IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

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Regular exploratory examination of the need for revision of DMPs – a feasibility study using the example of the DMP "CHD"[1]

Executive Summary

[1] Translation of the executive summary of the working paper *Regelmäßige orientierende Prüfung des Überarbeitungs-bedarfs der DMP – eine Machbarkeitsstudie am Beispiel des DMP KHK* (Version 1.0; status: 7 October 2014). 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

The Institute for Quality and Efficiency in Health Care (IQWiG[3]) prepared the present working paper within the framework of the general commission.

Research question

The aim of the investigation was to test with regard to feasibility a method for regular exploratory examination of the need for revision of disease management programmes (DMPs) according to 137f Social Code Book V. New DMP-relevant information was to be identified in selected sources, with justifiable effort.

After testing of the method, an evaluation was made of its feasibility with regard to the time invested in relation to the information gain and relevance for DMPs.

The experiences gained within the framework of the feasibility study serve the further development of the method for regular exploratory examination of the need for revision of DMPs.

The exploratory examination of the need for revision is at the start of the process that can ultimately lead to an update of the requirements for the DMPs. The result of the exploratory examination is in particular to support the Federal Joint Committee (G-BA[4]) in the decision on the start of the process for updating a DMP.

Method to be tested:

A focused search was conducted for different current information for the DMP to be examined. On the basis of the Code of Procedure of the G-BA, the information required was operationalized as follows:

- medical evidence-based guidelines
- notifications of harms (drug safety mails by the Drug Commission of the German Medical Association [AkdÄ[5]]; recommendations on medical devices by the Federal Institute for Drugs and Medical Devices [BfArM[6]])
- (German) Pharmaceutical Guideline (changes in prescribability)
- IQWiG benefit assessments
- randomized controlled trials (RCTs) and systematic reviews

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Consideration was given only to information that had been published after the last search within the framework of the corresponding guideline synopsis on DMP updating (full report). The search for guidelines was conducted in guideline databases of the (German) Association of the Scientific Medical Professional Societies (AWMF[7]) as well as on websites of selected multidisciplinary and specialist guideline providers. For drugs, the search for notifications of harms was conducted on the AkdÄ website. For medical devices, the corresponding search was conducted on the BfArM website. The current Pharmaceutical Guideline was obtained from the G-BA website and current IQWiG benefit assessments were obtained from the Institute's website. The focused search for relevant systematic reviews and RCTs was conducted in the PubMED database. The searches for guidelines, notifications of harms, information from the Pharmaceutical Guideline, as well as IQWiG benefit assessments were conducted by one reviewer and the search result was checked by a second reviewer. The full texts of the resulting potentially relevant documents were then checked with regard to their relevance for DMPs by 2 reviewers independently of one another. Inconsistent results were discussed and then a consensus was reached. The guideline recommendations with the respective highest possible Grade of Recommendation (GoR) within the guideline classification system or, if no GoR was provided, with a Level of Evidence (LoE) corresponding to at least one well-conducted RCT, were extracted into tables and organized according to the health care aspects of the Risk Adjustment Scheme Amendment Act (RSA-ÄndV[8]) or the DMP Directive. The results of the other searches were also presented in tables and organized according to health care aspects.

The relevance of the results of the search in PubMED was assessed by 2 reviewers independently of one another. The research questions investigated in the individual studies and systematic reviews were summarized, organized according to health care aspects, and presented.

Finally, a synthesis was made of the new information that was neither mentioned in Appendix 5 of the 20th RSA-ÄndV nor in the DMP Directive nor justified a need for updating or supplementation in a DMP full report. In the synthesis, only those health care aspects of the 20th RSA-ÄndV or the DMP Directive were named for which new information was available. The type of new information and which sources the information was retrieved from were then described. Finally, it was evaluated whether a DMP revision could be necessary. The assessment of results in terms of a need for revision was summarized and discussed.

Feasibility study

The method was tested within the framework of a feasibility study using the DMP "Coronary heart disease" (CHD) as an example. New information was compiled for a first exploratory examination of the need for revision using the example of the DMP "CHD". After testing of the method, the feasibility of this method was evaluated with regard to the time invested in relation to the information gain and the relevance for DMPs.

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[8] Risikostrukturausgleichs-Änderungsverordnung

Consideration was given only to information that had been published after the last search (22 September 2010) within the framework of the guideline synopsis on updating of the DMP "CHD" (V09-05). The search for relevant systematic reviews and RCTs was conducted in the PubMED database and covered the period from September 2010 to August 2013.

Only the studies and systematic reviews identified for item 1.6 ("Rehabilitation") were assessed as an example with regard to the risk of bias, and the results were presented.

According to the method to be tested, the information identified was compared to Appendix 5 of the 20th RSA-ÄndV and to the results of the guideline synopsis for the updating of the DMP "CHD" (final report V09-05), and the need for revision of the DMP "CHD" was evaluated.

Results

Results of the testing of feasibility

The testing of feasibility showed that the goals set would not be achievable with justifiable effort. The method to be tested was therefore modified with regard to the following points, so that the meaningful applicability of the method could be examined under the specified conditions for time and resources:

- extraction of all DMP-relevant recommendations with the highest possible GoR or LoE and performance of the comparison of the recommendations with Appendix 5 of the 20th RSA-ÄndV only at information synthesis
- focus of the search on non-redundant data sources

The first change was made as the decision which recommendations are actually new is not always clear due to the different levels of detail of the recommendations and the legal regulation. The presentation of all recommendations gives the reader the opportunity to form his or her own judgement on this issue.

The second change referred to dispensing with a search for notifications of harms for drugs on the BfArM website, as drug safety mails are also published on the AkdÄ website. In addition, the search for notifications of harms for medical devices was restricted to BfArM recommendations, as these contain an assessment by BfArM of the respective notifications of harms.

A further modification arose during the course of the project for the methodology of the feasibility study:

- restriction of the method on critical assessment of the evidence from studies to an exemplary item

Only the studies and systematic reviews identified for item 1.6 ("Rehabilitation") were assessed methodologically with regard to the risk of bias, and the results were presented. The

method was modified, as a systematic assessment of 119 publications within the framework of a first exploratory examination of a DMP with regard to the need for revision would have been too time consuming.

The feasibility study showed that the method for regular exploratory examination of the need for revision of DMPs delivers results on the basis of which a need for revision of DMPs can be evaluated in terms of the research question.

Results of the examination of the need for revision of the DMP "CHD"

Current information for the DMP "CHD"

The following current information relevant for DMPs was identified: A total of 16 guidelines, 5 drug safety mails, 3 changes to the Pharmaceutical Guideline, 3 IQWiG benefit assessments, 1 IQWiG addendum, 73 studies, and 42 systematic reviews. The information was extracted and organized according to the items of Appendix 5 of the 20th RSA-ÄndV and presented in a tabular form.

Evaluation of the need for revision of the DMP "CHD"

Overall, for the following items new information was identified that was neither mentioned in Appendix 5 of the 20th RSA-ÄndV nor justified a need for updating or supplementation in final report V09-05:

- "sufficient diagnostic procedures" with regard to the occurrence of atypical symptoms in elderly patients with myocardial infarction
- "differentiated therapy planning" with regard to the use of prognostic scores
- "non-drug therapy" with regard to behavioural therapeutic procedures to facilitate lifestyle changes
- "drug therapy"
  - for the use of a score to estimate the probability of an adverse event and to initiate blood-lipid lowering measures
  - for further platelet aggregation inhibitors (ticagrelor, prasugrel)
  - for the combination therapy of prasugrel and acetylsalicylic acid (ASA) after myocardial infarction without ST-segment elevation (NSTEMI)
  - for longer treatment duration with dual platelet aggregation inhibition (DAPT) for patients after percutaneous coronary intervention (PCI)
  - for the use of proton pump inhibitors (PPIs) in patients treated with DAPT whose medical history showed gastrointestinal bleeding
  - for negative recommendations on chelating agents, phytotherapeutics, and vitamin supplementation

- "interventional therapy and coronary revascularization" with regard to clarification of the tolerability of necessary DAPT before providing a medical indication for stent implantation

Due to the large amount of new information it is proposed to initiate the process to revise the DMP at the G-BA.

Conclusion

The feasibility study has shown that the method for regular exploratory examination of the need for revision of DMPs delivers results by means of which an evaluation can be made in terms of the research question.

The evaluation of the need for revision was made on the basis of information from evidence-based guidelines, notifications of harms, the Pharmaceutical Guideline, IQWiG benefit assessments, as well as systematic reviews and studies. The investment in time and resources for working on the information source "systematic reviews and studies" did not stand in relation to the result. Thus there was only exemplary testing of this information source for one health care aspect of the DMP.

On the basis of the feasibility study, the method for examining the need for revisions of DMPs seems to be practicable with the following modifications:

- Instead of the information source "studies and systematic reviews", databases could be used that search for and assess evidence on clinical interventions and provide this evidence in a compact form.
- Regarding the Pharmaceutical Guideline, it is proposed to use this source only to examine the approval status and the indication-specific prescribability for drugs that justify an initiation of the process for updating of a DMP.

The information extracted in the feasibility study was compared with Appendix 5 of the 20th RSA-ÄndV and the results of final report V09-05. No urgent need for revision of the DMP "CHD" that would need to be implemented immediately arises from this comparison. However, due to the large amount of new information it is proposed to initiate the process to update the DMP at the G-BA.

Keywords: myocardial ischaemia, disease management programme, guidelines as topic

The full report (German version) is published under https://www.iqwig.de/de/projekte-ergebnisse/projekte/versorgungsqualitat/ga14-06-regelmassige-orientierende-prufung-des-ueberarbeitungsbedarfs-der-dmp-eine-machbarkeitsstudie-am-beispiel-des-dmp-khk.6345.html#overview