DZHK-SOP-C-01

Basic data

Version: V2.0
Valid as of: 23.03.2023

Replaces version: V 1.0
dated: 01.09.2014

Modification notice: Ethnicity and skin color not applicable

NEW: Vital status recording (end of study)

This SOP is a translation from the original German SOP and valid without signatures.

<table>
<thead>
<tr>
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<th>Expert Review</th>
<th>Endorsed by Section Head</th>
<th>Approved by DZHK</th>
</tr>
</thead>
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Basic data

The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
1 INTRODUCTION

1.1 LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full form</th>
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<tbody>
<tr>
<td>ASD</td>
<td>atrial septal defect</td>
</tr>
<tr>
<td>COPD</td>
<td>chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td>CT</td>
<td>computer tomography</td>
</tr>
<tr>
<td>HDL-cholesterol</td>
<td>High density lipoprotein cholesterol</td>
</tr>
<tr>
<td>LDL-cholesterol</td>
<td>Low density lipoprotein cholesterol</td>
</tr>
<tr>
<td>MRT</td>
<td>magnetic resonance tomography</td>
</tr>
<tr>
<td>pAVK</td>
<td>peripheral arterial occlusive disease</td>
</tr>
<tr>
<td>SOP</td>
<td>standard operating procedure</td>
</tr>
<tr>
<td>VSD</td>
<td>ventricular septal defect</td>
</tr>
<tr>
<td>TIA</td>
<td>Transitory ischemic attacks</td>
</tr>
</tbody>
</table>

1.2 OBJECTIVE
Uniform definitions are proposed in the context of this SOP when a corresponding risk factor/clinical diagnosis is considered to be present.

1.3 TARGET GROUP
This SOP is intended for individuals who make entries into the basic data module ‘Anamnesis’. These may be e.g. physicians or study assistants.

1.3.1 Inclusion Criteria
Included are all patients who meet the respective inclusion/exclusion criteria of the respective study.

1.3.2 Exclusion Criteria
None. If information cannot be collected in full, it should be collected to the greatest extent possible.

1.4 APPLICATION AND TASKS
The purpose of the anamnesis/clinical diagnoses is to accurately record known cardiovascular risk factors. The anamnesis is a core element of medical diagnostics. The findings obtained allow a detailed estimation of a person's cardiovascular risk.
Collection of the anamnesis/clinical diagnoses is an integral part of all observational and clinical studies of the DZHK. The exact implementation of the DZHK basic data set is described in the item catalog. There, as well as in all eCRFs, all mandatory basic items are marked with **.

1.5 Terms and Definitions

Date of examination
- is defined as the date on which the examination takes place.

Sex and date of birth
- are defined as the data which appear on the person’s identity card.

Height and weight
- height: Measured standing, without socks and without headgear. Weight: Measured in usual street clothes, without jacket and without shoes. Preferably, measurements should be taken; only if this is not possible (e.g. bedridden persons) should the data be estimated or based on anamnestic information from the participant.

Ethnicity: Caucasian
- ethnic origin is defined by a person's ancestry with respect to a particular population group. This can be determined biologically and or geographically by a certain settlement affiliation. The classification Caucasian means here light-skinned people of European origin.

Familial predisposition of myocardial infarction or stroke
- is defined as a medically diagnosed myocardial infarction or stroke in one or both biological parents, biological siblings (including half-siblings) or biological children, provided the female relative was under age 65, or the male relative under age 60 (at the time of the myocardial infarction/stroke).

Diabetes mellitus
- is defined as diabetes which has been diagnosed and/or treated by a physician.
  - American Diabetes Association criteria include:
    - hemoglobin A1c ≥ 6.5 % (48 mmol/mol Hb) or a fasting blood glucose level of ≥ 126 mg/dl (7.0 mmol/l) or a 2-hour blood glucose level of ≥ 200 mg/dl (11.1 mmol/l) during an oral glucose tolerance test.

Arterial hypertension
- is defined as a current or previous medical diagnosis of arterial hypertension, treated with diet, exercise, and/or medication. Systolic blood pressure values ≥ 140 mmHg and/or diastolic blood pressure values ≥ 90 mmHg measured by a physician on at least two separate days after a 5-minute resting phase qualify for a diagnosis of arterial hypertension.

Dyslipidemia

The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
is defined as a current or previous diagnosis of dyslipidemia which was diagnosed and/or is being treated by a physician.

one or more of the following criteria:
- total cholesterol ≥ 190 mg/dl (5 mmol/l),
- LDL cholesterol ≥ 115 mg/dl (3 mmol/l),
- HDL cholesterol < 40 mg/dl (men) (1 mmol/l) and < 45 mg/dl (1,2 mmol/l) (women).

Smoker

is defined as current or previous use of cigarettes, cigars, pipes, hookah, e-cigarette or smokeless tobacco.

'Yes' for daily or occasional smoking (≥ 1x/month) even with abstinence of less than 6 months;

'Ex-smoker' if abstinent for more than 6 months; ex-smoker since ...

'No' for 'never smoked'.

Current dialysis requirement

is defined as current regular, at least weekly, renal replacement therapy (including hemodialysis and peritoneal dialysis) within the last 30 days.

Coronary heart disease

is defined as a current or previous medical diagnosis with one or more of the following criteria:
- coronary artery stenosis of ≥ 50 % (diagnosed by cardiac catheterization or another direct coronary artery imaging method),
- previous coronary artery bypass operation,
- previous percutaneous coronary intervention,
- arteriosclerosis-induced myocardial infarction.

Condition post myocardial infarction

is a physician’s diagnosis of the disease. Rationale: Acute myocardial infarction is defined as evidence of myocardial necrosis in a clinical setting consistent with myocardial infarction.

One or more of the following criteria must apply:

- evidence of an increase or decrease of a cardiac biomarker (preferably troponin) with at least one value above the 99 % percentile of the upper reference limit and, additionally, at least one of the following factors:
  - Ischemic symptoms, ECG changes indicative of new ischemia, e.g. ST segment changes or a new left bundle branch block, development of pathological Q waves in the ECG,
  - imaging studies show a loss of viable myocardial tissue or new regional kinetic abnormalities,
  - angiographic evidence of stenosis/vascular occlusion.
Cardiomyopathy

- is defined as a physician’s diagnosis of a primary heart muscle disease.

Heart failure

- is defined as a current or previous physician-documented diagnosis of heart failure, based on the following symptoms: shortness of breath with mild exertion, recurrent shortness of breath when sitting, fluid overload or pulmonary rales, jugular venous congestion, pulmonary edema on physical examination or pulmonary edema on chest x-rays. Documentation of reduced left ventricular function alone without clinical signs of heart failure does not meet the criteria for heart failure.

Atrial fibrillation/flutter

- is defined as a current or previous physician’s diagnosis of atrial fibrillation or atrial flutter. It is defined as persisting for at least 30 seconds or evidence on surface ECG.

Current or previous medical diagnosis of heart valve disease

- is defined as heart valve disease (insufficiency or stenosis), which has been diagnosed and/or treated by a physician.

Physician-diagnosed congenital heart defect

- if a patient has a known congenital heart defect, this is coded here. Congenital heart defects include shunt vita (e.g. ASD, VSD), congenital valvular heart diseases (e.g. pulmonary stenosis) and cardiomyopathies diagnosed in the first five years of life.

Interventional coronary revascularization

- is defined as an intervention performed transcutaneously on a coronary vessel, on a coronary artery, e.g. PTCA, stent implantation, rotablation et cetera.

Coronary bypass surgery

- is defined as a surgical placement of bypass vessels (e.g., from the mammary artery or by use of arterial/venous grafts). If applicable, enter the date of the last operation.

Heart valve intervention

is defined as an intervention on a heart valve performed transcutaneously or by surgical procedure under vision.

Implantable cardiac pacemaker or defibrillator

- is defined as condition post implantation of a cardiac pacemaker or defibrillator.
CURRENT SECONDARY DIAGNOSES

PAD

- is defined as a current or previous physician’s diagnosis of peripheral arterial occlusive disease (pelvic-leg vessels or upper extremity from the subclavian artery to distal). Renal, coronary, cerebral and mesenteric blood vessels and aneurysms are excluded. Symptoms may include:
  - claudication,
  - amputation due to severe arterial vascular insufficiency,
  - vascular reconstruction, bypass surgery or percutaneous revascularization,
  - a positive non-invasive test (e.g. ankle-brachial index of ≤ 0.9, pathological TCPO2 measurement, evidence of at least 50 % or greater stenosis of a peripheral artery by ultrasound, CT, MRT, or angiography).

Stroke/TIA

- is defined as a current or previous diagnosis by a physician.

Chronic lung disease

- is defined as a physician’s diagnosis of a chronic lung disease (e.g. COPD, chronic bronchitis, pulmonary fibrosis) or current long-term therapy with inhaled or oral pharmaceuticals.

Depression

- is defined as a current or previous diagnosis by a physician. The administration of antidepressants alone does not qualify for a diagnosis of depression.

Cancer

- is defined as a current or previous medical diagnosis of malignant cancer. Basal cell carcinoma does not count as a malignancy. A distinction is made between more than 5 years ago and less than 5 years ago.

Blood pressure

- systolic blood pressure should be determined using a regularly maintained and calibrated blood pressure monitor. If possible, devices tested for epidemiological studies (e.g. Omron 705 IT) should be used. Blood pressure measurement begins after the patient has been sitting for at least 5 minutes.

Heart rate

- heart rate measurement starts after the participant has been sitting for at least five minutes. It can be performed simultaneously with the blood pressure measurement.
**Vital status**

- vital status (alive/deceased) must be recorded for each participating subject at the end of a study. If a person dies before the end of the study, the time of death, as well as the cause of death (cardiovascular/non-cardiovascular) must be documented. This is usually recorded on a separate eCRF form, as it is not collected at the same time as the other items of the basic dataset.

**RELATIONS TO OTHER INVESTIGATIONS**

Here, the interrelationships from the individual SOP to other procedures are described.

<table>
<thead>
<tr>
<th>Mandatory pretest (SOP ...):</th>
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<tbody>
<tr>
<td>Recommended pretest (SOP ...):</td>
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<td>Pretest (SOP) to be excluded</td>
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<td>Interference with other parts of the study:</td>
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| Mandatory follow-up (SOP ...):        | None specified |
| Recommended follow-up (SOP ...):      | None specified |
| Follow-up (SOP) to be excluded:       | None specified |

The contents of the DZHK-SOP-C-01 Basic Data Set are also part of the DZHK-SOP-C-02 Anamnesis/Clinical Diagnoses/Physical Examination. If DZHK-SOP-C-02 is performed, the DZHK basic data set is thus collected.

### 1.6 QUALITY LEVEL

**Quality data collection**

This SOP describes a data collection of quality level 2 of the DZHK. A higher quality level could possibly be achieved if, for example, standardized interviews such as those used in the German National Cohort were used. Because the studies planned so far in the DZHK do not require a quality level higher than 2, initially only SOPs for that level have been written.

<table>
<thead>
<tr>
<th>DZHK Quality Levels</th>
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</thead>
<tbody>
<tr>
<td><strong>Realisation</strong></td>
</tr>
<tr>
<td>Level 1</td>
</tr>
<tr>
<td>Level 2</td>
</tr>
</tbody>
</table>

The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
Level 3

The examination is performed according to the specifications of the DZHK SOP and certification of the investigators: Definition of intra-observer and inter-observer variability (standard of epidemiological studies).

2 PREREQUISITE OF THE INVESTIGATION

All circumstances are considered in order to ensure that the examination is conducted under suitable conditions.

2.1 REQUIREMENTS FOR ROOMS/EQUIPMENT

The examination room should have a room temperature of 22-26 °C. Generally, the room should have a table at which the proband and the interviewer can sit in a comfortable atmosphere in order to conduct the interview.

2.2 DEVICES/HARDWARE

PC with a monitor, keyboard, mouse, printer and printer paper. Depending on the respective study, the forms for standardized documentation of the proband’s responses should be available as source files, if needed.

2.3 DOCUMENTS REQUIRED

- Docket
- Barcode for scanning

2.4 INFORMATION REQUIRED

- Examiner number
- Survey number (label)
- Beginning of examination
- Proband number

2.5 STAFF

Persons using this SOP must have completed their training in the medical field (e.g. medical assistant, nurse, licensed physician). Students of medicine may use this SOP after they have successfully passed their first medical examination (German Physikum).

All users must have completed a prior course of instruction/certification for this SOP or DZHK-SOP-C-02 Anamnesis/Clinical Diagnoses, respectively.
3 IMPLEMENTATION PROCESS/WORK PROCESS/WORK STEPS

3.1 PROCESS FLOW CHART

- Appropriate Room (PC, printer, room temperature)
  - Start interview
  - Physical Examination
    - Recording of:
      - height (cm) & weight (kg)
      - Specific diseases (see 1.5 terms and definitions)
  - Question sequence
    1. Have you ever been told by a physician that you suffer from a 'disease'?
    2. Have you ever received a medical treatment against a 'disease'?
    3. Do you receive medication 'xy' against a disease??
  - Doublecheck Medication/indikation
  - Deviation of Data?
    - No
      - Archiving of documents
    - Yes
      - Search of previous documents
      - Disease query
        - Diabetes mellitus
        - Arterial hypertension
        - Dyslipidemia
        - Smoker
        - Dialysis requirement
        - Coronary heart disease
        - Condition after myocardial infarction
        - Cardiomyopathy
        - Heart failure
        - Atrial fibrillation/flutter
        - PAD
        - Stroke/TIA
        - Chronic lung disease
        - Depression
        - Malignancy

Legend:
- Result/Task
- Statement
- Leads to/further
- Decision
3.2 Preparing for the Examination

3.2.1 Preparing the Work Space
Find a suitable room with a table. Bring the room to a temperature between 22 and 26 °C.

3.2.2 Preparing the Equipment
All equipment (PC/laptop/printer) should be switched on and must be ready for operation. A form (source data documentation) should be at hand.

3.3 Carrying out the Examination

Physical examination – anthropometry

- height (in cm) and weight (in kg) are given either as self-reported values (level 1) or as measured values (level 2). In the eCRF, a mark is made to whether the values given are based on anamnestic information or measured values.

Anamnesis

A medical diagnosis is considered to be given if it has been diagnosed by a physician and/or therapy is being administered which is considered to specifically target a certain disease. All documentation in medical documents (e.g. doctor’s letters) justifies accepting the diagnosis as given.

When carrying out the examination, for each clinical diagnosis, the following questions should be asked in the interview:

1. Have you ever been told by a physician that you suffer from a “disease”?  
2. Have you ever received a medical treatment against a “disease”?  
3. Do you receive medication “xy” against a “disease”?

As a “cross-check”, the indication should be requested and documented for each medication the patient receives. A checking rule is stored in the database, which produces a corresponding message in the event of discrepancies (e.g. negative answers to 1-3, but taking corresponding medication).

In case of ambiguities (e.g. whether relevant diagnoses have been made, but the subject has consulted doctors for clarification), when and where those consultations took place should be noted as precisely as possible in the comments field. After the interview, documents of the respective consultancies shall be inquired.

Inquiry about specific diseases, see section 1.5.

FOLLOW-UP AND RECORDING OF DATA
A special debriefing session is not planned. The data should be entered without delay (usually within 7 days).

3.4 Dealing with Deviations
If a clear answer cannot be obtained for certain questions, this should be documented.
General particularities should always be noted in the commentary/notes field.

4 LITERATURE AND REFERENCES

ACCF/AHA Guidelines Circulation 2011;124:103-123

5 MODIFICATIONS

Modifications compared with the previous version.

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<th>Section</th>
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<td>Ethnicity: Skin colour not applicable</td>
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<td>Vital status (end of study)</td>
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6 LIST OF CONTRIBUTORS

<table>
<thead>
<tr>
<th>Name</th>
<th>Function</th>
<th>Contribution</th>
</tr>
</thead>
<tbody>
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<td>Reviewer</td>
<td>Expert review</td>
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<td></td>
<td></td>
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<td>WG Data standardization</td>
<td>Scientific review</td>
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<tr>
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<td>WG Data standardization</td>
<td>Scientific review</td>
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<td>Scientific review</td>
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<td>WG Data standardization</td>
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<tr>
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<tr>
<td>Dipl.-Ing. Jens Schaller</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
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<tr>
<td>Tabea Scharfe</td>
<td>WG Data standardization</td>
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<tr>
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<tr>
<td>Dana Stahl</td>
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<td>WG Data standardization</td>
<td>IT implementation</td>
</tr>
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<td>Dipl.-Inf. Sabine Hanß</td>
<td>WG Data standardization</td>
<td>IT implementation</td>
</tr>
<tr>
<td>Dr. Julia Hoffmann, Dr. Ilka Wilhelmi</td>
<td>WG Data standardization</td>
<td>Coordination</td>
</tr>
</tbody>
</table>
## 7 APPENDIX

### 7.1 ECRF Module

#### Anamnesis and Clinical Diagnoses (incl. Basic Data Set***)

**General information relating to the anamnesis**

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<table>
<thead>
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<td>I. Date of examination**</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>[unknown] [not assessed]</td>
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<td></td>
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<tr>
<td>II. Quality level**</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td>III. Level 1</td>
<td>The examination is performed in accordance with the guidelines of the medical associations.</td>
</tr>
<tr>
<td>III. Level 2</td>
<td>The examination is performed in accordance with the specifications of the DZHK SOP. Minimum requirements to ensure the quality of the implementation and the examiners are defined in the SOP.</td>
</tr>
<tr>
<td>III. Level 3</td>
<td>The examination is performed in accordance with the specifications of the DZHK SOP and certification of the examiners: Definition of intra-observer and inter-observer variability (standard of epidemiological studies).</td>
</tr>
</tbody>
</table>

#### 1. Physical Examination and Socio-demographic Data

<p>| | |</p>
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<td>1.1. Sex**</td>
<td>[male] [female] [diverse] [unknown] [not assessed]</td>
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<tr>
<td>1.2. Date of birth**</td>
<td>[mm/dd/yyyy]</td>
</tr>
<tr>
<td>1.3. Height**</td>
<td>[cm]</td>
</tr>
<tr>
<td>1.4. Weight**</td>
<td>[kg]</td>
</tr>
<tr>
<td>1.5. Ethnicity: Caucasian**</td>
<td>[yes] [no] [unknown] [not assessed]</td>
</tr>
<tr>
<td>1.6. Family history of myocardial infarction or stroke in parents, siblings or children under the age of 65 for women or under 60 for men**</td>
<td>[yes] [no] [unknown] [not assessed]</td>
</tr>
</tbody>
</table>

#### 2. Cardiovascular risk factors

*The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.*
Basic data

2.1. Diabetes mellitus**
- yes
- no
- unknown
- not assessed

** If defined as diabetes which has been diagnosed and/or treated by a physician.
1. American Diabetes Association criteria include:
   - hemoglobin A1c > 6.5 % (48 mmol/mol Hb) or a fasting blood glucose level of ≥ 126 mg/dl (7.0 mmol/l)
   - or a 2-hour blood glucose level of ≥ 200 mg/dl (11.1 mmol/l) during an oral glucose tolerance test.

2.2. Arterial hypertension**
- yes
- no
- unknown
- not assessed

** If defined as a current or previous medical diagnosis of arterial hypertension, treated with diet, exercise, and/or medication. Systolic blood pressure values > 140 mmHg and/or diastolic blood pressure values > 90 mmHg measured by a physician on at least two separate days after a 5-minute resting phase qualify for a diagnosis of arterial hypertension.

2.3. Dyslipidemia**
- yes
- no
- unknown
- not assessed

** If defined as a current or previous diagnosis of dyslipidemia which was diagnosed and/or is being treated by a physician.
One or more of the following criteria:
1. Total cholesterol ≥ 190 mg/dl (5 mmol/l),
2. LDL cholesterol ≥ 115 mg/dl (3 mmol/l),
3. HDL cholesterol < 40 mg/dl (1 mmol/l) (man) and < 45 mg/dl (1.2 mmol/l) (woman).

2.4. Smoker**
- yes
- no
- ex-smoker (stopped ≥ 6 months ago)
- unknown
- not assessed

** Ex-smoker since**
- unknown
- not assessed

** Pack years**
- unknown
- not assessed

** If defined as current or previous use of cigarettes, cigars, pipes, hookah, e-cigarette or smokeless tobacco.
1. Yes for daily or occasional smoking (≥ 1/week) even with abstinence of less than 6 months;
2. Ex-smoker if abstinent for more than 6 months; ex-smoker since … ;
3. No for ‘never smoked’.
4. Pack year is the product of the number of years of cigarette smoking multiplied by the average number of packs smoked per day.
Example: A patient who has smoked 2 packets of cigarettes per day for 20 years has 40 pack years

2.5. Drinks per week*
- unknown
- not assessed

** The number of alcoholic drinks consumed per week. One drink is defined as e.g. 0.25 l of beer, 0.1 l of wine or 0.02 l of spirits.
Example: A person who drinks 0.5 l beer twice a week in average has 4 drinks per week.

2.6. Medically diagnosed alcoholism**
- yes
- no
- unknown
- not assessed

** If defined as a current or previous physician’s diagnosis of alcoholism.

2.7. Renal failure*
- yes
- no
- unknown
- not assessed

2.7.1. Degree of renal dysfunction*
- 1 – eGFR 60 ml/min or higher
- 2 – eGFR 45-59 ml/min
- 3 – eGFR 30-44 ml/min
- 4 – eGFR 15-29 ml/min
- 5 – eGFR < 15 ml/min or current dialysis dependency
- unknown
- not assessed

** Any participating individual who has a renal function impairment as diagnosed by a physician.

Degree of renal dysfunction:
If known, the degree of renal dysfunction should be quantified using the estimated glomerular filtration rate.

The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
Basic data

There are different methods for estimation, but if available, the MDRD formula should be used (eGFR). Based on the results, the following grading classification is made:

1. eGFR ≥ 90 ml/min or higher
2. eGFR 60-89 ml/min
3. eGFR 30-59 ml/min
4. eGFR 15-29 ml/min
5. eGFR < 15 ml/min or current dialysis requirement

unknown
not assessed

2.8. Current dialysis dependency**

○ yes ○ no ○ unknown ○ not assessed

3. Cardiac Diagnoses (Anamnesis and Previous Findings)

3.1. Coronary heart disease**

○ yes ○ no ○ unknown ○ not assessed

Heart: is defined as current or previous medical diagnosis with one or more of the following criteria:

1. coronary artery stenosis of ≥ 50% (diagnosed by cardiac catheterization or another direct coronary artery imaging method),
2. previous coronary artery bypass operation,
3. previous percutaneous coronary intervention,
4. arteriosclerosis-induced myocardial infarction.

3.2. Condition post myocardial infarction**

○ yes ○ no ○ unknown ○ not assessed

Heart: is a physician’s diagnosis of the disease. Rationale: Acute myocardial infarction is defined as evidence of myocardial necrosis in a clinical setting consistent with myocardial infarction. One or more of the following criteria must apply:

1. Evidence of an increase or decrease of a cardiac biomarker (preferably troponin) with at least one value above the 99th percentile of the upper reference limit and, additionally, at least one of the following factors:
   - Ischemic symptoms,
   - ECG changes indicative of new ischemia, e.g. ST segment changes or a new left bundle branch block,
   - Development of pathological Q waves in the ECG,
   - Imaging studies show a loss of viable myocardial tissue or new regional kinetic abnormalities,
   - Angiographic evidence of stenosis/vascular occlusion.

3.3. Cardiomyopathy**

If the response to this question is “yes”, please complete the “Cardiomyopathy Diagnostics” form.

○ yes ○ no ○ unknown ○ not assessed

Heart: is defined as a physician’s diagnosis of a primary heart muscle disease. If the response to this question is “yes”, further data is collected in the “Cardiomyopathy Diagnostics” form.

3.4. Heart failure**

3.4.1. S.p. decompensation*

○ yes ○ no ○ unknown ○ not assessed

3.4.2. Initial diagnosis of heart failure*

○ yes ○ no ○ unknown ○ not assessed

3.4.3. Current NYHA class*

○ I ○ II ○ III ○ IV ○ unknown ○ not assessed

Heart: is defined as a current or previous physician-documented diagnosis of heart failure, based on the following symptoms: shortness of breath with mild exertion, recurrent shortness of breath when sitting, fluid overload or pulmonary rales, jugular venous congestion, pulmonary edema on physical examination or pulmonary edema on chest x-rays. Documentation of reduced left ventricular function alone in the absence of clinical signs of heart failure does not meet the criteria for heart failure.

Status post decompensation is defined as any previous admission to a hospital with symptoms of heart failure (see above).
The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
### Basic data

#### Other vascular operation* *(yes/no/unknown/not assessed)*

#### If yes, date of last intervention** *(mm/dd)*

#### Heart valve operation*** *(yes/no/unknown/not assessed)*

#### If yes, date of last intervention** *(mm/dd)*

#### Type of last intervention* *(open surgery/catheter-based/unknown/not assessed)*

#### If open surgery* *(replacement/reconstruction/unknown/not assessed)*

#### If more than one procedure on one valve was performed, please provide details of the last OP (= current state)*

<table>
<thead>
<tr>
<th>Valve Type</th>
<th>Procedure Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic valve*</td>
<td>native/reconstruction/mechanical/bioprosthesis/TAVI/unknown/not assessed</td>
</tr>
<tr>
<td>Pulmonic valve*</td>
<td>native/reconstruction/mechanical/bioprosthesis/unknown/not assessed</td>
</tr>
<tr>
<td>Mitral valve*</td>
<td>native/reconstruction/mechanical/bioprosthesis/unknown/not assessed</td>
</tr>
<tr>
<td>Tricuspid valve*</td>
<td>native/reconstruction/mechanical/bioprosthesis/unknown/not assessed</td>
</tr>
</tbody>
</table>

#### Implantable pacemaker or defibrillator** *(yes/no/unknown/not assessed)*

#### If yes, what was implanted?** *(pacemaker/defibrillator/unknown/not assessed)*

#### If yes, date of last event (implantation/exchange)** *(mm/dd)*

#### If pacemaker, please give pacemaker type* *(1-chamber/2-chamber/biventricular/unknown/not assessed)*

#### Other devices* *(yes/no/unknown/not assessed)*

#### Cardiac contractility modulation (CCM)** *(yes/no/unknown/not assessed)*

---

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### Basic data

#### 4.7.2. Intra-aortic balloon pump (IABP)
- [ ] yes
- [ ] no
- [ ] unknown
- [ ] not assessed

#### 4.7.3. Other devices

**Note:** Defined as other implantable devices for cardiac/vascular support. This includes devices for cardiac contractility management, for neuromodulation (e.g., vagus nerve stimulator, baroreceptor stimulator), intra-aortic balloon pumps and left ventricular cardiac assist devices.

#### 4.8. S.p. myocardial biopsy
- [ ] yes
- [ ] no
- [ ] unknown
- [ ] not assessed

#### 4.8.1. Date of myocardial biopsy
- [ ] mm
- [ ] yyyy
- [ ] unknown
- [ ] not assessed

#### 4.8.2. Biopsy sites
- [ ] left ventricle
- [ ] right ventricle
- [ ] left and right ventricle
- [ ] unknown
- [ ] not assessed

**Note:** Defined as status post bioplastic removal of tissue from the myocardium (e.g., during a right-left catheter examination or surgery). Where applicable, the sampling site as well as the date of the most recent myocardial biopsy should be coded.

### 5. Current secondary diagnoses

#### 5.1. PAOD**
- [ ] yes
- [ ] no
- [ ] unknown
- [ ] not assessed

#### 5.1.1. Fontaine stage
- [ ] I
- [ ] II
- [ ] III
- [ ] IV
- [ ] unknown
- [ ] not assessed

#### 5.1.2. Acute ischaemic occlusion**
- [ ] yes
- [ ] no
- [ ] unknown
- [ ] not assessed

**Note:** Defined as a current or previous diagnosis by a physician of peripheral arterial occlusive disease (pelvic-leg vessels or upper extremity from the subclavian artery to distal). Racial, coronary, cerebral and mesenteric vessels and aneurysms are excluded. Possible symptoms are:
1. Intermittent claudication,
2. Pain at rest,
3. Amputation due to severe arterial vascular insufficiency,
4. Vascular reconstruction, bypass surgery or percutaneous revascularization.
5. A positive non-invasive test (e.g., ankle-brachial index of < 0.9, pathological TCP02 measurement, evidence of 50% or greater stenosis of a peripheral artery by Doppler/tissue Doppler imaging, CTA, MRA, or angiography).

Classification of the degree of severity is done according to the Fontaine classification:

**Stage and Clinical Picture**

I. Asymptomatic PAOD

- Intermittent claudication

II. 1. with walking distances > 200 metres (Stage IIa)
2. with walking distances = 200 metres (Stage IIb)

III. Pain at rest

IV. Necrosis, gangrene

Acute ischaemic occlusion refers to a currently (in the last 30 days) occurring proven acute ischaemic occlusion of a peripheral arterial vessel.

#### 5.2. Stroke/TIA**
- [ ] yes
- [ ] no
- [ ] unknown
- [ ] not assessed

#### 5.2.1. Date
- [ ] mm
- [ ] yyyy
- [ ] unknown
- [ ] not assessed

#### 5.2.2. Aetiology
- [ ] ischaemic
- [ ] haemorrhagic
- [ ] unknown
- [ ] not assessed

#### 5.2.3. Diagnosis
- [ ] TIA
- [ ] Stroke
- [ ] unknown
- [ ] not assessed

#### 5.2.4. Stroke severity
- [ ] minor
- [ ] major
- [ ] unknown
- [ ] not assessed

#### 5.2.5. Consequences of the stroke
- [ ] disabling
- [ ] non-disabling
- [ ] unknown
- [ ] not assessed

---

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**Basic data**

**ится defined as a current or previous diagnosis by a physician of:**
1. **Ischaemic stroke**: Infarction of tissue of the central nervous system, either symptomatic or silent (asymptomatic).
2. **Transient ischaemic attack (TIA)**: A transient episode of neurological dysfunction caused by focal cerebral, spinal cord or retinal ischaemia without acute infarction, which resolves completely within 24 hours. This definition is not met by chronic (non-vascular) neurological diseases or other acute neurological diseases such as metabolic or ischaemic encephalopathy resulting from general hypoxia (e.g. respiratory failure, post-cardiovascular arrest).
3. **Haemorrhagic stroke**: Neurological dysfunction caused by intra-cranial bleeding.
4. **Stroke where there is uncertainty as to whether the cause was haemorrhagic or ischaemic.**

**Severity of the stroke**: A stroke is considered “minor” if neurological symptoms can be completely reversed within 30 days or the change in the NIH Stroke Scale (see Appendix 7.3 NIH Stroke Scale) is less than 3 points compared to the NIH Stroke Scale before the stroke. A stroke is considered “major” if neurological deficits are still detectable 30 days after the event or the NIH Stroke Scale is at least 3 points higher than prior to the stroke.

**Consequences of the stroke**: A stroke is considered “disabling” if the modified Rankin Scale score is greater than 2.90 days after the stroke. If the modified Rankin Scale score is 2 or less 90 days after the stroke, the stroke is considered “non-disabling”.

*The modified Rankin Scale of 0 to 6 describes the range from complete health to death.*

| 5.0 | No symptoms. |
| 5.1 | No significant impairment. Can perform daily activities despite some symptoms |
| 5.2 | Slight impairment. Is able to care for him or herself without assistance, but is limited in daily activities. |
| 5.3 | Moderate impairment. Requires assistance in daily life, but is able to walk without assistance. |
| 5.4 | More severe impairment. Requires assistance with personal hygiene; is not able to walk without assistance. |
| 5.5 | Severe impairment. Bedridden, incontinent, requires constant nursing assistance. |
| 5.6 | Death caused by apoplexy. |

### 5.3 Chronic lung disease**
- yes
- no
- unknown
- not assessed

**is defined as a diagnosis by a physician of a chronic lung disease (e.g. COPD, chronic bronchitis, pulmonary fibrosis) and/or their pharmacological treatment, for example, with inhalable or oral pharmaceuticals (e.g. betamimetics, anti-inflam-matory drugs, leukotene receptor antagonists, or steroids).**

### 5.4 Primary pulmonary Hypertension*
- yes
- no
- unknown
- not assessed

**is defined as physician-diagnosed and/or treated primary pulmonary hypertension.**

### 5.5 Depression**
- yes
- no
- unknown
- not assessed

**is defined as a current or previous medical diagnosis of depression. The administration of antidepressants alone does not qualify for a diagnosis of depression.**

### 5.6 Cancer more than 5 years ago**
- yes
- no
- unknown
- not assessed

**is defined as a current or previous medical diagnosis of malignant cancer. Basal cell carcinoma is not counted as a malignancy.**

### 5.7 Cancer within the last 5 years*
- yes
- no
- unknown
- not assessed

**is defined as malignant cancer diagnosed by a physician less than 5 years ago. Basal cell carcinoma is not counted as a malignancy.**

### 6. Blood pressure after 5 minutes at rest

<table>
<thead>
<tr>
<th>6.1 Systolic**</th>
</tr>
</thead>
<tbody>
<tr>
<td>mmHg</td>
</tr>
<tr>
<td>unknown</td>
</tr>
<tr>
<td>not assessed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6.2 Diastolic**</th>
</tr>
</thead>
<tbody>
<tr>
<td>mmHg</td>
</tr>
<tr>
<td>unknown</td>
</tr>
<tr>
<td>not assessed</td>
</tr>
</tbody>
</table>
7. Heart rate after sitting down for 5 minutes

<table>
<thead>
<tr>
<th>Heart rate**</th>
<th>√ par minute</th>
<th>○ unknown</th>
<th>○ not assessed</th>
</tr>
</thead>
</table>

Measurement of the heart rate begins after the patient has been sitting down for at least 5 minutes. This should take place after blood pressure measurement. A manual count of the radial pulse over 30 seconds is performed; this value multiplied by two should be entered into the CRF (beats/minute).

8. Other diagnosis

<table>
<thead>
<tr>
<th>Exertional Dyspnea*</th>
<th>○ yes</th>
<th>○ no</th>
<th>○ unknown</th>
<th>○ not assessed</th>
</tr>
</thead>
</table>

A patient who complains of dyspnea on exertion within the last 14 days and/or at present. In cases of known heart failure, for patients within NYHA stages II-IV, dyspnea on exertion should be coded.

<table>
<thead>
<tr>
<th>Dyspnea at rest*</th>
<th>○ yes</th>
<th>○ no</th>
<th>○ unknown</th>
<th>○ not assessed</th>
</tr>
</thead>
</table>

A patient who complains of shortness of breath even when at rest (e.g. while talking) within the last 14 days and/or at present. In cases of known heart failure, for patients in NYHA stage IV, dyspnea at rest should be coded.

<table>
<thead>
<tr>
<th>Peripheral edema*</th>
<th>○ yes</th>
<th>○ no</th>
<th>○ unknown</th>
<th>○ not assessed</th>
</tr>
</thead>
</table>

A patient who complains of bilateral clinically or self-perceived water retention in the extremities within the last 14 days and/or at present.

<table>
<thead>
<tr>
<th>Jugular venous distention*</th>
<th>○ yes</th>
<th>○ no</th>
<th>○ unknown</th>
<th>○ not assessed</th>
</tr>
</thead>
</table>

The diagnostic test for jugular vein congestion is conducted with the upper body of the patient positioned at a 45° angle. The height at which the jugular vein collapses is then determined. On pathological collapse is no later than the level of the jugular, which usually corresponds to an 8 cm water column or 5-6 mmHg anterior to the right atrium. If the jugular vein collapses above the jugulum, jugular venous congestion must be coded.

<table>
<thead>
<tr>
<th>Pulmonary edema*</th>
<th>○ yes</th>
<th>○ no</th>
<th>○ unknown</th>
<th>○ not assessed</th>
</tr>
</thead>
</table>

are defined as sounds heard over the lung during auscultation which are created by the movement of fluids and/or secretions during inspiration and expiration. They belong to the category of respiratory sounds that are superimposed on normal breath sounds and indicate a pathological change in the lung.

9. Laboratory diagnostics (blood)

In clinically stable individuals, these values may be no more than one week old, and must be determined again thereafter.

<table>
<thead>
<tr>
<th>Date blood sample was taken**</th>
<th>√ mm.day</th>
<th>○ unknown</th>
<th>○ not assessed</th>
</tr>
</thead>
</table>

If known, the date of the last value should be given here.

<table>
<thead>
<tr>
<th>Hemoglobin**</th>
<th>○ unknown</th>
<th>○ not assessed</th>
</tr>
</thead>
</table>

Unit**

- mmol/l
- g/dl

If the value is known, it must be given in mmol/l or g/dl.

<table>
<thead>
<tr>
<th>Creatinine (serum, heparin plasma)**</th>
<th>○ unknown</th>
<th>○ not assessed</th>
</tr>
</thead>
</table>

Unit**

- µmol/l
- mmol/l
Basic data

9.4. Total cholesterol**

Unit**

- unknown
- not assessed
- mmol/l
- mg/dl

If the value is known, it must be given in mmol/l or mg/dl.

10. The next three anamnestic questions are for women only

10.1. Menopause**

- yes
- no
- unknown
- not assessed

10.1.1 Year of menopause**

- if
- unknown
- not assessed

10.2. Day last menstrual period began**

- if
- unknown
- not assessed

This is defined as the time of the last spontaneous menstrual period in the life of a woman that is not followed by ovarian triggered bleeding from the uterus for at least 12 months. The year in which the menopause began is to be coded. The day on which the last menstrual period began is recorded only for perimenopausal women.

Mögliche Angaben

Bitte wählen Sie bei den oben mit Anmerkungen versehenen Feldern eine der hier aufgelisteten Angaben.

1)

2)

3)
## Basic data

### Vital status

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Was the vital status recorded?**</td>
<td>☑ yes</td>
<td>☑ no</td>
<td>☑ unknown</td>
</tr>
<tr>
<td>2.</td>
<td>Date of last contact**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Status of the patient**</td>
<td>☑ is alive</td>
<td>☑ is dead</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Date of death**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Cause of death**</td>
<td>☑ cardiovascular</td>
<td>☑ non-cardiovascular</td>
<td>☑ unknown</td>
</tr>
</tbody>
</table>

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