information should be provided to each participant:

1. A statement that the study involves research, an explanation of the purpose of the research, the expected duration of the individual's participation, a description of the procedures, and identification of any experimental procedures.
2. A description of any reasonably foreseeable risks or discomforts to the participants.
3. A description of any benefits to the participants (or to others) that may reasonably be expected from the research.
4. A statement describing the extent to which confidentiality of records identifying the participant is maintained.
5. An explanation as to whether any compensation or medical intervention is available if injury occurs and, if so, what it consists of, or where further information may be obtained.
6. An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights, and whom to contact in the event of a research-related injury to the participant.
7. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant may otherwise be entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant may otherwise be entitled.
8. Anticipated circumstances under which the individual's participation may be terminated by the investigator without regard to the individual's consent.

DASH Manual of Procedures

Process of Obtaining Informed Consent

Various studies indicate that the circumstances under which consent is obtained in clinical trials can have a profound influence on the participant's interpretation of information communicated during the consent discussion, and on the freedom of participants to make their own decision. All clinical centers will therefore follow the guidelines listed below when obtaining informed consent.

1. Participants should have adequate time to evaluate the pros and cons of participation. Allow the participant to take the consent form home to review if necessary.
2. Participants should be encouraged to discuss the study with anyone they wish, particularly family and friends who might be affected (e.g., persons who might be needed to provide transportation).
3. To be eligible for participation in the study, participants must have the capacity to give their own consent. If a participant is incapable of understanding what is expected of him or her as a participant in the study, it is not permissible to obtain informed consent from a guardian. The study requires daily responsibilities that cannot be easily assumed by other persons.
4. The setting in which the consent is obtained should be as private as possible so participants can freely ask questions without embarrassment.
5. To avoid pressuring the participant, only one person associated with the study should be present when the participant reviews the consent form.
6. The participant should be given a copy of the consent forms after they are signed and witnessed.
7. Participants should be encouraged to keep the consent form because it contains useful information about the study that they can review from time to time.
8. Where the person or organization responsible for obtaining the participant's consent is also involved in that participant's regular medical care, the participant must be told in no uncertain terms that they will be treated with the same degree of interest and concern regardless of whether they participate in the study. It is desirable, therefore, that someone other than the caregiver be the person responsible for obtaining the informed consent and also for providing the clinical contacts for the study.

DASH Manual of Procedures

Confidentiality

All participant information, and even the fact that an individual is participating in the study, is considered confidential. This confidentiality is assured in DASH through several mechanisms.

First, each participant is assigned an anonymous study ID, which is then used on all study forms. Only where absolutely necessary to assure data integrity is a participant's name also included on study forms.

Second, all study forms, biological specimens, and paper records that contain participant information (e.g., address lists, phone lists, etc.) are kept in secured, locked areas when not in use. In addition such materials, when in use, are kept away from public scrutiny. Materials and specimens that need to be discarded are destroyed.

Third, access to all participant data and information, including laboratory specimens, is restricted to authorized personnel. In the case of computerized data, this restricted access is assured in several ways. At the clinical centers, **[chris, can you briefly summarize password access, etc., for equipment at sites. we'll want to wait until pierre gets back to write this]**. At the Coordinating Center, access to computerized data is restricted in two ways. First, only authorized personnel are granted access to the data, and second, this access is further restricted by password protection. In addition, Coordinating Center personnel are annually required to sign a confidentiality statement affirming that they agree to abide by the Center for Health Research's policies on research confidentiality and ethics.

Finally, participants will not be identified by name in any reports or publications, nor will data be presented in such a way that the identity of individual participants can be inferred.

Site Specific Consent Procedures

Get each sites plans for doing IC and also copies of their consent forms. Assign to recr coord at each site to write.

Baltimore Appendix 3-1

Pennington Appendix 3-2

Boston Appendix 3-3

Baton Rouge Appendix 3-4

Copies of consent forms for each site are attached as appendices.

4. Recruitment

Study Population	3
Eligibility Criteria	3
Inclusion Criteria	3
Exclusion Criteria	4
Overview of Recruitment	8
Site Specific Recruitment Strategies	9
Record Keeping	10

Summary of Edits

New changes in version 2.0

- inserted formula for GFR
- misc. technical edits

New changes in version 2.1

- misc. technical edits
- definition of eligibility age clarified (≥ 22 years at start of run-in feeding)
- text under *Exclusion Criteria, Cardiovascular disease* rearranged for greater clarity. In second para, “peripheral vascular disease” changed to “peripheral arterial disease”
- formulas for GFR fixed
- exclusionary antacids clarified (p. 4-7), and a listing of allowed and excluded antacids now given in Appendix 4.1
- recruitment coordinators updated under Site Specific Recruitment Strategies
- text now added under *Record Keeping*
- added Lithium under Specific medication use

New changes in version 4.0

- Formatting changes
- Durham Recruitment Coordinator changed to Patrice Reams

New changes in version 4.1

- exclusion for renal insufficiency modified to reflect SC decision per call #41, August 23, 1995, to also consider serum creatinine level.
- under *Overview of Recruitment*, # cohorts changed from “4-6” to “5-6”
- section on *Record Keeping* has been rewritten to reflect new procedures implemented as part of the minority supplement award
- added to Appendix 4.1: allowed and excluded cold medications and other allowed medications, also modified section on medication exclusions accordingly
- Boston Recruitment Coordinator changed to Maureen MacDonald

DASH Manual of Procedures

Study Population

The study sample will consist of approximately 456 healthy, free-living adult men and women, age 22 years and older, with a DBP of 80-95 mm Hg and a SBP < 160 mm Hg. Given the disproportionate burden of hypertension and its complications in minority populations, two-thirds of DASH participants will be from a minority background. To reach this goal, the Pennington Biomedical Research Center will recruit a cohort that is 100% African-American and the other three sites will achieve at least 55% minority (though not necessarily African-American) participation.

In the event that a site exceeds its overall recruitment objective of 114 randomized participants, the minority target will pertain only to the initial 114 participants. Thus in absolute numbers the minority targets are 114 African-American participants for Pennington and 63 minority participants for each of the other sites.

Eligibility Criteria

To be eligible to participate in DASH, participants must meet a number of eligibility requirements. These requirements are assessed during the course of several screening visits and during a period of run-in feeding prior to randomization. This section lists the various eligibility requirements and gives the operational criteria by which they are determined.

Several of the eligibility criteria relate to laboratory tests conducted using blood or urine specimens. Any initially abnormal laboratory values that would result in exclusion may, at the discretion of the local PI, be repeated once and the participant retained if the second value falls within eligible limits. Exceptions to this rule are diabetes and hyperlipidemia. Repeat testing for these conditions requires fasting blood samples, and criteria are described below. All laboratory assessments for eligibility are performed locally and eligibility is based on local normal ranges.

Eligibility criteria were selected to exclude individuals with conditions, or on medications, that would affect micronutrient metabolism and those with potentially serious chronic health conditions.

Inclusion Criteria

- SBP < 160 mm Hg and DBP 80-95 mm Hg

Two blood pressures measurements are taken at each of the first three formal screening visits (SV1, SV2, and SV3), and the average of these six measurements must fall within the stated limits for both SBP and DBP. In order to identify participants not likely to meet these limits, somewhat wider eligibility limits are also established for the average cumulative blood pressures at each of SV1 and SV2 (see Chapters 7 and 8).

DASH Manual of Procedures

Participants who are excluded from the screening process due to blood pressure may re-start the screening process at a later date, but only as part of screening for a separate feeding wave.

- Age > 22 years

Participants must be 22 years of age or older at start of run-in feeding.

- Willing to eat at least one on site meal/day, five days/week, and willing to eat study diets and nothing else for 11 weeks
- Willing to provide written informed consent

In order to participate in the study, all subjects must provide written, informed consent using procedures that are reviewed and approved by each centers local IRB.

Exclusion Criteria

- Currently on cancer chemotherapy or with evidence of active malignancy or radiation therapy within past six months

The diagnosis of cancer and the status of therapy are based on the participant's self-report and do not need to be confirmed with the participant's physician unless a question exists about whether the cancer is currently active.

- Anemia

Defined as a hematocrit at least 5 percentage points below the local laboratory's gender-specific normal range (unless PI has reason to believe this is not due to nutritional deficiency).

- Cardiovascular disease

Participants not currently taking antihypertensive medications are excluded if they report a CVD event (defined as stroke, MI, heart failure, CABG, hospitalization for unstable angina, or coronary angioplasty) within the past six months. Confirmation is not necessary unless the participant is uncertain of the diagnosis and the clinical center still wishes to include him/her.

Participants who are taking antihypertensive medications at the time of the prescreening visit are excluded if they report ever having had a history of CVD (defined as stroke, MI, heart failure, CABG, hospitalization for unstable angina, coronary angioplasty, or peripheral vascular disease). Confirmation is not necessary unless the participant is uncertain of the diagnosis and the clinical center still wishes to include him/her. Note

DASH Manual of Procedures

that peripheral arterial disease is included as an exclusionary condition only for those currently taking blood pressure medications.

For purposes of the study, current antihypertensive medication use is defined as any use within 21 days of the prescreening visit or any use subsequent to the prescreening visit.

- Inflammatory bowel disease, colostomy, malabsorption, or any prior GI resections other than localized colonic resections

Defined based on self-report. Confirmation is not necessary unless the participant is unsure of the diagnosis and the clinical center still wishes to include him/her.

- Hepatitis

Defined as a transaminase level more than 1.5 times the local laboratory's upper range of normal.

- Unstable asthma or COPD

Defined as an emergency room visit hospital stay for asthma or COPD in last six months, or other evidence of recent instability in asthma or COPD. Health care utilization is based on participant self-report and need not be confirmed. "Other evidence of recent instability" must be determined by the local PI based on information provided by the participant.

- Renal insufficiency

Defined as a glomerular filtration rate (GFR) ≤ 60 ml/min and a serum creatinine level ≥ 1.2 mg / dl. The GFR is estimated using Cockcroft-Gault formula as listed below:

Men: $GFR = [(Wt \text{ in Kg}) (140 - \text{Age in years})] / [72 * \text{serum creatinine in mg/dl}]$

Women: $GFR = [(Wt \text{ in Kg}) * (140 - \text{Age in years})] / [72 * \text{serum creatinine in mg/dl}]$

- Hypo- or hypercalcemia

Defined as a serum calcium level more than 0.3 mg/dL above or below local laboratory's normal range.

- Hypo- or hyperkalemia

Defined as a serum potassium level more than 0.2 mg/dL above or below local laboratory's normal range.

DASH Manual of Procedures

- Non insulin-dependent diabetes

Defined as either a nonfasting random glucose > 180 mg/dL or a positive urine dipstick for glucose. Repeat testing to confirm the diagnosis may include either a fasting blood sugar (FBS) determination or measurement of HgbA1C. For FBS, the participant is still excluded if the blood sugar level is > 140 mg/dL. For HgbA1C, the participant is still excluded if the level is greater than or equal to eight (or whatever is the local lab equivalent to an average blood sugar at least 200 mg/dL).

- Urinary protein

Defined as a urine dipstick protein level greater than “1+”.

- Hypercholesterolemia

Defined as a total serum cholesterol level greater than 260 mg/dL. Repeat testing must be done using an overnight fasting blood specimen and may include either a fasting total cholesterol level or a lipid profile. For fasting cholesterol, participant is still excluded if the total cholesterol level still exceeds 260 mg/dL. For the lipid profile, the participant is still excluded if the LDL level is > 160 mg/dL or if the LDL level is between 130-159 mg/dL (inclusive) and the participant has two or more CHD risk factors present (see Protocol, Appendix 1, Fig. 2, for further detail).

- Any serious illness not otherwise specified that would interfere with participation

Based on self-report.

- Specific medication use

In addition to having any of the medical conditions listed above, participants are also excluded from participation if they report taking any of the following medications.

Current medication use is defined as any use within 21 days of the PSV visit or at any time thereafter. All participants are expected to bring their medication bottles to the SV2 visit for review by a clinic staff member.

- Lithium
- insulin
- oral corticosteroids
- unstable doses of psychotropics or phenothiazines
 (“unstable” in this context is left to the determination of the local PI)
- cholestyramine
- colestipol
- oral breathing medications (i.e., for asthma and/or COPD)
- dilantin

DASH Manual of Procedures

- antacids containing magnesium, potassium, or calcium, unless they can be discontinued (see list in Appendix 4.1)
- digitalis
- blood pressure drugs and not willing/able to withdraw
- certain cold and allergy medications (see Appendix 4.1)

Appendix 4.1 lists other medications that are approved for treatment of constipation, indigestion, and other aches and pains.

- Consumption of more than 14 alcoholic drinks per week.

This is determined at the prescreening visit and is based on self-report. One drink of alcohol is defined as one can or bottle of beer, one glass of wine, or one shot of liquor.

- Body mass index greater than 35 Kg/m²

Operationally this is determined in two stages. At the time of the PSV each participant is asked to give his weight and height. Since height is typically reported with a good degree of accuracy and weight is usually underreported, anyone whose self-reported BMI exceeds 35 Kg/m² is excluded. In addition, weight and height are formally measured as part of the SV2 visit and, if the BMI computed using these measurements exceeds 35 Kg/m², the participant is also excluded.

- Poor compliance during screening and/or run-in

At any time prior to randomization, each clinical center has the option of excluding participants for noncompliance with the study protocol. Noncompliance may include, for example, repeated no-shows or reschedules for clinic visits, poor attitude, or any other aspect of the participant's behavior that would suggest he/she is a poor candidate for the trial.

In addition, each participant's eating record is reviewed by the clinic staff just prior to randomization in order to assess his compliance with the feeding protocol. Participants who do not comply with the demands of the feeding protocol are excluded at this time. A more detailed discussion of dietary compliance is given in section 18, page 2.

- Investigator discretion for reasons of safety

Although participants not currently taking blood pressure medication at the time of enrollment should be at no risk for adverse health events as a result of their participation in the study, those who are taking blood pressure medications may be at some risk. In particular, withdrawal of blood pressure medications is likely to result in a gradual increase in blood pressure during the course of the trial, and a concomitant increase in the risk of a cardiovascular event. Those participants randomized to the reference (red)

DASH Manual of Procedures

diet will be eating a diet that does not meet current AHA guidelines for a “heart healthy” diet.

For these reasons participants are monitored closely during the withdrawal process, and only those who are good candidates for drug withdrawal are even asked to begin the process. At any time during the withdrawal process participants may be excluded at local investigator discretion if the investigator feels that the participant may be exposed to an unacceptable level of risk through further participation.

In addition to this discretionary exclusion process, the trial has built in mandatory exclusion levels based on single visit blood pressures. These are discussed in more detail in section 27, Safety Monitoring.

- Unwilling or unable to modify current diet

A necessary requisite for participation in the study is a willingness to comply with the study’s strict eating guidelines. In order to avoid randomizing participants who are not willing to comply with these guidelines, the protocol builds in several levels of review with the participant and a two-week period of run-in feeding prior to randomization.

Since this criterion, along with the blood pressure limits, are likely to account for the majority of study exclusions, it is imperative that the participant understands the nature and demands of the study as early into the screening process as possible.

- Current use of food supplements that cannot or will not be stopped
- Planning to leave the area prior to the anticipated end of the intervention period
- Pregnant or planning to conceive prior to the anticipated end of intervention (women only)

Operationally any woman who is pregnant or trying to conceive a child at the time of the prescreening visit is excluded from the study.

- Breast feeding

Women who are actively breast feeding at the time of the prescreening visit are excluded from the study.

Significant food allergies or preferences that would interfere with diet adherence.

Overview of Recruitment

Each DASH clinical center will recruit its participants in 5-6 cohorts (feeding waves). For each clinic, additional time is allotted at the end of scheduled recruitment in the

DASH Manual of Procedures

event that an additional feeding cohort is needed in order to meet the study's recruitment goals.

DASH participants will be recruited using a variety of approaches, including 1) targeted mailings to specific groups (e.g., employees of local industries, previous screenees), 2) mass mailings (e.g., vis-à-vis inserts in coupon packs and brochures to registered voters or licensed drivers), 3) community and worksite screenings, 4) mass media (e.g., radio and television advertisements and public service announcements).

Each center has a recruitment coordinator who oversees recruitment efforts and who serves on the recruitment subcommittee. The recruitment coordinator is the primary liaison with the coordinating center for issues related to recruitment.

The coordinating center monitors recruitment activities and facilitates recruitment efforts by providing regular recruitment reports, organizing meetings and conference calls, and distributing meeting/call minutes. Sample recruitment reports, along with a schedule for their distribution, are provided in section 25, Trial Monitoring. In addition to these regular trial monitoring reports, the coordinating center will develop additional reports (either on a regular or ad hoc basis) as requested by the recruitment committee or by the DSMB. The coordinating center also facilitates the preparation of recruitment materials for common use at the clinical sites.

Site Specific Recruitment Strategies

Baltimore

- primary strategy - mailings to previous screenees at Social Security and HCFA (n≈8000)
- participants from previous studies and screenees from other sites
- other strategies - mass mailings using lists supplied by the Department of Motor Vehicles (DMV)
- Recr Coordinator - Jeanne Charleston

Boston

- primary strategy - recruit from Brigham and Women's hospital staff, which includes about 7000 non-physician personnel
- other strategies - screenees from past studies
- church groups
- mass mailings using Val Pak
- Recr Coordinator - Maureen MacDonald

DASH Manual of Procedures

Baton Rouge

- primary strategy
 - face-to-face recruitment from church/school groups
 - targeted radio advertising
- other strategies
 - mass mailings using DMV and state employee lists
 - health fairs
- Recr Coordinator - Betty Kennedy

Durham

- primary strategy
 - a variety of free media advertising, including PSAs and press releases through Duke Univ.
 - employees of Duke University (about 23,000)
 - posted fliers
- other strategies
 - previous study participants
 - graduate and medical students
 - church groups
 - mass mailings using voter registration lists
 - paid radio/newspaper ads
 - announcements in coupon packs mailed to homes
- Recr Coordinator - Patrice Reams

Record Keeping

Beginning with cohort 5, sites are required to complete the entire PSV form on participants, even if answers to early questions indicate they are ineligible.

Data from all PSVs need to be entered into the computer. This includes forms completed on ineligible participants and PSVs from prior cohorts that were never entered.

Appendix 4.1

EXCLUDED AND ALLOWED MEDICATIONS

Antacids

DASH participants should avoid antacids which contain any nutrients we're trying to control (calcium, potassium, magnesium, and sodium). Unfortunately, most antacids contain one or more of these. If a participant takes an antacid not mentioned below (and there are many not listed), ask him/her to bring in the bottle and have PI check it.

ALLOWED:

Amphogel
Nephrox

EXCLUDED:

Maalox	Gelusil	Tums	Rolaids
Titralac	Mylanta	Di-Gel	Riopan
Alka Seltzer	Bromo Seltzer		

Cold and Allergy Medications

DASH participants should avoid any over-the-counter cold medications containing an oral decongestant, aspirin, or NSAIDs (e.g., Ibuprofen, Naprosyn), which can raise blood pressure. The medications listed below are recommended for symptoms of cold and allergies, such as runny nose, sneezing, stuffy nose, aches, pains, and fever.

ALLOWED:

Antihistamines (including Chlortrimeton; Hismanal; Seldane; Benadryl; Tavist)
Nasal sprays (including Afrin; Otrivin; Ayr [saline])
Tylenol; Extra Strength Tylenol

EXCLUDED:

Medications containing oral decongestants
Aspirin and NSAIDs (e.g., Ibuprofen, Naprosyn)(except for menstrual cramps- see below)

Other Medications

ALLOWED:

For constipation: Correctol; Senokot
For stomach upset/indigestion: Amphogel
For aches, pains, fever: Tylenol, Extra Strength Tylenol
For menstrual cramps: NSAIDs (but not less than 48 hrs before scheduled BP measurements)

5. Prescreening Visit (PSV)

Overview	3
Setting	3
Preparations for Prescreening Visit	3
Conducting the Prescreening Visit	4
Procedures for Conducting the Visit by Phone	4
Greet the Participant	4
Describe the Study and Administer Prescreen Eligibility Form	5
Ending the Prescreening Visit	5
Subjects Not Taking Blood Pressure Medications	6
Subjects Taking Blood Pressure Medications	6
Procedures for Conducting the Visit in Person	7
Describe the Study and Administer Prescreen Eligibility Form	7
Blood Pressure Assessment (Optional)	7
Ending the Prescreening Visit	8
Subjects Not Taking Blood Pressure Medications	8
Subjects Taking Blood Pressure Medications	8
Complete Refusal Survey if needed	9

DASH Manual of Procedures

Summary of Edits

New changes in version 2.1

- Formatting

New changes in version 4.0

- None

New changes in version 4.1

- Text amended to reflect use of Refusal Survey.
- References to “MOP Chapter 22” now replaced by “Forms Manual.”
- Text now requires sites to enter all PSV Forms and to complete all of the Form once they begin asking it.
- The scripts for reviewing the study with the participant have been amended to conform with memo #94. A DASH Fact Sheet is now included at the end of the chapter.

DASH Manual of Procedures

Overview

In order to be randomized, participants must complete a series of screening visits, a run-in period, and, if on antihypertensive medications, a period of medication withdrawal. Each screening visit includes questions and procedures designed to determine eligibility for the trial.

The PSV is intended as a fast, efficient way to identify ineligible participants and participants who must undergo medication withdrawal prior to completing the screening process. The visit includes questionnaire data for exclusion and a single, optional, non-RZ blood pressure measurement. Individuals who complete the PSV are either excluded from further participation, referred to the drug evaluation visit (DEV) pathway for possible medication withdrawal, or scheduled for screening visit #1 (SV1), which may occur concurrently with the PSV.

If more than 90 days elapse between the PSV and SV1, the PSV must be repeated.

Setting

The PSV may take place at the clinical center (e.g., coincident with the initial screening visit), via telephone, or at a location in the community convenient to the population being recruited. If the PSV is being conducted at an off-site location, the clinic staff need to make sure that adequate space and facilities (e.g., tables and chairs) are available to accommodate the participant flow and to assure privacy for the participants when answering questions.

Preparations for Prescreening Visit

The following materials are needed to conduct the prescreening visit.

- Standard (non-RZ) sphygmomanometer and stethoscope (optional)
- PSV reference chart (included at back of chapter)
- Participant Information Sheet (form #05)
- Informed consent form for PSV (if required by local IRB, see chapter 3)
- Pre Drug Withdrawal Questionnaire (form #30)
- Medical Eligibility Questionnaire (form # 09)
- Laptop computer
- DASH Refusal Survey (form #77)
- DASH Fact Sheet (included at back of chapter)

In the event that the laptop computer will not be used for this visit, the following additional paper form is needed.

- Prescreen Eligibility Form (form #01)

DASH Manual of Procedures

The number of forms and pieces of equipment is determined by local staffing configurations and the anticipated participant flow. If available, a spare laptop unit and sphygmomanometer should be on-hand as backups.

If either SV1 or the initial drug evaluation visit (DEV1) is to be held in conjunction with the PSV, additional forms and equipment are also needed (see chapters 6 and 7 for details).

Conducting the Prescreening Visit

The procedures for conducting the PSV vary depending on whether it is being done over the phone or in person, and whether or not the participant needs to complete the drug withdrawal process. This section provides procedures to cover each of these situations.

In general, however, the following sequence of activities will occur:

- Greet the participant
- Describe the study and answer participant's questions
- Administer informed consent form (if appropriate)
- Administer the Prescreen Eligibility Form
- Review Prescreen Eligibility Form to see if participant requires drug withdrawal
- If face-to-face, conduct a single, non-RZ blood pressure measurement
- Schedule or conduct SV1 or begin evaluation for drug withdrawal
- Complete Refusal Survey if needed

Procedures for Conducting the Visit by Phone

At most sites, the initial direct contact between participants and clinic staff will most often be by telephone. Potential participants will usually be responding either to a direct mailing, radio advertisement, or some other recruitment effort. The level of knowledge about the study will vary greatly among respondents depending on the manner in which the participant heard about the study. For example, if the participant has received a copy of the DASH brochure, she may already be aware of some of the study's feeding requirements and is likely to satisfy many of the PSV eligibility requirements.

Greet the Participant

Telephone staff should identify themselves by name and should indicate the name of the institution where they work. For example,

“Hello, name of institution, this is first name of staffer speaking. May I help you?”

DASH Manual of Procedures

The participant will then identify herself and ask to speak with someone about the study. They may either identify the study by name or they may refer to it as the “eating study” or using other similar language. Be sure that whoever answers the phones, if the line is used for more than one study, is familiar enough with the study and the recruitment materials to be able to properly refer the participant to a DASH staff member.

Describe the Study and Administer Prescreen Eligibility Form

The DASH staff member should quickly confirm that the participant is calling about participating in the study, provide a brief overview, and begin to administer the Prescreen Eligibility Form. For example,

"That's right, the name of the study is the dietary approaches to stop hypertension study, or DASH for short. Let me tell you a little bit about the study, and then if you are still interested I have a few quick questions to ask you to see if you might be eligible to participate."

[Review DASH Fact Sheet with participant. A copy is included at the end of this chapter.]

"Does the study sound like something you might be interested in?"

If No,

"Well thanks for your interest anyway. Do you mind if I ask how you heard about the study before I let you go?"

If Yes,

"Great. What I'd like to do then is to ask you a few questions and, if you are still eligible, schedule you for a clinic visit. Are you ready?"

Begin administering the Prescreen Eligibility Form, the instructions for which may be found in the Forms Manual. Complete the entire form, even if participant is ineligible.

Ending the Prescreening Visit

If, after completing the Prescreen Eligibility Form, the participant is ineligible, thank them for their time and interest and conclude the conversation. Enter the Prescreen Eligibility Form data into the computer.

If the participant is eligible and the visit is being conducted with a laptop, enter the visit outcome status and the computer will generate a study ID. Check to make sure the participant is not 1) already currently in the screening process for the current cohort or 2) previously randomized. Complete the Participant Information Sheet, noting the participant's ID number on the sheet.

DASH Manual of Procedures

If the participant is eligible and no laptop is being used, complete the Participant Information Sheet and enter the ID on it later. Note the visit outcome on the Prescreen Eligibility Form.

Subjects Not Taking Blood Pressure Medications

For eligible participants who are not currently taking blood pressure medications, schedule a date for the SV1 visit, note it on the Prescreen Eligibility Form, thank the participant for his interest in the study, and terminate the conversation.

Subjects Taking Blood Pressure Medications

For eligible participants who are currently taking blood pressure medications, give a quick overview of the withdrawal process. In addition, it is desirable to administer either or both of the Medical Eligibility Questionnaire and the Pre Drug Withdrawal Questionnaire in preparation for the DEV1 visit. For example,

"Well, it looks like you are eligible for the study so far, but in order to participate it will be necessary for you to stop taking your blood pressure medications for the duration of the study, which could be as long as six months. In order to do that we will need to ask you some more questions about your health to make sure that it's safe to take you off of your medications. We will also want to contact your physician to make sure he or she agrees it's safe to stop your medications.

"Once everyone has agreed that it is okay for you to stop taking your medications for a while, *name of clinician*, one of the study investigators, will ask you to begin decreasing the amount of medications that you take. Throughout the process, *name of clinician* will closely monitor you to make sure that your blood pressure does not rise too much.

"Does that sound okay?"

If No,

Ask participant what is troubling them and try to resolve any remaining questions they may have. If necessary ask if they would like *name of clinician* to contact them directly?

If Yes,

"Great! Let me just ask you a few more questions that *name of clinician* will want to review prior to your next visit with *him/her*. After that I will schedule a date for you to come in and see *name of clinician* to begin the process."

Ask Medical Eligibility Questionnaire and Pre Drug Withdrawal Questionnaire

Schedule a date for the DEV1 visit, note it on the Prescreen Eligibility Form, thank the participant for her interest in the study, and terminate the conversation.

DASH Manual of Procedures

Procedures for Conducting the Visit in Person

In some cases, such as health fairs, the initial contact with the participant will be in person. Depending upon the format of these screenings, the participants may or may not have heard about the study when they meet the study staff person. For example, they may simply think they are waiting for a free blood pressure screening, or they may have been given a copy of the DASH brochure to read while they are waiting in line. If blood pressure is measured as the first part of the visit and the participant is ineligible (see guidelines below), the Prescreen Eligibility Form need not be asked.

Describe the Study and Administer Prescreen Eligibility Form

Whenever it makes sense to do so in the context of the screening, the DASH staff member should introduce herself as part of the study, provide a brief overview of the study, and begin to administer the Prescreen Eligibility Form. For example,

"Your blood pressure is xxx over xxx, which is in the high end of the normal range, and as a result you might be eligible to participate in a study we are doing to help people reduce their blood pressure by changing what they eat. The name of the study is the dietary approaches to stop hypertension study, or DASH for short. Let me tell you a little bit about the study, and then, if you are still interested, I have a few quick questions to ask you to see if you might still be eligible to participate."

[Review DASH Fact Sheet with participant. A copy is included at the back of the chapter.]

"Does the study sound like something you might be interested in?"

If No,

"Well thanks for your interest anyway." Check off the appropriate box (health fair, worksite screening, etc.) on the Prescreen Eligibility Form.

If Yes,

"Great. What I'd like to do then is to ask you a few questions and, if you are still eligible, schedule you for a clinic visit. Are you ready?"

Begin administering the Prescreen Eligibility Form, the instructions for which may be found in the Forms Manual. Complete the entire form, even if participant is ineligible.

Blood Pressure Assessment (Optional)

Most likely the blood pressure assessment will occur as the first stage of these visits, though in some cases it may occur after the Prescreen Eligibility Form has been administered. The PSV blood pressure assessment consists of a single, non-RZ blood pressure measurement conducted in a seated position.

DASH Manual of Procedures

For individuals not currently taking antihypertensive medications, no eligibility limits are established for the PSV blood pressure measurement. It is recommended however, that individuals with a DBP less than 76 mm Hg be excluded. Individual clinics should establish their own upper eligibility limits, and participants whose blood pressure exceeds these limits should be excluded and referred to a physician for further follow-up.

Participants who meet the PSV eligibility criteria are scheduled for SV1, which may occur immediately.

Participants who are taking antihypertensive medications are excluded from participation if their PSV DBP \geq 90 mm Hg or if their SBP \geq 150 mm Hg. Those who meet the blood pressure and other PSV eligibility requirements and who indicate a willingness to withdraw from medications for the duration of the study are scheduled for the initial drug evaluation visit (DEV1).

Any participant who is on antihypertensive medications at the PSV but who is not identified as such until a later visit is referred to the drug withdrawal pathway at the time their antihypertensive medication use is determined. After completion of the drug withdrawal process, the participant then re-enters the screening process at SV1. Further, the preceding blood pressure exclusion criteria (\geq 150/90 mm Hg) apply to any blood pressure recorded while a participant is still on antihypertensive medications.

Ending the Prescreening Visit

If, after concluding the visit, the participant is ineligible, thank them for their time and interest and conclude the conversation. Enter the Prescreen Eligibility Form data into the computer.

If the participant is eligible and the visit is being conducted with a laptop, enter the visit outcome status and the computer will generate a study ID. Check to make sure the participant is not 1) already currently in the screening process for the current cohort or 2) previously randomized. Complete the Participant Information Sheet, noting the participant's ID number on the sheet.

If the participant is eligible and no laptop is being used, complete the Participant Information Sheet and enter the ID on it later. Note the visit outcome on the Prescreen Eligibility Form.

Subjects Not Taking Blood Pressure Medications

For eligible participants who are not currently taking blood pressure medications, schedule a date for the SV1 visit, note it on the Prescreen Eligibility Form, thank the participant for his interest in the study, and terminate the conversation.

Subjects Taking Blood Pressure Medications

For eligible participants who are currently taking blood pressure medications, give a quick overview of the withdrawal process. In addition, it is desirable to administer either or both of the

DASH Manual of Procedures

Medical Eligibility Questionnaire and the Pre Drug Withdrawal Questionnaire in preparation for the DEV1 visit. For example,

"Well, it looks like you are eligible for the study so far, but in order to participate it will be necessary for you to stop taking your blood pressure medications for the duration of the study, which may be as long as six months. In order to do that we will need to ask you some more questions about your health to make sure that it is safe to take you off of your medications. We will also want to contact your physician to make sure he or she agrees it's safe to take you off of your medications.

"Once everyone has agreed that it is okay for you to stop taking your medications for a while, *name of clinician*, one of the study investigators, will ask you to begin decreasing the amount of medications that you take. Throughout the process, *name of clinician* will closely monitor you to make sure that your blood pressure does not rise too much.

"Does that sound okay?"

If No,

Ask participant what is troubling them and try to resolve any remaining questions they may have. If necessary ask if they would like *name of clinician* to contact them directly?

If Yes,

"Great! Let me just ask you a few more questions that *name of clinician* will want to review prior to your next visit with *him/her*. After that I will schedule a date for you to come in and see *name of clinician* to begin the process."

Ask Medical Eligibility Questionnaire and Pre Drug Withdrawal Questionnaire.

Some sites may prefer to give the participant the Medical Eligibility Questionnaire to take home and complete, or just to complete by themselves before they leave. If this is the case, be sure to separate the last page ("office use only" section) and to give participants only the first two pages. Note the participants study ID number on all three pages and retain the last page in the participant's study chart. If the participant has not yet been assigned a study ID, write their name on each page and enter the ID later.

Schedule a date for the DEV1 visit, note it on the Prescreen Eligibility Form, thank the participant for her interest in the study, and terminate the conversation.

Complete Refusal Survey if needed

If a participant is eligible to participate in the study after completing the Prescreen Eligibility Form (questions 1-14) and subsequently refuses to participate, attempt to complete The Refusal Survey (form #77). This includes participants who are excluded based on the "interest question". However, participants who are excluded by the site based on blood pressure or medication use need not complete this form.

PSV Reference Chart

Body Mass Index Table (for use with Prescreen Eligibility Form)

Locate participant's height (from Q12) on the table below and note the accompanying threshold weight. If participant's weight (from Q13) equals or exceeds this threshold, the participant is ineligible based on BMI.

<u>height</u>	<u>threshold weight</u>	<u>height</u>	<u>threshold weight</u>	<u>height</u>	<u>threshold weight</u>
4'6"	145.2	5'5"	210.4	6'4"	287.6
4'7"	150.6	5'6"	216.9	6'5"	295.2
4'8"	156.1	5'7"	223.5	6'6"	302.9
4'9"	161.8	5'8"	230.2	6'7"	310.7
4'10"	167.5	5'9"	237.0	6'8"	318.6
4'11"	173.3	5'10"	244.0	6'9"	326.7
5'	179.2	5'11"	251.0	6'10"	334.8
5'1"	185.3	6'	258.1	6'11"	343.0
5'2"	191.4	6'1"	265.3	7'	351.3
5'3"	197.6	6'2"	272.6		
5'4"	203.9	6'3"	280.1		



Dietary Approaches to Stop Hypertension (DASH) Study

DASH FACT SHEET

Please use the following “script” to describe the key features of the study as a part of PSV screening. This will help ensure that all participants have a common knowledge base about the study and thus will increase the usefulness of the data from our Refusal Survey (Form #77).

- Purpose of the DASH Study is to find out if eating foods rich in certain nutrients will reduce BP.
- Provide all meals for 11 weeks (3 months)
- Must be available to come to (name of facility) every M-F for a meal (lunch or dinner).
- Food for the other 2 meals/day plus snacks and weekend meals will be provided to “Take-Home.”
- Must eat only study food for the 11 weeks (participants will be randomized to one of three diets).
- NOT a weight loss study; weight is monitored and amount of food provided is adjusted to make sure that weight does not change during study.
- BP monitoring at least weekly; twice during study, participants will wear a 24-hour ambulatory BP monitor.
- Three blood tests required (once during screening and twice during 11 week feeding).
- Three 24-hour urine collections required (once during screening and twice during 11 week feeding period).
- There will be a process of 3 screening visits (each visit at least 1 week apart) in which you must qualify (all 3 visits) before eligible to participate in study.
- At the end of the study, you will receive \$xxx.

IF Applicable

- DEXA scan also done (low level x-ray to evaluate body composition, i.e. bone density, body fat).
- Describe ATT testing

DASH Manual of Procedures

6. Drug Withdrawal

Overview of The Drug Withdrawal Process	3
Screening Questionnaires	5
Obtaining Physician Approval	5
Initial Drug Evaluation Visit (DEV1)	5
Blood Pressure Check	5
Screening Questionnaire Review and Symptom Questionnaire	6
Review of Drug Withdrawal Process	6
Tapering Schedule for Drug Withdrawal	6
Schedule of Visits During Drug Withdrawal	8
Initial Drug Tapering “Visit”	8
Subsequent Visits During Drug Tapering	8
Monitoring Visits After Drug Tapering	8
Initiation of SV1	9
Drug Withdrawal Failures	9
Record Keeping	10
Sample Letter to MD Requesting Permission to Withdrawal Medications	11
Sample Letter to Notify Personal Physicians About the Initiation of Drug Withdrawal	13

Summary of Edits

New changes in version 2.0

- misc. technical edits

New changes in version 2.1

- misc. technical edits
- Text revised to require use of either form #02 or form #29 to record summary BP information and tapering decisions.
- Text also revised (final para of *Record Keeping*) to make more explicit that BP and DEV symptom checklist must be recorded at each visit.

New changes in version 4.0

- none

New changes in version 4.1

- A new paragraph has been added to the end of the section entitled *Blood Pressure Check* to note that not all DEV blood pressures need be taken using RZ equipment and DASH certified techs.
- A new paragraph was added to the end of *Record Keeping* to note need to complete Refusal Survey on drop outs.

DASH Manual of Procedures

Overview of The Drug Withdrawal Process

DASH screenees meeting the PSV eligibility criteria but taking up to two different types of anti-hypertensive medications must undergo a drug withdrawal process in order to determine whether they qualify for the first screening visit (SV1). In order to start the drug withdrawal process, such individuals must have a systolic blood pressure <150 mmHg and a diastolic blood pressure < 90 mmHg (while on medication), must have signed a DASH informed consent statement pertaining to drug withdrawal, and must have completed the Medical Eligibility Questionnaire (form #09), the Pre-Drug Withdrawal Questionnaire (form #30), and the DEV Symptom Checklist (form #31). The first two questionnaires are designed to check for the standard DASH medical exclusions and to detect the presence of conditions, such as angina or congestive heart failure, for which discontinuation of anti-hypertensive medications would be inappropriate. The symptom checklist is used as a baseline against which to measure changes in symptoms during withdrawal. A DASH clinician must then review this information and decide that the participant is a suitable candidate for withdrawal. Finally, the participant's personal physician must provide verbal or written permission to withdraw the medications and must confirm that the participant's blood pressure medication is only required for control of blood pressure and not another condition.

Next, a DASH clinician must write a plan for discontinuing the anti-hypertensive medications. The drug withdrawal process itself is comprised of two phases: 1) drug tapering (if applicable) and 2) monitoring after drug stoppage. During drug tapering, antihypertensive medications are withdrawn gradually. During the second phase, blood pressure continues to be monitored. Once tapering has begun, participants must be evaluated at least every 21 days, and at least 21 days must elapse after the completion of medication withdrawal before the participant is eligible to start SV1. Participants are restarted on medications and excluded from further participation in the study if, at any point during the tapering/monitoring period, their systolic blood pressure rises to 160 mmHg or above or their diastolic blood pressure rises above 95 mmHg. Figure 6.1 provides an overview of the drug withdrawal process. As noted below, the timing of some events may differ from that shown in the figure. For example, the Medical Eligibility Questionnaire may be completed at the PSV, at home, or during the DEV1 visit.

The drug withdrawal process is carried out by clinical center medical staff under the direct supervision of a study clinician (e.g., physician, physician assistant, nurse). The staff explain the procedure to the participants, give written instructions at the initial drug evaluation visit, and review the progress of medication withdrawal during the subsequent visits. Participants are requested to bring their antihypertensive medications with them to each visit. The supervising DASH clinician oversees the DASH staff who are carrying out the drug withdrawal, and is available for questions, complications, medical emergencies, and other related issues.

With the exception of the dates on which drug withdrawal starts and is finished, information collected during drug withdrawal is for local use only. However each clinic

DASH Manual of Procedures

Figure 6.1: Outline of Drug Withdrawal Process

Prescreen Visit (PSV)

- check BP if feasible (eligible if SBP < 150 and DBP < 90)
- administer or distribute Medical Eligibility Questionnaire (Form #09)
- administer Pre-Drug Withdrawal Questionnaire (Form #30)
- obtain tentative consent for drug withdrawal from participant

↓

Before DEVI

- review case with DASH clinician
- develop plan for drug withdrawal (if feasible)
- obtain permission from participant's physician and confirm use of medication(s)

↓

Initial Drug Evaluation Visit (DEVI)

- check BP (eligible if SBP < 150 and DBP < 90)
- administer DEV Symptom Checklist (Form #31)
- review Medical Eligibility Questionnaire and medications
- review drug withdrawal process
- obtain signed informed consent for drug withdrawal
- provide emergency telephone number and written instructions (if available)
- document visit on drug withdrawal summary form

↓

Initial Drug Tapering "Visit"

- obtain BP if possible (eligible if SBP < 150 and DBP < 90)
- administer DEV Symptom Checklist
- review drug withdrawal process again
- if eligible for tapering/discontinuation, give initial dose or instruct to discontinue
- record "initial tapering date" in electronic database

↓

Subsequent Tapering Visits

- obtain BP (eligible if SBP < 160 and DBP < 95)
- administer DEV Symptom Checklist
- if eligible for further tapering/discontinuation, give next dose or instruct to discontinue
- record "final tapering date" (if applicable) in electronic database

↓

Monitoring Visits Occurring Less Than 21 Days After Final Tapering Date

- obtain BP (eligible to continue if SBP < 160 and DBP < 95)
- administer DEV Symptom Checklist
- if eligible to continue, schedule next monitoring visit

↓

Monitoring Visits Occurring 21 or More Days After Final Tapering Date

- if SBP < 160 and DBP = 78-95, conduct SV1
- if SBP ≥ 160 or DBP > 95, participant is ineligible, restart medications and notify participant's physician

DASH Manual of Procedures

- if SBP <160 and DBP <78, administer DEV Symptom Checklist and schedule additional monitoring visits
- must keep detailed records summarizing the process. In addition, participants excluded during this phase must be noted in the study database.

Screening Questionnaires

Prior to beginning drug withdrawal, each participant must complete two screening questionnaires to assure that they are eligible to participate in DASH and are good candidates for drug withdrawal. These questionnaires are the Medical Eligibility Questionnaire and the Pre-Drug Withdrawal Questionnaire. These questionnaires may either be completed at the time of the prescreening visit, at home between the PSV and the initial drug evaluation visit (DEV1), or at DEV1 visit. These questionnaires are reviewed by the DASH staff and, if the subject appears eligible to continue, by the supervising DASH clinician. If the Medical Eligibility Questionnaire is given to the participant to complete, first remove the last page and retain it in the participant's study chart.

Obtaining Physician Approval

Prior to initiation of drug withdrawal, the participant's personal physician or health care provider must be notified of the subject's intention to participate in the study. The physician is asked to confirm that the antihypertensive medication is not being used for treatment of conditions other than hypertension (e.g., angina or other forms of coronary heart disease; congestive heart failure; arrhythmias; migraine headache; prostatic hypertrophy). The physician must also give permission for drug withdrawal.

In the event that the participant's physician cannot be located or identified, the supervising DASH clinician may waive this requirement and initiate drug withdrawal on his/her own authority. This must be clearly documented in the participant's study chart, however, and the participant must be informed that this is the case. Sample letters and forms that could be sent to the participant's personal physician in order to secure approval are included at the end of this chapter.

Initial Drug Evaluation Visit (DEV1)

The initial drug evaluation visit (DEV1) is used to confirm that the pre-withdrawal blood pressure is within acceptable limits, to review the Medical Eligibility and Pre-Drug Withdrawal Questionnaires, and to thoroughly explain the drug withdrawal process to the participant. Appropriately trained medical staff (e.g., physician assistant or nurse) indicate the purpose of the drug withdrawal visits, tell the participant what to do if problems occur, and describe the importance of the follow-up schedule and the necessity for adhering to it.

Blood Pressure Check

DASH Manual of Procedures

At this and all subsequent visits during the drug withdrawal process, clinic staff should record two blood pressure measurements. At this initial (pre drug withdrawal) visit, the average of the two SBP measurements must be less than 150 mmHg and the average of the two DBP measurements must be less than 90 mmHg in order for the participant to be eligible to begin withdrawal.

Clinics are encouraged to use the laptop computers to record the blood pressure measurements, as they do all mathematical calculations for you and are preprogrammed with the necessary eligibility ranges and visit spacing requirements. In the event that laptops are not used, the Generic Blood Pressure Form (form #26) may be used to record blood pressures. Regardless of the system used to record individual blood pressure measurements, clinics should record all blood pressure measurements taken during the drug withdrawal process on a Drug Withdrawal Summary Form (either Form #02 or Form #29).

Prior to 21 days post-withdrawal, blood pressures may be made using any appropriately maintained sphygmomanometer and the technician need not be DASH certified. However, staff must still wait five minutes prior to taking the first measurement and 30 seconds between measurements. All DEV blood pressures taken 21 or more days past withdrawal must be taken using a random zero sphygmomanometer and following the procedures outlined in chapter 19.

Screening Questionnaire Review and Symptom Questionnaire

As noted previously, this visit should be used to review/complete the Medical Eligibility Questionnaire and the Pre Drug Withdrawal Questionnaire. In addition, the participant should complete the DEV Symptom Checklist at this time. This latter form will serve as a baseline against which to evaluate symptoms that are reported during the withdrawal process. Any questions that arise from these questionnaires need to be resolved by the supervising DASH clinician before medication withdrawal actually begins.

Review of Drug Withdrawal Process

It is very important that the participant is informed fully about the drug withdrawal process, including instructions on how to decrease the medication, potential side effects, and what to do if problems occur. Participants should also receive a phone number to use to contact DASH personnel for medical help related to drug withdrawal.

Tapering Schedule for Drug Withdrawal

Assuming the participant is still eligible for withdrawal at the conclusion of the DEV1 visit, the supervising DASH clinician determines an appropriate schedule for withdrawal of medications. This may happen either at the time of the DEV1 visit, or subsequent to this visit after review by the supervising DASH clinician. The tapering schedule (if

DASH Manual of Procedures

appropriate) will typically be accomplished over 0 to 4 weeks for those on one medication and over 2 to 8 weeks for those on two medications.

DASH Manual of Procedures

Schedule of Visits During Drug Withdrawal

Drug withdrawal must be monitored by appropriate medical staff and involves frequent blood pressure measurements. The number and frequency of visits during drug withdrawal depends on the number and type of anti-hypertensive medications to be withdrawn and on clinician discretion at each of the DASH clinical centers. However, visits must be scheduled no more than 21 days apart once drug withdrawal has begun. With the exception of obtaining blood pressure measurements and administering the DEV Symptom Checklist at each visit, the drug withdrawal procedures (frequency of visits and use of forms) are guidelines, not rules, for accomplishing drug withdrawal.

Typically, visits will occur more frequently (e.g., weekly) as the medication is tapered, and less frequently once all medications have been discontinued. A visit should be scheduled 21 days after medication is fully withdrawn, or shortly thereafter, since this is the soonest participants can become eligible for SV1.

The importance of attending scheduled visits for careful monitoring of drug withdrawal must be explained to each participant. If a participant does not show up for a scheduled visit and does not contact the clinic, the clinic staff will call the participant to reschedule the visit. If more than 21 days elapse between visits the participant is excluded from further participation in the study, although they still need to be seen one last time by the clinic staff. If 30 days should elapse without a return clinic visit, the clinic staff should contact the participant by phone, and in addition send a letter, with instructions to resume the original medication dose. The participant's physician of record should also be notified at this point.

Initial Drug Tapering "Visit"

Although drug tapering/withdrawal maybe started at the DEV1 visit, it is more likely that it will begin subsequent to that visit, perhaps by a phone call from the supervising DASH clinician to the participant informing her that it is okay to begin the withdrawal process. In the event that the participant is seen again in the clinic after DEV1 and prior to withdrawal, blood pressure measurements must continue to be taken and the participant excluded if either the SBP > 150 mmHg or the DBP > 90 mmHg. The DEV Symptom Checklist should also be asked again at this time, regardless of whether the "visit" is conducted in person or by phone.

The date that drug withdrawal is initiated is referred to as the *initial tapering date* and must be recorded on a permanent paper record and also entered into the electronic database using the laptop computer.

If the interval between approval by the participant's physician and the actual start of drug withdrawal is prolonged, the supervising DASH clinician may wish to notify the participant's physician that drug withdrawal has begun. A sample letter is included at the end of this chapter.

DASH Manual of Procedures

Subsequent Visits During Drug Tapering

As explained during the DEV1 visit, the participant is asked to return on a frequent basis for blood pressure measurements and medication dosing decisions during the drug tapering phase. These visits follow a protocol similar to the initial drug tapering visit. Blood pressure is measured according to the standard DASH protocol and symptom status is assessed. The average of the two blood pressure measurements, as well as the date of the visit, the current dose of the medication, and the medication decisions, should be recorded on a summary paper form that is kept in the participant's study chart. Symptoms should be assessed using the DEV Symptom Checklist. The medical staff (e.g., physician, physician assistant, or nurse) then review the measured blood pressure as well as any symptoms the participant may be experiencing.

The review of the DEV Symptom Checklist should focus on the development of new or worsening symptoms since the beginning of drug withdrawal. The staff, with direction from the supervising DASH clinician, must assess whether these symptoms represent a serious medical problem or side effects associated with drug withdrawal. The severity of the problem is an important factor in deciding if delaying or stopping the drug withdrawal protocol is warranted.

If both the average systolic blood pressure is < 160 mmHg and the average diastolic blood pressure is < 95 mmHg, further tapering of the medication can continue. If, however, either the average systolic blood pressure is > 160 mmHg or the average diastolic blood pressure is > 95 mmHg, the individual is ineligible to continue.

At the end of each drug tapering visit, the participant is told the dose of medication to be taken during the next week. Finally, the participant is scheduled for the next drug withdrawal visit. The date the participant is completely withdrawn from medications is referred to as the *final tapering date*, and should be noted on the participant's summary log and also entered into the laptop. In the event that a medication is withdrawn without tapering, the initial and final tapering dates are the same.

Monitoring Visits After Drug Tapering

After the final drug tapering visit, the participant needs to return to the clinic for blood pressure monitoring visits at least every 21 days. Also, the clinic should schedule a visit to occur 21 days after the final tapering date (or soon thereafter). This visit will determine, for most persons undergoing drug withdrawal, whether or not they are eligible for SV1.

The monitoring visits follow a protocol similar to the tapering visits. Blood pressure is measured according to the standard DASH protocol and symptom status is assessed. The average of the two blood pressure measurements, as well as the date of the visit should be recorded on a Drug Withdrawal Summary Form (Form #02 or For #29) which is kept in

DASH Manual of Procedures

the participant's study chart. Symptoms should be assessed using the DEV Symptom Checklist. The medical staff (e.g., physician assistant or nurse) then review the measured blood pressure as well as any symptoms the participant may be experiencing.

The review of the DEV Symptom Checklist should focus on the development of new or worsening symptoms since the beginning of drug withdrawal. The staff, with direction from the supervising clinician, must assess whether these symptoms represent a serious medical problem or side effects associated with drug withdrawal. The severity of the problem is an important factor in deciding if the participant can continue to remain off of medications.

In addition, the average systolic blood pressure must be < 160 mmHg and the average diastolic blood pressure < 95 mmHg in order for the participant to continue in the study. The average of the individual blood pressure measurements, as well as the date of the visit, should be recorded on a summary form.

If more than 21 days elapse between visits the participant is excluded from further participation in the study, although he still needs to be seen one last time by the clinic staff. If 30 days should elapse without a return clinic visit, the clinic staff should contact the participant by phone, and in addition send a letter, with instructions to resume the original medication dose. the physician of record should also be notified at this point.

Initiation of SV1

If, at any visit occurring 21 or more days after the final tapering date, a participant is seen for a monitoring visit and has an average SBP < 160 mm Hg and an average DBP between 78-95 (inclusive), she is considered to be eligible for SV1 and should begin the SV1 visit immediately. The participant's observed SBP and DBP values become the SV1 SBP and DBP measurements. The SV1 visit is described in chapter 7.

Note that, due to the BP exclusion limits during drug withdrawal, only participants whose SBP is < 160 mmHg and whose DBP is < 78 mmHg require a second visit past 21 days. All other participants will either be excluded or deemed SV1 eligible.

Drug Withdrawal Failures

Drug withdrawal is considered to be a failure if any of the following occur during either the tapering or monitoring phases:

- 1) At any one visit the average systolic blood pressure is > 160 mmHg and/or the average diastolic blood pressure is > 95 mmHg.
- 2) Contact is lost with participant after initiation of drug withdrawal or participant is prevented from attending visits by interim medical events.

DASH Manual of Procedures

- 3) An intolerable symptom occurs.

The participant should be restarted on medications and his physician should be notified that this has happened.

Record Keeping

With the exception of the initial and final tapering dates, data collected during drug withdrawal are not study data and do not need to be entered into the database. However individual clinics are expected to keep careful records of all visits and results and to maintain this information in the participant's chart.

Forms that must be kept in the charts include: the Medical Eligibility Questionnaire, the Pre Drug Withdrawal Questionnaire, the DEV Symptom Checklist, and a Drug Withdrawal Summary Form (Form #02 or #29) showing all blood pressure measurements and tapering decisions.

The DEV Symptom Checklist will be completed on multiple occasions. It must be administered at each visit during drug withdrawal until the participant qualifies for SV1 or becomes ineligible. Blood pressure must also be assessed at each of these visits.

Should a participant elect to drop out of the study during this period, staff need to complete the DASH Refusal Survey (form #77).

DASH Manual of Procedures

Sample Letter to MD Requesting Permission to Withdraw Medications

June 30, 1994

Dear Dr. _____:

Your patient, _____, has expressed interest in participating in the Dietary Approaches to Stop Hypertension (DASH) Study. This study, which is funded by the National Heart, Lung, and Blood Institute, is designed to assess the relationship between certain patterns of eating and blood pressure.

If your patient's blood pressure is well-controlled (<150/90) and if your patient appears basically healthy during a brief screening period, he/she will be assigned to one of three intervention dietary patterns (standard diet; high fruit and vegetable diet; and low fat, high fruit and vegetable diet). We will provide all of your patient's meals during an eleven week feeding period.

We would like permission to discontinue your patient's antihypertensive medication so that they may participate in DASH. We also need to be sure that the medications currently being taken for hypertension are not also being prescribed for other medical conditions that would contraindicate their discontinuation. We will wean your patient from his/her antihypertensive medication and will regularly monitor his/her blood pressure. If your patient's blood pressure rises to ≥ 160 mmHg or > 95 mmHg during withdrawal, or above 170/105 thereafter, she or he will be restarted on their original antihypertensive medication.

As is the practice in all of our studies, we have no capacity or interest in providing comprehensive medical care. Your patient will remain under your care throughout the study. We just ask that you allow us to discontinue their antihypertensive medications and let us monitor their blood pressure and determine the need, if any, for resumption of therapy.

The enclosed brochure provides additional details of the DASH program. If you have any questions, do not hesitate to call (410) 281-1600 and ask for _____.

Please complete and return the attached sheet in the envelope provided.

Thank you for your prompt reply.

Sincerely,

Paul K. Whelton, M.D., M.Sc.
(410) 955-6953

Lawrence J. Appel, M.D., MPH
(410) 614-0986

Enclosure

DASH Manual of Procedures

Sample Letter to Personal MD, (cont'd)

Patient's Name: _____

Patient's Anti-Hypertensive Medications: _____

Physician: _____

Physician's Phone Number: _____

___ Yes, my patient may discontinue his/her medication and participate in DASH

___ No, my patient may not discontinue his/her medication because it is needed for the following condition(s):

Signature

Date

DASH Manual of Procedures

Sample Letter to Notify Personal Physicians About the Initiation of Drug Withdrawal

June 30, 1994

Dr. _____

Address

City, State Zip

Dear Dr. _____:

Your patient, _____, is undergoing screening for Dietary Approaches to Stop Hypertension (DASH) study. DASH is a multi-center study designed to assess the relationship between certain patterns of eating and blood pressure. It is funded by the National Institutes of Health. This letter is to inform you that your patient is now undergoing tapering of his/her anti-hypertensive medication under our close supervision.

We will monitor your patient's blood pressure on a frequent basis during the tapering process and thereafter. If his/her blood pressure remains less than 160/96, he/she will remain off of drug therapy and be allowed to enroll in the study. Thereafter his/her blood pressure must remain below 170/105 to continue in the study (about 3-4 months duration). Our staff will be available to assist the participant at all times. If your patient's blood pressure does not remain below the above criteria, we will reinstate the medication which you prescribed.

We also monitor symptoms and reinstate medication in case any adverse effects develop.

If you have any questions or comments, please let me know.

Sincerely yours,

Medical Director, DASH Clinical Center

7. Screening Visit 1 (SV1)

Purpose _____	3
Setting _____	3
Preparations for SV1 Visit _____	3
Conducting the SV1 Visit _____	4
Confirm Participant ID and check for completed PSV _____	4
Review the study and confirm participant interest _____	5
Blood Pressure Assessment _____	5
General Dietary Information Questionnaire (form #28) _____	6
Medical Eligibility Questionnaire (form #09) _____	6
Participant Information Sheet _____	6
SV1 Flow Form _____	7
DEV Referrals _____	7
Ending SV1 _____	7

Summary of Edits

New changes in version 2.0

- misc. technical edits

New changes in version 2.1

- misc. technical edits
- second para added under *Setting*

New changes in version 4.0

- none

New changes in version 4.1

- Text amended under *Review the study and confirm participant interest* to note need to complete Refusal Survey for drop-outs. Form #77 added under *Preparation for SVI visit*.
- The last paragraph under *Blood Pressure Assessment* has been modified to reflect need to keep a hard copy record of all blood pressure measurements.

DASH Manual of Procedures

Purpose

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. Participants will also be instructed on how to fill out the Medical Eligibility Questionnaire if it has not already been completed as a part of the DEV process. The initial SV1 may occur at anytime, including the day of the PSV. However if the SV1 occurs more than 90 days after the PSV, the PSV data are invalid and must be recollected prior to obtaining SV1 data. If a participant fails SV1 because of blood pressure, subsequent SV1s on that individual may not be scheduled within windows of that cohort. The participant may, however, be rescreened for later cohorts.

Setting

The SV1 visit 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 visit. Persons who are eligible at PSV may immediately receive an SV1 visit or they may be scheduled for an SV1 visit at a later time. In order to conduct the SV1 visit in an off-site location, it is essential that appropriate space and facilities are available. This requires a quiet, private or semi-private setting where the required relaxed waiting time can occur before an RZ blood pressure is taken, and an interviewing setting that permits privacy of response to the questions that are asked.

If the SV1 visit is conducted at the same time as the PSV visit, the DASH staff person should leave the room at the end of the PSV visit and ask the participant to sit quietly for five minutes with his legs uncrossed. The SV1 visit is then conducted.

Preparations for SV1 Visit

The following materials are needed to conduct the SV1.

- Random zero (RZ) sphygmomanometer and stethoscope
- Standard mercury sphygmomanometer
- Consent materials (if required by local IRB, see chapter 3)
- SV1 Blood Pressure Form (form #4)
- Medical Eligibility Questionnaire (form #09)
- General Dietary Information Questionnaire (form #28)
- SV1 Flow Form (form #03)
- Study charts for scheduled participants (if available)
- Laptop computer

In addition, the following materials should also be on hand in case either the PSV needs to be redone, the participant is discovered to be taking blood pressure medications and needs to begin the DEV process, or the participant elects to drop out of the study.

DASH Manual of Procedures

- Participant Information Sheet (form #05)
- Prescreen Eligibility Form (form # 01)
- Pre Drug Withdrawal Questionnaire (form # 30)
- Refusal Survey (form #77)

The number of forms and pieces of equipment is determined by local staffing configurations and the anticipated participant flow. If available, a spare laptop unit and sphygmomanometer should be available as backups.

Conducting the SVI Visit

SVI activities are listed below. If required, obtain consent first. Whether consent is required or not, briefly redescribe DASH and obtain the participant's assurance that they are interested in participating. In general, blood pressure should be done before the other procedures because the forms need not be administered if the individual is not blood pressure eligible.

- Confirm participant ID
- Briefly redescribe the study; ask participant if they think they are interested in participating
- Obtain consent (if required by local procedures)
- Take two RZ blood pressure readings, enter data into computer, and note eligibility on SVI Flow Form
- Have participant fill out the General Dietary Information Questionnaire and note eligibility on SVI Flow Form and computer
- Instruct participant in how to complete the Medical Eligibility Questionnaire
- Record events and final eligibility status on the SVI Flow Form

Confirm Participant ID and check for completed PSV

All participants completing the SVI visit should first have completed a PSV visit and thus have a study ID. Upon arrival at the clinic, the receptionist or another staff person should check the laptop or a paper record to verify that the participant has completed the PSV and thus has a study ID. (Note that if the Prescreen Eligibility Form was completed but not entered into the computer the subject will not have been assigned a study ID.)

If a study ID exists for the participant then he/she is in the database and can begin the visit. Note the ID on the SVI Flow Form and instruct the participant to carry it with her throughout the visit and to turn it in before leaving. Indicate that the form is used to assure that the participant has completed all components of the visit or else to indicate that she has been found to be ineligible and hence does not need to complete the visit.

If no study ID exists, either the Prescreen Eligibility Form was completed and not entered or else it was never done. If the hard copy of the Prescreen Eligibility Form is available,

DASH Manual of Procedures

enter it into the laptop in order to confirm eligibility and to generate an ID. If a laptop is not available, complete the SV1 visit using paper forms and enter both the PSV and SV1 data into the computer later.

If no study ID exists and a hard copy of the Prescreen Eligibility Form is not available, a new one must be done before the visit can proceed. In this case any old versions of the Prescreen Eligibility Form, if subsequently found, should be discarded.

The SV1 visit must occur within 90 days of the PSV visit. If this is not the case, then the PSV must be repeated. This holds even if the data from the prior visit has been entered into the computer. In this latter case the computer will generate a new study ID for the participant.

*Review the study and confirm participant interest
(and obtain formal consent if required here by local procedure)*

Briefly describe DASH again, emphasizing the commitment required of participants. Ask if the individual thinks he would like to participate if eligible. Tell the participant that it is very important that those who participate follow through and complete the study. Of course, anyone has the right to drop out whenever they wish, but they should also understand that too many dropouts will invalidate the study.

If participant elects to drop out at this, or any, point in the visit, staff should seek to complete the Refusal Survey (form #77).

Blood Pressure Assessment

After expressing continued interest (and providing formal consent if required), take the participant's blood pressure using the RZ device and the procedures described in Chapter 19 of the MOP (Blood Pressure Assessment). For persons who have not been withdrawn from antihypertensive medications through the DEV process, if the average of two systolic blood pressures is less than 170 mm Hg and the average of the two diastolic pressures is between 78 and 100 mm Hg, they are eligible to continue to SV2. Persons who have stopped antihypertensive medications through the DEV process must have a systolic blood pressure less than 160 mm Hg and a diastolic pressure of 78-95 mm Hg in order to be eligible to continue to SV2.

Participants who are excluded based on blood pressure readings above the allowable limits may need to be referred to their physician for further evaluation. If the average of the SBP measurements is >170 mmHg or the average of the DBP measurements is > 105 mmHg, the participant should be referred to a physician.

At this and all subsequent DASH visits, blood pressure information should be entered directly into the laptop computer during the visit unless system problems prevent it. A backup should also be maintained.

DASH Manual of Procedures

General Dietary Information Questionnaire (form #28)

The General Dietary Information Questionnaire is a short form designed to identify people who have food allergies or medical conditions that limit the types of foods they can consume and thus could interfere with their participation in DASH. Have the participant complete this form. 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.

Medical Eligibility Questionnaire (form #09)

The Medical Eligibility Questionnaire is designed to identify persons who are ineligible for medical reasons. If the participant has been through drug withdrawal, he will have already completed this form and need not do so again. Otherwise remove the last page ("office use only" section) from the form, store it in the participant's study chart, and give the rest of the form to the participant to take home and return at the SV2 clinic visit. If the participant is not eligible for SV2, he should not receive this form. Be sure to record the participant's study ID on each page of the form. If an ID has not yet been assigned, write the participant's name on each page of the form.

The instructions for completing the questionnaire should be discussed with the participant at this time. Participants who have questions or are unsure about an item should check the "unsure" box and ask about it at the SV2 visit.

The questionnaire asks participants to indicate whether or not they are taking various medicines, including vitamins and other supplements. Ask participants to check their medication bottles for the names of their medications. In addition, instruct participants to bring to the SV2 visit all medications (including vitamins, supplements, and other non-prescription drugs) that they regularly take. A DASH staff person will list these medications in the "office use only" section of the Medical Eligibility Questionnaire at the SV2 visit.

Participant Information Sheet

Check to make sure that a copy of the Participant Information Sheet (form # 05) is on file. If one cannot be found, then complete one at this time and file it in the participant's study chart.

DASH Manual of Procedures

SV1 Flow Form

After each portion of the visit is completed, a DASH staff person should check the appropriate "Done?" box on the SV1 Flow Form and (if applicable) indicate whether the participant is eligible or not eligible to continue based on that portion of the visit. For some items, such as distributing the Medical Eligibility Questionnaire, eligibility is not determined and so "not applicable" should be checked. At the end of the visit a staff person should review this form to make sure that the participant has completed all of the necessary components. This person should also make sure that a single outcome status is coded at the bottom of the form and should enter their ID in the "staff ID" field.

If a participant is excluded due to investigator discretion (i.e., not as part of the regular screening activities for that visit), check "ineligible" under the Eligibility Summary section of the SV1 Flow Form and in addition complete the Participant Close Out screen on the laptop to record the reason for the exclusion. A paper copy of this form (form #24) can be used if the laptop is not available.

DEV Referrals

If, at any time during the SV1 visit, a participant is determined to be on anti-hypertensive medications, the SV1 visit should be terminated and the participant immediately referred for possible drug withdrawal. Explain the drug withdrawal process, determine if participant is willing to have her medications withdrawn, and complete/distribute the Medical Eligibility Questionnaire and the Pre Drug Withdrawal Questionnaire. If the participant successfully completes drug withdrawal, he needs to redo the SV1 visit.

Ending SV1

To complete the SV1 visit, do the following:

- Inform the participant of eligibility status - You may inform the participant of eligibility status and terminate the visit at any point that it is clear that the individual is not eligible for DASH. Explain the reasons for ineligibility to participant. Enter the visit outcome status into the laptop.
- If eligible, schedule an appointment for SV2 at least seven days from SV1 and note the scheduled date on the SV1 Flow Form.
- If an individual is ineligible to continue and has been withdrawn from antihypertensive medications for DASH screening, check with his physician as to whether to resume medication. If this physician is not available, use clinical judgment to determine whether to re-initiate therapy directly or to refer the participant back to his physician before re-starting medications.
- Enter the outcome status from the SV1 Flow Form into the computer.

8. Screening Visit 2 (SV2)

Purpose	3
Setting	3
Preparations for SV2	3
Conducting SV2	4
Confirm ID, check visit window, and obtain informed consent	4
Review/Complete Medical Eligibility Questionnaire	4
Blood Pressure Assessment	5
Measure Participant's Weight and Height and Check BMI	6
Collect Urine Sample For Dipstick Measures Of Protein And Glucose	6
Complete The Review Of The Medical Eligibility Questionnaire	6
Collect Blood Samples For Local Exclusionary Labs	6
Distribute And Instruct On The Food Frequency Questionnaire	7
Distribute Instructions And Urine Container For The 24-Hour Urine Sample	7
SV2 Flow Form	7
Ending SV2	7
SV2 Reference Chart	9

Summary of Edits

New changes in Version 2.2

- under *Confirm ID...*, first two paragraphs modified for greater clarity
- misc technical edits
- added SV2 Reference chart at end
- added requirements that BP cuff size should match that used at SV1

New changes in Version 4.0

- none

New changes in Version 4.1

- Text modified under *Ending SV2* to note need to complete Refusal Survey on dropouts.
- Final paragraph under *Blood Pressure Assessment* edited to note the need for paper backup and also the option to redo BP measurement if cuff size was not same as that used in SV1.

DASH Manual of Procedures

Purpose

The purpose of SV2 is to continue to identify ineligible participants as accurately and efficiently as possible. The activities of SV2 are listed below and include a review of the Medical Eligibility Questionnaire; measurement of blood pressure, height, and weight; collection of urine and blood samples; and distribution of the instructions and supplies for the Food Frequency Questionnaire and the 24-hour urine collection, both of which are to be completed by the participant before SV3.

Setting

The SV2 visit, and all subsequent DASH visits, takes place at the clinical center. It requires a quiet, private or semi-private setting where the participant can wait prior to the blood pressure measurement. Questionnaires also need to be administered/reviewed in a setting that permits privacy for the participant.

Preparations for SV2

The following materials are needed to conduct the SV2.

- Random zero (RZ) sphygmomanometer and stethoscope
- Standard mercury sphygmomanometer
- Stadiometer
- Scale
- Local laboratory chemistry panel blood supplies
- Urine dipsticks and urine sample containers
- Participant instructions and materials for 24-hour urine collection
- Consent materials (if required by local IRB, see chapter 3)
- Food Frequency Questionnaire (form #11)
- SV2 Flow Form (form #07)
- SV2 Blood Pressure Form (form #08)
- Study charts for scheduled participants
- Laptop computer

The following forms may also be needed and should therefore be on hand.

- Blank Medical Eligibility Questionnaire (form #09)
- Pre Drug Withdrawal Questionnaire (form # 30)
- Refusal Survey (form #77)

Finally, in the event that the laptop computer will not be used for this visit, the following form is also needed.

- SV2 Reference Chart (included at back of chapter)

DASH Manual of Procedures

The number of forms and pieces of equipment is determined by local staffing configurations and the anticipated participant flow. If available, a spare laptop unit and sphygmomanometer should be available as backups.

Conducting SV2

In general, performing the SV2 activities in the order listed below should provide the most efficient identification of ineligible subjects. SV2 may be politely concluded at any point after an exclusionary condition or situation has been identified.

- Confirm participant ID, check visit window, and obtain informed consent
- Briefly review the Medical Eligibility Questionnaire for obvious exclusions
- Take two RZ blood pressure readings, enter data into computer, and note eligibility on SV2 Flow form
- Weigh participant, measure height, and check BMI
- Collect urine sample for dipstick measures of protein and glucose
- Complete review of the Medical History Questionnaire
- Collect blood samples for local exclusionary labs
- Distribute Food Frequency Questionnaire and instruct participant in its use
- Distribute instructions and urine container for the 24-hour urine sample - instruct women to make the 24-hour urine collection when they are not menstruating
- Record events and eligibility status on the SV2 Flow Form

Confirm ID, check visit window, and obtain informed consent

Look up the participant in the electronic database and note the ID number on the SV2 Flow Form. If the visit is conducted at different “stations” in the clinic, instruct participant to carry this form with her throughout the visit and to turn it in before leaving. Indicate that the form is used to assure that the participant has completed all components of the visit or else to indicate that she has been found to be ineligible and hence does not need to complete the visit.

Check to make sure that at least seven days have expired since the SV1 visit. (The laptop will do this automatically; if it is not being used, check the date of the SV1 visit from the participant’s study chart.) No upper limit exists for the SV2 window, except that run-in cannot begin more than 120 days past SV1.

If necessary, obtain informed consent for the visit.

Review/Complete Medical Eligibility Questionnaire

The participant may have completed the Medical Eligibility Questionnaire at SV1 or as part of the drug withdrawal process. If so, then it does not need to be completed again.

DASH Manual of Procedures

Check to see if it is in the participant's study chart and, if so, mark the "Done?" and "NA" boxes on the SV2 Flow Form.

If a completed Medical Eligibility Questionnaire is not in the participant's study chart, he should be bringing one with him to the SV2 visit along with all of his medication bottles, vitamin bottles, and any other supplements he is taking. The "office use only" section of the questionnaire should be in the chart.

Before proceeding with the remainder of the visit, a staff person should briefly review the questionnaire for obvious exclusions and, if any are found, apologize and excuse the subject. Question 9 in particular should be checked. If answered "yes", the participant will either be ineligible or must undergo drug withdrawal (see instructions accompanying the form for details). In either case the SV2 visit should not be conducted.

Clarification of items checked as "unsure" and a review of the medications can be deferred to later in the visit. Detailed instructions for reviewing the form and determining eligibility may be found in MOP chapter 22.

Once the questionnaire review is complete, check the "Done?" box on the SV2 Flow Form and record the appropriate eligibility status. If the form was completed previously, check the "NA" box.

If the participant fails to bring the form with him to the visit, have him complete a new form. It will be necessary to call the participant at home to review his medications. In this case, check "incomplete" under Eligibility Summary if the participant is otherwise eligible to continue to SV3. When the medication review is completed, enter the Medical Eligibility results and update the visit outcome status in the laptop.

Blood Pressure Assessment

Take the participant's blood pressure using the RZ device and the procedures described in MOP chapter 19 (Blood Pressure Assessment). **Be sure to use the same cuff size as was used in SV1.** If the average of the SV1 and SV2 systolic blood pressure measurements is less than 165 mm Hg and the average of the SV1 and SV2 diastolic blood pressure measurements is between 79 and 98 mm Hg (inclusive), the participant is eligible to continue to SV3.

Independent of the above blood pressure limits, participants may need to be excluded and referred to their physician for further evaluation based on the average of the two SV2 blood pressure measurements. If the average of the SV2 SBP measurements is >170 mm Hg or the average of the SV2 DBP measurements is >105 mm Hg, the participant is excluded from further participation and must be referred to a physician. These limits correspond to escape level 2 as specified in the DASH Protocol.

DASH Manual of Procedures

At this and all subsequent DASH visits, blood pressure information should be entered into the laptop computer during the visit unless system problems prevent it. A paper backup should also be kept. If the cuff size is found to differ from that used during SV1 and the participant has not left the clinic, a replacement blood pressure should be taken using the proper cuff. Otherwise, the original measurement will stand.

Measure Participant's Weight and Height and Check BMI

Record the participant's weight and height per the protocol outlined in MOP chapter 21. Enter this information into the laptop computer and note the eligibility status on the SV2 Flow Form. If the visit is not being done using a computer, refer to the SV2 Reference Chart (located in the back of this chapter) to determine if the participant is BMI eligible.

Collect Urine Sample For Dipstick Measures Of Protein And Glucose

Collect a urine sample from the participant, measure protein and glucose using the appropriate dipstick devices, and record the results on the SV2 Flow Form. The participant is ineligible if either the urine dipstick protein is greater than 1+ or the urine dipstick glucose is positive, although each site has the option of conducting a confirmatory test at a later time. Consult the Protocol (page 11, section 5) for further details.

If the results are not acceptable and the participant will not be retested, check the "ineligible" box under Eligibility Summary on the SV2 Flow Form. Otherwise the participant is considered eligible for purposes of the SV2 Flow Form.

Regardless of the participant's eligibility status, the results from these analyses should be entered into the laptop under "Laboratory Results". This is the only way to indicate to the computer the results of the urine tests. In addition, if the participant is to be excluded based on a single out of range value (i.e., participant will not be retested), complete the Participant Close Out screen on the laptop to indicate that the participant was dropped due to lab values.

Complete The Review Of The Medical Eligibility Questionnaire

Complete the review of the Medical Eligibility Questionnaire, clarifying all "unsure" responses or comments. Record results on SV2 Flow Form. If the participant is eligible to continue and either listed any medications or checked any boxes as "unsure", a DASH clinician must review and sign the form.

Collect Blood Samples For Local Exclusionary Labs

Draw the necessary blood samples for the local exclusionary labs. Follow the procedures outlined in MOP chapter 20 for collection and processing. Remind participant that you may recall him for additional blood draws if any questions arise on these tests. The

DASH Manual of Procedures

results of the blood work are entered into the laptop at a later date and may be repeated once if abnormal (see DASH Protocol, page 11, section 5, for further details).

Distribute And Instruct On The Food Frequency Questionnaire

Distribute the Food Frequency Questionnaire to the participant and review the instructions for filling it out. Inform the participant that she needs to bring the completed form back with her to the SV3 visit. Make sure that the participant's study ID is written on each page of the form.

Distribute Instructions And Urine Container For The 24-Hour Urine Sample

Distribute the 24-hour urine container and instructions to the participant and review the instructions with the participant. Inform the participant that she needs to bring the container back within 24 hours of collection, and that it must be returned at or before the SV3 visit. Make sure that a label is affixed to the collection jug and that it is filled out with the appropriate identifying information.

Instruct women to make the 24-hour urine collection when they are not menstruating.

SV2 Flow Form

After each portion of the visit is completed, a DASH staff person should check the appropriate "Done?" box on the SV2 Flow Form and (if applicable) indicate whether the participant is eligible or not eligible to continue based on that portion of the visit. At the end of the visit a staff person should review this form to make sure that the participant has completed all of the necessary components. This person should also make sure that a single outcome status is coded at the bottom of the form and should enter his ID in the "staff ID" field.

If a participant is excluded due to investigator discretion (i.e., not as part of the regular screening activities for this visit), check "ineligible" and in addition complete the Participant Close Out screen on the laptop to record the reason for the exclusion. This includes participants who are excluded due to high levels of urinary glucose and/or protein. In this latter case the results must be entered into the laptop both using the Laboratory Results screen and also using the Participant Close Out screen. A paper copy of the Participant Close Out form (form #24) can be used if the laptop is not available.

Ending SV2

To complete the SV2 visit, do the following:

- Inform the participant of eligibility status - You may inform the participant of eligibility status and terminate the visit at any point that it is clear that the

DASH Manual of Procedures

individual is not eligible for DASH. Explain the reasons for ineligibility to participant. Enter the visit outcome status into the laptop.

- If eligible, schedule an appointment for SV3 at least seven days from SV2 and note the scheduled date on the SV2 Flow Form.
- If an individual is ineligible to continue and has been withdrawn from antihypertensive medications for DASH screening, check with his physician as to whether to resume medication. If this physician is not available, use clinical judgment to determine whether to re-initiate therapy directly or to refer the participant back to his physician before re-starting medications.
- Enter the outcome status from the SV2 Flow Form into the computer.
- Prepare and ship lab samples according to MOP procedures.
- If participant elects to drop out of the study during the visit, staff should attempt to complete the Refusal Survey (form #77).

SV2 Reference Chart

Body Mass Index Exclusion Cutpoints

Locate participant's height on the table below and note the accompanying maximum weight. If participant's weight equals or exceeds this value, the participant is ineligible based on BMI.

Height (cm)	Maximum weight (Kg)	Height (cm)	Maximum weight (Kg)
139	67.6	176	108.4
140	68.6	177	109.7
141	69.6	178	110.9
142	70.6	179	112.1
143	71.6	180	113.4
144	72.6	181	114.7
145	73.6	182	115.9
146	74.6	183	117.2
147	75.6	184	118.5
148	76.7	185	119.8
149	77.7	186	121.1
150	78.8	187	122.4
151	79.8	188	123.7
152	80.9	189	125.0
153	81.9	190	126.4
154	83.0	191	127.7
155	84.1	192	129.0
156	85.2	193	130.4
157	86.3	194	131.7
158	87.4	195	133.1
159	88.5	196	134.5
160	89.6	197	135.8
161	90.7	198	137.2
162	91.9	199	138.6
163	93.0	200	140.0
164	94.1	201	141.4
165	95.3	202	142.8
166	96.4	203	144.2
167	97.6	204	145.7
168	98.8	205	147.1
169	100.0	206	148.5
170	101.2	207	150.0
171	102.3	208	151.4
172	103.5	209	152.9
173	104.8	210	154.4
174	106.0	211	155.8
175	107.2	212	157.3
		213	158.8
		214	160.3

BMI=weight/ht² (Kg/m²)---exclude if ≥ 35

9. Screening Visit 3 (SV3)

Purpose _____	3
Setting _____	3
Preparations for SV3 _____	3
Conducting SV3 _____	4
Confirm ID, check visit window, and obtain informed consent _____	4
Process 24-Hour Urine Sample _____	5
Blood Pressure Assessment _____	6
Weigh Participant And Record Results In Computer _____	6
Measure Subscapular And Tricep Skinfolts And Enter In Computer _____	6
Review Study Food Checklist and DASH Study Menus With Participant _____	6
Review Participant's Food Frequency Questionnaire _____	7
Collect Additional Laboratory Specimens If Needed _____	7
Administer Physical Activity Questionnaire (form #14) _____	8
Ending SV3 _____	8

Summary of Edits

New changes in Version 2.1

- modified BP section to remind staff to use same cuff size as was used at SV1

New changes in Version 4.0

- none

New changes in Version 4.1

- *Preparations for SV3* modified to include forms 13 and 74 as required and Form #77 as “may be needed”. Study menus new referenced as Form #40
- new paragraph added to end of *Process 24-hour Urine Sample* section to refer to required, local-use form (#74).
- last paragraph of *Blood Pressure Assessment* amended to note need for paper backup and also option to redo BP measurement if cuff size not the same as that used at SV1.
- *Ending SV3* amended to note need to complete Refusal Survey on dropouts.

DASH Manual of Procedures

Purpose

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 skinfolds. The visit is also used to review the food frequency questionnaire, collect and process a 24-hour urine specimen, collect additional blood samples as needed, and review in detail the study foods and menus with the participant.

Setting

The SV3 visit takes place at the clinical center. It requires a quiet, private setting where the participants can wait prior to the blood pressure measurement and can have their skinfolds measured. Questionnaires also need to be administered/reviewed in a setting that permits privacy for the participant.

Preparations for SV3

The following materials are needed to conduct the SV3.

- Random zero (RZ) sphygmomanometer and stethoscope
- Standard mercury sphygmomanometer
- Scale
- Skin fold calipers
- Consent materials (if required by local IRB, see chapter 3)
- SV3 Flow Form (form #12)
- Study Foods Checklist (form #06)
- SV3 Blood Pressure Form (form #13)
- DASH Initial/Repeat 24-hour Urine Forms (form #74)
- DASH Study Menus (form #40)
- Study charts for scheduled participants
- Laptop computer

The following forms may also be needed and should therefore be on hand.

- Local laboratory chemistry panel blood supplies
- Urine dipsticks and urine sample containers
- Participant instructions and materials for 24-hour urine collection
- Food Frequency Questionnaire (form #11)
- Refusal Survey (form #77)

DASH Manual of Procedures

Finally, in the event that the laptop computer will not be used for this visit, the following form is also needed.

- Physical Activity Questionnaire (form #14)

The number of forms and pieces of equipment is determined by local staffing configurations and the anticipated participant flow. If available, a spare laptop unit and sphygmomanometer should be available as backups.

Conducting SV3

In general, performing the SV3 activities in the order listed below should provide the most efficient identification of ineligible subjects. The visit may be politely concluded at any point after an exclusionary condition or situation has been identified.

- Confirm participant ID, check visit window, and obtain informed consent
- Process 24-hour urine sample
- Take participant's RZ blood pressure readings, note eligibility on SV3 Flow Form, and enter data into computer
- Weigh participant and record results in computer
- Measure subscapular and tricep skinfolds and enter in computer
- Review Study Food Checklist with participant to identify possible problems
- Review DASH Study Menus with participant to identify possible problems
- Review participant's Food Frequency Questionnaire
- Collect additional laboratory specimens if needed
- Administer Physical Activity Questionnaire

Confirm ID, check visit window, and obtain informed consent

Look up the participant in the electronic database and note the ID number on the SV3 Flow Form. Instruct participant to carry this form with her throughout the visit and to turn it in before leaving. Indicate that the form is used to assure that the participant has completed all components of the visit or else to indicate that she has been found to be ineligible and hence does not need to complete the visit.

Check to make sure that at least seven days have expired since the SV2 visit. (The laptop will do this automatically. If it is not being used, check the date of the SV2 visit from the participant's study chart.)

If necessary, obtain informed consent for the visit.

DASH Manual of Procedures

Process 24-Hour Urine Sample

The participant may have completed the 24-hour urine collection at any time between SV2 and SV3. Since the specimen should be returned within 24 hours of collection, the participant may or may not be bringing a specimen container with her to the SV3 visit. If she does not bring a container, check her study chart to confirm that she returned it previously and that it was an acceptable specimen.

Check to be sure that urine collections were not obtained during menstruation. If they were, reschedule them.

The instructions below for processing the specimen should be followed no matter when the specimen is returned. More complete details on the processing of 24-hour urine specimens are contained in MOP chapter 20.

Take the 24-hour urine container from the participant, check to make sure that the labels on the tag attached to the jug are filled out correctly and completely, and verify that the ID listed on the label matches that of the participant. Also confirm that the participant voided her bladder at the start of collection and did not save the specimen, collected a final voiding at the end of the collection period, and returned the specimen within 24 hours of the final voiding.

The specimen is considered to be inadequate if any of the following are true.

- The total duration of the collection is less than 22 hours or greater than 26 hours
- The collection period did not start with an initial, discarded voiding
- More than one voiding (including the final voiding) was missed
- The total volume collected is less than 500 cc
- The collection was made during menstruation

If the specimen is inadequate, or if the participant failed to bring it in, another (acceptable) specimen must be obtained prior to the start of run-in. Give the participant a new set of collection materials, attach and fill out the labels correctly, and write in “missing” next to “24-hour urine collection” on the SV3 Flow Form. If the participant is otherwise eligible to continue at the end of the visit, code “incomplete” under Eligibility Summary on the SV3 Flow Form and update the visit status after the new specimen is returned.

Save an aliquot from the original sample as a backup in case the participant is not able to provide an adequate sample. In this latter case, analyze the aliquot from the original, inadequate sample and note on the shipping label that the sample was inadequate and why.

DASH Manual of Procedures

Assuming that the participant does bring in a specimen, either immediately take it to the clinic's lab area for processing or place it in a refrigerator until it can be processed. Avoid leaving the specimen at room temperature for any longer than is necessary. Check "Done?" on the SV3 Flow Form. The DASH Initial and Repeat 24-hour Urine Forms (form #74) are required local-use-only forms to help clinic staff properly process 24-hour urine specimens.

Blood Pressure Assessment

Take the participant's blood pressure using the RZ device and the procedures described in MOP chapter 19 (Blood Pressure Assessment). **Be sure to use the same cuff size as was used at SV1.** If the average of the SV1, SV2, and SV3 systolic blood pressure measurements is less than 160 mm Hg and the average of the SV1, SV2, and SV3 diastolic blood pressure measurements is between 80 and 95 mm Hg (inclusive), the participant is (blood pressure) eligible to continue to Run-In.

Independent of the above blood pressure limits, participants may need to be excluded and referred to their physician for further evaluation based on the average of the two SV3 blood pressure measurements. If the average of the SV3 SBP measurements is >170 mm Hg or the average of the SV3 DBP measurements is > 105 mm Hg, the participant is excluded from further participation and must be referred to a physician. These limits correspond to escape level 2 as specified in the DASH Protocol.

At this and all subsequent DASH visits, blood pressure information should be entered into the laptop computer during the visit unless system problems prevent it. A paper backup should also be kept. If the participant cuff size is found to differ from that used during used during SV1 and the participant has not left the clinic, a replacement blood pressure should be taken using the proper cuff. Otherwise the original measurement will stand.

Weigh Participant And Record Results In Computer

Record the participant's weight per the protocol outlined in MOP chapter 21. Enter this information into the laptop computer and check the "Done?" box on the SV3 Flow Form. This weight is not used for eligibility, but instead is used to help determine the participant's target weight for feeding.

Measure Subscapular And Tricep Skinfoldds And Enter In Computer

Measure the participant's subscapular and tricep skinfoldds using the procedures outlined in MOP chapter 21. Record the results directly into the laptop. If the measurements are not within predetermined tolerance limits the laptop will instruct you to repeat them. Check the "Done?" box on the SV3 Flow Form.

Review Study Food Checklist and DASH Study Menus With Participant

DASH Manual of Procedures

The SV1 visit included a brief review of common food items in the DASH diets to make sure the participant could eat them. During the SV3 visit 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 the three intervention groups. The purpose of this review is to make sure that the participant is fully aware of the foods/menus that he may be fed and is willing to eat these foods. It is important that the participant be willing to comply with all three 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.

This review, along with a review of the Food Frequency Questionnaire (see below), should take approximately 20 minutes. At the end of the review the DASH staff person reviewing the foods should classify the participant as eligible or ineligible to continue based on the review. This should then be noted both on the SV3 Flow Form and also in the laptop.

Review Participant's Food Frequency Questionnaire

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 Flow Form. The FFQ will be sent to the coordinating center for batch entry and will become part of the central database.

If the participant did not return a completed FFQ, give her a new one, reinstruct her on its use, and ask that she bring it in with her at the start of run-in feeding. Write "not returned" on the SV3 Flow Form and, if the participant is otherwise eligible to continue on to run-in, check the "Incomplete" box under Eligibility Summary on the SV3 Flow Form. A participant will not be allowed to start run-in unless a completed FFQ has been returned.

Collect Additional Laboratory Specimens If Needed

For participants whose SV2 exclusionary labs came back as ineligible, clinics have the option of repeating the analyses once. (For cholesterol and glucose/insulin the protocol for repeat analyses is somewhat more complex. Refer to the DASH Protocol, section 5, page 11 for details).

If the participant needs additional blood drawn, this can be done at this point. Note that some of the repeat tests require a fasting sample. In this case the participant should have been instructed ahead of time to fast prior to the visit, and this should be confirmed at the time of the visit. Check the "Done?" box on the SV3 Flow Form to indicate that the laboratory review was conducted and, if needed, a new sample was drawn.

DASH Manual of Procedures

Similarly the urine dipstick protein may be repeated at this visit. The participant is ineligible if the urine dipstick protein is greater than 1+. Record the result on the SV3 Flow Form and check the appropriate box to indicate if he is eligible or ineligible. Regardless of the participant's eligibility status, the results should be entered into the laptop under "Lab Follow-up". This is the only way to indicate to the computer the results of the urine tests.

If the participant is excluded based on laboratory results, complete the Participant Close Out screen on the laptop to indicate that the participant was dropped due to lab values. This needs to be completed even though the data is also entered into the Lab Follow-up screen.

Note that "incomplete" should not be checked under Eligibility Status on the SV3 Flow Form just because a participant has pending laboratory results. If this is the case and the participant is otherwise eligible to continue to run-in, check the "run-in eligible" box on the SV3 Flow Form.

Administer Physical Activity Questionnaire (form #14)

Complete the Physical Activity Questionnaire and record the results directly into the laptop. The computer will compute an initial caloric level to be used to start the run-in feeding. This value will be printed out as part of the participant history sheet after the data from the laptops are uploaded to the file server at the end of the day. Check the "Done?" box on the SV3 Flow Form.

Ending SV3

To complete the SV3 visit, do the following:

- Inform the participant of eligibility status - You may inform the participant of eligibility status and terminate the visit at any point that it is clear that the individual is not eligible for DASH. Explain the reasons for ineligibility to participant. Enter the visit outcome status into the laptop
- If the participant is eligible for run-in, remind her of the start date and provide other instructions as appropriate so that she is ready to begin. Remind participant, if needed, that final eligibility for run-in will depend on results of pending laboratory tests and the completion of pending questionnaires
- If an individual is ineligible to continue and has been withdrawn from antihypertensive medications for DASH screening, check with his physician as to whether to resume medication. If this physician is not available, use clinical judgment to determine whether to re-initiate therapy directly or to refer the participant back to his physician before re-starting medications
- If the participant was excluded due to escape level blood pressure criteria, refer him to his physician

DASH Manual of Procedures

- Enter the outcome status from the SV3 Flow Form into the computer.
- Send Food Frequency Questionnaire to the coordinating center
- Prepare and ship lab samples according to MOP procedures
- If participant elects to dropout of the study during the visit, staff should attempt to complete the Refusal Survey.

10. Participant Orientation to Study

Purpose Of Orientation	3
When To Orient Participants	3
Who Conducts Orientation	3
Format For Orientation	3
Procedures Covered In Orientation	4
Where, when, and how often to come for meals	4
Specific procedures occurring at visits	4
Guidelines for consumption of diet, including:	4
Working with holidays/social events	5
Storage of study foods/temperature strips	5
Completeness of menu checks	5
Use of daily diary	5
Review of the 'two meal passes per cohort' policy	6
Weight maintenance/calorie adjustments	6
Unit foods	6
Communication with staff	6
Materials Needed For Orientation	7
Written materials given to participants	7
Audiovisual material	7

Summary of Edits

New Changes in Version 2.1

- misc technical edits
- under *Procedures Covered in Orientation*, the following changes were made. Section 3d (iii) rewritten; section 5 sentence reading “They are provided with the Safe Food to Go pamphlet” has been deleted; final sentence of section F has been revised
- The section under *Written materials given to participants* has been redrafted.

New changes in Version 2.2

- Under *When to Orient Participants* deleted last sentence
- misc sentences added to entire chapter

New changes in Version 2.3

- Formatting
- Misc text changes in chapter including changes on forms #20 and #23 as referenced.

New changes in Version 4.0

- none

DASH Manual of Operations

Purpose Of Orientation

There are two major reasons for formally orienting participants to the DASH protocol:

- 1) To minimize dropouts from the study after randomization by making the expectations clear prior to entry into the study, and
- 2) 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.

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, and 2) participants may be pressed for time if it is combined with SV3.

Who Conducts Orientation

A dietitian or nutrition/foodservice representative should conduct the orientation since the orientation is focused primarily on dietary issues. Other DASH representatives (e.g., MD, RN, recruiter, coordinator) should be present to reinforce the team setting. It is recommended that a principal or co-investigator open the orientation with a greeting to participants, reinforcement of importance of the study, and an introduction of the study staff. The coordinator may wish to spend five minutes at the end to review blood pressure visits and any ancillary visits.

Format For Orientation

Orientation should begin with an introduction of study staff and other participants, and viewing of the DASH video. It is suggested that each center serve a meal from the ideal menu during the orientation visit. This way each participant can try the most potentially problematic menu prior to randomization and will be able to learn hands-on how to finish their food completely. The precise format for orientation may vary by site, but a suggested format follows:

Investigator introduction	5 minutes
View DASH video	10 minutes
Serve sample meal, review guidelines	30 minutes
Provide written material	5 minutes
Coordinator comments	5 minutes
Question and answer period	5 minutes

DASH Manual of Operations

Procedures Covered In Orientation

Where, when, and how often to come for meals

This varies according to study site, but the minimum allowable number of visits is one meal per day, five days per week. Study sites can be flexible regarding which meal subjects come in for, depending on their schedules. Lunch and dinner are the preferred meals. Times to arrive for each meal are outlined.

Specific procedures occurring at visits

Weight is measured each time the subject comes in for a meal, prior to eating the meal. Blood pressure is measured prior to eating the meal once per week. For full description of weight and blood pressure measurement procedures, see Chapters 19 and 21.

Guidelines for consumption of diet, including:

Finishing all foods. Subjects are expected to eat the edible portions of all foods provided, both on-site and off-site. They should consume potato peel and skins of vegetables and other fruits (e.g. apple). When participants are unsure of what is “edible,” they should call the center for direction (review no apple cores/seeds, orange skin, gristle from meat). They should clean up leftover gravies and sauces with a piece of bread, rice, potato, or rubber spatula to make sure that they consume everything. Salad dressings, butter pats, and other small packaged items should be emptied completely. When transferring items from our containers to a plate, they should use a rubber spatula to insure that everything is transferred.

No additional foods. Aside from “allowed beverages” (see below), subjects should not consume any other foods or fluids other than what we provide. Participants are encouraged to speak with the dietitian prior to an event (e.g., wedding) or party for advice on how to avoid temptations to consume other foods. Participants are encouraged to bring their own food to social events.

Substitutions. There should be no substitutions made for any foods unless directed by a staff member.

Allowed beverages (including alcohol). Show a display on a table of samples of the following three categories of allowed beverages:

- 1) Subjects are allowed to consume a total of three servings, in any combination, of (8 oz) coffee and/or (8 oz) tea and/or (12 oz) diet soda each day. Any brand of coffee or tea is allowed, but the coffee and tea may only contain artificial sweeteners and milk already contained in the diet. Diet soda must be chosen from the list provided.
- 2) Up to two servings of alcohol is allowed per day. A serving is considered a 12 oz beer, 6 oz glass of white wine, or 1 oz spirits. If hard liquor is to be consumed, it should be added to beverages that are already in their diet (e.g. juices). For example,

DASH Manual of Operations

they cannot have an orange juice and vodka drink unless the orange juice is on their menu.

- 3) Participants may consume an unlimited amount of water each day, and Poland Springs carbonated water with *essence* of fruit flavoring (not fruit juice).

Miscellaneous items. Brands and use of chewing gum, over the counter medications, and “free” spices are reviewed, with the items displayed on a counter.

Working with holidays/social events

Participants should eat a DASH meal *before* going to a social event, so that they are not hungry. Participants can bring some “fun foods” from their menus (e.g. fruit, nuts, crackers, cookies, or chips) to a party to consume so they have something to eat while others are eating. The same holds for dinner parties or lunch outings. They may want to take home special foods served at a party and save them in their freezer for consumption after the study. Participants are encouraged to let friends/family know of the purpose and importance of the study to get their support so others do not encourage non-compliance. During social events, subjects may also consume allowed beverages (as above).

Storage of study foods/temperature strips

Review the food safety/storage section of the MOP prior to orientation. Subjects should be carefully instructed on proper food handling and storage techniques for foods they take home. They should refrigerate their meals as soon as possible to avoid food spoilage. Special temperature strips are placed in each “take home” bag (show these to participants). If the middle dot turns black, it may mean the food is spoiled and they should contact the center immediately.

Completeness of menu checks

Subjects are provided with written menus of their meal plan. Exactly how this is done will vary by center, but show participants what the menu forms look like. They are to use these menus to cross-check with foods given to assure that they are not missing any “take home” foods. It may be suggested that they keep this menu with the telephone number of the center on their refrigerator.

Use of daily diary

The daily diary may be reviewed with use of an overhead projector. Dairies need to be filled out daily and should reflect what has happened during the previous day. On weekends, subjects are provided with two extra diaries to bring in on Mondays. Each item on the diary should be reviewed, including recording all allowed beverages and recording foods not eaten, with the reason, and additional foods eaten, with the reason. It should be stated that “it is very important for the study that you eat all of the food provided and nothing else. If something happens to your food, or you accidentally or otherwise consume something you are not supposed to eat or drink, it

DASH Manual of Operations

is important that you tell us and record it on your form in as much detail as possible.” The diary also provides a way for participants to communicate with staff regarding concerns relating to scheduling difficulties, medical problems, gastrointestinal symptoms, or any questions. The diaries should be reviewed daily by the staff to provide immediate feedback to the subjects. Review with participants the exact procedure for filling out daily diaries (e.g., as soon as they arrive).

Review of the ‘two meal passes per cohort’ policy

It is recommended that it be discussed during orientation only if someone asks what will happen if they have trouble coming in for meals. Sick day or late day rules: If subjects are sick, or foresee being late, they should alert the center immediately so that the staff can work out a meal shipment or replacement plan with the subject.

Weight maintenance/calorie adjustments

Subject should be told (numerous times) that this is not a weight loss study. We carefully monitor weight and if it changes by a certain amount we will increase or decrease calories. Participants should also be told that if they feel hungry or feel they have too much food, calories can be adjusted. However, we will continue to monitor weight to assure that it doesn’t change after these adjustments.

Unit foods

A display of the various unit foods is shown, and subjects are informed of the uses for unit foods (e.g., to increase calories, and for situations which may require more food, such as heavy exercise). Tell participants when unit foods are optional and when they are not. For example, if we have prescribed a certain number of unit foods to maintain weight, participants must consume them. We will provide participants with extra unit foods for those times when they are hungry, exercise more, etc. It is for these occasions only that the unit foods are optional.

Communication with staff

Subjects are asked to communicate with staff regarding issues concerning satisfaction or dissatisfaction with research diet, and social or medical concerns. Make sure they know who their primary contact is.

DASH Manual of Operations

Materials Needed For Orientation

Written materials given to participants

- “Orientation Form” with instructions for participants (form #23)
- “Guidelines For Beverages and Seasonings” (form #20)
- “Safe Foods TO GO” (form #69)

Audiovisual material

The DASH 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 guidelines on a continual basis.

11. Run-In and Randomization

Overview	4
Preparations for Run-In	5
Blood Pressure	5
Ambulatory Blood Pressure Monitoring	5
Blood Draw	5
24-Hour Urine Collection	5
DASH Initial and Repeat 24-hour Urine Forms (form #74)	5
Daily Feeding And Weight/Compliance Assessment	5
Side Effects/Medication Monitoring	6
Personal History Assessment	6
Summary of Run-In Activities	6
Obtain Informed Consent If Needed	9
Measure Weight At Each Clinic Visit	9
Collect Remaining Baseline Blood Pressure Measurements	9
Collect ABPM Data	10
Complete Patient History Questionnaire	10
Complete Side Effects Form	10
Complete Run-In Medication Questionnaire	11
Collect a 24-Hour Urine Sample During Week 3	11
Collect A Fasting Blood Sample And Perform Glucose Tolerance Test	12
DEXA Measurements	13
Prepare And Distribute Daily Meals	13
Review Daily Food Diaries To Assess Compliance	13
Conduct Overall Compliance Assessment Prior To Randomization	13
Randomize Participant	13
Transmission of Data	14

DASH Manual of Procedures

Summary of Edits

New changes in Version 2.0

- This chapter has been substantially revised. Please read entire chapter.

New changes in Version 2.2

- misc technical edits
- first sentence of *Overview* now explicitly equates the terms “reference diet,” “red diet,” and “diet #1.”
- under *Preparations for Run-In*, added section for *Side Effects/Medication Monitoring*
- Under *Summary of Run-In Activities*, a new para has been added after the bulleted list. This para lists a preferred order in which run-in activities should occur.
- table 11.1 has been revised for greater clarity and first 24-hour urine has been dropped
- section under *Measure Weight at Each Clinic Visit* amended so that **target weight** applies only to run-in
- first para under *Complete Patient History Questionnaire* amended to state that this form “can” be completed at home
- under *Collect a 24-Hour Urine Sample*, instructions for dealing with inadequate specimens have been expanded and the first of what had been two run-in urines has been dropped.
- The two sections on randomization have been combined into one and the text cleaned up.
- under *Collect Remaining Blood Pressure Measurements*, we added a note reminding staff that BP cuff size should always match that used at SV1.

New changes in Version 4.0

- none

New changes in Version 4.1

- In first sentence of *overview*, “reference” diet changed to “control” diet and “ diet#1 struck from inside parentheses.
- In second paragraph of *overview*, references to “four” feeding waves changed to “five”.
- Section on *Preparations for Run-In* amended to add subsection on *ABPM* and to include references to form #74 under *24-hour Urine Collection*.
- Under *Summary of Run-In Activities*, paragraph added at end regarding Refusal Survey.
- Table 11.1 modified to drop reference to first 24-hour urine.
- Definition of “target weight” revised to match current practice (page 9).

DASH Manual of Procedures

- Under first paragraph of blood pressure section, note added about replacing BPs when cuff sizes disagree. Last paragraph of this section edited to require hardcopy of BP
- Second paragraph of *Collect ABPM Data* expanded.
- Paragraph added to end of 24-hour urine section to refer to Form #74.
- Under *Randomize Participant*, paragraph 2 amended to refer to section 14 “of the Protocol”. Paragraph 4 amended to reflect new procedures (even though never formally adopted by SC).
- New section on *Transmission of Data* added at the end.

DASH Manual of Procedures

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 red diet) prior to randomization. The run-in phase has three main objectives: 1) to identify and exclude individuals who will not comply with the trial's eating and measurement requirements; 2) to determine, for each participant, the appropriate energy level needed to maintain weight; and 3) and to provide a common diet for participants against which to measure the impact of the intervention diets. The World Health Organization's equations, which are based on age, gender, and weight, are used to estimate resting energy expenditure. The energy expended during active periods is calculated using information derived from the Physical Activity Questionnaire. Total energy requirement will be estimated by multiplying the resting energy expenditure by a factor indicating overall physical activity level based on the Physical Activity Questionnaire.

Run-in feeding must begin within 120 days of SV1, and all laboratory eligibility criteria must be met prior to 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. For logistical reasons the clinics will conduct the feeding in five-to-six successive waves over a period of two years. In order to allow for dropouts and exclusions during the run-in phase, the run-in cohorts will vary in size from an average of 24 per site (six feeding waves) to an average of 29 per site (five feeding waves).

Run-in feedings are scheduled to start on the same day for all participants in a given feeding wave in a given clinic. However, participants may be allowed to start run-in feeding up to two days late if the clinic determines this 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 finish run-in feeding on the same day.

The run-in period lasts exactly 21 days. To provide consistent terminology, we shall refer to these as *days 1 through 21 of run-in feeding*. Thus a participant who starts run-in feeding two days late is said to start on day 3 of run-in feeding. This will provide a convenient and unambiguous framework for describing the activities that occur during this time.

In order for the clinics to assemble and prepare the necessary foods for the start of intervention feeding, randomization occurs during the beginning of the third week of run-in feeding (between days 15-17) rather than at the end of the run-in period. Participants will remain on the run-in diet until intervention feeding begins. Neither participants nor staff conducting measurements will be told of the randomization assignment.

DASH Manual of Procedures

Preparations for Run-In

Run-in consists of a series of visits, the preparations for which vary from day-to-day. Certain aspects, such as those related to the preparation and distribution of food, are nearly identical from day-to-day. Other activities, such as blood draws and blood pressure assessment, happen much less frequently. Table 11.1 lists the various activities that take place during run-in.

In this section we summarize the various activities and note the materials needed for each. Subsequent sections describe each of these activities in greater detail. Food preparation, feeding, and compliance assessment are comprehensively discussed elsewhere in the MOP as noted below.

Blood Pressure

- Random zero (RZ) sphygmomanometer and stethoscope
- Standard mercury sphygmomanometer
- Generic Blood Pressure Form (form #26)

Ambulatory Blood Pressure Monitoring

- ABPM devices
- ABPM Placement Form (form #64)
- Instructions to Participants Form (form #65)
- ABPM Participant Questionnaire (form #66)

Blood Draw

- Central laboratory supplies (see chapter 20)

24-Hour Urine Collection

- Participant instructions and materials for 24-hour urine collection (see chapter 20)
- DASH Initial and Repeat 24-hour Urine Forms (form #74)
- ABPM Initialization/Downloading checklist (form #68)

Daily Feeding And Weight/Compliance Assessment

- Scale
- Daily diary (form #22)
- Run-in compliance assessment form (form #18a)
- Run-in energy adjustment form (form #17a)
- Free choice beverage and seasonings form (form #20)
- Orientation form (form #23)

DASH Manual of Procedures

- Run-in Flow Form (form #53)
- Food Donation Tracking (Direct Shipment) (form #16a)
- Food Donation Tracking (Donated items) (form #16b)
- Food Inventory Control Form (form #19)
- Study Menus (form #40)
- Food Production Form (form #41)
- Tray Assembly Form (form #51)

Side Effects/Medication Monitoring

- Side Effects Form (form #60)
- Run-In Medication Questionnaire (form #61a)

Personal History Assessment

- Patient History Questionnaire (form #10)

In addition, the following materials should be available for each daily visit.

- Study charts for scheduled participants
- Laptop computer

Summary of Run-In Activities

The following activities all occur during run-in.

- Obtain informed consent if needed
- Measure weight at each clinic visit
- Collect remaining baseline blood pressure measurements
- Collect ABPM data
- Complete Patient History Questionnaire
- Complete Side Effects Form
- Complete Run-In Medication Questionnaire
- Collect a single 24-hour urine sample during week 3
- Collect a fasting blood sample
- Glucose tolerance test (Pennington and Brigham & Women's only)
- DEXA scans (Pennington and Duke only)
- Prepare and distribute daily meals
- Review daily food diaries to assess compliance
- Conduct overall compliance assessment prior to randomization
- Randomize participant

Blood pressure measurements, if collected, should be done first, followed by weight, compliance assessment, and then eating. Collection of the fasting blood sample and the

DASH Manual of Procedures

glucose tolerance test must also be done prior to eating. The timing of other one-time activities (i.e., before or after eating) is left to clinic discretion. However, the blood pressure and weight measurements should always be done first.

If a participant elects to drop out of the study during run-in, staff should attempt to complete the Refusal Survey (form #77).

Table 11.1
DASH Activity Sequence: Run-in Feeding Period
----- Day of Run-in -----
located in q:\mop\activity.doc

DASH Manual of Procedures

Obtain Informed Consent If Needed

If necessary, obtain informed consent for the run-in phase prior to the start of run-in feeding. Presumably this will have been done prior to the first day of run-in feeding, but if not, then it must be done at this time.

Measure Weight At Each Clinic Visit

All participants are weighed at each clinic visit during the run-in and intervention phases of the trial. Use the procedures outlined in MOP chapter 21, and enter the information into the laptop computer.

The average of the SV3 weight measurement and the first three days of run-in weight 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 chapter 18 (Participant Management and Compliance), weight is not supposed to change during the study. These daily weight measurements monitor weight changes for adjusting the overall caloric content of the participant's meals as needed in order to assure that the participant's weight remains stable throughout the study.

Collect Remaining Baseline Blood Pressure Measurements

As part of each participant's baseline blood pressure measurements, the Protocol requires that four sets of blood pressure measurements be taken during the final 13 days of run-in feeding (i.e., days 9-21 of run-in feeding). No other blood pressure measurements are taken during run-in. Clinic staff should measure blood pressure using an RZ device and follow the procedures described in MOP chapter 19 (Blood Pressure Assessment). **Be sure to use the same cuff size as was used at SV1.** If the cuff size is found to differ from that used at SV1 and the participant has not left the clinic, a replacement blood pressure should be taken using the proper cuff; otherwise, the original measurement will stand.

Of necessity, some of the four sets of run-in blood pressure measurements will occur after randomization. In order to minimize the potential for subjective biases in the measurement, the clinic staff who measure blood pressures must be blinded to intervention assignment.

Other than escape level exclusions, these blood pressure measurements are not used to determine eligibility; they are only used to help calculate baseline blood pressure. The Protocol defines two escape levels. Escape level 1 is defined as a single day's average SBP measurement in excess of 180 mmHg or a single day's average DBP in excess of 110 mmHg. Escape level 2 is defined as two successive SBP measurements in excess of 170 mmHg or two successive DBP measurements in excess of 105 mmHg. The second set of measurements must be made within seven days of the first measurement.

DASH Manual of Procedures

If a participant reaches either escape level prior to randomization, the participant is excluded from further participation in the trial and referred to a physician. If a participant reaches either escape level after randomization he is not excluded from the trial, but must still be referred to a physician for counseling. If the physician starts the participant on blood pressure medication, the participant is excluded from further participation at the time the medications are started. Consult chapter 27, Safety Monitoring, for further details.

The run-in blood pressure measurements can be entered into the laptop at the time of the visit or batch entered after the fact. In either case, the generic blood pressure form (form #26) must be used to provide a hardcopy record of each day's BP measurements.

Collect ABPM Data

All participants except those in the first feeding cohort complete a 24-hour period of ambulatory blood pressure monitoring. This monitoring must be done sometime during days 9-21 of run-in feeding.

Instructions for performing the measurement and downloading the data are given in Chapter 29. The Coordinating Center will retrieve the blood pressure data from off of the file server. Completed ABPM questionnaires should be photocopied and the originals sent to the Coordinating Center for data entry.

Complete Patient History Questionnaire

Sometime prior to randomization, run-in participants complete the Patient History Questionnaire (form #10). This is a self-administered questionnaire that can be completed at home. Clinic staff should review returned questionnaires for completeness and should resolve any unanswered or vague responses.

Participants cannot be randomized until after the Patient History Questionnaire has been satisfactorily completed. After randomization is complete, the clinic should photocopy the questionnaires and send the originals to the CC for data entry in accordance with procedures outlined Chapter 23, section on "Centrally entered data." The copies should be retained at the clinical center in a locked storage area until the study is completed.

Complete Side Effects Form

All participants complete the Side Effects Form (form #60) during week 3 of run-in. The questionnaire, which is repeated during intervention weeks 4 and 8, is primarily designed to document gastrointestinal symptoms associated with the diets. It also captures information on symptoms that may be related to high blood pressure.

DASH Manual of Procedures

The questionnaire should be completed by the participants and reviewed by clinic staff for completeness. Any positive responses must be reviewed by a study clinician, who determines if further follow-up is needed.

Completed questionnaire should also be photocopied and the original sent to the Coordinating Center for data entry.

Complete Run-In Medication Questionnaire

All participants complete a medication questionnaire (form #61a) during week 3 of run-in. The questionnaire, which is repeated during intervention weeks 4 and 8 (form #61b), is designed to identify those individuals who start taking medications during the course of the study.

The questionnaire should be administered in an interview format, and all positive responses must be reviewed by a staff clinician. Individuals taking exclusionary medications must either stop taking these medications or be excluded from further participation in the study.

Responses to the questionnaire should be entered in the laptop computers.

Collect a 24-Hour Urine Sample During Week 3

A 24-hour urine specimen needs to be collected during run-in week 3 (any time during days 15-21 of run-in feeding). A sample from this specimen is sent to the central laboratory for processing for subsequent group analyses.

Urine collections should not be made during menstruation. Advance or delay the collection period in order to avoid menstrual period collection times.

Distribute the 24-hour urine container and instructions to the participant and review the instructions with the participant. Make sure that a label is affixed to the collection jug and that it is filled out with the appropriate identifying information. If the specimen is to be returned the next day, have the participant start the collection before leaving the clinic (i.e., void the bladder into the toilet). If the collection is to be done over a weekend, inform the participant to bring the container back within 24 hours of collection.

The instructions below for processing the specimen should be followed no matter when the specimen is returned. More complete details on the processing of 24-hour urine specimens are contained in MOP chapter 20.

Take the 24-hour urine container from the participant, check to make sure that the labels on the tag attached to the jug are filled out correctly and completely, and verify that the ID listed on the label matches that of the participant. Also confirm that the participant

DASH Manual of Procedures

voided her bladder at the start of collection and did not save the specimen, collected a final voiding at the end of the collection period, and returned the specimen within 24 hours of the final voiding.

The specimen is considered to be inadequate if any of the following are true.

- The total duration of the collection is less than 22 hours or greater than 26 hours
- The collection period did not start with an initial, discarded voiding
- More than one voiding (including the final voiding) was missed
- The total volume of the sample is less than 500cc
- The urine is collected during menstruation

If the specimen is inadequate, or if the participant failed to bring it in, another (acceptable) specimen must be obtained. Give the participant a new set of collection materials, attach and fill out the labels correctly, and note on the label that the initial sample was missing or inadequate. Save an aliquot from the original sample as a backup in case the participant is not able to provide an adequate sample. If the participant does not bring a repeat specimen, or if the repeat specimen is also inadequate, analyze the aliquot from the original (inadequate) sample in its stead, and note on the shipping label that the sample was inadequate and why.

Assuming that the participant does bring in a specimen, either immediately take it to the clinic's lab area for processing or place it in a refrigerator until it can be processed. Avoid leaving the specimen at room temperature for any longer than is necessary. The DASH Initial and Repeat 24-hour Urine Forms (form #74) are required local-use-only forms to help clinic staff properly process 24-hour urine specimens.

Collect A Fasting Blood Sample And Perform Glucose Tolerance Test

During week three of run-in (days 14-21), subjects must provide a fasting blood sample. To be valid, the participant must have been fasting for a period of twelve hours (minimum of 10 required) and must have been in an upright position (defined as sitting or standing) for at least 1½ hours prior to the blood draw. This latter time limit is a target only; no minimum time has been set. However, this will affect the renin levels, so please try to meet the time requirement. Details on drawing and processing this specimen are given in chapter 20 (Laboratory Measures).

At the time of this fasting blood draw, a subset of participants (those at Boston and those at Baton Rouge) also completes a two-hour oral glucose tolerance test. The protocol for this test, and instructions for processing the specimens, is provided in chapter 20.

DASH Manual of Procedures

DEXA Measurements

Dual Energy X-Ray Absorptiometry (DEXA) measurements for body composition are conducted at the Pennington and Duke sites during run-in. Consult chapter 21 for details on the protocol for this measurement.

Prepare And Distribute Daily Meals

Kitchen staff must prepare and distribute food for participants on an ongoing basis throughout run-in. Details of feeding activities given in chapters 13-17.

Review Daily Food Diaries To Assess Compliance

Kitchen staff must assess compliance with the study's eating requirements on an ongoing basis. Details on compliance monitoring are given in chapter 18.

Conduct Overall Compliance Assessment Prior To Randomization

In addition to the exclusionary criteria applied during the screening visits, participants may be excluded during the first two weeks of the run-in for unusually large weight swings or for noncompliance with the protocol. All participants whose weight changes by five percent or more between SV3 and the first day of run-in are excluded from the trial at that point. Participants may also be excluded prior to randomization for missed meals, poor clinic attendance, and over- or-under consumption of food. Finally, clinics 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. A more detailed discussion of compliance assessment is provided in chapter 18 (Participant Management and Compliance).

Participants who exhibit noncompliant behavior during the final week of run-in feeding, but after randomization, are retained in the study and maximum effort to help the participant achieve compliance will be made.

Randomize Participant

Randomization occurs during the beginning of the third week of run-in feeding (some time during days 15-17 of run-in feeding). Following randomization, participants remain on the run-in diet until intervention feeding begins. Randomization is stratified by clinic and, within each clinic, structured to assure comparable treatment group sizes over time.

Participants are not told to which group they have been assigned and, except for staff involved in meal preparation, clinic personnel are also blinded to intervention

DASH Manual of Procedures

assignment. Blinding is discussed further in section 14 of the Protocol (Quality Control and Data Management).

The timing of events to complete randomization within the three day window demands tight coordination between the Coordinating Center and the intervention sites.

Day 14: All data through run-in day 13 need to be entered in the laptops by the end of run-in day 14. These data include the run-in log data from days 1-13, the results of the case-conference, and participant exclusion data (if applicable).

Day 15: The coordinating center accesses these data and creates site-specific eligibility reports for each run-in participant. If a participant appears to be ineligible for randomization, the reason(s) will be listed on this report. The clinic coordinators need to immediately review these reports to confirm that the information matches their records. After reviewing the report, the clinic coordinator needs to call Pierre at the coordinating center to confirm that the data are correct or to report discrepancies. The coordinating center will correct any discrepancies and then randomize all eligible participants.

Day 16: The coordinating center places on each site's file server an EXCEL file containing randomization status data for each run-in participant. This file will be password protected and readable only by an individual (designated by the PI), who does not collect any clinical measurements, other than weight, on study participants. This person will presumably be part of the kitchen staff. This file should be printed out and shared only with kitchen staff who need to be unblinded to treatment status.

Transmission of Data

Urine specimens, blood specimens, and questionnaire data are only analyzed for randomized participants. These items should be shipped to the central labs or Coordinating Center, as appropriate, within four weeks of the end of run-in feeding.

12. Intervention

Overview	4
Preparations for Intervention	4
Blood Pressure	5
Ambulatory Blood Pressure Monitoring	5
Blood Draw	5
24 Hour Urine Collection	5
Daily Feeding And Weight/Compliance Assessment	5
End of Study Physical Activity Assessment	5
Side Effects/Medication Monitoring	6
End-of Study Participation Survey	6
Summary of Intervention Activities	7
Measure Weight At Each Clinic Visit	7
Collect Remaining Baseline Blood Pressure Measurements	7
Collect A 24-Hour Urine Sample At End-of-Study	8
Complete Side Effects Form	10
Complete Intervention Medication Questionnaire	10
Complete Participation Survey	10
Collect Fasting Blood Sample	10
Assess Physical Activity Level	10
Collect ABPM Data	11
Transmission of Data	11
Early Termination of Feeding	11
Exit Interview and Counseling	11

Summary of Edits

New changes in Version 2.0

- page 4 and under blood draw, deleted name of form and under 24-hour urine collections deleted name of form and inserted Daily Feeding and Weight/Compliance Assessment
- This chapter has been substantially revised. Please read entire chapter.

New changes in Version 2.2

- second para under *Overview* is new
- table 12.1 included in this version, reference to 1st urine dropped
- misc. technical edits
- under *Summary of Intervention Activities*, new para added after bulleted section. This gives a preferred order in which activities should be done.
- under *Measure Weight at Each Clinic Visit*, “baseline weight,” defined as average of weights taken during final 13 days of run-in, is used in place of “target weight” for measuring weight changes during intervention.
- Blood pressure section and elsewhere now amended to reflect requirement of five termination blood pressure measurements, at least two of which are taken during intervention week 8. Note also added that BP cuff size should always match that used at SV1.
- Under *Collect A 24-Hour Urine Sample*, the procedures for handling inadequate specimens have been expanded. Also, the timeframe for the 24-hour urine has been changed to “during the final 13 days.”
- We added a new section entitled *Early Termination of Feeding* that describes the conditions under which feeding can be discontinued.

New changes in Version 2.3

- The section on *Collect ABPM Data* refers to chapter 29 for more details.

New changes in Version 4.0

- none

New changes in Version 4.1

- Third paragraph of *Overview* modified to add Participation Survey.
- Section on *Preparations for Intervention* amended to add subsections on *ABPM* and *End of Study Participation Survey*, and to include reference to Form #74 under *24-hour Urine Collection*.
- Table 12.1 modified to refer to Participation Survey.
- Under *Summary of Intervention Activities*, bullet added for Participation Survey and paragraph added at end regarding Refusal Survey.

DASH Manual of Procedures

- First two paragraphs of blood pressure section revised to note that BPs should not be taken on intervention day 1 and that BP measurements made with wrong cuff size should be repeated if possible using proper cuff. Last paragraph of this section edited to require hardcopy of BP.
- Paragraph added to end of 24-hour urine section to refer to Form #74.
- New sub-sections added on *Participation Survey* and *Transmission of Data*.
- Second paragraph of *Collect ABPM Data* expanded.

DASH Manual of Procedures

Overview

The eight-week intervention feeding period begins exactly 21 days after the scheduled start of run-in feeding. During this period participants continue to receive all of their food from the clinic and to eat on-site at least one meal per day, five days per week. As with the run-in feeding, the on-site meal should be a lunch or dinner meal if possible.

To provide consistent terminology, we shall refer to the eight weeks of intervention feeding as ***weeks 1 through 8 of intervention feeding*** even though week 1 of intervention feeding is the fourth week of overall feeding. Similarly day 1 of intervention feeding is really the 22nd day of overall feeding.

Weight is recorded at each clinic visit and blood pressure is assessed weekly. For the first six weeks the blood pressure assessment consists of a single day's set of two measurements. Five daily sets of two blood pressure measurements are recorded over the final 13 days of intervention feeding, including two sets during intervention week 8. A 24-hour ABPM reading is also recorded during these final 13 days. Additional intervention measurements include: a 24-hour urine (during the final 13 days of intervention feeding); fasting blood lipid levels (week 8); formal side effects and medication use monitoring (weeks 4 and 8); a repeat of the physical activity questionnaire (week 8); and a participation survey (week 8). A sample from the 24-hour urine specimen is sent to a central laboratory for assessment of Na, K, Mg, Ca, urea nitrogen, and creatinine for group analyses.

At the conclusion of each feeding wave study participants receive a summary of their study blood pressures and dietary counseling for heart disease prevention. Participants who were withdrawn from antihypertensive medications are also advised that they should consult their physicians about resuming their medications.

Preparations for Intervention

Intervention consists of a series of visits, the preparations for which vary from day-to-day. Certain aspects, such as those related to the preparation and distribution of food, are nearly identical from day-to-day. Other activities, such as blood draws and blood pressure assessment, happen much less frequently. Table 12.1 lists the various activities that take place during the intervention feeding phase.

In this section we summarize the various activities and note the materials needed for each. Subsequent sections describe each of these activities in greater detail. Comprehensive discussions of food preparation, feeding, and compliance assessment are provided elsewhere in the MOP as noted below:

DASH Manual of Procedures

Blood Pressure

- Random zero (RZ) sphygmomanometer and stethoscope
- Standard mercury sphygmomanometer
- Generic Blood Pressure Form (form #26)

Ambulatory Blood Pressure Monitoring

- ABPM devices
- ABPM Placement Form (form #64)
- Instructions to Participants (form #65)
- Participant Questionnaire (form #66)
- ABPM Initialization/Downloading checklist (form #68)

Blood Draw

- Central laboratory supplies (see chapter 20)

24 Hour Urine Collection

- Participant instructions and materials for 24-hour urine collection (see chapter 20)
- DASH Initial and Repeat 24-hour Urine forms (form #74)

Daily Feeding And Weight/Compliance Assessment

- Scale
- Daily diary (Form #22)
- Intervention compliance assessment form (form #18b)
- Intervention energy adjustment form (form #17b)
- Free choice beverage and seasonings form (form #20)
- Percent nutrient deviation record (form #21)
- Intervention Flow Form (form #54)
- Food Donation Tracking (Direct Shipment) (form #16a)
- Food Donation Tracking (Donated items) (form #16b)
- Food Inventory Control Form (form #19)
- Study Menus (form #40)
- Food Production Form (form 41)
- Tray Assembly Form (form 51)

End of Study Physical Activity Assessment

- Physical Activity Questionnaire (form #14)

DASH Manual of Procedures

Side Effects/Medication Monitoring

- Side Effects Form (Form #60)
- Intervention Medication Questionnaire (Form #61b)

End-of Study Participation Survey

- Participation Survey (Form #76)

In addition, the following materials should be available for each daily visit.

- Study charts for scheduled participants
- Laptop computer

Table 12.1 DASH Intervention Activity Sequence

Intervention Event	Intervention Week #							
	1	2	3	4	5	6	7	8
RZ Blood Pressure*	X	X	X	X	X	X	X	X
Weight	X	X	X	X	X	X	X	X
Central 24-hr Urine Tests							←==X==→	
ABPM (after 1st cohort)							←==X==→	
Physical Activity Questionnaire								X
Renin Level								X
Ionized Ca, PTH, Vitamin D								X
Fasting Lipids								X
Participation Survey								X
Medication Questionnaire				X				X
Side Effects Questionnaire				X				X
Intervention Feeding Activities	X	X	X	X	X	X	X	X
Compliance Monitoring	X	X	X	X	X	X	X	X

* once per week in weeks 1-6; five times during final 13 days (including twice in week 8)

DASH Manual of Procedures

Summary of Intervention Activities

The following activities all occur during intervention feeding.

- Measure weight at each clinic visit
- Assess blood pressure each week
- Collect a 24-hour urine sample
- Complete Side Effects Form
- Complete Intervention Medication Questionnaire
- Complete Participation Survey
- Collect a fasting blood sample
- Prepare and distribute daily meals
- Review daily food diaries to assess compliance
- Assess physical activity level at end of intervention
- Collect ABPM data at end of intervention
- Exit interview/counseling after intervention

Blood pressure measurements, if collected, should be done first, followed by weight, compliance assessment, and then eating. Collection of the fasting blood sample must also be done prior to eating. The timing of other one-time activities (i.e., before or after eating) is left to clinic discretion. However, the blood pressure and weight measurements should always be done first.

If a participant elects to drop-out of the study, staff should attempt to complete The Refusal Survey (form #77).

Measure Weight At Each Clinic Visit

All participants are weighed at each clinic visit during the intervention phase of the trial. Use the protocol outlined in MOP chapter 21, and enter the information into the laptop computer. The average of all weight measurement recorded during the final 13 days of run-in feeding 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 monitor weight changes for adjusting the overall caloric content of the participant's meals to assure that weight remains stable throughout the study. The intervention week 1 blood pressure should be taken as late in the week as possible, and under no circumstances should it be taken on the first day of intervention feeding. All such blood measurements shall be treated as run-in measurements.

Collect Remaining Baseline Blood Pressure Measurements

As part of each participant's final blood pressure measurements, the Protocol requires that five sets of blood pressure measurements be taken during the final 13 days of intervention feeding. Furthermore, at least two of these measurements should be taken during intervention week 8. In addition, blood pressure is assessed once (set of two RZ measurements) during each of weeks one through six of intervention feeding. The intervention week 1 blood pressure should be taken as late in the week as possible, and

DASH Manual of Procedures

under no circumstances should it be taken on the first day of intervention feeding. All such blood measurements shall be treated as run-in measurements.

Clinic staff measure blood pressure using an RZ device and follow the procedures described in MOP chapter 19 (Blood Pressure Assessment). In order to minimize the potential for subjective biases, **the clinic staff who measure blood pressure must be blinded to each participant's intervention assignment. Also, please be sure that all blood pressure measurements are made using the same cuff size as was used at SV1.** If the cuff size is found to differ from that used at SV1 and participant has not left the clinic, a replacement blood pressure should be taken using the proper cuff. Otherwise the original measurement will stand.

If the average of any day's two SBP measurements is >180 mm Hg or two DBP measurements is >110 mm Hg, the participant must be referred to his physician for possible therapy. If the participant is started on blood pressure medication, he is excluded from further participation in the trial. Clinic staff should therefore attempt to obtain as many daily blood pressure measurements as possible (up to a maximum of five days) from the time the participant is referred to his physician until the time he is started on medications. If the participant's physician decides that the participant does not need to go on medications, then the participant should continue to be followed in the study as usual. However the clinic staff should still have attempted to collect the five blood pressure measurements as a precaution.

If the average of any day's two SBP measurements is between 171 and 180 mm Hg (inclusive) or two DBP measurements is between 106 and 110 mm Hg (inclusive), the participant must have his blood pressure measured again within seven days. If this follow-up measurement is >170 mm Hg (SBP) or >105 mm Hg (DBP), then the participant must be referred to his physician for possible therapy. As with the first escape level, if the participant is started on blood pressure medication, then he is excluded from further participation in the trial. Clinic staff should therefore attempt to obtain as many daily blood pressure measurements as possible (up to a maximum of five days) from the time the participant is referred to his physician until the time he is started on medications. Similarly, if the participant's physician decides that the participant does not need to go on medications, then the participant should continue to be followed in the study as usual. However the clinic staff should still have attempted to collect the five blood pressure measurements as a precaution.

For reasons of safety, participants should not be asked to defer the start of therapy in order that the clinic be able to obtain a complete set of four measurements. More complete details on safety monitoring is included in chapter 27 (Safety Monitoring).

The intervention blood pressure measurements can be entered at the time of the visit into the laptop or batch entered after the fact. In either case, the generic blood pressure form (form #26) must be used to provided a hard copy record of each day's BP measurements.

Collect A 24-Hour Urine Sample At End-of-Study

NOTE: 24-hour urine collection should not be done during menstruation. Schedule urine collection to avoid collections during this time.

DASH Manual of Procedures

A 24-hour urine specimen needs to be collected during the final 13 days of intervention feeding. A sample from this specimen is sent to the central laboratory for processing for subsequent group analyses.

Distribute the 24-hour urine container and instructions to the participant and review the instructions with the participant. Make sure that a label is affixed to the collection jug and that it is filled out with the appropriate identifying information. If the specimen is to be returned the next day, have the participant start the collection before leaving the clinic (i.e., void the bladder into the toilet). If the collection is to be done over a weekend, inform the participant to bring the container back within 24 hours of collection.

The instructions below for processing the specimen should be followed no matter when the specimen is returned. More complete details on the processing of 24-hour urine specimens are contained in MOP chapter 20.

Take the 24-hour urine container from the participant, check to make sure that the labels on the tag attached to the jug are filled out correctly and completely, and verify that the ID listed on the label matches that of the participant. Also confirm that the participant voided her bladder at the start of collection and did not save the specimen, collected a final voiding at the end of the collection period, and returned the specimen within 24 hours of the final voiding.

The specimen is considered to be inadequate if any of the following are true.

- The total duration of the collection is less than 22 hours or greater than 26 hours
- The collection period did not start with an initial, discarded voiding
- More than one voiding (including the final voiding) was missed
- The total volume of the sample is less than 500 cc
- The urine is collected during menstruation

If the specimen is inadequate, or if the participant failed to bring it in, another (acceptable) specimen must be obtained. Give the participant a new set of collection materials, attach and fill out the labels correctly. Save an aliquot from the original sample as a backup in case the participant is not able to provide an adequate sample, and note on the label that the sample was inadequate. If the participant does not bring a repeat specimen, or if the repeat specimen is also inadequate, analyze the aliquot from the original (inadequate) sample in its stead, and note on the shipping label that the sample was inadequate and why.

Assuming that the participant does bring in a specimen, either immediately take it to the clinic's lab area for processing or place it in a refrigerator until it can be processed. Avoid leaving the specimen at room temperature for any longer than is necessary.

The DASH Initial and Repeat 24-hour Urine Forms (form #74) are required, local-use-only forms to help clinic staff properly process 24-hour urine specimens.

DASH Manual of Procedures

Complete Side Effects Form

All participants complete the Side Effects Form (form #60) during intervention weeks 4 and 8. The questionnaire is primarily designed to document gastrointestinal symptoms associated with the diets. It also captures information on symptoms that may be related to high blood pressure.

The questionnaire should be completed by the participant and reviewed by clinic staff for completeness. Any positive responses must be reviewed by a study clinician, who determines if further follow-up is needed.

The questionnaire should be photocopied and the original sent to the coordinating center for data entry.

Complete Intervention Medication Questionnaire

All participants complete an intervention medication questionnaire (Form #61b) during intervention weeks 4 and 8. The questionnaire is designed to identify those individuals who start taking medications during the course of the study.

The questionnaire should be administered in an interview format, and all positive responses must be reviewed by a staff clinician. Individuals taking exclusionary medications must either stop taking these medications or be excluded from further participation in the study.

Responses to the questionnaire should be entered in the laptop computers.

Complete Participation Survey

All participants complete a survey during intervention week 8 describing their reasons for participating in DASH.

Collect Fasting Blood Sample

During last eight days of intervention feeding subjects must provide a fasting blood sample. To be valid, the participant must have been fasting for a period of twelve hours (minimum of ten required) and must have been in an upright position (defined as seated or standing) for at least 1½ hours prior to the blood draw. The requirement to have been in an upright position for 1½ hours is a target. No minimum time has been established by the Steering Committee. Details on drawing and processing this specimen are given in chapter 20 (Laboratory Measures).

Assess Physical Activity Level

All participants must complete the Physical Activity Questionnaire during the final week of intervention feeding. This should be done in an interview format and entered into the laptop.

DASH Manual of Procedures

Collect ABPM Data

All participants except those in the first feeding cohort complete a 24-hour period of ambulatory blood pressure monitoring. This monitoring must be done sometime during final 13 days of intervention feeding.

Instructions for performing the measurement and downloading the data are given in Chapter 29. The Coordinating Center will retrieve the blood pressure data from the file server. Completed ABPM questionnaires should be photocopied and the originals sent to the Coordinating Center for data entry.

Transmission of Data

Urine specimens, blood specimens, and questionnaire data should be shipped to the central labs or Coordinating Center, as appropriate, within four weeks of the end of intervention feeding.

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. For example, at least two blood pressure measurements must be recorded during week 8 of intervention feeding. Thus, everyone must complete a minimum of 7 weeks and 2 days of intervention feeding. 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.

Exit Interview and Counseling

After feeding is concluded, all participants receive nutritional counseling and a summary of their data. See Chapter 28 for more details.

13. Study Menus

A detailed description of the Study Menus, on a day-by-day basis, is contained in Form 40 in the DASH Forms Manual.

14. Menu Validation and Monitoring

Overview	4
Menu Validation	4
Diet Monitoring	4
Sampling Design	5
Menu Validation	5
Monitoring	5
Shipment	9
Compositing	10
General Comments about the Biochemical Analyses	10
Sample Storage:	10
Archive Samples:	10
Assay Samples:	10
Reserve Samples:	10
Assay Quality Control:	10
Blinded Samples:	11
SOPs:	11
Assay Methods and Validation	11
Minerals (Na, K, Ca, Mg, Fe)	11
Total fat	11
Cholesterol	11
Moisture	12
Fatty acids (saturated, monounsaturated, polyunsaturated, omega-3)	12
Ash	12
Protein	12
Dietary Fiber	13
Laboratory Quality Assurance	15
FALCC SOP Numbers and Titles as of May 13, 1994	16
Pertinent Hazleton SOP Numbers and Titles	16
FALCC SOP 1025: Procedure for Collection and Shipping of Menus	16
Overview	17
Materials Needed at Clinical Centers	17
Materials To Be Supplied by FALCC	17
Procedures	17
Shipping	20
FALCC Form #F002	22
Procedure for Collection and Shipping of Unit Foods	26
Scope	26
Purpose	26
Overview	26
Materials	26
Receipt of Shipping Materials:	28
Documentation of Unit Food Batch Preparation	28

DASH Manual of Procedures

Sample Collection _____	28
Procedures for collecting and analyzing unit foods _____	29
Sample collection _____	29
Composition and assay _____	30

Summary of Edits

New changes in Version 2.2

- Major changes in formatting. Hopefully more clear. Please read entire chapter. FALCC SOP 1025 is most pertinent to site operations.
- inserted Tables 14.1-14.4 and attachments in back.

New Changes in Version 2.3

- Added Tables 14.7, 14.8, 14.9
- Updated Tables 14.5 and 14.6
- Added FALCC SOP numbers and Titles as of May 13, 1994
- Significant changes throughout. Read entire chapter.

New Changes in Version 4.0

- Procedures added for collecting and shipping unit foods
- Section added on documentation of unit food batch preparation

New Changes in Version 4.1

- Under Diet Monitoring, the last sentence about monitoring sodium and potassium in ad lib beverages was dropped.
- Menu monitoring schedules revised

DASH Manual of Procedures

Overview

Menu Validation

The DASH intervention menus were developed by the Diet Committee using nutrient information contained in existing computerized databases. The Diet Committee formulated eight weekday and four weekend menus for each of the three diets at each of the four calorie levels (144 total menus).

In order to validate the content of the menus and to select the subset of menus that would be used for the study, sample menus were prepared and shipped to a central laboratory, The Food Analysis Laboratory Control Center (FALCC) at Virginia Polytechnic Institute, for chemical analysis of nutrients. Each clinical center prepared selected weekday and weekend menus from the 2100 and 3100 calorie diets in a predetermined manner such that validation occurred on two sets of the same menus at both the 2100 and 3100 calorie levels, with each menu set prepared by two different clinical centers. A total of 144 menus was shipped frozen from the clinical centers to Hazleton Laboratories for compositing. Frozen composited samples were then shipped to the FALCC for nutrient analysis.

The following nutrients were analyzed: calcium, magnesium, potassium, sodium, iron, total fat, protein (via nitrogen), moisture, and ash. Carbohydrates and total calories were available as calculated values. Each menu was also assayed for fatty acids [total saturated (SFA), total monounsaturated (MUFA), total polyunsaturated (PUFA)] and cholesterol, but these data were not used for menu selection.

Menus that did not fall within the targeted nutrient ranges for calcium, magnesium, potassium, sodium, and total fat were discarded. Cost of preparation and the results of taste-testing studies were used to select the final 7-day menu cycle from among the remaining menus.

The unit foods for each of the three DASH diets are monitored on a diet-center-cohort basis. Samples from unit food batches prepared for the feeding cohorts are shipped frozen to the FALCC, where they are composited by diet-center-cohort. Each unit food composite is assayed in duplicate for calcium, magnesium, potassium, sodium, iron, total fat, protein (via nitrogen), moisture, and ash. Carbohydrates and total kcal are available as calculated values.

Diet Monitoring

Because nutrient levels may vary over time, both as a result of variations in foods available and as a result of local preparation practices, the DASH menus are monitored on a regular basis during the intervention phase of the trial. Each center prepares two menu cycles (seven days of menus) per diet during each cohort. These seven day menu sets are shipped frozen to the FALCC for compositing and assaying.

Nutrients analyzed during the diet monitoring phase include: calcium, magnesium, potassium, sodium, iron, total fat, protein (via nitrogen), moisture, and ash. Carbohydrates and total calories are available as calculated values. FALCC also assays each diet-clinical center combination once

DASH Manual of Procedures

during each cohort for fatty acids (total SFA, total MFA, total PUFA), cholesterol, and dietary fiber for the purposes of documentation, budget permitting.

Sampling Design

Menu Validation

Menus for the three diets were prepared at two different kcal levels (2100 and 3100) according to the schedule below. The prepared menus were shipped frozen on dry ice via overnight delivery to Hazleton Laboratories for compositing. The frozen, composited samples were then shipped by Hazleton to the FALCC for nutrient analysis.

Brigham/Women's	Duke	Hopkins	PBRC
Red Diet 2100	Green Diet 2100	Red Diet 2100	Green Diet 2100
Yellow Diet 2100	Red Diet 3100	Yellow Diet 2100	Red Diet 3100
Green Diet 3100	Yellow Diet 3100	Green Diet 3100	Yellow Diet 3100

Monitoring

During the first two feeding cohorts, staff at each clinical center prepare two full menu cycles (seven days of menus) for each of the three dietary patterns for shipment to the FALCC. These menus are prepared during the first six weeks of intervention feeding according to the sampling plan outlined in tables 14.1-14.4. Beginning with cohort 3 only one menu cycle is analyzed for each of the three dietary patterns. These menus are prepared during the first three weeks of intervention feeding.

The tables specify a particular diet-calorie level combination to be prepared each week. During any given week, the kitchen staff prepare extra meals corresponding to this combination and store them, frozen, for shipment. At the end of each week these extra meals are shipped to the FALCC for compositing and nutrient analysis.

A summary of the individual nutrients to be analyzed from each sample is included as an attachment to the end of this chapter (Tables 14.7 - 14.9).

DASH Manual of Procedures

Table 14.1 Menu Monitoring Schedule - Baton Rouge

Cohort	Week	Diet	Kcal	Cohort	Week	Diet	Kcal
1	1	R	2100	4	1	R	2100
1	2	G	2100	4	2	Y	2100
1	3	G	3100	4	3	G	2100
1	4	R	3100	4	4		
1	5	Y	2100	4	5		
1	6	Y	3100	4	6		
1	7	--	--	4	7	--	--
1	8	--	--	4	8	--	--
2	1	G	2600	5	1	Y	3100
2	2	G	1600	5	2	G	3100
2	3	R	1600	5	3	R	3100
2	4	R	2600	5	4		
2	5	Y	1600	5	5		
2	6	Y	2600	5	6		
2	7	--	--	5	7	--	--
2	8	--	--	5	8	--	--
3	1	G	3100	6	1		
3	2	Y	3100	6	2		
3	3	R	3100	6	3		
3	4			6	4		
3	5			6	5		
3	6			6	6		
3	7	--	--	6	7	--	--
3	8	--	--	6	8	--	--

R=Red = Control

Y=Yellow = Fruit & Vegetable
and Reduced Fat

G=Green = Fruit, Vegetable, Dairy

DASH Manual of Procedures

Table 14.2 Menu Monitoring Schedule - Durham

Cohort	Week	Diet	Kcal	Cohort	Week	Diet	Kcal
1	1			4	1	G	2100
1	2	G	1600	4	2	R	2100
1	3	R	2600	4	3	Y	2100
1	4	Y	1600	4	4		
1	5	R	1600	4	5		
1	6	G	2600	4	6		
1	7	Y	2600	4	7	--	--
1	8	--	--	4	8	--	--
2	1	Y	3100	5	1	G	3100
2	2	R	3100	5	2	Y	3100
2	3	G	3100	5	3	R	3100
2	4	R	2100	5	4		
2	5	G	2100	5	5		
2	6	Y	2100	5	6		
2	7	--	--	5	7	--	--
2	8	--	--	5	8	--	--
3	1	R	3100	6	1		
3	2	Y	3100	6	2		
3	3	G	3100	6	3		
3	4			6	4		
3	5			6	5		
3	6			6	6		
3	7	--	--	6	7	--	--
3	8	--	--	6	8	--	--

R=Red = Control

Y=Yellow = Fruit & Vegetable
and Reduced Fat

G=Green = Fruit, Vegetable, Dairy

DASH Manual of Procedures

Table 14.3 Menu Monitoring Schedule - Baltimore

Cohort	Week	Diet	Kcal	Cohort	Week	Diet	Kcal
1	1			4	1	G	3100
1	2	G	1600	4	2	Y	3100
1	3	G	2600	4	3	R	3100
1	4	R	1600	4	4		
1	5	Y	1600	4	5		
1	6	R	2600	4	6		
1	7	Y	2600	4	7	--	--
1	8	--	--	4	8	--	--
2	1	G	3100	5	1	R	2100
2	2	G	2100	5	2	Y	2100
2	3	Y	3100	5	3	G	2100
2	4	R	3100	5	4		
2	5	R	2100	5	5		
2	6	Y	2100	5	6		
2	7	--	--	5	7	--	--
2	8	--	--	5	8	--	--
3	1	R	2600	6	1		
3	2	G	2600	6	2		
3	3	Y	2600	6	3		
3	4	G	2100	6	4		
3	5	R	2100	6	5		
3	6	Y	2100	6	6		
3	7	--	--	6	7	--	--
3	8	--	--	6	8	--	--

Only 2100 kcal menus used from cohort 3

R=Red = Control

Y=Yellow = Fruit & Vegetable

G=Green = Fruit, Vegetable, Dairy
and Reduced Fat

DASH Manual of Procedures

Table 14.4 Menu Monitoring Schedule - Boston

Cohort	Week	Diet	Kcal	Cohort	Week	Diet	Kcal
1	1			4	1	G	3100
1	2	G	1600	4	2	Y	3100
1	3	R	2600	4	3	R	3100
1	4	Y	1600	4	4		
1	5	G	2600	4	5		
1	6	Y	2600	4	6		
1	7	R	1600	4	7	--	--
1	8	--	--	4	8	--	--
2	1	G	2100	5	1	G	2100
2	2	Y	3100	5	2	Y	2100
2	3	Y	2100	5	3	R	2100
2	4	R	2100	5	4		
2	5	G	3100	5	5		
2	6	R	3100	5	6		
2	7	--	--	5	7	--	--
2	8	--	--	5	8	--	--
3	1	R	1600	6	1		
3	2	Y	2100	6	2		
3	3	Y	1600	6	3		
3	4	R	2100	6	4		
3	5	G	1600	6	5		
3	6	G	2100	6	6		
3	7	--	--	6	7	--	--
3	8	--	--	6	8	--	--

Only 2100 kcal menus used from cohort 3

R=Red = Control

Y=Yellow = Fruit & Vegetable
and Reduced Fat

G=Green = Fruit, Vegetable, Dairy

Shipment

As noted above, validation samples were shipped to Hazleton laboratories for compositing before final shipment to the FALCC. Monitoring samples, on the other hand, are shipped directly to the FALCC for compositing.

The procedures for collecting and shipping of menus are given in FALCC Standard Operating Procedure (SOP) #1025 that, along with other pertinent FALCC SOPs, is contained in the back of this chapter. These procedures must be followed exactly. If a deviation occurs, then a discrepancy form (#F002) must be filled out and shipped with the menu samples.

DASH Manual of Procedures

Compositing

A menu is an entire day's food (breakfast, lunch, dinner, and snack). For the validation analysis, each menu was composited individually in one batch in a manner designed to provide a uniform subsample for each of the assays that were performed (Hazleton SOP # OPNC60 & OPNC64). Copies of internal procedures used by Hazleton and by the FALCC are maintained by the Coordinating Center but are not included here. Only procedures to be used by the clinics are included at the end of the chapter.

For the monitoring analyses, all the food contained in each seven-day cycle of menus for a given diet-kcal level is composited together in a manner designed to provide a uniform subsample for each of the assays performed (FALCC SOP #5029).

General Comments about the Biochemical Analyses

Sample Storage:

All composited samples are stored at -60°C or lower.

Archive Samples:

Archive samples are stored for the duration of the DASH study. Five (5) samples of each composite are placed into the archive location as designated by supervisor. The dispensation of these samples requires approval by the DASH Steering Committee.

Assay Samples:

Assay samples are used for the nutrient assays specified below.

Reserve Samples:

Reserve samples are extra samples taken by FALCC to accommodate repeat assays, additional assays, etc. There are a minimum of eight (8) reserve samples per composite. Reserve samples may be used at the discretion of the FALCC. Any samples that remain after completion of the nutrient assays are retained for a minimum of three months.

Assay Quality Control:

For each assay, an appropriate control sample (mixed diet composite) is included with each batch of samples or at least every 20 samples, whichever is less. A QC chart for this control 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 $\pm 2\text{SD}$ and $\pm 3\text{SD}$ are calculated from these data and plotted as a QC chart. The value for the control material in each assay batch is plotted on the QC chart. If the control value falls outside the $\pm 3\text{SD}$ limits, all data from the assay are rejected. The assay results are also rejected if the results of the duplicate assays are unacceptable. The assay system is evaluated for possible sources of error, corrected if indicated, then samples are rerun.

DASH Manual of Procedures

Blinded Samples:

An internal FALCC sample numbering system is used so that the analyst cannot readily decipher information about a sample from its number, in order to minimize analyst bias. The FALCC database maintains a link between the sample number and all information concerning that sample.

SOPs:

FALCC writes Standard Operating Procedures (SOPs) for all nutrient assays and laboratory procedures. Each SOP is signed and dated. Original copies are kept in a central notebook with disk copies on file as well. Non-current SOPs are archived. A list of all DASH FALCC SOPs (numbers and titles) is given at the end of this chapter.

Assay Methods and Validation

Minerals (Na, K, Ca, Mg, Fe)

Method: Sodium, potassium, calcium, magnesium, and iron are determined in wet-ashed diet composites using inductively coupled plasma spectroscopy (ICP) (FALCC SOP #5035). The ICP assay of the digested samples is sub-contracted to the Department of Crop and Soil Environmental Science at Virginia Tech. The FALCC includes blinded standards for each element and a blinded in-house quality control diet composite sample with each assay batch.

Validation: Validation of the method is based on analyses of a standard mixed diet reference material (NIST #1548) yielding results for Na, K, Fe, Ca, and Mg which were within the certified range of uncertainty (note: in initial runs, Ca value was high by 0.5%). Recoveries of each of the above minerals spiked into mixed diet composites (including two DASH Diet 1 and Diet 3 pilot menu composites) were > 98% for each element. Additionally, five selected diet composites (including high and low lipid content samples) were independently analyzed by an expert outside lab (USDA Nutrient Composition Laboratory); FALCC values were 100.5% of FCL values for Na, 97% for Fe, 105% for Ca, 101% for Mg, and 114% for K for each sample assayed.

Total fat

Method: Total lipid is determined gravimetrically after extraction of the diet composites with chloroform/methanol (see FALCC SOP #5024).

Validation: Validation of the method is based on > 95% recovery of canola oil spiked into composited mixed diets, and results for National Institute of Standards and Technology standard reference material (NIST SRM #1548) within the certified range.

Cholesterol

DASH Manual of Procedures

Method: A capillary gas chromatography method is used quantify cholesterol (see 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 #1563-2) within the certified range, agreement of results within 5% with those obtained by FCL for selected diet samples including the in house quality control mixed diet composite material.

Moisture

Method: Moisture in the diet composites is determined with a microwave moisture/solids analyzer (CEM Corp.) (FALCC SOP #5007). Moisture is measured in triplicate for each diet composite. These results are used to calculate all assay results for the composite on a dry weight basis.

Validation: Validation of the method is based upon agreement of the results by microwave drying (FALCC SOP #5007) with those from conventional vacuum oven drying (AOAC 934.01, modified) (FALCC SOP #5002) within 0.5%, and results obtained for FCL reference sample #Q93-FR-4495 within 2% of those obtained independently by FCL.

Fatty acids (saturated, monounsaturated, polyunsaturated, omega-3)

Method: Fatty acid composition is determined by gas-liquid chromatography of fatty acid methyl esters (FAMES) prepared from the saponified lipid extracts of diet composites (chloroform/methanol extracts, as prepared for total fat, (FALCC SOP #5025.) FAMES are reported as triacylglycerol equivalents (TAGs) according to the classification scheme shown in Table 14.6. Fatty acids as TAGs are normalized to the total fat content (determined as described above).

Validation: Validation is based upon >90% fatty acid recoveries from canola oil, menhaden oil, and coconut oil spiked into diet composites.

Ash

Method: Ashing is performed by heating pre-dried samples at 550°C until completely ashed (FALCC SOP #5011).

samples instead of ground freeze-dried samples. (see FALCC SOP #**).

Validation: Validation is based upon a determination of the ash content of NIST SRM #1548 within the certified value, and the FALCC ash data for the control sample within 5% of those obtained independently by FCL.

Protein

Method: Protein is determined as Kjeldahl nitrogen x 6.25 (FALCC SOP #5023). FALCC subcontracts Kjeldahl assay to the Department of Human Nutrition and Foods (HNF) at Virginia

DASH Manual of Procedures

Tech or Hazleton Laboratories which has a semi-automated system. FALCC control samples (blinded) and HNF internal QC samples are included in each assay batch.

Validation: Validation of the method is based on results obtained for the assay NIST SRM #1548 within the certified range, and FALCC results for the control sample within 5% of the results obtained independently by FCL.

Dietary Fiber

Method: AOAC method 991.43 (Lee et al., JAOAC Intl., 75: 395-416, 1992). will most likely be used to measure total dietary fiber. The procedure will be modified for the assay of wet homogenized diet

Validation: Validation of the method will most likely be based on results for NIST SRM #1548 within the certified range, and results for the AOAC dietary fiber collaborative study samples within **% of the certified values.

The FALCC assay data are reported in the units shown in table 14.5 below.

DASH Manual of Procedures

Table 14.5 Units for ASSAY data:

ASSAYED COMPONENT	UNITS
Na, K, Ca, Mg, Fe	mg/100g dry weight
total fat	g/100g dry weight
total SFA ¹	g/100g dry weight (as triglycerides)
total MUFA ¹	g/100g dry weight (as triglycerides)
total PUFA ¹	g/100g dry weight (as triglycerides)
cholesterol	mg/100g dry weight
protein	g/100g dry weight
ash	g/100g dry weight
dietary fiber	g/100g dry weight
moisture	g/100g
total weight	grams
CALCULATED COMPONENT	UNITS
Na, K, Ca, Mg, Fe	mg/menu
cholesterol	mg/menu
total dry weight	grams
carbohydrate	g/100g dry weight
total energy	Kcal
total fat	% of total Kcal
SFA	% of total Kcal
MUFA	% of total Kcal
PUFA	% of total Kcal

¹See Table 14.6 for a definition of each of these fatty acids classes.

Table 14.6 Classification of Fatty Acids

SFA	MUFA	PUFA	omega 3-FA
10:0	14:1	18:2	18:3n-3 (α -linolenic)
11:0	16:1	20:2	20:5n-3 (EPA)
12:0	17:1	20:3	22:6n-3 (DHA)
13:0	18:1	20:4	
14:0	19:1	22:6	
15:0	20:1		
16:0	22:1		
17:0			
18:0			
20:0			
22:0			
24:0			

NOTE: SFA: saturated fatty acids; MUFA: monounsaturated fatty acids; PUFA: polyunsaturated fatty acids; omega3-FA: omega-3 fatty acids; EPA: eicosapentaenoic acid; DHA: docosahexaenoic acid. The listings “C:n” denote fatty acids with “C” carbons in the fatty acid acyl chain and “n” double bonds. For example, 18:0 is the abbreviation for stearic acid. Omega3-FA are not included in total PUFA.

Laboratory Quality Assurance

FALCC laboratory quality control includes control samples, reference materials, blinded re-runs, quality control charts, independent review of results, use and documentation of SOPs, deviation documentation, complete notebook records for all assays, archiving composited samples, duplicate assay of all samples with documented acceptable limits for acceptable assay Relative Standard Deviations, weekly instrument and equipment calibration, and daily monitoring of the temperature of refrigerators and freezers (Monday - Saturday).

Because of the large volume of samples and the complexity of processing and assaying samples, the FALCC has developed an internal database to assign numbers and track data on any given sample. The database maintains a link between any given whole food sample and its composited subsamples. Assay data are linked to samples via the assay batch number for each component assayed.

Electronic data are stored on hard drives and floppy disk. Computers are backed up weekly Disk copies and/or hard copies of all data are archived in fire-resistant file cabinets.

DASH Manual of Procedures

FALCC SOP Numbers and Titles as of May 13, 1994

NUMBER	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 Sartorius Model R200D Semi-Microbalance (M1-31-3)
1012	Maintenance Protocol for Balance and Refrigerator 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 (DASH Protocol)
1026	Acid Washing of Glassware
1027	Procedure for Evaluating Pipetman pipettors
5002	Determination of Moisture in Diet Composites by Vacuum Oven Drying
5007	Determination of Moisture in Diet Composites 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 Chloroform-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
5019	GC Method for Fatty Acid Methyl Ester Analysis
5020	Saponification and Derivatization 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
5025	Fatty Acid Determination in Mixed Diets
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 by ICP

Pertinent Hazleton SOP Numbers and Titles

OPNC60 & OPNC64 Preparation of DASH Menu Composites

FALCC SOP 1025: Procedure for Collection and Shipping of Menus

Version 4.1 16-Feb-1996

Page 14-16

DASH Manual of Procedures

Overview

This describes the procedure for collecting prepared menus and shipping the foods to the FALCC as part of the DASH menu validation study.

READ THROUGH THIS ENTIRE PROCEDURE PRIOR TO FOOD COLLECTION.

If you have any questions, contact the FALCC at (703) 231-4361.

Materials Needed at Clinical Centers

prepared foods from menus

refrigerator (0-4°C)

freezer (-20°C or lower)

heavy paper (e.g. brown paper or newspaper)

dry ice (ca. 5 lbs per cooler)

Materials To Be Supplied by FALCC

Rubbermaid containers (12 per diet) **prelabeled with Diet, Menu and Center identifications**

stainless steel spatula(s)

cryogenic marker

fat-free powder-free gloves (disposable)

Form #F033 (sample transfer)

Form #F002 (deviation from SOP)

shipping cooler(s)

packing tape

Federal Express dry ice identification stickers

pre-addressed Federal Express shipping labels (1 per cooler)

pre-addressed envelope for returning forms to the FALCC Lab

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 E-mail FALCC@VTVM1.cc.vt.edu.

Procedures

Perform the following steps for each menu of foods to be collected. These procedures must be followed exactly. If a deviation occurs, fill out form #F002 and include it with the food shipment.

DASH Manual of Procedures

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 a 12-cup Rubbermaid container pre-labeled 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 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, date, and your initials on the sample label on the container.
5. Place the container in the refrigerator (0-4°C) until collection of total menu is complete (24 hrs).

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 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).

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

4. Completely seal the container and place it in the refrigerator (0-4°C) until collection of total menu is complete (24 hrs).

DASH Manual of Procedures

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 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).

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

4. Completely seal the container and place it in the refrigerator (0-4°C) until collection of total menu is complete (24 hrs).

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 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 analytical values will not reflect the composition of the menu.

4. Completely seal the container and place it in the **FREEZER** (-20°C or less). All foods from the menu should now be in the container.
5. The food must be **frozen at -20°C or less at least overnight prior to shipment.**

DASH Manual of Procedures

Shipping

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 FED EX PICK-UP

1. Assemble containers of food to be shipped: **FROZEN solid (at least OVERNIGHT at -20°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 five 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 (#F033)** in a sealed zip-lock bag (to protect from moisture) and place on top in cooler.
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 FedEx shipping label to the box, and send via Federal Express overnight delivery to Hazleton:

Attn: Rhonda Gulbranson
Hazleton, Wisconsin
3301 Kinsman Blvd.
Madison, WI 53704

DASH Manual of Procedures

12. Notify Hazleton and FALCC of shipment:

FALCC: Phone: (540) 231-4361 **or** FAX: (540) 231-9070 **or**
E-mail:FALCC@VTVM1.CC.VT.EDU

Hazleton: Rhonda Gulbranson, (608) 242-2738

13. Send Deviation from SOP form(s) (Form #F002), if any, directly to FALCC:

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

Send all FedEx airbill receipts for coolers sent to Hazleton directly to FALCC.

DASH Manual of Procedures

FALCC Form #F002

Food Analysis Laboratory Control Center (FALCC)

NOTIFICATION OF DEVIATION FROM STANDARD OPERATING PROCEDURE

FROM: _____

TO: Dr. K. Stewart
Dept. of Biochemistry
Room 304 Engel Hall
Virginia Tech
Blacksburg, VA 24061

SOP#: _____ **SOP date:** _____ **Date of deviation:** _____

Sample affected: _____

Name of operator: _____

Description of deviation:

DASH Manual of Procedures

Table 14.7

ASSAYS TO BE DONE				Date: October 7, 1994												
Project	DASH		Study: P1C1MO													
Y = to be done																
Week	Center	Diet	kcal	Rec'd.	Composited	Moisture	Protein	Ash	Total lipid	Fatty Acids	Chol.	Fiber	Sugars	Starch	Elements (Na,K,Fe,Ca,Mg)	Comments
COHORT FEEDING 1:																
	BWH				Y	Y	Y	Y	Y						Y	
	DUKE				Y	Y	Y	Y	Y						Y	
	JHU				Y	Y	Y	Y	Y						Y	
	PBRC				Y	Y	Y	Y	Y						Y	
	BWH	GREEN	1600		Y	Y	Y	Y	Y						Y	
	DUKE	GREEN	1600		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	JHU	GREEN	1600		Y	Y	Y	Y	Y						Y	
	PBRC	GREEN	2100		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	BWH	RED	2600		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	DUKE	RED	2600		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	JHU	GREEN	2600		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	PBRC	GREEN	3100		Y	Y	Y	Y	Y						Y	
	BWH	YELLOW	1600		Y	Y	Y	Y	Y						Y	
	DUKE	YELLOW	1600		Y	Y	Y	Y	Y						Y	
	JHU	RED	1600		Y	Y	Y	Y	Y						Y	
	PBRC	RED	3100		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	BWH	GREEN	2600		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	DUKE	RED	1600		Y	Y	Y	Y	Y						Y	
	JHU	YELLOW	1600		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	PBRC	YELLOW	2100		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	BWH	YELLOW	2600		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	DUKE	GREEN	2600		Y	Y	Y	Y	Y						Y	
	JHU	RED	2600		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	PBRC	YELLOW	3100		Y	Y	Y	Y	Y						Y	

DASH Manual of Procedures

Table 14.8

ASSAYS TO BE DONE			Date: January 10, 1995															
Project	DASH	Study: P1C2M																
Y = to be done																		
Week	Center	Diet	kcal	Rec'd.	Composited	Moisture	Protein	Ash	Total lipid	Fatty Acids	Chol.	Fiber	Sugars	Starch	Elements (Na,K,Fe,Ca,Mg)	Comments		
COHORT FEEDING 2:																		
	BWH	GREEN	2100		Y	Y	Y	Y	Y	Y	Y	Y			Y			
	DUKE	YELLOW	3100		Y	Y	Y	Y	Y	Y	Y	Y			Y			
	JHU	GREEN	3100		Y	Y	Y	Y	Y	Y	Y	Y			Y			
	PBRC	GREEN	2600		Y	Y	Y	Y	Y	Y	Y	Y			Y			
	BWH	YELLOW	3100		Y	Y	Y	Y	Y						Y			
	DUKE	RED	3100		Y	Y	Y	Y	Y	Y	Y	Y			Y			
	JHU	GREEN	2100		Y	Y	Y	Y	Y						Y			
	PBRC	GREEN	1600		Y	Y	Y	Y	Y						Y			
	BWH	YELLOW	2100		Y	Y	Y	Y	Y	Y	Y	Y			Y			
	DUKE	GREEN	3100		Y	Y	Y	Y	Y	Y	Y	Y			Y			
	JHU	YELLOW	3100		Y	Y	Y	Y	Y						Y			
	PBRC	RED	1600		Y	Y	Y	Y	Y	Y	Y	Y			Y			
	BWH	RED	2100		Y	Y	Y	Y	Y						Y			
	DUKE	RED	2100		Y	Y	Y	Y	Y						Y			
	JHU	RED	3100		Y	Y	Y	Y	Y	Y	Y	Y			Y			
	PBRC	RED	2600		Y	Y	Y	Y	Y						Y			
	BWH	GREEN	3100		Y	Y	Y	Y	Y						Y			
	DUKE	GREEN	2100		Y	Y	Y	Y	Y						Y			
	JHU	RED	2100		Y	Y	Y	Y	Y						Y			
	PBRC	YELLOW	1600		Y	Y	Y	Y	Y						Y			
	BWH	RED	3100		Y	Y	Y	Y	Y	Y	Y	Y			Y			
	DUKE	YELLOW	2100		Y	Y	Y	Y	Y						Y			
	JHU	YELLOW	2100		Y	Y	Y	Y	Y	Y	Y	Y			Y			
	PBRC	YELLOW	2600		Y	Y	Y	Y	Y	Y	Y	Y			Y			

DASH Manual of Procedures

Table 14.9

ASSAYS TO BE DONE			Date: January 10, 1995													
Project	DASH		Study: P1C3I													
Y = to be done																
Week	Center	Diet	kcal	Rec'd.	Composited	Moisture	Protein	Ash	Total lipid	Fatty Acids	Chol.	Fiber	Sugars	Starch	Elements (Na,K,Fe,Ca,Mg)	Comments
COHORT FEEDING 3:																
	BWH	RED	1600		Y	Y	Y	Y	Y						Y	
	DUKE	YELLOW	2600		Y	Y	Y	Y	Y						Y	
	JHU	RED	2600		Y	Y	Y	Y	Y						Y	
	PBRC	YELLOW	2100		Y	Y	Y	Y	Y						Y	
	BWH	YELLOW	2100		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	DUKE	RED	2600		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	JHU	GREEN	2600		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	PBRC	GREEN	2100		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	BWH	YELLOW	1600		Y	Y	Y	Y	Y						Y	
	DUKE	GREEN	1600		Y	Y	Y	Y	Y						Y	
	JHU	YELLOW	2600		Y	Y	Y	Y	Y						Y	
	PBRC	RED	2100		Y	Y	Y	Y	Y						Y	
	BWH	RED	2100		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	DUKE	YELLOW	1600		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	JHU	GREEN	2100		Y	Y	Y	Y	Y						Y	
	PBRC	GREEN	3100		Y	Y	Y	Y	Y						Y	
	BWH	GREEN	1600		Y	Y	Y	Y	Y						Y	
	DUKE	GREEN	2600		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	JHU	RED	2100		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	PBRC	YELLOW	3100		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	BWH	GREEN	2100		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	DUKE	RED	1600		Y	Y	Y	Y	Y						Y	
	JHU	YELLOW	2100		Y	Y	Y	Y	Y	Y	Y	Y			Y	
	PBRC	RED	3100		Y	Y	Y	Y	Y	Y	Y	Y			Y	

DASH Manual of Procedures

Procedure for Collection and Shipping of Unit Foods

Scope

This procedure applies to collection of unit foods samples for DASH protocol 1 diet monitoring, beginning with Cohort 2¹, as part of documentation of diet composition (DASH Protocol 1 [1994]).

Purpose

To describe the procedure for collecting samples from unit food batches prepared for DASH Protocol 1 and shipping the samples to FALCC for compositing and assay.

Overview

Each center will maintain a log of all unit food batch preparations for each feeding period. This log will include, for each batch, the date of preparation, unit food name, diet, and size of batch, the date of preparation, unit food name, diet, and size of batch. Each center will randomly select one unit from every batch of unit food prepared for each of the three diets RED, YELLOW, and GREEN. These unit batch samples will be collected together BY DIET into airtight containers labeled with center name, "Unit Foods," diet, and Cohort#) and kept frozen at -20°C. At the end of each Cohort feeding period, the collected unit foods will be shipped frozen, on dry ice, to the FALCC along with a copy of the batch preparation log sheet.

Materials

At Field Center:

- prepared unit foods
- freezer (-20°C or lower)
- heavy paper (e.g., brown paper or newspaper)
- dry ice
- plastic food wrap

Food Collection and Shipping Materials (supplied by FALCC):

- Unit Food Batch Preparation Log (Form #F031)
- RubbermaidTM container with label, for sample collection (1 container per diet per cohort)
- fat-free powder-free gloves (disposable)
- Form #F001 (sample transfer), with example form filled out
- Form (#F002 (deviation from SOP)
- shipping cooker
- packing tape²

¹ This procedure was not distributed until week #3 or 4 (depending on Center) of Cohort 2.

DASH Manual of Procedures

Federal Express dry ice identification stickers
pre-addressed Federal Express shipping labels (1 per cooler)

NOTE: Follow these procedures exactly. If any deviation occurs in preparation, packaging, ingredients, sampling, shipping, etc., fill out form #F002 and include it with the food shipment.

TAKE THE SAME CARE SERVING AND PACKING FOODS FOR ASSAY AS YOU DO FOR FOODS FOR PATIENTS.

To resolve any problems with this procedure, contact the DASH Coordinating Center (Njeri Karanja) or FALCC (Katherine Phillips)

² NOTE: The FALCC will supply each Field Center with a reasonable amount of packing tape for shipping foods to the FALCC - please reserve the tape for this use only.

DASH Manual of Procedures

Receipt of Shipping Materials:

Make sure you received all items listed above. If there is a discrepancy or if you should need additional labels or supplies, immediately notify the FALCC at (540) 231-4361, or FAX (540) 231-9070 or
E-mail: FALCC@VTVM1.CC.VT.EDU.

Documentation of Unit Food Batch Preparation

1. At the time a batch of unit food is prepared, do the following:

Record the date of preparation, batch ID number (if any), the unit food name, diet, and batch size (e.g., total number of units or total weight), and your initials.

2. Maintain the preparation log at your center, and **send a copy to the FALCC with the shipment of unit foods.**

Sample Collection

For each batch of each type of unit food prepared for each diet throughout the feeding period, do the following:

1. **Randomly select** one (1) unit.
2. **IMPORTANT: If the unit is wrapped in any (such as a muffin in a paper baking cup), carefully remove the wrapping (as if for consumption by participant).**
3. Place unit into the unit food collection container labeled with the corresponding diet and cohort identification. **Make sure the unit is placed in the appropriate container.**
4. Seal the container completely and check seal integrity.
5. Place container in the freezer (-20°C) unit all batch samples for the cohort feeding have been added.

SHIPPING - DO NOT SHIP ON FRIDAY!

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

1. Assemble all containers to be shipped: **FROZEN (at least OVERNIGHT at -20°C).**
2. If a container is partially full, fill out space inside container with clean plastic food wrap; ensure that each container is completely sealed and properly labeled.

DASH Manual of Procedures

3. Fill out a sample transfer form (#F001). Include all required information (see sample form included); **there should be one entry for each sample enclosed in the cooler.** Make a copy of the form for your records.
4. Place all containers in the cooler, then pack wads of brown paper, newspaper or other cushioning material around them.
5. 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.

6. Pack wads of newspaper or brown paper to fill out cooler and prevent movement.
7. Place completed sample transfer form (#F001), Deviation from SOP (Form(s) #F002), (if any), and a **copy** of the Unit Food Batch Preparation Log (Form #F031) in a sealed zip-lock bag (to protect from moisture), and place in cooler, on top.
8. Tightly seal the lid of the cooler with packing tape around seam.
9. 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.
10. Affix a pre-addressed pre-paid FedEx shipping label to the box, and send via Federal Express overnight delivery to FALCC:

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

11. **Notify FALCC of shipment, PRIOR TO SHIPPING: Phone (703) 231-4361 or FAX: (703) 231-9070 or E-mail: FALCC@VTVM1.CC.VT.EDU**

Procedures for collecting and analyzing unit foods

Sample collection

Each center will maintain a log of all unit food batch preparations for each feeding period. This log will include, for each batch, the date of preparation, unit food name, diet, and size of batch. Each center will randomly select one unit from every batch of unit food prepared for each of the three diets RED, YELLOW, and GREEN. If a center prepares only 1 batch for an entire feeding

DASH Manual of Procedures

cohort, they should send 10-12 unit foods for analyses. These unit batch samples will be collected together BY DIET into airtight containers labeled with center name, "Unit Foods", diet, and Cohort# and kept frozen at -20°C. At the end of each cohort feeding period, the collected unit foods will be shipped frozen, on dry ice, to the FALCC along with a copy of the batch preparation log sheet.

Composition and assay

The unit foods will be composited by cohort-center-diet (no separation by type of unit food). Thus 12 composites per cohort will be assayed (3 diets x 4 centers). The total number of constituent units and total weight of each composite will be documented.

Each unit food composite will be assayed for total fat, moisture, protein, ash, sodium, potassium, iron, calcium, and magnesium. Total fat as percent of total kcal (total kcal calculated from proximates) and mean kcal and mean sodium, potassium, iron, calcium, and magnesium per unit will be available as calculated values.

15. Food Procurement, Safety and Preparation

Food Procurement	3
Food Sources	3
Food Substitutions	4
Record Keeping	4
Maintaining Inventory	4
Ordering and Shipping Schedules	5
Billing Procedures	5
Food Safety	8
Introduction	8
Safety During Food Preparation and Serving	9
Off-site Food Safety	11
Participants' Responsibilities for "To Go" Foods	11
Food Preparation	11
Introduction	11
Weighing	12
First Weighing (beginning of each day)	12
Food Preparation Procedures	12

Summary of Edits

New changes in 2.0

- Renamed chapter *Food Procurement, Safety and Preparation*
- Moved *Weighing* from Chapter 16 to *Food Safety*
- Deleted *Storage* and renamed it *Food Safety*
- Moved *Food Safety* from Chapter 17
- Moved *Safe Food To Go* from Chapter 17 to after *Spices* (per Njeri's request)

New changes in 2.1

- Moved *Safety in Procuring, Storing, and Preparing Food* and all para to the end of the chapter under *Food Safety*
- Added new procedures under *Cooking*
- Moved *Safe Food To Go* and *To Protect Your Foods When On The Go* under *Food Safety*

New changes in 2.2

- Starting on page 3, new text for *Food Procurement*
- Starting page 5, new text for *Food Safety*
- Starting page 11, new text for *Food Preparations*
- Deleted tables and repeated cooking items
- New *Food Substitutions*

New changes in 4.0

- None

New changes in 4.1

- Added a paragraph in *Safe Food Preparation & Handling* section on foodborne diseases and added Common Foodborne Diseases (Table 15.6)
- Revised Table 15.1

DASH Manual of Procedures

Food Procurement

The purposes of this section are threefold: 1) to facilitate and document food procurement procedures at each center, 2) to provide a sample model for organizing food procurement and 3) to standardize ordering procedures for donated items.

Food Sources

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

Foods are procured from three primary sources: 1) donated items (mostly central procurement), 2) local distributors, and 3) retail food stores.

Donated Items

Eighteen companies have donated foods to the study. Each site will maintain a contact list which includes the companies, foods donated, and contact names and telephone numbers. Due to the personal nature of the information, this document is not included in the MOP but can be obtained by contacting the project lead dietitian.

Local Distributors

Purchased items and some donated items may be procured through local distributors. In selecting a distributor, consider number of food items carried, cost, and willingness to provide donated items free of charge, with a bill-back system to the donating company.

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.

A shopping list (with correct food items, brands, and package sizes) can be faxed or telephoned to the store in advance of the shopping. The store may have its own order form, or a specific DASH food order form may need to be developed. Guidelines for shopping for foods should be discussed in detail with the shopper so that substitutions do not occur.

Deliveries should be checked by study dietary personnel to verify full receipt of the order.

DASH Manual of Procedures

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

Food Substitutions

National brands were chosen over local brands during the menu planning process in DASH. This was done to standardize food sources and ensure continuous supplies throughout the study. A few of these brands are not available at some of the clinical sites. Table 15.5 (at end of chapter) lists all the DASH foods and brands in current use. When a specified brand is not available, an alternate brand should be chosen from Table 15.5 as a substitution. For example, the portion controlled grape juice from Libby’s and Minute Maid (page 1 of Table 15.5) may be interchanged with the Minute Maid brand, except the Minute Maid brand would need to be weighed since it is not sold in portion controlled containers.

Record Keeping

Record keeping for orders/deliveries will vary slightly depending on site-specific organization. It is recommended that each site have one notebook to track orders/deliveries from all sources. In the front of the notebook, an order/delivery schedule is suggested for easy reference (see example, Table 15.1). This should include, on a day to day basis, which orders need to be placed (to which company, with name and telephone number), and when deliveries are expected.

A table of contents page is included which outlines the sections of the notebook (Table 15.2). In each section, order forms used for each source are placed. For example, if a SYSCO order was placed on 1/1/95, it should be placed under SYSCO. When a shipment arrives, compare the order to the shipment and check that all items were received.

For donated items procured through a distributor or retailer, separate “donated” from “purchased” foods in your order forms.

For donated items which are shipped in bulk, use either of the “DASH Donation Tracking” forms (forms 16a and 16b). Some donating companies have their own order forms (ex: Comstock vegetables has separate order/fax form).

Maintaining Inventory

All foods should be securely locked. Storage of foods will vary from site to site, and inventory will likewise differ. However, inventory of items flows smoothly if it corresponds with ordering source. For example, an inventory of all SYSCO items can be placed on an “inventory” section of the SYSCO order form. It is recommended that for all foods (excluding perishable), a one-week’s supply be kept on hand. Depending on ordering schedules, sites can decide when to inventory their products.

DASH Manual of Procedures

Forecasting of needs is done easily using the product estimation computer program developed at Duke. This is found on the file server, as an excel file named **“dukefood.xls.”** Make sure to add fudge factors where necessary (e.g., with frozen vegetables).

Ordering and Shipping Schedules

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

Shipping schedules for products from McCormick, Hershey Co., and Campbell’s shelf-stable products are coordinated through the Brigham & Women’s Hospital (617-732-5861). McCormick and Hershey ship yearly in August, and Campbell’s sends shelf-stable items two or three times yearly (e.g., before each cohort). Preferred shipping schedules are listed on the table of contents (Table 15.2).

Purchased Items: The process for shipping and receiving with local food sources is worked out individually. For example, Boston receives retail foods with fresh produce twice weekly on a set schedule, and orders are placed with SYSCO distributors weekly.

Billing Procedures

Donated Items: Donating companies who ship directly to the sites will not send any bills. Donating companies who are providing products through a local source will either 1) allow to be back-billed by the source at the end of the cohort, or 2) reimburse a center for purchasing those items.

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

TABLE 15.1 DASH FOOD PROCUREMENT (EXAMPLE)

ORDER/DELIVERY SCHEDULE

(WEEKLY) DAY OF WEEK	SOURCE	CONTACT/NUMBER	DEL. DAY	DEL TIME
Tuesday	(order beef eye of rd & pork-teriyaki prep)	Polly ext. 7121, Call by 11:00 am	Wednesday	11:00 am CRC
Wednesday	Sysco PO CC 81044	Robin *Call by 5 pm	Thursday	~9:00 am ACC
	STAR Market	Greg or Bev 267-4684	Thursday	2:00 pm ACC
	Ardmore Farms/fz OJ	Polly by 11:00 am	Friday	8:00 am CRC
Friday	Sysco	as above	Monday	~9:00 am ACC
	STAR	as above	Monday	~2:00 pm ACC
(STANDING ORDERS)				
Pepperidge Farm	*Notify 3 days in advance	Don 508-832-9015	Monday	~9:00 am ACC
Milk	*Notify 3 days in advance	Charlie 1-800-628-8207	Monday	~10:00 am ACC

(ORDER AS NEEDED)

Comstock Vegetables	*FAX order 2 wks in advance using Comstock form	Peggy FAX: 716-383-8413		
SF butter pats	Beaver Meadows Pick up, cash payment \$35.00/case			
Wawona Frozen Fruit	notify day before p/u	Boston Gold Storage Donna or Jack @442-7207	Pick up	

(ORDERED VIA CRC)

Raw Chicken Breast	On hand, L-2	Give to staff at L-2	Available immediately
Kraft Salad Dressings Regular and Diet Syrup	order as needed	Polly X7121	

(JANIS/MEDFIELD)

Petty Cash
 Del Monte Chocolate Pudding - Shaw's, Stop & Shop
 Sunmaid Raisins - Shaw's
 Brach's Hard Candy and Jellybeans - Shaw's
 Sunmaid Fruit Tidbits - Stop & Shop
 Bachman's pretzels - 1 oz boxes - Stop & Shop

TABLE 15.2 DASH FOOD PROCUREMENT & DONATION TRACKING NOTEBOOK
TABLE OF CONTENTS

(*=Donated Items)

- I. ORDER/DELIVERY SCHEDULE
- II. STAR MARKET ORDERS
 - *Donations: Sunkist oranges, Dole bananas, Dannon yogurt, Quaker frozen, Arnold's breads
- III. SYSCO
 - *Donations: Ocean Spray juices, P.F. Cheese Danish
- IV. WEEKLY DELIVERIES (*Pepperidge Farm, Week's Milk)
- V. ORDER AS NEEDED - *COMSTOCK VEGETABLES
- VI. *SHIPMENTS EACH COHORT
 - Planter's Nuts and Seeds (Nabisco)
 - Campbell's Shelf Stable (pickles, gravies, Prego)
 - Minute Maid Juices
 - Ralston-Purina
- VII. *TWICE-YEARLY SHIPMENTS
 - Quaker
- VIII. *YEARLY SHIPMENTS
 - McCormick Spices
 - Royal Gelatin (Nabisco)
 - Hershey Pasta & Kit Kats
 - P&G - (Duncan Hines, Pringles, Tea & Jif)
 - Best Foods (Oil & Mayo)
 - Wawona Frozen Foods
 - Lifelines Technologies

DASH Manual of Procedures

Food Safety

Introduction

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

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

Each center is responsible for implementing appropriate procedures and training of 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/or 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 DASH 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 product to help guarantee the use of the oldest product first. Properly rotate foods.
- Keep potentially hazardous foods out of the dangerous temperature range of 45 - 140 degrees Fahrenheit.
- Use only designated areas for food storage space.
- Store only food packages and wrappers that are clean and free from dirt and spills.
- Keep storage areas clean and dry.

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° F. Most dry products will remain safe at temperatures of 60° to 70° F with a relative humidity of 50 - 60 percent. All food items should be placed off of the floor.

Refrigeration Storage

To prevent food borne illness outbreaks, store cold food items at 36° to 40° 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

DASH Manual of Procedures

that will receive no further cooking. Also, cover all foods in the refrigerator. To ensure proper holding temperatures, refrigerators should not be overloaded, preventing the circulation of air. Monitor refrigeration temperatures daily in each unit used on-site.

Freezer Storage

Freezer temperature must be maintained at or below 0° F. Between minus 10° and 0° 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.

Safety During Food Preparation and Serving

After the purchase and storage of foods, it is imperative that it be prepared and served safely. The greatest risk for contamination and temperature abuse is at this point in food production.

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. See form #15 for guidelines on monitoring food handlers.

Hand washing - Frequent and thorough hand washing is the most critical aspect of the personal 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.

Fingernails - To keep hands sanitary, fingernails need to be trimmed, unpolished, and cleaned.

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 (and/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.

Table 15.3 Principles of Time/Temperature Control of Potentially Hazardous Foods¹

1. *Cook food to a minimum temperature:*
 - 165° Poultry and Stuffing
 - 150° Pork
 - 140° Other entrees and casseroles
2. *Reheating foods for research diets:*
 - 165° minimum
3. *Cool foods (liquid formulas) rapidly to 45° in FOUR HOURS using:*
 - Shallow pans (2-3" depth)
 - Ice bath
 - Agitation
 - Loose fitting covers
 - No stacking
 - Placement of food in coldest part of cooling unit
4. *Equipment maintenance*
 - Refrigeration units 35° F - 45° F
 - Freezer units 0° F or below
5. *Provide thermometers to be used for checking foods for proper and safe temperatures.*

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 that has questionable freshness and/or safety is 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.

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.

DASH Manual of Procedures

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 (see Table 15.3).

Common symptoms of foodborne diseases caused by bacteria are nausea, cramps, diarrhea, vomiting, and headache. See Table 15.6 for a more detailed listing of symptoms and typical food carriers.

Off-site Food Safety

Feeding Sites' Responsibilities for "To Go" Foods

All feeding sites will do their best to provide safe and fresh food in "To Go" meals. All feeding sites are required to place a temperature strip either directly on perishable food items, or in the "To Go" container that contains perishable foods. This will serve as an indicator to the participants whether their perishable foods may be at risk of contamination. Feeding sites should instruct participants on the importance of timely refrigeration or freezing of the "To Go" foods once they leave the site. Sites will provide each participant with a copy of "Safe Foods To Go" (form #69).

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 will contact their feeding site whenever the freshness or safety of a food item is questionable.

Food Preparation

Introduction

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

DASH Manual of Procedures

Each center is responsible for implementing appropriate procedures and training of personnel to protect subjects from any food borne illness. "Critical control points are those areas in the chain of food production, from raw materials to finished products, where the loss of control can result in an unacceptable food safety risk."²

Critical areas to be addressed include treatment of foods and personal hygiene and health of the food handlers, as well as misuse of food taken off site by the subjects.

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 Carol Davis, NCL 301-504-8356.

First Weighing (beginning of each day)

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

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

Food Preparation Procedures

1. Meats

Weighing - All individual meat portions should be weighed to +/- .5 gram.

Defrosting - Defrost frozen meat in the refrigerator at a temperature not to exceed 50° F. Do not defrost in water or at room temperature.

Sanitation - Meat products, particularly poultry, are ideal for the growth of bacteria and food poisoning organisms. Raw meats should be handled carefully to avoid contamination of other food products. Separate cutting boards should be provided for cutting raw meats. Wash and sanitize any utensils, cutting boards, and counter tops that might have come in contact with uncooked meat.

² Ayers, op.ct. p.15

DASH Manual of Procedures

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 min. at 350° F.

Chicken, Pulled (Includes White and Dark Meat), Purchased Cooked, Frozen (Used for Chicken, Stewed) - Defrost in refrigerator overnight. Use in recipe as directed. Do not refreeze unused chicken.

Turkey, Deli Style, Cooked Breast, Smoked, Oscar Mayer - Slice turkey into approximate 1 oz. slices. Weigh into individual portions. Unopened package can be kept refrigerated until expiration date on package. When it is pulled for use, remove first slice. Turkey already sliced should be wrapped securely, labeled, dated, and refrigerated immediately. Sliced turkey can only be kept 3 days.

Beef, Eye of Round - Bake roast at 300° F to internal temperature of 145°F using a meat thermometer, 25-27 min. per lb. 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. Wrap unused beef securely, date, label, and refrigerate immediately. Do not keep cooked roast beef longer than 3 days. May be frozen.

Beef, Ground, Raw - Weigh into individual servings. Cook according to individual recipe instructions. Unused ground beef should be wrapped securely, dated, labeled and refrigerated. Do not keep longer than 3 days under refrigeration. May be frozen.

Beef, Ground, Frozen, Patties - Defrost in refrigerator (3-4 hours per lb). Cook in individual serving dishes.

Pork, Raw - Rinse raw pork loin under cold water. Pat dry.

2. Fish

Weighing - Fish should be weighed to +/- .5 gm.

Defrosting - Defrost frozen fish in refrigerator (1 lb / 3-4 hrs.). DO NOT REFREEZE.

Cod, Frozen - Defrost frozen fish in refrigerator. Pat dry with paper towel. Weigh portion into individual casserole dish. Follow recipe cooking instructions. Cook at 375° F for 8-12 min.

Tuna, Canned - Drain 5 minutes in colander. Weigh.

3. Vegetables

Weighing - All vegetables should be weighed to +/- .5 gm.

DASH Manual of Procedures

Storage - All vegetables should be refrigerated when not being prepared.

To cook vegetables in steamer, place vegetables in steamer pans and cook following steamer time table.

Frozen, Steamed - Tap vegetables to break up solid block. Steam vegetables in conventional steamer or in covered pot with steamer rack. Bring approximately 1 cup water to a boil in pot with a steamer rack, steam according to directions (see Table 15.4). Remove vegetables from stove, drain 5 minutes in colander, and weigh into individual portions. Refrigerate.

Table 15.4 Steaming Frozen Vegetables³

Vegetable	Cooking Time at 5 to 6 lbs pressure
Beans, baby lima	15 minutes
Beans, large lima	25 minutes
Beans, snap, green or wax	15 minutes
Broccoli spears, uncovered	10 minutes
Broccoli spears, covered	30 minutes
Cauliflower	5 minutes
Corn	4 minutes
Peas, green	5 minutes

Frozen vegetables should be cooked in their frozen state. Five-pound lots are the most that should be cooked at a time. Pans should be nonperforated shallow cafeteria pans (12 x 20 x 12 1/2 in.) or flat, narrow steam cooker pans. Most vegetables should be steam cooked uncovered for the approximate time specified below. Broccoli should be covered, if possible, to prevent loss of color. Material is available from equipment manufacturers giving recommended steaming times for their own equipment.

Canned - Wash top of can before opening. Drain vegetables in colander 5 minutes. Weigh directly into individual dishes or incorporate into recipe. Refrigerate.

Fresh - Wash fresh vegetables 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.

Spinach - Remove center stalk, wash and pat dry. Weigh into individual container.

³ The Professional Chef. The Culinary Institute of America and Institutions Magazine. 4th Ed. Folsom, L.A., Editor. LBS.

DASH Manual of Procedures

Raw greens (i.e. lettuce) - Remove outer leaves, wash, pat dry. Weigh into individual servings.

Tomatoes, peppers, celery, onions, zucchini, etc. - Wash, pat dry, weigh into individual servings as directed in recipe.

Baked Potatoes - Wash and scrub outside of potatoes. Pierce with fork. Bake 60 min. at 400° F. Remove from oven; cool 15 minutes. Weigh into individual portions.

4. Fruits

Weighing - Weigh to +/- .5 gm.

Storage - All fruits (except bananas) should be refrigerated when not being prepared.

Canned - Use individual portioned canned fruits as indicated.

Frozen - Defrost in refrigerator enough to break up. Weigh into serving dish.

Fresh - Banana - 32% refuse factor is reflected in the portion weight. Weigh with skin on. Cut from the stem end. Dip end in lemon juice. Wrap end in plastic wrap. (Ex. 100 gm banana = 132 banana with skin.

Apple - Keep refrigerated. Do not weigh. Use 1 whole, size 113 count (138gm). Wash & dry thoroughly.

Orange - Keep refrigerated. Do not weigh. Use 1 whole, size 138 count (140gm).

5. Pastas, Cereals, Grains

Rice, White, Cooked - Weigh uncooked rice according to amount needed and recipe proportion. Bring water to a 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. Weigh into individual servings.

100 gm uncooked white rice + 250 ml water = 295.7 gm. cooked rice (avg. of 297.5, 294, 295.6)

Rice, Brown, Cooked - Weigh uncooked rice according to amount needed and recipe proportion. Bring water to a 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. Weigh into individual servings.

100 gm uncooked brown rice + 250 ml water = 288 gm cooked rice. (avg. of 260.4, 294.3, 310.4)

DASH Manual of Procedures

Spaghetti - Weigh uncooked spaghetti according to amount needed and recipe proportion. Bring (500 gm dry/3 l. H₂O) water to a 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 (avg. of 258.4, 253.8, 258.2)

Macaroni, Cooked - Weigh uncooked macaroni according to amount needed and recipe proportion. Bring (500 gm dry / 3 l. H₂O) water to a boil. Add dry, weighed macaroni. Stir. Return to boil and boil uncovered 10 minutes. Drain in colander. Rinse 2 min. with cold water to cool. Drain 3 minutes. Weigh individual portions.

100 gm. uncooked egg noodles = 269.5 gm cooked macaroni (avg. of 281.5, 265.1, 262.1)

Egg Noodles, Cooked - Weigh uncooked egg noodles according to amount needed and recipe proportion. Bring (500 gm dry/3 l/ H₂O) water to a boil. Add dry, weighed noodles. Stir. Return to boil and boil uncovered 6 minutes. Drain in colander. Rinse with cold water 2 minutes to cool. Drain 3 minutes. Weigh individual portions.

100 gm uncooked egg noodles = 220 gm cooked noodles (avg. of 220.3, 225.3, 214.3)

Cereals (Breakfast & Wheat Germ) - Weigh or use portioned controlled box as directed. Weighed cereals should be stored in tightly sealed containers to avoid getting stale or soggy.

6. Bread Products

Bread, rolls, cookies, crackers, muffins waffles, pancakes, croissants

Weighing - All bread products are weighed to +/- .5 gm.

Storage - Bread products may be prepared and weighed ahead and frozen based upon acceptability.

Precooked (Bread, rolls, cookies, crackers) - Weigh as to individual serving. Package and seal.

Recipe, uncooked (Muffins, cornbread, gingerbread, unit foods) - Weigh raw batter into individual muffin tins as directed. Package and seal.

Frozen (Waffles, pancakes, croissants) - Remove from freezer. Weigh into individual portions. Package and seal.

7. Milk & Dairy Products

DASH Manual of Procedures

Weighing - Weigh to +/- .5 gm

Storage - Refrigerate and cover at all times. Label opened containers with date opened. Discard after 5 days.

Milk - Weigh directly into individual glass or container.

Cheese - Weigh and package. Keep refrigerated.

Sour Cream - Weigh directly into individual containers.

Yogurt - Use as portion controlled as indicated.

8. Fats and Oils

Weighing - Quantities > 10 gm weigh to .5 gm. Quantities < 10 gm weigh to .1 gm.

Storage - Oils do not have to be refrigerated. Olive oil may congeal at refrigeration temperatures. Butter, margarine, and opened mayonnaise containers should be refrigerated at all times.

All fats and oils will be weighed into individual portions or as recipe indicates.

Butter, margarine, and mayonnaise are portion-controlled packaging (pc's).

9. Spices and Condiments

Weigh to nearest .1 gm. Add to recipe.

DASH Manual of Procedures

Table 15.5 Food Substitution List

FOOD ITEM/WEIGHT/DESCRIPTOR	WEIGH	PC/WT	DESCRIPTION	BWH	JH	PEN	DKE
BEVERAGES							
Grape juice, unsweetened, 134g pc			Minute Maid				
Grape juice, unsweetened, pc		125 ml	Libby's Juice-Juice	X	X		
Grape juice, unsweetened	X		Minute Maid			X	
Grape juice, unsweetened, fz, pc		120 ml	Sysco				X
Grape juice, unsweetened, 267g pc			Minute Maid				
Grape juice, unsweetened		? 250 ml	Minute Maid	X	X	X	X
Cranberry juice cocktail, 126g pc			Ocean Spray				
Cranberry juice cocktail		118	Ocean Spray	X	X	X	X
Cranberry juice cocktail, 267g pc			Ocean Spray				
Cranberry juice cocktail		250 ml	Ocean Spray	X	X		X
Cranberry juice cocktail	X		Ocean Spray			X	
Tropical Fruit punch drink, 134g pc			Minute Maid				
Tropical Fruit punch	X		Minute Maid	X		X	X
Mixed Fruit Juice		125 ml	McCain		X		
Tropical Fruit punch drink 267g pc		250 ml	Minute Maid	X	X	X	X
Apple juice, unsweetened, 126g pc		118 ml	Ocean Spray	X		X	
Apple juice, unsweetened		125 ml	Libby's Juicy Juice		X		
Apple juice, unsweetened, fz, pc		120 ml	Sysco				X
Apple juice, unsweetened, 267g pc		250 ml	Minute Maid	X	X	X	X
Orange juice, unsweetened, 134g pc	X		Minute Maid			X	
Orange juice, unsweetened, fz, pc		120 ml	Ardmore Farms	X	X		
Orange juice, unsweetened, fz, pc		120 ml	Sysco				X
Orange juice, unsweetened, 267g pc			Minute Maid				
		250 ml	Minute Maid	X	X	X	X
Apricot nectar, 170.5g can		165 ml	Libby's	X	X	X	X
Prune juice, 170.5g pc/can		163 ml	Sunsweet	X	X	X	X
Lemonade flavor drink powder	X		Koolaid	X	X	X	X
Fruit punch flavor drink powder	X		Koolaid	X	X	X	X

DASH Manual of Procedures

FOOD ITEM	WEIGH	PC/WT	DESCRIPTION	BWH	JH	PEN	DKE
DAIRY PRODUCTS							
Yogurt, lowfat, 12g pro/8oz, plain		X	Dannon	X	X	X	X
Yogurt, lowfat, 9g pro/8oz, blueberry		X	Dannon	X	X	X	X
Yogurt, lowfat, 9g pro/8oz, peach		X	Dannon	X	X	X	X
Yogurt, blended, FF, straw-banana 4 oz		X	Dannon	X	X	X	X
Yogurt, blended, FF, peach 4 oz		X	Dannon	X	X	X	X
Cheese, parmesan, grated	X		Kraft	X		X	X
Cheese, parmesan, grated, pc		3.5g	M Love Joy		X		
Cheese, processed American	X		Kraft	X	X	X	X
Cheese, Swiss	X		Kraft	X	X	X	X
Cheese, cheddar, mild	X		Kraft	X	X	X	X
Milk, Whole							
Milk, whole, 240 ml, pc		240 ml	Greenspring Dairy		X		
Milk, whole, 240 ml, pc		240 ml	Hood's Dairy	X			
Milk, 1%, 120-122 ml	X					X	X
Milk, 1%, 120 ml, pc		120 ml	Greenspring Dairy		X		
Milk, 1%, 120 ml, pc		120 ml	Hood's Dairy	X			
BREADS/CEREALS/GRAINS							
Corn Flakes, 19.6g box		21 g	Kellogg's	X	X	X	X
Cereal, sugar frosted flakes, 30g pc		X	Kellogg's	X	X	X	X
Oatmeal, instant, cinn & spice, 46g pkt		X	Quaker	X	X	X	X
Bran Chex	X		Ralston Purina	X	X	X	X
Bran Flakes	X		Kellogg's Compete	X	X	X	X
Corn grits, instant, 1 oz pc		X	Quaker	X	X	X	X
Oat-Honey granola bar	X		Nature Valley	X	X	X	X
Blueberry muffins, dry mix	X		Duncan Hines	X	X	X	X
Oat bran muffins, dry mix	X		Pillsbury	X	X	X	X
English muffins	X		Pepperidge Farms	X	X	X	X
Cornbread muffins, dry mix	X		Jiffy	X	X	X	X

DASH Manual of Procedures

FOOD ITEM	WEIGH	PC/W T	DESCRIPTION	BWH	JH	PEN	DKE
BREADS/CEREALS/GRAINS, cont'd.							
Danish pastry, cheese	X		Pepperidge farm		X		X
	X		Sara Lee	X	X	X	
Waffles, frozen	X		Aunt Jemima	X	X	X	
Pancakes, frozen	X		Pillsbury			X	X
	X		Aunt Jemima	X	X		
Bread, white	X		Arnold's	X	X	X	X
Bread, wheat	X		Arnold's	X	X	X	X
Bread, wheat (last 3 wks, cohort 1)	X		Pepperidge Farm		X		
Bread, French	X		Pepperidge Farm	X	X	X	X
Bread, country dinner rolls	X		Pepperidge Farm	X	X	X	X
Bread, pita white	X		Sahara	X	X	X	X
Bread, sandwich roll, sesame	X		Pepperidge Farm	X	X	X	X
Spaghetti	X		Ronzoni	X	X	X	X
Macaroni	X		Ronzoni	X	X	X	X
Rice, brown, long grain	X		Uncle Ben's	X	X	X	X
Rice, white, long grain	X		Uncle Ben's	X	X	X	X
Crackers, saltines		X	Premium	X	X	X	X
Wheat germ, crude	X		Kreischner	X		X	
Wheat germ	X				X		
Wheat germ	X		Bulk				X
FATS/OILS							
Butter, salted, 5g pc		5 g	Land O' Lakes	X		X	
Butter, salted, 5g pc		5 g	Beaver Meadows		X		
Butter, salted, 5g pc		5 g	Sysco				X
Butter, unsalted, 5g pc			Land O' Lakes	X			
Butter, unsalted, 5g pc		5 g	Beaver Meadows	X	X		
Butter, unsalted, 5g pc		5 g	Sysco				X
		5 g	Grassland			X	
Margarine, soft, 5g pc		X	Promise	X	X	X	X
Oil, safflower	X		Hollywood	X	X	X	X
Oil, olive	X		Pompeian	X	X	X	X
Oil, corn	X		Mazola	X	X	X	X

DASH Manual of Procedures

FOOD ITEM	WEIGH	PC/W T	DESCRIPTION	BWH	JH	PEN	DKE
FATS/OILS, cont'd.							
Mayonnaise, 12g pc		X	Hellman's	X	X	X	X
Mayonnaise, FAT FREE, 12g pc		X	Kraft	X	X	X	X
VEGETABLES							
Cauliflower, frozen	X		Comstock	X	X	X	X
Cauliflower, fz	X		Sysco				X
Carrots, frozen	X		Comstock	X	X	X	X
Carrots, fz	X		Sysco				X
Broccoli, frozen	X		Comstock	X	X	X	X
Broccoli, fz	X		Sysco				X
Peas, frozen	X		Comstock	X	X	X	X
Peas, fz	X		Sysco				X
Spinach, frozen	X		Comstock	X	X	X	X
Spinach, fz	X		Sysco				X
Zucchini, frozen	X		Comstock	X	X	X	X
Zucchini, fz	X		Sysco				X
Green beans, frozen	X		Comstock	X	X	X	X
Green beans, fz	X		Sysco				X
Turnip greens, frozen	X		Comstock	X	X	X	X
Turnip Green, fz	X		Sysco				X
Lima beans	X		Comstock	X	X	X	X
Lima beans, fz	X		Sysco				X
Spinach, raw			Dole				
	X		Local	X	X	X	X
Lettuce, iceberg			Dole				
	X		Local	X	X	X	X
Lettuce, loose-leaf			Dole				
	X		Local	X	X	X	X
Carrots, raw			Dole				
	X		Local	X	X	X	X
Beans, kidney, red, cnd	X		Progresso	X		X	
Beans, kidney, red, cnd	X		Vancamp's		X		X
Beans, snap green, cnd	X		Del Monte	X	X	X	X
Beans, snap yellow, cnd	X		Del Monte	X	X	X	X
Sweet potatoes, cnd	X		Bush's/Trappy's			X	
Sweet potatoes, cnd	X		Royal Prince	X			
Sweet potatoes, cnd	X		Sysco		X		X
Tomatoes, stewed, cnd	X		Hunt's	X	X	X	
Tomatoes, stewed, cnd	X		Del Monte				X
Spaghetti sauce	X		Prego	X	X	X	X
Tomato sauce, canned	X		Hunts	X	X	X	X

DASH Manual of Procedures

FOOD ITEM	WEIGH	PC/W T	DESCRIPTION	BWH	JH	PEN	DKE
VEGETABLES, cont'd.							
Tomato paste, canned	X		Hunts	X	X	X	X
Squash, summer, fresh	X		Local	X		X	X
Summer squash, frozen	X		Sysco		X		
Onions, scallions, raw	X		Local	X	X	X	X
Peppers, raw	X		Local	X		X	X
Peppers, frozen chopped	X			X	X		
Garlic, raw - general produce	X		Local			X	X
Garlic, chpd, jar	X		Polamer	X	X		
Onions-general produce	X			X		X	X
Onions, chopped, frozen	X						
Tomatoes - general produce	X			X	X	X	X
Potatoes, raw - general produce	X		Idaho	X	X	X	X
Celery - general produce	X			X		X	X
FRUITS							
Melon balls, frozen	X		Wawona	X	X	X	X
Peaches & strawberries, frozen	X		Wawona	X	X	X	X
Peaches, frozen	X		Wawona	X	X	X	X
Blackberries, frozen	X		Wawona	X	X	X	X
Fruit cocktail, cnd lite syrup 120 pc		X	Del Monte	X	X	X	X
Banana	X		Dole	X	X	X	X
Oranges, California navel, 88 ct		X	Sunkist			X	
			Any available	X	X		X
Dried fruit mix, Fruit Tidbits	X		Sunmaid	X	X	X	X
Raisins, seedless	X		Sunmaid			X	X
Raisins, seedless 1 oz & 1/2 oz pc		X	Sunmaid	X			
Apricots, dried			Sunbird				
Apricots, dried	X		Del Monte			X	
Apricots, dried	X		Bulk				X
Apricots, dried	X		Sysco		X		
Apricots, dried	X		Mariani	X		X	
Dates, dried	X		Dromedary	X			X
Dates, dried	X		Ann's House of Nuts		X		
Dates, dried	X		Dole			X	

DASH Manual of Procedures

FOOD ITEM	WEIGH	PC/W T	DESCRIPTION	BWH	JH	PEN	DKE
CONDIMENTS/SPICES							
Pickles, cucumber dill	X		Vlassic	X	X	X	X
Pickle relish, sweet	X		Vlassic	X	X	X	X
Lemon Juice	X		Real Lemon	X		X	X
Lemon juice, pc		3.5 g	Real Lemon		X		
Mustard, 5g pc		X	Heinz	X	X	X	X
Catsup, 12g pc		X	Heinz	X	X	X	X
Cinnamon	X		McCormick	X	X	X	X
Parsley flakes	X		McCormack	X	X	X	
Parsley, fresh	X		Fresh				X
Pepper, black			McCormack	X	X	X	X
Onion powder			McCormack	X	X	X	X
Dressing, French, 12g pc		X	Kraft	X	X	X	X
Dressing, Italian, reg	X		Kraft	X	X	X	X
Dressing, Italian, 12g pc		X	Kraft	X	X	X	X
Barbecue sauce	X		Kraft	X	X	X	X
Bouillon, chicken granules	X		Wylers	X	X	X	X
Bouillon, beef granules	X		Wylers	X	X	X	X
Gravy, turkey, cnd	X		Franco American	X	X	X	X
Gravy, beef, cnd	X		Franco American	X	X	X	X
Maple Syrup 28g pc			Smuckers				
Syrup		32 g	Smuckers	X		X	
Syrup		30 ml	Smuckers		X		
Syrup	X		Mrs. Butterworth's				X
Syrup, reduced cal, imitation		X	Sysco		X		
Salt							
Salt, pc (NaCl)		0.5 g	Kraft	X	X		X
Sugar, granulated, 4g pc							
Sugar, gran, pc		4 g	Kraft	X			X
Sugar, gran, pc		4 g	Domino		X		
Jelly, 14 g pc							
Jelly, 14 g pc		X	Heinz	X			
Jelly, 14 g pc		X	Kraft				X

DASH Manual of Procedures

FOOD ITEM	WEIGH	PC/W T	DESCRIPTION	BWH	JH	PEN	DKE
CONDIMENTS/SPICES, cont'd.							
Marmalade, 14 g pc		X	Kraft	X	X		
Jam, 14g pc		X	Smuckers	X			
Jam, 14g pc		X	Kraft				X
Sugar-free Jelly, 14 g pc		14 g		X			X
Sugar-free jelly pc		14 g	Elwood		X		
Vinegar							
Vinegar	X		Heinz		X		X
	X		Kraft	X			
MEATS/FISH/FROZEN ENTREES							
Ham, smoked, boneless, 96% FF	X		Oscar Mayer	X	X	X	X
Ham, chopped, 85% FF	X		Oscar Mayer	X	X	X	X
Turkey breast, Hickory Smoked	X		Louis Rich		X	X	X
			Marvel	X			
Canadian bacon	X		Hormel	X	X	X	
Sausage, pork links	X		Hormel little sizzlers	X	X	X	
		1=2 oz	Hormel little sizzlers				X
Tuna fish, light meal in oil	X		Starkist	X	X	X	X
Tuna fish, light meat in water	X		Starkist	X	X	X	X
Tuna, light meat, water	X		Empress				X
Turkey pastrami, 96% FF	X		Louis Rich			X	
Turkey pastrami, 99% FF	X		Sara Lee		X		
Turkey pastrami, 96% FF	X		Marvel	X			
Turkey pastrami, 96% FF	X		Pudue				X
Zucchini lasagna, 311.8g, frozen, ea		X	Lean Cuisine, Stouff	X	X		X
Lasagna with meat sauce		X				X	
Chicken pot pie, frozen, ea		X	Swanson	X	X	X	X
Pizza, French bread deluxe, fz	X		Stouffers	X	X	X	X
Beef, ground, 20% fat, raw - local distrib	X		Sysco		X	X	
Beef, ground, 20% fat, raw - local distrib	X		Kinnealley	X			
Beef, ground chuck	X		Local				X
Pork, center loin, lean, raw - local distrib	X		Sysco		X	X	
Pork, center loin, lean, raw - local distrib	X		Local				X
Pork, center loin, lean, raw - local distrib	X		Kinealley	X			
Beef, eye of round, raw - local distrib	X		Sysco			X	
Beef, bottom round, raw - local distrib	X				X		
Beef, bottom round, raw - local distrib	X		Kinnealley	X			

DASH Manual of Procedures

FOOD ITEM	WEIGH	PC/W T	DESCRIPTION	BWH	JH	PEN	DKE
MEATS/FISH/FROZEN ENTREES, cont'd.							
Beef, bottom round, raw - local distrib	X		Local				X
Chicken, broilers or fryers, white mt, raw	X		Sysco		X	X	
Chicken, white mt, raw, local distrib	X			X			X
Beef, ground beef patties, fz, 25% fat, raw local distrib			Sysco	X	X	X	X
Cod, fz, loins, raw local distrib			Sysco	X	X	X	X
Turkey, light meat, ckd							
Turkey, light meat, ckd	X		Louis Rich, SF	X			
Turkey, light meat, ckd	X		Louis Rich		X		
Turkey, light meat, ckd	X		Kraft, Prestige				X
Chicken pulled, fz, ckd	X		Sysco	X	X	X	X
Chicken, pulled, fz, ckd	X		Biggers Bros.				X
DESSERTS/SNACKS							
Candy, sour balls, 5g pc		X	Brachs	X	X	X	X
Jelly beans		X	Brachs	X	X	X	X
Candy, Kit Kats		ea	Kit Kat	X	X	X	X
Candy, Snickers bar	X	ea	Snickers	X	X	X	X
Cake, pound-All butter	X		Sara Lee	X	X	X	X
Yellow cake mix	X		Duncan Hines	X	X	X	X
Brownie mix	X		Duncan Hines	X	X	X	X
Pumpkin pie, frozen - custard style	X		Mrs. Smith's	X	X	X	X
Graham crackers, plain or honey		X	Nabisco	X	X	X	X
Animal crackers, bx		bx	Nabisco, Barnums	X	X	X	X
Cookies, chocolate chip		ea	Nabisco, Chips Ahoy	X	X	X	X
Gelatin, sugar free strawberry	X		Royal	X	X	X	X
Dessert topping, nondairy	X		Cool Whip	X	X	X	
Frosting, chocolate	X		Duncan Hines	X	X	X	
Frosting vanilla	X		Duncan Hines	X	X	X	X
Pudding, chocolate, 114g pc		X	Del Monte	X	X	X	X

DASH Manual of Procedures

FOOD ITEM	WEIGH	PC/W T	DESCRIPTION	BWH	JH	PEN	DKE
DESSERTS/SNACKS, cont'd.							
Pretzels, salted, pc		1 oz	Bachman	X			
Pretzels, salted	X		Mr. Salty			X	
Pretzels, salted, pc		1 oz	Giant		X		
Potato chips, salted	X		Pringles	X	X	X	X
Almonds, blanched	X		Dole	X			
Almonds, blanched	X		Blue Diamond		X		
Almonds, blanched	X		Bulk				X
Almonds, blanched	X		Sysco			X	
Peanuts, salted	X		Planters	X		X	X
Mixed nuts, salted	X		Planters	X		X	X
Popcorn, microwave, salted	X		Bachman/Pop Secret			X	X
Popcorn, microwave, salted	X		Pop Secret	X	X		

Table 15.6 Common Foodborne Diseases Caused by Bacteria

Disease (causative agent)	Principal Symptoms	Typical Foods
<i>(Bacillus cereus)</i> food poisoning, diarrheal	Diarrhea, cramps, occasional vomiting	Meats products, soups, sauces, vegetables
<i>(Bacillus cereus)</i> food poisoning, emetic	Nausea, vomiting, sometimes diarrhea and cramps	Cooked rice and pasta
Botulism; food poisoning (heat-labile toxin of <i>Clostridium botulinum</i>)	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 infestation	Constipation, weakness, respiratory failure, sometimes death	Honey, soil
Campylobacteriosis <i>(Campylobacter jejuni)</i>	Diarrhea, abdominal pain, fever, nausea, vomiting	Infected food-source animals
Cholera <i>(Vibrio Cholerae)</i>	Profuse, watery stools; sometimes vomiting, dehydration, often fatal if untreated	Raw or undercooked seafood
<i>(Clostridium perfringens)</i> food poisoning	Diarrhea, cramps, rarely nausea and vomiting	Cooked meat and poultry
<i>(Escherichia coli)</i> foodborne infections enterohemorrhagic	Watery, bloody diarrhea	Raw or undercooked beef, raw milk
<i>(Escherichia coli)</i> foodborne infections enteroinvasive	Cramps, diarrhea, fever, dysentery	Raw foods
<i>(Escherichia coli)</i> foodborne infection enterotoxigenic	Profuse watery diarrhea; sometimes cramps, vomiting	Raw foods
Listeriosis (<i>Listeria monocytogenes</i>)	Meningoencephalitis; stillbirths, septicemia or meningitis in newborns	Raw milk, cheese and vegetables
Salmonellosis <i>(Salmonella species)</i>	Diarrhea, abdominal pain, chills, fever, vomiting, dehydration	Raw, undercooked eggs; raw milk, meat and poultry

DASH Manual of Procedures

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

16. Energy Assignment

Energy Assignment And Adjustment	3
Energy Assignment	3
Energy Adjustment	4

Summary of Edits

New changes in 2.1

- Renamed chapter to Energy Assignment
- Deleted *Weighing* and moved to Chapter 15
- Deleted *Records and reports* and moved to Chapter 17
- Deleted *Discretionary beverages and seasonings*.
- Deleted *Procedures for dealing with diet refusals and spillage* and moved to Chapter 18

New changes in 2.2

- Misc changes and additions to entire chapter

New changes in 4.0

- none

New changes in 4.1

- Under Energy Adjustment, the sentence about target weights should define the average of weights taken at SV3 and the first THREE days of run-in.
- Table 16.3 has been corrected.
- In Table 16.4, all references to “2 lb” have been changes to “1 kg.”

DASH Manual of Operations

Energy Assignment And Adjustment

Energy Assignment

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 16.1) using the weight taken at SV3. Physical activity levels will be estimated by a 7-day Physical Activity Recall Interview administered at SV3 (see chapter 9). The physical activity questionnaire overestimates energy needs for participants with energy needs above 3500 kcal. To offset this bias, the activity factor estimated by the exercise questionnaire should be adjusted using information shown in table 16.2.

Table 16.1 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	$(15.3 \times \text{wt}^c) + 679$	0.65	151
	>30-60	$(11.6 \times \text{wt}) + 879$	0.60	164
	>60	$(13.6 \times \text{wt}) + 487$	0.79	148
Female	18-30	$(14.7 \times \text{wt}) + 496$	0.72	121
	>30-60	$(8.7 \times \text{wt}) + 829$	0.70	108
	>60	$(10.5 \times \text{wt}) + 596$	0.74	108

^aFrom WHO (1985). Technical Report Series 724.

^bCorrelation coefficient (R) of reported BMRs and predicted values, and standard deviation (SD) of the differences between actual and computed values.

^cWeight of person in kilograms.

Table 16.2 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

^dBased on traditional factors used to adjust energy needs for physical activity (ref.).

DASH Manual of Operations

The above WHO formulae are programmed into the computerized data entry system, as well as the calculation of physical activity factor. Thus, once the SV3 weight and physical activity data are entered into the laptop, 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 four caloric levels that were used for menu development (1600, 2100, 2600, and 3100). An additional level of 3700 Kcal, combining 1600 Kcal and 2100 Kcal, was also created to accommodate higher caloric needs. Table 16.3 depicts the guideline for energy assignment.

Table 16.3 Guideline for Energy Assignment

Calculated Energy Requirement (Kcal)	Assigned Menu Energy	Supplement of Unit Foods
Kcal \leq 2000	1600 Kcal	as needed up to 400 Kcal
2000 <Kcal \leq 2500	2100 Kcal	as needed up to 400 Kcal
2500 <Kcal \leq 3000	2600 Kcal	as needed up to 400 Kcal
3000 <Kcal \leq 3600	3100 Kcal	as needed up to 500 Kcal
Kcal > 3600	3700 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 unit foods. Since unit 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 unit foods, an additional 200 Kcal of unit 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. The target weight for the run-in period (initial weight) is defined as the average of weights taken at SV3 and the first three days of run-in. The target weight for the

DASH Manual of Operations

intervention period (baseline weight), however, is defined as the average weight of the last 13 days of run-in.

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 monitoring. See weekly monitoring (energy adjustment) form (Form #17a).

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 ($\pm 2\%$ of the target weight), caloric adjustment will be made using Table 16.4 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 16.4 Guideline for Energy Adjustment

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

17. Diet Training and Quality Assurance

Training Module 1 - Dietary Screening	4
Overview	4
Training Activities	4
Training Sequence	4
Performance Objectives	5
Overall Objectives	5
Specific Objectives	5
Training Materials and Curriculum	6
Training Materials	6
Training Curriculum	7
Training Module 2 - Food Acquisition	8
Overview	8
Training Activities	8
Recordkeeping	8
Acquisition of Donated Foods	8
Training Module 3 - Orientation	10
Overview	10
Training Activities	10
Performance Objectives	10
Training Materials	10
Training Module 4 - Compliance Assessment	11
Overview	11
Training Activities	11
Training Sequence	11
Performance Objectives	12
Overall Objectives	12
Specific Objectives	12
Training Materials	13
Role Playing Guide for Good Communication	14
Compliance Assessment Quality Control Activities	16
Training Module 5 - Food Preparation and Distribution	
Overview	17
Training Activities	17
Training Sequence	17
Performance Objectives	18
Overall Objectives	18
Specific Objectives	18
Training Materials and Curriculum	19
Training Materials	19
Training Curriculum	19
Food Preparation and Safety Quality Control Activities	21
Training Module 6 - Exit Interview	23
Overview	23
Training Activities	23

DASH Manual of Procedures

Training Sequence _____	23
Performance Objectives _____	24
Overall Objectives _____	24
Specific Objectives _____	24
Training Materials and Curriculum _____	24
Training Materials _____	24
Training Curriculum _____	25

DASH Manual of Procedures

Summary of Edits

New changes in Version 4.1

- Completely new chapter; old chapter has been deleted

DASH Manual of Procedures

Training Module 1 - Dietary Screening

Overview

Procedures for screening DASH participants are outlined in chapters 7, 8, and 9 of the DASH 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.

Training Activities

The lead trainer at each site should follow procedures outlined in this module to orient all new staff who conduct screening. The module should also be used to certify staff once a year.

Training Sequence

1. Review performance objectives with staff person being trained (Training Module 1, Dietary Screening Performance Objectives)
2. Ask trainee to review the relevant MOP chapters outlined under “Training Materials” below.
3. Conduct training in the sequence identified under “Training Curriculum” below.
4. Assess the performance of each trainee using the Screening Performance Evaluation Module 1 provided separately.
5. Complete a separate Dietary Screening QA checklist (Form #11a) for each trainee. This form is to be stored at each site for audit purposes.
6. Complete the Dietary Screening Certification (Form #72) for each staff member trained and mail to the coordinating center.

DASH Manual of Procedures

Performance Objectives

Overall Objective

At the completion of this module, the DASH staff person will be able to explain the main uses of the four dietary screening forms, to administer them to participants, and conduct all required editing of these forms. Each staff person will be evaluated by the lead nutritionist using the *Dietary Screening QA Checklist (Form 11a)*.

Specific Objectives

1. State the primary uses of the General Dietary Information Questionnaire (Form # 28) and the Study Food Checklist (Form #06).
2. Explain the purpose of each of the sections in Forms # 28 and # 06.
3. State the primary uses of the Food Frequency Questionnaire (FFQ) (Form #11).
4. Explain the purpose of each of the 4 sections of the FFQ.
5. Distribute the FFQ and other forms to participants according to procedures specified in the DASH Manual of Operations. The specific procedures are found in the instructions to Form #11 "Instructions for processing the FFQ."
6. Conduct a pre-mailing review of the FFQ in accordance with procedures specified in the DASH Manual of Operations. The specific procedures are found in the instructions to Form #11 "Instructions for processing the FFQ."
7. Learn how to conduct a post-coding FFQ interview with participants using non-leading questions and answer participant questions as outlined in the DASH Manual of Operations. The specific procedures are found in the instructions to Form #11 "Instructions for processing the FFQ."
8. Explain how the *Dietary Screening QA Checklist (Form #11a)* will be used to monitor quality assurance of dietary assessment throughout the trial.

DASH Manual of Procedures

Training Materials and Curriculum

Training Materials

- Dash MOP Chapter 7
- Dash MOP Chapter 8
- Dash MOP Chapter 9
- Form #06 - Study Food Checklist and instructions
- Form #11 - Food Frequency Questionnaire and instructions
- Form #28 - General Dietary Information Questionnaire and instructions
- Form #62 - Lay menus
- Form #11a - Dietary Screening Quality Assurance Checklist

DASH Manual of Procedures

Training Curriculum

Sequence	Training Curriculum	Time frame
1.	Discuss the primary uses of the General Dietary Information form, the Study Food Checklist, and study menus	20
2.	Review all three forms directly, explaining each major section	5
3.	Discuss the uses, criteria for development, and schedule for completing the FFQ	10
4.	Review structure of FFQ Restaurant eating and special diets (Q1&2) Individual food items (Q3) Open-ended Questions (Q4) Summary questions (Q5-11) Weight cycling (Q12-14)	15
5.	Review procedures for distributing the FFQ (Pg 2-5 of form 11 instructions)	15
6.	Review procedures for checking returned FFQs Cursory Review Pre-mailing Review	10
7.	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
8.	Post-coding interviews with participants (asking non-leading questions)	15
9.	Review Form 11a <i>Dietary Screening QA Checklist</i> and how it will be used to monitor quality at each site. Review Performance Evaluation Module 1. The trainee should complete the evaluation module separately.	20
	Total Time	2.0 hours

DASH Manual of Procedures

Training Module 2 - Food Acquisition

Overview

The goal of this function is to develop a system of maintaining food inventory such that the possibility of running out of required items is reduced. An electronic program for predicting required food items, based on participant census, is available at each site. Use this program to plan shopping lists for each week.

Training Activities

Because food acquisition procedures are different at each site, the major activity of this module should be to familiarize the trainee with the procedures for your site.

Recordkeeping

The following records should be kept at all feeding sites to provide documentation of appropriate food acquisition for the DASH Trial:

1. Purchased Foods: Acquisition of purchased foods should be documented and receipts filed. This provides both documentation of costs of food for the trial *and* records of acquisition of appropriate purchased items.
2. Donated Foods: Delivery of donated foods should be recorded on either the food donation tracking forms or other site-specific records. It is important to know how much and when each donated item was received.
3. Substitutions: Any time a substitution is used, the site should record this on the Food Substitution Record (Form #78). Sites will be asked to review *new* substitutions (both permanent and temporary) during conference calls. Marji McCullough will keep the Coordinating Center aware of any additions to the official "Substitutions List," which is table 15.5 of MOP Chapter 15.
NOTE: Through cohorts 1,2,and 3, substitutions are only formally noted on composite forms, and however each site has chosen to document substitutions.
4. Inventory control: It is recommended that each site develop a system of taking inventory at least once a month during each cohort to further assess needs and ensure that inventory is not being lost.

Acquisition of Donated Foods

Refer to Form #70 when ordering donated foods. Please note which companies prefer yearly shipments and which can provide per cohort. Requests for yearly deliveries should be made by July 31, 1995 for the 1995-1996 delivery.

DASH Manual of Procedures

Also note that Marji McCullough at the Brigham & Women's Hospital orders the donated items FOR ALL SITES for Hershey's, McCormick Spices, and Coca-Cola (Minute Maid).

DASH Manual of Procedures

Training Module 3 - Orientation

Overview

Procedures for conducting the orientation session are outlined in chapter 10 of the DASH MOP.

Training Activities

1. Review orientation performance objectives with trainee.
2. Administer and evaluate the trainee using the orientation quiz provided in the performance evaluation Module 2.
3. Complete the Orientation Quality Assurance Checklist (Form 79) and store with other QA pieces at your site. Mail a copy to the coordinating center.

Performance Objectives

At the end of the orientation, each trainee should be 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.

Training Materials

- DASH MOP Chapter 10
- Form #20 - Guidelines for Beverages and Seasonings
- Form #23 - Orientation Form
- Form #69 - Safe Foods to Go
- Form #79 - Orientation Quality Assurance Checklist
- DASH Orientation Video

DASH Manual of Procedures

Training Module 4 - Compliance Assessment

Overview

Procedures for promoting compliance are outlined in chapter 18 of the DASH Manual of Operations. The goal of compliance assessment is to standardize the way compliance is scored so that uniformity is achieved across sites.

Training Activities

The lead trainer at each site should follow procedures outlined in this module to orient all new staff who assess compliance. The module should also be used to certify staff once a year.

Training Sequence

1. Review performance objectives with staff person being trained listed in Training Module 4: Compliance Assessment Performance Objectives.
2. Ask the trainee to review the relevant MOP chapters (Training Module 4: Training Materials).
3. Conduct the training in the sequence outlined (Training Module 4: Training Curriculum).
4. Administer and assess the performance of each trainee using the Performance Evaluation Module 4 provided separately.
5. Review and discuss the communication script (Training Module 4: Role Playing Guide)
6. Complete the Compliance Assessment Quality Assurance Checklist (Form #83) and mail it to the coordinating center. Keep a copy at your site for audit purposes.

DASH Manual of Procedures

Performance Objectives

Overall Objectives

At the completion of this module, the DASH staff person will: 1) be able to explain the main uses of the Compliance Assessment Forms; 2) be able to transcribe data accurately from daily diary to compliance assessment forms then to the computer database; 3) know how to do quality control checks and follow-up, if necessary, on transcribed compliance data; and 4) understand good communication skills and roadblocks to listening. Each staff person will be evaluated by the lead nutritionist using the Compliance Assessment Quality Assurance Checklist (Form #83).

Specific Objectives

1. State the primary uses and purpose for each of the following:
The Daily Dairy (Form #22), the Body Weight and Energy Adjustment Records (Forms #17a & #17b), the Compliance Assessment Forms (Forms #18a & 18b), the Guidelines for Beverages and Seasonings (Form #20), and the Standardized Portion Guidelines for Compliance Assessment (Form #71).
2. Complete the practice quiz on compliance assessment scoring (in Performance Evaluation Module 3: Compliance Assessment Scoring test).
3. Complete practice quality control checks on transcription of data from daily diaries to compliance assessment forms using the Compliance Assessment Transcription Record (Form #81). Discuss appropriate follow-up measures.
4. Complete entering one week's worth of actual data from Forms #17a, #17b, #18a, and #18b into the computer database for two participants.
5. Complete the Weight Data Entry Record (Form #80) and Data Entry Quality Control Record (Form #82) for transcription of compliance and weight forms into the computer for one week's worth of data on two participants.
6. Role play good and not-so-good communication skills using the enclosed role play examples. Discuss good communication skills and roadblocks to listening.

DASH Manual of Procedures

Training Materials

- DASH MOP Chapter 11
- DASH MOP Chapter 12
- DASH MOP Chapter 16
- DASH MOP Chapter 18
- Forms #17a and 17b - Run-In/Intervention Body Weight and Energy adjustment records and instructions
- Forms #18a and 18b - Run-In/Intervention Compliance Assessment forms and instructions
- Form #20 - Guidelines for Beverages and Seasonings
- Form #22 - Daily Diary and instructions
- Form #71 - Standardized Portion Guidelines for Assessing Compliance
- Form #80 - Weight Data Entry Record
- Form #81 - Compliance Assessment Transcription Record
- Form #82 - Data Entry Quality Control Record
- Form #83 - Compliance Assessment QA Checklist
- Role Playing Guide (in this chapter)

DASH Manual of Procedures

Role Playing Guide for Good Communication

Instructions: The attached scripts are examples of good and not-so-good participant-staff interactions. This segment of the Compliance Assessment Training module focuses on promoting participant compliance through participant-staff interactions. It is designed to allow you to practice, compare, and contrast these interactions.

SCRIPT #1 is an example of a less effective participant-staff interaction through the use of close-ended questions and roadblocks or barriers to listening.

Required Activity: Role play Script #1 with the lead nutritionist or with another staff person where the lead nutritionist is observing.

SCRIPT #1

C=Counselor P=Participant

C: You haven't been eating all of your food when you come in for meals. Are you too full?

P: No.

C: Was something wrong with the food?

P: No.

C: You do remember the study requirements to eat all of the food provided, don't you?

P: Yes.

C: Why is it that you aren't eating all of it?

P: I've been sick with the flu.

C: Oh, I'm really sorry to hear that. That's such a shame.

P: I know, this has just been my unlucky week!

C: Um hmm. Now we need to deal with this problem of leaving food uneaten. If everyone doesn't eat all of the required foods we won't be able to have a successful study. Do you think you could try a little harder to eat everything?

P: I can try. What do you think I should do?

C: Here are some things that you could do to make sure you eat all your required foods. Don't eat any unallowed foods. Limit your social activities that involve food. And be on time for your on-site meals.

P: But I don't want to stop going to parties. They're important to me.

C: Maybe you should, just for a while. Remember, you made a commitment and it's real important to this study. I hope you keep trying. We really need you. Thanks for coming. We'll see you tomorrow.

DASH Manual of Procedures

SCRIPT #2 is an example of a more effective participant-staff interaction using open-ended questions, reflective listening and summarizing statements.

Required Activity: Role play Script #2 with the lead nutritionist or with another staff person where the lead nutritionist is observing.

SCRIPT #2

C=Counselor P=Participant

- C: I've been noticing that you haven't been eating all of your food when you come in for meals. I'm a little concerned about this and was wondering if you could tell me what's been going on that might be making it difficult for you to eat everything.
- P: Well, actually, I've been dealing with an upset stomach because of this touch of the flu bug I've had over the past few days.
- C: That makes sense. When you're not feeling well it certainly is harder to eat everything. How are you feeling tonight?
- P: I seem to be getting over it. I feel a little better and I was able to eat most everything tonight.
- C: I'm glad to hear you're feeling better and I appreciate your extra effort tonight in finishing more of your meal. It sounds like this was a temporary problem. Are there any other concerns you have about being able to finish these meals?
- P: Actually, there is something else keeping me from meeting the study food requirements. It's that my life is so busy.
- C: So, not only have you been sick with the flu but you've been juggling a busy schedule. With your new job responsibilities, I imagine you've got your hands full.
- P: I really do! And it makes me feel guilty when I can't follow through with the things I've agreed to do for this study.
- C: So, you feel like you're letting the study down and that doesn't feel good to you.
- P: No, it doesn't.
- C: That sounds frustrating. I'd like to understand more about how your work is affecting finishing your study meals. Can you tell me more about that?
- P: Yes, I guess I'm worried about work more than I used to be and sometimes that makes me feel like not eating. I don't seem to have any time to take breaks or relax at work. And I hate to eat when I'm stressed out. But I am coming to eat my meals I'm just not ready to eat when I get here.
- C: Let me see if I've got it right so far. You've recently had the flu, you're really busy at work and this is stressful, you don't have time to relax and that makes eating the meals more difficult for you. How'd I do?
- P: That pretty well sums it up.
- C: Any thoughts on what might work for you in helping you relax around meal time?
- P: If I could just sit and unwind before I ate it would help. Maybe I could come a few minutes early for the dinner meal. Would this be any problem for your staff?
- C: No, I think that's a great idea. You could sit and relax in the lobby if you'd like.
- P: I think that would work.
- C: When would you like to try that?

DASH Manual of Procedures

P: Tomorrow would work for me.

C: Great! See you then.

Required Activity: Discuss the interactions with the lead nutritionist. The following discussion questions may be used.

DISCUSSION QUESTIONS

1. Which model did you like better?
2. How did that feel to those observing? Uncomfortable? Comfortable?
3. Was it effective? Ineffective? How?
4. Was it motivating? Unmotivating? Why?
5. Did the participant feel listened to and understood?
6. How did the counselor feel? Pushy? Relaxed? Able to roll with resistance?
7. Who was working harder? Counselor? Or Participant? Who should be working harder?

Compliance Assessment Quality Control Activities

Monitoring compliance and weight data in this study is a complex process. It is therefore important that this process be checked weekly by a person other than the one transcribing and entering compliance and weight information. Forms #80, #81, and #82, and instructions on how to use them are provided to you for this purpose.

The staff person completing these forms should conduct the quality control checks on 10% of the cohort every week. Care should be taken to choose these participants in a random fashion.

DASH Manual of Procedures

Training Module 5 - Food Preparation and Distribution

Overview

Procedures for food procurement preparation and distribution are outlined in chapter 15 of the DASH Manual of Operations. The overall goal of this function is to ensure that study meals are provided to participants in a safe and accurate manner.

Training Activities

The lead trainer should follow the sequence below to orient all new kitchen staff and conduct yearly certification.

Training Sequence

1. Review the overall, and specific objectives of the training (Training Module 5 - Performance Objectives).
2. Use the outline provided in Module 5 “Training Materials and Curriculum” to conduct the training.
3. Complete the Kitchen Staff Certification and QA Checklist (Form 85). Keep a copy at the site and mail original to the CC for each newly trained or newly certified staff member.
4. Evaluate the staff person using the Performance Evaluation Module 5. Each question is worth 5 points, for a total possible score of 50 points. A person must have a score of 45 or better to be certified.

DASH Manual of Procedures

Performance Objectives

Overall Objectives

At the completion of this module, the DASH food preparation staff will be able to produce and package DASH meals as written on the DASH menus, production sheets, and recipes and in accordance with food safety and sanitation guidelines. Each food preparation staff will be evaluated by the lead nutritionist using the DASH Food Preparation and Distribution Test (in Performance Evaluation Module 5).

Specific Objectives

The DASH food preparation staff will be able to:

1. Read Production Sheets (or other variation of these) and correctly identify brand of product, gram amount of product, and number of servings needed for production of DASH food.
2. Read Tray Assembly Forms (or other variation of these) and assemble and/or package the correct product and amount of product to be served as DASH meals.
3. Read DASH recipes and correctly identify the product and amount of product for the number of servings or batch size needed, and demonstrate ability to produce a recipe in accordance with the instructions listed on the recipe.
4. Demonstrate appropriate use of scales and correctly identify allowed measurement ranges specific to production of DASH meals.
5. Identify appropriate packaging materials to use for DASH take-home foods.
6. Identify which food items or meals require the use of temperature dots and demonstrate appropriate use of temperature dots.
7. Identify location of DASH food preparation instructions including recipes and cooking instructions.
8. Demonstrate sanitary and safe practices in handling DASH foods.
9. Identify appropriate DASH Staff who are authorized to answer questions, concerns, or comments regarding DASH food products and/or production.

DASH Manual of Procedures

Training Materials & Curriculum

Training Materials

- DASH MOP Chapter 15-Food Procurement, Safety and Preparation
- Form # 41 - Food Production Form Green Diet
- Form # 41 - Food Production Form Red Diet
- Form # 41 - Food Production Form Yellow Diet
- Form # 52 - All DASH recipes
- Form # 51- Tray Assembly Form (some sites only)
- Form # 15- Food Service Sanitary Self-Inspection
- Form #84 - Spot Checking of DASH Recipes, Meals, and Food Items
- Form #85 - Kitchen Staff Certification & QA Checklist
- DASH Food Preparation & Distribution Test (in Performance Evaluation Module 4)
- Other food production forms specific to site
- Scale, powder-free gloves, hair net or hat, apron
- DASH food for one selected recipe
- DASH packaging/traying materials and labeling materials
- Temperature dots

Training Curriculum

Sequence	Training Curriculum	Time Frame
1.	Discuss organizational structure including identification of the DASH staff person whom each kitchen staff should report to for comments, problems, concerns, or questions regarding DASH food production.	5 minutes
2.	Review DASH production sheets (and other related food preparation sheets) including instructions on the following: <ul style="list-style-type: none"> • how to identify which diet and day of the week the production form is to be used for food preparation • how to identify which food items go into which meals (Breakfast, Lunch, Dinner or Snack) • how to identify food item needed and correct product • how to identify gram amount to be weighed or unit (p.c.) to use for each food item and each calorie level. • how to identify when a DASH recipe is to be followed • where to find most up-to-date DASH Production forms 	1 hour

DASH Manual of Procedures

3.	<p>Review DASH recipes. Include explanations for the following:</p> <ul style="list-style-type: none"> • how to identify correct recipe (by name and diet type) to be used from item listed "Recipe: "on production sheet • how to calculate number of servings needed for each calorie level or batch amount needed • how to read recipe for gram amounts of each item needed specific for each calorie level • review cooking procedures for recipes • where to find most up to date DASH recipes 	30 minutes
4.	<p>Review MOP food preparation procedures. Emphasize the following:</p> <ul style="list-style-type: none"> • pages 15-13 - 15-18 (meats; fish; vegetables; fruits; pasta; cereal; grains; bread products; milk and dairy products; fats and oils; spices • food preparation methods and times • where to find most up to date MOP cooking instructions • how to portion food items so that they are edible and presentable (for example, slice bread into pieces for sandwich without using small scraps to make correct weight) 	30 minutes
5.	<p>Review MOP guidelines for weighing foods and review proper use of scales</p> <ul style="list-style-type: none"> • All foods weighed to the +- 0.5 grams, except fats and oils when < 10 grams needed and all spices should be weighed to +- 0.1 grams • Scales should be properly zeroed between weighing items <p>Demonstrate proper weighing technique.</p>	15 minutes
6.	<p>Review and demonstrate proper food packaging/tray assembly. Include the following:</p> <ul style="list-style-type: none"> • proper materials to be 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 • proper use of the temperature dot on perishable foods/meals 	15 minutes
7.	<p>Review food safety and sanitation in food preparation and storage. Include the following:</p> <ul style="list-style-type: none"> • Review MOP pages 15-8 - 15-10. • Review form #15- Food Service Sanitary Self-Inspection 	30 minutes
	<p>Total time (estimate based on re-training DASH kitchen staff, may need to allot more time for new DASH kitchen staff training)</p>	3 hours 5 minutes

DASH Manual of Procedures

Food Preparation and Safety: Quality Control Activities

The day-to-day monitoring of the accuracy of meals distributed to participants is an important quality control measure. The following section outlines the six areas of food preparation that are important for the accuracy and safety of meals. The frequency of monitoring quality must be conducted as suggested and the necessary documentation kept at each site.

During all DASH cohorts, each DASH site should have mechanisms in place to monitor the following :

1. Proper food preparation technique used
2. Completeness DASH meals trayed/packaged
3. Accurately weighed DASH foods
4. Correct brand of food product used
5. Delivery of correct diet, calorie level, and type and number of unit foods to participants
6. Safe and sanitary food preparation and delivery of dash foods

Item to be Monitored	Method of Monitoring	Documentation	Frequency of Monitoring
1. Proper food preparation technique used in RECIPES	Each DASH recipe should be observed for accuracy by Food Preparation Trainer.	Form #84 - Spot Checking of Recipes, Meals, and Food Items.	Each recipe should be observed one time each cohort, suggest observing Red Recipes during the first week of Run-in and Green and Yellow recipes during the first two weeks of Intervention
2. Completeness of DASH meals trayed/packaged	Spot checking: One meal from each diet and each calorie level should be checked for completeness (for both on-site meals and carry-out meals)	Form #84	Daily

DASH Manual of Procedures

<p>3. Accurately weighed DASH foods</p>	<p>Spot checking: Three samples of two different weighed food items should be re-weighed for accuracy.</p> <p>Care should be given to randomly select food items from each diet, from each calorie level , with small weights, with large weights, weekend foods, and food items weighed prior to cooking</p>	<p>Form #84</p>	<p>2 times a week during Run-in and Intervention</p>
<p>4. Correct brand of food product used</p>	<p>Correct product is verified during at least one of the following: QA check for completeness of meals, QA for accuracy of weights of DASH foods, Menu Validation collection, inventory, food procurement</p>	<p>At least one of the following: - Food procurement records - Form #41 - Form #84 - FALCC Notification of Menu Deviation Form</p>	<p>Daily</p>
<p>5. Delivery of correct diet, calorie level, and type and number of unit foods given to participants</p>	<p>Color coding of trays/packages, use of patient names or identification number, use of white board, use of tracking form to ensure correct meals and units given</p>	<p>Optional: Tracking Form (Duke)</p>	<p>Daily</p>
<p>6. Safe and sanitary food preparation and delivery of DASH foods</p>	<p>Inspection and monitoring of employees preparing DASH foods</p>	<p>Form # 15, Food Service Sanitary Self-Inspection</p>	<p>Every two weeks</p>
	<p>Inspection of refrigeration and freezer units for temperature.</p>	<p>Site specific Refrigerator Temp Form</p>	<p>Daily</p>

DASH Manual of Procedures

Training Module 6 - Exit Interview

Overview

Procedures for conducting the exit interview are outlined in Chapter 28 of the DASH Manual of Operations. The dietary aspects of the exit interview can be conducted in group or individual format. Its purpose is to provide the participant with generic health and nutrition information as it relates to heart disease.

Training Activities

The lead trainer should follow the sequence below to orient all new kitchen staff and conduct yearly certification.

Training Sequence

1. Review the overall, and specific objectives of the training (Training Module 6 - Performance Objectives).
2. Use the outline provided in Module 6 “Training Materials and Curriculum” to conduct the training.
3. Complete the Exit Interview QA Checklist (Form #86). Keep a copy at the site and mail original to the CC for each newly trained or newly certified staff member.
4. Evaluate the staff person using the Performance Evaluation Module 6. Each question is worth 10 points, for a total possible score of 100 points. A person must have a score of 80 or better to be certified.

DASH Manual of Procedures

Performance Objectives

Overall Objectives

The overall objectives of the exit interview are to assure similar feedback to participants at the end of the trial about their blood pressure and other study-related information and to discuss and develop standardized minimum guidelines for nutritional counseling for heart disease prevention.

Specific Objectives

1. Understand that intervention status and individual blood pressure measurements remain blinded.
2. List close-out activities that must occur.
3. Identify materials needed to conduct the close-out activities.
4. Identify when, with whom, and how the close-out activities should be conducted.
5. Explain the administration of the Post-Study Anonymous survey (Form 42).
6. Identify general topic areas to be covered during nutritional education sessions.
7. Demonstrate nutritional education activities and materials used.

Training Materials and Curriculum

Training Materials

- DASH MOP Chapter 28 - Participant Closeout & Counseling
- DASH exit summary (available from the file server)
- Participant's study charts
- SV2 eligibility lab results
- Handouts on heart disease prevention and general nutrition
- Form #42 - Post Study Anonymous Survey

DASH Manual of Procedures

Training Curriculum

Sequence	Training Curriculum	Time Frame
1.	<p>Review the format, purpose, timing, and blinded nature of the exit interview. Summarize activities of the interview.</p> <p><i>Purpose:</i> At the end of the cohort to provide feedback to DASH participants about their blood pressure and heart disease prevention, with an emphasis on nutritional education.</p> <p><i>Unblinding:</i> Study staff <u>must</u> remain blinded to treatment assignment and blood pressure results.</p> <ul style="list-style-type: none"> • DASH participants, therefore, remain blinded to their intervention group status and individual blood pressure measurements. • Kitchen staff must <u>not</u> provide blood pressure results. <p>At the conclusion of the <u>entire</u> trial, DASH participants will receive information on their treatment assignment, their individual blood pressures, and the overall findings of the DASH trial.</p> <p><i>Timing:</i> Individual or group sessions occur at the end of the feeding cohort.</p> <p><i>Staff:</i> Only those blinded to treatment assignment may present the blood pressure data.</p> <ul style="list-style-type: none"> • A qualified dietitian, nurse or health educator may provide counseling on heart disease prevention. <p><i>Activities:</i></p> <ul style="list-style-type: none"> • Provide summary of blood pressure results • Provide summary of local laboratory results • Counsel on heart disease prevention • Distribute and complete the Post-Study Anonymous Survey 	15 minutes

DASH Manual of Procedures

2.	<p>Review the purpose, structure and procedures for distributing the exit interview report.</p> <p><i>Purpose:</i> Provides to each participant an average summary of their study blood pressures, their height, weight, BMI, and skinfold measurements.</p> <p><i>Structure:</i> Lists "Physical Characteristics," "Skinfold Measurements," and "Blood Pressure."</p> <p>Specific for each participant.</p> <p><i>Procedures For Using:</i> Distributed to appropriate participant during group or individual sessions; if in group, must give participant the opportunity to ask for individual, confidential advice.</p>	15 minutes
3.	<p>Review the purpose, structure, and procedures for distributing the post study anonymous survey.</p> <p><i>Purpose:</i> Gathers anonymous information from the participants about their compliance to the feeding protocol and other study-related information.</p> <p><i>Structure:</i> Questions regarding experiences with the DASH study and open-ended questions for suggestions.</p> <p>Questions regarding meal habits; reasons for participating, difficulties encountered with study demands and foods; compliance to diets.</p> <p>Questions regarding demographics.</p> <p><i>Procedures For Using:</i> Distribute to participants; note questionnaire is anonymous and results cannot be linked to the individual.</p> <p>Give questionnaire and stamped, pre-addressed (to CC) envelope.</p> <p>Encourage to complete at clinic and deposit in mail box.</p> <p>If participant not at clinic to pick-up questionnaire, mail to the participant.</p>	15 minutes

DASH Manual of Procedures

4.	<p>Review the purpose, format, and content of the health and nutrition education sessions</p> <p><i>Purpose:</i> To give participants knowledge of the risk factors for cardiovascular disease and how to follow a healthy diet for its prevention.</p> <p><i>Format:</i> Group session or individual visit.</p> <ul style="list-style-type: none"> • Attendance is not mandatory, but should be encouraged. <p><i>Content:</i> Include general topic areas; specific content left to the discretion of each field center.</p> <ul style="list-style-type: none"> • Dietary recommendation will not specifically stress DASH-related topics. • Participants must <u>not</u> be told of their dietary treatment. 	20 minutes
5.	<p>Review procedures for sharing study results with participants at the end of the study.</p> <p><i>Notification of intervention status:</i> At the conclusion of the entire DASH trial</p> <ul style="list-style-type: none"> • Participants will receive letter describing their intervention diet, summarizing the results of the study, and thanking them for their contribution. • Participants will receive listing of their individualized blood pressure measurements. <p><i>Premature study termination:</i> When possible, participants who are unable to complete the study for any reason should receive an end-of-study briefing similar to the exit interview.</p> <ul style="list-style-type: none"> • Should occur soon after termination. • Information may be sent by mail. 	5 minutes
Total time		1 hour 10 minutes

18. Participant Management and Compliance

Overview	4
Measuring and Monitoring Compliance	4
Measures of Compliance	4
Prior to Randomization	4
Post Randomization	6
Tools For Monitoring Compliance	6
Subjective Compliance	6
Objective Compliance	6
Promoting Participant Compliance and Motivation	7
Participant and Staff Relations	7
Participant Management	7
Procedures for Dealing with Potential Compliance Deviations	11
Overview	11
Excused Missed Meals	11
Uneaten Foods	13

Summary of Edits

New changes in Version 2.0

- misc technical edits

New changes in 2.1

- misc formatting changes
- the initial section on *Promoting Compliance* has been dropped. It is redundant with a similarly named section later in the chapter.
- specific references to form numbers have been added in several places for easier reference
- Under *Promoting Compliance*, the sentence referring to the use of substitute foods to accommodate individual preferences has been dropped. This practice, while allowed, is discouraged.
- Under *Objective Compliance*, the second para, which deals with frequency of body weight measurements, has been amended to reflect current practice. The following para, dealing with frequency of 24-hour urine collections, has also been amended to reflect current practice.
- The section entitled *Guidelines for the Definition of Compliance* has been dropped. It was out-of-date and has since been superseded by other sections in the chapter.
- The *Sodium* and *Potassium* sections have been revised for greater clarity. Please review them.
- Added *Procedures for dealing with diet refusals and spillage* from chapter 16

New Changes in Version 2.2

- Major formatting changes
- Title page has been consolidated and rearranged into new main headings
- New *Overview* heading
- New *Measuring and Monitoring Compliance* heading
- New subtitle *Re-entering participants who withdraw* added
- Page 8: All new and revised: *Promoting Participant Compliance and Motivation*. Read entire section.
- *Staff, Facility, Maintenance and Equipment* subtitle dropped

New Changes in Version 4.0

- none

DASH Manual of Procedures

New Changes in Version 4.1

- All references to 24-hour urine collections in relation to diet adherence and counseling have been dropped.
- Under Post Randomization, the sentence in the “clinic rating” paragraph about the “sum of scores” has been dropped. Also, the sentences in the “daily diary and intervention log” paragraph referring to “nutrient deviation” have been dropped.
- Under Participant Management, it was clarified that payment incentives were for completing study requirements.
- Under Uneaten Foods, statements have been added regarding recording these items.

DASH Manual of Procedures

Overview

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

During the orientation group, prior to run-in, clinic staff will have their best opportunity to make clear the overall expectations of adherence to the experimental routine and diets of the study. 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 to commit. Once the participant has completed run-in and begins the feeding intervention, staff will be faced with specific compliance challenges and must be willing to work with participants to assure that study protocol is being met while at the same time fostering participant satisfaction.

Measuring and Monitoring Compliance

Measures of Compliance

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

Prior to Randomization

daily diary & run-in-log

All participants are expected to maintain a daily diary (Form #22) summarizing study foods and beverages that were not consumed and nonstudy foods that were consumed. Participants also complete questions each day summarizing problems or illnesses they may be having that might interfere with their compliance. This information is reviewed by the intervention staff at each of the daily feedings and summarized into a run-in log (form #18a) for purposes of analysis. The daily diary and run-in logs are intended to be used as monitoring tools, and no compulsory action is taken based on diary information other than as noted below.

missed meals

Clinic staff take the following actions in response to missed meals.

- For the **first missed meal**, participants are counseled by the clinic staff on the importance of compliance with the study diet.

DASH Manual of Procedures

- Participants are excluded from further participation if they miss a **second meal** and do not have a good reason for having done so. Participants having good reasons may be counseled or excluded at local discretion.
- All participants missing a **third meal** during the first two weeks of run-in are excluded from further participation, regardless of reason. 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 meals for that day). Exceptions based on extraordinary circumstances may be appealed to the coordinating center.

Participants who miss a scheduled clinic meal and do call in to explain are treated as having simply missed a single meal and may be kept in the study provided they make arrangements to pick up their other meals.

missed foods & non-study foods Clinics shall use the daily diary to estimate the number of study foods that are not eaten and the number of nonstudy foods that are consumed. Participants for whom these numbers add up to 10 or more during the second week of run-in feeding are considered noncompliers and shall be seriously considered for exclusion during the case conference.

case conference At the end of the second week of run-in and prior to randomization, the clinic staff review each participant's overall compliance history and decide whether the participant is a good candidate for the trial or 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, variance from the diet to date, and urinary electrolyte levels.

DASH Manual of Procedures

Post Randomization

daily diary & intervention log All participants are expected to maintain a daily diary (form #22) summarizing study foods and beverages that were not consumed and nonstudy foods that were consumed. Participants also complete questions each day summarizing problems or illnesses they may be having that might interfere with their compliance. This information is reviewed by the intervention staff at each of the daily feedings and summarized into an intervention log (forms #18b) for purposes of analysis.

clinic rating Clinic staff provide a subjective measure of daily compliance for each participant based on the information provided in the daily diary and firsthand observations of foods eaten in the clinic. This score is recorded on form #18b.

Re-entering participants who withdraw Persons who withdraw from the feeding program after randomization are asked to re-enter their assigned feeding wave 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.

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

The daily visit to the research facility ensures that study personnel have a chance to observe 1/3 of the research diet being consumed. Additionally, all participants maintain a daily food diary, which is summarized into various logs for analysis (forms #18a, #18b, and #21).

The daily visit is also a way for study personnel to evaluate a given subjects' attitude and attendance record. This information is used to formulate subjective staff judgment of compliance.

At the end of the study, subjects are given an anonymous questionnaire and asked to indicate aspects of the study with which they did not comply (Post-Study Anonymous Survey, Form #42). Because the questionnaire is anonymous, it will be used along with other measures of compliance to assess overall compliance to study diets in a retrospective fashion.

Objective Compliance

Two separate measures are used to objectively assess compliance. These are attendance at meals and body weight. Meal attendance is monitored and recorded for each subject. At the end of

DASH Manual of Procedures

each week, the number of meals missed is tallied and used to determine a given subjects adherence to the protocol.

When food intake is constant and weight has stabilized at a given energy level, fluctuations in weight can 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 is be measured daily (5 days per week) throughout the 11-week feeding period and is tracked using forms #17a and #17b.

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, as part of the screening visit schedule. 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:

- The participant will come to the center every weekday to eat one meal and pick up packaged meals to be eaten off-site
- The participant will eat only food provided to them by the study and nothing else
- The participant will consume all food provided to them in its entirety
- The participant will be 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 Chapter 10: Participant Orientation to Study.

To assist the participant in making time for the various commitments of the study run-in and intervention, 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 a second meal should he miss the first meal on any given day. In addition, each center is to adopt procedures designed to provide easy access to its research facility and staff by the participants.

DASH Manual of Procedures

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 plays a key role in promoting trust between participants and staff.

Key elements of quality interactions that promote rapport and trust with participants are:

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

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 has 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

DASH Manual of Procedures

manager on-duty is to interact with the participant, either one-on-one or in small conversation groups. They will field participant questions and concerns, document interactions, and plan follow-up courses of action.

It is recommended that the manager on-duty manage no more than 15-25 participants per meal. They also 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.

Case Management

A staff person, referred to here as the "case manager," will manage the progress of participants throughout the intervention. It is recommended that the case manager manage no more than 8 participants per cohort. The duties will involve ongoing chart review, assessment of the participants' progress, planning, follow-up, and case conferencing, if necessary. The case manager will communicate with each participant on a regular basis, providing counsel as needed. The case manager will be required to arrange for a back-up manager to follow participants in her absence. The case management schedule will include the following:

- A minimum of one face-to-face contact with each participant during weeks 1 and 2 of run-in.
- A minimum of one face-to-face contact with each participant during the first week of intervention.
- A minimum of one face-to-face contact with each participant during the 5th or 6th week of intervention.
- 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.

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:

- Non-verbal communication

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

- Open-ended questions

DASH Manual of Procedures

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?"

- Reflective listening

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

- Summarizing statements

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

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 practicing 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 situational triggers, these "triggers" being birthday parties, business travel, or house guests, 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 in developing 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.)

DASH Manual of Procedures

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. Role play the scenario with the participant or suggest they role play with another participant.
6. Follow-up with the participant in a timely manner. Find out how the plan worked for them.

Incentives and Motivators

Each center is expected to use whatever incentives and motivators 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 of incentives, they 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 which enhance the participant's sense of value as a study subject.

At the close of intervention, a group dinner at a nice restaurant 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 unexcused. Unexcused meals constitute a participant being absent from an on-site meal without a valid reason 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.

DASH Manual of Procedures

Storm meals

Storm meals are to be used in the event of inclement weather such as hurricanes and snowstorms where participants cannot get to the site to eat their scheduled meal. Each site will designate one menu of choice, prepare it, and send it home with the participant to be kept in their freezer during intervention pending such an event.

Carry out meals for special circumstances

Carry out meals are for unusual or special circumstances. The participant must arrange this occasion in advance with clinic staff. The participant will be provided one additional carry out menu (1 day's food) per diet period.

Meal passes

Two meal passes per participant are allowed. 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 an on-site meal when real life events occur that he/she cannot anticipate. This gives the participant the choice of determining whether or not an event that prevents him/her from 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 contact the kitchen staff of their need to use the pass and must get the approval of the staff to eat their meal off-site.

DASH Manual of Procedures

Uneaten Foods

Uneaten portions

If the subject is still at the feeding site, give any food that is left back 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 participant refuses to eat the left over meal, document missed foods and record appropriate compliance score.

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, DASH study foods will be provided. Storm meals are allowed to be consumed by participants in this situation. If so, the clinic will prepare a replacement storm meal in a timely manner. The participant is to document any substitutions in their daily diary.

Diet refusals

If the participant can no longer tolerate a given menu, another menu can be substituted for that person. This means the participant would have the same menu twice in a cycle.

19. Blood Pressure Assessment

Overview	3
Equipment Required	3
Stethoscope	3
Sphygmomanometers	4
Cuffs	5
Preparation for Blood Pressure Measurement	5
Measurement Procedures	6
Measurement # 1	7
Measurement #2	7
Missing BP Information	8
Changing the Peak Inflation Level	8
Training and Certification	8
Introduction	8
Y-Tube Stethoscope Observations	10
Observation of BP Measurement Procedures and Techniques	10
Requirements for Blood Pressure Certification and Recertification	10
Quality Control	11
Maintenance of Random-Zero and Conventional Sphygmomanometers	12
Introduction	12
Safety Responsibility	12
General Guidelines	12
Common Problems with - and Solution for - both Manometers	13
Inspection of the Random-Zero Manometer	14
Comparison of a Random-Zero Device with a Conventional Device	17
Procedures for Training and Certifying BP Technicians - For Trainers' Use Only	18
Lecture #1 - Blood Pressure Measurement - Problems and Solutions	19
Lecture #2 - The Random-Zero Device	22
Lecture #3 - Procedures in Blood Pressure Recording	23
Lecture #4 - Equipment Maintenance And Mercury Toxicity Safety	28
Lecture #5 - Training Observers In The Clinical Center	34
Initial Certification Procedures And Criteria	36
Three Steps Needed For Certification	36
Instructions for Taking the Videotest	37
Study Forms Required For Certification Procedures	37
Blood Pressure Measurement Quality Control	38
Overview	38
Monitoring for Digit Preference	39
Bi-Annual Y-Tube Stethoscope Observations	41
Responsibilities of the Coordinating Center and the Training Supervisors	41
Acknowledgment of Adaptation	43

DASH Manual of Procedures

Summary of Edits

New changes in Version 2.3

- misc technical edits and formatting changes (note changes to table of contents)
- note added under *Equipment Required, Cuffs*, that the cuff size used at SV1 for any individual should be used at all subsequent visits.
- The section entitled *Instructions for Completion of Blood Pressure Form* has been dropped. This seemed to relate more to TOHP forms than to DASH forms. Also, this is covered separately in instructions accompanying each BP form.
- Under *Training and Certification*, discussion of height and weight certification has been dropped. This should be covered in Chapter 21.
- The forms originally included at the end of this chapter have been moved to Chapter 22. References to form numbers are now included in text.
- The section entitled *Monitoring for Digit Preference* has been expanded to reflect policies adopted at December 1 SC Meeting.

New changes in Version 4.1

- Jeanne Charleston and Laura Svetkey made numerous updates throughout, primarily clarifying current procedures. Basic procedures have not changed significantly.
- All forms moved out of chapter into DASH Forms Manual.

DASH Manual of Procedures

Overview

Correct measurement of blood pressure (BP) is of the utmost importance to the success of DASH. It is essential that the procedures described in this chapter for measuring BP be followed exactly. Precision is essential for valid comparisons of blood pressure between groups of people and in individuals on different occasions.

In DASH, sitting BP is measured using two readings with a random zero (RZ) sphygmomanometer. The essential distinction between the RZ and standard devices is a mechanism designed to produce a variable level of mercury in the mercury tube when the actual pressure in the cuff is zero. This is accomplished through an adjustable bellows chamber that is interconnected with the mercury reservoir at one end and the mercury tube at the other. The adjustment is made by the observer, who spins an external thumbwheel that contacts and rotates an internal, beveled cam; the position at which the cam comes to rest after spinning determines where the beveled edge will meet the movable diaphragm of the mercury chamber. When air pressure is applied through the cuff with the bellows cock in the open position, the diaphragm is displaced until it rests against the cam, and the mercury not accommodated by the new volume of the chamber is displaced into the mercury tube. The bellows cock, or valve, is controlled by the observer and locks the chamber system after the maximum inflation pressure desired has been applied, so that at the end of the reading, and only at the end, the mercury comes to rest at its "randomly" determined zero-pressure level. When this value is subtracted from the recorded readings the corrected readings give the corresponding true pressure levels. Thus, by adding this mechanism for varying the zero level of mercury, the RZ device obscures to the observer the true levels of pressure observed until after they have been read and the zero level subtracted. In this way, some of the recognized difficulties in observer performance are substantially reduced, particularly observer bias when readings fall near critical BP levels.

The procedures described herein are based on those used in the Trials of Hypertension Prevention (TOHP) study.

Equipment Required

Stethoscope

A standard Littman stethoscope with a bell is used. Korotkoff sounds **are best heard with the bell** because of their low pitch frequency. Stethoscope tubing should be about 10-12 inches from the bell piece to the Y branching. This length provides optimal acoustic properties and allows the observer to read the sphygmomanometer at eye level in a comfortable position. Ear pieces should fit comfortably and snugly in the ears.

DASH Manual of Procedures

- a. The ear pieces should be directed downward and forward into the external ear canal.
- b. The ear pieces should fit tightly enough to exclude outside sound but not so tightly that they cause discomfort.
- c. The valve between the bell and the diaphragm should be turned in the correct direction.
- d. The bell of the stethoscope should be placed lightly on the skin overlying the brachial artery. Light pressure accentuates low-pitched sound and avoids compression murmurs. Pressing too heavily with the stethoscope over the brachial artery causes turbulent flow in the artery and results in a murmur which may prolong the apparent duration of phase 4.

Sphygmomanometers

Standard Hawksley RZ instruments are used for all study BPs. Standard Baum manometers are used to determine peak inflation level.

The standard mercury manometer consists of a screw cap, a face with numbers, a lined glass column, a reservoir containing mercury, rubber tubing, and a metal case. The rubber tubing from the mercury manometer connects to rubber tubing from the inflatable rubber bladder of the cuff. As the bladder is inflated, the air pressure in the bladder travels through the connecting rubber tubing and pushes the mercury out of the reservoir and into the lined glass column. The number for each line is read when the rounded top of the mercury, the meniscus, is level with it. If the meniscus is exactly between the lines, the reading is made from the line immediately above, i.e., **rounded up to the nearest even number**.

The RZ manometer has all the parts of the standard mercury device. In addition, it has a device built into the box-shaped back that changes the level of mercury in the calibrated glass tube. This device includes a second mercury reservoir area, the size of which can be changed to hold a larger or smaller amount of the mercury, thus allowing different amounts of mercury to remain in the calibrated glass tube and outside reservoir. The size of the second, inner reservoir is changed by turning a wheel on the side of the box. The second reservoir opens and closes with a bellows control valve on the face of the manometer.

DASH Manual of Procedures

Cuffs

Proper cuff size is essential for accurate BP measurement. Clinical centers must have four standard cuffs available: small adult, adult, large adult, and thigh cuff. The cuffs used must be Baumanometer calibrated V-Lok cuffs with Baum brand bladders. The range markings on these and all commercial cuffs will overlap with the ranges DASH uses and do not offer a precise guideline. Therefore, all Baum cuffs used in DASH must be clearly marked on the inside surfaces with new range markings which correspond to the arm circumference ranges shown below for each cuff size.

<u>Arm Circumference</u>	<u>Cuff Size</u>
<24 cm	Small adult
24-32 cm	Adult
>32-41 cm	Large Adult
>41-52 cm	Thigh

The correctly determined cuff size used to record SV1 blood pressure should be the same cuff size used to record all of a participant's blood pressure measurements.

Preparation for Blood Pressure Measurement

In relating to the DASH participants, remember that participation in the study is voluntary. Participants should be given a full explanation and instructions about the steps involved in BP measurement, as well as an opportunity to ask questions. Participants should be told in advance that their blood pressure readings will not be made available to them until the end of the study. However, they will be informed if their blood pressure exceeds the acceptable range. If a participant insists, a staff member may obtain an additional reading with a standard sphygmomanometer and inform him or her of the results.

The setting at which BP readings are taken must be a separate, quiet room where no other activity is taking place and where temperature fluctuations are minimal. It is recommended that the room temperature be 65-75° F. Clinic scheduling procedures should also establish consistent appointment times to minimize, insofar as possible, the impact of daily BP variations.

Participants should be told not to engage in vigorous exercise, ingest food or caffeine, or smoke within 1/2 hour of BP measurements. If a half-hour has not elapsed, the BP measurements must be delayed until 1/2 hour has passed.

DASH Manual of Procedures

Measurement Procedures

In DASH, BP will be measured two times during each designated visit. It will take approximately 15 minutes to take the two readings, including an initial 5-minute rest period. The BP measurements are obtained during the visit before measurements of height and weight, or blood drawing.

Once the participant has had the procedures explained and the equipment has been checked, BP measurement begins. The following steps must be followed precisely.

The right arm should always be used for the measurements. If the participant indicates that there is a medical reason for not having BP measured on his or her right arm (such as surgery, or if the right arm is missing), reverse chairs and proceed with the left arm. Write a note on the BP form indicating that the left arm has been used. If the participant seems particularly apprehensive about the procedure, delay wrapping the cuff until after the five-minute wait. Otherwise, check for correct cuff size.

Have participant stand erect holding the forearm horizontal at a 90° angle. Arm length is measured using a measuring tape in metric units, measuring from the acromion or bony extremity of the shoulder girdle, to the olecranon or tip of elbow. The midpoint is marked on the dorsal surface of the arm. Have participant relax their arm. With the participant's arm relaxed at their side, measure the arm circumference at the midpoint.

Seat the participant with the right arm on the table. The bend at the elbow (cubital fossa) should be at heart level. Legs should be uncrossed and feet comfortably flat on the floor. If necessary, place a book, footstool, or other flat object beneath the participant's feet so that they do not dangle.

Palpate the brachial artery (just medial to and above the cubital fossa) and mark this location for placement of the center of the bladder and stethoscope placement.

Allow a five-minute wait before taking the BP. Conversation should be limited during this period. However, a brief explanation of the procedure can be repeated at this time, if necessary.

After five minutes, take a 30-second pulse (radial artery) and record. Then connect the cuff to a standard mercury manometer to establish the pulse obliteration pressure. Palpate the radial pulse. Rapidly inflate the cuff to 80 mmHg and then slowly inflate it 10 mmHg at a time until the radial pulse can no longer be felt. Deflate and disconnect the cuff. Record the pulse obliteration pressure (POP).

DASH Manual of Procedures

Calculate and record the peak inflation level (pulse obliteration pressure + 60). The peak inflation level used for each BP measurement must be ≥ 180 . If the POP + 60 is not ≥ 180 , use 180 mmHg during the actual measurements and record 180 in item 1.e. on the form.

Measurement # 1

Connect the cuff to the RZ manometer. Place ear pieces of the stethoscope in the ears with the tips down and forward. Open the bellows control valve and wait until the mercury settles. Using downstrokes only, turn the thumbwheel two or three times. NOTE: Do not spin the thumbwheel. Inflate rapidly but smoothly to the RZ peak inflation level. The eyes of the observer should be level with the mid-range of the manometer scale. Holding the pressure constant with the bulb, close the bellows and control valve. Place the bell of the stethoscope on the brachial artery just below and not touching the cuff or tubing, and slowly deflate the cuff (2 mm per second) while listening. Record the first and fifth phases, reading the pressure in mmHg to the nearest even number. The first sound heard in a series of at least two sounds is recorded for systolic BP (phase 1). For diastolic BP (phase 5), record the first silence in a series of at least two silences, NOT the last sound heard. After noting the DBP, continue to deflate at 2 mmHg per second until 10 mmHg below DPB, then rapidly deflate the cuff by opening the thumb valve. If there is an absent 5th phase (sounds heard to 00 mmHg), the beginning of the 4th phase should be used. Make a note if there is an absent 5th phase. Remove the stethoscope ear pieces. Disconnect the cuff and record the zero reading. **DO NOT SUBTRACT THE ZERO READING UNTIL BOTH MEASUREMENTS ARE COMPLETED.**

The zero reading should be greater than 00 and less than or equal to the stated upper limits of a particular RZ device. If a zero reading for a measurement is 00 mmHg or above the upper limits for that device, the RZ may be used to complete the set of readings for that participant, with an appropriate adjustment in the peak inflation level. However, the device should be recalibrated before it is used with another participant. If a zero reading of less than 00 mmHg is observed, the device should immediately be recalibrated or a different device should be used and all BP measurements on that participant repeated. (Older RZ models may have a zero of 00 in their specifications. If this is the case for your model, then the minimum zero value may be 00 mmHg.)

Measurement #2

After waiting 30 seconds with the participant's arm passively elevated for 5 seconds and on the table for 25 seconds, repeat as in measurement #1. After both readings are completed, the bellows control valve should be left in the OPEN position. If two identical consecutive zero readings are obtained, the maximum and minimum zeros should be checked before the device is used with another participant.

DASH Manual of Procedures

When finished recording the two RZ BP measurements, subtract the zero value from the reading to get the actual (corrected) systolic and diastolic values. Because of the importance of BP data in DASH, all arithmetic must be done with a calculator after two readings have been completed. Be sure to perform these calculations away from the participant in order to keep them blinded to their readings.

Missing BP Information

If for any reason the observer is unable, or has forgotten, to complete any portion of this protocol and the participant has left this area, draw two horizontal lines through the relevant spaces on the data collection form. This is the correct way to indicate the missed information. If an entire reading is missed and the participant is still sitting at the BP work station, completely deflate the cuff and start over with a replacement reading. Under NO other circumstances may a replacement reading be obtained. Always wait at least 30 seconds between readings.

Changing the Peak Inflation Level

Occasionally, the Korotkoff sounds may be heard as soon as one places the stethoscope over the brachial pulse. If this happens, the peak inflation level used was too low. Immediately deflate the cuff by releasing the thumbscrew and disconnecting the cuff tube. The participant should then hold the cuff-wrapped arm above the head level for five seconds. Draw a line through the previously recorded pulse obliteration pressure and peak inflation level. Increase each number by 10 and write the new number above the original one, as shown below.

	130
Pulse Obliteration Pressure	120
	<u>+60</u>
	190
RZ Peak Inflation Level	180

Proceed with BP measurement, starting at the new peak inflation level.

Training and Certification

Introduction

High quality blood pressure reading is fundamental to any sound program measuring and controlling blood pressure levels. Yet many factors, including influences of the subject, the observer, the equipment, and the circumstances of measurement, work against the attainment of this objective. Thus, good results cannot be taken for granted and special attention must be focused on blood pressure measurement procedures.

DASH Manual of Procedures

Before the actual initiation of standardized measurements, a program of training and certification must be provided so that all staff responsible for recording blood pressure readings will be certified as having met a stipulated level of performance. Each clinic BP observer/trainer will be re-certified centrally at an annual training session.

The DASH certification process includes training and the successful completion of:

- a written test
- a live evaluation of technique and ability to hear sounds accurately
- a videotape test

Before the first session, trainees should be given this chapter to read and review. Trainees should be instructed to wear short or loose sleeves.

The training strategy adopted by DASH is a two-stage program. Before the program begins, each Clinical Center will identify two specific Training Supervisors for that clinic. These Training Observers from each Clinical Center (and other blood pressure observers, if the Centers desire) will meet centrally in May 1994 for the first stage of training. The full training program will be presented at this time. The training observers who pass the program will be certified as Blood Pressure Trainer Observers. The Trainers can, in turn, train additional observers in the Clinical Centers as well as designate another observer as a trainer. This is the second stage of training. To this end, each Center will be provided with the full set of training materials needed to reproduce the same program for their field and clinic staff. In this second stage, the Coordinating Center will receive documentation of each observer's training performance from the Training Observers in the Clinical Centers (including the successful completion of the written test and the live evaluation). However, scoring of the video test will be done by the Coordinating Center, WHICH IS RESPONSIBLE FOR IDENTIFYING WHO IS A CERTIFIED DASH BLOOD PRESSURE OBSERVER. Results of the certification tests will be telephoned (and subsequently mailed) to a Clinical Center within three (3) working days of receipt of the test data from that clinic. Through this scheme, training will be the responsibility of both the clinical Centers and the Coordinating Center will, in addition, remain responsible for overall monitoring and quality control (as will be described in section 7).

Staff will be trained according to the following schedule:

- All blood pressure trainers will receive their annual retraining (which also constitutes their own recertification for that six-month period) during the Spring/early Summer DASH meeting (i.e., June 22-23, 1995 and May or June of 1996).
- All blood pressure technicians are recertified by their local trainers during the month of January and during the four week interval following the Spring/early Summer DASH meeting (i.e., following the annual retraining of trainers).

DASH Manual of Procedures

- All blood pressure technicians are required to meet these recertification deadlines unless they have been specially certified (e.g., new hires) during the three months prior to the start of the recertification window. If they have been certified for less than three months prior to this time they may wait for the following certification window before being recertified.

TOHP certification for blood pressure measurement is sufficient for DASH certification since the procedures are nearly identical. It is required that copies of the DASH documentation for certification be sent to Pierre La Chance at the DASH CC.

Y-Tube Stethoscope Observations

Y-tube stethoscope observations are made for certification and recertification. The observer and trainer listen with the Y-tube and record the values on separate sheets (see Blood Pressure and Weight Certification form). Three measurements on each of three subjects should be obtained. Readings by the trainer and trainee should agree within ± 4 mmHg on any reading (systolic or diastolic), and averages should agree within ± 3 mmHg.

Observation of BP Measurement Procedures and Techniques

All BP observers must be checked to ensure that they are following procedures correctly and utilizing proper measurement techniques. This is necessary for both certification and recertification. If these measurements are made on a DASH study subject, the observed blood pressure measurements for training may not be used for DASH data. The trainer uses the BP Procedure Checklist to grade the trainee while he or she follows the entire BP protocol to obtain three readings on a non-study or study individual, using a regular stethoscope. The trainer should be outside the immediate work area of the observer and should not make any comments during measurement. This part of the certification process should be done separately from the Y-tube certification.

Requirements for Blood Pressure Certification and Recertification

Certification

1. Attend DASH Training Session, or receive training from a certified DASH blood pressure trainer observer.
2. Read Blood Pressure Assessment (Chapter 19 of the MOP).
3. Successfully complete DASH blood pressure measurement technique and procedure. Record and submit results on DASH Blood Pressure Observation Form (Form #45).
4. Successfully complete three Y-stethoscope readings (average of three readings ± 4 of trainer measurements), using three different people, with DASH BP certifier.

DASH Manual of Procedures

Record and submit results on the Blood Pressure and Weight Certification Form (Form #46) .

5. Successfully complete the Blood Pressure Written Exam (Form #44) (100% correct).
6. Successfully complete 12 blood pressure examples on Videotape Test Sheet (Form #63) (100% correct).

Recertification

1. Required every six months for clinic staff and for DASH Blood Pressure trainers. All trainers must be recertified either on site or centrally every six months. At least one trainer at each site must be recertified centrally on an annual basis.
2. Successfully complete DASH blood pressure measurement technique and procedure. Record and submit results on DASH Blood Pressure Observation Form (Form #45).
3. Successfully complete three Y-stethoscope and dual readings using three different subjects. Record and submit results on Blood Pressure and Weight Certification form (Form #46).
4. Successfully complete the Blood Pressure Written Exam (Form #44) on blood pressure measurement (100% correct).
5. Successfully completed 12 blood pressure examples on Videotape Test Sheet (Form #63) (100% correct).
6. Must be actively taking blood pressure measurements using a random zero sphygmomanometer (at least 15 measurements per month).

Quality Control

To ensure the accuracy of BP measurements throughout the study, quality control measures will be developed centrally and implemented at all clinical centers uniformly. These measures include:

1. Recruitment of the most qualified personnel
2. Standardized training and certification of observers
3. Retraining and recertification of all observers at 6-month intervals and trainers on a yearly basis.
4. Observation of data collection by trainers every two months, using the DASH Blood Pressure Observation Checklist form.
5. Frequent staff meetings to provide feedback to observers
6. Review and edits of hard copy data
7. On-line edits by Laptop data entry utility.
8. Simultaneous Y-tube observation of each technician by the training supervisor
9. Implementation of a standardized equipment maintenance program.

DASH Manual of Procedures

In addition, the CC administers a BP quality control assurance program to review data from each clinic on a regular basis. Reports are generated periodically for each clinic which detail by technician and by clinic such things as digit preference, mean BPs and intra-visit variation.

Maintenance of Random-Zero and Conventional Sphygmomanometers

Introduction

Each clinical center is responsible for the proper operation and maintenance of its BP equipment. Responsibility for proper maintenance is assumed by the clinic coordinator, and all staff are instructed to report promptly any real or suspected equipment problems to that person. All checks, inspections, and cleanings are documented and recorded by date in a permanent log. Problems and solutions are also recorded there. Logs will be reviewed by CC staff at periodic site visits.

The standard and RZ manometers should be checked during each use for problems in the following areas:

1. The zero level of the standard manometer
2. Mercury leakage
3. Dirt or mercury oxide deposit in the manometer column
4. The condition of all tubing and fittings

The equipment should be cleaned if inspection indicates that cleaning is necessary, or at least once per year. In addition, every three months the accuracy of the RZ device should be checked using a standard manometer and a Y-tube.

Safety Responsibility

The condition of the instruments for blood pressure measurement is too often ignored in common practice and should be a special responsibility of the training supervisor or other designated staff member. This person **should be acquainted with mercury toxicity safety procedures** as well as construction and function of all the blood pressure equipment. The cleanliness and general working order of the cuffs and stethoscopes can usually be determined by simple inspection. For both the conventional and Random-Zero (RZ) type manometers, however, proper handling of breakable parts and of mercury and oxidized waste requires more careful attention. Guidelines for maintenance of the manometers are outlined here in some detail.

General Guidelines

DASH Manual of Procedures

1. The objective of maintenance of all sphygmomanometers is to ensure their accuracy for blood pressure measurement. The manometer column must be clean and the system free of mercury leakage. The zero level for the conventional device should be accurately read as 0 mmHg at the top of the mercury meniscus. The "zero" levels for the Random-Zero (RZ) device should have a range of approximately 20 mmHg between the maximum and the minimum "zero" level, and 30 mmHg or less for the maximum "zero" level. These values should remain constant for a given instrument, and the maximum "zero" for each instrument should be indicated by label on the front of the machine itself, for comparison to zero levels obtained during actual readings taken with the device.
2. These devices should be cleaned and checked thoroughly on a quarterly basis or approximately every three months. More frequent inspections should be made to ensure there has been no mercury spillage or leakage and no obvious malfunction of the device. Instruments used in clinics should be inspected weekly. Those inspections should include a check of zero levels, mercury leakage, operation of valves, manometer columns for dirt or mercury oxide deposit, and condition of all tubing and fittings.
3. Procedures for inspecting the RZ Manometer (RZM) are outlined below. The manometer portions of both instruments are produced by W.A. Baum Company (Copiague, New York 11726), so that maintenance for this portion of the two devices is the same, as is the case for cuffs, bulbs, and air control valves. More detailed instructions covering these parts are provided in the Baumanometer Service Manual, which is available from the W.A. Baum Company.
4. **Work Area and Mercury Spillage.** All blood pressure devices used in DASH contain mercury, which is a volatile metal at room temperature. In view of the problem of spillage and retrieval of this material, a definite work area should be designated for all manipulations. This area should be in a well-ventilated room. Rugs should not be present. The work bench should be a flat, smooth surface which can be easily cleaned, with adequate space. All work should be done in a large tray or basin with edges that will contain any mercury spill that may inadvertently occur in the process of maintaining the machines. A mercury cleaning solution which inactivates elemental mercury and prevents it from vaporizing should be kept in stock in the work area and the person doing the work should wear a lab coat with no pockets and should remove rings, watches or other metallic objects from his/her hands. A procedure should also be developed for proper handling of accidental mercury spills, and all staff made aware of those procedure.

Common Problems with - and Solution for - both Manometers

Dirty manometer column

DASH Manual of Procedures

- a. This is due to dirty or oxidized mercury and is usually evident near the zero. Oxide and dirt near RZM "zero" can result in too high "zero" readings because mercury hangs on the column wall above its equilibrium level. This does not affect conventional manometer readings, but it is hard to see the meniscus, and hence to check actual zero.
- b. Remove the glass manometer column. See Baum instructions for removal of column from conventional manometer.
- c. Clean the glass column from its top towards its zero, with the "super" pipe cleaners available from Baum. Hold the column over a container to catch mercury as the cleaner is pushing through, and brush the soiled end of the cleaner into the container.

Mercury leakage

This can be due to any of the following:

- a. loose or leaky screw cap at top of manometer
- b. manometer column cracked or chipped, or improperly seated
- c. leaky manometer column gaskets
- d. tilting RZM with mercury reservoir valve open
- e. loose or leaky RZM bellows air bleed screw cap

The mercury level will not remain constant when the bulb valve is closed.

- a. Connect the manometer to a cuff which is around a one pound coffee can. Pump up the cuff and begin to pinch the tubing closed, starting at the manometer tubing.
- b. By a process of pinching the tubing at 1-2 inch intervals up to the cuff and then down to the bulb, you will locate an air leak.
- c. If an air leak is found to be in the cuff bladder or the tubing other than the connections, the bladder may need to be replaced.
- d. If the air leak is found in the connections or in the bulb valve, a little silicone spray may alleviate the problem.

Inspection of the Random-Zero Manometer

Unless obviously damaged due to dropping or other accident, the RZM is expected to operate without disturbance of its measurement performance. Periodic checking should be

DASH Manual of Procedures

done, however, to ensure against undetectable internal leakage, or malfunction of the "randomizing" mechanism.

1. Place device in usual operating position, with reservoir valve open (to side).
2. Remove mounting screws from the front and rear of the wooden casing and remove the casing, keeping the instrument upright at all times.
3. Inspect the base and moving parts for any evidence of mercury leakage.
4. Bleed the air out of the R-Z system and check for mercury leaks. Using a 30 ml or larger syringe and a length of tubing, apply greater than 200 mmHg pressure to the mercury column. (A syringe gives faster and better control than a cuff and a bulb for this purpose, but the observer must be careful not to pull negative pressure.) If a cuff is used, it can be wrapped around a one pound coffee can. Watch the rise of mercury in the chamber, and maintain or increase the pressure until the mercury rise into the narrow vertical stem at the top of the chamber. If mercury does not enter the stem despite prolonged high pressure, deflate the cuff and repeat, after slightly opening the thumbscrew at the top of the stem. This will permit escape of any trapped air. When the mercury has entered the stem, close the thumbscrew firmly (but not excessively tight), and deflate the cuff.
5. Verify the maximum "zero" obtainable
 - a. The bellows valve should be in the "OPEN" position, and no pressure should be in the cuff. The cam should rotate freely.
 - b. Set the cam manually in such a position that the level on the end of the cam will contact the moving wall of the chamber after the shortest possible displacement of this wall toward the cam. (This position draws the least mercury into the reservoir and produces the highest "zero" level for the amount of mercury in the device at this time.)
 - c. Inflate the cuff above 200 mmHg, and maintain it at this pressure until the chamber wall has come to rest against the bevel of the cam.
 - d. Turn the valve to "CLOSE," wait a full 5 seconds, and deflate and disconnect the cuff.
 - e. Record the zero level it should compare closely (within 2 mmHg) with the valve on the label on the face of the manometer.
6. Verify the minimum "zero" obtainable
 - a. Repeat exactly as for (5) above, except set the cam so that the moving wall of the reservoir will move its maximum distance before contacting the cam. (This

DASH Manual of Procedures

position draws the most mercury into the reservoir and produce the lowest "zero" level for the amount of mercury in the device at this time.)

- b. Ensure that full pressure in the cuff is maintained until the wall of the chamber comes to rest against the bevel of the cam; this may take several seconds.
- c. Turn the bellows valves to "CLOSE," and deflate and disconnect the cuff.
- d. Record this "zero" level; it should compare closely (± 2 mmHg) with the value determined when the machine was calibrated.

7. Adjust zero levels if needed

Changes of zero levels are due either to loss of mercury or to air leakage at the bellows air bleed screw; accuracy of readings is not affected. To adjust zero levels, however, mercury must be added or removed from the system.

CAUTION: Mercury vapor is very toxic: Tiny droplets vaporize more rapidly than bulk. All loose mercury must be collected and inactivated. One effective and convenient product for mercury vapor reduction is HgX, a powder produced by Acton Associates, 1180 Raymond Boulevard, Newark, NJ 07102. It is recommended that all work be done in a container such as a plastic dish pan when mercury is to be transferred.

a. If the zero levels are too low:

- (1) Open the bellows control valve and the valve at the top of the mercury reservoir, unscrew and remove the knurled cap at the top of the manometer column, and remove the air bleed screw at the top of the bellows chamber.
- (2) Pour clean mercury into the top of the manometer tube, using a hypodermic syringe barrel or tight paper cone as a funnel. (As Baum writes, mercury can be cleaned of floating dirt and oxides by pouring it through a rolled cone of ordinary scratch paper with a pinhole at its apex. Note that some mercury will stick on and in the paper, so handle with care). About 400 grams (or 14 ounces) of mercury are needed to fill an instrument for a zero range of near 10 to 30 mm.
- (3) Firmly screw the knurled cap onto the top of the manometer column, and apply pressure to the mercury reservoir until the mercury rises into the vertical air column at the top of the bellows chamber. Tighten the air bleed screw quickly and firmly, while the mercury is a short distance into the vertical air column.
- (4) Apply enough additional pressure to raise the mercury to near the top of the manometer column (if it is not already that high); then release the pressure, thus to collect mercury droplets and clear the column of air bubbles. There are likely to be air bubbles trapped on the walls of the plastic tube at the bottom rear; these can sometimes be removed by tapping the tube sharply, but they are, at any rate, of no consequence.
- (5) Determine zero range and adjust as needed.

DASH Manual of Procedures

- b. If the zero levels are too high: Unscrew and remove the knurled cap from the top of the manometer column. Using a syringe with a small tube, such as a catheter, remove the mercury from the manometer. (Or, if these are unavailable, pour surplus mercury from the open manometer column. See Baum instructions; be sure that the mercury reservoir valve is closed before inverting the manometer to pour the mercury out.)

8. Check whether the spin wheel and cam spin freely

- a. Turn the bellows valve on the front of the manometer to "OPEN," and allow the wall of the chamber to move back to its resting position.
- b. Spin several times the rubber-rimmed wheel used in setting the "zero" level for each reading. Note whether the cam spins freely, and whether it is excessively loose.
- c. Adjust the spin by slightly loosening or tightening the mounting screw at the end of the cam.
- d. After any such adjustment, recheck the spinning wheel repeatedly to ensure against tightness or looseness of the cam.

If spin wheel and cam are stuck (with bellows control cock open and all pressure released) or the rise of the mercury column is jerky as pressure is raised, there is usually binding or friction between the bellows plate center boss and the centering pin. Accuracy of readings has not been affected. A drop of good, light machine oil takes care of most such problems.

9. To remove the manometer column for cleaning or for inspection of it and of gaskets:

- a. Set the cylindrical cam for maximum bellows volume, and open the bellows control valve.
- b. Raise the reservoir pressure to about 280.
- c. Close the bellows valve, and release pressure on the reservoir.
- d. Tilt the RZM to the right (reservoir on down side) until all mercury has disappeared below the manometer column. Close the reservoir valve (handle to front). Rest the RZM on its right side, with the spin wheel above the table surface.
- e. The manometer column may now be removed.

10. Maintenance requirements are minimal, but essential.

- a. A very occasional drop of light machine oil is recommended on moving parts including the bellows plate centering pin.
- b. Do not, however, oil the bellows control valve stem or the mercury reservoir valve.
- c. Ensure that moving parts are free without too much slack.

Comparison of a Random-Zero Device with a Conventional Device

DASH Manual of Procedures

To compare two manometers, connect them through a "Y" or "T" fitting to a common pressure source. (Aquarium "T" fittings and tubing of plastic, 5/32" or 4 mm in diameter, are excellent, cheap, and commonly available.) Then compare readings at several different pressures, and average two or three readings at each. Keep the random zero valve in the open position during this procedure. Compare measurements at 50, 120, and 200 mmHg. If the readings are not compatible, check the R-Z zero levels.

Procedures for Training and Certifying BP Technicians - For Trainers' Use Only

When the supervisor feels that the trainee has reached a satisfactory level of proficiency in determining the systolic and diastolic blood pressure level, the trainee should be given The Live Blood Pressure Reading Performance Evaluation. The observer must demonstrate to the training supervisor one or more complete and correct blood pressure determination procedures for 1) cuff selection by correct arm measurement, 2) palpating the brachial artery to center the cuff, 3) proper placement of the cuff with the center of the bladder over the brachial artery, 4) determination of peak inflation level using the random-zero sphygmomanometer, 5) correct blood pressure measurement following the protocol. The final test to certify an observer will be a videotape test. The test involves watching a mercury column on a sphygmomanometer and listening to the simultaneous Korotkoff sounds during blood pressure levels for each on the videotape test sheet. The sheet is then sent to the Coordinating Center where it is graded "pass" or "fail." The systolic and diastolic readings are entered into a computer and scored.

Five lectures (two with slides) are offered in this section to acquaint the trainee with the subject of blood pressure and its measurement. The training of potential blood pressure observers should begin with a general discussion of blood pressures and some of the history of blood pressure measurement. The first lecture, "Blood Pressure Measurements - Problems and Solutions," addresses three topics and also reviews some of the problems and solutions in blood pressure measurement. This presentation is quite limited with respect to the physiology of blood pressure regulation and the hemodynamics leading to production of the Korotkoff sounds. The objective instead is to provide sufficient information for any trainee of high school graduate level or beyond, without prior clinical training, to appreciate the significance of the auscultatory signals for blood pressure reading and to recognize those factors of greatest importance for the quality of the readings.

The second lecture, "The Random-Zero Device," is accompanied by a slide series that aids in the explanation of the mechanics and the proper use of this device.

The third lecture, also accompanied by slides, is entitled, "Procedures in Blood Pressure Recording." This presentation gives instructions in the blood pressure measurement technique adopted by HDFP, TOHP, and now DASH. Procedures for using both the conventional and the random-zero devices are given.

DASH Manual of Procedures

The fourth and fifth lectures will give the local Training Supervisors a broad overview of the maintenance of the blood pressure equipment with special emphasis on mercury safety and tips/requirements for local blood pressure training.

Lecture #1 - Blood Pressure Measurement - Problems and Solutions

What is blood pressure? This question can be answered in many ways - for example, in terms of physiologic and sometimes pathologic processes which contribute to blood pressure regulation. Or, blood pressure can be described in terms of the striking excess in risk of death and disease which accompany high blood pressure levels. For our immediate purposes a more useful and more appropriate answer is, simply: Blood pressure is what is recorded when the measurement methods learned through this training program are carried out.

If we are defining blood pressure in terms of the means of measuring it, the nature of this measurement must be understood. A brief historical sketch is helpful. Measurement of blood pressure by means of the usual mercury manometer, cuff and stethoscope is a method less than 100 years old, although Hales described experimental direct arterial pressure measurements over 200 years ago and Harvey described the circulation of the blood more than 300 years ago.

The start of this century was the period when current, indirect methods were introduced. These were more practical than the lethal method of Hales and qualify as what we would term today a "non-invasive" technique. This indirect method, now almost universally employed, combines the work of Riva-Rocci, an Italian physician who developed the inflatable cuff, and Korotkoff, the Russian physician who described his auscultatory findings, heard through a stethoscope placed over the brachial artery, as an improvement over mere palpation of the radial pulse, a technique limited to detecting systolic pressure alone.

DASH Manual of Procedures

The report of Korotkoff's first observation is an informative summary of the specific sounds he described: On the basis of his observation, the speaker has come to the conclusion that the completely compressed artery under normal circumstances does not produce any sounds. Utilizing this phenomenon, he proposes the auditory method of determining the blood pressure in man. The cuff of Riva-Rocci is placed on the middle third of the upper arm, the pressure within the cuff is quickly raised up to the complete cessation of circulation below the cuff. Then, letting the mercury of the manometer fall, one listens to the artery just below the cuff with a children's stethoscope. At first, no sounds are heard. With the falling of the mercury in the manometer, done to a certain height, the first short tones appear; their appearance indicates the passage of part of the pulse wave under the cuff. It follows that the manometer figure at which the first tone appears corresponds to the maximal pressure. With the further fall of the mercury in the manometer, the systolic compression murmurs are heard, which fade again into tones (second). Finally, all sounds disappear. The time of the cessation of sounds indicates the free passage of the pulse wave; in other words, at the moment of the disappearance of the sounds, the minimal blood pressure within the artery preponderates over the pressure in the cuff. Consequently, the manometric figures at this time correspond to the minimal blood pressure. Experiments on animals gave confirmative results. The first sound-tones appear (10 to 12 mm) earlier than the pulse, for the palpation of which (e.g., in the radial artery) the inrush of the greater part of the pulse wave is required. [Quoted from Ruskin, A. Classics in Arterial Hypertension, Charles C. Thomas, Springfield, 1956 (pp. 127-128)].

With further refinement in criteria by which changes in sound quality are to be judged, we arrive very nearly, but not quite, at the level of technological advance applicable to the conventional mercury sphygmomanometer today. In summary then, we may define blood pressure as the phenomenon measured when the cuff, mercury manometer and stethoscope are used in the standard manner by a trained observer to assess the cardiovascular status of a subject.

Discussion of blood pressure in these terms would be seriously incomplete, however, if we did not take account of the fact that important problems of measurement exist. It is imperative that these problems be recognized and, as far as possible, overcome. What are they?

An excellent review by Evans and Rose (7) distinguishes first random variation within each subject, and second, systematic variation which they subclassify as follows: "(i) alarmingly large differences in estimation between observers, sometimes as large as 15 mmHg..., (ii) effects of the circumstances of measurement, both emotional and physical (especially recent physical activity or change of position), (iii) seasonal changes, and (iv) relatively small errors due to overestimation of pressures in fat arms..."

If these are the major categories of problems, what can be done to deal with them? With respect to random individual variation for each person, we obtain multiple readings on each

DASH Manual of Procedures

occasion of observation and use as our estimate of blood pressure an average of two readings, always excluding the first inflation of the cuff (used only to estimate the peak inflation level).

What about the systematic biases? Taking those listed in reverse order, we may say the following. The fat arm should be wrapped in a cuff of appropriate size - to exclude the effect of a single cuff size in giving falsely high readings for participants with excessive arm girth. Effects of circumstances, especially activity and posture, can be dealt with by requiring that all reading be taken in the sitting position, only after a minimum period of 5 minutes seated at rest, according to carefully prescribed procedures. As to differences between observers, a systematic difference as large as 15 mmHg would indeed be alarming, and in fact, unacceptable. In still another publication dealing with measurement of blood pressure, Rose presented in greater detail some components of the remaining observer differences in blood pressure readings. These components are considered as of two types, one type affecting chiefly the mean of a series of measurements, the other type chiefly distorting the reported frequency distribution of readings. This latter type includes terminal digit preference, which is the unconscious tendency to choose one digit over others in assigning the value of a reading and the prejudice against certain values. Factors affecting mean differences between observers include mental concentration or reaction time, hearing acuity, confusion of auditory or visual cues, interpretation of sounds, rates of inflation and deflation of the cuff, and reading of the moving column of mercury.

Are there answers to these problems? Regarding hearing acuity, deficiencies can be excluded by satisfactory performance on the videotape test. Regarding the effects of prejudicial reading, a device can be used that is designed primarily to overcome this tendency, the Random-zero device. For all the remaining problems, we have a single answer: TRAINING. We will talk shortly about the random-zero device and about the standard procedures to control the circumstances of measurement. Training will occupy the rest of our attention to blood pressure measurement, for a good number of hours. The method of training and its specific objectives are therefore, worth brief discussion now.

Training in blood pressure measurement will take three forms. First, there will be lecture and slide presentations to acquaint you with the proper procedures for measuring blood pressure and also to familiarize you with the random-zero device. Second, you will take actual live blood pressure readings. The objective of live reading practice is to become thoroughly familiar with the details of standard procedure so that their performance becomes a matter of habit. Proficiency in this aspect of training will be assessed under observation by the training supervisor. And third, your ability to measure blood pressure accurately as a result of this training will be tested using a videotape to simulate the fall of mercury with accompanying Korotkoff sounds during an actual blood pressure measurement. You will be required to determine the systolic and diastolic levels for each subject in the film, within predetermined limits.

DASH Manual of Procedures

Our responsibility, in supervision of this training program, is to offer all possible assistance to each of you, individually, in meeting these requirements and in completing each step necessary for your certification as a qualified blood pressure observer. We trust that you will take every opportunity to raise questions and indicate to us any problems you may have in working with these materials and completing the program satisfactorily. Accurate blood pressure measurement is critical, and there are methods available to substantially reduce the systematic errors that we have recognized. Your participation in this program will take advantage of these methods to assure a highly qualified group of observers.

Lecture #2 - The Random-Zero Device

The random-zero device is essentially a mercury sphygmomanometer like the conventional device in common use. It differs in the important aspect that a mechanical addition allows the mercury level in the column to be varied for each reading and concealed from the observer until the systolic and diastolic readings have been completed. This arrangement thus avoids the observer bias which is often at play when the observer knows the actual pressure level as the reading is carried out.

How this device is operated and how its mechanical features fulfill the objectives of its design can best be appreciated by inspecting the device, by practicing its use, and by preliminary inside view. We will take this preliminary view first, through a series of slides, and later practice with it. Copies of the slides are maintained at the Baltimore clinical center (copies will be distributed to all sites and to the Coordinating Center). Listed below is the script to accompany each slide.

Slide# Script for Slide

1. As we have already discussed, the random-zero device and the conventional mercury sphygmomanometer are essentially very similar. This can be seen in comparing the two devices side by side. The random-zero device is unique, however, as the following slides will show.
2. The crucial distinction is the wheel on the right-hand side of the random-zero casing. To get a little closer to the workings of the device, we may remove the front of the casing.
3. The manometer column, the cuff and its connections, and one notable feature: a lever controlling the reservoir outlet. This lever is always closed for carrying the device (i.e., turned to the left) and opened (i.e., turned to the right) for operating it. You might notice also that the mercury rests at a level well above 0 mm, even though the cuff is not inflated. Let's take a close look at the mechanism, that accomplishes this to see how simple it really is.

DASH Manual of Procedures

4. To remove the rear portion of the casing (which should be done only by the Training Supervisor or other authorized staff member, and only when necessary for adjustment or standardization) one needs only to remove two screws from the upper face of the device, and two from the lower rear.
5. Now we can get a better look at the inside. You will notice right away that the wheel you spin from outside is larger in diameter than you might have guessed, and it occupies a central position in the internal mechanism of the device. The movable rear wall of the chamber is the large round disk up above, which is ringed with its rubber seal.
6. From directly behind you can see the wheel in relation to the chamber wall, and also the black rubber air hose connecting the cuff with the top of the mercury-filled plastic hose which connects the bottom of the reservoir with the chamber.
7. In this view you can see the control knob which the observer operates to open and close the connection between chamber and reservoir. Also, nearly the whole movable chamber wall can be seen. What gets in the way is a long aluminum cylinder cam which we will want to focus on in a moment. From the side we can see the three key elements that give this device its special value: the rubber-edged wheel which is spun (from the outside) before each reading; the cylindrical aluminum cam which contains the rubber rim of the wheel and spins at the same time (and its beveled forward end which extends forward in varying degrees depending on where it comes to rest); and finally the movable rear wall of the chamber, which will be arrested in its backward movement when pressure is applied as soon as it contacts the cam. When the cuff is inflated, pressure on the reservoir will force mercury into the chamber until the wall reaches the cam and stops. The amount of mercury in the chamber at this point will determine the "zero" reading for this one time, aiding the observer to make objective readings unaffected by the knowledge of the true reading.

Lecture #3 - Procedures in Blood Pressure Recording

These procedures in blood pressure recording were developed after extensive consideration and discussion of numerous approaches to measurement techniques. In addition to the selection of instruments and specification criteria for measurement, we specify methods for the entire sequence of steps in blood pressure recording. For all observers, whether inexperienced in blood pressure measurement or accustomed to different procedures, it will be important to become intimately familiar with these procedures and to carry them out, as early as possible, as a matter of habit. As an introduction, the following series of slides is presented to demonstrate the steps involved for the recording of blood pressure. The sequence presented here illustrates use of both the random-zero and the conventional sphygmomanometers. Copies of the slides are maintained at the Baltimore clinical center (copies will be distributed to all sites and to the Coordinating Center). Listed below is the script to accompany each slide.

DASH Manual of Procedures

Slide# Script for Slide

DASH Manual of Procedures

Equipment and Supplies

1. The equipment needed by each observer includes a random-zero sphygmomanometer in good condition,
2. A conventional sphygmomanometer
3. Access is needed to the full set of cuff sizes for this population. These are commonly referred to as the child (or pediatric) or small adult, adult (or regular), large, and thigh (or extra large) cuffs, respectively.
4. The inflation bulb should operate smoothly and should perhaps be individualized to each observer.
5. The stethoscope, in good condition, should be switched for use of the bell in listening to the Korotkoff sounds.
6. A watch with a sweep second hand or with a digital second display, or a stop watch, is needed for measurement of the pulse rate and for timing certain other steps until they become a matter of habit.
7. A measuring tape in metric units is required for determination of the correct cuff size for each participant.
8. A ball point pen should be used for all data recording, preferably with medium or larger point, and black ink.
9. Requirements for furniture are simple but must provide for a comfortable resting position of the arm with mid-cuff at heart level.
10. The appropriate study form must be in place before measurement begins.
11. Stand for RZ and standard monitor so equipment can be read at eye level.

Arm Measurement

12. The right arm should always be used for measurements unless there is a medical reason not to use the right arm.
13. Measurement of the arm is required for selection of the proper cuff. For this measurement, the arm should be bare.

DASH Manual of Procedures

14. The measurements are taken on the right arm, with the participant standing, holding the forearm horizontal.
15. Arm length is measured from the acromion or bony extremity of the shoulder girdle,
16. To the olecranon, or tip of the elbow.
17. The full arm length from acromion to olecranon is measured, and
18. The midpoint is marked on the dorsal surface of the arm.
19. With the participant's arm relaxed at the side, the arm circumference is measured by drawing the tape snugly (without indenting the skin) around the arm at the level of the midpoint marking. Care must be taken to keep the tape horizontal.
20. The chart of arm circumference measurements and corresponding cuff sizes is consulted, and
21. The proper cuff size is checked. Indicate the cuff size on the form.

Preparation for Actual Readings

22. The participant should then be seated with the elbow and forearm resting comfortably on a table with the palm of the hand turned upward. The area to which the cuff must be applied must be bare. The bend of the elbow should be at heart level.
23. Legs should be uncrossed and feet comfortably flat on the floor.
24. The brachial artery is located by palpation and marked, (just medial to and above the cubital fossa).
25. As is the midpoint of the rubber bladder within the cuff. Often this point is marked on the cuff itself.
26. The cuff is then wrapped about the arm so that the midpoint of the bladder lies over the brachial artery, and the mid-height of the cuff is at heart level.
27. Allow a five minute wait before taking the BP. Conversation should be limited during this time. You should leave the room after a brief explanation.

DASH Manual of Procedures

Pulse

28. After the period of 5 minutes at rest has been completed, the radial pulse is counted for a timed interval of exactly 30 seconds.
29. The 30-second count is recorded.
30. The standard mercury sphygmomanometer is then connected with the cuff.
31. The manometer is positioned so that the midpoint of the column is at the observer's eye level when in position to carry out the measurement of blood pressure.
32. The radial pulse is located, and palpated.
33. The cuff is inflated quickly to 80 mmHg.
34. Slowly inflate at 10 mmHg at a time until the radial pulse can no longer be felt.
35. The cuff is quickly and completely deflated.
36. Record the pulse obliteration pressure (POP).
37. Calculate and record the peak inflation level (pulse obliteration pressure + 60). The peak inflation level used for BP measurement must be ≥ 180 mmHg.

First Blood Pressure Reading

38. To perform the measurement of blood pressure itself, the brachial artery is again palpated. Note that the arm remains bare.
39. The wheel of the random-zero is gently spun with the valve in the OPEN position.
40. The stethoscope ear pieces are put in place with the ear pieces positioned forward.
41. The bell of the stethoscope is placed carefully and without excessive pressure over the brachial artery, just between the elbow crease and lower edge of the cuff.
42. With the valve still in the OPEN position, the cuff is inflated quickly and smoothly to the peak inflation level or to 180 mmHg, whichever is higher. Hold the mercury at this pressure for 5 seconds.
43. The valve is then turned to the CLOSE position.

DASH Manual of Procedures

44. The cuff is then deflated very steadily at 2 mmHg per second,
45. To a level 10 mmHg lower than the level of the last Korotkoff sound heard.
46. The mercury level is now dropped quickly to the "zero" level for this reading.
47. The observed values for the SBP, DBP, and "zero" values are recorded.
48. Remove stethoscope ear pieces.
49. Disconnect the cuff and record the zero reading. **DO NOT SUBTRACT THE ZERO READING UNTIL ALL THREE MEASUREMENTS ARE COMPLETED.**

Between Reading

50. Have participant raise arm for 5 seconds, then rest arm on table for 25 seconds.

Second and Third Blood Pressure Reading

51. The second and third readings are carried out exactly as the first.
52. After finishing both RZ BP measurements subtract the zero value from the readings to get the actual systolic and diastolic values.
53. All arithmetic must be done with a calculator after both readings have been completed.

Lecture #4 - Equipment Maintenance And Mercury Toxicity Safety

(This lecture is essentially a repeat of the material covered under pages 11-18).

The condition of the instruments for blood pressure measurement is too often ignored in common practice and should be a special responsibility of the blood pressure observer. This person should be acquainted with mercury toxicity safety procedures as well as construction and function of all the blood pressure equipment. The cuffs and stethoscope, cleanliness and general working order can usually be determined by simple instruction. For either the conventional or random-zero sphygmomanometer, handling of breakable parts and of mercury and oxidized waste requires more careful attention. guidelines for suggested maintenance procedures for the manometers are outlined here.

DASH Manual of Procedures

General Guidelines.

1. The objective of maintenance of all sphygmomanometers is to ensure their accuracy for blood pressure measurement. The manometer column must be clean and the system free of mercury leakage. The zero level for the conventional device should be accurately read as 0 mmHg at the top of the mercury meniscus. The "zero" levels for the random-zero device should have a range of approximately 20 mmHg between the maximum and the minimum "zero" levels, the absolute values being 4 mmHg or more for the minimum "zero" level and 30 mmHg or less for the maximum "zero" level. These values should remain constant for a given instrument, and the maximum "zero" for each instrument should be indicated by label on the front of the machine itself for use in the calculation of peak inflation levels for each reading with the device.
2. These devices should be cleaned and checked thoroughly on a quarterly basis (approximately every three months). More frequent inspections should be made to ensure there has been no mercury spillage or leakage and no obvious malfunction of the device. Instruments used in clinics should be inspected weekly. These inspections should include a check of zero levels, mercury leakage, operation of valves, manometer columns for dirt or mercury oxide deposit, and condition of all tubing and fittings.
3. Procedures for inspecting the random-zero manometer are outlined below in the section called Inspection of the Random-zero Manometer. The manometer portions of both instruments are produced by W.A. Baum Company (Copiague, New York 11726) so that maintenance for this portion of the two devices is the same, as is the case for cuffs, bulbs, and air control valves. More detailed instructions covering these parts are provided in the Baumanometer Service Manual which is available from the W.A. Baum Company.

Common Problems with -- and Solutions for -- the Manometer

1. Problem: Dirty manometer column.

Solution:

- a. This is due to dirty or oxidized mercury and is usually evident near the zero. Oxide and dirt near random-zero machine "zeros" can result in too high "zero" readings because mercury sticks on the column wall above its equilibrium level. This does not affect conventional manometer readings, but it is too hard to see the meniscus, and hence to check the actual zero.
- b. Remove the glass manometer column. See Baum instructions for removal of column from conventional manometers.

DASH Manual of Procedures

- c. Clean the glass column from its top towards its zero, with the "super" pipe cleaners available from Baum. Hold the column over a container to catch mercury as the cleaner is pushing through and brush the soiled end of the cleaner into the container.

2. Problem: Leaked mercury

Solution:

This can be due to any of the following:

- a. Loose or leaky screw cap at top of manometer
- b. Manometer column cracked or chipped, or improperly seated
- c. Leaky manometer column gaskets
- d. Tilting the random-zero manometer with the mercury reservoir valve OPEN.
- e. Loose or leaking random-zero manometer bellow on blood screw cap

3. Problem: The mercury level will not remain constant when the bulb valve is closed.

Solution:

- a. Connect the manometer to a cuff which is around a one pound coffee can. Pump up the cuff and begin to pinch the tubing closed, starting at the manometer tubing.
- b. By a process of pinching the tubing at 1 to 2 inch intervals up to the cuff and then down the bulb, you will locate an air leak.
- c. If an air leak is found in the cuff bladder or in the tubing other than the connections, the bladder may need to be replaced.
- d. If the air leak is found in the connections or in the bulb valve, a little silicone spray may alleviate the problem.

Inspection of the Random-zero Manometer.

Unless obviously damaged due to dropping or other accident, the random-zero sphygmomanometer is expected to operate without disturbance of its measurement performance. Periodic checking should be done, however, to ensure against undetectable internal leakage or malfunction of the "randomizing" mechanism.

1. Place device in usual operating position. with reservoir valve OPEN (to side).

DASH Manual of Procedures

2. Remove mounting screws from the front and rear of the wooden or plastic casing and remove the casing keeping the instrument upright at all times.
3. Inspect the base and moving parts for any evidence of mercury leakage.
4. Bleed the air out of the system and check for mercury leaks. Using a 30 ml or larger syringe and a length of tubing, apply greater than 200 mmHg pressure to the column. (A syringe gives faster and better control than a cuff and bulb for this purpose, but the observer must be careful not to pull negative pressure. If a cuff is used, it can be wrapped around a one pound coffee can.) Watch the rise of mercury in the chamber and maintain or increase the pressure until the mercury rises into the narrow vertical stem at the top of the chamber. If mercury does not enter the stem despite prolonged high pressure, deflate cuff and repeat, after slightly opening the thumbscrew at the top of the stem. This will permit escape of any trapped air. When the mercury has entered the stem, close the thumbscrew firmly (but not excessively tight), and deflate the cuff.
5. Verify the maximum "zero" obtainable.
 - a. The bellows valve should be in the OPEN position and no pressure should be in the cuff. The cam should rotate freely.
 - b. Set the cam manually in such a position that the level on the end of the cam will contact the moving wall of the chamber after the shortest possible displacement of this wall toward the cam. This position draws the least mercury into the reservoir and produces the highest "zero" level for the amount of mercury in the device at this time.
 - c. Inflate the cuff above 200 mmHg and maintain it at this pressure until the chamber wall as come to rest against the bevel of the cam.
 - d. Turn the valve to CLOSE, wait a full 5 seconds, and deflate and disconnect the cuff.
 - e. Record the zero level. It should compare closely (within 2 mmHg) with the label on the face of the manometer.
6. Verify the minimum "zero" level obtainable.
 - a. Repeat exactly as for (5) above, except to set the cam so that moving wall of the reservoir draws the most will move its maximum distance before contacting the cam. This position mercury into the reservoir and produces the lowest "zero" level for the amount of mercury in the device at this time.

DASH Manual of Procedures

- b. Ensure that full pressure in the cuff is maintained until the wall of the chamber comes to rest against the bevel of the cam. This may take several seconds.
 - c. Turn the bellows valve to CLOSE and deflate and disconnect the cuff.
 - d. Record this "zero" level. It should compare closely (within 2 mmHg) with the value determined when the machine was calibrated.
7. Adjustment of zero levels. Changes of zero levels are due either to loss of mercury or to air leakage at the bellows air bleed screw. Accuracy of readings is not affected. To adjust zero levels, however, mercury must be added to or removed from the system.

CAUTION: Mercury vapor is very toxic. Tiny droplets vaporize more rapidly than bulk. All loose mercury must be collected and inactivated. One effective and convenient product for vapor reduction is "HgX", a powder produced by Acton Associates, 1180 Raymond Blvd., Newark, NY 07102. It is recommended that all work be done in a container such as a plastic dish when mercury is to be transferred.

- a. If the zero levels are too low:
 - (1) Open the bellows control valve and the valve at the top of the mercury reservoir, unscrew and remove the knurled cap at the top of the manometer column, and remove the air bleed screw at the top of the bellows chamber.
 - (2) Pour clear mercury into the top of the manometer tube, using a hypodermic syringe barrel or tight paper cone as a funnel. (As Baum writes, mercury can be cleared of floating dirt and oxides by pouring it through a rolled cone of ordinary scratch paper with pinhole at its apex. Note that some mercury will stick on and in to paper, so handle with care). about 400 grams (or 14 ounces) of mercury are needed to fill an instrument for a zero range of near 10 to 30 mm.
 - (3) Firmly screw the knurled cap onto the top of the manometer column and apply pressure to the mercury reservoir until the mercury rises into the vertical air column at the top of the bellows chamber. Tighten the air bleed screw quickly and firmly while the mercury is a short distance into the vertical air column.
 - (4) Apply enough additional pressure to raise the mercury to near the top of the manometer column if it is not already that high. Then release pressure, thus to collect mercury droplets and clear the column of air bubbles. These are likely to be air bubbles trapped on the walls of the plastic tube at the bottom rear. These can sometimes be removed by tapping the tube sharply, but they are, at any rate, of no consequence.
 - (5) Determine zero range and adjust as needed (see above).

DASH Manual of Procedures

- b. If the zero levels are too high: Unscrew and remove the knurled cap from the top of the manometer column. Using a syringe with a small tube, such as a catheter, remove the mercury from the manometer. (Or, if these are unavailable, pour surplus mercury from the open manometer column. See Baum instructions. Be sure that the mercury reservoir valve is closed before inverting the manometer to pour the mercury out.)
8. Check whether the spin wheel and cam spin freely.
 - a. Turn the bellows valve on the front of the manometer to OPEN and allow the wall of the chamber to move back to its resting position.
 - b. Spin several times the rubber-rimmed wheel used in setting the "zero" level for each reading. Note whether the cam spins by freely and whether it is excessively loose.
 - c. Adjust the spin by slightly loosening or tightening the mounting screw at the end of the cam.
 - d. After any such by adjustment, recheck the spinning wheel repeatedly to ensure against excessive tightness or looseness of the cam. If spin wheel and cam are stuck (with bellows control cock open and all pressure released) or the rise of the mercury column is jerky as pressure is raised, there is usually binding or friction between the bellows plate center boss and the centering pin. Accuracy of readings has not been affected. A drop of good, light machine oil takes care of most such problems.
9. To remove the manometer column for cleaning or for inspection of it and of gaskets:
 - a. Set the cylindrical cam for maximum bellows volume and open the bellows control valve.
 - b. Raise the reservoir pressure to about 280.
 - c. Close the bellows valve and release pressure on the reservoir.
 - d. Tilt the sphygmomanometer to the right (reservoir on down side) until all mercury has disappeared below the manometer column. Close the reservoir valve (handle to front). Rest the device on its right side with the spin wheel above the table surface.
 - e. The manometer column may now be removed.

DASH Manual of Procedures

10. Maintenance requirements are minimal, but essential:

- a. A very occasional drop of light machine oil is recommended on moving parts including the bellows plate centering pin.
- b. Do not, however, oil either the bellows control valve stem or the mercury reservoir valve.
- c. Ensure that moving parts are free without too much slack.

Lecture #5 - Training Observers In The Clinical Center

There are three distinct sections involved in the responsibility of the local Training Supervisors. First is the preparation for the training session. Second is the time scheduling of the sessions. And third is the documentation of certification to the Coordinating Center.

Preparation for Training Observers

A. Gather all the blood pressure equipment.

1. Both the conventional and random-zero manometers.
2. All four basic sizes of blood pressure cuffs with bulbs
3. A bell stethoscope

Familiarize yourself with all the blood pressure equipment. Prepare for mercury safety procedures and prepare an equipment maintenance schedule. Check all random-zero sphygmomanometers for maximum and minimum zero levels. The standard sphygmomanometers should be checked so that the top of the mercury meniscus is at the zero marking. The stethoscopes should be clean and turned to the bell. The cuffs and air valve should be checked for air leaks.

B. Gather all the Training Materials.

1. This training manual
2. The appropriate forms and paper
3. 2x2 slide projector and carousel
4. Videotape machine

DASH Manual of Procedures

5. Black ball-point pen

You should carefully familiarize yourself with all the training materials. Only you know how much practice will be needed for you to present the lectures to your trainees. Be sure you have plenty of photo copies of all the forms (the Written Examination, the Live blood Pressure Performance Evaluation Sheet, and the Videotape Test Sheet). Familiarize yourself with the operation of the slide projector and videotape machine.

Training Tips

- A. Schedule the training sessions over a period of days. An unhurried schedule gives the trainee a chance to absorb and demonstrate the procedures and knowledge with more confidence. Remember, you may be training someone who needs to unlearn previously learned blood pressure procedures. Also remember the stethoscope can cause ear discomfort when used for several hours at one time.
- B. Try to keep the group size workable. The lectures may work for a large group, but consider the waiting/noise factor when scheduling the written test, blood pressure practice/evaluation and the videotape viewing.
- C. The certification of the trainee and duties as an observer should not be planned for the same day. The trainee cannot complete the certification and begin taking participant blood pressures that same day. Plan time to allow for the return of all the documentation to the Coordinating Center, and return of the notice of certification. If scheduling requires, it may be possible to confirm certification of observers by telephone once all materials have been received. We realize that infrequently a crisis will arise. The videotape test values may be called in by telephone and scored that day, with the written documentation following in the mail, but this should be a rare occasion.

Documentation of Certification

- A. Each person in the Clinical Center that will be filling out any part of a blood pressure form will need a study ID code. This includes the blood pressure observers. Only one code number should ever be assigned to one person, no matter how many changes in status might occur.
- B. The Written Examination should be taken by the trainee and graded by the supervisor. If there are any differences in responses, it should be discussed and clarified. The supervisor should indicate those responses that were discussed by initializing them.

DASH Manual of Procedures

- C. The Live Blood Pressure Reading Performance Evaluation should be carefully followed to ascertain that the trainee has a clear understanding of the procedures. This evaluation should be completed by the supervisor as a passive observer. Avoid prompting the trainee. The trainee should complete one or more complete and uninterrupted exercises of the full procedure. Errors of procedure should be reviewed, discussed and corrected. When carried out without procedural errors, this record should be completed, signed and included with the certification packet of the trainee.

- D. When the videotape test is taken, remind the trainee to insert leading zero's where necessary and to complete the entire form. The test will be graded upon arrival at the Coordinating Center. If a systematic problem is discovered via computer scoring, the Coordinating Center will instruct you as to the type of problem discovered. The specific problem would not be identified to the trainee, as this may artificially bias the trainee's responses. Retraining, possibly by Y-tube readings, may help to identify and correct the problem. If the problem is not corrected within several retrainings, the problem is probably auditory and trainee would need to be excluded from taking blood pressures. The Coordinating Center will need to have complete documentation of the certification before the trainee can be employed as a blood pressure observer. We suggest the supervisor keep the originals and send photocopies to the Coordinating Center. The Coordinating Center will instruct the Training Supervisor when recertifications should be scheduled, on a bi-annual basis.

Initial Certification Procedures And Criteria

Three Steps Needed For Certification

In order to standardize the previously described methods of blood pressure measurement and to ensure that a high level of performance is attained, a three part training session has been developed. After successful completion, an observer is certified to take blood pressures in the study program. The three steps needed for certification are enumerated below.

1. The first step is a series of blood pressure readings presented on a videotape to test the observer's identification of the systolic and diastolic Korotkoff sounds. The tape mimics the actual blood pressure measurement setting by providing a series of blood pressure readings which consist of both the visible falling of the mercury in a sphygmomanometer and the audible Korotkoff sounds. An observer is certified if the criteria of the scoring procedure are successfully met. The criteria of the scoring procedure are not available to the Clinical Center or to the observers. The scoring will be done via computer at the Coordinating Center upon the receipt of observer's test sheets.

DASH Manual of Procedures

2. The second step of blood pressure training is the completion of the Written Examination after lectures 1-3 have been presented. This is a short examination consisting of questions that test the blood pressure observer's knowledge and understanding of the measurement technique detailed in the training course.
3. The third step is the successful completion of The Live Blood Pressure Reading Performance Evaluation. The training supervisor is to verify the correct procedure for blood pressure measurement by observing the trainee in one or more complete and uninterrupted exercises of the full procedure, in addition to three y-tubed readings with the trainer and observer recording blood pressure on three different individuals. When carried out without procedural errors, this record should be completed, signed, and included with the certification packet for the trainee. Errors of procedure should be reviewed, discussed, and corrected until one completed determination is accomplished without error.

As a means of maintaining a high level of quality and standardization over time, blood pressure observers will be recertified biannually (every 6 months). This recertification will involve, at a minimum, repeated testing by viewing the videotape and submitting a completed test sheet, as well as live measurement performance evaluation. The Coordinating Center will notify the Clinical Centers as to the schedule and requirements of the recertification. A further description is in the section called Annual Recertification and Retraining.

Instructions for Taking the Videotest

Viewing of the videotape, "Measuring Blood Pressure," may be done in a group or individually. The videotape consists of one practice reading followed by twelve systolic and diastolic sequences. After each sequence, the observer should record, on the recording sheet provided, the systolic and diastolic reading for that sequence. All entries should be completed legible and written in black ink. The manometer in the videotape is read exactly as one would read in actual practice. Each blood pressure should be read to the nearest even digit.

Study Forms Required For Certification Procedures

Four study forms are required for certification.

1. Written Examination (form #44) (and its key);
2. DASH Blood Pressure Observation Checklist form (form #45).
3. DASH Blood Pressure and Weight Certification Form (form #46).

DASH Manual of Procedures

4. The Videotape Test Sheet (form #63).

These four forms may be found in the DASH Forms Manual.

Annual Recertification and Retaining

As with the initial certification process this recertification process includes the successful completion of:

- a written test
- a live evaluation
- a videotape test

Training Supervisors will be retrained centrally every spring. recertifications for the other Blood Pressure Observers will also be biannually, but after the recertification of the Supervisors (unless an Observer is centrally certified).

The recertification procedures for the Blood Pressure Observers will be conducted at the Clinical Centers. However, scoring of the video tests will be done by the Coordinating Center, **which is responsible for identifying who is a certified blood pressure observer.** Results of the recertification tests will be telephoned (and subsequently mailed) to a Clinical Center within three (3) working days of receipt of the test data from the clinic. A report based upon the results of these tests may be presented to the Steering Committee and the Data, Safety, and Monitoring Board. This report would describe how well the observers are measuring blood pressure levels under standardized conditions, and how many observers had difficulty being recertified.

Of course, the results of the tests may indicate that an observer may need to be retrained in some or all aspects of blood pressure measurement. If this is required, this person will discontinue the measurement of blood pressure levels for the trial until he or she is successfully recertified by the Coordinating Center. Central retraining may be required.

Also, if an observer misses a recertification cycle, he or she must repeat the training program.

Blood Pressure Measurement Quality Control

Overview

Two primary methods exist for monitoring the performance of trained observers in the measurement of blood pressures during the course of a clinical trial. The first is the completion of an Biannual Recertification set of procedures. The second is the regular monitoring by the Coordinating Center of all observers for digit preference.

DASH Manual of Procedures

In addition to these, DASH has adopted and instituted a comprehensive program to insure the collection of high quality blood pressure measurements. Factors contributing to this include:

1. Recruitment of the most qualified personnel.
2. Standardized training and certification.
3. Retraining of observers having difficulties with standardized measurements.
4. Bimonthly (every other month) observations by the Training Supervisors of data collection techniques of the Blood Pressure Observers on either a patient or DASH personnel, using the checklist at the end of this chapter. One checklist is used for each blood pressure observer. These should be kept on file and will be reviewed at site visits.
5. Biannual (every 6 months) simultaneous Y-Tube observations of each Observer by the blood pressure Training Supervisor on either a participant or DASH personnel (described in Bi-Annual Y-Tube Stethoscope Observations.).
6. Frequent staff meetings to provide feedback.
7. Continuous editing and analysis of data by the Coordinating Center.
8. Presentation of data analysis to the Clinical Centers by the Coordinating Center to provide feedback three times per year.
9. Equipment maintenance program (described in Local Blood Pressure Equipment Maintenance And Mercury Toxicity Safety Responsibility).

Monitoring for Digit Preference

It is well documented in other large blood pressure studies that even well trained observers have the capability to lapse into an unconscious digit preference over time. Digit preference is defined as a predilection to record the terminal digit of a blood pressure measurement as either a "0" or a "2", or a "4", or a "6", or "8", rather than the actual value. For example, an observer with a "0" digit preference may record an 82 mmHg DPB (or a 78 mmHg) as 80 mmHg.

NO OBSERVER SHOULD EVER HAVE A DIGIT PREFERENCE.

DASH Manual of Procedures

The Coordinating Center will provide monthly reports on digit preference of certified DASH blood pressure technicians. Because of the numbers of analyses, it is assumed that some of these reports will indicate "significant" digit preference by chance alone. Many others will serve as evidence of mild digit preference. Since there are five possible terminal digits for each blood pressure (0,2,4,6,8), the expectation of any large number of readings is that 20% of readings will end in each of those digits. For the purposes of responding to digit preference reports on individual technicians involving 30 or more blood pressure readings, the Coordinating Center will act as follows:

1. No statistically significant digit preference - report to centers; center will share individual data with each technician;
2. Statistically significant digit preference, but no terminal digits occurring less than 16% or greater than 29% of the time - report to centers; center will share individual data with technician and counsel to be careful about technique;
3. Statistically significant digit preference and one or more digits reported on 30-39% or 10-14% of readings - report to centers; center will share individual data and review technique with technician;
 - a. Statistically significant digit preference of this magnitude persists on next report - formal re-certification must occur within one week of second report; observation and counseling should follow;
 - b. Statistically significant digit preference absent on next report and observed distribution includes no digits >29% or <16% - return to usual monitoring schedule;
 - c. Digit preference improved, but still statistically significant - review technique; monitor for continued digit preference; if significant on third consecutive report, regardless of range, re-certification is required within one week of third report;
4. Statistically significant digit preference; one or more digits reported $\geq 40\%$ and/or <10% of the time and/or odd-numbered terminal digits reported - Coordinating Center will notify PI/project director and discuss case individually; re-certification required as soon as possible, but in no case later than one week after notification.

In addition, the Coordinating Center will raise for discussion any situations that appear to be problematic for the trial. This might include individual technicians exhibiting extremes of digit preference or repeated, uncorrected levels of digit preference or centers that collectively exhibit unusual levels of digit preference. The Steering Committee may take action specific to such cases at its discretion.

DASH Manual of Procedures

Coordinating Center reports on digit preference will not reveal the specific digit that is biased.

Bi-Annual Y-Tube Stethoscope Observations

Y-Tube stethoscope observations are made in conjunction with the initial training and or bi-annual recertification. The Training Supervisor has the Observer go through the entire blood pressure measurement procedure using a quality control checklist. The Observer and Supervisor listen with the Y-tube and record the value on separate sheets.

Three measurements on three subjects are obtained and originals sent to the Coordinating Center. A copy is kept on file at the clinical center.

It should be emphasized again that some difference (no more than average ± 4 mmHg in 3 readings on a single individual) between Supervisor and Trainee is to be expected, and that exact correspondence should not be expected nor taken even implicitly as a criterion of accurate performance by the Trainee. Rather, this process is intended to formalize the "live reading", to provide a written record of the results, and to identify gross problems that could be detected only by the Supervisor's close involvement with the Blood Pressure Observer. Any problems identified by the Supervisor or raised by the Observer should be discussed and, as far as possible, resolved.

Responsibilities of the Coordinating Center and the Training Supervisors

It is the responsibility of the Coordinating Center to centrally train and certify the Training Supervisors. While it is primarily the responsibility of the Training Supervisors to return to the Clinical Centers and train other observers, these other observers may also be trained centrally by the Coordinating Center. However, only the Coordinating Center is able to certify an observer as described above.

Each site is required to have at least two certified trainers. If, between recertifications, the Coordinating Center and/or a Training Supervisor have evidence that an Observer is not performing well, the three parties will meet to discuss the matter. It may be necessary for the Coordinating Center to temporarily rescind a certification and retrain the Observer. In this case, until the Observer is recertified, he or she may not take blood pressure measurements for DASH.

It is also the responsibility of the Coordinating Center to monitor the specific activities of the Training Supervisors. In addition to the continuous monitoring of all incoming blood pressure data (e.g., for digit preference or bad values), the files of the bimonthly (every other month) blood pressure checklists and maintenance logs will be reviewed at each site visit for completeness and accuracy. Also at these site visits, the Training Supervisors themselves will undergo checklist monitoring. Finally, the Training Supervisors themselves

DASH Manual of Procedures

will be recertified centrally every spring, before the annual recertification of the other Blood Pressure Observers.

DASH Manual of Procedures

Acknowledgment of Adaptation

DASH
Blood Pressure Measurement
Training and Quality Control
Adapted by
Jeanne Charleston

Adapted from the
Procedures of the MDRD, SHEP, TOHP and AASK
which were based on the
Procedures of the Hypertension Detection and Follow-up Program (HDFP)
by:
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20. Central Laboratory Procedures

Introduction	3
Equipment and supplies	3
General Instructions	4
Instructions for Collection and Processing of Fasting Blood Specimens	5
Local Laboratory Chemistry Panels	6
Verify Fasting State	6
Venipuncture	6
Requirements for the Oral Glucose Tolerance Test (Selected sites only)	7
Processing of Blood Samples	7
Log sheet	9
Storage	9
Instructions for Collection and Processing of 24-Hour Urine Specimens	9
Processing of 24-Hour Urine Specimens	9
Shipping Instructions	10
Quality Control for Laboratory Procedures	11
Central Laboratories	11
Clinical Centers	12

DASH Manual of Procedures

Summary of Edits

New changes in Version 2.0

- Page 3-3rd bullet: “all subjects at selected sites”.
- Page 10, last sentence: Beginning with the second urination of the day, collect all urine for the next 24 hours from the time of discarded urine.
- Page 23 same as page 10 above.
- Page 3-2nd and 4th bullet added Plasma
- Page 3-5th bullet merged with bullet 7.
- Page 8 - Deleted Yellow top tubes and two paragraphs afterwards. Inserted (Plasma and buffy coat) after 10-ml purple top tubes.
- Page 9 Inserted paragraph containing buffy coats.
- Page 17 under Container Type, insert From two purple, etc. and deleted size & number.

New changes in Version 2.1

- Page 11 inserted *Quality Control for Laboratory Procedures*

New changes in Version 2.2

- Page 20-8, purple top for renin should be aliquoted into 2 (not 3) 2-ml microtubules (table on 20-17 was correct)
- Page 20-9, TBA purple top should be aliquoted into 2 (not 3) 2-ml microtubules (table on 20-18 was correct)
- Page 20-12, item 6 changed from yellow top to purple top (text and tables were correct before)

New changes in Version 4.0

- none

DASH Manual of Procedures

Introduction

The objectives of the DASH central laboratory studies are:

- To analyze sodium, potassium, calcium, magnesium, urea nitrogen and creatinine, in 24-hour urine samples taken during screening, run-in, and intervention (CNRU Lab).
- To analyze plasma renin levels in all subjects during run-in and at end of intervention (CNRU Lab).
- To analyze glucose and insulin levels (oral glucose tolerance test) in all subjects at selected sites during run-in. (CNRU lab).
- To analyze plasma lipids (HDL cholesterol, triglycerides, and calculated LDL cholesterol) during run-in and at the end of intervention (Lipid Lab).
- To freeze for future analysis samples of urine and blood as well as a preserved buffy coat for DNA analyses.
- To analyze serum calcium regulating hormones (1,25 di-hydroxyvitamin D, parathyroid hormone), and ionized calcium during run in and at the end of intervention.

Please review these procedures carefully and if you need help or have questions about laboratory procedures, call Kate Nilan (CNRU Laboratory (503) 494-6847) or Carol Marsh (Lipid Laboratory (503) 494-2005).

Although these procedures are written expressly for the central laboratory procedures, it is recommended that, where applicable, they also be followed for local laboratory procedures in order to maximize uniformity and familiarity with the procedures.

Equipment and supplies

Provided by Clinical Centers

- Centrifuge (refrigerated)
- Refrigerator
- -70°C freezer (a non-cycling -20°C is acceptable if specimens are shipped within seven days of collection)
- Blood tubes - purple (10 ml), yellow (8.5 ml), tiger (13 ml), tiger (5 ml), grey (5 ml)
- Racks for tubes
- Phlebotomy supplies including vacutainers
- Ziplock plastic bags for shipping samples (see shipping instructions)
- Distilled or deionized water
- Sharpie markers or other indelible ink markers

DASH Manual of Procedures

- Biological waste bags
- Source for dry ice used to ship samples
- 2 L plastic graduated cylinder for measuring urine volume
- Automatic pipette with disposable tips or disposable 10-ml graduated plastic pipettes for urine aliquoting
- Disposable plastic pipettes (for buffy coat isolation)

Provided by CNRU and Lipid Laboratory and Coordinating Center

- Shipping and sample boxes
- Labels and microtubes and cryovials for sample aliquots
- 24-hour collection containers including urine aliquot tubes
- HCl preservative
- Log sheets (Forms 32-39)
- Shipping labels
- Sample labels from Coordinating Center

General Instructions

Review the equipment list - Prior to beginning the study, review the list of standard laboratory equipment and supplies you should have on hand at your site. Order anything missing. You will be receiving supplies from the two laboratories involved in the study a few weeks prior to starting.

Table of Laboratory Studies by Visit

Study	SV2	SV3	RI1	RI3	INT2-4INT8	
24-hr Urine	Instructions	X	X	X	X	X
Local Chem pan.	X	X (if needed)				
Lipids				X		X
Buffy coat				X		
Renin				X		X
Vit.D/PTH,Ca++				X		X
Glucose Tol. (2 sites)				X		
TBD* (tiger)				X		X
TBD* (purple)				X		X

* TBD - "To Be Determined" sample for storage

Sample collection at each visit - The laboratory specimens collected at each visit are summarized above and in the tables at the end of the chapter.

Urines - Five 24-urine aliquots are collected (at SV3, Run-in week 1, Run-in week 3, once during Intervention weeks 2-4, and Intervention week 8). Materials and instructions for the SV3 urine should be distributed at SV2.

DASH Manual of Procedures

Local Chemistry Panel - Blood is drawn for a local chemistry panel to determine eligibility at SV2. Follow-up blood testing may be done at SV3 if necessary to further assess eligibility.

Blood for Central Laboratories - Blood is collected during the third week of run-in (RI3) and during the last week of Intervention (INT8). The last blood collection does not include buffy coat, insulin or glucose (GTT), or “to be determined samples”. Only two sites will conduct the glucose tolerance test.

Instructions for fasting and 24 hour urine - Be sure you have instructions to hand out for fasting as well as for 24-hour urine collection and make sure they are understood by all subjects. Review the instructions, then have the subject explain the procedures in their own words.

Establish sample quality control procedures - The instructions below are specific to drawing, preparing, and shipping specimens to the central laboratories for DASH analysis. Blood specimens will also be drawn during screening for shipment to local laboratories to determine DASH eligibility. Procedures for drawing blood should be followed for these specimens as indicated below. Labeling and shipping requirements will be specific to the local laboratories. However, quality control procedures must be established by the clinical centers to assure that mislabeling, spoilage of samples, and damage to samples are minimized. These quality control procedures will be reviewed by the coordinating center as a part of their quality control reviews.

Aliquoting and storage - The plasma, serum or buffy coat obtained from blood draws as well as urines will be aliquoted to appropriate tubes at the clinical centers, then temporarily stored (-70°C) by the clinical centers before shipment to the central laboratories (CNRU and Lipid Laboratory).

Labeling - It is important that the sample tubes be labeled with subject ID, date drawn, visit number (e.g. SV3, RI3, I8), center ID number, and time blood was drawn (for glucose tolerance and insulin tests). The Coordinating Center will supply you with labels for each urine container, urine aliquot tube, blood tube, cryotube, and microtube.

Instructions for Collection and Processing of Fasting Blood Specimens

Blood for central laboratory testing is obtained at run-in week 3 and at the end of intervention. Since lipids are measured from these samples, subjects should be in the fasting state, even though not all of the measurements require fasting.

DASH Manual of Procedures

Local Laboratory Chemistry Panels

In some cases (e.g. where a participant's laboratory test makes him/her ineligible by a small margin) clinical sites may elect to repeat one or more local lab eligibility blood tests. These repeat tests may be done at any time prior to run-in (usually at SV3). Procedures for collecting and shipping these local blood samples will vary according to instructions from local laboratories. Except where such local procedures specifically contradict the instructions for central laboratory specimens, the processing of blood samples should be the same for each tube type as those outlined for central laboratory studies. Each clinical site should append to this chapter its own specific procedures for processing the local blood tests.

Verify Fasting State

Verify that the subject has indeed been fasting for 12 hours. Fasting (12 hour) is absolutely required for meaningful laboratory results. Example: A 12-hour fasting sample is obtained from someone who has not ingested any food or drink for twelve hours prior to having their blood drawn (**draw sample only if fasting for a minimum of 10 hours**). Participants should be encouraged to drink water during this period. If a blood draw is scheduled for 7:00 a.m., nothing should be eaten after 7:00 p.m. the night prior to having blood drawn. If the subject is not fasting, reschedule his/her blood draw as soon as possible. Instructions for the participants are attached as appendix 20.1.

Venipuncture

Put on gloves.

A preprinted label showing the participant's ID code (supplied by coordinating center) should be placed on each vacutainer tube. (The labels provided for SV3 will not include the participant's ID code. You will need to write it on the label before attaching the label to the tube.) It is essential to check the ID code and be certain it is correct. This can best be done by holding the tube next to the ID number on the participant's chart and calling out the number. Then ask the participant to say her/his name aloud and verify it against the name on the chart.

Draw blood from an antecubital vein whenever possible. Use a tourniquet to produce venous distension so that a needle can be inserted. A blood pressure cuff inflated midway between systolic and diastolic blood pressure is most effective and is highly recommended.

Do not leave the tourniquet in place for more than two minutes. This is to avoid excessive hemoconcentration. If the two minute interval is exceeded, abandon the arm temporarily and attempt to obtain the specimen from the other arm.

Draw blood using vacutainer tubes (see detailed instructions below). A syringe may be used for participants with veins that are too small or fragile for the vacutainer system.

DASH Manual of Procedures

Blood tubes should be drawn in the following order when drawn together:

1. 10 ml purple tube for renin (RI3, I8)
2. 13 ml tube for Vit. D, PTH, ionized calcium (RI3, I8)
3. 5 ml SST, tiger top for insulin tolerance (selected sites, RI3 only))
4. 10 ml purple for lipids (RI3, I8)
5. 5 ml grey for glucose tolerance (selected sites, RI3 only)
6. 8.5 ml yellow for buffy coat (RI3 only)
7. 13 ml SST tiger top “to be determined” (RI3, I8)
8. 10 ml purple “to be determined” (RI3, I8)

Requirements for the Oral Glucose Tolerance Test (Selected sites only)

If your site is conducting the Oral Glucose Tolerance Test:

1. Participant must be fasting for 12 hours as noted above.
2. Participants should not have exercised vigorously within two hours of the test.
3. The other blood tubes (renin, lipids, storage samples, etc.) should be collected before drinking the glucose.
4. Subjects are given a 75 gm glucose load which they should drink within five minutes.
5. During the two hours of the test, subjects may sit, lie, or walk quietly.
6. Blood samples are collected for glucose and insulin levels just before the glucose is drunk and 60, 90, and 120 minutes afterwards (label tubes with exact time since glucose drink). Time “0” is defined as the time the subject finishes drinking the glucose.
7. Blood can be collected via individual venipunctures, a hep lock, a K.O. IV line, or vacutainer, whichever is most suitable. If you use a K.O. IV line, the IV solution should not contain any glucose. A syringe may be used if other methods are not suitable.
8. The test is complete after the 120-minute sample is collected.
9. The insulin test sample is collected, like glucose, at each of the four blood draws.

Processing of Blood Samples

Filling microtubes - Fill microtubes about 3/4 full (1/4” from top) to leave room for expansion.

Centrifuging - Because sizes of centrifuges differs, all centrifuge instructions are provided in terms of gravities. To convert rpm rates to Relative Centrifugal Force (RCF) in gravities, determine the rotating radius of your centrifuge and apply the following formula: $RCF \text{ (gravities)} = 1.118 \times 10^{-5} \times r \times n^2$
where r = rotating radius in centimeters,
and n = rotating speed in revolutions per minutes.

SST tiger top tubes (two 13 ml tubes at RI3, two 13 ml tubes at I8; sites doing the GTT also have a 5 ml tube at RI3) - After the blood is drawn, gently invert the tube several

DASH Manual of Procedures

times. Allow the blood to clot at room temperature for not more than 15 minutes. Centrifuge at 4°C (room temperature if a refrigerated centrifuge is not available) at 2,500 rpm for 15 minutes.

-13-ml SST tiger top (“to be determined”) - Aliquot immediately into 3 white top microtubes. Freeze and record on log form 35.

-13- ml SST tiger top tube for Vit D, PTH, ionized Ca - Aliquot into three 2-ml microtubes and **cap with brown, green, and orange caps**, respectively. Freeze and record on log form 34.

- 5-ml SST tiger top for insulin (only sites doing GTT) - The 5 ml tiger top tube is drawn four times (at the same time the four grey tops are taken during the glucose tolerance test). Each 5 ml tube should be aliquoted into **two red capped microtubes**. It is VERY IMPORTANT TO LABEL THE SAMPLE with the DRAW TIME to distinguish the draw times of each blood sample. A sample without the draw time noted will be invalid. Freeze in Sarstedt box at -70°C. Record on the log (form 33).

5-ml grey top tubes (only sites doing GTT at RI3). After blood is drawn, invert to mix, then spin at 2,500 rpm for 15 minutes at 4°C. Aliquot the plasma portion into two 2-ml microtubes **and cap with clear caps**. It is VERY IMPORTANT TO LABEL THE SAMPLE with the DRAW TIME to distinguish the times of the tolerance test. A sample without the draw time noted will be invalid. Freeze in Sarstedt box at -70°C. Record in sample log (form 33).

10-ml purple top tubes (Plasma and buffy coat). From each subject, three 10 ml purple top tubes are drawn at run-in, week 3 visit and three at the Intervention, week 8 visit. These are filled completely and gently inverted six to eight times to distribute the anticoagulant.

First purple tube (for lipids; RI3 and I8). Within 30 minutes of drawing, centrifuge for 15 minutes at 1,500 g to separate plasma from blood cells. Aliquot two 2-ml microtubes and **cap with blue caps** and freeze in Sarstedt box at -70°C. Record on sample log (Form 39).

Second purple tube (for renin; RI3 and I8)). The second 10-ml purple top is spun immediately at 1,500 g for 15 minutes at 4°C. Aliquot into two 2-ml microtubes and **cap with purple caps**. Freeze immediately in Sarstedt box at -70°C. Record on sample log (Form 36).

Buffy Coats. After the plasma has been removed from the two purple top tubes, using a plastic pipet, aspirate the buffy coat layer. Pool the buffy coats from both tubes into 1 2-ml cryotube. Follow the same directions for labeling and capping the cryotube as for the serum samples. Place cryotubes upright in the shipping box and store at -70°C. Record on shipping log (form 38).

DASH Manual of Procedures

Third purple top tube (“to be determined”; RI3 and I8). Spin immediately at 1,500 g for 15 minutes at 4°C. Aliquot into two 2-ml microtubes and **cap with yellow caps.**

Log sheet

Fill out the log sheets (Forms 33-39) completely with information on each corresponding sample. Each sample box has a separate log sheet.

Storage

Vials are organized with a cardboard storage box and stored frozen at -70°C until shipment to the laboratories (Lipid and CNRU Laboratories).

Instructions for Collection and Processing of 24-Hour Urine Specimens

Instructions for 24-Hour Urine Collection.

NOTE: Do not collect a 24-hour urine sample from women who are menstruating. Reschedule the collection for as soon as possible after menstrual bleeding stops.

Prior to distributing the urine collection devices, attach a “DASH Central Urine Collection” label to one side of the tag on the jug. Attach a “spills and voids missed” label on the other side of the tag on the jug. On the collection jug itself attach an instruction label.

The following instructions below for 24-hour urine collection should be given to the participant. Written instructions are attached at the end of this chapter as appendix 20.2.

“To collect a 24-hour urine, you will need a sample container (women may want to use a collection device referred to as a hat). If using a collapsible container, remove the lid before you begin filling it and inflate by pulling out the sides to produce a box-like shape. If you want to use the hat to help collect your sample, place it under the toilet seat, urinate into the hat, then carefully empty the contents of the hat into the jug. In the event of a spill, please estimate the amount spilled; write the amount on the recording label. If you happen to miss a sample, record this on the label. The first urine of the day is not collected, but note the time of this first morning urination on the label of the urine container. Beginning with the second urination of the day, collect all urine for the next 24 hours from the time of the discarded urine. Every time you have to urinate, collect the whole sample in the container. The last sample collected should be voided 24 hours after the first morning urination (the time on the recording label (for example: 7:30 a.m. start time and 7:30 a.m. stop time) and placed in the container. Write the date and time of your final urination on the label of your container. Store the container in a refrigerator or a cooler between voids. Bring your sample into the center that day.”

Processing of 24-Hour Urine Specimens

DASH Manual of Procedures

- Record the sample identification, dates, and times onto the log sheet (Form 32).
- Invert the sample container at least 8 times to ensure a uniform sample.
- Measure the total urine volume (use a graduated cylinder). Note the volume on the log sheet (Form 32).
- Label tubes with patient ID, date collection started, center ID, and circle the appropriate visit code.
- Label and prepare six 10-ml plastic tubes as follows:
Tubes 1, 2, and 3 - Add nothing and mark a line through "HCl" on the label;
Tubes 4, 5, and 6 - Add 3 drops of 6 N HCl and circle "HCl" on label;
- Add 9-ml of well-mixed urine, using individual disposable 10-ml graduated plastic pipettes. Leave approximately 1/2 inch for expansion. Put on cap and twist 1/2 turn past the first stop. Invert to mix.
- Fill out sample log sheet.
- Place samples in shipping box and freeze until ready to ship to OHSU.
- The remaining urine may be discarded. Be sure to use distilled/deionized water to rinse your graduated cylinders between samples to avoid cross-contaminating the specimen.
- (HCl sample containers, shipping boxes, and log sheets will be supplied by OHSU.)
- Store aliquots at -70°C until shipped.

Shipping Instructions

DO NOT ALLOW SAMPLES TO THAW!

Shipping of samples should be done at the end of each wave of feeding if they have been stored at -70°C. If stored at -20°C, they should be shipped within a week. For each shipment, please FAX the laboratory with the date and time of shipment so they know when to expect it, and lost samples can be quickly identified. Also, for each shipment, a log sheet (Form 32 for urine, forms 33-39 for blood) is completed which lists the samples included in the box. Wrap the sample boxes in an absorbent material, secure with rubber bands, seal in 2 Ziplock bags, and SHIP ON DRY ICE (7 lbs lasts 3 days) via Fed Ex overnight service. **The two Ziplock bags and the absorbent materials are legally required for shipping these specimens. (Note also: dry ice/biohazard labeling and dangerous goods airbill requirements).** PLEASE SHIP ONLY ON MONDAY, TUESDAY, OR WEDNESDAY to avoid samples sitting over the weekend. The lab will return the empty shipping carton so you will have one available for the next shipment. Don't forget to include a sample log with each sample box as well as keeping a copy for yourself. The Federal Express account number will be provided. The address to ship to is:

- **Lipids and Buffy Coat:**

Carol Marsh
OHSU Lipid Lab, MRB Rm 421, Dock 4/R421

DASH Manual of Procedures

3181 SW Sam Jackson Park Road
Portland, OR 97201-3098
(503) 494-2005

- **Insulin, Renin, Glucose, Urine, VitD, ICa, PTH, “To Be Determined” Samples**

Kate Nilan/Bela Reiner
OHSU CNRU Lab
Dock 4/R912
OHSU, Department of Nephrology
3181 SW Sam Jackson Park Road
Portland, OR 97201-3098
(503) 494-6847

Plasma samples and buffy coats can be frozen for batch shipment. Clinical centers all have access to a -70°C freezer. Batch shipping of samples for participants in a single cohort/wave is acceptable if the materials are stored at this temperature. If a -20°C non-cycling freezer is used, weekly shipment (or transfer to a -70°C freezer within 48 hours) of specimens is necessary.

You will be shipping frozen samples, so make arrangements to get dry ice.

Quality Control for Laboratory Procedures

Central Laboratories

The two OHSU central laboratories submitted information on their experience, methods, and quality control procedures prior to their selection as the site for DASH laboratory analyses. These materials were distributed to the Steering Committee and are on file at the Coordinating Center. They were judged acceptable after some minor adjustments that resulted from the review. To assure continued quality control, a panel of laboratory experts will visit the Central Laboratories during the start-up phase of the first cohort and one year later (about mid-way through the intervention phase). The panel, selected by the Chair of the trial, will examine the procedures used for shipping, receiving, analyzing, and reporting the specimens. They will make recommendations for improvements and note problems. Their reports will be available to the DASH Steering Committee which is responsible for assuring that any needed remedial actions are taken.

DASH Manual of Procedures

Clinical Centers

The principal investigators at each center are ultimately responsible for assuring that all personnel carry out laboratory procedures in a timely manner and with appropriate quality control. To this end, each center will establish procedures and identify the persons responsible for assuring the following:

1. All personnel performing phlebotomy and handling DASH laboratory specimens are properly trained and instructed in correct and safe procedures, and are fully aware of, and carry out precisely, all proper DASH laboratory procedures; local procedures will establish how these responsibilities are established and monitor their accomplishment.
2. The local laboratory will develop and implement procedures to assure that DASH specimens are stored adequately in freezers at the required temperature, that alternative procedures exist to protect the specimens in the event of power failures, and that the proper implementation of these procedures is regularly checked and assured; these procedures along with identification of the individuals responsible must be written and reviewed with staff affected by them.
3. The Central Laboratory will analyze specimens from each cohort as they arrive, usually in a large batch at the end of the cohort. Problems with the specimens from individual sites will be identified and forwarded to the involved sites. Each site must respond in writing within 14 days of receipt of such notices of deficiency to the central laboratory with a copy to the Coordinating Center, on how each problem has been addressed at the clinical center.
4. Buffy coat specimens will be analyzed at an unspecified future time. The Central Laboratory will insure that procedures for long-term storage are adequate and appropriate for subsequent DNA analyses. In addition, the central laboratory will insure that specimen labeling is permanent and can withstand long-term storage. The laboratory will also request that each site send a small number of duplicate samples of buffy coats periodically for immediate defrosting and cell counting in order to assure that adequate numbers of leukocytes are being obtained.
5. Local laboratories should be required to report DASH results to the clinical centers within 48 hours of receipt of samples. Clinical sites will work with their local laboratories to assure that collection procedures and training are appropriate. Clinical sites will also develop procedures for certifying their technicians in relevant local laboratory procedures.

Summary of Procedures Order of Blood tubes

Blood tubes should be drawn in the following order when drawn together:

1. 10 ml purple tube for renin
2. 13 ml tube for Vit. D, PTH, ionized calcium
3. 5 ml SST, tiger top for insulin tolerance (if drawn)
4. 10 ml purple for lipids
5. 5 ml grey for glucose tolerance (if drawn)
6. 8.5 ml purple for buffy coat (if drawn)
7. 13 ml SST tiger top "To Be Determined" (if drawn)
8. 10 ml purple "To Be Determined" (if drawn)

Summary of Procedures Processing of 24-Hour Urine Specimens

- Record the sample identification, dates, and times onto the log sheet (Form 32).
- Invert the sample container at least 8 times to ensure a uniform sample.
- Measure the total urine volume (use a graduated cylinder). Note the volume on the log sheet (Form 32).
- Label tubes with patient ID, date collection started, center ID, and circle the appropriate visit code.
- Label and prepare six 10-ml plastic tubes as follows:
 - Tubes 1, 2, and 3: Add nothing and mark a line through “HCl” on the label.
 - Tubes 4, 5, and 6: Add 3 drops of 6 N HCl and circle "HCl" on label.
- Add 9-ml of well-mixed urine, using individual disposable 10-ml graduated plastic pipettes. Leave approximately 1/2 inch for expansion. Put on cap and twist 1/2 turn past the first stop. Invert to mix.
- Fill out sample log sheet.
- Place samples in shipping box and freeze until ready to ship to OHSU.
- The remaining urine may be discarded. Be sure to use distilled/deionized water to rinse your graduated cylinders between samples to avoid cross-contaminating the specimen.
- Store aliquots at -70°C until shipped.

DASH Manual of Procedures

Screening Visit 2 (SV2)

Distribute Urine Containers and Instructions for Collection at SV3

Ship to:	Test Name	Container Type	Size	Number	Processing	Number of Aliquots	Shipping Log
OHSU CNRU Lab	Urine (24-hour collection for electrolytes, Ca ²⁺ , Mg ²⁺ , creatinine, urea nitrogen)	Urine collection bags	2-liter	1; 2 if urine volume >2-liters	At SV3		

DASH Manual of Procedures

Screening Visit 3 (SV3)

Ship to:	Test Name	Container Type	Size	Number	Processing	Number of Aliquots	Shipping log
OHSU CNRU Lab	Urine (24-hour collection for electrolytes, Ca ²⁺ , Mg ²⁺ , creatinine, urea nitrogen)	Urine collection bags	2-liter	1 or more if urine volume >2-liter	Invert, aliquot (\pm HCl), freeze	6 (3 with and 3 without HCl)	Log Form: 32

DASH Manual of Procedures

RUN IN (week 1)

Ship to	Test Name	Container Type	Size	Number	Processing	Number of Aliquots	Shipping Log
OHSU CNRU Lab	Urine (24-hour collection for electrolytes, Ca ²⁺ , Mg ²⁺ , creatinine, urea nitrogen)	Urine collection bags	2-liter	1 or more if urine volume >2-liters	Invert, aliquot (\pm HCl), freeze	6 (3 with and 3 without HCl)	Log Form: 32

DASH Manual of Procedures

RUN-IN (week 3)

Ship to:	Test Name	Container Type	Size	Number	Processing	Number of Aliquots	Shipping Log
OHSU Lipid Lab	Lipids, HDL-cholesterol	Purple (EDTA)	10-ml	1	Mix, let sit, spin, aliquot, freeze	2 microtubes (blue caps)	Log Form: 39
	Buffy coat	From the two purple (EDTA) tubes			Pipette buffy coats, pool	1 (2-ml cryotube)	Log Form: 38
OHSU CNRU Lab	Renin	Purple (EDTA)	10-ml	1	Mix, spin, aliquot, freeze	2 microtubes (purple caps)	Log Form: 36
	“To be determined”	Tiger (SST)	13-ml	1	Mix, spin, aliquot, freeze	3 microtubes (white caps)	Log Form: 35
	Vitamin D Ionized calcium PTH	Tiger (SST)	13 mml	1	Clot, spin, aliquot, freeze	1 microtube (brown cap) 1 microtube (green cap) 1 microtube (orange cap)	Log Form: 34
	Glucose tolerance *Glucose *Insulin	Grey (oxalate) Tiger (SST)	5-ml 5-ml	4 4	Mix, spin, aliquot, freeze NOTE TIME EACH SPECIMEN DRAWN!	2 microtubes (clear caps) 2 microtubes (red caps)	Log Form: 33

DASH Manual of Procedures

RUN-IN (week 3), (cont'd)

Ship to:	Test Name	Container Type	Size	Number	Processing	Number of Aliquots	Shipping Log
OHSU CNRU Lab	"To be determined"	Purple EDTA	10 ml	1	Mix, spin, aliquot, freeze	2 microtubes (yellow caps)	Log Form: 37
OHSU CNRU Lab	Urine (24-hour collection for electrolytes, Ca ²⁺ , Mg ²⁺ , creatinine, urea nitrogen)	Urine collection bags	2-liter	1 or more if urine volume >2-liter	Invert, aliquot (\pm HCl), freeze	6 (3 with and 3 without HCl)	Log Form: 32

DASH Manual of Procedures

INTERVENTION (one collection during weeks 2 through 4)

Ship to:	Test Name	Container Type	Size	Number	Processing	Number of Aliquots	Shipping Log
OHSU CNRU Lab	Urine (24-hour collection for electrolytes, Ca ²⁺ , Mg ²⁺ , creatinine, urea nitrogen)	Urine collection bags	2-liter	1 or more if urine volume >2-liter	Invert aliquot ((±HCl), freeze	6 (3 with and 3 without HCl)	Log Form: 32

DASH Manual of Procedures

INTERVENTION (week 8)

Ship to:	Test Name	Container Type	Size	Number	Processing	Number of Aliquots	Shipping Log
OHSU Lipid Lab	Lipids, HDL-cholesterol	Purple (EDTA)	10-ml	1	Mix, let sit, spin, aliquot, freeze	2 mic-tubes (blue caps)	Log Form: 39
OHSU CNRU Lab	Renin	Purple (EDTA)	10 ml	1	Mix, spin, aliquot, freeze	2 microtubes (purple caps)	Log Form: 36
	“To be determined”	Tiger (SST)	13-ml	1	Mix, spin, aliquot, freeze	3 microtubes (white caps)	Log Form: 35
	Vitamin D, PTH, ionized calcium	Tiger (SST)	13 ml	1	Clot, spin, aliquot, freeze	1 mic-tube (brown cap) 1 mic-tube (orange cap) 1 mic-tube (green cap)	Log Form: 34
	“To be determined”	Purple EDTA	10 ml	1	Mix, spin, aliquot, freeze	2 microtubes (yellow caps)	Log Form: 37
	Urine (24-hour collection for electrolytes, Ca ²⁺ , Mg ²⁺ , creatinine, urea nitrogen)	Urine collection bags	2-liter	1 or more if urine volume >2-liter	Invert, aliquot (±HCl), freeze	6 (3 with and 3 without HCl)	Log Form: 32

DASH Manual of Procedures

BLOOD PROCESSING TABLE

Order	Tube	“Sitting”	Conditions	Spinning	Spin Time		Aliquot and freeze
Order	Tube (Log#)	Time (maximum)	Temperature	Gravities	minutes	Temperature	
1	10 ml purple Renin (36)	≤15 min	4°C	1,500	15	4°C	2 microtubes (purple caps)
2	13 ml SST Vitamin D, PTH, ICa (34)	≤15 min	r.t. (room temperature)	1,500	15	4°C	3 microtubes (1 green, 1 brown, 1 orange)
3	5 ml SST Insulin (33)	≤15 min	r.t.	1,500	15	4°C	2 microtubes (red caps)
4	10 ml purple lipids (39)	30 min	r.t.	1,500	15	4°C	2 microtubes blue caps
5	5 ml grey GTT glucose (33)	<4 hours	r.t.	1,500	15	4°C	2 microtubes (clear caps)
6	8.5 ml yellow Buffy coat (38)	<24 hours	r.t.	1,500	15	4°C	1-2 ml cryovial
7	13 ml SST TBD (35)	≤15 min	r.t.	1,500	15	4°C	3 microtubes (white caps)
8	10 ml purple TBD (37)	≤15 min	4°C	1,500	15	4°C	2 microtubes (yellow caps)

DASH Manual of Procedures

Appendix 20.1

Instructions for DASH Glucose Tolerance Test

1. Do not eat any food or drink anything except water for twelve hours prior to your appointment time. You may drink water during this period. If your appointment is scheduled for 7:00 a.m., do not eat anything after 7:00 p.m. the night prior to having your blood drawn.
2. Do not exercise vigorously for at least two hours prior to your appointment.

DASH Manual of Procedures

Appendix 20.2

Instructions for DASH 24 hour Urine Collection

To collect a 24-hour urine, you will need a plastic sample container (women may also want to use a collection device referred to as a hat). The container should be labeled with your study identification number, the date and time you begin the urine collection and the date and time you complete the collection. It is important to collect all of the urine you pass during the 24-hour collection. However, if you do forget, and miss a collection, it is equally important that you indicate how many voidings were missed on the tag at the end of the collection.

Before you begin filling the container, remove the lid and pull out the sides of the container to produce a box-like shape. If you want to use the hat to help collect your sample, place it under the toilet seat, urinate into the hat, then carefully empty the contents of the hat into the jug. Otherwise, urinate directly into the jug. In the event of a spill, please estimate the amount spilled; write the amount on the recording tag (e.g., "1 cup spilled"). If you miss a sample, record this on the tag in the place provided.

Do not collect the first urine of the day, but note the time of this first morning urination on the tag of the urine container. This is the start of your collection period. Beginning with the second urination of the day, collect all urine for the next 24 hours from the time of the discarded urine. Every time you have to urinate, collect the entire sample in the container. The last sample collected should be voided 24 hours after the first morning urination (the times on the recording tag might be 7:30 a.m. start time and 7:30 a.m. stop time, for example) and should also go into the container. Write the date and time of your final urination on the tag of your container. Store the container in a refrigerator or a cooler between voids if possible. Bring your sample into the center as soon as possible after collection is complete.

DASH Manual of Procedures

21. Other Clinical Measurements

Skinfold Procedure	3
Purpose	3
Supplies/Equipment	3
Equipment Preparation	3
Subject Preparation	3
Specific Procedures	3
Training and Certification	4
Dual Energy X-Ray Absorptiometry (DEXA) for Body Composition	5
Purpose	5
Supplies/Equipment	5
Subject Preparation	6
Training and Certification	9
Data from DEXA Scans	9
References	9
Height and Weight Measurements	9
Height	9
Weight	10
Equipment Maintenance	11
Training and Certification	11
Weight Certification (Kg)	13
Height Certification (Cm)	13

DASH Manual of Procedures

Summary of Edits

New changes in Version 2.2

- a variety of formatting changes
- sections dealing with training and certification have been revised-please review

New changes in Version 4.0

- Cambridge Scientific changed to Beta Technology Inc.
- Skinfold Training and Certification section expanded
- Additions to DEXA Sections on Subject Preparation (Female Subject Safety issues; Items affecting Scan results), and Data from DEXA Scans

DASH Manual of Procedures

Skinfold Procedure

Purpose

To identify and measure skinfolds that can be loosely lifted away from underlying muscle between the thumb and index finger. Triceps and Subscapular skinfold measurements will be made on all subjects.

Supplies/Equipment

- Lange Skinfold Calipers
- Lange Calibration Blocks

These supplies may be obtained through Beta Technology Incorporated, Cambridge, Maryland.

Equipment Preparation

- Calipers will be calibrated before use with the same calibration block.
- Calipers with more than a 0.5 mm discrepancy from the calibration block will be returned to Cambridge Scientific for reconditioning.

Subject Preparation

- All subjects will wear an examination gown and may wear underwear during the procedure.
- Unless otherwise directed, the subject will stand with feet together in an upright position. Arms will be relaxed at the subject's sides.

Specific Procedures

CONSISTENCY of the measurements is of utmost importance.

Identify anatomical sites with proper caliper positioning

1. Lift all skinfolds with the left thumb and index finger, forming a ridge of about 4 cm long and 2.5 cm high.
2. Hold the skinfold caliper in the right hand, with the points of the skinfold caliper open and gently placed on opposite sides of the fold of skin.
3. Place the calipers about 1 cm below the top of the fold. Make three independent measurements for each skinfold.

DASH Manual of Procedures

Triceps skinfold measurement

1. Select the subject's bare right arm for measurement.
2. Have the subject bend his/her arm at a right angle with the hand across the stomach.
3. Instruct the subject to relax the right arm at his/her side. Stand behind the subject and pick up a vertical fold of skin and fat with the thumb and index finger of the left hand about one centimeter above the midpoint of the dorsal aspect of the upper arm. This will ensure that the pressure at the midpoint of the upper arm is exerted by the skinfold calipers and not by the your fingers. Pick up the skinfold firmly and cleanly from the underlying muscle.
4. If you doubt if you are picking up muscle, instruct the subject to contract and relax the arm muscles to ensure no muscle is in the fold.
5. Hold the calipers parallel to the floor and avoid slanting them.
6. Place the calipers over the fatfold at the marked midpoint at a depth of about equal to the thickness of the fatfold. Release the calipers but not the pinch. Take the first reading immediately after the caliper needle stabilizes. Record to the nearest 1 mm.
7. Obtain two additional readings using the same procedure. Release the pinch between readings.
8. Record all three results on page 2 of the SV3 Blood Pressure Form (form #13).

Subscapular skinfold measurement:

1. This skinfold measurement assesses the amount of adipose tissue and skin thickness on the back of the torso. Measure this skinfold about 2-3 cm below the inferior angle of the right scapula.
2. Open the back of the standing subject's gown, so as to expose the right scapula and the skin inferior to it; shoulders will be erect but relaxed.
3. To locate the fold, palpate the right scapula, running fingers down along the lateral border and proceeding toward an inferior aspect, until the inferior angle is identified.
4. Raise a diagonal fold of skin with left thumb and index finger about 1 cm diagonal to the mark. The fold will be lifted at a 45 degree angle to the long axis of the trunk.
5. Place the jaws of the calipers on the fold site at right angles to the fold. Take the measurement 3 seconds after release of the jaws and record to nearest 1 mm.
6. Take two additional readings, releasing the skinfold between each determination. All three readings must be recorded.
7. If the subject is obese, place subject's arm behind the back to aid in identifying the proper site.

Training and Certification

DASH Manual of Procedures

All examiners assessing skinfolds must be trained and certified in this procedure. Initial training of master trainers is performed once on-site. Agreement of master trainers' readings will be checked after the first cohort at a Steering Committee meeting. Master trainers train local personnel who conduct the measurements. Recertification of each person is conducted twice per year. The master trainer will cover the appropriate skinfold determination techniques with prospective skinfold examiners as outlined earlier. Certification will consist of duplicating the master trainer's skinfold determinations on at least two test subjects with the following degree of accuracy:

- If the subject's true skinfold (as determined by the average of 3 readings from the trainer) is less than 15mm, the trainee's average must fall within 2mm of that reading.
- If the subject's true reading is 16-30mm, the trainee's reading must be within 3mm of that figure.
- If the subject's true reading is greater than 30mm, the trainee's reading must be within 4mm of that figure.

(A sample certification form is included)

Dual Energy X-Ray Absorptiometry (DEXA) for Body Composition

Purpose

This is a general procedure for measuring, for the whole body and by region: lean mass, fat mass, percent fat, bone mineral content, and bone mineral density.

The procedure is being conducted only at two DASH sites. The data will be used to assess the relationship, if any, between response to the DASH diets and percent body fat, lean body mass, and fat mass.

Supplies/Equipment

- Hologic QDR-2000 X-Ray Densitometer
- Patient gown
- Detecto scale

DASH Manual of Procedures

Subject Preparation

Female subject safety issues

For women volunteers, the following questions will be added to the DEXA protocol asked prior to the scanning procedure:

- Are you pregnant?
- When was your last menstrual period?
- Is there any question or possibility that you could be pregnant?

Pregnant women should not be tested. For women who indicate that they could be pregnant, a urinary pregnancy test must be performed and DEXA cannot be done unless the results are negative. If it has been more than 5 weeks since last menstruation in a regularly cycling woman, it is requested that she take a pregnancy test.

Clothing

- The subject should dress in the gown provided.
- All jewelry (rings, earrings, wrist and ankle bracelets, necklaces, etc.) and any clothing with metal fasteners must be removed.

Items affecting scan results

All participants should be asked if they are taking or using any of the following. If so, remove where possible, or exclude from DEXA scan.

- Iodine
- Barium
- Thorotrast
- Radiopaque catheters and tubes
- EKG leads
- Ostomy devices
- Pacemaker leads
- Radioactive implants
- Silicone implants
- Staples
- Foreign bodies (bullets, shrapnel, etc.)
- Bone pins and screws
- Mercury, lead, or other heavy metal poisoning
- Aortic calcification

DASH Manual of Procedures

- Kidney stones
- Treatment with colloidal gold for arthritis

The following is a list of the T½ radionuclides that interfere with a DEXA scan. Participants who have taken the indicated agents within the indicated time prior to the test should not receive a DEXA scan.

<u>Radionuclide</u>	<u>Wait Before Scan</u>
51Cr	3 mos.
67Ga	1 mos.
99mTc	3 days
111In	1 mos.
123I	1 week
125I	No wait
131I	2 mos.
133Xe	1 day
201Ti	1 mos.

If a subject has undergone a nuclear medicine (isotope) study within the past seven days, the isotope activity (if over 1 mR per hour) may affect results. If so, exclude from DEXA determination.

Procedure

Weigh the subject and record (see weighing procedure).

Set-up for DEXA Scan (Subject Data Entry and Positioning)

1. Obtain biographical information from subject history and enter into his/her file through patient information. Press F10 to save.
2. Make sure the mattress is flush to the back of the examination table and centered left and right to the ends of the examination table.
3. Instruct subject to lie supine on the table with his/her head at the right end of the table (when operator faces the table).
4. Position the subject's body so that it is straight on the mat, as measured against the solid longitudinal whole body lines on the mat. The subject's head should be two fingers width below the head end of the table.
5. Position the subject's feet within the foot line of the table.
6. Place the subject's legs slightly apart to ensure consistent scan-to-scan positioning for comparison purposes. The arms and hands (palms down) should lie to the sides of the body without touching the trunk or thighs, but within the outer limit

DASH Manual of Procedures

- lines. A large subject can place hands vertically next to thighs to ensure that hands and arms remain within the limits.
7. Set the T-Bar next to the subject at the foot end of the table within the outer limits, but not touching the subject.
 8. Tuck the subject's gown snugly around his/her body.
 9. Instruct the subject to remain completely still for a six-minute (approx.) X-ray scan. The X-ray scan is a multiple beam with an entrance exposure of 0.5 mR.
 10. After subject is positioned, choose "Whole Body."
 11. Select "Array." Press any key to initiate c-arm and table positioning.
 12. After positioning is complete, the "Select Scan Parameters" screen will appear.
DO NOT CHANGE THE PARAMETERS!
 13. Press F10 to initiate scanning. Screen will prompt to ensure that the T-Bar is properly positioned. After checking positioning, press "Enter" to begin scanning.
 14. The subject will be allowed to move parts of the body when the scanner has moved past that area of the body.
 15. When the entire skeleton appears on the screen, press any key to stop the scan and save it.
 16. At the end of the scan, re-center the exam table will be using manual controls located on the C-arm. Press "End" to analyze scan. Allow the subject to get dressed in the dressing room.
 17. Analyze the subject's data at the end of the day.
 18. Choose "Analyze." Press "*" to highlight the entire region. Center this region on the skeleton image.
 19. Use the following procedure as described by the Hologic manual to properly set regions (see Attachment #1).
 20. The system processes the whole body image. After analysis is complete, a report screen displays.
 21. Use "Pge Up" and "Pge Dn" to scroll through report screens. Press "Print Screen" to print report pages.
 22. Press "Shift F9" for region analysis.
 23. The image will appear elongated with a small box in the center. A maximum of seven boxes can be created using the "/" key. Press "*" to shape boxes into various sizes and shapes. "Ctrl-PgDn" moves box more slowly.
 24. The shape of box is subjective, depending upon the region expected to be evaluated.
 25. Press "End" to analyze scan.
 26. Press "Print Screen" to print report. "PgDn" and "PgUp" will scroll report pages.
 27. Body composition personnel will archive all files at the end of each day.

DASH Manual of Procedures

Training and Certification

Trained densitometer technicians are available at each of the two DASH sites that will conduct densitometry. All scans will be conducted on the Hologic 2000 DEXA scanner. Staff should follow Hologic's procedures for training, certification, and quality assurance. Apart from initial joint training of technicians from the two sites, further joint training is not necessary unless a new technician is added. However, data diskettes will be jointly read and interpreted at the end of the study.

Data from DEXA Scans

Clinical sites performing DEXA scans will enter the results of all scans (two per eligible individual) on a computer screen using the remote data entry equipment located in the clinical centers. The data should be entered in batch at the end of each cohort. Data entry fields include: percent fat (__ __ . __); fat gms (__ __ __ __ __ . __); lean body mass, gms (__ __ __ __ __ . __); and bone mineral content, gms (__ __ __ __ __ . __).

References

Hologic QDR-2000 X-Ray Densitometer (1991). Document no. 8001-225-00, Rev. A.

North, David, Sc.M. Certified Medical Physicist at Miriam Hospital.

Height and Weight Measurements

Height

Certified DASH clinical staff will measure height to the nearest centimeter at the second screening visit (SV2). Heights should be measured with the participant standing on a firm, level surface, at a right angle to the vertical board of the height measurement device. A height board mounted at a 90 degree angle to a calibrated vertical height bar should be used. Check to be sure that the floor is level, that the vertical height bar is mounted at a 90 degree angle to the floor, and that the wall on which the height bar is mounted is straight.

Instruct subject to remove shoes and headgear and to stand with heels together and feet flat on the floor, with his/her back against the calibrated vertical height bar and to look straight ahead with his/her head in the Frankfort horizontal plane. The weight of the subject should be distributed evenly on both feet. Both arms should hang freely by the sides of the trunk with palms facing the thighs. The scapulae and buttocks should also be in contact with the vertical board. The head of the person taking the height

DASH Manual of Procedures

measurement should be in the same horizontal plane as the subject's head in order to obtain the most accurate measurement.

Ask the subject to inhale deeply and maintain a fully erect position without altering the load on the heels. The height board should be brought down snugly, but not tightly, on the top of the head. Record the height to the nearest centimeter, with > half centimeter rounded up and < half centimeter rounded down.

Weight

Certified DASH clinical staff will measure body weight throughout the study. The weight measurement taken at the second screening visit (SV2) will be used in conjunction with the height measurement to exclude candidates whose Body Mass Index is in excess of 35 Kg/m².

Insofar as possible, weight measurements for each participant should be taken at about the same time of day in order to minimize variability due to daily eating patterns and activities. Therefore, all clinic visits for a given individual should be scheduled at about the same time of day.

Instruct subject to remove shoes, headgear, coat, etc., or heavy items in the pockets (e.g., keys or wallet) in order to be weighed in light indoor clothing. All body weights in DASH should be measured on a double balance beam scale placed on a firm, level surface. If this surface is carpeted, a sheet of wood or hard plastic should be placed beneath the scale. Be sure the scale is balanced so that the indicator is at zero when no weight is on the scale. Before each weight is measured, the sliding scale weights must be moved to zero.

Ask the participant to stand in the center of the scale platform, since standing off-center may affect the weight measurement. It is suggested that marks be made on the platform to ensure the proper feet position. The participant should stand with head erect and eyes looking straight ahead.

Adjust the weight on the indicator until it is balanced, and record the results to the nearest one-tenth of a Kg. Use extreme care in adding the lower beam weight to the upper beam weight, as they use different increments. After weighing a subject, the weights should be left in place to prevent jarring which can occur if the indicator floats at zero.

DASH Manual of Procedures

Equipment Maintenance

Scales should have been certified at the start of the trial by the local Bureau of Weights and Measures or an equivalent body. Recertification must be completed annually thereafter and posted in the appropriate column of the scale log sheet with any documents provided by the inspector kept on file. This same log sheet is to be used to record monthly in-house checks of scale accuracy using from 25 to 50 Kg (or 50 to 100 pound) weights held by the technician and added to the technician's weight so as to ensure accuracy in the range of weights to be measured during the trial. These records are requested periodically and checked during site visits (Figure 21.1). Scales must be initially calibrated using certified weights. Thereafter, free weights may be used to look for drift. In the event that this occurs, the scale must be recalibrated using certified weights.

Training and Certification

All Examiners assessing height and weight are trained and certified in these procedures. Initial training of master trainers is performed centrally. Master trainers train local personnel who conduct the measurements. Master trainers are certified annually during the Spring/Summer Steering Committee meeting. Recertification of local staff occurs biannually (in January and in the month following the Spring/Summer Steering Committee meeting). (See Certification form at end of this chapter).

DASH Manual of Procedures

ID# _____

Weight Certification (Kg)

- _____ (1) Weights placed to the left “0” position before the participant is measured (correction made immediately if machine does not “zero” properly)
- _____ (2) Participant in light, indoor clothing only, without shoes
- _____ (3) Participant standing in center of platform
- _____ (4) Weight taken to the nearest tenth Kg (0.1Kg)

Height Certification (Cm)

Certification required until screening has ended

- _____ (1) Shoes and headgear removed, heels together, feet flat on the floor
- _____ (2) Participant looking straight ahead with his/her head in the Frankfort horizontal plane
- _____ (3) Head of the person taking the measurement in the same horizontal plane as the participant
- _____ (4) Height board brought down snugly (as opposed to tightly) on top of participant’s head
- _____ (5) Rounding done properly ($\geq .5$ cm round up, $< .5$ cm round down)

I certify that this trainee has completed all procedures correctly

Trainer’s Name (Please Print)

ID#

Comments:

DASH Manual of Procedures

ANTHROPOMETRIC TRAINING AND CERTIFICATION

TRAINEE _____ DATE _____

OBSERVER _____ ID # _____

Triceps Skinfold, mm	Ave.	Observer Ave.	Certified (Y/N)
1 _____			
2 _____	_____	_____	_____
3 _____			
Subscapular Skinfold, mm			
1 _____			
2 _____	_____	_____	_____
3 _____			
Other Skinfold, mm			

1 _____			
2 _____	_____	_____	_____
3 _____			
Other Skinfold, mm			

1 _____			
2 _____	_____	_____	_____
3 _____			
Height, 0.1 cm			
1 _____			
2 _____	_____	_____	_____
Weight, 0.1 kg			
1 _____			
2 _____	_____	_____	_____
Other Measure			

1 _____			
2 _____	_____	_____	_____
3 _____			
Other Measure			

1 _____			
2 _____	_____	_____	_____
3 _____			

Comments:

DASH Manual of Procedures

ANTHROPOMETRIC TRAINING AND CERTIFICATION

TRAINEE _____ DATE _____

OBSERVER _____ OTHER INFORMATION _____

Triceps Skinfold, mm	Ave.	Observer Ave.	Certified (Y/N)
1 _____			
2 _____			
3 _____			
Subscapular Skinfold, mm			
1 _____			
2 _____			
3 _____			
Other Skinfold, mm			
1 _____			
2 _____			
3 _____			
Other Skinfold, mm			
1 _____			
2 _____			
3 _____			
Height, 0.1 cm			
1 _____			
2 _____			
Weight, 0.1 kg			
1 _____			
2 _____			
Other Measure			
1 _____			
2 _____			
3 _____			
Other Measure			
1 _____			
2 _____			
3 _____			

Comments:

22. Forms and Questionnaire Data

The study forms and accompanying instructions have been moved to a separate Study Forms Manual, which has its own table of contents and version numbering system.

DASH Manual of Procedures

Summary of Edits

New Changes in Version 2.10

- Forms moved to a separate Forms Manual

New Changes in Version 4.0

- none

DASH Manual of Procedures

23. Data Management

Data Intake	3
Directly entered data	3
Batch-entered data	3
Centrally entered data	4
Detecting and reporting data errors	5
Data Flow and Archiving	5
Directly entered data	5
Batch-entered data	5
Centrally entered data	6
Centralized Lab Tracking	6
Screening	6
Electronic Mail Procedures and File Server Management	6
Introduction	6
Directory structure	6
Schedule	7
Housekeeping	7
Personal Computer System Manual for DASH Project Desktop System	8
Personal Computer System Manual for DASH Project Portable Systems	16
Automated Data Entry System User's Manual	21

DASH Manual of Procedures

Summary Edits

New changes in Version 2.0

- Moved *Data Management Handbook* and *Automatic System User's Guide* into MOP.

New changes in Version 2.1

- Misc technical edits
- Under *Centralized Labs Tracking, Screening*, the name and content of the SV3 urine form was clarified.

New changes in Version 4.0

- None

New changes in Version 4.1

- Modified paragraph on screening in section on *Centralized Lab Tracking*

DASH Manual of Procedures

Data Intake

Directly entered data

Real time quality control. The primary responsibility in terms of data quality that entry technicians will have when directly entering study data to the laptop computers is assuring that the data are entered with the correct participant ID. Data entry forms will prominently display the participant ID, which is an alphanumeric code containing the first 3 letters of the participant's last name and the first 2 letters of the participant's first name. These alpha data will be followed by 5 sequentially assigned numbers. Additionally, the participant's date of birth, sex, and mother's maiden name will be readily viewable. These fields must be reviewed carefully to assure data are not entered with an incorrect ID link.

The overwhelming majority of quality control measures for directly entered data will be applied at the time of entry with guidance from the computer. Range and logic checks coded into the entry utilities will prevent the entry of exceptional data. Confirmation boxes for sensitive data, such as blood pressure readings, will prompt technicians to review data and confirm it before committing it to the database. Additional computer code will prevent missing data by not allowing the technician to exit the form without entering the data.

Batch-entered data

Though batch-entered data will represent the exception, traditional quality control methodology will need to be followed in this case. Though it is true that quality control methods embedded in the laptops will continue to screen for the following potential problems, for batch-entered forms the laptops will only be able to identify these problems after the participant has left, making it difficult or impossible to apply corrections. Thus, it will be necessary to manually employ these quality control methods in real-time before the participant leaves the intervention site. These methods include:

Patient identification and record linkages. Each form will need to check the participant ID for transposition errors. The format must be "aaaaannnn." The initial 3 alpha characters must be the same as the first three letters of the participant's last name, which is written at the top of the form. The next 2 alpha characters must be the same as the first two letters of the participant's first name (also written at the top of the form). The last five digits are a unique identifying number for that participant. Each page of multi-page forms must have the same ID number.

Legibility. All data must be checked for illegible handwritten replies, spelling errors, etc. All checked response boxes must have checks within designated spaces.

DASH Manual of Procedures

Form admissibility. All forms must be checked to determine if the form was completed within the specified time window. All forms must be checked to assure that the completed form is the correct one for the indicated visit or activity.

Missing information. All forms must be checked for unanswered items or sections of an otherwise completed form. The entry technician must assure that all necessary forms have been completed for the indicated visit or activity.

Consistency. All data must be checked to assure that information supplied in one section is consistent with data in another section of the same form. All forms for the same participant for a given visit must be checked to assure consistency.

Range and inadmissible codes. All data must be checked to assure they do not contain values either outside specified ranges or undefined alphabetic or numeric codes.

The forms manual provides detailed instructions for entry procedures for each study form.

Centrally entered data

Though little of the data will be entered centrally (patient history data, for example), traditional quality control methodology will need to be followed in this case, just as with batch entered data. These quality control methods will need to be employed during the visit before the participant leaves the site. These methods include:

Patient identification and record linkages. Each form will need to check the participant ID for transposition errors. The format must be “aaaaannnnn.” The initial 3 alpha characters must be the same as the first three letters of the participant’s last name which is written at the top of the form. The next 2 alpha characters must be the same as the first two letters of the participant’s first name (also written at the top of the form). Each page of multi-page forms must have the same ID number.

Legibility. All data must be checked for illegible handwritten replies, spelling errors, etc. All checked response boxes must have checks within designated spaces.

Form admissibility. All forms must be checked to determine if the form was completed within the specified time window. All forms must be checked to assure that the completed form is the correct one for the indicated visit or activity.

Missing information. All forms must be checked for unanswered items or sections of an otherwise completed form. The entry technician must assure that all necessary forms have been completed for the indicated visit or activity.

Consistency. All data must be checked to assure that information supplied in one section is consistent with data in another section of the same form. All forms for the same participant for a given visit must be checked to assure consistency.

DASH Manual of Procedures

Range and inadmissible codes. All data must be checked to assure they do not contain values either outside specified ranges or undefined alphabetic or numeric codes.

The forms manual provides detailed instructions for entry procedures for each study form.

Detecting and reporting data errors

Routine SAS programs will access and query all study databases searching for data errors. Errors will be processed in two ways. First, errors will be loaded into a coordinating center-maintained spreadsheet containing data on participant id, date of error, type of error, form, field, type of entry, staff id, site, and error outcome. This spreadsheet will allow the coordinating center to easily produce summary error reports used to detect error trends and patterns by error type, form, field, entry type, staff, and site. A copy of this spreadsheet will be placed on field sites' computers for resolution.

Data Flow And Archiving

Directly entered data

Data entered directly to the laptops will flow to the coordinating automatically by being uploaded to the file server by way of the docking bay. The uploaded data will be transferred daily by phone lines from the file server to the coordinating center's master database. Archiving will occur automatically at the coordinating center, which will contain one week's worth of daily data on-line and all historical data off-line, yet easily mountable if restoration is needed.

Batch-entered data

Data entered in batch will also flow to the coordinating automatically by being uploaded to the file server by way of the docking bay. The uploaded data will be transferred daily by phone lines from the file server to the coordinating center's master database. However, in addition to the archiving process described above for direct entered data, these batch entered data will need to be archived for the life of the study in hard-copy form so that copies may be sent to the coordinating center as needed for data management. Requests for copies of archived batch entered data will be made on a form by form basis by the coordinating center.

DASH Manual of Procedures

Centrally entered data

Centrally entered data will need to flow to the coordinating center for entry. Before sending to the coordinating center, sites should make copies of all forms for onsite archiving for the length of the study. Forms should be sent to the coordinating center bundled by form type. A mailing report for each form type included in a mailing should accompany each mailing summarizing what forms were sent. A copy of this report should be archived at the mailing site for reference and confirmation of form receipt. When receiving bundled mailings, the coordinating center staff will review the mailing report and assure that all reported forms were received. This should be noted on the report, which will then be archived at the coordinating center. Any discrepancies will be immediately reported to the site, who will help resolve the problem, which may include making additional copies of their archived data and remailing them to the coordinating center. Routine mailing schedules will be specified as data collection begins. The mailing report is in Form #27 Shipping Log.

Centralized Lab Tracking

Screening

Screening Visit 3 contains a 24 hr urine sample, which is the only centrally analyzed laboratory data collected prior to Run-in. As with all screening activities, the collection of this sample will be recorded on the visit flow sheet and summarized during entry to the laptop computer. These data along with with data from shipping logs will be scanned by computers. Reports will be routinely distributed to all sites summarizing these data.

Electronic Mail Procedures and File Server Management

Introduction

The CC will make daily electronic connections with site file servers via "PC Anywhere." The purpose of these connections will be four-fold: 1) to transfer study data from the sites to the CC; 2) to update forms as needed; 3) to repair data as needed; and, 4) to swap electronic mail (Email). This section describes the procedures for the fourth purpose, Email.

Directory structure

Email activity at the sites will occur in one of two subdirectories. These subdirectories are **C:\Dash\Receive** and **C:\Dash\Transfer**. C:\Dash\Receive will be used by the CC for placing documents and files that come from the CC for use by the site. C:\Dash\Transfer will be used by the sites for placing documents and files that they want picked up by the CC for CC use or transfer to another site. Simply, C:\Dash\Receive will be the site incoming mail box and C:\Dash\Transfer will be the site outgoing mail box.

DASH Manual of Procedures

Schedule

Pickup and delivery will generally occur once a day. Unreachable systems may cause pickup and delivery to occur less frequently. Special Pickups and Deliveries may be arranged on an individual basis by calling the CC, who will process these special request as time allows.

Housekeeping

The C:\Dash\Receive and C:\Dash\Transfer subdirectories should be used by sites as staging areas, rather than archives for historical files and documents. Just as you wouldn't use your mailbox at home for long-term storage or filing of your mail, neither should you use these directories for this purpose. Files that are received in C:\Dash\Receive should be moved to an appropriate subdirectory immediately. The selection and/or creation of the appropriate subdirectory, other than C:\Dash\Receive or C:\Dash\Transfer is left to the discretion of the sites. The CC will delete files from C:\Dash\Transfer as they are transferred from the site to the CC. **IMPORTANT** - This means that if the sites wish to maintain copies of these transferred files they will need to maintain their copies in another subdirectory. In addition to good housekeeping principles, the other reason for this process is that if the CC sees files in the receive directory the day after sending the files to a site, they can assume that the receipt of the files has not been acknowledged. This is important if the files need timely attention. Along the same lines, if a site sees files in the C:\Dash\Transfer subdirectory the day after placing the files there, they will know that the CC has failed to grab these files. This, too, is important if the files need timely attention.

DASH Manual of Procedures

**Kaiser Permanente
Center for Health Research**

**Personal Computer System Manual
For
DASH Project
Desktop System**

Table of Contents

Data Intake	3
Directly entered data	3
Batch-entered data	3
Centrally entered data	4
Detecting and Reporting Data Errors	5
Data Flow And Archiving	5
Direct Entered Data	5
Batch entered data	5
Centrally entered data	6
Centralized Lab Tracking	6
Screening	6
Electronic Mail Procedures and File Server Management	6
Introduction	6
Directory Structure	6
Schedule	7
Housekeeping	7
<u>Setting up the Computer System</u>	<u>12</u>
<u>Operating the Personal Computer System</u>	<u>12</u>
To power on the system	12
To power off the system	12
<u>Starting and Stopping Microsoft Windows for Workgroups</u>	<u>12</u>
<u>Naming and Storing Files</u>	<u>13</u>
Files can be named (filename.extension):	13
Files can stored on:	13
Diskettes (drives A and B)	13
Hard disk drive (drive C)	13
"Users" directory	13
"DASH" directory	13
<u>Starting, Switching and Stopping Microsoft Office Applications</u>	<u>13</u>
To start applications using Office Manager	13
To switch open Office applications	13
To stop an Office application	13
<u>Managing Microsoft Office Word, Excel and Powerpoint Files</u>	<u>13</u>
To create a new document or file	13
To open an existing document or file	13
To close an open document or file	14
To save a document or file (same name and location)	14

DASH Manual of Procedures

To save a document or file (different name and/or location) _____	14
To copy a document or file _____	14
To delete a document or file _____	14
To search for documents or files _____	14
To print document or files _____	14
<u>Transferring and Receiving Documents and files</u> _____	14
<u>Printing to the HP Deskjet 520</u> _____	14
<u>Getting Help</u> _____	14
Call Computer Hot Line (Computer Operations) _____	14
On-line Help for applications _____	14
Computer-based Training for applications _____	15
<u>Setting up the Computer System Docking Station</u> _____	18
<u>Operating the Portable without the Docking Station</u> _____	18
To power on the system _____	18
To power off the system _____	18
<u>Operating the Portable in the Docking Station</u> _____	18
To power on the system _____	18
To power off the system _____	18
<u>Starting and Stopping Microsoft Windows for Workgroups</u> _____	19
<u>Sharing File Services on the Portable/Docking Station</u> _____	19
<u>Connecting to File Services on the Portable from the Server</u> _____	19
<u>Disconnecting from File Services on the Portable from the Server</u> _____	19
<u>Battery Power Management and Conservation</u> _____	20
<u>Getting Help</u> _____	20
Call Computer Hot Line (Computer Operations) _____	20
<u>Data Management</u> _____	23
Connecting the NoteBook. _____	23
Disconnecting the Notebook. _____	23
Downloading information to the notebook. _____	23
Uploading information to the file server. _____	24
What about Problems: _____	24
<u>Data Entry</u> _____	25
Starting the Data Entry Application. _____	25

DASH Manual of Procedures

Using the application.	25
Dash Data Entry Menus. The Dash Menu system organizes the screening tasks according to the rules outlined in the <u>Dash Protocol</u> . The menu system is activated by following the steps outlined in starting the application.	29
File Menu Choices:	29
Window Menu Choice.	31
Help Menu Choice.	31
Entering Screening Data:	32
The Participant Window.	32
Adding a participant.	34
Entering Blood Pressures.	34
Entering Lab results.	36
Follow up labs.	37
Height and Weight Measurements.	37
Medical Eligibility Review and Study Foods Checklist Review.	38
Special Information.	39
Visit Eligibility Outcomes.	39
Participant Close Out Form.	40
Other Screening Data.	41
Entering Run-in Data:	42
The Participant Window.	42
Entering Daily Log and Compliance Assessment information.	42
Entering Run-in Blood Pressures.	45
Entering Run-in Lab Information.	47
Entering Dexa Information and Personal Hx Questionnaire.	48

DASH Manual of Procedures

Setting up the Computer System

- Set up main system
 - Plug power strip in wall outlet (with power strip switched off)
 - Place system in position on table
 - Plug black power cord into back of system and into power strip
- Attach monitor
 - Place monitor on top of system
 - Plug beige power cord into back of monitor and into power strip
 - Connect monitor cable to 15-pin connector on back of system (first connector on the right)
- Attach keyboard to connector on back of system (first round connector on the left)
- Attach mouse to connector on back of system (second round connector from the left)
- Attach phone line to modem connector "telco" on back of system.
- Attach printer
 - Place printer in position on table
 - Plug power cord into the bottom of printer and into power strip
 - Connect printer cable to 25-pin connector on back of system (second connector from the right) and to the bottom of printer

Operating the Personal Computer System

To power on the system

- Turn on power strip (if necessary)
- Remove all diskettes from the diskette drives (if any)
- Turn on the printer
- Turn on the PC
- Wait 5 seconds and turn on the monitor

To power off the system

- Save and close all open files
- Exit all software applications
- Exit Microsoft Windows
- Remove all diskettes from the diskette drives (if any)
- Turn off the PC
- Turn off the monitor
- Turn off the printer

Starting and Stopping Microsoft Windows for Workgroups

- Windows for Workgroups is configured to start automatically when the personal computer is powered on.
- If you exit from Windows, you can restart Windows by typing "WIN" at the "C:\>" DOS prompt and pressing return.
- If you exit from Windows to DOS using the Windows "MS-DOS command prompt" program you can return to Windows by typing "EXIT" at the "C:\>" DOS prompt and pressing return.

DASH Manual of Procedures

Naming and Storing Files

Files can be named (filename.extension):

- Filename consists of 1-8 characters
- Extension consists of 1-3 characters
- When created from an application such as Word, only the filename is used
- When created at the DOS level, the extension may also be used

Files can stored on:

Diskettes (drives A and B)

- Drive A, 1.44MB 3.5 inches high density, double-sided
- Drive B, 1.2MB 5.25 inches high density, double-sided

Hard disk drive (drive C)

- "Users" directory
- "DASH" directory

Starting, Switching and Stopping Microsoft Office Applications

To start applications using Office Manager

Click the button of the Office application you want to run on the Office Manager toolbar.

NOTE: To see a text label for each button, position the mouse pointer on a button and wait a few seconds. The name of the application appears.

To switch open Office applications

Click the button of the Office application you want to switch on the Office Manager toolbar.

To stop an Office application

Hold down ALT and click the application button on the Office Manager toolbar.

Managing Microsoft Office Word, Excel and Powerpoint Files

To create a new document or file

- File New command
- New toolbar button

To open an existing document or file

- File Open command
- File Find Open command
- Open toolbar button

DASH Manual of Procedures

To close an open document or file

- File Close
- File Find Close command
To save a document or file (same name and location)
- File Save command
- Save toolbar button
To save a document or file (different name and/or location)
- File Save As command
To copy a document or file
- File Find Commands Copy command
To delete a document or file
- File Find Delete command
To search for documents or files
- File Find Search command
To print document or files
- File Print
- File Find Print command
- Print toolbar button

Transferring and Receiving Documents and files

- Documents or files that you are transferring should be saved or copied into the “C:\DASH\TRANSFER” directory.
- Documents or files that you receive from the Coordinating Center will be also be transferred to the “C:\DASH\RECEIVE” directory.

Printing to the HP Deskjet 520

The printer is attached and configured as in Windows for Workgroups as LPT1 with the Hewlett-Packard Deskjet 520. Your applications are configured to print to LPT1.

Getting Help

Call Computer Hot Line (Computer Operations)

- (503) 335-6671
- *On-line Help for applications*
- Toolbar help button
- Word, Excel or Powerpoint Help Contents, Search for Help on or Index Menus

DASH Manual of Procedures

Computer-based Training for applications

- Word, Excel or Powerpoint Help Examples and Demos Menu

DASH Manual of Procedures

**Kaiser Permanente
Center for Health Research**

**Personal Computer System Manual
For
DASH Project
Portable Systems**

Table of Contents

<u>Setting up the Computer System Docking Station</u>	18
<u>Operating the Portable without the Docking Station</u>	18
To power on the system	18
To power off the system	18
<u>Operating the Portable in the Docking Station</u>	18
To power on the system	18
To power off the system	18
<u>Starting and Stopping Microsoft Windows for Workgroups</u>	19
<u>Sharing File Services on the Portable/Docking Station</u>	19
<u>Connecting to File Services on the Portable from the Server</u>	19
<u>Disconnecting from File Services on the Portable from the Server</u>	19
<u>Battery Power Management and Conservation</u>	20
<u>Getting Help</u>	20
Call Computer Hot Line (Computer Operations)	20

DASH Manual of Procedures

Setting up the Computer System Docking Station

- Set up main docking system
 - Place system in position on table
 - Plug gray power cord into back of system and into power strip
 - Connect docking station to server
 - Remove one terminator cap from docking station and server
 - Connect thin-wire coaxial cable to docking station and server

Operating the Portable without the Docking Station

To power on the system

- **Make sure that the portable is turned off** and the screen is closed
- Connect the AC adapter to the portable
- Connect the power cord to the AC adapter
- Plug the power cord from the AC adapter into a power outlet
- Remove all diskettes from the diskette drives (if any)
- Open the portable screen
- Turn on the portable

To power off the system

- Save and close all open files
- Exit all software applications
- Exit Microsoft Windows for Workgroups
- Remove all diskettes from the diskette drives (if any)
- **Turn off the portable**
- Close the portable screen
- Unplug the power cord from the power outlet
- Disconnect the AC adapter from the portable
- Disconnect the power cord from the AC adapter

Operating the Portable in the Docking Station

To power on the system

- Make sure that the portable is turned off and the screen is closed
- Make sure that connector slide cover in back of portable is open
- Slide the portable forward into top of docking station
- Push the portable all the way into docking station
- Remove all diskettes from the diskette drives (if any)
- Open the portable screen
- **Turn on the docking station (not the portable)**

Note: If the docking station powers on but the portable does not power on, turn off the docking station and reseat the portable in the docking station. This is usually an indication that the portable is not properly connected to the docking station.

To power off the system

- Save and close all open files
- Exit all software applications
- Exit Microsoft Windows for Workgroups
- Remove all diskettes from the diskette drives (if any)

DASH Manual of Procedures

- **Turn off the docking station (not the portable)**
- Eject the portable from the docking station
 - Push the lever on the top right side of the docking station
 - Slide the portable forward and out of the docking station

Starting and Stopping Microsoft Windows for Workgroups

- **To start Windows for Workgroups for use in stand-alone mode** type “**WIN /N**” at the “C:\” DOS prompt and press return. This starts Windows for Workgroups without network services.
- **To start Windows for Workgroups for use in sharing files** type “**WIN**” at the “C:\” DOS prompt and press return. This starts Windows for Workgroups without network services.
- If you exit from Windows, you can restart Windows by typing “WIN” at the “C:\” DOS prompt and pressing return.
- If you exit from Windows to DOS using the Windows “MS-DOS command prompt” program you can return to Windows by typing “EXIT” at the “C:\” DOS prompt and pressing return.

Sharing File Services on the Portable/Docking Station

- “C:\DASH” directory is set up to be shared automatically as shared service “DASH”
- Can be shared manually through Windows for Workgroups Main | File Manager | Disk | Share As menu.
- Can stop sharing manually through Windows for Workgroups Main | File Manager | Disk | Stop Sharing menu.

Connecting to File Services on the Portable from the Server

- Double-click on the Norton Desktop Connect Toolbar button
- Enter a drive letter in the “Drive:” dialog box
- Double-click on the portable’s icon in the “Show Shared Directories on:” dialog box
- Double-click on the “DASH” icon in the Shared Directories on:” dialog box

Disconnecting from File Services on the Portable from the Server

- Double-click on the Norton Desktop Disconnect Toolbar
- Double-click on the drive icon that you want to disconnect

DASH Manual of Procedures

Battery Power Management and Conservation

- Power management configurations
 - High, Medium, None and Custom
 - Press the Function key and the F7 Key at the same time to toggle on/off the different modes
- Standby mode
 - Saves battery life by temporarily placing portable into suspended state
 - Automatic with High, Medium or Custom power management configurations
 - Toggled manually by pressing Standby button
- Displaying battery life
 - Press the Function key and the F8 Key at the same time to toggle on/off the battery time remaining indicator
- Charging the battery
 - The battery will charge when the portable is turned off and is connected to a power outlet with the AC adapter
 - The battery will charge when the portable is turned off and connected to the docking station which is turned on.

Getting Help

Call Computer Hot Line (Computer Operations)

- (503) 335-6671

DASH Manual of Procedures

**Kaiser Permanente
Center for Health Research**

**AUTOMATED DATA ENTRY SYSTEM
USER'S MANUAL**

**For
DASH Project**

Table of Contents

<i>Data Management</i>	23
Connecting the NoteBook.	23
Disconnecting the Notebook.	23
Downloading information to the notebook.	23
Uploading information the file server.	24
What about Problems:	24
<i>Data</i>	
Entry	25
.....	25
Starting the Data Entry Application.	25
Using the application.	25
Dash Data Entry Menus.	29
File Menu Choices:	29
Window Menu Choice.	31
Help Menu Choice.	31
Entering Screening Data:	32
The Participant Window.	32
Adding a participant.	34
Entering Blood Pressures.	34
Entering Lab results.	36
Follow up labs.	37
Height and Weight Measurements.	37
Medical Eligibility Review and Study Foods Checklist Review.	38
Special Information.	39
Visit Eligibility Outcomes.	39
Participant Close Out Form.	40
Other Screening Data.	41
Entering Run-in Data:	42
The Participant Window.	42
Entering Daily Log and Compliance Assessment information.	42
Entering Run-in Blood Pressures.	45
Entering Run-in Lab Information.	47
Entering Dexa Information and Personal Hx Questionnaire.	48

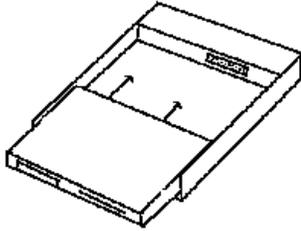
Comment [cre1]:

DASH Manual of Procedures

Data Management

Connecting the NoteBook.

1. Slide the notebook into the docking station firmly pushing it so the back of the notebook is seated into the docking station.



2. Open the notebook and turn the docking station on with the switch in the lower right hand side of the docking station.
3. If the screen of the notebook does not come on, the notebook is not seated firmly into the docking station. Eject the notebook using the eject lever to the right and repeat steps 1 and 2.
4. When the DOS prompt (C:\>) appears type win to start windows.
5. Make sure the file server is turned on and windows is running.

Disconnecting the Notebook.

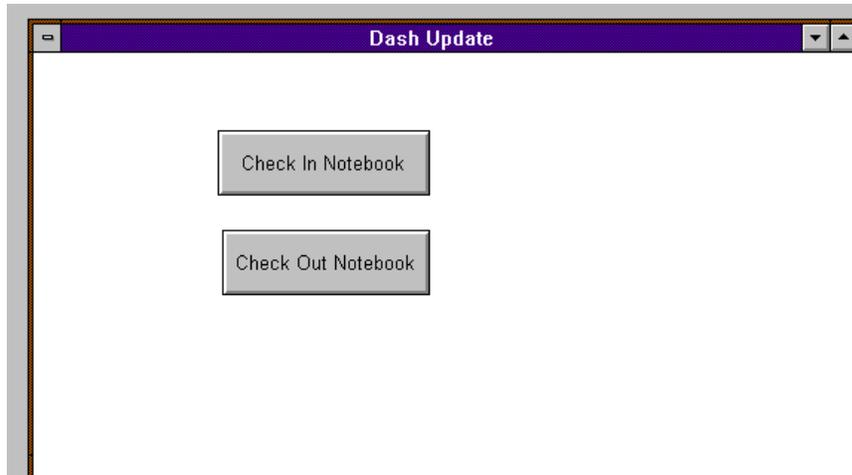
1. Exit windows on the notebook by choosing File | Exit from the windows menu. Click "Okay" when prompted to exit windows.
2. Turn off the docking station with the switch located in right hand corner.
3. Push the eject lever located on the right hand side of the docking station and slide out the notebook.

See section on Data Entry for information on using the Dash Data Entry System.

Downloading information to the notebook.

1. Follow the steps for connecting the notebook to the file server.
2. Double click the left mouse button on the Dash Data Management Icon located on the lower left hand corner of the file server. If the icon is not visible double click the right mouse button to bring up the Quick Access menu and then double click the left mouse button on the Dash Data Management Icon.
3. Paradox will start and the Dash Update screen will come up.

DASH Manual of Procedures



4. Click the button labeled "Check Out Notebook" to begin the down load process. You will see messages at the bottom indicating that the information is being downloaded to the notebook. When the process has completed you will get a message indicating that the notebook has been checked out.

Uploading information to the file server.

1. Follow the steps for connecting the notebook to the file server.
2. Double click the left mouse button on the Dash Data Management Icon located on the lower left hand corner of the file server. If the icon is not visible double click the right mouse button to bring up the Quick Access menu and then double click the left mouse button on the Dash Data Management Icon.
3. Paradox will start and the Dash Update screen will come up.
4. Click the button labeled "Check In Notebook" to begin the upload process. You will see messages at the bottom indicating that the information is being uploaded to the fileserver. When the process has completed you will get a message indicating that the notebook has been checked in.

At this point the computer will check to see if all notebooks are checked in. If so, you will get a message indicating that the update process has begun. This is an automatic process. You will see a message at the bottom of the screen indicating the files are being updated.

When the update process is complete a message will be displayed. Data from each notebook have now been merged with the master files for you site. The next time data are downloaded all information from the previous session of data entry will be available on each notebook.

What about Problems:

Unable to Connect... A message will appear indicating that this is a problem. This generally means that the notebook is not in the docking station correctly. Follow the steps for disconnecting the notebook and then repeat the steps for connecting the notebook. Repeat the process for Downloading the information.

Notebook must be checked out...

Notebook must be checked in...

DASH Manual of Procedures

These messages indicate that you are trying to check out a notebook already checked out or you are trying to check in a notebook that is already checked in. Take appropriate action.

All notebooks must be checked in to...

This message indicates that the notebook you are requesting to check out was checked out earlier and then checked in. However, other notebooks have been checked out since the last file server update and not checked back in. To insure that data are complete all notebooks must be checked in before this notebook can be checked out again. If there are other notebooks available that have not been checked out since the last update you may check those out now for data entry.

Cannot attach to table ...

Checkout Error, Please call system support

Can't add records to table...

Notebook not found in system library...

If you get any of the messages above, please note the specific table indicated (if any) and call System Support. These messages indicate a problem with the specific notebook, therefore, the notebook should not be used and System Support should be called to analyze the problem (503-335-6650).

Data Entry

The data entry application provides an organized way to collect and evaluate the information necessary to determine each participants eligibility for the study.

Starting the Data Entry Application.

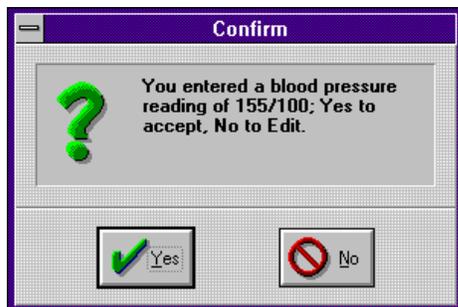
1. Follow the steps outlined for Downloading information to the Notebook.
2. Open the notebook and turn it on with the switch in the upper left corner of the machine.
3. When the DOS prompt appears (C:\>) type **win/n** to start windows. After the file manager window appears there will be a group icon called Dash. Double click on this icon to open it and then double click on the Dash icon to start the application. Paradox will start and the main screen will appear.

Using the application.

Form Types:

Several types of forms are used in the application to collect data and display information.

Question Forms: These forms are used when data must be confirmed in order to process the information.



DASH Manual of Procedures

Read the instructions on the form and then press the Yes button or No button to continue.

Information Forms. These forms present information about the data or the task you are trying to perform.

The image shows two screenshots of data entry forms. The top form has a purple header with the word "Protocol" and a blue information icon (a lowercase 'i') next to the text "Person is Ineligible to continue based on average BP readings." Below the text is a button with a green checkmark and the text "OK". The bottom form has a purple header with the word "STOP" and a red hand icon next to the text "This information has already been entered for this participant." Below the text is a button with a green checkmark and the text "OK".

Take note of the instructions or information presented and press enter to continue or click on the Okay button. If the information was related to eligibility, you will be required to record this in the visit outcome form explained in the section on entering Data.

Dash data entry forms: Each form is designed to collect and evaluate information related to a specific screening task as described in the Dash Protocol.

The forms are organized and accessed by selecting a menu choice that describes the task to be accomplished (see section below Dash Menus).

For information on what data are collected and the rules associated with the collection and evaluation of that data, please refer to the Dash Protocol and the Manual of Procedures. It is strongly recommended that these documents be read prior to using the data entry application.

Tasks and features common to all data entry forms: Although the data collected on each form are specific to the screening task at hand, every form has common controls.

DASH Manual of Procedures

Blood Pressure

Study_id : Visit : Visit_Date :

Cuff Size: Small Adult Adult Large Adult Thigh

Resting 30-sec. Pulse :

Pulse obliteration pressure:

SYSTOLIC1 : Zero Value

DIASTOLIC1 :

SYSTOLIC2 :

DIASTOLIC2 :

Staff ID :

Form Title: Each form is titled according to the specific screening information that the form was designed to collect.

Form Header: Study ID and Visit information will be displayed on each form. The values for these fields are filled in from the participant screen and can not be edited.

Moving the form: The form can be moved around the screen by placing the mouse pointer in the title bar and pressing and hold the left mouse key. Move the screen to a new position and release the mouse key.

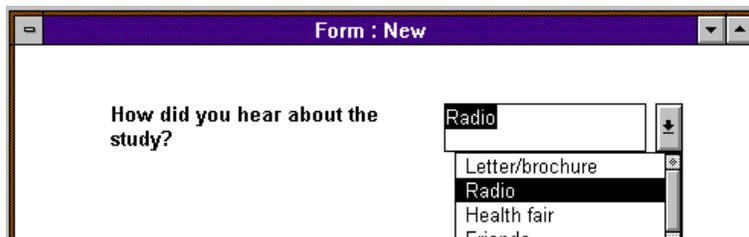
Date Fields: Enter all date fields in the MM/DD/YY format. To enter today's date put the cursor on the date field and press the space bar until the date is filled in.

Text Fields: Enter the information requested. All letters will be converted to uppercase automatically for data uniformity.

Numeric Data: Enter the information requested. Enter decimal values only when required.

Drop Down Edit List. These fields are indicated by the arrow in the right hand side of the field. Click on the arrow with mouse to drop down a list of choices for the field. Select the appropriate choice by selecting it with the mouse. Or you can select by using the arrow keys to move through the list and pressing enter when the selection you want is highlighted.

DASH Manual of Procedures



The screenshot shows a window titled "Form : New" with a question "How did you hear about the study?". A dropdown menu is open, showing options: "Radio", "Letter/brochure", "Radio", "Health fair", and "Friends".

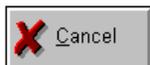
Radio Buttons: These fields display all possible answers as a button. Select the appropriate answer using the mouse. You can use the arrow key to toggle to the appropriate answer and then press enter.



Two radio buttons are shown: "Eligible" and "Not Eligible".



Accept Button: This button is marked by a check mark. The button is activated by clicking on it with the mouse or by pressing enter when a dashed line appears around the word "Accept". Activate this button when all data have been entered on the form. The form will be evaluated for completeness of data and eligibility if appropriate. If eligibility is evaluated a message indicating the outcome of this evaluation will be displayed. Information entered on the form will be saved at this point and no further edits will be allowed.



Cancel Button: This button is marked by a "X". The button is activated by clicking on it with the mouse or by pressing enter when a dashed line appears around the word "Cancel". Activating this button will cancel the data entry on this form and exit the form. Information entered on the form will not be saved. The screening information collected on this form will have to be entered again in order for the participant to continue in the screening process.

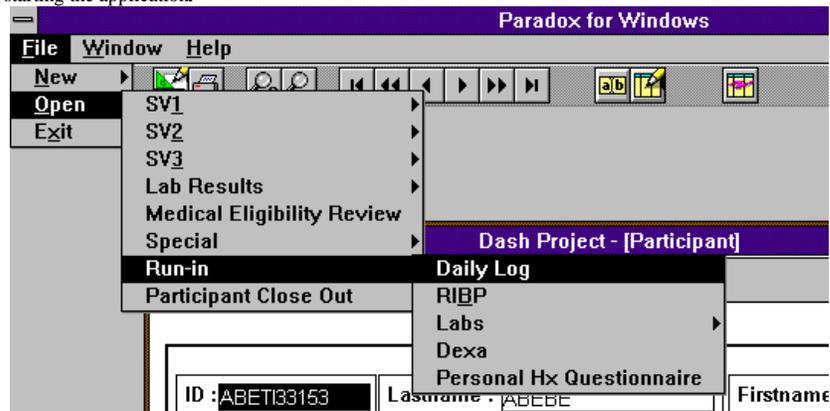


Form Control Button: This is located in the upper left hand corner of the form. Clicking on this button will close the form and cancel data entry. It is therefore equivalent as to clicking on the cancel key.

Moving through the form: To move the cursor from field to field, enter the appropriate value and press the enter key. To move from field to field without entering a value use the tab key. To move in reverse direction use Shift Tab. The current field will be indicated by reverse color or a blinking line ("I") indicating the cursor. You may also move to a specific field on the form by moving the mouse pointer to that field and clicking with the left mouse button.

DASH Manual of Procedures

Dash Data Entry Menus. The Dash Menu system organizes the screening tasks according to the rules outlined in the [Dash Protocol](#). The menu system is activated by following the steps outlined in starting the application.



To Activate a particular menu choice select the choice with mouse by clicking on it. If the choice requires further selection then click on the appropriate selection until the task that you wish to accomplish is selected. Click the mouse to activate that choice and open the appropriate form.

You may also select a menu choice by pressing F10 and then using the arrow keys to move to the appropriate choice. Press enter to activate that choice.

File Menu Choices:

File | Participant This choice is available from the main menu presented on application start up. It opens the participant window and provides access to the rest of the menu choices.

File | Exit This choice exits out of the current form. If there are no forms visible this choice exits the application.

File | New | Prescreen. This choice activates the prescreen process and adds an individual to the data base if they are eligible.

File | Open | SV1 | SV1BP. This opens the blood pressure form to complete the required blood pressure readings for screening visit 1 (SV1).

File | Open | SV1 | Review Study Foods Checklist. This choice opens the form to record the outcome of the Study Foods checklist.

File | Open | SV1 | SV1 Outcome. This choice activates the Visit Eligibility Outcome form. Select the appropriate outcome based on the evaluation of all data entered during the visit.

File | Open | SV2 | SV2BP. This opens the blood pressure form to complete the required blood pressure readings for screening visit 2 (SV2).

File | Open | SV2 | Ht & Wt. Allows entry of the persons height and weight for use in calculations to determine study eligibility.

DASH Manual of Procedures

File | Open | SV2 | SV2 Outcome. This choice activates the Visit Eligibility Outcome form. Select the appropriate outcome based on the evaluation of all data entered during the visit.

File | Open | SV3 | SV3BP. This opens the blood pressure form to complete the required blood pressure readings for screening visit 3 (SV3).

File | Open | SV3 | Weight. Allows entry of the persons weight for study analysis.

File | Open | SV3 | Physical Activity Questionnaire. Allows entry of the Physical Activity Questionnaire. Used for determination of caloric levels.

File | Open | SV3 | Skinfold Measurements. Allows entry of the skinfold measurements.

File | Open | SV3 | 24 Urine. Allows entry of collection and send date of the 24 urine sample. This is separate from the dipstick urine lab tests that will be performed during prescreen.

File | Open | SV3 | SV3 Outcome. This choice activates the Visit Eligibility Outcome form. Select the appropriate outcome based on the evaluation of all data entered during the visit.

File | Open | Lab Results | Initial. This allows entry of the results of the lab analysis of the non fasting blood sample (cholesterol, creatinine, blood sugar, transaminase, Ca and K) and the urine dipstick for protein and glucose. Only the effect on eligibility (Eligible or Not eligible) will be recorded.

File | Open | Lab Results | follow-up. This allows you to record the effect on eligibility of follow-up labs. Only initial labs effects of Not eligible will have follows.

File | Open | Lab Results | Review. This checks the database on the current status of lab results. Only labs recorded as Not eligible or not done are reported. If all labs are completed a message will be displayed indicating so.

File | Open | Medical Eligibility Review. This allows the user to record whether the person is medically eligible for the study based on analysis of the medical eligibility Questionnaire.

File | Open | Special | DEV | DEV1 Medical Eligibility Review. This allows the user to record whether the person is medically eligible for the study based on analysis of the medical eligibility Questionnaire for Drug Evaluation (DEV).

File | Open | Special | DEV | Date Withdrawal Begin. Allows the user to record the date that drug withdrawal began.

File | Open | Special | DEV | Date Withdrawal Ended. Allows the user to record the date drug withdrawal ended.

File | Open | Special | DEV | DEV&BP. This opens the blood pressure form to complete the required blood pressure readings for DEV visits.

File | Open | Run-in | Daily Log. This choice activates the Daily Log and Compliance Assessment data entry form.

File | Open | Run-in | RIBP. This choice activates the RI Blood Pressure data entry form.

File | Open | Run-in | Labs | 1st 24 Urine. This choice activates the data entry form for entering the date completed and date sent for the 1st 24 hour urine test completed in run-in.

File | Open | Run-in | Labs | 2nd 24 Urine. This choice activates the data entry form for entering the date completed and date sent for the 2nd 24 hour urine test completed in run-in.

File | Open | Run-in | Labs | Fasting Blood Sample. This choice activates the data entry form for entering the completed date for the fasting blood sample taking in run-in.

DASH Manual of Procedures

File | Open | Run-in | Labs | Glucose Tolerance Test This choice activates the data entry form for entering the completed data and date sent for the run-in Glucose Tolerance Test.

File | Open | Run-in | Dexa This choice activates the data entry form to enter the completion date of the Dexa (Not applicable at all sites).

File | Open | Run-in | Personal Hx Questionnaire This choice activates the data entry form to enter the completion date of the Personal Hx Questionnaire.

File | Open | Participant Close Out. This allows the user to record a final resolution on a participant not associated with a specific visit.

Window Menu Choice.

Used to display windows open on the desktop.

Help Menu Choice.

Provides access to electronic version of the user's manual.

DASH Manual of Procedures

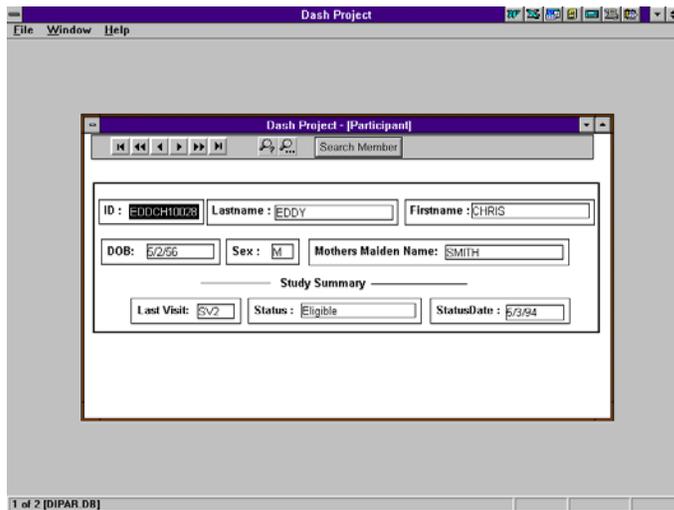
Entering Screening Data:

The Participant Window.

The application is designed to enter data on a specific participant. To enter data you must first select the participant.

Selecting a participant. Because all data are entered for a specific participant it is important to select the correct participant prior to entering data.

1. Choose File | Open | Participant from the menu system. This opens the participant window.



The screenshot shows a window titled "Dash Project - [Participant]" with a menu bar (File, Window, Help) and a toolbar with navigation icons and a "Search Member" button. The form contains the following fields:

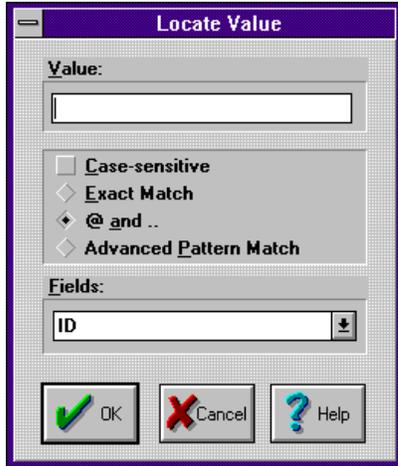
ID : EDDCH1002	Lastname : EDDY	Firstname : CHRIS
DOB: 5/2/56	Sex : M	Mothers Maiden Name: SMITH
Study Summary		
Last Visit: SV2	Status : Eligible	StatusDate : 5/3/94

At the bottom left of the window, it says "1 of 2 [DIPAR DB]".



If you know the persons ID number then you can look then up by clicking the Magnifying Glass Icon with the ? on the top of the screen. You will be prompted to enter the ID you wish to lookup. Click the okay button and search the data base for that ID.

DASH Manual of Procedures

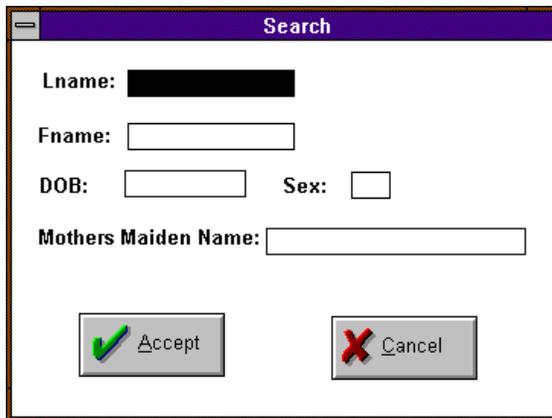


The 'Locate Value' dialog box features a purple title bar. It contains a 'Value:' text input field. Below it are four options: 'Case-sensitive' (unchecked checkbox), 'Exact Match' (selected radio button), '@_and..' (selected radio button), and 'Advanced Pattern Match' (selected radio button). A 'Fields:' section includes a dropdown menu currently showing 'ID'. At the bottom are three buttons: 'OK' with a green checkmark, 'Cancel' with a red X, and 'Help' with a blue question mark.



A rectangular button with a light gray background and a thin border, containing the text 'Search Member'.

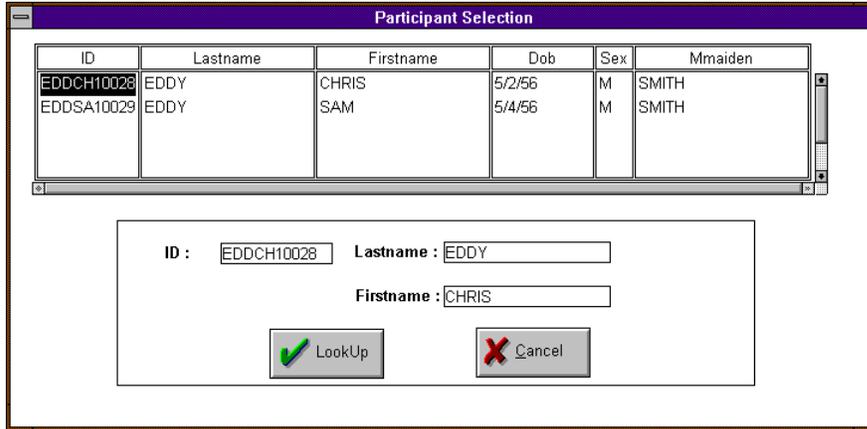
Alternatively, use the mouse to press the Select Member. You will be presented with a form to enter key information on the participant.



The 'Search' form has a purple title bar. It contains several input fields: 'Lname:' followed by a blacked-out field, 'Fname:' followed by an empty text box, 'DOB:' followed by an empty text box, and 'Sex:' followed by an empty checkbox. Below these is a 'Mothers Maiden Name:' label followed by a wide text input field. At the bottom are two buttons: 'Accept' with a green checkmark and 'Cancel' with a red X.

Enter as much information as you like and press the Accept Button with the mouse. All participants matching the fields you type in will be presented to you in a table.

DASH Manual of Procedures



ID	Lastname	Firstname	Dob	Sex	Mmaiden
EDDCH10028	EDDY	CHRIS	5/2/56	M	SMITH
EDDSA10029	EDDY	SAM	5/4/56	M	SMITH

ID : Lastname :

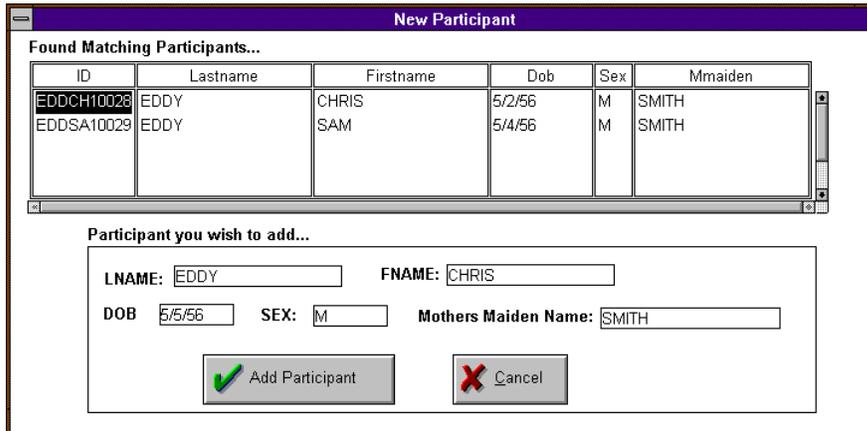
Firstname :

Scroll through choices using the arrow keys and when the participant you wish to select shows in the boxes with the buttons, press Lookup with the mouse. This will return you to the participant screen and look up the individual you selected.

Adding a participant.

If the participant is not in the database then a prescreen must be completed to add the participant to the data base.

Choose File | New | Prescreen. To initiate the prescreen process. After answering the questions the form will be evaluated for eligibility. If the person is eligible for the study the data base will search for all members with the same or similar last name of the participant you are entering. You will then be presented with the selections and asked to decide if the participant you are adding is truly a new participant.



ID	Lastname	Firstname	Dob	Sex	Mmaiden
EDDCH10028	EDDY	CHRIS	5/2/56	M	SMITH
EDDSA10029	EDDY	SAM	5/4/56	M	SMITH

Participant you wish to add...

LNAME: FNAME:

DOB: SEX: Mothers Maiden Name:

Press the Add Participant Button to generate a Study ID and add the participant to the data base. Press the Cancel button to cancel the operation.

Entering Blood Pressures.

DASH Manual of Procedures

Blood pressure readings will be entered at each screening visit, Drug Evaluation Visits (DEV), and Escape Level 2 visits as described in the Protocol. In addition an optional blood pressure may be entered during the prescreen.

To enter blood pressures choose the appropriate menu selection for the visit as described in the section on Data Entry Menus.

The screenshot shows a software window titled "Blood Pressure". At the top, there are three input fields: "Study_id" with the value "EDDCH10028", "Visit" with the value "SV3", and "Visit_Date" which is currently blank. Below these, there is a "Cuff Size" section with four radio button options: "Small Adult", "Adult", "Large Adult", and "Thigh". To the right of these options are two input fields: "Resting 30-sec. Pulse" and "Pulse obliteration pressure". In the center, there are two rows of input fields for blood pressure readings. The first row has "SYSTOLIC1" and "DIASTOLIC1" fields, with a "Zero Value" label and a corresponding input field to the right. The second row has "SYSTOLIC2" and "DIASTOLIC2" fields, also with a "Zero Value" label and a corresponding input field to the right. Below the readings is a "Staff ID" input field. At the bottom, there are two buttons: "Accept" (with a green checkmark icon) and "Cancel" (with a red X icon).

Enter the date of the reading by typing in the date in MM/DD/YY format.

Select the appropriate cuff size by clicking on the corresponding radio button with the mouse or using the arrow key to toggle through the selections. Press enter when the appropriate selection is highlighted by a dash line.

Enter the BP readings. You will be asked to confirm each reading. Press Yes to accept or No to edit.

The screenshot shows a "Confirm" dialog box with a purple title bar. On the left, there is a large green question mark icon. To the right of the icon, the text reads: "You entered a blood pressure reading of 155/100; Yes to accept, No to Edit." At the bottom of the dialog, there are two buttons: "Yes" (with a green checkmark icon) and "No" (with a red circle and slash icon).

DASH Manual of Procedures

Once you have confirmed the specific readings you will not be allowed to edit them.

After all readings are entered press accept to save the data and evaluate for eligibility. The result of this evaluation will be presented to you. Press Cancel to close the form and not save the data.

Entering Lab results.

Enter initial lab results by selecting File | Open | Lab Results | Initial. You will be presented with a list of labs that have no initial value recorded.

The screenshot shows a window titled "Lab Results" with a purple header. Below the header, there are two input fields: "ID: EDDCH10030" and "OUTCOME DATE: 5/5/94". The main area contains a list of lab tests, each with two radio buttons: "Eligible" and "Not Eligible". The "Eligible" radio button is selected for "Cholesterol". At the bottom of the list are two buttons: "Accept" (with a green checkmark icon) and "Cancel" (with a red X icon).

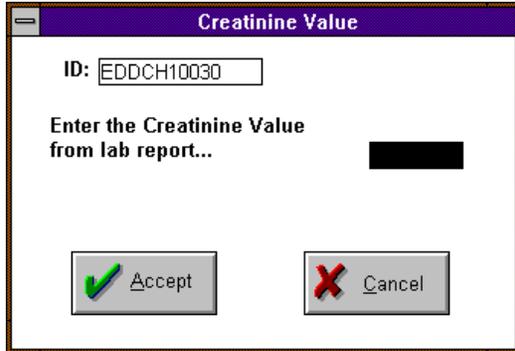
Lab Test	Eligible	Not Eligible
Cholesterol	<input checked="" type="radio"/>	<input type="radio"/>
Creatinine	<input type="radio"/>	<input type="radio"/>
Blood Sugar	<input type="radio"/>	<input type="radio"/>
Transaminase	<input type="radio"/>	<input type="radio"/>
Serum Ca	<input type="radio"/>	<input type="radio"/>
Serum K	<input type="radio"/>	<input type="radio"/>
Hematocrit	<input type="radio"/>	<input type="radio"/>
Urinary Protein	<input type="radio"/>	<input type="radio"/>
Urinary Glucose	<input type="radio"/>	<input type="radio"/>

On all labs accept creatinine you will enter only the affect on eligibility (Eligible of Not Eligible.) Select the appropriate answer by clicking on the radio button or by toggling with the arrow key and then pressing enter.

Use the tab key to leave the selection blank.

When you clicking on the creatinine value or pressing enter you will be prompted for the specific creatinine value.

DASH Manual of Procedures



Enter the specific value including decimal and press the accept button. The CGV will be calculated based on the creatinine value, the person's sex and weight. The participant's eligibility will be based on evaluation of the CGV score.

Follow up labs.

Follow up labs can be entered for those lab results that determined the person to be ineligible for the study as indicated in the Protocol.

Enter follow up results the same way as initial results. If you are entering follow up results for blood sugar or cholesterol you will be prompted for the specific test as described in the protocol.

Height and Weight Measurements.

Height and Weight measurements are taken at several points in the screening process. A self reported height and weight will be entered at prescreen. The height will be entered in feet and inches. Weight will be entered in pounds. The value entered will be used to calculate the BMI of the individual for eligibility evaluation.

How tall are you? ft inches
How much do you weigh? lbs

Height and weight will be measured at screening visit 2. As before, these values will be used to calculate the BMI of individual for eligibility evaluation. These values will also be used along with the creatinine value to calculate the CGV for the individual. Enter the height in centimeters and the weight in kilograms. In addition, another weight will be taken a SV3 for study analysis. Enter this value in kilograms.

DASH Manual of Procedures

Height and Weight Measurements

ID: Visit: Visit_date : 5/6/94

Enter height in centimeters:

Enter weight in Kg:

Medical Eligibility Review and Study Foods Checklist Review.

For these questionnaires, you will be asked to enter only the effect on eligibility. Choose the appropriate menu choice and then enter whether the review makes the person Eligible or Ineligible by pressing the appropriate button.

Medical Eligibility Review

ID : Review Type : Review Date :

Eligibility Status...

- Eligible
- Ineligible
- Uncertain

DASH Manual of Procedures

Special Information.

This menu selection includes choices for entering information necessary for Drug Evaluation participants and Escape Level 2. Participants.

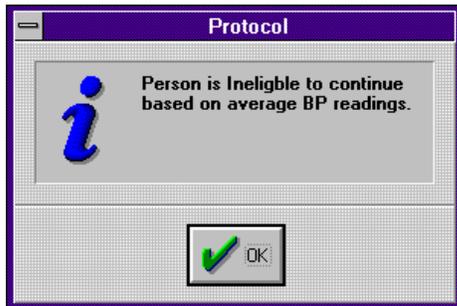
DEV If a person reports taking blood pressure medications they must complete the steps of Drug Withdrawal and meet Blood pressure guidelines as described in the protocol before beginning the screening process. Consult the Protocol for rules involving these data. Information needed for these participants includes the following:

1. Date withdrawal began. Enter the date in MM/DD/YY format.
2. Date withdrawal Ended. Enter the date withdrawal ended in MM/DD/YY.
3. DEV Blood pressure. Enter the DEV blood pressure readings following the instruction for Blood Pressures above.

Visit Eligibility Outcomes.

Because information for the visit can be collected on multiple notebooks, all information needed to determine a persons eligibility may not be available on each notebook. Therefore, you must fill out a visit eligibility form.

As data that affects eligibility are entered, they will be evaluated to determine eligibility status based on the rules described in the protocol. The result of this evaluation will be displayed in an information window.



Record this outcome on the visit flow sheet. Enter the outcome of the visit using the Visit Outcome Screen. Open the visit outcome form by making the appropriate menu selection as described in the section Dash Menus.

DASH Manual of Procedures

Visit Eligibility Summary

ID : EDDSA10029 Visit : SV3 Visit_date : [REDACTED]

Eligibility Status...

- Eligible
- DEV
- Escape Level 2
- Ineligible BP Readings
- Ineligible Consent Form
- Ineligible Medical Eligible
- Time Limit Exceeded
- Ineligible Study Foods Chklist
- Ineligible Food Frequency
- Ineligible Height and Weight
- Ineligible on Lab Review
- Refused

Accept

Cancel

If after completing each task for that visit the person is still eligible for the study, enter the date of the visit and click the radio button next to eligible. Press Accept to process the form. If on the other hand the person was determined to be ineligible or if the persons BP reading for that visit indicated Escape Level 2 as defined in the protocol, select the appropriate button.

The result will be displayed on the participant window. Once all the data from each notebook is uploaded to the file server, the data will be analyzed to insure that the appropriate visit outcome was entered.

Participant Close Out Form.

This form is designed to record participant drop outs or exclusions not associated with a regular screening visit. If the person is determined to be ineligible during a regular screening event this form does not need to be completed.

To open this form select File | Open | Participant Close Out from the menu.

DASH Manual of Procedures

Participant Exclusion Form

ID : Date :

InEligible Reasons...

- Lab
- Unresolved DEV
- Failed escape level 2
- Time limit exceeded
- Diet Compliance
- Other Compliance
- Investigator Discretion - Safety

Refusal Reasons...

- Unwilling or unable to modify diet
- Clinic Location
- Illness
- Too much time required
- MD advice
- No show for visits
- Refuse to continue

Select the appropriate exclusion reason and press Accept. The reason will be reflected on the participant window.

Once a person has been excluded from the study or found to be Not Eligible they may not be considered for re-entry until the amount of time for re-consideration as defined in the protocol has elapsed. At this time there data will be archived and they may be considered again beginning with the prescreen.

Other Screening Data.

For other screening tasks not specifically described, select the appropriate menu selection as described in the section on menus and enter the data as prompted. Follow the rules and guidelines for the specific data as defined in the Protocol and Manual of Procedures (MOP).

DASH Manual of Procedures

Entering Run-in Data:

The Participant Window.

To enter run-in data you must first select the participant. For information on selecting the participant please refer to pages 11-13 of the Dash users manual. After you have selected the person you wish to enter run-in data on, select the run-in item you want to enter as defined below.

Note: If no run-in information has been entered on the individual selected in the participant window, their data will be checked for eligibility. If they are eligible for run-in you will be asked to enter the date the person will begin run-in. According to the protocol this date must be within 2 days of the date the cohort started run-in.

Run-in Start Date

ID : Cohort ID :

Cohort Start Date :

Please Enter Date Individual will start Run-in:

The application will force you to enter this date prior to allowing entry of run-in data.

Entering Daily Log and Compliance Assessment information.

Daily Log and Compliance Assessment information can be entered Daily or in batch mode on a weekly bases.

To activate the form select the participant you wish to enter the information on and the select File | open | run-in | Daily Log from the Dash menu system.

DASH Manual of Procedures

RI Daily Log and Compliance Assessment

ID :

Date	Wt	Attend	MissedMealOk	MissedMealNok	ExtraFood	MissedFood	Score	Menstruation
8/31/94	88.00	0	0.00	0.00	0.00	0.00	0.00	Yes
9/1/94	85.00	0	0.00	0.00	0.00	0.00	0.00	Yes
9/2/94	81.00	0	0.00	0.00	1.00	1.00	0.00	Yes
9/3/94	81.00	0	0.00	0.00	1.00	0.00	0.00	Yes
9/4/94	85.00	0	0.00	0.00	0.00	0.00	0.00	Yes
9/5/94	86.00	0	0.00	0.00	0.00	0.00	0.00	Yes
9/6/94	88.00	0	0.00	0.00	0.00	0.00	0.00	Yes

Information presented will be in a spreadsheet format. To review previous information entered you may scroll though the table using the cursor keys or by clicking on the scroll bar to the right of the table with your mouse.

DASH Manual of Procedures

To enter new information press the add button with the mouse. This will open up a new record for data entry.

RI Daily Log and Compliance Assessment

ID :

Date	Wt	Attend	MissedMealOk	MissedMealNok	ExtraFood	MissedFood	Score	Menstruation
9/1/94	85.00	0	0.00	0.00	0.00	0.00	0.00	Yes
9/2/94	81.00	0	0.00	0.00	1.00	1.00	0.00	Yes
9/3/94	81.00	0	0.00	0.00	1.00	0.00	0.00	Yes
9/4/94	85.00	0	0.00	0.00	0.00	0.00	0.00	Yes
9/5/94	86.00	0	0.00	0.00	0.00	0.00	0.00	Yes
9/6/94	88.00	0	0.00	0.00	0.00	0.00	0.00	Yes

✓ Accept

✗ Cancel

Date. Enter the date of the run-in record.

Wt. Enter the weight in kilograms for each clinic visit. If the person did not attend (attend=0) the clinic then weight is not required. If this is the first run-in record being added the weight entered will be used to calculate the target wt according to the procedures outlined in the protocol.

Attend. Enter the appropriate value according to procedures outlined in the protocol.

0 = attended, 1 = excused absence, 2 = non-excused absence.

MissedMealOK. Enter the number of excused missed meals.

MissedMealNOK. Enter the number of non-excused missed meals.

ExtraFood. Enter the number of extra (Non-diet) foods eaten.

MissedFood. Enter the number of foods (Diet foods) not eaten.

Score. Enter the appropriate compliance as described in the protocol.

0 = Compliant, 1= Not Compliant.

Menstruation. Enter Yes or No.

After you have entered the data press the accept button to evaluate the record and add it to the data base. After the record is evaluated for missing values you will be asked if you want to post (add) the record to the file. Answer Yes to post the record or No to continue making edits to the record.

Press the Cancel Button to delete the record.

To continue adding records for the individual ID shown in the ID frame, press the add button. If you are done adding daily log records for this individual press the Done button. Pressing the done button will return you to the participant window.

DASH Manual of Procedures

Entering Run-in Blood Pressures.

Refer to the protocol for information on required BP readings for run-in. You must enter 5 sets of BP readings in the last 9 days of run-in (i.e., days 13-21 of run-in feeding). However, you may enter more as needed for BP monitoring.

To activate the run-in Blood Pressure form select File | Open | Run-in | RIBP from the Dash menu system.

Run-in Blood Pressure

ID : Visit : Visit_Date :

Time of Blood Pressure measurement: : AM PM

Cuff Size: Small Adult Adult
 Large Adult Thigh

Resting 30-sec. Pulse :

Pulse obliteration pressure:

Peak Inflation Level:

BP Device Number :

SYSTOLIC1 : Zero Value

DIASTOLIC1 :

SYSTOLIC2 :

DIASTOLIC2 :

Staff ID :

Enter the information asked for on the form. You will be asked to confirm each BP reading and zero value. Once you have confirmed these values you will not be allowed to edit the entry.

After all information has been entered press accept to save and evaluate the data. As outlined in the protocol, only BP Escape levels will be monitored for exclusion. Press the cancel button to close the form and not save the data.

DASH Manual of Procedures

Once you have added one record for the individual you will be allowed to continue adding readings for the individual without returning to participant screen.

Run-in Blood Pressure

ID : Visit : Visit_Date :

Time of Blood Pressure measurement: : AM PM

Cuff Size: Small Adult Adult
 Large Adult Thigh

Resting 30-sec. Pulse :

Pulse obliteration pressure:

Peak Inflation Level:

BP Device Number :

SYSTOLIC1 : <input type="text" value="155"/>	<u>Zero Value</u>
DIASTOLIC1 : <input type="text" value="100"/>	<input type="text" value="10"/>
SYSTOLIC2 : <input type="text" value="155"/>	
DIASTOLIC2 : <input type="text" value="100"/>	<input type="text" value="10"/>

Staff ID :

Press the Add button to add a new BP record for the ID shown in the ID frame. Press the done button to complete data entry on the individual and return to the participant screen.

DASH Manual of Procedures

Entering Run-in Lab Information.

To enter run-in lab information select File | Open | Run-in | Labs .. and the appropriate lab selection. Enter the information requested on the lab form only for the lab sample that is sent to central labs for processing.

Run-in Lab Track

ID : Lab Event :

Collect Date :

Sent Date :

Collect date. The date the sample was collected in the clinic.

Sent Date. The date the sample was sent to central labs for processing.

Press the accept key to save the data and return to the participant screen. Press the Cancel button to not save the data and return to the participant screen.

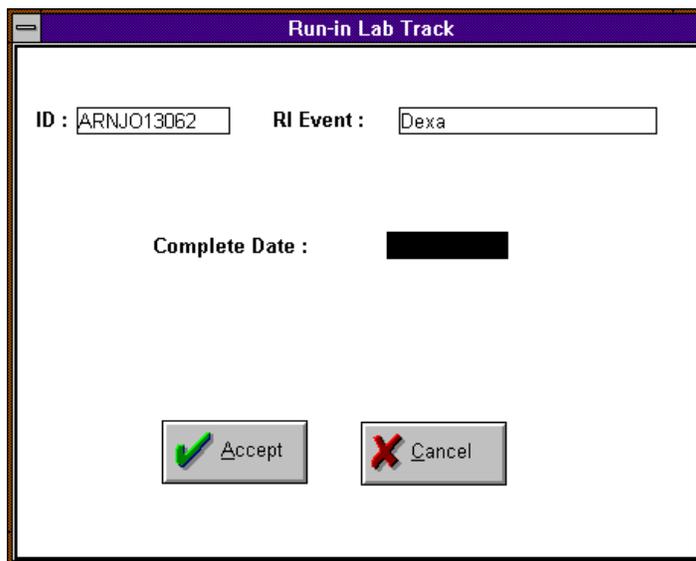
Note: The Glucose Tolerance test is only being completed at Pennington and Brigham and Women's.

DASH Manual of Procedures

Entering Dexa Information and Personal Hx Questionnaire.

Only the date of completion will be entered for these tasks.

To enter the completion date of the Dexa select File | Open | Run-in | Dexa from the Dash menu system. To enter the completion date of the personal Hx Questionnaire select File | Open | Run-in | Personal Hx Questionnaire.



The screenshot shows a dialog box titled "Run-in Lab Track". It contains the following elements:

- ID :** ARNJO13062
- RI Event :** Dexa
- Complete Date :** [Redacted]
- Buttons:** "Accept" (with a green checkmark icon) and "Cancel" (with a red X icon).

Press the accept key to save the data and return to the participant screen. Press the Cancel button to not save the data and return to the participant screen.

Note: The Dexa will only be completed at Pennington and Duke.

DASH Manual of Procedures

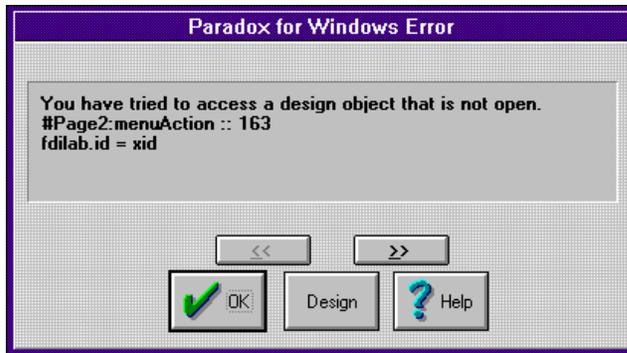
What About Problems.

Most problems that occur during data entry will be related to rules defined in the protocol. The application is designed to enforce these rules and may prevent data from being entered or make the person ineligible. If you feel these errors are in error or if you feel data on a specific individual are incorrect, report the discrepancy to the coordinating center and it will be evaluated.

Another problem that may occur is entering the right data on the wrong person. It is important to make the proper participant selection to avoid this problem. See the section on Selecting the participant. If you notice this has happened, please report the problem to the coordinating center for resolution (503) 335-6650.

If you feel the application is not allowing you to do something that you should be allowed to do, please report the problem to the coordinating center for resolution.

When an application error occurs you will be presented with something similar to the following.



Record what you were doing at the time of the error any information displayed. Click the okay button and exit the form. Call system support for resolution (503) 335-6650. You may continue to use other forms on this notebook. Data for the specific task where the error occurred may be recorded and entered later.

Data Errors.

The data will be analyzed for errors such as values out of range eligibility discrepancies and reported on by the coordinating center.

24. Data Analysis

Analysis of Primary Blood Pressure Change Endpoint _____	3
Analysis of Secondary Outcome Measures _____	4
Analysis of Other Outcome Measures _____	4

Summary of Edits

New changes in Version 2.1

- misc technical edits
- In the fourth para under *Analysis of Primary BP Change Endpoint*, the statement of what is meant by an “intention to treat” analysis was clarified
- third para under *Analysis of Other Outcome Measures* expanded to cover analysis of standardized effect sizes for ABPM/RZ comparison

New changes in Version 4.0

- none

New changes in Version 4.1

- Deleted reference numbers (from Protocol) on page 3
- On page 3, last para, changed “Section 8 (outcome measures)” to “Section 12 of the DASH Protocol (outcome measures)”

Analysis of Primary Blood Pressure Change Endpoint

The primary outcome measure for DASH is the change in DBP from baseline to end of intervention. The primary analysis will adjust only for clinic. We will use multiple linear regression analysis to compare the change in DBP between the treatment groups after adjusting for differences in overall blood pressure change among the clinics. Dummy variables will be used to indicate the two intervention diets (intermediate and ideal) and the individual clinics. A secondary analysis will further adjust for the potentially confounding effects of race, sex, age, body mass index, and baseline DBP. Additional dummy variables will be used in this analysis to indicate African-American and "other minority" racial groups.

Because we anticipate that the largest treatment differences will be between the typical American dietary pattern and the two intervention diets, we will use a hierarchical procedure to compare the treatment groups. First, we will examine the coefficients of the two intervention group indicator variables. These coefficients will have the interpretation of the difference in DBP change between the specific intervention group and the typical American group. If neither of these coefficients is significant at the $\alpha=.05/2 = .025$ level (Bonferroni adjustment for two comparisons) the three treatment groups would be declared not significantly different. If either coefficient is significant, then the two intervention diets would be compared at the same significance level, $\alpha=.025$.

This procedure is similar to the Fisher Least Significant Difference (LSD) procedure, whereby a global F-test is performed and unadjusted pairwise comparisons are made only if the global statistic is significant. Our procedure can be viewed the same way, except that our global statistic is the maximum of the t-statistics comparing each intervention group to the control group, and the comparison of the intervention diets is made at significance level $\alpha=.025$ instead of .05 to make all of the pairwise tests comparable. Our procedure offers strong control of the Type I error rate.

Participants not completing the post-randomization follow-up (either due to nonattendance at data collection visits or to protocol escape levels) are likely to represent a nonrandom subset of the overall randomized population. For example, those individuals who are required to initiate antihypertensive medications are likely to be the participants who would have had the highest end-of-study blood pressure levels. End-of-study blood pressure values for such participants are discussed in section 12 of the DASH Protocol (Outcome Measures). We will use an intention-to-treat analysis whereby each randomized participant will be included in the analysis according to his randomly assigned diet group. The only exception to this will be for participants who either (i) drop out of the study after randomization and before beginning intervention feeding or (ii) drop out of the study after intervention feeding begins and before any intervention blood pressures are recorded. Participants in the first category will be excluded from all analyses, since their loss should be totally unrelated to randomization assignment. Participants in the second category will be excluded from analysis of blood pressure change, but will be included in compliance assessments.

DASH Manual of Procedures

Fortunately, the run-in period should identify the majority of noncompliers prior to randomization, and the number of participants needing to go on medications during follow-up should also be small. Thus the number of participants with censored data should be minimal.

Analysis of Secondary Outcome Measures

Secondary blood pressure outcomes of interest include change in SBP recorded using the random zero sphygmomanometers and changes in both SBP and DBP as measured using ambulatory blood pressure monitoring. These outcomes will be evaluated in the same manner as described above for change in DBP.

Analysis of Other Outcome Measures

In order to determine if any observed treatment effects differ for various subgroups, we will incorporate the appropriate interaction terms into our statistical model and test whether the interaction model significantly improves the fit to the data relative to the basic model. Specific subgroups of interest are male versus female and African American versus non-African American. Additional analyses will test whether baseline renin status and insulin resistance influence treatment differences.

We will also compare the effects of the three dietary patterns on serum lipid levels. Specific outcomes of interest for this analysis are total cholesterol, LDL cholesterol, and triglycerides. For each of these outcomes we will compute within-participant differences as for blood pressure and then conduct a multivariate analysis of variance (MANOVA) to simultaneously test whether treatment differences exist for any of the outcomes. If this test is significant, we will conduct separate analyses for each of the three outcomes using an approach analogous to that described for change in DBP.

An additional outcome of interest is whether ABPM provides greater precision for measuring blood pressure change in clinical trials than do standard blood pressure measurement techniques (i.e., use of random zero sphygmomanometers). We will evaluate this hypothesis by using the Morgan-Pitman test statistic for correlated variances to compare the variance of blood pressure change estimates made using ABPM with those made using RZ sphygmomanometers. For ABPM, blood pressure will be measured as the average 24-hour mean blood pressure. In order to compare effect sizes as measured using the two measurement techniques, we will also regress within participant change in ABPM blood pressure on within participant change in standard blood pressure and test whether the slope of the regression line is significantly different from unity. Finally, we will use this same regression technique to compare standardized effect sizes. Specifically, let (D_i, D'_i) denote blood pressure change measured the standard way and by ABPM, respectively, for the i th participant. Let σ and σ' denote the estimated standard deviations of the D s and D' s, respectively. Since these standard deviations will be based on a large number of observations, we can treat these as population standard deviations σ and σ' , and compute standardized effect sizes $E_i = D_i/\sigma$ and $E'_i = D'_i/\sigma'$. Comparing these standardized effect sizes will most directly answer the question of primary interest, namely, is ABPM a more

DASH Manual of Procedures

sensitive technique than standard blood pressure measurement for assessing blood pressure change in clinical trials?

In addition to the baseline and final blood pressure measurements, numerous intermediate blood pressure measurements will be available on each individual. In the event that we observe significant mean differences in overall blood pressure change between the treatment groups, these intermediate blood pressure measurements can be used to evaluate the pattern of change over time. Such an analysis would be largely descriptive in nature and would be used to determine whether the observed declines occurred steadily over time or followed a more curvilinear pattern. For example, one hypothesis is that the bulk of the blood pressure decline would occur fairly soon after the introduction of a new diet and that blood pressure levels would remain fairly stable after that. Random effects models will be used to test for a nonlinear pattern of decline.

25. Trial Monitoring Reports

Introduction	3
Types of Reports	3
Recruitment/Follow-up Reports	3
Baseline Data Report	3
Quality Control Reports	3
Laboratory QC and Results Reports	3
Side Effects Report	3
Outcome Measures and Safety Issues Reports	4
Distribution of Reports	4
Monthly Trial Monitoring Reports	4
End of Cohort Reports	4
List of Dash Reports	4
Recruitment/Follow-up Reports	4
Baseline Data Report	5
Quality Control Reports	5
Laboratory QC and Results	5
Side Effects	6
Outcome Measures and Safety Issues	6

Summary of Edits

New Changes in Version 2.1

- Deleted 102 Prescreening Outcomes by Demographics, #103, 202, 302, 402, 403
- added: 06 Treatment Comparison After Rand., 07 Rand Target [After Rand.] 08 Site Specific Rand Summary {After Rand}, 09 Recruitment Activity Summary [Biweekly] 2

New Changes in Version 2.2

- Formatting
- Section on Study Outcome and Safety Monitoring Reports added
- Section on Transmission of Reports changed

New Changes in Version 4.0

- none

New Changes in Version 4.1

- Chapter has been updated and reorganized by type of report and timing of distribution of reports.
- Table 25.1 has been revised and changed from a table to a list -“DASH Reports.”
- Sample reports have been deleted.

DASH Manual of Procedures

Introduction

During the trial's course, the Coordinating Center produces a variety of reports to help the Steering Committee and the DSMB monitor the progress of the trial. Additional reports, produced for the DSMB only, permit it to monitor the efficacy and safety of the interventions. These reports include not only standardized reports issued at regular intervals, but also *ad hoc* reports as requested.

The reports prepared for the Steering Committee focus on the recruitment of participants into the trial. These reports allow the Steering Committee to make sure that recruitment is proceeding in a timely manner and to identify potential recruitment problems at an early enough stage that they can be corrected. In addition, the Steering Committee also receives reports summarizing the completeness and quality of the study database.

Types of Reports

Recruitment/Follow-up Reports

Recruitment and Follow-up Reports summarize recruitment activity and follow-up to date. These reports assist field sites in meeting recruiting needs and in scheduling eligible participants for upcoming screening visits.

Baseline Data Report

This report compares the baseline characteristics of the randomized participants. Data are presented both by site and by treatment status. All of the information reflects baseline, pre-intervention data and therefore should be comparable across treatment groups.

Quality Control Reports

Quality Control Reports include a number of reports related to the integrity of the DASH database and adherence to trial protocol by both participants and sites.

Laboratory QC and Results Reports

Laboratory quality control reports summarize lab tracking including receipt, receipt status, and the collection of process measures such as start and stop times for 24-hour urine samples that will be used to establish the usability of data. Results reports for these data will summarize results from laboratory analyses.

Side Effects Report

The side effects report summarizes side effects reported by DASH participants during the course of the study.

DASH Manual of Procedures

Outcome Measures and Safety Issues Reports

These reports are only sent to members of the DSMB. They constitute unblinded study data.

Distribution of Reports

Monthly Trial Monitoring Reports

These are distributed the first week of each month. They consist of:

- Recruitment Projection Report
- Digit Preference Report

End of Cohort Reports

End of Cohort Reports are distributed at the end of each cohort. They consist of:

- All Recruitment/Follow-up Reports

Reports for Steering Committee and DSMB meetings

These reports are prepared for Steering Committee and DSMB meetings. They consist of:

- All Recruitment/Follow-up Reports
- Quality Control Reports
- Study Outcome and Safety Monitoring Reports
- Baseline Data Reports
- Lab QC and Reports
- Side Effects Report

List of Dash Reports

Recruitment/Follow-up Reports

- Prescreening Outcome Report
- SV1 Outcome Report
- SV2 Outcome Report
- SV3 Outcome Report
- Blood Pressure Eligibility Report
- Recruitment Activity Summary
- Randomization Target Report
- Run-in Randomization Rate Summary
- Run-in Dropout/Exclusion Report
- Recruitment Projection Report
- Intervention Follow-up Report

DASH Manual of Procedures

- Study Dropout/Exclusion Report

Baseline Data Report

- Baseline Comparison of DASH Treatment Groups
- Baseline Anthropometric Report
- Baseline Characteristics - Demographic Variables
- Baseline Characteristics - BP Control

Quality Control Reports

Blood Pressure

- Blood Pressure Digit Preference Reports
- Blood Pressure QC Audit Reports
- Table 1 - Within-visit change in BP across clinics
- Tables 2a-2d and 3a-3d - Similar to Table 1, presented by site
- Tables 4a-4d and 5a-5d - Differences in mean daily BP by site
- Blood Pressure Protocol Report

ABPM

- Table 1 - ABPM Monitor Data Available
- Table 2 - Summary ABPM Statistics
- Table 2a - Summary ABPM Statistics - comparing daytime and nighttime measures.
- Table 3 - Comparison of baseline ABPM data
- Table 4 - Average waking times and bedtimes
- Table 5 - Completeness of baseline ABPM data.

Other QC Reports

- Data Collection Summary
- Forms Received Report
- Screening Visit Window Report

Laboratory QC and Results

Bloods

- Lipid Collection Summary
- Central Lab Collection Report
- Lipid Results
- Blood Results
- GTT Results

DASH Manual of Procedures

Urines

- Urine Collection Summary
- Urine Results
- Urine Results - Creatinine Adjusted

Side Effects

- Side Effects Data - by Site
- Side Effects Data - by Treatment Status

Outcome Measures and Safety Issues

- Intervention Follow-up Report
- Study Dropout/Exclusion Report
- Blood Pressure Escape Summary Report
- Summary of Monitoring and Validation
- Analysis of BP Change
- Lipid Results
- Blood Results
- Urine Results
- Urine Results - Creatinine Adjusted

26. Trial Communications

Importance of Trailed Communications	3
Principles of DASH Communications	3
Central Contact Person at Each Location	3
Rapid Turnaround of Minutes	3
Rapid Turnaround of Queries	4
Elements of Communications Network	4
Sending and Receiving Mail/Documents on the File Server	4

Summary of Edits

New Changes to version 4.0

- none

New Changes to version 4.1

- added section on *Sending and Receiving Mail / Documents on the File Server*

DASH Manual of Operations

Importance of Trialwide Communications

Maintaining lines of good communication is one of the keys to the successful operation of a long-term collaborative clinical trial. During the course of the DASH study the coordinating center will be responsible for the following tasks that depend heavily on effective communication channels and skills:

1. arranging orientation and initial training of clinical center personnel,
2. monitoring project adherence,
3. reporting to Project Office and committees and DSMB,
4. responding to clinical center and Project Office requests,
5. staffing trial committees, including logistic arrangements and distribution of meeting minutes.

The tools of communications for DASH include: regular meetings of the Steering Committee and its subcommittees, conference calls, sequential memos, telephone calls, data edit reports, and routine trial monitoring reports.

This section summarizes the principles for DASH communications and describes the procedures for sending communications between participating institutions.

Principles of DASH Communications

Central Contact Person at Each Location

A key component of the DASH communications protocol is that each participating institution identify a single person who serves as the contact person for that site. All DASH communications directed to a site should be sent to that person, who is then responsible for forwarding copies of the document as appropriate. In the event that this individual is not available, backup coverage is arranged so that someone else checks for incoming correspondence on a daily basis.

This procedure assures, for example, that an urgent fax is not left unread for several days because the individual to whom it was sent is out of town. Instead, the contact person would review the message and forward it to someone else who can respond in a timely manner.

Rapid Turnaround of Minutes

Especially during the initial planning stages of a trial, the work of the trial is done by committees who meet to design the trial and work out the various procedures. In order that this process proceed smoothly, it is critical that accurate minutes of committee meetings be taken and then distributed in a timely manner. The coordinating center takes notes during all DASH committee meetings and will attempt to send out within two weeks of their occurrence.

DASH Manual of Operations

Rapid Turnaround of Queries

All participating institutions in the trial shall make every effort to promptly respond to queries. Phone messages or written queries should be answered within a maximum of five working days.

Elements of Communications Network

During the initial, planning phase of the trial communication have relied mainly on a combination of FAX, Internet/Bitnet, regular mail, and Federal Express (or equivalent) to send written study communications and materials.

As of May, 1994, each of the clinical centers will have in place an operational PC file server as part of the DASH data management system. In addition to using the file server to transmit study data to the coordinating center, the file server can also be used to send electronic mail and formatted study documents.

The coordinating center will use the files servers to send meeting minutes, memo, and updates to the protocol and MOP to the clinical centers, largely bypassing the need for FAX, Internet, and Federal Express communications with the clinical centers. These latter mechanisms will still be used for communications with the Project Office.

Sending and Receiving Mail/Documents on the File Server

Introduction

The CC will make daily electronic connections with site file servers via "PC Anywhere." The purpose of these connections will be four-fold: 1) to transfer study data from the sites to the CC; 2) to update forms as needed; 3) to repair data as needed; and, 4) to swap electronic mail (Email). This section describes the procedures for the fourth purpose, Email.

Directory Structure

Email activity at the sites will occur in one of two subdirectories. These subdirectories are **C:\Dash\Receive** and **C:\Dash\Transfer**. C:\Dash\Receive will be used by the CC for placing documents and files that come from the CC for use by the site. C:\Dash\Transfer will be used by the sites for placing documents and files that they want picked up by the CC for CC use or transfer to another site. Simply, C:\Dash\Receive will be the site incoming mail box and C:\Dash\Transfer will be the site outgoing mail box.

Schedule

Pickup and delivery will generally occur once a day. Unreachable systems may cause pickup and delivery to occur less frequently. Special Pickups and Deliveries may be

DASH Manual of Operations

arranged on an individual basis by calling the CC, who will process these special request as time allows.

Housekeeping

The C:\Dash\Receive and C:\Dash\Transfer subdirectories should be used by sites as staging areas, rather than archives for historical files and documents. Just as you wouldn't use your mailbox at home for long-term storage or filing of your mail, neither should you use these directories for this purpose. Files that are received in C:\Dash\Receive should be moved to an appropriate subdirectory immediately. The selection and/or creation of the appropriate subdirectory, other than C:\Dash\Receive or C:\Dash\Transfer, is left to the discretion of the sites. The CC will delete files from C:\Dash\Transfer as they are transferred from the site to the CC.

IMPORTANT - This means that if the sites wish to maintain copies of these transferred files they will need to maintain their copies in another subdirectory. In addition to good housekeeping principles, the other reason for this process is that if the CC sees files in the receive directory the day after sending the files to a site, they can assume that the receipt of the files has not been acknowledged. This is important if the files need timely attention. Along the same lines, if a site sees files in the C:\Dash\Transfer subdirectory the day after placing the files there, they will know that the CC has failed to grab these files. This, too, is important if the files need timely attention.

27. Safety Monitoring

Blood pressure _____	3
Procedures for subjects taking antihypertensive medication at entry _____	3
Procedures applying to all subjects during screening and feeding _____	3
DASH blood pressure escape criteria _____	4
Comorbid conditions _____	4
Laboratory abnormalities _____	5
Adverse effects of intervention _____	5
Food safety _____	5

DASH Manual of Procedures

Summary of Edits

New changes in Version 2.1

- Under *Blood Pressure*, a new item #3 was inserted. Original items #3-6 now #4-7.
- Editorial notes struck from *Food Safety* section and reference now given to MOP Chapter 17.

New changes in Version 4.0

- none

New changes in Version 4.1

- In the section *DASH blood pressure escape criteria*, the paragraph beginning After randomization was changed and a paragraph added to reflect the importance of collecting EOS measurements on participants who have an escape BP.
- In the section *Adverse effects of intervention*, a paragraph was added regarding reporting of adverse events and a sentence added regarding EOS measurements.

DASH Manual of Procedures

Blood pressure

In order to prevent a prolonged period of untreated hypertension (outside the eligibility range of DASH), several blood pressure safety procedures are observed.

Procedures for subjects taking antihypertensive medication at entry

- At PSV, subjects taking more than two antihypertensive medications are excluded.
- At DEV1, prior to withdrawal of antihypertensive medication, a DASH clinician confirms that:
 1. The subject's MD has given written or verbal approval for discontinuing antihypertensive medication;
 2. The subject's MD has confirmed that antihypertensive medications are prescribed only for hypertension, and not for concomitant conditions such as angina, arrhythmia, etc.
 3. The responses to the Medical Eligibility Questionnaire indicate the subject is eligible.
 4. The Pre-drug Withdrawal Questionnaire does not indicate the presence of a potential health risk associated with discontinuing antihypertensive medication;
 5. The DEV Symptom Checklist shows no evidence of significant hypertension-related symptoms.
 6. Treated systolic blood pressure is less than 150 mm Hg and diastolic blood pressure is less than 90 mm Hg;
 7. Informed consent for medication withdrawal has been obtained.
- Following the start of drug withdrawal and prior to formal screening, at each subsequent DEV visit, a DASH clinician will confirm that:

Systolic blood pressure is less than 160 mm Hg and diastolic blood pressure is \leq 95mm Hg;

The DEV symptom checklist shows no evidence of significant hypertension-related symptoms.

Procedures applying to all subjects during screening and feeding

DASH Manual of Procedures

Blood pressure is measured at each screening visit and regularly throughout the run-in and intervention feeding periods. If a subject reaches a blood pressure escape level, appropriate evaluation and therapy follow.

DASH blood pressure escape criteria

Escape level #1: The mean blood pressure recorded at any single visit exceeds either a SBP of 180 mm Hg or a DBP of 110 mm Hg.

Escape level #2: The mean blood pressure for each of two successive blood pressure readings, spaced no more than one week apart, exceeds either a SBP of 170 mm Hg or a DBP of 105 mm Hg. If mean blood pressure on any given day exceeds these levels, a second measurement must be obtained in one to seven days.

The following constitutes appropriate evaluation and therapy for an escape level blood pressure:

During screening: exclusion from DASH and referral to a physician. For escape level two the repeat measurement is not required. The decision to prescribe antihypertension medications is left to the discretion of the subject's physician.

During Run-in and Prior to randomization: exclusion from DASH and referral to physician. The decision to prescribe antihypertensive medication is left to the discretion of the subject's physician.

After randomization: referral to physician. The decision to prescribe antihypertensive medication is left to the discretion of the subject's physician. However, until medication is started by the physician, the subject is still considered an active DASH subject. To the extent possible without jeopardizing or unduly delaying clinical care, DASH personnel should obtain a complete set of end-of-study measurements. However, if this is not possible, first priority should be given to collecting the five end-of-study blood pressure measurements prior to initiation of antihypertensive medication.

In addition to the above, detailed follow-up of individuals with escape blood pressures needs to be done for all DEV participants, regardless of when they hit escape, and for anyone hitting escape during feeding. This detailed follow-up should include whether they ever saw or talked to their provider and whether they started back on BP meds. For all other individuals hitting escape BPs, staff merely need to document that referral was made.

Comorbid conditions

- At PSV, comorbid conditions, such as insulin-dependent diabetes and renal disease, will lead to exclusion from DASH (see Chapter 4).

DASH Manual of Procedures

- At DEV1 (for subjects on antihypertensive medication at entry), or by the end of SV2 (for subjects not on antihypertensive medication at entry), a DASH clinician will confirm that the Medical Eligibility Questionnaire does not indicate the presence of a comorbid condition that would constitute an exclusion criterion (see Chapter 4 and instructions for Form #9).
- At all DEV visits, a Symptom Check List will be administered. A DASH clinician will review any new or clinically significant symptoms related to untreated hypertension or to study interventions. Further evaluation, treatment, and/or referral will be at the discretion of the DASH clinician.

Laboratory abnormalities

Subjects are informed immediately of any clinically significant laboratory abnormalities, whether or not they constitute an exclusion to DASH. These laboratory data are supplied to the subject and/or her physician for follow-up.

Some DASH laboratory tests are performed in the Central Laboratory in a batch run at the end of each cohort (e.g., fasting lipid panel). Subjects are informed of any clinically significant abnormalities noted on centrally analyzed laboratory tests as soon as these results are available, which is expected to be shortly after that cohort has completed the intervention. The subjects are advised to obtain follow-up with their physician.

Adverse effects of intervention

Throughout run-in and intervention feeding periods, subjects are questioned daily about possible adverse effects of study foods. Particular attention is paid to symptoms of lactose intolerance and to other gastrointestinal symptoms. Severe or potentially clinically significant symptoms are brought to the attention of a DASH clinician. Feeding is terminated if symptoms or signs related to a DASH diet are deemed by the participant or DASH clinician to be intolerable or dangerous. To the extent possible, collect end-of-study measurements, giving first priority to the five end-of-study blood pressures.

Although DASH does not use a formal adverse events form, sites are expected to document the occurrence of any unusual health problems and report these to the coordinating center.

Food safety

DASH participants will be instructed to report any symptoms that may arise from food borne illness. Such reports will trigger the clinical site to investigate whether other participants have experienced similar symptoms, to review the subject's procedures for food storage and preparation at home, to review procedures at the clinical site, and to determine if further action is required. See MOP Chapter 17 for a further discussion of this issue.

28. Participant Close-out and Counseling

Purpose	3
Unblinding	3
Timing and Context of Close-out Activities	3
Preparations for Close-out	4
Counsel on Heart Disease Prevention	4
Heart Disease Risk Reduction--General Guidelines	4
Heart Disease Risk Reduction Through Nutrition	5
Review Blood Pressure Data	5
Post-Study Anonymous Survey	5
Provide a Summary of Local Laboratory Results	6
Notification of Intervention Status	6
Premature Study Termination	6

Summary of Edits

New Changes in Version 2.2

- The chapter has been completely reorganized to reflect the fact that individualized “exit interviews” are not required and that most, if not all, of the activity will take place in a group setting.

New Changes in Version 4.0

- none

New Changes in Version 4.1

- Paragraph added at end of section on *Premature Study Termination* regarding end-of-study measurements.

DASH Manual of Procedures

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 ongoing care. At the conclusion of each feeding wave, study participants receive a summary of their blood pressure measurements and the results of local laboratory tests. They also receive education for heart disease prevention, with an emphasis on nutritional education. Participants who were withdrawn from antihypertensive medications are also advised that they should consult their physicians about resuming their medications. At the conclusion of the full trial, study participants are unblinded to their treatment assignment, receive a record of their individual study blood pressures, 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 may 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 each other. 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.

DASH participants are kept blinded to their intervention group status and individual blood pressure measurements until the end of the study. Members of the kitchen staff should not provide blood pressure results because they are already unblinded to treatment status.

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 events are scheduled after all feeding has ceased for the cohort so that a complete record of blood pressure and other clinical measurements is available for the participants. While the structure and content of these close-out activities is left largely up to the individual sites, the following must occur:

- counsel on heart disease prevention
- provide a summary of blood pressure results
- distribute and have participants complete the Post-Study Anonymous Survey
- provide a summary of local laboratory results

The counseling should be conducted by someone qualified to provide counseling on heart disease prevention (e.g., nurse, health educator, etc.). However, only staff who are blinded to treatment assignment may disclose the aggregate blood pressure data.

DASH Manual of Procedures

Preparations for Close-out

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

- handouts on heart disease prevention and general nutrition
- a copy of the Exit Interview Report, generated by the file server
- the Post-Study Anonymous Survey (form #42x)
- the participant's study chart
- a copy of the SV2 eligibility lab results

Prior to the close-out visit(s), request an "Exit Interview Report" from the file server. This includes the participant's name, date of birth, sex, and study ID, as well as the average of all blood pressure measurements (SBP and DBP) taken since SV1. The report will also include the participant's height, SV2 weight, and body mass index.

Counsel on Heart Disease Prevention

At the completion of each of the DASH cohorts, all participants are offered health and nutrition education on reducing cardiovascular disease risk in thanks for their participation in the study. The purpose of the session is to give participants knowledge of the risk factors for cardiovascular disease and on how to follow a healthy diet for its prevention.

The education will take place either in a group session or, when necessary, in an individual visit. Although attendance at this group session is not mandatory, staff should make every effort to get participants to attend.

The format and educational content of this session is left to the discretion of each clinical center. The general outline should include information on cardiovascular risk reduction and nutrition. The dietary recommendations for cardiovascular risk reduction should follow current guidelines and will not specifically stress DASH-related topics. Participants should not be told their dietary assignment during the session. General topic areas to be covered are listed below.

Heart Disease Risk Reduction--General Guidelines

- have blood pressure measured regularly
- have blood cholesterol measured regularly
- do not smoke
- increase physical activity

DASH Manual of Procedures

Heart Disease Risk Reduction Through Nutrition

- healthy eating patterns (to include fruits and vegetables)
- lower total dietary fat and saturated fat
- weight control and reduction
- lower sodium intake
- how to read food labels (to identify foods high in fat and salt)
- lower alcohol consumption

Review Blood Pressure Data

All participants receive a summary of their study blood pressures. This is included on the Exit Interview Report. A blinded study clinician should have reviewed the data in advance and made notes about the significance of any measurements. Explain to the participant that he may keep these results and may want to share them with his doctor. (DEV participants are told that they should share this information with their doctor.)

The blood pressure data may be distributed either as part of the group counseling session or as part of an individual exit interview. In the former case the information must be distributed in a confidential manner, and participants must be given the opportunity to ask for individual, confidential advice.

Post-Study Anonymous Survey

All subjects should be given a copy of the Post-Study Anonymous Survey to complete. Explain the importance of having accurate data on participant compliance with the feeding requirements of the trial and note the limitations of the methods we used to assess compliance (e.g., some people may be embarrassed to admit in the daily diary that they didn't follow the diet.) Ask the participant to complete the questionnaire, noting that it is totally anonymous and cannot be linked to any specific participant. Each field center will receive only a summary of the results.

Give participants the questionnaire and a stamped, pre-addressed envelope to the Coordinating Center. Encourage them to complete the questionnaire at the clinic, place and seal it in the envelope, and deposit the envelope in a specially marked drop box as they leave.

In order to be able to link results to specific sites, the form number of the survey is site-specific (i.e., 42x, where x is the site number; 1=JHU, 2=Penn, 3=B&W, 4=Duke). Check that you have the proper form number on your site's forms and notify the Coordinating Center if this is not the case.

DASH Manual of Procedures

Provide a Summary of Local Laboratory Results

Clinics should provide participants with a summary of their local laboratory results from SV2 if they have not already done so. Clinically significant findings should be noted and the participant given an appropriate referral.

Notification of Intervention Status

At the conclusion of the study, the clinical centers should send each participant a letter describing his intervention diet, summarizing the results of the study, and thanking him for his contribution. The letter should include a generalized description of the diet in lay terms. Participants should also receive a listing of their individualized blood pressures at this time.

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, DASH 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.

29. Ambulatory Blood Pressure Monitoring

Introduction	3
Advance Notification of the Participant	3
Programming/"Initializing" the BP Monitor	3
Placement of the BP Monitor on the Participant	4
Reading/ "Down-Loading" the Monitor	5
To Read the Monitor:	5
Procedure for uploading ABPM data to the file server in Windows	6
Procedure for uploading ABPM data to the file server in DOS	7
ABPM Training and Certification of Clinical Center Trainers	7
Training and Certification of staff at individual centers:	8
Certification Criteria	8
Re-certification criteria	8

Summary of Edits

Changes in Version 1.0

- Draft of a new chapter.

Changes in Version 1.1

- Programming/initializing the BP Monitor - instructions added about placing participants name on monitor and carrying case.
- Other minor edits.

Changes In Version 4.0

- none

Changes in Version 4.1

- Changed “automated to “ambulatory” in “ABPM.”
- Added section on Training and Certification, including ABPM Certification Written Test and Certification form for ABPM placement.
- Other minor edits

DASH Manual of Operations

Introduction

Twenty-four-hour Ambulatory Blood Pressure Monitoring (ABPM) will be performed at the end of run-in and at the end of intervention. This procedure should be performed during the same time period when we are measuring RZ blood pressures, i.e., the last 13 days each of run-in and intervention.

Advance Notification of the Participant

Inform the participants one or two days in advance that 24-hour ABPM will be measured and that this visit will take 10-15 minutes longer than a normal blood pressure check. Ask the participant to wear a short-sleeved shirt or blouse, or a garment with loose sleeves, to accommodate placement of the cuff.

Programming/"Initializing" the BP Monitor

The DASH procedure for programming the monitor to take automatic blood pressure readings is as follows:

1. Insert fresh batteries into the monitor (if new batteries were not inserted at the end of last session).
2. Log in to your computer and call the ABPM program <ABPPCI>.
3. Turn on monitor.
4. Be sure the ABPM cable is attached to the appropriate port on the computer and to the monitor (arrow toward arrow).
5. From the "Main Menu," choose "1. ABP Communications."
6. From the "Communications Menu," choose "1. Initialize ABP Monitor."
7. Accept the default settings at the top of page one and move cursor to the "Patient Name" field (See Table 1).

TABLE 1

ABP DEFAULT SETTINGS

Monitor Initialization Default Settings
 Display Active on Monitor (Y/N) : N
 Number of Cycle Periods (1 - 12) : 2

Period	Starting Hour	Ending Hour	Cycle Time	Tone (Y/N)
1	0	6	30	N
2	6	0	30	Y

8. If you know who will be wearing the monitor, enter the subject’s full DASH ID. In the “Patient ID Number” field, enter the five numbers of the DASH identifier (for example, if the full DASH identifier is SVELA12345, enter 12345). If you are initializing the monitor for future use (i.e. don’t know the name of the subjects), enter 9999 both in the “name” field and in the “ID number” field. You must then enter the correct DASH ID and number when you download later.
9. Hit the “end” key to start the initialization process. Disconnect monitor from cable, turn it off, and place monitor in its padded carrying case.
10. Fill out the top section of the **DASH ABPM Initialization/Downloading Checklist (form #68)**. The day before placing ABPMs on participants, put a patient ID label on each monitor and a patient name label on the padded carrying case. This will ensure that the correct ID is used when data are downloaded.

Placement of the BP Monitor on the Participant

The DASH clinician will take two RZ readings as per the usual DASH protocol and record these on the usual BP data form and also on the **DASH ABPM Placement Form (form #64)**. While the subject is still seated, place the ABPM blood pressure cuff on the participant's non-dominant arm (e.g., on the left arm if the subject is right handed). Use the same cuff size as used for standard RZ readings. Record which arm you used on the **ABPM Placement Form**. Be sure that the cuff is set-up to be used on the arm where you are placing it. If not, reverse the orientation of the bladder inside the cuff before placing it. Position the cuff with the arrow directly overlying the brachial artery. Place an “X” over the participant’s brachial artery so they know where the arrow should point. Keep the lower edge of the cuff (toward the elbow) at least one inch above the antecubital fossa. Pull the self-tightening cuff so that it is snug but not uncomfortable. As you are doing this, show the patient how to orient the arrow on the cuff and how to loosen and tighten the cuff.

DASH Manual of Operations

Next, allow the subject to remove the cuff altogether and replace it. Once it has been correctly replaced, connect the tubing of the cuff to the ABP monitor itself. Turn the monitor on and initiate a BP reading by pressing the blue button on the top of the monitor and hold the button down for 5 seconds. The monitor display will show a numerical countdown sequence and begin to inflate. After the monitor has deflated and the reading is completed, check the systolic, diastolic, and pulse rate values on the monitor display. Record these values on **DASH ABPM Placement Form**.

IMPORTANT: Record the time that the ABP monitoring was initiated. Wait 30 seconds and take another blood pressure by pressing the blue start button and record these values as well. If these two blood pressure readings do not indicate an “error” signal on the display, the unit has been successfully placed. Manually abort the next three readings by pressing the blue button once to start and once to stop (do this three times). This is done to prevent the participant from seeing their BP (the monitor displays BP for the first five readings only).

Give the subject the **Instructions to Participants (form #65)**. Review these instructions verbally. The subject is then ready to leave the clinic. Complete the remaining fields on the **DASH ABPM Placement Form**.

Reading/ “Down-Loading” the Monitor

When the subject returns to the clinic the day after the monitor has been placed, the monitor can be removed if it has been worn for a full 24 hours (check ABPM Placement Form for time placed). If not, ask the subject to wait a short time until a 24-hour recording has been obtained (if possible). You may then remove the cuff from the subject's arm and take the cuff and monitor to the ABPM computer. Ask the participant to complete the **DASH ABPM Participant Questionnaire (form #66)**. Enter the participant's DASH ID number on the top of the form.

To Read the Monitor:

1. Turn on the computer, log into the SpaceLabs software <ABPPCI>, connect the monitor via the cable (the monitor is still “on”), and select “1. ABP Communications” from the Main Menu and then “2. Read ABP Monitor” from the Function Menu.
2. The screen will display the subject's DASH ID and identification number (this may be 9999 if that's how the monitor was initialized). Hit any key.
3. The next screen requests a File Name. Enter the five numbers of the subject's DASH identifier--followed by “R” if this is a run-in reading or “I” if during intervention. Add a “1” or “2” after the R or I, indicating whether this reading was the first attempt or a repeat of an unsuccessful attempt. Then hit <RETURN>.

DASH Manual of Operations

Example: The File Name assigned to subject # 12345 for his end-of-run-in ABPM recording would be 12345R1.

4. The next screen asks for the subject's name and ID number. Enter the participant's DASH ID in the name field and then the five numbers of the DASH ID into the ID field. We typically will not be entering anything in the COMMENTS field except ABPM monitor ID. Hit the <END> key.
5. The next screen displays the BP readings. Count to be sure there are at least 14 acceptable readings between 6:00 AM and 12:00 midnight. If so, the monitoring is acceptable. If fewer than 14, the subject should be asked to repeat the monitoring.
6. Complete the center section of the **DASH ABPM Initialize /Downloading Checklist (Form 68)**. Hit <END>.
7. The next screen asks for a name for the report file. If you don't want to print out a formal report now, hit <ESCAPE> key (this returns you to "Communications Menu") and either exit the program or change the batteries in the monitor and re-initialize it for the next subject. If you do want to print a report now, enter the subject's five number DASH identifier followed by R (if run-in) or I (if intervention) plus 1 or 2, then follow instructions for generating a report or hit return. Even if you do not generate a report now, you can always come back and do it later via "3. Report Generator" on the Main Menu.
8. To initialize the monitor for the next subject, hit <ESCAPE> key to return to the Communications Menu.

Procedure for uploading ABPM data to the file server in Windows

1. Copy individual ABPM files from the PC your site is using for ABPM processing to a floppy disk.
2. Take floppy disk to file server and insert it into the file server floppy drive.
3. Double click with the mouse on the floppy drive icon (this will be icon A or B depending on the size of your floppy disk). This will display the files you have stored on the floppy drive.
4. Double click on the C drive icon. This will display the directory structure of the C drive.
5. Select the C:\DASH\ABPM subdirectory.
6. Select with the mouse the files on the floppy disk as shown in the floppy disk display you wish to transfer to C:\DASH\ABPM by clicking once with the left mouse button

DASH Manual of Operations

on the first file you wish to select and then once with the right mouse button for each additional file you wish to select.

7. Using the mouse, move the cursor into the highlighted area on the floppy drive display, push down the left mouse button and do not release it, move the cursor into the C drive display and release the mouse button. The computer will display a confirmation box asking if you really wish to copy these files to C:\DASH\ABPM. If you really do want to do this, select yes, if not, select no.
8. Remove floppy disk from the file server floppy drive.

Procedure for uploading ABPM data to the file server in DOS

1. Place floppy disk containing ABPM data into floppy drive.
2. Access the ABPM subdirectory by typing ***CD c:\DASH\ABPM***
3. At the c:\DASH\ABPM prompt, type ***copy a:*.mon/v*** if floppy is in drive A. If floppy is in drive B, type ***copy b:*.mon/v***.

ABPM Training and Certification of Clinical Center Trainers

Ambulatory blood pressure monitoring (ABPM) provides objective measurement of blood pressures for a specified period of time (e.g., 24 hours), and eliminates observer bias. However, in order to obtain accurate ABPM readings, placement must be done in a correct and consistent manner. Therefore, all staff responsible for placing ABP monitors must be trained and certified in proper ABPM placement procedures.

Each center must have an observer/trainer for ABPM who will be responsible for ensuring certification of staff involved in ABPM placement. Each ABPM trainer will be re-certified centrally at the annual training session.

Before training and certification (or recertification), trainees should read the MOP Chapter on ABPM (Chapter 29).

The DASH study trainer will certify and re-certify all *site* observer/trainers. This trainer will review 1) proper equipment use, 2) use of SpaceLabs software for uploading and downloading monitors, and 3) DASH study criteria. He/she will demonstrate ABPM placement, illustrating exactly what needs to be done and which DASH forms need to be used. The leader will observe each sites' observer/trainer place two monitors on subjects and will observe their adherence to the DASH protocol. In addition, all of the sites' observer/trainers must correctly download the monitors and create appropriate computer files (according to the DASH protocol). Finally, the trainees will be required to successfully complete the written exam.

DASH Manual of Operations

Training and Certification of staff at individual centers:

Once certified, site trainers may certify staff at their individual sites using the same criteria required for their certification. The trainers will need to review the following with their site's staff.

1. Proper equipment use.
2. Demonstrating proper ABPM placement procedures.
3. Uploading and downloading monitors using SpaceLabs computer software.
4. Transferring completed data to fileserver.
5. Determining a successful ABPM session based on DASH criteria.
6. Creating appropriate transfer file.

Certification Criteria

The trainees will need to successfully complete the following to be certified:

1. Pass a written test, which includes review of ABPM data on the SpaceLabs computer software to ensure that trainee can appropriately assess whether specified ABPM measurements meet DASH criteria.
2. Observed placement of ABPM device on two patients. Observer should make sure that trainee uses each ABPM form appropriately and follows all steps outlines in the MOP chapter on ABPM. Also, the trainee must correctly download monitor's data to the desktop P.C.
3. Wear an ABPM successfully for a 24-hour period (optional, but highly desirable).

All staff will need to be re-certified every 6 months. The completed certification form must be sent or faxed to the Coordinating Center (Attn: Pierre La Chance) for review. Each site must maintain records on who is certified for ABPM placement, and the date they were certified. The Coordinating Center will also keep records on certification.

Re-certification criteria

1. Pass the written test
2. Placement of 6 ABPM in last 6 months according to the DASH ABPM protocol.
3. Observed placement of one monitor per DASH protocol.

DASH Manual of Operations

ABPM CERTIFICATION WRITTEN TEST

Name: _____ Date: _____

ID#: _____ Center: _____

1. On which arm should the ABPM be placed? R L Non-dominant

2. As part of DASH criteria, you should record two ABPM readings on the Placement form. How many readings should you then abort before the patient leaves the office?
 - A. 3
 - B. 5
 - C. 2
 - D. You don't need to abort readings

Why would you need to abort any readings? _____

3. How often will the monitor take a reading?
 - A. Every 20 minutes
 - B. Every 30 minutes
 - C. Every 60 minutes
 - D. Depends on time of day

4. Please explain why it is important for a patient to have his/her arm relaxed, straight, and motionless during an ABP reading.

5. If a patient calls and says there is an error reading, what would you advise them to check?

DASH Manual of Operations

6. For a reading to be successful for the DASH study, how many blood pressure measurements must be recorded?
- A. 12
 - B. 14
 - C. 16
 - D. 24

During which hours should there be this many readings?

- A. 6 AM to 6AM
 - B. Midnight to Midnight
 - C. Midnight to 6 AM
 - D. 6 AM to Midnight
7. What size cuff should be placed on patients for ABPM?
- A. Follow the SpaceLabs guidelines
 - B. The same size used for that patient for manual readings
 - C. Whatever fits around the arm best
8. How often do I need to replace the 4 AAA batteries in the monitor?
- A. Batteries can be re-used once (every two patients)
 - B. Batteries must be replaced for each 24-hour reading
 - C. The batteries last indefinitely
9. After subject smija12345 has repeated his run-in ABPM (the first one was inadequate), and you are storing his ABP data in the computer, what file name do you use?
- A. 12345F2
 - B. 12345R1
 - C. 12345R2
 - D. 12345I2

10. After having worn the monitor yourself, what point do you find most helpful to tell study participants?

DASH Manual of Operations

CERTIFICATION FORM

ABPM Placement

Name of person begin certified: _____ Date _____

Name of Reviewer: _____

I. WEAR ABPM FOR 24 HOURS _____ (check if done)

II. CHECK EXISTING ABP FILES FOR COMPLETENESS

Indicate next to the file names below if the ABPM reading was successful:

YOLANDA1 Yes No Explain: _____

MARJIT1 Yes No Explain: _____

YOCHUM1 Yes No Explain: _____

LAURAI Yes No Explain: _____

MARILYN1 Yes No Explain: _____

JONES1 Yes No Explain: _____

SALES1 Yes No Explain: _____

YOLANDT2 Yes No Explain: _____

III. Place devices on two participants. Initialize, place, and download. Complete the required forms and attach to this form.

Names of files for ABP Monitors placed:

_____ Reviewer Comments: _____

_____ Reviewer Comments: _____