IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

IQWiG Reports – Commission No. V14-04

Systematic guideline search and appraisal, as well as extraction of relevant recommendations, for a DMP "chronic back pain"[1]

Extract

1 Translation of Chapters 1 to 6 of the final report *Systematische Leitlinienrecherche und -bewertung sowie Extraktion relevanter Empfehlungen für ein DMP Chronischer Rückenschmerz* (Version 1.0; Status: 18 November 2015). 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:

Systematic guideline search and appraisal, as well as extraction of relevant recommendations, for a DMP "chronic back pain"

Commissioning agency:

Federal Joint Committee

Commission awarded on:

21 August 2014

Internal Commission No.:

V14-04

Address of publisher:

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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 Appendix A.11 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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Keywords: back pain, disease management programme, methodological guideline appraisal

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Key statement

Research question

The aim of the present investigation is to identify current, topic-relevant, evidence-based guidelines, extract their recommendations and designate those recommendations that are relevant for the care of patients in a disease management programme (DMP) "chronic back pain".

Conclusion

On the basis of a "Grade of Recommendation" (GoR) or alternatively a "Level of Evidence" (LoE) of the extracted recommendations from current evidence-based guidelines, relevant and potentially relevant recommendations on all prespecified healthcare aspects were identified for a DMP "chronic back pain", with the exception of the healthcare aspect "treatment goals". These commonly referred to recommendations advising against the use of a measure (negative recommendation).

The guidelines provide recommendations on diagnostics (standardized recording of symptoms, recording of psychosocial risk factors, imaging procedures, blood tests, diagnostic nerve blocks) and on recurrence prophylaxis (physical activity, shoe insoles and orthoses [negative recommendation], lumbar support belts [negative recommendation]).

For non-drug measures, recommendations were identified on massages and manual therapy, exercise and physiotherapy, as well as aqua gymnastics and yoga. Furthermore, negative recommendations were found on bed rest, behavioural therapy, transcutaneous electrical nerve stimulation (TENS) and percutaneous electrical nerve stimulation (PENS), device-supported traction treatment, orthoses, short-wave diathermy, therapeutic ultrasound, as well as on interference, magnetic field, and laser therapy.

The recommendations on drug therapy referred to oral analgesics such as flupirtine (negative recommendation), nonsteroidal anti-inflammatory drugs (NSAIDs), opioid analgesics, muscle relaxants, antidepressants and other psychotropic drugs (negative recommendation), the additional administration of proton pump inhibitors, as well as intravenous or intramuscular administration of pain medication (negative recommendation). For invasive therapy, recommendations were identified on joint injections (negative recommendation), proliferation therapy (negative recommendation), and counselling about surgical treatment options.

Recommendations were also identified on the healthcare aspects of patient training, rehabilitation measures, and cooperation of healthcare sectors.

Inconsistent recommendations were identified on discography, non-drug therapy with acupuncture, as well as drug therapy with paracetamol and phytotherapeutics; these were proposed for further evaluation of their DMP relevance.

In addition, specific recommendations were identified for different patient subgroups (patients with radiculopathy and/or disc-related back pain, spinal canal stenosis, post-nucleotomy syndrome, lumbar facet joint pain, sacroiliac joint pain).

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List of abbreviations

Abbreviation	Meaning
AAN	American Academy of Neurology
AGREE	Appraisal-of-Guidelines-for-Research-&-Evaluation-Instrument
APS	American Pain Society
APTA	American Physical Therapy Association
ASIPP	American Society of Interventional Pain Physicians
DMP	disease management programme
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
GoR	Grade of Recommendation
IOM	Institute of Medicine
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
LBP	low back pain
LoE	Level of Evidence
NSAID	nonsteroidal anti-inflammatory drug
NVL	Nationale VersorgungsLeitlinie (National Care Guideline)
PENS	percutaneous electrical nerve stimulation
RCT	randomized controlled trial
SSNRI	selective serotonin norepinephrine reuptake inhibitor
SSRI	selective serotonin reuptake inhibitor
TENS	transcutaneous electrical nerve stimulation
tNSAID	traditional nonsteroidal anti-inflammatory drug
TOP	Toward Optimized Practice

1 Background

Disease management programmes

Disease management programmes (DMPs) are structured treatment programmes for chronically ill people, which are based on the findings of evidence-based medicine. Within the framework of 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 the quality of life of patients. 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].

Relevant disorder

“Back pain” generally describes pain of the human back of differing severity that can have very different causes. Low back pain (LBP) is pain in the area of the back below the rib cage and above the gluteal folds, with or without radiation of the pain to other areas and potential further complaints [3].

The pain is classified according to cause, duration, severity, and stage of chronification. With regard to the causes, the pain can be further distinguished into non-specific or specific. Non-specific back pain is back pain for which a cause cannot be found with simple clinical techniques [4]. Specific back pain originates from a specific cause, for instance, fracture, tumour, infection, radiculopathy or neuropathy [3].

On the basis of the course of disease, the pain is distinguished in acute, subacute, chronic, or chronic recurring back pain. Chronic or chronic recurring back pain is back pain lasting longer than 3 months [4,5].

The severity of chronic back pain is usually determined by means of the grading of pain following von Korff et al. [6]. The grading scheme distinguishes back pain according to the extent of pain intensity and the pain-related impairment of daily activities [5]. Results from the German Back Pain Study 2003/2006 show that the prevalence of back pain at the time of the study (without information on the severity of complaints) lay between 32% und 49% in different regions of Germany [4]. The reported lifetime prevalence (back pain at least once in a lifetime) lay between 74% and 85%. This means that only about 20% of the study participants had never experienced back pain. The results of this study also show that 7% of the respondents reported severe back pain and 9% reported back pain causing considerable impairment. The telephone health surveys of the Robert Koch Institute (2003 and 2009) show that, at the time of the survey, more women than men reported that they suffered from chronic back pain (almost daily pain) [4]. A nearly linear increase in the frequency of chronic back pain is shown with age. Back pain is also one of the most commonly reported complaints in children and adolescents [4].

According to the health report of the Robert Koch Institute, in comparison with other countries the German population shows a rather high prevalence of back pain [4].

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” [7] 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” [8] .

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) with a low risk of bias are generally awarded the highest LoE. However, guideline developers use different systems to grade evidence and, within the LoE, acknowledge a varying importance of the different clinical and epidemiological study types, as well as, if applicable, of further potentially biasing factors.

2 Research question

The aim of the present investigation is to identify current, topic-relevant, evidence-based guidelines, extract their recommendations and designate those recommendations that are relevant for the care of patients in a DMP “chronic back pain”.

3 Methods

The investigation included guidelines that had been developed specifically for chronic back pain. The population comprised patients with chronic back pain (i.e. LBP), defined as:

- pain in the area of the back below the rib cage, above the gluteal folds, with or without radiation to other areas
- without suggestion of a specific cause
- chronic or chronically recurring course (longer than 12 weeks' duration), and
- typically with a varying intensity of pain

Only evidence-based guidelines applicable to the German healthcare system and published since 1 January 2009 were included. The recommendations had to be clearly designated as such.

For this purpose, a systematic Internet search for guidelines was conducted in guideline databases, as well as on the websites of multidisciplinary and specialist guideline providers. The search was conducted in November 2014 and the update search was conducted in August 2015. In addition, information was screened from the hearing procedure on the preliminary report plan. The selection of relevant guidelines was performed by means of the screening of titles and abstracts, with subsequent assessment of the full texts of the potentially relevant guidelines. The selection of the guidelines to be included was performed by 2 reviewers independently of one another. The assessment of the relevance of the additional information from the hearing procedure was also performed by both reviewers; discrepancies were solved through discussion between them.

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 a total of 23 appraisal criteria. Six domains are allocated to these criteria, each of which describes a separate dimension of methodological guideline quality. The assessments were performed by 2 reviewers independently of one another. These 2 reviewers then assessed the overall quality of the guidelines. The results of the AGREE II appraisal were not a criterion for the inclusion of guidelines in the investigation, but served to transparently present the methodological strengths or weaknesses of the evidence-based guidelines included.

The guideline recommendations relevant for the research question were extracted into tables, together with the related GoR and LoE for the respective healthcare aspects. In this context, 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 health care situation, as well as on the strength of the underlying evidence or the LoE. The LoE reported by the guideline authors represents an assessment of internal validity of the studies underlying the recommendations; in this

context, systematic reviews of RCTs are generally awarded the highest LoE. In addition, when extracting the recommendations for each individual GoR and LoE, for the assessment of their DMP relevance, it was reported whether the recommendations were allocated to a high (↑) or (↓) low GoR/LoE.

The guideline recommendations and the definitions of the disorder were summarized in a structured information synthesis. The relevant GoR, or if not reported, alternatively the LoE, were used to evaluate the relevance of recommendations on a topic (of a healthcare aspect) for a DMP “chronic back pain”.

- DMP relevance was determined if different guidelines provided consistent recommendations on a topic, mostly with a high GoR, or alternatively a high LoE.
- Potential DMP relevance was determined for recommendations in which consistent statements were made on a topic, but were only partly and not mostly allocated to a high GoR, or alternatively a high LoE. In the following text, the latter is referred to as an inconsistent GoR or alternatively an inconsistent LoE. In addition, potential DMP relevance was determined if only one guideline provided recommendations on a topic and they were allocated to a high GoR or alternatively a high LoE.
- Further evaluation of DMP relevance was proposed in cases where different guidelines provided inconsistent recommendations on a topic, with at least partly a high GoE or alternatively a high LoE.
- No statement on DMP relevance could be made if no GoR or LoE were provided on a topic for the majority of recommendations or if the GoR or LoE could not be clearly allocated to the recommendations.
- No DMP relevance was determined if a GoR or alternatively an LoE was provided on a topic for at least half of the recommendations, but no high GoR, or alternatively no high LoE, was awarded.

For all (potentially) DMP relevant recommendations it was evaluated whether contradicting statements existed in IQWiG reports. In addition, in the event of (potentially) DMP relevant recommendations on drug therapy, the indication-specific prescribability and the approval status in Germany were evaluated.

4 Results

4.1 Results of information retrieval

The systematic Internet search yielded 59 potentially relevant documents after the screening of titles and abstracts; these documents were screened in full text. After evaluation of the criteria for guideline exclusion, 6 relevant guidelines were included.

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

Abbreviation	Publisher
AAN 2010 [9]	American Academy of Neurology (AAN)
APS 2009 [10]	American Pain Society (APS)
APTA 2012 [11]	American Physical Therapy Association (APTA)
ASIPP 2013 [12,13]	American Society of Interventional Pain Physicians (ASIPP)
NVL 2013 [5]	Nationale VersorgungsLeitlinie (NVL) [National Medical Care Guideline]
TOP 2011 [14]	Toward Optimized Practice (TOP)

4.2 Characteristics of the guidelines included

Five of the guidelines included were published by institutions from the United States (n = 4) and Canada (n = 1). One guideline originates from Germany (NVL 2013).

All 6 guidelines address the treatment of chronic LBP, whereby one guideline (AAN 2010) focusses exclusively on transcutaneous electrical nerve stimulation (TENS). Three guidelines (APS 2009, NVL 2013, TOP 2011) also contain recommendations on diagnostics. Further areas of application covered by the guidelines are prevention (APS 2009, NVL 2013, TOP 2011) as well as rehabilitation (APS 2009).

The patient population included by the individual guidelines ranges from patients with pain related to neurological diseases (AAN 2010), patients with LBP of any duration with or without radiation to the legs (APS 2009), patients with chronic back pain (ASIPP 2013) to patients with non-specific LBP (NVL 2013). Only one guideline (TOP 2011) specifically mentions the age group as well as the excluded patient population. The patient population of APTA 2012 comprises both patients with specific and non-specific LBP.

The target groups mentioned by 4 guidelines (APS 2009, ASIPP 2013, NVL 2013, TOP 2011) are medical doctors, members of non-medical professions, as well as patients and their relatives. The other guidelines (AAN 2010, APTA 2012) do not mention target groups.

All guidelines include a classification system for the LoE and/or GoR, whereby one only mentioned an LoE (ASIPP 2013).

4.3 Methodological quality of the guidelines

4.3.1 Results of the appraisal with AGREE

Overall on average the guidelines received the highest standardized domain scores in the domain “clarity and presentation”. The clearest deficits were determined in the domain “applicability”. This means that the information was insufficient in the guidelines on the support of their implementation, on beneficial and detrimental factors, as well as on the presentation of resource needs.

In the overall assessment, guideline NVL 2013 received the best evaluation, followed by guidelines ASIPP 2013 and TOP 2011 and then by APS 2009, APTA 2013, and AAN 2010.

4.4 Guideline authors’ handling of unpublished or incompletely published data

Of the 6 guidelines included, 2 (APS 2009, ASIPP 2013) contains details on information retrieval of unpublished or incompletely published data. Furthermore, 1 of the 2 guidelines (APS 2009) refers to the consideration of conference abstracts and unpublished studies in the assessment of evidence. In its summary of evidence regarding treatment with antidepressants, guideline NVL 2013 refers to the biased reporting of study results. However, guidelines APS 2009 and NVL 2013 do not make any statement about the specific impact on the generation of recommendations.

4.5 Synthesis of recommendations

The guideline synopsis is based on the analysis of 6 guidelines. Of these, 3 address the complete care of people with LBP and 3 refer to specific interventions ([i] TENS, [ii] interventional treatments, and [iii] interventional treatments, surgery, and interdisciplinary rehabilitation). Overall, recommendations on the following healthcare aspects were identified in the guidelines: definition, diagnostic clarification, treatment goals, conservative non-drug, drug and invasive treatment procedures, rehabilitation, cooperation of healthcare sectors, patient training, and treatment for specific symptoms and findings.

In the following text the guideline recommendations are summarized for the single healthcare aspects, for which, according to the methodology applied, a relevance or potential relevance arises or for which further evaluation of DMP relevance for a DMP “chronic back pain” is proposed (see Chapter 3).

4.5.1 Definition of (chronic) back pain

A total of 4 guidelines contain a definition of chronic back pain or LBP.

The definitions of chronic LBP or back pain presented in the guidelines are not designated as recommendations. For the understanding of the recommendations presented in this report, the definitions reported by the guidelines are described in short in the following text.

One guideline characterizes chronic back pain as a complex problem to the development of which biological, psychosocial and environmental factors contribute.

Two further guidelines define back pain according to Chapter 1 “Background”. One guideline defines back pain as pain in the back area without symptoms or signs of a serious physical or psychological disease. These 3 guidelines propose classifying LBP as acute (< 6 weeks of pain), subacute (> 6 weeks of pain) or chronic/chronic recurring (> 12 weeks of pain). In terms of the biopsychosocial disease model, the following factors should be considered for LBP in deliberations about the development and persistence of the condition, and in this sense also in diagnostic and therapeutic concepts: somatic (e.g. predisposition, functionality), psychological (e.g. problem-solving competence, self-efficacy expectation) or social factors (e.g. social networks, healthcare status, workplace).

4.5.2 Diagnostic clarification

A total of 5 guidelines contain recommendations on the diagnostic approach to LBP.

Two guidelines advise against further diagnostic measures for the time being if there is no indication of a dangerous course or serious pathologies (“red flags”); (recommendations are DMP relevant).

In patients with persistent back pain despite guideline-conform treatment over 4 weeks, one guideline recommends the recording of psychosocial risk factors (“yellow flags”) by the primary healthcare provider. After 12 weeks of persistent LBP, within the framework of an interdisciplinary assessment, one guideline recommends further somatic diagnostic procedures and comprehensive recording of psychosocial influencing factors. One guideline recommends validated questionnaires for recording pain, function and restriction of movement, which can also be used during the course of the disease as monitoring instruments (recommendations are potentially DMP relevant).

Diagnostic imaging procedures

For patients with chronic LBP one guideline recommends an X-ray of the spine only if clinical warning signals are present (“red flags”); (recommendation is potentially DMP relevant). A further guideline makes the medical indication for conducting an imaging procedure in patients with chronic LBP dependent on the presence of psychosocial risk factors (“yellow flags”). Patients without “yellow flags” should undergo a one-off diagnostic imaging procedure. Patients with “yellow flags” should undergo such a procedure only in the case of a very specific suspicion of an underlying organic pathological cause (recommendations are potentially DMP relevant).

If a dangerous course is suspected (“red flags”), according to the statements in 2 guidelines, diagnostic imaging procedures should be conducted depending on the suspected diagnosis and urgency (recommendations are DMP relevant).

Discography

The effectiveness of discography to identify the disc as the trigger of back problems is viewed to be not proven and for this reason is not recommended by 2 guidelines. A further guideline recommends discography under certain conditions (proposal to further evaluate DMP relevance).

Laboratory diagnostics

Two guidelines recommend a blood test within the framework of diagnostics in patients with LBP only if specific suspected diagnoses (such as tumours or infections) exist (recommendations are DMP relevant).

Diagnostic blocks

If the cause of back pain is suspected to be in the sacroiliac joint, according to one guideline, a diagnostic nerve block in this joint can be performed. A 75% reduction in pain after the injection or pain-free movement is regarded to be positive evidence (recommendation is potentially DMP relevant).

4.5.3 Treatment goals

Only one guideline contains general statements on treatment goals; these recommendations are not DMP relevant.

4.5.4 Non-drug therapy in patients with chronic non-specific LBP

A total of 4 guidelines contain recommendations on non-drug therapy in chronic non-specific LBP.

Non-drug measures for recurrence prophylaxis of chronic non-specific LBP

Two guidelines in general recommend physical activity as recurrence prophylaxis of recurrent chronic non-specific LBP (recommendations are DMP relevant).

One guideline provides recommendations against the use of shoe insoles/orthoses and lumbar support belts for recurrence prophylaxis of chronic non-specific LBP (recommendations are potentially DMP relevant).

Non-drug measures for treatment of chronic non-specific LBP

The guidelines name numerous non-drug measures for treatment of chronic non-specific LBP. In the following text these measures are presented separately according to “recommended”, “non-drug measures with a negative recommendation” or “non-drug measures without a clear recommendation (inconsistent content)”.

Recommended non-drug measures

Massages

Two guidelines recommend massages in combination with exercise therapy in patients with chronic non-specific LBP (recommendations are potentially DMP relevant).

Manual therapy

According to the statements of 2 guidelines, manipulation or mobilization within the framework of manual therapy can improve mobility and reduce pain in patients with chronic non-specific LBP. In one guideline this recommendation is restricted to the combination of manual treatment procedures with exercise therapy. A further guideline states that there is insufficient proof of the effectiveness of manual therapy (recommendations are potentially DMP relevant).

Exercise and physiotherapy

Several guidelines recommend exercise and physiotherapy as a primary non-drug therapy measure for patients with chronic non-specific LBP (recommendations are DMP relevant).

Aqua gymnastics

One guideline recommends aqua gymnastics for patients with chronic non-specific LBP (recommendation is potentially DMP relevant)

Yoga

One guideline recommends yoga for the treatment of chronic non-specific LBP, but only Viniyoga und Iyengar yoga (recommendation is potentially DMP relevant).

Behavioural therapy

Two guidelines recommend cognitive behavioural therapy for patients with chronic non-specific LBP, which should be incorporated in a multimodal treatment concept (recommendations are DMP relevant)

Non-drug measures with a negative recommendation

Bed rest

One guideline advises against adherence to bed rest within the framework of treatment of patients with chronic non-specific LBP (recommendation is potentially DMP relevant).

Traction treatment

Three guidelines advise against device-supported traction treatment in patients with chronic non-specific LBP (recommendations are DMP relevant).

Orthoses

One guideline advises against orthoses for the treatment of patients with chronic non-specific LBP (recommendation is potentially DMP relevant).

Short-wave diathermy

One guideline advises against treatment with short-wave diathermy in patients with chronic non-specific LBP (recommendation is potentially DMP relevant).

Therapeutic ultrasound

Two guidelines advise against the use of therapeutic ultrasound in patients with chronic non-specific LBP (recommendations are potentially DMP relevant).

Interference therapy

Two guidelines advise against interference therapy in patients with chronic non-specific LBP (recommendations are potentially DMP relevant).

Transcutaneous electrical nerve stimulation

Three guidelines advise against TENS therapy in patients with chronic non-specific LBP (recommendations are DMP relevant).

Percutaneous electrical nerve stimulation

One guideline advises against percutaneous electrical nerve stimulation (PENS) therapy for the treatment of patients with chronic non-specific LBP (recommendation is potentially DMP relevant).

Magnetic field therapy

One guideline advises against magnetic field therapy for the treatment of patients with chronic non-specific LBP (recommendation is potentially DMP relevant).

Laser therapy

Two guidelines advise against laser therapy for the treatment of patients with chronic non-specific LBP (recommendations are potentially DMP relevant).

Non-drug measures without a clear recommendation (inconsistent content)

Acupuncture

One guideline provides only a limited recommendation for acupuncture treatments in patients with chronic non-specific LBP. In contrast, a further guideline recommends acupuncture as sole therapy or as concomitant treatment for patients with chronic non-specific LBP (proposal to further evaluate DMP relevance).

4.5.5 Drug therapy for patients with chronic non-specific LBP

A total of 2 guidelines contain recommendations on drug therapy of chronic non-specific LBP.

Analgesics

According to one guideline, paracetamol should be used in patients with chronic non-specific LBP only after taking a detailed drug history and only for treatment of short exacerbations. In contrast, a further guideline recommends paracetamol therapy without restrictions (proposal to further evaluate DMP relevance).

One guideline advises against flupirtine for drug therapy in patients with chronic non-specific LBP (recommendation is potentially DMP relevant).

Nonsteroidal anti-inflammatory drugs

Nonsteroidal anti-inflammatory drugs (NSAIDs) can be used for drug therapy of patients with chronic non-specific LBP and are recommended by one guideline without restriction (recommendation is potentially DMP relevant). However, a further guideline advises against parenteral administration of traditional NSAIDs (tNSAIDs); (recommendation is potentially DMP relevant).

If NSAIDs (especially tNSAIDs) are prescribed, 2 guidelines recommend additional administration of proton pump inhibitors[3] (recommendations are potentially DMP relevant).

Opioid analgesics

Two guidelines recommend weak opioids for treatment of chronic non-specific LBP (e.g. codeine, tramadol, tilidine/naloxone), but only after unsuccessful pain therapy with non-opioid analgesics (recommendation is potentially DMP relevant). One guideline recommends evaluating opioid therapy after 3 months at the latest. If no alleviation of pain/improvement in function occurs, continuation of opioid therapy is contraindicated (recommendation is potentially DMP relevant).

Muscle relaxants

Two guidelines recommend muscle relaxants if non-drug measures or the sole administration of non-opioid analgesics do not result in an improvement in patients with chronic non-specific LBP. However, due to their side effects, they should only be used with caution and not longer than 2 weeks in a row (recommendations are potentially DMP relevant).

Antidepressants and other psychotropic drugs

According to one guideline, tricyclic antidepressants can be used for the treatment of chronic non-specific LBP, but they only have small or moderate effects and the dosage should lie clearly under that for treatment of depression (recommendation is potentially DMP relevant).

[3] No information on the additional administration of proton pump inhibitors is available in the summary of product characteristics on NSAIDs. The therapeutic indications mentioned in the summary of product characteristics on the proton pump inhibitors pantoprazole 20 mg, stomach-acid resistant tablets, as well as on omeprazole ("Omeprazol-ratiopharm") also comprise the treatment of gastroduodenal ulcers caused by the use of NSAIDs. However, the therapeutic indication mentioned in the summary of product characteristics on omeprazole exclusively refers to patients aged > 60 [15,16].

Two guidelines advise against the regular use of selective serotonin norepinephrine reuptake inhibitors (SSNRIs) and selective serotonin reuptake inhibitors (SSRIs) for the drug treatment of patients with chronic non-specific LBP. SSNRIs are only recommended if severe depression or an anxiety disorder exists in combination with chronic back pain (recommendations are potentially DMP relevant).

Phytotherapeutics

One guideline advises against the use of phytotherapeutics (plant remedies) for pain therapy in chronic non-specific LBP. A further guideline states that certain phytotherapeutics can be helpful for acute exacerbations of chronic non-specific LBP, and names the extract of the African devil’s claw, a combination of extracts of violet willow (salix daphnoides) and purple willow (salix purpurea), as well as capsaicin heat plasters (proposal to further evaluate DMP relevance).

Intramuscular or intravenous administration of drugs

One guideline advises against intramuscularly or intravenously applied pain medication, glucocorticoids or mixed infusions for the treatment of chronic non-specific LBP (recommendation is potentially DMP relevant).

4.5.6 Invasive therapy for patients with chronic non-specific LBP

A total of 3 guidelines contain recommendations on invasive therapy for patients for chronic non-specific LBP.

One guideline advises against all invasive therapy procedures for the treatment of patients with chronic non-specific LBP (recommendation is potentially DMP relevant). A further guideline specifically advises against corticoid injections at the facet joints and injections in the spinal disc for the treatment of patients with persistent non-radicular LBP (recommendations are potentially DMP relevant).

Two guidelines advise against the use of proliferation therapy (prolotherapy) as the sole treatment for patients with chronic non-specific LBP (recommendations are DMP relevant).

4.5.7 Rehabilitation measures

A total of 3 guidelines contain recommendations on the topic of rehabilitation measures.

Three guidelines recommend interdisciplinary and multimodal rehabilitation programmes for those patients with chronic non-specific LBP in whom less intensive, non-interdisciplinary therapies have not led to an improvement of symptoms. Before the start of the rehabilitation programme, a structured assessment with a subsequent interdisciplinary team meeting should be performed for the development of a therapy plan, if possible. Preparing for the time after treatment should be an integral part of the therapy plan. This primarily refers to the guidance to independently conduct physical activities. Supplementary therapeutic measures should be initiated according to the recommendations of the final therapy report or the reassessment

report. In the rehabilitative and also in the therapeutic area, measures to support occupational reintegration should be evaluated with regard to their appropriateness and, if applicable, initiated. In general, the following elements should be part of a rehabilitation programme: (i) training on back pain, (ii) self-management programmes, (iii) gradual reuptake of normal movement/activity, and (iv) physiotherapy (recommendations are DMP relevant).

4.5.8 Cooperation of healthcare sectors

A total of 3 guidelines contain recommendations on the cooperation of the different healthcare sectors.

One guideline recommends that the responsibility of healthcare coordination lies with a medical doctor (no more precise definition); this person is the first contact point for the patient and coordinates all treatment steps (recommendation is potentially DMP relevant).

Within the framework of making a diagnosis, 2 guidelines recommend collaboration with medical specialists, particularly if a serious disease is suspected. In this context, one guideline recommends that for further somatic diagnostics, all patients with chronic non-specific back pain should receive an interdisciplinary/multidisciplinary assessment (recommendations are DMP relevant).

One guideline recommends that patients with chronic non-specific LBP and relevant restrictions of daily activities despite therapy should be referred to a multidisciplinary team for the treatment of chronic pain. In patients with severe chronic LBP, consultation by a surgical specialist with regard to the medical indication for vertebral fusion (spondylodesis) can be advisable. However, the preconditions for the consultation are unsuccessful intensive therapy over at least 6 months (including psycho- and physiotherapy) as well as the lack of significant psychological stress (“yellow flags”); (recommendations are potentially DMP relevant).

4.5.9 Patient training

A total of 3 guidelines provide recommendations on the training of patients with chronic non-specific LBP.

Several guidelines recommend the following content/messages for patient training/counselling (recommendations are potentially DMP relevant):

(i) support of the confidence in the anatomic/structural strength of one’s own spine

(ii) if possible, no detailed and pathoanatomical explanations for LBP, as this could increase anxiety and the perceived threat

(iii) neuroscientific explanations for the perception of pain

(iv) explanation of the overall good prognosis of LBP (duration of pain usually 1 to 6 weeks) and the low probability of a dangerous cause of disease

(v) use of coping strategies to reduce anxiety and catastrophizing tendencies

(vi) reuptake of physical activity (even if pain still exists) and the meaning of increase in physical activity

(vii) information and training material that focuses on the self-responsibility of patients as well as workplace ergonomy.

According to one guideline, patients with chronic non-specific LBP who are interested in learning pain-coping strategies should be referred to structured, local self-help groups. If no local self-help groups exist, the patients should be referred to professional self-management counsellors (recommendations are potentially DMP relevant).

4.5.10 Treatment of chronic LBP with specific symptoms and findings

A total of 3 guidelines provide treatment recommendations for patients in whom structural changes were recognized as the main cause of their complaints.

4.5.10.1 Recommendations for patients with disc-related LBP, spinal canal stenosis, radiculopathy, and post-nucleotomy syndrome (failed back surgery syndrome)

A total of 3 guidelines contain recommendations on the treatment of patients with specific LBP.

Epidural (steroid) injection

According to the statements of 3 guidelines, the advantages and disadvantages of epidural steroid injection should be clearly presented by the treating medical doctor. In patients with radiculopathy, for example, triggered by a prolapsed disc, an epidural steroid injection may sometimes lead to short-term, and sometimes even long-term, alleviation of pain. The injection should be performed under fluoroscopic control (recommendations are potentially DMP relevant).

Surgical procedures

One guideline recommends counselling with regard to surgical procedures as a treatment option for patients with disc-related radiculopathy or impairing pain in the leg due to spinal canal stenosis (recommendations are potentially DMP relevant).

4.5.10.2 Patients with lumbar facet joint pain

A total of 2 guidelines contain recommendations on the treatment of patients with facet joint-related pain.

One guideline recommends that an experienced spine specialist should perform the diagnostics (recommendation is potentially DMP relevant).

According to the recommendations of 2 guidelines, in patients with complaints that are clearly caused by lumbar facet joints, the following interventions may result in an improvement or

alleviation of symptoms: (i) therapeutic facet joint blocks (ramus medialis blocks); (ii)) intra-articular facet joint injections (blocks); and (iii) radiofrequency neurotomy (neurotomy of the ramus medialis), ([i and ii: recommendation is potentially DMP relevant]; [iii: recommendation is DMP relevant]).

4.5.10.3 Patients with sacroiliac joint pain

According to one guideline, within the framework of the medical indication for invasive treatment of the sacroiliac joints, a controlled diagnostic nerve block can be applied (recommendation is potentially DMP relevant).

5 Classification of the work results

Definition of (chronic) back pain and the target groups of the guidelines

Four guidelines contain definitions of the disorder LBP or back pain. In the other guidelines, the relevance for the guideline synopsis can be inferred via the description of the target groups. Five of the 6 guidelines included address patients with LBP, that is, the complaints affect the lumbar region. One guideline (ASIPP 2009), which exclusively provides recommendations on interventional procedures, addresses patients with "chronic spinal pain", without restriction to a certain section of the spine. Furthermore, this guideline differs from the others by the fact that it considers "chronic spinal pain" separately from acute events or diseases or triggering pathological processes. The guideline explicitly delimits these symptoms from a complex "pain syndrome" with physical, psychological, emotional, and social components. Patients with precisely this complex experience of pain are the sole target group of the guidelines NVL 2013 and TOP 2011. Two further guidelines (APS 2009, APTA 2012) explicitly address patients both with identifiable somatic pathology (specific LBP) as well as those without such pathology (non-specific LBP). One guideline (AAN 2010) does not further restrict the target group. According to different target groups, recommendations on invasive treatment procedures are presented separately in the guideline synopsis for patient groups with specific or non-specific LBP.

Diagnostic clarification

The diagnostic clarification in patients with LBP follows 2 goals: in the acute phase, the exclusion of dangerous causes of back pain requiring urgent targeted treatment (fractures, other injuries, infections and inflammations, tumours, and serious nerve root compressions). If necessary, this clarification should be repeated in the subacute case if, despite guideline-conform care, symptoms have not improved. The choice of diagnostic procedure depends on the specific suspected clinical diagnosis (e.g. prolapsed disc, spinal canal stenosis). The second aim of diagnostics in patients with subacute LBP is the multidimensional (physical, psychological, social) recording of risk factors of chronification ("yellow flags") [4]. Only one guideline (NVL 2013) recommends comprehensive recording of risk factors of chronification by means of a multi-dimensional assessment. Therefore only potential DMP relevance could be determined for this healthcare aspect.

However, in the guidelines the allocation of guideline recommendations to the phases of disease mentioned was not performed stringently or imprecise terms (e.g. no further examinations "for the time being") were used. This imprecision reflects the finding that the terminology "non-specific back pain" refers to a diagnosis using simple clinical means and that this is a "diagnosis subject to recall" [4].

Evidence base on non-drug procedures and on rehabilitation

The guidelines provide recommendations on 29 non-drug treatment procedures or procedures for recurrence prophylaxis. These include 18 treatment procedures or procedures for recurrence prophylaxis for which this report determined a (potential) DMP relevance

(relevant: 5 procedures; potentially relevant: 12 procedures). The guidelines advised against the use of 12 of these 18 procedures (relevant: 3; potentially relevant: 9):

Positive recommendations on the basis of strong recommendations, that is, with the determination of (potential) relevance for a future DMP, were issued for 6 procedures (relevant: 3; potentially relevant: 3).

It is notable that for nearly all (potentially) DMP relevant positive and negative recommendations, the evidence base is not clearly comprehensible, as either the LoE is not reported (NVL 2013) or, due to the information provided by the guideline authors, the LoE could not be clearly allocated to category Ia/Ib of the Federal Joint Committee (G-BA). It thus remains open whether the evidence base for these recommendations is actually robust.

Similar aspects apply to the recommendations on rehabilitation. Here too, recommendations with a strong GoR are often not supported by robust statements on the evidence base.

As a result, in particular the recommendations on non-drug treatment procedures for recurrence prophylaxis and therapies, as well as on rehabilitation, do not correspond to the demand formulated in standards for guideline development that strong recommendations should as matter of principle also be supported by evidence [17,18].

Inconsistent recommendations

Acupuncture

Two guidelines provide inconsistent recommendations on the use of acupuncture for the treatment of chronic LBP.

With a strong GoR, guideline TOP 2011 contains a positive recommendation for acupuncture, whereby it is unclear whether the LoE corresponds to the G-BA category Ia/Ib. Two guidelines are cited as the evidence base.

With a medium GoR, guideline NVL 2013 states that acupuncture should only be applied to a very limited extent. No LoE is provided for this recommendation. Two guidelines, 2 systematic reviews, and 3 RCTs are cited for this recommendation.

Both guidelines contain explanations of a varying degree of detail for their recommendations. Whereas guideline TOP 2011 solely refers to the low rate of serious adverse events, NVL 2013 discusses the evidence base in more detail and discusses the lack of the possibility of applying acupuncture to patients in daily practice.

The different evidence base of recommendations on acupuncture in the 2 guidelines, as well as the evidently more comprehensive process of consideration in guideline NVL 2013, may represent reasons for the different statements in the guidelines.

In the year 2006 the G-BA decided that patients with chronic back pain insured by statutory health insurance can receive acupuncture therapy with needles as a standard healthcare service of their health insurance fund [19].

Drug therapy with paracetamol

Two guidelines contain inconsistent recommendations on the treatment of chronic non-specific LBP with paracetamol.

With a high GoR and without restriction, guideline TOP 2011 recommends paracetamol (acetaminophen) therapy, whereby it is unclear whether the LoE corresponds to the G-BA category Ia/Ib.

With a low GoR, guideline NVL 2013 recommends paracetamol therapy for chronic non-specific LBP only after taking a detailed drug history and only for treatment of short exacerbations. No LoE is provided for this recommendation.

Whereas no discussion of the evidence is performed in the accompanying document of guideline TOP 2011, guideline NVL 2013 discusses the effectiveness and possible side effects and risks of paracetamol therapy and includes several citations.

The different evidence base of recommendations on paracetamol therapy in the 2 guidelines, as well as the evidently more comprehensive process of consideration in NVL 2013, may represent reasons for the different statements in the guidelines.

A current systematic review also investigates the effectiveness of paracetamol compared with placebo for the treatment of LBP [20]. The systematic review included 3 RCTs on back pain, of which 2 referred to acute and one (with 40 patients) referred to chronic back pain. This shows that there is a lack of suitable evidence on paracetamol therapy in patients with chronic back pain.

Against this background it should be evaluated whether recommendations on paracetamol therapy should be supported by a supplementary systematic literature search in a potential DMP “chronic back pain”.

Drug therapy with phytotherapeutics

Guidelines TOP 2011 and NVL 2013 contain inconsistent recommendations on the use of phytotherapeutics for pain therapy.

With a high GoR, guideline TOP 2011 recommends the use of certain phytotherapeutics, for example, for acute exacerbations of chronic non-specific LBP, whereby it is unclear whether the LoE awarded corresponds to the G-BA category Ia/Ib. The literature citations are provided in the accompanying document for the guideline, but the evidence is not discussed.

With a low GoR, guideline NVL 2013 as a matter of principle advises against the use of phytotherapeutics for pain therapy. An LoE is not provided, but the guideline refers to a Cochrane review in which, according to the guideline authors, short-term effects of dry extract from the devil’s claw or willow bark are reported regarding the reduction in or elimination of pain in patients with exacerbations of chronic non-specific LBP. According to the authors of guideline NVL 2013, as the studies included in the review showed clear methodological deficits, as early as 2007 this evidence was, for example, not regarded to be proof of effectiveness in the guideline of the Drug Commission of the German Medical Association [5].

One reason for the different recommendations on phytotherapeutic therapy may therefore possibly be the different assessment of the reliability of the evidence base by the authors of the 2 guidelines. Recommendations on the use of phytotherapeutics in a potential DMP “chronic back pain” should thus, if applicable, be substantiated by a supplementary systematic literature search.

6 Conclusion

On the basis of a GoR (or alternatively an LoE) of the extracted recommendations from current evidence-based guidelines, relevant and potentially relevant recommendations on all prespecified healthcare aspects were identified for a DMP “chronic back pain”, with the exception of the healthcare aspect “treatment goals”. These commonly referred to recommendations advising against the use of a measure (negative recommendation).

The guidelines provide recommendations on diagnostics (standardized recording of symptoms, recording of psychosocial risk factors, imaging procedures, blood tests, diagnostic nerve blocks) and on recurrence prophylaxis (physical activity, shoe insoles and orthoses [negative recommendation], lumbar support belts [negative recommendation]).

For non-drug measures, recommendations were identified on massages and manual therapy, exercise and physiotherapy, as well as aqua gymnastics and yoga. Furthermore, negative recommendations were found on bed rest, behavioural therapy, TENS and PENS, device-supported traction treatment, orthoses, short-wave diathermy, therapeutic ultrasound, as well as on interference, magnetic field, and laser therapy.

The recommendations on drug therapy referred to oral analgesics such as flupirtine (negative recommendation), NSAIDs, opioid analgesics, muscle relaxants, antidepressants and other psychotropic drugs (negative recommendation), the additional administration of proton pump inhibitors, as well as intravenous or intramuscular administration of pain medication (negative recommendation). For invasive therapy, recommendations were identified on joint injections (negative recommendation), proliferation therapy (negative recommendation), and counselling about surgical treatment options.

Recommendations were also identified on the healthcare aspects of patient training, rehabilitation measures, and cooperation of healthcare sectors.

Inconsistent recommendations were identified on discography, non-drug therapy with acupuncture, as well as drug therapy with paracetamol and phytotherapeutics; these were proposed for further evaluation of their DMP relevance.

In addition, specific recommendations were identified for different patient subgroups (patients with radiculopathy and/or disc-related back pain, spinal canal stenosis, post-nucleotomy syndrome, lumbar facet joint pain, sacroiliac joint pain).

Details of the report

This section is included in the full (German) report:

https://www.iqwig.de/en/projects-results/projects/quality-of-health-care/v14-04-systematic-guideline-search-and-appraisal-as-well-as-extraction-of-relevant-recommendations-for-a-dmp-chronic-back-pain.6255.html

References for English extract

Please see full final report for full reference list.

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