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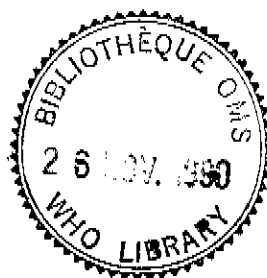
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CONSULTATION ON LONG-TERM COHORT STUDIES FOR RISK FACTOR ASSESSMENT

Report on a WHO Meeting

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## 1. Introduction

Following the previous consultations in Moscow and Bristol on long-term cohort studies for risk factor assessment, the WHO Regional Office for Europe held a third consultation in Oslo from 11 to 15 August 1986.

At the Moscow consultation the draft outline of the study design was agreed. At the Bristol consultation details of the protocol were discussed and questionnaires produced.

The Oslo meeting was attended by participants from Czechoslovakia, Federal Republic of Germany, Greece, Norway, the United Kingdom and the USSR (listed in Annex 4). The Regional Office for Europe was represented by Dr A. Romensky.

The consultation was opened by Dr A. Romensky, who conveyed to the group the greetings of the Regional Director for Europe, Dr J.E. Asvall. Participants were welcomed by Professor T. Bjerkedal, University of Oslo, Department of Preventive Medicine and Dr T. Heide from the Directorate of Health, Oslo.

Professor T. Bjerkedal was elected as Chairman and Dr Laura Pello, United Kingdom, as Rapporteur.

The purpose of the consultation was to finalize the various instruments and the questionnaires and to make final recommendations for further pilot investigations.

## 2. Aims

The scope and purpose of the Oslo meeting was not only to discuss the objectives agreed in the two previous consultations in relation to the HFA2000 programme, but also to consider the results of the first phase of the pilot results, the design of the 6-month and later questionnaires and finalise the overall study design.

The major objectives of the study continue to be:

(a) to determine the social, psychological, biological and environmental factors associated with causes of morbidity in the infant and child and to assess whether the same factors are predictive to a similar degree in each country;

(b) to monitor the overall prevalence of chronic illness, impairment, disability and handicap in the different countries of Europe.

The proposed longitudinal population study will include a comprehensive approach to risk factor assessment. It will take into account not only the physical conditions of the parents and of the child itself, but also all the other factors which affect the child's development, such as the environment, parents' personalities and attitudes and medical services. In order to attempt to achieve the objectives outlined in the HFA2000 strategy, it is essential that one should first understand the factors that influence the health of the child. The proposed cohort study should give a background of facts upon which one may build effective intervention strategies. It is hoped that, as a result both morbidity and mortality will be reduced.

## 3. Pre-piloting

The following questionnaires, discussed in outline during the Bristol consultation, and subsequently designed in Bristol, had been pre-piloted by the All-Union Semasko Institute for Research on Social Hygiene and Public Health, Moscow, and the Department of Child Health, University of Bristol:

- (1) First Questionnaire;
- (2) Second Questionnaire;
- (3) Delivery Questionnaire;
- (4) Post-Partum Questionnaire;
- (5) Temperament Questionnaire;
- (6) Neonatal Admissions Questionnaire.

The results of the pre-piloting were discussed and as a consequence some changes were made for each questionnaire. It was also noted by the group that for each country it may be necessary to make specific changes, to take account of differing cultures and health systems. Nevertheless, it was hoped that these would be kept to a minimum. During the piloting of each questionnaire it was suggested that there should be a specific question for the mother as to her willingness to fill in more questionnaires in the future, should she be asked.

None of the questionnaires seemed to cause too many difficulties to the mothers, and they were filled in by them in a relatively short period of time, between 20 and 30 minutes.

The information from the first questionnaire, piloted in Bristol was compared with that on the obstetric notes. There was little discrepancy between the mother's information and the data from the clinical records. All the questionnaires had been accepted by the Ethics Committee in Bristol. As a result there is strong evidence that this survey, pre-piloted in two different cultures (USSR and United Kingdom) should work and produce good comparable results. Copies of the reports of the meetings in Moscow and Bristol are available in WHO/EURO/EST.

#### 4. Six-month questionnaire

The 6-month questionnaire was designed and fully discussed. It was suggested that the information should be collected in a range from two weeks before to two weeks after the 6 month age. The mother would fill in details of the baby's major signs and symptoms, feedings, accidents and hospital admissions. She will also fill in a section related to her attitude to the child, her health, and life style together with measures of psychosocial stress using the life-events battery of questions. The last section relates to objective medical information already available on clinic notes, such as baby's weight, head circumference and neurological development. It was suggested that because source of information would differ from country to country comparable objective data might not always be available. Pre-piloting, carried out by the Department of Child Health, Bristol, and the All-Union Semasko Institute for Research on Social Hygiene and Public Health, Moscow should help resolve any problems and the results should be available by March 1987.

#### 5. 18-month, 3-year and 7-year questionnaires

The balance of opinion at the Oslo consultation was that the next contact should be at 18 months (rather than 12 months which had been originally suggested). The 18 months is thought to be more reliable on providing sound information on the child's development. It was suggested that collaborating paediatricians should be consulted and an 18 month questionnaire piloted and tested in the field.

The following items will be included in the 18-month survey (as agreed at the Moscow and Bristol consultations):

- life events (
- temperament (answered by the mother
- development (
- mother's attitude to the child (
- impairment or chronic illness
- hospital admissions
- medication
- weight, length, head circumference
- immunisation and other health services
- changes in the social and environmental situation
- mother's work pattern
- care of the child
- maternal separation.

The following items will be included in the 3-year questionnaires:

- changes in social and environmental situation of the mother;
- mother's work pattern and who is taking care of the child;
- child's behaviour;
- mother's attitude to the child;
- her social support network;
- simple tests of neurological development;
- height and weight;
- arm circumference and head circumference;
- question on feeding pattern;
- signs and symptoms;
- major accidental injuries;
- impairment;
- hospital inpatient and outpatient attendance;
- medication (current);
- separations of mother from child;
- use of health services.

The 7-year questionnaire will be drafted and piloted after the next meeting.

It was strongly felt that there was a lack of information on family interaction, father's health and attitudes, and those of other members of the family. Dr Dragonas and Dr Golding offered to investigate these further.

#### 6. Outline document

The main issue of the Oslo meeting has been the outline of a document to be sent to all Member States of the WHO European Region. During the consultation a draft was discussed. This should be finalised in the near future. It was felt that all other national centres wishing to join the project should do so prior to the pilot phase. They should then have the opportunity to pilot all the questionnaires and then attend a consultation to finalise the details of the study.

The WHO Regional Office for Europe will send the document (see Annexe 2) together with a letter of invitation to all European Member States. The letter will have a specific paragraph which will be adapted to each country, specifying the names of persons already known to be interested or involved in the planning process.

#### 7. Pilot phase for 1987

4 The pilot phase will be carried out during 1987 with data processing of the results taking place during the first half of 1988.

The All-Union Semasko Institute for Research on Social Hygiene and Public Health in Moscow and the Department of Child Health in Bristol will be responsible for coordinating the pilot studies.

The Paediatric Clinic of the Institute of Postgraduate Education in Medicine in Prague hopes to pilot longitudinally, as does Dr Ignatyeva.

A uniform approach was recommended to the pilot phase for all the centres involved. The sample size for the pilot phase should be of 100-150 subjects, for each questionnaire. The same subjects may or may not be involved in the piloting of different questionnaires.

#### 8. Geographic area

Each national centre should define a specific geographic area (region, district, town, etc.), preferably with a low outward migration rate. The study area should have a birth rate of at least 5 000 a year. Description of each participating area, environment, economics, medical care system and some other demographic details should be obtained as a useful background to the comparative study.

Data produced by Professor Bjerkedal (Annex 3) indicated that if the prevalence of the condition was 5%, with 5 000 population the 95% confidence interval would be 4.2%-5.8% whereas with a population of 1 000 the limits would be 3.4%-6.6%. The latter were considered far too wide for the study.

9. Suggestions for establishing Coordinating Centres

The study group recommended the Semasko Institute, Moscow and the Department of Child Health, Bristol, as Coordinating Centres. The two centres should act as Coordinating Centres for the coordination of the study but with the comparative analyses taking place centrally at Bristol. It was strongly felt that Dr Ignatyeva and Dr Golding, as supervisors for the two centres, should meet during the pilot phase for discussion and comparison of the data collection and processing. The participants of the consultation suggested that these two institutes be designated as Coordinating Centres for the future coordination of this activity.

10. Funding

The cost of the pilot phase (staff, equipment, data coding and processing) would be borne by the participating countries themselves, and the WHO Regional Office for Europe will only be able to give limited financial support to the Coordinating Centres in Moscow and Bristol. It was suggested that the next consultation could be held in the autumn of 1988.

Annex 1

Scope and purpose of the 1988 meeting

1. Procedural problems arising from piloting;
2. Specific results of piloting studies:
  - discussion of results for each specific question on each questionnaire (i.e. pilot frequencies);
3. Decisions concerning changes in data to be collected;
4. Decision on whether a questionnaire should be administered at 12 or 18 months (to be discovered from paediatricians from each country);
5. Consideration of the 3-year and 7-year questionnaires;
6. Problems with coding or transfer of data for central analysis;
7. Quality controls;
8. Preparation of the final protocol.

Annex 2

Outline of the document to go to each country

1. Introduction

Longitudinal studies-benefits and hazards  
HFA2000  
New approach needed

2. Aims

The major overall objectives of the study are two-fold:

(a) to determine the social, psychosocial, biological or environmental factors associated with causes of morbidity in the infant and child (including low birthweight) and to assess whether the same factors are predictive to a similar degree in each country:

(b) to monitor the overall prevalence of chronic illness, impairment, disability and handicap in the different countries of Europe.

3. Study design

- prospective
- geographic population
- numbers required
- ability to opt out, if required
- philosophy of participation: authorship, central survey offices analysis
- funding
- overall design: pictorial representation

4. Instruments

- structured extract of records: each questionnaire will be described with outline of types of questions, reasons for inclusion, how they should be administered;
- length of time needed for each questionnaire to:
  - (a) complete
  - (b) code
  - (c) key

5. Procedures for piloting

- translation
- testing and amending
- back translation
- numbers required
- cross-sectional
- coding and analysis

6. Time scale for pilot

- completion of data collection - December 1987
- coding and analysis - January to June 1988
- consultation of all participants - second half of 1988

7. Completion of final protocol

- start of main survey - end 1989.

Annex 3

Approximate size of standard deviation in per cent  
(Health Survey 1975, Central Bureau of Statistics of Norway, Oslo, 1977)

Percentages

Number of respondents	1 (99)	5 (95)	10 (90)	15 (85)	20 (80)	25 (75)	30 (70)	35 (65)	40 (60)	45 (55)	50 (50)
25	2,4	5,3	7,4	8,8	9,8	10,6	11,2	11,7	12,0	12,2	12,3
50	1,7	3,8	5,2	6,2	6,9	7,5	7,9	8,3	8,5	8,6	8,7
75	1,4	3,1	3,2	5,1	5,7	6,1	6,5	6,8	6,9	7,0	7,1
100	1,2	2,7	3,7	4,4	4,9	5,3	5,6	5,8	6,0	6,1	6,1
150	1,0	2,2	3,0	3,6	4,0	4,3	4,6	4,8	4,9	5,0	5,0
200	0,9	1,9	2,6	3,1	3,5	3,8	4,0	4,1	4,2	4,3	4,3
250	0,8	1,7	2,3	2,8	3,1	3,4	3,6	3,7	3,8	3,9	3,9
300	0,7	1,5	2,1	2,5	2,8	3,1	3,2	3,4	3,5	3,5	3,5
400	0,6	1,3	1,8	2,2	2,5	2,7	2,8	2,9	3,0	3,1	3,1
600	0,5	1,1	1,5	1,8	2,0	2,2	2,3	2,4	2,5	2,5	2,5
800	0,4	0,9	1,3	1,6	1,7	1,9	2,0	2,1	2,1	2,2	2,2
1 000	0,4	0,8	1,2	1,4	1,6	1,7	1,8	1,9	1,9	1,9	1,9
1 500	0,3	0,7	1,0	1,1	1,3	1,4	1,5	1,5	1,6	1,6	1,6
2 000	0,3	0,6	0,8	1,0	1,1	1,2	1,3	1,3	1,3	1,4	1,4
2 500	0,2	0,5	0,7	0,9	1,0	1,1	1,1	1,2	1,2	1,2	1,2
5 000	0,2	0,4	0,5	0,6	0,7	0,8	0,8	0,8	0,8	0,9	0,9
7 500	0,1	0,3	0,4	0,5	0,6	0,6	0,6	0,7	0,7	0,7	0,7
10 000	0,1	0,3	0,4	0,4	0,5	0,5	0,6	0,6	0,6	0,6	0,6

Annex 4

LIST OF PARTICIPANTS

OBSERVER

Dr T. Heide  
Directorate of Health, Oslo, Norway

TEMPORARY ADVISERS

Professor T. Bjerkedal (Chairman)  
University of Oslo, Department of Preventive Medicine, Oslo, Norway

Dr Thalia Dragonas  
Foundation for Research in Childhood, Athens, Greece

Professor J. Dunovsky  
Paediatric Clinic, Institute of Postgraduate Education in Medicine, Prague, Czechoslovakia

Dr Jean Golding (Co-Rapporteur)  
Department of Child Health, University of Bristol, Bristol, United Kingdom

Dr R.K. Ignatyeva  
Head of Unit, All-Union Semasko Institute for Research on Social Hygiene and Public Health,  
Ministry of Health of the USSR, Moscow, USSR

Dr Laura Pello (Rapporteur)  
Nuffield Department of Obstetrics and Gynaecology, John Radcliffe Hospital, Oxford, United  
Kingdom

Professor K.W. Tietze<sup>1</sup>  
Institut für Sozialmedizin und Epidemiologie, Bundesgesundheitsamt Berlin, Berlin (West)

WORLD HEALTH ORGANIZATION

Regional Office for Europe

Dr A. Romensky (Secretary)  
Statistician, Epidemiology and Information Support

Mrs Myriam Andersen  
Secretary, Epidemiology and Information Support

<sup>1</sup> Participation expenses not paid by WHO

Annex 5

LIST OF WORKING PAPERS AND BACKGROUND MATERIAL

- ICP/HST 114/1 Provisional list of working papers and background material
- ICP/HST 114/2 Scope and purpose
- ICP/HST 114/3 Provisional agenda
- ICP/HST 114/4 Provisional programme
- ICP/HST 114/5 Provisional list of participants
- ICP/HST 114/6 Assessment of Life Events, by Thalia G. Dragonas
- ICP/HST 114/7 The Role and Impact of the Long-Term Cohort Investigation in Relation to HFA 2000, by J. Dunovsky
- ICP/HST 114/8 Report on the Piloting of International Cohort Studies - Questionnaire in the USSR, by R.K. Ignatyeva
- ICP/HST 102 s02 Report on the Consultation on Field Studies for Risk Factor Assessment, Bristol, 29 October - 1 November 1985
- Questionnaires prepared by Jean Golding and Thalia Dragonas
- Results of the piloting of the questionnaires by Jean Golding