THE FRAMINGHAM STUDY
Sequence of Events
Protocol for dataset vr_soe_2013_a_0550d

This dataset contains events for

	Event dates
Original Cohort	10/1948 - 09/2013
Offspring Cohort	03/1971 - 11/2013
New Offspring Spouse Cohort	02/1987 - 09/2011
Generation 3 Cohort	02/1980 - 07/2013
Omni 1 Cohort	06/1978 - 11/2013
Omni 2 Cohort	08/1982 - 01/2013

Number of events and individuals in each cohort

Original Cohort	Events	=	12,915	Individuals	=	5141
Offspring Cohort	Events	=	4,979	Individuals	=	2339
New Offspring Spouse Cohort	Events	=	53	Individuals	=	32
Generation 3 Cohort	Events	=	246	Individuals	=	177
Omni 1 Cohort	Events	=	219	Individuals	=	114
Omni 2 Cohort	Events	=	46	Individuals	=	27
Total			18,458			7830

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CRITERIA FOR EVENTS

1. Cardiovascular Disease

Cardiovascular disease is considered to have developed if there was a definite manifestation of coronary heart disease, intermittent claudication, congestive heart failure, or stroke or transient ischemic attack in the absence of a previous manifestation of any of these diseases. Criteria for all these events are given below. A person having more than one cardiovascular manifestation within the follow-up period is counted as an incident case only at the time of the first event.

2. Coronary Heart Disease

Subjects are diagnosed as having developed coronary heart disease (CHD) if upon review of the case a panel of three investigators (the Framingham Endpoint Review Committee) agrees on one of the following definite manifestations of CHD: myocardial infarction, coronary insufficiency, angina pectoris, sudden death from CHD, non-sudden death from CHD. Persons with pre-existing CHD at Exam 1 are excluded from the population at risk of developing CHD but may be eligible for studies of prevalent CHD. Pre-existing CHD at Exam 1 is identified by any one of the following diagnoses at Exam 1: definite angina pectoris, definite history of myocardial infarction, definite myocardial infarction by electrocardiogram, doubtful myocardial infarction by electrocardiogram, definite coronary insufficiency by electrocardiogram and history.

The various manifestations of CHD are these:

Angina Pectoris

Brief recurrent chest discomfort of up to 15 minutes duration, precipitated by exertion or emotion and relieved by rest or by nitroglycerine is regarded as angina pectoris (AP) if two physicians interviewing the subject at a Framingham clinic visit or the Framingham Endpoint Review Committee, upon review of medical records, agree that this condition was definitely present. This diagnosis is based solely on evaluation of subjective manifestations. Abnormality of the resting or exercise electrocardiogram is not required for this diagnosis.

Myocardial Infarction

Recent or acute myocardial infarction (MI) is designated when there were at least two of three findings:
1) symptoms indicative of ischemia;
2) changes in biomarkers of myocardial necrosis;
3) serial changes in the electrocardiograms indicating the evolution of an infarction, including the loss of initial QRS potentials (that is, development of "pathologic" Q-waves of 0.04 second duration or greater).

An old or remote myocardial infarction is considered to be present when the electrocardiogram shows a stable pattern including a pathologic Q-wave of 0.04 second or greater or loss of initial QRS potential R-wave in those leads in which this would not be expected to occur. Also, an interim unrecognized MI is indicated when changes from a previous tracing show development of loss of R-wave potential or appearance of pathologic Q-waves not otherwise explained, in persons in whom neither the patient nor his physician considered the possibility of MI. If the patient was asymptomatic for chest pain or upper abdominal pain during the interval at which the unrecognized MI occurred, the event is classified as silent, unrecognized. More weight is given to this finding if a T-wave abnormality is also associated with Q-wave abnormality.

An autopsy report showing an acute, new, or recent infarction of the myocardium is accepted as evidence of an incident myocardial infarction. Because it is not possible to date an old infarction found on autopsy, such evidence is not used in the clinical diagnosis of a new event, unless there was an interim clinical event suspected of being an infarction.

Coronary Insufficiency

The coronary insufficiency syndrome is designated when a history of prolonged ischemic chest pain (> 15 minutes duration) was accompanied by transient ischemic S-T segment and T-wave abnormality in the electrocardiographic tracing but not accompanied by development of Q-wave abnormality or by serum enzyme changes characteristic of myocardial necrosis.

Coronary Heart Disease Death

Death from coronary heart disease is diagnosed as either sudden or nonsudden. For a detailed description of these diagnoses, see 6 below.

3. Stroke

The diagnosis of cerebrovascular disease is based on the occurrence of a clinically evident stroke documented by clinical records reviewed by at least two neurologists. Stroke is defined as the sudden or rapid onset of a focal neurologic deficit persisting for greater than 24 hours. Stroke is further categorized into infarction or hemorrhage.

Hemorrhagic Stroke

The diagnosis of subarachnoid hemorrhage is based on a history suggestive of this process such as abrupt onset headache, with or without change in the level of consciousness, and signs of meningeal irritation with or without other localizing neurological deficits. Intracerebral hemorrhage is diagnosed clinically by the occurrence of abrupt focal neurologic deficit, often with altered level of consciousness and symptoms of increased intracranial pressure. Hemorrhages are confirmed by imaging.

Ischemic Stroke

A diagnosis of cerebral embolism is made when an established source for embolus including atrial fibrillation, rheumatic heart disease with mitral stenosis, recent myocardial infarction, bacterial endocarditis or other known source is determined. A clinical course consistent with embolic infarction or evidence of other systemic embolism may be present. Symptoms are usually rapid with maximal severity at onset.

Antherothrombotic brain infarction is defined as the sudden onset of a focal neurologic deficit lasting longer than 24 hours, in the absence of:
1) known source of embolism (atrial fibrillation, rheumatic heart disease with mitral stenosis, myocardial infarction within preceding six months, bacterial endocarditis);
2) intracranial hemorrhage (intracerebral or subarachnoid);
3) known hypercoagulable states;
4) other disease processes causing focal neurologic deficits (brain tumor, subdural hematoma, hypoglycemia).
Confirmatory imaging supports the diagnosis.

Silent stroke may be documented at the stroke review sessions when a stroke event is determined and an incidental infarct is seen on brain imaging in the absence of a reported clinical event.

Transient ischemic attack

A transient ischemic attack is defined as a focal neurologic deficit of sudden or rapid onset that fully resolves in less than 24 hours.

Stroke Death

Death attributed to stroke is designated when a documented focal neurologic deficit of greater than 24 hours duration preceded death and was responsible for the fatality.

4. Intermittent claudication

Minimum criteria for the subjective diagnosis of intermittent claudication consists of a cramping discomfort in the calf clearly provoked by walking some distance with the pain appearing sooner when walking quickly or uphill and being relieved within a few minutes by rest. This diagnosis is designated if two physicians at a Framingham clinic visit or the Framingham Endpoint Review Committee, upon review of medical records, agree that this condition is definitely present. A diagnosis of intermittent claudication is based solely on evaluation of subjective manifestations.

5. Congestive heart failure

A definite diagnosis of congestive heart failure requires that a minimum of two major or one major and two minor criteria be present concurrently. The presence of other conditions capable of producing the symptoms and signs are considered in evaluating the findings.

Major Criteria:

1) Paroxysmal nocturnal dyspnea or orthopnea;
2) Distended neck veins (in other than the supine position);
3) Rales;
4) Increasing heart size by x-ray;
5) Acute pulmonary edema on chest x-ray;
6) Ventricular S(3) gallop;
7) Increased venous pressure > 16 cm H_20;
8) Hepatojugular reflux;
9) Pulmonary edema, visceral congestion, cardiomegaly shown on autopsy;
10) Weight loss on CHF Rx: 10 lbs./5days.

Minor criteria:

1) Bilateral ankle edema;
2) Night cough;
3) Dyspnea on ordinary exertion;
4) Hepatomegaly;
5) Pleural effusion by x-ray;
6) Decrease in vital capacity by one-third from maximum record;
7) Tachycardia (120 beats per minute or more);
8) Pulmonary vascular engorgement on chest x-ray.

6. Coronary heart disease death

Death from coronary heart disease is diagnosed as either sudden or nonsudden.

Nonsudden death from CHD

If the terminal episode lasted longer than one hour, if the available information implies that the cause of death was probably CHD, and if no other cause can be ascribed, this is called nonsudden death from CHD. In making this diagnosis, the review panel uses prior clinical information as well as information concerning the final illness.

Sudden death from coronary heart disease

If a subject, apparently well, was observed to have died within a few minutes (operationally documented as under one hour) from onset of symptoms and if the cause of death cannot reasonably be attributed on the basis of the full clinical information and the information concerning death to some potentially lethal disease other than coronary heart disease, this is called sudden death and is attributed to coronary heart disease.

7. Cardiovascular disease death

This cause of death is designated when any disease of the heart or blood vessels is considered responsible.

8. All-cause mortality

The fact of death is supported by a death certificate. Additional information is obtained from records supplied by hospital, attending physician, pathologist, medical examiner, or family. The Framingham Endpoint Review Committee reviews all evidence to arrive at the cause of death.

SOE CODES-numerical

SOE 01 Myocardial Infarction recognized, with diagnostic ECG
SOE 02 MI recognized, without diagnostic ECG, with enzymes & history
SOE 03 MI recognized, without diagnostic ECG, with autopsy evidence, new event
SOE 04 MI unrecognized, silent
SOE 05 MI unrecognized, not silent

NOTE: Recognized means at time of occurrence, an MI was known to have taken place
Unrecognized means MI was not known or recognized by person or doctor to have taken place until later
Unrecognized MI's are dated the midpoint between the dates of the diagnostic ECG's
Silent MI means free of any complaints
Not silent means complaint between last known no MI to the time that recognition of an MI took place

SOE 06 Angina Pectoris, first episode dated only, by history
SOE 07 Coronary insufficiency (definite); by history and ECG
SOE 08 MI, questionable, at exam 1, date same as exam 1.
Any questionable MI episode at exam 1, including definite history only without questionable MI or CI by ECG
SOE 09 Acute MI by autopsy.
This is the same event as SOE 01-02, within the same hospitalization

SOE 10 CVA, definite CVA at exam 1, but a questionable type
SOE 11 Atherothrombotic infarction of brain
SOE 12 Transient ischemic attack, only first episode is coded
SOE 13 Cerebral embolism
SOE 14 Intracerebral hemorrhage
SOE 15 Subarachnoid hemorrhage
SOE 16 Other CVA
SOE 17 CVA, definite CVA, type unknown
SOE 19 Questionable CVA at exam 1, date of exam 1

SOE 20 Death, not reviewed
SOE 21 Death, Sudden death, attributed to coronary heart disease, within 1 hour
SOE 22 Death, CHD nonsudden, 1-23 hours
SOE 23 Death, CHD nonsudden, 24-47 hours
SOE 24 Death, CHD nonsudden, 48 hours or more
SOE 25 Death, CVA
SOE 26 Death, other CVD
SOE 27 Death, Cancer
SOE 28 Death, other causes
SOE 29 Death, cause unknown

SOE 30 Intermittent Claudication, date of first event only, by history
SOE 39 IC, questionable IC at exam 1, exam 1 date

SOE 40 CHF, not hospitalized
SOE 41 CHF, hospitalized
SOE 49 CHF, questionable at exam 1, use exam 1 date