Classification algorithm for the ICD-11 chronic pain classification (CAL-CP): development and results from a preliminary pilot evaluation

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Abstract

The ICD-11 chronic pain classification includes about 100 chronic pain diagnoses on different diagnostic levels. Each of these diagnoses requires specific operationalized diagnostic criteria to be present. The classification comprises more than 200 diagnostic criteria. The aim of the Classification Algorithm for Chronic Pain in ICD-11 (CAL-CP) is to facilitate the use of the classification by guiding users through these diagnostic criteria. The

diagnostic criteria were ordered hierarchically and visualized in accordance with the standards defined by the Society for Medical Decision Making Committee on Standardization of Clinical Algorithms. The resulting linear decision tree underwent several rounds of iterative checks and feedback by its developers, as well as other pain experts. A preliminary pilot evaluation was conducted in the context of an ecological implementation field study of the classification itself. The resulting algorithm consists of a linear decision tree, an introduction form, and an appendix. The initial decision trunk can be used as stand-alone algorithm in primary care. Each diagnostic criterion is represented in a decision box. The user needs to decide for each criterion whether it is present or not, and then follow the respective yes or no arrows to arrive at the corresponding ICD-11 diagnosis. The results of the pilot evaluation showed good clinical utility of the algorithm. The CAL-CP can contribute to reliable diagnoses by structuring a way through the classification and by increasing adherence to the criteria. Future studies need to evaluate its utility further and analyze its impact on the accuracy of the assigned diagnoses.

Keywords: ICD-11, chronic pain, pain classification, classification algorithm, decision trees

Introduction

The latest revision of the International Classification of Diseases (ICD-11), published by the World Health Organization (WHO), will come into effect in January 2022 [41]. The ICD-11 includes a comprehensive new classification of chronic pain, developed by a taskforce of the International Association for the Study of Pain (IASP) [37]. This classification defines chronic pain as pain that persists or recurs for more than three months [34,35]. It is divided into seven main categories, or level 1 diagnoses, all of which have been described in detail

elsewhere: MG30.0 Chronic primary pain [21], MG30.1 Chronic cancer-related pain [2], MG30.2 Chronic postsurgical or post traumatic pain [30], MG30.3 Chronic secondary musculoskeletal pain [24], MG30.4 Chronic secondary visceral pain [1], MG30.5 Chronic neuropathic pain [29], and MG30.6 Chronic secondary headache or orofacial pain [3].

Each of these main categories has several sub-categories, or child categories, on three or four diagnostic levels to provide more detailed diagnoses, and to represent the majority of chronic pain diagnoses with specific diagnostic codes. See Textbox 1 for details on the different diagnostic levels ("parent" and "child" diagnoses in WHO terminology). Further details can be found in the ICD-11 Reference Guide [39] and the ICD-11 User Guide [40] provided by the WHO.

================ PLEASE INSERT TEXTBOX 1 HERE==================

In total, the ICD-11 includes about 100 different chronic pain entities on levels 1 to 4 [38]. For each of these diagnoses, specific operationalized diagnostic criteria must be fulfilled. That is to say, a given diagnosis can only be assigned if all specified criteria are present in a given patient (for example, significant emotional distress or functional disability must be present to fulfil the criteria for MG30.0 Chronic primary pain). Existing criteria, such as the criteria of the third edition of the International Classification of Headache Disorders (ICHD-3) [10] and the Rome IV criteria for functional gastrointestinal disorders [7], have been integrated in the ICD-11 chronic pain classification. In total, the ICD-11 chronic pain classification relies on more than 200 different diagnostic criteria. On average, each diagnosis is based on four to seven diagnostic criteria. Child categories inherit all criteria from their parent category. For example, the above-mentioned criterion of emotional distress or functional disability applies to all level 1 to 4 diagnoses of chronic primary pain. Further, more specific criteria are specified on the lower diagnostic levels only.

To guide users of the ICD-11 chronic pain classification through the multitude of criteria, we developed a classification algorithm that provides a standardized way through the criteria leading to the specific diagnoses. The algorithm aims at structuring and facilitating the classification process, as the use of algorithms generally improves the reliability of the diagnoses [17,28]. Within a large international field study to evaluate the ICD-11 chronic pain classification [16], clinicians provided preliminary feedback on the algorithm.

Methods

Development of the classification algorithm for the ICD-11 chronic pain classification

The Classification ALgorithm for Chronic Pain in ICD-11 (CAL-CP) was developed and structured according to the guidelines formulated by the Society for Medical Decision Making Committee on Standardization of Clinical Algorithms [31]. The guideline regulates the exact graphical elements and their functions. It recognizes arrows and different kinds of boxes: "clinical state boxes" (rounded rectangles), "decision boxes" (hexagons), and "action boxes" (rectangles). The boxes are linked by the arrows that flow from top to bottom and from left to right. Each arrow visualizes a given "yes" or "no" decision. All boxes are numbered consecutively with the consecutive numbering of all boxes following the flow of the arrows. Annotations on a given box may be added, for example, to add more details or clarifications to a decision box [31].

In a first step of the development of the CAL-CP, all diagnostic criteria of the ICD-11 chronic pain classification, except for chronic headache or orofacial pain, were brought into a hierarchical order for each of the six main categories. The reason for the exclusion of chronic headache or orofacial pain in the present algorithm is that with the ICHD-3 [10] and the International Classification of Orofacial Pain (ICOP) [11], extensive classifications for primary and secondary headache and orofacial pain already exist. While ICHD-3 and ICOP

definitions and diagnostic criteria for the more general diagnostic levels have been harmonized with the ICD-11 [3,21], the CAL-CP avoided interference with these existing classification efforts. Furthermore, algorithms for some of the ICHD-3 headaches are available [27].

Each criterion was represented in a corresponding decision box. In the next step, arrows were added to link the boxes to form a linear decision tree: each box is linked to the next box by a yes and a no arrow to represent the decision taken. Diagnoses were added in clinical state boxes. They represent the ICD-11 diagnoses reached and extend to different levels. Diagnoses to which the concept of double parenting applies (see Textbox 1) were added to the branch of the primary parent category. An action box within the branch of the second parent category links to the branch of the primary parent. For example, the level 3 diagnosis "Chronic central neuropathic pain associated with spinal cord injury" (ID 869493945) is a child category of MG30.50 Chronic central neuropathic pain as well as MG30.20 Chronic post traumatic pain. Therefore, this diagnosis is not only implemented in the branch for chronic neuropathic pain, but an action box within the branch of chronic post traumatic pain also links to this entry.

The resulting linear decision tree was subject to several rounds of consecutive checks and feedback. The members of the IASP taskforce who developed the classification, and who were involved in the development of the algorithm, reviewed whether the diagnostic boxes and the arrows connecting the boxes were correct. They also provided feedback on ambiguous diagnostic decisions. Three independent specialists verified the algorithm's completeness, i.e., that all diagnostic criteria and diagnoses were included. Furthermore, they checked whether all arrows were correct and whether diagnoses to which the new ICD-11 concept of "double parenting" applies were represented within all applicable branches.

The algorithm underwent two rounds of external review and feedback by two pain specialists who were not involved in its development, and who had only minimal prior knowledge regarding the ICD-11 chronic pain classification. The first pain specialist provided feedback on the general concept and the instructions ("Does it make sense?"). After the feedback implementation, the second pain specialist applied the algorithm to a mock patient case before providing detailed feedback on its use as well as any difficulties and problems encountered. The test was whether the pain specialist arrived at the correct diagnoses for the mock patient using the CAL-CP. An observer evaluated difficulties and problems that arose during the mock assessment.

In the course of these iterative rounds of checks and feedback, several additional elements were added to the decision tree: detailed instructions, an introduction form, and an appendix.

After the pilot use of the algorithm in the context of a large ecological implementation field study of the ICD-11 chronic pain classification itself [16] (see below), final corrections were made, and final feedback from the pilot users as well as from all taskforce members was implemented. The final version of the CAL-CP was approved by all taskforce members who were involved in its development, and who are co-authoring the present publication.

Pilot evaluation of the CAL-CP

A preliminary pilot evaluation of the CAL-CP was integrated in the first phase of the ecological implementation field study of the classification itself (ICD-11 Chronic Pain Codes Ecological Testing and Assessment: ICE TEA). The study protocol for the ICE TEA study describes the methods in detail [16]. The first phase of the ICE TEA study was conducted in different countries with varying income levels (Cuba, India, and New Zealand). Ethical approval was obtained prior to data collection, and all participating clinicians and patients gave their informed consent.

In total, 21 trained pain specialists in four different pain clinics in Cuba, India, and New Zealand used a preliminary version of the CAL-CP to assign ICD-11 chronic pain diagnoses to 350 patients with chronic pain. Following the diagnostic assessment and code assignment, the participating clinicians rated the perceived ease of use, diagnostic confidence, and utility of the classification algorithm on three separate numerical rating scales (NRS) ranging from 0 *very difficult/not confident at all/not useful at all* to 10 *very easy/very confident/very useful.* Using SPPS 27 (IBM, Armonk, NY, USA), the mean and standard deviation for each rating scale was computed, and a compound utility score calculated. The pain specialists involved in the ICE TEA study also provided informal feedback on the algorithm, which was recorded at the time, and addressed before the final version of the algorithm was approved by all authors.

Results

Structure of the Classification Algorithm for Chronic Pain in ICD-11 (CAL-CP)

The complete CAL-CP is available as Supplemental Digital Content 1 (SDC 1, available at http://links.lww.com/PAIN/B277). This PDF document includes the instructions, the introduction form, the full decision tree including all branches, as well as the appendix.

As described above, the algorithm was developed and graphically implemented following the guidelines of the Society for Medical Decision Making Committee on Standardization of Clinical Algorithms [31]. Figure 1 shows examples of the different forms of boxes as implemented in the CAL-CP. The final algorithm consists of a linear decision tree comprising 26 branches and 354 boxes in total. To facilitate the use of the algorithm by providing a clear starting point, an initial decision "trunk" was added. This trunk guides the user to the first branch of the decision tree that is applicable to a given patient, as well as any following relevant branches when a patient has several comorbid chronic pain conditions, by leading to

all level 1 diagnoses that apply. Thus, it forms the basis of the CAL-CP (hence, "trunk"). The

initial decision trunk can be seen on page 8 of the SDC 1, available at

http://links.lww.com/PAIN/B277. Importantly, this initial decision trunk can also be used as

stand-alone algorithm in less specialized settings, such as primary care. Figure 2 shows the

initial decision trunk/primary care algorithm.

============== PLEASE ENTER FIGURES 1 AND 2 HERE=================

Each branch of the CAL-CP begins with a clinical state box (rectangles with rounded

corners). In this box, the starting point (e.g., "chronic pain") is given. In most cases, the

starting point of a branch is a level 1 or level 2 diagnosis for which the diagnostic criteria

have been met in a previous branch (see the branches on page 10 of SDC 1 for an example,

available at http://links.lww.com/PAIN/B277). In these instances, the respective level 1 or

level 2 diagnosis is stated in a clinical state box that represents the starting point for that

respective branch. These clinical state boxes are thus called "diagnosis boxes" in the CAL-

CP. Figure 3 shows an example branch of the CAL-CP.

============== PLEASE ENTER FIGURE 3 HERE=================

As mentioned above, all diagnostic criteria of the ICD-11 chronic pain classification are

represented in individual decision boxes (hexagons). Here, the user must make a dichotomous

diagnostic decision, i.e., judge whether the criterion is present or absent (for example,

whether a given underlying disease is confirmed by a diagnostic test or not). If the diagnostic

criteria require a judgement as to whether an underlying disease has been confirmed by a

diagnostic test or by imaging, the user may refer to existing test results or images if he or she

judges them to be conclusive. Depending on the diagnostic decision, the user then follows the

yes or no arrow to the next box. If the user needs to continue in a different section (branch),

of the algorithm, action boxes (rectangles) including a page reference have been implemented

(e.g., page 39 in SDC 1, available at http://links.lww.com/PAIN/B277).

Hyperlinks facilitate the navigation through the algorithm when the document is used in its PDF version in a program that enables hyperlinks. For use as a printed document and as a further means of orientation, all page references are included as comments.

When the user follows the boxes and arrows strictly, he or she arrives at a diagnosis box that states the applicable ICD-11 chronic pain diagnosis. All diagnostic codes listed in the CAL-CP are based on the 09/2020 version of the ICD-11 (ICD-11 Mortality and Morbidity Statistics, MMS, version for preparing implementation) [37]. Different forms of lines of the diagnosis boxes (continuous line vs. dotted line) indicate the diagnostic level of a given diagnosis

The algorithm aims at arriving at the most detailed diagnosis (i.e., level 3 or 4) whenever possible in a specialty setting (diagnosis box with a continuous line). Diagnoses can be assigned on a less detailed level in less specialized settings (e.g., primary care) or in settings with fewer resources. In these settings, the initial decision trunk may be used to assign diagnoses on the first diagnostic level. Hyperlinks and comments for diagnosis boxes instruct the user where to continue to arrive at the diagnosis on the next level.

Entries below the ICD-11 shoreline (see Textbox 1) are coded with the ICD-11 diagnostic code of the parent level and can be distinguished further by their Foundation ID. Each entry of the ICD-11 Foundation layer has a unique Foundation ID or uniform resource identifier (URI). The diagnosis boxes for level 3 diagnoses state the respective Foundation IDs instead of a formal ICD-11 code. See Textbox 1 for further explanations.

Very specific chronic pain conditions that do not have an individual entry in the Foundation layer can still be coded with the applicable ICD-11 code of the more general parent category. For example, chronic pain associated with carpal tunnel syndrome can be coded as MG30.51 Chronic peripheral neuropathic pain without being specified further by an individual ID. For these cases, level 2 diagnosis boxes are repeated at the end of each level 3

branch (see Figure 3 for an example). For a better overview, these boxes are labeled as "other specified", even though this is not part of the official ICD-11 diagnosis. If a chronic pain condition cannot be allocated to any of the level 2 diagnoses, a specific decision box will guide the user to the respective residual category. See Textbox 1 for more details on the ICD-11 residual categories of "other specified" and "unspecified".

When arriving at a diagnosis box for a chronic secondary pain condition (see Textbox 2), the ICD-11 chronic pain code must be combined with the ICD-11 code of the underlying disease associated with that given chronic pain condition. The ICD-11 Coding Tool [36] provided by the WHO can be used for this complete coding.

=============== PLEASE INSERT TEXTBOX 2 HERE =================

As mentioned above, all boxes are numbered consecutively. Explanatory comments accompany some boxes. In these cases, the number of the box automatically serves as the footnote for the comment that goes with the respective box. The comments are added below each branch or on the following page. Some comments give further instructions (e.g., page references in addition to the hyperlinks), others list details or examples for a given diagnostic criterion (e.g., examples of diseases that may be associated with a given chronic secondary pain diagnosis, such as rheumatoid arthritis and MG30.30 Chronic secondary musculoskeletal pain from persistent inflammation). Each diagnosis box has a feedback loop to remind the user to check the pain location chart (page 7, SDC 1, available at http://links.lww.com/PAIN/B277) and initial decision trunk (page 8, SDC 1, available at http://links.lww.com/PAIN/B277) to ensure all chronic pain syndromes of the patient have been accounted for. If additional chronic pain syndromes are present, the user must continue with the next applicable branch of the CAL-CP as highlighted in the initial decision trunk. This ensures that, despite the linear structure of the decision tree, no chronic pain condition is missed in patients with several comorbid chronic pain conditions.

How to use the CAL-CP

As outlined above, the CAL-CP consists of detailed instructions for its use (p. 1-5, SDC 1, available at http://links.lww.com/PAIN/B277), an introduction form (p. 6-7, SDC 1, available at http://links.lww.com/PAIN/B277), and an appendix (p. 41-45, SDC 1, available at http://links.lww.com/PAIN/B277), besides the actual decision tree (p. 8-40, SDC 1, available at http://links.lww.com/PAIN/B277). With regard to the procedure for its use, the user begins with the introduction form. This comprises a general red flags question. In this context, red flags include the presence of an underlying disease (such as cancer or osteoarthritis) without reference to its seriousness. The user should assess whether the patient presents with any symptoms suggestive of an underlying disease that has not been diagnosed previously (e.g., an undiagnosed cancer that might explain the pain). The assessment of these red flags should follow the standard guidelines and diagnostic routines in the respective field of expertise. Unnecessary diagnostic examinations should be avoided. If an underlying undiagnosed disease is suspected, the user should take the appropriate steps (e.g., referral or further diagnostics) as he or she would usually do. The algorithm can be continued after these examinations have clarified the situation.

If a patient presents with chronic headache or orofacial pain, the user will need to refer directly to the ICHD-3 [10] or ICOP [11] for the respective diagnostic criteria, as well as to the ICD-11 Coding Tool [37] for diagnostic coding. Action boxes have been implemented in the CAL-CP to facilitate these references. Furthermore, the initial decision trunk / primary care version refers to the broader diagnoses that are available in the ICD-11 for chronic primary and secondary headache or orofacial pain.

Once the user has ensured that no red flags warrant further medical attention, he or she should continue with the assessment of the so-called chronic pain specifiers (see Textbox 2). Importantly, these should be rated by the patient. Furthermore, as far as possible, the timing

of the onset of the chronic pain should be documented. Then, the patient should highlight all body regions on the pain location chart where he or she experiences chronic pain. This chart guides the user through the algorithm. For example, if two separate body regions are highlighted, the user will see at one glance that he or she should account for both locations in his or her diagnosis. Then, the decision tree itself begins with an initial decision trunk as outlined above. The user marks all sections he or she will need to assess depending on the patient's medical history (i.e., known presence or absence of any underlying disease that might be associated with the chronic pain) and first diagnostic criteria. In addition to the pain location chart, the marks on this trunk also facilitate the assessment of patients with several comorbid chronic pain conditions. The initial decision trunk also gives page references and hyperlinks to facilitate the beginning with the first branch of the decision tree that is relevant to a given patient. This initial decision tree leads to the level 1 diagnoses and can be used as a stand-alone algorithm in less specialized or primary care settings. In specialized pain treatment settings, such as multimodal pain treatment, the full algorithm should be used. Following the initial decision trunk, the user assesses the relevant branches as described above. If the medical history of a patient does not suggest that an underlying disease is associated with the chronic pain, the user will directly begin with the assessment of chronic primary pain. No extensive exclusion diagnostics are required.

During the use of the CAL-CP, the user may refer to the appendix with a list of exemplary diseases that may be associated with chronic pain, if needed (p. 41-45, SDC 1, available at http://links.lww.com/PAIN/B277). The appendix is based on the descriptions of each chronic pain entity in the ICD-11 Browser [38] as well as the publications on the different chronic pain categories [1,2,21,24,29,30] and expert feedback by the taskforce members. It aims at giving an overview of which chronic secondary pain category can be associated with which underlying diseases (e.g., sickle cell disease may be associated with

MG30.41 Chronic visceral pain from vascular mechanisms). The presence of any of these diseases is not automatically associated with chronic pain. Even if an underlying disease is present, the branch for the chronic pain condition that accompanies it should be assessed carefully.

Results of the pilot evaluation

The pain specialists participating in the ICE TEA study rated the ease of use, diagnostic confidence, and perceived utility of the algorithm as very high. Table 1 gives the mean score and standard deviation for each scale. Combining these three measures to one global utility score revealed a mean utility rating of 8.48 ± 1.67 (NRS 0-10).

================= PLEASE INSERT TABLE 1 HERE ====================

Discussion

With CAL-CP, we present a comprehensive classification algorithm for the ICD-11 chronic pain classification for use in clinical practice and pain research. The CAL-CP provides a structured linear decision tree for the new classification of chronic pain, covering all four diagnostic levels of the classification. Its use will facilitate and standardize the process of finding the correct ICD-11 chronic pain diagnosis, contributing to the reliability of the diagnoses.

The different diagnostic levels enable the use of the algorithm in specialty settings, where a very detailed diagnosis on level 3 or 4 of the classification is needed, as well as in less specialized settings (e.g., primary care), where a diagnosis on levels 1 or 2 may be sufficient [34]. Importantly, the initial decision trunk (see Figure 2) serves as primary care version of the CAL-CP. It leads to all level 1 diagnoses that apply to a given patient, and thus represents a time-efficient and easy-to-use tool in settings where time is a limited resource, and where a

more detailed diagnosis might not be necessary. In research settings, use of the full CAL-CP can contribute to increased standardization by providing a clearly defined way through the classification process. Importantly, the CAL-CP can also be used with patient records when these include all of the clinical information needed.

An introduction form as well as an initial decision trunk provide guidance for the assessment of a given patient (i.e., which sections (branches) are relevant). The introduction form provides helpful guidance for the use of the CAL-CP, but it might not be needed when the CAL-CP us used to code a patient based on medical records. The appendix, which gives a list of common diseases that may be associated with chronic pain, is a helpful guide when a patient who presents with a medical history extending beyond the user's main field of expertise is assessed. For example, a clinician involved in multimodal pain treatment might not have specialist knowledge regarding the details of internal diseases that can be associated with chronic pain. Here, it might be difficult to judge whether chronic pain in the context of a given disease (e.g., vasculitis), falls within the category of MG30.41 Chronic secondary visceral pain from vascular mechanisms or within the category of MG30.42 Chronic secondary visceral pain from persistent inflammation. In these instances, the user may refer to the appendix for further guidance.

Hyperlinks simplify the navigation through the algorithm. They are supplemented by complete page references, which are included in the comments. This enables the use of a digital PDF version as well as a printed version of the CAL-CP. Furthermore, a feedback loop in the comments section refers users to the pain location chart and the initial decision trunk once a diagnosis box is reached. This ensures that all comorbid chronic pain conditions are considered during the assessment, and that no chronic pain condition is overlooked in a patient.

It should be noted that the CAL-CP does not substitute for a thorough clinical examination of the patient's pain problem. The CAL-CP will not find out whether a patient's chronic pain is caused by an underlying disease process. Rather, the algorithm facilitates navigating through the ICD-11 chronic pain criteria when the user has all the necessary clinical information. Of course, it may also highlight in which area such information may still be lacking. If a user suspects that a hitherto undiagnosed condition causes the pain, clinical judgement is needed to take the appropriate diagnostic steps. This is in line with other medical algorithms where the developers also point out that an algorithm only assists in describing, summarizing, and classifying available information, and can never substitute for thorough clinical decision making [12,15,42]. The CAL-CP, as with many classification algorithms, is a decision aid and cannot make the decision in lieu of a clinician. At the same time, it should be noted that the goal should not be to formally exclude any possible underlying disease with extensive diagnostics. Rather, red flags should be assessed as always in routine clinical practice, and unnecessary diagnostic procedures should be avoided [5,25].

Classification algorithms are common in a variety of medical fields and have been proposed for different classifications, including epilepsy [28], gastrointestinal disorders [15], neuropathic pain [8], low back pain [22], osteoarthritis [18], periodontal diseases [33], and abdominal pain [14]. The CAL-CP hence represents an important addition to existing algorithm efforts.

The advantages of algorithms to aid classification processes in medicine, including pain medicine, have been described extensively in the literature: algorithms can provide valuable assistance for diagnostic and classification processes by illustrating the decisions to be made by the user (e.g., in the case of the CAL-CP, whether a diagnostic criterion is present) in a comprehensible step-by-step sequence [12], and by providing guidance through a classification with its different criteria [33]. The structured assessment of the diagnostic

criteria is facilitated considerably by this logical decision tree [15,18,23]. Furthermore, adherence to the diagnostic criteria increases when algorithms are used [4]. By guiding the user through all criteria that have to be assessed, the CAL-CP ensures that none of the compulsory criteria are missed when assigning an ICD-11 chronic pain diagnosis. This, in turn, contributes to efficiency [4,32], diagnostic accuracy [20], diagnostic consistency [6,27], as well as increased reliability of the diagnoses [17,28]. Furthermore, the use of algorithms during diagnostic and classification processes can reduce, but not eliminate, errors [12].

Reliable diagnoses contribute to increased clinical utility of the ICD-11 chronic pain classification itself, including patient management and documentation [9]. Furthermore, they are essential for pain research as reliable diagnoses form the basis of accurate sample descriptions as well as data collection.

The data from the preliminary pilot evaluation of the algorithm indicate its high utility. The clinicians judged it easy to use and reported high diagnostic confidence. This is in line with other research on algorithms which also highlight their clinical utility as well as their practical value (e.g., ease of interpretation, user friendliness) [18–20,26]. Notably, the pilot evaluation was conducted in different countries with different income levels (Cuba, India, New Zealand). Hence, the results provide an initial demonstration that the algorithm is applicable in a variety of settings.

A further important future application of the CAL-CP involves training and education. This is especially relevant as the ICD-11 chronic pain classification is new, and its worldwide implementation is imminent. An urgent task ahead of implementation is training: pain clinicians and pain researchers from all fields (medicine, psychology, physical therapy, among others) as well as clinicians with other specialties and professional coders will have to be trained and familiarize themselves with the new criteria and diagnoses. It has been shown that minimal training is sufficient for reliable diagnoses when decision trees are used as a

way to navigate through new diagnostic criteria [17]. Furthermore, decision trees similar to the CAL-CP have been demonstrated to be even more helpful to novices during a diagnostic process compared to experts [20]. Here, the diagnostic accuracy increased more in novices than in experts when an algorithm provided guidance through diagnostic criteria to assign a diagnosis. This highlights the importance and utility of algorithms for training purposes.

Although it was a reasoned decision not to include chronic headache or orofacial pain in the CAL-CP, some might consider this a limitation of the present algorithm. However, references to the ICHD-3 [10] and the ICOP [11] have been integrated into the decision tree using action boxes that refer to these classifications. Furthermore, comments of the respective action boxes list the ICD-11 diagnoses for chronic primary headache or orofacial pain and chronic secondary headache or orofacial pain, respectively. The ICHD-3 and the ICOP should be to be available alongside the ICD-11 in clinical settings. Furthermore, the CAL-CP in its current form is a long document, and its application will need prior training.

Future studies should investigate whether the preliminary results of the pilot evaluation are corroborated. A computer-based international evaluation study is currently in preparation. Detailed case vignettes will be implemented in the form of virtual patients. The use of standardized case vignettes allows control over patient variables [13]. In order to gather the diagnostic information as needed, participants will be able to elicit information from virtual patients through chatbot technology. The computer-based implementation of this study also allow assessment of the time users need to use the CAL-CP. Future plans for the algorithm also include its preparation as a digital application or online format. However, a successful online evaluation is a prerequisite of such an effort. Future research should also include clinicians with different backgrounds such as, e.g., primary care physicians who work with patients with chronic pain.

In conclusion, the CAL-CP provides a useful and easy to use decision aid that can guide pain clinicians as well as pain researchers through the new ICD-11 classification of chronic pain.

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Disclosure

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Figure legend

Figure 1. Example boxes of the CAL-CP

Note. A: decision box (p. 8, SDC 1), B: action box (p. 12, SDC 1), C: diagnosis box for a level 1 diagnosis (p. 10, SDC 1). Underlined text has been implemented as a hyperlink in the CAL-CP. Supplemental digital content is available at http://links.lww.com/PAIN/B277.

Figure 2. Primary care version of the CAL-CP (initial decision trunk)

Note. This initial decision trunk (p. 8, SDC 1, available at http://links.lww.com/PAIN/B277) can be used as a stand-alone algorithm to assign diagnoses on the first diagnostic level in settings where a more detailed diagnosis is not necessary (e.g., primary care). Comments for some of the boxes can be found on p. 9, SDC 1. When a diagnosis is assigned on level 1,

check if all chronic pain has been accounted for. If additional chronic pain syndromes are present, go through this "trunk" again to assign all diagnoses that apply. All boxes of the CAL-CP are numbered consecutively. Underlined text has been implemented as a hyperlink in the CAL-CP.

Figure 3. Example branch of the CAL-CP.

Note. This branch shows the branch for chronic primary musculoskeletal pain. Underlined text has been implemented as a hyperlink in the CAL-CP. This branch has been implemented on page 13 of the CAL-CP (SDC 1, available at http://links.lww.com/PAIN/B277). This sign is a reminder to check in the pain location chart and the initial decision trunk whether all chronic pain has been accounted for. All boxes of the CAL-CP are numbered consecutively.

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Table 1. Results of the pilot evaluation of the classification algorithm.

Item	Mean (*M*)	Standard deviation (*SD*)
Ease of use	8.53	1.68
Diagnostic confidence	8.43	1.84
Utility	8.49	1.82
Global utility score	8.48	1.67

Note. Ratings of 350 patients with chronic pain by 21 pain specialists. Ease of use, diagnostic confidence, and utility of the algorithm were rated on three separate NRSs from 0 (very difficult/not confident at all/not useful at all) to 10 (very easy/very confident/very useful). The global utility score is the compound measure of these
three ratings.

A

14

Pain distribution
neuroanatomically
plausible

B

56

Go to branch for
chronic
neuropathic pain

C

34

MG30.0
Chronic
primary pain

```
                    ┌ ─ ─ ─ ─ ─ ─ ┐ 58
                      MG30.02
                      Chronic primary
                      musculoskeletal
                      pain
                    └ ─ ─ ─ ─ ─ ─ ┘
                           │
                           ▼
                    ╱─────────╲ 59              ┌──────────────┐ 60
                   ╱ Pain located ╲    yes      │   MG30.02      │
                  ╱  in the lumbar  ╲──────────▶│ Chronic primary low │
                   ╲    region     ╱            │   back pain    │
                    ╲─────────╱                 │ (ID 1291385632) │
                         │                      └──────────────┘
                         │ no
                         ▼
                    ╱─────────╲ 61              ┌──────────────┐ 62
                   ╱ Pain located ╲    yes      │ MG30.02 Chronic │
                  ╱  in the neck    ╲──────────▶│ primary cervical │
                   ╲    region     ╱            │     pain       │
                    ╲─────────╱                 │ (ID 2014134682) │
                         │                      └──────────────┘
                         │ no
                         ▼
                    ╱─────────╲ 63              ┌──────────────┐ 64
                   ╱ Pain located ╲    yes      │ MG30.02 Chronic │
                  ╱  in thoracic    ╲──────────▶│ primary thoracic │
                   ╲   region      ╱            │     pain       │
                    ╲─────────╱                 │ (ID 642165115) │
                         │                      └──────────────┘
                         │ no
                         ▼
                    ╱─────────╲ 65              ┌──────────────┐ 66
                   ╱ Pain located ╲    yes      │ MG30.02 Chronic │
                  ╱  in one or more ╲──────────▶│ primary limb pain │
                   ╲    limbs      ╱            │ (ID 413174579)  │
                    ╲─────────╱                 └──────────────┘
                         │
                         │ no
                         ▼
                    ┌ ─ ─ ─ ─ ─ ─ ┐ 67
                      MG30.02
                      Chronic primary
                      musculoskeletal
                      pain, other
                      specified
                    └ ─ ─ ─ ─ ─ ─ ┘
```