Internationale Feldstudien zur Evaluation der Klassifikation chronischer Schmerzen in der 11. Revision der Internationalen statistischen Klassifikation der Krankheiten und verwandter Gesundheitsprobleme (ICD-11)

Dissertation

zur Erlangung des Doktorgrades der Naturwissenschaften

(Dr. rer. nat.)

dem Fachbereich Psychologie der Philipps-Universität Marburg

vorgelegt von

Beatrice Korwisi

geb. Fuld

aus Bad Homburg vor der Höhe

Marburg, Dezember 2020

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Inhalt

1 Zusammenfassung und Abstract

1.1 Zusammenfassung

Am 1. Januar 2022 wird die 11. Revision der Internationalen statistischen Klassifikation der Krankheiten und verwandter Gesundheitsprobleme (ICD-11) international in Kraft treten. Die Einsatzgebiete der ICD sind breit gefächert und umfassen neben Mortalitäts- und Morbiditätsstatistiken auch die klinische Dokumentation, Abrechnung medizinischer Leistungen und gesundheitspolitische Entscheidungen. Trotz hoher Prävalenzen und erheblicher Krankheitslast wurden chronische Schmerzen in der bisherigen 10. Revision der ICD (ICD-10) nur unzureichend abgebildet. Daher wurde für die ICD-11 eine umfassende Klassifikation chronischer Schmerzen entwickelt, welche sieben Hauptkategorien chronischer Schmerzen definiert. Diagnostische Klassifikationssysteme sollten verschiedene Gütekriterien erfüllen. Hierzu zählen Validität und Reliabilität, die wiederum wichtige Voraussetzungen für die klinische Nützlichkeit des Klassifikationssystems darstellen. Eine Verbesserung der klinischen Nützlichkeit wurde neben globaler Anwendbarkeit als Hauptziel des ICD-Revisionsprozesses festgelegt. Das übergeordnete Ziel der vorliegenden Dissertation war die Evaluation der ICD-11-Klassifikation chronischer Schmerzen im Rahmen von internationalen formativen und evaluativen Feldstudien.

Formative Feldstudien werden im Laufe der Entwicklung eines Klassifikationssystems durchgeführt, um notwenige Anpassungen der Struktur zu ermöglichen. Daher hatte Studie 1 zum Ziel, die Hauptkategorien der ICD-11-Klassifikation chronischer Schmerzen im Rahmen einer formativen Feldstudie zu überprüfen. Die Studie wurde in der klinischen Routineversorgung in Schmerz- und allgemeinmedizinischen Kliniken in Australien, Deutschland, Japan und Norwegen durchgeführt. Es zeigte sich, dass die sieben Hauptkategorien 97 % der vorliegenden chronischen Schmerzsyndrome erfassten. Nur 2 % der Schmerzsyndrome fielen in mehr als eine Kategorie. Mit der vollständigen Erfassung zugrundeliegender Schmerzsyndrome und dem gegenseitigen Ausschluss der Kategorien erfüllt die neue Klassifikation zwei wichtige Eigenschaften diagnostischer Klassifikationssysteme.

In einer weiteren formativen Feldstudie (Studie 2) sollte die neue Klassifikation dahingehend überprüft werden, ob sie sich in die übergeordnete Struktur der ICD-11

integrieren lässt und ob sich die von der Weltgesundheitsorganisation (WHO) definierten Kodierregeln auf die neuen Schmerzdiagnosen anwenden lassen. Hierzu wurde eine internetbasierte Feldstudie international durchgeführt. Schmerzspezialistinnen und -spezialisten ordneten diagnostischen Begriffen die jeweilige ICD-10- und ICD-11-Diagnose zu. Weiterhin erfolgte eine Zuordnung von ICD-11-Diagnosen zu kurzen Fallvignetten. Die ICD-11-Diagnosen waren den ICD-10-Diagnosen hinsichtlich korrekter Kodierung, Einfachheit, Detailtiefe und Ambiguität überlegen. Die Kodierregeln wurden bei einem Großteil der Vignetten korrekt angewendet. Die klinische Nützlichkeit der neuen Diagnosen wurde als sehr hoch eingeschätzt.

Um die Anwendung der Klassifikation zu vereinfachen und um die Diagnosevergabe für Forschung und Praxis zu standardisieren, wurde im Rahmen von Studie 3 ein Klassifikationsalgorithmus entwickelt. Im Rahmen einer Pilotevaluation wurde der Algorithmus von Schmerzspezialistinnen und -spezialisten hinsichtlich seiner Nützlichkeit evaluiert. Die Struktur des Algorithmus folgt international etablierten Richtlinien. Der Algorithmus stellt einen linearen Entscheidungsbaum dar. Wer den Boxen und Pfeilen des Baumes folgt, wird zu den entsprechenden ICD-11-Diagnosen für chronische Schmerzen geleitet. Hyperlinks und Seitenverweise erleichtern die Anwendung des PDF-Dokuments. Im Rahmen der Pilotevaluation wurde der Algorithmus als sehr nützlich eingeschätzt.

In Ergänzung zu den formativen Feldstudien (Studien 1 und 2) wurde im Rahmen der vorliegenden Dissertation auch eine umfassende evaluative Feldstudie international durchgeführt (Studie 5). Zunächst wurde ein Studienprotokoll für diese naturalistische Implementierungs-Feldstudie entwickelt (Studie 4). Das Studienprotokoll definiert zwei Erhebungswellen für die Feldstudie, welche in Ländern aller Einkommensgruppen durchgeführt werden sollen. Die Teilnehmende sollen die neuen ICD-11-Schmerzdiagnosen auf konsekutive Patientinnen und Patienten anwenden. Die Interrater-Reliabilität der Diagnosen sowie deren eingeschätzte klinische Nützlichkeit stellen die Hauptergebnismaße dar. Im Rahmen von Studie 5 wurde das Studienprotokoll in Schmerzkliniken in Indien (niedrig-mittlerer Einkommensstatus), Kuba (hoch-mittlerer Einkommensstatus) und Neuseeland (hoher Einkommensstatus) umgesetzt. Für elf Diagnosen konnte die Interrater-Reliabilität bestimmt werden, die für zehn Diagnosen im substanziellen Bereich lag. Die klinische Nützlichkeit der neuen Diagnosen wurde als sehr hoch eingeschätzt.

Insgesamt liefert die vorliegende Dissertation Befunde für die hohe Qualität der neuen ICD-11-Klassifikation chronischer Schmerzen, die sich in den berichteten Feldstudien als global anwendbar erwies und somit die übergeordneten Hauptziele der ICD-11 erfüllt.

1.2 Abstract

The 11th revision of the International Classification of Diseases and Related Health Problems (ICD-11) will come into effect worldwide on January 1st, 2022. The ICD-11 has many different applications, including clinical documentation, reimbursement of medical services, public health decisions as well as mortality and morbidity statistics. Despite high prevalence rates and a significant disease burden, chronic pain is not represented adequately in the current 10th revision of the ICD (ICD-10). Therefore, a comprehensive classification of chronic pain, which defines seven main categories of chronic pain, was developed for the ICD-11. Diagnostic classification systems should meet different psychometric criteria, including validity and reliability. Validity and reliability, in turn, are important prerequisites for the clinical utility of a classification system. The improvement of clinical utility as well as global applicability were defined as main goals of the ICD revision process. The overall aim of the present doctoral thesis was the evaluation of the ICD-11 classification of chronic pain in international formative and evaluative field studies.

Formative field studies are conducted during the development of a classification system to enable necessary adjustments of its overall structure. Therefore, study 1 aimed at evaluating the main categories of the ICD-11 chronic pain classification in a formative field study. The study was implemented in routine clinical care in pain clinics as well as primary care clinics in Australia, Germany, Japan, and Norway. Results showed that the seven main categories accounted for 97 % of chronic pain syndromes. Only 2 % of the chronic pain syndromes were allocated to more than one category. With the exhaustiveness of capturing all underlying pain syndromes and the mutual exclusiveness of the categories, the new classification fulfils two important psychometric criteria of diagnostic classification systems.

A further formative field study (study 2) aimed at evaluating whether the new classification can be integrated within the overall structure of the ICD-11, and whether the coding rules as defined by the World Health Organization (WHO) can be applied to the new chronic pain diagnoses. An online field study was conducted internationally. Pain specialists

assigned ICD-10 and ICD-11 diagnoses to diagnostic statements. Furthermore, they assigned ICD-11 diagnoses to brief case vignettes. The ICD-11 diagnoses performed better than the ICD-10 diagnoses with regard to correct code assignment, ease of use, level of detail, and ambiguity. The coding rules were applied correctly to the majority of case vignettes. The clinical utility of the new diagnoses was rated as very high.

In order to facilitate the application of the classification as well as to standardize code assignment in research and in clinical practice, a classification algorithm was developed (study 3). In a pilot evaluation, pain specialists evaluated the algorithm with regard to its utility. The overall structure of the algorithm, which is a linear decision tree, conforms with internationally established guidelines. When following the boxes and arrows consequently, the algorithm leads users to the ICD-11 chronic pain diagnoses that apply. Hyperlinks and page references facilitate the use of the pdf document. In the pilot evaluation, the algorithm was rated as very useful.

In addition to the formative field studies (studies 1 and 2), an extensive international evaluative field study was conducted as well, as part of the present doctoral thesis (study 5). First, the study protocol for an ecological implementation field study was developed (study 4). The study protocol defines two phases of data collection, which will be implemented in countries of all income groups. Participants will assign the new ICD-11 chronic pain diagnoses to consecutive patients. The inter-rater reliability as well as ratings of their clinical utility are the main outcomes of the study. Study 5 implemented this study protocol in pain clinics in India (lower-middle-income country), Cuba (high-middle-income country), and New Zealand (high-income country). Inter-rater reliability was computed for 11 diagnoses. For 10 of these diagnoses, inter-rater reliability was substantial. The clinical utility of the new diagnoses was rated as very high.

In conclusion, the present doctoral thesis provides findings of the high quality of the new ICD-11 chronic pain classification. The classification was applicable globally in the present field studies. Therefore, the new classification meets the main goals of the ICD-11.

2 Hintergrund

2.1 Die Internationale statistische Klassifikation der Krankheiten und verwandter Gesundheitsprobleme (ICD)

Die Internationale statistische Klassifikation der Krankheiten und verwandter Gesundheitsprobleme (*International Classification of Diseases and Related Health Problems*, ICD) ist ein weltweit genutzter diagnostischer Kodierstandard für Erkrankungen und andere Faktoren, welche die Gesundheit einer Person beeinflussen, z. B. Verletzungen (Jakob, 2018b; Reed, 2010). Historisch gesehen wurde die ICD vor mehr als 150 Jahren erstmals zur Dokumentation von Todesursachen veröffentlicht (Jakob, 2018b). Seit 1948 wird die ICD von der Weltgesundheitsorganisation (*World Health Organization,* WHO) herausgegeben (Jakob et al., 2007). Sie ist Teil der Familie der internationalen gesundheitsrelevanten Klassifikationen, welche neben der ICD unter anderem auch die Internationale Klassifikation der Funktionsfähigkeit, Behinderung und Gesundheit (*International Classification of Functioning, Disability and Health,* ICF) umfasst (Jakob et al., 2007).

Das Einsatzgebiet der ICD geht inzwischen über die Dokumentation von Todesfällen hinaus. Heute wird die ICD unter anderem auch für nationale und internationale Gesundheitsstatistiken (z. B. Morbidität), klinische Dokumentation, Forschungszwecke, epidemiologische Untersuchungen und Vergütung im Gesundheitswesen eingesetzt (Boerma et al., 2016; Jakob, 2018a, 2018b). Des Weiteren stellt die ICD international die Grundlage für die Verteilung von Ressourcen für die globale Gesundheitsversorgung durch die WHO dar (Jakob, 2018b). In vielen Gesundheitssystemen sind ICD-Codes zudem ausschlaggebend dafür, welche Behandlung eine Patientin oder ein Patient erhält (Boerma et al., 2016; Rief et al., 2012). Aus den vielfältigen Anwendungsgebieten der ICD lässt sich ableiten, dass auch der Kreis der Nutzerinnen und Nutzer sehr umfangreich ist. Neben Ärztinnen und Ärzten sowie Psychotherapeutinnen und Psychotherapeuten wird die ICD beispielsweise auch von Pflegenden, Versicherern, Programmiererinnen und Programmierern sowie in der Gesundheitspolitik und dem öffentlichen Gesundheitswesen genutzt. (Jakob, 2018b).

Die neuste Revision der ICD, die ICD-11, wurde im Mai 2019 von der Weltgesundheitsversammlung verabschiedet und wird am 01.01.2022 international in Kraft treten (World Health Organization, 2019). Der Revisionsprozess dauerte zehn Jahre, mehr als

20 Arbeitsgruppen waren daran beteiligt (Jakob, 2018b). Im Unterschied zur aktuellen ICD-10 zeichnet die ICD-11 sich durch eine elektronische Infrastruktur aus (Boerma et al., 2016; Jakob, 2018b). Dies ermöglicht neben einer vereinfachten Anpassung an spezielle Einsatzgebiete wie beispielsweise die hausärztliche Primärversorgung oder spezialisierte Fachgebiete (Jakob, 2018b) auch die Bereitstellung verschiedener Hilfsmittel für eine erleichterte Kodierung, z. B. eine Kodiersuchmaschine (Boerma et al., 2016; Jakob, 2018b).

Die ICD-11 steht im Internet kostenlos zur Verfügung (World Health Organization, 2020a). Dies spiegelt auch den digitalen Fortschritt des 21. Jahrhunderts wider, in dem elektronische Dokumentation eine immer wichtigere Rolle spielt (Boerma et al., 2016; The Lancet, 2018). Des Weiteren kann die kostenfreie elektronische Verfügbarkeit die Wahrscheinlichkeit erhöhen, dass die ICD implementiert wird, insbesondere auch in Ländern und Settings mit weniger Ressourcen (Stein & Reed, 2019). Eine erste Implementierungsstudie konnte zeigen, dass sich die digitale Infrastruktur der ICD-11 erfolgreich in das elektronische Dokumentationssystem eines Entwicklungslandes (Ruanda) einbetten lässt (Mugisha et al., 2020).

2.2 Chronische Schmerzen

2.2.1 Definition

Die *International Association for the Study of Pain* (IASP) definiert Schmerzen als „eine unangenehme sensorische und emotionale Erfahrung, welche mit einer tatsächlichen oder potentiellen Gewebeschädigung verbunden ist, oder als solche erscheint“ (Raja et al., 2020, S. 1977). Es wird weiter spezifiziert, dass Schmerzen multifaktoriell bedingt sind. Biologische, psychologische und soziale Faktoren haben einen Einfluss auf die Schmerzen. Des Weiteren kann aus der Definition abgeleitet werden, dass Schmerz immer über die reine Nozizeption hinausgeht (Raja et al., 2020).

Die Abgrenzung chronischer Schmerzen von akuten Schmerzen ist essenziell. Chronische Schmerzen werden definiert als Schmerzen, die über einen Zeitraum von mehr als drei Monaten andauern oder wiederkehren (Treede et al., 2015, 2019). Akute Schmerzen treten dagegen in der Regel im Zusammenhang mit einem noxischen Reiz auf und haben somit eine Warn- und Schutzfunktion für das Individuum (Kröner-Herwig, 2017; Treede, 2019). Im Gegensatz dazu ist bei chronischen Schmerzen häufig keine eindeutige Ursache mehr für den

Schmerz identifizierbar, die Schmerzen haben ihre Warn- und Schutzfunktion verloren (Kröner-Herwig, 2017; Treede, 2019).

Verschiedene Faktoren tragen zur Entstehung und Aufrechterhaltung chronischer Schmerzen bei. Auf biologischer Ebene wurden beispielsweise die zentrale sowie die periphere Sensibilisierung als wichtige Mechanismen der Schmerzchronifizierung postuliert (Flor, 2017; Treede, 2019). In ihrer Übersichtsarbeit fassen Turk & Monarch (2002) psychologische Mechanismen zusammen, die zu chronischen Schmerzen beitragen können. Hierzu zählen demnach Lernmechanismen, kognitive Faktoren (z. B. Kontrollüberzeugungen, Selbstwirksamkeit) sowie affektive Faktoren (z. B. Ängstlichkeit, Depressivität). Weitere wichtige psychologische Mechanismen der Schmerzchronifizierung und -aufrechterhaltung sind Vermeidungsverhalten (Vlaeyen & Linton, 2000) sowie Schmerzkatastrophisierung (Eccleston & Crombez, 2007). Morlion et al. (2018) betonen in ihrer Übersichtsarbeit die Rolle von sozialer Unterstützung und dem Bildungsniveau einer Person als wichtige soziale Faktoren, die Einfluss auf die Schmerzchronifizierung nehmen können. Auch der Erwerbsstatus einer Person sowie ihr persönliches Einkommensniveau können das Risiko, chronische Schmerzen zu entwickeln, beeinflussen (van Hecke et al., 2013). In letzter Zeit wurde auch die Rolle von genetischen und epigenetischen Risikofaktoren für die Entstehung chronischer Schmerzen diskutiert (Denk et al., 2014; Gatchel et al., 2007).

2.2.2 Prävalenz chronischer Schmerzen

Europaweit leiden fast 19 % der Bevölkerung an chronischen Schmerzen – also fast jede fünfte Person (Breivik et al., 2006). Bei einem großen Anteil der Betroffenen (21 %) dauern die Schmerzen bereits seit mehr als 20 Jahren an. Gleichzeitig befindet sich nur ein Bruchteil der Betroffenen in spezifischer schmerztherapeutischer Behandlung (Breivik et al., 2006). Die jährliche Inzidenz chronischer Schmerzen wird auf 5 % geschätzt (Landmark et al., 2018). In Deutschland liegt die Prävalenz chronischer Schmerzen mit ca. 28 % sogar über dem europaweiten Durchschnitt (Häuser et al., 2014).

Frauen sind häufiger von chronischen Schmerzen betroffen als Männer (Breivik et al., 2006; Dahlhamer et al., 2018; Fayaz et al., 2016; Tsang et al., 2008). Des Weiteren nimmt die Prävalenz chronischer Schmerzen mit dem Alter zu (Breivik et al., 2006; Dahlhamer et al., 2018;

Fayaz et al., 2016; Häuser et al., 2014; Tsang et al., 2008). Je länger die chronischen Schmerzen bereits andauern, desto schlechter ist die Prognose (Landmark et al., 2018).

Ein Großteil der Weltbevölkerung lebt in Ländern mit niedrigem oder mittlerem Einkommensstatus (*low- and middle-income countries,* LMIC, Onofa et al., 2019). Chronische Schmerzen betreffen in LMIC ebenso viele Menschen wie in Industrienationen (Nunes Sá et al., 2019; Tsang et al., 2008). Auch in LMIC konnten die oben beschriebenen Alters- und Geschlechtseffekte gezeigt werden (Jackson et al., 2016).

2.2.3 Folgen chronischer Schmerzen

Chronische Schmerzen haben weitreichende individuelle und gesamtgesellschaftliche Folgen. In der oben beschriebenen epidemiologischen Untersuchung von Breivik et al. (2006) gab ein Viertel der Personen mit chronischen Schmerzen an, dass die Schmerzen einen Einfluss auf ihren Beschäftigungsstatus haben. Im Schnitt wurden nahezu acht Arbeitsunfähigkeitstage aufgrund der Schmerzen innerhalb der letzten sechs Monate berichtet. Eine Analyse deutscher Versichertendaten der BARMER GEK zeigte, dass Personen mit der ICD-10-Diagnose einer anhaltenden Schmerzstörung (F45.40 oder F45.41, siehe Kapitel 2.3.1 für eine Beschreibung der Kodierung chronischer Schmerzen in der ICD-10) im Durchschnitt an 86 Tagen pro Jahr arbeitsunfähig waren (Häuser et al., 2013). Chronische Schmerzen können nicht nur in Arbeitsunfähigkeit resultieren, sondern auch die Arbeitsleistung einschränken (Blyth et al., 2003; van Leeuwen et al., 2006). Des Weiteren wirken chronische Schmerzen sich häufig negativ auf Freizeitaktivitäten, Haushalt und zwischenmenschliche Beziehungen aus (Froud et al., 2014).

Neben der funktionellen Beeinträchtigung können chronische Schmerzen sich auch auf das emotionale Befinden der betroffenen Person auswirken. So litt in der Studie von Breivik et al. (2006) jede fünfte Person neben ihren chronischen Schmerzen auch unter Depressionen. In der deutschen Stichprobe von Häuser et al. (2014) gaben 17-39 % der Teilnehmenden an, durch ihre chronischen Schmerzen psychisch belastet zu sein. Die Auswirkung chronischer Schmerzen auf das psychische Befinden konnte auch in LMIC gezeigt werden (Jackson et al., 2016; Tsang et al., 2008). Weiterhin können chronische Schmerzen sich negativ auf die allgemeine Lebensqualität auswirken (Wang et al., 2018). Viele betroffene Patientinnen und Patienten erleben sich als Belastung für andere (Kowal et al., 2012).

Wie bereits erwähnt, haben chronische Schmerzen neben diesen Folgen für das Individuum auch gesamtgesellschaftliche Auswirkungen. Rückenschmerzen und Kopfschmerzen tragen maßgeblich zur globalen Krankheitslast bei und gehören zu den drei Ursachen, die weltweit die meisten mit Beeinträchtigung gelebten Jahre verursachen (*years lived with disability,* YLD, James et al., 2018). Allein Schmerzen im unteren Rücken verursachten im Jahr 2017 ca. 64 Millionen YLD. Im Zeitraum von 1990 bis 2017 nahmen die durch Rückenschmerzen verursachten YLDs weltweit um 30 % zu (James et al., 2018). Es ist davon auszugehen, dass die durch chronische Schmerzen verursachte Krankheitslast durch die alternde Bevölkerung in den kommenden Jahren weiter ansteigen wird, v. a. in LMIC (Blyth et al., 2019; Blyth & Noguchi, 2017).

In Deutschland wurden die jährlichen volkswirtschaftlichen Kosten, die durch chronische Schmerzen verursacht werden, auf bis zu 28,7 Milliarden Euro geschätzt (Deutscher Bundestag, 2003). Dies beinhaltet sowohl direkte Kosten (z. B. Medikamente, ärztliche Behandlung) als auch indirekte Kosten (z. B. Arbeitsunfähigkeit, vorzeitige Berentung). Pro Person mit chronischen Schmerzen entstehen neueren Schätzungen zufolge in Deutschland im Durchschnitt 5.550 Euro volkswirtschaftliche Kosten pro Jahr (Häuser et al., 2013). Rückenschmerzen sind deutschlandweit die häufigste Ursache für Arbeitsunfähigkeitstage, wobei hier jedoch nicht nach akuten und chronischen Rückenschmerzen unterschieden wird (Knieps & Pfaff, 2019).

Zusammenfassend lässt sich aus den hohen Prävalenzzahlen chronischer Schmerzen sowie den einschneidenden Auswirkungen für die betroffenen Personen und die entstehenden volkswirtschaftlichen Kosten ableiten, dass chronische Schmerzen eine Priorität sowohl für das nationale als auch internationale öffentliche Gesundheitswesen sein sollten (D. S. Goldberg & McGee, 2011).

2.3 Klassifikation chronischer Schmerzen

2.3.1 Chronische Schmerzen in der ICD-10

Bereits vor mehr als 40 Jahren wurde erstmals die Bedeutung einer einheitlichen Klassifikation chronischer Schmerzen betont, welche auch in die ICD als internationaler Kodierstandard aufgenommen werden sollte (Bonica, 1979). Trotzdem gleicht die Repräsentation chronischer Schmerzen in der aktuellen ICD-10 nach wie vor einem „Turm zu

Babel“ (Bonica, 1979, S. 247). Verschiedene Diagnosecodes sind auf unterschiedliche Kapitel verstreut – z. B. „M54 Rückenschmerzen“, „G43 Migräne“ – und häufig nicht klar definiert – z. B. R52.2 sonstiger chronischer Schmerz (Rief et al., 2010, 2012). Verschiedene Formen chronischer Schmerzen, z. B. chronische Schmerzen im Zusammenhang mit einer Krebserkrankung, können mit der ICD-10 überhaupt nicht kodiert werden (Rief et al., 2012). Des Weiteren entspricht die Repräsentation chronischer Schmerzen in der internationalen Version der ICD-10 nicht dem biopsychosozialen Schmerzmodell (Rief, Treede, et al., 2008; Treede et al., 2010). Während im ICD-10-Kapitel für psychische Erkrankungen mit dem Code „F45.4 anhaltende Schmerzstörung“ international zwar eine Diagnose für chronische Schmerzen, bei denen psychische Faktoren eine Rolle spielen, zur Verfügung steht, schließt diese Diagnose gleichzeitig das Vorliegen eines somatischen Krankheitsfaktors aus (Arnold et al., 2017; Rief, Zenz, et al., 2008; Treede, 2010). Für die F-Diagnose der anhaltenden Schmerzstörung wird von einer rein psychischen Genese der Schmerzen ausgegangen.

Die unsystematische und unvollständige Klassifikation chronischer Schmerzen in der ICD-10 hat weitreichende Folgen. Zum einen erschwert das Fehlen einer internationalen Standardklassifikation für chronische Schmerzen die Kommunikation sowohl in der Forschung als auch in der Praxis (Bonica, 1979). Die künstliche Dichotomisierung zwischen somatisch bedingten Schmerzen auf der einen Seite und psychisch bedingten Schmerzen auf der anderen Seite entspricht nicht dem biopsychosozialen Schmerzmodell und ist in der Praxis meist schwierig und kaum umsetzbar (Rief, Zenz, et al., 2008; Treede et al., 2010). Zudem hängt von den vergebenen ICD-Codes in vielen nationalen Gesundheitssystemen, u. a. in Deutschland, direkt ab, welche Behandlungsmöglichkeiten mit den Versicherern abgerechnet werden können und somit für eine Patientin oder einen Patienten zur Verfügung stehen (Rief et al., 2012; Rief, Treede, et al., 2008). Ohne einen F-Code sind in Deutschland Patientinnen und Patienten von psychotherapeutischer Behandlung im ambulanten als auch im stationären Setting ausgeschlossen, was eine interdisziplinäre multimodale Schmerztherapie unmöglich macht (Nilges & Rief, 2010; Rief, Treede, et al., 2008). Dies betrifft aufgrund der künstlichen Dichotomisierung in der internationalen ICD-10 alle Patientinnen und Patienten, bei denen körperliche Faktoren (z. B. Muskelverspannungen, Bandscheibenvorfall, rheumatoide Arthritis) eine Rolle bei der Genese der chronischen Schmerzen spielen (Rief, Zenz, et al., 2008; Treede et al., 2010).

Weiterhin hat die mangelhafte Klassifikation chronischer Schmerzen zur Folge, dass die wahre Krankheitslast in den entsprechenden nationalen und internationalen Untersuchungen unterschätzt wird, da chronische Schmerzen im Zusammenhang mit einer anderen Grunderkrankung (z. B. rheumatoide Arthritis, HIV, diabetische Polyneuropathie) nicht abgebildet werden (Blyth et al., 2019; Rice et al., 2016; Treede, 2010). Des Weiteren kann in nationalen und internationalen Registerstudien nicht nach akuten und chronischen Schmerzen unterschieden werden, wenn ein somatischer Code wie beispielsweise „M54.5 Kreuzschmerz“ vergeben wird (Chenot et al., 2014; Knieps & Pfaff, 2019), was die Interpretation entsprechender Registerdaten erschwert.

Mit der Einführung der Diagnose „F45.41 Chronische Schmerzstörung mit somatischen und psychischen Faktoren“ in die deutschsprachige Version der ICD-10 im Jahr 2009 wurde ein Meilenstein für eine bessere Schmerzklassifikation erreicht (Nilges & Rief, 2010; Rief, Treede, et al., 2008; Treede et al., 2010). Die neue Diagnose F45.41 betont sowohl die Rolle von somatischen als auch psychischen Faktoren für die chronischen Schmerzen (Nilges & Rief, 2010). Somit wurde das biopsychosoziale Schmerzmodell erstmalig in die ICD implementiert, wodurch die künstliche Dichotomisierung zwischen somatisch und psychisch bedingten Schmerzen aufgelöst wird (Arnold et al., 2017; Treede, 2010).

Die Einführung der F45.41 in Deutschland konnte die Dokumentation chronischer Schmerzen sowie den Zugang zu angemessenen interdisziplinären Behandlungs-möglichkeiten verbessern (Nilges et al., 2018; Treede et al., 2010). Registerdaten der BARMER GEK zeigen, dass die Diagnose F45.41 inzwischen häufiger vergeben wird als die bisherige Diagnose der „anhaltenden somatoformen Schmerzstörung“ (international F45.4, in Deutschland seit 2009 F45.40), was auf die hohe Akzeptanz der biopsychosozialen Diagnose F45.41 unter Anwenderinnen und Anwendern hindeutet (Häuser et al., 2013).

Wie oben erwähnt, steht die Diagnose der chronischen Schmerzstörung mit psychischen und somatischen Faktoren weiterhin nur im deutschen Sprachraum zur Verfügung. Alle oben genannten Probleme und die daraus entstehenden Konsequenzen bestehen international unverändert fort.

2.3.2 Chronische Schmerzen in der ICD-11

Um die in Kapitel 2.3.1 beschriebenen Probleme, welche durch die unzulängliche Klassifikation chronischer Schmerzen in der ICD-10 entstehen, zu überwinden, entwickelte eine internationale Arbeitsgruppe der IASP eine umfassende Klassifikation chronischer Schmerzen für die ICD-11 (Treede et al., 2015, 2019). Eine adäquate Klassifikation, welche international zur Verfügung steht, ist eine Grundvoraussetzung, um sowohl Forschungs- als auch Behandlungsmöglichkeiten zu verbessern (Rief et al., 2010).

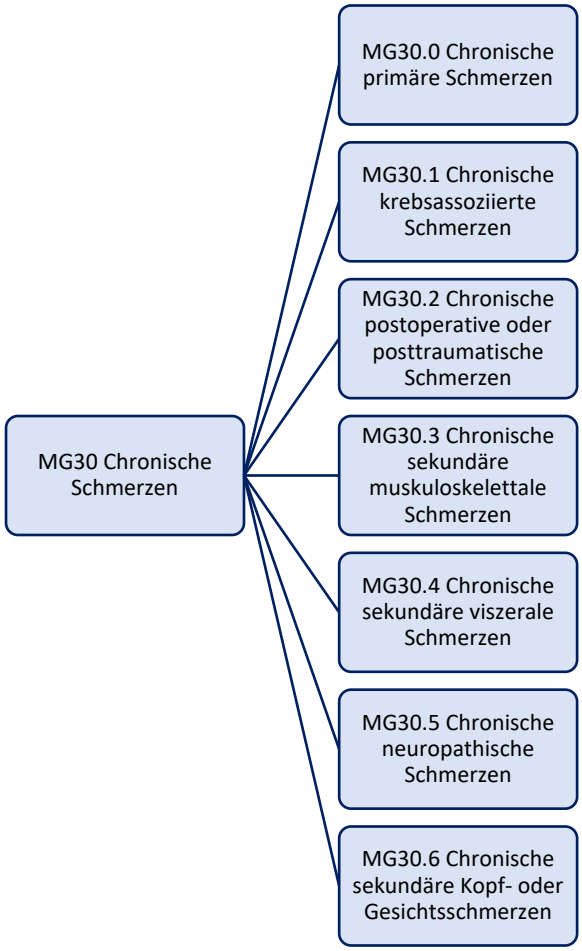
Die ICD-11-Klassifikation chronischer Schmerzen umfasst sieben Hauptkategorien (Treede et al., 2019), welche in Abbildung 1[1] dargestellt sind. Jede Kategorie hat auf weiteren Diagnoseebenen Unterkategorien mit zunehmendem Spezifitätsgrad. So ist beispielsweise „MG30.02 chronische primäre muskuloskelettale Schmerzen“ eine Unterkategorie von „MG30.0 chronische primäre Schmerzen“ (Nicholas et al., 2019). In der ICD-11-Klassifikation chronischer Schmerzen ist erstmalig auch das biopsychosoziale Modell per Definition verankert (Treede et al., 2019).

Chronische primäre Schmerzen treten in einer oder in mehreren Körperregionen auf und haben für die betroffene Person eine erhebliche emotionale Belastung (z. B. Frustration, Niedergeschlagenheit, Ängstlichkeit) oder eine erhebliche funktionelle Beeinträchtigung (z. B. bei Alltagsaktivitäten) zur Folge (Nicholas et al., 2019). Es werden keine spezifischen Annahmen über den jeweiligen Beitrag somatischer, psychischer und sozialer Faktoren für die Entstehung und Aufrechterhaltung der Schmerzen gemacht – die Schmerzen sind multifaktoriell bedingt, werden aber nicht durch eine erkennbare Grunderkrankung (z. B. rheumatoide Arthritis) verursacht (Nicholas et al., 2019). Ehemals häufig verwendete Begriffe für Schmerzen ohne klar identifizierbare Ätiologie wie „unspezifisch“, „funktionell“ oder „somatoform“ werden vermieden. Chronische primäre Schmerzen sind durch positive Diagnosekriterien definiert und somit keine Ausschlussdiagnose (Nicholas et al., 2019).

[1] Da die ICD-11 bislang nur auf Englisch vorliegt (World Health Organization, 2019b), stellen die in der Abbildung und im Folgenden genannten deutschen Diagnosenamen keine offiziellen Übersetzungen dar.

Abbildung 1

Die sieben Hauptkategorien chronischer Schmerzen in der ICD-11.



Anmerkung: Es sind die ICD-11-Hauptkategorien chronischer Schmerzen nach Treede et al. (2019) abgebildet. Die Diagnosecodes entsprechen der aktuellen Version der ICD-11 (World Health Organization, 2020b).

Chronische primäre Schmerzen umfassen den chronischen Ganzkörperschmerz, das komplexe regionale Schmerzsyndrom (CRPS), chronische primäre Kopf- oder Gesichtsschmerzen (z. B. chronische Migräne, chronische Spannungskopfschmerzen), chronische primäre viszerale Schmerzen (z. B. chronische Schmerzen in Verbindung mit dem Reizdarmsyndrom) und chronische primäre muskuloskelettale Schmerzen (Nicholas et al., 2019). Letztere Unterkategorie umfasst u. a. auch chronische primäre Rückenschmerzen, welche ehemals als „unspezifische“ Rückenschmerzen bezeichnet wurden (Nicholas et al., 2019). Bei bis zu 90 % der Patientinnen und Patienten mit Schmerzen im unteren Rücken lässt

sich keine klare ätiologische Ursache finden (Koes et al., 2006). Demnach ist davon auszugehen, dass ein Großteil chronischer Schmerzen im unteren Rücken in die neue Kategorie chronischer primärer Schmerzen fällt.

Chronische primäre Schmerzen verstehen den Schmerz als eigenständigen Gesundheitszustand (Treede et al., 2019). Dem gegenüber stehen sechs Kategorien chronischer sekundärer Schmerzen. Hier treten die Schmerzen als Symptom einer Grunderkrankung (z. B. Krebs, Morbus Crohn, Gicht) auf, haben aber nichtsdestotrotz einen spezifischen Behandlungsbedarf und können auch über eine erfolgreiche Behandlung der Grunderkrankung hinaus weiter bestehen bleiben (Treede et al., 2019). Eine erste Untersuchung von Unterschieden zwischen Patientinnen und Patienten mit chronischen primären versus sekundären Schmerzen zeigte, dass erstere Gruppe im Durchschnitt eine höhere schmerzbedingte Belastung sowie eine größere funktionelle Beeinträchtigung bei jüngerem Durchschnittsalter und längerer Schmerzdauer aufwies (Hornemann et al., 2020).

Chronische krebsassoziierte Schmerzen werden unterschieden in chronische Schmerzen, die direkt durch einen Tumor oder Metastasen ausgelöst werden, sowie in chronische Schmerzen, die durch die Krebsbehandlung (z. B. Chemotherapie, Hormontherapie, Strahlenbehandlung) entstehen (Bennett et al., 2019). Bis zu ein Drittel der Patientinnen und Patienten mit aktivem Krebs leiden an chronischen Schmerzen (Bouhassira et al., 2017). In dieser Studie ließen sich in fast der Hälfte der Fälle die Schmerzen direkt auf den Krebs zurückführen und in einem Viertel der Fälle auf die Krebsbehandlung. Insgesamt wird die Prävalenz chronischer krebsbedingter Schmerzen in Deutschland auf 1,4 % geschätzt (Häuser et al., 2014).

Chronische postoperative oder posttraumatische Schmerzen entwickeln sich aufgrund einer Operation oder einer Verletzung (Schug et al., 2019). Diese Kategorie umfasst auch chronische Schmerzen, welche sich durch eine Operation oder Verletzung weiter verschlimmern. In beiden Fällen müssen die Schmerzen im Bereich der Verletzung lokalisiert sein bzw. von dort in die Head-Zonen übertragen werden (im Falle einer Organverletzung oder -operation) oder in das Innervierungsbiet eines betroffenen Nervs ausstrahlen (Schug et al., 2019). Zu den Operationen, die häufig chronische Schmerzen nach sich ziehen, zählen beispielsweise Amputationen, Kaiserschnitte und Bypass-Operationen (Schug & Bruce, 2017). Die Prävalenz

chronischer posttraumatischer Schmerzen unter Patientinnen und Patienten mit schweren Verletzungen wird auf 72 % geschätzt (Holmes et al., 2010).

Chronische sekundäre muskuloskelettale Schmerzen betreffen Gelenke, die Wirbelsäule, Muskeln, Knochen oder Sehnen (Perrot et al., 2019). Sie werden meist durch chronische Entzündungsprozesse (z. B. Autoimmunerkrankungen wie rheumatoide Arthritis), strukturelle Veränderungen (z. B. Arthrose) oder neurologische Erkrankungen (z. B. Versteifungen bei Morbus Parkinson) ausgelöst (Perrot et al., 2019). Die neue Diagnose für chronische sekundäre muskuloskelettale Schmerzen ist von besonderer Bedeutung, da Arthrose und rheumatoide Arthritis zu den häufigsten Ursachen für chronische Schmerzen gehören (Breivik et al., 2006). Die neuen Diagnosen können Schmerzen im Zusammenhang mit diesen Erkrankungen endlich sichtbar machen und multimodale Behandlungswege eröffnen.

Chronische sekundäre viszerale Schmerzen werden durch eine Erkrankung der inneren Organe verursacht (Aziz et al., 2019). Hierzu zählen Erkrankungen mit vaskulären Mechanismen (z. B. Vaskulitis, Sichelzellenkrankheit), chronische Entzündungen (z. B. Morbus Crohn, Endometriose) sowie Erkrankungen mit mechanischen Faktoren wie beispielsweise Gallensteine (Aziz et al., 2019). Die Schmerzintensität muss jedoch nicht zwangsläufig mit der Schwere der zugrundeliegenden Erkrankung korrelieren, diesbezüglich wird kein linearer Zusammenhang vorausgesetzt (Aziz et al., 2019). Chronische viszerale Schmerzen spielen in der schmerztherapeutischen Versorgung eine untergeordnete Rolle (Frettlöh et al., 2009). Die meisten Patientinnen und Patienten mit chronischen viszeralen Schmerzen erhalten keine multimodale Schmerztherapie, sondern werden beispielsweise gynäkologisch, internistisch oder allgemeinmedizinisch versorgt (Elsenbruch et al., 2015).

Chronische neuropathische Schmerzen entstehen aufgrund einer Erkrankung oder Verletzung des somatosensorischen Nervensystems (Scholz et al., 2019). Chronische periphere neuropathische Schmerzen werden von chronischen zentralen neuropathischen Schmerzen unterschieden – je nachdem, ob das periphere Nervensystem (z. B. Radikulopathie, Polyneuropathie) oder das zentrale Nervensystem (z. B. Schlaganfall, multiple Sklerose) betroffen ist (Scholz et al., 2019). Das etablierte Gradierungsschema für neuropathische Schmerzen von Finnerup et al. (2016) wurde in die diagnostischen Kriterien neuropathischer Schmerzen für die ICD-11 integriert (Scholz et al., 2019). Die Prävalenz chronischer

neuropathischer Schmerzen in der Allgemeinbevölkerung beträgt ca. 7 % (Bouhassira et al., 2008; Ohayon & Stingl, 2012). Chronische neuropathische Schmerzen zeichnen sich im Vergleich zu chronischen Schmerzen ohne neuropathische Mechanismen u. a. durch eine höhere Schmerzintensität (Bouhassira et al., 2008; Inoue et al., 2017) sowie mehr schmerzbedingte Krankentage aus (Inoue et al., 2017; Ohayon & Stingl, 2012).

Chronische sekundäre Kopf- oder Gesichtsschmerzen werden durch eine entsprechende Erkrankung im Bereich des Kopfes oder Gesichtes ausgelöst (Benoliel et al., 2019). Die etablierte Internationale Klassifikation von Kopfschmerzerkrankungen (ICHD-3, Headache Classification Committee of the International Headache Society (IHS), 2018) sowie die neue Internationale Klassifikation orofazialer Schmerzen (ICOP, International Classification of Orofacial Pain, 1st edition (ICOP), 2020) wurden in die ICD-11-Klassifikation chronischer Kopf- oder Gesichtsschmerzen integriert (Benoliel et al., 2019). Beispiele chronischer sekundärer Kopf- oder Gesichtsschmerzen umfassen chronische Kopfschmerzen bei übermäßigem Medikamentengebrauch (z. B. Triptane) und chronische Zahnschmerzen (z. B. im Zusammenhang mit Karies). Parallel zur ICHD-3 verlangt die ICD-11-Diagnose chronischer sekundärer Kopf- oder Gesichtsschmerzen ein zusätzliches Zeitkriterium: die Kopfschmerzen müssen an mindestens 15 Tagen pro Monat vorliegen (Benoliel et al., 2019; Headache Classification Committee of the International Headache Society (IHS), 2018). Die Prävalenz chronischer Kopfschmerzen in der Allgemeinbevölkerung wird auf 3 % geschätzt (Stovner et al., 2007).

Die ICD-11-Klassifikation chronischer Schmerzen ermöglicht es, auch die Schmerzschwere sowie den zeitlichen Verlauf der Schmerzen und den Einfluss psychosozialer Faktoren zu kodieren (Treede et al., 2019). Hierbei setzt sich die Schmerzschwere aus der Schmerzintensität, schmerzbezogener Beeinträchtigung (z. B. bei Alltagsaktivitäten) und schmerzbezogener Belastung (z. B. Hilflosigkeit, Sorgen, Wut) zusammen. Die Kodierung der Schmerzschwere ermöglicht es, die Schmerzen auch dimensional zu beschreiben und bietet die Möglichkeit, u. a. in der Forschung die Vergleichbarkeit von Stichproben zu erhöhen (Barke et al., 2020). Es ist hervorzuheben, dass diese Zusatzkodierung für alle Formen chronischer Schmerzen, sowohl primäre als auch sekundäre Schmerzen, zur Anwendung kommen sollte (Treede et al., 2019). Des Weiteren ermöglichen Codes für schmerzspezifische Funktionsbereiche (z. B. Gehen, bezahlte Tätigkeit, intime Beziehungen) auf Grundlage der

ICF eine Integration der ICD-11-Schmerzdiagnosen mit der Kodierung der Funktionsfähigkeit (Nugraha et al., 2019).

In der hausärztlichen Primärversorgung lässt sich fast jeder vierte Arztbesuch auf chronische Schmerzen zurückführen (Frießem et al., 2009). Eine weitere Stärke der neuen Klassifikation ist es, dass sie durch die unterschiedlichen Diagnoseebnen auch in der Primärversorgung und ähnlichen Settings, in denen spezifische Diagnosen nicht notwendig oder nicht möglich sind (z. B. Notfallversorgung, ressourcenschwache Settings) anwendbar ist (Smith et al., 2019). In diesen Kontexten können die Diagnosen auf der obersten Diagnoseebene wie in Abbildung 1 dargestellt angewendet werden.

Die neue ICD-11-Klassifikation chronischer Schmerzen hat zum Ziel, durch klar definierte Schmerzsyndrome sowie operationalisierte Diagnosekriterien sowohl die Versorgung von Patientinnen und Patienten mit chronischen Schmerzen als auch die Schmerzforschung zu verbessern (Treede et al., 2019). Des Weiteren bieten die klar definierten und operationalisierten Diagnosen eine bessere Grundlage für gesundheitspolitische Entscheidungen und können so auch den Behandlungszugang zu angemessener schmerztherapeutischer Versorgung verbessern (Treede et al., 2019). Klar definierte Diagnosen sind eine wichtige Grundvoraussetzung für epidemiologische Untersuchungen (Steingrímsdóttir et al., 2017) sowie für die Berücksichtigung chronischer Schmerzen im öffentlichen Gesundheitswesen (D. S. Goldberg & McGee, 2011). Die neuen ICD-11-Schmerzdiagnosen leisten hier einen essenziellen Beitrag (Nunes Sá et al., 2019). Chronische Schmerzen im Zusammenhang mit einer Grunderkrankung werden in epidemiologischen Untersuchungen und Registerstudien erstmals sichtbar, was die Schätzung der durch Schmerzen bedingten Krankheitslast verbessert (Blyth & Huckel Schneider, 2018; Rice et al., 2016). Dies wiederum ist eine wichtige Voraussetzung, damit chronische Schmerzen im öffentlichen Gesundheitswesen auf nationaler und internationaler Ebene angemessen berücksichtigt werden (Blyth & Huckel Schneider, 2018).

2.4 Diagnostische Klassifikationssysteme

2.4.1 Gütekriterien eines diagnostischen Klassifikationssystems

Diagnostische Klassifikationssysteme haben zum Ziel, durch die Bildung von Kategorien einzelne Fälle, bzw. Erkrankungen von Patientinnen und Patienten, besser

beschreiben zu können (Jablensky, 1988). Dies reduziert für Nutzerinnen und Nutzer des Klassifikationssystems die kognitive Beanspruchung und kann auch zur Generierung von Forschungshypothesen beitragen (Jablensky, 1988). So kann ein Klassifikationssystem beispielsweise Forschungslücken aufzeigen und entsprechende Untersuchungen ermöglichen (Fillingim et al., 2014). Zudem werden Stichproben zwischen Studien vergleichbar, wenn ein standardisiertes Klassifikationssystem angewendet wird (Fillingim et al., 2014).

Die Kategorien oder Diagnosen eines diagnostischen Klassifikationssystems sollten die Grundgesamtheit der Zielsyndrome vollständig erfassen und gleichzeitig klar voneinander abgrenzbar sein (Fillingim et al., 2014; Jablensky, 2016). Die klare Abgrenzung einzelner Kategorien bzw. Diagnosen voneinander ist zudem auch eine wichtige Voraussetzung für die Validität eines Klassifikationssystems (Bruehl et al., 2016; Kendell & Jablensky, 2003). In Bezug auf diagnostische Klassifikationssysteme kommt v. a. der prädiktiven Validität, also dem Maß, inwiefern die Diagnosen Aussagen z. B. über den Krankheitsverlauf ermöglichen, eine besondere Bedeutung zu (Kendell, 1989). Die Entwicklung eines Klassifikationssystems durch ein Gremium aus Expertinnen und Experten lässt Rückschlüsse auf die Inhaltsvalidität der Diagnosen zu (Bruehl et al., 2016). Da es für chronische Schmerzen keinen externen Referenzstandard gibt, kann die Kriteriumsvalidität eines entsprechenden Klassifikationssystems kaum untersucht werden (Bruehl et al., 2016).

Reliabilität ist ein weiteres wichtiges Gütekriterium eines diagnostischen Klassifikationssystems (Bruehl et al., 2016). Wenn es für Diagnosen keinen objektiven externen Referenzstandard (z. B. Blutwerte) gibt, wie es bei chronischen Schmerzen der Fall ist (Bruehl et al., 2016), können operationalisierte Kriterien die Reliabilität einer Klassifikation erhöhen (Jablensky, 2016; Kendell & Jablensky, 2003).

Sowohl Validität als auch Reliabilität sind grundlegende Voraussetzungen für die klinische Nützlichkeit eines diagnostischen Klassifikationssystems und seiner einzelnen Kategorien (First, 2010; Mullins-Sweatt & Widiger, 2009; Reed, 2010). Ein diagnostisches Klassifikationssystem ist klinisch nützlich, wenn die Diagnosen die Kommunikation (z. B. zwischen Behandelnden, aber auch mit Patientinnen und Patienten) erleichtern, in der Praxis einfach anwendbar und effektiv sind, zur Wahl einer geeigneten Behandlung beitragen, Prognosen (z. B. zum Krankheitsverlauf oder dem Ansprechen auf ein bestimmtes Therapieverfahren) ermöglichen, die Dokumentation erleichtern, das Management der

Beschwerden der Patientinnen und Patienten verbessern sowie Forschung und Gesundheitspolitik unterstützen (Fillingim et al., 2014; First, 2010; First et al., 2004; Kendell & Jablensky, 2003; Mullins-Sweatt & Widiger, 2009; Reed, 2010).

Im Rahmen des ICD-Revisionsprozesses wurden die Verbesserung der klinischen Nützlichkeit sowie die globale Anwendbarkeit der Klassifikation in unterschiedlichen Settings (inkl. Primärversorgung und LMIC) als wichtige Ziele formuliert (International Advisory Group for the Revision of ICD-10 Mental and Behavioural Disorders., 2011; Reed, 2010). Wenn Nutzerinnen und Nutzer eine Klassifikation als klinisch nützlich empfinden, steigt ihre Akzeptanz derselben (First, 2010). Dies wiederum kann die Wahrscheinlichkeit erhöhen, dass das neue Klassifikationssystem eingesetzt wird (First, 2010; Stein et al., 2020).

Um die Reliabilität von Diagnosen und somit auch die eines diagnostischen Klassifikationssystems zu erhöhen, können Klassifikationsalgorithmen angewendet werden (Malt, 1986; Moloney et al., 2015; Rinaldi et al., 2000). Des Weiteren wird durch die Anwendung eines Klassifikationsalgorithmus auch die Effizienz der Diagnostik erhöht (Bollestad et al., 2015). Die Diagnosen werden konsistent vergeben (Coleman, 2016), die Akkuratheit der Diagnosen steigt (Morgan et al., 2000) und Fehler werden reduziert (Jablonski et al., 2011).

2.4.2 Evaluation eines diagnostischen Klassifikationssystems

Bereits vor 50 Jahren formulierten Robins & Guze (1970) fünf Phasen, um ein diagnostisches Klassifikationssystem (für psychische Erkrankungen) zu validieren: die Diagnosen sollten klar beschrieben werden, mittels Laborstudien sollten Unterschiede auf physiologischer Ebene untersucht werden, Ausschlusskriterien für die Abgrenzung einzelner Diagnosen sollten formuliert werden, die Stabilität der Diagnosen sollte mittels Follow-Up-Studien untersucht werden und familiäre Häufungen der Diagnosen sollten mit Familienstudien überprüft werden.

Aufgrund der großen Bedeutung der klinischen Nützlichkeit für den aktuellen ICD-Revisionsprozess (International Advisory Group for the Revision of ICD-10 Mental and Behavioural Disorders., 2011) liegt auf dieser auch der Fokus der WHO-Feldstudien zur Evaluation der ICD-11 (Keeley et al., 2016). Hierbei werden formative Feldstudien, welche im Rahmen der Entwicklung eines Klassifikationssystems durchgeführt werden, von evaluativen

Feldstudien abgegrenzt, welche die finale Klassifikation untersuchen (Keeley et al., 2016; Reed, 2010). Formative Feldstudien haben zum Ziel, die allgemeine Struktur des Klassifikationssystems zu überprüfen und ggf. anzupassen. Evaluative Feldstudien hingegen untersuchen die fertige Klassifikation hinsichtlich ihrer Reliabilität, klinischen Nützlichkeit und Anwendbarkeit (Keeley et al., 2016; Reed, 2010). Im Rahmen der Evaluation der ICD-11-Diagnosen für psychische Erkrankungen werden sowohl vignettenbasierte Fall-Kontroll-Studien als auch naturalistische Implementierungs-Feldstudien im klinischen Setting vorgeschlagen (Keeley et al., 2016). Keine dieser Methoden ist der jeweils anderen überlegen, vielmehr ergänzen sie sich (Keeley et al., 2016). Aussagen zur klinischen Nützlichkeit eines Klassifikationssystems sind jedoch nur möglich, wenn die Diagnosen und deren Bewertung sich auf echte Patientinnen und Patienten in einem klinischen Setting beziehen (First, 2010).

Naturalistische Implementierungs-Feldstudien eignen sich besonders gut, um die klinische Nützlichkeit und Anwendbarkeit der neuen Diagnosen im klinischen Alltag zu untersuchen (Bruehl et al., 2016; Mullins-Sweatt & Widiger, 2009; Reed, Sharan, et al., 2018). Die üblichen Ergebnismaße bei naturalistischen Implementierungs-Feldstudien sind die vergebene(n) Diagnose(n), die eingeschätzte klinische Nützlichkeit der Diagnosen sowie deren Interrater-Reliabilität (Keeley et al., 2016). Da die direkte Messung der klinischen Nützlichkeit eines diagnostischen Klassifikationssystems in der Routineversorgung nur schwer umsetzbar ist, kommt der subjektiven Einschätzung der klinischen Nützlichkeit durch die Teilnehmenden eine besondere Bedeutung zu (First, 2010). Um die Aussagekraft dieser Einschätzung zu erhöhen, sollte auch das aktuell verwendete Klassifikationssystem hinsichtlich seiner klinischen Nützlichkeit bewertet werden (First, 2010). Dies erhöht auch die Interpretierbarkeit der Einschätzungen. Des Weiteren sollte die Einfachheit der Diagnosevergabe als Maß für die Akzeptanz des neuen Klassifikationssystems unter den Teilnehmenden erhoben werden (First et al., 2004).

Wie bereits erwähnt, ist die globale Anwendbarkeit der ICD-11 neben klinischer Nützlichkeit eines der Hauptziele des Revisionsprozesses (International Advisory Group for the Revision of ICD-10 Mental and Behavioural Disorders., 2011). Aus diesem Grund sollten Feldstudien, welche ICD-11-Diagnosen überprüfen, international durchgeführt werden (Keeley et al., 2016). Hierbei sollten neben spezialisierten Settings auch die Primärversorgung und LMIC berücksichtigt werden (Rief et al., 2012). Die globale Durchführung der Feldstudien

in einer Vielzahl von Settings ermöglicht die Überprüfung der globalen Anwendbarkeit der Klassifikation und erhöht die Generalisierbarkeit der Ergebnisse (D. P. Goldberg et al., 2016; Reed, Sharan, et al., 2018).

In Feldstudien zur Evaluation eines neuen diagnostischen Klassifikationssystems findet für die teilnehmenden Ärztinnen und Ärzte, bzw. Psychologinnen und Psychologen o. ä. üblicherweise vor der Datenerhebung eine kurze Einführung in die neuen Diagnosen und Kriterien statt (Clarke et al., 2013; Keeley et al., 2016; Medina-Mora et al., 2018; Reed, Sharan, et al., 2018; Regier et al., 1994). Meist sind für die Bestimmung der Interrater-Reliabilität zwei Teilnehmende an der Erhebung einer Patientin oder eines Patienten beteiligt, um dieselbe Grundlage für Diagnostik und Bewertung sicherzustellen (Keeley et al., 2016; Medina-Mora et al., 2018; Reed, Sharan, et al., 2018). Als Maß für die Interrater-Reliabilität von Diagnosen (bzw. Kategorien des Klassifikationssystems) in naturalistischen Implementierungs-Feldstudien wird kappa (κ) bestimmt (Bruehl et al., 2016; Clarke et al., 2013; Medina-Mora et al., 2018; Reed, Sharan, et al., 2018). Hierbei ermöglicht Fleiss' κ die Bestimmung der Interrater-Reliabilität pro Kategorie, wenn insgesamt mehr als zwei Teilnehmende an der Studie beteiligt sind und die einzelnen diagnostischen Einschätzungen somit von jeweils unterschiedlichen Paaren vorgenommen werden (Bortz et al., 2008; Hallgren, 2012). Trotz der großen Wichtigkeit, Feldstudien zur Evaluation eines neuen Klassifikationssystems in einem globalen Setting inkl. LMIC durchzuführen (International Advisory Group for the Revision of ICD-10 Mental and Behavioural Disorders., 2011; Rief et al., 2012), wurde ein Großteil solcher Studien, z. B. im Kontext der Evaluation der ICD-10 (Regier et al., 1994) oder des Diagnostischen und statistischen Leitfadens psychischer Störungen (DSM-5) (Clarke et al., 2013) nur in westlichen Industrienationen durchgeführt. Auch bezüglich der ICD-11 wurden bisher nur sehr wenige naturalistische Implementierungs-Feldstudien in einem globalen Kontext durchgeführt (Reed, Keeley, et al., 2018; Reed, Sharan, et al., 2018).

3 Darstellung des Dissertationsvorhabens

3.1 Relevanz und Herleitung der Fragestellung

Um die Probleme zu überwinden, welche aus der mangelhaften Repräsentation chronischer Schmerzen in der ICD-10 resultieren (Rief et al., 2010, 2012), wurde eine umfassende Klassifikation chronischer Schmerzen von einer Arbeitsgruppe der IASP entwickelt und in die ICD-11 aufgenommen (Treede et al., 2015, 2019). Die ICD-11 wird im Januar 2022 international in Kraft treten (World Health Organization, 2019). Um die Qualität eines diagnostischen Klassifikationssystems zu sichern (z. B. Reliabilität, klinische Nützlichkeit, Abgrenzbarkeit der Kategorien), ist dessen Evaluation von essenzieller Bedeutung (Bruehl et al., 2016; Keeley et al., 2016; Reed, 2010). Hierzu werden formative und evaluative Feldstudien unterschieden (Keeley et al., 2016; Reed, 2010). Das übergeordnete Ziel der vorliegenden Dissertation war die Evaluation der neuen ICD-11-Klassifikation chronischer Schmerzen im Rahmen von sowohl formativen als auch evaluativen Feldstudien.

In einem ersten Schritt des Dissertationsvorhabens wurde eine formative Feldstudie durchgeführt, um die sieben Hauptkategorien der ICD-11-Schmerzklassifikation hinsichtlich der vollständigen Erfassung chronischer Schmerzen und klarer Kategoriengrenzen zu untersuchen (Studie 1). Des Weiteren fand durch die subjektive Einschätzung der Teilnehmenden eine initiale Erhebung der empfunden klinischen Nützlichkeit statt. Durch die Angabe der diagnostischen Sicherheit der Teilnehmenden wurden Rückschlüsse ermöglicht, wie einfach die neue Klassifikation in der Anwendung ist.

Die neue Klassifikation chronischer Schmerzen wurde in die offizielle ICD-11 aufgenommen (World Health Organization, 2020b). Damit die neue Schmerzklassifikation international umgesetzt werden kann, muss sie sich in die übergeordnete Struktur und Funktionsweise der ICD-11 einbetten lassen. Daher wurde im Rahmen einer zweiten formativen Feldstudie (Studie 2), welche internetbasiert durchgeführt wurde, überprüft, ob sich die ICD-11-Klassifikation chronischer Schmerzen erfolgreich in die Struktur der ICD-11 integrieren lässt und ob die von der WHO festgelegten Kodierregeln auf die neuen Schmerzdiagnosen anwendbar sind.

Insgesamt besteht die neue ICD-11-Klassifikation chronischer Schmerzen aus ca. 100 Diagnosen auf mehreren Diagnoseebenen (World Health Organization, 2020c). Die Diagnosen umfassen über 200 operationalisierte Kriterien. Die große Menge an Diagnosen und Kriterien könnte die Nutzung der neuen Klassifikation erschweren. Zudem wurde in Studien 1 und 2 nicht kontrolliert, ob die Kriterien richtig angewendet wurden und die vergebenen Diagnosen somit korrekt waren. Klassifikationsalgorithmen können die Reliabilität von Diagnosen erhöhen (Malt, 1986; Rinaldi et al., 2000) und die Anwendung eines Klassifikationssystems vereinfachen (Kellow & Drossman, 2010; Martel-Pelletier et al., 2019; Park et al., 2015). Zudem steigt bei der Anwendung eines Klassifikationsalgorithmus die Einhaltung der diagnostischen Kriterien (Bollestad et al., 2015), was vor allem im Forschungskontext von besonderer Relevanz ist. Ziel von Studie 3 war es, einen Klassifikationsalgorithmus als standardisierten Weg durch die neuen Kriterien und Diagnosen zu entwickeln, um die Reliabilität der Diagnosen zu erhöhen und die Anwendung der Klassifikation zu standardisieren. Der Algorithmus sollte die verschiedenen Diagnoseebenen mit jeweils unterschiedlichem Spezifitätsgrad widerspiegeln und dadurch in einer Vielzahl von Settings (inkl. Primärversorgung und LMIC) in Forschung und Praxis anwendbar sein. Der Algorithmus hat weiterhin zum Ziel, den Diagnoseprozess für Nutzerinnen und Nutzer zu vereinfachen, dadurch die subjektive Diagnosesicherheit zu erhöhen und somit die Anwendung der Klassifikation zu vereinfachen. Daher war ein weiteres Ziel von Studie 3, zu überprüfen, ob und inwieweit der entwickelte Klassifikationsalgorithmus diese Ziele erreicht.

Im Gegensatz zu formativen Feldstudien ermöglichen evaluative Feldstudien die Überprüfung eines diagnostischen Klassifikationssystem nach Abschluss seiner Entwicklung (Keeley et al., 2016; Reed, 2010). Naturalistische Implementierungs-Feldstudien gehören zu den evaluativen Feldstudien und ermöglichen es, die Anwendung und Implementierung eines neuen Klassifikationssystems in realen klinischen Settings zu untersuchen (Keeley et al., 2016). Sie bieten zudem eine ideale Möglichkeit, die klinische Nützlichkeit der neuen Diagnosen sowie deren Reliabilität zu evaluieren (Bruehl et al., 2016). Klinische Nützlichkeit sowie globale Anwendbarkeit sind die Hauptziele des ICD-Revisionsprozesses (International Advisory Group for the Revision of ICD-10 Mental and Behavioural Disorders., 2011; Reed, 2010). Ziel von Studien 4 und 5 war die Evaluation der ICD-11 Klassifikation chronischer Schmerzen hinsichtlich Reliabilität und klinischer Nützlichkeit in Ländern mit

unterschiedlichem Einkommensstatus. Hierfür wurde eine naturalistische Implementierungs-Feldstudie in Schmerzkliniken in Kuba, Indien und Neuseeland durchgeführt (Studie 5). Vorab wurde ein detailliertes Studienprotokoll entwickelt und veröffentlicht (Studie 4).

3.2 Fragestellungen des Dissertationsvorhabens

Aus der beschriebenen Darstellung der aktuellen Forschungslage lassen sich die folgenden Fragestellungen für die vorliegende Dissertation ableiten:

Studie 1: Werden mit den sieben Hauptkategorien der ICD-11-Klassifikation chronischer Schmerzen alle Schmerzsyndrome vollständig erfasst? Sind die Kategorien klar voneinander abgrenzbar? Wie werden die klinische Nützlichkeit und Einfachheit der Hauptkategorien in einem klinischen Setting eingeschätzt?

Studie 2: Ist die Klassifikation in die übergeordnete Struktur der ICD-11 integrierbar und sind die Kodierregeln der WHO auf sie anwendbar? Werden die korrekten Diagnosecodes gefunden? Wie wird die klinische Nützlichkeit der neuen Diagnosen eingeschätzt?

Studie 3: Wie kann bei der großen Anzahl an Diagnosen und operationalisierten Kriterien der Klassifikationsprozess kontrolliert, strukturiert und vereinfacht werden? Wie wird die Nützlichkeit des entstandenen Klassifikationsalgorithmus eingeschätzt?

Studie 4: Wie kann eine naturalistische Implementierungs-Feldstudie zur Evaluation der ICD-11-Klassifikation chronischer Schmerzen in der Routineversorgung von Schmerzkliniken international umgesetzt werden?

Studie 5: Sind die Diagnosen der neuen Klassifikation reliabel? Wie schätzen Schmerzspezialistinnen und Schmerzspezialisten die neuen Diagnosen hinsichtlich ihrer klinischen Nützlichkeit ein, wenn sie in der Routineversorgung angewendet werden? Ist die neue Klassifikation weltweit anwendbar?

4 Zusammenfassungen der Studien

4.1 Studie 1: Pilotfeldstudie der ICD-11-Klassifikation chronischer Schmerzen: Ergebnisse einer naturalistischen Kodierstudie

Barke, A., Korwisi, B., Casser, H.-R., Fors, E. A., Geber, C., Schug, S. A., Stubhaug, A., Ushida, T., Wetterling, T., Rief, W. & Treede. R.-D. (2018). Pilot field testing of the chronic pain classification for ICD-11: The results of ecological coding. *BMC Public Health, 18,* 1239. https://doi.org/10.1186/s12889-018-6135-9

Hintergrund. Bis zu ein Fünftel der Bevölkerung sind von chronischen Schmerzen betroffen (Breivik et al., 2006). Trotz dieser großen Bedeutung werden chronische Schmerzen in der ICD-10 jedoch nur unzureichend abgebildet (Rief et al., 2010). Die neue ICD-11-Klassifikation chronischer Schmerzen umfasst sieben Hauptkategorien (Treede et al., 2015, 2019). Einige dieser neuen Kategorien waren in der ICD-10 überhaupt nicht abbildbar (Treede et al., 2015). Jede neue Klassifikation muss hinsichtlich ihrer Qualitätsmerkmale evaluiert und überprüft werden (Reed, 2010). Hierbei können formative Feldstudien im Rahmen der Entwicklung eines Klassifikationssystems von evaluativen Feldstudien nach Abschluss der Entwicklung abgegrenzt werden (Reed, 2010). Ziel der Pilotstudie war es, im Sinne einer formativen Feldstudie die sieben Hauptkategorien der ICD-11 Klassifikation chronischer Schmerzen hinsichtlich der vollständigen Erfassung von Schmerzsyndromen, klarer Kategoriengrenzen, eingeschätzter klinischer Nützlichkeit sowie subjektiver Diagnosesicherheit in einem naturalistischen Kliniksetting zu überprüfen.

Methoden. Die Pilotstudie wurde während der laufenden Entwicklung der ICD-11 Klassifikation chronischer Schmerzen im Juli und August 2016 durchgeführt. Insgesamt nahmen 14 spezialisierte Schmerzzentren in Japan, Australien, Deutschland und Norwegen sowie ein allgemeinmedizinisches Zentrum in Norwegen an der Studie teil. Die Ärztinnen und Ärzte wendeten die sieben ICD-11-Hauptdiagnosen auf insgesamt 507 konsekutive Patientinnen und Patienten an. Des Weiteren dokumentierten sie die entsprechenden ICD-10-Diagnosen bzw. im Falle des allgemeinmedizinischen Zentrums die entsprechenden Diagnosen der Internationalen Klassifikation für die Primärversorgung (ICPC-2). Die Ärztinnen und Ärzte schätzten auch die klinische Nützlichkeit der Diagnosen sowie ihre subjektive diagnostische Sicherheit auf einer jeweils vierstufigen Skala von 0 *überhaupt nicht*

nützlich/sicher bis 3 *vollkommen nützlich/sicher* ein. Die häufigsten Diagnosen sowie die eingeschätzte klinische Nützlichkeit und subjektive Diagnosesicherheit wurden deskriptiv analysiert. Des Weiteren wurde untersucht, wie viel Prozent der chronischen Schmerzsyndrome der Patientinnen und Patienten mit den Hauptkategorien erfasst werden konnten und ob die Kategorien klar voneinander abgrenzbar waren (prozentualer Anteil an Schmerzsyndromen, die in mehr als eine Kategorie eingeordnet werden).

Ergebnisse. Am häufigsten wurden die Diagnosen „Chronische primäre Schmerzen" sowie „Chronische sekundäre muskuloskelettale Schmerzen" vergeben. Die klinische Nützlichkeit wurde im Mittel als 1,9 ± 1,0 eingeschätzt, die mittlere subjektive Diagnosesicherheit als 2,0 ± 1,0. Die sieben Hauptkategorien erfassten 97,0 % der vorliegenden chronischen Schmerzsyndrome. Nur 3,0 % der Schmerzsyndrome konnten keiner Hauptkategorie zugeordnet werden und würden im finalen ICD-11-System in die Restkategorie „Chronische Schmerzen, unspezifisch" fallen. Nach einer Artefaktbereinigung wurden lediglich 2,0 % der Schmerzsyndrome in mehr als eine Kategorie eingeordnet. Durch den unvollständigen Stand der Klassifikation zum Zeitpunkt der Pilotstudie war es zu Kodierfehlern gekommen, die durch die finale Klassifikation verhindert werden. Diese Fehler wurden im Rahmen der Artefaktbereinigung gelöst, um eine aussagekräftige Interpretation der Daten zu ermöglichen.

Diskussion. Die Pilotfeldstudie war die erste Studie, welche die Anwendbarkeit der neuen ICD-11-Klassifikation chronischer Schmerzen in einem naturalistischen klinischen Setting evaluierte. Der hohe Anteil an Patientinnen und Patienten, welche die neue Diagnose „chronische primäre Schmerzen" erhielten, deutet darauf hin, dass diese neue Diagnose von Anwenderinnen und Anwendern gut akzeptiert wird. Die ICD-11-Diagnosen wurden insgesamt als sehr nützlich für die klinische Praxis eingeschätzt. Obwohl die teilnehmenden Ärztinnen und Ärzte kein formelles Training zu den neuen Diagnosen erhalten hatten, schätzen sie ihre subjektive Sicherheit bei der Diagnosevergabe sehr hoch ein. Die neue Klassifikation erfasste fast alle chronischen Schmerzsyndrome der Patientinnen und Patienten. Nur ein sehr geringer Anteil konnte keiner der sieben Hauptkategorien zugeordnet werden. Des Weiteren wurde deutlich, dass nach einer Artefaktbereinigung ein ebenfalls nur sehr geringer Anteil an Schmerzsyndromen in mehrere Kategorien gleichzeitig eingeordnet wurde. Dies belegt, dass die sieben Hauptkategorien klar voneinander abgrenzbar sind. Durch die

weitere Ausarbeitung der Klassifikation kann den hier begegneten Artefakten vorgebeugt werden. Zukünftige Studien sollten die finale Klassifikation evaluieren und hierbei auch ein Maß für die Reliabilität der Diagnosen berücksichtigen. Weiterhin sollten diese auch nicht-ärztliche Anwenderinnen und Anwender der ICD (z. B. professionelle Kodiererinnen und Kodierer) einschließen.

4.2 Studie 2: Die Klassifikation chronischer Schmerzen in der ICD-11: Ergebnisse der WHO-Feldstudie aus dem Jahr 2017

Barke, A., Korwisi, B., Jakob, R., Konstanjsek, N., Rief, W. & Treede, R.-D. (submitted). Classification of chronic pain for the International Classification of Diseases (ICD-11): Results of the 2017 international WHO field testing. Manuscript submitted for publication in *BMC Medicine.*

Hintergrund. Um die unsystematische Repräsentation chronischer Schmerzen in der ICD-10 (Rief et al., 2010, 2012) zu verbessern, wurde für die ICD-11 eine neue Klassifikation chronischer Schmerzen entwickelt (Treede et al., 2015). Die ICD-11 wurde im Mai 2019 offiziell verabschiedet (World Health Organization, 2019). Ein Hauptziel des ICD-Revisionsprozesses war die Verbesserung der klinischen Nützlichkeit (Jakob, 2018b; Reed, 2010). Neben klinischer Nützlichkeit muss aber auch die korrekte Anwendung der in der ICD-11 gelisteten Codes gewährleistet sein. Ziel der WHO-Feldstudie war es, die ICD-11-Klassifikation chronischer Schmerzen hinsichtlich korrekter Kodierung, Einfachheit, Detailtiefe und Ambiguität mit der ICD-10 zu vergleichen. Des Weiteren sollte überprüft werden, ob die von der WHO definierten Kodierregeln auf die neuen Schmerzdiagnosen anwendbar sind und wie die klinische Nützlichkeit der neuen Diagnosen eingeschätzt wird.

Methoden. Die internetbasierte Datenerhebung fand von Juni bis August 2017 über die offizielle Studienplattform der WHO, das ICD *Field Implementation Tool* (ICD-FiT, Donada et al., 2017) im Rahmen der offiziellen WHO-Feldstudien statt. Insgesamt nahmen n = 177 Schmerzspezialistinnen und Schmerzspezialisten aus 35 Ländern an der Studie teil. Alle Teilnehmenden hatten die Möglichkeit, sich vorab über die ICD-11-Schmerzklassifikation sowie die für die Studie relevanten Internet-Plattformen (z. B. ICD-FiT, ICD-11-Browser) zu informieren. Die Studie bestand aus zwei Teilen sowie einer abschließenden allgemeinen Bewertung: In einem ersten Teil, dem „Line Coding“, ordneten die Teilnehmenden ICD-10- und ICD-11-Diagnosecodes 18 kurzen diagnostischen Begriffen zu („lines“, z. B. „chronic dental pain“ [chronische Zahnschmerzen]). Es wurde erfasst, ob die Teilnehmenden Schwierigkeiten bei der Code-Zuweisung (*ja*/*nein*) hatten, ob Ambiguität bzgl. der Diagnosen vorlag (*ja*/*nein*), ob die korrekten Diagnosecodes zugewiesen wurden (*ja*/*nein*) und ob die Detailtiefe der Codes angemessen war *(zu wenig Detail*/*genau richtig*/*zu detailliert)*. Im zweiten Teil, dem „Case Coding“, ordneten die Teilnehmenden ICD-11-Codes kurzen Fallvignetten

(„cases“) zu und gaben an, ob die Kodierregeln in der Fallvignette korrekt angewendet wurden. Des Weiteren schätzten sie die klinische Nützlichkeit der Klassifikation auf einer Skala von 0 *überhaupt nicht nützlich* bis 5 *sehr nützlich* ein. In der abschließenden allgemeinen Bewertung wurden die Detailtiefe der Klassifikation (*nicht detailliert genug*/*genau richtig*/*zu detailliert*), die Einfachheit der Nutzung (1 *sehr schwierig* bis 5 *sehr einfach*) sowie die Gesamtabdeckung der Klassifikation (1 *sehr schlecht* bis 5 *sehr gut*) bewertet. Für das Line Coding wurden unterschiede zwischen ICD-10 und ICD-11 mit dem McNemar-Test (korrekte Kodierung, Ambiguität, Schwierigkeiten) bzw. dem McNemar-Bowker-Test (Detailtiefe) analysiert. Für das Case Coding wurde der prozentuale Anteil korrekter Kodierungen sowie der Mittelwert der eingeschätzten klinischen Nützlichkeit und die Anwendung der Kodierregeln deskriptiv ausgewertet. Für die abschließende Gesamtbewertung wurden Häufigkeiten für die Einschätzungen der Detailtiefe, der Einfachheit und der Gesamtabdeckung berechnet.

Ergebnisse. Die Teilnehmenden bearbeiteten insgesamt 2576 diagnostische Begriffe im Line Coding. Die ICD-11-Kodierung war der ICD-10-Kodierung hinsichtlich des Anteils an korrekten Kodierungen [$\chi^2(1, N = 2576) = 229{,}23$, $p < 0{,}001$], Schwierigkeiten [$\chi^2(1, N = 2576) = 863{,}81$, $p < 0{,}001$], Ambiguität [$\chi^{2(}(1, N = 2512) = 1003{,}84$, $p < 0{,}001$] und Detailtiefe [$\chi^2(3\ \ N = 2515) = 1073{,}01$, $p < 0{,}001$] überlegen. Im Case Coding bearbeiteten die Teilnehmenden insgesamt 1342 Fallvignetten. Für 83,9 % der Vignetten wurde der korrekte ICD-11-Code zugeordnet; bei 98,4 % der Vignetten waren hierbei keine Schwierigkeiten aufgetreten. Die klinische Nützlichkeit der Klassifikation wurde im Mittel als $4{,}3 \pm 0{,}90$ bewertet. Bei 74,1 % der Vignetten wurden die Kodierregeln korrekt angewendet. Bei der abschließenden Gesamtevaluation gaben 85,5 % der Teilnehmenden an, dass die Detailtiefe der Klassifikation genau richtig sei, 88,2 % gaben an, dass die Klassifikation leicht oder sehr leicht zu nutzen sei und 97,3 % gaben an, dass die Gesamtabdeckung der chronischen Schmerzen gut oder sehr gut sei.

Diskussion. Die WHO-Feldstudie stellt eine weitere formative Feldstudie der neuen ICD-11-Klassifikation chronischer Schmerzen dar und kann somit auf den Ergebnissen der oben beschriebenen Pilotstudie (Barke et al., 2018) aufbauen. Es konnte gezeigt werden, dass die Schmerzdiagnosen nach ICD-11 hinsichtlich korrekter Kodierung, Einfachheit, Detailtiefe und Ambiguität der ICD-10 überlegen sind. Ein Großteil der Kodierungen nach ICD-11 in

beiden Studienteilen war korrekt, die Einfachheit der Nutzung wurde als sehr gut eingeschätzt. Auch die WHO-Kodierregeln wurden für einen Großteil der Fallvignetten korrekt angewendet. Dies stellt eine wichtige Grundvoraussetzung für die erfolgreiche Implementierung der Schmerzklassifikation in der ICD-11 dar. Des Weiteren wurden die klinische Nützlichkeit der neuen Schmerzklassifikation sowie ihre Gesamtabdeckung als sehr hoch eingeschätzt.

4.3 Studie 3: Ein Klassifikationsalgorithmus für die Klassifikation chronischer Schmerzen in der ICD-11: Entwicklung und Ergebnisse einer ersten Pilotevaluation

Korwisi, B., Hay, G., Attal, N., Aziz, Q., Bennet, M. I., Benoliel, R., Cohen, M., Evers, S., Giamberardino, M. A., Kaasa, S., Kosek, E., Lavand'homme, P., Nicholas, M., Perrot, S., Schug, S., Smith, B. H., Svensson, P., Vlaeyen, J. W. S., Wang, S.-J., Treede, R.-D., Rief, W. & Barke, A. (in press). Classification algorithm for the ICD-11 chronic pain classification (CAL-CP): Development and results from a preliminary pilot evaluation. Manuscript accepted for publication in *PAIN*.

Hintergrund. Die ICD-11-Schmerzklassifikation setzt sich aus sieben Hauptkategorien mit jeweils bis zu vier Unterkategorien zusammen (World Health Organization, 2020c). Insgesamt beinhaltet die ICD-11 etwa 100 verschiedene Diagnosen für chronische Schmerzen mit unterschiedlichem Spezifitätsgrad. Um eine dieser Diagnosen vergeben zu können, müssen spezifische operationalisierte Diagnosekriterien erfüllt sein. Insgesamt enthält die ICD-11-Klassifikation chronischer Schmerzen mehr als 200 verschiedene Diagnosekriterien. Die Reliabilität von Diagnosen kann durch die Anwendung von Algorithmen erhöht werden (Malt, 1986; Rinaldi et al., 2000). Daher war das Ziel, einen Klassifikationsalgorithmus zu entwickeln, der einen strukturierten Weg durch die neue Klassifikation bietet und dadurch den Klassifikationsprozess vereinfachen und standardisieren kann. Im Rahmen einer naturalistischen Implementierungs-Feldstudie (Korwisi et al., 2020, siehe Studie 5) wurde eine Pilotversion des Algorithmus hinsichtlich seiner klinischen Nützlichkeit evaluiert.

Methoden. Die Entwicklung und graphische Implementierung des Klassifikationsalgorithmus folgte etablierten Richtlinien (Society for Medical Decision Making Committee on Standardization of Clinical Algorithms, 1992). Zunächst wurden alle Diagnosekriterien der Klassifikation in eine hierarchische Reihenfolge gebracht und, entsprechend der genannten Richtlinien, mit Entscheidungspfeilen verknüpft. Hierbei wurden die Kriterien in sogenannten Entscheidungsboxen dargestellt. Der entstandene lineare Entscheidungsbaum durchlief mehrere Prüfungen durch die Mitglieder der IASP-Arbeitsgruppe sowie externe Schmerzspezialistinnen. Eine Pilotversion des Algorithmus wurde im Rahmen einer naturalistischen Implementierungs-Feldstudie (siehe Studie 5) hinsichtlich seiner Nützlichkeit von Schmerzspezialistinnen und -spezialisten auf einer Skala von 0 *überhaupt nicht nützlich* bis 10 *sehr nützlich* bewertet.

Ergebnisse. Der finale Entscheidungsbaum besteht aus insgesamt 26 „Ästen“ und 354 Boxen. Er umfasst alle ICD-11-Kategorien chronischer Schmerzen außer chronischen Kopf- oder Gesichtsschmerzen. Ein einführender „Stamm“ leitet zu den sechs Hauptkategorien und vereinfacht somit den Einstieg in den Algorithmus. Für jedes Diagnosekriterium entscheidet die Nutzerin oder der Nutzer, ob es erfüllt ist und folgt entsprechend dem Ja- oder Nein-Pfeil zur nächsten Box. Die Boxen und Pfeile führen zu Diagnoseboxen auf den unterschiedlichen Diagnoseebenen. An einigen Stellen sind Aktionsboxen in den Entscheidungsbaum implementiert, beispielsweise um eine Sprungregel zu einem anderen Ast des Baumes zu visualisieren. Alle Boxen des Algorithmus sind konsekutiv nummeriert. Manche Boxen haben zugehörige Kommentare, in denen sich z. B. Seitenverweise oder Spezifikationen zu einem Kriterium finden. Alle Seitenverweise sind auch als Hyperlink in den Algorithmus implementiert. An die Diagnoseboxen ist eine Rückkopplungsschleife zurück zum Beginn des Algorithmus geknüpft, um trotz der linearen Struktur des Entscheidungsbaumes sicher zu stellen, dass im Falle mehrerer komorbider Schmerzsyndrome *alle* zutreffenden Diagnosen kodiert werden. Neben dem eigentlichen Entscheidungsbaum beinhaltet der Algorithmus auch detaillierte Instruktionen, eine Einführung, welche unter anderem eine Grafik für die Schmerzlokalisation enthält, sowie einen Anhang, der beispielhaft eine Auswahl von Erkrankungen auflistet, welche mit chronischen Schmerzen assoziiert sein können. Im Rahmen der Evaluation der Pilotversion des Algorithmus nutzten $k = 21$ Schmerzspezialistinnen und Schmerzspezialisten den Algorithmus, um insgesamt $n = 350$ Patientinnen und Patienten mit chronischen Schmerzen nach ICD-11 zu kodieren. Die mittlere klinische Nützlichkeit des Algorithmus wurde als $8{,}48 \pm 1{,}67$ eingeschätzt.

Diskussion. Der Klassifikationsalgorithmus stellt einen standardisierten Wegweiser durch die ICD-11-Klassifikation chronischer Schmerzen dar. Diagnoseboxen auf allen vier Ebenen der Klassifikation ermöglichen seine Nutzung sowohl in der spezialisierten Schmerzversorgung als auch in weniger spezialisierten Settings (z. B. Primärversorgung). Der Einstiegsstamm kann als alleinstehender Algorithmus in weniger spezialisierten Settings, wo eine Diagnose auf der obersten Ebene der Klassifikation ausreicht, genutzt werden. Hyperlinks vereinfachen die digitale Nutzung der PDF-Version des Algorithmus. Schriftliche Seitenverweise ermöglichen jedoch auch die Nutzung einer Papierversion. Schmerzspezialistinnen und -spezialisten schätzten den Algorithmus als sehr nützlich ein.

4.4 Studie 4: Evaluation der Klassifikation chronischer Schmerzen in der ICD-11: Studienprotokoll für eine naturalistische Implementierungs-Feldstudie in Ländern mit niedrigem, mittlerem und hohem Einkommen

Korwisi, B., Treede, R.-D., Rief, W. & Barke, A. (2020). Evaluation of the International Classification of Diseases-11 chronic pain classification: Study protocol for an ecological implementation field study in low-, middle-, and high-income countries. *PAIN Reports, 5*, e825.

Hintergrund. Die von einer internationalen Arbeitsgruppe der IASP entwickelte Klassifikation chronischer Schmerzen (Treede et al., 2015, 2019) wurde in die ICD-11 aufgenommen (World Health Organization, 2020b), welche im Januar 2022 weltweit in Kraft treten wird (World Health Organization, 2019). Die Verbesserung der klinischen Nützlichkeit sowie die globale Anwendbarkeit der ICD-11 waren die Hauptziele des Revisionsprozesses (International Advisory Group for the Revision of ICD-10 Mental and Behavioural Disorders., 2011). Klinische Nützlichkeit bezieht sich darauf, wie gut ein Klassifikationssystem zur Behandlungswahl, Kommunikation, Dokumentation und Patientenmanagement beiträgt (First, 2010; First et al., 2004; Mullins-Sweatt & Widiger, 2009). Naturalistische Implementierungs-Feldstudien ermöglichen es, ein neues Klassifikationssystem und dessen Umsetzung in einem „echten" klinischen Setting zu evaluieren (Keeley et al., 2016; Reed, Sharan, et al., 2018). Das Ziel der beschriebenen naturalistischen Implementierungs-Feldstudie ist die Überprüfung der Reliabilität sowie der klinischen Nützlichkeit der ICD-11-Klassifikation chronischer Schmerzen in Ländern mit unterschiedlichem Einkommensstatus.

Methoden. Die naturalistische Implementierungs-Feldstudie wird in zwei Erhebungswellen umgesetzt. Als Studienzentren werden Schmerzkliniken (erste und zweite Welle) sowie weitere spezialisierte Behandlungszentren (z. B. Palliativversorgung) und allgemeinmedizinische Zentren (zweite Welle) eingeschlossen. Teilnehmende Kliniken befinden sich in Ländern, welche alle von der Weltbank definierten Einkommensgruppen (World Bank, 2019) sowie alle WHO-Weltregionen repräsentieren. Die Teilnehmenden der Studie unterscheiden sich in zwei Gruppen: zum einen Schmerzspezialistinnen und -spezialisten, welche die Klassifikation anwenden, sowie zum anderen erwachsene Patientinnen und Patienten mit chronischen Schmerzen, auf die die ICD-11-

Schmerzklassifikation angewendet wird. Nach einem einführenden Training wenden die Schmerzspezialistinnen und -spezialisten die neue Klassifikation auf 75–100 konsekutive neue Patientinnen und Patienten pro Klinik an. Die ersten 20 Patientinnen und Patienten pro Klinik werden von jeweils zwei Spezialistinnen oder Spezialisten beurteilt, um die Bestimmung der Interrater-Reliabilität der Diagnosen zu ermöglichen. Die folgenden Patientinnen und Patienten werden von jeweils einer Spezialistin oder einem Spezialisten kodiert und beurteilt. Ein Klassifikationsalgorithmus (siehe Studie 3) strukturiert den Diagnoseprozess. Nach der Diagnostik der Patientin oder des Patienten dokumentieren die Spezialistinnen und Spezialisten alle ICD-11-Schmerzdiagnosen sowie die in der jeweiligen Klinik üblicherweise vergebenen Schmerzdiagnosen nach dem aktuell dort genutzten Klassifikationssystem. Weiterhin schätzen sie die klinische Nützlichkeit der jeweils vergebenen Diagnosen auf einer Skala von 0 *überhaupt nicht nützlich/sehr schwierig/überhaupt nicht sicher* bis 10 *sehr nützlich/einfach/sicher* ein. Die Skala zur Bewertung der klinischen Nützlichkeit umfasst u. a. Items zu Einfachheit, Kommunikation, Datenerhebung und Behandlungswahl. Um die Interrater-Reliabilität der Diagnosen zu bestimmten, werden Kappa-Koeffizienten für alle Diagnosen, die im Rahmen der Reliabilitäts-Kodierung bei mindestens 15 Patientinnen oder Patienten kodiert wurden, berechnet. Die klinische Nützlichkeit wird zunächst deskriptiv berichtet. Unterschiede zwischen den Kliniken werden mittels Varianzanalyse analysiert.

Diskussion. Die naturalistische Implementierungs-Feldstudie ermöglicht die Evaluation der neuen ICD-11-Klassifikation chronischer Schmerzen in der klinischen Routineversorgung, was die externe Validität erhöht. Es ist besonders hervorzuheben, dass die Studie wird Ländern mit unterschiedlichen kulturellen Hintergründen und unterschiedlichem Einkommensstatus durchgeführt wird. Dies verbessert die Generalisierbarkeit der Ergebnisse und wird erste Hinweise auf die globale Anwendbarkeit der Klassifikation liefern (D. P. Goldberg et al., 2016; Reed, Sharan, et al., 2018). Die Ergebnisse aus der ersten Erhebungswelle zur Umsetzbarkeit und Machbarkeit des Studienprotokolls in der Routineversorgung können wiederum die Umsetzung der zweiten Erhebungswelle optimieren. Durch den Einschluss bestimmter Behandlungszentren, wie beispielsweise Zentren der Palliativversorgung, in der zweiten Erhebungswelle kann die Verteilung der Patientinnen und Patienten auf die sieben Hauptkategorien in der finalen Stichprobe zu einem

gewissen Grad kontrolliert werden, was gegebenenfalls auch Vergleiche der Interrater-Reliabilitäten zwischen einzelnen Ländern oder WHO-Regionen ermöglichen wird.

4.5 Studie 5: Die Reliabilität und klinische Nützlichkeit der Klassifikation chronischer Schmerzen in der ICD-11 aus einer globalen Perspektive: Ergebnisse einer naturalistischen Implementierungs-Feldstudie in Indien, Kuba und Neuseeland

Korwisi, B., Garrido Suarez, B. B., Goswami, S., Gunapati, N. R., Hay, G., Hernández Artega, M. A., Hill, C., Jones, D., Joshi, M., Kleinstäuber, M., López Mantecón, A. M., Nandi, G., Papagari, C. S. R., Rabí Martínez, M. C., Sarkar, B., Swain, N., Templer, P., Tulp, M., White, N., Treede, R.-D., Rief, W. & Barke, A. (submitted). Reliability and clinical utility of the ICD-11 chronic pain classification from a global perspective: Results from the first phase of the ICD-11 chronic pain codes ecological testing and assessment (ICE TEA) in India, Cuba, and New Zealand. Submitted for publication in *The Lancet Global Health*.

Hintergrund. Ein Großteil der Weltbevölkerung lebt in LMIC (Onofa et al., 2019). Mit ca. 18 % ist die Prävalenz chronischer Schmerzen in LMIC ähnlich hoch wie in Ländern mit hohem Einkommensstatus (Nunes Sá et al., 2019). Weltweit tragen chronische Schmerzen substanziell zur globalen Krankheitslast bei (James et al., 2018). Die Krankheitslast durch chronische Schmerzen wird in den kommenden Jahren weiter steigen, v. a. in LMIC (Blyth et al., 2019). Diese Studie stellt die erste Erhebungswelle einer globalen naturalistischen Implementierungs-Feldstudie dar (siehe Studie 4), welche die ICD-11-Klassifikation chronischer Schmerzen in Indien (niedrig-mittlerer Einkommensstatus), Kuba (hoch-mittlerer Einkommensstatus) und Neuseeland (hoher Einkommensstatus) hinsichtlich Interrater-Reliabilität und klinischer Nützlichkeit evaluierte.

Methoden. Für diese Studie wurde das unter Studie 4 beschriebene Studienprotokoll (Korwisi et al., 2020) in vier Schmerzkliniken in Indien (Kalkutta und Hyderabad), Kuba (Havanna) und Neuseeland (Dunedin) umgesetzt. Aus Gründen der Machbarkeit wurden auch Patientinnen und Patienten, die sich in der jeweiligen Klinik bereits in Behandlung befanden, in die Stichprobe unter der Voraussetzung eingeschlossen, dass die diagnostische Beurteilung von einer Person durchgeführt wurde, die in vorherige diagnostische Entscheidungen nicht involviert war. Aufgrund der COVID-19-Pandemie musste die Datenerhebung in Hyderabad vorzeitig abgebrochen werden. Als Maß für die Interrater-Reliabilität wurden Fleiss' κ und 95 %-Konfidenzintervalle für alle Diagnosen bestimmt, die für ≥ 15 Patientinnen oder Patienten von min. einem der zwei Schmerzspezialistinnen oder -spezialisten vorlagen. Um die klinische Nützlichkeit der ICD-11-Schmerzdiagnosen zu

analysieren, wurde eine 2 x 4 *mixed* ANOVA mit dem *within*-Faktor Klassifikationssystem (ICD-11/aktuelles System) und dem *between*-Faktor Zentrum (Kalkutta/Hyderabad/ Dunedin/Havanna) durchgeführt. Effekte wurden mit Games-Howell post-hoc Tests und *simple effects* weiter analysiert.

Ergebnisse. Insgesamt wendeten 21 Schmerzspezialistinnen und -spezialisten die neuen ICD-11-Schmerzdiagnosen auf 353 Patientinnen und Patienten an. Drei Patientinnen und Patienten mussten aus der Datenanalyse ausgeschlossen werden. Fleiss' κ konnte für insgesamt elf Diagnosen bestimmt werden und lag zwischen $\kappa = 0{,}596$ (chronische primäre muskuloskelettale Schmerzen) und $\kappa = 0{,}783$ (chronische sekundäre muskuloskelettale Schmerzen). Somit lassen sich zehn von elf κ -Werten als „substantiell" einordnen (Landis & Koch, 1977). Die klinische Nützlichkeit der ICD-11-Klassifikation chronischer Schmerzen wurde im Mittel als 8.45 ± 1.69 eingeschätzt. Die *mixed* ANOVA ergab einen Haupteffekt für das Klassifikationssystem mit einer höheren Nützlichkeit für ICD-11 ($F(1, 345) = 113{,}08$, $p < 0{,}001$, $\eta^2 = 0{,}25$), einen Haupteffekt für Zentrum ($F(3, 345) = 172{,}95$, $p < 0{,}001$, $\eta^2 = 0{,}60$) sowie eine Interaktion Klassifikationssystem x Zentrum ($F(3, 345) = 35{,}43$, $p < 0{,}001$, $\eta^2 = 0{,}24$). Die klinische Nützlichkeit der ICD-11-Diagnosen wurde in Dunedin ($F(1, 345) = 81{,}42$, $p < 0{,}001$) und Havanna ($F(1, 345) = 113{,}08$, $p < 0{,}001$) höher eingeschätzt als das bisherige System. In Kalkutta ($F(1, 345) = 0{,}24$, $p = 0{,}622$) und Hyderabad ($F(1, 345) = 0{,}17$, $p = 0{,}679$) wurde die Nützlichkeit für beide Systeme gleich hoch eingeschätzt.

Diskussion. Die naturalistische Implementierungs-Feldstudie konnte die substanzielle Interrater-Reliabilität sowie die sehr hohe klinische Nützlichkeit der neuen ICD-11-Klassifikation chronischer Schmerzen in zwei LMIC sowie einem Land mit hohem Einkommensstatus zeigen. Die sehr gute Interrater-Reliabilität der Diagnosen wurde erreicht, obwohl die Teilnehmenden vorab nur eine kurze Schulung erhalten hatten. Die potenzielle Sprachbarriere scheint weder die Interrater-Reliabilität der Diagnosen noch deren eingeschätzte klinische Nützlichkeit beeinflusst zu haben. In Kalkutta und Hyderabad ließ sich kein Unterschied in der klinischen Nützlichkeit zwischen der ICD-11 und den jeweils aktuell verwendeten Diagnosesystemen feststellen. Hier wurde die Nützlichkeit beider Systeme jeweils sehr hoch eingeschätzt. Im Vergleich zu den aktuell in allen Kliniken genutzten jeweils unterschiedlichen Textdiagnosen bieten die ICD-11-Diagnosen den Vorteil einer standardisierten Kodierung und können daher trotzdem als überlegen angesehen

werden. Insgesamt ermöglichen die Ergebnisse dieser Studie auch Rückschlüsse auf die globale Anwendbarkeit der Klassifikation (Gaebel et al., 2020).

5 Diskussion und Ausblick

Das übergeordnete Ziel der vorliegenden Dissertation war es, die neue ICD-11-Klassifikation chronischer Schmerzen im Rahmen von formativen und evaluativen Feldstudien zu überprüfen, sowie einen Klassifikationsalgorithmus zu entwickeln, der die Reliabilität der Diagnosen erhöht und den Diagnoseprozess standardisiert.

Studie 1 war die erste formative Feldstudie der ICD-11-Klassifikation chronischer Schmerzen. Schmerzspezialistinnen und Schmerzspezialisten der Primär- und Tertiärversorgung in Australien, Deutschland, Japan und Norwegen ordneten über 500 Patientinnen und Patienten in die sieben Hauptkategorien der neuen Klassifikation ein und bewerteten die klinische Nützlichkeit der neuen Diagnosen sowie ihre subjektive diagnostische Sicherheit. Die formative Feldstudie konnte zeigen, dass die Hauptkategorien nahezu alle Schmerzsyndrome in der Stichprobe erfassten und es zwischen den einzelnen Kategorien keine bedeutsame Schnittmenge gab. Mit der vollständigen Erfassung der Schmerzsyndrome und der klaren Abgrenzung der Kategorien voneinander erfüllt die ICD-11-Klassifikation chronischer Schmerzen zwei grundlegende Voraussetzungen für diagnostische Klassifikationssysteme (Fillingim et al., 2014; Jablensky, 2016). Obwohl die teilnehmenden Ärztinnen und Ärzte keine Schulung zu den neuen Diagnosen und Kriterien erhalten hatten, schätzten sie sowohl die klinische Nützlichkeit der Hauptkategorien als auch ihre subjektive Diagnosesicherheit als hoch bis sehr hoch ein. Vor allem Diagnosen, die in bisherigen Klassifikationssystemen nicht kodiert werden konnten (z. B. chronische neuropathische Schmerzen, chronische krebsassoziierte Schmerzen) wurden als sehr nützlich bewertet. Die hohe subjektive Diagnosesicherheit ermöglicht bei der Anwendung der Hauptkategorien erste Rückschlüsse auf die Einfachheit der Klassifikation. Die Ergebnisse zeigten, dass keine grundlegenden Änderungen an der Hauptstruktur der neuen Klassifikation notwendig waren.

Studie 2 war eine weitere formative Feldstudie, die ebenfalls international durchgeführt wurde. In dieser internetbasierten Studie im Kontext der offiziellen WHO-Feldstudien ordneten Schmerzspezialistinnen und -spezialisten aus allen WHO-Weltregionen ICD-10- und ICD-11-Diagnosecodes kurzen diagnostischen Begriffen zu und wendeten die Kodierregeln der WHO auf Fallvignetten an. Es konnte gezeigt werden, dass die neuen

ICD-11-Diagnosen für chronische Schmerzen den in der ICD-10 zur Verfügung stehenden Diagnosen hinsichtlich korrekter Diagnosezuweisung, Ambiguität, Einfachheit und Detailtiefe überlegen waren. Des Weiteren konnten die Kodierregeln der WHO korrekt auf die Schmerzdiagnosen angewendet werden. Diese Ergebnisse zeigen, dass sich die neue Klassifikation chronischer Schmerzen erfolgreich in die übergeordnete Struktur der ICD-11 integrieren lässt. Auch in dieser Studie wurde die klinische Nützlichkeit der neuen Diagnosen als hoch bewertet.

In den Studien 1 und 2 wurde nicht kontrolliert, ob die Klassifikation mit ihren operationalisierten Diagnosekriterien korrekt angewendet wurde. Um die Diagnosevergabe in zukünftigen Studien sowie in der Praxis zu standardisieren und den Diagnoseprozess zu vereinfachen, wurde im Rahmen von Studie 3 ein Klassifikationsalgorithmus entwickelt. Die Entwicklung des Algorithmus folgte international etablierten Richtlinien für den Aufbau und die Gestaltung medizinischer Algorithmen (Society for Medical Decision Making Committee on Standardization of Clinical Algorithms, 1992). In einer ersten Pilotevaluation wurde die Nützlichkeit des Algorithmus von Schmerzspezialistinnen und -spezialisten als sehr hoch eingeschätzt. Langfristig kann der entstandene Klassifikationsalgorithmus nicht nur zur korrekten Anwendung der Klassifikation beitragen (Morgan et al., 2000), sondern diese Anwendung auch vereinfachen (Bollestad et al., 2015; Kellow & Drossman, 2010) und die Reliabilität der vergebenen Diagnosen erhöhen (Malt, 1986; Rinaldi et al., 2000). Der Algorithmus führt Nutzerinnen und Nutzer zu Diagnosen auf allen Ebenen der Klassifikation, was seine Anwendung in der Primärversorgung und ähnlichen Settings, in denen keine spezifischen Diagnosen notwendig sind, ermöglicht. Insgesamt stellt der entwickelte Klassifikationsalgorithmus somit ein essenzielles Handwerkszeug für die korrekte Anwendung der ICD-11 Klassifikation chronischer Schmerzen in Forschung und Praxis dar.

In Ergänzung zu den formativen Feldstudien (Studien 1 und 2) wurde eine internationale naturalistische Implementierungs-Studie als evaluative Feldstudie geplant, welche die Evaluation der ICD-11 Klassifikation chronischer Schmerzen im „echten“ klinischen Setting ermöglicht und dadurch die externe Validität der Studie erhöht (Keeley et al., 2016). Die Studie wurde in vier Schmerzkliniken in drei Ländern umgesetzt (Studie 5). Vorab wurde das Studienprotokoll veröffentlicht (Studie 4). Das Studienprotokoll (Studie 4) beschreibt, dass die naturalistische Implementierungs-Feldstudie in insgesamt zwei

Erhebungswellen in Schmerzkliniken (erste Welle), aber auch in der Primärversorgung und weiteren Settings, in denen Patientinnen und Patienten mit chronischen Schmerzen behandelt werden (zweite Welle, z. B. Palliativversorgung, innere Medizin), durchgeführt werden soll. Hierbei orientiert sich das Protokoll an den offiziellen WHO-Feldstudien für psychische Erkrankungen (Keeley et al., 2016), was die Einordnung der Ergebnisse erleichtert. Die Teilnehmenden sollen die finale Version der ICD-11-Klassifikation chronischer Schmerzen auf konsekutive Patientinnen und Patienten anwenden. Neben der Interrater-Reliabilität der neuen ICD-11-Diagnosen ist die Bewertung der klinischen Nützlichkeit des aktuell genutzten Diagnosesystems sowie der ICD-11-Diagnosen ein weiteres Hauptergebnis. Die Studie soll global in Ländern aller Einkommensgruppen durchgeführt werden, um die Generalisierbarkeit der Ergebnisse zu erhöhen und Rückschlüsse auf die weltweite Anwendbarkeit der Klassifikation zu ermöglichen. Im Gegensatz zu Studien 1 und 2 wurde in Studien 4 und 5 durch ein kurzes Training vor der Datenerhebung der Wissenstand aller Teilnehmenden zu den ICD-11-Schmerzdiagnosen auf einen konstanten Stand gebracht.

Studie 5 wurde in Schmerzkliniken in Dunedin (Neuseeland, Land mit hohem Einkommensstatus), Havanna (Kuba, Land mit hoch-mittlerem Einkommensstatus) sowie Kalkutta und Hyderabad (Indien, Land mit niedrig-mittlerem Einkommensstatus) durchgeführt. Die Interrater-Reliabilität konnte für insgesamt elf Diagnosen auf den ersten drei Ebenen der Klassifikation bestimmt werden. Fleiss' κ lag für zehn Diagnosen im erheblichen Bereich und für eine Diagnose im moderaten Bereich, eingeordnet nach Landis & Koch (1977). Des Weiteren zeigte sich, dass die ICD-11-Klassifikation chronischer Schmerzen in Havanna und Dunedin nützlicher eingeschätzt wurde als das jeweils aktuell genutzte Diagnosesystem. In Kalkutta und Hyderabad wurden sowohl die ICD-11-Diagnosen als auch die aktuellen Systeme als sehr nützlich eingeschätzt. Da alle teilnehmenden Schmerzkliniken aktuell Textdiagnosen auf Grundlage unterschiedlicher Referenzen anwendeten, spricht das Ergebnis für eine Überlegenheit der ICD-11-Schmerzklassifikation, da diese zu einer Standardisierung der Diagnosen beitragen kann. Die hohe Reliabilität der Diagnosen sowie deren als sehr hoch eingeschätzte klinische Nützlichkeit in allen untersuchten Ländern deuten auf die weltweite Anwendbarkeit der ICD-11-Klassifikation chronischer Schmerzen hin. Weiterhin schafft Studie 5 die Grundlage für die in Studie 4 beschriebene zweite

Erhebungswelle, da die Umsetzbarkeit des Studienprotokolls in der Routineversorgung gezeigt werden konnte.

Insgesamt zeichnen sich die Studien der vorliegenden Dissertation durch ihren internationalen Charakter aus. Alle Feldstudien wurden in verschiedenen Ländern durchgeführt, was die Generalisierbarkeit der Ergebnisse erhöht (Gaebel et al., 2020; D. P. Goldberg et al., 2016; Reed, Keeley, et al., 2018). Für die Studien 4 und 5 wurde zudem beachtet, Länder mit verschiedenen kulturellen Hintergründen und unterschiedlichem Einkommensstatus einzuschließen. Obwohl Klassifikationssysteme wie die ICD oder auch das DSM weltweit zum Einsatz kommen und dieser globale Einsatz der Systeme daher auch in Evaluationsstudien berücksichtigt werden sollte, wurden in einer Vielzahl solcher Studien bislang nur westliche Industrienationen mit hohem Einkommensstatus eingeschlossen (Clarke et al., 2013; Regier et al., 1994). Es ist somit eine besondere Stärke von den Studien 4 und 5, dass diese auch in LMIC umgesetzt werden. Die Durchführung der Feldstudien im klinischen Setting erhöht die externe Validität der Ergebnisse. In Studie 1 konnte bereits gezeigt werden, dass die ICD-11-Klassifikation chronischer Schmerzen wichtige Eigenschaften diagnostischer Klassifikationssysteme erfüllt. In den folgenden Studien zeigte sich weiterhin die klinische Nützlichkeit der neuen Klassifikation (Studien 2, 4, 5) sowie die hohe Interrater-Reliabilität der Diagnosen (Studie 5). Somit erfüllt die ICD-11-Klassifikation chronischer Schmerzen zwei weitere wichtige Eigenschaften eines diagnostischen Klassifikationssystems (Bruehl et al., 2016; First, 2010; Reed, 2010).

5.1 Limitationen

Neben den eben beschriebenen Stärken der Studien müssen bei der Interpretation der vorliegenden Ergebnisse auch einige Limitationen beachtet werden. Studie 1 war eine Pilotstudie, was einige Einschränkungen mit sich brachte. So wurden weder für die teilnehmenden Ärztinnen und Ärzte noch für die teilnehmenden Patientinnen und Patienten formelle Ein- und Ausschlusskriterien formuliert. Es konnte nicht überprüft werden, ob es sich tatsächlich um eine Stichprobe aus konsekutiven Patientinnen und Patienten handelte, oder ob einzelne Patientinnen und Patienten gezielt von der Datenerhebung ausgeschlossen wurden. Aus diesem Grund wurde in den Studien 4 und 5 besonders auf Ein- und Ausschlusskriterien sowie auf eine konsekutive Stichprobe geachtet. Weiterhin standen den

teilnehmenden Ärztinnen und Ärzte in Studie 1 nur sehr begrenzte Informationen zu der neuen ICD-11Klassifikation chronischer Schmerzen zur Verfügung.

In Studie 2 stand den Teilnehmenden zwar Informationsmaterial zu den neuen ICD-11-Diagnosen für chronische Schmerzen sowie den ICD-Plattformen zur Verfügung, jedoch konnte nicht kontrolliert werden, ob dies in Anspruch genommen wurde. Daher ist auch in dieser Studie davon auszugehen, dass die Teilnehmerinnen und Teilnehmer einen unterschiedlichen Wissensstand zur ICD-11-Klassifikation chronischer Schmerzen sowie zur Nutzung der ICD insgesamt hatten. Aus diesem Grund wurde für die Studien 4 und 5 eine kurze Schulung für alle Teilnehmenden entwickelt. Die Teilnahme an dieser Schulung wurde als Einschlusskriterium festgelegt, um den Wissensstand der Teilnehmenden konstant zu halten. Des Weiteren war die Stichprobengröße in Studie 2 sehr begrenzt. Dies ist teilweise auf den komplizierten mehrstufigen Registrierungsprozess für die von der WHO bereitgestellte Studienplattform ICD-FiT zurückzuführen, was zu einer hohen Drop-Out-Rate führte.

Der in Studie 3 entwickelte Klassifikationsalgorithmus liegt aktuell nur als PDF vor. Die Handhabung des PDF wird jedoch durch Hyperlinks vereinfacht. Während chronische Kopf- oder Gesichtsschmerzen nicht Teil des Algorithmus sind, wird an mehreren Stellen auf die entsprechenden Klassifikationssysteme verwiesen. Die Ergebnisse der Pilotevaluation liefern wichtige Daten in Bezug auf die hohe Nützlichkeit des Algorithmus. Eine formelle Evaluation, welche auch die Korrektheit der Diagnosen und den Zeitbedarf für die Anwendung des Algorithmus im Vergleich zum ICD-11-Browser berücksichtigt, steht noch aus. Eine entsprechende internetbasierte Studie ist aktuell in Vorbereitung (Hay et al., 2020).

Die Studien 4 und 5 bauen auf den formativen Feldstudien 1 und 2 auf und versuchen, deren Limitationen zu überwinden. Während in Studie 1 nur die Hauptkategorien der Klassifikation berücksichtigt werden konnten, wurde in den Studien 4 und 5 die finale Version der Klassifikation angewendet. Im Gegensatz zu den Studien 1 und 2 sind alle teilnehmenden Schmerzspezialistinnen und -spezialisten durch das vorangehende Training in den Studien 4 und 5 auf dem gleichen Wissensstand in Bezug auf die Klassifikation. Durch die Anwendung des Klassifikationsalgorithmus in den Studien 4 und 5 kann, anders als in den Studien 1 und 2, von einer korrekten Anwendung der Klassifikation ausgegangen werden. Gleichzeitig können natürlich auch in den Studien 4 und 5 einige Limitationen nicht ausgeschlossen werden. Aufgrund der Umsetzung der Studien in der Routineversorgung konnte nur für eine

begrenzte Anzahl an Patientinnen und Patienten die Interrater-Reliabilität der ICD-11-Diagnosen bestimmt werden. Für seltenere Diagnosen (z. B. chronische sekundäre viszerale Schmerzen, chronische krebsassoziierte Schmerzen) war dies nicht möglich. Die in Studie 4 beschriebene zweite Erhebungswelle wird durch den Einschluss spezialisierter Zentren versuchen, diese Einschränkung zu überwinden (z. B. Palliativversorgung, um mehr Patientinnen und Patienten mit chronischen krebsassoziierten Schmerzen einschließen zu können). Da die Datenerhebung zu Studie 5 in Hyderabad aufgrund der COVID-19-Pandemie vorzeitig abgebrochen werden musste, war die finale Stichprobe kleiner als ursprünglich geplant.

In den Studien 1 und 2 wurde die klinische Nützlichkeit nur für die neuen ICD-11-Diagnosen eingeschätzt, nicht jedoch für die jeweiligen ICD-10- bzw. ICPC-2-Diagnosen. Die Aussagekraft dieser Bewertungen wird jedoch erhöht, wenn auch das aktuelle Diagnosesystem hinsichtlich seiner klinischer Nützlichkeit bewertet wird (First, 2010). Ein solcher direkter Vergleich der Diagnosesysteme konnte in den Studien 4 und 5 umgesetzt werden. Des Weiteren sollte bedacht werden, dass die Teilnehmerinnen und Teilnehmer in den Studien 1, 2 und 5 durch den Kontext ihrer Teilnahme an einer offiziellen Feldstudie gegebenenfalls einen Bias in Richtung einer positiven Bewertung der neuen ICD-11-Diagnosen hatten (Onofa et al., 2019; Reed, Keeley, et al., 2018). Weiterhin wurde die klinische Nützlichkeit der ICD-11-Diagnosen bisher nur durch subjektive Einschätzungen evaluiert (Studien 1, 2, 4, 5). Die Operationalisierung klinischer Nützlichkeit in der Routineversorgung ist schwierig, weshalb solche subjektiven Bewertungen dem aktuellen Standard entsprechen (First, 2010). Zukünftige Studien sollten trotzdem versuchen, zusätzlich auch ein objektives Maß für die klinische Nützlichkeit der Diagnosen (z. B. Zeitbedarf für die Kodierung) zu erheben. Weiterhin ist denkbar, dass Variablen auf Seiten der teilnehmenden Schmerzspezialistinnen und -spezialisten (z. B. klinische Erfahrung, Zeitbedarf für die Diagnosefindung) in den Studien 1, 2 und 5 die Diagnosen und deren Bewertungen beeinflusst haben (Gaebel et al., 2020).

Die ICD-11-Klassifikation chronischer Schmerzen soll weltweit in unterschiedlichen Settings anwendbar sein (Treede et al., 2019). Dies umfasst neben der spezialisierten Schmerztherapie auch die Primärversorgung oder die Anwendung durch professionelle Kodiererinnen und Kodierer. Studie 1 wurde zwar auch in einem allgemeinmedizinischen

Zentrum durchgeführt, jedoch wurden die Ergebnisse nicht getrennt für Primärversorgung und spezialisierte Schmerztherapie ausgewertet. Ähnliches gilt für Studie 2, in der das Fachgebiet der Teilnehmenden erfasst, jedoch in späteren Auswertungen nicht berücksichtig werden konnte. Die Studien 3 und 5 wurden ausschließlich in spezialisierten Schmerzkliniken durchgeführt. Das in Studie 4 entwickelte Studienprotokoll sieht jedoch vor, dass die naturalistische Implementierungs-Feldstudie im Rahmen der zweiten Erhebungswelle auch in weiteren Settings umgesetzt wird.

Im Rahmen der hier berichteten Studien 1 bis 5 konnte die Validität der ICD-11-Klassifikation chronischer Schmerzen mangels externem Referenzstandard nicht direkt überprüft werden (Bruehl et al., 2016). Die Entwicklung der Klassifikation durch ein Gremium aus Expertinnen und Experten, die klare Beschreibung der neuen Diagnosen sowie die in Studie 1 gezeigte Abgrenzbarkeit der Hauptkategorien untereinander ermöglichen trotzdem wichtige Rückschlüsse auf die Validität der neuen Klassifikation (Bruehl et al., 2016; Kendell & Jablensky, 2003; Robins & Guze, 1970). So erhöht die Entwicklung der Klassifikation durch Expertinnen und Experten die Inhaltsvalidität – die Kategorien umschreiben die jeweiligen Zielsyndrome (Bruehl et al., 2016). Die klare Abgrenzbarkeit der Kategorien voneinander trägt wiederum zur diskriminanten Validität bei – die einzelnen Kategorien erfassen jeweils unterschiedliche chronische Schmerzsyndrome (Bruehl et al., 2016).

Bei den Studien 1, 4 und 5 handelt es sich um naturalistische Implementierungs-Feldstudien im klinischen Setting. Diese sind essenziell für die Evaluation eines neuen diagnostischen Klassifikationssystems (Keeley et al., 2016; Mullins-Sweatt & Widiger, 2009). Die hohe externe Validität solcher naturalistischen Studien kann gleichzeitig als Stärke und als Limitation gesehen werden. Variablen auf Seiten der Patientinnen und Patienten können in naturalistischen Feldstudien nicht kontrolliert werden und die Bewertung der Richtigkeit der vergebenen Diagnosen ist kaum möglich. Daher stellen experimentelle Fall-Kontroll-Studien, welche ebenfalls den evaluativen Feldstudien zuzuordnen sind, eine wichtige Ergänzung zu naturalistischen Implementierungs-Feldstudien dar (Keeley et al., 2016; Mullins-Sweatt & Widiger, 2009). Die experimentelle Überprüfung der ICD-11-Klassifikation chronischer Schmerzen mittels einer solchen Fall-Kontroll-Studie steht noch aus.

5.2 Perspektiven

5.2.1 Perspektiven für die Forschung

Aus den beschriebenen Studien und Limitationen der vorliegenden Dissertation lassen sich verschiedene Perspektiven und Implikationen für zukünftige Forschungsarbeiten ableiten. So steht zum einen noch die formelle Evaluation des in Studie 3 präsentierten Klassifikationsalgorithmus aus. Aktuell ist eine entsprechende internetbasierte Studie in Vorbereitung (Hay et al., 2020). In dieser werden Schmerzspezialistinnen und Schmerzspezialisten eine digitale Version des Algorithmus sowie den ICD-11-Browser auf virtuelle Patientinnen und Patienten anwenden. Die Vorgabe dieser beiden Bedingungen (Algorithmus vs. ICD-11-Browser) wird im Sinne eines *within-subject* Studiendesigns randomisiert. Als Ergebnismaße werden die Korrektheit und Vollständigkeit der Diagnose, die subjektiv empfundene Nützlichkeit des Algorithmus sowie der Zeitbedarf für die Diagnosestellung erfasst. Die Erfassung des Zeitbedarfs stellt hier, wie in Kapitel 5.1 beschrieben, als objektives Maß für die klinische Nützlichkeit eine wichtige Ergänzung zur subjektiven Bewertung der klinischen Nützlichkeit durch die Teilnehmenden dar.

Studie 5 stellt die Hauptergebnisse der ersten Erhebungswelle einer internationalen naturalistischen Implementierungs-Feldstudie vor. Das Studienprotokoll wurde vorab veröffentlich (Studie 4) und beschreibt auch eine zweite Erhebungswelle, in der die ICD-11-Klassifikation chronischer Schmerzen in der Primärversorgung und weiteren Fachgebieten zur Anwendung kommen soll. Unterschiede in der Interrater-Reliabilität und empfundenen klinischen Nützlichkeit können so erstmalig zwischen Fachgebieten (z. B. Schmerzmedizin, Allgemeinmedizin, innere Medizin) bestimmt werden, was Rückschlüsse über die fächer- und settingübergreifende Anwendbarkeit der Klassifikation ermöglichen wird. Es ist vorgesehen, dass in der größeren Stichprobe nach der zweiten Erhebungswelle alle Hauptkategorien chronischer Schmerzen repräsentiert sind. Dies wird es ermöglichen, die Interrater-Reliabilität und klinische Nützlichkeit nicht nur zwischen Ländern und Fachgebieten, sondern auch zwischen einzelnen Kategorien zu vergleichen. Daneben wird die größere Stichprobe Analysen zum Einfluss verschiedener Variablen auf Seite der Teilnehmenden ermöglichen, beispielsweise über Regressionsanalysen oder hierarchische Modelle (z. B. Kliniken auf Level 1 und Einkommensstatus des jeweiligen Landes auf Level 2). Hier ist beispielsweise eine Regressionsanalyse denkbar, die den Einfluss des Zeitbedarfs für die Diagnosestellung oder

der klinischen Erfahrung der Teilnehmenden (Prädiktoren) auf die Bewertung der klinischen Nützlichkeit der neuen Diagnosen (Kriterium) analysiert (Gaebel et al., 2020). Weitere Sekundäranalysen der Ergebnisse der Studien 4 und 5 sowie weitere Erhebungen könnten auf den Ergebnissen von Hornemann et al. (2020) aufbauen und Unterschiede zwischen Patientinnen und Patienten mit chronischen primären und chronischen sekundären Schmerzen untersuchen (z. B. in Bezug auf die Komponenten der Schmerzschwere oder das Vorliegen psychosozialer Faktoren).

Wie in Kapitel 5.1 beschrieben, stellen experimentelle Fall-Kontroll-Studien eine sinnvolle Ergänzung zu naturalistischen Implementierungs-Feldstudien dar (Bruehl et al., 2016). Im Kontext der Evaluation eines diagnostischen Klassifikationssystem bieten sich hierfür Vignettenstudien an (Keeley et al., 2016). Vignettenstudien ermöglichen es, Kontrolle über die Variablen auf Seiten der Patientin oder des Patienten zu haben (z. B. Alter, Geschlecht, Symptome). Diese Variablen können im Rahmen einer Vignettenstudie gezielt manipuliert werden (Keeley et al., 2016). Während sich naturalistische Implementierungs-Feldstudien durch ihre sehr hohe externe Validität auszeichnen, haben experimentelle Vignettenstudien eine hohe interne Validität und können somit genutzt werden, um die Ergebnisse aus naturalistischen Feldstudien weiter abzusichern (Evans et al., 2015; Keeley et al., 2016). Übertragen auf die ICD-11-Klassifikation chronischer Schmerzen ist eine Vignettenstudie denkbar, in der als abhängige Variable die Wahl der korrekten Diagnose erfasst wird (Keeley et al., 2016). Verschiedene unabhängige Variablen sind in diesem Kontext von Interesse. So könnte in einem *between-subjects* Studiendesign beispielsweise das Maß an funktionaler Beeinträchtigung, emotionaler Belastung, das Alter oder Geschlecht der Patientin oder des Patienten oder das Vorliegen einer strukturellen Veränderung experimentell manipuliert werden. Da es in der Praxis häufig schwierig zu beurteilen ist, ob eine vorliegende strukturelle Veränderung (z. B. Degeneration einzelner Wirbel) chronische Schmerzen erklären kann oder nicht (Barke et al., *in press*), ist die Fragestellung, wie sich ein entsprechender Befund auf die Diagnosestellung auswirkt, von besonderer aktueller Relevanz. Ein zweiter Messzeitpunkt im Abstand von zwei oder vier Wochen zum ersten Messzeitpunkt (*within-subject*) würde es ermöglichen, in Ergänzung zur Interrater-Reliabilität auch die Test-Retest-Reliabilität der neuen ICD-11-Schmerzdiagnosen zu analysieren und somit ein Maß für die Stabilität der Diagnosezuschreibungen über die Zeit liefern (Bruehl et al., 2016).

Ein wichtiges Ziel der ICD-11-Klassifikation chronischer Schmerzen ist es, den Behandlungszugang für betroffene Patientinnen und Patienten zu verbessern, beispielsweise durch das Sichtbarmachen von chronischen Schmerzen im Rahmen einer Grunderkrankung wie rheumatoider Arthritis oder Krebs (Treede et al., 2019). Des Weiteren sind Verbesserungen der Behandlungswahl sowie des Behandlungsergebnisses wichtige Komponenten der klinischen Nützlichkeit der neuen Diagnosen (First, 2010; First et al., 2004). Die neue Klassifikation ermöglicht es, durch die klar konzeptualisierten und voneinander abgrenzbaren Kategorien den spezifischen Effekt bestimmter Behandlungsmöglichkeiten für die einzelnen neuen Diagnosen zu bestimmen. Hierzu bietet sich beispielsweise die Methode der Netzwerk-Metaanalyse an, welche es ermöglicht, für einzelne Kategorien der neuen Klassifikation die Wirksamkeit verschiedener Behandlungsmöglichkeiten (z. B. medikamentöse Therapie, kognitive Verhaltenstherapie, Physiotherapie, multimodale Schmerztherapie) zu vergleichen (Koechlin et al., 2019).

Insgesamt sollte die ICD-11-Klassifikation chronischer Schmerzen, welche sich im Rahmen der vorliegenden Dissertation als reliabel, klinisch nützlich und global anwendbar gezeigt hat, in der Schmerzforschung umgesetzt und angewendet werden. Wenn klinische Studien, aber auch die experimentelle Grundlagenforschung und epidemiologische Untersuchungen, Stichproben mithilfe der neuen Kategorien bzw. Diagnosen beschreiben, wird dies die Vergleichbarkeit der Stichproben erhöhen und zu einer Standardisierung in der Schmerzforschung beitragen (Barke et al., 2020; Treede et al., 2019).

5.2.2 Perspektiven für die Praxis

Aus den Ergebnissen der vorliegenden Dissertation lassen sich auch Implikationen und Perspektiven für die Praxis ableiten. Die ICD wird in vielen Ländern, darunter Deutschland, täglich von Ärztinnen und Ärzten, Psychotherapeutinnen und Psychotherapeuten sowie weiteren Mitarbeitenden des Gesundheitswesens für Diagnostik, Dokumentation und Behandlungswahl eingesetzt (Jakob, 2018a, 2018b). Die ICD-11-Klassifikation chronischer Schmerzen hat das Ziel, durch die Bereitstellung klar definierter Diagnosen und operationalisierter Kriterien u. a. die Dokumentation und die Behandlungswahl zu vereinfachen sowie den Behandlungszugang zu verbessern (Treede et al., 2019). Die Ergebnisse der vorliegenden Dissertation bezüglich der klinischen Nützlichkeit der neuen Diagnosen weisen darauf hin, dass dieses Ziel in der Praxis erreicht werden kann.

Die in Kapitel 5.2.1 beschriebenen möglichen Untersuchungen zur Wirkung bestimmter Behandlungsverfahren bei den unterschiedlichen Kategorien chronischer Schmerzen werden eine wichtige Grundlage für die Entwicklung von Behandlungsleitlinien sein (Koechlin et al., 2019). Weitere Implikationen für die Praxis lassen sich aus den Facetten der klinischen Nützlichkeit direkt ableiten (First, 2010; First et al., 2004; Mullins-Sweatt & Widiger, 2009; Reed, 2010). So kann die neue Klassifikation neben einer Verbesserung von Behandlungswahl, Dokumentation und Datenerhebung auch zu einer verbesserten Kommunikation über chronische Schmerzen sowohl unter Behandelnden als auch mit Patientinnen und Patienten beitragen. Persönliche Erfahrungen während der Datenerhebung zu Studie 5 zeigten, dass Patientinnen und Patienten sich in den neuen Diagnosen wiederfinden und vor allem das Konzept der chronischen primären Schmerzen sehr gut annehmen. Der in Studie 3 entwickelte Klassifikationsalgorithmus bietet für die Praxis ein wichtiges Handwerkszeug für die korrekte und reliable Anwendung der Klassifikation im klinischen Alltag (Morgan et al., 2000). Sollte sich der Algorithmus auch in der formellen Evaluationsstudie als reliabel und nützlich erweisen, ist die langfristige Nutzung in Form einer Anwendungssoftware („App“) denkbar (Strotbaum & Reiß, 2017).

Des Weiteren ist mit den im Rahmen von Studie 5 als reliabel gezeigten Diagnosen eine wichtige Voraussetzung erfüllt, um chronische Schmerzen in epidemiologischen Studien besser abbilden zu können (Blyth et al., 2019; Blyth & Huckel Schneider, 2018; Rice et al., 2016). Dies wird sich auf gesundheitspolitische Entscheidungen (z. B. Mittelzuweisung, Forschungsförderung) auswirken. Somit kann die im Rahmen der Dissertation als reliabel und klinisch nützlich gezeigte Klassifikation langfristig weltweit zu einem besseren Behandlungszugang für Patientinnen und Patienten mit chronischen Schmerzen beitragen (D. S. Goldberg & McGee, 2011).

5.3 Fazit

Die vorliegende Dissertation konnte zeigen, dass die neue ICD-11-Klassifikation chronischer Schmerzen wichtige Gütekriterien für diagnostische Klassifikationssysteme sowie die Ziele der ICD-11, klinische Nützlichkeit und globale Anwendbarkeit (International Advisory Group for the Revision of ICD-10 Mental and Behavioural Disorders., 2011; Reed, 2010), erfüllt. Mit den sieben Hauptkategorien der Klassifikation können fast alle chronischen Schmerzsyndrome erfasst werden und die Kategorien sind klar voneinander abgrenzbar, was

auch ein Hinweis auf die Validität der Klassifikation ist (Bruehl et al., 2016; Kendell & Jablensky, 2003). Des Weiteren konnte gezeigt werden, dass die neue Klassifikation chronischer Schmerzen sich erfolgreich in die übergeordnete Struktur der ICD-11 einbetten lässt, was eine wichtige Voraussetzung für ihre Implementierung ist. Es zeigte sich, dass die Kodierung chronischer Schmerzen mit den neuen ICD-11-Diagnosen hinsichtlich Korrektheit, Einfachheit, Ambiguität und Detailtiefe den ICD-10-Diagnosen überlegen ist. In einer naturalistischen Implementierungs-Feldstudie wurde die hohe bis sehr hohe Interrater-Reliabilität der ICD-11 Klassifikation chronischer Schmerzen gezeigt. Weiterhin wurde die klinische Nützlichkeit der neuen Klassifikation als hoch bis sehr hoch eingeschätzt Es ist zu betonen, dass diese Studie in Ländern mit hohem (Neuseeland), hoch-mittlerem (Kuba) und niedrig-mittlerem (Indien) Einkommensstatus durchgeführt wurde, was die Generalisierbarkeit der Ergebnisse gegenüber Evaluationen, die lediglich in westlichen Industrienationen durchgeführt werden, deutlich erhöht und Rückschlüsse auf die globale Anwendbarkeit der Klassifikation ermöglicht (D. P. Goldberg et al., 2016; Reed, Keeley, et al., 2018). Der im Rahmen dieser Dissertation entwickelte Klassifikationsalgorithmus kann langfristig in der Forschung und Praxis zu einer einfachen, standardisierten und reliablen Diagnosevergabe chronischer Schmerzen beitragen (Malt, 1986; Martel-Pelletier et al., 2019; Morgan et al., 2000; Rinaldi et al., 2000) und somit die klinische Nützlichkeit der Klassifikation weiter erhöhen. Damit stellt der Klassifikationsalgorithmus das zentrale Handwerkszeug für die Anwendung der ICD-11-Klassifikation chronischer Schmerzen dar. Die substanzielle klinische Nützlichkeit der neuen Klassifikation erhöht die Wahrscheinlichkeit, dass diese in Forschung und Praxis umgesetzt wird (Stein et al., 2020).

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7 Anhang

7.1 Anhang A: Studien

7.1.1 Anhang A.1: Studie 1

Barke, A., Korwisi, B., Casser, H.-R., Fors, E. A., Geber, C., Schug, S. A., Stubhaug, A., Ushida, T., Wetterling, T., Rief, W. & Treede. R.-D. (2018). Pilot field testing of the chronic pain classification for ICD-11: The results of ecological coding. *BMC Public Health, 18,* 1239. https://doi.org/10.1186/s12889-018-6135-9

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Pilot field testing of the chronic pain classification for ICD-11: the results of ecological coding

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Abstract

Background: A task force of the International Association for the Study of Pain (IASP) has developed a classification of chronic pain for the ICD-11 consisting of seven major categories. The objective was to test whether the proposed categories were exhaustive and mutually exclusive. In addition, the perceived utility of the diagnoses and the raters' subjective diagnostic certainty were to be assessed.

Methods: Five independent pain centers in three continents coded 507 consecutive patients. The raters received the definitions for the main diagnostic categories of the proposed classification and were asked to allocate diagnostic categories to each patient. In addition, they were asked to indicate how useful they judged the diagnosis to be from 0 (not at all) to 3 (completely) and how confident they were in their category allocation.

Results: The two largest groups of patients were coded as either chronic primary pain or chronic secondary musculoskeletal pain. Of the 507 patients coded, 3.0% had chronic pain not fitting any of the proposed categories (97% exhaustiveness), 20.1% received more than one diagnosis. After adjusting for double coding due to technical reasons, 2.0% of cases remained (98% uniqueness). The mean perceived utility was 1.9 ± 1.0, the mean diagnostic confidence was 2.0 ± 1.0.

Conclusions: The categories proved exhaustive with few cases being classified as unspecified chronic pain, and they showed themselves to be mutually exclusive. The categories were regarded as useful with particularly high ratings for the newly introduced categories (chronic cancer-related pain among others). The confidence in allocating the diagnoses was good although no training regarding the ICD-11 categories had been possible at this stage of the development.

Keywords: Field testing, Chronic pain, Classification, Clinical utility, Diagnostic categories, Ecological coding, ICD-11

Background

The International Association for the Study of Pain (IASP) defines pain as an unpleasant sensory or emotional experience associated with actual or potential tissue damage or described in terms of such damage [1]. Chronic pain is pain that persists or recurs for longer than three months [2, 3]. Chronic pain affects more than 20% of the population worldwide [4–7], accounts for up to 20% of physician visits [8, 9], and emerged as an important component in the global burden of disability [10]. However, despite their importance, in the current version of the *International Classification of Diseases* (ICD-10), chronic pain conditions are not recognized in a systematic way. Adequate representation in the ICD has far-reaching consequences. The ICD is the global standard of diagnostic classification and serves a wide range of purposes: by international treaty, it supports the world-wide collection of health statistics and the collected data provide the basis most governments use for their health policy, planning, and resource allocation [11]. In addition, the codified criteria identify the

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conditions for research, so the ICD diagnoses inform research agendas. Lastly, adequate diagnoses are essential for treatment choices [12, 13].

Responding to this need, the IASP established a task force consisting of pain experts from around the world to develop a pragmatic classification of chronic pain for the inclusion into the eleventh revision of the ICD. The task force has presented a pragmatic, research-based classification proposal, which comprises seven categories of chronic pain conditions [2, 3]:

1. Chronic primary pain (e.g. irritable bowel syndrome, 'non-specific' chronic low back pain, fibromyalgia) [14]
2. Chronic cancer-related pain (e.g. chronic cancer pain, chronic post-chemotherapy pain) [15]
3. Chronic postsurgical and posttraumatic pain (e.g. chronic pain after amputation, chronic pain after burns injury) [16]
4. Chronic neuropathic pain (e.g. chronic painful polyneuropathy, chronic central post-stroke pain) [17]
5. Chronic secondary headache or orofacial pain (e.g. chronic orofacial muscle pain) [18]
6. Chronic secondary visceral pain (e.g. chronic visceral pain from persistent inflammation or from vascular mechanisms) [19]
7. Chronic secondary musculoskeletal pain (e.g. chronic musculoskeletal pain from persistent inflammation, chronic musculoskeletal pain associated with osteoarthritis) [20].

Importantly, several of these chronic pain conditions hitherto have not been represented in the ICD, e.g. chronic primary pain, chronic neuropathic pain and chronic cancer-related pain. The seven large classes of chronic pain comprise more detailed subdiagnoses, capturing well-described pain problems (see examples in parentheses). A patient presenting with chronic back pain, for example, should be screened for red flags related to chronic secondary musculoskeletal back pain [20]; if there are no red flags, he or she would receive the diagnosis of chronic primary musculoskeletal pain, which is a more detailed subcategory of chronic primary pain [14]. This contrasts with the situation in ICD-10, in which there are a great number of codes for chronic back pain, many of them widely criticized [14, 20, 21]. In addition, the only diagnoses represented are ones that are regarded as chronic secondary musculoskeletal pain by the new classification. All chronic pain diagnoses can be combined with optional specifiers encoding pain severity (which includes pain intensity, pain-related disability, and pain-related emotional distress), the temporal course of the pain, and the presence of psychosocial factors [2, 3].

With the ICD-11, the WHO has introduced several new features [22]. Among others, the *World Health Organisation* (WHO) implemented multiple parenting. Multiple parenting means that diagnostic entities can have more than one so-called parent, i.e. be listed under more than one heading. This overcomes the problem that, previously, one and the same disease could be classified, e.g. according to etiology (as a neoplasm) and according to site (genitourinary system) with different codes. Now, the different places will all link to one and the same code. In the area of pain, an entity such as "Chronic chemotherapy-induced pain" can now be subordinate to, e.g. "Chronic cancer pain" (etiology) and "Chronic neuropathic pain" (mechanism). By allowing the same entity to be included in two or more categories, multiple parenting represents an advance in the systematic structure [2] that often also corresponds to different medical specialties (i.e. oncologist and neurologist).

Please note that the present authors use the term 'diagnosis' in a technical sense. The WHO recognizes diseases, disorders, signs, symptoms, injuries, and reasons for encounter as entities in the foundation of ICD-11. We use the term diagnosis for the allocation of a code for a cluster of frequently co-occurring symptoms, for which further inclusion and exclusion criteria apply. This may be a disease or a disorder. We do not intend to imply any further claims regarding a possible etiology or disease entity by calling something 'a diagnosis'.

Any new classification must demonstrate its quality [11, 13]. Three relevant dimensions determining a classification's quality are reliability, validity, and utility. Reliability refers to the question of whether the same entity is coded in the same way on different occasions, either by different raters (inter-rater reliability) or by the same rater (intra-rater reliability). Several factors impact reliability measures: on the raters' side, reliability may be improved by training and conscientious practice; on the classification's side, clear, operationalized criteria and limited complexity facilitate reliable classification [23, 24]. Validity has been discussed with reference to particular diagnoses and whole classification systems [25, 26]. Applied to a classification as a whole, a valid classification would be one where the boundaries of the diagnostic categories defined in the conceptual realm correspond to separate entities in external reality. It is apparent that this is an ideal, attainable only in part and difficult to test empirically. With respect to pain classification, the difficulty is exacerbated since pain is a subjective experience and external references are lacking [27]. Clinical use, alongside public health use, is one of the main purposes of the ICD [28], and the (WHO) has prioritized improvement of clinical utility during the ICD revision [11, 26, 28]. Clinical utility is defined as the

degree to which a classification system conceptualizes diagnostic entities, contributes to the selection of adequate treatment interventions, predicts clinical management needs, is applicable in clinical practice [29], provides information about prognosis and treatment outcome [26], and facilitates communication about the phenomena described. Moreover, a clinically useful classification system is easy to use [11]. Reliability as well as clinical utility is improved if the categories of a classification system have clear boundaries [13] and the categories are mutually exclusive, exhaustive, reliable, biologically plausible, and simple [30].

Two types of field tests can be distinguished to evaluate clinical utility [11]. Formative field tests are implemented during the process of developing a new classification in order to obtain information on how to improve the structure and content of the classification system. Evaluative field tests are administered once a first draft of the new classification system has been finalized, to evaluate different aspects of its application [29]. The field test described here represents a formative field test. This implies that the classification was tested at the implementation level it had at the time of testing, which meant that only the seven top level diagnoses could be tested. The fact that only the top level diagnoses could be tested had important consequences: One of the consequences for the testing presented here was that due to multiple parenting some diagnoses are correctly subsumed under more than one heading. In the final version (available at the website of the ICD-11: https://icd.who.int/dev11), this will be solved on the next level of the classification and does not constitute a problem with a category boundary.

The goal of the present pilot field test was the assessment of:

1) the exhaustiveness of the basic categories of the proposed classification for chronic pain: how many cases of chronic pain cannot be classified by the proposed classification and would be relegated to the category “Chronic pain, unspecified”?
2) the clarity of the category boundaries: how many cases of chronic pain would be allocated to more than one category?
3) the perceived usefulness of the categories;
4) the confidence with which the coding clinicians chose each category.

In order to gather pilot data with regard to these questions, clinicians from several pain centers and one primary care center participated and classified a number of consecutive patients on the basis of the proposed classification.

Methods

Participating institutions and raters

Several institutions on three continents participated in the preliminary testing, which was carried out from 15 July – 31 August 2016 upon request by the WHO. The participating raters worked at tertiary pain centers, except for one Norwegian primary care center. (See Table 1 for an overview of the participating centers). The choice of participating centers was mainly guided by their ability to carry out the testing in the timeframe of the ICD-11 preparation process, both in terms of resources and numbers of patients with chronic pain seen by them. Centers were selected from IASP collaboration centers. The raters were clinicians experienced with regard to chronic pain, but without any formal training with respect to the ICD-11, because such training was unavailable at that stage in the development. The definitions themselves and the overview article [2] were the only aid. Raters allocated ICD-11 codes to consecutive patients as they were seen, and at conclusion of the data collection time had coded a total number of 507 patients.

Material

All institutions received the definitions as they are provided in the ICD-11 and operationalized diagnostic criteria for the following seven diagnoses:

1. Chronic primary pain
2. Chronic cancer-related pain
3. Chronic postsurgical and posttraumatic pain
4. Chronic neuropathic pain
5. Chronic secondary headache or orofacial pain
6. Chronic secondary visceral pain
7. Chronic secondary musculoskeletal pain

These diagnoses represent the top level of the classification. Including the individual diagnostic categories below the top level was not possible because they had not been implemented in the ICD-11 foundation layer at the time.

Procedure

The participating institutions were asked to code 100–150 consecutive patients according to the criteria provided and report on the diagnoses, whether the raters thought the patients’ conditions would fall under more than one category (to assess category boundaries) or whether they did not fit any of the categories (to assess the exhaustiveness of the categories combined). In addition, the raters were asked to rate the utility of each diagnosis and subjective diagnostic certainty with which they allocated it.

Table 1 Participating institutions, cases coded by each center and the number of raters

Institution	Country	Type	Patients rated	Number of raters
Several Multidisciplinary Pain Centers (Aichi Med. Univ., Ehime Univ., Jikei Med. Univ., Kyushyu Univ., Univ. Tokyo, Osaka Univ., Saga Univ., Toyama Univ., Nihon Univ., Fukushima Med. Univ., Juntendo Univ.)	Japan	Tertiary pain centers	91	14
Pain Medicine Center Royal Perth Hospital	Australia	Tertiary pain center	62	4
Deutsches Rotes Kreuz Schmerzzentrum (Mainz)	Germany	Tertiary pain center	150	2
Oslo University Hospital, Dept. of Pain Management and Research	Norway	Secondary and tertiary care	103	4
Edda Medical Center/Leangen Medical Center/Heimdal Helsehus Medical Center (Trondheim)	Norway	Primary care	101	3

Diagnostic code

For each coded patient, it was recorded which diagnoses he or she had received routinely on the basis of ICD-10 and the diagnoses he or she would receive according to the ICD-11 diagnostic categories (1–7). For primary care, patients also had received pain diagnoses from the International Classification of Primary Care, Second Edition (ICPC-2).

Category exhaustiveness

If the diagnosis did not fit any of the ICD-11 categories, the raters were instructed to record this fact. For this purpose, it was asked: "Did the patient have chronic pain that did not fit any of the categories?" The answers were used to investigate the proportion of diagnoses the seven categories in combination could classify. A high number of affirmative answers to this question would mean that many instances of chronic pain cannot be classified with the proposed system; conversely, low numbers of affirmative answers point to good coverage of the field of chronic pain by the proposed classifications.

Category boundaries

In order to determine the clarity of the category boundaries, the raters were asked whether the pain the patient reported fitted into more than one category and, if so, into which categories. Affirmative answers to this question were taken to indicate a possible problem with category boundaries with a few provisos. Positive answers to this question may have different causes. Firstly, the patient could have two comorbid pain complaints (i.e., chronic tension-type headache and knee osteoarthritis) and would naturally receive two diagnoses. These cases were easily discerned on the basis of the ICD-10 codes, and were counted as co-existing pain conditions rather than double categories. Secondly, the patient could have a pain disorder that would be an instance of double parenting, such as cancer pain of a neuropathic nature. In the actual classification, this would receive a single diagnostic code that will be accessible via cancer-related pain and via neuropathic pain. Because the present field testing only extended to a level at which the double parenting could not be expressed, double category assignments of this nature were regarded as artifacts of the testing procedure. The remaining double codings were deemed to be due to a lack of clarity of the category boundaries. These cases were counted and high proportions of these cases could indicate a possible problem with category boundaries or their perception by the raters.

Perceived clinical utility and subjective diagnostic certainty

In order to assess perceived clinical utility each clinician rated on a four-point scale from 0 (*not at all*), 1 (*somewhat*), 2 (*very*) to 3 (*completely*) how useful they felt the diagnosis was for each patient. The subjective feeling of diagnostic certainty was rated on a four-point scale from 0 (*not at all confident*), 1 (*somewhat*), 2 (*very*) to 3 (*completely confident*). Mean scores for perceived utility and diagnostic certainty were calculated for each category, with higher scores indicating higher utility and confidence, respectively.

Data analysis

The data were analyzed by descriptive methods. We counted the diagnoses that the patients received using the old ICD-10 classification and calculated the average number per patient. For the new classification for ICD-11, we also counted how many diagnostic codes each patient had received. The maximum here would be 7 (all diagnoses applied to the person) and the minimum 0 (none of the 7 categories applied). To establish category boundaries, theoretically, each patient should fall into only one of the seven categories. Cases in which the number of diagnoses allocated was higher than 1 were therefore taken as indicative of a possible problem with category boundaries, provided, they were not occasioned by one of the possibilities outlined above in Section "Category Boundaries". Cases in which the number was 0, were counted and assessed separately as cases in which no diagnosis could be assigned by the raters: this represents the case of chronic pain that cannot be classified within the system. In order to be certain that it had not just been an oversight, we counted the answers to

the explicit question of whether the patient had chronic pain that was unclassifiable by the categories provided and calculated the percentage of all cases that remained unclassifiable within the tested classification. A high percentage of unclassifiable cases would be indicative of a problem with the exhaustiveness of the categories. For each category, means and standard deviations for the raters' subjective diagnostic confidence and utility judgements are reported.

Results

Diagnostic codes

The most frequently given codes were chronic primary pain and chronic secondary musculoskeletal pain, probably partly reflecting their high incidence in primary, secondary, and tertiary care. However, the low frequency of chronic cancer-related pain, chronic headache or orofacial pain and chronic secondary visceral pain may also reflect a recruitment bias in this small group of participating centers. The patients received on average 1.2 ± 0.7 ICD-11 codes (range 1–3). (See Fig. 1 for the distribution across the seven ICD-11 categories). The patients received, on average, 1.7 ± 1.2 ICD-10 codes (range: 1–7). The most frequent ICD-10 codes were: F45.4 persistent somatoform pain disorder ($n = 60$), M54.4 lumbago with sciatica ($n = 48$), and M54.5 low back pain ($n = 43$); the most frequent ICPC-2 codes were L18 muscle pain ($n = 13$), A01 Pain general/multiple sites ($n = 9$), L02 Back symptom/complain ($n = 8$). In seven cases (1.2%), the rater used a clearly erroneous ICD-11 code (as compared with the ICD-10 codes and comments provided), e.g. coding a knee problem as visceral pain.

Exhaustiveness

Of the 507 coded patients, 15 were reported to have chronic pain that failed to be represented by any of the seven categories. These constitute 3.0% of the total and, following ICD-11 procedure, would be classified as "Chronic pain, unspecified".

Category boundaries

Of the 507 patients coded, 102 patients (20.1%) were classified as belonging to more than one category. Of these, 36 (7.1%) were due to co-existence of two separate pain conditions, and 23 (4.5%) to the fact that the level of testing could not take into account multiple parenting. In 33 (6.5%) cases, it appears that chronic primary pain was given as an additional comorbid diagnosis in order to express the presence of psychosocial factors influencing a diagnosis of secondary pain. These instances will later be solved by use of an extension code for psychosocial factors with all chronic pain diagnoses, and hence will not constitute a problem with category boundaries. After removal of all three types of artificial cases, only 10 cases remained as potential double classifications (2.0%) (see Fig. 1).

Perceived clinical utility and confidence

Generally, the diagnoses were rated as very useful (mean: 1.9 ± SD: 1.0; theoretical range: 0–3). The categories judged as most useful were "Chronic cancer-related

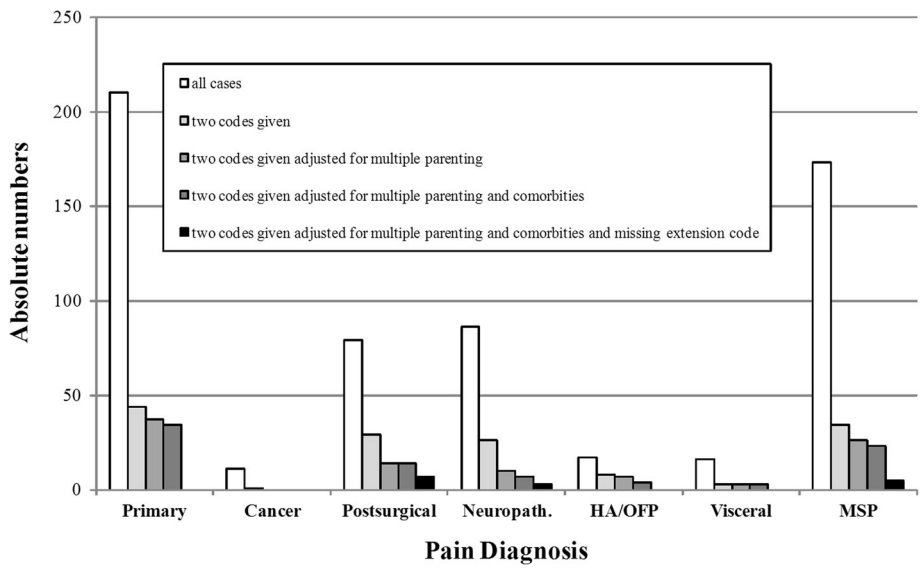

Fig. 1 All cases (absolute numbers) and cases in which more than one diagnostic code was assigned, adjusted for various coding artefacts, such as true comorbidity, multiple parenting, and missing extension codes. HA/OFP: Chronic headache or orofacial pain, MSP: Chronic secondary musculoskeletal pain

pain" (2.7 ± 0.5) and "Chronic neuropathic pain" (2.3 ± 0.8). The raters were confident in applying the diagnoses (2.0 ± 1.0). The highest confidence was expressed with regard to chronic cancer-related pain (2.8 ± 0.4) and chronic neuropathic pain (2.2 ± 0.8). In general, the divergence between the diagnostic categories was small (see Table 2).

Discussion

The present study is the first to present field testing data regarding the proposed classification of chronic pain for the ICD-11. In a naturalistic setting, clinicians in four countries applied the ICD-11 classification to consecutive patients testing the feasibility of its application. They provided ratings of the clinical utility of the suggested categories and their subjective diagnostic confidence. We explored whether the combined categories exhausted the encountered pain conditions and whether overlapping category assignments pointed to a problem with category boundaries.

The clinicians involved in the testing were (except in Australia) wholly independent of the task force that had developed the classification. The general feedback received from the participating institutions was very favorable, emphasizing the usability of, and need for, such a classification. The individual diagnoses proposed were, generally, judged useful. This was particularly true for diagnoses not hitherto included in the ICD, namely "Chronic cancer-related pain", "Chronic neuropathic pain", and "Chronic postsurgical and posttraumatic pain". It is likely the utility will increase further, once sub-level diagnoses are included, such as chronic post-radiotherapy pain or chronic post-stroke pain. All participating clinicians were experienced in ICD-10 (ICPC-2, respectively) coding and familiar with pain syndromes, but specific training with regard to the proposed ICD-11 codes was not available at that stage of development of the classification. The fact that they still expressed good confidence indicates that the proposed system is readily usable. It is to be expected that – with training and practice – the reliability and subjective confidence will increase even further.

The proposal aimed at a good coverage of chronic pain syndromes. In the present field test, about 3% of cases were deemed not classifiable by the proposed classification and would have to be classed as "Chronic pain, unspecified". It would be instructive to compare the data obtained by use of the ICD-11 with those in previous studies using the ICD-10. However, as chronic pain was not represented systematically in previous versions, epidemiological studies on chronic pain were not able to rely on ICD-10 codes [31–34], rendering it impossible to determine the percentage of patients who previously fell into the residual categories in the ICD-10. Our result indicates that the proposed ICD-11 categories capture a large majority of encountered chronic pain diagnoses. This is an excellent result since relegating conditions to a residual category is associated with a lack of information about treatment choice for the individual patient [35]. Scientifically, residual categories are associated with a shortage of research [36].

Unclear category boundaries limit the reliability of diagnostic categories. We therefore investigated the number of cases in which more than one category was assigned to a patient. Only in 20.1% of cases, two diagnoses were allocated. This number decreased substantially when true comorbidities were taken into account, and it was adjusted for cases that were due to the artificial situation that only the top level was coded where multiple parenting remained invisible. It is expected that the provision of second level diagnoses and their operationalized criteria in subsequent field trials will eliminate this problem. Excluding these cases, only 11.6% were left. A third type of case was observed in connection with chronic primary pain: a secondary pain syndrome with a clear underlying disease, e.g. chronic osteoarthritis, was exacerbated by psychological factors, e.g. anxiety. Sometimes, this seems to have led raters to conclude that the patient should also receive a diagnosis of chronic primary pain. This is not correct and the problem will be addressed once the specifiers are included in

Table 2 Mean ratings of usefulness for the proposed categories and subjective confidence in allocating the cases to the respective categories

Diagnostic entity	Perceived utility (mean ± SD)	Subjective confidence (mean ± SD)
Chronic primary pain	1.7 ± 1.0	1.8 ± 1.0
Chronic cancer-related pain	2.7 ± 0.5	2.8 ± 0.4
Chronic postsurgical and posttraumatic pain	2.0 ± 0.9	2.2 ± 0.9
Chronic neuropathic pain	2.2 ± 0.8	2.2 ± 0.8
Chronic secondary headache or orofacial pain	1.9 ± 0.7	2.0 ± 0.6
Chronic secondary visceral pain	1.8 ± 0.8	1.8 ± 0.9
Chronic secondary musculoskeletal pain	1.9 ± 0.9	2.0 ± 0.9

Theoretical range of the ratings: 0 (not at all) to 3 (completely)

the field testing (which was not an option at this time). Since the specifier "with psychosocial factors" can be combined with all diagnoses in the classification, it will be easy to represent such cases. If the numbers are adjusted for all these cases, only 2.0% of cases remain in which two diagnoses were allocated for a single condition. This points to a very good demarcation between the categories.

In addition, we had asked the raters to judge the perceived utility of the diagnosis for each individual case and all diagnoses were rated as very useful, with the highest scores for chronic cancer-related pain, chronic neuropathic pain and chronic postsurgical and posttraumatic pain. However, the utility to be expected from the implementation of the new diagnoses could not be fully represented in the ratings of the clinicians for individual cases. The extremely positive ratings for categories like cancer and neuropathic pain could be additionally motivated by preferences of some raters (and health care systems), especially in tertiary care, for pathology-rooted categories. Considering the presently unsatisfactory situation with regard to (what will in future be called) "primary pain conditions", the relative improvement in utility for the classification of primary pain could be much higher than captured here.

It should be noted that the reported numbers of the encountered diagnoses do not indicate prevalence of the conditions. Sampling consecutive cases after a start date does not allow for any such conclusion; it only shows what kinds of conditions were encountered in the participating pain centers during that time. Still, the newly introduced "Chronic primary pain" diagnosis was the most frequently used single diagnosis. These first results indicate that this new diagnosis is well accepted, and a major improvement compared to existing concepts (e.g., somatoform pain disorder; functional pain syndromes). We had also asked for ICD-10 codes and ICPC-2 codes for the patients, and inspection of these codes showed that many patients had three and more ICD-10 codes. Although no definite conclusion can be drawn due to the different levels of the coding (top level in the field testing vs. individual codes), it was also apparent that with the new classification, for a majority of these cases, fewer, and more suitable, diagnoses would become available.

Recommendations

Individual comments received on cases and formulations were reviewed carefully by the task force and should be used to improve details of the classifications further. When implementing the classification, the relevant subcategories should be added. Formal training in the use of the classification should be available after its introduction into routine practice. Future research should address questions of inter-rater reliability and validity in different settings.

Limitations and future directions

The field testing was part of a formative field test and helped to gain first insight into the clinical utility of the classification in routine practice prior to its implementation in the ICD-11. To be of relevance for the ICD-11 preparation process, the formative nature of the testing also meant that it had to be completed within a short time frame. Only this way would have allowed changes to main categories if a problem had been revealed by the testing. The main aim was to investigate *mutual category exclusiveness* and *joint exhaustiveness* rather than the smooth applicability in various settings. For this purpose, centers were chosen from the list of IASP cooperation centers, if enough patients with a variety of chronic pain complaints were seen and resources allowed clinicians to engage in double coding, i.e. accomplish the double coding in addition to discharging their clinical duties. These conditions were typically met by tertiary centers, but we are happy that one primary center participated. This represents a trade-off between speed of data collection/variety of patients over the investigation of a variety of settings. The relevance of the new pain classification in primary care centers is discussed elsewhere [21].

Further limitations were its pilot character, which implied the use of the classification's top-level structure only, the lack of formal inclusion and exclusion criteria for the patients or in-depth data regarding their conditions. Moreover, no checks were implemented to assure that indeed consecutive patients were recruited, and that patients were not selectively excluded from this list. All raters were physicians who worked with patients with chronic pain and were experienced ICD-10 users, but had not received formal training using ICD-11 classifications. Different numbers of raters coded different patients of differing populations. This allowed the main purpose of the study (testing category boundaries and exhaustiveness) but made further analyses impossible. These analyses will be the focus of future field testing of the new classification that will implement various field testing strategies as e.g. elaborated by Keeley and colleagues [37]. Since it will no longer be a study of the formative phase, it will be able to use a full version of the classification as it has now been implemented in the ICD-11 and address questions of reliability and clinical utility.

This article was concerned mainly with clinicians allocating diagnoses on the basis of patient examinations. A further group of persons working with the ICD codes are non-clinicians coding diseases and health complaints from documentation for statistical or reimbursement purposes. Testing how the new classification of chronic

pain performs in this context was beyond the scope of the present study, but will be part of a large WHO-led study regarding technical aspects of the ICD-11 codes, coding rules, the browser infrastructure and its search options as well as coding tools.

Conclusion

This pilot field testing indicated that the proposed classification of chronic pain into one group of chronic primary pain syndromes and six groups of chronic secondary pain syndromes performed promisingly in real life, both in specialized pain centers and in one primary care center. The categories were exhaustive with very few cases being relegated to residual categories. They were also mutually exclusive and the raters were able to allocate single categories to the majority of cases even without any formal training. All proposed categories were regarded as clinically useful by the raters with a particular emphasis on the newly introduced categories of chronic cancer-related pain, chronic neuropathic pain, and chronic postsurgical and posttraumatic pain. Finally, the acceptance of the classification, and the subjective confidence in allocating the diagnoses was good and one of the participating sites continues to use the ICD-11 codes in their clinical practice.

Abbreviations

CRPS: Complex regional pain syndrome; IASP: International Association for the Study of Pain; ICD: International Classification of Diseases; ICPC: International Classification of Primary Care; WHO: World Health Organisation

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

AB, WR and RDT designed the study, HRC, EAF, CG, SAS, AS, TU, TW assessed patients, and collected data, AB analysed the data, AB and BK wrote the first draft of the manuscript, WR and RDT commented on the first draft, BK, HRC, EAF, CG, SAS, AS, TU, TW, RDT and WR commented on the final draft. All authors have read and approved the manuscript.

Ethics approval and consent to participate

In Germany, a general ethics commitment for epidemiology and consumer surveys was agreed (www.adm-ev.de), that allows the conduct of single projects without specific ethical approval, as long as the principles of this commitment for epidemiological, social and consumer satisfaction purposes are accepted (e.g., only use of fully anonymized data for the specific purpose). These principles were observed and the procedure discussed with all centers. Raters were clinicians that volunteered their participation; no explicit consent was required in the participating countries.

Consent for publication

Not applicable.

Competing interests

ABs position is funded by the *International Association for the Study of Pain* (IASP). AS, BK, CW, HRC, SAS, TU, TW declare no competing interest. RDT reports grants from European Union and EFPIA companies, grants from Pfizer, grants from BMBF, during the conduct of the study; grants from Boehringer Ingelheim, Astellas, AbbVie, Bayer, personal fees from Astellas, Grünenthal, Bauerfeind, Hydra, Bayer, outside the submitted work; in addition, RDT has a patent DE 103 31,250.1–35 with royalties paid to MRC Systems. WR reports grants from IASP during the course of the study; personal fees from Heel and Berlin Chemie, outside the submitted work.

Publisher's Note

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7.1.2 Anhang A.2: Studie 2

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Classification of Chronic Pain for the International Classification of Diseases (ICD-11): Results of the 2017 International WHO Field Testing

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Abstract

Background: Chronic pain has been poorly represented in the International statistical classification of diseases and related health problems (ICD) up to its 10th revision despite chronic pain's significant contribution to the burden of disease worldwide. To improve the management of chronic pain, its accurate coding in the ICD is a prerequisite. The objective of this field test was to determine the coding properties of the new classification of chronic pain developed by the International Association for the Study of Pain (IASP) for the inclusion into the 11th revision of the (ICD-11).

Methods: The web-based survey using the WHO-FiT platform was online from June to August 2017 and recruited 177 health-care professionals from all WHO regions. Following a training session on coding chronic pain hosted by the IASP website, participants evaluated 18 codes (lines) of the 2017 frozen version of the ICD-11 and 12 vignettes (cases) describing chronic pain conditions. Correctness, ambiguity and perceived difficulty of the coding were compared between the ICD-11 and the ICD-10 and the applicability of the morbidity rules for the ICD-11 verified.

Results: In the line coding, 43.0% of correct chronic pain diagnoses assigned with the ICD-10 contrasted with 63.2% with the ICD-11. Especially in cases in which the chronic pain is regarded as the symptom of an underlying disease, the ICD-11 (63.5%) commanded more correct diagnoses than the ICD-10 (26.8%). The case coding was on average 83.9% accurate, only in 1.6% of cases any difficulty was perceived. The morbidity rules were applied correctly in 74.1% of cases.

Conclusions: From a coding perspective, the ICD-11 is superior to the ICD-10 in every respect, offering better accuracy, difficulty and ambiguity in coding chronic pain conditions. The classification of chronic pain (MG30) is included in the ICD-11 version approved by the World Health Assembly in 2019.

Keywords: ICD; field testing; chronic pain; classification; diagnosis; diagnosis; WHO

1. Background

Chronic pain is very frequent [1-3] and one of the most common causes for patients to seek medical attention [4, 5]. It is a major contributor to the global burden of disease [6, 7] leading to individual suffering and substantial direct and indirect societal costs [8-12]. Yet, up to now, in the International Classification of Diseases (ICD), chronic pain diagnoses were not represented systematically [13-15]. Reporting of mortality and morbidity on an international level, visibility in health statistics, consideration in public health policies and research agendas depends on what is listed in the ICD. In addition, many health care systems make the referral for multidisciplinary pain treatment conditional upon suitable ICD codes as indicators of such health needs. The lack of appropriate codes contributes to the paucity of clearly defined treatment pathways for patients with chronic pain.

A systematic classification of chronic pain was developed by an international and multidisciplinary task force of the International Association for the Study of Pain (IASP) [15, 16]. Chronic pain is defined as pain that lasts or recurs for longer than three months. The classification contains seven main diagnostic categories, distinguishing chronic primary pain [17] and chronic secondary pain syndromes [18-22], and integrates existing pain diagnoses including headaches [23]. The seven main categories contain detailed subdiagnoses to achieve a more fine-grained classification. For every diagnosis, precise descriptions, operationalized criteria and characteristic features are provided according to the WHO content models for the ICD-11. These pain diagnoses have been implemented in the 11th version of the ICD that was released by WHO in June 2018 [24] and approved by the World Health Assembly in May 2019 [25]. The ICD-11 will come into effect on 1st January 2022 for international health reporting [25].

The WHO's main revision objective was improving the ICD's clinical utility [26-29]. Clinical utility reflects the degree to which a classification system offers a conceptualization of the diagnostic entities, fosters the selection of adequate treatments, is easy and feasible to use and applicable in clinical practice, predicts prognosis and treatment outcomes and facilitates communication and documentation [30-33].

The ICD relies on codes to standardize the collection and communication of health data. The correct code assignment once a diagnosis has been named is of paramount

importance since the assigned code forms the basis of all further information processing in the health systems. So-called morbidity rules (see Box 1) govern which condition should be coded as the main condition for which healthcare was sought in any particular encounter if more than one health complaint is present [34]. Such records are central for statistical purposes, the assessment and auditing of services and as basis for public health decisions. New diagnoses included in the ICD-11 must demonstrate that they integrate with this system and allow reliable code assignments (tested in the line coding) and applications of the morbidity rules (tested in the case coding).

--- Insert Box 1 about here ---

In the present study, we aim to provide an empirical basis for including the new diagnostic categories of chronic primary and secondary pain in the ICD-11. We compare correctness and ambiguity of the new ICD-11 codes with those of the ICD-10, evaluate perceived ease of use, clinical utility, and appropriateness of coding details, and examine the compatibility with the ICD-11 morbidity rules. Since the WHO intends the ICD-11 to provide a user-friendly version that does not require specifically trained coders, participants were recruited from professions involved in the clinical management of patients with chronic pain.

2. Methods

2.1 Recruitment and participant sample characteristics

From June to August 2017, the IASP conducted one of several specialty-specific field trials parallel to the WHO field testing of ICD-11 MMS 2017 [35]. Data of participants from Germany were simultaneously forwarded to a set of field trials commissioned by the German Ministry of Health [36]. Health care professionals working with patients affected by chronic pain were invited through the IASP, as well as other medical and psychological societies; we did not recruit professional coders. Participants preregistered their email address, received a brief online training and were invited to the ICD-FiT [37] online portal as the platform became available.

A total of n=177 participants (mean age 43.8±11.1 years, 57.6% men, 42.4% women) from 35 countries accepted the invitation and rated a grand total of 2576 lines and 1342 cases; for comparison: the WHO field trial recruited 1673 participants from 31 countries and

evaluated 112,383 code assignments [35]. Participants in the present study stemmed from all WHO regions with the largest subsamples from Germany (20.9%), UK (13.0%), China and Australia (9.0% each). Their professions included medicine (63.8%), physiotherapy (19.8%), clinical psychology (9.6%), dentistry (2.8%) and other (4%).

2.2 Material

The field-testing consisted of two parts (line coding and case coding) and an additional section in which the participants provided a general evaluation of the new ICD-11 classification compared to the current ICD-10 classification. To familiarize the participants with the novel pain classification, they could watch training slides on the IASP website and received a document with training material explaining the new diagnoses and the use of the different WHO platforms (ICD-11 Browser, ICD-Fit, Coding Tool.). The testing itself was conducted in English with the ICD-FiT online tool (version 2.7.1) [37]. The training material was available in Chinese, English, French, German, Japanese, Portuguese and Spanish.

For all testing, the ICD-10 version of 2016[38] and the ICD-11 Mortality and Morbidity Linearization was used in the frozen version of 2nd April 2017 (version for quality control) to ensure a constant reference. The frozen version comprised 33 genuine chronic pain diagnoses (excluding the automatically generated categories of 'other' and 'unspecified'). The current 2018 frozen version ('for preparation of implementation') has evolved since then, now including further chronic pain entities.

2.2.1 Line Coding

For line coding, eighteen diagnostic terms ('lines') were selected to reflect the range of chronic pain conditions relevant for morbidity coding [15] and reference codes were prepared for the ICD-11 as well as reference codes for the ICD-10. For the ICD-11, reference standards were the 2017 MMS codes. For the ICD-10, only in 50% of the cases a reference standard existed; in the other cases, the 'correct' diagnosis was an auxiliary way of expressing the syndrome in ICD-10. The auxiliary code consisted of a combination of etiological codes plus some code for chronic pain (R52.1 or R52.2) (cf S1, Supplementary information). The auxiliary codes were allowed in order to give the ICD-10 the best chance in spite of the large number of missing diagnoses for chronic pain [14].

For each line presented, the participant had to determine the appropriate codes in the ICD-10 (via link to the ICD-10 browser, 2016 version) and the ICD-11 (via link to 2017 frozen version of the ICD-11 Mortality and Morbidity Linearization and a special coding tool). The starting point (ICD-10 or ICD-11) was randomized. After coding the lines, the participants were asked whether they had encountered any difficulty in assigning the code (yes / no); whether the level of specificity was appropriate (not detailed enough / just right / too detailed) and whether they had experienced any ambiguity in making the assignment (no / yes, because …).

2.2.2 Case Coding

The case coding examined the ICD-11 only. The main objective was testing the morbidity rule application concerning the chronic pain diagnoses. To this purpose, twelve short case vignettes (mean length=78 words, range: 50-113) were prepared. Each vignette featured two or more health conditions, at least one of which was a chronic pain condition. The vignette stated a main condition and an 'other condition', without listing the ICD-11 codes. (Table 1, vignette texts, cf supplementary information S2).

--- Insert Table 1 about here ---

In ten of the vignettes, the main condition was specified correctly according to the morbidity rules; in two of the vignettes, the rules had been misapplied intentionally to test the participants' application of the rules in connection with chronic pain. In a first step, the participants had to provide the appropriate ICD-11 codes for each condition. In a second step, they had to judge whether the main condition was identified correctly (yes / no). For each diagnosis, we recorded whether they met with any difficulty in finding the code. At the end of each vignette, the participants rated the clinical utility of the new chronic pain code (0=not at all to 5=very useful) according to three questions: How useful is this classification (1) …to describe this case in communications to colleagues? (Communication); (2) … in facilitating the management of patients? (Management) and (3) …for the collection of data (e.g. for clinical or population databases)? (Documentation).

2.3.3 General evaluation

After the participants had completed rating the lines or cases, an additional questionnaire became available in which the participant rated the overall coverage of the conditions in the ICD-11 (5=very good to 1=very poor), the level of detail (not detailed enough/ just right / too detailed) and the ease of use (5=very easy to 1=very difficult). In addition, textboxes were provided for the participants to mention whether they perceived gaps and redundancies.

2.4 Data analysis

2.4.1 Line Coding

For ICD-10 and ICD-11, the percentage of correct codes for each diagnosis and the percentage of difficulties with assigning the code was computed. The variable for the reported ambiguity of assigning the diagnosis was transformed into a binary variable (yes / no) and the frequencies determined. The frequencies of correctly assigned diagnoses, cases without difficulties and cases without ambiguity were compared between ICD-10 and ICD-11 with the McNemar test. The respective frequencies for specificity (too little detail, too much detail, just right) were calculated and compared between ICD-10 and ICD-11 with the McNemar-Bowker test. We also compared the groups of chronic primary and chronic secondary pain with regard to correctly assigned diagnoses, difficulties, ambiguity and specificity.

2.4.2 Case Coding

The percentage of correct codes per pain diagnosis was calculated and the mean judgements of the three facets of clinical utility for each pain diagnosis computed. The correct selection of the main condition according to the Morbidity Rules was analysed between the rules by $\chi 2$ test.

2.4.3 Evaluation

Frequencies for coverage, ease of use and level of detail were calculated. The textboxes were scrutinized for relevant comments and coded whether the participant reported gaps (No

comment / no gap / gap) or redundancies (no comment / no redundancy / redundancy) and frequencies reported.

3. Results

3.1 Line coding

In total, the participants rated 2576 lines. They assigned more codes correctly using the ICD-11 (63.3%) than the ICD-10 (42.1%) [$\chi 2(1, N=2576)=229.23, p<.001$)], encountered fewer difficulties assigning ICD-11 diagnoses (no difficulty 86.6%) than ICD-10 diagnoses (47.2%) [$\chi 2(1, N=2576)=863.81, p<.001$)] and perceived fewer cases of ambiguity for the ICD-11 (no ambiguity: 75.5%) than for the ICD-10 (29.1%) [$\chi 2(1, N=2512)=1003.84, p<.001$)].

Six of the lines referred to what is called 'chronic primary pain' in the ICD-11 and twelve referred to chronic secondary pain. The diagnostic accuracy did not differ significantly in the ICD-11 between chronic primary (62.2%) and secondary pain syndromes (63,8%) [$\chi 2(1, N=2576)=0.64, p>.4$]. In the ICD-10, however, coding of chronic secondary pain was poor (27.2%) while existing chronic primary pain conditions were recognized correctly (70.8%) [$\chi 2(1, N=2576)=722.51, p<.001$]. Regarding the perceived difficulty of the code assignment, primary and secondary pain did not differ in the ICD-11 [$\chi 2(1, N=2576)=0.004$ $p>.9$], but in ICD-10 [$\chi 2(1, N=2576)=58.87, p<.001$), with secondary pain being more difficult. A parallel picture is revealed for ambiguity of code assignment. In the ICD-11 no difference between primary and secondary pain was observed [$\chi 2(1, N=2576)=0.09, p>.7$), but in the ICD-10 more ambiguity was reported for code assignments for secondary pain [$\chi 2(1, N=2576)=49.14, p<.001$)].

--- Figure 1 about here ---

The differences in performance of the ICD-10 and the ICD-11 were also significant for the majority of individual lines (See Figure 2 for correctness; supplementary material S3-4 for difficulty and ambiguity).

--- Figure 2 about here ---

Regarding the level of detail provided in the classification, the participants' ratings favoured the ICD-11 over the ICD-10 for every diagnostic code assessed. A majority (74.1%)

judged the level of detail in the ICD-11 codes as 'just right' vs 24.8% for the ICD-10. [χ2(3, N=2515)=1073.01, p<.001]. Most participants regarded the level of detail in ICD-10 (68.7%) as "too low". (Figure 3). Some lines in ICD-11 were perceived as allowing too little coding details (for a line-by-line analysis cf S5); > 30% regarded the codes for chronic non-specific back pain, for post-herniotomy and post-mastectomy pain, and painful diabetic neuropathy and central post stroke pain as too broad.

--- Figure 3 about here ---

3.2 Case coding

One of the prepared cases referred to a diagnosis (peripheral neuropathic pain) that had not been implemented in the ICD-11 at the time of the field trial, and therefore was excluded from evaluation, leaving thirteen pain diagnoses for eleven cases to be rated per participant. Taken together, the participants rated 1342 cases, each case was rated by between 67% (119/177) and 75% (132/177) of participants. Participants assigned the correct code for the pain diagnosis in 83.9% of cases and in 98.4% reported having no difficulty in assigning the diagnosis (Table 2). The aggregated clinical utility (the mean for the individual facets) was high across all cases (4.3±0.90) on a scale ranging from 0 (not at all useful) to 5 (very useful) and all single cases (Table 2).

--- Table 2 about here ---

Overall, the morbidity rules for the selection of the main condition for encounter with the health system were applied correctly in 74.1% of all cases, irrespective of whether the rule was violated in the vignette or not (χ2(1,N=1461)=3.67, p>.05). Rule 1 (74.4% correct) and 2 (71.3% correct) did not differ from each other [χ2(1, N=1187)=1.50, p>.2], but from rule 3 (96.0% correct) [Rule 1 vs 3: χ2(1, N=832)=48.51, p<.001; Rule 2 vs 3: χ2(1, N=807)=58.50, p<.001] (Fig.4).

--- Figure 4 about here ---

3.3 General evaluation

In the general evaluation, 88.2% of the participants rated the ICD-11 classification of chronic pain as easy or very easy to use (Figure 5A). Regarding the classification itself, 97.3% of the participants rated the coverage as good or very good (Figure 5B). They perceived no

redundancies (82.9%) (Figure 5C) and rated it as having just the right level of detail (85.5%) (Figure 5D).

--- Figure 5 about here ---

In cases where participants indicated gaps, they referred mainly to chronic postsurgical or post traumatic pain and chronic neuropathic pain.

4. Discussion

With this study, we supply comprehensive data of an evaluative field test investigating whether the new chronic pain diagnoses conform to the WHO requirements for ICD-11 coding. In particular, we investigated whether the new diagnoses conform to the WHO requirements necessary for ICD-11 coding.

In the line coding, the new ICD-11 classification was tested against the established system of ICD-10 and outperformed it in almost any way: With ICD-11, coding was more accurate, easier and less ambiguous to use than ICD-10. In particular, chronic secondary pain was difficult to code in ICD-10 (73.2% false). The lack of unique codes for these conditions in the ICD-10 required the co-selection of unspecific codes (R52) to indicate the presence of chronic pain. Most participants failed to use this code combination and offered a broad variety of codes and combinations instead. This demonstrated that reliable coding of chronic pain conditions with the ICD-10 is difficult. This difficulty is reflected by the fact that these codes are rarely used in healthcare statistics. Regarding chronic secondary pain, the ICD-11 fared significantly better. For six of the nine lines with existing reference codes, no performance difference was found between the ICD-10 and the ICD-11. Of the remaining three lines, Fibromyalgia was coded more accurately in the ICD-11, chronic non-specific back pain and tension-type headache in the ICD-10. Especially in the case of chronic non-specific back pain, this can be attributed to the use of the ICD-11 frozen version, which did not penetrate to chronic primary low back pain, but required that the participants select chronic primary musculoskeletal pain. Although the concept of chronic primary pain is new [15, 17], the codes were correctly identified in both, the ICD-10 and the ICD-11. However, perceived difficulty and ambiguity were less in ICD-11 for both chronic primary and secondary pain conditions. In drawing conclusions from this result, it is especially important to bear in mind that the

participants had much more experience in coding ICD-10 than ICD-11 where they received a brief online training only. To sum up, by demonstrating a reliable translation of diagnoses into code, the chronic pain section in ICD-11 conforms to the requirements of the WHO and promises substantial improvements over ICD-10.

The case coding tested the selection of appropriate ICD-11 codes in the context of vignettes that provided meaningful clinical information. The code assignments were very accurate (83.9% correct) and only 1.6% reported difficulty assigning the diagnosis. This excellent performance was obtained from clinicians, not professional coders. The case coding demonstrated that the chronic pain section performs well within the framework of morbidity rules and allows a correct rule-based selection of the main condition that was the reason for the healthcare episode, regardless of whether the chronic pain in question is classed as chronic primary or chronic secondary pain. This is very encouraging as the morbidity rules were only introduced with ICD-11, so that they were unfamiliar to the coders who had only received a brief section on them in the course of the online training. Further improvements in code assignments and rule application are to be expected when the chronic pain classification is available to a more fine-grained level than it was in the frozen version.

Line coding and case coding showed a reliable translation of diagnoses into code, demonstrating that the chronic pain section in ICD-11 conforms to the requirements of the WHO and promises substantial improvements over ICD-10.

The participating pain specialists perceived the clinical utility of the new classification as high and agreed with the utility judgements obtained in the formative field testing [39].

The participants also indicated that the ICD-11 classification of chronic pain offers a good coverage of chronic pain syndromes, again corroborating the results from the informal field testing [39]. The majority felt the level of detail to be appropriate and reported few gaps and very few redundancies. The main areas in which a need for more detailed diagnoses was perceived were chronic neuropathic pain and chronic postsurgical or post traumatic pain. Here, the frozen version meant that the coding reached only down to the levels of chronic postsurgical or post traumatic pain, or chronic central or chronic peripheral neuropathic pain. This does not reflect the classification [21, 22], but the granularity of the frozen version. At present, this is still the level to which the classification is shown with codes in the ICD-11,

although the level below, allowing for the relevant detail, has been included as index terms ("inclusion terms") and has been assigned uniform resource identifiers.

To sum up, the field test demonstrated that the classification of chronic pain in the ICD-11 improves clinical utility and thus fulfills a central aim of the ICD revision process [26, 29]: the ICD-11 was easier to use and less ambiguous than the ICD-10 and reflected all relevant categories of chronic pain without redundancy. The descriptions in the foundation were published in a series of papers (for review see [16]) meeting the WHO's aim of scientific evidence for the diagnoses entered. This predicts that in the field of pain medicine, but also for chronic pain cases in primary care, ICD-11 will be easy to implement in clinical practice [40]. Codes were easier to find in ICD-11 browser than ICD-10 browser (less difficulty, less ambiguity). Thus, for morbidity coding, directing patient flow, and providing a basis for reimbursement, ICD-11 should be easy to implement. The excellent mapping of chronic pain syndromes onto clinically meaningful codes will improve the health care statistics and epidemiological studies and contribute to an improved visibility of chronic pain. This, in turn is expected to lead to research programs and advances in access to treatment benefitting millions of chronic pain patients.

Limitations

The new pain classification allows for more detailed coding than had been implemented in the frozen version at the time. Further limitations were the complex registration process for the WHO-FiT and the short timeline for the completion of the field testing, limiting the number of participants; nonetheless, all WHO regions and relevant health care professions were represented in the field test.

Conclusions

In conclusion, the ICD-11 is superior to the ICD-10 and equally suitable for coding chronic primary and chronic secondary pain. The chronic pain section in the ICD-11 appeared to be easy, unambiguous and intuitive for clinicians to use, resulting in accurate code assignments and correct identification of the main condition that was the reason for encounter with the health service. According to results of this field test, it will be more precise and less ambiguous in representing chronic pain conditions in health care statistics in the future.

Declarations

Ethics approval and consent to participate

In Germany, a general ethics commitment for epidemiology and consumer surveys was agreed (www.adm-ev.de), that allows the conduct of single projects without specific ethical approval, as long as the principles of this commitment for epidemiological, social and consumer satisfaction purposes are accepted (e.g., only use of fully anonymized data for the specific purpose). These principles were observed. All raters were clinicians that volunteered their participation as professionals, received full information of the nature of the study and provided informed consent; no explicit ethics statement was required.

Consent for Publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

Antonia Barke reports other from International Association for the Study of Pain, during the conduct of the study. It did not play a role in study design, data collection, analysis an interpretation of the data or writing the manuscript. Beatrice Korwisi, Robert Jakob, Nenad Kostanjsek, Winfried Rief have nothing to disclose. Rolf-Detlef Treede reports grants from European Union IMI, grants from TEVA, personal fees from Bayer, Grünenthal, GSK, Sanofi, grants from Deutsche Forschungsgemeinschaft, outside the submitted work.

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Authors' contributions

AB: Method, data collection, data analysis, writing of initial draft, rewriting manuscript; BK: Method, data collection, data analysis, commenting on manuscript; RJ: Design, commenting on manuscript; NK: Design, method, commenting on manuscript; WR: Supervision, commenting on manuscript; RDT: Supervision, commenting on manuscript

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Figure legends:

Fig. 1: Performance of the ICD-10 and the ICD-11 in the line coding of chronic pain conditions.

Correctness (A), difficulty (B) and ambiguity (C) of coding diagnostic terms of chronic primary pain conditions using the ICD-10 (filled bars) and the ICD-11 (open bars). Frequencies are shown in percent of all lines. Statistical testing with McNemar's test. *** $p < .001$

Fig. 2: Correct code assignments per line for the ICD-10 and the ICD-11.

Correct code assignments in the ICD-10 (filled bars) and the ICD-11 (open bars). Frequencies are shown as percent of the respective condition.

Notes: CRPS: Complex regional pain syndrome; Chr.: Chronic; IBS: Irritable Bowel Syndrome; CIPN: Chronic painful chemotherapy-induced polyneuropathy; TMD: temporo-mandibular disorder; msp: musculoskeletal; assoc.: associated; RA: rheumatoid arthritis; PA: osteoarthritis. Statistical testing with McNemar's test. * $p < .05$; *** $p < .001$.

Fig. 3: Level of specificity of the codes in the ICD-10 and the ICD-11 across all lines.

Fig. 4: Performance of the morbidity rules with the chronic pain conditions

Frequencies of correct (filled bars) and incorrect (open bars) applications of the rules. Frequencies are shown in percent of the application of each rule.

Fig. 5: Global evaluation of the section on chronic pain in the ICD-11

Participants' ratings of ease of use (A), coverage (B), redundancies (C) and level of detail of the diagnoses (D) in the ICD-11.

Additional File (Additional File.pdf)

S1. Line coding: Lines with their respective reference standards according to the ICD-10 and ICD-11

S2. Case coding: Full vignette texts for the vignettes used in the case coding

S3. Line coding: Number of diagnoses (in percent) for which no difficulty in the assignment was reported for ICD-10 and ICD-11 including results of the McNemar test.

S4. Line coding. Number of diagnoses (in percent) for which no ambiguity in the assignment was reported for ICD-10 and ICD-11 including results of the McNemar test.

S5. Line coding. Number of diagnoses (in percent) for which the level of detail was judged as too low, just right or too high for ICD-10 and ICD-11 including results of the McNemar-Bowker test.

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Table 1. Chronic pain and other conditions featured in the vignettes in the case coding

Chronic pain diagnoses	**ICD-11 code**[b]	**Other condition**
[a]Fibromyalgia	MJ60.12	Obstructive sleep apnoea syndrome
Chronic migraine	8A40.3	Recurrent major depression
[c]Chronic primary visceral pain and	MJ60.11	--[a]
[c]Chronic widespread primary pain	MJ60.12	
Chronic cancer pain	MJ60.21	Small cell carcinoma of bronchus or lung, malignant neoplasm metastasis in bone or bone marrow, vertebral column
Chronic painful chemotherapy-induced polyneuropathy	MJ60.23	Malignant neoplasms of colon, unspecified
Chronic postsurgical pain	MJ60.32	Emphysema, unspecified
Chronic central neuropathic pain	MJ60.61	Relapsing-remitting multiple sclerosis
Chronic dental pain	MJ60.72	Pulpitis, Dental caries
Chronic visceral pain from persistent inflammation	MJ60.53	Endometriosis
[d]Chronic musculoskeletal pain from persistent inflammation due to autoimmune disorders	MJ60.413	Rheumatoid arthritis, unspecified
[c]Chronic primary musculoskeletal pain	MJ60.13	--[a]
and [c]Chronic migraine	8A40.3	
Chronic peripheral neuropathic pain	MJ60.62	Type 2 diabetes mellitus, diabetic polyneuropathy

Notes: [a] In vignette 1, MB1 was violated by preselecting 'obstructive sleep apnoea' as the main condition when the vignette clearly suggested that the reason for the encounter was chronic widespread pain.

[b] The codes displayed here, are the codes as implemented in the ICD-11 in 2017, they were updated since.

[c] in these vignettes, two chronic pain conditions were present, rather than one chronic pain condition and one other.

[d] In vignette 10, MB2 was violated by selecting unspecified rheumatoid arthritis as main condition and chronic musculoskeletal pain from persistent inflammation due to autoimmune disorders as other condition, whereas according to MB2, chronic musculoskeletal pain from persistent inflammation due to autoimmune disorders should be the main condition since care was given for this.

Table 2. Case coding. The numbers of participants (in percent) who chose the correct ICD-11 pain diagnosis and numbers of participants (in percent) who did not report any difficulty in assigning the pain diagnosis and mean ratings of clinical utility for each diagnosis.

	Correct pain diagnosis (%)	No difficulty assigning pain diagnosis (%)	Aggregated clinical utility		Valid n
			Mean	SD	
All (without [a])	83.9	98.4	4.3	0.90	1342
Fibromyalgia	87.1	97.7	4.2	0.93	132
Chronic migraine	51.2	97.6	4.4	0.79	127
Chronic primary visceral pain	81.6	95.2	4.2	1.09	125
Chronic cancer pain	86.0	98.3	4.3	0.97	121
CIPN	92.6	99.2	4.3	0.97	121
Chronic postsurgical pain	89.2	97.5	4.3	0.88	120
Chronic central neuropathic pain	95.0	100.0	4.4	0.77	120
Chronic dental pain	87.4	99.2	4.4	0.81	119
Chronic visceral pain from persistent inflammation	89.1	100.0	4.2	0.93	119
Rheumatoid arthritis	75.6	100.0	4.4	0.75	119
Chronic primary musculoskeletal pain	89.9	98.3	4.3	0.92	119
[a]Chronic peripheral neuropathic pain	---	---	---	---	

CIPN: Chemotherapy-induced painful polyneuropathy;

[a] For chronic peripheral neuropathic pain, the correct code was not our code and no crosslinks had been implemented in the frozen version of the browser at time of the study

Box 1. Morbidity coding rules

Morbidity coding rules

Morbidity Rule 1: *Several conditions recorded as the 'main condition'*

Select the 'main condition' for which the patient received care. Extension codes may be used to indicate different types of main condition (e. g., reason for admission, main resource condition). In cases where the main condition cannot be determined based on documentation, select the condition that is mentioned first.

Morbidity Rule 2: *Condition recorded as 'main condition' is presenting symptom of diagnosed, treated condition*

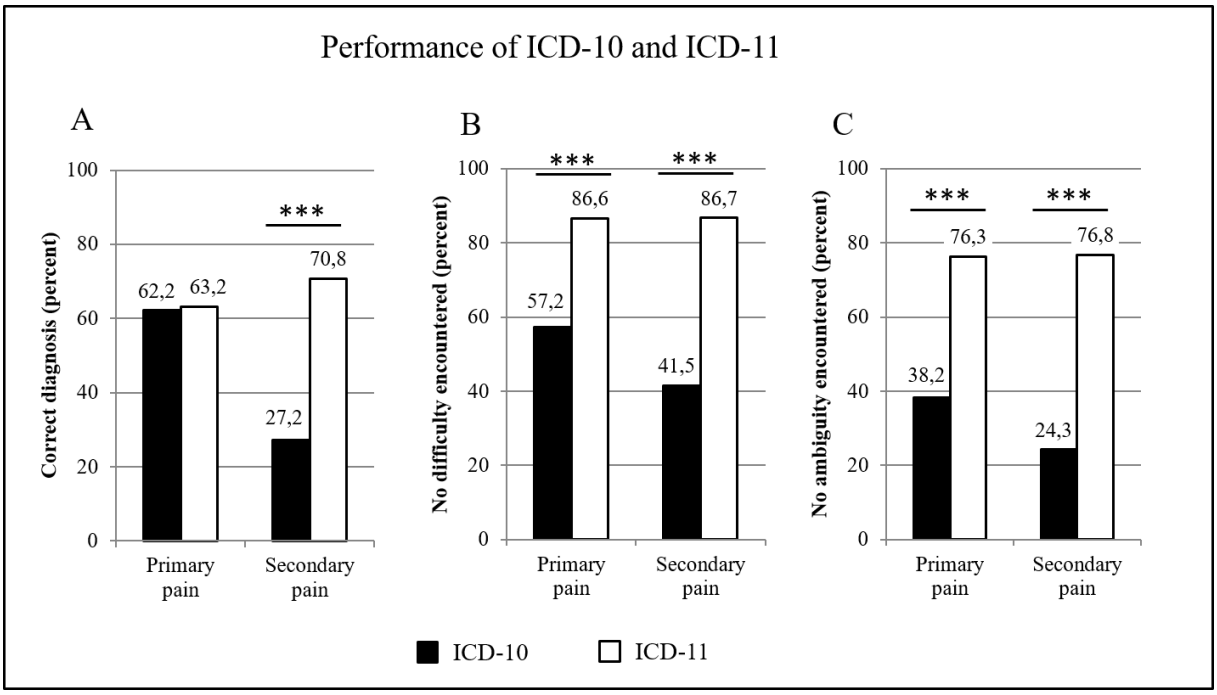
If a symptom or sign (ICD-11 chapter 21) or a problem (ICD-11 chapter 24) is recorded as the 'main condition', and this is obviously a sign, symptom or problem of a diagnosed condition coded elsewhere, and care was given to the latter, reselect the diagnosed condition as the 'main condition'.

Morbidity Rule 3: *Signs and symptoms*

When a symptom or sign is documented as the 'main condition', and it is documented that it could be caused by either one condition or another, select the symptom or sign as 'main condition'.

Figure 1

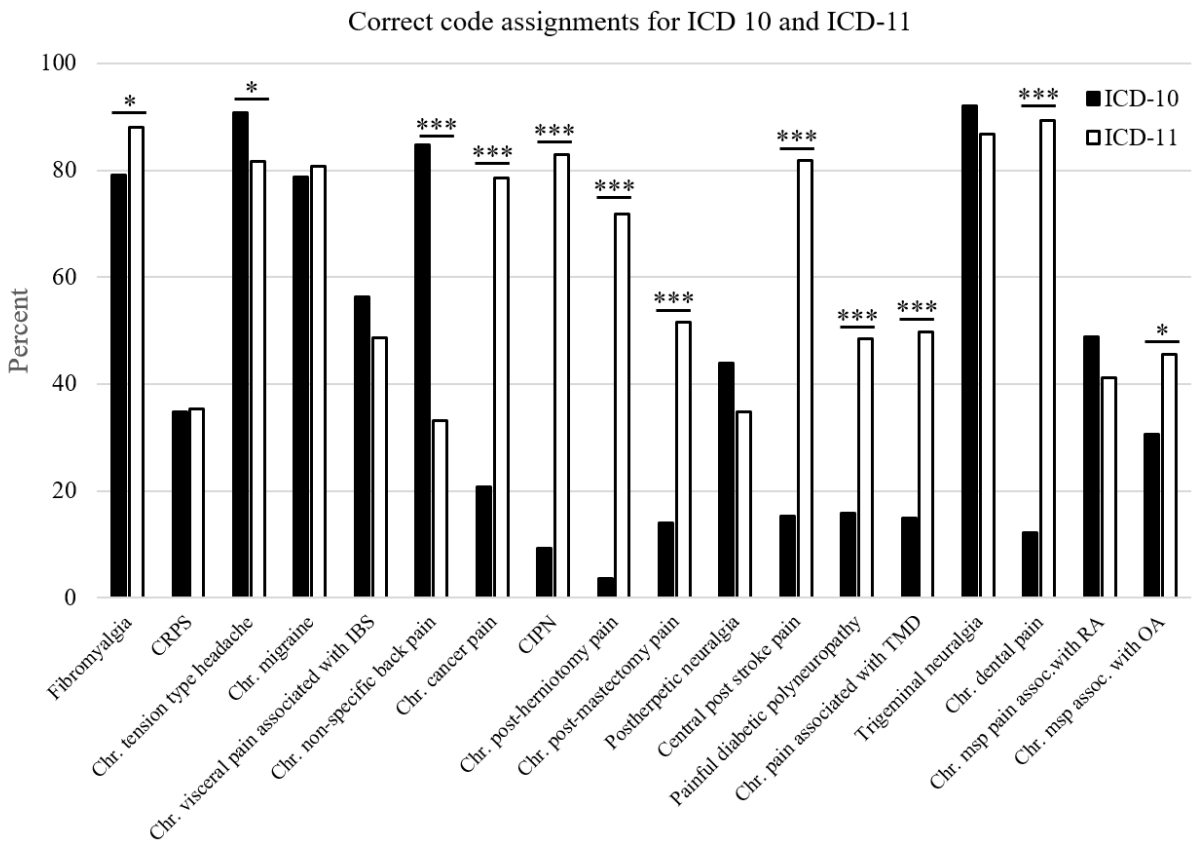
Performance of the ICD-10 and the ICD-11 in the line coding of chronic pain conditions



Note. Correctness (A), difficulty (B) and ambiguity (C) of coding diagnostic terms of chronic primary pain conditions using the ICD-10 (filled bars) and the ICD-11 (open bars). Frequencies are shown in percent of all lines. Statistical testing with McNemar's test. *** $p < .001$

Figure 2

Correct code assignments per line for the ICD-10 and the ICD-11.



Note. Correct code assignments in the ICD-10 (filled bars) and the ICD-11 (open bars). Frequencies are shown as percent of the respective condition.

Notes: CRPS: Complex regional pain syndrome; Chr.: Chronic; IBS: Irritable Bowel Syndrome; CIPN: Chronic painful chemotherapy-induced polyneuropathy; TMD: temporo-mandibular disorder; msp: musculoskeletal; assoc.: associated; RA: rheumatoid arthritis; PA: osteoarthritis. Statistical testing with McNemar's test. * $p < .05$; *** $p < .001$.

Figure 3

Level of specificity of the codes in the ICD-10 and the ICD-11 across all lines.

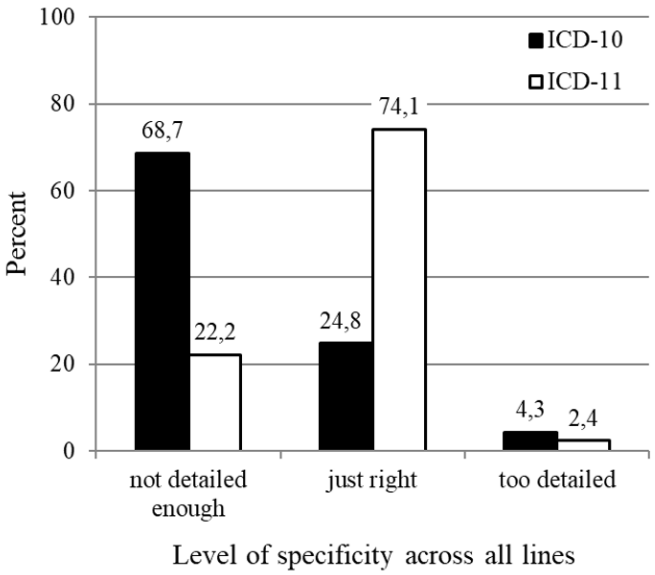
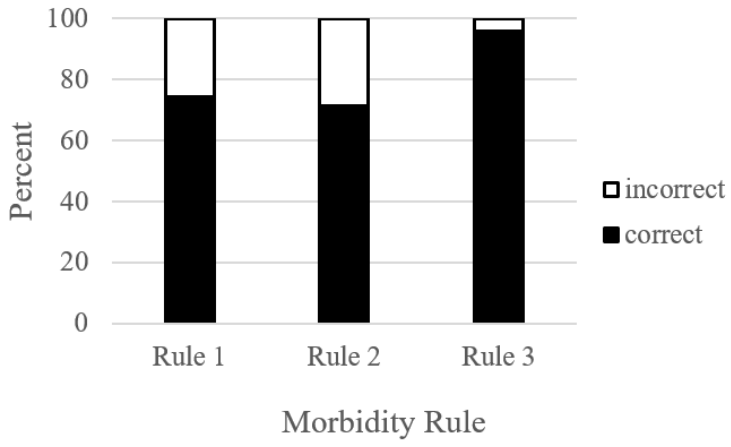


Figure 4

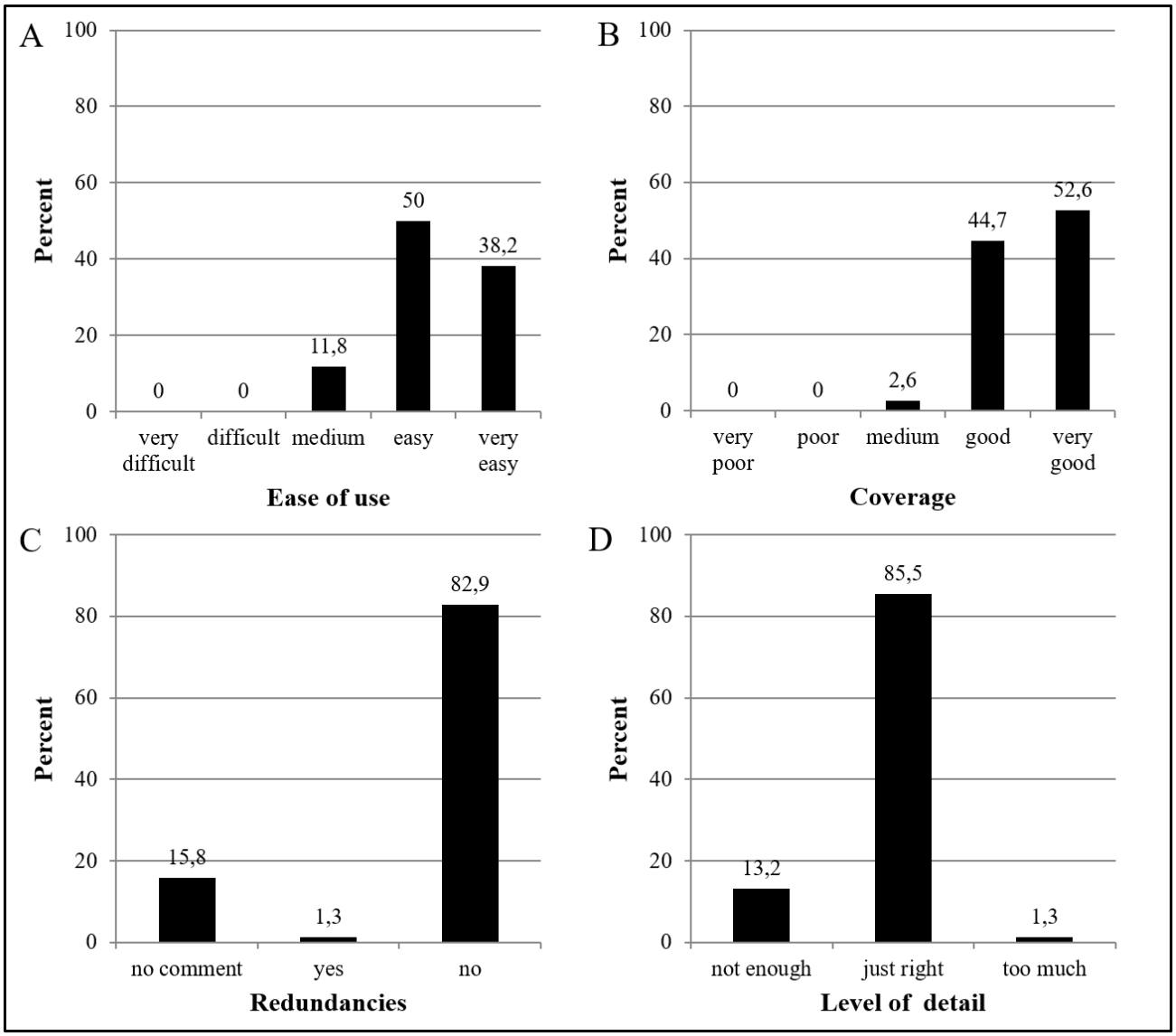
Performance of the morbidity rules with the chronic pain conditions



Note. Frequencies of correct (filled bars) and incorrect (open bars) applications of the rules. Frequencies are shown in percent of the application of each rule.

Figure 5

Global evaluation of the section on chronic pain in the ICD-11



Note. Participants' ratings of ease of use (A), coverage (B), redundancies (C) and level of detail of the diagnoses (D) in the ICD-11.

S1. Lines with their respective reference standards.

#	Line	Code at time of testing (ICD-11, MMS 2017)	Current code (ICD-11, MMS 2018)	Title*	Code (ICD-10) counted as correct	Title
1	Central post-stroke pain	MJ60.61	MG30.50	Chronic central neuropathic pain	I69.4 + R52.1/R52.2	Sequelae of stroke, not specified as hemorrhage or infarction + some type of chronic pain
2	Chemotherapy-induced painful polyneuropathy	MJ60.23	MG30.11	Chronic post-cancer treatment pain	G62.0 + R52.1/R52.2	Drug-induced polyneuropathy + some type of chronic pain
3	Chronic cancer pain	MJ60.21	MG30.10	Chronic cancer pain	C80.9 + R52.1/R52.2	Malignant neoplasm + some type of chronic pain
4	Chronic dental pain	MJ60.72	MG30.61	Chronic dental pain	K08.9 + R52.1/R52.2	Disorder of teeth and supporting structures, unspecified + some type of chronic pain
5	Chronic migraine	8A40.3	8A80.2	Chronic migraine	G43/G43.9/G43.3	Chronic migraine
6	Chronic musculoskeletal pain associated with osteoarthritis	MJ60.42	MG30.31	Chronic secondary musculoskeletal pain associated with structural changes	M15.9/M19.9 + R52.1/R52.2	Polyarthrosis unspecified/Arthrosis unspecified + some type of chronic pain
7	Chronic musculoskeletal pain associated with rheumatoid arthritis	MJ60.413	MG30.30	Chronic secondary musculoskeletal pain from persistent inflammation	M06.9	Rheumatoid arthritis unspecified
8	Chronic non-specific back pain	MJ60.13	MG30.02	Chronic primary musculoskeletal pain	M54.5/M54.9	Low back pain / Dorsalgia unspecified

9	Chronic pain associated with temporomandibular disorder	MJ60.74	MG30.63	Headache or orofacial pain attributed to chronic secondary temporomandibular disorders	K07.6 + R52.1/R52.2	Temporomandibular joint disorders + some type of chronic pain
10	Chronic post-herniotomy pain	MJ60.32	MG30.21	Chronic postsurgical pain	K40/K45/K46 + R52.1/R52.2	Bilateral inguinal hernia / other specified hernia / unspecified hernia + some type of chronic pain
11	Chronic post-mastectomy pain	MJ60.32	MG30.21	Chronic postsurgical pain	Z90.1 + R52.1/R52.2	Acquired absence of breast(s) + some type of chronic pain
12	Chronic tension type headache	8A41.3	8A81.2	Chronic tension type headache	G44.2	Tension type headache
13	Chronic visceral pain associated with irritable bowel syndrome	MJ60.11	DD91.0	Irritable bowel syndrome	K58.1/K58.2	Irritable Bowel Syndrome with and without diarrhea
14	Complex regional pain syndrome	8C4A.1	8D8A.0	Complex regional pain syndrome	M89.0	Algoneurodystrophy
15	Fibromyalgia	MJ60.12	MG30.01	Chronic widespread pain	M79.7	Fibromyalgia
16	Painful diabetic polyneuropathy	MJ60.62	MG30.51	Chronic peripheral neuropathic pain	G63.2 + R52.1/R52.2	Diabetic polyneuropathy + some type of chronic pain
17	Postherpetic neuralgia	MJ60.62	1E91.5	Postherpetic neuralgia	G53.0	Postzoster neuralgia
18	Trigeminal neuralgia	8B10.31	8B82.0	Trigeminal neuralgia	G50.0	Trigeminal neuralgia

MMS: Mortality and Morbidity Statistics Linearization;

*Note: In the final version, some of the diagnoses (1, 6, 7, 8, 10, 11, 13, 16, 17) will be represented by a child of the entity presently assigned. These children had not been implemented at the time of testing. R52.1: Chronic intractable pain; R52.2: Other chronic pain.

S2 Vignette texts (case coding)

Case number	Vignette text
1	The patient presented to a tertiary pain center with chronic pain in her shoulders, arms, hands, lower back, and legs. The pain began 4 years ago and worsened gradually in the last 8 months. Its intensity was now rated around 7 on a 0-10 scale. She reported feeling demoralized and fatigued, and had a very disturbed sleep recently. An obstructive sleep apnoea was diagnosed in additional sleep laboratory testing. After six months of multi-disciplinary pain therapy, the pain level decreased to 4-5 and the quality of life improved.
2	A 45-year old female suicidal patient was transferred to the psychiatric hospital. She was diagnosed with a severe episode of depression. She had suffered three milder episodes before. In addition, she also had chronic migraine for 10 years, which presented with at least 20 headache days per month, of which, 10 days with migraine. During her three-week hospital stay, she was enrolled in a cognitive-behavioral therapy program, and prescribed antidepressant medication. She also received migraine preventive agents and triptans for her chronic migraine. When leaving the hospital after three weeks, her depression had decreased.
3	A 37 year-old female patient with Fibromyalgia presented with a constant dull, aching pain in the lower abdomen and pelvis that had persisted for 7 months leading to time off work. Laboratory blood tests were normal. A 3-months treatment with amitriptyline, combined with psychological support, improved her abdominal pain symptoms and allowed her return to work.
4	A 64-year-old patient presented with lung cancer and progressing vertebral bone metastases. He complained of radiating pain in the lower back that could be traced back to the site of the metastases. The pain began 4 months previously. The patient received 5 doses of radiotherapy 3 months ago to the respective vertebrae with very limited benefit. No further treatment for the cancer was given. The pain was treated with morphine, which reduced pain intensity.
5	A 56-year old patient with colon cancer presented with persistent painful feet, which he first noticed 4 months ago, after completing 6 cycles of platinum-based chemotherapy. The pain was constant but worsened at night and when standing. He described it as numb, tingling, and pricking, and sometimes radiating into the lower leg. On examination, there was a loss of touch sensation over both feet and reduced temperature discrimination. The examination concluded that the pain in the feet was due to a polyneuropathy caused by the chemotherapy treatment. Education and pain management were offered, which decreased the pain to a tolerable level.
6	A 52-year-old patient required a left-sided thoracotomy for lung volume reduction surgery in severe emphysema. Now, six months later, he presented with significantly improved respiratory function and remaining emphysema symptoms, but complained of severe pain in his left rib cage. The pain was significantly aggravated by deep inspiration. The pain was diagnosed as being due to the thoracotomy. Gabapentin was prescribed, which alleviated the pain.

7	A 54-year-old female patient presented to a pain clinic with severe ongoing pain at a pain clinic. She had a relapsing-remitting multiple sclerosis and central neuropathic pain associated with the multiple sclerosis. The pain was present in both legs. It was described as burning and squeezing. Cold weather and stress increased the pain. The patient had abnormal sensation to pinprick and cold and warmth in the area. The pain negatively affected her concentration and mood. She was given gabapentin with a slowly increasing dose with moderate effect.
8	A 20-year old male patient presented with sharp, paroxysmal intraoral pain in the lower left mandibular region that began 6 months ago. The pain was mostly spontaneous and severe but could also be triggered by hot and cold drinks. Examination and testing suggested irreversible pulpitis of the left second mandibular molar and severe caries in several teeth. The molar underwent initial treatment by pulp extirpation followed by root canal treatment and caries treatment given resulting in resolution of symptoms.
9	A 35-year old female patient presented to her gynecologist with chronic pelvic pain which had persisted for 4 months. Blood samples revealed signs of inflammation. Endometriosis was hypothesized, but other inflammatory origins could not be ruled out and the etiology of the pain remained uncertain. The patient was treated with NSAIDS (Ibuprofen), which improved her pain.
10	A 55-year-old female patient presented at a pain center for diffuse chronic musculoskeletal pain with recurring pain episodes during the past five 5 years. Four years ago, rheumatoid arthritis was diagnosed and she had received treatment with TNF-inhibitors ever since. The TNF-inhibitors had some efficacy on joint inflammation and deformities, but the patient still suffered moderate to severe pain. She was enrolled in a multimodal pain program, which improved the pain.
11	The patient presented with persisting lower back pain after he had worked heavily at renovating his house 12 months ago. Radiography and neurological examination revealed no abnormalities. In addition, he had chronic migraine since childhood. He received multimodal pain treatment and physiotherapy for the back pain, which improved his symptoms.
12	A 56-year old woman with type 2 diabetes mellitus for 2 years complains about pain in the feet which started approximately 4 months ago. The pain intensity is described as 5 to 7 on a scale from 0 to 10. The pain may get worse at night or when she is walking. Additionally, she noticed numbness and tingling in the feet. The examination reveals a stocking-like distribution of deficits in the sense of touch. The Achilles tendon reflex is weak. The patient has a body mass index of 30. Her fasting blood glucose concentration is 132 mg/dl, the HbA1 measures 7%. She was prescribed Gabapentin for the pain leading to a moderate improvement.

S3. Line coding. Number of diagnoses (in percent) for which no difficulty in the assignment was reported. Numbers for each of the two classifications and the results of the McNemar test are shown.

	No difficulty assigning ICD-10 (%)	No difficulty assigning ICD-11 (%)	χ^2 / *df*=1 (McNemar)	Valid n
Fibromyalgia	81.9	95.5	16.53***	177
Complex regional pain syndrome	21.1	85.7	89.91***	161
Chronic tension type headache	90.2	96.1	--[a] n.s.	153
Chronic migraine	48.7	95.5	65.62***	156
Chronic visceral pain associated with IBS	43.6	77.9	33.47***	140
Chronic non-specific back pain	54.5	65.5	4.17*	145
Chronic cancer pain	23.6	97.1	99.09***	140
CIPN	42.6	97.2	75.01***	141
Chronic post-herniotomy pain	23.0	80.7	76.01***	135
Chronic post-mastectomy pain	15.4	71.3	70.31***	136
Postherpetic neuralgia	59.8	89.4	28.31***	132
Central post-stroke pain	25.8	78.8	66.13***	132
Painful diabetic polyneuropathy	56.8	86.4	29.47***	132
Chronic pain associated with TMD	55.1	68.7	6.22*	147
Trigeminal neuralgia	93.3	94.7	--[a] n.s.	150
Chronic dental pain	30.3	99.2	89.01***	132
Chronic musculoskeletal pain associated with rheumatoid arthritis	35.3	91.7	73.01***	133
Chronic musculoskeletal pain associated with osteoarthritis	30.6	85.1	67.33***	134
All	47.2	86.6	863.81***	2576

IBS: Irritable bowel syndrome; CIPN: Chemotherapy-induced painful polyneuropathy; TMD: Temporo-mandibular disorder; * $p < .05$; *** $p < .001$

[a] binomial distribution used (fewer than 25 cases changed value between the two conditions) therefore no χ^2 statistic available.

S4. Line coding. Number of diagnoses (in percent) for which no ambiguity in the assignment was reported. Numbers for each of the two classifications and the results of the McNemar test are shown.

	No ambiguity assigning ICD-10 (%)	No ambiguity assigning ICD-11 (%)	χ^2 / *df*=1 (McNemar)	Valid n
Fibromyalgia	62.1	85.3	25.33***	170
CRPS	11.2	67.7	75.69***	153
Chronic TTH	68.0	89.5	22.88***	150
Chronic migraine	33.3	90.4	74.21***	153
Chronic visceral pain associated with IBS	18.6	65.0	50.89***	137
Chronic non-specific back pain	26.2	46.9	16.98***	142
Chronic cancer pain	8.6	88.6	104.22***	135
CIPN	24.8	91.5	89.10***	138
Chronic post-herniotomy pain	11.1	60.7	57.69***	131
Chronic post-mastectomy pain	6.6	61.8	69.12***	133
Postherpetic neuralgia	43.9	77.3	28.00***	131
Central post-stroke pain	9.1	61.4	61.35***	128
Painful diabetic polyneuropathy	33.3	68.9	32.66***	130
Chronic pain associated with TMD	25.2	66.0	43.51***	144
Trigeminal neuralgia	79.3	86.7	2.38	147
Chronic dental pain	15.9	96.2	102.01***	130
Chronic musculoskeletal pain associated with rheumatoid arthritis	17.3	78.2	76.11***	130
Chronic musculoskeletal pain associated with osteoarthritis	12.7	73.1	73.30***	130
All	29.1	75.5	1003.84***	2512

IBS: Irritable bowel syndrome; CIPN: Chemotherapy-induced painful polyneuropathy; TMD: Temporo-mandibular disorder; *** $p < .001$

S5. Line coding. Number of diagnoses (in percent) for which the level of detail was judged as too low, just right or too high. Numbers for each of the two classifications and the results of the McNemar-Bowker test are shown.

	ICD-10			ICD-11			χ^2 / *df*=3 (McNemar-Bowker)	Valid n
	Too low %	Just right %	Too high %	Too low %	Just right %	Too high %		
Fibromyalgia	35.0	59.3	3.4	11.9	84.7	1.7	26.52***	173
Complex regional pain syndrome	78.3	12.4	5.0	22.4	69.6	5.0	79.73***	152
Tension type headache	35.3	56.9	4.6	7.8	88.9	2.0	33.63***	148
Chronic migraine	62.8	26.3	9.0	9.0	86.5	3.2	80.65***	153
Chronic visceral pain associated with IBS	79.3	15.7	2.9	30.7	64.3	3.6	61.88***	137
Chronic non-specific back pain	74.5	16.6	6.9	46.9	48.3	2.9	35.01***	140
Chronic cancer pain	89.3	5.7	2.1	7.9	88.6	2.1	116.04***	136
CIPN	74.5	21.3	2.8	7.8	87.2	4.3	90.17***	139
Chronic post-herniotomy pain	88.1	5.2	3.0	42.2	54.8	2.2	63.06***	130
Chronic post-mastectomy pain	89.7	4.4	2.9	39.7	56.6	2.9	67.39***	132
Postherpetic neuralgia	53.0	40.9	6.1	20.5	78.0	1.5	34.81***	132
Central post-stroke pain	85.6	11.4	1.5	34.8	64.4	0.8	62.83***	132
Painful diabetic polyneuropathy	61.4	34.8	3.0	37.1	62.9	0.0	[a]	132
Chronic pain associated with TMD	73.5	19.0	4.8	25.2	69.4	2.7	66.40***	143
Trigeminal neuralgia	23.3	68.0	6.0	9.3	86.0	2.7	16.04**	146
Chronic dental pain	84.8	11.4	3.0	9.1	89.4	1.5	101.00***	131
Chronic musculoskeletal pain associated with rheumatoid arthritis	82.7	9.8	6.0	16.5	78.9	3.8	88.24***	131
Chronic musculoskeletal pain associated with osteoarthritis	82.1	12.7	3.7	28.4	70.1	0.7	70.79***	131
All	68.7	24.8	4.3	22.2	74.1	2.4	1073.01***	2515

IBS: Irritable bowel syndrome; CIPN: Chemotherapy-induced painful polyneuropathy; TMD: Temporo-mandibular disorder; *** $p < .001$

[a] Could not compute as one cell was 0.

7.1.3 Anhang A3: Studie 3

Korwisi, B., Hay, G., Attal, N., Aziz, Q., Bennet, M. I., Benoliel, R., Cohen, M., Evers, S., Giamberardino, M. A., Kaasa, S., Kosek, E., Lavand'homme, P., Nicholas, M., Perrot, S., Schug, S., Smith, B. H., Svensson, P., Vlaeyen, J. W. S., Wang, S.-J., Treede, R.-D., Rief, W. & Barke, A. (in press). Classification algorithm for the ICD-11 chronic pain classification (CAL-CP): Development and results from a preliminary pilot evaluation. Manuscript accepted for publication in *PAIN*.

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

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Disclosure

BK reports other from IASP (NGO), during the conduct of the study. GH has nothing to disclose. NA reports personal fees from Lilly, personal fees from Pfizer , personal fees from Sanofi, personal fees from Grunenthal, personal fees from Ipsen, personal fees from Air Liquide, personal fees from Novartis, personal fees from Aptinyx, personal fees from Novartis, outside the submitted work. QA reports grants and personal fees from Grunenthal pharmaceutical, grants and personal fees from Allergan Pharmaceuticals, grants from Alimentary Health, outside the submitted work. MIB has nothing to disclose. RB reports personal fees from Quintessence Publishing, outside the submitted work. MC has nothing to disclose. SE reports personal fees from Allergan, personal fees from Novartis, personal fees from TEVA, personal fees from Lilly, outside the submitted work. MAG reports personal fees from HELSINN HEALTHCARE, personal fees from EPITECH GROUP, personal fees from IBSA, outside the submitted work. SK has nothing to disclose. EK reports personal fees from Lundbeck, personal fees from Eli Lilly, outside the submitted work. PL has nothing to disclose. MN has nothing to disclose. SP has nothing to disclose. StS has nothing to disclose. BHS has nothing to disclose. PS has nothing to disclose. JWSV reports grants from Asthenes long-term structural funding–Methusalem grant by the Flemish Government, Belgium (METH/15/011), outside the submitted work; . SJW reports grants and personal fees from Eli-Lilly, personal

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Previous presentations of the research

The development of the classification algorithm was presented as a poster abstract at the 2018 IASP World Congress on Pain in Boston, MA, USA (initial developmental stage) and at the 2020 German Pain Conference, online (preliminary version).

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). 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. 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). 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).

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) and initial decision trunk (page 8, SDC 1) 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), an introduction form (p. 6-7, SDC 1), and an appendix (p. 41-45, SDC 1), besides the actual decision tree (p. 8-40, SDC 1). 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). 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

BK reports other from IASP (NGO), during the conduct of the study. GH has nothing to disclose. NA reports personal fees from Lilly, personal fees from Pfizer , personal fees from Sanofi, personal fees from Grunenthal, personal fees from Ipsen, personal fees from Air Liquide, personal fees from Novartis, personal fees from Aptinyx, personal fees from Novartis, outside the submitted work. QA reports grants and personal fees from Grunenthal pharmaceutical, grants and personal fees from Allergan Pharmaceuticals, grants from Alimentary Health, outside the submitted work. MIB has nothing to disclose. RB reports personal fees from Quintessence Publishing, outside the submitted work. MC has nothing to disclose. SE reports personal fees from Allergan, personal fees from Novartis, personal fees from TEVA, personal fees from Lilly, outside the submitted work. MAG reports personal fees from HELSINN HEALTHCARE, personal fees from EPITECH GROUP, personal fees from IBSA, outside the submitted work. SK has nothing to disclose. EK reports personal fees from Lundbeck, personal fees from Eli Lilly, outside the submitted work. PL has nothing to disclose. MN has nothing to disclose. SP has nothing to disclose. StS has nothing to disclose. BHS has nothing to disclose. PS has nothing to disclose. JWSV reports grants from Asthenes long-term structural funding–Methusalem grant by the Flemish Government, Belgium (METH/15/011), outside the submitted work; . SJW reports grants and personal fees from Eli-Lilly, personal fees from Daiichi-Sankyo, grants and personal fees from Norvatis, grants from Minister of Science and Technology, Taiwan, grants from The Featured Areas Research Center Program within the framework of the Higher Education Sprout Project by the Ministry of Education (MOE), from null, outside the submitted work. RDT reports grants from Teva, personal fees from Bayer, Grünenthal, GSK, Sanofi, outside the submitted work. WR has nothing to disclose. AB reports other from IASP (NGO), outside the submitted work.

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.

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

Note. This initial decision trunk (p. 8, SDC 1) 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).  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.

Supplemental Digital Content 1. Classification algorithm for chronic pain in ICD-11 (CAL-CP). PDF

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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.

Textbox 1. Basic ICD-11 terminology

Foundation layer

The Foundation layer [39] of the ICD-11 comprises all entities that are part of the ICD-11. It is an evolving structure and forms the basis for the linearizations. Each entity of the foundation has a uniform resource identifier (URI), or Foundation ID.

Linearization

Linearizations are subsets of the Foundation layer. Different specific entities are summarized as diagnoses with a diagnostic code. Currently, the Mortality and Morbidity Statistics linearization (MMS) for preparing implementation [38] has been released by the WHO. Countries that implement the ICD-11 may create their own linearizations.

Diagnostic shoreline

The ICD-11 MMS draws a "shoreline" at six-digit codes: Specific diagnoses on lower levels of the classification do not receive an individual code. Rather, they should be coded with the respective six-digit code of the level above (the "parent") and specified further by their individual Foundation ID. For example, both chronic primary low back pain and chronic primary cervical pain should both be coded as MG30.02 Chronic primary musculoskeletal pain. They can be specified further and distinguished from one another by their respective ID (1291385632 chronic primary low back pain, 2014134682 chronic primary cervical pain).

Parent and child diagnoses

Different levels and sublevels are referred to as parent and child categories. With regard to the ICD-11 chronic pain classification, a level 1 diagnoses (e.g., MG30.0 Chronic primary pain) is the parent of all level 2 diagnoses it comprises (e.g., MG30.02 is a child category). In turn, the level 2 diagnoses are parents of the level 3 diagnoses that follow.

Double parenting

An entity in the ICD-11 can have multiple parent categories. It may be linked to all parent diagnoses that apply. Despite multiple parents, the entities still have only one immutable diagnostic code with which they are linked to the additional parents. For example, MG30.62 Chronic neuropathic orofacial pain has MG30.6 Chronic secondary headache or orofacial pain as its primary parent. MG30.5 Chronic neuropathic pain is an additional parent. Therefore, MG30.62 Chronic neuropathic orofacial pain is linked there as well. This makes it easier for users to find a specific diagnosis that is relevant to different categories or chapters of the ICD-11.

Residual categories

The ICD-11 distinguishes two different residual categories: "unspecified" and "other specified". Both categories are available at the general level of chronic pain as well as for each of the seven main categories. The "other specified" diagnoses may be used when the user encounters a patient with a very specific disease or syndrome that cannot be allocated to any of the available categories. For example, chronic pain associated with a disease of the skin would be coded as MG30.Y Other specified chronic pain. If the information available is insufficient to decide whether the diagnostic criteria of a given level 1 or level 2 diagnosis are met, the "unspecified" code should be used. For example, a clinician might have sufficient information to determine that a patient has chronic secondary musculoskeletal pain, but not which level 2 diagnosis applies (e.g., due to lack of resources); then the code MG30.3Z Chronic secondary musculoskeletal pain, unspecified should be assigned.

Coding Tool

The ICD-11 Coding Tool [37] should be used for the actual coding. Users enter the diagnostic term they would like to code (e.g., "chronic back pain"). The coding tool shows the diagnoses and their respective ICD-11 codes that match the term. Links to the MMS enable the user to access further information (e.g., descriptions) for the different diagnoses found.

Note. All explanations are based on the ICD-11 Reference Guide [40] and the ICD-11 User Guide [41].

Textbox 2. New concepts of the ICD-11 chronic pain classification

Pain severity

Pain severity is one of the newly defined chronic pain specifiers. It is a compound measure of pain intensity, pain-related distress, and pain-related Interference. The patient is requested to rate the three dimensions of pain severity on a 0 to 10 NRS or a 10cm visual analogue scale (VAS). These ratings can be converted to the WHO severity categories 'mild', 'moderate', and 'severe'.*

Chronic primary pain

In chronic primary pain, the pain is a health condition in its own right. Chronic primary pain is characterized by significant emotional distress or functional interference. It is multifactorial with different biological, psychological, and social factors contributing to it. Furthermore, chronic primary pain is not better accounted for by another (secondary) chronic pain diagnosis.

Chronic secondary pain

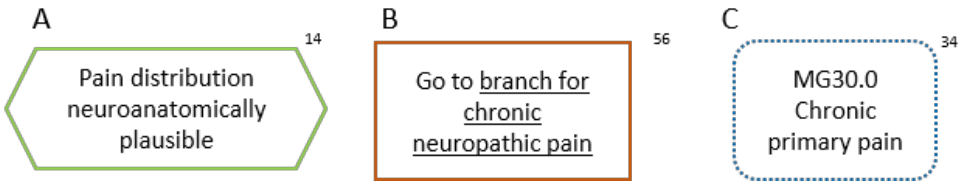
Chronic secondary pain, as any pain, is also multifactorial. However, chronic secondary pain is pain that develops as a symptom in the context of an underlying disease (eg, rheumatoid arthritis, cancer). Nevertheless, it warrants tailored pain treatment. The severity of chronic secondary pain is not necessarily equal to the severity of the underlying disease process. In some cases, the pain persists after the underlying disease has been treated successfully.

The ICD-11 chronic pain classification comprises six different categories of chronic secondary pain: chronic cancer-related pain (eg, associated with a tumor or cancer treatment), chronic postsurgical or post traumatic pain (eg, after spinal surgery or after bone fractures), chronic neuropathic pain (eg, associated with polyneuropathy or stroke), chronic secondary headache or orofacial pain (eg, associated with infection), chronic secondary visceral pain (eg, associated with Crohn's disease or sickle cell disease), chronic secondary musculoskeletal pain (eg, associated with spondylosis or gout).

Note. Further details can be found in Treede et al., 2019.[35] *At the time of publication, implementation of pain severity into the ICD-11 as an extension code is still pending.

Figure 1

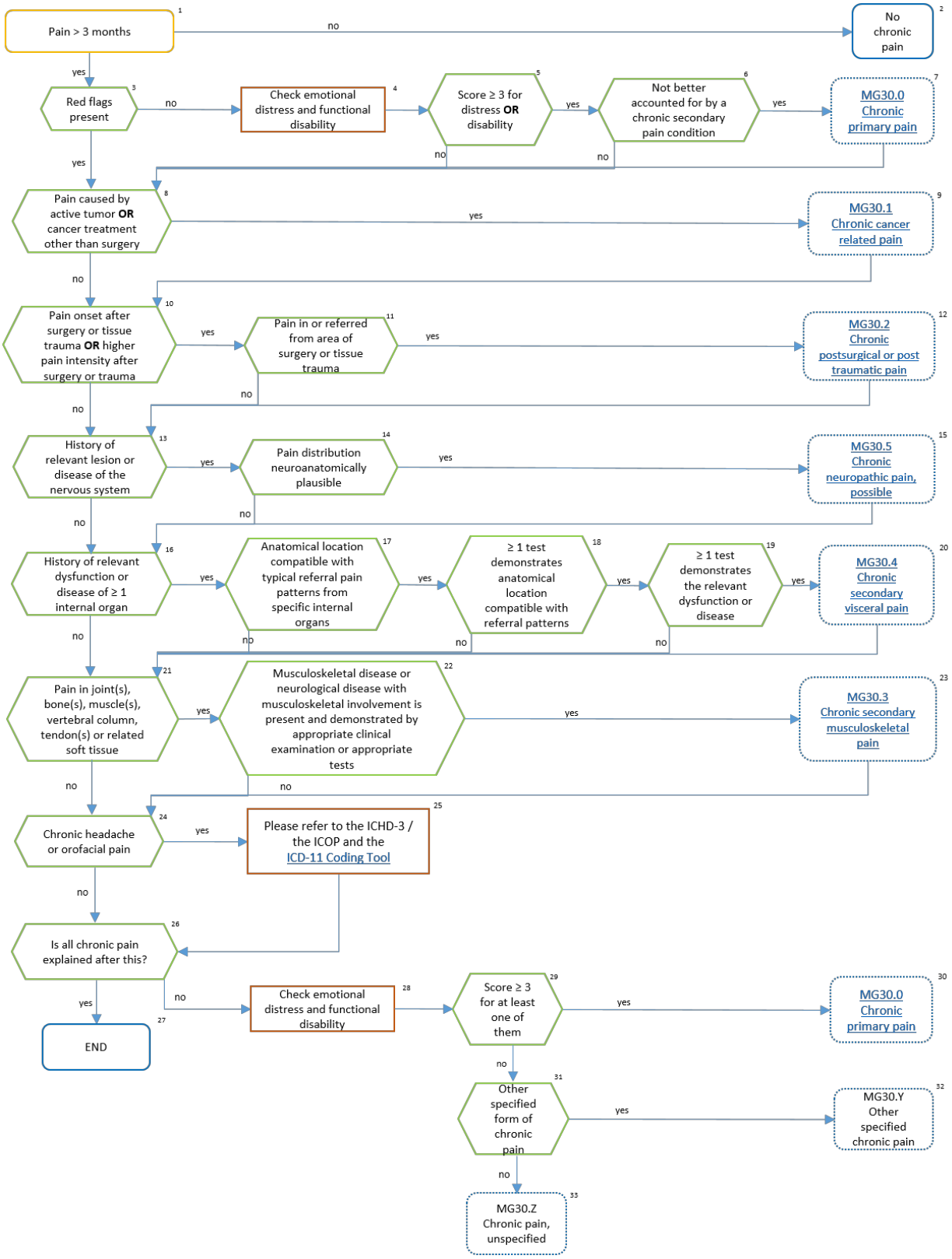
Example boxes of the CAL-CP



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.

Figure 2

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

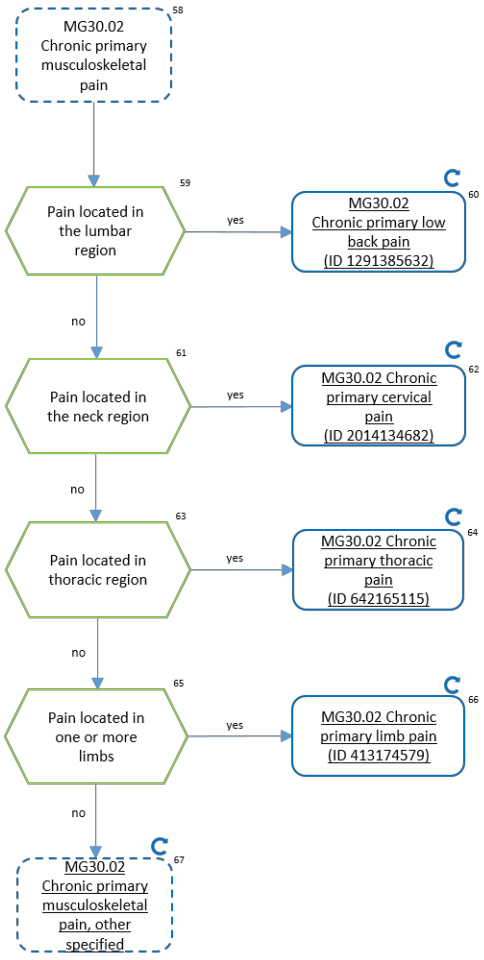


Note. This initial decision trunk (p. 8, SDC 1) can be used as a stand-alone algorithm to assign diagnoses on the first diagnostic level in settings where a more detailed diagnosis is not

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). C 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.

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

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Summary

The CAL-CP is a linear decision tree that guides through the diagnostic criteria of the ICD-11 chronic pain classification, hence facilitating the diagnostic process.

Supplemental Digital Content 1. Classification algorithm for chronic pain in ICD-11 (CAL-CP). PDF

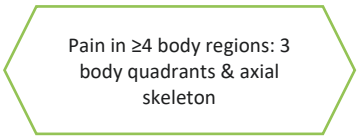
Classification Algorithm for the ICD-11 Chronic Pain Classification (CAL-CP)

What is the CAL-CP?

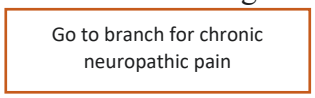
- The CAL-CP is a linear decision tree to guide through the ICD-11 diagnostic criteria of chronic pain.
- It was developed for pain specialists, practice, and research.
- It is based on the guidelines of the Society for Medical Decision Making Committee on Standardization of Clinical Algorithms (1992).
- The aim of the CAL-CP is to facilitate and standardize the classification process; we cannot guarantee that diagnoses are correct.
- In primary care and settings with limited resources, the initial decision trunk (p. 8) can be used as a stand-alone algorithm to find a diagnosis on the first diagnostic level.
- In specialty settings, such as multimodal pain treatment, using the full version of the algorithm is strongly recommended.
- The neuropathic pain grading scheme (Finnerup et al., 2016) has been incorporated in the branches for chronic neuropathic pain.
- The algorithm does not aim at finding an underlying disease that causes the pain, but which has not yet been diagnosed.
    - Instead: Find the chronic pain code that goes with a known underlying disease if the pain is not of a primary nature.
    - Does this patient show any symptoms suggestive of an underlying disease that has not been diagnosed previously? Please assess these red flags as you would usually do in your field of expertise. Avoid unnecessary testing.
    - If you suspect that an underlying, not yet diagnosed disease is present and causes the pain (e.g., rheumatoid arthritis, cancer), please take the appropriate diagnostic steps. Go back to the algorithm after that diagnostic process.
- If the criteria require that a diagnostic test confirms an underlying disease, you can refer to existing test results from your medical records if you judge them to be conclusive.
- This algorithm is not applicable for chronic headache or orofacial pain (neither primary nor secondary). When a patient presents with chronic headache, please refer to the 3rd edition of the International Classification of Headache Diseases (ICHD-3, IHS, 2018) for diagnostic criteria. When a patient presents with chronic orofacial pain, please refer to the International Classification of Orofacial Pain (ICOP, 2020) for diagnostic criteria. In both instances, you will also need to refer to the ICD-11 Coding Tool in order to find the corresponding ICD-11 code.
- In the case of chronic secondary pain, you will need to use the ICD-11 Coding Tool to find the diagnostic code for the underlying disease(s).
- To learn more about the ICD-11, go to the ICD-11 website or to the ICD-11 Reference Guide.

Structure of the CAL-CP

- The algorithm consists of a linear decision tree with several branches and an initial decision trunk.
- There are different forms of boxes:
  - Decision box (hexagon): This box requires you to make a diagnostic decision, i.e., judge whether a diagnostic criterion is present or absent. A yes or no arrow leads you to the following box.

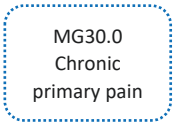


  - Action box (rectangle): This box informs you to take a certain action, e.g., continue with a different branch of the algorithm

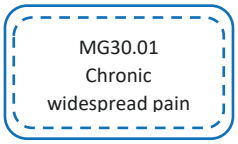


  - Diagnosis box (rectangle, rounded corners): Whenever you arrive at a diagnosis, this box also gives the respective ICD-11 code. Different lines (continuous line vs. dotted line) indicate different levels of diagnostic granularity (levels 1 to 4). Whenever possible, you should arrive at box with a continuous line in a specialty setting (level 3 diagnosis or level 4 in rare cases). A continuous line (example on the left side) indicates the diagnosis with most detail (level 3 or level 4 where applicable). A dashed line indicates a diagnosis that is slightly less specific (example on the right side, level 2). You will find instructions on whether you need to continue to the next level in the comment for each diagnosis box. Hyperlinks will also guide you to the next relevant branch.

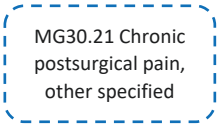
  You can assign a code that is in a box with a dotted line as well, but this code is less specific (level 1) and should only be used in primary care settings and settings with fewer resources:



  - Some boxes have two lines. Here, the diagnosis on the next level applies to only some patients. You may stop at the double lined box, even if it is a level 2 diagnosis. Decide whether you need to continue to the next level on an individual basis.



- All level 3 diagnoses share the level 2 diagnostic code, but also have an individual uniform resource identifier (Foundation ID) to distinguish them further. This is due to the "diagnostic shoreline" of the ICD-11: Diagnoses are assigned on the 6-digit level (e.g., MG 30.21 Chronic postsurgical pain). Diagnoses that are more specific are part of the so-called ICD-11 Foundation layer and are summarized under the 6-digit code. For example: Chronic pain after herniotomy has the diagnostic code MG30.21, and the Foundation ID 10263346. In the CAL-CP, Foundation IDs are listed as "ID" in all level 3 and level 4 diagnosis boxes (see example box above).
- Chronic pain syndromes that do not have a specific Foundation ID may still be classified as a level 2 diagnosis, for example, MG30.21 Chronic postsurgical pain also applies to chronic pain after Caesarean section. Therefore, you will find the level 2 diagnosis box again after going through a branch with level 3 diagnoses. For a better overview, these boxes are called "other specified" (e.g., MG30.21 Chronic postsurgical pain, other specified). Please note that this supplement "other specified" has not been entered in the ICD-11 Browser (there, you will find only MG30.21 Chronic postsurgical pain). For example:



- **All boxes are numbered.** Some boxes have comments (e.g., diagnostic tests you may use, or specifications of symptoms). If boxes have comments, their numbers also serve as footnotes to the respective comments. You find all comments below the respective branch or on the next page. **It is essential that you always check whether a box has a comment that goes with it. Here, you will find page references and instructions on where to continue.**
- The **Appendix gives an exemplary list of diseases** that may be associated with chronic secondary pain (p. 41). This list also indicates which category of chronic pain may be associated with it (e.g., chronic secondary musculoskeletal pain from persistent inflammation due to rheumatoid arthritis). Refer to this list if you are unsure what form of chronic pain may be caused by a given disease. The algorithm also specifies cases in which you can refer to this list. Please note: chronic pain is not automatically associated with a given underlying disease. You still need to go through the algorithm if a disease (e.g., rheumatoid arthritis or cancer) is present. This is to make sure that the diagnostic criteria for the respective chronic pain condition are met.

Procedure

1. Go through the introduction form (p. 6–7) with the patient to assess **red flags**, to code the **chronic pain specifiers**, and to go through the **pain location chart**.
    - If a patient has several chronic pain conditions (e.g., chronic back pain and chronic abdominal pain): assess the specifiers separately for each chronic pain condition, if possible.
    - If the head or the orofacial region is highlighted: refer to the ICHD-3, the ICOP, and the ICD-11 as outlined above.

2. The decision tree begins with an **initial decision trunk** (p. 8), covering all categories of chronic pain on the first diagnostic level.
    - Highlight all categories you will need to assess further with an X and begin with the first one.
    - If red flags for chronic secondary pain are present, you will start with the respective chronic secondary pain branch. Please refer to the initial decision trunk for page numbers. Hyperlinks are given as well.
    - If no red flags are present, and if the pain is not better accounted for by a chronic secondary pain diagnosis, you will begin with the branch for chronic primary pain.
3. Generally:
    - Check for each diagnostic criterion if it is met and follow the respective arrow (yes: the criterion is met vs. no: the criterion is not met).
    - **Each time you arrive at a diagnosis box, you need to decide whether all chronic pain has been accounted for.**
        - Go back to the pain location chart on page 7 and the initial decision trunk on page 8 to check whether you need to go through the algorithm for another form of chronic pain.
        - **This also applies if you want to assign a diagnosis on level 2 without continuing to the next diagnostic level.**
        - For diagnoses on the final level of the classification the following sign will remind you to go back: ↻
    - Hyperlinks have been implemented to facilitate navigating through the different branches of the decision tree (blue underlined text indicates a hyperlink). In addition, all page references are listed in the comments of a given box if applicable.
    - In the case of chronic secondary pain, you need to assign a diagnostic code for the underlying disease as well. Go to the ICD-11 Coding Tool to assign the applicable diagnostic code.
    - For some level 3 diagnoses, the new ICD-11 concept of **double parenting** applies. This means that a diagnosis can be conceptualized as belonging to two (or more) of the seven main chronic pain categories. These entities always have only one diagnostic code. For example: MG30.50 Chronic central neuropathic pain associated with spinal cord injury (ID869493945) has as parents MG30.50 Chronic central neuropathic pain as well as MG30.20 Chronic post traumatic pain. You will arrive at the correct diagnosis regardless if you choose to use the branch for chronic post traumatic pain or the branch for chronic neuropathic pain. The comment of the diagnosis box will state the second parent of a given diagnosis where applicable.
4. Other vs. unspecified chronic pain:
    - In the branches for level 2 diagnoses, you will find the distinction between other specified chronic pain and chronic pain unspecified. These are residual categories for chronic pain conditions that meet the criteria of the main chronic pain category, but that do not fit any of the subcategories. You will find

specific examples in the comments of each “other specified” box. Select “other specified” in instances where you can identify a specific form of chronic pain (e.g., rare cases of chronic neuropathic pain that are both central and peripheral). If the information available at time of diagnosis is very unspecific, if information is missing to assign a specific diagnosis, or if the criteria of more specific sub-levels are not met, please choose “unspecified”. You may also assign an unspecified diagnosis if you are not sure which specific chronic pain diagnosis applies to a patient.

References

Finnerup, NB; Haroutnunian, S; Kamerman, P; Baron, R; Bennett, DLH; Bouhassira, D; Cruccu, G; Freeman, R; Hansson, P; Nurmikko, T; Raja, SN; Rice, ASC; Serra, J; Smith, BH; Treede, RD; Jensen T, Finnerup NB, Haroutounian S, Kamerman P, Baron R, Bennett DLH, Bouhassira D, Cruccu G, Freeman R, Hansson P, Nurmikko T, Raja SN, Rice ASC, Serra J, Smith BH, Treede RD, Jensen TS. Neuropathic pain: an updated grading system for research and clinical practice. PAIN 2016;157:1599–1606. http://dx.doi.org/10.1097/j.pain.0000000000000492

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CAL-CP – Introduction Form

Before you begin: Does this patient show any symptoms suggestive of an underlying disease that has not been diagnosed previously? Please assess these red flags as you would usually do in your field of expertise and decide whether further diagnostic processes or referral are necessary.

1. **Chronic Pain Specifier**

Note: If the patient presents with several forms of chronic pain, please assess the chronic pain specifier separately for each chronic pain condition.

a. When did the pain begin? (month/year):

_____ / _____

Note: Pain must have been present for longer than 3 months to be considered as chronic!

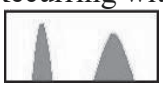
b. Ask the patient to rate his or her average pain intensity over last week:

0	1	2	3	4	5	6	7	8	9	10
No pain										Worst pain imaginable

c. Ask the patient to describe the temporal pattern of the pain over time:

- Persistent

- Recurring with pain-free intervals



- Persistent with overlapping pain attacks

d. Pain-related distress: Ask the patient to rate his or her average pain-related distress over the last week on the following scale (for example, how much it has caused worries, a sense of helplessness, low self-esteem, or anger):

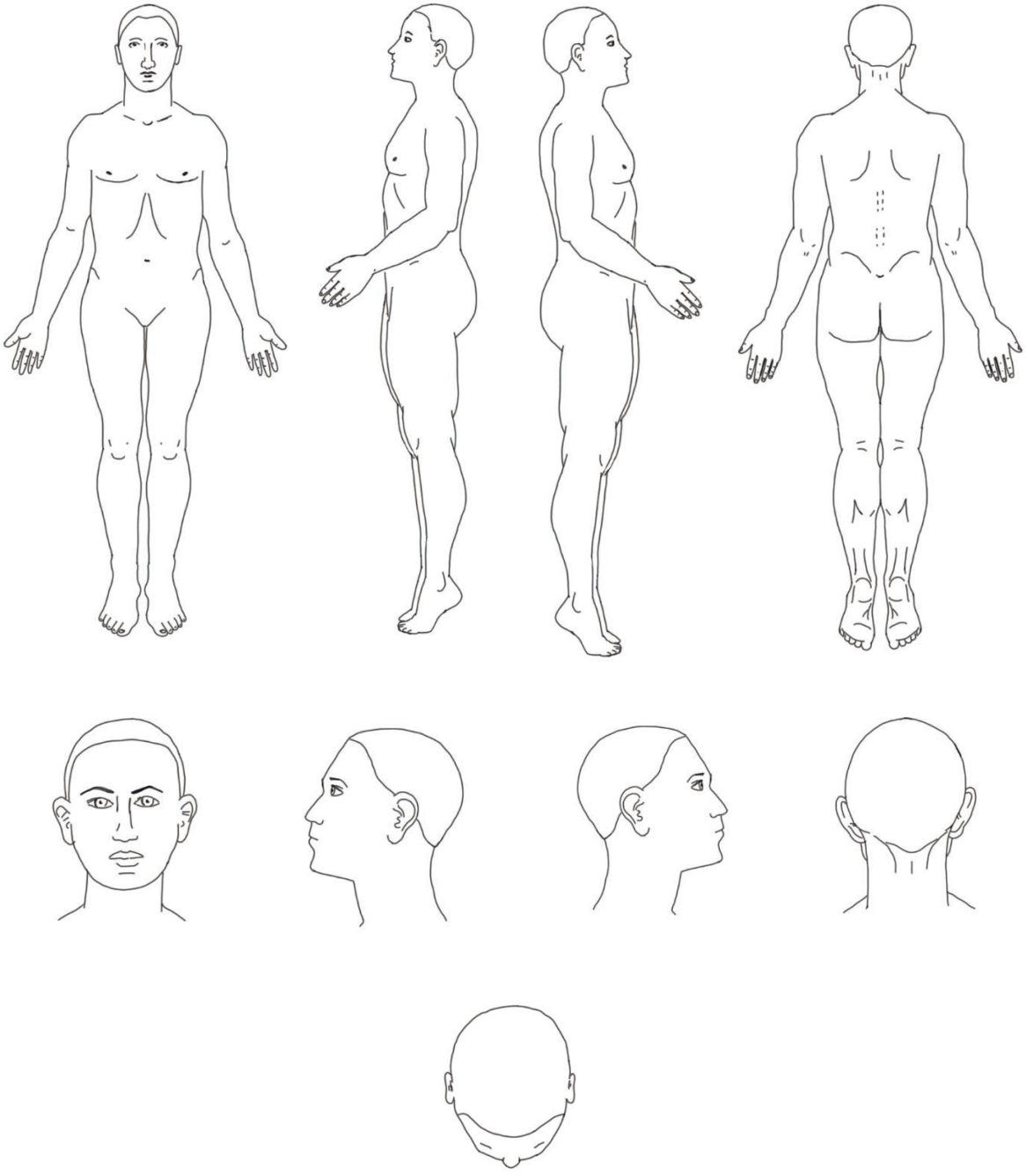
0	1	2	3	4	5	6	7	8	9	10
No pain-related distress										Extreme pain-related distress

e. Pain-related interference: Ask the patient to rate his or her average pain-related interference in daily activities over the last week (for example, regarding work, school, household duties, exercise, or sleep):

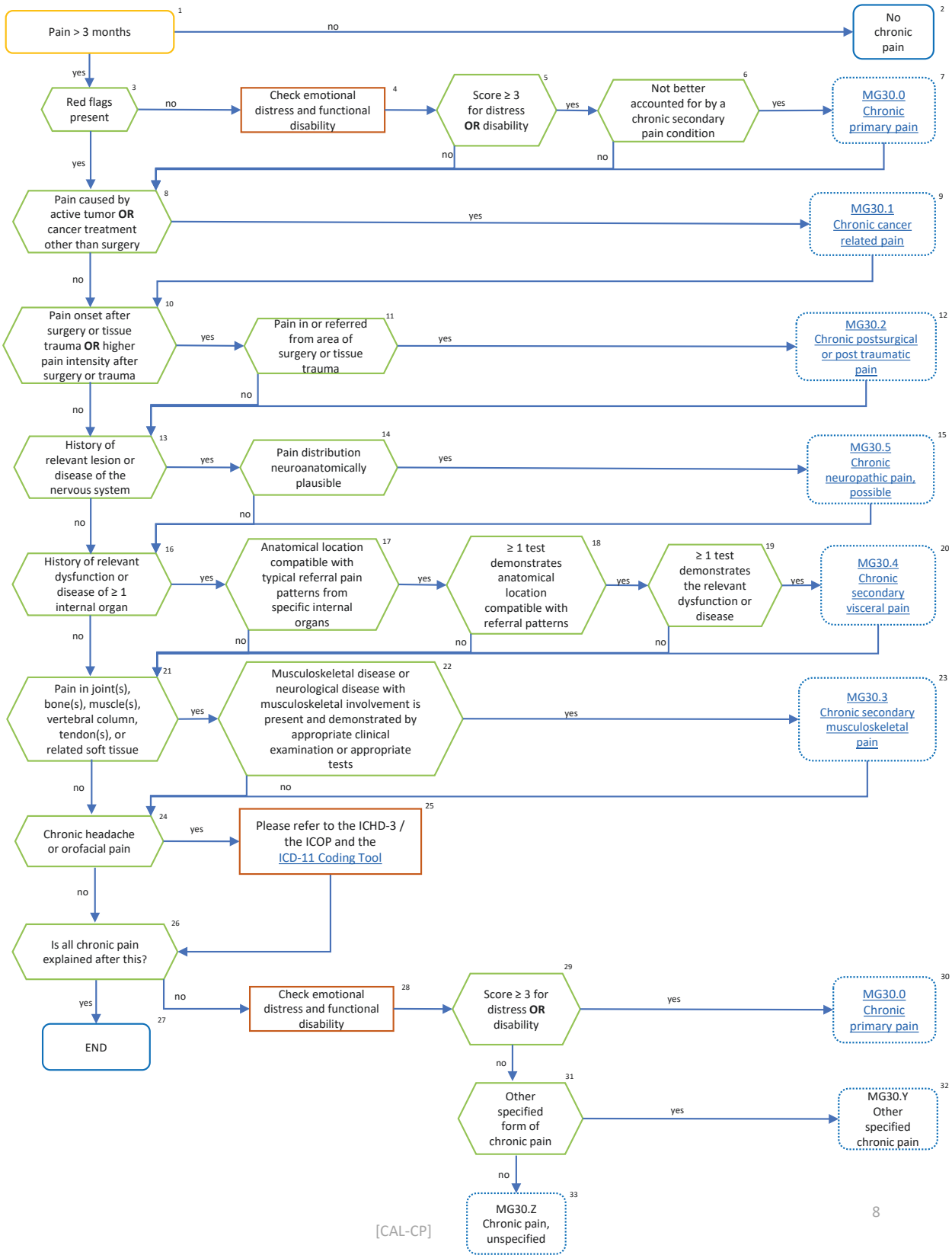
0	1	2	3	4	5	6	7	8	9	10
No interference										Unable to to carry on activities

2. Pain location chart

Note: Review the pain location chart together with the patient and ensure that no location of chronic pain is missing. Only go to the relevant sections of the algorithm.



Initial decision trunk



[3] Yes, if the patient has a history of any of the following: history of cancer or cancer treatment, pain began or intensified after a surgery or trauma, history of a disease or lesion of the central or peripheral nervous system, history of inflammatory disease of one or more internal organs, history of alterations of arterial or venous blood vessels from or to internal organs, history of mechanical factors affecting one or more internal organs, history of inflammatory musculoskeletal disease, history of structural changes of the musculoskeletal system, history of a neurological disease that may affect the musculoskeletal system.

[4, 28] Check NRS on page 6. Pain-related emotional distress and pain-related interference should be assessed in all patients with chronic pain, chronic primary pain as well as chronic secondary pain. The ratings can be converted into the WHO severity scheme and can be coded as an extension code. However, in chronic primary pain, the presence of emotional distress or functional disability also is a diagnostic criterion, and thus represents a prerequisite to assign this diagnosis.

[7, 30] Continue on page 10. This is the first diagnostic level. Continue to find the appropriate diagnosis on the next level.

[7, 9, 12, 15, 20, 23, 30, 32, 33] Only if you are assigning a diagnosis on this first diagnostic level: Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

[8] If the chronic pain began after cancer surgery, it should be coded as chronic postsurgical or post traumatic pain, continue with box 10.

[9] Continue on page 16. This is the first diagnostic level. Continue to find the appropriate diagnosis on the next level.

[12] Continue on page 21. This is the first diagnostic level. Continue to find the appropriate diagnosis on the next level.

[13] History of lesion or disease of the peripheral or central somatosensory nervous system, for example: polyneuropathy, nerve injury, stroke (see Appendix on page 41 for a list of examples).

[15] Continue on page 27. This is the first diagnostic level. Continue to find the appropriate diagnosis on the next level.

[16] History of inflammatory disease of one or more internal organs or history of alterations of arterial and/or venous blood vessels from or to internal organs, or history of mechanical factors affecting one or more internal organs. For example: Morbus Crohn, sickle cell disease, stenosis (see Appendix on page 41 for a list of examples).

[19] For example: blood sampling, ultrasound.

[20] Continue on page 32. This is the first diagnostic level. Continue to find the appropriate diagnosis on the next level.

[21] The pain may be spontaneous or movement induced.

[22] At least one of the following is fulfilled:

a) Musculoskeletal disease with inflammation due to infection, auto-immunity, auto-inflammation, or metabolic disorders (crystals) is present (demonstrated by appropriate clinical examination or appropriate tests) and causes the local activation of nociceptors.

b) Musculoskeletal disease with structural/biomechanical factors (demonstrated by appropriate clinical examination or appropriate tests) is present and causes the local activation of nociceptors.

c) Neurological disease (classified elsewhere) is present, and causes altered biomechanical function (demonstrated by appropriate clinical examination or appropriate tests) that is responsible for the activation of nociceptors.

See Appendix (page 41) for examples of relevant diseases.

Examples for diagnostic tests include, e.g., blood tests for systemic inflammation, X-ray, uric acid.

[23] Continue on page 37. This is the first diagnostic level. Continue to find the appropriate diagnosis on the next level.

[25] Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition (ICHD-3). Cephalalgia 2018;38:1–211. https://doi.org/10.1177/0333102417738202

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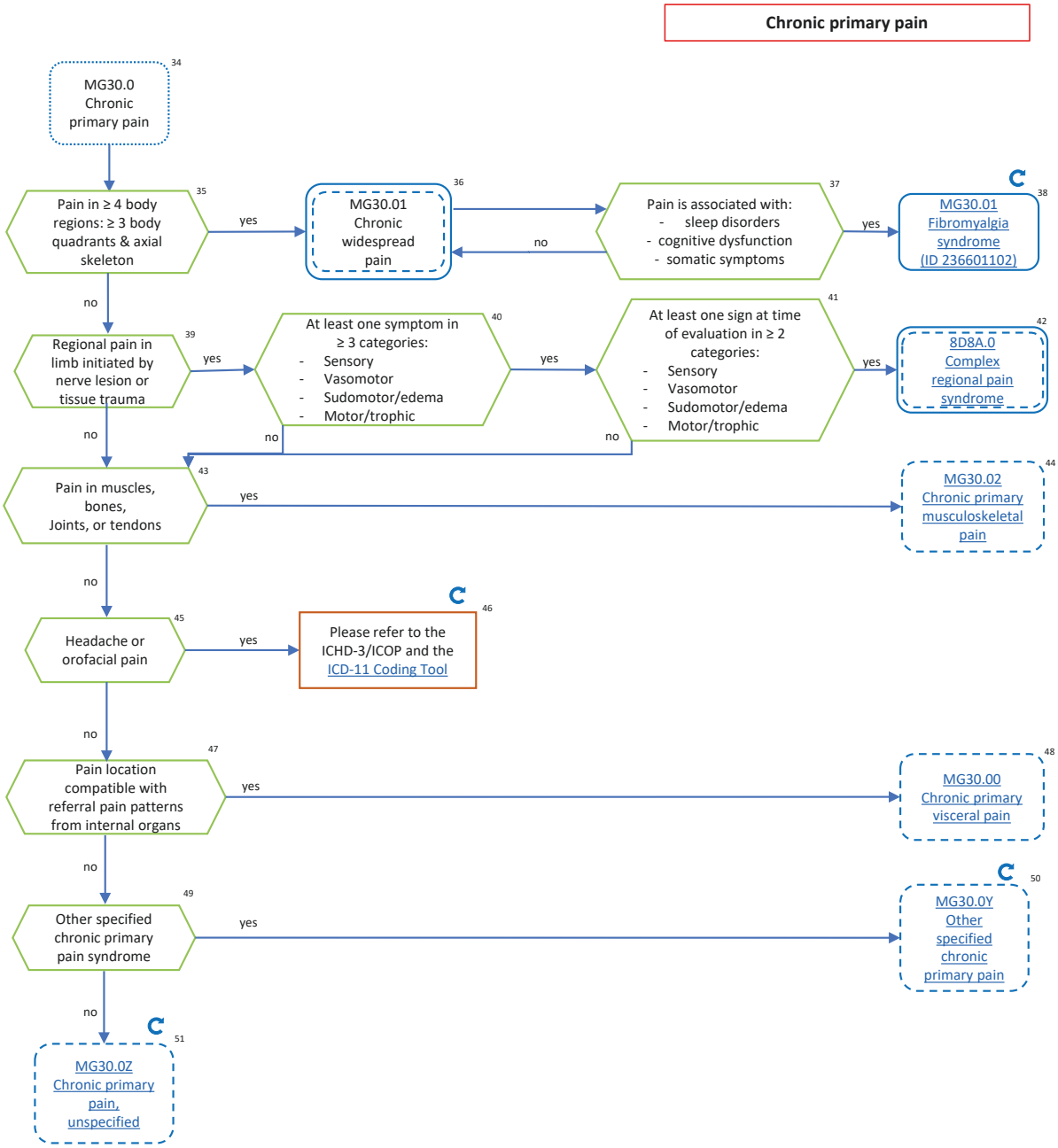
World Health Organization. ICD-11 Coding Tool. Mortality and Morbidity Statistics (MMS) 2020-09. Available at: https://icd.who.int/ct11/icd11_mms/en/release

On a general level, the following diagnoses for chronic primary and secondary headache or orofacial pain are available in the ICD-11: MG30.03 Chronic primary headache or orofacial pain, MG30.6 Chronic secondary headache or orofacial pain

[31] For example: chronic pain associated with a disease of the skin.


Chronic primary pain
34
MG30.0
Chronic
primary pain
35
Pain in ≥ 4 body regions: ≥ 3 body quadrants & axial skeleton
yes
36
MG30.01
Chronic
widespread
pain
37
Pain is associated with:
- sleep disorders
- cognitive dysfunction
- somatic symptoms
yes
38
MG30.01
Fibromyalgia
syndrome
(ID 236601102)
no
no
39
Regional pain in limb initiated by nerve lesion or tissue trauma
yes
40
At least one symptom in ≥ 3 categories:
- Sensory
- Vasomotor
- Sudomotor/edema
- Motor/trophic
yes
41
At least one sign at time of evaluation in ≥ 2 categories:
- Sensory
- Vasomotor
- Sudomotor/edema
- Motor/trophic
yes
42
8D8A.0
Complex
regional pain
syndrome
no
no
43
Pain in muscles, bones, Joints, or tendons
yes
44
MG30.02
Chronic primary
musculoskeletal
pain
no
45
Headache or orofacial pain
yes
46
Please refer to the ICHD-3/ICOP and the ICD-11 Coding Tool
no
47
Pain location compatible with referral pain patterns from internal organs
yes
48
MG30.00
Chronic primary
visceral pain
no
49
Other specified chronic primary pain syndrome
yes
50
MG30.0Y
Other
specified
chronic
primary pain
no
51
MG30.0Z
Chronic primary
pain,
unspecified

[35] Body quadrants are defined by upper-lower/left-right side of the body; axial skeleton: neck, back, chest, and abdomen.

[36] This is the second diagnostic level. Decide whether you need to continue to the next level.

[40, 41] – Sensory signs and symptoms: hyperalgesia (to pinprick) and/or allodynia (to light touch or deep somatic pressure, or joint movement)

- Vasomotor symptoms: temperature asymmetry and/or skin color changes and/or asymmetry

- Sudomotor/edema: edema and/or sweating changes and/or sweating asymmetry

- Motor/trophic symptoms: decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nails, skin)

[42] Decide whether you need to continue. If yes, continue on page 12. This diagnosis has two parents: MG30.0 Chronic primary pain, MG30.2 Chronic postsurgical or post traumatic pain. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

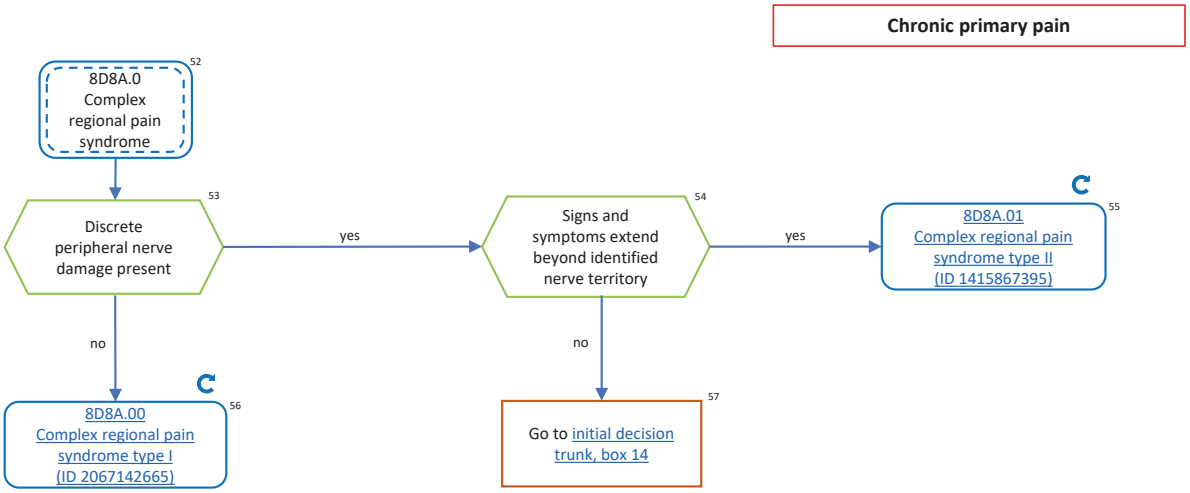
[44] Continue on page 13. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

[46] Coding Tool available at https://icd.who.int/ct11/icd11_mms/en/release

[47] The referral pain pattern should be demonstrated by at least one test.

[48] Continue on page 14. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

[38, 46, 50, 51] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

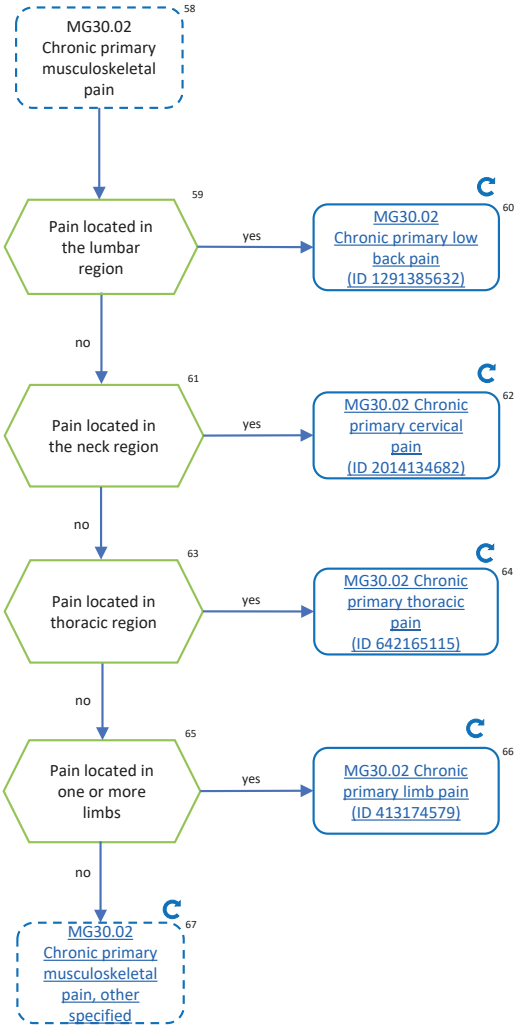


[53] As indicated by neurological examination, electrodiagostic testing, or quasi-objective testing

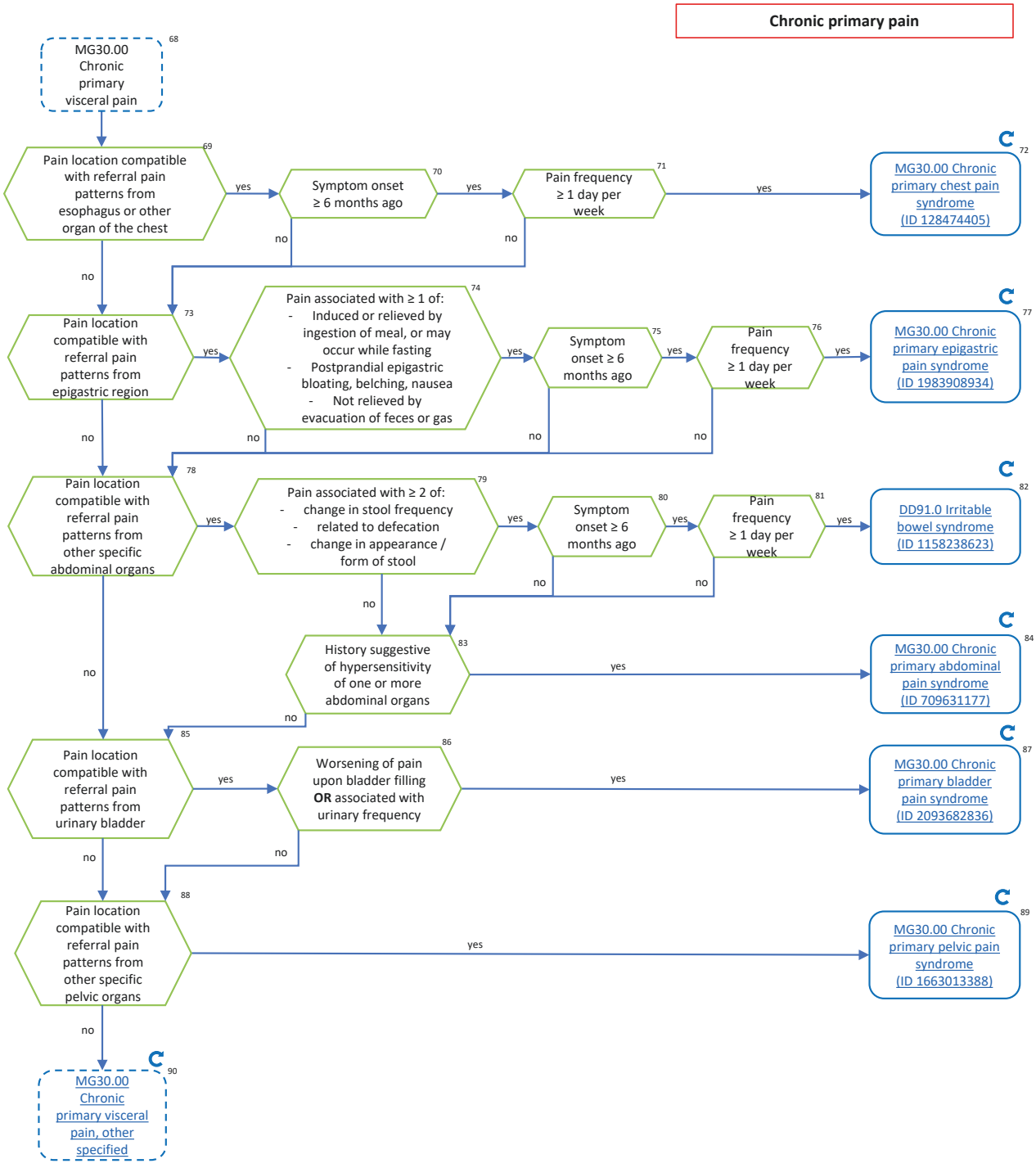
[55, 56] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue. These diagnoses have two parents: MG30.0 Chronic primary pain, MG30.2 Chronic postsurgical or post traumatic pain.

[54] See boxes 36 and 37 on page 10 for the signs and symptoms

[57] Continue on page 8, box 14.



[60, 62, 64, 66, 67] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.


Chronic primary pain
MG30.00 Chronic primary visceral pain
Pain location compatible with referral pain patterns from esophagus or other organ of the chest
Symptom onset ≥ 6 months ago
Pain frequency ≥ 1 day per week
MG30.00 Chronic primary chest pain syndrome (ID 128474405)
Pain location compatible with referral pain patterns from epigastric region
Pain associated with ≥ 1 of:
- Induced or relieved by ingestion of meal, or may occur while fasting
- Postprandial epigastric bloating, belching, nausea
- Not relieved by evacuation of feces or gas
Symptom onset ≥ 6 months ago
Pain frequency ≥ 1 day per week
MG30.00 Chronic primary epigastric pain syndrome (ID 1983908934)
Pain location compatible with referral pain patterns from other specific abdominal organs
Pain associated with ≥ 2 of:
- change in stool frequency
- related to defecation
- change in appearance / form of stool
Symptom onset ≥ 6 months ago
Pain frequency ≥ 1 day per week
DD91.0 Irritable bowel syndrome (ID 1158238623)
History suggestive of hypersensitivity of one or more abdominal organs
MG30.00 Chronic primary abdominal pain syndrome (ID 709631177)
Pain location compatible with referral pain patterns from urinary bladder
Worsening of pain upon bladder filling OR associated with urinary frequency
MG30.00 Chronic primary bladder pain syndrome (ID 2093682836)
Pain location compatible with referral pain patterns from other specific pelvic organs
MG30.00 Chronic primary pelvic pain syndrome (ID 1663013388)
MG30.00 Chronic primary visceral pain, other specified
yes
no

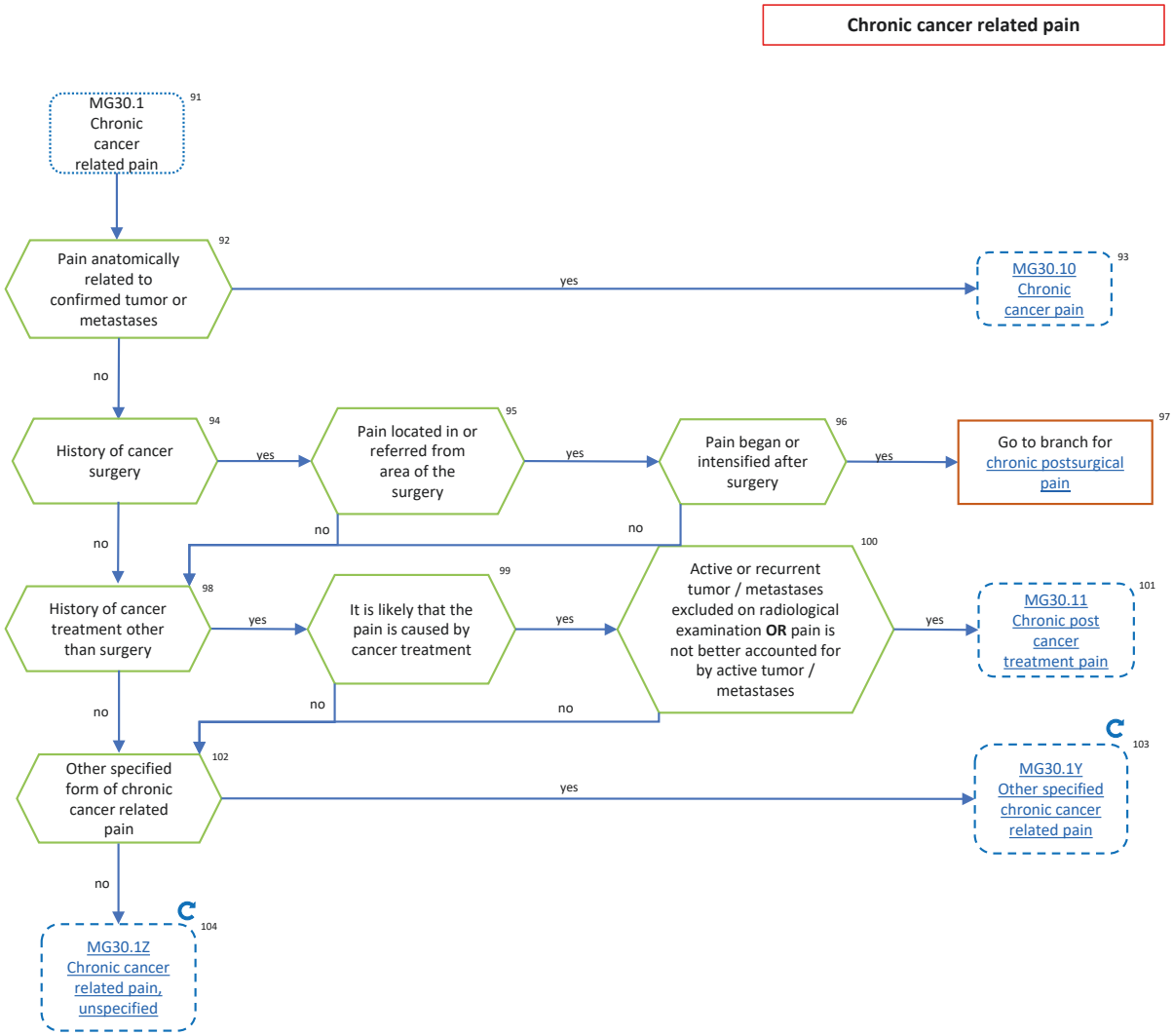
[72, 77, 82, 84, 87, 89, 90] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

[77] Heartburn is not a dyspeptic symptom but may often coexist. Other digestive symptoms (such as from gastro-esophageal reflux disease and irritable bowel syndrome) may coexist with chronic primary epigastric pain syndrome.

[86] Urinary frequency during day-time and/or nighttime

[87] This diagnosis also applies to what has previously been termed chronic interstitial cystitis.

[89] This diagnosis also applies to chronic dysmenorrhea and nonbacterial/idiopathic chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS).



[92] Tumor or metastases should be confirmed on clinical and radiological examination.

[93] Continue on page 17. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

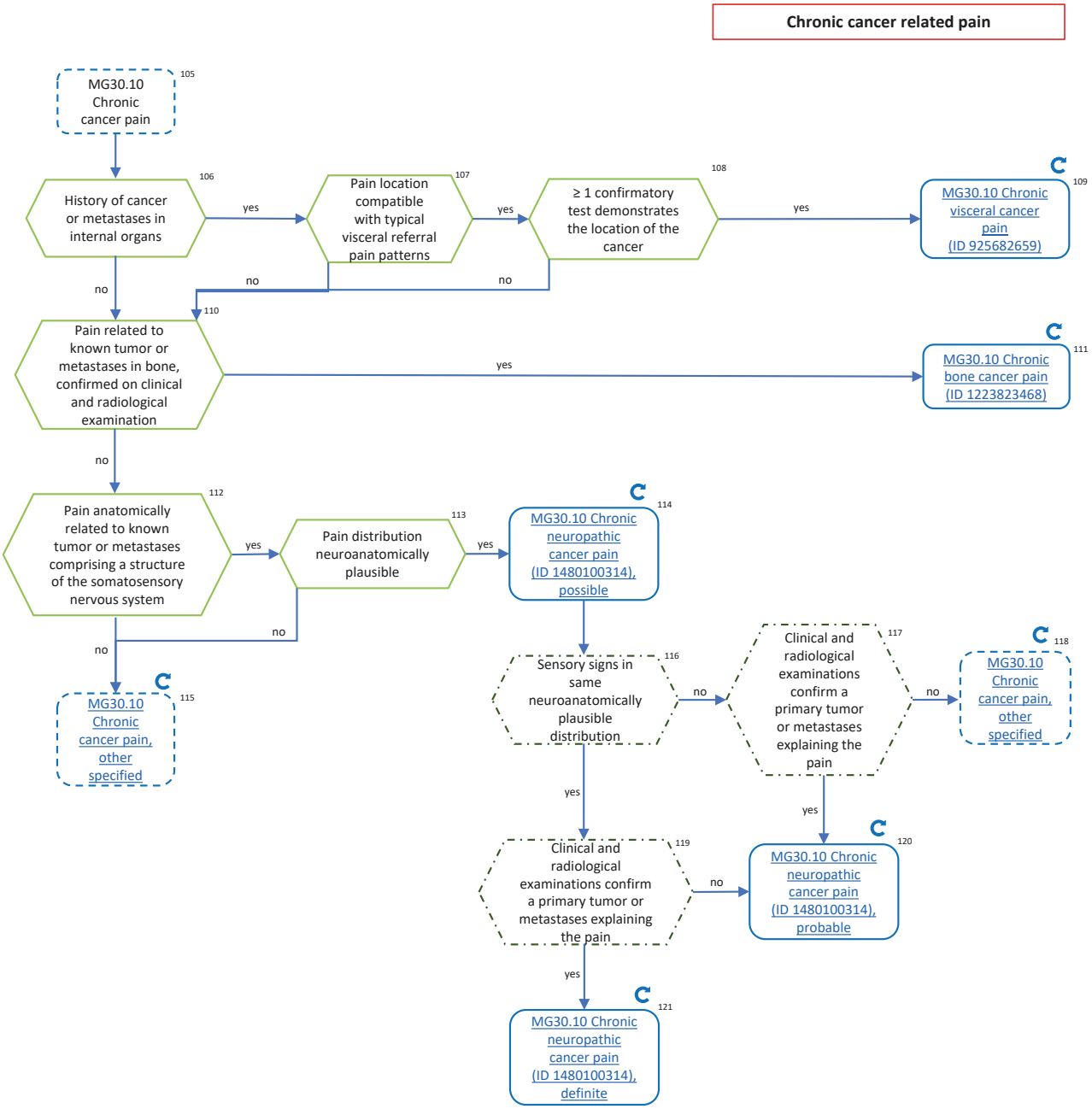
[97] Continue on page 22.

[98] Relevant cancer treatments include but are not limited to surgery, chemotherapy, hormonal treatment, radiotherapy, biological therapies.

[101] Continue on page 18. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

[102] For example: painful soft-tissue invasion by tumor, skin pain in T-cell lymphoma, painful lymph node metastases, pain after insertion of esophageal or rectal stent.

[103, 104] Check the pain location chart on page 7whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.



[108] For example: radiological examination, MRI.

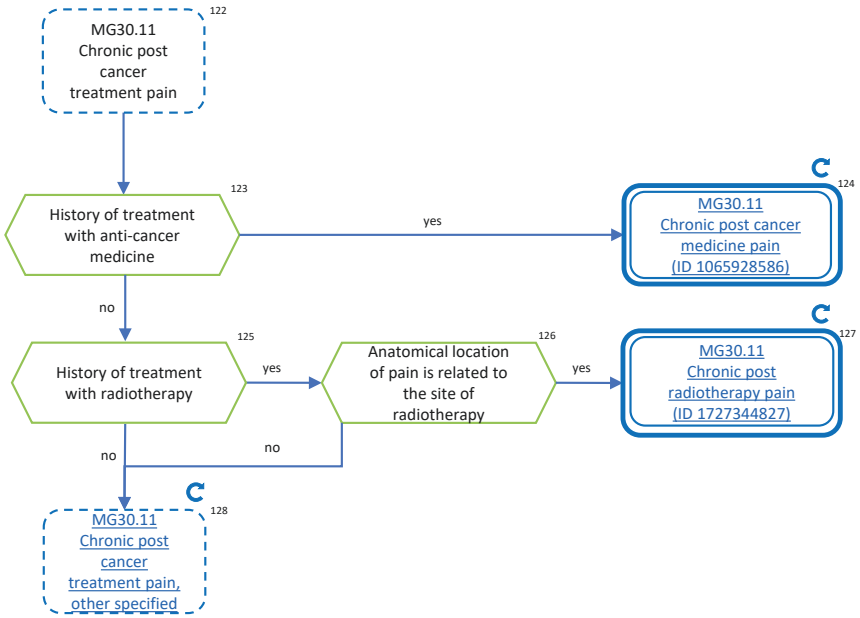
[109, 111, 114, 115, 118, 120, 121] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

[109] This diagnosis has two parents: MG30.1 Chronic cancer related pain, MG30.4 Chronic secondary visceral pain.

[114, 120, 121] This diagnosis has two parents: MG30.1 Chronic cancer related pain, MG30.5 Chronic neuropathic pain.

[116, 117, 119] Negative or positive sensory signs consistent with the distribution of the pain may be sufficient to indicate the presence of a lesion or disease of the somatosensory nervous system. The clinical examination may be supplemented by laboratory tests, e.g., quantitative sensory testing. Tests that reveal the relevant lesion or disease affecting the somatosensory system may, e.g., consist of surgical or radiological confirmation of nerve compression, nerve conduction study, laser-evoked potentials, blink reflex, or skin biopsy confirmation of reduced nerve fiber terminals. Positive findings in these investigations may provide important diagnostic hints at the source of pain. However, all clinical and diagnostic aspects of the pain need to be considered before assuming causality. **If clinical examination or diagnostic testing are performed, and the results are negative, neuropathic pain is unlikely (or less likely). Consider using another chronic pain diagnosis.**

Chronic cancer related pain

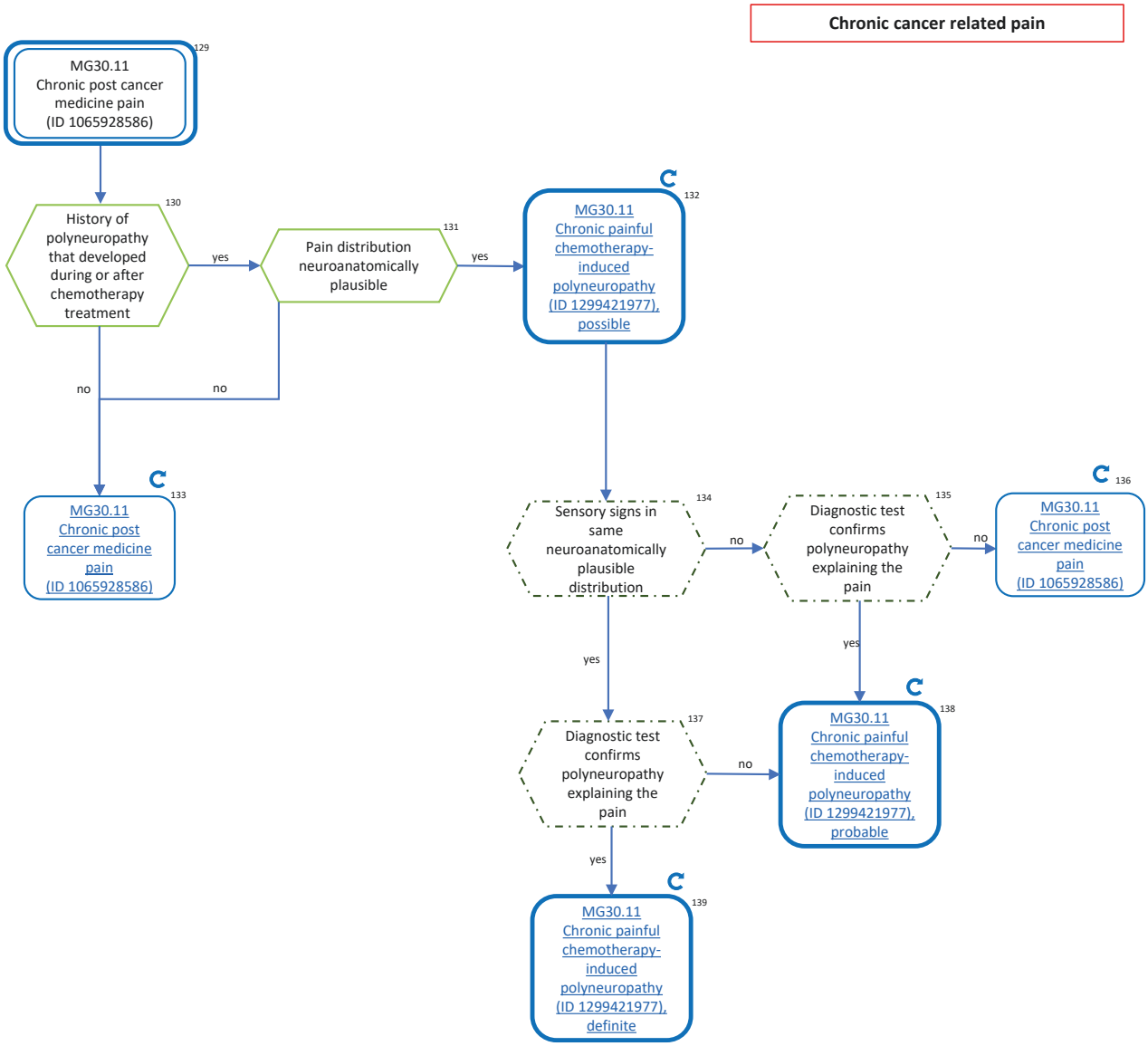


[123] For example: systemic chemotherapy, hormonal treatment, biological therapies.

[124, 127, 128] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

[124] Decide whether you need to continue. If yes, continue on page 19. This is the third diagnostic level. Continue to find the correct diagnosis on level 4.

[127] Decide whether you need to continue. If yes, continue on page 20. This is the third diagnostic level. Continue to find the correct diagnosis on level 4.

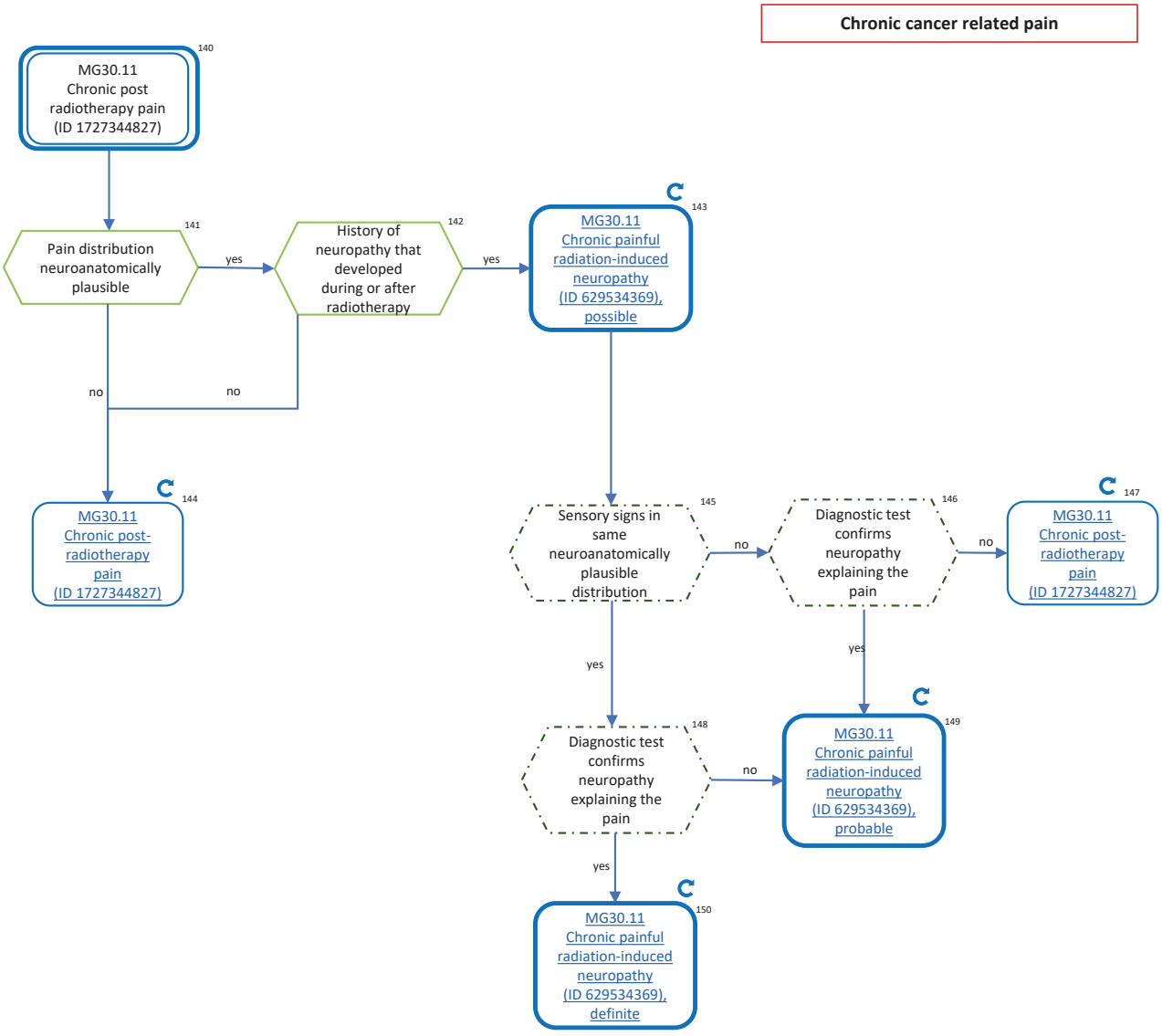


[131] Typically distal symmetric.

[134, 135, 136, 137] Negative or positive sensory signs consistent with the distribution of the pain may be sufficient to indicate the presence of a lesion or disease of the peripheral somatosensory nervous system. The clinical examination may be supplemented by laboratory tests, e.g., quantitative sensory testing. Tests that reveal the relevant lesion or disease affecting the somatosensory system may, e.g., consist of surgical or radiological confirmation of nerve compression, nerve conduction study, laser-evoked potentials, blink reflex, or skin biopsy confirmation of reduced nerve fiber terminals. Positive findings in these investigations may provide important diagnostic hints at the source of pain. However, all clinical and diagnostic aspects of the pain need to be considered before assuming causality. **If clinical examination or diagnostic testing are performed, and the results are negative, neuropathic pain is unlikely (or less likely). Consider using another chronic pain diagnosis.**

[132, 133, 136, 138, 139] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

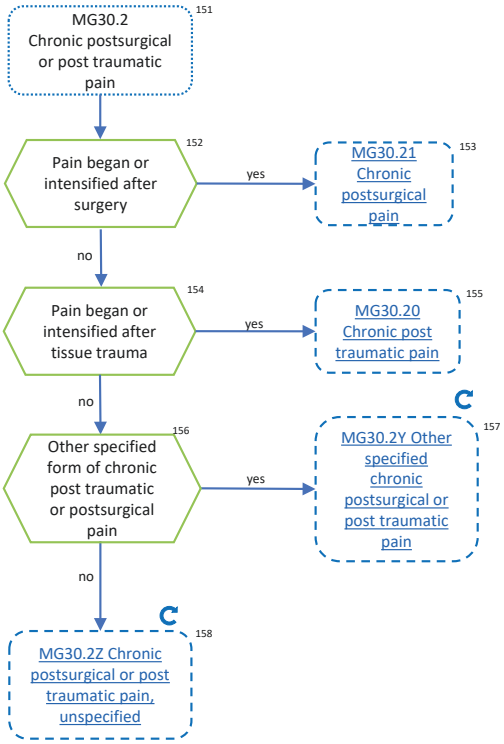
[132, 138, 139] This diagnosis has two parents: MG30.11 Chronic post cancer treatment pain, MG30.51 Chronic peripheral neuropathic pain.



[145, 146, 148] Negative or positive sensory signs consistent with the distribution of the pain may be sufficient to indicate the presence of a lesion or disease of the peripheral somatosensory nervous system. The clinical examination may be supplemented by laboratory tests, e.g., quantitative sensory testing. Tests that reveal the relevant lesion or disease affecting the somatosensory system may, e.g., consist of surgical or radiological confirmation of nerve compression, nerve conduction study, laser-evoked potentials, blink reflex, or skin biopsy confirmation of reduced nerve fiber terminals. Positive findings in these investigations may provide important diagnostic hints at the source of pain. However, all clinical and diagnostic aspects of the pain need to be considered before assuming causality. **If clinical examination or diagnostic testing are performed, and the results are negative, neuropathic pain is unlikely (or less likely). Consider using another chronic pain diagnosis.**

[143, 144, 147, 149, 150] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

[143, 149, 150] This diagnosis has two parents: MG30.11 Chronic post cancer treatment pain, MG30.51 Chronic peripheral neuropathic pain.

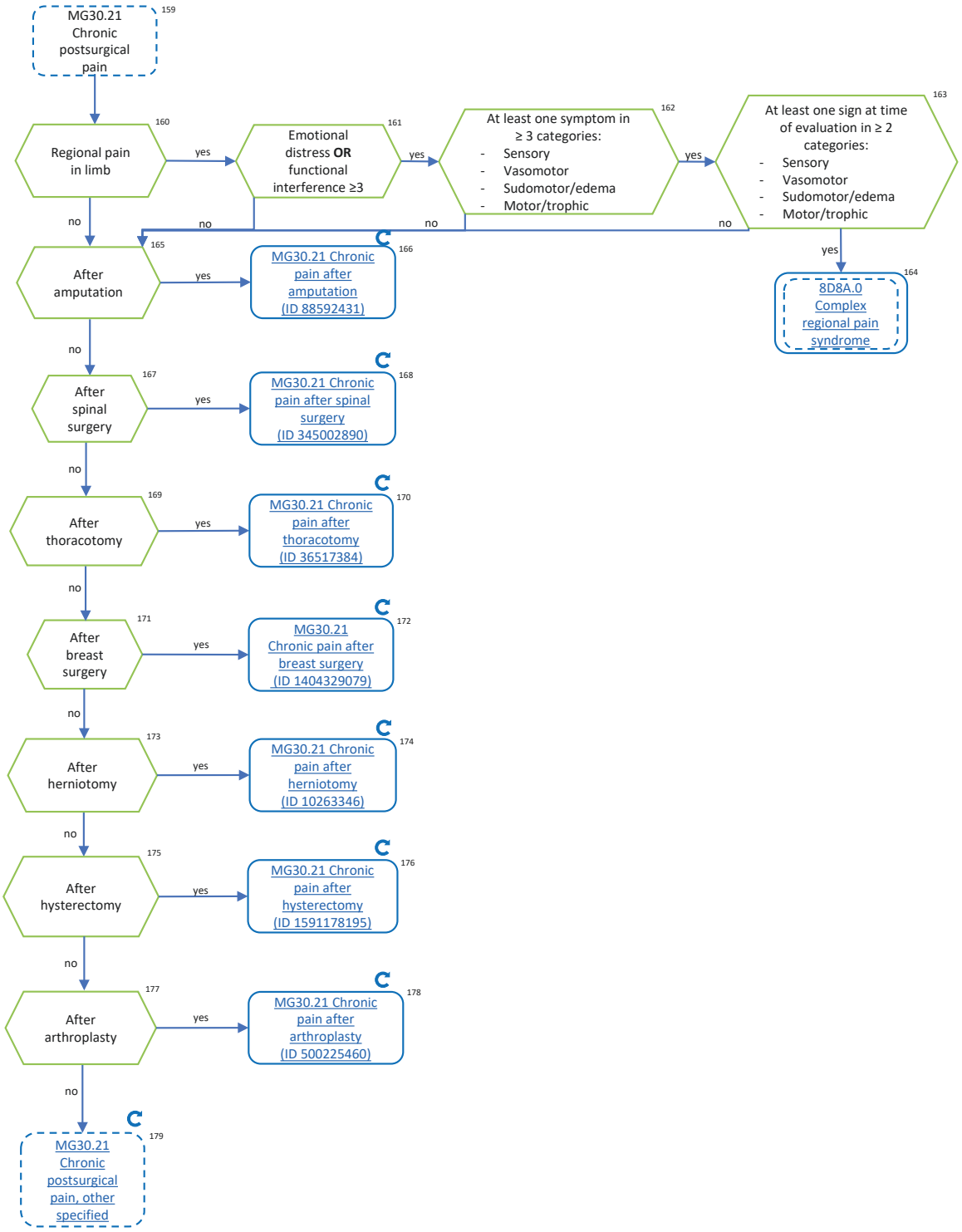


[153] Continue on page 22. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

[155] Continue on page 24. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.
If you do not wish to continue, and the pain is associated with an injury of the nervous system, go to the initial decision trunk on page 8, box 14 to check whether the criteria for chronic neuropathic pain are met, and to find the correct diagnosis on the second diagnostic level. If the pain is located in a limb, and associated with sensory, vasomotor, sudomotor / edema, motor or trophic symptoms, go to the initial decision trunk on page 8, box 4, to check whether the criteria for chronic primary pain are met, and continue.

[157, 158] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

Chronic postsurgical or post traumatic pain



[162, 163] – Sensory symptoms: hyperalgesia (to pinprick) and/or allodynia (to light touch or deep somatic pressure, or joint movement)

- Vasomotor symptoms: temperature asymmetry and/or skin color changes and/or asymmetry

- Sudomotor/edema: edema and/or sweating changes and/or sweating asymmetry

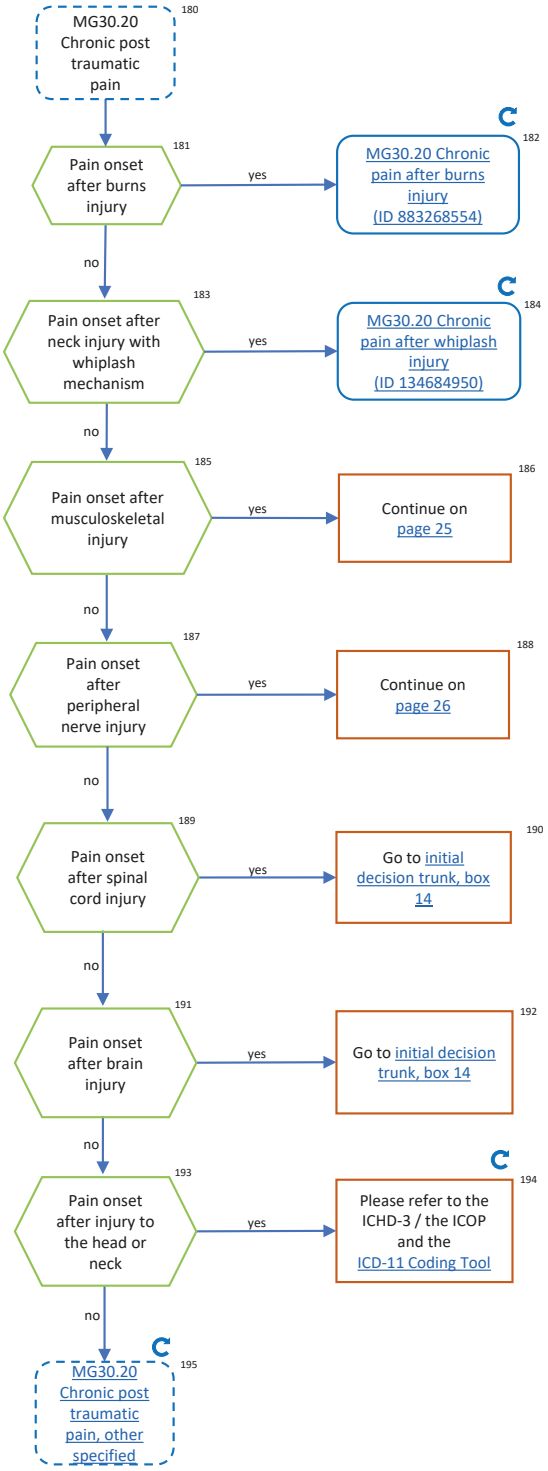
- Motor/trophic symptoms: decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nails, skin)

[164] Decide whether you need to continue. If yes, continue on page 12. This diagnosis has two parents: MG30.0 Chronic primary pain, MG30.2 Chronic postsurgical or post traumatic pain. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

[166] This diagnosis has two parents: MG30.21 Chronic postsurgical pain, MG30.51 Chronic peripheral neuropathic pain.

[166, 168, 170, 172, 174, 176, 178, 179] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

[179] This also includes chronic pain after abdominal surgery (bowel and colorectal), Caesarean delivery, cholecystectomy, craniotomy, dental surgery, inguinal herniotomy, melanoma resection, sternotomy, vasectomy, traumatic amputation, contusion, among others.



[182, 184, 194, 195] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

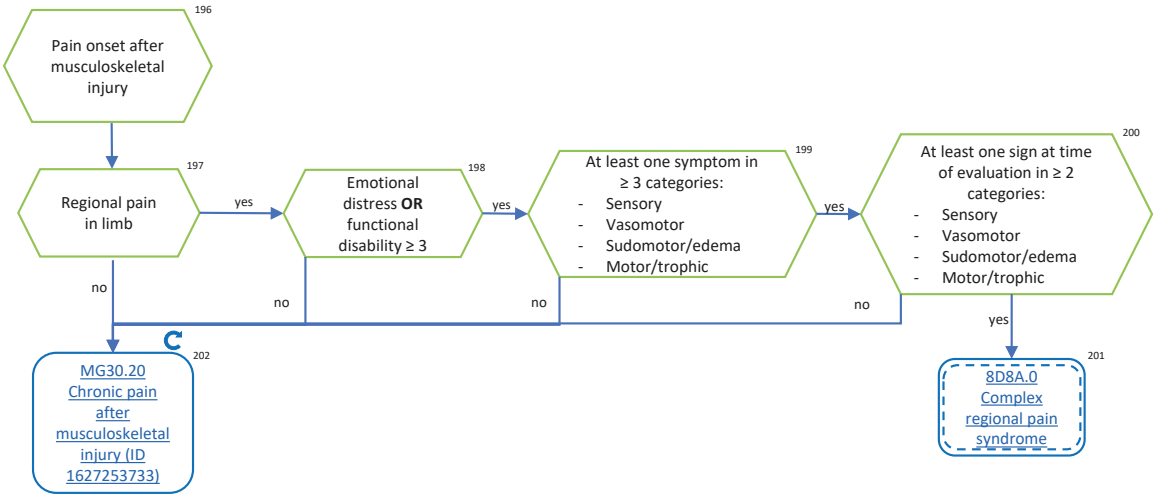
[185] For example: muscle injury, bone fractures, joint trauma.

[187] This may be a mechanical, thermal, radiation, or chemical injury.

[190, 192] Continue on page 8, box 14.

[194] Coding Tool available at https://icd.who.int/ct11/icd11_mms/en/release

Chronic postsurgical or post traumatic pain



[198] Check NRS on page 6.

[199, 200] – Sensory symptoms: hyperalgesia (to pinprick) and/or allodynia (to light touch or deep somatic pressure, or joint movement)

- Vasomotor symptoms: temperature asymmetry and/or skin color changes and/or asymmetry

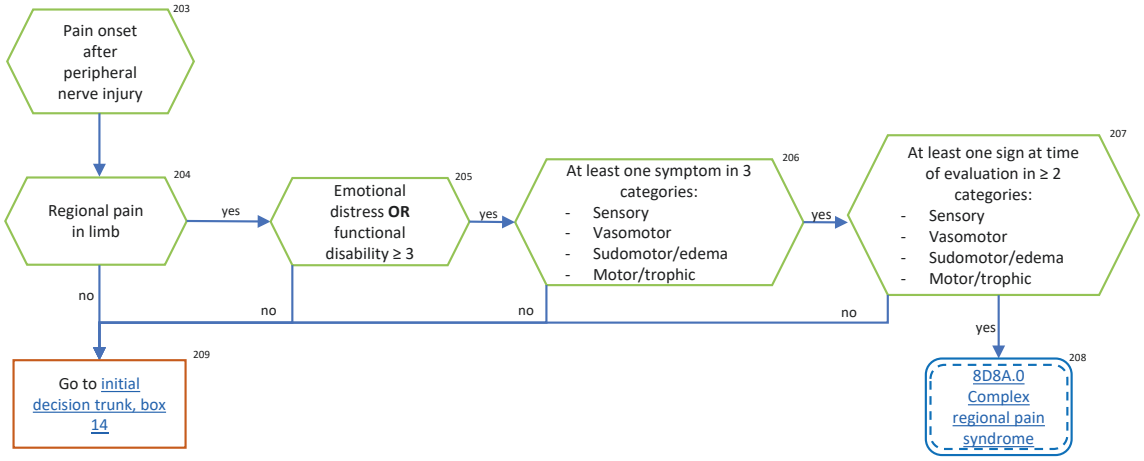
- Sudomotor/edema: edema and/or sweating changes and/or sweating asymmetry

- Motor/trophic symptoms: decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nails, skin)

[201] Decide whether you need to continue. If yes, continue on page 12. This diagnosis has two parents: MG30.0 Chronic primary pain, MG30.2 Chronic postsurgical or post traumatic pain. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

[202] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

Chronic postsurgical or post traumatic pain



[205] Check NRS on page 6

[206, 207] – Sensory symptoms: hyperalgesia (to pinprick) and/or allodynia (to light touch or deep somatic pressure, or joint movement)

- Vasomotor symptoms: temperature asymmetry and/or skin color changes and/or asymmetry

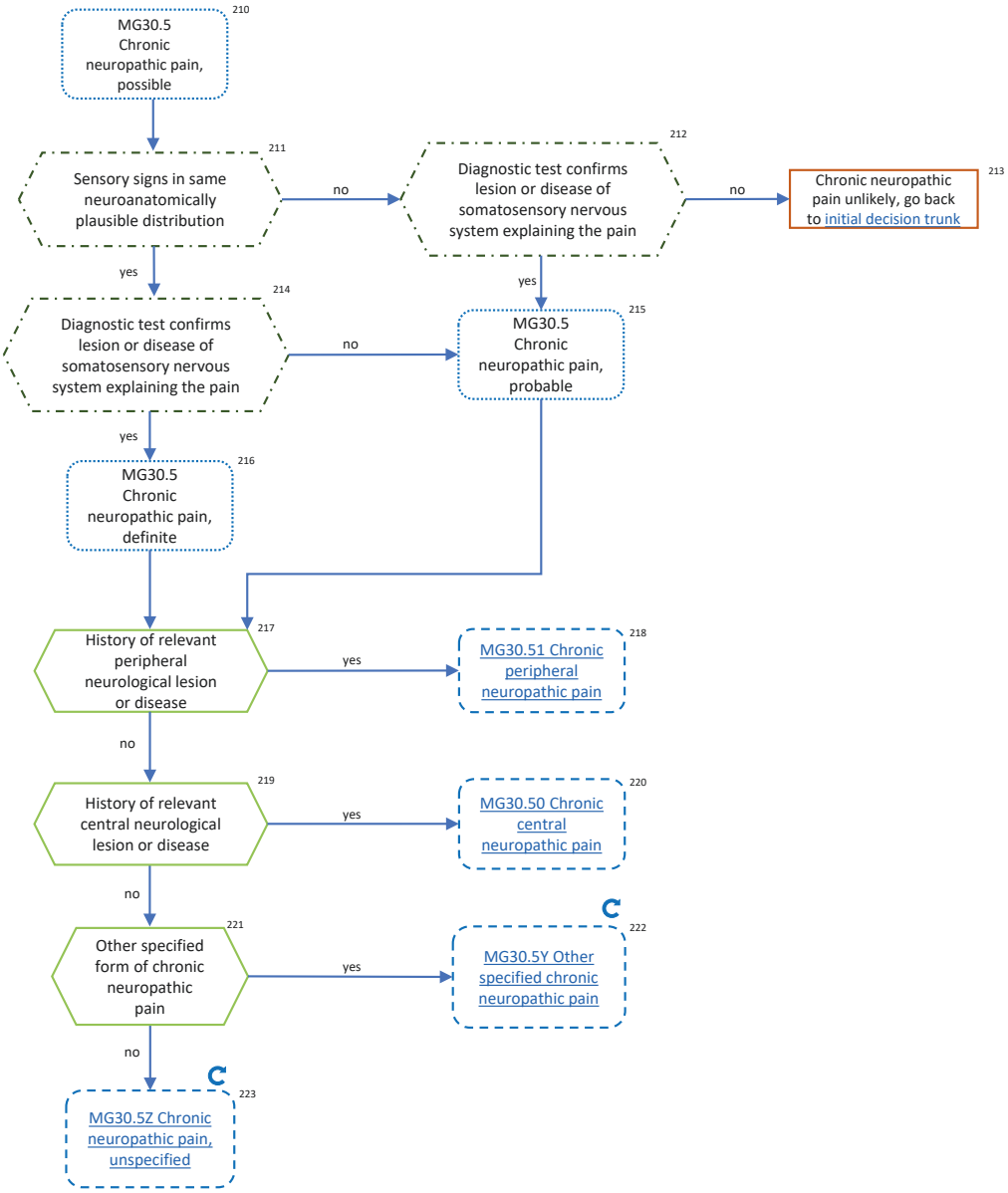
- Sudomotor/edema: edema and/or sweating changes and/or sweating asymmetry

- Motor/trophic symptoms: decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nails, skin)

[208] Decide whether you need to continue. If yes, continue on page 12. This diagnosis has two parents: MG30.0 Chronic primary pain, MG30.2 Chronic postsurgical or post traumatic pain. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

[209] Continue on page 8, box 14.

Chronic neuropathic pain



[211, 212, 214] Negative or positive sensory signs consistent with the distribution of the pain may be sufficient to indicate the presence of a lesion or disease of the somatosensory nervous system. The clinical examination may be supplemented by laboratory tests, e.g., quantitative sensory testing. Tests that reveal the relevant lesion or disease affecting the somatosensory system may, e.g., consist of surgical or radiological confirmation of nerve compression, nerve conduction study, laser-evoked potentials, blink reflex, or skin biopsy confirmation of reduced nerve fiber terminals. Positive findings in these investigations may provide important diagnostic hints at the source of pain. However, all clinical and diagnostic aspects of the pain need to be considered before assuming causality. **If clinical examination or diagnostic testing are performed, and the results are negative, neuropathic pain is unlikely (or less likely). Consider using another chronic pain diagnosis.**

For an overview of screening instruments that may assist you to assess chronic neuropathic pain, see:

Attal N, Bouhassira D, Baron R. Diagnosis and assessment of neuropathic pain through questionnaires. The Lancet Neurology 2018;17:456–466. https://doi.org/10.1016/S1474-4422(18)30071-1

[213] Go to initial decision trunk on page 8.

[215, 216] This is the first diagnostic level. Continue to find the appropriate diagnosis on the next level.

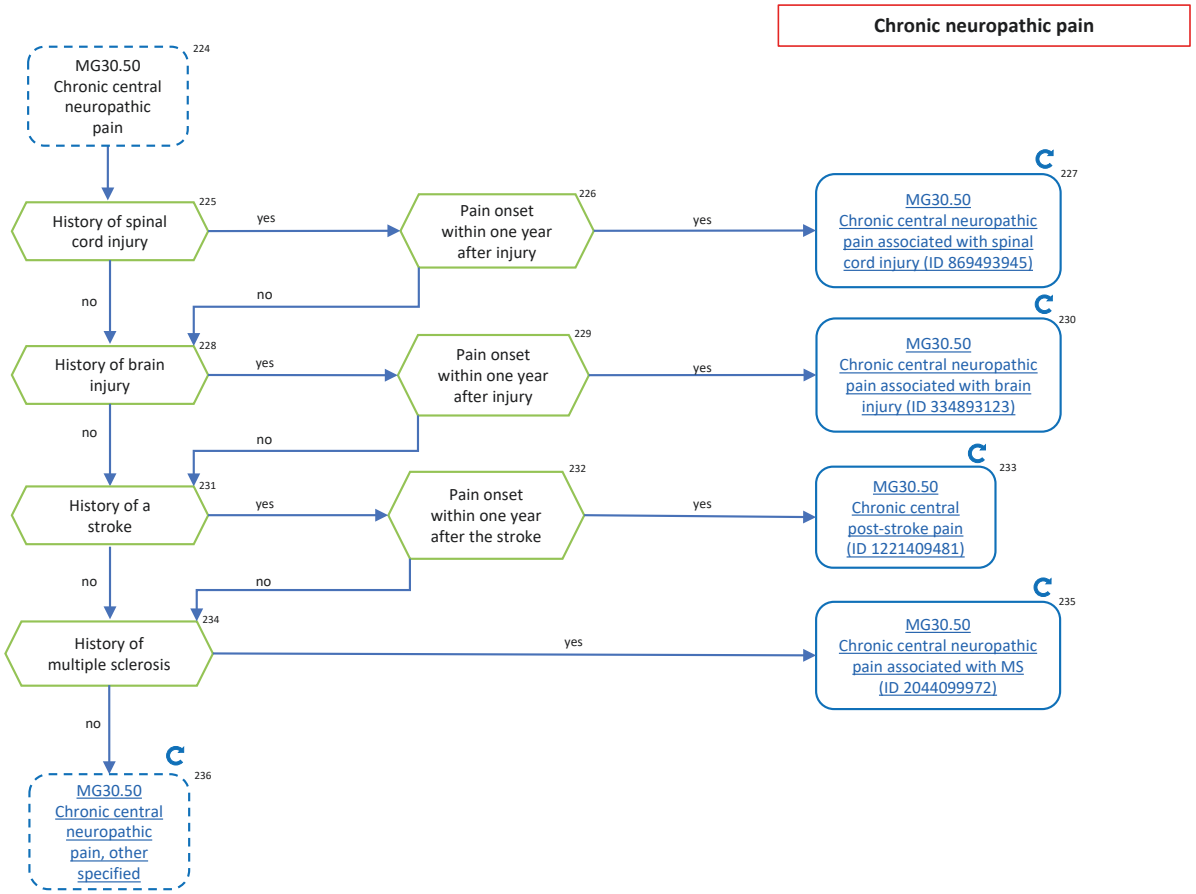
[217] For example: herpes zoster, radiculopathy (see Appendix on page 41 for a list of examples).

[218] Continue on page 30. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

[219] For example: brain injury, stroke (see Appendix on page 41 for a list of examples).

[220] Continue on page 29. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

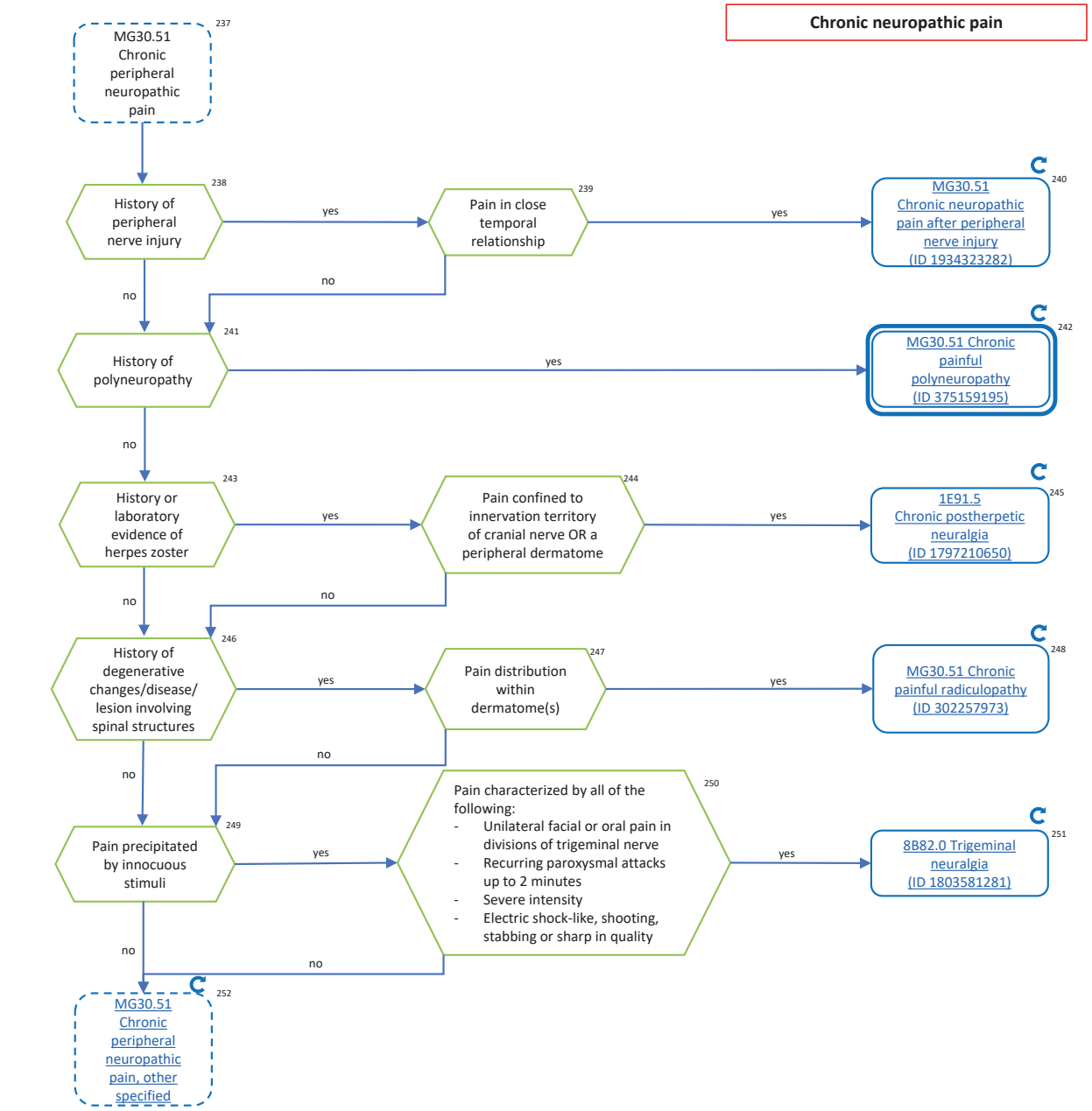
[222, 223] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.



[227, 230, 233, 235, 236] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

[227] This diagnosis has two parents: MG30.50 Chronic central neuropathic pain, MG30.20 Chronic post traumatic pain.

[230] This diagnosis has two parents: MG30.50 Chronic central neuropathic pain, MG30.20 Chronic post traumatic pain.



[240] This diagnosis has two parents: MG30.51 Chronic peripheral neuropathic pain, MG30.20 Chronic post traumatic pain.

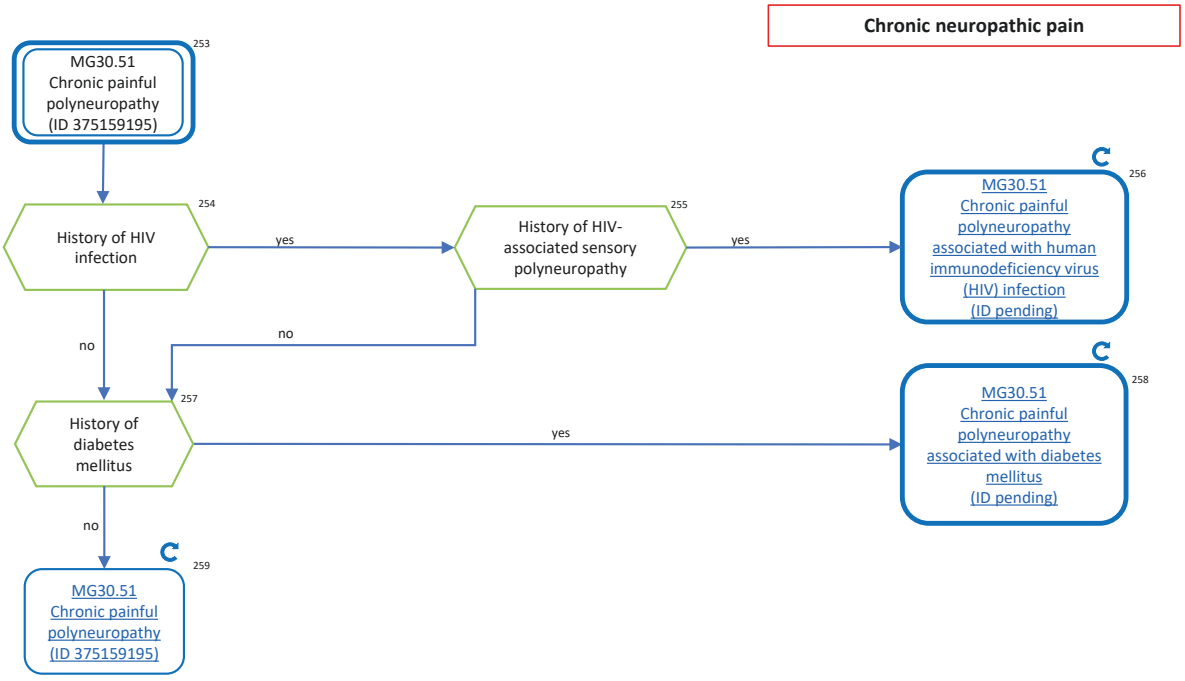
[242] Decide whether you need to continue. If yes, continue on page 31. This is the third diagnostic level. Continue to find the correct diagnosis on level 4.

[240, 242, 245, 248, 251, 252] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

[249] Pain location typically within the affected trigeminal territory and always on the ipsilateral side of the face.

[251] This diagnosis has two parents: MG30.50 Chronic peripheral neuropathic pain, MG30.62 Chronic neuropathic orofacial pain.

[252] This also includes, e.g., chronic neuropathic pain associated entrapment, for example carpal tunnel syndrome, Morton's neuroma, pudendal syndrome, neuropathies after intensive care unit (ICU) treatment.



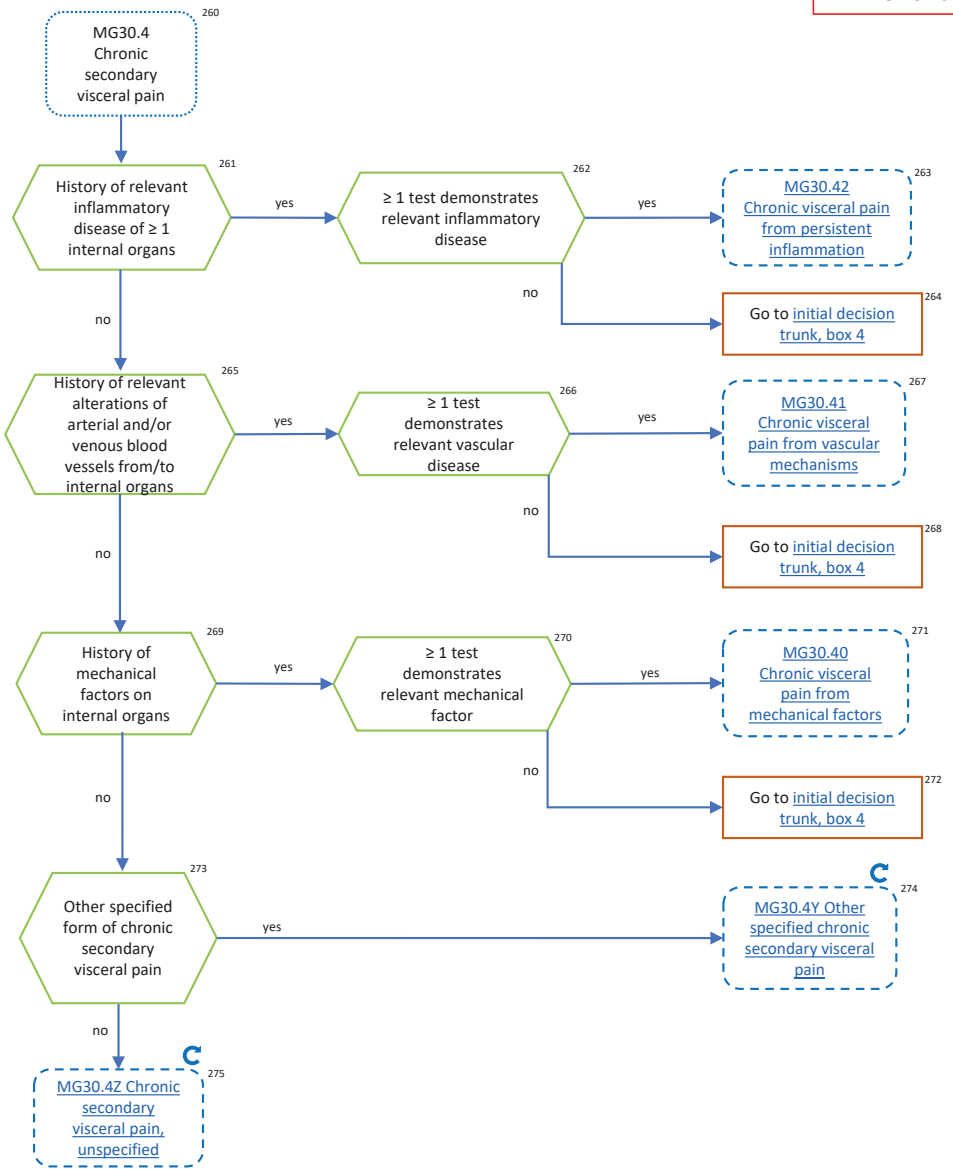
[257] Demonstrated by at least one diagnostic test.

[256, 258, 259] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

[256, 258] At the date of publication, the implementation of these entities into the ICD-11 is still pending.

[259] Other causes of chronic painful polyneuropathy include, e.g.,: leprosy, alcohol use disorder, metabolic disorders, toxins, genetic conditions, immune system diseases, with vitamin insufficiency (see Appendix on page 41 for a list of examples).

Chronic secondary visceral pain



[260] No minimal frequency of pain attacks has been defined for chronic secondary visceral pain. It depends on the clinical judgment of each individual case to decide whether visceral pain associated with an underlying disease that has been recurring in attacks for longer than 3 months should be considered as chronic secondary visceral pain.

[261] For example: endometriosis, chronic pancreatitis, chronic gastritis, reflux disease (see Appendix on page 41 for a list of examples).

[262] For example: indices of inflammation in blood or serum, indices of bacterial infections in blood or serum.

[263] Continue on page 34. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

[264, 268, 272] Go to the initial decision trunk on page 8, box 4.

[265] For example: ischemic heart disease, vasculitis, sickle cell disease (see Appendix on page 41 for a list of examples).

[266] For example: angiogram, blood or serum sampling.

[267] Continue on page 35. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

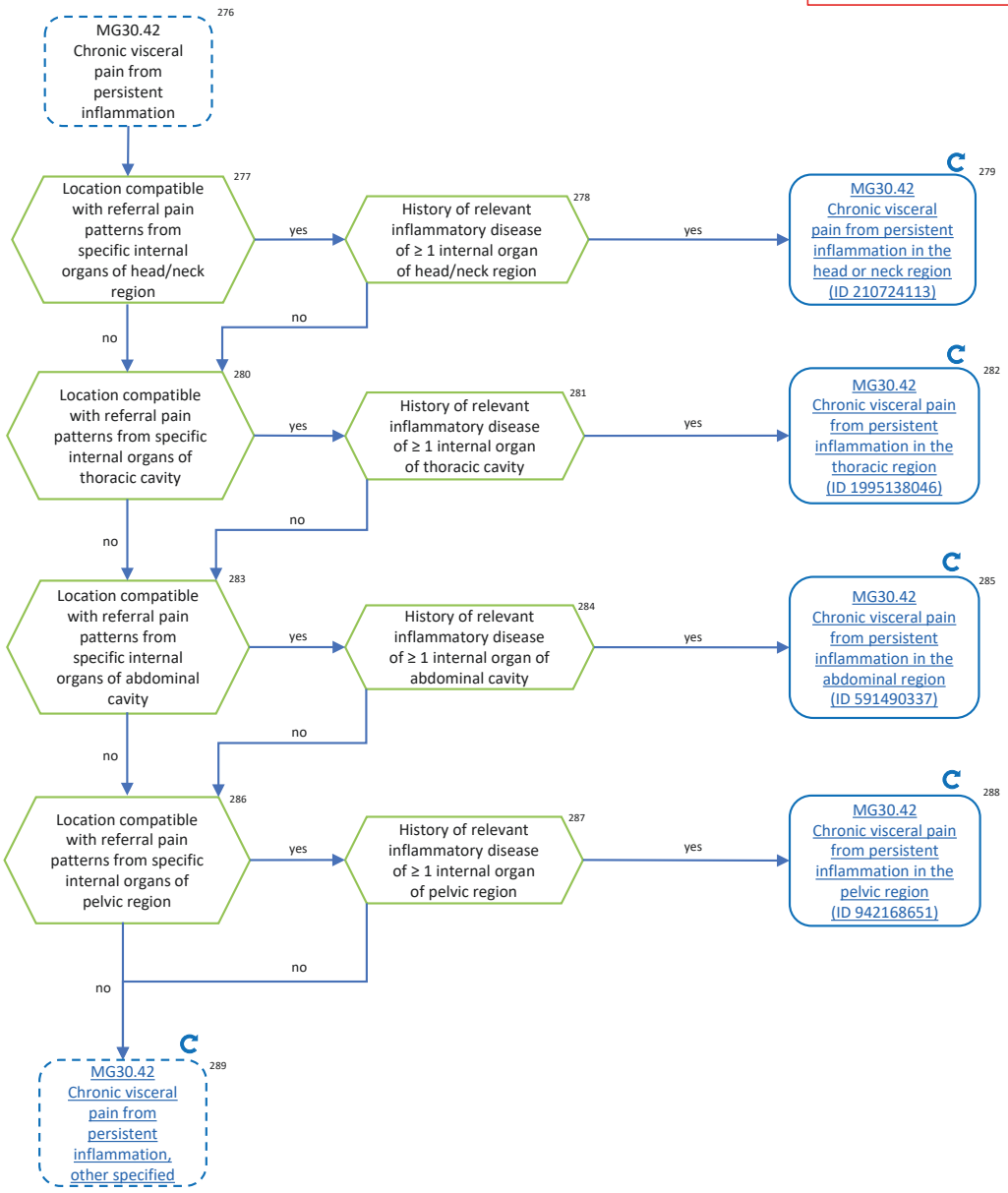
[269] For example: obstruction/distension of hollow internal organs or traction/compression of ligaments and vessels to internal organs, for example: stones obstructing the biliary or renal tracts, ureteric kinking (see Appendix on page 41 for a list of examples).

[270] For example: ultrasound.

[271] Continue on page 36. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

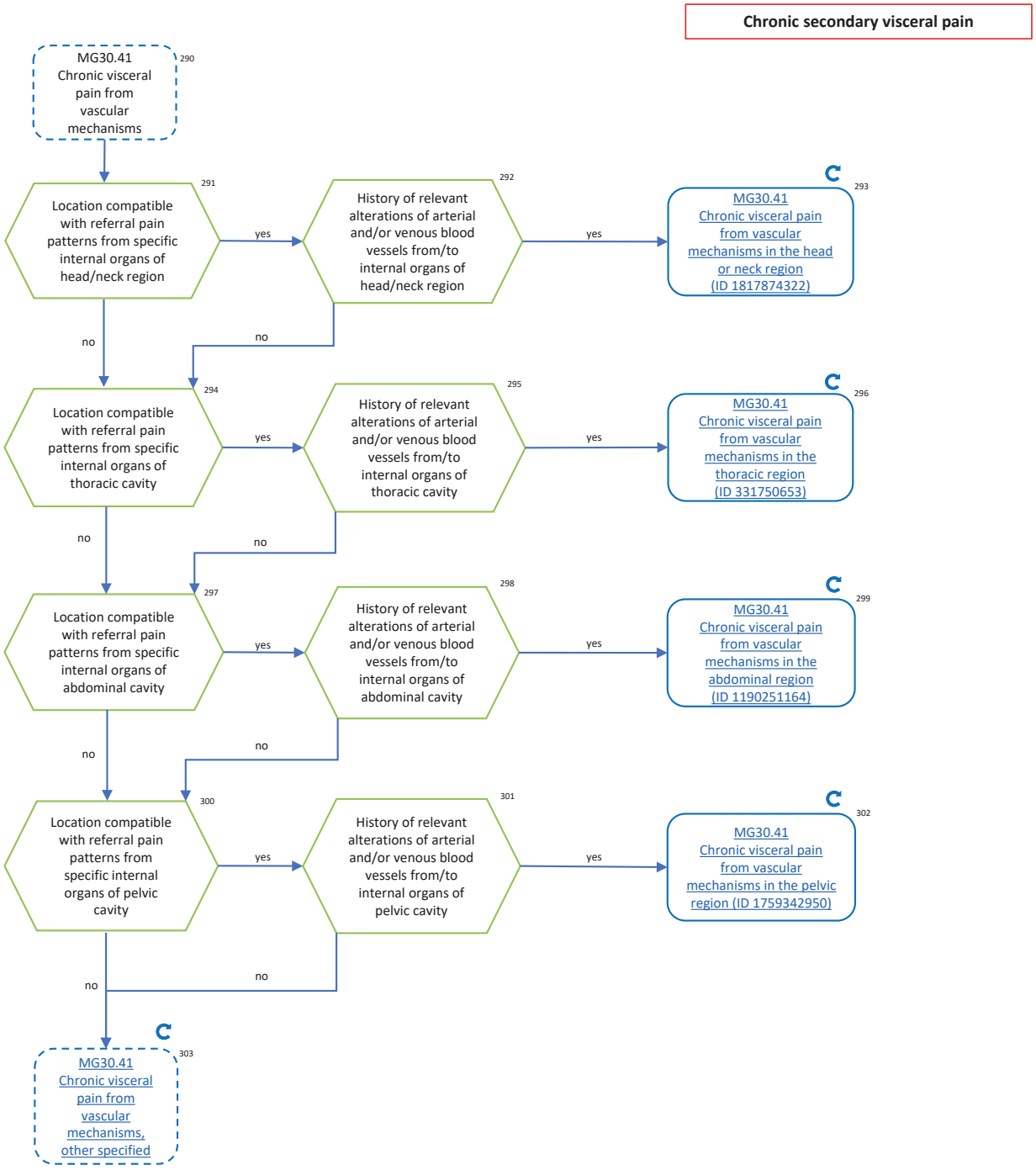
[273] For example: degenerative neuropathies (identified recently in gastrointestinal tract).

[274, 275] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.



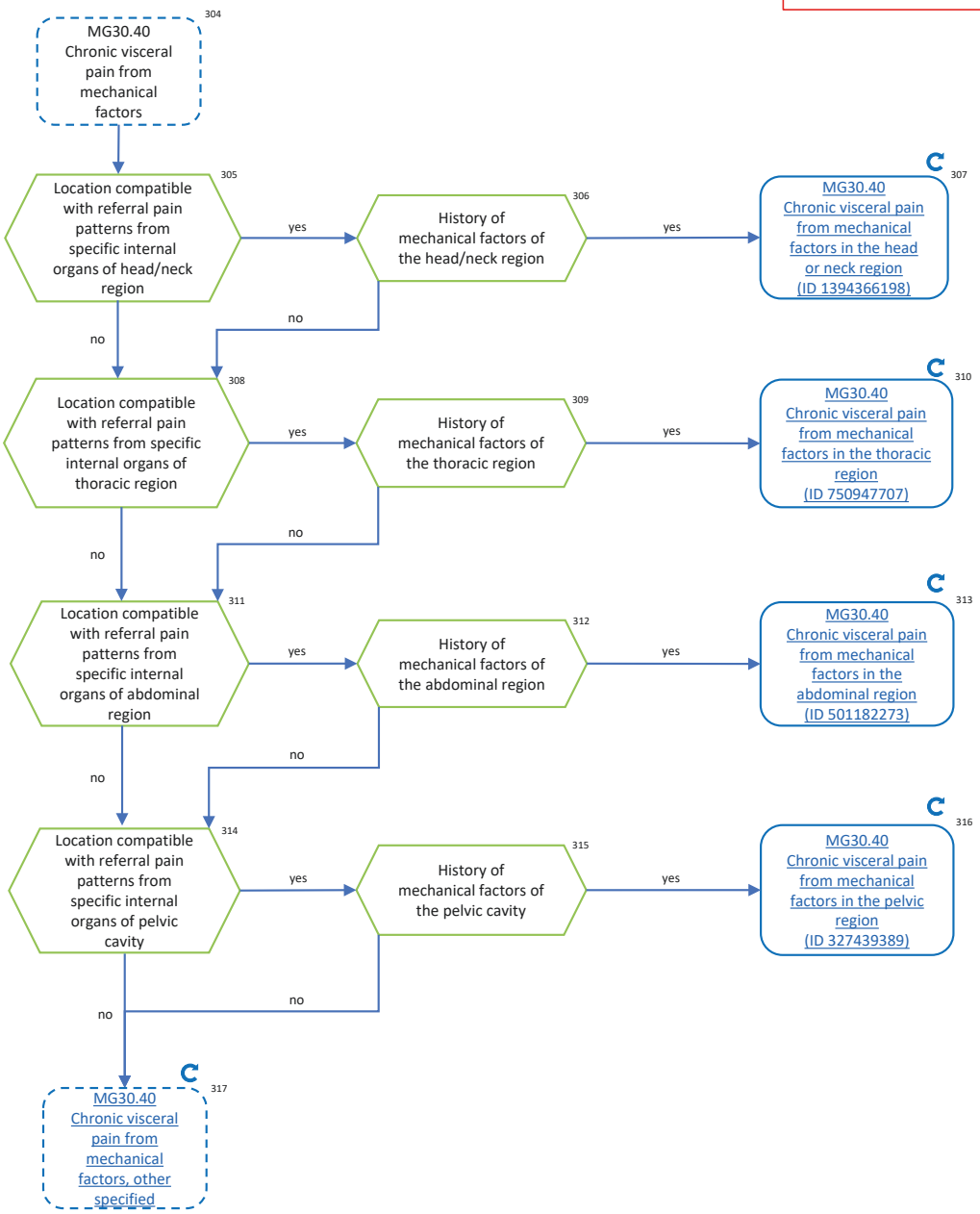
[278, 281, 284, 287] See Appendix (page 41) for a list of examples

[279, 282, 285, 288, 289] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.



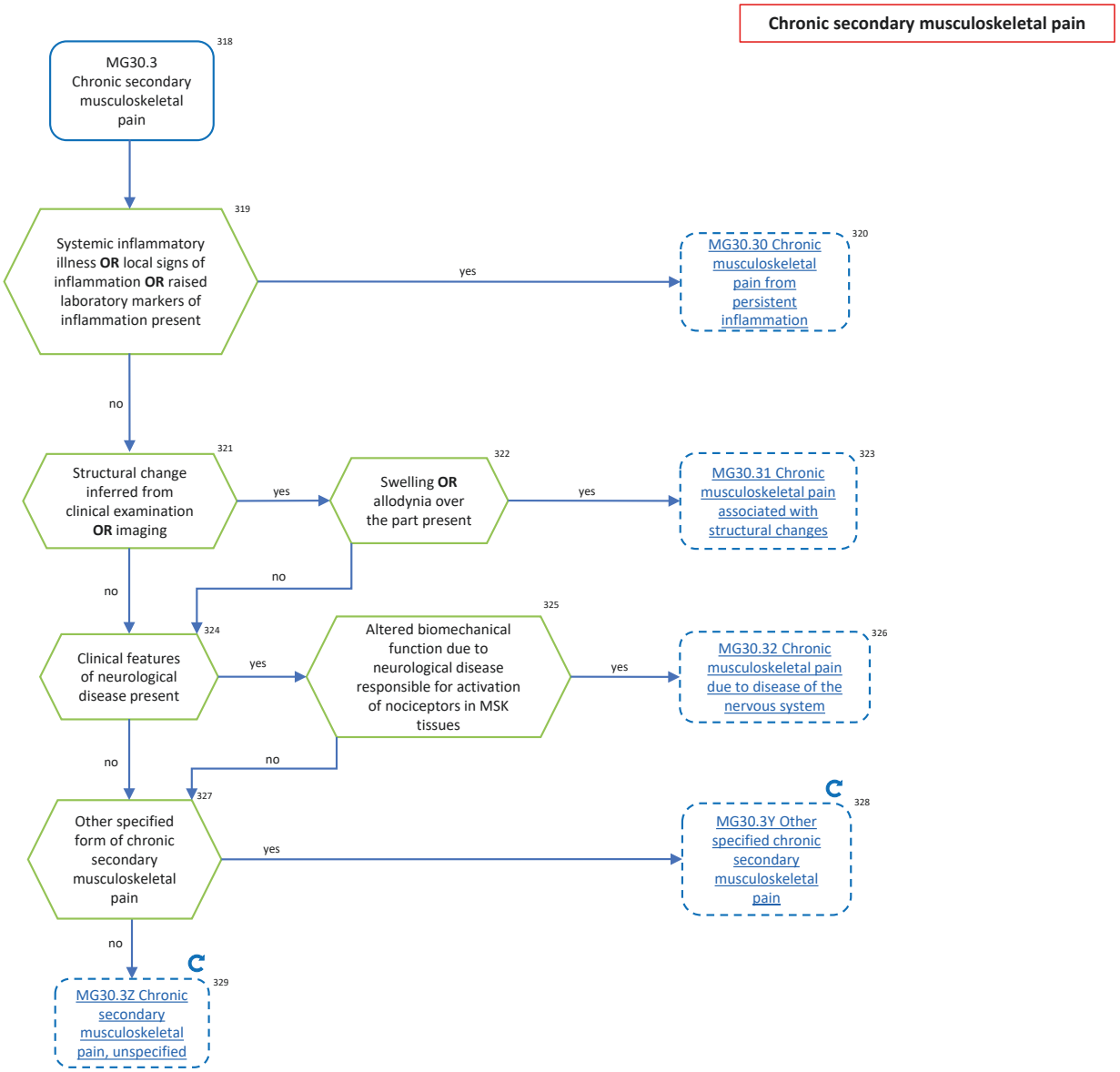
292, 295, 298, 301 See Appendix (page 41) for a list of examples.

293, 296, 299, 302, 303 Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.



306, 309, 312, 315 See Appendix (page 41) for examples.

307, 310, 313, 316, 317 Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.



[319] For example: Lyme disease, gout, rheumatoid arthritis (see Appendix on page 41 for a list of examples).

[320] Continue on page 38. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

[321] For example: osteoarthritis, spondylosis (see Appendix on page 41 for a list of examples).

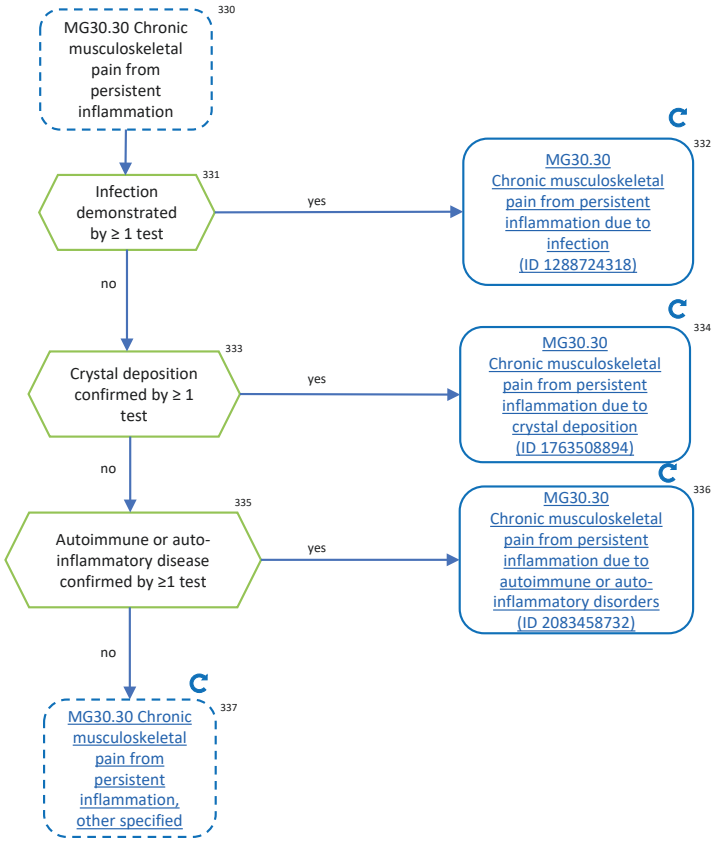
[323] Continue on page 39. This is the second diagnostic level. Continue to find the correct diagnosis on level 3. If you do not wish to continue, and the pain is associated with structural changes due to a musculoskeletal injury, go to the initial decision trunk on page 8, box 11, to check whether the criteria for chronic postsurgical or post traumatic pain are met, and to find the correct diagnosis on the second diagnostic level

[324] For example: motor neuron disease, Morbus Parkinson (see Appendix on page 41 for a list of examples).

[326] Continue on page 40. This is the second diagnostic level. Continue to find the correct diagnosis on level 3.

[327] For example: chronic pain from overuse.

[328, 329] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.



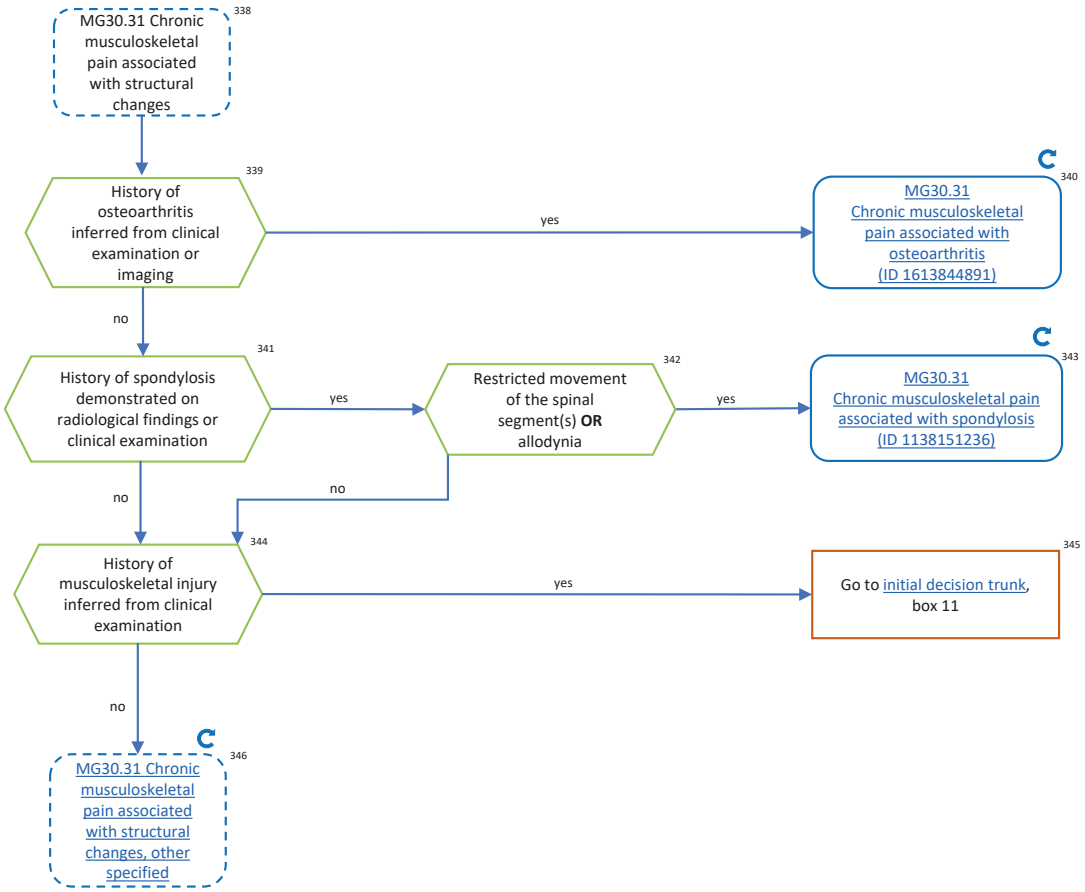
[331] For example: blood sampling.

[332, 334, 336, 337] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

[333] For example: uric acid.

[335] For example: blood sampling.

[337] This also includes, e.g., chronic musculoskeletal pain associated with plantar fasciitis, tendinopathy, or inflammatory rotator-cuff-syndrome.

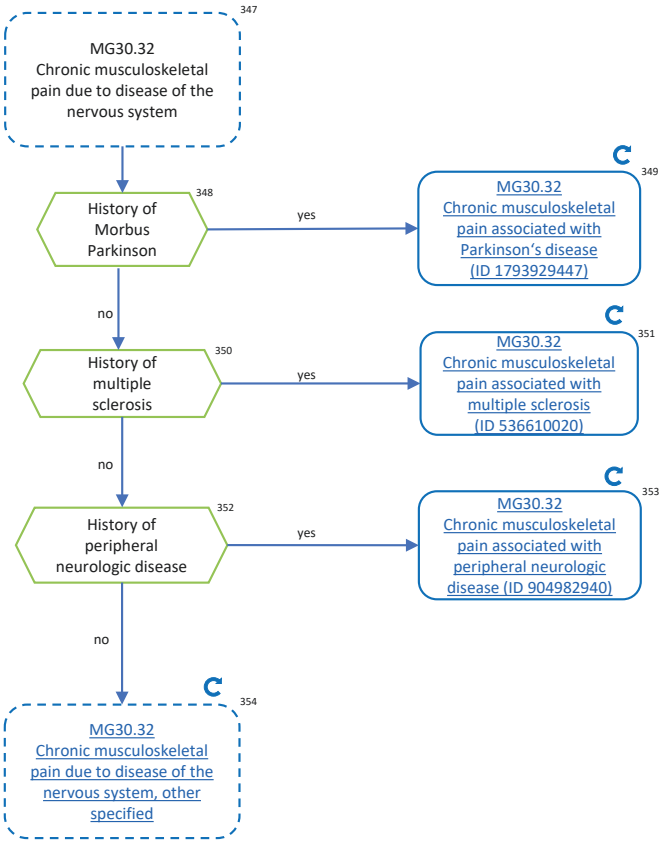


[341] Radiological findings demonstrate changes to intervertebral disc ± osteoarthritis of zygapophyseal joints.

[340, 343, 346] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

[345] Go to the initial decision trunk on page 8, box 11.

[346] This also includes, for example: chronic pain associated with rotator-cuff syndrome, plantar fasciitis, tendinopathy.



[348, 350, 352] As classified elsewhere.

[352] For example: Charcot joint disease in peripheral neuropathy.

[349, 351, 353, 354] Check the pain location chart on page 7 whether all chronic pain has been explained. If additional chronic pain syndromes are present, refer to the initial decision trunk on page 8 to check where to continue.

Appendix: List of exemplary diseases that may be associated with chronic secondary pain

This list gives examples of diseases, injuries, and medical procedures that may be associated with chronic pain. Please note that the chronic pain diagnosis cannot be assigned solely based on the presence of one of these examples. In all cases where an underlying potential cause of chronic secondary pain is present, you need to ensure that all chronic pain diagnostic criteria are met. This list is not exhaustive.

MG30.10 Chronic cancer pain & MG30.11 Chronic post cancer treatment pain

Most tumors and metastases, as well as most cancer treatments, may be associated with chronic pain.

MG30.21 Chronic postsurgical pain

Surgeries that may be associated with chronic postsurgical pain include:

- Abdominal surgery (bowel, colorectal)
- Amputation
- Breast surgery
- Caesarian delivery
- Cholecystectomy
- Cosmetic surgery
- Craniotomy
- Dental surgery
- Herniotomy
- Hip arthroplasty
- Hysterectomy
- Inguinal herniotomy
- Knee arthroplasty
- Mastectomy
- Melanoma resection
- Rectum amputation
- Spinal fusion
- Spinal surgery
- Sternotomy
- Thoracotomy
- Vasectomy

MG30.20 Chronic post-traumatic pain

Injuries that may be associated with chronic post-traumatic pain include:

- Bone fractures
- Brachial plexus injury
- Brain injury
- Burns injury
- Contusion
- Joint injuries
- Ligament injuries
- Muscle injuries
- Peripheral nerve injury
- Spinal cord injury
- Traumatic amputation
- Whiplash injury

MG30.51 Chronic peripheral neuropathic pain
Diseases or lesions of the peripheral nervous system that may be associated with chronic neuropathic pain include:

- Entrapment
    - Carpal tunnel syndrome
    - Morton's neuroma
    - Pudendal syndrome
- Herpes zoster (shingles)
- Nerve injury
- Polyneuropathy, for example due to (the list is not exhaustive):
    - Diabetic polyneuropathy
    - Other metabolic polyneuropathy
    - Polyneuropathy associated with a disease of the immune system
    - Polyneuropathy associated with genetic conditions
    - Polyneuropathy associated with vitamin insufficiency (e.g., vitamin B1 or B12)
    - Polyneuropathy in alcohol abuse
    - Polyneuropathy in human immunodeficiency virus disease (HIV)
    - Polyneuropathy in leprosy
    - Toxic polyneuropathy
- Radiculopathy
- Trigeminal neuralgia

Other factors that may be associated with chronic peripheral neuropathic pain include:

- Alcohol abuse or addiction
- Degenerative changes in nerves
- Exposure to environmental or occupational toxins
- Treatment with neurotoxic drugs

MG30.50 Chronic central neuropathic pain
Diseases or lesions of the central nervous system that may be associated with chronic neuropathic pain include:

- Brain injury
- HIV / AIDS
- Multiple sclerosis
- Spinal cord injury
- Stroke

MG30.42 Chronic secondary visceral pain from persistent inflammation
Inflammatory diseases of internal organs that may be associated with chronic secondary visceral pain include:

- Behçet's disease
- Bronchiectasis
- Chronic appendicitis
- Chronic duodenitis
- Chronic Eosinophilic esophagitis
- Chronic gastritis
- Chronic infectious esophagitis
- Chronic laryngitis
- Chronic oophoritis
- Chronic pancreatitis
- Chronic pericarditis
- Chronic pharyngitis
- Chronic pleurisy
- Chronic prostatitis
- Chronic salpingitis
- Chronic tonsillitis
- Chronic vaginitis
- Crohn's disease
- Cystitis
- Endometriosis
- Gastro-esophageal reflux disease
- Recurrent diverticulitis
- Systemic lupus erythematosus
- Ulcer of esophagus
- Ulcerative colitis
- Urethritis
- Wegner's Granulomatosis

MG30.41 Chronic secondary visceral pain from vascular mechanisms
Alterations of arterial and/or venous blood vessels from/to internal organs that may be associated with chronic secondary visceral pain include:

- Aneurysms (e.g., carotid artery, thoracic aorta)
- Aortic dissection
- Iliac artery aneurysms
- Ischemic colitis
- Ischemic heart disease
- Mesenteric angina
- Pelvic congestion syndrome
- Polyarteritis nodosa
- Sickle cell disease
- Vascular entrapment syndromes
    - Nutcracker syndrome
    - May-Thurner syndrome
    - Median arcuate ligament syndrome
    - Superior mesenteric artery syndrome
- Vasculitis

MG30.40 Chronic secondary visceral pain from mechanical factors

Mechanical factors affecting one or more internal organs that may be associated with chronic secondary visceral pain include:

- Chronic intestinal pseudo-obstruction
- Lithiasis of lower urinary tract
- Obstruction or distension of hollow internal organs
- Recurrent urinary colic
- Sclerosing cholangitis or luminal obstructions of the gastrointestinal tract
- Stenosis
- Stones obstructing the biliary or renal tracts
- Traction or compression of ligaments and vessels to internal organs
- Ureteric kinking

MG30.30 Chronic secondary musculoskeletal pain from persistent inflammation
Infections that may be associated with chronic secondary musculoskeletal pain include:

- Borrelia burgdorferi / Lyme disease
- Brucella
- Chikungunya
- Epstein-Barr virus
- Hepatitis B
- Hepatitis C
- Herpes virus
- HIV
- Human T-lymphotropic virus 1 (HTLV-1)
- Infection of prosthetic joints
- Mycobacteria
- Parvoviruses
- Rickettsia

Crystal depositions that may be associated with chronic secondary musculoskeletal pain include:

- Calcium pyrophosphates
- Hydroxyapatite
- Uric acid / gout

Autoimmune and auto-inflammatory diseases that may be associated with chronic secondary musculoskeletal pain include:

- Psoriatic arthritis
- Rheumatoid arthritis
- Sjögren's syndrome
- Spondyloarthritis
- Systemic lupus erythematosus

MG30.31 Chronic secondary musculoskeletal pain associated with structural changes
Structural changes of the musculoskeletal system that may be associated with chronic secondary musculoskeletal pain include:

- Anatomical changes after bone fracture
- Anatomical changes in entheses
- Anatomical changes in tendons
- Osteoarthritis
- Spondylosis

MG30.32 Chronic secondary musculoskeletal pain associated with a disease of the nervous system
Neurological diseases that may be associated with chronic secondary musculoskeletal pain include:

- Charcot joint disease in peripheral neuropathy
- Extrapyramidal disorders
- Motor neuron disease
- Multiple sclerosis
- Parkinson disease

7.1.4 Anhang A.4: Studie 4

Korwisi, B., Treede, R.-D., Rief,W. & Barke, A. (2020). Evaluation of the International Classification of Diseases-11 chronic pain classification: Study protocol for an ecological implementation field study in low-, middle-, and high-income countries. *PAIN Reports, 5,* e825.

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Research Protocol

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Evaluation of the *International Classification of Diseases-11* chronic pain classification: study protocol for an ecological implementation field study in low-, middle-, and high-income countries

Beatrice Korwisi[a,*], Rolf-Detlef Treede[b], Winfried Rief[a], Antonia Barke[c]

Abstract

Introduction: The purpose of the present ecological implementation field study is to evaluate the new classification of chronic pain as implemented in the 11th revision of the *International Classification of Diseases* (*ICD-11*) with regard to clinical utility and interrater reliability. To evaluate the classification in a variety of settings, the study will be implemented in different low-, middle-, and high-income countries.

Methods: The study will be conducted in 2 phases. Participating pain clinics of the first phase are located in India, Cuba, and New Zealand. Two or more clinicians per study center will use the *ICD-11* classification of chronic pain to diagnose 75 to 100 consecutive new chronic pain patients per center. A structured classification algorithm will guide the diagnostic process. Interrater reliability will be analyzed for the first 20 consecutive new patients per center. Before the coding, a training workshop will introduce the clinicians to the new classification. The main outcome parameter of the ecological implementation field study is clinical utility. More specifically, this entails clinical utility ratings, interrater reliability, as well as the exhaustiveness of the classification and the mutual exclusiveness of the new chronic pain categories. Differences between countries with different cultural backgrounds and income levels will be analyzed.

Perspective: The ecological implementation field study presented here will be implemented in several countries with different income levels. This increases the generalizability of the results and allows initial insight into the global applicability of the new chronic pain classification. A positive evaluation can facilitate the implementation of the classification.

Keywords: Chronic pain, *ICD-11*, Pain classification, Field study, Implementation study, Clinical utility

1. Introduction

Chronic pain is a highly prevalent condition affecting up to 20% of the global population[6] and contributing significantly to the global burden of disease.[25,33] Despite its significance, chronic pain is not represented adequately in the current version of the *International Classification of Diseases* (*ICD-10*).[26,27] To overcome these problems, an international task force of the International Association for the Study of Pain (IASP) developed a new classification of chronic pain for the *ICD-11*.[31,32]

In this new classification of chronic pain for the *ICD-11* (hereafter termed "the *ICD-11* chronic pain classification"), chronic pain is defined as pain that persists or recurs for longer than 3 months.[31,32] The classification distinguishes 7 categories of chronic pain: chronic primary pain,[19] chronic cancer-related pain,[3] chronic postsurgical or posttraumatic pain,[29] chronic neuropathic pain,[28] chronic secondary headache or orofacial pain,[4] chronic secondary visceral pain,[1] and chronic secondary musculoskeletal pain.[20] Each category of chronic pain comprises several subcategories or diagnostic levels to allow diagnosis on a more granular level (eg, chronic widespread pain as a sublevel or level 2 diagnosis of chronic primary pain).[19] **Table 1** gives an overview of the classification with its different levels, including the new diagnostic codes.[35] Furthermore, the classification allows

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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Table 1

Overview of the ICD-11 chronic pain classification.

Main chronic pain category	*ICD-11* main category code	Examples for diagnoses on level 2 (ICD-11 code)	Examples for diagnoses on level 3
Chronic primary pain (CPP)	MG30.0	Chronic primary headache or orofacial pain (MG30.03)	Chronic migraine Chronic primary temporomandibular disorder pains
		Chronic primary visceral pain (MG30.00)	Chronic primary chest pain syndrome Chronic primary pelvic pain syndrome
		Chronic primary musculoskeletal pain (MG30.02)	Chronic primary low back pain* Chronic primary cervical pain
Chronic cancer-related pain	MG30.1	Chronic cancer pain (MG30.10)	Chronic visceral cancer pain Chronic bone cancer pain
		Chronic postcancer treatment pain (MG30.11)	Chronic postcancer medicine pain Chronic postradiotherapy pain
Chronic postsurgical or posttraumatic pain	MG30.2	Chronic postsurgical pain (MG30.21)	Chronic pain after spinal surgery Chronic pain after amputation
		Chronic posttraumatic pain (MG30.20)	Chronic pain after musculoskeletal injury† Chronic pain after burns injury
Chronic neuropathic pain	MG30.5	Chronic central neuropathic pain (MG30.50)	Chronic central poststroke pain Chronic central neuropathic pain associated with multiple sclerosis
		Chronic peripheral neuropathic pain (MG30.51)	Chronic painful radiculopathy Chronic painful polyneuropathy
Chronic secondary headache or orofacial pain	MG30.6	Headache or orofacial pain attributed to chronic secondary temporomandibular disorders (MG30.63)	Chronic secondary orofacial muscle pain Chronic secondary temporomandibular joint pain
Chronic secondary visceral pain	MG30.4	Chronic visceral pain from persistent inflammation‡ (MG30.42)	Chronic visceral pain from persistent inflammation in the abdominal region Chronic visceral pain from persistent inflammation in the pelvic region
		Chronic visceral pain from vascular mechanisms§ (MG30.41)	Chronic visceral pain from vascular mechanisms in the head/neck region Chronic visceral pain from vascular mechanisms in the thoracic region
Chronic secondary musculoskeletal pain	MG30.3	Chronic secondary musculoskeletal pain from persistent inflammation‖ (MG30.30)	Chronic secondary musculoskeletal pain from persistent inflammation due to infection Chronic secondary musculoskeletal pain from persistent inflammation due to autoimmune or autoinflammatory disorder
		Chronic secondary musculoskeletal pain associated with structural changes (MG30.31)	Chronic secondary musculoskeletal pain associated with osteoarthritis Chronic secondary musculoskeletal pain associated with spondylosis

Clinicians will use the level 3 diagnoses for the ICE TEA study. Level 3 diagnoses did not have individual *ICD-11* codes at the time of publication. Codes listed as implemented in the *ICD-11 MMS, version 2018* (WHO, 2018).

* Formerly termed *nonspecific low back pain*.

† eg, bone fractures.

‡ eg, associated with endometriosis.

§ eg, associated with sickle cell disease.

‖ eg, associated with rheumatoid arthritis.

ICD-11, International Classification of Diseases-11.

any chronic pain condition to be described further by assigning so-called extension codes.[31] That is to say, patients rate the intensity of their pain as well as their pain-related distress and pain-related interference on a 0 to 10 numerical rating scale (NRS) or on a visual analogue scale. The combination of these ratings represents the specifier of pain severity. The temporal course of the chronic pain can be coded as persistent, recurring with pain-free intervals, or persistent with pain attacks, and forms a second specifier. Finally, the presence or absence of pain-related psychosocial factors such as pain catastrophizing or fear avoidance can be recorded as well.[31]

The *ICD-11* chronic pain classification has been added to the *ICD-11* platform[36] and is now part of the frozen version of the *ICD-11* Mortality and Morbidity Statistics (MMS) for preparing implementation by member states.[35] In May 2019, the World Health Assembly agreed to adopt the *ICD-11*, which will come into effect in 2022.[37]

Any new diagnostic classification needs to be evaluated. Ecological implementation field studies allow evaluation of the reliability of a new classification as well as evaluation of its clinical utility in a realistic clinical setting.[14] Furthermore, ecological implementation field studies enable evaluation of the implementation of the new classification into the clinical setting.[23] Clinical utility refers to the degree by which a classification contributes to the communication of clinical information, to adequate treatment decisions, to facilitated documentation, and to patient management.[9,10,18] The World Health Organization (WHO) emphasized the improvement of clinical utility as one of the main goals of the

ICD-11 revision, alongside global applicability.[12] A pilot evaluation study of the *ICD-11* chronic pain classification, conducted in different primary care as well as specialty pain treatment centers in 4 countries, showed that clinicians rated the clinical utility of the 7 new main categories as good to very good.[2] A following online field study in cooperation with the WHO revealed that pain specialists assigned the correct *ICD-11* code to the majority of chronic pain diagnoses after having received minimal training (Barke, Korwisi, Jakob, Konstanjsek, Rief & Treede, manuscript in preparation.) For most diagnoses, *ICD-11* performed better than *ICD-10* with regard to correct code assignment. Furthermore, the clinical utility of the *ICD-11* chronic pain classification was rated as very useful.

It is essential for a classification system that it is clinically useful in a variety of settings, including primary care and countries with fewer resources than high-income countries.[21] Furthermore, conducting ecological implementation field studies in multiple countries with different income levels and different cultural backgrounds enhances the generalizability of the results, thus contributing to the knowledge regarding the global applicability of the classification.[11,22]

Ecological implementation field studies for the evaluation of new classification systems that have to be based on self-reported information rather than observable biological markers usually include clinical interviews or assessments conducted by at least 2 independent raters to establish interrater reliability.[7,17,23,24] Commonly, participating clinicians of ecological implementation field studies are familiarized with the new diagnostic guidelines to be evaluated before data collection.[7,14,17,23,24]

The goal of this study (*ICD-11* Chronic Pain Codes Ecological Testing and Assessment: ICE TEA) is to evaluate the *ICD-11* chronic pain classification in terms of clinical utility and interrater reliability. Furthermore, the exhaustiveness of the classification and mutual exclusiveness of the diagnostic categories will be analyzed. It is expected that conducting the study in countries with different cultural backgrounds and with different income levels will enable conclusions about the global applicability of the classification.

2. Methods

The study protocol presented here is guided by the description of the official WHO ecological implementations field studies for mental and behavioral disorders by Keeley et al.[14] The study will be implemented in 2 phases of data collection. For the first phase, ethical approval has been obtained before data collection from the Department of Psychology at the University of Marburg, Germany (approval number 2018-41k) as well as the following participating study centers: Havana, Cuba (approval number 13 on November 18, 2018), Kolkata, India (approval number 010/2018), and Dunedin, New Zealand (approval number H19/105). The study center in Hyderabad, India, did not require an on-site ethical approval because the approval from Marburg as coordinating center was accepted there. For the second phase, ethical approval will also be obtained from all participating study centers before data collection.

2.1. Study setting

The ICE TEA study will be conducted in pain clinics (mostly outpatient) in low-, lower-middle-, upper-middle-, and high-income countries as defined by the World Bank.[34] As was done in similar studies, the study centers are selected based on their interest in participation as well as available resources needed for implementation of the study.[11] For the first phase, pain clinics in India (lower-middle-income country), Cuba (upper-middle-income country), and New Zealand (high-income country) have been selected as study centers. **Table 2** gives an overview of some characteristics of the study centers of the first phase. The second phase will include at least 2 clinics per income category, covering all WHO regions (eg, Iran, Thailand, Germany, and United States) as well as low-income countries. Furthermore, specialty treatment centers other than pain clinics as well as primary care centers will be irecruited in this second phase to ensure that all 7 main chronic pain categories are represented in the final sample (eg, palliative care to include chronic cancer-related pain, internal medicine to include a variety of chronic visceral pain.)

2.2. Participants

The ICE TEA study will include 2 sets of participants: (1) 2 or more participating clinicians per study center who will evaluate the new classification of chronic pain after using it for their diagnoses (hereafter termed "clinicians"); and (2) 75 to 100 consecutive new chronic pain patients per study center (hereafter termed "patients") who will be diagnosed by the clinicians.

2.2.1. Clinicians

Participating clinicians will work at pain centers. They will have a specialist education in pain medicine or have worked with patients with chronic pain for more than 3 years. This includes specialists in different disciplines such as physicians and clinical psychologists licensed to perform psychological treatment, who are standardly involved in multidisciplinary diagnostic processes

Table 2

Characteristics of the study centers of the first phase of data collection.

Study center	WHO region	World Bank income group	Language(s) for patient communication	Clinic setting	Diagnosis as usual
Kolkata, India	South-East Asia	Lower-middle income country	Bengali, Hindi	Specialty pain clinic within governmental hospital*	Textbook diagnoses[13,16]
Hyderabad, India	South-East Asia	Lower-middle income country	Telugu, English	Specialty pain clinic within private hospital	Textbook diagnoses[5]
Dunedin, New Zealand	Western Pacific	High-income country	English	Specialty pain clinic within public hospital†	Textual diagnoses
Havana, Cuba	Americas	Upper-middle income country	Spanish	Specialty pain clinic within public hospital	Textual diagnoses

* Only for government insurance scheme, mainly factory workers.
† Triage system applied for referrals.

of chronic pain with additional physical examinations performed by physicians. In the second phase, clinicians of other specialties (eg, primary care, palliative care, oncology, and internal medicine) with extensive experience with chronic pain will be included. Before the coding, all participating clinicians will take part in a brief on-site training workshop. At least 2 clinicians per study center will participate to establish interrater reliability. This will also serve to prevent that data can be connected to an individual clinician. All clinicians will provide their informed consent before their participation.

Clinicians will be eligible for participation if they meet the following inclusion criteria:

(1) Participation in the training workshop
(2) Very good level of English
(3) Working at a pain clinic (physician or licensed clinical psychologist)
(4) Available at the study center until the end of the data collection.

2.2.2. Patients

Each consecutive new patient who presents at the study center (inpatients and outpatients) will be invited to participate in the study. Only patients who provide their informed consent will be included in the study. New patients are defined as patients who consult the respective pain clinic or specialty center for the first time for the current chronic pain problem.

Patients will be eligible to participate in the study if they meet the following inclusion criteria:

(1) Aged at least 18 years
(2) Pain for longer than 3 months
(3) Able to communicate in English or another language spoken by the clinician (eg, Bengali, Hindi, Spanish, or Telugu for the first phase)
(4) Able to participate in a structured diagnostic process.

2.3. Study material

Clinicians will provide basic information at the beginning of the study. All patients will complete a set of questionnaires before the diagnostic assessment. The clinician will use a standardized classification algorithm to establish the chronic pain diagnoses for each patient. After this diagnostic process, the clinician will complete a Code Assignment and Evaluation Form (CAEF) for each patient. This evaluation form is intended to measure the main outcome. Because the *ICD-11* is only available in English until it will come into effect in 2022, all study material for the clinicians will be in English. The clinician measures, patient measures, and CAEF are available in the supplemental digital content (SDC 1, available at http://links.lww.com/PR9/A64). The classification algorithm is currently being prepared as a separate publication.

2.3.1. Classification algorithm

The assessment of each patient will follow a standardized classification algorithm. It will be documented on the algorithm introduction form. The algorithm is a linear decision tree that will guide the clinician through the new diagnostic criteria for all chronic pain conditions. Where necessary, clinicians may refer to existing medical records (eg, referral documentation) if these are judged still to be conclusive. The diagnostic codes listed in the classification algorithm are based on the *ICD-11 MMS, 2018 version*.[35]

2.3.2. International Classification of Diseases-11 *classification handout*

In addition to the classification algorithm, the definitions and diagnostic criteria for all *ICD-11* chronic pain conditions will be available during the diagnostic assessment and the following code assignment. Due to limited internet access at some of the participating study centers of the first phase, all raters will have access to an *ICD-11* classification handout. This is a printed or PDF version of the definitions and diagnostic criteria of the *ICD-11* chronic pain classification as implemented in the current version of the *ICD-11*.[35]

2.3.3. Clinician measures

During the training workshop, clinicians will provide basic demographic information as well as information regarding their professional experience (eg, years of experience working with chronic pain patients) and an initial evaluation of the *ICD-11* chronic pain classification (baseline measure before its application) on an 11-point NRS from *0* (not useful at all) to *10* (very useful).

2.3.4. Patient measures

The patient measures will include basic demographic data, a pain history questionnaire, a pain localization chart, items to assess the chronic pain specifiers, as well as a set of questionnaires to assess pain-related variables such as pain-related disability and other psychological symptoms.

2.3.4.1. Pain Disability Index

The Pain Disability Index[30] is a 7-item questionnaire that assesses how much the pain interferes with different daily activities, such as occupation and social activities. All items are rated on an 11-point NRS from *0* (no disability) to *10* (total disability). The Pain Disability Index will be included as a measure of pain-related interference.

2.3.4.2. Brief Symptom Inventory-53

The Brief Symptom Inventory[8] is a 53-item questionnaire that lists different problems and complaints, such as nervousness or dizziness. Patients indicate how much they were bothered by these symptoms in the past week on a 5-point NRS from *0* (not at all) to *4* (extremely). The Brief Symptom Inventory-53 allows calculating a global symptom index and will be included as a measure of pain-related distress.

2.3.5. Code Assignment and Evaluation Form

The clinician who conducted the diagnostic assessment will complete the CAEF within 24 hours of the assessment. Analysis of the CAEFs will form the basis for answering the main research questions. During the interrater reliability coding, both clinicians who are present for the assessment complete the CAEF, blind to each other's answers. The CAEF includes the following:

(1) All *ICD-11* chronic pain diagnoses assigned to the patient (*ICD-11 MMS 2018 version*[35])
(2) All chronic pain diagnoses as usually assigned in the clinic (see **Table 2** for details)
(3) In the case of chronic secondary pain, the name of the underlying disease (second phase only: *ICD-11* code of the underlying disease)

(4) Time taken to complete the diagnostic assessment and code assignment
(5) Five items on diagnostic tests, if required (eg, whether a test was required by the diagnostic criteria, whether it could be performed, reasons why a test was not performed)
(6) Presence or absence of psychosocial factors
(7) Clinical utility rating on an 11-point NRS from *0* (very difficult/not confident at all/not useful at all) to *10* (very easy/very confident/very useful) (ease of use, diagnostic confidence, overall utility, specific utility regarding: communication with colleagues and patients, data collection, documentation, patient management, treatment selection, improvement of outcome)
(8) Clinical utility rating of the current diagnostic system on the same 0 to 10 NRS
(9) Evaluation of the classification algorithm in its pilot version regarding difficulty, confidence, and utility on the same 0 to 10 NRSs (first phase only)

2.4. Procedure

Both phases of data collection will follow the same procedure. The first part of the ICE TEA study for each study center will consist of an introductory training course. Then, the actual coding of consecutive new patients for this center will begin. This is divided into 2 parts: the first part will be an interrater reliability coding with 2 raters present. The second part will be a continued consecutive coding by just one clinician. B.K. will be present during the training workshop as well as for the interrater reliability phase, to facilitate implementation of the study.

Patients will provide their informed consent and complete the questionnaires before the diagnostic assessment. Then, the clinician will diagnose the patient using the standardized classification algorithm. After the diagnostic assessment, the clinician will assign the respective diagnostic codes (*ICD-11* and code as usual, eg, textbook diagnosis[5,13,16]), and evaluate the chronic pain classification and the algorithm with the CAEF. **Figure 1** gives an overview of the procedure.

2.4.1. Training workshop

At each study center, a brief training workshop for participating clinicians will be held before the actual coding by one of the authors (B.K.). This workshop will last approximately 4 to 6 hours and will be mandatory for the participating clinicians. The plan of the training workshop follows the clinician training of previous ecological field studies.[7,17,23,24] The training workshop will comprise a review of the study protocol and all study material, a presentation of all *ICD-11* chronic pain diagnoses and the chronic pain specifiers, as well as an introduction to the classification algorithm. During this last part, clinicians will have the opportunity to use the algorithm with a chronic pain patient for practice purposes. At the end of the training workshop, all clinicians will provide their informed consent for study participation and complete a brief knowledge test.

2.4.2. Interrater reliability coding

In a first step, an interrater reliability coding will take place. Due to the limited amount of resources, it will not be feasible to assess each patient by 2 clinicians. However, a limited interrater reliability coding comprising the first n = 20 consecutive new patients per study center will take place after the training workshop to establish measures of interrater reliability. During this coding, one assessment will be conducted per patient with 2 clinicians (Clinician A and Clinician B) being present simultaneously. Clinician A will assess the patient by referring to the classification algorithm. Clinician B will attend as observer. The assessment will be conducted in the patient's language (ie, English, Bengali, Hindi, Spanish, or Telugu). B.K. will be present for guidance. At the end of the assessment, Clinician B and B.K. may ask additional questions, if needed.

This follows the procedures as implemented in similar field studies.[14,17,23] Both clinicians will assign the respective chronic pain codes independently and blind to each other's assignments. If more than 2 clinicians participate in a study center, these trios will be changed alternately. Clinicians will take turns regarding the role of interviewer and observer.

2.4.3. Continued consecutive coding by one clinician

After the interrater reliability coding, the following n = 55 to 80 consecutive new patients per study center will be assessed. During this part of the coding, only one clinician will be present for the diagnostic assessment and to complete the CAEF.

2.4.4. Code assignment and evaluation

After each diagnostic assessment, the clinician will complete a CAEF. On this form, the clinician will assign the pain diagnoses he or she would routinely use (eg, textual diagnosis) as well as the new *ICD-11* chronic pain diagnoses (level 3 diagnoses wherever possible, see **Table 1** for examples). See **Table 2** for an overview of the current diagnostic systems used at the study centers. The *ICD-11* codes and diagnostic criteria will be available during the coding. Furthermore, the CAEF will include questions regarding the clinical utility of the classification and the classification algorithm (see above).

2.5. Outcome

The ICE TEA study will focus on 4 aspects of clinical utility: clinical utility ratings, interrater reliability, exhaustiveness of the classification, and mutual exclusiveness of the categories of the *ICD-11* chronic pain classification. Furthermore, differences between countries will be analyzed.

(1) Clinical utility ratings: How do clinicians perceive the clinical utility of the *ICD-11* chronic pain classification regarding ease of use, diagnostic confidence, communication, treatment selection, patient management, documentation, data collection, and improved outcome? A general clinical utility rating of the current diagnostic system will be obtained as well. (*Mean values of the clinicians' ratings*)
(2) Interrater reliability: If 2 clinicians have the same diagnostic information on a given patient, do they assign the same chronic pain code? (*Measure of inter-rater reliability*)
(3) Exhaustiveness: Can all patients with chronic pain be classified according to the classification? (*Proportion of patients who fall into the unspecified residual category*)
(4) Mutual exclusiveness of the categories: Can the chronic pain conditions of all patients be classified into exactly one of the new categories? (*Number of patients who cannot be clearly assigned a category*)
(5) Influence of available resources and cultural background: Does the clinical utility as operationalized in the above variables differ between low- (only second phase), lower-middle-, upper-middle-, and high-income countries?

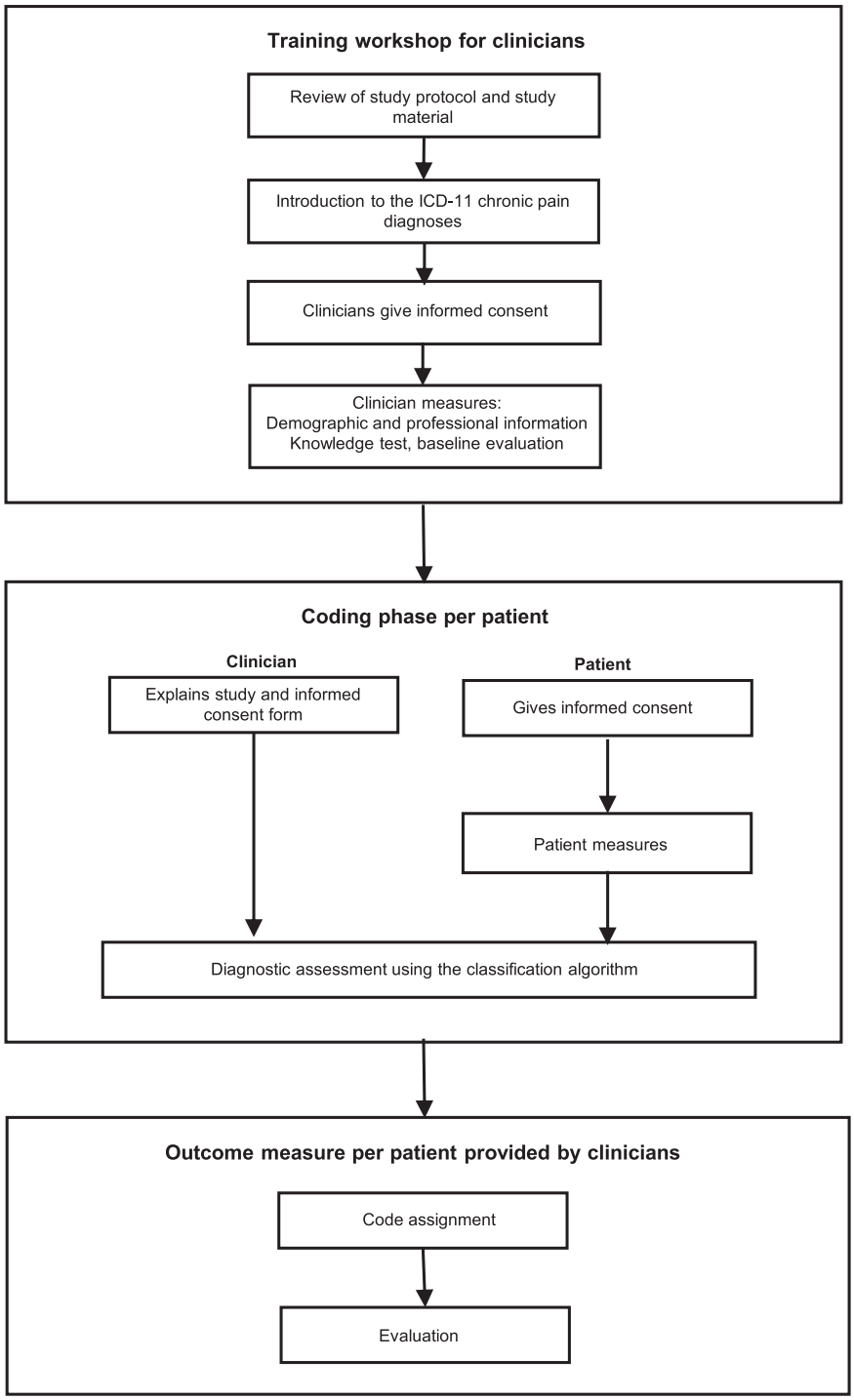

Figure 1. Study procedure. This procedure does not differ between the first and the second phase of data collection. *ICD-11, International Classification of Diseases-11*.

In addition, the first phase of data collection will also focus on feasibility aspects of the study implementation.

2.6. Statistical analyses

To establish interrater reliability, Kappa coefficients will be calculated for each diagnosis that is present in at least 15 patients who have been coded by 2 clinicians.[24] Kappa coefficients will be computed in a cascading way, first for level 1 diagnoses, followed by computations for level 2 and 3 diagnoses whenever possible.

For each study center, the mean clinical utility ratings will be computed. Differences in the clinical utility ratings between the countries will be analyzed with separate one-way analyses of variance. To examine the exhaustiveness of the classification, the percentage of pain syndromes that are classified as "unspecified" will be analyzed per study center. The mutual exclusiveness of the new diagnostic categories will be computed as the percentage of

chronic pain syndromes per study center for which more than one diagnosis applies, excluding cases of comorbid chronic pain conditions.

2.7. Sample size

The sample size was determined in cooperation with the participating study centers as the maximum number of patients for whom the study procedure can be implemented during routine clinical practice.

3. Discussion

The ICE TEA study is an ecological implementation field study that aims to evaluate the *ICD-11* chronic pain classification in 2 phases of data collection. This evaluation will investigate the clinical utility and interrater reliability of the classification as well as the exhaustiveness and mutual exclusiveness of the new categories. The study will be conducted in several countries with different resources and a variety of cultural backgrounds, which increases the generalizability of the results and enables initial analysis of the global applicability of the classification.[11,23] Although the study does not focus on the validity of the new chronic pain classification, an important aspect of validity may still be inferred from the mutual exclusiveness of the different chronic pain categories.[15]

The study protocol presented here is guided by the procedure of the official WHO field tests for mental and behavioral disorders,[14] thereby enabling its integration with other *ICD-11* field testing efforts and facilitating the comparison and interpretation of the results. It is another strength of the study proposed here that differences in clinical utility between countries will be analyzed as well, which has been done only for a small number of similar previous field studies.[22] The results of the first phase of data collection will enable an initial analysis of country differences. These results will be corroborated in the second phase, where the amount of countries and settings will increase substantially. Furthermore, there might be ways to introduce a quantifiable outcome measure apart from self-reported information (eg, a time measure for documentation) in the second phase of data collection if possible at the study centers.

As was done in similar field studies of classification systems with multiple raters and patients potentially presenting with several diagnoses,[7,17,23,24] kappa coefficients will be computed as a measure of interrater reliability. Due to the limited resources available for this type of study in the context of routine patient care and the resulting limited sample size of the interrater reliability coding, it probably will not be possible to compute kappa for each of the 7 main categories after the first phase of data collection. The inclusion of specialty treatment centers and more centers per income category will enable computations for less frequent level 1 diagnoses (eg, chronic cancer-related pain) and more level 2 and 3 diagnoses. Furthermore, depending on the final sample size per diagnostic category in each study center, it might be possible to compare kappa coefficients between countries or income levels for the most prevalent diagnoses after the second phase of data collection.

The ICE TEA study builds on previous field testing efforts of the *ICD-11* chronic pain classification while aiming at overcoming some of the limitations encountered there.[2] The 2016 pilot field study[2] only assessed the 7 main chronic pain categories, causing a diagnostic bias of double diagnoses, which would have been resolved on the next diagnostic level. By coding patients with more specific diagnoses on the third diagnostic level (see **Table 1** for examples), this study enables a more accurate analysis of mutual exclusiveness and a more realistic coding compared to the 2016 study. Furthermore, the participating clinicians of this study will receive training before using the new classification, which was not possible in the 2016 pilot study. Although only one global clinical utility rating with regard to the main categories was obtained in 2016, this study will assess clinical utility more extensively and with regard to the more specific diagnoses. This increases the validity of the clinical utility ratings.

The 2017 online field study (Barke, Korwisi, Jakob, Konstanjsek, Rief, Treede, manuscript in preparation) was conducted as part of the official WHO field testing efforts. Here, clinicians assigned *ICD-11* codes to diagnostic statements and rated the clinical utility of the new diagnoses when applied to short case vignettes. A brief online training was provided, but it could not be controlled whether participants completed it before their study participation. Although the use of standardized case vignettes enabled control over reported patient characteristics, this study will provide important additional aspects of evaluation by analyzing the implementation of the new classification in routine clinical practice, involving real patients. Furthermore, participation in the training will be controlled in this study, ensuring that all participating raters have the same amount of knowledge with regard to the new classification.

Although the diagnostic spectrum of participating patients in the first phase of data collection cannot be controlled, the inclusion of specialty treatment centers for underlying diseases that are often associated with chronic pain (such as palliative care) in the second phase will ensure that all categories of chronic pain will be represented in the final sample. The increased number of study centers from all WHO world regions in the second phase will corroborate the interrater reliability further and ensure the generalizability of the results in a global context. Strengths and limitations as well as obstacles from the first phase will directly influence the implementation of the second phase. However, it is likely that the amount of patients per category will differ between the study centers nevertheless.[2] These differences between the study centers may confound country differences and will need to be taken into consideration when interpreting the results.

An important strength of ecological implementation field studies is that they allow to evaluate the new classification in the clinical setting where it will be used later.[14] This ecological validity of such implementation studies comes at the price of less control over other aspects such as the patients' chronic pain conditions and other influencing factors. Here, case-controlled field studies involving standardized case vignettes can provide additional information and should also be conducted in the future.[14]

In conclusion, the ecological implementation field study presented here will assess the clinical utility and interrater reliability of the new *ICD-11* classification of chronic pain in a global context. The exhaustiveness and mutual exclusiveness of the categories will be analyzed as well as quality indicators of the new classification. High clinical utility can facilitate the classification's global implementation, as clinicians are more likely to use a new classification consistently if it is perceived as useful.[22]

Disclosures

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Appendix A. Supplemental digital content

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7.1.5 Anhang A.5: Studie 5

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Reliability and Clinical Utility of the ICD-11 Chronic Pain Classification from a Global Perspective: Results of the ICD-11 Chronic Pain Codes Ecological Testing and Assessment (ICE TEA) in India, Cuba, and New Zealand

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Abstract

Background: Chronic pain contributes substantially to the global burden of disease. The 11th revision of the International Classification of Diseases (ICD-11) includes a comprehensive classification of chronic pain. The aim of this ecological implementation field study was to evaluate the classification's inter-rater reliability and clinical utility in countries with different income levels.

Methods: Twenty-one pain specialists in four pain clinics in Cuba, India, and New Zealand used the ICD-11 to diagnose n=353 patients with chronic pain. Of these, 111 patients were assessed by two clinicians and Fleiss' kappa was calculated to establish inter-rater reliability for any diagnosis assigned to ≥ 15 patients. The clinician's ratings of the diagnoses' clinical utility were analyzed with a 2x4 mixed ANOVA.

Findings: The inter-rater reliability was substantial for 10 diagnoses and moderate for one (kappa: 0·596-0·783). The mean clinical utility of the ICD-11 chronic pain diagnoses was rated as 8·45 ± 1·69. Clinical utility was rated higher for ICD-11 than for the commonly used classification system ($p<0·001$, $\eta^2=0·25$) and differed between all centers ($p<0·001$, $\eta^2=0·60$). The utility of the ICD-11 diagnoses was rated higher than the commonly used diagnoses in Dunedin and Havana, and no difference was found in Kolkata and Hyderabad.

Interpretation: The study showed the high inter-rater reliability of the new chronic pain diagnoses. The perceived clinical utility of the diagnoses indicates their superiority or equality compared to the classification systems currently in use. These results suggest the global applicability of the classification.

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Introduction

The latest revision of the International Classification of Diseases (ICD-11) will come into effect for global health reporting in 2022.[1] An important innovation of the ICD-11 is its electronic infrastructure, which makes it freely available online and enables different tools to assist with the coding process,[2] thereby contributing significantly to global health.[3] Usage of the ICD-11 will go beyond statistical health reporting of global mortality and morbidity to include information such as patient documentation, healthcare reimbursement, epidemiological data collection, and research.[4] The ICD-11 will be used worldwide by a variety of professionals, from health care providers, including doctors and medical coders, to scientists and insurers, among others.[4]

For the first time, the ICD-11 includes a comprehensive classification of chronic pain, which distinguishes seven main categories of chronic pain (Figure 1).[5] Specific chronic pain diagnoses are available on several sublevels of the classification. Chronic pain is a frequent non-communicable health condition equally affecting people in all countries. Studies in high-income countries (HIC) revealed prevalence rates between 19% and 43%.[6–8] In low- and middle-income countries (LMIC), prevalence rates were as high as 48% for chronic musculoskeletal pain.[9] Nunes Sá et al. reported a corrected pooled chronic pain prevalence of 18% in LMIC.[10]

=== PLEASE INSERT FIGURE 1 HERE ===

Worldwide, chronic pain significantly impacts the lives of those affected. Low back pain is the leading cause for years lived with disability (YLDs) in many HIC as well as LMIC, followed by neck pain, headache disorders, and other diseases often associated with chronic pain, such as diabetes and human immunodeficiency virus (HIV).[11] Thus, chronic pain contributes significantly to the global burden of disease. Due to the aging population, this burden is likely to increase further in the coming years, especially in LMIC.[12]

The high worldwide prevalence of chronic pain, its associated disability, and the resulting burden highlight why chronic pain should be regarded as a global public health priority.[13] It has been argued that access to adequate pain treatment is a basic human right.[14] The consideration that the majority of the world's population lives in LMIC,[15] where access to

adequate chronic pain treatment often is limited,[16,17] further increases the importance of chronic pain on the global health agenda.[13]

The aim of the ICD-11 Chronic Pain Codes Ecological Testing and Assessment (ICE TEA) is to evaluate the ICD-11 chronic pain classification with regards to inter-rater reliability and clinical utility in countries with low, middle, and high income status.[18] In this publication, results from the first phase of data collection in India (lower-middle income country), Cuba (upper-middle income country), and New Zealand (high-income country) are reported. Notably, clinical utility as well as global applicability were defined as the main goals of the ICD revision process.[19]

Methods

Study Design and Setting

The ICE TEA study is an ecological implementation field study, as defined by Keeley et al.[20] The study protocol, which describes all methods in detail, has been published elsewhere.[18] In this publication, results of the first phase of the ICE TEA study in four pain clinics in India (lower-middle-income country), Cuba (upper-middle-income country), and New Zealand (high-income country) are reported. Ethical approval was obtained from the University of Marburg (coordinating center, Germany), as well as the pain clinics in Kolkata (India), Havana (Cuba), and Dunedin (New Zealand) prior to data collection. The pain clinic in Hyderabad (India) accepted the ethical approval from the University of Marburg, with no additional approval requirements. All participants gave their informed consent for study participation. Data collection in Hyderabad had to be terminated prematurely due to the COVID-19 outbreak in early 2020.

Participants

Pain specialists (physicians and licensed clinical psychologists) working at the participating pain clinics with a very good command of English participated in the study after providing informed consent.

Patients were included if they gave informed consent, were at least 18 years old, had pain for longer than three months, were able to communicate with the clinician, and were able

to participate in the structured diagnostic process. For feasibility reasons, patients were included even if they had consulted the pain clinic before. Importantly, in these cases, the clinicians who assessed patients were blind to the patients' chronic pain diagnoses. Therefore, only a clinician who had not been involved in prior diagnostic assessments of a patient was permitted to conduct the assessment in the context of the ICE TEA study.

Material

All material is described in detail in the study protocol.[18] In summary, for clinicians, the material consisted of forms for the collection of information on demographics and professional experience, a knowledge test of the material covered in the training, and a baseline evaluation of the ICD-11 chronic pain classification. For patients, the material consisted of a form for collection of demographic and pain-related data (e.g., pain intensity, pain-related interference, pain-related distress), as well as the Pain Disability Index (PDI[21]) and the Brief Symptom Inventory-53 (BSI[22]). For each patient, a classification algorithm to facilitate the diagnostic assessment, an electronic (PDF) or printed version of the ICD-11 chronic pain classification, and a code assignment and evaluation form (CAEF) to measure the main outcome were used. The CAEF was completed by the clinician for each patient. On the CAEF, clinicians documented the following: the chronic pain diagnoses as they were commonly used in the respective clinic, ICD-11 chronic pain diagnoses, name of the underlying disease associated with the chronic pain (only applicable in cases of chronic secondary pain), presence or absence of psychosocial factors contributing to the pain, a clinical utility rating for the assigned ICD-11 chronic pain diagnoses, and a clinical utility rating for the commonly used diagnostic system. For all ratings, an 11-point numerical rating scale (NRS) from 0 *very difficult/not confident at all/not useful at all* to 10 *very easy/very confident/very useful* was used.

Procedure

A detailed description of the procedure can be found in the study protocol[18]. At each study center, a brief on-site training workshop to familiarize clinicians with the ICD-11 chronic pain classification and all study materials was conducted prior to the actual coding of the first study patients. The training concluded with a knowledge test and a baseline evaluation of the new classification. The inter-rater reliability coding then took place, during which at least 20

patients per center were assessed by two clinicians. During the subsequent continued consecutive coding, each patient was assessed by only one clinician. After each patient assessment, clinicians completed the CAEF. For the inter-rater reliability coding, both clinicians present for the assessment completed a separate CAEF for each patient, blind to each other's diagnoses and ratings.

Statistical Analyses

Patient characteristics were analyzed based on the patient report in the patient questionnaires. If pain-related data were missing in the patient questionnaires, however, were available in the algorithm introduction form, these data were substituted for the missing patient ratings. For the PDI, the sum score was computed for all patients who provided at least five ratings. Missing ratings were replaced with the patient's mean rating. For the BSI, the global severity index (GSI), was computed as a measure of emotional distress.

Inter-rater reliability was computed in a cascading way from the top diagnostic level to more specific diagnostic levels for all diagnoses that were assigned by at least one clinician in ≥ 15 patients of the inter-rater reliability coding. Fleiss' kappa, standard error, and 95% confidence intervals (CIs) were computed.

A mixed 2 x 4 analysis of variance (ANOVA) with the within factor *classification system* (ICD-11/current system) and the between factor *study center* (Kolkata/ Hyderabad/ Havana/ Dunedin) was performed to analyze the clinical utility ratings followed by Games-Howell post hoc tests and simple effects analyses. If patients were part of the inter-rater reliability coding, two ratings were available per patient. In these cases, the mean of both ratings was computed and entered into the analysis. All statistical analyses were performed using SPSS 27 (IBM, Armonk, NY, USA).

Role of the Funding Source

The study was funded by the Philipps-University of Marburg, in Marburg, Germany. Data collection in Dunedin was funded by the Dunedin School of Medicine Deans Bequest Grant 2019 (principal investigator (PI): Maria Kleinstäuber) and the Pain@Otago Research Theme (grant in aid; PI: Maria Kleinstäuber). BK was partly supported by IASP. The funders of the study had no role in study design, data analysis, data interpretation, or writing of the

report. The corresponding author had full access to all data in the study and had the final responsibility for the decision to submit for publication.

Results

Sample Characteristics

Clinicians

In total, 21 clinicians participated in the study. This sample includes nine (42·9 %) female and 12 (57·1 %) male clinicians with a mean age of 43·1 ± 13·3 years. Nineteen (90·5 %) clinicians were physicians and two (9·5 %) were licensed clinical psychologists. On average, clinicians had 10·8 ± 11·3 years of experience with chronic pain patients, and they rated their experience with chronic pain as 8·0 ± 1·3 on a scale from 0 to 10. Table 1 displays the details on the clinician sample overall and per study center.

=== PLEASE INSERT TABLE 1 HERE ===

Patients

A total of 353 patients were included in the study. Three patients were excluded from the data analyses: one patient withdrew the informed consent, one patient did not meet the inclusion criterion of pain duration ≥ three months, and the diagnostic assessment of one patient was aborted prematurely due to external circumstances. The final sample of 350 patients is described in detail in Table 2. Most patients were included in Dunedin (n = 105, 30·0 %), followed by Kolkata (n = 97, 27·7 %), Havana (n = 92, 26·3 %), and Hyderabad (n = 56, 16·0 %). Overall, 214 (61·1 %) were female, 135 (38·6 %) were male, and one (0·3 %) patient reported to be diverse. The mean age of the patients was 49·0 ± 16·2 years. 129 (36·8 %) patients were employed full-time while 62 (17·7 %) patients were not able to work due to the pain. The patients reported a mean pain duration of 7·3 ± 11·8 years (range 0·25–52·0) years. Pain intensity was rated on average as 6·9 ± 2·0, mean pain-related distress was rated as 5·8 ± 3·0, and mean pain-related interference was rated as 6·5 ± 2·4 on a scale from 0 to 10, respectively.

=== PLEASE INSERT TABLE 2 HERE ===

Inter-Rater Reliability

Fleiss' kappa values could be computed for a total of 11 diagnoses, five at level 1, four at level 2, and two at level 3 (Table 3). Kappa values ranged from $\kappa = 0{\cdot}649$ to $\kappa = 0{\cdot}783$ on the first diagnostic level (chronic primary pain, chronic postsurgical or post traumatic pain, chronic neuropathic pain, chronic secondary visceral pain, and chronic secondary musculoskeletal pain), from $\kappa = 0{\cdot}596$ to $\kappa = 0{\cdot}708$ for level 2 diagnoses (chronic widespread pain, chronic primary musculoskeletal pain, chronic peripheral neuropathic pain, and chronic secondary musculoskeletal pain associated with structural changes), and from $\kappa = 0{\cdot}615$ to $\kappa = 0{\cdot}720$ for the two level 3 diagnoses (Fibromyalgia syndrome and chronic secondary musculoskeletal pain associated with osteoarthritis). Only the kappa value of $\kappa = 0{\cdot}596$ for chronic primary musculoskeletal pain is rated as "moderate" while all other kappa values are rated as "substantial" according to Landis & Koch.[23]

=== PLEASE INSERT TABLE 3 HERE ===

Clinical Utility

Overall, the clinical utility of the ICD-11 chronic pain classification was rated as 8·45 ± 1·69 on a scale from 0 to 10.

The mixed ANOVA revealed a main effect for the classification system used with higher clinical utility for the ICD-11 ($F(1, 345) = 113{\cdot}08$, $p < 0{\cdot}001$, $\eta^2 = 0{\cdot}25$), a main effect for center, ($F(3, 345) = 172{\cdot}95$, $p < 0{\cdot}001$, $\eta^2 = 0{\cdot}60$), and an interaction classification system x center ($F(3, 345) = 35{\cdot}43$, $p < 0{\cdot}001$, $\eta^2 = 0{\cdot}24$).

Games-Howell post-hoc tests showed that utility ratings differed significantly between all centers. They were highest in Hyderabad (compared to Kolkata (1·18, 95%-CI [0·85-1·52], $p < 0{\cdot}001$), Dunedin (3·96, 95%-CI [3·52-4·41], $p < 0{\cdot}001$), and Havana (0·67, 95%-CI [0·24- 1·10], $p = 0{\cdot}001$)), followed by Havana (compared to Kolkata (0·51, 95%-CI [0·05-0·97, $p = 0{\cdot}023$]) and Dunedin (3·29, 95%-CI [2·74-3·84], $p < 0{\cdot}001$)), and then Kolkata (compared to Dunedin (2·78, 95%-CI [2·30-3·26], $p < 0{\cdot}001$)) with overall ratings the lowest in Dunedin.

As displayed in Figure 2, the clinical utility of the ICD-11 chronic pain classification was rated significantly higher than the clinical utility of the commonly used classification systems in Dunedin and Havana, however equally high in Kolkata and Hyderabad. The

ICD-11 classification was rated very useful across all centers (minimum rating 7·0 ± 1·91 on a scale from 0 to 10 in Dunedin), but the current classification in Kolkata and Hyderabad was apparently considered better than in Dunedin and Havana. Simple effects analyses of the interaction confirmed this in that differences between the ICD-11 utility rating and the utility rating of the commonly used classification system were significant in Dunedin ($F(1, 345) = 81{\cdot}42$, $p < 0{\cdot}001$) and Havana ($F(1, 345) = 113{\cdot}08$, $p < 0{\cdot}001$), but not in Kolkata ($F(1, 345) = 0{\cdot}24$, $p = 0{\cdot}622$) or Hyderabad ($F(1, 345) = 0{\cdot}17$, $p = 0{\cdot}679$).

=== PLEASE INSERT FIGURE 2 HERE ===

Discussion

This is the first study to exhibit substantial inter-rater reliability as well as high to very high ratings of clinical utility of the new ICD-11 chronic pain diagnoses in specialized clinical settings, obtained in different LMIC (India, Cuba) and in one HIC (New Zealand). The results are also a first indicator of the global applicability of the ICD-11 chronic pain classification.[24]

Results from the inter-rater reliability coding revealed substantial reliability for all but one of the analyzed diagnoses, which still reached moderate reliability (chronic primary musculoskeletal pain). Notably, the clinicians received minimal training before applying the new classification. The potential language barrier did not impede the reliability of the diagnoses. Kappa values decreased with increasing degree of specificity of the diagnoses. For example, the reliability of chronic primary musculoskeletal pain, a level 2 diagnosis, was moderate compared to the substantial reliability of the respective level 1 diagnosis of chronic primary pain. These results align with the reliability of diagnoses of mental disorders as analyzed for ICD-10,[25] DSM-5,[26] and ICD-11[27] where decreasing reliability with increasing degree of specificity was found as well. Furthermore, especially in the case of chronic primary musculoskeletal pain, the distinction from chronic secondary musculoskeletal pain might have been difficult in some patients. Chronic secondary musculoskeletal pain has a clear underlying etiology, for instance a structural change of the vertebrae, while the etiology of chronic primary musculoskeletal pain is vague.[28] However, in many patients, it is difficult to judge whether a confirmed structural change explains the pain or not.[29] In these instances, some clinicians might have coded a patient with chronic primary musculoskeletal pain, while others

chose chronic secondary musculoskeletal pain when radiological examinations indicated a structural change. Notably, the kappa coefficients found in the present study are in a range comparable to kappa coefficients of mental disorders in ICD-10[25] and ICD-11[27], and higher than most of the reliability coefficients found for mental disorders in the DSM-5 field trials.[26] Similar to mental disorders in DSM-5 and in the ICD, specific operationalized diagnostic criteria were defined for the ICD-11 chronic pain diagnoses, allowing comparison of the reliability analyses.

The high inter-rater reliability of the diagnoses contributes strongly to their utility, for example by improving communication among clinicians (i.e., discussing the same condition), standardizing sample selection for research, and facilitating treatment decisions.[27]

Clinicians at all study centers rated the clinical utility of the new ICD-11 chronic pain classification as high to very high and more (or equally) useful than the system that was commonly used in the respective clinic. In Dunedin and Havana, the new classification was perceived as more useful than the current diagnostic system. In Kolkata and Hyderabad, the perceived utility of the ICD-11 chronic pain classification did not differ from the current system, and both were rated as very high. It should be noted that all participating pain clinics used textual diagnoses as current classification systems. Considering the revision aims and the intended public health use of the collected diagnoses, the ratings of ICD-11 was at least as useful, and often better than the current system, providing a strong argument for the adoption of the ICD-11 classification across the settings, since its international standardization confers tremendous additional benefits. The clinical utility ratings in Dunedin were slightly lower than in the other pain clinics. However, many patients with up to as many as seven different chronic pain conditions presented at the pain clinic in Dunedin while the range of chronic pain conditions was smaller at the other pain clinics. It is likely that these complex patient cases influenced the utility ratings.

The results of this first phase of the ICE TEA study will inform the second phase of data collection. The study proved feasible in routine practice in pain clinics in LMIC as well as in HIC. Reliability and perceived clinical utility were high to very high despite the fact that all diagnoses and study material were available in English only. Minimal training was sufficient for successful use of the new diagnoses in all settings. Clinicians indicated that the study could

also be implemented when remote training and guidance are provided, which is an essential feedback in the context of conducting field studies during a global pandemic.

Some limitations need to be considered when interpreting the results. While the results provide strong initial evidence of global applicability of the classification system, generalizing them to all countries and settings would be rash.[30] Inter-rater reliability could be computed for the most frequent subset of diagnoses only. The reliability of the remaining ICD-11 chronic pain diagnoses will have to be explored in the second phase of the study. Furthermore, diagnoses might have been distributed differently between the participating pain clinics, influencing the respective utility ratings and reliability.[18] The premature termination of the study at the pain clinic in Hyderabad (India) resulted in a reduced sample size. Lastly, when interpreting the clinical utility ratings, it should be contemplated that the participating clinicians might have been biased towards a positive evaluation of the new diagnoses given the context of participating in an official field testing.[31]

The second phase of the ICE TEA study will aim at corroborating the results obtained during this first phase.[18] The inclusion of different settings (e.g., primary care, palliative settings) will also contribute to enhanced generalizability. The larger sample size after the second phase will enable the analysis of inter-rater reliability for more diagnoses and possible analyses of country differences of reliability. Furthermore, the second phase will include more specialized settings, such as cancer pain clinics, to ensure that all ICD-11 chronic pain categories are represented in the final sample. This will also enable investigation whether the clinical utility differs between ICD-11 chronic pain categories.

In conclusion, the results of the first phase of the ICE TEA study provide initial evidence that the new ICD-11 chronic pain classification can contribute significantly to global public health. By providing a standard definition of chronic pain with reliable and clinically useful diagnoses, pain research is facilitated and access to adequate pain treatment can be improved globally.[5] A classification that is clinically useful, reliable, and applicable worldwide is more likely to be adopted by clinicians, facilitating the implementation of the ICD-11 chronic pain classification.[32] Finally, and most importantly, chronic pain becomes visible in epidemiological and registry studies, making chronic pain more tangible for the global public health agenda.[33]

Contributors

BK contributed to the conception, design, and methodology of the study, prepared the study material, wrote the original draft, visualized the outcome, and administered the project.

AB contributed to the conception, design, methodology, and resources of the study, repeatedly reviewed and edited the draft critically, and provided supervision.

WR and RDT contributed to the conception, design, and resources of the study, and critically reviewed and edited the draft.

MK contributed to data acquisition and data curation, resources for the study, and critically reviewed and edited the draft.

BBGS, SG, MJ, contributed to data acquisition and resources for the study, and critically reviewed and edited the draft.

MHA, NRG, CH, DJ, AMLM, GN, CSRP, MCRM, , BS, NS, PT, MT, NW contributed to data acquisition and critically reviewed and edited the draft.

GH contributed to the preparation of the study material, project administration, and critically reviewed and edited the draft.

All authors gave their final approval of the version to be published, and agree to be accountable for all aspects of the work.

Declaration of interests

BK reports other from IASP (NGO), during the conduct of the study. AB reports other from IASP (NGO), outside the submitted work. RDT reports grants from Teva, personal fees from Bayer, Grünenthal, GSK, Sanofi, outside the submitted work. The remaining authors have nothing to disclose.

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Figure Legend

Figure 1. Overview of the ICD-11 chronic pain classification.

Note. This figure shows the ICD-11 chronic pain diagnoses on the first diagnostic level.

Figure 2. Clinical utility ratings at each study center.

Note. This figure shows the clinical utility ratings of the ICD-11 classification and the current diagnostic system at all study centers. * $p < 0{\cdot}001$.

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Research in Context

Evidence before this study: Since the ICD-11 is a new classification system that includes chronic pain for the first time, a systematic review could not be performed before the study. One pilot field test of the chronic pain classification conducted by ourselves existed prior to this study; this was a formative field study, conducted with a preliminary version of the ICD-11 chronic pain classification during its development.

Added value of this study: For the first time, an ecological implementation field testing of the ICD-11 chronic pain classification was conducted in different settings, including a lower-middle and an upper-middle-income country. The current study is the first evaluative field study that examines the final classification in routine clinical settings. For the first time, pain clinics in middle-income countries are included and inter-rater reliability of the new diagnoses is analyzed.

Implications of all available evidence: This study provides evidence for substantial inter-rater-reliability and high clinical utility of the new ICD-11 chronic pain diagnoses in a lower-middle, upper-middle, and high-income country. The evidence suggests that the classification is applicable in a global setting, being either superior or equally useful compared to existing local classification systems. This has significant importance for global public health. The ICD-11 will come into effect for global health reporting in 2022 and with the new classification, chronic pain will become visible in large epidemiological studies, allowing better estimates of the true burden of chronic pain. This, in turn, is a prerequisite for improved access to adequate pain treatment, especially in low- and middle-income countries.

Table 1. Description of clinicians.

	Kolkata, India	Hyderabad, India	Dunedin, New Zealand	Havana, Cuba	Overall
Number of clinicians	7	4	6	4	21
Sex n (%)	..	..	..	..	..
Female	1 (14·3)	1 (25·0)	4 (66·7)	3 (75·0)	9 (42·9)
Male	6 (85·7)	3 (75·0)	2 (33·3)	1 (25·0)	12 (57·1)
Age (years)	..	..	..	..	..
M ± SD	33·9 ± 9·6	38·8 ± 9·0	46·0 ± 13·6	59·0 ± 4·4	43·1 ± 13·3
English proficiency	..	..	..	..	..
M ± SD	7·5 ± 1·5	9·0 ± 1·2	9·8 ± 0·4	6·3 ± 1·7	8·2 ± 1·8
Profession n (%)	..	..	..	..	..
Physician	7 (100)	4 (100)	4 (66·7)	4 (100)	19 (90·5)
Psychologist	0	0	2 (33·3)	0	2 (9·5)
Specialty n (%)	..	..	..	..	..
Anesthesiology	4 (57·1)	4 (100)	4 (66·7)	1 (25·0)	13 (61·9)
Pain medicine	7 (100)	3 (75·9)	3 (50·0)	0	13 (61·9)
Cognitive-behavior therapy	0	0	2 (33·3)	0	2 (9·5)
Surgery	0	0	0	1 (25·0)	1 (4·8)
TCM	0	0	0	1 (25·0)	1 (4·8)
Rheumatology	0	0	0	1 (25·0)	1 (4·8)
Years of experience with chronic pain	..	..	..	..	..
M ± SD	4·2 ± 3·6	9·3 ± 10·6	10·4 ± 14·4	24·3 ± 4·1	10·8 ± 11·3
Rating experience with chronic pain	..	..	..	..	..
M ± SD	8·0 ± 1·2	8·8 ± 1·0	7·2 ± 1·7	8·3 ± 1·0	8·0 ± 1·3
Quiz score	..	..	..	..	..
M ± SD	11·7 ± 0·5	10·8 ± 2·5	11·2 ± 1·7	10·3 ± 0·5	11·1 ± 1·2

Note. English proficiency and experience with chronic pain rated from 0 to10. Specialty allowed several answers, specialty TCM: traditional Chinese medicine, mean quiz score 0–12.

Table 2. Description of the patients.

	Kolkata, India	Hyderabad, India	Dunedin, New Zealand	Havana, Cuba	Overall
Total number of patients	97	56	105	92	350
Number of IRR patients n (%)	20 (20·6)	20 (35·7)	51 (48·6)	20 (21·7)	111 (31·7)
Sex n (%)	..	..	..	..	..
Female	46 (47·4)	27 (48·2)	76 (72·4)	65 (70·7)	214 (61·1)
Male	51 (52·6)	29 (51·8)	28 (26·7)	27 (29·3)	135 (38·6)
Diverse	0	0	1 (0·9)	0	1 (0·3)
Valid n	97 (100)	56 (100)	105 (100)	92 (100)	351 (100)
Age (years)	..	..	..	..	..
M ± SD	47·6 ± 11·2	48·5 ± 16·0	45·2 ± 19·1	55·5 ± 15·3	49·1 ± 16·2
Valid n (%)	97 (100)	55 (98·2)	104 (99·0)	91 (98·9)	347 (99·1)
Mother tongue n (%)	..	..	..	..	..
Bengali	60 (61·9)	0	0	0	60 (17·1)
English	1 (1·0)	2 (3·6)	99 (94·3)	1 (1·1)	103 (29·4)
Hindi	28 (28·9)	4 (7·1)	0	0	32 (9·1)
Spanish	0	0	1 (1·0)	91 (98·9)	92 (26·3)
Telugu	4 (4·1)	38 (67·9)	0	0	42 (12·0)
Other	10 (10·3)	15 (26·8)	0	0	25 (7·1)
Valid n (%)	97 (100)	56 (100)	100 (95·2)	91 (98·9)	344 (98·3)
Education n (%)	..	..	..	..	..
Currently in school	0	0	3 (2·9)	1 (1·1)	4 (1·1)
No school leaving certificate	75 (77·3)	7 (12·5)	23 (21·9)	1 (1·1)	106 (30·3)
School leaving certificate	13 (13·4)	18 (32·1)	44 (41·9)	50 (54·3)	125 (35·7)
University degree	6 (6·2)	28 (50·0)	30 (28·6)	40 (43·5)	104 (29·7)
Valid n (%)	94 (96·9)	53 (94·6)	100 (95·2)	92 (100)	339 (96·9)
Employment status n (%)	..	..	..	..	..
Full-time	36 (37·1)	19 (33·9)	30 (28·6)	44 (47·8)	129 (36·9)
Part-time	12 (12·4)	4 (7·1)	16 (15·2)	9 (9·8)	41 (11·7)
Unemployed	25 (25·8)	13 (23·2)	3 (2·9)	0	41 (11·7)
Not able to work due to pain	23 (23·7)	9 (16·1)	27 (25·7)	3 (3·3)	62 (17·7)
Retired	6 (6·2)	10 (17·9)	21 (20·0)	23 (25·0)	60 (17·1)

Homemaker	7 (7·2)	3 (5·4)	2 (1·9)	13 (14·1)	25 (7·1)
Valid n (%)	96 (99·0)	55 (98·2)	100 (95·2)	91 (98·9)	342 (97·7)
Duration of pain (years)	..	..	..	..	..
M ± SD	5·2 ± 5·0	4·8 ± 5·8	8·6 ± 10·4	9·9 ± 10·1	7·4 ± 8·7
Min	0·25	0·25	0·25	0·33	0·25
Max	20·0	34·0	52·0	45·0	52·0
Valid n (%)	97 (100)	56 (100)	105 (100)	90 (97·8)	348 (99·4)
Chronic pain severity M ± SD	..	..	..	..	..
Pain intensity	6·8 ± 1·7	7·1 ± 2·3	6·6 ± 1·9	7·1 ± 2·1	6·9 ± 2·0
Pain-related distress	6·1 ± 2·6	5·3 ± 3·2	5·7 ± 2·8	5·9 ± 3·3	5·8 ± 3·0
Pain-related interference	6·1 ± 2·3	6·8 ± 2·4	6·8 ± 2·2	6·5 ± 2·5	6·5 ± 2·4
Valid n (%)	97 (100)	56 (100)	105 (100)	92 (100)	350 (100)
PDI	..	..	..	..	..
Score M ± SD	34·3 ± 14·3	32·0 ± 19·1	40·0 ± 14·7	35·0 ± 17·9	35·8 ± 16·4
Valid n (%)	97 (100)	50 (89·3)	100 (95·2)	90 (97·8)	337 (96·3)
BSI-53	..	..	..	..	..
GSI M ± SD	1·0 ± 0·6	0·7 ± 0·7	1·0 ± 0·7	0·7 ± 0·7	0·9 ± 0·7
Valid n GSI (%)	86 (88·7)	47 (83·9)	99 (94·3)	86 (93·5)	318 (90·9)
Number of diagnoses M ± SD (range)	..	..	..	..	..
Usual	1·1 ± 0·3 (1–2)	1·1 ± 0·3 (0–2)	1·4 ± 1·0 (1–4)	1·1 ± 0·4 (1–3)	1·2 ± 0·6 (0–4)
ICD-11	1·1 ± 0·3 (1–2)	1·3 ± 0·5 (1–3)	1·7 ± 1·1 (1–7)	1·1 ± 0·4 (1–3)	1·3 ± 0·8 (1–7)

Note: IRR: inter-rater reliability coding; mother tongue and employment status allowed several answers; all item of the severity scale were rated on an NRS from *0* (no pain / no distress / no interference) to *10* (worst pain imaginable / extreme pain-related distress / unable to carry in activities); PDI = Pain Disability Index, sum score: range 0–70; BSI-53 = Brief Symptom Inventory 53, items rated on a scale from *0* (not at all) to *4* (extremely); number of diagnoses as assigned by rater 1.

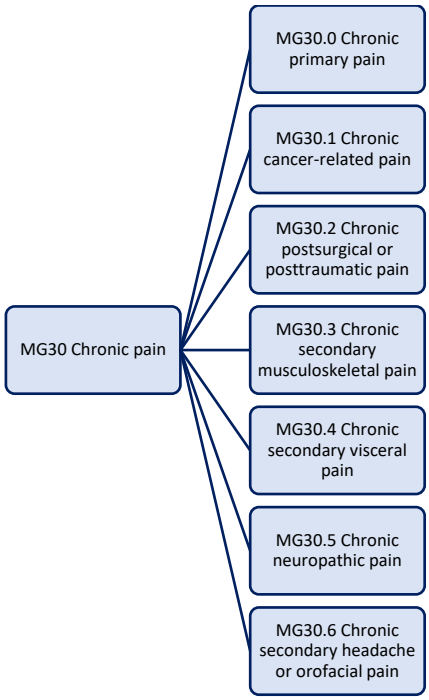
Table 3. Fleiss' kappa values for selected diagnoses.

Diagnosis	ICD-11 code	Diagnostic level	N[+]	Fleiss κ	SE[†]	95% CI	Interpretation[#]
Chronic primary pain	MG30.0	1	44	0·738	0·095	0·552–0·924	Substantial
Chronic widespread pain	MG30.01	2	20	0·708	0·095	0·522–0·894	Substantial
Fibromyalgia syndrome	n. a.*	3	16	0·720	0·095	0·534–0·906	Substantial
Chronic primary musculoskeletal pain	MG30.02	2	15	0·596	0·095	0·410–0·782	Moderate
Chronic postsurgical or post traumatic pain	MG30.2	1	29	0·734	0·095	0·548–0·920	Substantial
Chronic secondary musculoskeletal pain	MG30.3	1	59	0·783	0·095	0·597–0·969	Substantial
Chronic secondary musculoskeletal pain associated with structural changes	MG30.31	2	27	0·706	0·095	0·520–0·892	Substantial
Chronic secondary musculoskeletal pain associated with osteoarthritis	n. a.*	3	21	0·615	0·095	0·429–0·801	Substantial
Chronic secondary visceral pain	MG30.4	1	15	0·720	0·095	0·534–0·906	Substantial
Chronic neuropathic pain	MG30.5	1	30	0·649	0·095	0·463–0·835	Substantial
Chronic peripheral neuropathic pain	MG30.51	2	20	0·663	0·095	0·477–0·849	Substantial

Note. *Diagnoses on level 3 are coded with the diagnostic code of the level 2 diagnosis and can be specified further with their unique foundation uniform resource identifier. [+]Number of patients to whom at least one clinician assigned the respective diagnosis during the inter-rater reliability coding. [†]standard error, [#]interpretation of the kappa values according to Landis & Koch [23].

Figure 1.

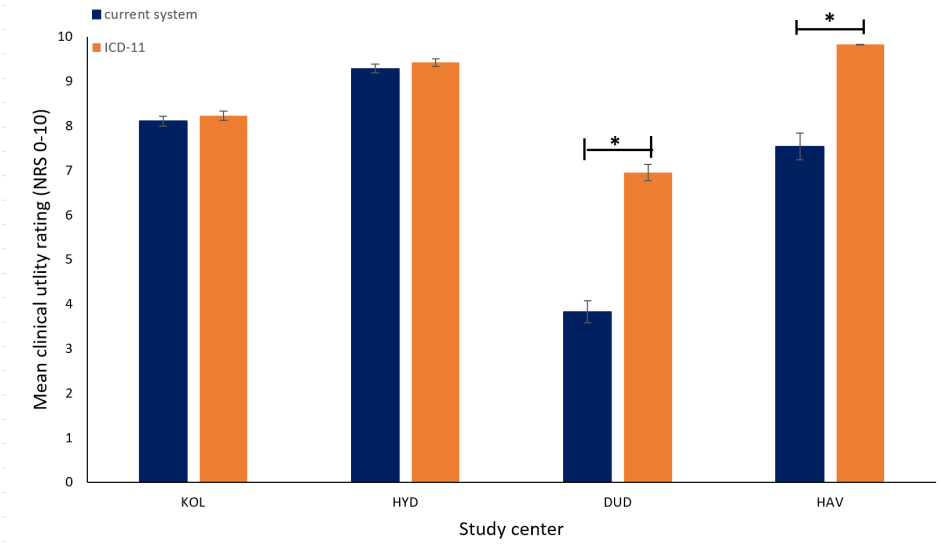
Overview of the ICD-11 chronic pain classification.



Note. This figure shows the ICD-11 chronic pain diagnoses on the first diagnostic level.

Figure 2.

Clinical utility ratings at each study center.



Note. This figure shows the clinical utility ratings of the ICD-11 classification and the current diagnostic system at all study centers. * $p < 0{\cdot}001$.

7.2 Anhang B: Curriculum vitae und Publikationsverzeichnis

7.2.1 Anhang B.1: Tabellarischer Lebenslauf

Der Lebenslauf ist nicht Teil dieser Veröffentlichung.

7.2.2 Anhang B.2: Publikationsverzeichnis

Artikel in internationalen peer-reviewed Fachzeitschriften

(Unterstreichungen kennzeichnen gleichberechtigte Autorenschaften.)

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7.3 Anhang C: Eidesstattliche Erklärung

Hiermit versichere ich, Beatrice Korwisi, dass ich meine Dissertation mit dem Titel

„Internationale Feldstudien zur Evaluation der Klassifikation chronischer Schmerzen in der 11. Revision der Internationalen statistischen Klassifikation der Krankheiten und verwandter Gesundheitsprobleme (ICD-11)“

selbstständig und ohne unerlaubte Hilfe angefertigt zu haben. Ich habe mich dabei keiner anderen als der von mir ausdrücklich bezeichneten Quellen und Hilfen bedient.

Die Dissertation wurde in der jetzigen oder einer ähnlichen Form noch bei keiner anderen Hochschule eingereicht und hat noch keinen sonstigen Prüfungszwecken gedient.

Marburg, Dezember 2020

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Beatrice Korwisi