MONICA Manual, Part III: Population Survey

Section 1: Population Survey Data Component

December 1997

This section provides the equivalent of a manual of operations for the collection and processing of data for this MONICA data component.

Contents

- Introduction
- <u>1.Sample selection procedures</u> (including sample size requirements)
 - 1.1 Sample size
 - 1.2 Sample selection
 - 1.3 Frequency of screening
- 2.Survey serial numbers
 - 2.1 Survey serial number inventory
- 3. Eligibility for the sample, respondents and non-respondents
- <u>4.Procedures for respondents</u>
 - 4.1 Smoking history
 - 4.2 Blood pressure and arm circumference measurement
 - 4.3 Serum cholesterol
 - 4.4 Serum thiocyanate
 - 4.5 Expired air carbon monoxide measurement
 - 4.6 Height, weight, waist and hip measurement
 - 4.7 Core data transfer form and instructions
 - 4.8 Quality assurance procedures
 - 4.9 Error correction
- 5.Procedures for non-respondents
- References

Forms

- Smoking questionnaire
- · Survey serial number inventory format
 - Current version (Version 3)
 - Former version (Version 2) used for data transfer to the MONICA Data Centre
- Survey core data transfer format
 - Current version (Version 7)
 - Former versions (Version 3 and Version 6) used for transfer of data to the MONICA Data Centre
- · Non-respondent data transfer format
 - Current version (Version 3)
 - Former version (Version 2) used for data transfer to the MONICA Data Centre
- © Copyright World Health Organization (WHO) 1998. All rights reserved.
 - Copyright notice
 - Manual acknowledgements
 - Document identification:
 - WHO MONICA Project e-publications (ISSN 2242-1246), No. 1.2
 - URL:http://www.thl.fi/publications/monica/manual/part3/iii-1.htm
 - URN:NBN:fi-fe19981151

Queries and comments on this section to be addressed to:

Professor Alun Evans
Division of Epidemiology
The Queen's University of Belfast
Mulhouse Building
Grosvenor Road
Belfast, Northern Ireland BT12 6BJ

Fax + 44 1232 236 298 Email: a.evans@gub.ac.uk

Earlier versions

- Proposal for the multinational monitoring of trends and determinants in cardiovascular disease and protocol (MONICA Project). WHO/MNC/82.1 Rev.1; May 1983.
- Multinational monitoring of trends and determinants in cardiovascular diseases MONICA Project. Manual of operations. WHO/MNC/82.2, Draft MOO; November 1983.
- Description of data collection procedures for the MONICA Project. MONICA Memo 49; June 1985.
- WHO MONICA Project. MONICA Manual. CVD/MNC/Version 1.1, December 1986; Sect. 3.
- WHO MONICA Project. MONICA Manual. Geneva: World Health Organization, Cardiovascular Diseases Unit; November 1990; Part III, Sect. 1.
- Revision of MONICA Manual, Part III, Sect. 1, March 1992. MONICA Memo 214; May 1992.

Changes made after March 1992 revision

- · Misprints corrected
- Instructions for blood pressure measurement (Subsection 4.2) rewritten. The old instructions were difficult to follow. The current instructions correspond to the procedures taught in MONICA training seminars for risk factor measurement
- An inconsistency between Subsections 4.6 and 4.8 in checking of scales used for measurement of weight has been corrected.

Introduction

The population survey data, collected on separate random samples, on at least two different occasions during the tenyear period of the MONICA Project, will provide estimates of the levels and changes of known cardiovascular disease risk factors. The core study is concerned with the three major risk factors: blood cholesterol, blood pressure, and smoking habits, as well as height and weight.

1. Sample selection procedures

(INCLUDING SAMPLE SIZE REQUIREMENTS)

1.1 Sample size

Statistical calculations indicate that 200 subjects are needed in each age and sex group to show the expected changes of risk factor levels, in most situations.

The total sample size should be 1200 or 1600, depending on whether or not the youngest age group (optional) is included or not.

Age	Males	Females
25-34	200	200
35-44	200	200
45-54	200	200
55-64	200	200
Total	800 (or 600)	800 (or 600)

Grand total: 1600 (or 1200)

Such estimates assume 100% participation which is usually unrealistic. Therefore, each centre must estimate the expected participation on the basis of previous experience and/or of a pilot study and enlarge the sample size accordingly. It must be stated that every effort should be expended on achieving as high a response rate as possible and therefore it is preferable to select fewer subjects and see as many of them as possible, rather than drawing a larger sample and screening a smaller proportion of subjects. The following points are also important:

- a. in general, within the specified age groups, a lower participation rate may be expected in younger people, and in men as compared with women;
- b. the self selection resulting from low participation rates may introduce biases in the estimation of means and rates, and their trends.

1.2 Sample selection

For sample selection each of the following points should be taken into account:

- 1. Samples for the different surveys must be independent. This means that the sample for the second or the third survey should be selected irrespective of whether or not individuals were included in previous surveys.
- 2. Within an age/sex group, simple random sampling, or systematic random sampling if the ordering of the sampling frame can be regarded as random, is preferred. In practice, simple random sampling may pose serious organizational problems. Multistage sampling (where first a set of clusters is selected and then individuals are selected within the clusters) or some other complex sampling is often easier for logistic or organizational purposes. Such a sampling technique can be used, but the number of individuals selected should be increased. When multistage sampling or some other complicated sampling technique is used, the final method must be reviewed by the statistician at the MONICA Data Centre (MDC).
- 3. The sampling frame and the sample selection procedure used, corresponding to point 2 above, must be documented in detail. The document must be included in the local manual of operations and a copy must be sent to the MDC.
- 4. Great care must be taken when planning, not to use a sampling scheme for the 2nd and the 3rd survey which differs from that for the previous surveys. Such a situation should be avoided, but if it is unavoidable, the planned change should be discussed with the statistician of the MDC.

1.3 Frequency of screening

Since a ten-year collection of mortality and morbidity data is required, it is recommended that screening occurs at the beginning (year 1), at the middle (year 5) and at the end (year 10). However, if the entry screening cannot take place at year 1 because the centre is unable to start screening and monitoring at the same time, the screening can be carried out at years 2 and 3; then at years 5 and 6; and then at years 8 and 9. The middle survey is optional.

Two years are indicated each time as the screening of 1600 or more people may involve field work lasting longer than a 12-month period. In any case the subsequent screening should cover the same seasons of the year as they did previously.

2. Survey serial numbers

Every individual selected in a sample must be issued a Survey Serial Number by the MCC. The serial number consists of six digits. Each serial number must be unique within each MONICA Reporting Unit and within each of the two or three surveys. Different MONICA Reporting Units may use the same serial numbers.

Log books of serial number histories: The MCC must keep a log book of the history of every serial number issued. The items of the SURVEY SERIAL NUMBER INVENTORY FORM should be included in the log book. The log book can be part of the checklist.

Correctness of the serial number: The serial number is one of the key items of a survey record. The Form Identification, MONICA Collaborating Centre Code, MONICA Reporting Unit Code, Number of the Population Survey and Serial Number are all necessary in order to identify an individual uniquely. Each MCC should have some kind of security system to help ensure that the serial number is error free. One possibility is to have the last digit of the serial number as a check digit which is used to control the correctness of the other digits, at least until the individual record has been computerized.

A check digit needs to be calculated when the serial number is issued. It is useful only if this is done correctly. This can be guaranteed by letting the computer generate the serial numbers with the check digits and print the numbers on stickers or labels which are then fixed on log books and data collection forms.

2.1 Survey serial number inventory

As a final check that no data have been lost during the various stages of data flow between the sample selection and inclusion of data in the master file of the MDC, the MCC should submit the *serial number inventory data* to the MDC. The data should be submitted for each individual selected in the original sample in the Survey Serial Number Inventory Format.

3. Eligibility for the sample, respondents and non-respondents

For data collection purposes, those selected for the original sample will fit into one of three categories: ineligibles, respondents and non-respondents. Every individual selected for the original sample belongs to only one of these three categories.

Ineligibles

In principle, the sample should be selected from the 25-64 (25-34 optional) year old residents of the MONICA Reporting Units. In practice, such sample selection is not usually possible because the sampling frame is not fully updated at the time of the sample selection. The individuals selected in the original sample who died or moved out of the reporting unit area before the survey examination are called ineligibles. No survey examination should be done on the ineligibles, and no survey respondent or non-respondent data should be collected for them.

Note, however, that if a person selected for the age group 25-64 (25-34 optional) of the original sample does not meet the age criteria on the day of examination because it was not possible to assess the exact date of survey examination at the time when the sample was selected, the person should be regarded as eligible for the sample.

The MCC should document the reason for ineligibility for every ineligible.

Respondents and non-respondents

It is important to try to get the full survey core data from as many persons selected and eligible for the sample as possible. Each MCC should develop an algorithm to decide for each subject when sufficient attempts have been made. After the result of the attempts are known, the persons should be classified as respondents and non-respondents according to the following definition:

A non-respondent is a person selected and eligible in the original sample who could not be found or contacted, or a person who did not provide questionnaire data at the clinic or during a home visit.

Those eligible for the sample who are not non-respondents are classified as respondents.

The data requirements will be considered separately for respondents and non-respondents.

4. Procedures for respondents

4.1 Smoking history

<u>The smoking questionnaire</u> appended to this section is part of the general questionnaire and was produced in its near final form by the October 1981 Geneva Working Group.

It represents a compromise among different proposals and is derived from the WHO Cardiovascular Survey Methods questionnaire [1]. It can be self administered if it is sent to the home of the invited persons together with the invitation to the examination; or it can be administered by a technician or nurse at the screening site.

The same procedure, however, should be applied throughout the study in the same centre.

In the case of self-administered procedures, the questionnaire should be checked by a technician or a nurse for completeness and consistency of answers.

In the case of direct administration, some general rules should be followed:

- use the same wording as written in the questionnaire;
- ask the questions a second time and in the same way if on the first occasion the subject does not answer or appears not to have understood;

- ask the questions a third time using different wording but having the same meaning if the subject again does not answer or understand;
- · do not induce certain answers;
- ask all questions and record all answers, unless otherwise stated.

Interviewers should be trained and their performance evaluated and tested for precision and accuracy.

The smoking questionnaire should be validated by expired air carbon monoxide, serum cotinine or serum thiocyanate measurement on 100% of subjects. While serum thiocyanate estimation remains an option it is no longer part of the core study and the quality control procedures have been withdrawn. Carbon monoxide measurement is cheap, gives an instant readout, has a comparatively short half-life, shows diurnal variation in smokers and is confounded to some extent by environment or an occupational exposure to carbon monoxide [2]. Cotinine is very specific, sensitive but expensive [3]. Measurement only in sub-samples should be avoided if possible, but the minimum requirement in such an event is 10% of subjects, irrespective of their smoking history. Instructions for carbon monoxide measurement are given in subsection 4.5. Standardization of serum thiocyanate measurements is described in Part III, Section 3.

4.2 Blood pressure and arm circumference measurement

It is important that measurement of blood pressure BP) is as precise as possible. This is essential for valid comparisons to be drawn. Therefore a strict routine for BP measurement should be adhered to. The measurement should be planned to precede any painful or anxiety producing procedures such as blood taking or electrocardiography; ideally it should follow the administration or checking of the questionnaire.

- 1. The subject should be instructed to avoid the following activities for at least one hour before the BP measurement: strenuous exercise, eating, drinking of anything other than water, smoking, drugs that affect the blood pressure; a full bladder affects the blood pressure and patients should be advised accordingly. Most MONICA surveys are done with the subject non-fasting; taking blood pressure in patients who have fasted for a long time for blood lipid estimations will result in poor comparability with other survey populations.
- 2. The participant should have removed outer garments, jackets, etc. The sleeve of shirts, blouses, etc. should be rolled up so that the upper right arm is bare for the blood pressure cuff. The garment should not be constrictive and the blood pressure cuff should not be over the garment. Garments must be removed if obstructing and a short-sleeved jacket provided.
- 3. The examination should take place in a quiet room with comfortable temperature. The room temperature should be recorded routinely.
- 4. The recommended instrument is the random-zero sphygmomanometer, although a standard mercury sphygmomanometer is admissible. In any case Centres should adhere to the instrument used in earlier surveys. It is now generally accepted that the key to good blood pressure measurement in MONICA is in training, certification of the measurers, constant monitoring of performance and feedback.
- 5. The cuff size (bladder-size) should be 12-13 cm wide and sufficiently long (recommended length: width-ratio >2:1) to surround at least two thirds of the upper arm. The centre of the inflatable part of the cuff (bladder) must be positioned over the brachial artery of the inner side of the upper arm. The cuff should neither be applied too loosely or too tightly in order to avoid over or under estimation of the pressure required to obliterate the artery.

NOTE: The MCC should not change the size(s) of a cuff used for blood pressure measurement between the surveys. If several cuff sizes are used, the rule for using each should also be kept unchanged and the information recorded.

- 6. The BP should be measured after resting with no change of position for at least 5 minutes, in a sitting position and using the right arm unless there is a deformity. When seated the subject's arm should be allowed to rest on a desk so that the antecubital fossa is level with the heart. To achieve this either the chair should be adjusted, or the arm may be raised or lowered on a comfortable support. The subject must always be in an upright position and feel comfortable.
- 7. Measure the upper arm circumference with a tape, and record the value, rounded to the nearest centimetre. The upper arm circumference is measured with the arm in the normal blood pressure measurement position, i.e. forearm resting on the table and the antecubital fossa at the level of the heart. Read the measurement tape at the greatest circumference of the upper arm with the arm relaxed.
- 8. It is recommended that the bell of the stethoscope should be used, even if the diaphragm was used in earlier surveys. The lower edge of the cuff should be 2-3 cm. above the cubital fossa, to allow sufficient room for the bell of the stethoscope. The top edge of the cuff should not be restricted by clothing.
- 9. The observer should be in a comfortable position in relation to the examination table. The sphygmomanometer's mercury column should be in a perfectly upright position, the centre of it at the eye level of the examiner. The mercury column should face the observer and should not be visible to the subject.

The cuff should now be connected to the sphygmomanometer.

10. A. Blood Pressure Measurements with the Random Zero Sphygmomanometer

- i. The subject should rest for 5 minutes in a sitting position during which the whole process of BP measurement should be explained to him/her. If the subject is spoken to during the period of resting before the measurement, the staff involved should speak quietly and calmly. The subject should not be involved in animated conversation, joking or teasing as this will give a high blood pressure reading.
- ii. Locate the brachial pulse. The bell of the stethoscope should be placed immediately below the cuff at the point of maximal pulsation. If it is not possible to feel the brachial pulse, the bell of the stethoscope should be placed over the area of the upper arm immediately inside the biceps muscle tendon. The bell should not touch the cuff, rubber or clothing.
- iii. Ensure that the mercury reservoir valve is in the operating position, i.e. turned fully to the right and extending past the right side of the case (applies only to older devices). Turn the bellows cock on the face of the device to the position marked OPEN.
- iv. Turn the thumb wheel at the right side of the device, by gently stroking it twice in the same direction with the thumb of the right hand. If the wheel is not free to spin in either direction, the bellows are not completely deflated and the bellows check position should be rechecked.
- v. Before each measurement, the observer has to make sure that the mercury column is precisely at the RZ baseline level.
- vi. Feel the subject's radial pulse with the fingers of your left hand.
- vii. Close the valve of the inflation bulb and the valve at the bottom of the device's case. Looking at the manometer with the centre of the scale at eye level, and the column perfectly upright, inflate the cuff rapidly to a pressure equal to the peak inflation level, that is, 30 mmHg above the level where the radial pulse disappears. Hold the pressure at this level for five seconds (count to five slowly), and then turn the bellows cock to the position marked CLOSE.
- viii. By carefully controlling the valve at the bottom of the device's case, with the bell of the stethoscope over the brachial artery, deflate the cuff at 2 mm/second. Continue to reduce pressure steadily at this rate until the occurrence of the systolic level and the phase 5 diastolic level, i.e. the disappearance of Korotkoff sounds. Continue to deflate until the mercury is 4 to 6 mm below the diastolic level.
 - ix. Then open the inflation bulb valve fully, allowing the mercury to fall to its zero level for this reading.
 - x. Record the systolic and 5th phase diastolic readings, uncorrected.
 - xi. Read the zero level for this reading and record it on the form in the spaces provided beneath the uncorrected systolic and 5th phase diastolic readings. Subtract the zero level to obtain the correct readings and record them on the form.
- xii. Blood pressure values should be recorded to the nearest 2 mmHg (reading from the top of the rounded meniscus). If the top of the meniscus falls half way between two markings, choose the marking immediately above. The subject should not be informed about the blood pressure value at this point.
- xiii. Wait for at least 30 seconds to allow the distribution of the blood in the forearm to return to normal. Furthermore, the arm may be raised for about 5 seconds to reduce venous congestion resulting from reactive hyperaemia. Then repeat the measurement in exactly the same way that the first one was carried out. This includes resetting of the thumb wheel on the right side of the manometer case. Whenever experiencing difficulties in hearing the sounds, the cuff must be completely deflated and at least 30 seconds must elapse before making the next measurement.
- xiv. Record the value of both measurements.

10. B. Blood Pressure Measurement with the Standard Mercury Sphygmomanometer

- i. The subject should rest for 5 minutes in a sitting position during which the whole process of BP measurement should be explained to him/her. If the subject is spoken to during the period of resting before the measurement, the staff involved should speak quietly and calmly. The subject should not be involved in animated conversation, joking or teasing as this will give a high blood pressure reading.
- ii. Locate the brachial pulse. The bell of the stethoscope should be placed immediately below the cuff at the point of maximal pulsation. If it is not possible to feel the brachial pulse, the bell of the stethoscope should be placed over the area of the upper arm immediately inside the biceps muscle tendon. The bell should not touch the cuff, rubber or clothing.
- iii. Feel the subject's radial pulse. Inflate the cuff rapidly until the radial pulse disappears. Inflate the cuff by a further 30 mmHg. This is called the 'peak inflation level' and it is the level to which the pressure should be raised for each of the ensuing blood pressure measurements.
- iv. Wait for at least 30 seconds to allow the distribution of the blood in the forearm to return to normal. Furthermore, the arm may be raised for about 5 seconds to reduce venous congestion resulting from reactive hyperaemia.
- v. Looking at the manometer with the centre of the scale at eye level, and the column perfectly upright, inflate the cuff rapidly to a pressure equal to the peak inflation level. Then let the column of mercury fall at a rate of 2 mmHg per second.

- vi. Continue to reduce pressure steadily at this rate until the occurrence of the systolic level and the phase 5 diastolic level, i.e. the disappearance of Korotkoff sounds. Then deflate the cuff rapidly by fully opening the valve of the inflation bulb.
- vii. Blood pressure values should be recorded to the nearest 2 mmHg (reading from the top of the rounded meniscus). If the top of the meniscus falls half way between two markings, choose the marking immediately above. The subject should not be informed about the blood pressure value at this point.
- viii. Wait for at least 30 seconds to allow redistribution of blood in the forearm. In addition, the arm may be raised for about five seconds to further reduce venous congestion in the forearm resulting from reactive hyperaemia. Then repeat the measurement in exactly the same way that the first one was carried out. Whenever experiencing difficulties in hearing the sounds, the cuff must be completely deflated and at least 30 seconds must elapse before making the next measurement.
- ix. Record the value of both measurements.

NOTE: It may well be that the European Union will ban the use of Mercury sphygmomanometers of all types for health reasons. This will have implications for cardiovascular epidemiology. Therefore, the use of reliable automatic devices which are validated against the reference method of sphygmomanometry may become necessary.

4.3 Serum cholesterol

The procedures for serum cholesterol measurement are given in <u>Part III, Section 2</u>: Standardization of Lipid Measurements.

4.4 Serum thiocyanate (Optional)

The procedures for thiocyanate measurements are given in Part III, Section 3.

4.5 Expired air carbon monoxide measurement (Optional)

Carbon monoxide (CO) is a gas produced by incomplete combustion and is commonly present in the environment as a result of smoking, car exhaust, gas appliances, etc.

Since everybody is exposed to trace amounts of CO as well as producing small amounts by metabolism, it is normal to have a concentration of CO in expired air in the range of 2-8 parts per million (ppm). Individuals who have been exposed to relatively high doses of CO from inhaling cigarette smoke typically have levels in the range of 9-40 ppm.

A portable carbon monoxide monitor should be used [4]. It is a cheap, quick- to-use instrument which runs on batteries. The following instructions are relevant for one such instrument: the Bedfont EC50.

- 1. The monitor is switched on and the observer ensures that the reading is at zero.
- 2. A disposable mouthpiece is attached to the monitor.
- 3. The subject is asked to hold the monitor and an explanation of the procedure is given:
 - a. Breathe out fully
 - b. Breathe in deeply
 - c. Hold breath for 15 seconds
 - d. Blow out fully into the mouthpiece.
- 4. Carry out the procedure.
- 5. Record the reading.
- 6. Repeat the procedure to obtain a second reading.
- 7. Record the average of the two readings.
- 8. The disposable mouthpiece is removed and discarded.

4.6 Height, weight, waist and hip measurement

HEIGHT - Procedure:

- 1. Height is measured in conjunction with the weight measurement. It may precede or follow this procedure.
- 2. The height rule must be taped vertically to a hard flat surface, with no moulding (skirting board), with the base at floor level. A carpenter's level should be used to ensure vertical placement of the rule.

NOTE: The correct position of the height rule should be checked daily and corrected as necessary. If the position of the height rule is found to be inaccurate by more than 1 cm, the measurements taken since the rule was last checked should not be used or reported to the MDC.

- 3. The floor surface must be hard (tile, cement, etc.) and must not be carpeted or be covered with other soft materials. If only a carpeted surface is available, a wooden platform should be laid down to serve as a floor.
- 4. The participant is asked to remove his/her shoes and heavy outer garments.
- 5. To measure height, the participant should stand with his/her back to the height rule. The back of the head, back, buttocks, calves and heels should be touching the upright, feet together. The top of the external auditory meatus (ear canal) should be level with the inferior margin of the bony orbit (cheek bone). The position is aided by asking participant to hold the head in a position where he/she can look straight at a spot, head high, on the opposite wall.
- 6. Place the triangle on the height rule and slide down to the head so that the hair (if present) is pressed flat.
- 7. Record information on survey form to the nearest centimetre. For example, if 187.4, record as 187; if 187.5, record as 188; if 187.6, record as 188.
- 8. Self-reported heights are not acceptable in mobile participants and should not be reported (mark as refusal). Only persons who are immobile (e.g. amputees) may self-report their heights. Be sure to note this on the form.
- 9. To measure extreme heights, a short rule is used in addition. It is placed at the top of the long rule and the extra height is added.

WEIGHT - Procedure

The use of balance scales is recommended. If the MCC uses digital scales, testing with standard weights is of particular importance.

- 1. The floor surface on which the scale rests must be hard and should not be carpeted or covered with other soft material.
- 2. The scale should be balanced with both weights at zero and the balance bar aligned.

NOTE: Check the scales using standard weights at least monthly and whenever the scales are installed at a new location. If the error is more than 1 kg the measurements taken since the scales were last checked should not be used or reported to the MDC. Check for the zero level every day before starting measurement and immediately afterwards. If there is an error of more than 1 kg the measurements taken since the scales were last checked should not be used or reported to the MDC.

- 3. The participant should have removed his/her shoes and heavy outer garments (jacket, coat, etc.).
- 4. The participant should stand in the centre of the platform as standing off-centre may affect measurement.
- 5. The weights are moved until the beam balances (the arrows are aligned).
- 6. The weight is read and recorded on the form. Record weights to the nearest 200 g.
- 7. Self-reported weights are not acceptable in mobile persons. Refusals to be weighed should be recorded as refusals. Only participants who are immobile (e.g. amputees) may self-report their weights. Be sure to note this on the form. Participants must not read the scales themselves.

WAIST CIRCUMFERENCE - Procedures

- 1. Record the measurement of the circumference at a level midway between the lower rib margin and iliac crest in cms to the nearest 0.0 or 0.5 cm. Example: If the exact measurement is 87.7 cm, code the item 0875.
- 2. The circumference should preferably be measured on subjects while they are semi-clothed, i.e. waist uncovered with the subjects wearing underclothes only. If it is not possible to follow this procedure in the MCC, the alternative is to measure the circumference on subjects without heavy outer garments with all tight clothing, including the belt, loosened and with the pockets emptied.
- 3. Participants should stand with their feet fairly close together (about 12- 15 cm) with their weight equally distributed on each leg. Participants should be asked to breathe normally and at the time of the reading of the measurement asked to breath out gently. This will prevent subjects from contracting their muscles or from holding their breath.
- 4. A plastic metric tape should be used. The tape should be held firmly and its horizontal position should be ensured. It is recommended that the observer sits beside the participant while the readings are taken. The tape should be loose enough to allow the recorder to place one finger between the tape and the subject's body. The importance of the tightness of the tape should be emphasized in training.
- 5. The length of tape should be checked before starting the survey and the length should be rechecked against a standard measure at least once a month and replaced as appropriate.
- 6. The two sides of the tape should be differently coloured or have a scale only on one side. If the tape is uniformly coloured, with readings on both sides, one side should be blanked out.
- 7. MCCs which have collected these data in the past, but using a different technique, should not change their technique but should contact the MDC.

HIP CIRCUMFERENCE - Procedures

- 1. Record measurement of maximum circumference over the buttocks in cms to the nearest 0.0 or 0.5 cm. Example: if the exact measurement is 93.2 cm, code the item 0930.
- 2. The same general comments made for waist circumference measurement apply to the measurement of hip circumference.
- 3. MCCs which have collected hip circumferences in the past, but using a different technique, should not change their technique but should contact the MDC.

4.7 Core data transfer format and instructions

The survey core data to be sent to the MDC are specified in the <u>Core Data Transfer Format - Survey Data</u>, which is appended to this section.

4.8 Quality assurance procedures

Training and certification

It is clear that the survey procedures used at the two or three different points in time within a centre must be comparable so that the trends identified reflect actual changes in measurements between the samples and not changes in the data collection or measurement procedures. The general principles described in Cardiovascular Survey Methods 1982 [1] should be followed.

The reproducibility of the survey methods can be tested in pilot studies and at intervals throughout the main study. Every effort should be made to maximize the participation of individuals selected for the survey.

It is necessary to pay attention to the sequence of various measurements in the surveys. For instance, blood pressure should always be measured before venipuncture. Furthermore, the sequence as well as the measurement techniques must be identical in each survey.

Smoking

The standard set of questions should be used and the results of the questionnaire should be validated by serum thiocyanate, serum cotinine or expired carbon monoxide measurements. The survey personnel should be trained to check the main questions of the self-administered questionnaires concerning smoking habits which are needed for the core study. This checking is aimed at reducing the frequency of missing or inadequate information, and also at detecting incorrect self- reporting by simply asking the main questions again.

Blood pressure

The procedures should be described in the local manuals of the MCCs. This description should include a list of equipment, including cuff sizes. MCCs should send this list to the MDC together with their survey data.

Training is the most vital part of the quality assurance for blood pressure measurement.

The training course should be organized before each survey and it should deal in detail with all the elements involved in BP measurement (see subsection 4.2).

- 1. the principles of Korotkoff sound and their sequence
- 2. the equipment: (a) stethoscope (with bell); (b) sphygmomanometer (type) and its maintenance
- 3. observer: (a) hearing test, (b) digit preference
- 4. the technique of measurement
- 5. sources of error: systematic; random

Practical training:

1. Tape recordings:

Among the existing training programmes, the method developed by RJ Prineas is recommended (the timex can be replaced by 3 stop-watches) [5].

2. Training on subjects:

Measurement with double (Y-tube connected) stethoscopes with each observer operating the bulb in turn. Comparison should be made between observers (interobserver variation between supervisor and observer -systematic error - and between repeated measurements - intraobserver variation). The measurements should be recorded on training sheets and kept for further comparison.

The method of measuring blood pressure can be learned quickly and it is far from being a "doctor's job" only. Paramedical personnel can perform it sometimes more precisely, as they are free from preconceptions. But whoever takes up the task of measuring BP must be trained and tested beforehand.

Within one MCC, in different MONICA populations and different surveys, if more than one observer measures blood pressure, they should be as alike as possible. For example, all of them should be paramedical technicians. (Consider the likelihood that subjects react differently to nurses than to doctors.)

The aim of a training and retraining programme is to develop maximum precision and standard recording. This is necessary to avoid both random and systematic error. *Random error* will occur if an observer *occasionally* neglects the controllable factors during BP measurement. *Systematic error* will arise from actions which *consistently* result in a higher or lower BP reading. Examples: severe hearing loss for low frequency sounds, digit preference, prejudice, i.e. "anticipating a BP", consistently using another technique (left arm, lying position, etc.). Therefore, constant attention should be paid to BP measurement techniques and training. During the practical training, the means of measurement are used for comparison between observers and the supervisor.

If the mean value or range of an observer's measurements differs markedly from those of other observers, further training is necessary. Retraining and retesting of observers should be carried out at regular intervals in order to maintain the validity of BP measurement.

Any observer continually measuring blood pressure should be retested at 6 monthly intervals. Observers with a mean value of measurements differing from other observers should be retested earlier. Observers with consistent systematic errors should not be certified for BP measurement. Each MCC should nominate an investigator to certify and recertify the blood pressure observers. Copies of the certificates should be kept available.

During the surveys the investigators should continuously track the inter and intraobserver variation and the last digit preference in order to detect possible problems.

Serum total and HDL-cholesterol

See Part III, Section 2: Standardization of Lipid Measurements. If plasma cholesterol is measured, the MDC should be notified.

Body weight

The procedures for measuring body weight must be described in detail in the local manuals of the MCCs. Only accurate balance scales should be used. All scales should be checked using standard weights at least monthly and whenever the scales are installed at a new location. The type of scales used in the surveys in each MCC must be described in the local manual.

Also, the weight observers require training, as some observers tend towards a last digit preference in recording body weights; this should be taken into consideration in training.

Local data checking

The MCC should have procedures to ensure that the data collection process is complete and accurate. This can be accomplished by following the procedures listed below.

Processing check list

Keep a check-list to follow the status of data collection for every subject selected in the sample. The contents of the check-list may vary between the MCCs, but should record these items as a minimum:

- Survey Serial Number
- · name and address
- eligibility for the survey

- · that interview data were received
- that medical examination was performed
- that blood samples were received
- · that laboratory results were received
- that data were submitted for keying
- that shipment was made to the MDC.

The check-list may be used to generate the **Survey Serial Number Inventory Form**.

Keying of data forms

Before submitting the forms for keying

- check that all parts of the form (interview, laboratory results, medical examination results etc.) are together.
- check the forms visually for completeness and logical flow.

It is preferable to have all data verified or keyed twice to keep keying errors to a minimum. The method of verification will depend on the MCC's data entry system. Punched cards can be verified and most data entry programs have the ability to double-enter the data. As an alternative, two data files can be independently created and compared.

Check serial numbers

After the data have been keyed and verified, the serial numbers should be checked again by comparing the keyed value with the original form. The use of a check digit is strongly recommended since a computerized check of the serial number can then be performed.

Other checks

Before the data are appended to the local master file, checks and other quality control routines similar to those described in <u>Part V, Section 1.3.3</u> should be performed. Checks for duplicate records, missing values, etc., are particularly important at this stage.

When verifying the accuracy of the data, all suspect data items should be checked against the original documents on which data were collected. Any erroneous values should be corrected. On the other hand, **suspect values which cannot be shown to be erroneous should not be changed**. Instead, such values, even though very unusual, should be submitted to the MDC.

Store the forms for future reference.

4.9 Error correction

The procedure for correcting errors in data which have already been submitted to the MDC are described in <u>Part V</u>, <u>Section 1.3.3</u>.

5. Procedures for non-respondents

Even though it is not possible to get the complete data required for the core study for the non-respondents, the MCC should try to collect information about their age, sex, marital status, education, smoking history and blood pressure. The objective is to estimate the selection bias which non-response inflicts on the core study. Age and sex are often known at the time of the sample selection. For other data, a telephone interview or a postal questionnaire can be tried. It is recommended that all non-respondents are asked to provide the information. However, it is acceptable that only a random sample of non-respondents are investigated in full. The reason for non-response should be recorded in all cases.

The survey non-respondent data (<u>Form 8: Data transfer format, survey non-respondent data</u>) should be submitted to the MONICA Data Centre for every non-respondent, regardless of how much information was received from the non-respondent. In most cases the MCC should at least elicit the age group, sex and reason for non- response.

References

1. Rose GA, Blackburn H, Gillum RF, Prineas RJ. Cardiovascular survey methods (Second Edition). World Health Organization, Monograph Series No. 56, 1982

- 2. Jarvis MJ, Tunstall Pedoe H, Feyerabend C, Vesey C, Saloojee Y. Comparison of tests used to distinguish smokers from non-smokers. Am J Public Health, 1987; 77:1435-8
- 3. Feyerabend C, Russell MAH. A rapid gas-liquid chromatographic method for determination of cotinine and nicotine in biological fluids. J Pharm Pharmcol, 1990; 42:450-2
- 4. Irving JM, Clark EC, Crombie IK, Smith WCS. Evaluation of a portable measure of expired-air carbon monoxide. Prev Med 1988; 17:109-115.
- 5. Prineas RJ. Blood pressure sounds: their measurement and meaning. A training Manual. Gamma Medical Products Corporation, Philadelphia, 1977