



J. HOKURO: Meeting of Investigators

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REPORT OF MEETING OF INVESTIGATORS OF
JOINT HQ/EURO PROJECT ON MULTINATIONAL MONITORING OF TRENDS AND DETERMINANTS
IN CARDIOVASCULAR DISEASES (MONICA PROJECT)

Geneva, 30 November to 3 December 1982

WHODOC 2/2

The meeting was opened by Dr B. Sankaran, Director of the Division of Diagnostic, Therapeutic and Rehabilitative Technology. Professor F. Epstein was elected Chairman and Professor H. Tunstall Pedoe Rapporteur. Dr Pisa reviewed progress. Forty-four centres in 28 countries had expressed interest in the project - 19 in the European region, 1 in the Eastern Mediterranean, 2 in South-East Asia, 4 in the Western Pacific and 2 in the Americas. Twenty-seven had submitted progress reports for the Monica Newsletters. Twelve centres had already written manuals of operation and eight had tested them.

The agenda of the meeting is shown in Annex I and the list of participants in Annex II.

Decisions

The following decisions were adopted by all the participants.

1. Definite and possible nonfatal myocardial infarction: The protocol was amended to state that definite nonfatal myocardial infarction was the primary nonfatal end point and that sources revealing 90-95% of these in a pilot study should be used routinely. Possible nonfatal events were a secondary end point.
2. Manuals of operations should be submitted for approval to Dr M.J. Karvonen, WHO Consultant, CVD Unit, Geneva, as soon as possible. Any revisions of manuals should also be notified as they occur. Manuals should be translated where necessary into English.
3. Timetable: All centres should submit their timetable for action before the end of the year by completing the questionnaire circulated by Dr M.J. Karvonen. Definitive monitoring should begin before 1 January 1984 after pilot studies.
4. Centre size: No centre would be rejected from the project just because the population size was rather small, but this factor would be considered with any others that might make a centre unsuitable. Principal investigators should note that, in populations generating less than 200 fatal coronary events in men per year, it would be difficult to establish trends in event rates with confidence and produce autonomous results of interest to their local funding bodies. The results from small centres could be pooled with others for the collaborative project. Centres could extend age limits above 65 to generate more events but only events occurring in those below 65 would be analysed centrally. Three hundred events per year was probably optimal but it was not a magic number; the alpha and beta, expected change, and method of analysis all had an effect.

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5. Screening sample size: The field studies could be done with 200 subjects in each age/sex group, rather than 400 if certain assumptions were made (see revised protocol - document WHO/MNC/82.1, Annex 1(b)). The middle of the three screening studies was not strictly necessary for the ten-year trend analysis. Centres would need to consider the strategy of concentrating screening resources at the two ends of the study versus the danger of leaving a very long time period between screenings. The middle screening might be needed for other reasons such as monitoring preventive campaigns. A video recording of screening procedures might act as a record for a future occasion.
6. Strokes: These would be covered by 60% of centres and would remain in the core study, although other centres would be permitted to collaborate without monitoring them if this proved impracticable.
7. Smoking questionnaire: The protocol questionnaire was taken from part of that in "Cardiovascular Survey Methods", 1982, but some between-centre variation was apparent in those centres that had started. The results of the Helsinki conference on standardization of smoking questionnaires would be considered and proposals sent out in 3-4 months. It was hoped to recommend a standard means of biochemical validation such as thiocyanate.
8. Lipid workshop: Total cholesterol measurement was obligatory but not high density lipoprotein cholesterol as stated in the report, although all centres measuring the former or both of these must standardize on the WHO Reference Centre in Prague. Although not all centres would comply, 90% would be using enzymatic methods on serum. Because the fasting state was not necessary for the core study and also is difficult to achieve and confirm, a decision on taking fasting or non-fasting samples was left to each centre, but these must keep the procedure consistent from one screening to the next. Time of day was said not to matter but, as it affects most physiological variables, it would be recorded on the record form.
9. ECGs: Budapest would standardize on current Minneapolis practice and would circulate testing ECGs to certify centres and/or coders. Recertification will occur yearly. The first occasion for certification would be in approximately September 1983.
10. Psychosocial: The core screening study should include questions on education and on marital status. A recommendation of routine use of the Bortner and other scales was not accepted as obligatory. The responsibility for further development was delegated to Dr V. Zaitsev, WHO, Copenhagen, and interested centres.
11. Exercise: Further development will be managed by Dr D. Brunner, Tel Aviv.
12. Nutrition: It was recommended that all centres used food frequency records. Dr P. Puska agreed to run a consultation centre on nutrition studies which would be optional.
13. Serum banks: Dr D. Grafnetter would circulate details of how to store deep-frozen serum for future use.
14. Health Services:
 - (a) Medical care in the attack: It was agreed that acute medical care should be monitored but monitoring of all events would not be necessary. Care should be monitored on two occasions at least (obligatory) covering enough cases to give a trend for key items. An additional record should be made without introducing bias into routine recording. A suggested questionnaire was tabled and will be finalized by the Steering Committee.

(b) Medical Services: Attempts should be made to obtain information on:

- (1) doctors, nurses and other services
- (2) hospital admission rates
- (3) beds including CCU and utilization
- (4) coronary artery bypass surgery rates (CABG).

Ideally age specific information should be recorded.

(c) Drug use in the community: National or regional data should be obtained on drugs used and converted into defined daily doses (DDD) as the tables become available.

Data should be produced covering drug usage in DDDs in relation to the target population and the time period. If possible such data should be provided in relation to age groups and sex and reason for prescribing. A list of drugs was tabled and will be finalized by the Steering Committee.

Approaches should be made to national governmental or commercial organizations that have the data, both locally and through the Cardiovascular Diseases Unit, WHO Headquarters.

15. Endpoint Diagnosis: Changes to the protocol and manual of operation (to be finalized by the Steering Committee):

- (a) Recording of new tests
- (b) Number of ECGs to be recorded (0, 1, 2, 3 or more)
- (c) Previous history of AMI

1. Each centre should adopt the most thorough method possible for identifying previous events

2. The method adopted should be reported to the coordinating centre and not be changed for the duration of Monica (unless the change is applied to all events); and

3. The pooling cards should be altered to record the previous history by the following categories:

- Yes, Definite (previous record reviewed and at least one old event meets WHO criteria for "Definite")
- Yes, Possible (previous record reviewed; event meets WHO criteria for "Possible")
- Yes, Documented (known previous hospitalization or diagnosis for MI or stroke but record not reviewed)
- Yes, ECG (ECG with pathologic Q waves (1-1 or 1-2 except 1-2-6))
- Yes, Undocumented (history in current record only)
- No, Documented (search of previous records made)
- No, Undocumented (current record notes no previous history)
- Not recorded.

(d) Minor changes to diagnostic criteria to clarify them.

16. Record linkage: The value of this was stressed but it remained a local option.

17. Steering Committee

The meeting of consultants held in July 1982 on statistics and data analysis had not made as much progress with the study as was hoped; no data analysis centre had yet emerged. The Working Group charged WHO as a matter of urgency with setting up a panel of principal investigators and data analysts who would get to work as a "ghost data centre" in planning details of data format, transmission, quality control checks, etc. A Steering Committee should start planning now and meet early in 1983 sending results of their decisions to the centres.

Accordingly, for these and other reasons, a steering committee was elected with the following constitution:

WHO:	Dr Z. Pisa, Chief, CVD, Geneva Dr M.J. Karvonen, Consultant, CVD, Geneva Dr V. Zaitsev, Regional Officer, CHRD, Copenhagen
Principal investigators:	Dr P. Puska Dr S. Fortmann Dr A. Menotti
Data Centre Chief:	Vacant
Coopted adviser:	Dr R. Prineas
Rapporteur:	Dr H. Tunstall Pedoe

It is planned that the principal investigators will rotate through the committee over a period of time (e.g. one replaced every year).

The committee was charged with the following responsibilities:

1. To meet urgently and carry forward the work of the project
2. To anticipate the functions of the data centre in determining the format of records and of data transmission, making all necessary changes to the protocol and operating manual, which should be finalized soon.
3. To institute measures for quality control that will be managed by the data centre.
4. To assist the CVD unit at WHO Geneva in the management and administration of the project, to advise and assist in fund raising, choice of the data centre and coordination.
5. To advise on the suitability of proposed collaborating centres and on termination of membership by a centre that fails.

18. Fund Raising: Central funding was needed urgently to support a data analysis centre and a coordinating centre. Collaborating institutes were asked to approach their funding bodies or governments with the support of WHO. They should also approach their heart foundations and other charities who might be able to make a local contribution (e.g. \$10 000 per year per centre) or who might fund a very substantial part of the work. The target needed for coordination and data analysis was considered to be in the region of \$500 000 per annum.

19. Next meeting

The next meeting is scheduled for the week of 28 November to 2 December 1983 in Geneva.



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Annex 1
CVD/MNC/WP/82.2 rev. 1
ENGLISH ONLY

JOINT HQ/EURO PROJECT ON MULTINATIONAL MONITORING OF TRENDS
AND DETERMINANTS IN CARDIOVASCULAR DISEASE (MONICA PROJECT)

Geneva, 30 November to 3 December 1982

Location: EB Room

D R A F T A G E N D A

1. Opening of the meeting at 09.00 a.m. on Tuesday, 30 November 1982
2. Election of officers
3. Progress reports
 - 3.1 WHO
 - 3.2 Collaborating centres
4. Protocol and Manual of Operations
 - 4.1 General comments
 - 4.2 Statistics and data processing
 - 4.2.1 Report of the meeting of the Statistical Advisory Committee
 - 4.2.2 Statistical and data processing centre
 - 4.3 Lipid standardization
 - 4.3.1 Report on the recommendations of the meeting
 - 4.3.2 Lipid coordinating centre
 - 4.4 ECG coding
 - 4.4.1 Procedures
 - 4.4.2 ECG coordinating centre
 - 4.5 Use of random zero sphygmomanometer
 - 4.6 Psychosocial aspects
 - 4.7 Physical activity
 - 4.8 Dietary assessment
 - 4.9 Health services
 - 4.10 Summary of decisions concerning Protocol and Manual of Operations
5. Coordination and management of the project
 - 5.1 Policy advisory board
 - 5.2 Steering committee
 - 5.3 Role of WHO
 - 5.4 Funds
 - 5.5 Communications
 - 5.5.1 Interim and annual reports
 - 5.5.2 Tabulations
 - 5.5.3 Newsletter
6. Plan of action
 - 6.1 Intervention programmes
7. Conclusions and recommendations

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