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Systematic guideline search and appraisal, as well as extraction of new and relevant recommendations, for the DMP module "Heart failure"[1]

Executive Summary

[1] Translation of the executive summary of the final report "Systematische Leitlinienrecherche und -bewertung sowie Extraktion neuer und relevanter Empfehlungen für das DMP-Modul Herzinsuffizienz" (Version 1.0; Status: 19.12.2011). 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.

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This report was prepared in collaboration with external experts and an external reviewer. According to § 139b (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 information on conflicts of interest provided by the external experts and external reviewers is presented in Appendix H of the full report. The Institute received the completed form "Disclosure of conflicts of interest" from each expert. The information provided was reviewed by a Committee of the Institute specifically established to assess conflicts of interests. No conflicts of interest were detected that could endanger professional independence with regard to the work on the present commission.

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Background

On 17.12.2009, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to undertake a literature search for guidelines on the subject of heart failure in coronary heart disease (CHD). In this context, the recommendations extracted from evidence-based guidelines were to serve as the basis for the legally specified regular update of the DMP module “Heart failure” (DMP module HF).

Research question

The aim of this study was to identify a potential need for updating and supplementation of the existing DMP module HF by means of a systematic search for new evidence-based guidelines relevant to the subject and by the synthesis of the guideline recommendations.

The study was organized as follows:

- Literature search for and selection of current guidelines on the subject of HF in patients with CHD
- Appraisal of the methodological quality of the selected guidelines
- Extraction and synthesis of guideline recommendations relevant to the existing DMP module HF
- Identification of recommendations that might justify the need to revise the DMP module

Methods

A systematic literature search for specific guidelines on the topic on the Internet was conducted via the guideline databases of the German Association of Scientific Medical Societies (AWMF), the Guidelines International Network (G-I-N), the National Guideline Clearinghouse (NGC) and also on the websites of multidisciplinary and specialist guideline providers. In addition, a search was conducted in the bibliographical databases MEDLINE and EMBASE. The publication period started in 2005 and covered the period up to July 2011. A further inclusion criterion, in addition to the publication language of German, English and French, was the country in which the guidelines were compiled. According to the commission, only guidelines that were transferable to the German health care system were to be searched for and selected. Stratum A of the division of states of the World Health Organization (WHO) report of 2003 was used to judge such transferability. The documented evidence base of a guideline was an additional important inclusion criterion. “Evidence-based guidelines” are taken in the following report to mean guidelines whose recommendations were based on a systematic literature search, whose recommendations had been assigned a level of evidence (LoE) and/or grade of recommendation (GoR), and whose recommendations were linked to the references of the primary and/or secondary literature on which they were based.

The methodology of the included guidelines was assessed using the Appraisal of Guidelines for Research & Evaluation (AGREE) instrument by 2 reviewers working independently of each other.

The recommendations relevant to the research question were extracted and collated with the health care aspects of Appendix 5a of the 20th Amendment of the Act on the Risk Adjustment Scheme (RSA-ÄndV) of 23.06.2009. Finally, a synthesis of the extracted recommendations according to the items of Appendix 5a of RSA-ÄndV was carried out and compared with the requirements of the DMP module HF.

The procedure used to identify a potential need for updating and supplementation was as follows: in the case of recommendations whose contents were consistent and in the majority of cases substantiated by a high grade of recommendation (GoR) and/or level of evidence (LoE), a potential need for updating and supplementation was demonstrated. With recommendations that were consistent with regard to content across different guidelines and at least sometimes assigned a high GoR and/or LoE, a potential need for updating and supplementation was raised for discussion. This was also the case even if new aspects for the DMP were only shown by a single guideline but were provided with a high GoR and/or LoE. The two highest GoR and LoE were taken into account for all guidelines with their different grading systems. In addition, a potential need for updating and supplementation was only raised for discussion if the respective topic had not already been dealt with by the overall DMP CHD.

Recommendations that were shown with neither a GoR nor an LoE were not used to identify a potential need for updating and supplementation and were also not included in the synthesis (Section 5.4 of the full final report).

In addition, in the case of a potential need for updating and supplementation in respect of an item in Appendix 5a of the RSA-ÄndV, the eligibility for the indication-specific prescription in Germany of the drugs named in the guidelines was checked.

Results

A total of 27 evidence-based guidelines were included, appraised and their recommendations extracted. The included guidelines had been issued by institutions from Germany (n = 3) and Europe (n = 11) as well as the USA (n = 8) and Canada (n = 5). Two guidelines had been developed in the context of a collaboration between the American specialist medical societies – the American College of Cardiology and the American Heart Association - and the European Society of Cardiology.

Of the 27 included guidelines, 10 were devoted to the diagnosis and treatment of patients with heart failure (DEGAM 2006, NVL 2009, ESC 2008, SIGN HF 2007, AACC 2007, ACC / AHA 2009, CCS 2007, CCS 2006, HFSA 2010, ICSI 2009). One German guideline was solely concerned with the pharmacological treatment of heart failure (AkdÄ 2007). Seven

guidelines covered the treatment of atrial and ventricular arrhythmias (ESC AF 2010, ESC DE 2010, NCCCC 2006, SIGN AR 2007, ACC / AHA AF 2011, ACC / AHA 2006, CCS MR 2011). Fifteen concentrated on specific interventional techniques (NVL 2009, ESC 2008, ESC 2007, ESC AF 2010, ESC DE 2010, ESC RE 2010, SIGN AR 2007, SIGN HF 2007, ACC / AHA 2009, ACC / AHA 2008, ACC / AHA 2006, ACC / AHA AF 2011, CCS 2006, CCS HF 2011, HFSA 2010). Other guidelines dealt with specific aspects of heart failure (e.g. biomarkers [AACC 2007]).

The methodological assessment with the AGREE tool produced the following result: the highest standardized domain scores were achieved in Domains 1 (Scope and Purpose), 3 (Rigour of Development), 4 (Clarity of Presentation) and 6 (Editorial Independence). The highest possible standardized domain score was awarded twice in Domain 1 (Scope and Purpose) (DEGAM 2006 and NCCCC 2006) and 6 times in Domain 6 (Editorial Independence) (DEGAM 2006, ESC AF 2010, ESC DL 2011, ESC RE 2010, ACC / AHA 2008, CCS HF 2011). The lowest possible standardized domain score was awarded in Domain 5 (Applicability) once (HFSA 2010).

Recommendations were identified and extracted from all included guidelines whose content could be assigned to one of the health care aspects of items 1.1 to 1.6 and 4.2 of Appendix 5a of the RSA-ÄndV.

Most recommendations of the 27 guidelines included in the report dealt with the respective care aspects in a more detailed manner than the requirements of Appendix 5a of the 20th RSA-ÄndV of 23.06.2009. The included guidelines covered almost all relevant aspects of the medical care of heart failure in CHD patients. Except for a few differences, the recommendations of the included guidelines essentially agreed with the requirements of Appendix 5a of the RSA-ÄndV. These differences are described first below, followed by a list of those items deemed not in need of updating and supplementation. Finally, items are discussed for which no conclusions about a potential need for updating or supplementation could be drawn on the basis of this report.

A potential need for updating and supplementation was identified for the following points:

Item 1.4 “Therapeutic measures”: 3 guidelines gave recommendations, mostly with a high GoR and/or LoE, for the treatment of arterial hypertension. The guidelines contained additional recommendations compared to those of Appendix 5a of the RSA-ÄndV. There is therefore a potential need for updating and supplementation as regards the treatment of arterial hypertension.

Item 1.4.1 “General non-pharmacological measures”: 4 guidelines gave recommendations, mostly with a high GoR and/or LoE, for the treatment of sleep apnoea in patients with heart failure and thus contained additional recommendations compared to Appendix 5a of the RSA-ÄndV. To date, these recommendations on general non-pharmacological measures are not

part of Appendix 5a of the RSA-ÄndV. There is a potential need for updating and supplementation with regard to the treatment of sleep apnoea syndrome.

Several guidelines gave recommendations, mostly with a high GoR and/or LoE, with regard to physical activity that were additional to those in Appendix 5a of the RSA-ÄndV. Four guidelines, mostly with a high GoR and/or LoE, gave recommendations regarding counselling in respect of sexual activity. Such counselling recommendations are currently not part of the RSA-ÄndV and hence there is a potential need for updating and supplementation.

Several guidelines gave recommendations, mostly with a high GoR and/or LoE, with regard to vaccination against influenza. The guidelines contained additional recommendations compared to Appendix 5a of the RSA-ÄndV. Recommendations concerning vaccinations are currently not part of this Appendix and hence there is a potential need for updating and supplementation with regard to vaccination against influenza.

Three guidelines, gave recommendations, mostly with a high GoR and/or LoE, on the management of elderly patients with heart failure that were additional to those in Appendix 5a of the RSA-ÄndV. Since the management of elderly patients with heart failure is currently not part of this Appendix, there is a potential need for updating and supplementation with regard to the management of elderly patients.

Item 1.4.2 “Pharmacological therapy”: 3 guidelines, mostly with a high GoR and/or LoE, gave recommendations concerning the treatment of diabetes in patients with heart failure that were additional to those in Appendix 5a of the RSA-ÄndV. Since the treatment of diabetes is currently not part of this Appendix, there is a potential need for updating and supplementation with regard to this disease.

Item 1.4.3 “Specific interventional measures”: 5 guidelines gave recommendations, mostly with a high GoR and/or LoE, with regard to treatment with cardiac pacemakers that were additional to those of the RSA-ÄndV. Since this point is currently not part of Appendix 5a of the RSA-ÄndV, there is a potential need for updating and supplementation in respect of cardiac pacemaker therapy.

Four guidelines gave recommendations, mostly with a high GoR, with regard to the use of electrical cardioversion for symptomatic patients with atrial fibrillation. Since this point is also currently not part of Appendix 5a of the RSA-ÄndV, there is a potential need for updating and supplementation in respect of electrical cardioversion.

Item 1.4.3.1 “Cardiac Resynchronization Therapy (CRT)”: several guidelines gave recommendations, mostly with a high GoR and/or LoE, with regard to CRT that were additional to those of the RSA-ÄndV. Four guidelines recommended, mostly with a high GoR and/or LoE, CRT for patients with atrial fibrillation. Since CRT in atrial fibrillation is currently not part of Appendix 5a of the RSA-ÄndV, there is a potential need for updating and supplementation with regard to CRT for atrial fibrillation.

A potential need for updating and supplementation should be discussed for the following areas:

Item 1.4.1 “General non-pharmacological measures”: several guidelines gave recommendations with inconsistent GoR or LoE concerning vaccinations against pneumococci. The guidelines contained additional recommendations to those in Appendix 5a of the RSA-ÄndV. Since recommendations regarding vaccinations are currently not part of this Appendix, a potential need for updating and supplementation can be discussed for vaccination against pneumococci.

Two guidelines gave recommendations with inconsistent GoR and/or LoE with regard to travel. The guidelines thus contained additional recommendations to those in Appendix 5a of the RSA-ÄndV. Since advice about travel is also currently not part of this Appendix, a potential need for updating and supplementation can be discussed with regard to this point.

Several guidelines gave recommendations with inconsistent GoR and/or LoE with regard to the psychological, psychosomatic and psychosocial care of patients with heart failure. The guidelines contained additional recommendations to those in Appendix 5a of the RSA-ÄndV. The psychosocial primary care of heart failure patients is currently not part of this Appendix. Because this aspect is not explicitly mentioned in the overall DMP CHD, Item 1.5.1.4, a potential need for updating and supplementation can be discussed.

One guideline gave recommendations with a high LoE with regard to checking the fitness for work after the first diagnosis of heart failure. The guideline contained additional recommendations to those in Appendix 5a of the RSA-ÄndV. Since fitness for work is currently not part of this Appendix, a potential need for checking the fitness for work after the first diagnosis of heart failure can be discussed.

Item 1.4.2 “Pharmacological therapy”: two guidelines gave negative recommendations with inconsistent GoR or LoE with regard to long-term treatment with positive inotropic drugs. The guidelines contained additional recommendations to those in Appendix 5a of the RSA-ÄndV. Since these drugs are currently not part of this Appendix, a potential need for updating and supplementation regarding them can be discussed.

Two guidelines gave recommendations with inconsistent GoR or LoE with regard to pharmacological cardioversion with amiodarone (see also Footnote 11 in the full report). The guidelines contained additional recommendations to those of the RSA-ÄndV. Since pharmacological cardioversion with amiodarone is currently not part of Appendix 5a of the RSA-ÄndV, a potential need for updating and supplementation regarding this approach can be discussed.

Item 1.4.3 “Specific interventional measures”: one guideline recommended, with the highest GoR, medical prophylactic measures for patients after heart transplantation. Care of heart transplant recipients who had been previously been included in the DMP module HF because

of heart failure is currently not part of Appendix 5a of the RSA-ÄndV. A potential need for updating and supplementation can be discussed.

There is no need for updating or supplementation for the following points:

Item 1.2 "Criteria for defining the target group"

Item 1.3 "Goals of treatment"

Item 1.4 "Therapeutic measures" regarding myocardial revascularization (causal treatment)

Item 1.4.1 "General non-pharmacological measures"

- with regard to diet, fluid intake and weight
- with regard to smoking

Item 1.4.2 "Pharmacological therapy"

- with regard to the sub-item "Treatment with angiotensin-converting enzyme (ACE) inhibitors"
- with regard to the sub-item "Treatment with beta-receptor blockers (beta-blockers)"
- with regard to the sub-item "Treatment with angiotensin-II antagonists (AT1 receptor antagonists)"
- with regard to the sub-item "Treatment with aldosterone antagonists"
- with regard to the sub-item to 1.4.2 "Treatment with diuretics"
- with regard to the sub-item "Treatment with cardiac glycosides (digitalis)"
- with regard to the sub-item "Oral anticoagulant therapy"
- with regard to platelet aggregation inhibitors
- with regard to statins
- with regard to the combination of dihydralazine and isosorbide dinitrate
- with regard to nutritional supplements

Item 1.4.3.2 "Treatment with implantable cardioverter defibrillators (ICD)"

Item 1.4.3 "Specific interventional measures" with regard to surgical myocardial revascularization

Item 1.5 "Monitoring"

Item 1.6.1 "Referral from the treating physician to the appropriately qualified specialist or qualified institution"

Item 1.6.2 “Transfer to a hospital”

Item 1.6.3 “Instigation of a rehabilitation measure”

Item 4.2 “Education of the insured”

No conclusions can be drawn with respect to the potential need for updating and supplementation for the following point:

No recommendations in the included guidelines were identified in relation to Item 1.1 “Definition of heart failure” of Appendix 5a of the RSA-ÄndV. If a definition of the clinical picture was present in a guideline, it was at best supported by literature, but not given a level of evidence or a grade of recommendation.

Conclusion

Through the comparison of the extracted recommendations from current evidence-based guidelines with the requirements of Appendix 5a of the RSA-ÄndV which form the basis of the DMP module “Heart failure” (DMP module HF), aspects of care could be identified where potential updating and supplementation are necessary or can be discussed. A potential need for such revision can arise both for the general non-pharmacological measures and the pharmacological measures as well as for the specific interventional measures.

For Item 1.4 “Therapeutic measures”, there is a potential need for updating and supplementation with regard to the treatment of arterial hypertension.

For Item 1.4.1 “General non-pharmacological measures”, there is a potential need for updating and supplementation with regard to the treatment of sleep apnoea, advice concerning sexual activity and the management of elderly heart failure patients. There is also a potential need for updating and supplementation regarding vaccinations against influenza.

As regards vaccinations against pneumococci, travel advice, primary psychosomatic care and the checking of the fitness for work at first diagnosis of heart failure, a potential need for updating and supplementation can be discussed.

For Item 1.4.2 “Pharmacological therapy”, a potential need for updating and supplementation exists with regard to the treatment of the comorbidity of diabetes in patients with heart failure. In addition, a potential need for updating and supplementation can be discussed with regard to the inclusion of a negative recommendation concerning long-term treatment with positive inotropic substances and pharmacological cardioversion with amiodarone.

For Item 1.4.3 “Specific interventional measures”, a potential need for updating and supplementation exists with regard to cardiac pacemaker therapy and CRT for atrial fibrillation and also for electrical cardioversion for symptomatic patients with heart failure and atrial fibrillation. A potential need for updating and supplementation can be discussed for the care of patients of the DMP module HF following heart transplantation.

No conclusions can be drawn from the included evidence-based guidelines concerning a potential need for updating and supplementation of the DMP module concerning Item 1.1 “Definition of heart failure”.

It is unclear whether the lack of consideration of unpublished data in the included guidelines has biased the external evidence on which the recommendations were based. If this is indeed the case, then the information available does not enable the direction and extent of this bias to be assessed.

Keywords: heart failure, disease management programme, methodological guideline appraisal, evidence-based guidelines

The full report (German version) is published under www.iqwig.de