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Primary care physicians’ use of the proposed classification of common mental disorders for ICD-11

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Abstract

Background. The World Health Organization is revising the classification of common mental disorders in primary care for ICD-11. Major changes from the ICD-10 primary care version have been proposed for: (i) mood and anxiety disorders; and (ii) presentations of multiple somatic symptoms (bodily stress syndrome). This three-part field study explored the implementation of the revised classification by primary care physicians (PCPs) in five countries.

Methods. Participating PCPs in Brazil, China, Mexico, Pakistan and Spain were asked to use the revised classification, first in patients that they suspected might be psychologically distressed (Part 1), and second in patients with multiple somatic symptoms causing distress or disability not wholly attributable to a known physical pathology, or with high levels of health anxiety (Part 2). Patients referred to Part 1 or Part 2 underwent a structured diagnostic interview. Part 3 consisted of feedback from PCPs regarding the classification.

Results. In Part 1, anxious depression was the most common disorder among referred patients. PCPs assigned the highest severity ratings to anxious depression, and the next highest to current depression; current anxiety was rated as least severe. Considerable overlap was found between bodily stress syndrome (BSS) and health anxiety (HA). The psychiatric interview recorded higher rates of mood and anxiety disorders diagnoses among patients with BSS than did PCPs. PCPs’ satisfaction with the revised classification was high.

Conclusions. Results generally supported the inclusion of the new categories of anxious depression, BSS and HA for ICD-11 PHC and suggested that PCPs could implement these categories satisfactorily.

Key words: Anxiety, classification, depression, ICD-11, primary care, somatoform disorders.
Introduction

The World Health Organization (WHO) is preparing a revision of the International Classification of Disease and Related Health Problems, with the Eleventh Revision (ICD-11) planned for release in 2018. Revisions to the ICD-10 classification of mental disorders commonly encountered in primary care settings (1) have been proposed by a Working Group consisting of primary care physicians (PCPs) with a special interest in mental disorders, and mental health professionals engaged in training PCPs in mental health skills. The proposed primary care classification for ICD-11 mental and behavioural disorders (ICD-11 PHC) (2) consists of 27 mental disorders judged to be clinically important in primary care settings, either because they are common or because they are important for PCPs to recognize. Comments on the proposed ICD-11 PHC were invited from a wide range of experts across the world, and results from Focus Groups held with PCPs in seven countries were published in this journal (3).

Many of the proposed categories for ICD-11 PHC have been changed in only minor ways from the ICD-10 version (1), and their reliability in primary care settings has been previously evaluated (4). Field studies for ICD-11 PHC have therefore emphasized high prevalence disorders associated with substantial clinical burden in global primary care settings whose descriptions have been significantly modified. These include mood and anxiety disorders as well as complaints of multiple somatic symptoms. This paper is based on the results of a three-part field study exploring the implementation of the revised classification by PCPs in five countries. In contrast to other papers resulting from this study (5,6), the current paper focuses specifically on data related to PCPs' implementation of the proposed ICD-11 system and their evaluation of it.

Part 1 of the study focused on the application of the proposed diagnostic guidelines for anxiety, depression and anxious depression in ICD-11 PHC, including two new screening scales (5). An important proposed change, overwhelmingly supported by PCPs participating in the focus groups (3), is a distinction between depression with and without anxiety. As proposed, anxious depression is diagnosed when depression and current anxiety are both at case level and is characterized by poorer prognosis, greater severity, increased risk of suicide and greater disability associated with this form of depression (7–9). Depression (non-anxious) is diagnosed when depressive symptoms are present at case level but without significant symptoms of anxiety. Current anxiety consists of significant anxiety symptoms, but with the same duration—2 weeks—as used for depression, given that such briefer durations of anxiety predictive of subsequent psychopathology and disability (10). A diagnosis of subclinical mixed anxiety and depression can applied when significant symptoms of both anxiety and depression are present, but the diagnostic requirements for depression or current anxiety separately are not met. This pattern has been shown to be a major cause of primary care psychiatric morbidity (11).

PCPs participating in the study were provided with two 5-item scales to assess depression and anxiety derived from an earlier international study of mental disorders in general medical and primary care settings in 14 countries (12). Sensitivity of the 5-item depression scale for major depression had been found to be 90% and specificity 88.5%; sensitivity of the 5-item anxiety scale for generalized anxiety disorder had been found to be 79.8% and specificity 72.5% (12). In order to make administration as efficient as possible given the time pressures of primary care practice, each scale includes two screening questions, with three further questions to be asked if the reply to either of these is positive.

Part 2 of the study evaluated two new diagnostic constructs in ICD-11 PHC: bodily stress syndrome (BSS) and health anxiety (HA) (6). The presentation of patients with multiple symptoms not wholly explained by an identified medical condition is an important problem in primary care practice (3,13,14). For the ICD-11 PHC, a category of bodily stress syndrome (BSS) has been proposed based in large part on the work of Fink and colleagues (15,16), which emphasizes the effects of the individual's physical response to stress (e.g. chronic autonomic arousal) rather than the 'unexplained' nature of the symptoms. The Working Group saw this formulation as opening a therapeutic dialogue with patients, with less implication that they are exaggerating or imagining their symptoms. Health anxiety (HA) is a related condition, diagnosed when the patient exhibits persistent, intrusive ideas or fears of having illness or intense preoccupation with minor bodily sensations or problems that are misinterpreted as signs of serious disease. Both of these constructs had been endorsed in the focus groups (3). Participants in focus groups had also indicated that they preferred a cut-off for number of symptoms in order to diagnose BSS. A cut-off of three symptoms was used in the present study (6).

Part 3 consisted of feedback from PCPs regarding their views of the proposed classification.

As a basis for comparison with PCP ratings in Part 1 and Part 2 of the study, standardized diagnostic assessments were made using a comprehensive computerized psychiatric interview, the revised Clinical Interview Schedule (CIS-R) (17). The diagnostic algorithms in the CIS-R are based on the ICD-10, it has good psychometric properties, and it was designed for administration by lay interviewers, making it a suitable choice for the present study. In the present study, administration was computer-guided, so did not depend on the judgment or accuracy of the interviewer in following complex skip patterns or deciding which questions to ask, making for highly reliable administration. Spanish, Portuguese and Cantonese versions of the CIS-R have been validated in other studies (17–19). The Urdu version of the CIS-R was developed for the current study at the Institute of Psychiatry, Rawalpindi, Pakistan (by authors FM and BR). The diagnostic algorithms in the CIS-R were altered for the purpose of this study to reflect the changes proposed for mood and anxiety disorders for ICD-11 PHC, namely the assignment of a diagnosis of anxious depression when both anxious and depressive symptoms were at case level and had lasted for at least 2 weeks, and the reduction of the duration requirement for current anxiety to 2 weeks to match that of depression (5).

The aims of the study were: First, to test the implementation of these key parts of the classification in primary care settings, using ratings made by PCPs themselves and comparing these with diagnoses obtained using the CIS-R. Second, to establish whether PCPs were able to use a more dimensional model of these mental disorders, as proposed for ICD-11, and whether they had accurate perceptions of the disability associated with them (20). Third, to describe PCPs' evaluations of the descriptions proposed for the ICD-11-PHC.

Methods

The study took place in five different countries: Brazil (Rio de Janeiro and São Paulo), China (Hong Kong), Mexico (Zapopan), Pakistan (Rawalpindi) and Spain (Oviedo). Primary care centres included in the study were selected due to their interest and the availability of local resources and infrastructure to support their participation. The lead investigator at each study centre recruited the participating PCPs and provided them with a half-day training session using slides
prepared by WHO, allowing for questions and discussion. Research Assistants (RAs) were individuals with university degrees in psychology or social work known to the local investigators. They were also trained using slides prepared by WHO, observing a practice interview, and conducting a practice interview while being observed.

In the Part 1 of the study, participating PCPs were asked to recruit up to 30 patients they suspected of being psychologically distressed. For patients agreeing to participate in the study, PCPs administered the two 5-item scales of depression and anxiety and also made ratings of symptom severity and disability.

In Part 2 of the study, PCPs were asked to recruit up to 10 patients with three or more somatic symptoms not wholly attributable to a known physical pathology and associated with significant distress and/or disability or with high levels of health anxiety. The description of likely symptoms provided to PCPs emphasized the same clusters of symptoms that have been emphasized in studies by Fink and colleagues (15,16), but there was no requirement that at least three symptoms be present in the same body system (6).

In both Parts 1 and 2 of the study, participating PCPs rated the severity of the psychological disorder of each referred patient using a 5-point scale (from 0 for ‘no disorder present’ to 4 for ‘severe disorder’). They also rated disability related to the presenting symptoms on a 4-point scale (from 0 for ‘no disability whatever’ to 3 for ‘impaired in all activities’). In Part 2 of the study, PCPs were also asked to indicate co-occurring mood and anxiety disorder diagnoses, but were not asked to use the screening scales used in Part 1. All data collected from the PCPs for Part 1 and Part 2 of the study were recorded on a Patient Encounter Form for that part of the study.

After completion of the appropriate Patient Encounter Form by the PCP, participants were then referred the RA, who administered the computerized CIS-R (17). This was nearly always completed on the same day as the PCP evaluation, but in cases in which the patient was willing to participate in the study but did not have time to complete the CIS-R on the same day, a follow-up appointment was scheduled as close to the time of the PCP visit as possible. CIS-R diagnostic algorithms were modified as described above for anxious depression, depression (non-anxious) and current anxiety in order to be consistent with the proposals for ICD-11 PHC. The RA also administered the 12-item version of the WHO Disability Assessment Scale, Version 2.0 (WHODAS 2.0) (20).

In Part 3 of the study, PCPs were asked to complete a questionnaire regarding their views of each of the 27 disorders proposed for the ICD11-PHC, and about their experience of the revised diagnostic concepts they had been using in Parts 1 and 2. In some centres this was done in groups of six PCPs with open discussion, but in others the PCPs completed a postal questionnaire which allowed them to express their views privately.

Results

One hundred and twenty four PCPs participated in the study across the five countries.

Part 1: Patients with possible psychological distress (anxiety or depression)

In referring patients to the study, PCPs were asked to err on the side of inclusion if they were undecided whether a patient exhibited psychological distress. Of the 1854 patients referred to Part 1, 41 declined to participate, 148 did not complete the CIS-R interview and 15 had to be eliminated because of data recording problems, leaving 1650 participants (89.0%).

Table 1 shows the diagnoses made by the PCPs based on their brief evaluation, compared with diagnoses derived from the computerized CIS-R interview; anxious depression was the most common diagnosis according to both PCPs and the CIS-R. PCPs and the CIS-R agreed on ‘caseness’—that is whether or not patients were given a mood or anxiety disorder diagnosis—in 74.8% of case but there was an exact diagnostic match in only 44.9%.

Table 2 shows the PCP-assigned diagnoses in the five countries. The proportion of patients referred to the study that turned out to be cases (i.e. to have a mood or anxiety disorder diagnosis on the CIS-R) was expressed as a percentage of referrals confirmed as cases by the CIS-R (PPV in Table 2). The overall PPV was 86.6%, but varied from 68.4% in China to 97.1% in Mexico. In Brazil, Mexico and Spain, anxious depression was by far the disorder most commonly identified by PCPs, but in China current anxiety was almost as common. Anxious depression was the most common CIS-R diagnosis in all centres. In Pakistan, many of those diagnosed by the CIS-R as anxious depression were labelled by the PCP as non-anxious depression.

The CIS-R distinguishes between mild, moderate and severe depressions; severe cases of depression were significantly more likely than moderate or mild depressions to be identified by PCPs, with detection rates increasing with ascending severity: 51.1% for CIS-R cases of mild depression, 58.1% for moderate depression and 70.2% for severe depression.

We also examined the relationship between PCP-assigned diagnoses and PCP-assessed disorder severity using the 5-point severity rating (from 0 for ‘no disorder present’ to 4 for ‘severe disorder’). According to PCPs, Anxious Depression was the most severe disorder, with 64.0% of patients assigned that diagnosis considered to have a moderate or severe disorder, compared to 47.4% of those with non-anxious depression, and 22.7% of those with current anxiety. Pairwise comparisons among these proportions were all significant, using Holm correction for multiple family wise comparisons and a parameter of \( P < 0.05 \). However, the proportion of individuals who PCPs assigned a diagnosis of current anxiety that were judged to have a moderate or severe disorder was not significantly different than the proportion of referred individuals to whom PCPs assigned ‘no’ mood or anxiety disorder diagnosis that were judged to have a moderate or severe disorder (17.7%).

Part 2: Patients with multiple somatic symptoms

Part 2 of the study involved patients who met the diagnostic requirements for bodily distress disorder (BSS) or health anxiety (HA) according to their PCP’s assessment. Of the 722 patients referred to Part 2, 33 declined to participate, 48 did not meet the study entry requirements, 50 did not complete CIS-R interview and 4 were eliminated due to data recording problems, leaving 587 (81.3%) eligible for the study.

Table 3 shows the proportions of PCP-assigned diagnoses of BSS and HA among the 587 patients. Across countries, BSS and HA were found to overlap in 70.4% of cases (\( n = 413 \)), BSS occurring on its own in 24.7% of cases (\( n = 145 \)), and HA on its own in only 4.9% of cases (\( n = 29 \)). The combination of BSS and HA was less common in Brazil and China. China and Mexico had higher rates of HA alone than other countries. PCPs rated disorder severity and disability as greater in patients with BSS and HA than in patients with BSS alone. PCPs in Spain rated BSS patients as more disabled, and those in Mexico rated their patients’ disorders as more severe, than PCPs in other countries, whether or not they exhibited HA.
Table 1. PCP-assigned mood and anxiety disorder diagnoses compared to CIS-R-derived diagnoses among patients viewed by the PCP as possibly psychologically distressed (Study Part 1)

<table>
<thead>
<tr>
<th>Mood/anxiety disorder on the CIS-R</th>
<th>No mood/anxiety disorder</th>
<th>Subclinical mixed anxious depression</th>
<th>Current anxiety</th>
<th>Depression</th>
<th>Anxious depression</th>
<th>Total n</th>
</tr>
</thead>
<tbody>
<tr>
<td>No mood/anxiety disorder (n, %, [CI95%])</td>
<td>83, 37.7% [31.3%–44.2%]</td>
<td>6, 2.7% [0.6%–4.9%]</td>
<td>33, 15.0% [10.3%–19.7%]</td>
<td>14, 6.4% [3.1%–9.6%]</td>
<td>84, 38.2% [31.7%–44.6%]</td>
<td>220, 100%</td>
</tr>
<tr>
<td>Current anxiety (n, %, [CI95%])</td>
<td>87, 31.9% [26.3%–37.4%]</td>
<td>5, 1.8% [0.2%–3.4%]</td>
<td>102, 37.4% [31.6%–43.1%]</td>
<td>13, 4.8% [2.2%–7.3%]</td>
<td>66, 24.2% [19.1%–29.3%]</td>
<td>273, 100%</td>
</tr>
<tr>
<td>Depression (n, %, [CI95%])</td>
<td>56, 17.3% [13.2%–21.5%]</td>
<td>13, 4.0% [1.9%–6.2%]</td>
<td>51, 15.8% [11.8%–19.8%]</td>
<td>39, 12.1% [8.5%–15.6%]</td>
<td>164, 50.8% [45.3%–56.2%]</td>
<td>323, 100%</td>
</tr>
<tr>
<td>Anxious depression (n, %, [CI95%])</td>
<td>102, 12.2% [10.0%–14.5%]</td>
<td>21, 2.5% [1.5%–3.6%]</td>
<td>143, 17.2% [14.6%–19.7%]</td>
<td>57, 6.8% [5.1%–8.5%]</td>
<td>511, 61.3% [58.0%–64.6%]</td>
<td>834, 100%</td>
</tr>
<tr>
<td>Overall (n, %, [CI95%])</td>
<td>328, 19.9% [18.0%–21.8%]</td>
<td>45, 2.7% [1.9%–3.5%]</td>
<td>329, 19.9% [18.0%–21.9%]</td>
<td>123, 7.5% [6.2%–8.7%]</td>
<td>511, 61.3% [58.0%–64.6%]</td>
<td>834, 100%</td>
</tr>
</tbody>
</table>

For each cell, the table shows n, %, and 95% confidence intervals.

Table 2. PCP-assigned mood and anxiety disorder diagnoses among patients viewed by the PCP as possibly psychologically distressed by participating country (Study Part 1)

<table>
<thead>
<tr>
<th>Country</th>
<th>No mood/anxiety disorder</th>
<th>Current anxiety</th>
<th>Depression</th>
<th>Anxious depression</th>
<th>n, PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil (n, %, [CI95%])</td>
<td>16, 7.6% [4.0%–11.2%]</td>
<td>65, 31.0% [24.7%–37.2%]</td>
<td>32, 15.2% [10.4%–20.1%]</td>
<td>97, 46.2% [39.4%–53.0%]</td>
<td>210, 92.4%</td>
</tr>
<tr>
<td>China (n, %, [CI95%])</td>
<td>95, 31.6% [26.3%–36.8%]</td>
<td>79, 26.3% [21.3%–31.2%]</td>
<td>38, 12.6% [8.9%–16.4%]</td>
<td>89, 29.6% [24.4%–34.7%]</td>
<td>301, 68.4%</td>
</tr>
<tr>
<td>Mexico (n, %, [CI95%])</td>
<td>12, 2.9% [1.3%–4.6%]</td>
<td>53, 13.0% [9.7%–16.3%]</td>
<td>36, 8.6% [6.1%–11.6%]</td>
<td>307, 75.3% [71.0%–79.4%]</td>
<td>408, 97.1%</td>
</tr>
<tr>
<td>Pakistan (n, %, [CI95%])</td>
<td>61, 13.7% [10.5%–16.8%]</td>
<td>26, 5.8% [3.6%–8.0%]</td>
<td>185, 41.4% [36.8%–46.0%]</td>
<td>175, 39.2% [34.6%–43.7%]</td>
<td>447, 94.6%</td>
</tr>
<tr>
<td>Spain (n, %, [CI95%])</td>
<td>36, 12.7% [8.8%–16.6%]</td>
<td>50, 17.6% [13.2%–22.0%]</td>
<td>32, 11.3% [7.6%–15.0%]</td>
<td>166, 58.5% [52.7%–64.2%]</td>
<td>284, 87.3%</td>
</tr>
<tr>
<td>Overall (n, %, [CI95%])</td>
<td>220, 13.3% [11.7%–15.0%]</td>
<td>273, 16.6% [14.8%–18.3%]</td>
<td>232, 19.6% [17.7%–21.5%]</td>
<td>834, 50.6% [48.1%–53.0%]</td>
<td>1650, 86.6%</td>
</tr>
</tbody>
</table>

PPV = Positive Predictive Value, the probability that a person referred to the study was a ‘case’ according to the CIS-R.
Table 4 shows the effects of having a CIS-R depressive or anxiety disorder on PCPs’ ratings of disorder severity and disability associated with BSS, with and without HA. In both groups, the presence of a co-occurring mood or anxiety disorder was associated with higher PCP ratings of both severity and disability. The presence of ‘any’ co-occurring mood or anxiety disorder was only identified by the PCP in 47.7% of positive CIS-R cases (n = 213 out of 447).

Table 5 shows the PCP ratings of associated disability compared with scores on the WHODAS 2.0 for both Part 1 and Part 2 of the field study. The PCPs were able to use a simple dimensional rating of associated disability that was consistent with the WHODAS 2.0.

Part 3: PCPs’ opinions about the revised classification of mental disorders

Of the 124 PCPs in the total sample, 101 (84%) completed the questionnaire. The majority of participants endorsed the value all the 27 proposed categories for the classification of mental and behavioural disorders in primary care. PCPs were almost equally divided about whether anxious depression and non-anxious depression (separate 42.3%; together 40.1%). Most participants were in favour of representing BSS as a category in the ICD-11 PHC (definitely 34.5%; probably 49.8%). Nearly all participating PCPs (98.2%) described BSS as fairly or very common in primary care. Almost as many wanted HA to be represented as a separate category (definitely 23.5%; probably 46.2%). Despite the large overlap between BSS and HA described in this paper, when asked whether they should be combined, opinions were almost equally divided (separate 29.9%; together 24.5%).

Additional free text comments were provided by 18 PCPs in three countries (China, Mexico and Pakistan). The diagnostic descriptions of BSS and Anxious Depression were positively received by these participants:

Table 3. Variations among countries for the three combinations of BSS and HA, Study Part 2 (n = 587)

<table>
<thead>
<tr>
<th>Country</th>
<th>BSS alone</th>
<th>BSS and HA</th>
<th>HA alone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>33 (60%), 1.7, 1.0</td>
<td>21 (31.1%), 2.3, 1.0</td>
<td>1 (1.2%), 1.0, 0.0</td>
</tr>
<tr>
<td>China</td>
<td>32 (43.2%), 1.6, 0.9</td>
<td>31 (41.9%), 2.1, 1.3</td>
<td>11 (14.9%), 1.9, 1.0</td>
</tr>
<tr>
<td>Mexico</td>
<td>32 (18.3%), 2.6, 0.7</td>
<td>128 (73.1%), 2.7, 1.4</td>
<td>15 (8.6%), 2.2, 0.8</td>
</tr>
<tr>
<td>Pakistan</td>
<td>33 (15.4%), 2.0, 0.9</td>
<td>181 (84.6%), 2.6, 1.4</td>
<td>0</td>
</tr>
<tr>
<td>Spain</td>
<td>15 (21.7%), 2.5, 1.9</td>
<td>52 (75.4%), 2.1, 1.8</td>
<td>2 (2.9%), 1.0, 2.0</td>
</tr>
<tr>
<td>All Countries</td>
<td>145 (24.7%), 2.0, 1.0</td>
<td>413 (70.4%), 2.5, 1.4</td>
<td>29 (4.9%), 2.0, 1.1</td>
</tr>
</tbody>
</table>

Disorder severity rated on a 5-point scale from 0 for ‘no disorder present’ to 4 for ‘severe disorder’.
Disability related to the presenting somatic symptoms rated on a 4-point scale from 0 for ‘no disability whatever’ to 3 for ‘impaired in all activities’.
Superscripts indicate significant differences among means for PCP-rated severity and disability between those who do and do not have a co-occurring mood or anxiety disorder, with Bonferroni corrections for multiple comparisons, with ‘a’ indicating a significantly lower value, and ‘b’ a significantly higher value.

Table 4. Effects of having an additional CIS-R mood/anxiety disorder on both the PCP-rated severity and PCP-rated disability in cases of BSS or BSS with HA, Study Part 2 (n = 558)

<table>
<thead>
<tr>
<th>Disorder</th>
<th>BSS only</th>
<th>BSS and HA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mood or anxiety disorder</td>
<td>110 2.2b, 1.1b</td>
<td>337 2.6b, 1.5b</td>
</tr>
<tr>
<td>No mood anxiety disorder</td>
<td>35 1.5b, 0.7b</td>
<td>76 2.1b, 1.2b</td>
</tr>
</tbody>
</table>

Data for HA alone (n = 29) not shown, as numbers are too low.
Disorder severity rated on a 5-point scale from 0 for ‘no disorder present’ to 4 for ‘severe disorder’.
Disability related to the presenting somatic symptoms rated on a 4-point scale from 0 for ‘no disability whatever’ to 3 for ‘impaired in all activities’.
The superscripts indicate significant differences among means for PCP-rated severity and disability between those who do and do not have a co-occurring mood or anxiety disorder, with Bonferroni corrections for multiple comparisons, with ‘a’ indicating a significantly lower value, and ‘b’ a significantly higher value.

Table 5. PCP ratings of associated disability compared with scores on the WHO Disability Assessment Schedule (WHODAS 2.0) for both parts of the field study, Study Parts 1 and 2

<table>
<thead>
<tr>
<th>PCP ratings of disability (n, mean WHODAS 2.0 score)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No disability</td>
</tr>
<tr>
<td>Depression and/or anxiety study (Part 1, n = 1650)</td>
</tr>
<tr>
<td>BSS and/or HA study (Part 2, n = 587)</td>
</tr>
</tbody>
</table>

Superscripts indicate significant differences among mean WHODAS 2.0 scores by levels of PCP-rated disability, with Bonferroni corrections for multiple comparisons; ‘a’ indicates lowest mean; ‘d’ is highest; bold values indicate a significance level of 0.05.
This is exactly what we see clinically in the primary health care settings in Pakistan. We see a lot of somatic presentation, aches, and pains as a consequence of stressors. Health anxiety and BSS are both useful.

In our settings we see so many patients who have anxiety symptoms with depression. This new system will help in diagnosis as the patients present to us with both symptoms.

Overall, the revised classification for primary care received enthusiastic endorsement, with over half the PCPs being in favour of the inclusion of ‘all’ of the new proposed categories. According to those who provided free text responses, this was related to the perceived utility of the classification to enable identification and management of the mental health problems presented in primary care settings:

It is important to include each one of these categories in order to identify and remit to treatment (or treat by ourselves) the problems presented.

I like this classification because mental disorders are frequent but they are not taken into account as specific problems.

Among those clinicians who disagreed with some aspects of the proposed ICD-11 PHC, the main reasons were the perceived lack of validity and reliability of the diagnoses:

The whole classification is based on superficial... symptoms, in which the validity and reliability are rather low when compared with other organic medical disease, because misunderstanding and overconfidence in the operational definitions of mental illness are commonly seen in public and even within medical professionals.

Some diagnoses were considered to require a specialist in mental health both for identification and management:

There are some diagnoses that are so specific; I think they must be treated by specialists, not by first contact clinicians.

Finally, there were also comments about the need for additional therapeutic guidance, for example:

Recommended treatments and indications for special referral are useful.

Discussion
The Field Trials broadly supported the revised diagnostic guidelines as implemented in primary care settings, and feedback from the PCPs based on their experience using them was generally supportive. Based on the results of Part 1, it is clear that while the two screening tests work well as indicators for whether the patient is a ‘case’ or a non-case according to ICD-11, they are much less helpful in making exact diagnoses (Table 1). PCPs demonstrated the ability assess both severity and disability associated with these common disorders (Tables 3 to 5).

The results of Part 1 indicate that the proportion of patients referred by their PCPs because they considered these patients to exhibit distress who had diagnosable mood and anxiety disorders was quite high (86.6%). It is likely that the use of the two five item screening scales helped to alert PCPs to the presence of significant distress; this was the rationale for including many patients on the threshold for a significant psychological disorder. The two scales are especially suitable for PCPs working in low- and middle-income countries, where many patients may be unable to benefit from a printed questionnaire due to reasons of language or literacy. The relatively low rate (43.4%) of ‘exact diagnosis’ across the five countries is not surprising. The notion that mood and anxiety disorders are sharply distinct from one another is inconsistent with current evidence from primary care settings (12). In terms of clinical implications, precise distinctions among different mood and anxiety disorders are probably less important than identifying that a disorder is present. Once that is done, mood and anxiety may be most appropriately viewed as related symptom dimensions.

Two limitations require additional comment. First, Part 1 was not a prevalence study, but one that concentrated on those patients who were judged by PCPs to be experiencing psychological distress, and therefore cannot address the numbers of patients who may have been cases among those not referred to the study. Second, it is possible that some of the observed differences between the five countries are related to social and demographic differences between the samples studied. Understanding these patterns will require further study and we hope that the ICD-11 PHC will be a useful basis for such research.

In Part 2, it was shown that the overlap between BSS and HA is substantial, and indeed HA on its own is rare. The great majority (80.1%) of patients with BSS also had a mood or anxiety disorder on the CIS-R. Co-occurring mood and anxiety disorders among BSS patients were substantially under-identified by PCPs, but in Part 2 PCPs were not given the anxiety and depression screening scales to work with. Once the PCP recognized the individual as being a case of multiple somatic symptoms, it is possible that additional diagnostic options were not fully explored. At the same time, PCPs described these cases as being more severely ill and having greater disability. The co-occurrence of BSS and mood and anxiety disorders has important treatment implications given that patients are likely to reject treatments that do not address the physical symptoms they are concerned about and to be resistant to the suggestion that they have a psychological disorder. The conceptualization of BSS is intended to help address these issues in effectively treating these patients.

Conclusions
The PCPs in this study broadly supported the substantial revision of mood and anxiety disorders, BSS, and HA proposed for the ICD-11 PHC and suggested that these categories could be usefully implemented in global primary care settings. Using the proposed diagnostic guidelines for ICD-11 PHC, PCPs were able to use accurately a dimensional model of symptoms, severity, and associated disability to define cases of common mental disorders. PCPs’ evaluation of the utility of the proposed diagnostic guidelines based on their experience of using them in the study was very positive overall.

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References