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**Systematic guideline search
and evaluation, as well as
extraction of new and relevant
recommendations, for the DMP
“Coronary heart disease”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 Koronare Herzkrankheit” (Version 1.0; Status: 28.02.2008). Publication date of translation: 20.05.08. 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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Executive summary

Background

The German Federal Joint Committee (G-BA²) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to conduct a literature search for current clinical practice guidelines (CPGs) on coronary heart disease (CHD). In this context, the key recommendations extracted from evidence-based CPGs were to serve the legally specified regular update of fundamentals of the disease management programme (DMP) for patients with CHD (as defined in Appendix 5 of the 7th Act on the Amendment of the Risk Adjustment Scheme³ [RAS-Amendment], 2003).

Research questions

The aim of this study was to specify a possible need for revision of the existing DMP-CHD by means of a systematic search for current evidence-based CPGs and a synthesis of their generated key recommendations.

The study was organised as follows:

- Literature search for and selection of current evidence-based CPGs on CHD, which were to be transferable to the German health care setting;
- Appraisal of the methodological quality of selected CPGs;
- Synthesis of CPG key recommendations and extraction of recommendations relevant to the existing DMP-CHD;
- Documentation of the evidence on which, according to the CPG, the key recommendations were based.

It was not the aim of the study to issue recommendations in the sense of an IQWiG benefit assessment. The recommendations extracted from the CPGs are to be understood as citations whose underlying evidence as such was not reassessed.

Methods

A systematic search for CPGs on CHD was conducted in the CPG databases Leitlinien.de and Guidelines International Network (G-I-N), and in the bibliographic databases MEDLINE and EMBASE. One inclusion criterion specified by the GB-A was “Publication period between 2002 and June 2007”. The additional, most relevant inclusion criteria were “German, English or French language publications” and “Documentation of the evidence base of the CPG”.

The evidence base of the CPG was based on the following 3 criteria:

² Gemeinsame Bundesausschuss

³ Risikostrukturausgleichsverordnung

- (1) Conduct of a systematic search for primary and secondary literature;
- (2) Support of most key recommendations through citations of the underlying primary and secondary literature;
- (3) Allocation of a Level of Evidence (LoE) and/or a Grade of Recommendation (GoR) to the key recommendations.

The methodological CPG appraisal was performed with the German Instrument for Methodological Guideline Appraisal (DELBI⁴), and key recommendations were extracted. The key recommendations identified were recommendations labelled accordingly by the CPG authors. After comparison with the DMP legal fundamentals outlined in the Act on the RAS, recommendations were highlighted that implied a potential need for amendment of the DMP-CHD, as defined in Appendix 5 of the Act on the RAS-Amendment.

Results

A total of 21 evidence-based CPGs were included and appraised, and their recommendations extracted. Three of these 21 CPGs were developed in Germany, following a systematic review of the scientific evidence, and mostly under consideration of international CPGs. The relevant German scientific societies participated in the development and consensus process.

The National Health Care Guideline (NVL⁵) is explicitly directed towards those who issue DMPs, with the aim of serving as a basis for the design of these programmes. The specificity of the NVL for the German health care system and in particular for the DMP-CHD should be considered in the assessment of the potential need for modification or supplementation of Appendix 5 of the Act on the RAS-Amendment.

The DELBI assessments showed that there was potential for improvement in the documentation of the CPG development, in particular in the areas “Participation of interest groups” (DELBI domain 2) and “General applicability of the CPG” (DELBI domain 5), but also in the area “Methodological precision of the CPG development” (DELBI domain 3). Even though, according to the authors, the CPGs were based on a systematic literature search and criteria for the inclusion of primary literature were defined, often neither the search (e.g. the presentation of a search protocol) nor the inclusion criteria were documented adequately in the CPGs themselves or in methods papers published on them. In addition, the description of the methodological approach regarding the adaptation of other CPGs was often inadequate.

Recommendations were extracted from all CPGs included that could be allocated to one of the health care aspects of the items 1.3 to 1.7 of Appendix 5 of the Act on the RAS-Amendment, and were labelled with an LoE and/or a GoR. Many of the CPGs included dealt with several health care aspects in a more detailed manner than Appendix 5. However, in

⁴ Deutsches Instrument zur methodischen Leitlinienbewertung

⁵ Nationale VersorgungsLeitlinie

many areas these extensions did not represent novelties that would imply a necessary modification of DMP content.

With regard to the following areas, no relevant need for modification compared with Appendix 5 resulted from the detailed recommendations of the included CPGs: “Adequate diagnostic procedures”, “Nutritional advice”, “Physical activity”, “Psychological aspects”, “Rehabilitation”, and “Cooperation between health care levels”. In contrast, potential need for modification regarding the recommendations specified in the DMP was found in the areas “Risk assessment” (risk factor: overweight and obesity); “General measures” (weight reduction; influenza vaccination); and “Counselling on smoking cessation” (nicotine replacement therapy or other drug therapies for smokers). With regard to drug therapy for CHD, there were no contradictions between the content of Appendix 5 of the Act on the RAS-Amendment and the recommendations extracted, but there were some extensions or specifications concerning the following substance groups: ACE-inhibitors, aldosterone blockers, statins, and menopausal hormone replacement drugs. The indication spectrum was extended or specified in the areas “Coronary angiography” and “Revascularization”. Regarding the decision to conduct a percutaneous coronary intervention (PCI) or a coronary artery bypass graft (CABG), bypass surgery was recommended with higher GoRs than beforehand.

Conclusion

Through the comparison of extracted key recommendations from current evidence-based CPGs on CHD with Appendix 5 of the Act on the RAS-Amendment (which is the basis of the DMP-CHD), areas could be identified where potential updating should be discussed. For these areas, the performance of a supplementary search for current primary and secondary literature and an evaluation thereof should be considered.

Extensions of the recommendations specified in Appendix 5 were found in particular in the areas: “Risk assessment” (risk factor: overweight and obesity); “General measures” (weight reduction; influenza vaccination); and “Counselling on smoking cessation” (nicotine replacement therapy or other drug therapies for smokers).

Specifications and further aspects compared with the recommendations in Appendix 5 of the Act on the RAS-Amendment were also found for the drug therapy of chronic CHD. These mainly referred to 4 substance groups: ACE-inhibitors, aldosterone blockers, statins, and menopausal hormone replacement drugs.

A potential need for modification should be discussed for the areas “Coronary angiography” and “Revascularization”, in particular with regard to the indication for a PCI or CABG procedure.

Key words

Disease management programme, coronary heart disease, methodological guideline appraisal, evidence-based clinical practice guidelines, key recommendations