

vere forms (dementia) remains unclear and not consistently developed for application in ICD-11.

- Concerning the predominantly vascular forms of neurocognitive disorders, neither the close similarity of the terms “vascular cognitive impairment” and “vascular dementia” nor the latter’s existing option for post-coordination with the detailed category of “cerebrovascular diseases” in chapter 8 are reflected in the proposal. Hence, the proposal to relocate, rename or replace vascular dementia by VCI is neither consistent with current classification principles⁶ nor ready for implementation.
- Accordingly, using the term VCI and proposing pure vascular cognitive “impairment” as a separate category is not convincing. Moreover, “vascular” as a collective term refers to very different cerebrovascular diseases, which may interact with other aetiologies, and whose role may change over lifetime. Therefore, “vascular” should not be used as a fixed combination in a broad-spectrum term like VCI, spanning several diagnostic stages and aetiologies of cognitive impairment.

Given the scientific state of the art^{3,5}, the classificatory rules of ICD-11⁶, and the existing ICD-11 classification and coding of neurocognitive disorders across chapters 6 and 8¹, the following modifications were proposed:

- For “vascular dementia”, a coding note says that “this category should never be used in primary tabulation”. By post-coordination, “6D81 Vascular dementia” optionally could already be “associated with” various “cerebrovascular diseases” from chapter 8, with “6D86 Behavioural or psychological disturbances in dementia”, and with an additional severity code. “6D80.2 Alzheimer disease dementia, mixed type, with cerebrovascular disease” already provides an opportunity to code mixed etiological forms of dementia as suggested in the above proposal. In case of multiple aetiologies, all that applies could be coded.
- For classificatory consistency, however, vascular dementia should be reformulated as “dementia due to cerebrovascular disease” following the pre-coordinated formulation (“dementia due to...”) of other dementia categories in chapter 6 and should mandatorily be post-coordinated with the respective category of cerebrovascular diseases in chapter 8.

- A related issue is the aetiological underpinning of “6D71 Mild neurocognitive disorder”. Post-coordination offers an opportunity to add as causing conditions a number of “diseases classified elsewhere”, from chapter 8 and others. However, the option for also adding “cerebrovascular diseases” or multiple conditions is missing. This should be corrected.
- Together with these proposed modifications, the current ICD-11 version of vascular related neurocognitive disorders would already allow coding for the mild and severe stages of vascular or mixed neurocognitive disorders.

In conclusion, the implementation of a new category of VCI in chapter 8 seems premature and not acceptable from the perspective of: a) the underdeveloped status of the classificatory concept of this entity, and b) its lack of adaptation to the present structure and coding options of ICD-11 neurocognitive disorders.

On October 20/21, 2018, the authors of the VCI proposal posted an agreement⁷ with the above proposals and renounced the introduction of VCI in chapter 8. After being conveyed to responsible WHO bodies, the debate’s outcome and resulting actions were officially endorsed at the WHO Family of International Classifications ICD-11 conference in Seoul.

Since December 18, 2018, the proposed changes are implemented both in the frozen and the maintenance version of ICD-11 (<https://icd.who.int/browse11/l-m/en>).

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Public stakeholders’ comments on ICD-11 chapters related to mental and sexual health

A unique strength of the development of the World Health Organization (WHO)’s ICD-11 classification of mental, behavioural and neurodevelopmental disorders has been the active input from multiple global stakeholders.

Draft versions of the ICD-11 for Morbidity and Mortality Statistics (MMS), including brief definitions, have been available

on the ICD-11 beta platform (<https://icd.who.int/dev11/l-m/en>) for public review and comment for the past several years¹. Submissions were reviewed by the WHO for the development of both the MMS version of the ICD-11 and the version for clinical use by mental health specialists, the Clinical Descriptions and Diagnostic Guidelines (CDDG)¹. Here, we summarize common

themes of the submissions for the categories that generated the greatest response.

All comments and proposals were reviewed for categories currently classified in the chapter on mental and behavioural disorders in ICD-10, although some of these have been reconceptualized and moved to new ICD-11 chapters on sleep-wake disorders and conditions related to sexual health².

Between January 1, 2012 and December 31, 2017, 402 comments and 162 proposals were submitted on mental, behavioural and neurodevelopmental disorders, sleep-wake disorders, and conditions related to sexual health. The largest number of submissions related to mental, behavioural and neurodevelopmental disorders focused on compulsive sexual behaviour disorder (N=47), complex post-traumatic stress disorder (N=26), bodily distress disorder (N=23), autism spectrum disorder (N=17), and gaming disorder (N=11). Submissions on conditions related to sexual health mainly addressed gender incongruence of adolescence and adulthood (N=151) and gender incongruence of childhood (N=39). Few submissions were related to sleep-wake disorders (N=18).

We performed qualitative content analysis to identify the main themes of submissions related to categories on which there were at least 15 comments. Thus, 59% of all comments and 29% of all proposals were coded. Submissions were independently rated by two assessors. Multiple content codes could apply to each submission. Inter-rater reliability was calculated using Cohen's kappa; only codings with good inter-rater reliability ($\kappa \geq 0.6$) are considered here (82.5%).

Compulsive sexual behaviour disorder received the highest number of submissions of all mental disorders (N=47), but often from the same individuals (N=14). The introduction of this diagnostic category has been passionately debated³ and comments on the ICD-11 definition recapitulated ongoing polarization in the field. Submissions included antagonistic comments among commenters, such as accusations of a conflict of interest or incompetence (48%; $\kappa=0.78$) or claims that certain organizations or people would profit from inclusion or exclusion in ICD-11 (43%; $\kappa=0.82$). One group expressed support (20%; $\kappa=0.66$) and considered that there is sufficient evidence (20%; $\kappa=0.76$) for inclusion, whereas the other strongly opposed inclusion (28%; $\kappa=0.69$), stressing poor conceptualization (33%; $\kappa=0.61$), insufficient evidence (28%; $\kappa=0.62$), and detrimental outcomes (22%; $\kappa=0.86$). Both groups cited neuroscientific evidence (35%; $\kappa=0.74$) to support their arguments. Few commenters proposed actual changes to the definition (4%; $\kappa=1$). Instead, both sides discussed nosological questions such as conceptualization of the condition as impulsivity, compulsivity, behavioural addiction or expression of normal behavior (65%; $\kappa=0.62$). The WHO believes that the inclusion of this new category is important for a legitimate clinical population to receive services⁴. Concerns about overpathologizing are addressed in the CDDG, but this guidance does not appear in the brief definitions available to beta platform commenters.

A number of submissions related to complex post-traumatic stress disorder supported its inclusion in ICD-11 (16%; $\kappa=0.62$),

with none explicitly arguing against inclusion ($\kappa=1$). However, several submissions suggested changes to the definition (36%; $\kappa=1$), submitted critical comments (24%; $\kappa=0.60$) (e.g., concerning the conceptualization), or discussed the diagnostic label (20%; $\kappa=1$). Several comments (20%; $\kappa=0.71$) emphasized that recognition of this condition as a mental disorder would stimulate research and facilitate diagnosis and treatment.

A majority of submissions regarding bodily distress disorder were critical, but were often made by the same individuals (N=8). Criticism mainly focused on conceptualization (48%; $\kappa=0.64$) and the disorder name (43%; $\kappa=0.91$). Use of a diagnostic term that is closely associated with the differently conceptualized bodily distress syndrome⁵ was seen as problematic. One criticism was that the definition relies too heavily on the subjective clinical decision that patients' attention directed towards bodily symptoms is "excessive". A number of comments (17%; $\kappa=0.62$) expressed concern that this would lead to patients being classified as mentally disordered and preclude them from receiving appropriate biologically-oriented care. Some contributors submitted proposals for changes to the definition (30%; $\kappa=0.89$). Others opposed inclusion of the disorder altogether (26%; $\kappa=0.88$), while no submission ($\kappa=1$) expressed support for inclusion. The WHO decided to retain bodily distress disorder as a diagnostic category⁶ and addressed concerns by requiring in the CDDG the presence of additional features, such as significant functional impairment.

Submissions concerning conditions related to sexual health showed strong support for removal of sexual dysfunctions and gender diagnoses from the mental disorders chapter and creation of a separate chapter (35%; $\kappa=0.88$)⁷. Many submissions (25%; $\kappa=0.97$) used a template message provided by the World Association for Sexual Health. Several submissions argued that retaining gender incongruence in the disease classification would harm and stigmatize transgender people (14%; $\kappa=0.80$), proposed a different phrasing of the definition (18%; $\kappa=0.71$) or a different diagnostic label (23%; $\kappa=0.62$). The WHO changed the definitions in part based on the comments received⁷.

Interestingly, a large group of submissions on the proposed ICD-11 definition for gender incongruence of childhood expressed opposition to current standards of care by explicitly objecting to social transition and gender-affirming treatment of minors (46%; $\kappa=0.72$), matters that, although important and controversial, have to do with treatment rather than with classification. The proposed definition was criticized or opposed in 31% of submissions ($\kappa=0.62$), with some using a template provided by the World Association for Sexual Health to urge a revision based on consultation from the community (15%; $\kappa=0.93$). Others opposed the diagnosis expressing fear of pathologizing childhood gender diversity (15%; $\kappa=0.93$) and claiming that it is unnecessary because there would be neither distress (11%; $\kappa=0.80$) nor need for gender-affirming health care (28%; $\kappa=0.65$) in children. Some also argued that a diagnosis is not necessary for research purposes, pointing out that research on homosexuality has flourished since its removal from the ICD (9%; $\kappa=0.745$). While acknowledging the controversies surrounding

treatment, the WHO retained the category to help ensure access to appropriate clinical care while addressing stigma through its placement in the new chapter of conditions related to sexual health as well as through additional information in the CDDG⁷.

In interpreting these comments, it is clear that many of the submissions have been made from an advocacy perspective, often focused on a particular category. It is appropriate for scientific experts to review their recommendations in the light of patient experience and feedback. The WHO has used the comments and proposals on the beta platform in combination with other sources of information, particularly developmental field studies^{8,9}, as a basis for making modifications in the MMS and CDDG.

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The controversy about cognitive behavioural therapy for schizophrenia

The effectiveness of cognitive behavioural therapy (CBT) in schizophrenia is currently disputed. For example, the UK National Institute for Health and Care Excellence (NICE)¹ recommends this therapy, whereas another influential UK organization, the Cochrane Collaboration, has argued since 2012 that there is no clear evidence that it is effective²⁻⁴.

Of clear relevance here is a network meta-analysis of psychological interventions in schizophrenia published in this journal⁵ which found pooled evidence that CBT is effective against positive symptoms. On the contrary, a 2014 meta-analysis by Jauhar et al⁶ failed to find clear evidence of effectiveness against this class of symptoms. Since it is important to understand what factors give rise to different results in meta-analyses⁷, we, as the authors of those two meta-analyses, decided to examine why such a discrepancy might have arisen.

Bighelli et al⁵'s examination of CBT for positive symptoms was based on 27 trials out of a total dataset of 40 that met their inclusion criteria (the remaining studies contained data relevant to one or more of the other outcomes they examined, e.g., overall symptoms, negative symptoms, relapse/rehospitalization, depression, quality of life, functioning and mortality). In these 27 studies, the pooled effect size was at the upper end of the small range, against both treatment as usual (-0.30; 95% CI: -0.45 to -0.14, 18 trials) and inactive control interventions (-0.29; 95% CI: -0.55 to -0.03, 7 trials). A larger effect size was found for CBT compared to supportive therapy (-0.47; 95% CI: -0.91 to -0.03, two trials). Leaving aside the findings for supportive therapy, where the number of trials was small, these findings in themselves are not greatly different from the overall effect size that Jauhar et al⁶ found for positive symptoms against all controls (-0.25; 95% CI: -0.37 to -0.13, 33 trials).

Where the two meta-analyses diverged, however, was in relation to the findings in blind trials. Bighelli et al⁵ continued to

find a significant effect against treatment as usual (-0.27; 95% CI: -0.41 to -0.13) in 15 blind trials, but not against inactive control (-0.14; 95% CI: -0.37 to 0.09), although the number of studies here was smaller (n=5). In contrast, Jauhar et al⁶ found that the pooled effect size for positive symptoms against all controls dropped to very low levels in their sub-analysis of 20 blind trials (-0.08; 95% CI: -0.18 to 0.03).

The divergent findings in blind studies did not reflect differences in the way in which criteria for blindness were applied to the trials included in the two meta-analyses. The approach used was similar, and cross-checking revealed that discrepancies about whether individual studies were rated as "blind", "non-blind" or "unclear" were trivial.

The most important difference between the two meta-analyses was found to concern the inclusion criteria used. While Jauhar et al⁶ employed a broad strategy similar to those used by NICE¹ and the Cochrane Collaboration²⁻⁴, the focus in Bighelli et al⁵'s meta-analysis was planned from the outset⁸ to be on the efficacy of psychological interventions for treating positive symptoms (the indication CBT was initially developed for). Consequently, trials carried out in patients with predominantly negative symptoms and those enrolling stable patients (i.e., relapse prevention studies) were excluded. Bighelli et al⁸ also decided to exclude studies that were carried out in first-episode patients; this was on the grounds that such studies have been found to have significantly higher treatment response rates compared with those in chronic patients.

This methodological difference turned out to be consequential. Although the number of studies of CBT included were not greatly different in the two meta-analyses (27 vs. 33), only 14 of the studies in Bighelli et al⁵ were also included by Jauhar et al⁶. This means that Bighelli et al⁵ had more studies with positive symptoms as explicit inclusion criteria (14 in Jauhar et al⁶ vs.