IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

Systematic guideline search and appraisal, as well as extraction of relevant recommendations, for the DMP "Chronic obstructive pulmonary disease"[1]

Executive Summary

[1] Translation of the executive summary of the final report "Systematische Leitlinienrecherche und -bewertung sowie Extraktion relevanter Empfehlungen für das DMP chronisch obstruktive Lungenerkrankung" (Version 1.0; Status: 5 November 2013). 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. 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 Institute received the completed form "Disclosure of 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 on potential conflicts of interest provided by the external experts is presented in Appendix H of the full report. No conflicts of interest were detected that could endanger professional independence with regard to the work on the present commission.

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Executive summary

In its letter of 15 March 2012, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to undertake a systematic literature search for and appraisal of guidelines and to extract new and relevant recommendations for the DMP "Chronic obstructive pulmonary disease" (COPD).

Research question

The aim of this study was to specify a potential need for updating and supplementation of the existing DMP "COPD" 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 COPD
- appraisal of the methodological quality of the selected guidelines
- extraction and synthesis of guideline recommendations relevant to the existing DMP "COPD"
- identification of recommendations that might justify the potential need to revise and supplement the DMP "COPD"

It was not the aim of the study to provide recommendations in terms of an IQWIG benefit assessment.

Methods

A systematic Internet search for topic-specific guidelines was conducted via the guideline databases of the AWMF, the Guidelines International Network (G-I-N), and the National Guideline Clearinghouse (NGC), as well as by searching the websites of multidisciplinary and specialist guideline providers. The publication period was limited to guidelines published from November 2007 onwards. The search covered the period from November 2007 to May 2013. The main inclusion criteria were German- and English-language publications, as well as the country in which the guidelines had been developed. According to the commission, only guidelines transferable to the German health care system were to be searched for. The classification of nations from the World Health Report 2003, published by the World Health Organization (WHO), was used to operationalize the transferability of guidelines to the German health care system. The 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 in principle been assigned a level of evidence (LoE) and/or grade of recommendation (GoR), and whose recommendations were in principle directly or indirectly linked to the references of the primary and/or secondary literature on which they were based.

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 23 appraisal criteria. Six domains are allocated to these criteria, each of which describes a separate dimension of methodological guideline quality. Each criterion within the individual domains was assessed on a 7-point scale. The scale indicates to what extent a criterion is fulfilled in the guideline to be assessed. The results of the AGREE II appraisal are not a criterion for the inclusion or exclusion of guidelines in the study. By means of the AGREE instrument it was to be presented transparently whether, and in which domains of the instrument, the evidence-based guidelines included showed particular methodological strengths or weaknesses.

The recommendations relevant to the research question were extracted and allocated to the health care aspects of the G-BA's directive on the regulation for the design of structured treatment programmes according to §137f (2) Social Code Book (SGB) V of 16 February 2012 (DMP directive). Finally, a synthesis of the extracted recommendations according to the health care aspects of the DMP directive was carried out and compared with the requirements of the DMP "COPD".

In order to achieve comparability of the largely different systems of the GoR and LoE, for this report the GoR and/or LoE used in the guidelines were in each case allocated to a reference standard. The GoR used in the guidelines were allocated to 1 of 3 recommendation categories according to the procedure of the National Care Guideline (Nationale VersorgungsLeitlinie; NVL). The LoE used in the guidelines were transferred to the evidence classification used in the G-BA's Rules of Procedure.

A potential need for updating and supplementation of the DMP was determined for recommendations that were consistent in content and largely featured a high GoR (strength of recommendation "A" according to the NVL classification) or LoE. With recommendations that were consistent in content across different guidelines and sometimes featured a high GoR/LoE category (inconsistent GoR/LoE category), a potential need for updating and supplementation of the DMP could be raised for discussion. This was also the case if new aspects for the DMP were only presented by a single guideline but featured a high GoR. If a guideline did not provide a GoR, alternatively to the highest GoR a high LoE (Ia/Ib according to the G-BA's evidence classification) was used to determine a need for updating and supplementation. Recommendations that featured neither a GoR nor LoE were not used for identifying a potential need for updating and supplementation.

In the event of a potential need for updating and supplementation with regard to a health care aspect, it was consistently checked whether further IQWiG reports on this topic were available. When determining a potential need for updating and supplementation, the corresponding IQWiG reports were then taken into account.

In addition, the recommendations on drugs were evaluated with regard to their indication-specific reimbursability in Germany, as well as their approval status. This was performed in those areas where a potential need for updating and supplementation exists or is being discussed. In the case of discrepancies between guideline recommendations on drugs and their German approval status as well as their indication-specific reimbursability, this was explained conclusively and considered in the synthesis.

Results

A total of 13 guidelines were included, appraised and their recommendations extracted. The guidelines were issued by institutions in Germany (n = 1), Europe (n = 4), the United States (n = 2), Australia (n = 1), and Canada (n = 4). One guideline was prepared and published by an international group of authors.

Four of the 13 guidelines included deal comprehensively with the care of patients with COPD. Six guidelines address specific health care modalities. The German guideline exclusively deals with smoking cessation in COPD patients, and 2 Canadian guidelines focus on pneumological rehabilitation. A British guideline deals with the "hospital at home" (HaH) scheme, specific outpatient care for severely ill COPD patients, and 2 further British guidelines deal with non-invasive ventilation (NIV) in the hospital. The other 3 guidelines refer to subgroups of COPD patients: 2 Canadian guidelines address the care of COPD patients with dyspnoea, of which one focuses on nursing care. The other addresses the care of patients with alpha-1-antitrypsin-deficiency.

In the methodological appraisal with the AGREE II instrument, which was performed by 2 independent reviewers, on average the highest standardized domain values were primarily awarded in Domain 4 (Clarity of Presentation). In contrast, on average the lowest standardized domain values were achieved in Domain 5 (Applicability). The lowest standardized domain value was awarded in Domain 1 (Scope and Purpose) and Domain 6 (Editorial Independence), in each case for one guideline. The highest standardized domain value was awarded in Domain 4 for 3 guidelines and in Domain 6 for one guideline. In the other domains largely moderate to high standardized domain values were awarded.

Of the 13 guidelines included in the investigation, only 3 made statements on how guideline authors should handle unpublished data.

Potential need for updating and supplementation

Recommendations in the 13 guidelines included were found for all aspects of the medical care of COPD patients named in the DMP directive [1]. With regard to content they are largely consistent with the statements of the DMP directive; only few discrepancies were found. However, most extracted recommendations are more detailed compared with the text of the DMP directive.

The results of the comparison are presented in the following text, sorted by health care aspects.

Health care aspect "Definition of COPD" (1.1 of the DMP directive)

Several guidelines contain definitions on COPD. As the statements on the definition of COPD are not recommendations, no information on GoR/LoE is available. The statements are largely consistent with the DMP directive. Due to the missing information on GoR/LoE, no statement regarding the potential need for updating or supplementation can be made.

Health care aspect "Sufficient diagnostics for inclusion in the structured treatment programme for COPD" (1.2 of the DMP directive)

One guideline provides recommendations, without information on GoR/LoE, on sufficient diagnostics. Due to the missing information on GoR/LoE, no statement regarding the potential need for updating or supplementation can be made.

Health care aspect "Medical history, symptoms, and physical examination" (1.2.1 of the DMP directive)

Several guidelines provide recommendations, with a largely moderate/low GoR/LoE category, on the health care aspect "Medical history, symptoms, and physical examination". In comparison with the DMP directive the guidelines contain additional recommendations. They describe diagnostic procedures that have so far not been mentioned in the DMP directive. Due to the largely moderate/low GoR/LoE categories, there is no need for updating or supplementation.

Health care aspect "Step-by-step diagnostics of analytical lung function" (1.2.2 of the DMP directive)

Several guidelines provide recommendations, with a largely moderate/low GoR/LoE category, on the use of step-by-step diagnostics of analytical lung function within the framework of the confirmation of diagnosis, control of course of disease and treatment, and classification of degree of severity of COPD. The recommendations are largely consistent with the DMP directive. There is no need for updating or supplementation.

One guideline provides a negative recommendation, with a low GoR, for a routine reversibility test with bronchodilators or corticosteroids. For the justification of the recommendation, the same guideline lists conclusions that are largely awarded a moderate GoR category. The recommendations of the guideline are in contrast to the recommendation of the DMP directive. Due to the largely moderate/low GoR categories, there is no need for updating or supplementation.

Health care aspect "Treatment goals" (1.3 of the DMP directive)

Two guidelines provide recommendations, without information on GoR/LoE, on treatment goals. The recommendations are largely consistent with the DMP directive, Due to the lack of

information on GoR/LoE, no statement on the potential need for updating or supplementation can be made.

Health care aspect "Differentiated planning of treatment" (1.4 of the DMP directive)

Two guidelines provide recommendations, with a largely moderate/low GoR category, on differentiated planning of treatment. The recommendations are largely consistent with the DMP directive, but more differentiated. The guidelines provide inconsistent recommendations on alpha-1-antitrypsin-deficiency augmentation therapy in patients with this deficiency. In this context, one guideline specifically refers to non-smoking patients with a confirmed alpha-1-antitrypsin-deficiency. Due to the moderate/low GoR categories, there is no need for updating or supplementation.

Health care aspect "General non-pharmaceutical measures" (1.5.1.1 of the DMP directive)

Several guidelines provide recommendations, with a largely moderate/low GoR/LoE category, on the health care aspect "General non-pharmaceutical measures". In comparison with the DMP directive the guidelines contain additional recommendation on the use of health care aids, advice on air travel, and the use of short-burst oxygen therapy. Due to the largely moderate/low GoR/LoE categories, there is no need for updating or supplementation.

Health care aspect "Smoking cessation" (1.5.1.2 of the DMP directive)

One guideline provides a recommendation, with a high GoR category, on smoking cessation. It recommends the use of a combination therapy of pharmaceutical and psychosocial support. In comparison with the DMP directive this is an additional recommendation. A potential need for updating and supplementation can be discussed.

Two guidelines provide specific recommendations, with a largely low GoR/LoE category, on pharmaceutical smoking cessation. In comparison with the DMP directive the guidelines contain additional recommendations.

- One guideline recommends, without information on GoR and with non-allocatable LoE, nicotine replacement therapy with varenicline or bupropion in combination with a smoking cessation programme. Due to the lack of information on GoR and non-allocatable LoE, no statement can be made on the potential need for updating or supplementation.
- One guideline also provides a recommendation, with a low LoE category, on pharmaceutical measures for smoking cessation in hospitalized patients with exacerbation. Due to the low LoE category, there is no need for updating or supplementation.

Approval status and indication-specific reimbursability of recommended drugs

The recommended drugs varenicline and bupropion for pharmaceutical nicotine replacement therapy are approved in Germany. However, they cannot be reimbursed by the statutory health insurance as they are classified as lifestyle drugs [2-4].

Health care aspect "Physical training" (1.5.1.3 of the DMP directive)

Several guidelines provide recommendations, with a largely moderate/low GoR/LoE category, on physical training. The recommendations are largely consistent with the DMP directive, but more detailed. There is no need for updating or supplementation.

Health care aspect "Structured training and treatment programmes" (1.5.1.4 of the DMP directive)

Contents of training

Several guidelines provide recommendations, with a largely high GoR/LoE category, on specific contents of training. In comparison with the DMP directive these are additional recommendations. There is a potential need for updating or supplementation

Adaptation and implementation of structured training and treatment programmes

Several guidelines provide recommendations, with a largely moderate/low GoR category, on the adaptation and implementation of structured training and treatment programmes. The recommendations are largely consistent with the DMP directive, but more detailed. There is no need for updating or supplementation.

Health care aspect "General physiotherapy (breathing therapy)" (1.5.1.5 of the DMP directive)

Several guidelines provide recommendations, with a moderate/low GoR category, on general physiotherapy (breathing therapy). The recommendations are largely consistent with the DMP directive, but more detailed with regard to the aim and techniques of breathing therapy. There is no need for updating or supplementation.

Health care aspect "Long-term oxygen therapy" (1.5.2 of the DMP directive)

Two guidelines provide recommendations, with a largely high GoR category, on thresholds for oxygen partial pressure for use in long-term oxygen therapy. In comparison with the DMP directive these are additional recommendations. There is a potential need for updating or supplementation

One guideline provides recommendations, with a high GoR category, and one guideline provides recommendations, without information on GoR/LoE, on the daily duration of use of long-term oxygen therapy. In comparison with the DMP directive these are additional recommendations. A potential need for updating or supplementation can be discussed.

Health care aspect "Home ventilation" (1.5.3 of the DMP directive)

One guideline provides recommendations, with a low GoR category, on how to apply home ventilation. The recommendations are largely consistent with the DMP directive, but more detailed. There is no need for updating or supplementation.

Health care aspect "Rehabilitation" (1.5.4 of the DMP directive)

Several guidelines provide recommendations, with a largely moderate/low GoR category, on the aims, contents and implementation of pneumological rehabilitation. The recommendations are largely consistent with the DMP directive, but more detailed. There is no need for updating or supplementation

Health care aspect "Surgical procedures" (1.5.5 of the DMP directive)

One guideline provides recommendations on surgical procedures:

- Bullectomy as a surgical procedure is recommended, with a moderate GoR category. The recommendation is largely consistent with the DMP directive. There is no need for updating or supplementation.
- Reduction in lung volume as a surgical procedure for a clearly defined patient group is recommended, with a high GoR category. The recommendation is largely consistent with the DMP directive, but more detailed. There is no need for updating or supplementation.
- Lung transplantation as a surgical procedure for a clearly defined patient group is recommended, with a moderate GoR category. In comparison with the DMP directive this is an additional recommendation. Due to the moderate GoR category, there is no need for updating or supplementation.

Health care aspect "Mental, psychosomatic and psychosocial care" (1.5.6 of the DMP directive)

Two guidelines provide recommendations, with a moderate/low GoR category, on mental, psychosomatic, and psychosocial care. In comparison with the DMP directive one guideline contains additional recommendations. For patients with limiting COPD, the guideline recommends the use of psychosocial measures within the framework of rehabilitation and does not restrict itself to the evaluation of the indication, as stipulated in the DMP directive. Due to the moderate/low GoR categories, there is no need for updating or supplementation.

Health care aspect "Pharmaceutical measures" (1.5.7 of the DMP directive)

General statements on the guidelines included

Several guidelines provide recommendations, with a largely moderate/low GoR category, on general aspects of pharmaceutical therapy. The recommendations are largely consistent with the DMP directive. There is no need for updating or supplementation.

Bronchodilators

One guideline provides a recommendation, with a high LoE category, on the preferential use of inhaled formulations in pharmaceutical therapy. In comparison with the DMP directive the guideline contains an additional recommendation. A potential need for updating or supplementation can be discussed.

One guideline provides a recommendation, with a high LoE category, on the preferential use of long-acting anticholinergic and beta-2-sympathomimetic drugs over short-acting ones. In comparison with the DMP directive, the guideline contains an additional recommendation. A potential need for updating or supplementation can be discussed.

One guideline provides a recommendation, with a moderate GoR category, on rescue therapy with short-acting beta-2-sympathomimetic or anticholinergic drugs. The recommendation is largely consistent with the DMP directive. There is no need for updating or supplementation.

One guideline provides a recommendation, with a high GoR category, on maintenance therapy with long-acting beta-2-sympathomimetic or long-acting anticholinergic drugs. The recommendation is largely consistent with the DMP directive. There is no need for updating or supplementation.

One guideline provides a recommendation, without information on GoR and with non-allocatable LoE, on maintenance therapy with long-acting anticholinergic drugs. The recommendation is largely consistent with the DMP directive. There is no need for updating or supplementation.

One guideline provides a recommendation, with a high LoE category, on combination therapy of short-acting beta-2-sympathomimetic with short-acting anticholinergic drugs. The recommendation is largely consistent with the DMP directive. There is no need for updating or supplementation.

Two guidelines provide recommendations, with an inconsistent GoR/LoE category, and one guideline provide recommendations, without information on GoR and with non-allocatable LoE, on combination therapy of long-acting beta-2-sympathomimetic with long-acting anticholinergic drugs. In comparison with the DMP directive the guideline contains additional recommendations. A potential need for updating or supplementation can be discussed.

One guideline provides recommendations, with a moderate/low GoR category, and one guideline provide recommendations, without information on GoR and with non-allocatable LoE, on combination therapy of long-acting beta-2-sympathomimetic drugs (with or without long-acting anticholinergic drugs) with inhaled corticosteroids. In comparison with the DMP directive the guidelines contain additional recommendations. Due to the moderate/low GoR category, there is no need for updating or supplementation.

Two guidelines provide recommendations, with a largely low GoR category, on monotherapy with theophylline. The recommendations are largely consistent with the DMP directive, but are more differentiated with regard to determining the indication. There is no need for updating or supplementation.

One guideline provides recommendations, with a high GoR category, on the use of theophylline in combination with beta-2-sympathomimetic or anticholinergic drugs, if monotherapy with bronchodilators does not improve symptoms. In comparison with the DMP directive the guideline contains additional recommendations. A potential need for updating or supplementation can be discussed.

Corticosteroids

One guideline provides recommendations, with a high LoE category, on the use of inhaled corticosteroids in long-term therapy of patients with (very) severe COPD and frequent exacerbations. The recommendations are largely consistent with the DMP directive. There is no need for updating or supplementation.

One guideline provides a negative recommendation, with a high LoE category, on monotherapy alone with inhaled corticosteroids. In comparison with the DMP directive the guideline contains an additional recommendation. A potential need for updating or supplementation can be discussed.

One guideline provides a negative recommendation, with a high LoE category, on the use of oral corticosteroids in long-term therapy. In comparison with the DMP directive the guideline contains an additional recommendation. A potential need for updating or supplementation can be discussed.

One guideline provides a negative recommendation, with a high GoR category, on the use of corticosteroids in the reversibility test for the prediction of probable response to therapy. In comparison with the DMP directive this is an additional recommendation. A potential need for updating or supplementation can be discussed.

Further pharmaceutical measures

Phosphodiesterase inhibitors

One guideline provides a recommendation, with a high LoE category, on the use of roflumilast. In comparison with the DMP directive this is an additional recommendation. A potential need for updating or supplementation can be discussed.

Mucolytic drugs

One guideline provides a recommendation, with a largely moderate/low GoR category, on the use of mucolytic drugs. The recommendations are largely consistent with the DMP directive. There is no need for updating or supplementation.

Care of patients with cor pulmonale

One guideline provides negative recommendations, with a largely moderate GoR category, on different drugs in the care of patients with cor pulmonale. In comparison with the DMP directive the guideline contains additional recommendations. Due to the largely moderate GoR, there is no need for updating or supplementation.

Antitussive drugs

One guideline provides a negative recommendation, with a largely low GoR category, on the use of antitussive drugs. In comparison with the DMP directive this is an additional recommendation. Due to the low GoR category, there is no potential need for updating or supplementation.

Antioxidants

One guideline provides a negative recommendation, with a high GoR category, on both monotherapy and combination therapy with the antioxidants alpha-tocopherol and beta-carotene. In comparison with the DMP directive this is an additional recommendation. A potential need for updating or supplementation can be discussed.

Approval status and indication-specific reimbursability of recommended drugs

Antioxidants such as alpha-tocopherol and beta-carotene are not approved in Germany and antioxidants cannot be reimbursed by statutory health insurance.

Care of COPD patients with end-stage disease

Two guidelines provide recommendations, with a moderate/low GoR category, on the pharmaceutical therapy of COPD patients with end-stage disease. In comparison with the DMP directive these are additional recommendations. Due to the moderate/low GoR categories, there is no potential need for updating or supplementation.

Health care aspect "Vaccinations" (1.5.7.1 of the DMP directive)

Several guidelines provide recommendations, with a largely high LoE category, on influenza vaccination in COPD patients. The recommendations are largely consistent with the DMP directive. There is no need for updating or supplementation.

Several guidelines provide recommendations, with a largely moderate/low LoE category, on pneumococcal vaccination in COPD patients. The recommendations are largely consistent with the DMP directive. There is no need for updating or supplementation.

Health care aspect "Exacerbations / respiratory infections" (1.5.7.2 of the DMP directive)

Definition of exacerbation

Several guidelines contain definitions of exacerbation. As these statements are not recommendations, no information on GoR/LoE is available. The statements in the guidelines

are largely consistent with the DMP directive. Due to the missing information on GoR/LoE, no statement can be made on the need for potential updating or supplementation.

Diagnosis of exacerbations / respiratory infections

Several guidelines provide recommendations, with a largely moderate/low GoR/LoE category, on the diagnostics of exacerbation. In comparison with the DMP directive the guidelines contain additional recommendations. Due to the moderate/low GoR/LoE categories, there is no potential need for updating or supplementation.

Pharmaceutical therapy

One guideline provides recommendations, with a moderate/low LoE category, and one guideline provides recommendations, with an inconsistent LoE category, on the treatment of exacerbation with short-acting beta-2-sympathomimetic and anticholinergic drugs. The statements in the guidelines are largely consistent with the DMP directive, but more detailed. There is no need for updating or supplementation.

Several guidelines provide recommendations, with a largely high GoR/LoE category, on the treatment of exacerbation with systemic (oral) corticosteroids. The recommendations are largely consistent with the DMP directive, but are more differentiated. There is no need for updating or supplementation.

One guideline provides recommendations, with a low GoR category, on the treatment of exacerbations with theophylline, but only if all therapy attempts with bronchodilators and corticosteroids are unsuccessful. In comparison with the DMP directive the guideline contains new recommendations. Due to the low GoR category, there is no need for updating or supplementation.

Several guidelines provide recommendations, with a largely high GoR/LoE category, on the use of antibiotics, but only in patients with purulent sputum or signs of pneumonia. The recommendations are largely consistent with the DMP directive. There is no need for updating or supplementation.

Non-pharmaceutical therapy

Two guidelines provide recommendations, with a moderate/low GoR category, on oxygen therapy for exacerbations. In comparison with the DMP directive these are additional recommendations. Due to the moderate/low GoR categories, there is no need for updating or supplementation.

One guideline provides recommendations, with a largely moderate/low GoR category, on determining the indication for invasive and non-invasive ventilation for exacerbations. In comparison with the DMP directive these are additional recommendations. Due to the largely moderate/low GoR category, there is no need for updating or supplementation.

Health care aspect "Cooperation of health care sectors" (1.6 of the DMP directive)

Several guidelines provide recommendations, with a largely low GoR/LoE category, on the cooperation of health care sectors. In comparison with the DMP directive, these are additional recommendations on palliative care, on specialized nurses and social workers. Due to the largely low GoR/LoE categories, there is no need for updating or supplementation.

Health care aspect "Coordinating physician" (1.6.1 of the DMP directive)

One guideline provides recommendations, with a largely low GoR category, on the health care aspect "Coordinating physician". The recommendations are largely consistent with the DMP directive, but more detailed. There is no need for updating or supplementation.

Health care aspect "Referral by coordinating physician to respective qualified specialist or qualified institution" (1.6.2 of the DMP directive)

Two guidelines provide recommendations, with a low GoR category, on referral to a specialist or specialist institution. In comparison with the DMP directive the guidelines contain additional recommendations by naming further indications for a referral to a specialist or specialist institution. Due to the low GoR categories, there is no need for updating or supplementation.

Health care aspect "Admission to hospital" (1.6.3 of the DMP directive)

Two guidelines provide recommendations, with a largely moderate/low GoR category, on this health care aspect. The recommendations are largely consistent with the DMP directive, but more detailed. There is no need for updating or supplementation.

Health care aspect "Initiation of a rehabilitation service" (1.6.4 of the DMP directive)

Three guidelines provide recommendations, with a high GoR category, for determining the indication for a rehabilitation service in patients with moderately severe COPD. In comparison with the DMP directive, which only plans for rehabilitation in patients with severe COPD; the guidelines contain additional recommendations. There is a potential need for updating or supplementation.

One guideline provides recommendations, with inconsistent GoR categories, and one guideline provides recommendations, without information on GoR and with non-allocatable LoE, on the indication for rehabilitation in "condition after exacerbation". In comparison with the DMP directive these are additional recommendations. A potential need for updating or supplementation can be discussed.

One guideline provides a stronger recommendation, with a high GoR category, for inpatient rehabilitation than for outpatient rehabilitation. In comparison with the DMP directive the guideline contains an additional recommendation. A potential need for updating or supplementation can be discussed.

Two guidelines provide recommendations, with a low GoR category, on the evaluation of the success of rehabilitation, on determination of the indication in patients with comorbidities, and on the entry examination. In comparison with the DMP directive these are additional recommendations. Due to the low GoR category, there is no need for updating or supplementation.

Conclusion

By comparing the recommendations extracted from current evidence-based guidelines with the requirements of the DMP directive forming the basis of the DMP "COPD", health care aspects could be identified for which a potential need for updating or supplementation exists or can be discussed.

There is a potential need for updating or supplementation for the following health care aspects

- "Structured training and treatment programmes" regarding the contents of training
- "Long-term oxygen therapy" regarding thresholds for oxygen partial pressure for use in long-term oxygen therapy
- "Initiation of a rehabilitation service" for determining the indication for a rehabilitation service in patients with moderately severe COPD

A potential need for updating or supplementation can be discussed for the following health care aspects

- "Smoking cessation" regarding the use of combination therapy of pharmaceutical and psychosocial support
- "Long-term oxygen therapy" regarding the daily duration of use
- "Pharmaceutical measures"
  - for the use of inhaled formulations of bronchodilators in pharmaceutical therapy
  - for the preferential use of long-acting anticholinergic and beta-2-sympathomimetic drugs
  - for the combination therapy of long-acting beta-2-sympathomimetic drugs with long-acting anticholinergic drugs
  - for the use of theophylline in combination with beta-2-sympathomimetic drugs or anticholinergic drugs
  - for the negative recommendation for monotherapy alone with inhaled corticosteroids
  - for the negative recommendation on the use of oral corticosteroids in long-term therapy
  - for the negative recommendation on the use of corticosteroids in the reversibility test for the prediction of probable response to therapy

  - for the use of roflumilast for prophylaxis of exacerbations, as well as
  - for the negative recommendation on mono- and combination therapy of the antioxidants alpha-tocopherol and beta-carotene
- "Initiation of a rehabilitation service" for the indication for rehabilitation in "condition after exacerbation", as well as inpatient rehabilitation

It is unclear whether the lack of consideration of unpublished data in the guidelines included results in bias in the external evidence underlying the recommendations. If this does lead to bias, the direction and extent of bias is not assessable on the basis of the information available.

Keywords: pulmonary disease – chronic obstructive, disease management programme, methodological guideline appraisal

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