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ORIGINAL ARTICLE

Face validity of the ICD-10 criteria of substance abuse and dependence for patients prescribed cannabis-based medicines for chronic pain—A survey of pain medicine physicians in Canada, Germany and Israel

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Abstract

Background and Objective: A major concern with cannabis-based medicines (CbM) and medical cannabis (MC) is the risk of abuse and dependence. The face validity of the International Classification of Diseases (ICD-10) criteria for cannabis dependence in patients prescribed CbM for chronic pain has not been assessed.

Databases and Data Treatment: Physicians from Canada, Germany and Israel were recruited via the mailing lists of national pain societies. To be eligible, physicians had to have prescribed CbM for chronic pain treatment in the past 12 months. Participants were asked to rate the appropriateness of items adapted from the substance use module of the Composite International Diagnostic Interview Version 3.0 to assess dependence in the context of chronic pain treatment with CbM and the appropriateness of two additional items. In case of disagreement, participants were asked to give reasons. Furthermore, they were asked to suggest potential additional criteria.

Results: On average 69.0% of 178 participating physicians indicated agreement with the appropriateness of the ICD-10 criteria, while 20.6% indicated disagreement. The highest disagreement rate was observed for the item on repeated use despite legal problems (35.4% disagreement or strong disagreement). Reasons for disagreement were summarized into six content categories using qualitative methods of analysis. Additional criteria suggested by participants were summarized into 10 content categories.

Conclusions: A collaboration of psychiatrists and pain physicians is required to define criteria and develop instruments to capture abuse and dependence of CbM in chronic pain patients.

Significance: Sixty-nine per cent of 178 pain medicine physicians in Canada, Germany and Israel who participated in a survey on the appropriateness of

the ICD-10 criteria for cannabis abuse and dependence for patients prescribed cannabis-derived products for chronic pain assessed the criteria as appropriate, whereas 20.6% deemed the criteria as not appropriate.

1 | INTRODUCTION

Cannabinoid products are available as therapeutic options in the form of herbal products derived from the plant *Cannabis sativa*, referred to as medicinal cannabis (MC), or as pharmaceutical products, referred to as cannabis-based medicinal products (CbM), with specific indications in some countries. Driven by public advocacy, politicians and the media, CbM/MC have bypassed the traditional evidence-based medicine decision process by drug agencies and have been approved as therapeutic products by legislative bodies in various countries for medical use, often including reimbursement options by the health care systems (Fitzcharles & Eisenberg, 2018; Krcevski-Skvarc et al., 2018). Concomitantly, cannabis has been legalized for recreational purposes in some countries. The main objections to the use of CbM/MC for patients with chronic pain are the lack of high-quality evidence for efficacy (Fisher et al., 2021) and safety concerns (Mohiuddin et al., 2021).

A major safety concern is the risk of abuse and dependence when CbM/MC are used to manage chronic pain (Feingold et al., 2020) or other medical conditions. The United Nations' Report of the International Narcotics Control Board for 2018 declared that dependence is a probable outcome of daily medical cannabis use and that the risk of dependence might be as high as one in three persons (International Narcotics Control Board, 2019). Those using THC-related compounds daily (e.g. for chronic pain) may have a greater risk of dependence over those using it weekly for chemotherapy-induced nausea (International Narcotics Control Board, 2019). These concerns are based mainly on data derived from recreational cannabis use, where cannabis use disorder is reported with a prevalence of up to 10% (Mohiuddin et al., 2021).

The World Health Organization's (WHO) International Classification of Diseases (ICD) and the American Psychiatric Association's (APA) Diagnostic and Statistical Manual (DSM) are commonly used in both research and clinical practice to assess illicit substance use. Neither of these systems was specifically designed to address the medical use of CbM/MC (or opioids) in a clinical setting (Campbell et al., 2016). APA explicitly states its criteria are not appropriate for patients taking opioids under adequate medical supervision (American Psychiatric Association, 2013). However, APA did not comment on cannabis-derived products for medical use. Furthermore, criteria on tolerance and withdrawal symptoms, which are used as key criteria for substance use disorders in psychiatric and medical settings, have been removed from ICD-11 for patients medically treated with opioids by a licensed clinician (World Health Organization, 2021).

Surprisingly, there has been no discussion in the pain and psychiatric communities on the validity and clinical utility of ICD-10 criteria on substance abuse and dependence in patients prescribed CbM/MC for chronic pain. To our knowledge, pain medicine physicians were not involved in the WHO and APA working groups that created the diagnostic criteria for substance dependence (ICD-11) and substance use disorder (DSM-5). The objective of our survey was to assess the face validity of the ICD-10 criteria on cannabis abuse and dependence for patients prescribed cannabis-derived products by pain medicine physicians who legally prescribe CbM/MC for pain management.

2 | METHODS

2.1 | Participants

Data were collected using an anonymous, multilingual online survey in a cross-sectional design. The survey targeted physicians in Canada, Germany and Israel who prescribed CbM/MC for the treatment of chronic pain for at least one patient in the last 12 months. Participants were recruited through the mailing lists of pain societies in Canada, Germany and Israel. These countries were selected for two reasons: CbM and MC have been available for prescription in these countries for several years for the treatment of chronic pain, and there is ongoing collaboration among the study authors on various aspects of CbM and MC in pain management. Participation was open in Canada from June 22 to August 27, 2021, Germany from June 7 to July 12, 2021, and Israel from June 16 to August 27, 2021.

2.2 | Survey

The survey was developed by some authors of this communication in three consensus rounds (SB, WH and MAF). The main purpose of the survey was to assess the face validity (clinical appropriateness) of existing ICD-10 criteria and possible alternative or complementary criteria for substance dependence in the context of

chronic pain treatment with CbM/MC. Adapted items of the substance use module from the World Mental Health (WMH) Survey Initiative version of the WHO Composite International Diagnostic Interview Version 3.0 (WMH-CIDI), a validated fully structured diagnostic instrument, were used to assess the face validity of existing criteria (Kessler & Ustün, 2004). For the items used, "MARIJUANA OR HASHISH" was replaced with "medical cannabis" and the time frame was limited to the past 12 months. To assess the face validity of two possible alternative criteria, two items were added to capture the reasons for the use of CbM/MC other than pain management and the use of other substances (e.g. sedating opioids and illicit drugs) that was known to the treating physician. *Participants were asked to rate the appropriateness of these Items to assess* "addiction" in the context of chronic pain treatment with CbM/MC on a 5-point Likert scale ranging from "strongly disagree" to "strongly agree", which was supplemented by an additional "I don't know" category. If participants indicated that they disagreed or strongly disagreed with the appropriateness of a specific item, they were asked to provide the reasons for their rating in an open statement. Additionally, participants were asked to suggest additional alternative or complementary criteria to capture substance dependence related to medical use of CbM/MC in patients with chronic pain. Furthermore, the survey collected the following personal information from participating physicians: age, gender, years in medical practice, primary specialty, years of experience prescribing CbM/MC for chronic pain and number of patients prescribed CbM/MC by the participating physician in 2020. Export of the survey is provided in Data S1.

2.3 | Ethics

The survey was approved by the Ethics Committee of the University of Göttingen (number 25/6/21). In Israel and Canada, approval from an ethics committee is not required for an anonymous survey among physicians.

2.4 | Data analysis

The statistical analyses of demographic characteristics and the appropriateness ratings of the adapted CIDI items were performed using quantitative methods, while qualitative methods were used to analyse alternative criteria suggested by participants and reasons for disagreement with the appropriateness of the adapted CIDI items. Qualitative data analysis was conducted primarily using Microsoft Excel (Microsoft Corporation, 2018). Analysis and graphical representation of quantitative data were performed in R Version 3.6.1 (R Core Team, 2020).

2.4.1 | Quantitative analysis

Descriptive statistics of demographic data and item ratings are reported as absolute and relative frequencies or as means with standard deviations, depending on the respective level of measurement of each variable. To represent the appropriateness ratings of the adapted CIDI items, the response categories "neither agree nor disagree" and "I don't know" were aggregated as "neutral" category. For reporting the results in the text, the "strongly disagree" and "disagree" categories were aggregated as "disagreement", and the "strongly agree" and "agree" categories were aggregated as "agreement." Statistical comparisons of demographic characteristics were made between participating physicians who were included in the analysis and those who were excluded from the analysis using Chi-square tests and *t*-tests, depending on the respective level of measurement of each variable. Appropriateness ratings of the adapted CIDI items were compared between participating physicians with a low prescription rate of CbM in the past 12 months (fewer than 50 cases) and participating physicians with a high prescription rate of CbM in the past 12 months (more than 50 cases), as well as between male and female physicians and countries using Chi-squared tests. Since only $n = 2$ participants identified neither as male nor female, no additional group was included in these analyses. For all Chi-squared tests, *p*-values were computed using a Monte Carlo test with 100,000 replicates. Adjustment of *p*-values to correct for multiple testing was performed using the Benjamini–Hochberg method. Only adjusted *p*-values are reported in the text. However, the summary tables additionally contain the uncorrected *p*-values. For metric variables, the effect size is reported as Cohen's *d*; for factor variables, it is reported as Cramer's V. All statistical tests were two sided and an adjusted *p*-value of <0.05 was considered significant.

2.4.2 | Qualitative analysis

Qualitative data analysis was carried out separately by two authors of the article (LS and SL) using an inductive approach, similar to the inductive procedure in qualitative content analysis (Mayring, 2015). Due to the comparatively short answers, the procedure for forming the category system was adapted to the data material by paraphrasing and generalizing the responses only when necessary. First, the analysis of reasons for disagreement was performed. For this purpose, all responses were translated

into English. These translated responses were independently summarized into content categories by the two authors. A category system was formed in a consensus process based on the defined categories. The validity of the category system was verified by independent recoding of all responses. In a renewed consensus process, all responses assigned to different categories were examined and the category system was expanded. A response was assigned to multiple categories if necessary. A response was excluded from the analysis only if none of the authors involved in the analysis was able to assign the content of that response to an existing category or combine it into a new category. The procedure was repeated for the alternative criteria proposed. In this case, responses that contained only a general statement about existing criteria, rather than a proposal for a new criterion or a substantive addition to an existing criterion, were also excluded from the analysis.

3 | RESULTS

The survey was accessed by 816 potentially eligible physicians who were contacted through the mailing lists of national pain societies. Among them, 551 closed the survey directly without interacting with it; thus, no further information can be provided about this subsample. A total of 57 physicians were excluded from participating in the survey because they indicated that they had not prescribed CbM/MC in the past 12 months. Thirty participants were excluded from primary statistical analyses because they answered only sociodemographic items but did not rate the appropriateness of at least one adapted CIDI item. The sample included in the primary statistical analysis comprised $N = 178$ participants, corresponding to a completion rate of 21.8%. Of these, $n = 125$ were from Germany, $n = 36$ from Canada and $n = 17$ from Israel. A statistical comparison was made regarding the sociodemographic characteristics of the participants included in the primary statistical analysis and the participants who were excluded from this analysis, with no significant differences found. A comprehensive presentation of the results of these comparisons is provided in Tables S1 and S2.

3.1 | Sample characteristics

The mean age of the sample was $M = 54.8$ years ($SD = 8.11$). 57.3% of the participants identified themselves as male, 41% as female and 1.1% as other (0.6% missing). 62.5% of participants reported anaesthesia as their primary specialty, 15.7% general medicine, 4.5% rheumatology, 3.4% neurology and 1.7% internal medicine (10.7% other). Furthermore, 80.9% of participants reported pain medicine as additional designation and 44.4% reported palliative medicine as additional designation (1.1% missing). On average, participants reported practicing medicine for $M = 26.4$ years ($SD = 9.1$) and prescribing CBM/ MC for $M = 7.5$ years ($SD = 6.4$). 30.9% of participants reported having prescribed CbM/MC in <10 cases in the past 12 months, 43.8% in 10–50 cases, 10.1% in 51–100 cases, 8.4% in 101–500 cases, 3.4% in 501–1000 cases and 3.4% in more than 1000 cases. For a complete presentation of sample characteristics by country, see Table 1.

3.2 | Appropriateness of ICD-10 criteria

On unweighted average, 69.0% of 178 participants expressed agreement with the appropriateness of the adapted CIDI items to capture substance dependence related to medical use of CbM/MC in patients with chronic pain, while 20.6% expressed disagreement (9.2% neutral and 1.2% missing). For the adapted CIDI items, the highest agreement rate was found for the item on the use of CbM/MC in larger amounts or longer than intended (80.6% agreement, 5.7% neutral, 13.1% disagreement and 0.6% missing), followed by the item on failure to fulfil major role obligations due to recurrent use of CbM/MC (79.4% agreement, 8.0% neutral, 12.0% disagreement and 0.6% missing). In contrast, the highest disagreement rate was found for the item on repeated use despite legal problems (52.0% agreement, 10.3% neutral, 35.4% disagreement and 2.3% missing), followed by the item on withdrawal symptoms (63.4% agreement, 9.1% neutral, 25.7% disagreement and 1.7% missing). For the first additional item proposed by the authors, “Did you use medical cannabis for reasons other than pain relief? (If yes: to reduce anxiety/nervousness, to improve sleep, to increase appetite, to get ‘high’ (euphoric), to be relaxed, other reasons)” an agreement rate of 86.6% was found (10.9% neutral, 13.1% disagreement and 7.4% missing). For the second additional item, "Have you taken other substances (e.g. sedatives, opioids, illicit drugs) since being prescribed cannabis medication without informing your treating physician?" an agreement rate of 78.3% was found (5.1% neutral, 9.1% disagree and 7.4% absent). For a comprehensive presentation of agreement ratings for each item, see Table 2.

No significant associations were found between the prescribing group (high prescriber: $n = 133$ and low prescriber: $n = 45$) and the agreement ratings for the adjusted CIDI items and the additional items. The effect sizes of the associations were small for all items. Summary statistics of χ^2 tests for every item are shown in Table S3. Significant associations with medium effect sizes between country and the agreement ratings were found for

TABLE 1 Sample characteristics in total and by country.

	Total sample ($N = 178$)	Country		
		Germany ($n = 125$)	Canada ($n = 36$)	Israel ($n = 17$)
Age (Years)				
Mean ± SD	54.8 ± 8.11	54.8 ± 7.26	55.0 ± 10.8	54.4 ± 8.27
Missing *n* (%)	4 (2.2)	2 (1.6)	2 (5.6)	0 (0)
Medical practice (Years)				
Mean ± SD	26.4 ± 9.12	27.1 ± 7.92	25.4 ± 12.4	23.9 ± 9.09
Missing *n* (%)	2 (1.1)	2 (1.6)	0 (0)	0 (0)
Experience prescribing CbM (Years)				
Mean ± SD	7.45 ± 6.39	7.12 ± 6.58	6.91 ± 4.72	10.9 ± 7.20
Missing *n* (%)	2 (1.1)	1 (0.8)	1 (2.8)	0 (0)
Gender *n* (%)				
Male	102 (57.3)	73 (58.4)	18 (50.0)	11 (64.7)
Female	73 (41.0)	52 (41.6)	15 (41.7)	6 (35.3)
Other	2 (1.1)	0 (0)	2 (5.6)	0 (0)
Missing	1 (0.6)	0 (0)	1 (2.8)	0 (0)
Primary specialty *n* (%)[a]				
Anaesthesia	114 (64.0)	100 (78.7)	3 (9.4)	11 (57.9)
General Medicine	28 (15.7)	10 (7.9)	17 (53.1)	1 (5.3)
Rheumatology	8 (4.5)	0 (0)	7 (21.9)	1 (5.3)
Neurology	6 (3.4)	6 (4.7)	0 (0)	0 (0)
Internal medicine	3 (1.7)	2 (10.5)	0 (0)	1 (0.8)
Other	19 (10.7)	10 (7.9)	5 (15.6)	4 (21.1)
Missing	0 (0)	0 (0)	0 (0)	0 (0)
Pain medicine *n* (%)				
Yes	144 (80.9)	119 (95.2)	10 (27.8)	15 (88.2)
No	34 (19.1)	6 (4.8)	26 (72.2)	2 (11.8)
Missing	0 (0)	0 (0)	0 (0)	0 (0)
Palliative medicine *n* (%)				
Yes	79 (44.4)	74 (59.2)	3 (8.3)	2 (11.8)
No	97 (54.5)	49 (39.2)	33 (91.7)	15 (88.2)
Missing	2 (1.1)	2 (1.6)	0 (0)	0 (0)
Patients treated with CbM *n* (%)				
<10	55 (30.9)	46 (36.8)	6 (16.7)	3 (17.6)
10–50	78 (43.8)	60 (48.0)	16 (44.4)	2 (11.8)
50–100	18 (10.1)	11 (8.8)	6 (16.7)	1 (5.9)
101–500	15 (8.4)	6 (4.8)	5 (13.9)	4 (23.5)
501–1000	6 (3.4)	2 (1.6)	1 (2.8)	3 (17.6)
>1000	6 (3.4)	0 (0)	2 (5.6)	4 (23.5)
Missing	0 (0)	0 (0)	0 (0)	0 (0)

[a]Multiple answers are possible. Percentages refer to columns.

the items on the development of tolerance ($\chi^2 = 45.89$, $p < 0.001$, $V = 0.37$), withdrawal symptoms ($\chi^2 = 37.89$, $p = 0.001$, $V = 0.33$), persistent desire to use CbM/MC and unsuccessful efforts to reduce use ($\chi^2 = 31.50$, $p = 0.004$, $V = 0.30$). Descriptively, higher disagreement rates were found for these items for participants from Canada. For

TABLE 2 Agreement rating with the appropriateness of ICD-10 criteria to capture substance dependence related to medical use of CbM/MC in patients with chronic pain.

		Rating, *n* (%)				
	Missing *n* (%)	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Adapted CIDI Items						
Was there a time when you often had such a strong desire to use medical cannabis that you couldn't stop using it or found it difficult to think of anything else?	(0.0)	18 (10.3)	14 (8.0)	11 (6.3)	63 (36.0)	69 (39.4)
Did you ever have times when you used medical cannabis even though you planned not to or when you used a lot more than you had intended?	1 (0.6)	9 (5.1)	14 (8.0)	10 (5.7)	52 (29.7)	89 (50.9)
Were there times when you tried to stop or cut down on your use of medical cannabis and found that you were not able to do so?	0 (0.0)	11 (6.3)	25 (14.3)	15 (8.6)	59 (33.7)	65 (37.1)
Was there ever a time when your use of medical cannabis frequently interfered with your work or responsibilities at school, on the job, or at home?	1 (0.6)	10 (5.7)	18 (10.3)	14 (8.0)	57 (32.6)	75 (42.9)
Was there ever a time when your use of medical cannabis caused arguments or other serious or repeated problems with your family, friends, neighbors, or coworkers? Did you continue to use medical cannabis even though it caused problems with these people?	1 (0.6)	16 (9.1)	24 (13.7)	20 (11.4)	55 (31.4)	59 (33.7)
Did you ever have times when you gave up or greatly reduced important activities because of your medical cannabis use – like sports, work, or seeing friends and family?	1 (0.6)	9 (5.1)	12 (6.9)	14 (8)	68 (38.9)	71 (40.6)
Were there times in your life when you were often under the influence of medical cannabis in situations where you could have been hurt, for example when riding a bicycle, driving, operating a machine, or anything else?	4 (2.3)	16 (9.1)	24 (13.7)	19 (10.9)	55 (31.4)	57 (32.6)
Were you arrested or stopped by the police more than once because of driving under the influence of medical cannabis or because of your behavior while you were under the influence of medical cannabis?	4 (2.3)	32 (18.3)	30 (17.1)	18 (10.3)	39 (22.3)	52 (29.7)
Did you ever have several days or more when you spent so much time purchasing, using or recovering from the effects of medical cannabis use that you had little time for anything else?	3 (1.7)	13 (7.4)	21 (12.0)	21 (12.0)	51 (29.1)	66 (37.7)

(Continues)

TABLE 2 (Continued)

		Rating, *n* (%)				
	Missing *n* (%)	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Did you ever continue to use medical cannabis when you knew you had a serious physical or emotional problem that might have been caused by or made worse by using medical cannabis?	3 (1.7)	14 (8.0)	17 (9.7)	18 (10.3)	48 (27.4)	75 (42.9)
Did you ever need larger amounts of medical cannabis to get an effect, or did you ever find that you could no longer get the effect from the amount you used to use?	4 (2.3)	15 (8.6)	25 (14.3)	18 (10.3)	45 (25.7)	68 (38.9)
Did you ever have a time when you stopped, cut down or went without using medical cannabis and then experienced withdrawal symptoms such as restlessness, nervousness, anxiety, depression, sleep disorders, loss of appetite, abdominal pain, sweating, cold shivers, headaches?	3 (1.7)	19 (10.9)	26 (14.9)	16 (9.1)	49 (28.0)	62 (35.4)
Additional Items						
Did you use medical cannabis for reasons other than pain relief? (If yes: to reduce anxiety/ nervousness, to improve sleep, to increase appetite, to get 'high' (euphoric), to be relaxed, other reasons)	13 (7.4)	5 (2.9)	18 (10.3)	19 (10.9)	47 (26.9)	73 (41.7)
Since you were prescribed cannabis medications, have you taken other substances, (e.g. sedatives, opioids, illicit drugs) without informing your treating physician?	13 (7.4)	6 (3.4)	10 (5.7)	9 (5.1)	32 (18.3)	105 (60.0)

Note: $n = 178$. Percentages refer to rows. "Neutral" category includes "I don't know" and " Neither agree nor disagree".

the other adapted CIDI items and the additional items, the effect sizes were small and the associations were not statistically significant. Summary statistics of χ^2 tests for every item can be found in Table S4. No significant associations were found between gender and the agreement ratings for the adapted CIDI items and the additional items. Summary statistics of χ^2 tests for every item can be found in Table S5.

3.3 | Reasons for disagreement

On average, 65.5% of the participants who indicated disagreement with the appropriateness of the adapted CIDI items or the additional items responded to the request to clarify their reasons for disagreement in an open-ended response. The median length of the responses was $Mdn = 15$ words (min = 1, max = 191) with 58.5% of the responses containing at least 10 words. A total of 26 responses (5.5%) were excluded from the analysis because the coders were unable to extract a specific reason for disagreement. The responses were summarized into six content categories that included specific subcategories. Each content category contained specific reasons for disagreement that could be distinguished from one another. An assignment to multiple content categories was made when more than one of these reasons was mentioned in the response. At the median, responses were assigned to $Mdn = 2$ content categories (min = 1, max = 4). Below a summary of each content category is provided, including examples of the responses assigned to those categories.

Wording: $n = 103$ responses (26.9%) were assigned to the content category "Wording." Responses assigned to this category expressed criticism of the wording of the item in terms of comprehensibility. Example:

> [...] Perhaps rather: had you performed these activities while under cannabis medications,

> even though you were medically advised not to? [...]
>
> (ID 106, Item 7)

Doubts: $n = 87$ responses (22.7%) were assigned to the content category "Doubts." Responses assigned to this category expressed general disbelief in the appropriateness of the item. Example:

> "Does not apply from experience"
>
> (ID 110, Item 4)

Medical use: $n = 81$ responses (21.1%) were assigned to the content category "Medical use." Responses assigned to this category expressed the assumption that the item could be answered in the affirmative even in case of nondependent medically intended use of CbM/MC or is not applicable in the case of medical use at all. Example:

> Regular intake behavior is desirable in chronic pain syndrome.
>
> (ID 140, Item 1)

Substance related: $n = 58$ responses (15.1%) were assigned to the content category "Substance related." The responses assigned to this category referred to specific aspects of cannabis use, which are related to the substance but not necessarily to dependence or abuse. Example:

> There are many family members who are strongly against the use of cannabis for any reason, and so if people have conflicting opinions from their health care provider and well-meaning family it can cause significant arguments.
>
> (ID 473, Item 5)

Pain specific: $n = 47$ responses (12.3%) were assigned to the content category "Pain specific." Responses assigned to this category expressed the assumption that the item could be incorrectly answered in the affirmative due to symptoms of the existing pain disorder. Example:

> Periods of increased cannabis use could coincide with pain severity interfering with social activity. This would be confounding.
>
> (ID 492, Item 6)

Differentiation: $n = 7$ responses (1.8%) were assigned to the content category "Differentiation." Responses assigned to this category called for specific differentiation between certain aspects of the content of the item. Example:

> Mostly my patients are using CBD. There is little 'influence' other than symptom relief. It's a nonsensical question in this context.
>
> (ID 462, Item 7)

The frequency distribution of the content categories across the items is displayed in Figure 1. A description of the corresponding subcategories with examples and a representation of the number of responses assigned to the specific subcategories is given in Table 3.

3.4 | Qualitative analysis of alternative criteria suggested by participants

Participants who suggested additional alternative or comprehensive criteria for detecting dependence in patients prescribed with CbM/MC for chronic pain were answered by 83 participants (46.6%). The median length of the responses was $Mdn = 17$ words (min = 1, max = 167), with 71.1% of the responses being at least 10 words long. A total of 19 responses (22.9%) were excluded from the analysis because they represented a general comment on the existing criteria (e.g. *"the problem is that addicted people do not tend to answer those questions"* (*ID 725*)), could not be interpreted by the authors (e.g. "*None*" (*ID 37*)) or represented a comment on medical practice in prescribing CbM/MC for chronic pain (e.g. *"what are the intended treatment goals? are these being achieved with THC/CBD? if no, the drug should not be further used/prescribed and should be withdrawn"* (*ID 159*)).

The remaining 64 responses were summarized into 10 content categories. An assignment to multiple content categories was made when more than one additional criterion was suggested. At the median, responses were assigned to two content categories (min = 1, max = 4). A complete description of all content categories, including examples and the number of responses assigned to each category, is shown in Table 4. The most common content category, "Intake deviation" included additional criteria on intake behaviour that deviates from prescribed intake, e.g. by independent dose increase. Overall $n = 28$ responses were assigned to this category. Example:

> Have you independently increased CbM dose/admission frequency without consultation? [...]
>
> (ID 116)

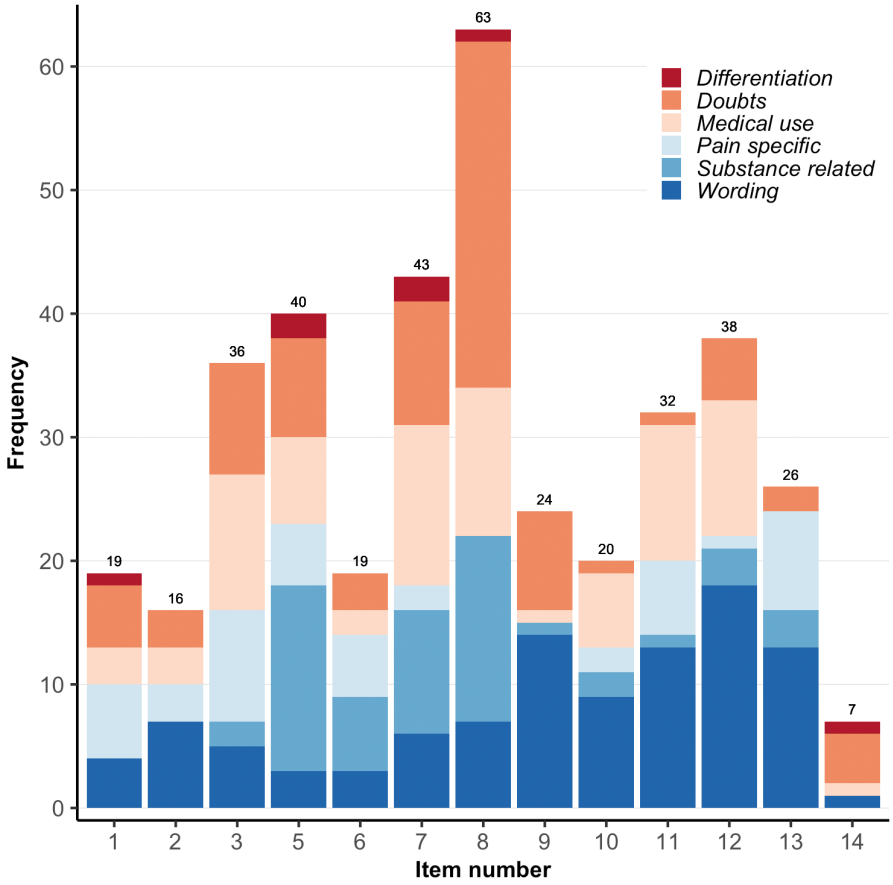

FIGURE 1 Stacked bar chart showing the frequency distributions of content categories from qualitative analysis of reasons for disagreement per item. Items 1 to 12 adapted CIDI items. Items 13 and 14 are additional items suggested by the authors.

The second-most common content category, "sources of supply," included additional criteria addressing the use of cannabis from alternative sources of supply (illicit or other medical sources) by the patients in addition to the prescribed CbM/MC. Overall $n = 23$ responses were assigned to this category. Example:

> Have you obtained cannabis products from other sources? [...]
>
> (ID 439)

Fewer than 20 responses were assigned to each of the remaining content categories.

4 | DISCUSSION

4.1 | Summary of main results

Physicians ($N = 178$) from Canada, Germany and Israel, with experience in prescribing CbM/MC for chronic pain, participated in an online survey addressing the face validity of the ICD-10 criteria to capture abuse and dependence of CbM/MC prescribed for chronic pain. On average, 69.0% of participating physicians indicated agreement with the appropriateness of the ICD-10 criteria, while 20.6% indicated disagreement (9.2% neutral and 1.2% missing). The highest agreement rate was found for the item on the use of CbM/MC in larger amounts or longer than intended (80.6% agreement) and the item on failure to fulfil major role obligations due to recurrent use of CbM/MC (79.4% agreement). In contrast, the highest disagreement rate was found for the item on repeated use despite legal problems (35.4% disagreement). Reasons given for disagreement with certain ICD-10 criteria included (1) that they could be affirmed even in the case of nondependent, medically intended use, (2) that they could be affirmed based on symptoms of the existing pain disorder and (3) that they refer to certain aspects of cannabis use that are related to the substance itself but not necessarily to dependence or abuse. Significant differences between the agreement ratings of participating physicians from Canada, Germany and Israel were found for the criteria on the development of tolerance, for the criteria on withdrawal symptoms and for the criteria on persistent desire to use CbM/MC. For the two additional criteria proposed by the authors, high agreement rates of 86.6% and 78.3% were found. Additional criteria suggested by the participating physicians included criteria on intake behaviour that deviates from prescribed intake and criteria on the use of cannabis from alternative sources of supply.

TABLE 3 Subcategories of reasons for disagreement.

Categories	Frequency	Explanation	Example quote
Wording	2		
General criticism	17	Criticism of item comprehensibility without addressing specific aspects or making suggestions for improvement.	"The sentence is too complicated and therefore I do not think it is suitable." (*ID 151, Item 3*)
Specific criticism	84	Criticism of item comprehensibility accompanied by suggestions for improvement (e.g. on the content or terms used).	"[...] Perhaps rather: had you performed these activities while under cannabis medications, even though you were medically advised not to? [...]" (*ID 106, Item 7*)
Doubts	14		
Patients' response	19	The Item might not be answered honestly resp. differentiated by the patients.	"Negative attitudes towards medical therapy are also a possible reason for answering this question positively." (*ID 98, Item 5*)
Clinical experience	54	The item determined to be inappropriate based on experience in daily medical practice.	"Never happened before, no arguments about timing or frequency at all." (*ID 119, Item 5*)
Pain specific	14		
Pain symptoms	24	The Item might be affirmed by patients due to primary symptoms of an existing pain disorder.	"Periods of increased cannabis use could coincide with pain severity interfering with social activity. This would be confounding." (*ID 492, Item 6*)
Concomitants	9	The Item might be affirmed by patients due to concomitant symptoms of an existing pain disorder.	"Sleep problems, loss of appetite and anxiety are co-symptoms of chronic pain and cannot be separated clinically." (*ID 738, Item 13*)
Medical use	11		
Intake	51	The intake behaviour described in the Item contradicts the medically prescribed intake behaviour.	"Regular intake behavior is desirable in chronic pain syndrome." (*ID 140, Item 1*)
Dose	13	The necessary medically prescribed dosage/consumption may lead to an affirmation of the Item by the patients.	"Dose adjustments were made as needed in both directions." (*ID 119, Item 11*)
Exclusion criteria	5	The presence of the criterion described in the Item precludes treatment with CbM and is clarified in advance.	"This should be an exclusion criterion for prescribing from the outset." (*ID 321, Item 10*)
Substance related	4		
Social stigma	14	The Item might be affirmed due to negative environmental attitudes toward cannabis use (e.g. by family members of the patient) regardless of the reasons for the use.	"There are many family members who are strongly against the use of cannabis for any reason, and so if people have conflicting opinions from their health care provider and well-meaning family it can cause significant arguments." (*ID 473, Item 5*)
Legal situation	19	The legal framework in which CbM is prescribed is in conflict with the Item.	"Withdrawal of driving license in case of detection of THC in case of ingestion of CbM in the course of a routine control has already occurred in Germany." (*ID 99, Item 8*)

(Continues)

TABLE 3 (Continued)

Categories	Frequency	Explanation	Example quote
Side effects	21	The symptoms mentioned in the item as criteria for dependence correspond to side effects of CbM intake.	"Cannabis, as a side effect, can also impair cognitive abilities when used medicinally, just as other centrally -acting drugs do." (*ID 181, Item 4*)
Differentiation	0		
CBD versus THC	5	When using the item or applying the criterion, a greater differentiation is necessary between CBD and THC.	"Mostly my patients are using CBD. There is little 'influence' other than symptom relief. It's a nonsensical question in this context." (*ID 462, Item 7*)
Abuse versus Dependence	2	When using the item or applying the criterion, a greater differentiation is necessary between CBD and THC.	"[...] Abuse and addiction must be separated So different questionnaires" (*ID 36, Item 14*)

TABLE 4 Content categories of additional criteria suggested by the participants.

Categories	Frequency	Explanation	Example Quote
Deviating intake behaviour	28	Intake behaviour that deviates from prescribed intake, e.g. by independent dose increase.	"Have you independently increased CbM dose/admission frequency without consultation? [...]" (*ID 116*)
Alternative sources of supply	23	Use of cannabis from alternative sources of supply, including other medical sources and illicit sources.	"Have you obtained cannabis products from other sources? [...]" (*ID 439*)
Pharmaceutical presentation	14	Insistence on a particular pharmaceutical presentation of CbM (e.g. flowers).	"Do you exclude oral intake of cannabis for medical reasons? (or: do you insist on a prescription of cannabis in flower form?)" (*ID 66*)
Reasons for CbM intake	12	Reasons for using CbM that are not related to pain management (e.g. use for nonmedical psychoactive effect).	Do you find yourself wanting to use CbM even when you are not having significant pain. (ID 478)
Concomitant disorders	10	Concomitant disorders in addition to existing pain symptoms (e.g. trauma, anxiety, depression, psychotic symptoms).	"I would consider adding a screening question or two about psychotic symptoms." (*ID 492*)
Previous cannabis use	9	Cannabis use prior to pain management.	"Have you used CbM prior to your pain syndrome? [...]" (*ID 653*)
Insistence on CbM treatment	5	Insistence on treatment with CbM, resp. rejection of alternative treatments.	"Have you ever refused standard pain therapies because you only wanted to be prescribed cannabis medicines?" (*ID 182*)
Knowledge/behaviour associated with illicit cannabis use	3	Knowledge and behaviour associated with illicit cannabis use (e.g. drug hoarding or selling).	"Questions about knowledge of varieties, prices, cultivation, cost of cultivation." (*ID 140*)
Losing control of CbM intake	2	Compulsion to use CbM, resp. losing the ability to control the intake.	"Do you feel you have lost your ability to control your use of cannabis?" (*ID 350*)
Polytoxomania	2	Use of other substances (e.g. opioids) that the treating physician was unaware of.	"Are you using other illicit drugs while using cannabis without telling your physician?" (*ID 536*)

4.2 | Comparison with other studies

We are not aware of any other study examining the face validity of the ICD-10 criteria for substance abuse and dependence for patients prescribed CbM/MC for chronic pain. Therefore, we have referred to the appropriateness of the ICD-10 items for substance abuse and dependence for patients prescribed opioids for chronic pain to understand the perception of clinicians regarding CbM/MC. Several arguments raised by participants of the current survey as to whether some ICD-10 criteria are inappropriate in the context of patients using CbM/MC have also been previously raised for opioids: including items addressing craving and strong desire, use in larger amounts than intended and unsuccessful efforts to reduce use. In an attempt to seek symptom relief, patients may exhibit aberrant and/or problematic medication use behaviours, a phenomenon that has been described as pseudo-addiction for opioids based on a case report of possibly uncontrolled pain (Weissman & Haddox, 1989). The concept, however, remains controversial and unvalidated for chronic opioid use (Ballantyne & LaForge, 2007). One approach to address this problem is to distinguish between the need to increase the amount of product used in an effort to better manage pain compared to increase the reasons beyond symptom management, e.g. the desire to "get high" (Elander et al., 2003), also considering the need to maintain reasonable doses in long-term management. Despite the critical comments, this overall concern was generally supported in the survey by the high agreement with the item on higher amount or longer use than intended. In addition, participants suggested considering this aspect in view of trust or trustworthiness within the patient–physician relationship ("increase without consultation" and "product from other sources"). To our knowledge, there is no information about the role of craving within the context of use of CbM/MC. It is typically a symptom of cannabis withdrawal, and may indicate a higher risk of relapse in cannabis use disorder, but seems to be less pronounced than in opioid use (Bonnet & Preuss, 2017).

The understanding of items addressing recurrent use in hazardous situations or despite legal problems may be unclear to a patient driving a car or operating a machine. Guidelines on the use of CbM/MC have given recommendations under which circumstances patients prescribed CbM/MC can drive a car or operate a machine and when this activity is not recommended (Allan et al., 2018; Häuser et al., 2018).

Items addressing the continuous use despite recurrent social/interpersonal problems due to use need consideration of contextual factors such as the attitude of the patient and family members (Schlag et al., 2021). Different opinions about the use of CbM/MC for medical and/or recreational reasons can result in family conflicts without implying abuse/dependence. This is particularly relevant when CbM/MC are used with the supervision of a health care professional.

Tolerance and withdrawal are to be expected with prolonged use of prescribed centrally acting agents such as some anticonvulsants (pregabalin) or opioids (Edlund et al., 2014). It is important to avoid confusing the desire to continue taking a medication for relief of chronic symptoms which re-emerge when the drug is discontinued, with the wish to decrease symptoms associated with withdrawal (Bialas, Böttge-Wolpers, et al., 2022; Bonnet & Preuss, 2017). APA for DSM-5 and WHO for ICD-11 explicitly state that these criteria are not appropriate for individuals taking opioids under adequate medical supervision (American Psychiatric Association, 2013; World Health Organization, 2021).

Although the additional item on use of cannabis for reasons other than for pain relief was strongly supported by the participants, this item is problematic without additional specification. Observational studies have demonstrated that some chronic pain patients experience relief of symptoms beyond pain relief, e.g. relief of anxiety or sleep problems (Bialas, Fitzcharles, et al., 2022). Patient preference to continue treatment with CbM/MC for overall positive effects may have important clinical relevance. Therefore, the use of CbM/MC for relief of symptoms other than pain should not be seen as a symptom of abuse or dependence, in contrast to use for promoting euphoria. The other supported additional item on use of other substances without informing the treating physician indicates a symptom of abuse/dependence as using legal (e.g. alcohol) or illegal (e.g. cocaine) substances together with CbM/MC may achieve a psychoactive effect or "high".

4.3 | Strengths of the study

To our knowledge, this is the first study examining the face validity of the ICD-10 criteria for substance abuse and dependence for patients prescribed CbM/MC for chronic pain. In addition to capturing face validity, the mixed methods approach of the study allowed for a content analysis of reasons for disagreement with specific ICD-10 criteria and a summary of additional criteria suggested by participants.

4.4 | Limitations of the study

The participation rate was low, and we are unaware whether the participating physicians were representative of the physicians prescribing CbM/MC in their respective countries. It is not clear what caused the low participation rate. It is possible that this was a consequence of the summer vacations in the northern hemisphere, which fell during the survey period. We did not test additional items

of modified screening tools for abuse and dependence on prescribed opioids which have been used in studies on abuse and dependence for prescribed CbM/MC (Ware et al., 2018). We did not ask if participating physicians actually use the ICD-10 criteria for the diagnosis of substance dependence in patients prescribed CbM/MC for chronic pain, or which (specific) criteria they use for the diagnosis of substance dependence at all. Furthermore, we missed to ask physicians to rate the agreement level to the fact that the criteria are not originally specific for chronic pain patients under medical follow-up, although this may have been an implicit assumption.

5 | CONCLUSION

Although there was overall high agreement with the ICD criteria, criteria had varying levels of agreement and disagreement, indicating limitations of face validity in the context of use of CbM/CM. This was further highlighted by the specific comments and criticisms raised by the participants as well as the suggested additional criteria.

Criteria supplementing ICD 10/11 and DSM-5 are needed to define and diagnose abuse and dependence on prescribed centrally acting medications. The development of new criteria with collaboration of the psychiatric and pain medicine community should clarify issues of abuse and misuse when CbM/MC are used for the management of chronic pain conditions. To date, there is no specific scale to assess dependence when CbM/MC are used as a therapy. A respective questionnaire is currently in the development phase with the intention to be used in Project TWENTY21 (the largest UK registry of medical cannabis patients: https://drugscience.org.uk/project-twenty21/). It is hoped that a high number of respondents over a longitudinal timeframe will better inform the medical community of the risks and/or associations of problematic MC use in various patient populations (Schlag et al., 2021).

5.1 | Implications for future research

a. Criteria supplementing ICD-10/11 and DSM-5 are needed to define and diagnose abuse and dependence on prescribed centrally acting medications. The development of new criteria with the collaboration of the psychiatric and pain medicine community will clarify issues of abuse and misuse when CbM/MC are used for the management of chronic pain conditions.
b. As a next step in this discussion, a survey should be conducted with specialists in substance abuse and dependence, informed by the results of the current survey.
c. The development of a specific scale to assess dependence when CbM/MC are used as a therapy is needed.

5.2 | Implication for clinical practice

In the absence of a validated tool to assess abuse/misuse of CbM/MC when prescribed for patients with chronic pain, we urge physicians to be vigilant in patient care, alert to possible deviations in patient behaviour, but empathetic to patient needs.

5.3 | Implication for policy

We urge that patients should not immediately be judged as having substance abuse or dependence based on current criteria for abuse or dependence on recreational cannabis.

AUTHOR CONTRIBUTIONS

Winfried Häuser, Frank Petzke, Mary-Ann Fitzcharles, Silviu Brill and John X. Pereira designed the study. Sören Lauff and Leonie Schouten analysed the data. Winfried Häuser and Sören Lauff wrote the manuscript. All authors discussed the results and commented on the manuscript.

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The authors declare no financial conflicts with regard to the manuscript. Silviu Brill and Winfried Häuser were the heads of EFIC's task force conceptioning a position paper on cannabis-based medicines and medical cannabis for chronic pain. Frank Petzke and Winfried Häuser were members of the task force of the German Pain Society on the same topic. Mary-Ann Fitzcharles was the head of a task force of the Canadian Association of Rheumatology conceptioning a position paper on medical cannabis for rheumatic diseases.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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