DZHK-SOP-K-02

Anamnesis/Clinical Diagnoses

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*Adapted from the SOPs of the Competence Network Heart Failure
1 INTRODUCTION

1.1 LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviations</th>
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<tr>
<td>ASD</td>
<td>atrial septal defect</td>
</tr>
<tr>
<td>COPD</td>
<td>chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td>CRT</td>
<td>cardiac resynchronization therapy</td>
</tr>
<tr>
<td>CT</td>
<td>computed tomography</td>
</tr>
<tr>
<td>eCRF</td>
<td>electronic Case Report Form</td>
</tr>
<tr>
<td>eGRF</td>
<td>estimated Glomerular Filtration Rate</td>
</tr>
<tr>
<td>ECG</td>
<td>electrocardiogram</td>
</tr>
<tr>
<td>FFR</td>
<td>fractional flow reserve</td>
</tr>
<tr>
<td>GFR</td>
<td>glomerular filtration rate</td>
</tr>
<tr>
<td>HDL cholesterol</td>
<td>high-density lipoprotein cholesterol</td>
</tr>
<tr>
<td>IABP</td>
<td>intra-aortic balloon pump</td>
</tr>
<tr>
<td>ICD</td>
<td>implantable cardio-verter defibrillator</td>
</tr>
<tr>
<td>IVUS</td>
<td>intra-vascular ultrasound</td>
</tr>
<tr>
<td>LDL cholesterol</td>
<td>low-density lipoprotein cholesterol</td>
</tr>
<tr>
<td>MDRD formula</td>
<td>Modification of Diet in Renal Disease formula</td>
</tr>
<tr>
<td>MRT/MRI</td>
<td>magnetic resonance tomography/magnetic resonance imaging</td>
</tr>
<tr>
<td>NIH Stroke Scale</td>
<td>National Institutes of Health Stroke Scale</td>
</tr>
<tr>
<td>NYHA</td>
<td>New York Heart Association</td>
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<tr>
<td>OCT</td>
<td>optical coherence tomography</td>
</tr>
<tr>
<td>PAOD</td>
<td>peripheral arterial occlusive disease</td>
</tr>
<tr>
<td>PTCA</td>
<td>percutaneous transluminal coronary angioplasty</td>
</tr>
<tr>
<td>QRS</td>
<td>QRS complex in ECG (action potential duration)</td>
</tr>
<tr>
<td>RV</td>
<td>right ventricle</td>
</tr>
<tr>
<td>$S_{Cr}$</td>
<td>serum creatinine</td>
</tr>
<tr>
<td>TIA</td>
<td>transient ischemic attack</td>
</tr>
<tr>
<td>VSD</td>
<td>ventricular septal defect</td>
</tr>
<tr>
<td>CVP</td>
<td>central venous pressure</td>
</tr>
<tr>
<td>s/p</td>
<td>status post</td>
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</table>
1.2 PURPOSE
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
These SOPs are targeted at individuals responsible for entering data into the basic data module “Anamnesis”. These may be e.g. doctors or study nurses.

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 evidence collected during the anamnesis enables a detailed assessment of a patient’s cardiovascular risk.

Collection of the anamnesis/clinical diagnoses is an integral part of all observational and clinical studies of the DZHK.

1.5 TERMS, DEFINITIONS AND EXPLANATIONS FOR THE eCRF MODULE

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 is measured in the standing position, without shoes and without head covering. Weight is measured in normal street clothing, without a jacket and without shoes. Preferentially, measured data should be collected; only when this is not possible (e.g. in the case of bedridden patients) should one estimate the values or resort to information provided by the proband.
Ethnicity and skin colour

- A person’s ethnic origin is defined by their ancestry in relation to a specific ethnic group. This can be determined biologically and/or geographically on the basis of membership of a certain settlement group. Accordingly, a person’s skin colour can also be broadly defined. The colour spectrum can be differentiated from light to dark skin colour.

Family history 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 55 (when the myocardial infarction/stroke occurred).

Diabetes mellitus

- is defined as diabetes which has been diagnosed and/or treated by a doctor.
  - The American Diabetes Association criteria are:
    - haemoglobin A1c ≥ 6.5 % or a fasting blood glucose level of ≥ 126 mg/dl or a 2-hour blood glucose level of ≥ 200 mg/dl in the oral glucose tolerance test.

Arterial hypertension

- is defined as a current or previous diagnosis of arterial hypertension which was diagnosed and/or is being treated by a doctor. Treatment can consist of e.g. dietary changes, physical activity and/or medication. Systolic blood pressure values ≥ 140 mmHg and/or diastolic blood pressure values ≥ 90mmHg measured by a doctor on at least two separate days after a 5-minute resting phase qualify for a diagnosis of arterial hypertension.

Dyslipidaemia

- is defined as a current or previous diagnosis of dyslipidaemia which was diagnosed and/or is being treated by a doctor.

  - One or more of the following criteria:
    - total cholesterol ≥ 200 mg/dl,
    - LDL cholesterol ≥ 130 mg/dl,
    - HDL cholesterol < 40 mg/dl (men) and < 50 mg/dl (women).

Smoker

- is defined as current or previous use of cigarettes, cigars, pipes or smokeless tobacco.
  - “Yes” for daily or occasional smoking (≥ 1x/month);
  - “Ex-smoker” for abstinence of more than 6 months; ex-smoker since ...
  - “No” for “never smoked”

Pack years

- 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.

**Drinks per week**
- is 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 patient who drinks 0.5 l beer on average two times every week has 4 drinks per week.

**Medically diagnosed alcoholism**
- is defined as a current or previous diagnosis of alcoholism which was diagnosed and/or is being treated by a doctor.

**Renal failure**
- This includes all patients who exhibit reduced renal function. If known, the degree of renal dysfunction should be quantified by the estimated Glomerular Filtration Rate (eGFR). Different estimation methods exist; if available, the formula that follows the MDRD formula should be used. This is:

\[
eGFR(\text{ml/min}) = 186 \times (S_{Cr})^{-1.154} \times (\text{Age})^{-0.203} \times (0.742\text{fallen weiblich}) \times (1.210\text{falls schwarze Hautfarbe})
\]

\[
= \exp(5.228 - 1.154 \times \ln(S_{Cr}) - 0.203 \times \ln(\text{Age}) - (0.299\text{fallen weiblich}) + (0.192\text{falls schwarze Hautfarbe}))
\]
- eGFR: estimated Glomerular Filtration Rate
- \(S_{Cr}\): serum creatinine in mg/dl
- age: age in years

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

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

**Status post myocardial infarction**
• is a diagnosis of the disease by a doctor. Explanation: Acute myocardial infarction is defined as demonstrated evidence of myocardial necrosis in a clinical setting which is 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:
  ▪ symptoms of ischaemia, angina pectoris,
  ▪ ECG changes indicative of new ischaemia, e.g. ST segment elevations 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 wall motion abnormalities,
  ▪ angiographic evidence of stenosis/blood vessel blockage.

**Cardiomyopathy**

• is defined as a diagnosis by a doctor of a primary heart muscle disease. If the response to this question is “yes”, further data is collected in the “Cardiomyopathy Diagnostics” form.

**Heart failure**

• is defined as a current or previous diagnosis and documentation by a doctor 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, distention of the neck veins, pulmonary oedema on physical examination or pulmonary oedema 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).

Initial diagnosis of heart failure is defined as the time point when heart failure was diagnosed for the first time by a doctor. Hence it does not refer to the time point of first onset of symptoms, which is often much earlier.

**NYHA class:** Classification of the patient’s symptoms based on the New York Heart Association classification of heart failure:

• NYHA I: No symptoms
• NYHA II: Symptoms with heavy physical exertion
• NYHA III: Symptoms with light physical exertion
• NYHA IV: Symptoms while at rest

**Atrial fibrillation/flutter**
• is defined as a current or previous diagnosis by a doctor of atrial fibrillation or atrial flutter. It is defined as an episode of atrial fibrillation or atrial flutter lasting at least 30 seconds or atrial fibrillation with evidence on the surface ECG or during pacemaker interrogation.

**Current or previous medical diagnosis of heart valve disease**

• is defined as heart valve disease (incompetence or stenosis), which has been diagnosed and/or treated by a doctor. A more precise differentiation and classification of the degree of severity of the heart valve disease is conducted using the “Echocardiogram” form, if an echocardiogram is to be documented in the context of the study.

**Diagnosis by a doctor of endocarditis**

• If at any time, currently or in their previous medical history, a patient has been diagnosed by a doctor with endocarditis (heart valve inflammation), it will be documented here.

**Diagnosis by a doctor of a congenital heart defect**

• If a patient has a known congenital heart defect, it will be coded here. Congenital heart defects include shunt defects (e.g. ASD, VSD), congenital valvular heart diseases (e.g. pulmonary stenosis) and cardiomyopathies diagnosed in the first five years of life. Patent foramen ovale does not belong to the class of congenital heart defects.

**Interventional coronary revascularization**

• is defined as a percutaneously performed intervention on a coronary artery, e.g. PTCA, stent implantation, rotablation et cetera. Purely diagnostic measures (intravascular ultrasound (IVUS), optical coherence tomography (OCT)) as well as functional measurements (e.g. fractional flow reserve (FFR) measurements) are not interventional coronary revascularization procedures. Where applicable, the date of the last intervention should be entered.

**Peripheral revascularization**

• is defined as a percutaneously performed intervention on a peripheral artery (not including coronary arteries or bypass grafts) e.g. PTA, stent implantation, rotablation et cetera. Where applicable, the date of the most recent intervention should be entered. Ablation procedures (e.g. renal denervation) are not peripheral revascularization procedures. Where applicable, the date of the most recent intervention should be entered.
Coronary bypass operation

• is defined as operative myocardial revascularization by means of a bypass graft (e.g. from the internal thoracic artery or using arterial/venous grafts). Where applicable, the date of the most recent operation should be entered.

Other vascular operation

• is defined as an operation of any kind on non-coronary blood vessels. Where applicable, the date of the most recent operation should be entered.

Heart valve operation

• is defined as a minimally invasive percutaneous (catheter-based) or open surgical procedure on a heart valve. This includes the surgical reconstruction/replacement of heart valves, valvuloplasty procedures as well as interventional treatment of heart valve diseases (e.g. dilation, implantation of protheses, heart valve repair). Where applicable, the date of the most recent operation should be entered. The most recent event is to be coded according to type, whereby any transapical aortic valve replacements are to be coded as “catheter-based”. In addition, details of the surgical procedure should be given.

Implantable cardiac pacemaker or defibrillator

• is defined as status post implantation of a cardiac pacemaker or cardio-verter defibrillator (ICD). Where applicable, the date of the most recent operation (implantation/exchange) is to be entered. In addition, the number of leads currently connected to the pacemaker power supply should be coded. A device with only one lead should be coded as a 1-chamber pacemaker, a device with an atrial and a ventricular lead should be coded as a 2-chamber pacemaker. Devices for cardiac resynchronization therapy, with 2 ventricular leads, should be coded as biventricular (CRT) pacemakers.

Other devices

• are defined as other implantable devices for cardiac/vascular support. This includes devices for cardiac contractility modulation, for neuromodulation (e.g. vagus nerve stimulator, baroreceptor stimulator), intra-aortic balloon pumps and left ventricular cardiac assist devices.

Status post myocardial biopsy

• is defined as status post biopptic removal of tissue from the heart muscle (e.g. during a right/left catheter examination or operation). Where applicable, the sampling site as well as the date of the most recent myocardial biopsy should be coded.

CURRENT SECONDARY DIAGNOSES

PAOD
is defined as a current or previous diagnosis by a doctor of peripheral arterial occlusive disease (in the blood vessels of the pelvis and legs, or from the upper extremity of the subclavian artery to the distal extremity). Renal, coronary, cerebral and mesenteric blood vessels and aneurysms are excluded. Possible symptoms are:
- intermittent claudication,
- pain at rest,
- amputation due to severe arterial vascular insufficiency,
- vascular reconstruction, bypass operation or percutaneous revascularization,
- a positive non-invasive test (e.g. ankle-brachial index of ≤ 0.9, pathological TCPO2 measurement, evidence of 50 % or greater stenosis of a peripheral artery by Doppler/duplex sonography, CT, MRT, or angiography).

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

**Classification according to Fontaine**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Clinical Picture</th>
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<tbody>
<tr>
<td>I.</td>
<td>Asymptomatic PAOD</td>
</tr>
<tr>
<td>II.</td>
<td>Intermittent claudication</td>
</tr>
<tr>
<td></td>
<td>- with walking distances &gt; 200 metres (Stage IIa)</td>
</tr>
<tr>
<td></td>
<td>- with walking distances &lt; 200 metres (Stage IIb)</td>
</tr>
<tr>
<td>III.</td>
<td>Pain at rest</td>
</tr>
<tr>
<td>IV.</td>
<td>Necrosis, gangrene</td>
</tr>
<tr>
<td></td>
<td>- IVa: trophic disorder, dry necroses</td>
</tr>
<tr>
<td></td>
<td>- IVb: bacterial infection of the necrosis, wet gangrene</td>
</tr>
</tbody>
</table>

- Acute ischaemic occlusion describes a recent (in the last 30 days) occurrence of demonstrated acute ischaemic occlusion of a peripheral arterial vessel.

**Stroke/TIA**

is defined as a current or previous diagnosis by a doctor of:

- Ischaemic stroke: Infarction of tissue of the central nervous system, either symptomatic or silent (asymptomatic).
- Transient ischaemic attack (TIA): A transient episode of neurological dysfunction caused by focal brain, 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. in the case of respiratory insufficiency, following a cardiac/circulatory arrest).
- Haemorrhagic stroke: Neurological dysfunction caused by intra-cranial bleeding.
- Stroke where there is uncertainty as to whether the cause was haemorrhagic or ischaemic.
**Severity of the stroke:** A stroke is described as “minor” when the neurological symptoms can be completely reversed within 30 days or the change in the NIH Stroke Scale (see Appendix 7.3 NIH Stroke Scale) amounts to less than 3 points in comparison with the NIH Stroke Scale before the stroke. A stroke is described as “major” when a neurological deficit can still be demonstrated 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 described as “disabling” when more than 2 points are scored on modified Rankin Scale 90 days after the stroke. If the modified Rankin Scale score is 2 points or less 90 days after the stroke, the stroke is described as “non-disabling”.

The modified Rankin Scale from 0 to 6 describes states from full health to death.

- 0 - No symptoms.
- 1 - No significant disability. Can perform day-to-day activities despite some symptoms.
- 2 - Slight disability. Is able to care for him or herself without assistance, but is restricted in day-to-day activities.
- 3 - Moderate disability. Requires assistance in daily life, but is able to walk without assistance.
- 4 - High level of disability. Requires assistance with personal hygiene; is not able to walk without assistance.
- 5 - Severe disability. Confined to bed, incontinent, requires constant nursing care.
- 6 – Death caused by apoplexy.

**Chronic lung disease**

- is defined as a diagnosis by a doctor 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-inflammatory drugs, leukotriene receptor antagonists, or steroids).

**Primary pulmonary hypertension**

- is defined as a diagnosis and/or treatment by a doctor of primary pulmonary hypertension.
Depression

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

Cancer more than 5 years ago

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

Cancer within the last 5 years

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

Additional details; women only

Menopause

- is defined as the time point of the last spontaneous menstrual period in the life of a woman after which no further bleeding from the uterus induced by the ovaries occurs 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 required only for perimenopausal women.

PHYSICAL EXAMINATION

Blood pressure

- The systolic blood pressure should be measured using a blood pressure monitor that is serviced and calibrated on a regular basis. Where possible, tested devices (e.g. Omron 705 IT) should be used for epidemiological trials. Blood pressure measurement begins after the patient has been at rest for at least 5 minutes. Three readings are taken at intervals of 2 minutes; the average values of the second and third readings are entered into the CRF.

Heart rate

- Measurement of the heart rate begins after the patient has been sitting down for at least 5 minutes. This should take place after measuring the blood pressure. This should be done manually by counting the radial pulse for 30 seconds; that value multiplied by two should be entered into the CRF (beats/minute).
Clinical Symptoms and Examination Findings

Dyspnoea on exertion

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

Dyspnoea at rest

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

Peripheral oedema

- A patient who complains of bilateral accumulation of fluid in the extremities within the last 14 days and/or at present, whether clinically observed or perceived by the patient.

Jugular venous distention

- The diagnostic test for jugular venous distention is conducted with the upper body of the patient positioned at a 45° angle. The level at which the jugular vein collapses is then determined. A non-pathological finding is if the vein collapses at least at the level of the supra-sternal notch, which normally corresponds to an 8 cm water column or 5-6 mmHg before the right atrium. If the jugular vein collapses above the supra-sternal notch, jugular venous distention must be coded.

Figure 1: Diagnostic test for jugular venous distention (CVP measurement & positioning at a 45° angle)
**Pulmonary rales**

- 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 adventitious breath sounds overlying normal breath sounds and indicate a pathological change in the lung.

### 1.6 Correlations to Other Examinations

Here the correlations between the individual SOPs and other examination procedures are described.

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<tr>
<td>Recommended preliminary examination (SOP ...):</td>
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<td>Exclusion of preliminary examination (SOP ):</td>
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<tr>
<td>Adverse effects on other parts of the examination:</td>
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</table>

<table>
<thead>
<tr>
<th>Mandatory following examination (SOP ...):</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Recommended following examination (SOP ...):</td>
<td></td>
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<tr>
<td>Exclusion of following examination (SOP):</td>
<td></td>
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</tbody>
</table>

### 1.7 Level of Quality

*Quality of the data collection method*

This SOP describes a data collection method that corresponds to 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 one SOP for that level has been drafted.

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

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*In this eCRF, items marked with two asterisks (**) must be completed (basic data set). Items marked with one asterisk (*) should be completed to the greatest extent possible.*
Level 2 | 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.

Level 3 | 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).

2 EXAMINATION CONDITIONS

All circumstances are taken into account 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 EQUIPMENT/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 SPECIAL CLINICAL CONSUMABLES

None.

2.4 DOCUMENTS REQUIRED

- Routing slip
- Scan barcode

2.5 INFORMATION REQUIRED

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

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

All users must have completed a prior course of instruction/certification for this SOP.
3 IMPLEMENTATION PROCESS/WORK PROCESS/WORK STEPS

3.1 PROCESS FLOW CHART

Geeigneter Raum (PC, Drucker, Zimmertemp.)

Frageabfolge
1) Hat Ihnen jemals ein Arzt gesagt, dass Sie an einer „Erkrankung“ leiden?
2) Haben Sie jemals eine Behandlung gegen eine „Erkrankung“ erhalten?
3) Bekommen Sie Medikament „XY“ gegen „Erkrankung“?

Körperliche Untersuchung
Erfassung von:
• Größe (cm) & Gewicht (kg)
• Erfassung von spezifischen Erkrankungen (siehe 1.5 Begriffe und Definitionen)

Gegencheck-Medikamente/Indikation

Erkrankungsabfrage:
• Diabetes Mellitus
• Arterielle Hypertonie
• Dyslipidämie
• Raucher
• Dialysepflichtigkeit
• Koronare Herzerkrankung
• Zustand nach Myokardinfarkt
• Kardiomyopathie
• Herzinsuffizienz
• Vorhofflimmern/-flattern
• pAVK
• Schlaganfall/TIA
• Chronische Lungenerkrankung
• Depression
• Malignom

Legende:
• Ereignis/Aufgabe
• Feststellung/Aussage
• Führt zu/weitergehend
• Entscheidung

Archivierung der Dokumente

Abweichung der Daten?

ja

Suche nach vorherigen Dokumenten

nein

Interview beginnen

SOP-02
Valid as of: 01.09.2014
Version: V1.0
Author: R. Wachter

*In this eCRF, items marked with two asterisks (**) must be completed (basic data set). Items marked with one asterisk (*) should be completed to the greatest extent possible.
3.2 PREPARING FOR THE EXAMINATION

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

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

3.2.3 Principles for Preparing the Proband for the Examination
Special preparation of the proband is not necessary.

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). Whether the values given are based on anamnestic or measured values shall be marked in the CRF.

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

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

1. Has a doctor ever told you that you suffer from a “disease”?
2. Have you ever received treatment for a “disease”?
3. Are you taking drug “xy” for the “disease”?

As a “counter-check”, the interviewer should inquire about and document the indication for each medication the patient is taking. A validation rule will be added to the database which will produce a notification when inconsistencies arise (e.g. negative responses to questions 1-3, but the subject is taking the corresponding medication).

When uncertainties arise (e.g. as to whether the 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 remarks field.
Inquiry about the following specific diseases, see section 1.5:

- Diabetes mellitus
- Arterial hypertension
- Dyslipidaemia
- Smoker
- Positive family history of cardiovascular disease
- Dialysis dependency
- Coronary heart disease
- Status post myocardial infarction
- Cardiomyopathy
- Heart failure
- Atrial fibrillation/flutter
- PAOD
- Stroke/TIA
- Chronic lung disease
- Depression
- Malignancy

3.4 Post-processing and Registering the Data
A special debriefing session is not planned. The data should be entered without delay (usually within 7 days).

3.5 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.

<table>
<thead>
<tr>
<th>Section</th>
<th>Description of the modification compared with the previous version</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
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<tr>
<td>....</td>
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6 LIST OF CONTRIBUTORS

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<thead>
<tr>
<th>Name</th>
<th>Function</th>
<th>Contribution</th>
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</thead>
<tbody>
<tr>
<td>PD Dr. Rolf Wachter</td>
<td>Author</td>
<td>Drafted the SOP</td>
</tr>
<tr>
<td>Dr. Sebastian Kufner</td>
<td>Reviewer</td>
<td>Expert review</td>
</tr>
<tr>
<td>Prof. Dr. Matthias Nauck</td>
<td>Head of Scientific Infrastructure</td>
<td>Expert review</td>
</tr>
<tr>
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<td>Phentyping &amp; QM Group</td>
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<tr>
<td>Prof. Dr. Carsten Tschöpe</td>
<td>Phentyping &amp; QM Group</td>
<td>Expert review</td>
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<tr>
<td>Dr. Benjamin Meder</td>
<td>Phentyping &amp; QM Group</td>
<td>Expert review</td>
</tr>
<tr>
<td>Dr. Christina Dösch</td>
<td>Phentyping &amp; QM Group</td>
<td>Expert review</td>
</tr>
<tr>
<td>Prof. Dr. Christoph Knosalla</td>
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<td>PD Dr. Renate Schnabel</td>
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<td>PD Dr. Stefanie Schulz</td>
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<tr>
<td>Dr. Annika Jagodzinski</td>
<td>Phentyping &amp; QM Group</td>
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<tr>
<td>Dr. Matthias Lutz</td>
<td>Phentyping &amp; QM Group</td>
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</tr>
<tr>
<td>Dr. Elham Kayvanpour</td>
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</tr>
<tr>
<td>Dr. Alexander Joost</td>
<td>Phentyping &amp; QM Group</td>
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</tr>
<tr>
<td>Matthias Quade</td>
<td>Phentyping &amp; QM Group</td>
<td>IT implementation</td>
</tr>
<tr>
<td>Mahsa Lee</td>
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<td>IT implementation</td>
</tr>
<tr>
<td>Linda Gusky</td>
<td>Phentyping &amp; QM Group</td>
<td>IT implementation</td>
</tr>
<tr>
<td>Sophia Lamp</td>
<td>Phentyping &amp; QM Group</td>
<td></td>
</tr>
<tr>
<td>Daniel Engler</td>
<td>Layout, coordination</td>
<td></td>
</tr>
<tr>
<td>Dr. Stephanie Lesser</td>
<td>Coordinator</td>
<td></td>
</tr>
</tbody>
</table>
## 7 AnNEX

### 7.1 eCRF Module

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

**General information relating to the anamnesis**

<table>
<thead>
<tr>
<th>I. Date of examination**</th>
<th>Kommentar Query</th>
</tr>
</thead>
<tbody>
<tr>
<td>II. Quality level**</td>
<td>Bitte auswählen &gt;</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>1.1. Sex**</th>
<th>Kommentar Query</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2. Date of Birth**</td>
<td>Kommentar Query</td>
</tr>
<tr>
<td>1.3. Height**</td>
<td>Kommentar Query</td>
</tr>
<tr>
<td>1.4. Weight**</td>
<td>Kommentar Query</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.5. Ethnicity: Caucasian**</th>
<th>Kommentar Query</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.6. Black skin colour?**</td>
<td>Kommentar Query</td>
</tr>
<tr>
<td>1.7. Family history of myocardial infarction or stroke in parents, siblings or children under the age of 65 for women or under 65 for men**</td>
<td>Kommentar Query</td>
</tr>
</tbody>
</table>

#### 2. Cardiovascular risk factors

<table>
<thead>
<tr>
<th>2.1. Diabetes mellitus**</th>
<th>Kommentar Query</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2. Arterial hypertension**</td>
<td>Kommentar Query</td>
</tr>
<tr>
<td>2.3. Dyslipidaemia**</td>
<td>Kommentar Query</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.4. Smoker**</th>
<th>Kommentar Query</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Ex-smoker since**</th>
<th>Kommentar Query</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pack years**</td>
<td>Kommentar Query</td>
</tr>
</tbody>
</table>

| 2.5. Drinks per week* | Kommentar Query |

#### 2.6. Medically diagnosed alcoholism*

| Kommentar Query |

| 2.7. Renal failure | Kommentar Query |

| 2.7.1. Degree of renal dysfunction* | Kommentar Query |

<table>
<thead>
<tr>
<th>1 – GFR 90 ml/min or higher</th>
<th>Kommentar Query</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 – GFR 80–89 ml/min</td>
<td>Kommentar Query</td>
</tr>
<tr>
<td>3 – GFR 30–59 ml/min</td>
<td>Kommentar Query</td>
</tr>
<tr>
<td>4 – GFR 15–29 ml/min</td>
<td>Kommentar Query</td>
</tr>
<tr>
<td>5 – GFR &lt; 15 ml/min or current dialysis dependency</td>
<td>Kommentar Query</td>
</tr>
</tbody>
</table>

*In this eCRF, items marked with two asterisks (**) must be completed (basic data set). Items marked with one asterisk (*) should be completed to the greatest extent possible.
### 2.8. Current Dialysis Dependency
- Yes
- No
- Unknown
- Not assessed

### 3. Cardiac Diagnoses (Anamnese and Previous Findings)

#### 3.1. Coronary heart disease
- Yes
- No
- Unknown
- Not assessed

#### 3.2. Status post myocardial infarction
- Yes
- No
- Unknown
- Not assessed

#### 3.3. Cardiomyopathy
- Yes
- No
- Unknown
- Not assessed

**Note:** If the response to this question is "yes", please complete the "Cardiomyopathy Diagnostics" form.

#### 3.4. Heart failure
- Yes
- No
- Unknown
- Not assessed

##### 3.4.1. S.p. decompensation
- Yes
- No
- Unknown
- Not assessed

##### 3.4.2. Initial diagnosis of heart failure
- [ ]

##### 3.4.3. Current NYHA class
- I
- II
- III
- IV
- Unknown
- Not assessed

#### 3.5. Atrial fibrillation/flutter
- Yes
- No
- Unknown
- Not assessed

#### 3.6. Current or previous diagnosis by a doctor of heart valve disease
- Yes
- No
- Unknown
- Not assessed

#### 3.7. Diagnosis by a doctor of endocarditis
- Yes
- No
- Unknown
- Not assessed

#### 3.8. Diagnosis by a doctor of a congenital heart defect
- Yes
- No
- Unknown
- Not assessed

### 4. Previous cardiovascular interventions

#### 4.1. Interventional coronary revascularization
- Yes
- No
- Unknown
- Not assessed

##### 4.1.1. If yes, date of last intervention
- [ ]

#### 4.2. Peripheral revascularization
- Yes
- No
- Unknown
- Not assessed

##### 4.2.1. If yes, date of last intervention
- [ ]

#### 4.3. Coronary bypass operation
- Yes
- No
- Unknown
- Not assessed

##### 4.3.1. If yes, date of last intervention
- [ ]

#### 4.4. Other vascular operation
- Yes
- No
- Unknown
- Not assessed

##### 4.4.1. If yes, date of last intervention
- [ ]

#### 4.5. Heart valve operation
- Yes
- No
- Unknown
- Not assessed

##### 4.5.1. If yes, date of last intervention
- [ ]

##### 4.5.2. Type of last intervention
- Open surgery
- Catheter-based
- Replacement
- Reconstruction
- Unknown
- Not assessed

#### 4.5.3. If more than one procedure on one valve was performed, please provide details of the last operation
- Aortic valve
  - Native
  - Reoperation
  - Mechanical
  - Bioprosthesis
  - TAVI
  - Unknown
  - Not assessed

*In this eCRF, items marked with two asterisks (**) must be completed (basic data set). Items marked with one asterisk (*) should be completed to the greatest extent possible.*
### 4.6. Implantation of a PaceMaker or Defibrillator

- **4.6.1. If yes, what was implanted?**
  - Options: pacemaker, defibrillator, unknown, not assessed
- **4.6.2. If yes, date of last event (implantation/exchange):**
  - Format: DD MM YYYY
- **4.6.3. If pacemaker, please give pacemaker type**
  - Options: 1-chamber pacemaker (e.g. VVI), 2-chamber pacemaker (e.g. DDD), biventricular pacemaker (CRT)

### 4.7. Other Devices

- **4.7.1. Cardiac Contractility Modulation (CCM)**
  - Options: yes, no, unknown, not assessed
- **4.7.2. Intra-aortic balloon pump (IABP)**
  - Options: yes, no, unknown, not assessed
- **4.7.3. Other devices**

### 4.8. S.p. Myocardial Biopsy

- **4.8.1. Date of myocardial biopsy**
  - Format: DD MM YYYY
- **4.8.2. Biopsy sites**
  - Options: left ventricle, right ventricle, left and right ventricle, unknown, not assessed

### 5. Current Secondary Diagnoses

- **5.1. PAC**
  - Options: yes, no, unknown, not assessed
- **5.1.1. Fontaine stage**
  - Options: I, IIa, IIb, III, IV, unknown, not assessed
- **5.1.2. Acute Ischaemic Occlusion**
  - Options: yes, no, unknown, not assessed
- **5.2. Stroke/TIA**
  - Options: yes, no, unknown, not assessed
- **5.2.1. Date**
  - Format: DD MM YYYY
- **5.2.2. Aetiology**
  - Options: ischaemic, haemorrhagic, unknown, not assessed
- **5.2.3. Diagnosis**
  - Options: TIA, stroke, unknown, not assessed
- **5.2.4. Stroke severity**
  - Options: minor, major, unknown, not assessed
- **5.2.5. Consequences of the stroke**
  - Options: disabling, non-disabling, unknown, not assessed
- **5.3. Chronic Lung Disease**
  - Options: yes, no, unknown, not assessed

### 5.4. Primary Pulmonary Hypertension

- **5.5. Depression**
  - Options: yes, no, unknown, not assessed

---

*Note: In this eCRF, items marked with two asterisks (**) must be completed (basic data set). Items marked with one asterisk (*) should be completed to the greatest extent possible.*
is "yes", please complete the "Depression" form.

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

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

6. The next three anamnestic questions are for women only

6.1. Menopause?***
   - yes
   - no
   - unknown
   - not assessed

6.1.1. Year of menopause**
   

6.2. Day last menstrual period began**
   

7. Blood pressure after 5 minutes at rest

7.1. Systolic**
   - mmHg

7.2. Diastolic**
   - mmHg

8. Heart rate after sitting down for 5 minutes

8.1. Heart rate**
   - per minute

9. Further diagnoses

9.1. Dyspnoea on exertion*
   - yes
   - no
   - unknown
   - not assessed

9.2. Dyspnoea at rest*
   - yes
   - no
   - unknown
   - not assessed

9.3. Peripheral oedema*
   - yes
   - no
   - unknown
   - not assessed

9.4. Jugular venous distention*
   - yes
   - no
   - unknown
   - not assessed

9.5. Pulmonary rales*
   - yes
   - no
   - unknown
   - not assessed

10. Laboratory diagnostics (blood)

For clinically stable patients, not more than 1 week old, otherwise up to date!

10.1. Date blood sample was taken**
   - Where applicable, give date for the oldest value

10.2. Haemoglobin***
   - Unit***
     - mmol/l
     - g/dl

10.3. Creatinine (serum, heparin plasma)***
   - Unit***
     - μmol/l
     - mg/dl

10.4. Total cholesterol***
   - Unit***
     - mmol/l
     - mg/dl
# Cardiomyopathy Diagnostics

## General Diagnostic Information

| I. Were cardiomyopathy diagnostics collected?* | Yes □ No □ Unknown □ Not assessed |
| II. Quality level* | Bitte auswählen □ |

## Cardiomyopathy Diagnostics

1. Dilated cardiomyopathy* □ Yes □ No □ Unknown □ Not assessed
   - If "yes"* □ Hereditary □ Inflammatory □ Toxic □ Other □ Unknown □ Not assessed
   - Please specify:

2. Left ventricular non-compaction cardiomyopathy* □ Yes □ No □ Unknown □ Not assessed

3. Hypertrophic cardiomyopathy* □ Yes □ No □ Unknown □ Not assessed
   - Non-obstructive □ Obstructive □ Unknown □ Not assessed
   - Hereditary □ Non-familial □ Unknown □ Not assessed

3.1. Positive pressure gradient at rest (echocardiography)* □ Yes □ No □ Unknown □ Not assessed
   - mmHg □

3.2. Positive pressure gradient on exertion (stress echocardiography)* □ Yes □ No □ Unknown □ Not assessed
   - mmHg □

3.3. Wall thickness measured by* □ MRT □ Echocardiography □ Unknown □ Not assessed
   - Septum* □ Yes □ No □ Unknown □ Not assessed
   - Lateral* □ Yes □ No □ Unknown □ Not assessed
   - mm □

4. Arrhythmogenic right ventricular cardiomyopathy* □ Yes □ No □ Unknown □ Not assessed

4.1. Positive biopsy for plakoglobin* □ Yes □ No □ Unknown □ Not assessed

5. Myocarditis* □ Yes □ No □ Unknown □ Not assessed

5.1. Viral myocarditis* □ Yes □ No □ Unknown □ Not assessed

5.2. Autoimmune myocarditis* □ Yes □ No □ Unknown □ Not assessed

5.3. Toxic myocarditis □ Yes □ No □ Unknown □ Not assessed

5.4. Other* □ Yes □ No □ Unknown □ Not assessed
<table>
<thead>
<tr>
<th></th>
<th>Toxic cardiomyopathy*</th>
<th>Alcohol-induced*</th>
<th>Status post chemotherapy*</th>
<th>Diagnosis*</th>
<th>Family history*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>yes</td>
<td>no</td>
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<td></td>
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</table>

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7.2 DEFINITION KARDIOMYOPATHIEN AUS TORCH-REGISTER

7.2.1 Definition of cardiomyopathies included in the registry

7.2.1.1 Definition of hereditary dilated cardiomyopathy

The definition of hereditary dilated cardiomyopathy (DCM) established for DZHK TORCH has been adopted from the following criteria for the study of familial dilated cardiomyopathies provided by the Collaborative Research Group of the European Human and Capital Mobility Project on Familial Dilated Cardiomyopathy in 1999 and by the European Society of Cardiology Working Group on Myocardial and Pericardial Diseases position statement on the Classification of the cardiomyopathies in 2008. For the purpose of our registry, these recommendations have been updated in regards to imaging modalities used for characterization and in regards to the range of exclusion criteria.

DCM is defined by the presence of both left ventricular dilatation and left ventricular systolic dysfunction in the absence of abnormal loading conditions (hypertension, valve disease) or relevant coronary artery disease sufficient to cause global systolic impairment. Right ventricular dilation and dysfunction may be present but are not necessary to establish the diagnosis.

**Major criteria**

**Dilatation**: Left ventricular end-diastolic diameter (LVEDD) > 117 % of the predicted value corrected for age and body surface area [Henry-Formel (LVEDD= 45.3 * BSA1/3 – 0.03*Age – 7.2) as ascertained by echocardiography or MRI.

**Systolic dysfunction**: Ejection fraction (EF) of the left ventricle <45% as ascertained by echocardiography or MRI.

**Minor criteria**

- Unexplained supraventricular (atrial fibrillation or sustained arrhythmias) or ventricular arrhythmias, frequent (>1000 . 24 h^-1) or repetitive (three or more beats with >120 beats . min^-1) before the age of 50
- Left ventricular dilatation >112% of the predicted value
- Left ventricular dysfunction: ejection fraction <50%
- Unexplained conduction disease: II or III atrioventricular conduction defects, complete left-ventricular bundle branch block, sinus nodal dysfunction
- Unexplained sudden death or stroke before 50 years of age
• Segmental wall motion abnormalities (<1 segment, or 1 if not previously present) in the absence of intraventricular conduction defect or ischaemic heart disease.

• Elevated NTproBNP: In patients presenting with non-acute dyspnea (> 14 days), a value exceeding 125 ng/L (age < 75 years) or 450 ng/L (> 75 years) is considered abnormal. In patients with acute dyspnea or signs of heart failure, a value below 300 ng/L excludes acute heart failure (age-independent rule-out). An age-dependent value exceeding 900 ng/L (<50 years), 1,200 ng/L (50-69 years) or 1,800 ng/L (>70 years) is considered abnormal. Values between rule-out and age-dependent rule-in cutoff are called greyzone values and merit attention. Cut-off for BNP are different and are not dependent on age or gender. A value > 35 ng/L is considered abnormal for non-acute presentation, and 100 ng/L for acute manifestation.

• Data for cardiac troponins are less established: Detectable cTn concentrations are associated with midterm and longer term adverse outcomes. For hscTn hazard for death and hospitalization for heart failure has been reported to start below the 99th percentile value. A value > 99th percentile, e.g. 14 ng/L for hscTnT is definitely elevated and presumably of prognostic importance.

• Cardiac limitation during spiroergometry:
  - peakVO2 > 85% predicted value
  - VO2 at anaerobic threshold (AT) < 40% predicted VO2
  - Breathing Reserve (BR) ≥ 30% (at least ≥ 15 L/min)
  - Heart Rate Reserve (HRR) > 15/min
  - Aerobic Capacity (dVO2/dWR) ≤ 8 mL/min*W
  - Relative Dead Space Ventilation (VD/VT) ≤ 35% at rest and exercise

Exclusion criteria

• Pre-existing other cardiac diseases such as significant valvular, congenital, ischemic or pericardial diseases

• Severe arterial hypertension (RR> 160/100mmHg or hypertension despite therapy with at least 3 different drugs)

• Primary pulmonary artery hypertension

• Chronic advanced disorders requiring treatment or being the predominant clinical finding on initial presentation (rheumatic, autoimmune, malignancy, insulin dependent DM, endocrine, ESDR, liver failure, etc.)

• History of treatment with cardiotoxic agents and radiation

• Drug and alcohol abuse

Categorization which will be applied in the registry:

• Definite DCM: An individual is defined as definitely affected in the presence of both major or left ventricular dilatation (>117%) plus one minor criterion or three minor criteria – without the presence of an exclusion criterion.
• Probable DCM: An individual is defined as probably affected in the presence of left ventricular dilatation (>112% of the predicted value) and left ventricular dysfunction (ejection fraction <50%) – without the presence of an exclusion criterion.

• Possible DCM: An individual is defined as possibly affected in the presence of left ventricular dysfunction (ejection fraction <50%) – without the presence of an exclusion criterion.

See references no. 41-45

7.2.1.2 Clinical and biopsy-based definition of inflammatory dilated cardiomyopathy and acute myocarditis

The definitions of inflammatory dilated cardiomyopathy (DCMi) and acute myocarditis established for DZHK TORCH have been adopted from criteria described in the 1995 Report of the World Health Organization/International Society and Federation of Cardiology Task Force on the Definition and Classification of Cardiomyopathies, the World Heart Federation consensus conferences’ definition of inflammatory cardiomyopathy (myocarditis) in 1999 (Marburg Classification) and in the European Society of Cardiology Working Group on Myocardial and Pericardial Diseases position statement on the Classification of the cardiomyopathies in 2008.

Myocardial inflammation (autoimmune, viral, or postviral) is mediated by the effector cells of the immune system. In contrast to active myocarditis, which is by definition an acute inflammatory disorder with inflammatory cell associated myocyte necrosis of the heart, with often preserved left ventricular size, inflammatory DCM is defined by the presence of inflammatory cells in association with left ventricular dilatation and reduced systolic function (dilatation and systolic function analog to definition of hereditary or post-inflammatory/infectious DCM). Histology and/or immunocytocchemistry are required for the diagnosis. A proportion of individuals with inflammatory DCM have persistence of viral genomes or proteins in the myocardium. (The term viral persistence in DCM should only be applied in those cases, in which viral RNA or DNA but no inflammation is present.) Viral persistence can be associated with or without inflammation.

World Health Organization Marburg Classification

First biopsy:

• Acute/active myocarditis: a clear-cut infiltrate (diffuse, focal or confluent) of >14 leukocytes/mm² (preferably activated T cells). The amount of the infiltrate should be quantified by immunohistochemistry. Necrosis or degeneration is compulsory; fibrosis may be absent or present and should be graded.

• Chronic myocarditis (histologically described as borderline myocarditis): an infiltrate of >14 leukocytes/mm² (diffuse, focal or confluent, preferably activated T cells). Quantification
should be made by immunohistochemistry. Necrosis or degeneration is usually not evident; fibrosis may be absent or present and should be graded.

- No myocarditis: No infiltrating cells or <14 leukocytes/mm².

Subsequent biopsies: (histology and immunohistochemistry)

- Ongoing (persistent) myocarditis. Criteria as in active or chronic myocarditis.
- Resolving (healing) myocarditis. Criteria as in acute or chronic myocarditis, but the immunologic process is sparser than in the first biopsy.
- Resolved (healed) myocarditis. Corresponds to the Dallas classification and the immunohistochemical evaluation.

The amount and distribution of fibrosis should be described similarly as no (grade 0), mild (grade 1), moderate (grade 2), or severe (grade 3). Localisation or formation of fibrosis should be outlined as endocardial, replacement or interstitial.

Expanded criteria for clinical and biopsy-based diagnosis of myocarditis

- Suspicious for myocarditis = 2 positive categories
- Compatible with myocarditis = 3 positive categories
- High probability of being myocarditis = all 4 categories positive.
- Definite proof of myocardial inflammation and/or viral infection demands biopsy analysis (positive category 4)

NOTE: Any matching feature in category = positive for category; the categories I-III define the clinical diagnosis of myocarditis/inflammatory CMP only. A definite proof demands biopsy analysis (positive for category IV).

Category I: clinical symptoms

- Clinical heart failure
- Fever
- Viral prodrome
- Fatigue
- Dyspnoea on exertion
- Chest pain
- Palpitations
- Pre-syncope or syncope
Category II: clinical evidence of cardiac structural/functional perturbation in the absence of regional coronary ischaemia

- Echo evidence
- Regional wall motion abnormalities
- Cardiac dilation
- Regional cardiac hypertrophy
- Troponin release
- Troponin result has high sensitivity (>0.1 nanogram/mL)
- Positive indium-111 antimony scintigraphy and normal coronary angiography or absence of reversible ischaemia by coronary distribution on perfusion scan

Category III: cardiac MRI

- Increased myocardial T2 signal on inversion recovery sequence
- Delayed contrast enhancement following gadolinium-diethylenetriamine pentaacetic acid (DTPA) infusion.

Category IV: myocardial biopsy, pathologic or molecular analysis as definite proof of myocardial inflammation and viral infection

- Pathology findings compatible with Dallas criteria supplemented by immunohistochemistry
- Presence of viral genome by PCR or in situ hybridisation.

See references no. 46-51

7.2.1.3 Definition of hypertrophic cardiomyopathy

The definition of hypertrophic cardiomyopathy (HCM) and in specific, hypertrophic obstructive cardiomyopathy (HOCM) established for DZHK TORCH has been adopted from the American/European Consensus Document on Hypertrophic Cardiomyopathy in 2003 referenced below. For the purpose of our registry, these recommendations have been updated in regards to imaging modalities used for characterization and in regards to the range of exclusion criteria.

Evidence of left ventricular hypertrophy and/or increased left ventricular mass.

Definition of hypertrophy:

- Wall thickness (including asymmetric hypertrophy in individual segments) ≥15mm
- Septal/posterior wall thickness ratio >1.3 in normotensive patients, or
- Septal/posterior wall thickness ratio >1.5 in hypertensive patients.
Exclusion criteria:

Hemodynamic stressors sufficient to explain hypertrophy

- systemic arterial hypertension
- Valvular disease
- athlete's heart

Systemic storage disorders

- Amyloidosis
- Glycogen storage disease
- Anderson-Fabry disease

Categorization which will be applied in the registry:

- Definite HCM: An individual is defined as definitely affected in the presence of left ventricular hypertrophy as stated above and/or increased left ventricular mass between ≥122 g/m² (women) and ≥149 g/m² (men) and impaired longitudinal function – without the presence of an exclusion criterion.
- Probable HCM: An individual is defined as probably affected in the presence of left ventricular hypertrophy with a wall thickness (including asymmetric hypertrophy in individual segments) between 11 – 14 mm (women) and 12 – 14 mm (men) and/or increased left ventricular mass between 109-121 g/m² (women) and 132-148 g/m² (men) and impaired longitudinal function – without the presence of an exclusion criterion.
- Possible HCM: An individual is defined as probably affected in the presence of left ventricular hypertrophy with a wall thickness (including asymmetric hypertrophy in individual segments) between 10 – 11 mm (women) and 11 – 12 mm (men) and/or increased left ventricular mass between 96-108 g/m² (women) and 116-131 g/m² (men) and impaired longitudinal function – without the presence of an exclusion criterion.

Specific: Hypertrophic obstructive cardiomyopathy

Evidence of HCM according to criteria listed above

AND

- Evidence of a significant left ventricular outflow tract obstruction (gradient ≥ 30 mmHg) at rest during stable pre-/afterload
- Evidence of a significant dynamic left ventricular outflow tract obstruction (gradient \( \geq 50 \text{mmHg} \)) (either during exercise, after glyceryl trinitrate (GTN) administration, or the Valsalva maneuver) during stable pre-/afterload

**Specific: Suspected familial HCM**

In family members of a HCM index patient, the following criteria are applied to define suspected HCM cases (1 major or 2 minor echocardiographic criteria, or 1 major echocardiographic criterion and 2 minor electrocardiographic criteria).

<table>
<thead>
<tr>
<th>European Echo criteria</th>
<th>European ECG criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Major:</strong></td>
<td><strong>Major:</strong></td>
</tr>
<tr>
<td>MWT ( \geq 13 \text{mm anteroseptal or posterior} )</td>
<td>Abnormal Q-waves ( \geq 2 ) leads</td>
</tr>
<tr>
<td>MWT ( \geq 15 \text{mm posteroseptal, lateral or severe SAM} )</td>
<td>T-wave Inversion ( \geq 2 ) leads</td>
</tr>
<tr>
<td><strong>Minor:</strong></td>
<td><strong>Minor:</strong></td>
</tr>
<tr>
<td>MWT ( \geq 12 \text{mm anteroseptal or posterior} )</td>
<td>deep S in lead V2</td>
</tr>
<tr>
<td>MWT ( \geq 14 \text{mm posteroseptal, lateral or moderate SAM} )</td>
<td>repolarization changes</td>
</tr>
</tbody>
</table>

MWT = „myokardial wall thickness“; SAM = „systolic anterior motion“

See references no. 52-69

**7.2.1.4 Definition of left ventricular non-compaction cardiomyopathy**

For the lack of common standardized diagnostic criteria for the left ventricular non-compaction cardiomyopathy (LVNC) following definition was established for DZHK TORCH according to the published studies.

To prevent over diagnosing of LVNC the results by echocardiography and cardiac MRI must be concordant.

**Diagnosis is considered definite when the following criteria are present:**

1. Absence of congenital heart disease, infiltrative/hypertrophic cardiomyopathy or documented coronary artery disease
2. Echocardiographic diagnostic features
According to Stöllberger et al.: More than three confirmed trabeculations within one image plane, apical to the insertion of the papillary muscles. Trabeculations with the same echogenicity as the myocardium and synchronous movement with ventricular contractions. Perfusion of the intertrabecular spaces from the left ventricular cavity. Ratio of compacted to non-compacted segment at least 1:2 (≤ 0.5). Acquisition of the images: apical four chamber view and three chamber view; angulation of the transducer and acquisition of pictures in atypical views to obtain the technically best picture quality for differentiation between false chords/aberrant bands and trabeculations.

3. MRI diagnostic features
Petersen et al.: Ratio between the non-compacted and compacted layer > 2.3. Measurement: at end-diastole.

See references no. 70-76

7.2.1.5 Definition of arrhythmogenic right ventricular cardiomyopathy

The definitions of arrhythmogenic right ventricular cardiomyopathy (ARVC), also called arrhythmogenic right ventricular dysplasia (ARVD), established for DZHK TORCH have been adopted from criteria described in the 2010 revised Task Force Criteria by Marcus et al. (Original International Task Force criteria from the European Society of Cardiology and the International Society and Federation of Cardiology published in 1994).

Presence of ARVC/ARVD is established following the combination of the below listed criteria as:

- **definite:**
  - two major criteria, or
  - one major plus two minor criteria, or
  - four minor criteria
    with each criterion being from a different category

- **borderline:**
  - one major and one minor, or
  - three minor criteria
    with each criterion being from a different category

- **possible:**
  - one major, or
  - two minor criteria
    with the criteria being from a different category
I. Global or regional dysfunction and structural alterations

Major

By 2D echo:

• Regional RV akinesia, dyskinesia, or aneurysm and 1 of the following (end diastole):
  - PLAX RVOT $\geq 32$ mm (corrected for body size [PLAX/BSA] $\geq 19$ mm/m²)
  - PSAX RVOT $\geq 36$ mm (corrected for body size [PSAX/BSA] $\geq 21$ mm/m²)
  - or fractional area change $\leq 33$ percent

By MRI:

• Regional RV akinesia or dyskinesia or dyssynchronous RV contraction and 1 of the following:
  - Ratio of RV end-diastolic volume to BSA $\geq 110$ mL/m² (male) or $\geq 100$ mL/m² (female)
  - or RV ejection fraction $\leq 40$ percent

By RV angiography:

• Regional RV akinesia, dyskinesia, or aneurysm

Minor

By 2D echo:

• Regional RV akinesia or dyskinesia and 1 of the following (end diastole):
  - PLAX RVOT $\geq 29$ to $< 32$ mm (corrected for body size [PLAX/BSA] $\geq 16$ to $< 19$ mm/m²)
  - PSAX RVOT $\geq 32$ to $< 36$ mm (corrected for body size [PSAX/BSA] $\geq 18$ to $< 21$ mm/m²)
  - or fractional area change $> 33$ percent to $\leq 40$ percent

By MRI:

• Regional RV akinesia or dyskinesia or dyssynchronous RV contraction and 1 of the following:
  - Ratio of RV end-diastolic volume to BSA $\geq 100$ to $< 110$ mL/m² (male) or $\geq 90$ to $< 100$ mL/m² (female)
  - or RV ejection fraction $> 40$ percent to $\leq 45$ percent

II. Tissue characterization of wall

Major

• Residual myocytes <60 percent by morphometric analysis (or <50 percent if estimated), with fibrous replacement of the RV free wall myocardium in ≥1 sample, with or without fatty replacement of tissue on endomyocardial biopsy
**Minor**

- Residual myocytes 60 percent to 75 percent by morphometric analysis (or 50 percent to 65 percent if estimated), with fibrous replacement of the RV free wall myocardium in ≥1 sample, with or without fatty replacement of tissue on endomyocardial biopsy

**III. Repolarization abnormalities**

**Major**

- Inverted T waves in right precordial leads (V₁, V₂, and V₃) or beyond in individuals >14 years of age (in the absence of complete right bundle-branch block QRS ≥120 ms)

**Minor**

- Inverted T waves in leads V₁ and V₂ in individuals >14 years of age (in the absence of complete right bundle-branch block) or in V₄, V₅, or V₆

- Inverted T waves in leads V₁, V₂, V₃, and V₄ in individuals >14 years of age in the presence of complete right bundle-branch block

**IV. Depolarization/conduction abnormalities**

**Major**

- Epsilon wave (reproducible low-amplitude signals between end of QRS complex to onset of the T wave) in the right precordial leads (V₁ to V₃)

**Minor**

- Late potentials by SAECG in ≥1 of the following 3 parameters in the absence of a QRS duration of ≥110 ms on the standard ECG
  - Filtered QRS duration (fQRS) ≥114 ms
  - Duration of terminal QRS <40 µV (low-amplitude signal duration) ≥38 ms
  - Root-mean-square voltage of terminal 40 ms ≤20 µV
- Terminal activation duration of QRS ≥55 ms measured from the nadir of the S wave to the end of the QRS, including R', in V₁, V₂, or V₃, in the absence of complete right bundle-branch block
V. Arrhythmias

Major

• Nonsustained or sustained ventricular tachycardia of left bundle-branch morphology with superior axis (negative or indeterminate QRS in leads II, III, and aVF and positive in lead aVL)

Minor

• Nonsustained or sustained ventricular tachycardia of RV outflow configuration, left bundle-branch block morphology with inferior axis (positive QRS in leads II, III, and aVF and negative in lead aVL) or of unknown axis

• >500 ventricular extrasystoles per 24 hours (Holter)

VI. Family history

Major

• ARVC/D confirmed in a first-degree relative who meets current Task Force criteria

• ARVC/D confirmed pathologically at autopsy or surgery in a first-degree relative

• Identification of a pathogenic mutation\(\Delta\) categorized as associated or probably associated with ARVC/D in the patient under evaluation

Minor

• History of ARVC/D in a first-degree relative in whom it is not possible or practical to determine whether the family member meets current Task Force criteria

• Premature sudden death (<35 years of age) due to suspected ARVC/D in a first-degree relative

• ARVC/D confirmed pathologically or by current Task Force Criteria in second-degree relative

See references nr. 77-78
7.2.1.6 Definitions for biopsy diagnosis of cardiomyopathies

Active Myocarditis:

Infiltrating lymphocytes (CD3) and/or monocytes/macrophages (CD68 in paraffin fixed tissues, CD11b in unfixed/frozen tissues) + inflammatory cell associated myocyte necrosis. Locally or diffusely enhanced expression of cell adhesion molecules.

Specific disease entities:

Giant cell myocarditis, eosinophilic myocarditis, granulomatous myocarditis (e.g. sarcoidosis)

Borderline-Myocarditis/inflammatory cardiomyopathy:

>14 infiltrating leukocytes with up to 4 monocytes/mm² with the presence of CD 3 positive T-lymphocytes ≥7 cells/mm² or > 35 monocytes/macrophages (CD68 in paraffin fixed tissues, CD11b in unfixed/frozen tissues) without inflammatory cell associated myocyte necrosis in addition to an enhanced expression of cell adhesion molecules (HLA-1 or HLA-DR, CD54/ICAM-1, CD106/VCAM-1) or

Focal infiltrates of inflammatory cells (lymphocytes, monocytes/macrophages, leukocytes) in histologically (paraffin) or immunohistologically (frozen) stained tissues.

No Myocarditis/DCM:

Cell numbers of infiltrating lymphocytes or monocytes/macrophages are below those defining Borderline-Myocarditis or inflammatory CMP; a mildly enhanced expression of cell adhesion molecules (HLA-1/-DR and CD54/ICAM-1) may be present in postinflammatory tissues (resolved inflammatory cell infiltrates).

No focal inflammatory cell infiltrates in histologically or immunohistochemically analyzed tissues

Histology: cardiomyocyte hypertrophy, interstitial fibrosis, and scars may be present and indicate progressive disease

Viral myocarditis cardiomyopathy:

Positive proof of viral genomes (PCR) with or without myocardial inflammation. Consideration of virus subtypes, virus loads, and replicative intermediates (mRNA) indicating active/recent infection or virus reactivation (myocardial tissue, blood).
HCM:

Often no specific histological or immunohistochemical features, since endomyocardial biopsy may be regular. Myocyte hypertrophy, fibrosis, scars, myocardial inflammation and viral genomes may be present. Amyloidosis and storage diseases have to be excluded.

ARVD/C:

Due to the main localization of the disease process, there are often no specific histological or immunohistochemical features and endomyocardial biopsy specimens may be regular. Myocyte hypertrophy or atrophy, fibrosis, scars, myocardial inflammation and viral genomes may be present. A reduced expression of gap junction proteins (immunohistochemistry) may indicate ARVD. In the advanced stage of the disease, fibro-fatty degeneration of myocardial tissue proves ARVD.

Genetic/hereditary:

Genetic testing for specific gene defects/SNPs. In addition, histology, immunohistochemistry and molecular biology as defined above.

See references nr. 46-51

7.2.2 References


17. Lang RM, Bierig M, Devereux RB, Flachskampf FA, Foster E, Pellikka PA, Picard MH, Roman MJ, Seward J, Shewewise JS, Solomon SD, Spencer KT, Sutton MS, Stewart WJ. Recommendations for chamber quantification: a report from the American Society of Echocardiography’s Guidelines and Standards Committee and the Chamber Quantification Writing Group, developed in conjunction with the European Association of Echocardiography, a branch of the European Society of Cardiology. J AM Soc Echocardiogr 2005;18:1440-1463.


59. Lang RM, Bierig M, Devereux RB, Flachskampf FA, Foster E, Pellikka PA, Picard MH, Roman MJ, Seward J, Shanewise JS, Solomon SD, Spence KT, Sutton GS, Stewart WJ. Recommendations for chamber quantification: a report from the American Society of Echocardiography’s Guidelines and Standards Committee and the Chamber Quantification Writing Group, developed in conjunction with the European Association of Echocardiography, a branch of the European Society of Cardiology. J Am Soc Echocardiogr 2005;18:1440-1463.


7.3 ANLAGE NIH STROKE SCALE

<table>
<thead>
<tr>
<th>13</th>
<th>Bewusstseinslage (Vigilanz)</th>
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<tbody>
<tr>
<td>(0)</td>
<td>Wach, unmittelbar antwortend.</td>
</tr>
<tr>
<td>(1)</td>
<td>Reagiert oder antwortet, wenn durch geringe Reize oder Ansprache aktiviert wird.</td>
</tr>
<tr>
<td>(2)</td>
<td>Reagiert, aber nicht in einer angemessenen Weise auf direkte Reize oder direkten Anordnungen.</td>
</tr>
<tr>
<td>(3)</td>
<td>Still, aber ansprechbar.</td>
</tr>
<tr>
<td>(4)</td>
<td>Still, nicht antwortend oder nicht mit aktivem Gegenstand.</td>
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Anmerkung: Bei Koma erhöht Skala 7 (Extremitätenalter) 0 Punkte.

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<tr>
<td>(1)</td>
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<tr>
<td>(2)</td>
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Anmerkung: Bei fehlender Beurteilbarkeit 0 Punkte.

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<tr>
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<tr>
<td>(2)</td>
<td>Aufforderung nur in Teilbereichen befolgt.</td>
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</tbody>
</table>

Anmerkung: Bei fehlender Beurteilbarkeit 0 Punkte.

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<th>12</th>
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<td>(0)</td>
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<tr>
<td>(1)</td>
<td>Blickbewegungen nach einem oder beiden Augenabnormalitäten.</td>
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<tr>
<td>(2)</td>
<td>Blickbewegungen nach mehr als einem Augenabnormalitäten.</td>
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Anmerkung: Keine Blickbewegungen nicht übersehen werden kann.

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<tr>
<td>(1)</td>
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<tr>
<td>(2)</td>
<td>Einschränkungen der ganzen Gesichtsfeldhälfte.</td>
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Anmerkung: Keine Einschränkungen nicht übersehen werden können.

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<td>(2)</td>
<td>Schwere Einschränkungen der Mund- und Augenbewegungen.</td>
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Anmerkung: Keine Fazialisparese nicht übersehen werden können.

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<th>15</th>
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<td>(1)</td>
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<tr>
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<td>Abweichungen, die den Arm in 90° Position halten können.</td>
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Anmerkung: Keine Abweichungen nicht übersehen werden können.

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<th>16</th>
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<td>(1)</td>
<td>Abweichungen, die die Beine in 30° Position halten können.</td>
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Anmerkung: Keine Abweichungen nicht übersehen werden können.

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Anmerkung: Keine Sensibilität nicht übersehen werden können.

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Anmerkung: Keine Sprache nicht übersehen werden können.

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<th>20</th>
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Anmerkung: Keine Dysarthrie nicht übersehen werden können.

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Anmerkung: Keine Neglect nicht übersehen werden können.
DZHK-SOP-K-02
Anamnese/Klinische Diagnosen

Version: V1.0  Gültig ab: 01.09.2014

Ersetzte Version: Vom:

Änderungshinweis:

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<th>Freigabe DZHK</th>
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<tbody>
<tr>
<td>Name</td>
<td>Rolf Wachter (Göttingen)*</td>
<td>Sebastian Kufner (München)</td>
<td>Matthias Nauck</td>
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*Adaptiert von den SOPs des Kompetenzzentrum Herzinsuffizienz

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DZHK-SOP-K-02
Anamnese/Klinische Diagnosen

Version: V1.0  Gültig ab: 01.09.2014
Ersetzte Version: Vom:
Änderungshinweis:

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<td>Thomas Eschenhagen</td>
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<tr>
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<td>(München)</td>
<td>26.08.2014</td>
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*Adaptiert von den SOPs des Kompetenznetzes Herzinsuffizienz

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**DZHK-SOP-K-02**

**Anamnese/Klinische Diagnosen**

Version: V1.0  
Gültig ab: 01.09.2014

Ersetzte Version:  
Vom:

Änderungshinweis:

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