

IQWiG Reports – V15-01

Exploratory examination of the need for revision of the DMP “coronary heart disease”¹

Extract

¹ Translation of Chapters 1 to 6 of the rapid report *Orientierende Überprüfung des Überarbeitungsbedarfs des DMP Koronare Herzkrankheit* (Version 1.0; Status: 18 February 2016). 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:

Exploratory examination of the need for revision of the DMP “coronary heart disease”

Commissioning agency:

Federal Joint Committee

Commissioned on:

18 June 2015

Internal Commission No.:

V15-01

Address of publisher:

Institute for Quality and Efficiency in Health Care

Im Mediapark 8

50670 Köln

Germany

Tel.: +49 221 35685-0

Fax: +49 221 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 A10 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

- Stefan Frantz, University Clinic and Outpatient Clinic Internal Medicine III, University Clinic, Halle (Saale), Germany
- Thomas Frese, University of Leipzig, Germany
- Johannes Haerting, Institute for Medical Epidemiology, Biometry and Informatics, Martin Luther University Halle-Wittenberg, Germany
- Marcin Maciolek, University Clinic and Outpatient Clinic Internal Medicine III, University Clinic, Halle (Saale), Germany
- Markus Schürmann, University Clinic and Outpatient Clinic Internal Medicine III, University Clinic, Halle (Saale), Germany
- Susanne Unverzagt, Institute for Medical Epidemiology, Biometry and Informatics, Martin Luther University Halle-Wittenberg, Germany

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

IQWiG employees²

- Susanne Ein Waldt
- Eva Höfer
- Marco Knelangen
- Mandy Kromp
- Ulrich Siering

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

Keywords: coronary artery disease, coronary heart disease, disease management programme, guidelines as topic

Key statement***Research question***

The aim of this investigation is the exploratory examination of the need for revision of the disease management programme “coronary heart disease” (DMP CHD). This examination was conducted on the basis of current information relevant for the DMP CHD from selected sources.

Conclusion

In the different information sources, new or deviating information was found on the healthcare aspects of diagnostics, differentiated planning of treatment, therapeutic measures, monitoring and follow-up, as well as rehabilitation and training of patients.

The individual components of the new or deviating information identified do not create an urgent need for revision of the DMP CHD. However, due to the abundance of new information it is proposed to initiate the procedure of updating the DMP CHD.

Table of contents

	Page
Publishing details	i
Key statement	iv
Table of contents	v
List of tables	vi
List of abbreviations	vii
1 Background	1
2 Research question	4
3 Methods	5
4 Results	7
4.1 Results of information retrieval	7
4.1.1 Search in guideline databases and on websites of guideline providers	7
4.1.2 Searches in tertiary sources	7
4.1.3 Search for safety notices.....	8
4.1.4 Search in the Pharmaceutical Directive	8
4.1.5 Search for IQWiG benefit assessments	8
4.2 Need for revision	8
4.2.1 Relevant information for the evaluation of the need for revision.....	8
4.2.1.1 Sufficient diagnostics for inclusion in a DMP	9
4.2.1.2 Differentiated planning of treatment on the basis of individual risk assessment.....	9
4.2.1.3 General measures, risk factor management, and handling of co- or multimorbidity	10
4.2.1.4 Drug therapy	10
4.2.1.5 Monitoring and follow-up.....	11
4.2.1.6 Rehabilitation	12
4.2.1.7 Patient training	12
4.2.2 Evaluation of the need for revision.....	12
5 Classification of the work result	14
6 Conclusion	15
References for English extract	16

List of tables

	Page
Table 1: Abbreviations of the guidelines included and the publishing institutions	7

List of abbreviations

Abbreviation	Meaning
ACCF	American College of Cardiology Foundation
ACE inhibitors	angiotensin-converting enzyme inhibitors
AHA	American Heart Association
AP	angina pectoris
CHD	coronary heart disease
DMP	disease management programme
ECG	electrocardiogram
ESC	European Society of Cardiology
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
GoR	Grade of Recommendation
HbA1c	glycosylated haemoglobin
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
LoE	Level of Evidence
LV	left ventricular
NVL	Nationale VersorgungsLeitlinien (National Care Guideline)
PCSK9 inhibitors	proprotein convertase subtilisin/kexin type 9

1 Background

Systematically prepared guideline synopses of the Institute for Quality and Efficiency in Health Care (IQWiG) serve the Federal Joint Committee (G-BA) as a basis for revision of the requirements for the design of disease management programmes (DMPs).

Before the G-BA commissions IQWiG to prepare a systematic guideline synopsis, according to its Code of Procedure it evaluates whether there are indications of a possible need for revision of requirements for existing DMPs.

Disease management programmes

DMPs are structured treatment programmes for chronically ill people that are based on the findings of evidence-based medicine. Within 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 their quality of life. 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].

The requirements for the design of the DMP are regulated in the G-BA's directives [3,4] and, according to the Social Code Book (SGB) V, must be regularly examined [1,2]. The G-BA's Code of Procedure also stipulates a regular examination of the requirements for the DMP [5].

Approach of the G-BA when examining the existing directives

The regular examination of the requirements of existing DMPs is performed in several steps according to the G-BA's Code of Procedure [5].

Initially it is examined whether there are indications of a possible need for revision of existing directives. At this point the examination starts. The exploratory examination of the need for revision aims to provide information to the G-BA to support its decision-making as to whether a need for revision exists for a DMP. If, after examining all the necessary information, the G-BA determines that there is a need for revision, it subsequently initiates the procedure for revision of the respective DMP.

For the exploratory examination of the need for revision of DMPs, a methodology was tested in a feasibility study (working paper GA14-06) [6] on the basis of which the present project was commissioned.

Working paper GA14-06

In the working paper GA14-06 "Regular exploratory examination of the need for DMP revision – a feasibility study using the example of the DMP 'coronary heart disease' (CHD)" [6] it was tested to what extent a need for revision of DMPs can be determined by means of the exploratory examination of guidelines, safety notices, the (German) Pharmaceutical Directive, IQWiG's benefit assessments, as well as studies and systematic reviews.

In the conclusion of the working paper it was noted, among other things, that the need for revision of a DMP could be estimated with the chosen approach. According to a further result of the working paper, instead of a search in bibliographic databases for studies and systematic reviews, web-based information sources should be used that search for and assess evidence on clinical interventions and make it available in a summarized form (referred to as “tertiary sources” in the following text).

Also against this background, when the G-BA commissioned IQWiG with the present report, it noted that the exploratory examination of the need for revision of the DMP CHD should roughly follow the methodology of working paper GA14-06, but that in particular it should dispense with the search for and assessment of studies, as well as systematic reviews.

Coronary heart disease

CHD manifests itself as arteriosclerosis (also called atherosclerosis) of the coronary arteries [7,8]. The starting point of the disease is damage to the endothelial function resulting in pathological lipid accumulation in the vessel wall and in the development of atherosclerotic plaques. In most cases, no clinical symptoms exist in the early stage of disease. In the advanced stage, the increasing stenosis of the vessels leads to an imbalance between the need for oxygen and the oxygen supply in the heart muscle and subsequently to myocardial ischaemia. This commonly manifests itself as angina pectoris (AP), that is, sudden pain in the chest, jaw, arm or other regions, lasting seconds to minutes [9]. The development of heart failure, myocardial infarction, or sudden cardiac death may be consequences of CHD [10].

CHD is a chronic disease. Stable AP is a clinical form of manifestation of CHD that reproducibly occurs under physical or mental stress and is constant over months. In contrast, acute phases of CHD that are directly life-threatening or fatal are summarized under the term “acute coronary syndrome”. This also includes unstable AP occurring under slight or no physical activity, myocardial infarction with or without ST-segment elevations, as well as sudden cardiac death [11,12].

Risk factors for the development of CHD include increasing age, male sex, smoking, obesity, hypertension, hypercholesterolaemia, and diabetes mellitus [11,13].

Guidelines

For the present report the term “guidelines” is used according to the definition of the US Institute of Medicine (IOM): “practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” [14] 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” [15].

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 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 varying importance of the different clinical and epidemiological studies, as well as of further potentially biasing factors, if applicable.

2 Research question

The aim of this investigation is the exploratory examination of the need for revision of the DMP CHD. This examination was conducted on the basis of current information relevant for the DMP CHD from selected sources.

3 Methods

To estimate the need for revision of the DMP CHD, information was compiled from current evidence-based guidelines, tertiary sources, safety notices, the Pharmaceutical Directive, and IQWiG's benefit assessments. The information drawn upon in addition to the guidelines was used to obtain indications of new developments in health care not yet considered in the guidelines.

The target population of the investigation were men and women with diagnosed CHD (chronic CHD or acute coronary syndrome). These are patients whose symptoms, medical history (including concomitant diseases) and results of the clinical examination and stress electrocardiogram (stress ECG) result in a probability of at least 90% for the existence of CHD.

Evidence-based guidelines were included that had been specifically developed for patients with CHD, were applicable to the German healthcare system, and published from September 2010 onwards. In addition, the recommendations had to be clearly formally designated. Information from tertiary sources was included if it represented new or deviating information in comparison with the DMP CHD and was supported by literature published from 2010 onwards. The safety notices included Drug Safety Mails ("Rote-Hand-Briefe") and safety notices from the Federal Institute for Drugs and Medical Devices (BfArM) published from 2010 onwards. Information from the current Pharmaceutical Directive had to contain statements on changes in prescribability and IQWiG's benefit assessments had to be published from 2010 onwards.

To identify DMP-relevant guidelines a focused Internet search was conducted in the guideline database of the German Association of the Scientific Medical Professional Societies (AWMF), as well as on the websites of selected multidisciplinary and specialist guideline providers. Information from tertiary sources was identified via the websites of BMJ Clinical Evidence, UpToDate, and DynaMed; safety notices were identified via the websites of the Drug Commission of the German Medical Association (AkdÄ) and the Federal Institute for Drugs and Medical Devices. Furthermore, information on changes in prescribability was identified from the current Pharmaceutical Directive and IQWiG's benefit assessments were identified via the IQWiG website.

DMP-relevant guidelines were selected on the basis of title and abstract screening with subsequent full-text evaluation of the potentially relevant guidelines. Title and abstract screening was performed by one reviewer and a second reviewer checked the result. The full-text evaluation and the selection of guidelines to be included were performed by 2 reviewers independently of one another. In addition, it was evaluated and documented whether information on upcoming updates of DMP-relevant guidelines was available.

The search for information from tertiary sources, for safety notices, information from the Pharmaceutical Directive, and IQWiG benefit assessments, as well as assessment of the

search results with regard to their DMP relevance, were in each case conducted by one reviewer and checked by another. Discrepancies were solved through discussion.

To identify new or deviating information, the relevant search results were subsequently compared with the requirements for the DMP CHD and checked by a second person. Discrepancies were solved through discussion. With regard to the information from the guidelines, only the extracted guideline recommendations with the highest possible GoR within the classification system of a guideline were compared with the requirements for the DMP CHD and evaluated with regard to new or deviating content. Alternatively, if no GoR was available, the highest possible LoE of the highest reported evidence level was used instead. If no recommendations on a healthcare aspect were available in the guidelines supported by the highest possible GoR or alternatively the highest possible LoE, the recommendations with the highest reported GoR on the respective healthcare aspect (or alternatively the highest reported LoE) were evaluated with regard to new or deviating content.

The new and deviating content identified was organized in tables according to healthcare aspects. In the tables it was also described whether the new or deviating information was relevant for evaluation of the need for revision of the DMP CHD. The information rated as relevant was subsequently summarized in writing.

Finally, there was an evaluation as to whether the new or deviating information identified would potentially lead to a change (amendment, deletion etc.) of the requirements of the DMP CHD, that is, whether a revision of this DMP CHD should be initiated. The need for its revision was to be rated as urgent if indications of specific healthcare risks existed.

4 Results

4.1 Results of information retrieval

4.1.1 Search in guideline databases and on websites of guideline providers

The systematic Internet search yielded 36 potentially relevant documents after title and abstract screening, which were screened in full text. After evaluation of the general and methodological inclusion criteria, 13 relevant guidelines were included.

In 5 of these guidelines, information on planned updates was identified.

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

Abbreviation	Publisher	Information on updates provided
ACC 2014 [16]	American College of Cardiology (ACC), American Heart Association (AHA)	no
ACCF 2013 [17]	American College of Cardiology Foundation (ACCF), American Heart Association (AHA)	no
ACCF 2012 [18]	American College of Cardiology Foundation (ACCF), American Heart Association (AHA)	no
AHA 2014 [19]	American College of Cardiology (ACC), American Heart Association (AHA)	no
AHA 2011 [20]	American Heart Association (AHA), American College of Cardiology Foundation (ACCF)	no
ESC 2013 [21]	European Society of Cardiology (ESC)	no
ESC 2012 [22]	European Society of Cardiology (ESC)	no
ESC 2011 [23]	European Society of Cardiology (ESC)	no
NCGC 2011 [24]	National Clinical Guidelines Centre (NCGC)	Next review Sep/2015
NICE 2014 [25]	National Institute for Health and Care Excellence (NICE)	Next review Sep/2015
NICE 2013 [26]	National Institute for Health and Care Excellence (NICE)	Next review Dec/2015
NVL 2014 ^a [12]	German Medical Association (BÄK), National Association of Statutory Health Insurance Physicians (KBV), German Association of the Scientific Medical Professional Societies (AWMF)	1 Aug 2016
SIGN 2013 [27]	Scottish Intercollegiate Guidelines Network (SIGN)	2016

a: Comments on the consultation version of the NVL CHD could be submitted up to 4 December 2015.
CHD: coronary heart disease; NVL: Nationale VersorgungsLeitlinie (National Care Guideline)

4.1.2 Searches in tertiary sources

The searches yielded a total of 15 documents from the websites UpToDate (n=10), DynaMed (n=4) and BMJ Clinical Evidence (n=1).

4.1.3 Search for safety notices

After title and abstract screening, the search for information on the safety risks of drugs on the website of the Drug Commission of the German Medical Association yielded a total of 13 potential relevant Drug Safety Mails, which were screened in full text. After evaluation of the general inclusion criteria, 12 relevant Drug Safety Mails were included in the report.

After title screening, the search for safety notices for medical devices on the website of the Federal Institute for Drugs and Medical Devices yielded a total of 3 potentially relevant documents from this institute, which were screened in full text. After evaluation of the general inclusion criteria, none of its recommendations was included in the report.

4.1.4 Search in the Pharmaceutical Directive

After title screening, the search for information on the Pharmaceutical Directive on the G-BA website yielded 3 potentially relevant documents, which were screened in full text. After evaluation of the general inclusion criteria, 2 documents were included in the report.

4.1.5 Search for IQWiG benefit assessments

After title screening, the search for benefit assessments on the IQWiG website yielded 22 potentially relevant benefit assessments and one potentially relevant addendum, which were screened in full text. After evaluation of the general inclusion criteria, 4 relevant benefit assessments and 1 addendum were included in the report.

4.2 Need for revision

4.2.1 Relevant information for the evaluation of the need for revision

The information identified via the search was examined with regard to whether it referred to new or deviating information that could justify a need for revision of the DMP.

New or deviating recommendations in the guidelines that could justify a need for revision were identified on the following healthcare aspects: diagnostics, differentiated planning of treatment on the basis of individual risk assessment, therapeutic measures, monitoring and follow-up, rehabilitation, and patient training.

In the tertiary sources, new or deviating information that was supported by studies published from 2010 onwards and could justify a need for revision was identified on the following healthcare aspects: diagnostics, differentiated planning of treatment on the basis of individual risk assessment, therapeutic measures, and rehabilitation.

No new or deviating information that could justify a need for revision could be identified via the safety notices, the Pharmaceutical Directive, and the IQWiG benefit assessments.

In the following text, for the single healthcare aspects only the new or deviating information relevant for the evaluation of the need for revision is summarized.

4.2.1.1 Sufficient diagnostics for inclusion in a DMP

Three guidelines (ACCF 2012, ESC 2013, NVL 2014) and one tertiary source (UpToDate) contain statements on diagnostics in patients with CHD.

Laboratory tests

To optimize drug therapy, guideline ESC 2013 recommends screening CHD patients for type 2 diabetes and determining glycosylated haemoglobin (HbA1c) and fasting glucose levels. According to the guideline, an oral glucose tolerance test (oGTT) is indicated if the results for HbA1c and fasting glucose are ambiguous. Furthermore, in all patients creatinine levels should be measured and renal function estimated.

Within basic diagnostics, besides clarifying cardiac risk factors, guideline NVL 2014 recommends determining haemoglobin, fasting lipid, and fasting glucose levels.

Technical diagnostic procedures

Guideline ESC 2013 recommends conducting resting echocardiography for all patients, among other things to exclude alternative causes for AP or assess local wall motion abnormalities. Echocardiography is recommended to assess left-ventricular (LV) systolic (ACCF 2012, ESC 2013) and diastolic ventricular function (ACCF 2012, ESC 2013), as well as to assess abnormalities of the myocardium, the heart valves, and the pericardium (ACCF 2012). Guidelines ACCF 2012 and NVL 2014 recommend resting echocardiography in patients with indications of heart failure, after myocardial infarction, with pathological Q waves in the ECG, with ventricular arrhythmia or heart murmurs suggestive of heart defects.

Guideline ESC 2013 recommends a stress test with a supplementary imaging test in patients with a pretest probability of 66 to 85% or an LV ejection fraction of less than 50% without anginal symptoms.

According to guideline NVL 2014, an imaging test under pharmacological stress should be performed in patients with an intermediate pretest probability or in patients in whom an ECG is uninterpretable due to limited physical functioning.

The tertiary source UpToDate names magnetic resonance imaging as a further non-invasive diagnostic procedure to assess myocardial ischaemia.

4.2.1.2 Differentiated planning of treatment on the basis of individual risk assessment

Two guidelines (AHA 2014, ESC 2011) and a tertiary source (DynaMed) contain statements on the differentiated planning of treatment.

The guideline ESC 2011 and the tertiary source DynaMed name the use of established risk scores to assess the prognosis and the risk of bleeding. Guideline AHA 2014 also recommends the use of risk scores to assess the prognosis in patients with non-ST segment

elevation myocardial infarction. In addition, the guideline recommends risk stratification models for the treatment.

4.2.1.3 General measures, risk factor management, and handling of co- or multimorbidity

Two guidelines (ACCF 2013, AHA 2014) and a tertiary source (DynaMed) contain statements on general measures, risk factor management, and the handling of co- or multimorbidity.

According to the guidelines ACCF 2013 and AHA 2014 the patients should receive a detailed and evidence-based treatment plan describing drug intake, time of follow-up, suitable measures of physical activity and diet, as well as adherence to measures of secondary prevention.

The tertiary source DynaMed notes that telephone-based care (telehome care) reduces readmissions to hospitals and improves quality of life.

4.2.1.4 Drug therapy

Five guidelines (ACCF 2012, AHA 2014, AHA 2011, ESC 2013, ESC 2011) and 2 tertiary sources (DynaMed, UpToDate) contain statements on drug therapy.

Vaccinations

Guidelines ACCF 2012 and AHA 2014 recommend an annual influenza vaccination.

Guideline AHA 2014 recommends a pneumococcal vaccination for patients ≥ 65 years and for high-risk patients.

Lipid-lowering drugs

Guideline ESC 2013 recommends early monitoring of liver function after starting statin therapy. Furthermore, according to the guideline, creatine kinase should be measured in patients taking statins and complaining of myopathy symptoms.

The tertiary source UpToDate notes that new studies raise concerns about the safety and effectiveness of the combination of niacin (nicotinic acid)³ and statins.

Furthermore, the tertiary source UpToDate refers to proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors as new agents in addition to statins within lipid management in patients with chronic CHD.

³ Niacin is not on the market. It is not approved by the European Medicines Agency (EMA).

Inhibitors of the renin-angiotensin-aldosterone system (RAAS)

Besides the comorbidities of arterial hypertension, diabetes mellitus and LV dysfunction ($\leq 40\%$), the guidelines ACCF 2012, AHA 2011 and ESC 2011 name chronic renal failure as a further therapeutic indication for treatment with angiotensin-converting enzyme (ACE) inhibitors. Guideline ESC 2011 recommends that all patients should receive ACE inhibitors for secondary prevention to prevent the reoccurrence of ischaemic events.

Besides the comorbidities of arterial hypertension, diabetes mellitus, and systolic heart failure, in patients with stable AP and intolerance to ACE inhibitors, guideline ACCF 2012 names chronic renal failure as a further therapeutic indication for administration of an angiotensin II receptor antagonist.

Symptomatic treatment and prophylaxis of angina pectoris

The tertiary sources DynaMed and UpToDate note that ranolazine can be used to treat anginal symptoms instead of beta-blockers if the latter cause side effects, are contraindicated or ineffective.

4.2.1.5 Monitoring and follow-up

Three guidelines (ACCF 2012, ESC 2013, NVL 2014) contain statements on monitoring or follow-up.

For patients with stable AP, guideline ACCF 2012 recommends a follow-up at least once a year. In this context, symptoms, clinical functions, complications, effectiveness, and adherence to treatment should be recorded and cardiac risk factors should be monitored.

Guideline ESC 2013 recommends follow-up appointments for initially 4 to 6 months and later once yearly. Follow-up should be taken care of by a general practitioner and, if necessary, he or she should refer patients to a cardiologist. It should include a detailed medical history and clinically justified laboratory tests.

Guideline ESC 2013 recommends an annual resting ECG and a further ECG in cases where the anginal status has changed, symptoms suggest arrhythmia, or a change in drug therapy could lead to changes in the electrical conduction of the heart. Furthermore, the guideline recommends annual monitoring of blood lipids, glucose metabolism, and creatinine for all patients with stable AP.

Guideline NVL 2014 recommends a stress ECG in patients with known CHD, changes in symptoms and findings, as well as suspected progression.

According to guideline NVL 2014, in high-risk patients, risk stratification and regular monitoring by means of non-invasive procedures should be conducted in close collaboration with a cardiologist. According to the guideline, high-risk patients include patients with chronic CHD and restricted LV function, multi-vessel disease, proximal stenosis of the ramus

interventricularis anterior (RIVA stenosis), survived sudden cardiac death, diabetes mellitus, suboptimal interventional result, or safety critical activities.

According to guidelines ACCF 2012 and NVL 2014, routine echocardiography should not be conducted in patients with stable clinical symptoms and without planned treatment changes.

Guideline ACCF 2012 does not recommend the routine reassessment (< 1 year) of LV function by means of imaging procedures in patients without change in clinical status or if no change in treatment is being considered.

4.2.1.6 Rehabilitation

Two guidelines (AHA 2011, NVL 2014) and 2 tertiary sources (DynaMed, UpToDate) contain statements on rehabilitation.

According to guideline AHA 2011, low-risk patients can participate in outpatient instead of inpatient rehabilitation. The tertiary sources DynaMed and UpToDate state that outpatient and inpatient rehabilitation are equally effective in low-risk patients. In elderly patients, inpatient and outpatient rehabilitation is equally effective with regard to quality of life and physical functioning.

Guideline NVL 2014 recommends that relatives should also be included in counselling and training.

Furthermore, the tertiary source UpToDate names smartphone-based rehabilitation as an alternative to inpatient rehabilitation.

According to the tertiary source UpToDate, outpatient rehabilitation can be supported by telemedicine.

4.2.1.7 Patient training

One guideline (ACCF 2012) contains statements on patient training.

According to guideline ACCF 2012, patients should receive an individual training plan, which among other things contains the following items: a description of drug therapy and of risk management strategies in a language comprehensible to patients, an overview of all therapeutic options, as well as information on self-monitoring and on initiation of corresponding measures in the event of symptom deterioration.

4.2.2 Evaluation of the need for revision

To evaluate the need for revision, the following new or deviating information was identified from evidence-based guidelines and the tertiary sources DynaMed and UpToDate.

- Diagnostics with regard to

- indication for diagnostics by means of imaging and dependence on pretest probability (quantitative specification of reference values for risk [probability] information)
- naming of relevant laboratory parameters under consideration of comorbidities/risk factors
- naming of other non-invasive diagnostic methods
- Differentiated planning of treatment with regard to the definition of CHD risk scores relevant to the German (European) population
- General measures, risk factor management, and handling of co- or multimorbidity with regard to the provision of a treatment plan for patients
- Drug therapy with regard to
 - (annual) influenza and pneumococcal vaccination
 - early monitoring of liver function after start of statin therapy and of creatine kinase under statin therapy
 - additional administration of new agents (PCSK9 inhibitors) within lipid management
 - a potential negative recommendation for the combination therapy of niacin and statins within lipid management
 - naming of chronic renal failure as a further therapeutic indication for treatment with ACE inhibitors or angiotensin II receptor antagonists
 - treatment of all patients with ACE inhibitors for secondary prevention
 - treatment of anginal symptoms with ranolazine
- Monitoring and follow-up with regard to specification of follow-up periods, as well as diagnostic measures and measures for prognosis assessment
- Rehabilitation with regard to
 - alternative measures (outpatient rehabilitation, smartphone-based rehabilitation) besides inpatient rehabilitation
 - involvement of relatives
 - support by telemedicine
- Patient training with regard to the content of training mentioned above

The individual components of the new or deviating information identified do not generate an urgent need for revision of the DMP CHD, as they do not justify a need for action to eliminate specific healthcare risks.

However, due to the abundance of new information it is proposed to initiate the procedure for updating the DMP CHD.

5 Classification of the work result

According to the methodology, the following sources were used for the report to examine the need for revision of the DMP CHD: information from current evidence-based guidelines, tertiary sources, safety notices, the Pharmaceutical Directive, and IQWiG benefit assessments. In addition to the information included in this report from the sources named, during the preparation of the report further information on current developments was identified that could potentially lead to a need for revision in the near future.

National Care Guideline (NVL) “chronic CHD”

On 6 November 2015 the consultation version of the NVL “chronic CHD” was published [28]. Comments on the consultation version could be submitted up to 4 December 2015. It can thus be assumed that during the course of 2016 an updated version of this guideline will be published.

PCSK9 inhibitors within lipid management

In the tertiary source UpToDate, PCSK9 inhibitors are named as an additional drug to statins within lipid management with reference to several publications reporting positive effects during the use of PCSK9 inhibitors [29,30].

The first PCSK9 inhibitors have been approved in Germany since mid-September 2015; these drugs are currently being assessed within a benefit assessment according to § 35a Social Code Book V.

New study results

New study results, such as those of the SPRINT⁴ study (2015), which, among other things, reports results on aggressive blood pressure control in multimorbid and older patients [31], have potentially not yet been depicted in guidelines and tertiary sources, but can still justify a need for revision.

⁴ Systolic Blood Pressure Intervention Trial.

6 Conclusion

In the different information sources, new or deviating information was found on the healthcare aspects of diagnostics, differentiated planning of treatment, therapeutic measures, monitoring and follow-up, as well as rehabilitation and training of patients.

The individual components of the new or deviating information identified do not create an urgent need for revision of the DMP CHD. However, due to the abundance of new information it is proposed to initiate the procedure of updating the DMP CHD.

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: 25.06.2015]. 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]. 12.2014 [accessed: 16.12.2015]. URL: <http://www.bundesversicherungsamt.de/druckversion/weitere-themen/disease-management-programme/zulassung-disease-management-programme-dmp.html>.
3. Gemeinsamer Bundesausschuss. Richtlinie des Gemeinsamen Bundesausschusses zur Regelung der Anforderungen an die Ausgestaltung von Strukturierten Behandlungsprogrammen nach §137f Abs. 2 SGB V [online]. 20.11.2014 [accessed: 25.06.2015]. URL: https://www.g-ba.de/downloads/62-492-963/DMP-RL_2014-11-20_iK-2015-01-07.pdf.
4. Gemeinsamer Bundesausschuss. Richtlinie des Gemeinsamen Bundesausschusses zur Zusammenführung der Anforderungen an strukturierte Behandlungsprogramme nach § 137f Abs. 2 SGB V (DMP-Anforderungen-Richtlinie/DMP-A-RL) [online]. 19.06.2014 [accessed: 24.06.2015]. URL: https://www.g-ba.de/downloads/62-492-918/DMP-A-RL_2014-06-19.pdf.
5. Gemeinsamer Bundesausschuss. Verfahrensordnung des Gemeinsamen Bundesausschusses [online]. 16.04.2015 [accessed: 24.06.2015]. URL: https://www.g-ba.de/downloads/62-492-1002/VerfO_2014-12-18_iK-2015-04-16.pdf.
6. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Regelmäßige orientierende Prüfung des Überarbeitungsbedarfs der DMP: eine Machbarkeitsstudie am Beispiel des DMP KHK; Arbeitspapier; Auftrag GA14-06 [online]. 07.10.2014 [accessed: 10.11.2014]. (IQWiG-Berichte; volume 246). URL: https://www.iqwig.de/download/GA14-06_Arbeitspapier_DMP-Ueberpruefung.pdf.
7. Libby P, Ridker PM, Maseri A. Inflammation and atherosclerosis. *Circulation* 2002; 105(9): 1135-1143.
8. Ross R. Atherosclerosis: an inflammatory disease. *N Engl J Med* 1999; 340(2): 115-126.
9. Davies SW. Clinical presentation and diagnosis of coronary artery disease: stable angina. *Br Med Bull* 2001; 59(1): 17-27.
10. Bundesministerium für Gesundheit. Zwanzigste Verordnung zur Änderung der Risikostruktur-Ausgleichsverordnung (20. RSA-ÄndV). *Bundesgesetzblatt Teil 1* 2009; (35): 1542-1569.
11. Braunwald E, Fauci AS, Kasper DL, Hauser SL, Longo DL, Jameson JL (Ed). *Harrison's principles of internal medicine*. New York: McGraw-Hill; 2001.

12. Bundesärztekammer, Kassenärztliche Bundesvereinigung, Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften. Nationale VersorgungsLeitlinie Chronische KHK; Langfassung; Version 1 [online]. 12.2014 [accessed: 08.06.2015]. URL: http://www.awmf.org/uploads/tx_szleitlinien/nvl-0041_S3_KHK_2015-04.pdf.
13. Ridker PM, MacFadyen J, Libby P, Glynn RJ. Relation of baseline high-sensitivity C-reactive protein level to cardiovascular outcomes with rosuvastatin in the justification for use of statins in prevention: an intervention trial evaluating rosuvastatin (JUPITER). *Am J Cardiol* 2010; 106(2): 204-209.
14. Field MJ, Lohr KN (Ed). *Clinical practice guidelines: directions for a new program*. Washington: National Academy Press; 1990.
15. Graham RM, Mancher M, Miller-Wolman D, Greenfield S, Steinberg E (Ed). *Clinical practice guidelines we can trust*. Washington: National Academies Press; 2011.
16. Fihn SD, Blankenship JC, Alexander KP, Bittl JA, Byrne JG, Fletcher BJ et al. 2014 ACC/AHA/AATS/PCNA/SCAI/STS focused update of the guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines, and the American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *Circulation* 2014; 130(19): 1749-1767.
17. O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, De Lemos JA et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2013; 61(4): e78-e140.
18. Fihn SD, Gardin JM, Abrams J, Berra K, Blankenship JC, Dallas AP et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *J Am Coll Cardiol* 2012; 60(24): e44-e164.
19. Amsterdam EA, Wenger NK, Brindis RG, Casey DE Jr, Ganiats TG, Holmes DR Jr et al. 2014 AHA/ACC guideline for the management of patients with non-ST-elevation acute coronary syndromes: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2014; 64(24): e139-e228.

20. Smith SC Jr, Benjamin EJ, Bonow RO, Braun LT, Creager MA, Franklin BA et al. AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update; a guideline from the American Heart Association and American College of Cardiology Foundation endorsed by the World Heart Federation and the Preventive Cardiovascular Nurses Association. *J Am Coll Cardiol* 2011; 58(23): 2432-2446.
21. Montalescot G, Sechtem U, Achenbach S, Andreotti F, Arden C, Budaj A et al. 2013 ESC guidelines on the management of stable coronary artery disease. *Eur Heart J* 2013; 34(38): 2949-3003.
22. Steg PG, James SK, Atar D, Badano LP, Blömstrom-Lundqvist C, Borger MA et al. ESC guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. *Eur Heart J* 2012; 33(20): 2569-2619.
23. Hamm CW, Bassand JP, Agewall S, Bax J, Boersma E, Bueno H et al. New ESC guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. *Eur Heart J* 2011; 32(23): 2999-3054.
24. National Clinical Guidelines Centre. Stable angina: full guideline [online]. 07.2011 [accessed: 08.06.2015]. (Clinical Guidelines; volume 126). URL: <http://www.nice.org.uk/guidance/cg126/evidence/full-guideline-183176605>.
25. National Clinical Guideline Centre. Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease [online]. 07.2014 [accessed: 18.12.2015]. (Clinical Guidelines; volume 181). URL: <http://www.nice.org.uk/guidance/cg181/evidence/lipid-modification-update-full-guideline-243786637>.
26. National Clinical Guideline Centre. MI: secondary prevention; secondary prevention in primary and secondary care for patients following a myocardial infarction; partial update of NICE CG48; methods, evidence and recommendations [online]. 11.2013 [accessed: 23.07.2015]. (Clinical Guidelines; volume 172). URL: <http://www.nice.org.uk/guidance/cg172/evidence/myocardial-infarction-secondary-prevention-full-guideline-248682925>.
27. Karras C, Donlan SM, Aitchison R, Aitchison P, Wang E, Kharasch M. Acute coronary syndromes. *Dis Mon* 2013; 59(5): 202-209.
28. Bundesärztekammer, Kassenärztliche Bundesvereinigung, Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften. Nationale VersorgungsLeitlinie Chronische KHK: Langfassung; Konsultationsfassung [online]. 06.11.2015 [accessed: 03.12.2015]. URL: <http://www.leitlinien.de/mdb/downloads/nvl/khk/khk-4auf1-konsultation.pdf>.
29. Navarese EP, Kolodziejczak M, Schulze V, Gurbel PA, Tantry U, Lin Y et al. Effects of proprotein convertase subtilisin/kexin type 9 antibodies in adults with hypercholesterolemia: a systematic review and meta-analysis. *Ann Intern Med* 2015; 163(1): 40-51.

30. Robinson JG, Nedergaard BS, Rogers WJ, Fialkow J, Neutel JM, Ramstad D et al. Effect of evolocumab or ezetimibe added to moderate- or high-intensity statin therapy on LDL-C lowering in patients with hypercholesterolemia: the LAPLACE-2 randomized clinical trial. JAMA 2014; 311(18): 1870-1882.

31. Wright JT Jr, Williamson JD, Whelton PK, Snyder JK, Sink KM, Rocco MV et al. A randomized trial of intensive versus standard blood-pressure control. N Engl J Med 2015; 373(22): 2103-2116.

The full report (German version) is published under

<https://www.iqwig.de/en/projects-results/projects/quality-of-health-care/v15-01-exploratory-examination-of-the-need-for-revision-of-the-dmp-coronary-heart-disease-rapid-report.6731.html#documents>