CLINICAL PRACTICE GUIDELINE

Non-Specific, Functional, and Somatoform Bodily Complaints

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SUMMARY

Background: 4–10% of the general population and 20% of primary care patients have what are called “non-specific, functional, and somatoform bodily complaints.” These often take a chronic course, markedly impair the sufferers’ quality of life, and give rise to high costs. They can be made worse by inappropriate behavior on the physician’s part.

Methods: The new S3 guideline was formulated by representatives of 29 medical and psychological specialty societies and one patient representative. They analyzed more than 4000 publications retrieved by a systematic literature search and held two online Delphi rounds and three consensus conferences.

Results: Because of the breadth of the topic, the available evidence varied in quality depending on the particular subject addressed and was often only of moderate quality. A strong consensus was reached on most subjects. In the new guideline, it is recommended that physicians should establish a therapeutic alliance with the patient, adopt a symptom/coping-oriented attitude, and avoid stigmatizing comments. A biopsychosocial diagnostic evaluation, combined with sensitive discussion of signs of psychosocial stress, enables the early recognition of problems of this type, as well as of comorbid conditions, while lowering the risk of iatrogenic somatization. For mild, uncomplicated courses, the establishment of a biopsychosocial explanatory model and physical/social activation are recommended. More severe, complicated courses call for collaborative, coordinated management, including regular appointments (as opposed to ad-hoc appointments whenever the patient feels worse), graded activation, and psychotherapy; the latter may involve cognitive behavioral therapy or a psychodynamic-interpersonal or hypnotherapeutic/imaginative approach. The comprehensive treatment plan may be multimodal, potentially including body-oriented/non-verbal therapies, relaxation training, and time-limited pharmacotherapy.

Conclusion: A thorough, simultaneous biopsychosocial diagnostic assessment enables the early recognition of non-specific, functional, and somatoform bodily complaints. The appropriate treatment depends on the severity of the condition. Effective treatment requires the patient’s active cooperation and the collaboration of all treating health professionals under the overall management of the patient’s primary-care physician.


When the S2e guideline “Somatoform disorders” (1) expired, the German College of Psychosomatic Medicine (DKPM, Deutsches Kollegium für Psychosomatische Medizin) and the German Society of Psychosomatic Medicine and Medical Psychotherapy (DGPM, Deutsche Gesellschaft für Psychosomatische Medizin und Ärztliche Psychotherapie) determined to rework it comprehensively in an interdisciplinary way for the new edition. Under the coordination of these bodies, from 2008 to 2012, representatives of 28 medical and psychological specialist societies, the German Association for the Support of Self Help Groups (patient representative), and the Association of Scientific Medical Societies in Germany (AWMF, Arbeitsgemeinschaft medizinischer Fachgesellschaften) (eBox 1) developed the new S3 guideline “Management of patients with non-specific, functional, and somatoform bodily complaints” (NFS), of which the present article is the official short version (2–4).

Method

The guideline group included members from all areas of care and was balanced in terms of gender and seniority. At the inaugural meeting, key questions on all clinically relevant themes were formulated and divided up between nine working groups. Building on the 2002 S2e guideline, a seven-member steering group (eBox 1) carried out a systematic literature search of publications dating from 1 January 2000 to 1 January 2009 (for search terms see eBox 2), which was added to and brought up to date by the working groups up to May 2011 (3). After assessment of inclusion and exclusion criteria (eBox 3) and the quality and relevance of the studies (e1) (eTable 1), 761 publications were included for the guideline (Figure 1). The working groups analyzed the literature, evaluated the evidence levels (ELs) (e2) (eTable 2), and developed 148 recommendations, statements, and source texts. For the most important forms of therapy, examples of numbers needed to treat (NNTs) were calculated as a statistical measure of efficacy (Table 1). The guideline was modified in two online Delphi procedures and three consensus conferences, and finalized by consensus, in most cases strong consensus (e3) (eTable 3). The corresponding recommendation grades (RGs) were based on the evidence levels, but could be raised or lowered during the consensus procedure (e4) (eFigure). Recommendations

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regarded by the guideline group as representing a standard despite a lack of evidence were marked as “clinical consensus points” (CCPs) (e5). The guideline version passed by consensus was posted on the Internet in February 2012 for 4 weeks for public comment. It was reviewed by three external experts (eBox 1), approved by the participating medical societies and associations, and adopted by the AWMF on 15 April 2012 (register no. 051–001). It is valid for 5 years.

**Terms and objectives**

The plethora of terminology (e6) is a hindrance to care and to research (e7). With the aim of achieving an interdisciplinary perspective, the triple term “non-specific, functional, and somatoform bodily complaints” takes up the parallel classification of functional somatic syndromes (FSS) (somatic medicine) and somatoform disorders (psychosocial medicine), and complements the general medical perspective of non-specific bodily complaints (eBox 4). The guideline is concerned with what these disorders of adults have in common (5, 6, e8, e9). Its aim is to provide practical, interdisciplinary recommendations for all levels of care, to promote a biopsychosocial understanding of health and illness, to optimize early diagnosis, prevention, and treatment, to improve the quality of life and ability to function of those affected, and to reduce undertreatment and erroneous treatment.

**Characterization of the disorder**

**Clinical features**

The main symptoms of NFS are pain in various locations, impaired organ functions (gastrointestinal, cardiovascular, respiratory, urogenital), including autonomic complaints, and exhaustion/fatigue (7). If this anxiety dominates, a hypochondriac disorder is present (e10).

**Multifactorial disorder model**

Current etiopathogenetic models assume complex interactions between psychosocial factors, biological factors, iatrogenic factors or factors related to the medical system, and sociocultural factors, which can lead to neurobiological changes, and act together in disposition, triggering and maintenance of the complaints (7, 8, e11). A health system that focuses more on repair and care than on self-responsibility and prevention, and provides counterproductive financial incentives to illness-related behavior and technical measures rather than to healthy behavior, achievement through talking to the patient, and the avoidance of unnecessary treatment, has the effect of maintaining complaints (7, e11–e13). The iatrogenic chronification factors to be avoided (e14–e21) (CCP) are shown in Box 1.

**Epidemiology, co-morbidity, and health care utilization behavior**

NFS affect 4% to 10% of the population (2, 4, e22) and 20% of primary care patients (9, 10) (EL 1b), and are reported more frequently by women in all age groups (♀:♂ = 1.5–3:1) (e23, e24) (EL 2b). In specialized settings, such as specialist somatic medical outpatient
TABLE 1

<table>
<thead>
<tr>
<th>NFS</th>
<th>Therapy form</th>
<th>No. of studies/patients</th>
<th>Target variable</th>
<th>Statistical measure of effectivity: SDM, RR (95% CI)</th>
<th>NNT (95% CI)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>MUS and somatoform disorders</td>
<td>CBT</td>
<td>11/832</td>
<td>Physical symptoms</td>
<td>SDM = −0.25 (−0.38 to −0.12)</td>
<td>8 (6–17)</td>
<td>23</td>
</tr>
<tr>
<td>Fibromyalgia syndrome</td>
<td>CBT</td>
<td>12/568</td>
<td>Pain</td>
<td>SDM = −0.28 (−0.59 to 0.03)</td>
<td>7 (4–88)</td>
<td>e85</td>
</tr>
<tr>
<td></td>
<td>Hypnotherapy/guided imagery</td>
<td>5/166</td>
<td>Pain</td>
<td>SDM = −1.40 (−2.59 to −0.21)</td>
<td>2 (1–9)</td>
<td>e85</td>
</tr>
<tr>
<td></td>
<td>Aerobic exercise</td>
<td>32/1341</td>
<td>Pain</td>
<td>SDM = −0.40 (−0.55 to −0.26)</td>
<td>5 (4–8)</td>
<td>e76</td>
</tr>
<tr>
<td></td>
<td>Tricyclic antidepressants</td>
<td>10/520</td>
<td>Pain</td>
<td>SDM = −0.53 (−0.78 to −0.29)</td>
<td>4 (3–7)</td>
<td>e82</td>
</tr>
<tr>
<td></td>
<td>SNRI ( duloxetine, milnacipran)</td>
<td>10/6012</td>
<td>Pain</td>
<td>SDM = −0.23 (−0.29 to −0.18)</td>
<td>9 (7–11)</td>
<td>e82</td>
</tr>
<tr>
<td></td>
<td>Pregabalin</td>
<td>5/4121</td>
<td>Pain</td>
<td>SDM = −0.27 (−0.35 to −0.19)</td>
<td>8 (6–11)</td>
<td>e82</td>
</tr>
<tr>
<td>Irritable bowel syndrome</td>
<td>CBT</td>
<td>7/491</td>
<td>Persistent bowel-related symptoms</td>
<td>RR 0.59 (0.42 to 0.87)</td>
<td>3 (2–7)</td>
<td>e81</td>
</tr>
<tr>
<td></td>
<td>Gut-directed hypnotherapy</td>
<td>2/40</td>
<td>Persistent bowel-related symptoms</td>
<td>RR 0.48 (0.26 to 0.87)</td>
<td>2 (1.5–7)</td>
<td>e81</td>
</tr>
<tr>
<td></td>
<td>Psychodynamic therapy</td>
<td>3/211</td>
<td>Persistent bowel-related symptoms</td>
<td>RR 0.60 (0.39 to 0.93)</td>
<td>4 (2–25)</td>
<td>e81</td>
</tr>
<tr>
<td></td>
<td>Aerobic exercise</td>
<td>2/134</td>
<td>Persistent bowel-related symptoms</td>
<td>SDM = −0.49 (−0.84 to −0.15)</td>
<td>4 (3–14)</td>
<td>e74, e75</td>
</tr>
<tr>
<td></td>
<td>Tricyclic antidepressants</td>
<td>9/575</td>
<td>Persistent bowel-related symptoms</td>
<td>RR 0.68 (0.56 to 0.83)</td>
<td>4 (3–8)</td>
<td>e81</td>
</tr>
<tr>
<td></td>
<td>SSRIs</td>
<td>5/230</td>
<td>Persistent bowel-related symptoms</td>
<td>RR 0.62 (0.45 to 0.87)</td>
<td>4 (2–14)</td>
<td>e81</td>
</tr>
<tr>
<td>Chronic fatigue syndrome</td>
<td>CBT</td>
<td>6/373</td>
<td>Fatigue</td>
<td>SDM = −0.39 (−0.60 to −0.19)</td>
<td>5 (4–11)</td>
<td>e84</td>
</tr>
<tr>
<td></td>
<td>Aerobic training</td>
<td>5/286</td>
<td>Fatigue</td>
<td>SDM = −0.77 (−1.26 to −0.28)</td>
<td>3 (2–7)</td>
<td>e73</td>
</tr>
</tbody>
</table>

NFS, non-specific, functional, and somatoform bodily complaints; SDM, standard deviation of the mean (therapy group versus control group at the end of therapy); RR, relative risk (therapy group versus control group at the end of therapy); NNT, number needed to treat; 95% CI, 95% confidence interval; MUS, medically unexplained symptoms; CBT, cognitive behavioral therapy; SNRI, selective serotonin and norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor

*1 NNTs were calculated using the Wells Calculator Software of the Cochrane Musculoskeletal Group Editorial Office. A half standard deviation was chosen as the minimally important difference (MID) (e101).

units or practices, a percentage up to 50% may be assumed (2, 4, e25). In the general population, 10% of those affected with an FSS also fulfill the criteria of one or more other FSSs; in clinical populations this overlap may be as much as 50% (e8, e9, e26) (EL 2a). In both clinical and population-based samples, NFS show a comorbidity that increases with the severity of the NFS, including depressive, anxiety (11, e27, e28), and post-traumatic stress disorders (e29) as well as addiction disorders (medications, alcohol) (e30, e31). In severe cases (full-blown somatization disorder F45.0) there are often co-morbid personality disorders (e32, e33) (EL 2a). A majority show high, dysfunctional use of the health care system, especially in cases of psychological co-morbidity (9, e34) (EL 2b). The result is high direct (multiple diagnoses, overdiagnosis, inappropriate treatment) and indirect health costs (loss of productivity, long-term inability to work, early retirement) (13, e35). Also in older patients, NFS parts of the complaints should be considered, even if the differential diagnosis is more complex and uncertain because of multimorbidity and multimedication. (14, e36) (EL 2a, RG B).

Course and prognosis

Life expectancy for patients with NFS is presumably normal (e37, e38), but quality of life is more impaired than with somatic diseases (e39) (EL 2b). Suicide risk, especially among those in chronic pain, is greater than in the general population (e40, e41). In patients with fibromyalgia, the standardized mortality ratio for suicide was between 3.3 (95% confidence interval [95% CI] 2.2–5.1) (Danish retrospective cohort
A less severe course with improvement of functioning and quality of life is seen in 50% to 75% of those affected, and a more severe course (usually marked functional/somatoform disorders, with deterioration of functioning and quality of life) is seen in 10% to 30% (15) (EL 1b).

**Principles and preconditions of diagnosis and treatment**

**Attitude and physician–patient relationship**

Since the physician–patient relationship is often felt to be difficult on both sides (e42–e45), building up a sound working alliance on a partnership basis is of central importance (7, e46–e48). An active, supportive and biopsychosocial attitude (“as well/as attitude”) is recommended, focusing on symptoms and on coping with them. It is characterized by situational consistency; that is the right balance between reticence and authenticity (“I’m not going to say everything that would be authentic, but what I do say should be authentic”) (e52) (RB B).

**Communication skills**

First, the physician should allow the patient to describe the complaints spontaneously and explicitly (“accepting the complaint”) (e53) (EL 4, EG B), signaling attention, interest, and acceptance in both verbal and nonverbal ways (“active listening”) (EL 4, EG B). Psychosocial themes should be handled casually and indirectly rather than by confronting them, e.g., by accompanying the patient’s report switching to and fro between hinting at psychosocial stressors and returning to the complaints description (“tangential conversation”) (e51). Clues to psychosocial problems and factors (e14–e21) (CCP).

**Diagnostic investigations**

- Overdiagnosis and multiple organic diagnostic investigations as pure exclusion diagnostics
- Overestimation of non-specific somatic findings
- Insufficient consideration of psychosocial factors and mental co-morbidity
- Failure to take (adequately) into account social medical aspects (invalidity benefit, desire for pension) and other relieving aspects of the “sick role” (secondary gain from being ill)

**Communication skills**

- Presenting findings in a way that causes anxiety; giving “catastrophizing” medical advice
- Failure to give any diagnosis (“there’s nothing wrong with you”) or giving a stigmatizing diagnosis (“it’s all in the mind”)
- Giving poor information about the clinical picture without adequately explaining the patient’s complaints
- Not involving the patient sufficiently (his or her ideas about causes and goals)

**Treatment planning**

- Unstructured proceeding with complaint-led or even emergency appointments
- Insufficient treatment planning without setting therapy goals together with the patient

**Treatment**

- Promoting passive therapeutic approaches (e.g., passive physical procedures, injections, operations)
- Preferring and inappropriately prescribing invasive or addiction-promoting therapies
- Writing patients off sick for long periods without careful consideration
- Not referring patients to psychosocial care, or referring them late, or with inadequate preparation and/or follow-up of the referral
- Failing to initiate multimodal therapy that may be indicated

**Medication**

- Prescribing drugs without taking stock of whatever medications the patient may already be taking
- Insufficient analgesic treatment for acute pain
- Pain-contingent use of drugs “as needed” (especially analgesics)
- Unreflecting prescription of addictive drugs, especially opioids and benzodiazepines
- Non-indicated prescription of neuroleptics, e.g., “as a weekly/restaurative injection”
- Prescribing long-term psychopharmacotherapy as a monotherapy without appropriate psychotherapy
Starting point: unspecific bodily complaints

Principles and preconditions of diagnosis and therapy (attitude, physician–patient relationship, communication skills)

<table>
<thead>
<tr>
<th>Simultaneous somatic and psychosocial diagnostic process</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Basic history:</strong></td>
</tr>
<tr>
<td>Ask open questions, nature, location, number, duration, and intensity of complaints; pattern over time, triggers, coping strategies, whether can be influenced subjectively; complaints other than the main symptom; (casual) clues of psychosocial stressors; present ability to function in everyday life; psychological state; subjective beliefs about causes; dysfunctional assumptions and behaviors</td>
</tr>
<tr>
<td><strong>Somatic diagnostic investigations:</strong></td>
</tr>
<tr>
<td>Regular physical examination; systematic stepped diagnostic assessment: planned, not redundant, close together in time; limit in a responsible way and define an endpoint; prepare in a de-catastrophizing way (normal results expected); discuss results; additional diagnostic investigations only after careful consideration, if new symptoms or warning signs (red flags) occurred; protect patient from unnecessary or even damaging diagnostic investigations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is there any clearly defined physical disease?</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there any (other) psychological illness (depression, anxiety, addiction, PTSD)?</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td>(Primary/comorbid) non-specific, functional, or somatoform bodily complaints</td>
<td>Yes</td>
</tr>
<tr>
<td>If a defined functional/somatoform disorder (ICD-10) is diagnosed</td>
<td>No</td>
</tr>
<tr>
<td>Are there characteristics of a more severe course (yellow flags, see Table 2)?</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Basic treatment/psychosomatic care at the primary or specialist somatic medical care level</td>
<td>Yes</td>
</tr>
<tr>
<td>(see treatment algorithm, Figure 3)</td>
<td>No</td>
</tr>
<tr>
<td>Primary or specialist somatic medical care within a framework of regular appointments, time-limited and not complaint-led, and clear agreements with the patient + disorder-oriented specialist psychotherapy or speciality linked psychotherapy (see treatment algorithm, Figure 3)</td>
<td>No</td>
</tr>
<tr>
<td>Are there warning signs of preventable dangerous courses (red flags, see Table 2)?</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Diagnostic reassessment of severity after no more than 3 months adjustment/extension of somatic and psychosocial diagnostic investigations if appropriate</td>
<td>Yes</td>
</tr>
<tr>
<td>Refer immediately for appropriate interventions (see treatment algorithm, Figure 3)</td>
<td>No</td>
</tr>
<tr>
<td>When the risk has been averted</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**FIGURE 2**

Diagnostic algorithm: Stepped simultaneous diagnostic assessment depending on symptom severity (modified from 2, 4); PTSD, post-traumatic stress disorder
needs shall be picked up empathetically and spoken of as meaningful (e54) (EL 1b, RG A). In constructing the contextual interdependencies, phrases from the vernacular can help (“Is something making you heavy hearted?”) (EL 5, RG 0). The patient should be offered to make a joint decision together with the physician once enough information has been given (“shared decision making”) (e55) (EL 2b, RG A).

**Simultaneous biopsychosocial diagnostic assessment**

For early diagnosis of NFS, stepped simultaneous diagnostic assessment of both somatic and psychosocial conditioning factors should be carried out. If necessary further medical and/or psychotherapeutic specialists should be consulted (e56–e58) (EL 1b, RG A) (Figure 2). For patients with a chronic course, the first thing is to take stock of the results of previous diagnostic and therapeutic procedures (EL 5, RG 0). Waiting for the exclusion of somatic disease despite the presence of psychosocial stressors is contraindicated.

**Biopsychosocial history taking**

First, the bodily complaints should be recorded precisely (nature, location, number, frequency, duration, intensity) (e53) (EL 3b, RG B). Because accompanying complaints are often not reported spontaneously, history taking should be extended beyond the main symptoms, e.g., by systematic questioning about the different organ systems (2, 4) (EL 2b, RG A). The number of symptoms is an important predictor of the presence of NFS and of an unfavorable course (15) (EL 1b). For all bodily complaints, everyday functioning and psychological state should be assessed even at the first consultation (e59) (EL 2b, RG B). The patient’s subjective theory of the illness and illness/health behavior should be explored, including, if there are cues about psychosocial stressors or functional impairment, the context of the complaints (family, social network, work, biographical stressors, and resources) (CCP).

**Somatic diagnostic investigations**

Basic organic diagnostic investigation including physical examination is always necessary. Depending on the pattern of symptoms, specialist diagnostic procedures may also be required (e58) (EL 5, RG B). In the absence of “red flags” and so long as any dangerous illness appears unlikely, a “watchful waiting” approach is recommended, which will not increase the patient’s anxiety (e60) (EL 1b, RG B). Any tests should be discussed with the patient before and after they are carried out in a “de-catastrophizing” way (“normal results

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### TABLE 2

<table>
<thead>
<tr>
<th>Possible protective/prognostically favorable factors (green flags)</th>
<th>Clinical characteristics of more severe courses (yellow flags)</th>
<th>Warning signs of preventable severe courses (red flags)</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Active coping strategies (e.g., physical exercise, positive attitude, motivation for psychotherapy)</td>
<td>● Several complaints (polysymptomatic course)</td>
<td>● Very severe complaints</td>
</tr>
<tr>
<td>● Healthy life style (enough sleep, balanced diet, exercise and relaxation)</td>
<td>● Frequent or persistent complaints (complaint-free intervals non-existent or rare or brief)</td>
<td>● Occurrence of known warning signs of a somatically defined disease</td>
</tr>
<tr>
<td>● Secure relationships, social support</td>
<td>● Dysfunctional perception of health/illness (e.g., catastrophizing thoughts, substantial health-related anxiety)</td>
<td>● Indications of serious self-harming behavior</td>
</tr>
<tr>
<td>● Good work conditions</td>
<td>● Dysfunctional health/illness behavior (high use of health services, resting and avoidance behavior)</td>
<td>● Suicidality</td>
</tr>
<tr>
<td>● Sustainable physician-patient relationship</td>
<td>● Markedly reduced ability to function; inability to work &gt; 4 weeks, social withdrawal, physical deconditioning, possibly with physical sequelae</td>
<td>● Physical sequelae (e.g., faulty posture becomes fixed, limitation of movement up to severe restricted mobility of spared joints, contractures, serious weight gain, patient stays in bed)</td>
</tr>
<tr>
<td>● Biopsychosocial, decatastrophizing approach, avoiding unnecessary investigations and treatments</td>
<td>● Moderate to severe psychosocial stress (possibly biographical stressors) (e.g., low spirits, anxiety about the future, few social contacts)</td>
<td>● Particularly severe psychological co-morbidity (e.g., development of severe depression; anxiety that keeps the patient confined in the home)</td>
</tr>
<tr>
<td>● Health care system that is freely accessible but emphasizes self-responsibility and prevention</td>
<td>● Psychological co-morbidity (especially depression, anxiety, post-traumatic stress disorder, substance dependence disorders, personality disorders)</td>
<td>● Frequent change of treating physicians and therapists and frequent discontinuation of therapy</td>
</tr>
<tr>
<td></td>
<td>● Physician-patient relationship experienced (by both) as “difficult”</td>
<td>● Indications of severe iatrogenic damaging behavior</td>
</tr>
<tr>
<td></td>
<td>● Iatrogenic “somatizing” factors (Box 1)</td>
<td></td>
</tr>
</tbody>
</table>
expected”) and the reasons for doing them clearly explained (transparency) (e61). A reasonable endpoint for the somatic diagnostic pathway should be agreed and adhered to (EL 1b, RG A).

Severity assessment
Characteristics of more severe cases (“yellow flags”) and red flags for more severe, complicated courses including suicidality should be repeatedly evaluated (7, e62, e63) (EL 2b, RG B). Some protective factors (“green flags”) presumably have a favorable effect on the prognosis (e64) (EL 4) and should be recorded and supported (RG B) (Table 2).

Treatment
Treatment should adhere to a severity-staged, collaborative and coordinated model of care (7, 16, 17, e65) (RG A) (Box 2, Figure 3).

Basic treatment in primary care and specialist somatic medicine
The basis of treatment should be “Basic Psychosomatic Care” (CCP). Both complaints and findings should be explained clearly and reassuringly, and psychophysiological relationships should be explained (psychoeducation: e.g., vicious circles of resting, somatosensory amplification etc.) (17, e66) (EL 2a). This should connect with the patient’s subjective theory of the illness, so that a biospychosocial explanatory model can be built up (RG B). The physician should offer a positive description of the complaints (e.g., “non-specific,” “functional,” “bodily distress,” with a corresponding diagnosis if appropriate), but should not belittle (“There’s nothing wrong with you,”) or use stigmatizing terms (“hysteria”) (e66, e67) (EL 2b, RG B). Important elements are reassuring the patient that dangerous disease is unlikely (17, e56, e60) (EL 2b, RGA) and no unnecessary steps should be taken (“first, do no harm”, “quaternary prevention”) (e68) (EL 5, RG B), and furthermore long-term support with physical and social activation (7, e69, e70) (EL 2b). Medication (e.g., symptomatic medication for patients with irritable bowel syndrome, pain alleviation, treatment of psychological co-morbidity) should be discussed with the aim of alleviating symptoms within the framework of an overall treatment plan, carefully weighing the risks and benefits, and for a limited period (4) (CCP). Physicians should not be too quick to certify patients as unable to work, and should weigh the advantages (rest, relief from stress) against the disadvantages (avoidance, increased weakness due to rest, loss of participatory activity) early on (e83) (EL 4–5). Short-term sick notes (7 days, patient to attend again, another 7 days if appropriate) may be considered, in order to support spontaneous improvement of symptoms and promote the therapeutic relationship and/or adherence to treatment (RG B). Psychotherapy may be considered, e.g., if the patient wants to discuss psychosocial stressors or when the bodily complaints are incidental findings in, for example, a patient with depression (CCP).

Additional steps in severe courses
Even in severe courses, care at the primary level and specialist somatic medical level is at the center of management. Within the framework of a clear treatment plan, there should be a stronger structuring of the framework and content of treatment (e71) (EL 2a, RG B). Essential elements are regular appointments that are time-limited and are not complaint-led (e48, e71) (EL 2b) along with treatment of comorbid disorders in accordance with guidelines (RG B). Specific, realistic therapy goals should be developed with the patient (18, e72) (EL 2b, RG A), in the process of which the importance of self-responsibility and collaboration should be conveyed (EL 4). Physical activation (especially

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**BOX 2**

**Stepped, collaborative, and coordinated care model**

- **Stepped:**
  - Patients with less severe courses should if possible be cared for by their primary care physician (21, e96) (EL 2b, RG B).
  - Patients with more severe courses should be referred for early psychotherapeutic assessment and, if appropriate, concurrent psychotherapy (7, 22–24, e80) (EL 1a, RG A).
  - Patients with particularly severe courses require a multimodal therapeutic approach, i.e., interdisciplinary treatment including at least two specialties, one of them psychosomatic, psychological, or psychiatric, following a fixed treatment plan led by a qualified physician; because of lack of outpatient facilities, this often requires treatment to be on an inpatient or day clinic basis (for indications see Box 3) (CCP).

- **Collaborative:** Close collaboration between all contributing physicians and therapists is important, ideally within the framework of a mutually agreed treatment approach, which may be multimodal (e97) (EL 1b).

- **Coordinated:** The collaborative care should be coordinated by the primary care physician following a structured overall care plan (e71) (EL 1b, RG B).
Non-specific, functional, and somatoform bodily complaints

### Principles and preconditions of diagnosis and treatment (attitude, physician–patient relationship, communication skills)

- **Basic psychosomatic care/basic primary or specialist somatic medical level care:**
  - Reassurance, psychoeducation, counseling; building up a therapeutic relationship;
  - encourage collaboration by the patient; develop a biopsychosocial explanatory model that connects with the patient’s subjective theory of the illness; positive description of complaints;
  - physical/social activation; symptom alleviation with careful use of medication; psychosocial consultation

### Basic psychosomatic care/basic primary or specialist somatic medical level care:

Assess the success or failure of treatment together with the patient after 3 months at the latest

- Are there characteristics of a more severe course? (yellow flags, see Table 2)?
  - Yes
  - No

- Structure treatment: regular, time-limited appointments that are not complaint-led, clear agreements
  - Treatment of any accompanying disease according to appropriate guidelines

- Are there warning signs of preventable dangerous courses (red flags, see Table 2)?
  - Yes
  - No

### Primary or specialist somatic medical level:

- Basic psychosomatic treatment (see above)
- Structure setting/contents more firmly; stepped physical activation; involve further physicians and therapists as appropriate; develop realistic therapy goals; decide therapies together; talk about self-help strategies, illness anxieties, and resting or avoidance behaviors stemming from the search for security; gently prepare the way for psychotherapy; protect the patient from harm from non-indicated treatments

### Disorder- and resource-oriented psychotherapy:

- Basic psychosomatic treatment (see above)
- Further measures related to context (co-morbidity, social situation, ability to work); psychotherapy accompanying stepped physical activation; focus initially on symptoms and coping strategies, subjective explanatory model, and the patient’s own resources; later, as appropriate, focus on patient’s individual vulnerability factors, including those of life history and personality

### Possible additional general measures

- E.g., medication to alleviate symptoms (weigh risk–benefit ratio; be cautious with opioids, neuroleptics, anxiolytics, hypnotics/tranquilizers); alternately activating and relaxing exercises/physical measures that can later be carried out by the patient alone.

### Possible additional (body-centered) psychotherapeutic measures

- E.g., psychoeducation, nonverbal and relaxation techniques

### Inpatient or day clinic therapy indicated (see Box 3)?

- Yes
- No

### Inpatient or day clinic multimodal therapy

- After approx. 3 months, joint assessment of success of treatment, adapting the treatment plan if appropriate:
  - Adjust therapeutic goals, setting, and interventions in terms of additional therapeutic measures, dropping certain interventions, implementing a multimodal approach, more diagnostic review if appropriate (see diagnostic algorithm, Figure 2)
aerobic exercise [endurance training] and strength training of low to moderate intensity) should be carried out in stages, with slowly increasing work alternating with rest (7, e73–e76) (EL 2b, RG A) (Table 2) and should be accompanied by sustained encouragement. Similarly, the patient should be encouraged towards social activation (7, e69, e70). Some body-centered or nonverbal therapy elements and relaxation techniques (e.g., biofeedback, progressive muscle relaxation, autogenic training, tai chi, qi-gong, yoga, Feldenkrais, mindfulness training, meditation, writing as therapy, music therapy) may be recommended as additional elements within an overall treatment plan, but not as monotherapies (e77–e79) (EL 2a). In severe cases where pain predominates, low-dose, short-term antidepressant treatment should be given (7, 19, e80–e82) (EL 1a, RG A) (Table 1). In severe courses where pain does not dominate, treatment with antidepressants according to guidelines should be given only where there is relevant psychological co-morbidity (e5) (EL 2a, RG B). Referrals, especially psychosocial referrals, should be well organized and carefully discussed both before and after they take place (CCP).

### Psychosocial co-assessment

Requesting a specialist psychosocial assessment will reduce health service utilization (20) (EL 1a, RG A). A consultation/care recommendation letter provided to the primary care physician (information about the patient’s illness and specific recommendations for treatment including assessment whether inpatient or day clinic treatment is indicated [Box 3]), which may if necessary be repeated, leads to improvement in the level of functioning and saves costs when used as an additional measure, but not on its own (21, 22) (EL 1a, RG A).

### Disorder-oriented psychotherapy

In severe courses, psychotherapeutic interventions should be disorder- or symptom-oriented-focused, context-related (co-morbidity, social situation, ability to work), and resource-oriented (CCP). Wider evidence is available for various NFS – with low to moderate effect sizes – especially for cognitive behavioral therapy (22–24, e80, e81, e84, e85) (EL 1a), and also for psychodynamic (interpersonal) (7, 25, e81, e86) (EL 1b) and hypno/therapeutic/imaginative approaches (e81, e85, e87, e88) (EL 1a, RG A) (Table 1). Follow-up studies showing positive effects are available for psychotherapy and physical activation, but not for medications (e74, e75, e81, e89).

### Particularly severe courses: multimodal treatment, if necessary on an inpatient/day clinic basis

In particularly severe and chronic cases, multimodal treatment should already be initiated at the primary care and specialist somatic medical level (Box 2). Multimodal treatment has been shown to be effective especially for chronic pain syndrome (e90) (EL 1b, CCP). It should be assessed whether inpatient/day clinic treatment at a facility offering multimodal therapy at a clinic offering multimodal therapy is indicated, including when there are few or no options for treatment on an outpatient basis (Box 3) (e91, e92) (CCP).

### Rehabilitation

Rehabilitation should also follow a multimodal approach (e93). The main goals are improvement in ability to function and to work, and to prevent (further) chronification. The sociomedical baseline situation (e.g., duration of inability to work) appears essential for success (e94) (CCP). In suitable facilities (e.g., day clinics with the appropriate range of indications/treatments), rehabilitation measures should be done at first on an outpatient basis, in close collaboration between primary care physician/somatic medical specialist and psychotherapist, and only after that on an inpatient or partly inpatient basis.

### Reassessment after 3 months at the latest

To prevent cases become dangerous or chronic when this could have been prevented, complaints, diagnostic
categorization, and the severity of illness and the outcome of treatment should be reassessed after 3 months at the latest (e56, e95) (EL 2b, RG B). If appropriate, and in agreement with the patient and collaborating physicians and therapists, both somatic and psychosocial diagnostic investigations and treatment should be adjusted. Basic medical diagnostic investigations including physical examination should be regularly repeated, especially where complaints persist. In this way, changes in symptoms will be recognized, organic disease will be identified, the patient will be given a feeling of being looked after and taken seriously, and unnecessary tests will be avoided (EL 5, RG B). After 6 months, if treatment on an outpatient basis fails, treatment on an inpatient or day clinic basis should be considered (Box 3).

Discussion
In the S3 guideline “Management of patients with non-specific, functional, and somatoform bodily complaints,” a broad group of medical and psychological societies together with a patient representative have for the first time achieved an evidence-based consensus on terminology and care of these patients that is interdisciplinary and bridges the borders of health care sectors as well as psychosocial and somatic disciplines. The innovations are summarized in Box 4. To date, randomized controlled studies, reviews, and meta-analyses are available on only a few aspects (Figure 1), so that in places the present guideline has to rely on weaker evidence or clinical consensus. Overall, a very strong need is evident for fundamental research as well as research in treatment and health services. Guideline texts and practice materials may be downloaded from the AWMF website (www.awmf.org/leitlinien/detail/ll/051–001.html) and from the project website (www.funktionell.net). An important complement to this guideline is the Evidence-Based Guideline on Psychotherapy of Somatoform Disorders and Associated Syndromes by the Group for Clinical Psychology and Psychotherapy of the German Society of Psychology (24). This is primarily aimed at psychotherapists as an aid to choosing effective psychotherapeutic interventions.
Acknowledgments
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P. Henningsen has received lecture fees from Lilly.
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R. Schaefert, C. Hausteiner-Wiehle, M. Herrmann and J. Ronel declare that no conflict of interest exists according to the guidelines of the International Committee of Medical Journal Editors.

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Clinical Practice Guideline

Non-Specific, Functional, and Somatoform Bodily Complaints

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(*) The DGSS was involved in the development of the guideline in the persons of several DGSS members and pain experts representing other professional societies, but did not have its own representative. After the guideline had been finished, it was explicitly approved by the governing board of the DGSS.
eBOX 2

Search term list*1 (3)

Level 1: Clinical symptoms
a) Non-specific, functional, and somatoform bodily complaints:
   (somatoform disorder OR somat* OR somatic* OR conversion disorder* OR multisomatoform OR medically unexplained* OR organically unexplained* OR psychogenic OR nonorganic OR psychosomatic syndrome* OR functional somatic syndrome* OR functional disorder* OR functional illness* OR functional symptom* OR irritable bowel* OR functional bowel* OR functional gastrointestinal* OR functional dyspepsia* OR nonocular dyspepsia* OR food intolerance* OR irritablebowel* OR chronic widespread pain* OR widespread musculoskeletal pain* OR myofascial pain syndrome* OR tension-type headache* OR chronic pain* OR atypical chest pain* OR nonspecific chest pain* OR non-specific chest pain* OR atypical face pain* OR facial pain* OR chronic low back pain* OR back pain* OR panalgesia* OR (psychogen* AND pain) OR idiopathic pain* OR idiopathic pain disorder* OR fatigue* OR psychogenic OR fatigue syndrome* OR Fatigue Syndrome, Chronic* OR myalgic encephalomyelitis* OR myalgic encephalopathy* OR chronic Epstein Barr virus* OR chronic mononucleosis* OR chronic infectious mononucleosis like syndrome* OR chronic fatigue and immune dysfunction syndrome* OR effort syndrome* OR low natural killer cell syndrome* OR neuromyasthenia OR post viral fatigue syndrome* OR postviral fatigue syndrome* OR post viral syndrome* OR postviral syndrome* OR post infectious fatigue* OR postinfectious fatigue* OR royal free disease* OR royal free epidemic* OR (mitral valve prolapse* AND psychology) OR hypoglycaemia* OR sleep disorder* OR psychology OR nonorganic Insomnia* OR Multiple chemical sensitivit* OR idopathic environmental intolerance* OR electromagnetic hypersensitivity OR electrohypersensitivity OR electromagnetic OR IEI-EMF OR environmental illness* OR Sick Building Syndrome* OR Persian gulf syndrome OR Amalgam hypersensitivity* OR Dental Amalgam* OR toxicity OR dental amalgam* OR adverse effects OR silicone breast implant* OR implant intolerance* OR burning mouth* OR glossalgia* OR glossodynia* OR glossopyrosis OR bruxism OR temporomandibular joint disorder* OR temporomandibular disorder* OR temporomandibular joint dysfunction* OR temporomandibular joint dysfunction* OR craniofacial disorder* OR atypical odontalgia* OR prosthesis intolerance* OR (psychogen* AND gagging) OR chronic rhinopharyngitis* OR globus syndrome* OR globus hystericus* OR hyperventilation syndrome* OR dysphonia OR aphonyia OR nipitus OR Vertigo OR Dizziness OR repetitive strain injury* OR chronic whiplash syndrome* OR tension headache OR pseudoseizures OR hysterical seizures* OR (psychogen* AND dystonia) OR (psychogen* AND dystonia) OR (psychogen* AND dystonia) OR (psychogen* AND dysphagia) OR functional micturition disorder* OR functional urinary disorder* OR urethral syndrome* OR micturition dysfunction* OR (urinary retention* AND (psychogen* OR psychology)) OR irritable bladder* OR painful bladder syndrome* OR interstitial cystitis* OR enuresis diurnal et nocturnal* OR anogenital syndrome* OR sexual dysfunction* OR chronic pelvic pain* OR (skin disease* AND (psychology OR psychogen*)) OR (pruritus AND (psychology OR psychogen*)) OR ((reduced OR impaired) AND well-being*)

b) Health anxiety: A term for health anxiety was added to the bodily complaints, since this feature is frequent and characteristic in non-specific, functional, and somatoform physical complaints, and is important for their differential diagnosis:
   (OR hypochondria* OR illness phobia* OR health anxiety*)

Level 2: Level of medical care/setting and perspectives
a) Primary and secondary level medical care:
   (ambulatory care* OR primary health care* OR physicians, family* OR (specialties, medical* NOT psychiatry*) OR general pract* OR family pract* OR family doctor* OR family physician* OR family medicine* OR primary care*)

b) Psychosomatic medicine, psychiatry, psychology:
   (mental health services* OR Psychosomatic Medicine OR Psychiatry OR Psychology)

c) Workplace:
   (workplace OR occupational health* OR occupational health physicians* OR occupation*)

d) Physician perspective:
   (physician OR doctor* OR clinician* OR general pract* OR family pract*)

e) Patient perspective:
   (patient OR self-report* OR subjective*)

Level 3: Contents and themes
a) Relationship/own attitude:
   (attitude of health personnel* OR communication OR empathy OR professional-patient relations* OR physician’s practice patterns* OR role OR medical history taking* OR decision making* OR countertransference OR disease attributes* OR emotions OR interact* OR encounter* OR disposition* OR setting* OR approach* OR engag* OR deal* OR exposure* OR experience* OR hand* OR function* OR attitude* OR decline* OR prejud* OR reject* OR rigid* OR belief* OR concept* OR critical* OR legitim* OR motivat* OR stigma*)

b) Communication skills:
   (communicat* OR counsel* OR talk*)

c) Relationship/patient’s attitude:
   (attitude to health* OR physician-patient relations* OR role OR self-disclosure* OR disease attributes* OR transference OR personality OR social behavior* OR interpersonal relations* OR communication OR utilization OR relation* OR resistance* OR balint OR enactment OR psychodynamic* OR mirror* OR interact* OR attitude* OR belief* OR concept* OR criticism OR legitim* OR motivat* OR percept* OR prospect* OR stigma* OR reporting OR encounter*)

d) Positive criteria, characteristics of non-specific, functional, and somatoform bodily complaints:
eBOX 2 – CONTINUED

(disease attributes* OR attitude to health* OR physician-patient relations* OR behavior OR attitude OR health behavior* OR sick role* OR cognition OR emotions OR body image* OR personality OR motivation OR defense mechanisms* OR attention OR perception OR memory OR health services misuse* OR utilization* OR utility* OR abnormal illness behavior* OR illness percept* OR health anxiety* OR illness phobia* OR health related concern* OR fear of disease* OR attribut* OR explanat* OR attachment OR alexithym* OR reporting OR reassur*)
e) History/diagnosis/differential diagnosis/co-morbidity/somatic diagnostic investigations:
(psychological tests* OR questionnaires OR personality assessment* OR psychometrics OR interview, psychological* OR diagnosis OR diagnosis, differential OR differential diagnosis* OR diagnostic techniques and procedures* OR medical history taking* OR unnecessary procedures* OR workup* OR diagnosis OR differential OR diagnostic OR comorbidity OR overlap OR association OR associated OR Diagnostic and Statistical Manual of Mental Disorders* OR depression OR anxiety OR eating disorder* OR personality disorder*)
f) Referral:
(referral and consultation* OR hospitalization OR disease management *OR patient care OR referral OR consult*)
g) Practice organization and collaboration with other health professionals:
(organization and administration* OR practice management, medical* OR practice OR triage OR schedule* OR appointment* OR practice nurse* OR team approach* OR team conferenc* OR cooperat* OR network OR medical billing system*)
h) General therapy (including pharmacotherapy):
(therapy OR therapeutic* OR complementary therapies* OR treatment outcome* OR counseling OR education OR long term care)
i) Specialist psychotherapy:
(psychotherapy OR psychopharmacology OR psychotherap* OR drug therapy*)
j) Epidemiology:
(epidemiology OR public health* OR demography OR socioeconomic OR population OR gender* OR cultur*)
k) Prevention, rehabilitation, prognosis:
(risk assessment* OR risk factors* OR disease susceptibility* OR health promotion* OR prevention and control* OR disease progression* OR chronic disease* OR rehabilitation OR predict* OR iatrogen* OR somatic fixation* OR maintaining factor* OR exacerbating factor* OR prevent* OR prophyla* OR susceptibility)
l) Delivery of health care/economics:
(delivery of health care* OR health services* OR economics OR utilization OR medical billing system* OR pharmacoeconom* OR cost-benefit analysis* OR cost control* OR cost of illness*)
m) Medicolegal aspects:
(legislation and jurisprudence* OR insurance benefits* OR workers compensation* OR Jurisprud* OR disability evaluation* OR malpract* OR medical errors* OR litig* OR compensat* OR disabilit*)

*1 Results were filtered using the following conditions: Humans, English, German, alt; adult: 19+ years, adolescent: 13–18 years; publication date from 2000/01/01 to 2009/01/01.

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**eBOX 3**

**Inclusion and exclusion criteria for selection of evidence (3)**

**Inclusion criteria:**
- Study of a non-specific, functional, or somatoform bodily complaint including a defined diagnostic description
- Studies of treatment procedures: randomized studies with a control group, controlled studies without randomization, or case–control studies
- Etiological and pathophysiological studies: prospective cohort studies or systematic reviews of cross-sectional studies (level 3 case–control studies, ecological studies, case series)
- Study reports in English or German

**Exclusion criteria:**
- Study of a non-specific, functional, or somatoform bodily complaint without a defined diagnostic description or with a diagnosis described as a sequela of a defined organ pathology
- Experimental studies (duration < 1 week and/or use of a procedure once or twice, e.g., experimental studies of medication or hypnotherapy)
- Treatment studies without randomization or without control groups
- For pathophysiological studies: case–control studies, ecological studies, case series
- Incomplete publication (e.g., abstract)
- Case reports, reader letters, duplicate publication
Definition of terms: non-specific, functional, and somatoform bodily complaints

- **“Non-specific”:** Emphasizes the way in which many complaints cannot be categorized as belonging to a specific disease. Intended to prevent over-hasty labeling as “disease” and hence prevent medicalization.

- **“Functional”:** Assumes that it is principally the function of the affected organ or organ system that is impaired; the single medical specialties define a variety of functional somatic syndromes for particular complaints (e.g., irritable bowel syndrome, fibromyalgia syndrome).

- **“Somatoform disorder” in the narrow sense:** Is present when insufficiently explained bodily complaints persist for at least 6 months, leading to a significant impairment of the ability to function in everyday life. If any physical disorders are present, they do not explain the nature and extent of the symptoms or the distress and preoccupation of the patient. (do not change, ICD-10 definition). The ICD-10 criteria have been criticized for inconsistencies, limited validity, failure to cover the range of severity, and lack of positive psychobehavioral criteria (e98, e99). The revised definition of terms emphasizes the association with psychosocial stressors, which increases with the severity of the bodily complaints (e100).

---

**eFIGURE**

Association between evidence level (EL) and recommendation grade (RG) (from e4);
- *1 evidence level according to Oxford Centre of Evidence-Based Medicine (eTable 2);
- *2 recommendation grade in the Program for National Care Guidelines (Programm für Nationale Versorgungsleitlinien);
- *3 clinical consensus point, by analogy to the National Care Guideline for Unipolar Depression (e5)
### eTABLE 1

Global assessment of the study’s methodological quality (guided by the “summary assessment of risk of bias” of the Cochrane Collaboration [e1]), relevance for the guideline (3)

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Methodological quality</th>
<th>Influence on validity of study results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most relevant</td>
<td>Bias can be largely ruled out or cannot be identified</td>
<td>Low risk of bias; any bias will have at most a small effect on study results</td>
</tr>
<tr>
<td>Relevant</td>
<td>Bias can be largely ruled out, slight errors may exist in some areas or cannot be assessed</td>
<td>Low risk of bias; any bias will have at most a small effect on study results</td>
</tr>
<tr>
<td>Fairly relevant</td>
<td>Identifiable but not serious bias present in some areas</td>
<td>Uncertain risk of bias; study results may be affected</td>
</tr>
<tr>
<td>Relevance doubtful</td>
<td>Slight bias identified in several areas, or some areas cannot be assessed with sufficient certainty because of inadequate description</td>
<td>Risk of bias; study results probably affected</td>
</tr>
<tr>
<td>Not relevant</td>
<td>More than slight bias identified in several areas, or such bias cannot be ruled out with sufficient certainty because of inadequate description</td>
<td>High risk of bias; an effect on study results must be assumed</td>
</tr>
</tbody>
</table>

### eTABLE 2

Evidence levels (EL) according to the Oxford Centre for Evidence-Based Medicine (e2)

<table>
<thead>
<tr>
<th>Evidence level</th>
<th>Studies on diagnosis</th>
<th>Studies on treatment/etiology/prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>Systematic review of level 1 diagnostic studies or clinical decision rules, based on 1b studies, validated in different clinical centers</td>
<td>Systematic review of randomized controlled trials (RCT)</td>
</tr>
<tr>
<td>1b</td>
<td>Validating cohort study with good reference standards; or clinical decision rule validated within one clinical center</td>
<td>Individual RCT (with narrow confidence interval)</td>
</tr>
<tr>
<td>1c</td>
<td>Absolute SpPins und SnNouts *1</td>
<td>All-or-nothing principle *2</td>
</tr>
<tr>
<td>2a</td>
<td>Systematic review of well-designed cohort studies</td>
<td></td>
</tr>
<tr>
<td>2b</td>
<td>Individual well-designed cohort study or low quality RCT “Outcomes” research; ecological studies</td>
<td></td>
</tr>
<tr>
<td>3a</td>
<td>Systematic review of level 3 diagnostic studies</td>
<td>Systematic review of case-control studies</td>
</tr>
<tr>
<td>3b</td>
<td>Non-consecutive study; or without consistently applied reference standards</td>
<td>Individual case-control study</td>
</tr>
<tr>
<td>4</td>
<td>Case-control study, poor or nonindependent reference standard</td>
<td>Poor-quality case series or cohort and case-control studies</td>
</tr>
<tr>
<td>5</td>
<td>Expert opinion without explicit critical appraisal, or based on physiology, or laboratory research</td>
<td></td>
</tr>
</tbody>
</table>

*1 “absolute SpPin,” test specificity is so high that a positive result rules the diagnosis in with certainty;  
*2 “absolute SnNout,” test sensitivity is so high that a positive result rules the diagnosis out  
*2 Dramatic effects: this is the case if all patients died before the treatment was available, but after the introduction of the treatment some patients survive; or if some patients died before the treatment was available, but after introduction of the treatment no patients dies

### eTABLE 3

Grading of consensus strength (e3)

<table>
<thead>
<tr>
<th>Consensus strength</th>
<th>Agreement from … % of participants *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong consensus</td>
<td>&gt;95 %</td>
</tr>
<tr>
<td>Consensus</td>
<td>&gt;75%–95%</td>
</tr>
<tr>
<td>Majority agreement</td>
<td>50%–75%</td>
</tr>
<tr>
<td>No consensus</td>
<td>&lt;50%</td>
</tr>
</tbody>
</table>

* A minority vote with an explanatory statement was a possible option but was not used