

# Translation and validation of brief patient health questionnaire against DSM IV as a tool to diagnose major depressive disorder in Indian patients

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## ABSTRACT

**Context:** Depression is frequently encountered in the primary care setting but is often unrecognized and hence untreated. There is a need for a uniform user-friendly screening instrument for depression for primary healthcare personnel in India. **Aims:** Translation and validation of the brief patient health questionnaire (BPHQ) as a screening tool for depression in major Indian languages. **Materials and Methods:** This was a prospective study conducted at 18 sites, in psychiatric and general clinics. The English version of the BPHQ was translated into 11 Indian languages. The translations were reviewed by experts and volunteers and proofread for the final translated BPHQ. The validation exercise included more than 3000 subjects. A psychiatrist and a psychiatry social worker / coordinator conducted the study under the supervision of the principal investigator. For each language, the presence or absence of major depressive disorder (MDD) as diagnosed with the help of a patient-completed BPHQ and the psychiatrist DSM-IV diagnosis was matched. The kappa coefficient was used as a measure of inter-observer agreement between the two diagnostic methods. **Results:** Seven languages failed the primary validation exercise. These translations were reviewed and the updated versions, after proofreading were re-run for validation. The self-administered BPHQ was successfully translated and validated for diagnosis of MDD against DSM-IV diagnosis made by a psychiatrist, in English, Hindi, Marathi, Oriya, Malayalam, Assamese, Gujarati, Kannada, Telugu, Bengali and Tamil. **Conclusions:** BPHQ is a simple, quick and reliable instrument, which facilitates rapid and accurate diagnosis of depression in the primary care setting in our country.

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Mental disorders in primary care though common, are frequently unrecognized and thus go untreated.<sup>[1]</sup> Studies have explored the clinical presentation of common mental disorders in primary healthcare settings. Among all psychiatric disorders detected in primary care units, depressive and anxiety disorders undoubtedly constitute a large proportion.<sup>[2,3]</sup> Patients with depression, particularly those seen by primary care physicians, may report somatic symptoms, such as headache, constipation, weakness or back pain.<sup>[4,5]</sup> Some previous studies have suggested that patients in non-Western countries are more likely to report somatic symptoms than are patients in Western countries.<sup>[4,6-8]</sup> Moreover, patients from non-Western cultures and those of lower socioeconomic status are less willing or less able to express emotional distress.<sup>[4,9-11]</sup>

Despite the enormity and increasing awareness regarding psychiatric morbidity, primary care physicians often find themselves unequipped to diagnose and handle depression since they may not be adequately trained.<sup>[12,13]</sup> Several screening tools like self reporting questionnaire (SRQ), Hamilton depression rating scale (HDRS) and Beck depression inventory

(BDI) have been studied in Indian patients.<sup>[14-16]</sup> Although there have been efforts towards developing screening instruments for common mental disorders in primary care, there is a need for a uniform user-friendly screening instrument to be made available to primary healthcare personnel across most regions in India. The original Prime-MD today (primary care evaluation of mental disorders) questionnaire was accordingly designed as an effective screening tool to assist the primary care physicians.<sup>[17]</sup> The present study was aimed to provide such a screening tool for depression, by translation of the elements of the brief patient health questionnaire (BPHQ) pertaining to diagnosis of depression, (derived from Prime-MD Today) into various Indian languages and validation against a DSM-IV diagnosis arrived at by a clinical interview conducted by a psychiatrist.

## Materials and Methods

The development of the original Prime-MD Today questionnaire and also the present study in India was funded by Pfizer. The study was conducted by a group of eminent

psychiatrists -The Prime-MD study group (principal investigators of the study). The study was conducted at 18 sites, in psychiatric and general clinics. The investigator was responsible for obtaining the Ethics Committee approval at the institution. Written informed consent was obtained from each subject prior to his/her participation in the study. The protocol was developed in consultation with the Prime-MD study group. Pfizer personnel were not involved in the conduct of this exercise. The participating sites are listed in Table 1.

**Inclusion criteria:** Patients (age > 18 years) presenting with one or more of the following: Tiredness or weakness for > two weeks, multiple aches and pains without any obvious underlying organic causality, sleep disturbance for > two weeks, feeling down or worthless or recent noticeable weight change.

**Exclusion criteria:** Major medical disease or severe symptoms requiring immediate medical attention, pharmacotherapy which may alter patient's responses, e.g., hypnotics, any psychotropic medication, any cognitive deficits or mental retardation.

The exercise was carried out for the following languages: Assamese, Bengali, Gujarati, Hindi, Kannada, Malayalam, Marathi, Oriya, Punjabi, Tamil, Telugu and Urdu. The validation was also carried out for the English version of the BPHQ.

**Translation:** The English version of the BPHQ was translated into Indian languages by experienced translators affiliated to a major translator bureau (Bhasha Bharati). The relevant

translation was reviewed by healthcare professionals, including a psychiatrist, familiar with the local language at each site. The questionnaire was also administered to 10 nonpatient volunteers at each site and their input on understandability of language obtained. The site provided comprehensive feedback on the BPHQ which was discussed with the translator and appropriate modifications incorporated into the BPHQ. This was back translated to ensure intact content. This BPHQ was then reviewed and proofread by a different translator for the final translated BPHQ. The translation process is depicted in Figure 1.

### Validation

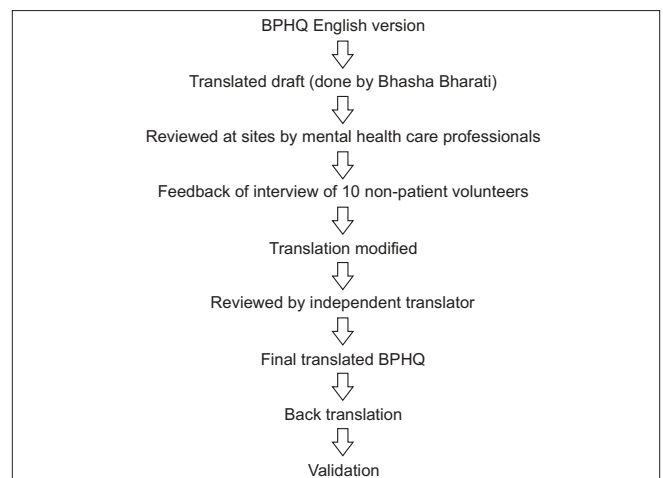
The validation exercise included approximately 300 subjects for each language. A psychiatrist and a psychiatry social worker / coordinator conducted the study under the supervision of the principal investigator. Subjects presenting to the general / medical and psychiatry outpatient clinics fulfilling the eligibility criteria were selected for further evaluation on obtaining consent. The subjects then completed the BPHQ and their response documented. In the event that the subject was illiterate, the BPHQ was read out to them without any modifications / explanations to the questionnaire. Subsequently they were referred to the study psychiatrists who were blinded to the results of the BPHQ. The psychiatrist conducted a detailed clinical interview and arrived at a DSM-IV diagnosis if relevant. This completed the study requirement for each subject and they were referred to the appropriate clinic for further follow-up or treatment. The BPHQ diagnosis and psychiatrist interview diagnosis were compiled for each subject by the coordinator. The validation process is depicted in Figure 2.

### Statistical analysis

For each language, the presence or absence of a major depressive disorder (MDD) as diagnosed with the help of a patient-completed BPHQ and the psychiatrist DSM-IV diagnosis was matched. Kappa coefficient was used as the measure of agreement between the two diagnostic methods. The kappa statistic measures agreement above and beyond that expected by chance alone. The sample size calculation was

**Table 1: List of participating sites**

Site	Language
Christian Medical College, Vellore	Tamil
Chhatrapati Shahuji Maharaj Medical University (Upgraded King George's Medical College), Lucknow	Hindi
Kasturba Hospital, Manipal	Kannada
B.J. Medical College and Civil Hospital, Ahmedabad	Gujarati
King Edward Memorial Hospital, Mumbai	English, Marathi, Hindi and Gujarati
Postgraduate Institute of Medical Education and Research, Chandigarh	Punjabi
K.S. Hegde Medical Academy, Mangalore	Malayalam, Kannada
Mental Health, SCB Medical College, Cuttack	Oriya
Guwathi Medical College Hospital, Assam	Bengali and Assamese
Institute of Mental Health, Vishakhapatnam	Telugu
Institute of Psychiatry, Kolkata	Bengali
R.G. Kar Medical College and Hospital, Kolkata	Bengali
Medical College and Hospital, Kolkata	Bengali
Clinic M, Kolkata	Bengali
Anantagram Hospital, Kolkata	Bengali
Institute of Mental Health, Hyderabad	Urdu
All India Institute of Medical Sciences, New Delhi	English, Punjabi
Madras Medical College and Government General Hospital, Chennai	Tamil



**Figure 1: Translation methodology**

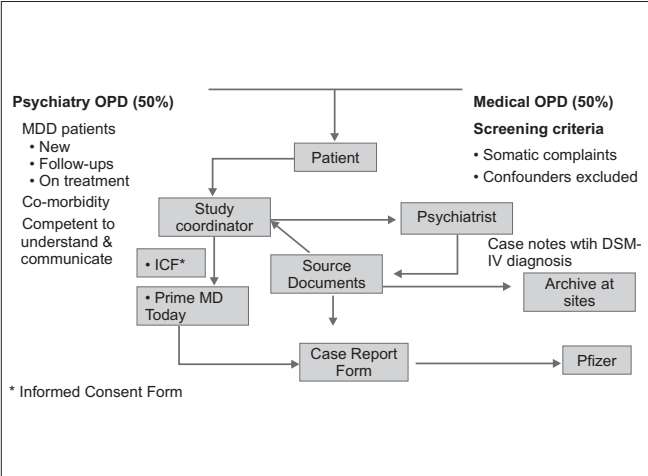


Figure 2: Validation methodology

based on the measure Kappa for MDD. It was expected that in the selected population of subjects who satisfied the eligibility criteria, the prevalence of depression would be around 50%. Based on the results in the PHQ Primary Care study,<sup>[1]</sup> it was expected that the Kappa would be around 0.6. To estimate the value of kappa in the population within an error of  $\pm 0.1$  with 95% confidence and 80% power, a sample of size 246 was required for each of the languages considered. To ensure that data for at least 246 subjects would be available, 300 subjects were enrolled for each language.

A Kappa coefficient of  $< 0.5$  was considered inadequate to confirm agreement between the two modalities of diagnosis irrespective of the sensitivity, specificity and overall accuracy. The analysis was carried out independently for each language. Other descriptive statistics such as sensitivity, specificity and overall accuracy were calculated. Data management was done independently by the Biometrics Division, Pfizer.

Results

The results of the validation exercise for all the languages are detailed in Table 2. The sensitivity, specificity, overall accuracy and the kappa coefficient of agreement of the BPHQ instrument in comparison to psychiatrist DSM-IV diagnosis are tabulated.

Seven languages namely Hindi, Gujarati, Kannada, Telugu, Bengali, Tamil and Punjabi failed the validation exercise. These translations (except Punjabi) were reviewed and language modifications were made in consultation with site personnel and local language experts, enhancing comprehension. The updated versions, after review and proofreading were taken up for a re-run of the validation exercise. The results of the validation exercise on the updated BPHQ instruments in Hindi, Gujarati, Kannada, Telugu, Bengali and Tamil are tabulated in Table 3.

The languages in which the BPHQ instrument was successfully validated are listed in Table 4. The validation exercise was unsuccessful for Punjabi and Urdu languages.

Table 2: Results of validation of brief patient health questionnaire (original translations)

Major depressive disorder - Original translations of brief patient health questionnaire					
Language	Total no. of subjects	Kappa coefficient	Sensitivity	Specificity	Overall accuracy
Assamese	251	0.715	0.8629	0.8947	0.8725
Bengali	300	0.8065	0.8065	0.5926	0.3437
English	306	0.6048	0.7905	0.8309	0.8170
Gujarati	298	0.3577	0.6260	0.7305	0.6846
Hindi	299	0.1469	0.2110	0.9158	0.6589
Kannada	299	0.4239	0.7692	0.7285	0.7391
Malayalam	297	0.5066	0.4776	0.9609	0.8519
Marathi	299	0.9465	0.9795	0.9673	0.9732
Oriya	299	0.5904	0.9524	0.6705	0.7893
Punjabi	319	0.6842	0.6842	0.7268	0.3951
Tamil	407	0.5676	0.5676	0.8888	0.4789
Telugu	299	0.4808	0.6667	0.9182	0.8953
Urdu	Inadequate subjects	NA	NA	NA	NA

Table 3: Results of validation of brief patient health questionnaire (revised translations)

Major depressive disorder - Revised translations of brief patient health questionnaire					
Language	Total no. of subjects	Kappa coefficient	Sensitivity	Specificity	Overall accuracy
Bengali	208	0.5157	0.9179	0.5675	0.7932
Gujarati	199	0.6628	0.9379	0.7037	0.8744
Hindi	283	0.9174	0.9955	0.9048	0.9753
Kannada	188	0.7584	0.9059	0.8641	0.8830
Tamil	261	0.6392	0.8661	0.7731	0.8238
Telugu	249	0.5504	0.8806	0.7637	0.7952

Table 4: Languages in which brief patient health questionnaire validation was successful

Languages	Validated brief patient health questionnaire - Version date
Assamese	August 2002
Bengali	July 2003
English	August 2002
Gujarati	September 2003
Hindi	February 2003
Kannada	February 2003
Malayalam	February 2003
Marathi	August 2002
Oriya	August 2002
Tamil	May 2003
Telugu	February 2003

Discussion

The present study successfully translated and validated the BPHQ in 11 languages as a tool to assist the physicians for diagnosing depression [Figure 3]. In developing countries such as India, major depression is projected to become the leading cause of disease burden by 2020. Although epidemiological data from large, well-conducted prevalence studies is lacking,


<b>Assessment of Depression</b> <b>9 symptoms (a - i)</b> 				
<b>Over the <u>last 2 weeks</u>, how often have you been bothered by any of the following problems?</b>	<b>Not at all</b>	<b>Several days (less than half the days)</b>	<b>More than half the days</b>	<b>Nearly every day</b>
<b>a. Little interest or pleasure in doing things</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>b. Feeling down, depressed, or hopeless</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>c. Trouble falling or staying asleep, or sleeping too much</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>d. Feeling tired or having little energy</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>e. Poor appetite or overeating</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>f. Feeling bad about yourself, or that you are a failure, or have let yourself or your family down</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>g. Trouble concentrating on things, such as reading the newspaper or watching television</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>h. Moving or speaking so slowly that other people could have noticed. Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>i. Thoughts that you would be better off dead, or of hurting yourself in some way</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Diagnosis of MDD to be made if answers to a or b and five or more of a - i are at least "more than half the days" (count i if presents at all)</b>				

Figure 3: Brief patient health questionnaire (English)

depression is thought to be quite common throughout India. A cross-cultural study conducted by WHO to study the prevalence of mental disorders in primary care settings estimated the prevalence of depression in Bangalore to be 9.1%.<sup>[4]</sup> Extrapolating this to the population of India, the number is overwhelming. Thus, to maximize healthcare benefits, a combined effort from both psychiatrists and physicians would be desirable. Moreover, depressed patients commonly approach the physicians first, before seeking a psychiatric opinion. Diagnosing depression is the primary step in this context that requires adequate understanding of the presenting symptoms.

The original Prime MD Today questionnaire was accordingly designed as an effective screening tool to assist the primary care physicians.<sup>[17]</sup> The Prime MD Today consists of a Patient Health Questionnaire (PHQ) and a BPHQ. The PHQ is a four-page questionnaire which helps to assess depression, anxiety, alcohol, somatoform and eating disorders in addition to psychosocial stressors and women's reproductive health. The BPHQ is a one-sheet questionnaire which helps to assess

depression and panic disorders.<sup>[1]</sup> Prime MD Today has been developed keeping in mind the needs of busy clinicians. It is a simple, quick and reliable instrument, which facilitates rapid and accurate diagnosis of depression. This instrument also finds mention in reputed textbooks such as Harrison's Principles of Internal Medicine<sup>[18]</sup> and Kaplan and Sadocks Comprehensive Textbook of Psychiatry.<sup>[19]</sup>

Internationally, Prime MD Today is available in English, Spanish, Greek, Italian and Vietnamese. To address the diversity in language and to suit the local needs, this study translated and validated the nine questions of the BPHQ pertaining to depression (PHQ-9), in a number of Indian regional languages with high sensitivity, specificity and accuracy. Patient questionnaires were translated in all major regional languages [Hindi, Marathi, Gujarati, Tamil, Malayalam, Kannada, Bengali, Oriya, Punjabi, Telugu and Assamese]. Each of these languages (including the English version) had been validated in approximately 300 patients per language leading to a total of >3000 patients.

In the first attempt the validation exercise failed in seven out of 11 languages. On further review and analysis, the following factors were determined to have contributed to the variation in accuracy for various languages. The profile of patients may have contributed to the discrepancy between Kappa values for various languages. The accuracy was higher in languages that were validated in metro cities and this could be due to the awareness and ease of responding to such questionnaires.

Secondly, in terms of the language of the translation, the Hindi and Marathi language translations were reviewed and it was observed that the Hindi translation included qualifiers, which were missing in the English (original) and Marathi version. The language used though technically accurate was complex and sometimes difficult to understand. The BPHQ translations not being simple enough for the local population was a possibility. The language of these questionnaires was modified and simplified while maintaining the integrity and content of the questions.

The BPHQ is simple because patients themselves can fill in the questions. It is quick since the primary care physician (PCP) takes less than three minutes to review the filled-in questionnaire and make a diagnosis of MDD. It is reliable as it has been field tested and validated in more than 3300 patient samples. The result of the validation study shows high sensitivity (ability to detect true positive cases of MDD) and specificity (ability to detect true negative cases of MDD). The entire exercise was accomplished over two years. Subsequently, workshops have been conducted across the country by psychiatrists to train the PCPs regarding the use of the tool.

One of the limitations of this study is the inclusion of patients both from the general OPDs as well as psychiatry clinics. However conducting this exercise exclusively in a primary care setting would have made the logistics for the validation process against a detailed psychiatric interview extremely difficult, thus requiring its conduct in multidisciplinary institutes. Another limitation is lack of using standardized instruments (e.g., SCID or CIDI) for the diagnostic interview. This can be justified on the grounds that the aim of this exercise was to validate this questionnaire against an accepted form of clinical diagnosis in the real world setting by psychiatrists in India. The principal investigators in this study were experienced senior psychiatrists from renowned institutions having academic as well as research backgrounds.

Future research directions could be targeted towards employing this instrument in the field/primary care setting and comparing the results against a standardized diagnostic instrument. Another exercise could be using this instrument to assess the prevalence of MDD in various outpatient settings like diabetic and pain clinics. Moreover, it could also be studied for its utility as a prognostic tool to assess improvement following antidepressant medication over time.

The BPHQ should be administered to patients in whom underlying depression is suspected or to those complaining of recurrent somatic symptoms without any biological basis. The

instrument can also be administered to patients with chronic disorders such as stroke, myocardial infarction and diabetes mellitus. It is estimated that MDD exists in 36% of patients with coexistent medical conditions and may be more common in hospitalized and elderly patients.<sup>[20]</sup>

## Conclusion

The self-administered BPHQ has been successfully translated and validated for diagnosis of MDD against DSM-IV diagnosis made by a psychiatrist, in the following Indian languages: Hindi, Marathi, Oriya, Malayalam, Assamese, Gujarati, Kannada, Telugu, Bengali, English and Tamil. It offers great utility as a brief, simple and effective screening tool for depression in the primary care setting in our country.

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## Annexure

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