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Switzerland's Participation in MONICA

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1. Introduction

The MONICA project ("Monitoring of Trends and Determinants in Cardiovascular Disease") is a multicenter study proposed and coordinated by the World Health Organization. The objective of the study is to measure the trends in cardiovascular mortality, incidence rate and case fatality, and to assess the extent to which these trends are related to changes in known risk factors and efficiency of medical care.

During the last few years, the Institute of Social and Preventive Medicine in Lausanne has repeatedly analysed mortality from cardiovascular disease (1,2,3). Participation in the WHO study MONICA has given us a good opportunity to also study incidence rate.

So as to satisfy the requirements for such a comprehensive study, a special MONICA team has been set up with collaborators from outside the Institute (see appendix).

Basic funding for the initial part of the study has been obtained through the Swiss National Science Foundation.

2. General Hypotheses

Changes in cardiovascular mortality, as they have been observed during the last few years in different countries, could be due to

1) changes in incidence rates related to changes in known risk factors

2) changes in case fatality rates related to changes in the efficiency of medical care.

To test these two hypotheses, the incidence rate of acute myocardial infarction (MI), both fatal and no-fatal cases, will be taken as an indicator for overall cardiovascular morbidity.

The following null hypotheses will be tested :

- For the study population there is no relationship between...

1) ten year trends in the incidence rate of MI and

ten year trends in the coronary risk score, derived from a 3 factor logistic equation for serum cholesterol, diastolic blood pressure and tobacco consumption.

2) ten year trends in the case fatality rate for MI (fatal within 28 days) and

ten year trends in the medical care of acute MI.

3. The protocol of MONICA - Switzerland

The ten year MONICA study includes the "Disease Monitoring" and three Population Surveys.

The "Disease Monitoring" involves the measurement of the incidence rate of myocardial infarction (fatal and no-fatal attacks) in male residents of the study area aged 25-74 and the measurement of the medical care given to those residents.

- Data on likely events treated in hospitals will be collected regularly and classified according to the study criteria in order to obtain the number of cases in the hospital population. Data on cases treated at home and in those medical institutions unlikely to treat MI will be obtained by periodic questionnaires.
- Acute coronary care will be monitored three times over the ten years, each period of monitoring including 500 consecutive myocardial cases, fatal and non-fatal.
- For three limited periods, a death certificate validation program is planned. Each death case in the target population will be validated if one of the diseases mentioned could be associated with a MI.

The population surveys involve the measurement of known risk factors in a representative sample of at least 2000 men and women aged 25-74. For each of the three surveys, a new, independent sampling will be made. Each person will be contacted in his "commune" and an appointment made to see him.

Table 1

CHARACTERISTICS OF THE TARGET AREA

Area	: 4'889 km^2
Altitude of populated area	: 372 to 1500 meters
number of "communes" with	
<1000 inhabitants	: 545
1001- 9999 inhabitants	: 96
≥10000 inhabitants	: 10
Total	: 651
- Number of residents	: 713'993
Population density	: 146 inhabitants/Km^2

Table 2

DISTRIBUTION OF THE RESIDENTS BY MOTHER TONGUE

German	French	Other
105.499 (15%)	510.725 (71%)	97.769 (14%)

Foreigners in the resident population

Foreign residents with :		
annual work permit (B)	4%	28.978
permanent residency permit (C)	12%	86.435
Swiss residents	84%	598.580
	100%	713.993

As target population, the official residents of the cantons of Vaud and Fribourg have been chosen. The choice of the canton of Vaud is justified by the previous experience of the MONICA-CH team : a community oriented lifestyle program has recently been completed

in Switzerland, with the participation of two cities in the canton of Vaud (4). In order to obtain a large enough target population, the residents of the canton of Fribourg have also been included. These two cantons are neighbouring, and there are close contacts between their health care systems. The characteristics of the target area, its population and health services are presented in tables 1-3.

Table 3

DEMOGRAPHIC FEATURES OF THE TARGET AREA (1980)

Residents

Age	Men	Women	Total
25 - 29	26394	25941	52335
30 - 34	29352	29182	58534
35 - 39	28092	27059	55151
40 - 44	22605	21870	44475
45 - 49	21593	21300	42893
50 - 54	19713	20772	40485
55 - 59	19121	20754	39875
60 - 64	15331	17377	32708
65 - 69	14340	17672	32012
70 - 74	12245	16547	28792
	208786	218474	427260

Mortality

A) Analyses of trends on the basis of routine codification

All death certificates (in Switzerland) are sent to the Federal Office of Statistics where the causes of death are coded by just two persons. This guarantees good comparability within Switzerland. Analysis of mortality trends within the target population is possible because computerized data are available, including :

- residence
- death in hospital
- primary cause of death
- immediate cause of death
- concomitant diseases.

B) Validation of death certificates in the target population

In-hospital death cases : Validation will be made on the basis of the study data requirements - including date of onset of attack, clinical symptoms, cardiac enzymes, ECG records, necropsy findings - in order to classify the cases into diagnostic categories.

Out of hospital death cases : In the Federal Office of Statistics, all the certificates from the target area will be reviewed by an independent person. If ischemic heart disease, angina pectoris or sudden death is mentioned as one of the causes, a questionnaire will be sent to the certifying doctor, asking him for all the information needed for the determination of the diagnostic category (e.g. date of onset of attack, admission or not to hospital during attack, fatality within 28 days of onset or not, clinical diagnoses, medical history of any myocardial infarction at least 28 days before the event).

The validation of the causes of death in the target population will be carried out only for a sub-sample, covering 6 months every 4 years.

Incidence of myocardial infarction

In the target area, the majority of male residents aged 25-74 with MI involving medical services will be treated in public hospitals.

A) In-patients

The number of MI treated in hospitals has to be established by different means, depending on how the hospital diagnostic data system is organized.

In most of the main hospitals, the medical record system of the VESKA (Swiss Hospital Federation) is used; in this system the diagnoses are codified according to ICD, 9th revision with a maximum of 10 possibilities for recording various diagnoses. The selection of likely events will be made on the basis of routine codification including every case with a code 410 - 414 (ischemic heart diseases).

But some hospitals do not use any diagnostic data system. For each hospital not codifying the diagnoses, a particular diagnoses recording system is established in order to record every case with an ischemic heart disease. The same procedure will be applied to the private clinics which are likely to treat acute MI.

For every likely case, the classification into diagnostic categories will be made following the study criteria on the basis of hospital documents (case history, enzymes, ECG). Every hospital will be visited regularly by a trained medical assistant in order to obtain abstracted data from clinical records. The ECG's will be coded following the Minnesota code (5). Finally, draft pooling records will be filled in by the responsible project officer.

In this way, the number of MI for the hospital population in the study area will be known. For patients hospitalized outside the study area, only cases treated in VESKA-hospitals can be recorded.

B) Out-patients

An estimate of the number of cases treated at home and in those medical institutions which are unlikely to treat acute MI (e.g. psychiatric, chronic disease institutions) will be made, three times during the ten year period, by means of questionnaires sent to every medical practitioner and the medical staff of the institutions in the study area.

In table 4, the procedure for the collection of MI cases is presented, and is completed by table 5, where the different categories of hospitals are listed.

The collection of all the above mentioned data will allow a determination of the incidence rate of MI in the target male population, taking available intercensal data as denominator.

Table 5

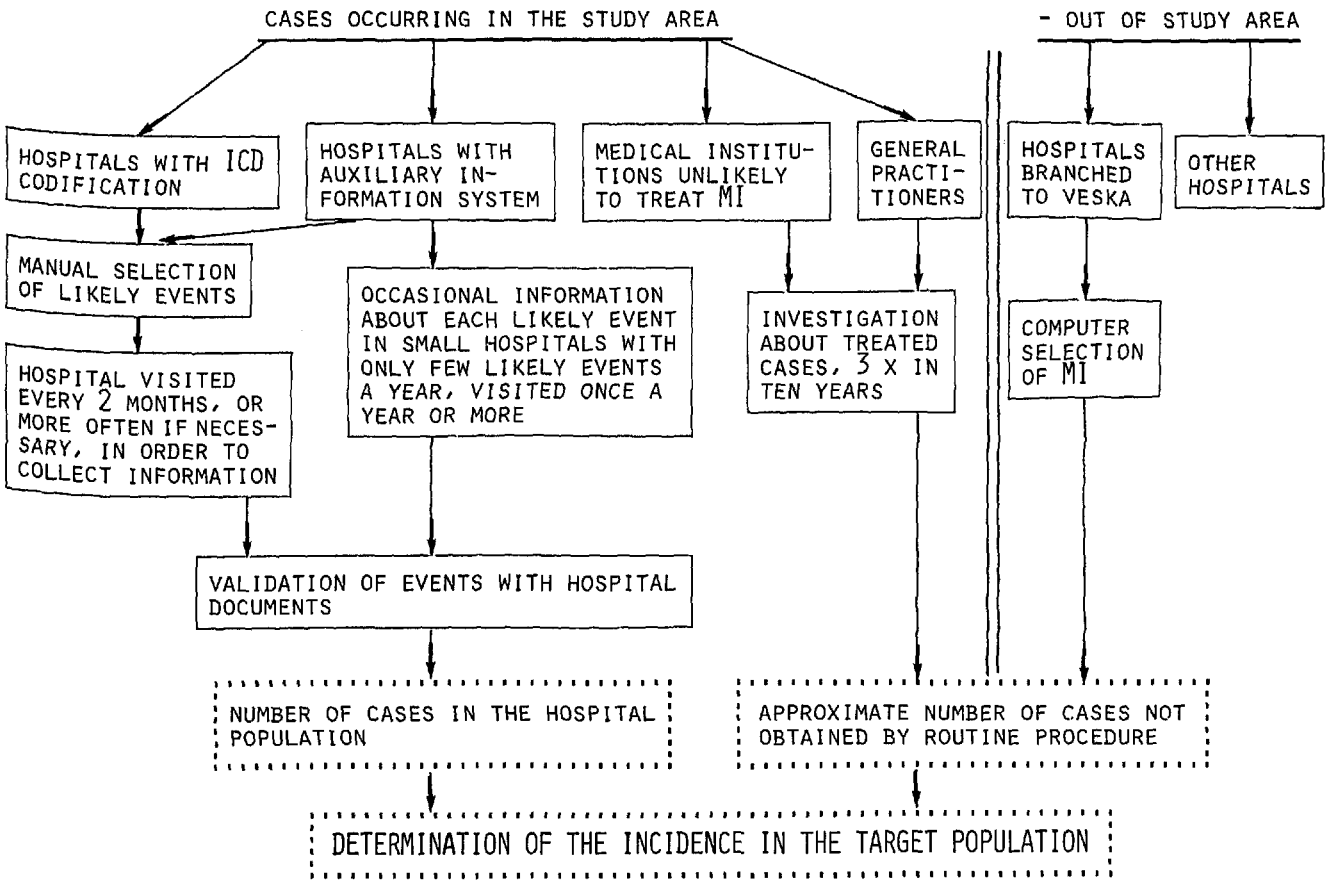
HOSPITALS IN WHICH LIKELY EVENTS ARE EXPECTED TO OCCUR

Hospitals with ICD codification	No.of Beds
Fribourg :	
Fribourg	452
Vaud :	
Aigle	108
Montreux	175
Morges	216
Nyon	145
Payerne	132
St-Loup	227
Samaritain	146
Yverdon	194
Orbe	100
Lausanne (CHUV)	1208
	3103

Hospitals without ICD codification	No.of Beds
Fribourg :	
Glâne	105
Gruyère	110
Broye	104
Châtel-St-Denis	72
Meyriez	78
St-Joseph	107
Vaud :	
Aubonne	59
Bex	28
Vallée	87
Pays d'Enhaut	43
Ste-Croix	65
Lavaux	80
Moudon	46
Rolle	65
6 private clinics	554
	1603

Table 4

PROCEDURE FOR THE COLLECTION OF MI CASES



Population survey

A) The sampling procedure

The target region includes a population of 427.000 between the ages of 25 and 74. In order to estimate the degree to which this population is exposed to the risk of cardiovascular disease, the study provides for the measurement of known risk factors in a representative sample of at least 2000 persons. As the minimal expected participation rate is 60%, the sample size is increased to 3.305 persons.

The sampling frame is the population register. A simple random selection of the individuals is not possible for the following reasons :

- the target region has no central population file. This type of file exists only at a "communal" level. As the region is divided into 651 "communes", this means there is a corresponding number of registers. Some are computerized, but most of them are traditional card files.
- For practical reasons, the selected individuals to be examined have to be concentrated in a limited number of "communes", so that the medical team can summon a minimum of ten people at any time.

Therefore a preliminary selection is made of the "communes" from which the individuals to be examined are chosen. This procedure will be carried out separately for the two cantons.

For the canton of Vaud, the "communes" with more than 10.000 inhabitants are automatically included. The others are divided according to population size into five strata, each strata covering approximately the same number of residents. Four "communes" are drawn by simple random selection from each stratum (except stratum 6 with 8 "communes"). The choice of population size as a stratification criterion can be justified by the fact that this factor is related to geographic and socio-economic characteristics.

For the canton of Fribourg, the only "commune" with a population greater than 10.000 - the town of Fribourg - is automatically included. The others are divided into four strata : one for the "communes" in the German-speaking part and three for the French-speaking part.

The WHO protocol suggests that there should be at least 200 individuals in each 10-year age and sex group. In this case the ideal procedure would be to draw a representative sample separately from each group. As we have to select the individuals from 51 different population registers such a sampling procedure is too laborious. Therefore the method consists in drawing just one sample, which is representative for the whole target population.

As far as possible, in each selected "commune" the individuals in the sample are drawn by a random process.

Main stratification

stratum	residents aged 25 - 74	sample size*
canton Vaud	323.000	2.500
canton Fribourg	104.000	805
Total	427.000	3.305

* proportionally to the number of residents aged 25-74

Substratification

stratum	number of "communes"	residents all ages	number of "communes" to be sampled
canton Vaud			
1	9	253.770	9
2	9	55.739	4
3	14	54.075	4
4	28	55.169	4
5	68	54.933	4
6	257	55.061	8
	385	528.747	33
canton Fribourg			
1	1	37.400	1
2	42	43.364	4
3	9	34.604	4
4	44	35.358	4
5	170	34.520	5
	266	185.246	18

B) Organization

The survey will be carried out in cooperation with non-profit making organizations : "Ligues de la Santé" in the canton of Vaud and "Ligue contre la tuberculose " in the canton of Fribourg. Either administrative and health education centres or mobile radiography units will be used as examination rooms, depending on the size of the "commune".

Contact will be made in the first place by letter, this being followed up by telephone or a second letter to make an appointment.

The team will be composed of a medical assistant and an assistant doctor. Regular visits will be made by the project officer.

c) The screening program

The program will include :

- Total plasma cholesterol and HDL-cholesterol
- Blood pressure measurements with random zero manometers
- Height an weight
- Smoking history validated by the measurement of plasma thiocyanate
- An estimate of physical activity, using a short questionnaire
- The assessment of psychosocial factors, including the Bortner scale (6)
- A dietary survey by means of a qualitative 24-hour recall questionnaire.

Health Services

A) Medical care in the acute phase

For the evaluation of medical care in the acute phase, 500 consecutive cases will be selected 3 times during the ten year period on the basis of hospital records. A list of items proposed by the international MONICA steering committee will be recorded.

B) Administrative data

The administrative data will be based on routine statistical recordings concerning : the number of physicians, nurses and other members of the medical staff; hospital admission rates; the number of beds in the hospitals, especially in intensive care units.

Quality Assurance

Control of the manual selection of likely events

The hospitals using the VESKA-medical record system transmit their data to the VESKA center at least once a year. It should be possible to control if every case in the central VESKA-file diagnosed as 410-414 has already been selected and reviewed by the MONICA collaborators.

Control of the ECG coding practice

In order to detect changes in the variability between the different coders, 10% of the ECG records will be recoded by a second person. In order to guarantee comparability over time, a pool of test ECG's will be elaborated.

Control of the final classification of events

This step depends on personal interpretation and therefore includes an important risk of systematic bias. 10% of the likely events will be classified twice by different persons. To guarantee comparability over time, a pool of test cases will be collected. Every six months, a series of test cases will be reviewed.

Quality assurance of blood pressure measurement

The name of the observer and the identification number of the manometer will be reported. Any unusual circumstances, such as special cuff for an "abnormal" arm circumference will also be reported.

Quality control of total and HDL cholesterol

The external quality control of the laboratory is guaranteed by the reference center in Prague (Dr. Grafnetter).

Timetable

Disease Monitoring Period : 1.10.1984 - 31.12.1993

Population surveys 1st : October 1984 - June 1985
2nd : October 1988 - June 1989
3rd : October 1992 - June 1993

4. The Current State of the Study

The population survey was started in October 1984. 27 "communes" had been visited by the end of February.

The registration of hospitalized patients with likely myocardial infarctions has been prepared in all public hospitals. The review of the clinical records will begin in spring'85.

5. A Possible Extension

Medical representatives of the canton of Ticino are very interested in the canton's participating in the MONICA study.

A solution has already been found for the survey of myocardial incidence. However, financial support for the population survey still has to be found.

Summary

Switzerland is currently participating in the multicenter study "Monitoring of Trends and Determinants in Cardiovascular Disease - MONICA". Incidence of acute myocardial infarction will be studied over a period of ten years in a target population. The results will be compared with changes in medical care and the spread of

known risk factors for cardiovascular disease in the population.

This paper describes how the different data will be registered in Switzerland and how far the work has progressed up to now.

Zusammenfassung

Die Schweiz beteiligt sich an MONICA

Die Schweiz beteiligt sich an der multizentrischen Studie "Monitoring of Trends and Determinants in Cardiovascular Disease - MONICA". Ueber einen Zeitraum von zehn Jahren wird für eine Studienbevölkerung die Inzidenz des akuten Myokardinfarktes erfasst. Diese Angaben sollen einerseits mit der Aenderung der Therapiegewohnheiten verglichen werden und andererseits mit der Verbreitung der bekannten Risikofaktoren für Herz-Kreislauf-Erkrankungen in der Bevölkerung. Es wird beschrieben, wie in der Schweiz die verschiedenen Daten erfasst werden sollen und wie weit die Arbeiten bislang gediehen sind.

Résumé

La Suisse participe à l'étude MONICA

La Suisse participe à l'étude multicentrique "Monitoring of Trends and Determinants in Cardiovascular Disease - MONICA" - observation des tendances et déterminants des maladies cardio-vasculaires.

Cette étude consiste à enregistrer tous les cas d'infarctus d'une population cible pendant une période de dix ans. Le changement dans le temps de cette incidence sera comparé d'une part à l'évolution des traitements dans la phase aigüe de l'infarctus, d'autre part aux modifications des facteurs de risque observées dans la population.

Cet article décrit les moyens mis en oeuvre pour la récolte des données et les étapes de l'étude déjà réalisées.

Références

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Appendix

The MONICA Team

Project Direction

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IUMSP, Lausanne :
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Mendrisio - G. Noseda
Viganello - C. Beretta-Piccoli

Expert for Psychosocial Factors

Institut für Sozial-und Präventivmedizin, Bern :
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