IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

IQWiG Reports – V14-01

Systematic guideline search and appraisal, as well as extraction of relevant recommendations, for a DMP "chronic heart failure"[1]

Extract

1 Translation of Chapters 1 to 6 of the final report *Systematische Leitlinienrecherche und -bewertung sowie Extraktion relevanter Empfehlungen für ein DMP Chronische Herzinsuffizienz* (Version 1.0; Status: 19 November 2015). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

Publishing details

Publisher:

Institute for Quality and Efficiency in Health Care

Topic:

Systematic guideline search and appraisal, as well as extraction of relevant recommendations, for a DMP “chronic heart failure”

Commissioning agency:

Federal Joint Committee

Commission awarded on:

21 August 2014

Internal Commission No.:

V14-01

Address of publisher:

Institute for Quality and Efficiency in Health Care
Im Mediapark 8 (KölnTurm)
50670 Cologne
Germany
Tel.: +49 (0)221 – 35685-0
Fax: +49 (0)221 – 35685-1
E-mail: berichte@iqwig.de
Internet: www.iqwig.de

This report was prepared in collaboration with external experts.

The responsibility for the contents of the report lies solely with IQWiG.

According to §139 b (3) No. 2 of Social Code Book (SGB) V, Statutory Health Insurance, external experts who are involved in the Institute's research commissions must disclose "all connections to interest groups and contract organizations, particularly in the pharmaceutical and medical devices industries, including details on the type and amount of any remuneration received". The Institute received the completed *Form for disclosure of potential conflicts of interest* from each external expert. The information provided was reviewed by a Committee of the Institute specifically established to assess conflicts of interests. The information provided by the external experts on potential conflicts of interest is presented in Chapter A.11 of the full report. No conflicts of interest were detected that could endanger professional independence with regard to the work on the present commission.

External experts

- Stefanie Butz, Institute for General Medicine, University Hospital Hamburg-Eppendorf, Germany
- Dagmar Lühmann, Institute for General Medicine, University Hospital Hamburg-Eppendorf, Germany
- Katrin Pistorius, Curschmann Clinic, Timmendorfer Strand, Germany
- Martin Scherer, Institute for General Medicine, University Hospital Hamburg-Eppendorf, Germany

IQWiG thanks the external experts for their collaboration in the project.

IQWiG employees[2]

- Eva Höfer
- Catharina Brockhaus
- Meike Hansen
- Ulrich Siering
- Ulrike Lampert

Keywords: heart failure, disease management programme, methodological guideline appraisal

[2] Due to legal data protection regulations, employees have the right not to be named.

Key statement

Research question

The aim of the present investigation is to identify current, topic-relevant, evidence-based guidelines, extract their recommendations and designate those recommendations that are relevant for the care of patients in a disease management programme (DMP) “chronic heart failure”.

Conclusion

On the basis of Grades of Recommendation (GoR) (or alternatively of Levels of Evidence [LoE]) of the extracted recommendations from current evidence-based guidelines, relevant and potentially relevant recommendations on all prespecified healthcare aspects were identified for a DMP “chronic heart failure”. In addition, relevant and potentially relevant recommendations were identified on the healthcare aspects of patients with decompensated heart failure, palliative care, heart failure in specific patient groups, treatment of concomitant diseases, right heart failure, DMPs, and nursing management of nursing facility residents with heart failure.

The diagnostic recommendations refer to basic and further diagnostics of heart failure, as well as to the diagnostics of right heart failure.

For non-drug therapy and general measures, recommendations were identified on lifestyle changes, diet, weight control, on physical activity/sports, as well as on vaccinations.

For drug therapy, the recommendations identified refer to general aspects of drug therapy, as well as to treatment with angiotensin converting enzyme inhibitors, beta-blockers, angiotensin II receptor blockers, aldosterone antagonists, diuretics, cardiac glycosides, oral anticoagulants and antiplatelet agents, antiarrhythmic drugs, isosorbide dinitrate/hydralazine, inotropic drugs, as well as other drugs. Treatment with nutritional supplements is also addressed.

For interventional therapy, the recommendations identified refer to cardiac resynchronization therapy, implantable cardioverter defibrillators, mechanical circulatory support, heart transplantation, and heart valve replacement or reconstruction.

Furthermore, recommendations on patient monitoring and on patient training were identified.

In addition, for patients with decompensated heart failure, recommendations were identified on diagnostics, hospital admission, treatment goals, non-drug and drug therapy, as well as on monitoring.

Furthermore, the recommendations identified refer to the care of patients after decompensation of chronic heart failure, to palliative care and to the cooperation of healthcare sectors.

Specific recommendations were identified for heart failure in pregnancy and in children and adolescents. In addition, for treatment of concomitant or triggering diseases, recommendations for patients with the following disorders were identified: sleep disorders, coronary heart disease, hypertension, myocarditis, arrhythmogenic right ventricular cardiomyopathy, constrictive pericarditis, ventricular rhythm disorders, atrial fibrillation, anaemia, depression, anxiety disorders or sexual dysfunction.

Recommendations were also identified on DMPs and on heart failure management in skilled nursing facilities.

Table of contents

List of tables

Page

List of abbreviations

Abbreviation	Meaning
ACC	American College of Cardiology
ACCF	American College of Cardiology Foundation
ACCP	American College of Chest Physicians
ACE	angiotensin converting enzyme
AGREE	Appraisal of Guidelines for Research & Evaluation
AHA	American Heart Association
ARB	angiotensin II receptor blocker
ARVC	arrhythmogenic right ventricular cardiomyopathy
AV	atrioventricular
BNP	brain (or B-type) natriuretic peptide
CCS	Canadian Cardiovascular Society
CHD	coronary heart disease
COPD	chronic obstructive pulmonary disease
CPAP	continuous positive airway pressure
CRT	cardiac resynchronization therapy
CSNZ	Cardiac Society of Australia and New Zealand
DMP	disease management programme
ECG	electrocardiogram
EPE	electrophysiological examination
ESC	European Society of Cardiology
GoR	Grade of Recommendation
HFSA	Heart Failure Society of America
ICD	implantable cardioverter defibrillator
ICSI	Institute for Clinical Systems Improvement
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
LoE	Level of Evidence
LVEF	left ventricular ejection fraction
MQIC	Michigan Quality Improvement Consortium
MRI	magnetic resonance imaging
NICE	National Institute for Health and Clinical Excellence
NYHA	New York Heart Association
RCT	randomized controlled trial

1 Background

Disease management programmes

Disease management programmes (DMPs) are structured treatment programmes for chronically ill people, which are based on the findings of evidence-based medicine. Within the framework of these programmes, treatment methods are primarily used that correspond to the current state of scientific knowledge [1]. Patients thus receive health care that aims to prevent as far as possible the risk of late complications and acute deterioration of the disease and increase the quality of life of patients. The goal of DMPs is, among other things, to optimize treatment, promote collaboration with service providers, and thus better interlink diagnostic and therapeutic procedures [2].

Relevant disorder

The relevance of heart failure is increasing from a medical and health economic point of view [3]. It is a complex clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection of blood [4]. It is clinically manifest if typical symptoms such as dyspnoea, fatigue (reduction in performance), and/or fluid retention exist on the basis of cardiac dysfunction [5,6].

Depending on the heart chamber affected, one distinguishes between left and right heart failure. If both heart chambers are affected, one speaks of global heart failure. Another criterion for the differentiation of heart failure is the pumping function (ejection fraction): one distinguishes between heart failure with preserved ejection fraction (diastolic heart failure) and heart failure with reduced ejection fraction (systolic heart failure) [4,6,7].

Furthermore, one distinguishes between chronic heart failure developing over a longer period of time and acute heart failure occurring due to a sudden event (e.g. massive myocardial infarction, acute bradycardic or tachycardic heart rhythm disorders) [6].

Guidelines

For the present report the term “guidelines” is used according to the definition of the Institute of Medicine (IOM): “practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” [8] and “include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options” [9].

Guideline authors often award a “Grade of Recommendation” (GoR) and a “Level of Evidence” (LoE). The GoR reflects the strength of a recommendation and is usually based on a weighing of the benefit and risks of a treatment, on each specific healthcare context, as well as on the strength of the underlying evidence or the LoE. The LoE represents an assessment of internal validity of the studies underlying the recommendations; in this context, systematic reviews of randomized controlled trials (RCTs) are generally awarded the highest LoE.

However, guideline developers use different systems to grade evidence and, within the LoE, acknowledge a varying importance of the different clinical and epidemiological study types, as well as, if applicable, of further potentially biasing factors.

2 Research question

The aim of the present investigation is to identify current, topic-relevant, evidence-based guidelines, extract their recommendations and designate those recommendations that are relevant for the care of patients in a DMP “chronic heart failure”.

3 Methods

The investigation included guidelines that had been developed specifically for chronic heart failure. The target population of the guideline synopsis comprised children, adolescents up to 18 years and adults with chronic heart failure manifesting itself in the form of systolic heart failure with reduced ejection fraction (< 35 to 40%), diastolic heart failure with preserved systolic function, or global heart failure.

Only evidence-based guidelines applicable to the German healthcare system and published from 1 January 2009 onwards were included. The recommendations had to be clearly designated as such.

For this purpose, a systematic Internet search for guidelines was conducted in guideline databases, as well as on the websites of multidisciplinary and specialist guideline providers. In addition, information was screened from the hearing procedure on the preliminary report plan (protocol). The selection of relevant guidelines was performed by means of the screening of titles and abstracts, with subsequent assessment of the full texts of the potentially relevant guidelines. The title and abstract screening was performed by one reviewer and a second reviewer checked the result. The assessment of the full texts and the selection of the guidelines to be included were performed by 2 reviewers independently of one another. The assessment of the relevance of the additional information from the hearing procedure was also performed by both reviewers; discrepancies were solved through discussion between them.

The methodology of the guidelines included was assessed using the Appraisal of Guidelines for Research & Evaluation (AGREE) II instrument. The AGREE II instrument is used to assess the methodological quality of a guideline and contains a total of 23 appraisal criteria. Six domains are allocated to these criteria, each of which describes a separate dimension of methodological guideline quality. The assessments were performed by 2 reviewers independently of one another. These 2 reviewers then assessed the overall quality of the guidelines. The results of the AGREE II appraisal were not a criterion for the inclusion of guidelines in the investigation, but served to transparently present the methodological strengths or weaknesses of the evidence-based guidelines included.

The guideline recommendations relevant for the research question were extracted into tables, together with the related GoR and LoE for the respective healthcare aspects. In this context, the GoR reflects the strength of a recommendation and is usually based on a weighing of the benefit and risks of treatment, on each specific health care situation, as well as on the strength of the underlying evidence or the LoE. The LoE reported by the guideline authors represents an assessment of internal validity of the studies underlying the recommendations; in this context, systematic reviews of RCTs are generally awarded the highest LoE. In addition, when extracting the recommendations for each individual GoR and LoE, for the assessment of their DMP relevance, it was reported whether the recommendations were allocated to a high or low GoR/LoE.

The guideline recommendations and the definitions of the disorder were summarized in a structured information synthesis. The relevant GoR, or if not reported, alternatively the LoE, were used to evaluate the relevance of recommendations for a DMP “chronic heart failure”.

- DMP relevance was determined if different guidelines provided consistent recommendations on a topic (of a healthcare aspect), mostly with a high GoR, or alternatively a high LoE.
- Potential DMP relevance was determined for recommendations in which consistent statements were made on a topic, but were only partly and not mostly allocated to a high GoR, or alternatively a high LoE. In the following text, the latter is referred to as an inconsistent GoR or alternatively an LoE. In addition, potential DMP relevance was determined if only one guideline provided recommendations on a topic and they were allocated to a high GoR or alternatively a high LoE.
- Further evaluation of DMP relevance was proposed in cases where different guidelines provided inconsistent recommendations on a topic, with at least partly a high GoE or alternatively a high LoE.
- No statement on DMP relevance could be made if no GoR or LoE was provided on a topic for the majority of recommendations or if the GoR or LoE could not be clearly allocated to the recommendations.
- No DMP relevance was determined if a GoR or alternatively an LoE was provided on a topic for at least half of the recommendations, but no high GoR, or alternatively no high LoE, was awarded.

For all (potentially) DMP relevant recommendations it was evaluated whether contradicting statements existed in IQWiG reports. In addition, in the event of (potentially) DMP relevant recommendations on drug therapy, the indication-specific prescribability and the approval status in Germany were evaluated.

4 Results

4.1 Results of information retrieval

The systematic Internet search was conducted from September 2014 to December 2014 and the search update was conducted from June 2015 to July 2015. After the screening of titles and abstracts it yielded 64 potentially relevant documents, which were screened in full text. After evaluation of the criteria for guideline inclusion, 22 relevant guidelines were included.

Table 1: Abbreviations of the guidelines included and the publishing institutions

Abbreviation	**Publisher**
ACCF 2013 [4]	American College of Cardiology Foundation / American Heart Association (ACCF/AHA)
ACCF 2009 [10]	American College of Cardiology Foundation / American Heart Association (ACCF/AHA)
ACCP 2012 [11]	American College of Chest Physicians (ACCP)
AHA 2015 [12]	American Heart Association / Heart Failure Society of America (AHA/HFSA)
CCS 2015 [13,14]	Canadian Cardiovascular Society (CCS)
CCS 2013 Child [15]	Canadian Cardiovascular Society (CCS)
CCS 2013 CRT [16]	Canadian Cardiovascular Society (CCS)
CCS 2013 CRT Impl [17]	Canadian Cardiovascular Society (CCS)
CCS 2013 HF [18]	Canadian Cardiovascular Society (CCS)
CCS 2013 Reha [19]	Canadian Cardiovascular Society (CCS)
CCS 2012 [20]	Canadian Cardiovascular Society (CCS)
CCS 2011 [21]	Canadian Cardiovascular Society (CCS)
CCS 2010 [22]	Canadian Cardiovascular Society (CCS)
CCS 2009 [23]	Canadian Cardiovascular Society (CCS)
CSNZ 2009 [24]	The Cardiac Society of Australia and New Zealand
ESC 2013 [25]	European Society of Cardiology (ESC)
ESC 2012 [7]	European Society of Cardiology (ESC)
ESC 2010 [26]	European Society of Cardiology (ESC)
HFSA 2010 [27]	Heart Failure Society of America (HFSA)
ICSI 2013 [28]	Institute for Clinical Systems Integration (ICSI)
MQIC 2013 [29]	Michigan Quality Improvement Consortium
NICE 2010 [30]	National Institute for Health and Clinical Excellence (NICE)

Within the framework of the scientific debate conducted after the publication of the preliminary report, it was noted that the European Society of Cardiology (ESC) planned to publish an updated guideline for heart failure patients in May 2016, which is supposed to contain major updates compared with the guideline ESC 2012.

4.2 Characteristics of the guidelines included

The guidelines included were published by institutions from Europe (n = 4), the United States (n = 7), Canada (n = 10) and New Zealand (n = 1). No guidelines from German institutions were included.

Eight guidelines address the diagnosis and treatment of heart failure in patients with reduced and preserved ejection fraction (ACCF 2013, ACCF 2009, CCS 2013 HF, CSNZ 2009, ESC 2012, HFSA 2010, ICSI 2013, NICE 2010), whereby 2 guidelines are restricted to the care of patients with chronic heart failure (ACCF 2009, CSNZ 2009), and one guideline to the diagnosis and treatment of right heart failure (CCS 2009). Two guidelines address monitoring (HFSA 2010, NICE 2010) and 2 address rehabilitation (CCS 2013 Reha, NICE 2010) in specific sections; 4 address cardiac resynchronization therapy (CRT) and the use of cardiac pacemakers (ESC 2013, ESC 2010, CCS 2013 CRT) and their implementation (CCS 2013 CRT Impl). The long-term use of antithrombotic drugs for prevention of cardiovascular diseases, and specifically in patients with left ventricular heart failure, is addressed by one guideline (ACCP 2010). One guideline specifically addresses the nursing management of nursing facility residents with heart failure (AHA 2015). Five guidelines in the guideline programme of the Canadian Cardiovascular Society (CCS) refer to specific patient populations, such as children (CCS 2013 child), patients with left ventricular assist devices (CCS 2012), patients with advanced heart failure (CCS 2011), patients from an ethnic minority (CCS 2010), and patients with right heart failure or myocarditis (CCS 2009). One guideline in the CCS guideline programme focusses on patients with heart failure and anaemia, on biomarkers, and on current study results with an impact on the care of heart failure patients (CCS 2015).

All guidelines contain a classification system for the LoE and/or GoR, whereby 2 guidelines only report an LoE (ICSI 2013, NICE 2010) and one reports only a GoR (ACCP 2012).

4.3 Methodological quality of the guidelines

4.3.1 Results of the appraisal with AGREE

Overall, the guidelines received on average the highest standardized domain scores in the domains "clarity and presentation" as well as "scope and purpose". The clearest deficits were visible in the domain "applicability". This means that insufficient information was provided in the guidelines on support of their implementation, on beneficial and detrimental factors, as well as on resource needs and on audit criteria.

In the overall assessment, guideline NICE 2010 received the best assessment, followed by guidelines ACCF 2013, ACCP 2012, and ESC 2013. The comparatively high methodological quality of guideline NICE 2010 is also shown by the fact that it received the best assessments in 3 out of 6 domains.

4.3.2 Guideline authors’ handling of unpublished or incompletely published data

Of the 22 guidelines included, 4 contained details on information retrieval of unpublished or incompletely published data. Specific details about the handling of unpublished or incompletely published data, and about how these data potentially influence the statements of single recommendations, are provided by 15 guidelines.

4.4 Synthesis of recommendations

The guideline synopsis is based on the analysis of 22 guidelines. Recommendations on the following healthcare aspects were identified in the guidelines: definition, diagnostics, treatment, monitoring, patient training, decompensated heart failure, care after decompensation, palliative care, cooperation of healthcare sectors, specific patient groups, concomitant diseases, DMPs, and nursing management of nursing facility residents with heart failure. Within these items recommendations are presented referring to the care of patients with chronic left heart failure or global heart failure. If necessary, within these sections it is distinguished between patients with systolic (reduced left ventricular ejection fraction, LVEF) and diastolic (preserved LVEF) heart failure. The specific characteristics of the care of patients with isolated right heart failure, which is largely caused by chronic bronchopulmonary diseases and generally requires different therapeutic approaches, are presented in a separate section. The same applies to recommendations on heart failure in children and adolescents as well as in pregnant women. In a further separate section, recommendations on the treatment of concomitant diseases are summarized. These concomitant diseases are largely disorders that can be seen as the cause of heart failure (e.g. coronary heart disease [CHD], hypertension, myocarditis, and heart rhythm disorders). However, recommendations are also provided on disorders that greatly increase the risk of complications or a poor prognosis of heart failure patients (e.g. sleep apnoea or anaemia).

Overarching recommendations on treatment goals were not found in the guidelines analysed.

In the following text only those guideline recommendations are summarized for the single healthcare aspects, for which, according to the methodology applied, a relevance or potential relevance arose (see Chapter 3).

4.4.1 Definition of heart failure

A total of 8 guidelines contain definitions of heart failure.

The definitions of heart failure presented in the guidelines are not designated as recommendations. For the understanding of the recommendations presented in this report, the definitions reported by the guidelines are described in short in the following text.

In 7 guidelines, heart failure is defined as a complex clinical syndrome caused by structural or functional abnormalities of the heart. The cardinal symptoms are dyspnoea (breathlessness),

fatigue, and fluid retention, which may manifest itself as peripheral oedema and pulmonary congestion.

Two different classification systems are used in the guidelines to describe the severity of heart failure: The 4-stage classification of the New York Heart Association (NYHA), which reflects the residual function of the heart and thus the functional capacity of the patient [7] as well as the classification, also 4-stage, of the American Heart Association (AHA), (see Table 2 and Table 3) [10,31].

Table 2: Classification of heart failure according to the NYHA[a]

Class	**Characteristics**
Class I	No limitation of physical activity. Ordinary physical activity does not cause undue breathlessness, fatigue, or palpitations.
Class II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in undue breathlessness, fatigue, or palpitations.
Class III	Marked limitation of physical activity. Comfortable at rest, but less than ordinary physical activity results in undue breathlessness, fatigue, or palpitations.
Class IV	Unable to carry on any physical activity without discomfort. Symptoms at rest can be present. If any physical activity is undertaken, discomfort is increased.
a: Wording as published in [7]. NYHA: New York Heart Association	

Table 3: Stages of heart failure according to AHA / ACC [10,31][a]

Stage	**Characteristics**
A	At high risk for HF but without structural heart disease or symptoms of HF. (e.g., patients with hypertension, arteriosclerotic disease, diabetes, obesity, metabolic syndrome etc.)
B	Structural heart disease but without signs or symptoms of HF. (e.g., patients with previous MI etc.)
C	Structural heart disease with prior or current symptoms of HF. (e.g. patients with known structural heart disease and shortness of breath and fatigue etc.)
D	Refractory HF requiring specialized interventions. (e.g., patients who have marked symptoms at rest despite maximal medical therapy etc.)
a: Original extract. ACC: American College of Cardiology; AHA: American Heart Association; HF: heart failure; MI: myocardial infarction	

4.4.2 Diagnostics of heart failure

A total of 13 guidelines contain recommendations on diagnostics in heart failure patients.

Five guidelines report that the diagnostics in patients with suspected or existing heart failure serve to confirm the diagnosis, including the determination of severity. In addition, they serve to clarify differential diagnoses and causes. Furthermore, one guideline names symptoms that suggest heart failure. A further guideline notes that diagnostic confirmation can be more difficult in certain ethnic minorities due to aetiological factors and deviating behaviour regarding the use of healthcare services (recommendations are potentially DMP relevant).

Basic diagnostics

Six guidelines recommend a detailed recording of medical history and a physical examination for all patients with suspected heart failure (recommendations are DMP relevant).

One guideline notes that the family history of patients with dilatative cardiomyopathy should cover 3 generations. According to the recommendations of 2 guidelines, screening for sleep-related breathing disorders (sleep apnoea) should also be performed (recommendations are potentially DMP relevant).

Furthermore, 4 guidelines recommend comprehensive blood and urine tests and, to exclude heart failure as the cause of the patient’s complaints, 9 guidelines recommend determining natriuretic peptides. In addition, 4 guidelines recommend determining the brain natriuretic peptide (BNP) value as a benchmark for prognostic risk stratification in heart failure patients (recommendations are DMP relevant).

To determine the heart rhythm and heart rate, as well as to evaluate QRS morphology and duration, 5 guidelines recommend the routine performance of a 12-channel surface electrocardiogram (ECG), (recommendations are DMP relevant). One guideline also states that P-wave signal-averaged ECG (SAECG) should not be performed routinely (recommendation is potentially DMP relevant).

Four guidelines recommend a chest X-ray to exclude other heart or lung diseases, but also to verify pulmonary congestion and assess the size of the heart. According to the recommendations of 7 guidelines, echocardiography should be performed to distinguish between systolic and diastolic heart failure and to assess cardiac structures and functions (recommendations are DMP relevant).

To adapt treatment accordingly, when diagnosing heart failure 2 guidelines recommend also determining the severity of heart failure (recommendations are DMP relevant).

Further diagnostics

For patients with an unclear clinical picture, 3 guidelines recommend supplementary blood tests, whereas one guideline does not recommend routine measurement of neurohormone levels within the diagnostics of heart failure (recommendations are potentially DMP relevant).

Two guidelines recommend performing magnetic resonance imaging (MRI) if echocardiography did not yield clear findings. In addition, 5 guidelines provide recommendations on the further use of MRI within the framework of diagnosis (recommendations are potentially DMP relevant).

Furthermore, 6 guidelines name specific constellations of symptoms or findings where it is recommended that coronary angiography is indicated. This intervention is particularly recommended for heart failure patients who may be eligible for revascularization therapy due to known CHD (recommendations are DMP relevant).

Within the diagnostics of heart failure, 3 guidelines advise against the routine performance of a myocardial biopsy when clarifying the cause of heart failure (recommendation is DMP relevant).

Likewise, according to one guideline, an exercise test should not be conducted routinely in all patients with suspected heart failure (recommendation is potentially DMP relevant).

Diagnostics of right heart failure

In patients with unexplainable exercise intolerance or hypotension in combination with increased jugular vein pressure, peripheral oedema and hepatomegaly, one guideline recommends considering the possibility of right heart failure. To make the diagnosis, the guideline recommends performing echocardiography to depict the structure and function of the heart and also to measure the elasticity of the vena cava inferior. In the case of an unclear diagnosis or refractory right heart failure, haemodynamic evaluation by means of a right heart catheter is recommended (recommendations are potentially DMP relevant).

4.4.3 Therapeutic measures

4.4.3.1 Non-drug measures

A total of 8 guidelines provide recommendations on non-drug therapeutic measures.

Lifestyle changes

Two guidelines recommend supporting patients to stop smoking. Furthermore, 2 guidelines recommend reducing alcohol consumption. In addition, one guideline recommends alcohol abstinence in patients with earlier or current excessive drinking behaviour (recommendations are potentially DMP relevant).

Diet recommendations / weight control

To counter fluid retention, 5 guidelines recommend a salt-reduced diet. In addition, for patients with advanced heart failure, 2 guidelines recommend fluid restriction to 1.5 to 2 litres per day (recommendations are potentially DMP relevant).

In patients with severe heart failure, one guideline recommends clarifying the cause of unexplainable weight loss and using high-caloric food, if necessary. The administration of anabolic steroids is explicitly not recommended (recommendations are potentially DMP relevant).

Physical activity / exercise

Eight guidelines recommend motivating heart failure patients to regularly undertake physical exercise, as this may have a positive impact on the course of the disease. This also applies to patients after decompensation or with severe heart failure. Physical exercise can at best be performed in supervised groups, but also potentially alone (recommendations are DMP relevant).

One guideline also notes that physical exercise should be of moderate intensity (recommendation is potentially DMP relevant).

For patients with advanced heart failure, 2 guidelines recommend first performing an exercise test to specify the exercise limit. One guideline recommends performing such an exercise test for all heart failure patients (recommendations are potentially DMP relevant).

Vaccinations

Three guidelines recommend a yearly influenza vaccination of all heart failure patients (recommendation is DMP relevant) and 2 guidelines recommend a pneumococcal vaccination (recommendation is potentially DMP relevant).

4.4.3.2 Drug therapy

A total of 14 guidelines provide recommendations on drug therapy.

General recommendations on drug therapy

Two guidelines state that in heart failure patients with AHA stage C, the same therapeutic approach is in principle to be chosen as for patients with AHA stages A and B. Furthermore, drugs with a known negative impact on the clinical state of heart failure patients should be avoided or discontinued (recommendations are DMP relevant).

One guideline points out that in the treatment of elderly heart failure patients following evidence-based recommendations, in individual cases the metabolic characteristics and tolerance thresholds for standard drugs, which change with age, are to be considered (recommendation is potentially DMP relevant).

Treatment with angiotensin-converting enzyme (ACE) inhibitors

Nine guidelines recommend treating patients with asymptomatic or symptomatic left heart failure with ACE inhibitors. According to 2 guidelines, this also includes patients with prior myocardial infarction (recommendations are DMP relevant).

Furthermore, one guideline states that asymptomatic heart failure patients with hypertension and reduced left ventricular ejection fraction (LVEF) should receive ACE inhibitors (recommendation is potentially DMP relevant).

Specific recommendations on ACE inhibitors in combination with other drugs

Five guidelines recommend treatment with a combination of ACE inhibitors and beta-blockers for symptomatic and asymptomatic heart failure patients, heart failure patients with prior myocardial infarction, dialysis patients with heart failure, and elderly heart failure patients (recommendations are DMP relevant).

One guideline recommends treatment with a combination of ACE inhibitors and beta-blockers for patients with hypertension and heart failure and a dilated left ventricle (recommendation is potentially DMP relevant).

One guideline advises against the routine use of ACE inhibitors in combination with angiotensin II receptor blockers (ARBs) and aldosterone antagonists in symptomatic heart failure patients. A further guideline advises against the routine use of ACE inhibitors in combination with ARBs in asymptomatic heart failure patients (recommendations are potentially DMP relevant).

Treatment with beta-receptor blockers (beta-blockers)

Eight guidelines recommend treatment with beta-blockers for heart failure patients with reduced ejection fraction and 2 guidelines for patients with preserved ejection fraction (recommendations are DMP relevant).

One guideline recommends beta-blocker therapy for patients with recent decompensation of heart failure (recommendation is potentially DMP relevant).

Three guidelines note that beta-blocker therapy should be started at a low dose and increased to the target dose or the highest tolerated dose (recommendation is DMP relevant).

Two guidelines name contraindications for beta-blocker therapy; these include, among other things, the presence of symptomatic hypotension, severe reactive airway disease (asthma, active bronchospasm), symptomatic bradycardia or an atrioventricular (AV) block without permanent pacemaker therapy (recommendations are DMP relevant).

Specific recommendations on beta-blockers in combination with other drugs

The recommendations of guidelines on the treatment of heart failure patients with a combination of beta-blockers and ACE inhibitors are presented in the section on ACE inhibitors in combination therapy.

Treatment with angiotensin II receptor blockers

Nine guidelines recommend the use of ARBs in heart failure patients who do not tolerate ACE inhibitors. This recommendation also explicitly applies to patients in the acute post-infarction phase and patients with reduced LVEF (< 40%), (recommendations are DMP relevant).

In addition, 3 guidelines provide recommendations on the replacement of ACE inhibitors by ARBs in different constellations. For instance, ARBs can be used as an alternative to ACE inhibitors if patients already receive the former for a different therapeutic indication and tolerate them well (recommendation is potentially DMP relevant).

Specific recommendations on angiotensin II receptor blockers in combination with other drugs

For the group of asymptomatic heart failure patients, one guideline advises against the routine combination of ACE inhibitors and ARBs. Six guidelines state that ARBs can be given in addition to beta-blockers and ACE inhibitors if patients are still symptomatic, are regarded to be at high risk of complications, or do not tolerate aldosterone antagonists (recommendations are potentially DMP relevant).

Because of the risk of hyperkalaemia, 4 guidelines advise against the routine use of a triple combination of ACE inhibitors, ARBs and aldosterone antagonists (recommendation is DMP relevant).

Treatment with aldosterone antagonists

Seven guidelines recommend that patients with systolic heart failure and an LVEF < 35% who are still symptomatic (NYHA II-IV) under combination therapy with ACE inhibitors (or ARBs) and beta-blockers, should additionally receive aldosterone antagonists as long as there is no contraindication (in particular renal). This recommendation also applies to symptomatic patients with an LVEF < 40% in the post-infarction phase and for patients with diabetes mellitus (recommendations are DMP relevant).

Furthermore, according to 4 guidelines, heart failure patients with stage NYHA III-IV and an LVEF of < 35% should be treated with aldosterone antagonists (recommendation is DMP relevant).

General comments on treatment with aldosterone antagonists

Three guidelines note that during treatment with aldosterone antagonists the electrolyte status and renal function of patients must be monitored. Potassium substitution is not required in patients without persistent hypokalaemia (< 4 mmol/l), (recommendations are DMP relevant).

Diuretic therapy

For symptom alleviation, 6 guidelines recommend diuretic therapy in heart failure patients with reduced ejection fraction and signs of fluid retention (e.g. pulmonary congestion), (recommendation is DMP relevant).

Furthermore, in one guideline there are recommendations on the choice or type of administration of specific diuretics. The guideline also notes that patients receiving diuretics need to be monitored carefully with regard to the occurrence of side effects such as electrolyte imbalance, hypotension or renal dysfunction (recommendations are potentially DMP relevant).

In addition, one guideline provides recommendations on the training of patients receiving diuretic therapy and of their relatives/caregivers (recommendation is DMP relevant).

Treatment with cardiac glycosides

One guideline states that asymptomatic heart failure patients should not receive cardiac glycosides. However, 5 guidelines recommend treatment with cardiac glycosides for heart failure patients with reduced ejection fraction if they show a sinus rhythm and do not tolerate beta-blockers or if they still remain symptomatic under combination therapy with beta-blockers, ACE inhibitors (or ARBs) and aldosterone antagonists. Moreover, 3 guidelines mention the option of treating heart failure patients with cardiac glycosides if these patients have persistent atrial fibrillation unresponsive to beta-blockers (recommendations are potentially DMP relevant).

In addition, one guideline states that the cardiac glycoside dose depends on the fat-free mass (FFM), the renal function, and the concomitant medication (recommendation is potentially DMP relevant).

Treatment with oral anticoagulants and antiplatelet agents

Four guidelines advise against anticoagulants in heart failure patients without atrial fibrillation and without specific risk factors for thromboembolic events (recommendations are DMP relevant).

Three guidelines recommend treating heart failure patients with oral anticoagulants if they had previously experienced thromboembolic events (including extensive anterior wall myocardial infarction and infarction with intracardiac thrombus formation), (recommendations are potentially DMP relevant).

Treatment with antiarrhythmic drugs

Five guidelines advise against the routine use of non-dihydropyridine calcium channel blockers for the treatment of heart rhythm disorders in heart failure patients (recommendation is DMP relevant).

Two guidelines recommend treating heart failure patients with amiodarone after successful cardioversion (recommendation is potentially DMP relevant). Two guidelines mention the option of using amiodarone for the treatment of ventricular arrhythmia (recommendation is DMP relevant).

However, one guideline provides a recommendation against the use of amiodarone for prevention of sudden cardiac death or for the treatment of asymptomatic rhythm disorders in heart failure patients. Due to an increased mortality and hospitalization risk, one guideline also advises to dispense with dronedarone and class I antiarrhythmic drugs (sodium channel blockers) in the treatment of heart failure patients (recommendations are potentially DMP relevant).

One guideline notes that, before deciding that a drug is indicated, potential drug interactions should be evaluated and the medication adjusted (recommendation is potentially DMP relevant).

Combination therapy with isosorbide dinitrate / hydralazine

Seven guidelines recommend treating African-American heart failure patients (NYHA III-IV) with isosorbide dinitrate and hydralazine in addition to ACE inhibitors and beta-blockers (recommendation is DMP relevant).

Treatment with inotropic drugs

Two guidelines state that long-term treatment with inotropic drugs is only indicated as a palliative measure in end-stage heart failure patients whose symptoms are not controllable with standard medication (recommendation is DMP relevant). One guideline also recommends the use of inotropic drugs for a limited period to control acute situations (recommendation is potentially DMP relevant).

Treatment with ivabradine

No DMP relevant or potentially DMP relevant recommendations were available.

Treatment with other drugs and nutritional supplements

Five guidelines recommend the use of omega-3 fatty acids in the concomitant treatment of heart failure patients to prevent hospitalization and reduce mortality rates (recommendations are potentially DMP relevant).

In addition, 3 guidelines advise against the use of nutritional supplements for prophylaxis of heart failure symptoms, except for polyunsaturated fatty acids (recommendation is DMP relevant).

Two guidelines advise against the use of anti-inflammatory drugs – including cyclooxygenase-2 inhibitors – in heart failure patients (recommendations are DMP relevant).

In each case one guideline advises against the use of nutriceuticals, glitazones, and hormones (beyond substitution therapy). One guideline also notes that endocarditis prophylaxis in heart failure patients is only recommended for specific cardiac diagnoses with an increased risk of endocarditis (recommendations are potentially DMP relevant).

4.4.3.3 Interventional measures

A total of 14 guidelines provide recommendations on specific interventional measures.

Four guidelines state that the decision that an interventional measure is indicated should always be made in cooperation with qualified specialists and that interventions should be performed in qualified specialist clinics (recommendation is DMP relevant). In addition, one guideline demands that the decision for an interventional measure should always be made in dependence of the patient’s life expectancy and general state of health (recommendation is potentially DMP relevant).

Cardiac resynchronization therapy

Five guidelines name preconditions that patients have to fulfil in order to decide that CRT is indicated. For instance, before a CRT the patient’s medication be adjusted adequately and his or her eligibility for this intervention should be evaluated. In addition, the patient should show a good functional status and his or her life expectancy should be more than a year (recommendations are DMP relevant).

One guideline also states that the clinic where the implantation of a CRT device is performed must adhere to strict hygiene standards (recommendation is potentially DMP relevant).

To improve symptoms, reduce hospitalization rates, and improve survival rates, CRT is recommended in patients with the following characteristics:

- 12 guidelines for patients with left bundle branch block with a QRS duration > 120 ms, sinus rhythm, LVEF ≤ 35%, and NYHA II-IV, despite optimal drug therapy (recommendation is DMP relevant)
- 5 guidelines for patients who already have a cardiac pacemaker, in stage NYHA III-IV, with LVEF < 35 %, and/or permanent atrial fibrillation, despite optimal drug therapy (recommendation is potentially DMP relevant)

When deciding on whether a CRT is indicated, according to 2 guidelines, it should also be evaluated whether a pacemaker or an implantable cardioverter defibrillator (ICD) is indicated. Patients in whom a CRT but not an ICD is indicated should be provided with a combination device with a pacemaker function (CRT-P), (recommendation is potentially DMP relevant).

Two guidelines do not recommend a CRT in patients with chronic heart failure and a QRS duration < 120 ms (recommendation is DMP relevant); one guideline does not recommend a CRT in heart failure patients in NYHA stage I or II, with other conduction disorders and a QRS duration < 150 ms (recommendation is potentially DMP relevant).

One guideline provides a recommendation against the routine use of an AV dual-chamber pacemaker in heart failure patients without bradycardia or a high-degree AV block. In addition, one guideline recommends that for perioperative anticoagulation, patients who have already been treated longer term with vitamin K antagonists (warfarin) should not be switched to heparin-based anticoagulation (recommendation is potentially DMP relevant).

Implantable cardioverter defibrillators

Seven guidelines name health prerequisites that patients have to fulfil so that the decision can be made that treatment with an ICD is indicated. For instance, the patient should show a good functional status and his or her life expectancy should be more than a year (recommendations are DMP relevant).

One guideline advises against the implantation of an ICD in NYHA-IV patients if the improvement of symptoms by the ICD is unlikely and the patient is not eligible for mechanical circulatory support or a heart transplant (recommendation is potentially DMP relevant).

In addition, one guideline states that the implantation of an ICD should be performed in close collaboration with specialists for heart failure and rhythm disorders (recommendations are potentially DMP relevant).

Several guidelines recommend an ICD to reduce the risk of sudden cardiac death in patients with the following characteristics:

- 4 guidelines for patients with ventricular rhythm disorders leading to haemodynamic instability (recommendation is DMP relevant)
- 8 guidelines for patients with symptomatic heart failure (NYHA II-III), LVEF ≤ 35 % (despite optimal drug therapy), an ischaemic aetiology, and more than 40 days after acute myocardial infarction (recommendation is DMP relevant)
- 6 guidelines for patients with symptomatic heart failure (NYHA II-III), an LVEF ≤ 35% (despite optimal drug therapy), and non-ischaemic cardiomyopathy (recommendation is DMP relevant)

- 2 guidelines for patients (AHA stage B and/or NYHA I) with ischaemic cardiomyopathy, an LVEF ≤ 30% (despite optimal drug therapy), and more than 40 days after an acute myocardial infarction (recommendation is potentially DMP relevant)
- 2 guidelines for patients (AHA stage C and/or NYHA I) with an LVEF ≤ 30% (despite optimal drug therapy), and more than 40 days after acute myocardial infarction (recommendation is DMP relevant)

According to the recommendations of 4 guidelines, when deciding on whether a CRT is indicated, it should also be evaluated whether a pacemaker or an ICD is indicated (recommendation is DMP relevant). One guideline recommends that a CRT defibrillator (CRT-D) is indicated in patients who have a left bundle branch block, a QRS duration > 130 ms, sinus rhythm, LVEF ≤ 30 %, and NYHA II, despite optimal drug therapy (recommendation is potentially DMP relevant). Furthermore, one guideline recommends that the decision that ICD is indicated should only be made 3 to 6 months after a treatment attempt with drugs (recommendation is potentially DMP relevant).

Mechanical circulatory support (artificial hearts)

Mechanical circulatory support systems are exclusively indicated in patients with end-stage heart failure in whom no improvement in symptoms, despite optimal drug and pacemaker therapy, can be achieved. Four guidelines recommend their use, in particular to bridge the interval until a suitable heart transplant is found or other treatment options are identified (recommendations are potentially DMP relevant).

One guideline states that both the decision that mechanical circulatory support is indicated, as well as its implantation, should take place in a specialist unit. Furthermore, one guideline states that, 2 months after implantation of a mechanical circulatory support, patients can use a motor vehicle privately if they are stable and can be assigned to NYHA I-III (recommendations are potentially DMP relevant).

Heart transplant

Three guidelines state that a heart transplant is a treatment option for selected patients with severe heart failure (AHA stage D) who, despite drug and other (surgical) treatment, do not reach symptom alleviation (recommendation is DMP relevant).

Revascularization therapy

Five guidelines recommend that the decision that a revascularization intervention is indicated in heart failure patients should only be made if anginal symptoms with coronary stenosis and myocardial ischaemia are also present (recommendation is DMP relevant). As a contraindication for revascularization treatment, one guideline names the lack of anginal symptoms and the lack of a functional myocardium (recommendation is potentially DMP relevant).

Heart valve replacement / reconstruction

One guideline recommends providing heart valve replacement or reconstruction for patients with asymptomatic heart failure and significant, haemodynamically effective valve stenosis or valve insufficiency with regurgitation. Another guideline notes that heart valve replacement or reconstruction in patients with a severe left ventricular functional disorder and severe mitral valve insufficiency with regurgitation due to ventricular dilatation should rather not be recommended (recommendations are potentially DMP relevant).

4.4.4 Monitoring

A total of 6 guidelines provide recommendations on the monitoring of heart failure.

One guideline provides the recommendation that stable patients should be reassessed by a medical doctor every 6 months or after shorter intervals in the event of necessary treatment adaptations or a deterioration of their condition (recommendation is potentially DMP relevant).

As examinations within the framework of monitoring, 3 guidelines recommend blood and urine tests, control of weight and volume status, determination of the extent to which the patients can fulfil activities of daily living, as well as recording of diet and drinking habits, smoking status, the medication actually taken (including over-the-counter drugs), and of alternative treatment methods use (recommendations are DMP relevant).

In addition, one guideline recommends checking the BNP value before discharging hospitalized patients with heart failure. Furthermore, one guideline advises against the routine examination of the LVEF by means of echocardiography within the framework of monitoring (recommendations are potentially DMP relevant).

4.4.5 Patient training

A total of 4 guidelines provide recommendations on the training of patients with heart failure.

Four guidelines recommend offering self-management training to all patients and also including the relatives of patients. Recommendations are provided on the content and implementation of the training; in this context, it is emphasized that the training should be adapted to the patients’ cognitive status (recommendations are potentially DMP relevant).

4.4.6 Patients with decompensated heart failure

A total of 3 guidelines provide recommendations on the care of patients with acute decompensated heart failure.

Diagnostics

To confirm the diagnosis in patients with suspected decompensated heart failure, one guideline recommends determining the BNP or N-terminal pro (NT-pro) BNP values.

Furthermore, it is mentioned that in patients hospitalized with decompensated heart failure, the following potentially triggering causes should be clarified: atrial fibrillation and other types of arrhythmia, uncontrolled hypertension, myocardial infarction, exacerbation of pulmonary congestion, anaemia, thyroid disease, drug interactions, and other rarer causes (recommendations are potentially DMP relevant).

Hospital admission / discharge

One guideline recommends hospitalizing patients with decompensated heart failure if any of the following conditions are present: hypotension, deterioration in renal function, a change in consciousness, resting dyspnoea (resting tachypnoea, potentially in patients with O_2 saturation < 90%) or haemodynamically relevant arrhythmia, including newly occurring atrial fibrillation and acute coronary syndrome (recommendations are potentially DMP relevant).

Treatment goals

One guideline mentions the following treatment goals for the treatment of patients with decompensated heart failure: improvement in symptoms, optimization of volume status, clarification of causal and triggering factors, optimization of permanent medication, and minimization of side effects. Furthermore, it is recommended to identify patients in whom revascularization therapy or a medical-technical intervention is indicated or who have an increased risk of thromboembolism and should thus start treatment with anticoagulants. According to the guideline a further treatment goal should be the implementation of patient training for self-management/self-medication and, if available, enrolment in a DMP (recommendations are potentially DMP relevant).

Treatment of decompensated heart failure

Non-drug measures

One guideline recommends the restriction of fluid intake to less than 2 litres per day for patients with moderate hyponatraemia (< 130 mEq/l) and for support of volume control in other patients. Furthermore, the guideline notes that oxygen should be routinely administered in patients with hypoxia, while this should be refrained from in patients without hypoxia (recommendations are potentially DMP relevant).

Drug therapy

Diuretic therapy

One guideline recommends initially treating patients with decompensated heart failure and signs of fluid overload with (mostly intravenous) loop diuretics. In this context, the dosage should be adapted in such a way that an optimal volume status is achieved with normalization of clinical symptoms. In addition, close monitoring of symptoms (pulmonary congestion) and body weight is recommended. However, a urinary catheter should only be inserted if close monitoring of urine volume is required or urinary obstruction is contributing to deterioration of renal function. Furthermore, the guideline notes that patients receiving diuretics should be monitored with regard to the occurrence of adverse effects such as deterioration in renal

function, electrolyte imbalance, decrease in blood pressure, and gout attacks. It is recommended in particular to determine potassium and magnesium levels daily (or, if appropriate, even more often) and to keep them within the normal range. Substitution of potassium may be indicated in the event of severe muscle cramps. According to the guideline, in the event of deterioration of renal function with fluid retention, diuretic therapy should be continued (recommendations are potentially DMP relevant).

In addition, patients who are hospitalized with decompensated heart failure and have not yet received anticoagulants should receive low-molecular heparin for prophylaxis of thromboembolism, as long as no contraindications exist (recommendations are potentially DMP relevant).

Treatment with vasodilators

One guideline recommends the intravenous administration of vasodilators for the treatment of patients with acute decompensated heart failure and notes that during treatment with vasodilators, patients' blood pressure should be closely monitored. According to this guideline, intravenously applied inotropic drugs should not be given, except in the event of increased left ventricular filling pressure or a severely affected cardiac index. The blood pressure of patients treated with inotropic drugs should also be monitored continuously or closely (recommendations are potentially DMP relevant).

Monitoring of decompensated heart failure

One guideline notes that, during their hospital stay, patients with decompensated heart failure should be monitored several times daily with regard to vital signs, daily with regard to fluid intake and excretion, and at least daily with regard to body weight, symptoms, electrolytes, and renal function (recommendation is potentially DMP relevant).

Two guidelines provide recommendations for deciding on whether invasive haemodynamic monitoring is indicated. Routine invasive haemodynamic monitoring of patients with decompensated heart failure is not indicated. However, it is recommended for patients who are refractory to initial therapy or whose volume status and intracardiac filling pressures are clear, as well as for patients with hypotension (systolic blood pressure < 80 mm Hg), patients with deteriorating renal function, patients awaiting a heart transplant or in whom outpatient intravenous treatment with inotropic drugs is indicated (recommendations are DMP relevant).

4.4.7 Care of patients after decompensation of chronic heart failure

One guideline provides recommendations on the care of patients after decompensation of chronic heart failure.

Against the background of an increased mortality rate in patients after decompensation of chronic heart failure, the guideline highlights the necessity of patient training and recommends using the time in hospital to review patient compliance and increase it by

training (including training of relatives) and by supportive measures of social services (recommendation is potentially DMP relevant).

Before the patient can be discharged from hospital, an appointment for a follow-up examination (7 to 10 days after discharge) should have been fixed. In addition, according to the guideline's recommendation, the triggering factors should have been eliminated, a nearly normal volume status should have been achieved, and the patient should have been successfully switched from intravenous to oral diuretic therapy. Furthermore, the LVEF should have been determined and drug therapy should have been adjusted to ACE inhibitors and beta-blockers (patients with reduced ejection fraction) or an existing intolerance should have been documented. Training of patients and relatives should also have been implemented and counselling on smoking cessation given (recommendations are potentially DMP relevant).

According to the guideline's recommendation, detailed discharge management should take place for patients with prior decompensated heart failure. In this context, the following criteria should be considered: (i) individual specifications on medication, salt restriction, and physical activity, (ii) monitoring of body weight, electrolytes, and renal function, (iii) timely follow-up contacts (personally or by phone) to assess volume status, as well as (iv) ensuring and evaluating patient compliance with medication, diet specifications (including reduction in alcohol consumption), and smoking cessation. In addition, it should be assessed whether the patient can be enrolled in a DMP (recommendations are potentially DMP relevant).

4.4.8 Palliative care

A total of 5 guidelines provide recommendations on the palliative care of patients with end-stage heart failure.

Two guidelines recommend that palliative care should always be provided by qualified institutions or medical doctors, whereby according to 2 guidelines, the decision on the form of palliative treatment should be made together with the patient depending on symptoms and needs. Four guidelines recommend that all patients with end-stage heart failure and their families should be informed about the possibilities and limits of palliative care (recommendations are DMP relevant).

The specific medical measures for this patient group named by 2 guidelines include, among other things, careful control of fluid balance and the continuous infusion of inotropic drugs for symptom alleviation. Partial left ventricular resection and intermittent infusion of inotropic drugs or vasodilators are explicitly not recommended (recommendations are potentially DMP relevant).

4.4.9 Cooperation of healthcare sectors

A total of 7 guidelines provide recommendations on the cooperation of healthcare sectors in the treatment of patients with heart failure.

All recommendations addressing decompensated heart failure, including hospital admission and follow-up care, are covered separately under the healthcare aspect “patients with decompensated heart failure” (Section 4.4.6) and “care of patients after decompensation of chronic heart failure” (Section 4.4.7).

Referral to a medical specialist / hospital admission / hospital discharge

One guideline provides general recommendations on hospital discharge for heart failure patients. It recommends giving patients preferably detailed instructions on diet, medication, physical activity, daily weight control, and follow-up appointments. In addition, patients should be instructed on how to behave in the event of a deterioration of symptoms (recommendations are potentially DMP relevant).

Initiation of a rehabilitation measure

Two guidelines generally support cardiological rehabilitation measures for heart failure patients, particularly after heart surgery. One guideline recommends evaluating whether patients of a working age can still work despite their illness, potentially with reduction of the weekly working time (recommendations are potentially DMP relevant).

4.4.10 Heart failure in specific patient groups

4.4.10.1 Heart failure and pregnancy

One guideline provides recommendations on heart failure and pregnancy.

Among other things, the guideline recommends that qualified specialists/specialist institutions should advise and care for patients with known heart failure and the wish to have children, as well as pregnant patients with heart failure. The healthcare plan for the ante-, peri- und post-partum periods should be based on a risk assessment. Close monitoring and informing about the risks of further pregnancies are also recommended (recommendations are potentially DMP relevant).

Furthermore, one guideline notes that, for the treatment of heart failure, only those drugs and diagnostic procedures should be used that are as safe as possible for pregnant women. In addition, pregnant patients with decompensated heart failure should receive intensive medical care (recommendations are potentially DMP relevant).

4.4.10.2 Heart failure in children and adolescents

One guideline addresses the definition, diagnostics, and treatment of heart failure in children and adolescents.

Definition

The definition of heart failure in children does not basically differ from the definition in adults; however, causes and manifestation of symptoms are different. A particular feature in children can be a congenital structural abnormality of the heart causing a disturbance of the

relation of the blood circulation between the pulmonary and systemic circulation systems. In addition, the type and severity of symptoms change during the development from newborn to adolescent.

The definition of heart failure in children and adolescents presented in the guideline is not designated as a recommendation.

Diagnostics

One guideline notes that in the case of feeding problems or failure to thrive, heart failure should be considered as the underlying cause. Decompensated heart failure in children and adolescents with cardiomyopathy can be the cause of fatigue, lethargy, abdominal pain, as well as inexplicable or disproportionate tachycardia and tachypnoea. From middle childhood, children with muscular dystrophy should be examined regularly by means of echocardiography. Furthermore, the guideline recommends excluding the differential diagnosis of myocarditis in children with prodromal signs of a virus infection or unclear respiratory or abdominal symptoms and simultaneous tachycardia, hypotension or rhythm disorders (recommendations are potentially DMP relevant).

In the case of suspected heart failure, the guideline first and foremost recommends recording a comprehensive medical history. The diagnostic measures, which should always be accompanied by a medical specialist, should be based on blood tests (including BNP), 12-channel surface ECG, chest x-rays, and echocardiography. If necessary, further examinations may be indicated. In addition, according to the guideline the severity of heart failure should be classified. In most cases, regular echocardiography is recommended to monitor the course of disease (recommendations are potentially DMP relevant).

Treatment

One guideline recommends ACE inhibitors for drug therapy. In children with additional myocarditis, the guideline recommends supplementary diuretic and inotropic therapy or, in severe cases, the use of mechanical circulatory support systems (recommendations are potentially DMP relevant).

4.4.11 Treatment of concomitant diseases

A total of 10 guidelines provide recommendations for treating concomitant diseases of heart failure.

4.4.11.1 Sleep disorders

A total of 3 guidelines provide recommendations on the care of heart failure patients with sleep apnoea syndrome.

One guideline recommends the involvement of sleep medicine experts in the care of heart failure patients with sleep apnoea, in order to distinguish between central and obstructive sleep apnoea. According to this guideline, treatment with continuous positive airway pressure

(CPAP) in patients with central sleep apnoea should only be initiated in centres with specific expertise in the diagnosis and treatment of centrally-related sleep disorders (recommendations are potentially DMP relevant).

Three guidelines recommend CPAP treatment of heart failure patients with obstructive sleep apnoea (recommendation is DMP relevant). For heart failure patients with sleep apnoea but without concomitant pulmonary diseases, one guideline advises against oxygen supplementation at night or during physical strain (recommendation is potentially DMP relevant).

4.4.11.2 Coronary heart disease

A total of 7 guidelines provide recommendations on the care of heart failure patients with CHD.

One guideline notes that both patients with structural myocardial changes (but without heart failure symptoms) as well as patients with stable CHD and heart failure should be treated according to established CHD guidelines (recommendation is potentially DMP relevant).

Five guidelines recommend treatment with antiplatelet agents in heart failure patients with manifest CHD for secondary prophylaxis of thromboembolic events (recommendation is DMP relevant).

Furthermore, 2 guidelines recommend that all patients with reduced ejection fraction after an acute coronary event should be treated with ACE inhibitors (or if not tolerated, with ARBs) and beta-blockers to prevent heart failure symptoms and reduce mortality, as well as with statins to prevent further coronary events. However, according to one guideline, statins are not indicated as concomitant treatment of heart failure, provided that no further therapeutic indication is present (recommendations are potentially DMP relevant).

For the treatment of anginal symptoms in CHD patients with heart failure, 2 guidelines recommend beta-blockers because of their synergistic effects on heart failure. If anginal symptoms are not controllable with monotherapy, 2 guidelines provide recommendations on the additional administration of further drugs such as ivabradine, oral or transcutaneous nitrates or amlodipine. If dual drug therapy shows insufficient effectiveness, 2 guidelines recommend that revascularization therapy is indicated as an alternative to triple drug therapy (recommendations are DMP relevant).

One guideline does not recommend the drug combination of (i) ivabradine, ranolazine and nicorandil, (ii) nicorandil and nitrates, and (iii) diltiazem and verapamil (recommendations are potentially DMP relevant).

4.4.11.3 Hypertension

A total of 5 guidelines provide recommendations on the care of patients with hypertension and heart failure.

Two guidelines recommend monitoring blood pressure in heart failure patients as specified in the established guidelines on the treatment of hypertension. Furthermore, to normalize blood pressure and reduce morbidity rates, 2 guidelines recommend treating heart failure patients with hypertension and preserved LVEF in accordance with the above guidelines (recommendation is DMP relevant).

One guideline recommends that the blood pressure of symptomatic and asymptomatic heart failure patients with preserved LVEF and myocardial hypertrophy is adjusted to values < 130/80 mm Hg and that blood pressure is monitored regularly. In addition, for the initial adjustment of blood pressure in heart failure patients, 3 guidelines recommend those drugs that have a synergistic effect on heart failure, that is, beta-blockers, ACE inhibitors (alternatively: ARBs) and aldosterone antagonists (recommendations are potentially DMP relevant).

In the event of treatment failure of such an initial drug combination, 2 guidelines recommend first adding a diuretic (recommendation is DMP relevant).

If blood pressure cannot be adjusted by this combination therapy either, then according to one guideline, amlodipine or hydralazine can be added, for example. According to one guideline, the additional administration of alpha receptor antagonists should be dispensed with due to safety concerns. According to one guideline, for patients with high blood pressure, symptomatic left heart failure with reduced ejection fraction and a dilated left ventricle, the following drug combinations are a potential treatment option: ACE inhibitors, ARBs, beta-blockers, aldosterone antagonists, hydralazine/isosorbide dinitrate and, if appropriate, loop diuretics (recommendations are potentially DMP relevant).

4.4.11.4 Myocarditis

A total of 2 guidelines provide recommendations on the care of heart failure patients with myocarditis.

The guideline recommends considering myocarditis in the following clinical constellations: cardiogenic shock of unknown cause, acute or subacute development of a left ventricular dysfunction of unknown cause or myocardial damage that cannot be explained by CHD or other known causes. One guideline recommends referring patients with suspected or existing myocarditis to a specialized centre. In this context, patients with progressive clinical deterioration and end-organ failure should be transferred to a specialized centre with the utmost urgency to decide on whether a heart transplant or a mechanical circulatory assist device is indicated. The same applies to patients who, despite intensive medical treatment, show symptoms of severe heart failure (recommendations are potentially DMP relevant).

Two guidelines do not recommend the routine use of immunological therapies in myocarditis (recommendation is DMP relevant).

4.4.11.5 Arrhythmogenic right ventricular cardiomyopathy

One guideline provides recommendations on the care of patients with arrhythmogenic right ventricular cardiomyopathy (ARVC).

One guideline states that the suspected diagnosis of ARVC should be made in patients with unexplained dilation of the right ventricle and prior rhythm disorders or syncopes, typical ECG changes or a positive family history. To confirm the diagnosis, the guideline recommends checking the criteria of the ESC / International Society and Federation of Cardiology (ISFC). In addition, the guideline notes that within the framework of clarification, echocardiography or cardiac MRI should be performed. Patients with ARVC who have already suffered cardiac arrest or longer periods of ventricular tachycardia should be offered the implantation of an ICD. Furthermore, the guideline recommends that patients with ARVC should avoid strenuous physical activity and be cared for in a specialized centre (recommendations are potentially DMP relevant).

4.4.11.6 Constrictive pericarditis

One guideline provides recommendations on the care of patients with constrictive pericarditis.

The guideline notes that constrictive pericarditis should be suspected in patients with otherwise unexplained right heart failure. To assess pericardial thickness the guideline recommends performing cardiac computed tomography (CT) or cardiac MRI in these patients. In addition, in patients with constrictive pericarditis the guideline recommends performing echocardiography to assess ventricle filling, as well as simultaneous left- and right-sided cardiac catheterization to evaluate the physiological consequences of the constriction. Patients should also be offered referral to a specialized centre (recommendations are potentially DMP relevant).

4.4.11.7 Ventricular rhythm disorders

A total of 4 guidelines provide recommendations on the care of heart failure patients with ventricular rhythm disorders.

In the event of ventricular arrhythmia, one guideline recommends searching for triggering factors such as electrolyte imbalance, drug interactions or ischaemia (recommendation is potentially DMP relevant). A further guideline recommends performing an electrophysiological examination (EPE) in heart failure patients who experienced a syncope without a clear non-cardiac cause. However, the guideline advises against the routine performance of EPE in heart failure patients with asymptomatic, temporary ventricular tachycardia (recommendations are potentially DMP relevant).

In patients with ventricular rhythm disorders, 2 guidelines recommend first optimizing the treatment of heart failure and of the underlying disease (e.g. CHD), (recommendation is DMP relevant). In addition, 2 guidelines provide specific recommendations on the use of ICDs, on drug therapy with amiodarone, and on catheter ablation in heart failure patients with persistent or recurrent ventricular arrhythmia (ventricular tachycardia, ventricular fibrillation),(recommendation is DMP relevant). One guideline advises against the routine use of amiodarone in patients without long-lasting ventricular arrhythmia (recommendation is potentially DMP relevant), and 2 guidelines advise against the use of other anti-arrhythmic drugs (especially class I [C] and III [dronedarone]), (recommendation is DMP relevant).

One guideline recommends performing resynchronization therapy for heart failure patients with bradycardic rhythm disorders (class I ([ACC/AHA] pacemaker indication) in NYHA stage III/IV, an LVEF < 35%, and a QRS duration ≥ 120 ms (recommendation is potentially DMP relevant).

4.4.11.8 Atrial fibrillation

A total of 8 guidelines provide recommendations on the care of heart failure patients with atrial fibrillation.

Two guidelines recommend that in heart failure patients with atrial fibrillation, the resting heart rate and heart rate under exercise should be determined (recommendation is DMP relevant).

Two guidelines recommend heart rate control in patients with symptomatic heart failure, persistent atrial fibrillation and preserved LVEF (recommendations are potentially DMP relevant).

Four guidelines provide recommendations on the importance of heart rate and rhythm control in symptomatic patients with heart failure and atrial fibrillation. Reconversion to sinus rhythm should not be routinely performed. Patients with reduced LVEF can be treated either with a strategy of heart rhythm control or with a strategy of sole heart rate control, whereby neither strategy is superior (recommendation is potentially DMP relevant).

Three guidelines provide recommendations on heart rate control with drug therapy in heart failure patients with persistent atrial fibrillation. Beta-blockers are named as the first-line drugs, followed by digoxin in the case of beta-blocker intolerance. If the sole administration of beta-blockers is insufficient to control the heart rate, digoxin can be added. Instead of digoxin, amiodarone can also be used as second-line therapy (recommendation is DMP relevant).

Two guidelines provide recommendations on rhythm control with drug therapy. For instance, only amiodarone is to be used for this purpose and due to their negative inotropic effect, no class I antiarrhythmic drugs should be used (recommendation is DMP relevant).

After evaluation of the benefit-risk ratio by means of the CHA2DS2-VASc[3] and HAS-BLED[4] scores, 5 guidelines recommend treatment with oral anticoagulants for patients with symptomatic heart failure and persistent atrial fibrillation and in particular for patients regarded to be at a high risk of stroke (recommendations are DMP relevant). In addition, one guideline recommends anticoagulation of heart failure patients in whom cardioversion is indicated (recommendation is potentially DMP relevant).

One guideline provides a recommendation on the choice of oral anticoagulants depending on risk factors, costs, tolerability, patient preferences, potential drug interactions, concomitant diseases and age (recommendation is potentially DMP relevant).

4.4.11.9 Anaemia

A total of 4 guidelines provide recommendations on the treatment of anaemia in patients with heart failure.

In heart failure patients with anaemia (Hb < 110 g/l), one guideline recommends clarifying the cause in detail and initiating causal treatment. The following potential causes are mentioned: chronic bleeding, inflammatory diseases as well as iron, vitamin B 12 or folic acid deficiency (recommendations are potentially DMP relevant).

Furthermore, 2 guidelines note that treatment with erythropoiesis-stimulating agents should not be routinely performed in heart failure patients with anaemia (recommendation is potentially DMP relevant).

4.4.11.10 Depression, anxiety, sexual dysfunction

One guideline provides recommendations on the care of heart failure patients with depression, anxiety or sexual dysfunction.

The guideline recommends that, at the time of diagnosis and then in regular intervals, heart failure patients should, if clinically indicated, be screened for depression or a prolonged depressive episode. In patients with sexual dysfunction, treatment options should be openly discussed with the patient. In patients receiving nitrates, phosphodiesterase-5 inhibitors are not recommended as a treatment for sexual dysfunction (recommendations are potentially DMP relevant).

4.4.12 Right heart failure

One guideline provides recommendations for the treatment of right heart failure.

[3] CHA2DS2-VASc = Congestive heart failure. Hypertension. Age (≥75 years: 2 points). Diabetes mellitus. Stroke or transitory ischaemic attack (TIA) or thromboembolism (2 points) - Vascular disease. Age. Sex category. For more details see http://www.mdcalc.com/cha2ds2-vasc-score-for-atrial-fibrillation-stroke-risk/.

[4] HAS-BLED = Hypertension. Abnormal renal/liver function. Stroke - Bleeding history or predisposition. Labile international normalized ratio. Elderly (> 65 years). Drugs/alcohol. For more details see http://www.mdcalc.com/has-bled-score-for-major-bleeding-risk/.

Right heart failure can be caused by left heart failure, pulmonary arterial hypertension, or valvular defects in the right heart. The guideline recommends treating patients with right heart failure according to the triggering cause. Furthermore, the guideline notes that patients should always be treated by qualified medical specialists or in qualified specialized centres (recommendations are potentially DMP relevant).

4.4.13 Disease management programmes

A total of 5 guidelines provide recommendations on the care of heart failure patients within DMPs.

Five guidelines recommend DMPs for the care of patients with chronic heart failure, particularly of high-risk patients with recurrent hospital admissions. The goal of these multidisciplinary care programmes is to ensure the guideline-conform care of heart failure patients and to prevent hospital admissions (recommendations are DMP relevant).

One guideline notes that, among others, medical specialists, nursing staff, pharmacists, and nutritionists should be involved in these DMPs. A further guideline recommends that the collaboration between general practitioners (GPs) and specialists for heart failure should be promoted within the DMP in the same manner as the collaboration with care facilities (home care) or rehabilitation facilities (recommendations are potentially DMP relevant).

In addition, as important aspects for a DMP, 5 guidelines name, among other things, individually adapted counselling and training, the learning of self-management strategies, behavioural training to promote compliance, optimization of drug therapy, close monitoring after hospital discharge, good access to medical care, and support in the event of social problems (recommendations are DMP relevant).

One guideline recommends the development and regular adaptation of a treatment plan. In addition, a further guideline notes that, until improvement in their clinical condition and demonstrated compliance with the treatment programme, patients should remain in the DMP. In this context, high-risk patients with advanced heart failure could also be permanently included, or patients previously discharged from the DMP but suffering from recurrent exacerbations could be readmitted (recommendations are potentially DMP relevant).

4.4.14 Heart failure management in skilled nursing facilities

One guideline provides recommendations on heart failure management in skilled nursing facilities.

One guideline provides recommendations on decision-making regarding the further care of nursing facility residents with signs of decompensated heart failure. For instance, the guideline notes that the care of these patients should be patient-centred and highly individualized and that the patients, their relatives and the nursing team should be involved in

decision-making. In addition, the decision should be made depending on the treatment goals agreed upon beforehand (recommendations are potentially DMP relevant).

In addition, the guideline provides information on drug therapy, whereby, among other things, it is noted that a personalized drug therapy plan should be developed for each resident. Due to the mostly advanced age of the patients, comorbidities, drug interactions and side effects should be given particular consideration. Furthermore, the guideline advises regular evaluation of treatment with regard to desired and undesired effects (recommendations are potentially DMP relevant).

Furthermore, the guideline provides recommendations on the extent and content of documentation, for example, which parameters should be recorded when residents are admitted and which parameters should then be regularly recorded by the nursing team. The guideline notes that the weight of residents should be regularly monitored over months in order to determine clinically relevant weight loss (recommendations are potentially DMP relevant).

The guideline recommends increasing the physical activity of all residents with heart failure, whereby their individual preferences, physical status, as well as disease severity, should be taken into account (recommendation is potentially DMP relevant).

The guideline also provides information on the care of patients with implanted cardiac pacemaker or defibrillator devices. For instance, at all new admissions of residents it should be checked whether they are carrying such a device. In addition, the guideline provides recommendations on the handling of residents with an ICD and the potential switching off and monitoring of implants. The guideline also notes that, when considering the implantation of an ICD or a CRT, besides prognosis and comorbidities, the nursing goals should also be taken into account (recommendations are potentially DMP relevant).

Furthermore, the guideline provides information on interface management, noting that if residents are transferred to another healthcare facility, an oral and written handover should take place, and also describes what information is required here. If residents are discharged into their own home, their independence should be evaluated and, if necessary, care should be arranged (recommendations are potentially DMP relevant).

The guideline also provides recommendations on the evaluation of the independence of residents and the criteria to be covered. The training of residents and their relatives should be adapted to the deficits identified and should enable residents to evaluate their own clinical condition (recommendations are potentially DMP relevant).

According to the guideline, the employees of the nursing facility should also be trained regularly and the training should be adapted to their tasks. The guideline also recommends topics for such training (recommendations are potentially DMP relevant).

The guidelines suggest that goals of palliative care should be discussed both on admission of residents and also if their condition deteriorates. Palliative care should be targeted towards the wishes of the residents and the goals of care. In addition, medication should be continued until oral intake is no longer possible or hypotension develops. The criteria for deactivation of electronic cardiac assist devices should already have been specified beforehand (recommendations are potentially DMP relevant).

For quality management in the nursing facilities, the guideline states that the implementation of heart failure guidelines for residents and those responsible for their care should be accompanied by training and behavioural therapeutic interventions (recommendations are potentially DMP relevant).

5 Classification of the work result

Healthcare aspects and concomitant diseases

The consideration of co- or multimorbidities is an important aspect in the care of patients with heart failure [32,33]. The description of the handling of comorbidities differs between guidelines. Specific treatment recommendations are provided for patients who suffer from heart failure and one of the following concomitant diseases: sleep disorders, CHD, hypertension, myocarditis, ARVC, constrictive pericarditis, ventricular rhythm disorders, atrial fibrillation, anaemia as well as depression, anxiety disorders and sexual dysfunction. In contrast, no specific recommendations are provided in the guidelines for the concomitant diseases of renal failure, diabetes mellitus and chronic obstructive pulmonary disease (COPD). They are only addressed indirectly by referring to special characteristics of these patient groups in recommendations on the diagnostics and treatment of heart failure. For instance, within the framework of recommendations on the diagnostic clarification of heart failure, the necessity to determine the glomerular filtration rate is noted. Furthermore, for certain drugs the guidelines recommend regularly monitoring these levels and, if applicable, adapting doses.

However, when formulating requirements for a DMP, common concomitant diseases not presented in the guideline synopsis (e.g. renal failure, diabetes mellitus, COPD) should also be considered.

None of the guidelines included referred to the care of multimorbid patients with heart failure (see the section on polypharmacy below).

Guideline statements without recommendatory character

The guidelines provide different definitions of heart failure that only differ in their focus on structural or functional aspects, but are basically consistent. In addition, the guidelines name classification systems that are a prerequisite for an implementation of recommendations specifically provided for a degree of disease severity. This refers to the AHA’s classification of stages and the NYHA’s classification of severity, which are also used in German-language text books [34] and guidelines [6]. As the definitions and classification systems do not represent recommendations, in the synthesis they are not rated as relevant aspects for a DMP directive.

Furthermore, algorithmic process used in the guidelines to depict the diagnostic process as a whole or to depict treatment strategies are not presented in the synthesis of recommendations, as the algorithms do not contain a designation by GoR or LoE (e.g. guidelines ICSI 2010 or NICE 2010). The same applies to additional information from tables. For instance, the guideline ESC 2012 contains a table with topics for patient training, which, in the opinion of the guideline authors, should by all means be addressed and communicated.

In "Clinical Practice Points" some guidelines provide additional information on recommendations, without allocation of a GoR or LoE. This additional information refers to, for example, the interpretation of findings in the area of diagnostics or to dosages, contraindications, and side effects in the area of treatment.

Chest X-ray

Only 4 of 22 guidelines recommend performing a chest X-ray. This reflects the perception that, in view of the more informative imaging procedure of echocardiography (which is also without radiation exposure), the importance of a chest X-ray as an imaging procedure has decreased and is at best relevant within the framework of verifying pulmonary congestion (e.g. in patients with acute decompensation). Recommendations that can be interpreted in this sense are found in the (no longer valid) German National Care Guideline (Nationale VersorgungsLeitlinie, NVL) "Chronische Herzinsuffizienz" (chronic heart failure) [6] and in IQWiG's final report on project V09-06 [31].

Polypharmacy

In the area of drug therapy only 2 guidelines (ICSI 2013, MQIC 2013) address the problem of polypharmacy and how to handle it. As no information on GoR or LoE is available, no statement could be made on the relevance of these recommendations for a DMP. Nonetheless, chronic heart failure is a disorder that commonly occurs within the context of multimorbidity, which in turn greatly increases the risk of polypharmacy. The lack of recommendations on handling multimorbidity in guidelines is a well-known and so far unsolved problem [35]. In the information synthesis on drug therapy it was attempted to at least partly solve this problem – the specific recommendations on the decision as to whether individual drugs are indicated were in each case followed by a section with recommendations on the combination of this drug with other drugs. These sections contain both positive and negative recommendations, but are restricted to one therapeutic indication. Interactions between drugs for different therapeutic indications (e.g. antihypertensive or antidiabetic drugs) are not covered. In a concluding section with general information on drug therapy, interactions in patients with comorbidities leading to restrictions to the therapeutic indication or to contraindications (e.g. beta-blockers in patients with peripheral arterial occlusive disease [PAOD] or asthma) are presented, as well as particular requirements for monitoring. However, recommendations on all 3 sections – therapeutic indication, combination, and general information – are only available in the guidelines for the most common drugs (ACE inhibitors, beta-blockers, ARBs).

Continuum of care

Chronic heart failure is not a monophasic disease. Rather, the course is characterized by changes in symptoms and stages. The most threatening condition is acute decompensation, which may develop from a chronic phase. If acute decompensation can be controlled with treatment, the disease then transitions into the chronic phase again. The period after recovering from an acute decompensation is regarded to be a particularly vulnerable phase

[36]. In consequence, the care of patients with heart failure must be adapted to the risk in the different phases; this means that rigid treatment recommendations cannot reflect the required intensity of care as a continuum. In guidelines it is mostly attempted to account for the different risk constellations in separate sections. In this respect, the present guideline synopsis follows the structure of the documents included. However, as an approximation to the continuum, it has dedicated a separate section to the high-risk phase between decompensation and chronic course (Section 4.4.7 as well as section A.3.4.7 of the full report).

Applicability

With high GoR, guidelines from the United States issue recommendations on the combination therapy of isosorbide dinitrate/hydralazine as an add-on to ACE inhibitors and beta-blockers for Afro-American patients with advanced heart failure (NYHA III–IV). In Germany, these recommendations are of far less importance due to the specific patient group to which they apply.

System-related differences are especially noticeable regarding less addressed healthcare aspects in the guidelines, such as monitoring, patient training, cooperation of healthcare sectors, and DMPs. For instance, the recommendations on rehabilitation measures in Anglo-American guidelines have a strong focus on physiotherapy and physical exercise (guideline CCS 2013 Reha), and thus tend not to depict the complex multimodal and interdisciplinary therapeutic approach chosen in the German rehabilitation system [37].

Amendments on the basis of comments and the scientific debate

In the oral scientific debate, persons who had submitted comments on the preliminary report noted that an updated ESC guideline is to be published in May 2016 and that important updates are to be expected in comparison with statements from guidelines included in the present report.

To improve symptoms, reduce hospitalization rates, and improve survival rates, the guidelines included in the present report recommend CRT for patients with a left bundle branch block with a QRS duration > 120 ms, sinus rhythm, LVEF ≤ 35%, and NYHA II-IV, despite optimal drug therapy. Persons who had submitted comments referred to current studies [38,39] suggesting that CRT leads to relevant effects only in patients with a QRS duration of > 140 ms.

Furthermore, they addressed the treatment of heart failure patients with central sleep apnoea by means of adaptive servoventilation (ASV) and referred to the results of the SERVE-HF study [40]. In this study, the effectiveness of ASV was compared with guideline-conform drug therapy of patients suffering from predominantly central sleep apnoea and symptomatic, chronic-stable heart failure (NYHA II-IV) with reduced LVEF. The study results indicate an increased mortality risk in the ASV group.

6 Conclusion

On the basis of GoR (or alternatively of LoE) of the extracted recommendations from current evidence-based guidelines, relevant and potentially relevant recommendations on all prespecified healthcare aspects were identified for a DMP “chronic heart failure”. In addition, relevant and potentially relevant recommendations were identified on the healthcare aspects of patients with decompensated heart failure, palliative care, heart failure in specific patient groups, treatment of concomitant diseases, right heart failure, DMPs, and nursing management of nursing facility residents with heart failure.

The diagnostic recommendations refer to basic and further diagnostics of heart failure, as well as to the diagnostics of right heart failure.

For non-drug therapy and general measures, recommendations were identified on lifestyle changes, diet, weight control, on physical activity/sports, as well as on vaccinations.

For drug therapy, the recommendations identified refer to general aspects of drug therapy, as well as to treatment with ACE inhibitors, beta-blockers, ARBs, aldosterone antagonists, diuretics, cardiac glycosides, oral anticoagulants and antiplatelet agents, antiarrhythmic drugs, isosorbide dinitrate/hydralazine, inotropic drugs, as well as other drugs. Treatment with nutritional supplements is also addressed.

For interventional therapy, the recommendations identified refer to CRT, ICDs, mechanical circulatory support, heart transplantation, and heart valve replacement or reconstruction.

Furthermore, recommendations on patient monitoring and on patient training were identified.

In addition, for patients with decompensated heart failure, recommendations were identified on diagnostics, hospital admission, treatment goals, non-drug and drug therapy, as well as on monitoring.

Furthermore, the recommendations identified refer to the care of patients after decompensation of chronic heart failure, to palliative care and to the cooperation of healthcare sectors.

Specific recommendations were identified for heart failure in pregnancy and in children and adolescents. In addition, for treatment of concomitant or triggering diseases, recommendations for patients with the following disorders were identified: sleep disorders, CHD, hypertension, myocarditis, ARVC, constrictive pericarditis, ventricular rhythm disorders, atrial fibrillation, anaemia, depression, anxiety disorders or sexual dysfunction.

Recommendations were also identified on DMPs and on heart failure management in skilled nursing facilities.

References for English extract

Please see full final report for full reference list.

1. Bundesministerium der Justiz. Sozialgesetzbuch (SGB) Fünftes Buch (V): Gesetzliche Krankenversicherung; (Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBl. I S. 2477) [online]. 11.08.2014 [accessed: 02.09.2014]. URL: http://www.gesetze-im-internet.de/bundesrecht/sgb_5/gesamt.pdf.

2. Bundesversicherungsamt. Zulassung der Disease Management Programme (DMP) durch das Bundesversicherungsamt (BVA) [online]. 01.2014 [accessed: 02.09.2014]. URL: http://www.bundesversicherungsamt.de/druckversion/weitere-themen/disease-management-programme/zulassung-disease-management-programme-dmp.html.

3. Zugck C, Müller A, Helms TM, Wildau HJ, Becks T, Hacker J et al. Gesundheitsökonomische Bedeutung der Herzinsuffizienz: Analyse bundesweiter Daten. Dtsch Med Wochenschr 2010; 135(13): 633-638.

4. Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Drazner MH et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation 2013; 128(16): e240-e327.

5. Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin. Herzinsuffizienz: Teil 1 [online]. 09.2006 [accessed: 24.09.2014]. (DEGAM-Leitlinien; volume 9). URL: http://www.degam.de/files/Inhalte/Leitlinien-Inhalte/Dokumente/DEGAM-S3-Leitlinien/LL-09_Langfassung_Herzinsuffizienz_1_E002BIndex.pdf.

6. Bundesärztekammer, Kassenärztliche Bundesvereinigung, Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften. Nationale VersorgungsLeitlinie: chronische Herzinsuffizenz; Langfassung; Version 7 [online]. 08.2013 [accessed: 08.12.2014]. URL: http://www.leitlinien.de/mdb/downloads/nvl/herzinsuffizienz/herzinsuffizienz-1aufl-vers7-lang.pdf.

7. McMurray JJV, Adamopoulos S, Anker SD, Auricchio A, Bohm M, Dickstein K et al. ESC guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. Eur Heart J 2012; 33(14): 1787-1847.

8. Field MJ, Lohr KN (Ed). Clinical practice guidelines: directions for a new program. Washington: National Academy Press; 1990.

9. Graham RM, Mancher M, Miller-Wolman D, Greenfield S, Steinberg E (Ed). Clinical practice guidelines we can trust. Washington: National Academies Press; 2011.

10. Hunt SA, Abraham WT, Chin MH, Feldman AM, Francis GS, Ganiats TG et al. 2009 focused update incorporated into the ACC/AHA 2005 guidelines for the diagnosis and management of heart failure in adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines; developed in collaboration with the International Society for Heart and Lung Transplantation. Circulation 2009; 119(14): e391-e479.

11. Vandvik PO, Lincoff AM, Gore JM, Gutterman DD, Sonnenberg FA, Alonso-Coello P et al. Antithrombotic therapy and prevention of thrombosis, 9th ed: ACCP guidelines; primary and secondary prevention of cardiovascular disease. Chest 2012; 141(2 Suppl): e637S-e668S.

12. Jurgens CY, Goodlin S, Dolansky M, Ahmed A, Fonarow GC, Boxer R et al. Heart failure management in skilled nursing facilities: a scientific statement from the American Heart Association and the Heart Failure Society of America. Circ Heart Fail 2015; 8(3): 655-687.

13. Moe GW, Ezekowitz JA, O'Meara E, Lepage S, Howlett JG, Fremes S et al. Erratum: „The 2014 Canadian Cardiovascular Society Heart Failure Management Guidelines Focus Update: anemia, biomarkers, and recent therapeutic trial implications" (Can J Cardiol 2015; 31(1): 3-16). Can J Cardiol 27.08.2015 [Epub ahead of print].

14. Moe GW, Ezekowitz JA, O'Meara E, Lepage S, Howlett JG, Fremes S et al. The 2014 Canadian Cardiovascular Society Heart Failure Management Guidelines Focus Update: anemia, biomarkers, and recent therapeutic trial implications. Can J Cardiol 2015; 31(1): 3-16.

15. Kantor PF, Lougheed J, Dancea A, McGillion M, Barbosa N, Chan C et al. Presentation, diagnosis, and medical management of heart failure in children: Canadian Cardiovascular Society guidelines. Can J Cardiol 2013; 29(12): 1535-1552.

16. Exner DV, Birnie DH, Moe G, Thibault B, Philippon F, Healey JS et al. Canadian Cardiovascular Society guidelines on the use of cardiac resynchronization therapy: evidence and patient selection. Can J Cardiol 2013; 29(2): 182-195.

17. Parkash R, Philippon F, Shanks M, Thibault B, Cox J, Low A et al. Canadian Cardiovascular Society guidelines on the use of cardiac resynchronization therapy: implementation. Can J Cardiol 2013; 29(11): 1346-1360.

18. McKelvie RS, Moe GW, Ezekowitz JA, Heckman GA, Costigan J, Ducharme A et al. The 2012 Canadian Cardiovascular Society heart failure management guidelines update: focus on acute and chronic heart failure. Can J Cardiol 2013; 29(2): 168-181.

19. Moe GW, Ezekowitz JA, O'Meara E, Howlett JG, Fremes SE, Al-Hesayen A et al. The 2013 Canadian Cardiovascular Society heart failure management guidelines update: focus on rehabilitation and exercise and surgical coronary revascularization. Can J Cardiol 2014; 30(3): 249-263.

20. Baskett R, Crowell R, Freed D, Giannetti N, Simpson CS. Canadian Cardiovascular Society focused position statement update on assessment of the cardiac patient for fitness to drive: fitness following left ventricular assist device implantation. Can J Cardiol 2012; 28(2): 137-140.

21. McKelvie RS, Moe GW, Cheung A, Costigan J, Ducharme A, Estrella-Holder E et al. The 2011 Canadian Cardiovascular Society heart failure management guidelines update: focus on sleep apnea, renal dysfunction, mechanical circulatory support, and palliative care. Can J Cardiol 2011; 27(3): 319-338.

22. Howlett JG, McKelvie RS, Costigan J, Ducharme A, Estrella-Holder E, Ezekowitz JA et al. The 2010 Canadian Cardiovascular Society guidelines for the diagnosis and management of heart failure update: heart failure in ethnic minority populations, heart failure and pregnancy, disease management, and quality improvement/assurance programs. Can J Cardiol 2010; 26(4): 185-202.

23. Howlett JG, McKelvie RS, Arnold JM, Costigan J, Dorian P, Ducharme A et al. Canadian Cardiovascular Society Consensus Conference guidelines on heart failure, update 2009: diagnosis and management of right-sided heart failure, myocarditis, device therapy and recent important clinical trials. Can J Cardiol 2009; 25(2): 85-105.

24. National Heart Foundation of New Zealand. New Zealand [guideline] for the management of chronic heart failure: 2009 update. Auckland: National Heart Foundation of New Zealand; 2010. URL: http://www.heartfoundation.org.nz/uploads/Guideline-Management-Chronic-Heart-Failure-5.pdf.

25. Brignole M, Auricchio A, Baron-Esquivias G, Bordachar P, Boriani G, Breithardt OA et al. 2013 ESC guidelines on cardiac pacing and cardiac resynchronization therapy. Eur Heart J 2013; 34(29): 2281-2329.

26. Dickstein K, Vardas PE, Auricchio A, Daubert JC, Linde C, McMurray J et al. 2010 focused update of ESC guidelines on device therapy in heart failure: an update of the 2008 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure and the 2007 ESC guidelines for cardiac and resynchronization therapy; developed with the special contribution of the Heart Failure Association and the European Heart Rhythm Association. Eur Heart J 2010; 31(21): 2677-2687.

27. Lindenfeld J, Albert NM, Boehmer JP, Collins SP, Ezekowitz JA, Givertz MM et al. HFSA 2010 comprehensive heart failure practice guideline. J of Card Fail 2010; 16(6): e1-e194.

28. Pinkerman C, Sander P, Breeding JE, Brink D, Curtis R, Hayes R et al. Heart failure in adults [online]. 07.2013 [accessed: 16.12.2014]. URL: https://www.icsi.org/_asset/50qb52/HeartFailure.pdf.

29. University of Michigan Health System. Heart failure: systolic dysfunction [online]. 08.2013 [accessed: 16.12.2014]. URL: http://www.med.umich.edu/1info/FHP/practiceguides/heart/HF.pdf.

30. National Clinical Guideline Centre. Chronic heart failure: national clinical guideline for diagnosis and management in primary and secondary care; full version of NICE clinical guideline no 108 [online]. 08.2010 [accessed: 08.12.2014]. URL: http://www.nice.org.uk/guidance/cg108/resources/cg108-chronic-heart-failure-full-guideline3.

31. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Systematische Leitlinienrecherche und -bewertung sowie Extraktion neuer und relevanter Empfehlungen für das DMP-Modul Herzinsuffizienz: Abschlussbericht; Auftrag V09-06 [online]. 19.12.2011 [accessed: 11.03.2013]. (IQWiG-Berichte; volume 109). URL: https://www.iqwig.de/download/V09-06_AB_Leitlinienrecherche_und-bewertung_fuer_das_DMP-Modul_Herzinsuffizienz.pdf.

32. Angermann CE. Comorbidities in heart failure: a key issue. European Journal of Heart Failure Supplements 2009; 8(Suppl 1): i5-i10.

33. Lip GY, Gibbs CR, Beevers DG. ABC of heart failure: aetiology. BMJ 2000; 320(7227): 104-107.

34. Herold G (Ed). Innere Medizin 2015. Köln: Herold; 2015.

35. Blozik E, Dubben HH, Wagner HO, Scherer M. Komorbidität in Leitlinien: Ist-Zustand, epidemiologische Modelle und Expertenmeinung im Vergleich. Z Evid Fortbild Qual Gesundhwes 2014; 108(4): 219-228.

36. Allen LA, O'Connor CM. Management of acute decompensated heart failure. CMAJ 2007; 176(6): 797-805.

37. Raspe H, Ekkernkamp M, Matthis C, Raspe A, Mittag O. Bedarf an rehabilitativen Leistungen: Theorie und Empirie. Rehabilitation (Stuttg) 2005; 44(6): 325-334.

38. Cleland JG, Abraham WT, Linde C, Gold MR, Young JB, Daubert JC et al. An individual patient meta-analysis of five randomized trials assessing the effects of cardiac resynchronization therapy on morbidity and mortality in patients with symptomatic heart failure. Eur Heart J 2013; 34(46): 3547-3556.

39. Ruschitzka F, Abraham WT, Singh JP, Bax JJ, Borer JS, Brugada J et al. Cardiac-resynchronization therapy in heart failure with a narrow QRS complex. N Engl J Med 2013; 369(15): 1395-1405.

40. Cowie MR, Woehrle H, Wegscheider K, Angermann C, D'Ortho MP, Erdmann E et al. Adaptive servo-ventilation for central sleep apnea in systolic heart failure. N Engl J Med 2015; 373(12): 1095-1105.

The full report (German version) is published under

https://www.iqwig.de/en/projects-results/projects/quality-of-health-care/v14-01-systematic-guideline-search-and-appraisal-as-well-as-extraction-of-relevant-recommendations-for-a-dmp-chronic-heart-failure.6252.html.