Utility of a New Procedure for Diagnosing Mental Disorders in Primary Care

The PRIME-MD 1000 Study

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Objective.—To assess the validity and utility of PRIME-MD (Primary Care Evaluation of Mental Disorders), a new rapid procedure for diagnosing mental disorders by primary care physicians.

Design.—Survey; criterion standard.

Setting.—Four primary care clinics.

Subjects.—A total of 1000 adult patients (369 selected by convenience and 631 selected by site-specific methods to avoid sampling bias) assessed by 31 primary care physicians.

Main Outcome Measures.—PRIME-MD diagnoses, independent diagnoses made by mental health professionals, functional status measures (Short-Form General Health Survey), disability days, health care utilization, and treatment/referral decisions.

Results.—Twenty-six percent of the patients had a PRIME-MD diagnosis that met full criteria for a specific disorder according to the *Diagnostic and Statistical Manual of Mental Disorders, Revised Third Edition.* The average time required of the primary care physician to complete the PRIME-MD evaluation was 8.4 minutes. There was good agreement between PRIME-MD diagnoses and those of independent mental health professionals (for the diagnosis of any PRIME-MD disorder, κ=0.71; overall accuracy rate=88%). Patients with PRIME-MD diagnoses had lower functioning, more disability days, and higher rates of health care utilization than did patients without PRIME-MD diagnoses (for all measures, $P<.005$). Nearly half (48%) of 287 patients with a PRIME-MD diagnosis who were somewhat or fairly well-known to their physicians had not been recognized to have that diagnosis before the PRIME-MD evaluation. A new treatment or referral was initiated for 62% of the 125 patients with a PRIME-MD diagnosis who were not already being treated.

Conclusion.—PRIME-MD appears to be a useful tool for identifying mental disorders in primary care practice and research.

(*JAMA.* 1994;272:1749-1756)

MENTAL disorders result in substantial patient suffering, disability, and health care costs[1-3] and are present as a primary or associated condition in at least 20% of primary care outpatients.[4-6] In fact, more patients with mental disorders are cared for in the primary care sector than in the mental health sector.[7-9] However, studies have consistently shown that primary care physicians (PCPs) in office settings fail to diagnose and treat 50% to 75% of patients suffering from common mental disorders.[4,5,10-12] Major obstacles to the recognition of mental disorders by PCPs include inadequate knowledge of the diagnostic criteria, uncertainty about the best questions to ask to evaluate whether those criteria are met, and time limitations inherent in a busy office setting.[13]

This article describes the validation of a new procedure designed to overcome these obstacles, thereby facilitating the rapid and accurate diagnosis of the most common mental disorders seen in primary care. The instrument is called PRIME-MD (an acronym for Primary Care Evaluation of Mental Disorders) and is a standardized but brief and easy diagnostic assessment procedure designed for the busy clinician and the primary care researcher.

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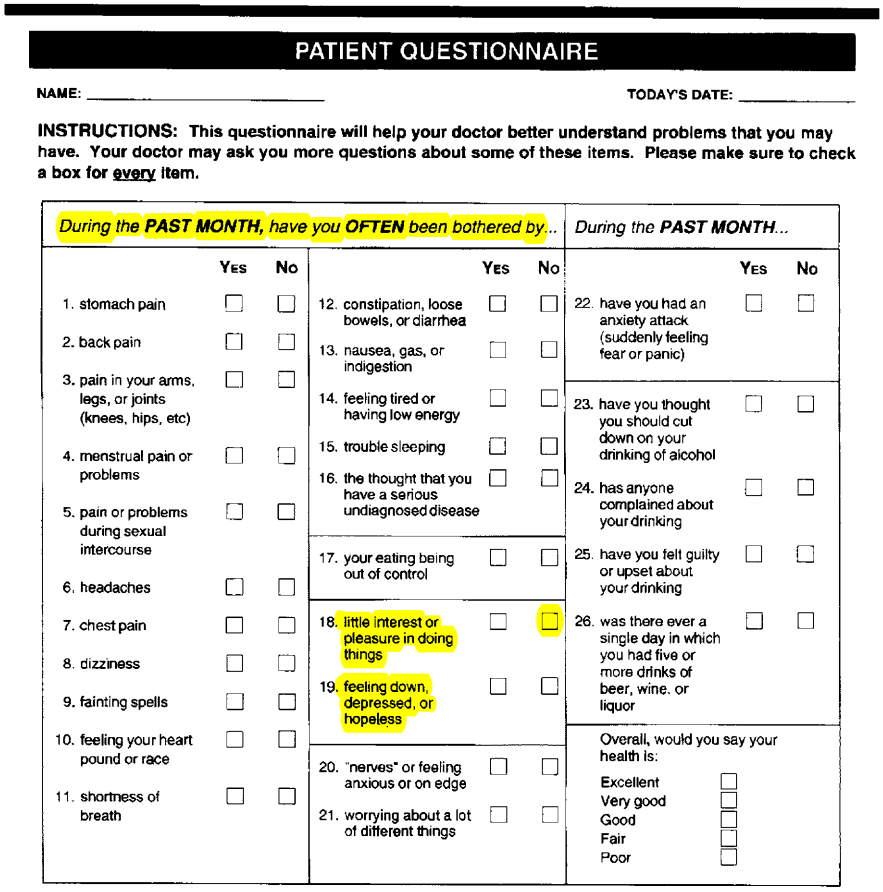
DESCRIPTION OF PRIME-MD

PRIME-MD evaluates the four groups of mental disorders (mood, anxiety, somatoform, and alcohol) most commonly encountered in the general population and primary care settings[14,15] and eating disorders, which have more recently been shown to be common in the general population.[16,17] PRIME-MD has two components: a one-page patient questionnaire (PQ) (Figure 1) that is completed by the patient before seeing the physician and a 12-page clinician evaluation guide (CEG), a structured interview form that the physician uses to follow up on positive responses on the PQ.

The PQ serves as an initial symptom screen for the mental disorders covered by the CEG evaluation. It consists of 26 yes/no questions about symptoms and signs present during the past month, divided into the five diagnostic areas just listed, plus one question about the patient's overall health. Patient responses to the PQ indicate to the physician which, if any, of the five diagnostic modules in the CEG should be used. The first 16 items on the PQ cover 15 physical symptoms that constitute the majority of physical complaints in primary care (excluding upper respiratory symptoms)[18,19] and one item to screen for hypochondriasis; three or more positive responses direct the physician to the somatoform module of the CEG. A single item screens for the eating disorder module, while one of two depressive symptoms triggers the mood module, and at least one of three anxiety symptoms triggers the anxiety module. These items were developed from the criteria for eating, mood, and anxiety disorders in the American Psychiatric Association's[20] *Diagnostic and Statistical Manual of Mental Disorders, Revised Third Edition* (*DSM-III-R*). Finally, at least one of four alcohol items trigger the alcohol module; three of these items about alcohol use are taken from a well-known screening instru-



PATIENT QUESTIONNAIRE

NAME: _____ TODAY'S DATE: _____

INSTRUCTIONS: This questionnaire will help your doctor better understand problems that you may have. Your doctor may ask you more questions about some of these items. Please make sure to check a box for every item.

During the ***PAST MONTH,*** *have you* ***OFTEN*** *been bothered by...*

	Yes	No
1. stomach pain	☐	☐
2. back pain	☐	☐
3. pain in your arms, legs, or joints (knees, hips, etc)	☐	☐
4. menstrual pain or problems	☐	☐
5. pain or problems during sexual intercourse	☐	☐
6. headaches	☐	☐
7. chest pain	☐	☐
8. dizziness	☐	☐
9. fainting spells	☐	☐
10. feeling your heart pound or race	☐	☐
11. shortness of breath	☐	☐
12. constipation, loose bowels, or diarrhea	☐	☐
13. nausea, gas, or indigestion	☐	☐
14. feeling tired or having low energy	☐	☐
15. trouble sleeping	☐	☐
16. the thought that you have a serious undiagnosed disease	☐	☐
17. your eating being out of control	☐	☐
18. little interest or pleasure in doing things	☐	☐
19. feeling down, depressed, or hopeless	☐	☐
20. "nerves" or feeling anxious or on edge	☐	☐
21. worrying about a lot of different things	☐	☐

During the ***PAST MONTH...***

	Yes	No
22. have you had an anxiety attack (suddenly feeling fear or panic)	☐	☐
23. have you thought you should cut down on your drinking of alcohol	☐	☐
24. has anyone complained about your drinking	☐	☐
25. have you felt guilty or upset about your drinking	☐	☐
26. was there ever a single day in which you had five or more drinks of beer, wine, or liquor	☐	☐

Overall, would you say your health is:

- Excellent ☐
- Very good ☐
- Good ☐
- Fair ☐
- Poor ☐

Figure 1.—PRIME-MD (Primary Care Evaluation of Mental Disorders) one-page patient questionnaire that is completed by the patient before seeing the physician (copyright held by Pfizer Inc, but may be photocopied ad libitum).

ment for alcohol dependence, the CAGE.[21]

The CEG can be administered at any time during the patient encounter, after the reason for the patient's visit is addressed. Using the CEG, the clinician determines the presence or absence of 18 possible current mental disorders (Table 1) in the five broad diagnostic categories by asking specific questions based on the diagnostic criteria (often simplified for primary care use) contained in *DSM-III-R*. Of the 18 diagnostic categories in the PRIME-MD system, nine correspond to specific *DSM-III-R* diagnoses: major depressive disorder, partial remission or recurrence of major depressive disorder, dysthymia, panic disorder, generalized anxiety disorder, bulimia nervosa, multisomatoform disorder (a severe form of *DSM-III-R* undifferentiated somatoform disorder), somatoform pain disorder, and hypochondriasis.

An additional six PRIME-MD diagnoses are considered "subthreshold" because the criteria encompass fewer symptoms than are required for any specific *DSM-III-R* diagnosis. These subthreshold diagnoses are included because psychiatric symptoms below diagnostic threshold in these areas are associated with considerable functional impairment[17,22-24] and because patients with these disorders may benefit from monitoring or treatment. The disorders include anxiety disorder not otherwise specified (NOS), eating disorder NOS, and somatoform disorder NOS, as well as minor depressive disorder and binge eating disorder. Alcohol abuse/dependence is also grouped as a subthreshold diagnosis and is made only as a probable diagnosis because further confirming information is often required.

Finally, three rule-out (R/O) diagnoses are added to qualify another mood or anxiety disorder: R/O bipolar disorder; R/O depressive disorder due to physical disorder, medication, or drug; and R/O anxiety disorder due to physical disorder, medication, or drug. In some cases, more than one diagnosis can be made within a single module, such as major depressive disorder and dysthymia within the mood module. The final diagnostic findings are recorded on a summary sheet that can be included in the patient's chart.

PRIME-MD is designed to be used flexibly. For example, it can be used routinely with all new patients or only with patients in whom mental disorders are suspected or whose management is difficult. In addition, all CEG modules triggered by the PQ can be used or only those CEG modules of particular interest, such as the mood and anxiety modules. Finally, physicians may choose to use a CEG module even if not triggered by the PQ if other information suggests it may be clinically appropriate.

An earlier 8-month development phase that included 450 patients at seven primary care sites involved weekly conference calls among the investigators during which they reviewed their experience using the procedure. Throughout this process revisions were made in the PQ items and the CEG questions, resulting in the final instrument that was tested in the current study.

STUDY PURPOSE

Our major purpose was to test the utility and validity of the PRIME-MD system in a demographically heterogeneous sample of primary care patients by answering the following questions:

1. Are the frequencies of mental disorders found by PRIME-MD comparable with those obtained in other primary care samples using structured but much longer diagnostic interview schedules administered by mental health professionals (MHPs)?
2. What is the average amount of time required by the PCP to complete the PRIME-MD evaluation?
3. To what extent do PCPs, using PRIME-MD, make diagnoses that agree with those made independently by MHPs?
4. Do patients with PRIME-MD mental disorders have significant functional impairment and greater health care utilization compared with patients without PRIME-MD diagnoses?
5. Is there a substantial relationship between physician-generated PRIME-MD diagnoses of mood, anxiety, and somatoform disorders and the patient scores on corresponding self-rated symptom severity scales?
6. Does the use of PRIME-MD increase recognition of mental disorders among PCPs?
7. Do PCPs find the information obtained with PRIME-MD of value in understanding and treating their patients, and does this affect clinical practice in terms of treatment and management?
8. Are patients comfortable having their PCPs ask them questions about psychological symptoms, and do they believe their answers will be helpful to their physicians in understanding and treating their problems?

METHODS

Sites and Selection of Subjects

The study was conducted at four pri-

mary care sites: New England Medical Center General Medical Associates, Boston, Mass (hospital-based group practice), Bronx (NY) Municipal Hospital Center of the Albert Einstein College of Medicine (city hospital clinic), Walter Reed Army Medical Center General Medicine Clinic, Bethesda, Md (for both active-duty and retired military personnel and their families), and the University of South Alabama College of Medicine, Mobile (family practice clinic). The study protocol was approved by the institutional review boards of each site, and each patient gave signed, informed consent.

We judged that to have fairly stable numbers for relatively rare disorders whose frequency during the developmental phase was approximately 4%, it would be useful to have a total sample size of 1000 patients. Therefore, from January 1992 to March 1993, 1360 patients who presented to the centers for medical care were approached to obtain 1000 patients with complete PRIME-MD diagnostic data. Reasons for nonparticipation were (1) already evaluated with PRIME-MD during the developmental phase (8%; n=109); (2) not providing informed consent (7%; n=89); (3) unable to speak English (6%; n=81); (4) too ill or frail (4%; n=53); (5) physician not available (1%; n=19); (6) age younger than 16 years (<1%; n=5); and (7) too demented (<0.1%; n=4).

The first 369 patients were selected by convenience but independently of the participating physicians' suspecting or knowing that a patient had any psychopathology. The remaining 631 patients were selected using site-specific methods to avoid sampling bias (New England Medical Center: all patients during a selected clinic session; Bronx Municipal Hospital Center: every third patient until physician's quota reached; Walter Reed Army Medical Center: consecutive patients during a selected session until physician's quota reached; and University of South Alabama: two consecutive patients per session, the first one chosen randomly from among the first five patients).

Data Collection

Patients.—Before seeing their physician, all patients completed the PQ. Physicians reviewed the PQ and administered all CEG modules triggered by the PQ. To evaluate whether patients with PRIME-MD diagnoses had significant functional impairment and greater utilization of health care resources and whether their PRIME-MD diagnoses corresponded with self-assessment symptom severity, all patients who entered the study were also given a seven-page validation questionnaire that included several items regarding health care utilization and disability days during the past 3 months, as well as the following standard rating scales: the Medical Outcomes Study Short-Form General Health Survey (SF-20),[25] the Zung Depression Scale,[26] the Zung Anxiety Scale,[27] and the Somatic Symptom Inventory.[28] The SF-20 measures functional status in six dimensions (all scored from 0 to 100; 100=best health), while the other measures each provide single-summary scores of symptom severity in their respective domains.

Table 1.—Prevalence of Psychiatric Disorders Detected by PRIME-MD in 1000 Primary Care Patients*

Mental Disorder	Total Sample, No. (%)	Site Range, %
Any psychiatric diagnosis	386 (39)	30-52
Any threshold diagnosis	257 (26)	18-38
Subthreshold only	129 (13)	10-14
Any mood disorder	260 (26)	19-35
Major depressive disorder	115 (12)	7-19
Dysthymia	78 (8)	5-15
Partial remission or recurrence of major depressive disorder	63 (6)	4-9
Minor depressive disorder	64 (6)	2-9
Rule out depressive disorder due to physical disorder, medication, or other drug	24 (2)	2-4
Rule out bipolar disorder	8 (1)	<1-1
Any anxiety disorder	178 (18)	10-25
Anxiety disorder not otherwise specified	90 (9)	7-13
Generalized anxiety disorder	70 (7)	2-13
Panic disorder	36 (4)	1-6
Rule out anxiety disorder due to physical disorder, medication, or other drug	19 (2)	1-3
Any somatoform disorder	139 (14)	9-29
Multisomatoform disorder	82 (8)	4-18
Somatoform disorder not otherwise specified	42 (4)	2-9
Hypochondriasis	22 (2)	<1-5
Somatoform pain disorder	8 (1)	1-1
Probable alcohol abuse/dependence	51 (5)	3-7
Any eating disorder	32 (3)	1-7
Binge eating disorder	30 (3)	1-7
Bulimia nervosa	1 (<1)	0-<1
Eating disorder not otherwise specified	1 (<1)	0-<1

*PRIME-MD indicates Primary Care Evaluation of Mental Disorders.

Physicians.—A total of 31 PCPs (seven to nine per site) participated in the study (including four of the authors). Their mean age was 40 years (SD, ±9.1 years), 60% were male, and the average number of years of practice since residency was 10 (SD, ±9.5 years). At three of the sites (76% of the 31 physicians), all were trained in internal medicine; at the University of South Alabama, all were trained in family practice. Eighty percent judged their interest in mental disorders to be greater than that of colleagues of similar age and training. All physicians had participated in a 1- to 3-hour training session with PRIME-MD, led by the authors. These training sessions did not include any discussion of the therapeutic or management implications of a PRIME-MD diagnosis.

The physicians answered study questions on all patients about the following: the time that they started and completed the CEG, how well they knew the patient ("not at all," "somewhat," or "fairly well"), their knowledge of any current mental disorders (answered before looking at the patient's PQ), types of current physical disorders (hypertension, heart disease, diabetes, liver disease, renal disease, arthritis, pulmonary disease, cancer, or other), and if the CEG was administered, the physician's judgment about the value of PRIME-MD for understanding and treating the patient. Midway through the study, for patients who were administered the CEG, another question was added about current and planned treatments or referrals for mental disorders.

Mental Health Professionals.—To determine agreement of PRIME-MD diagnoses with those of MHPs, midway through the study an MHP (a PhD clinical psychologist or a senior psychiatric social worker) attempted to reinterview by telephone all subsequently entered subjects from three of the four sites (for administrative reasons, New England Medical Center was unable to participate in this substudy). Of the 539 patients who were candidates for reinterview, 431 completed the reinterview. Reasons for nonparticipation were (1) unable to be reached by telephone within 48 hours (8%; n=44); (2) not providing informed consent for a reinterview (5%; n=29); (3) too ill, hard of hearing, or other communication problem during telephone call (4%; n=20); and (4) no telephone (3%; n=15). The telephone interviewer was blinded to the results of

the patient's PQ and whether a CEG had been administered. Reinterview by telephone was used because of its convenience and demonstrated comparability with face-to-face research interviews.[29,30] The semistructured telephone interview included many of the questions and diagnostic criteria found in the CEG but did not assess somatoform disorders because the telephone interviewer did not have information about the physical examination and any laboratory tests to judge whether endorsed physical symptoms had an adequate physical explanation. The telephone interview also included several open-ended questions about overall functioning, mood, recent stressors, and problems at work or with family to reveal psychopathology that might not be elicited by the more structured and limited CEG. These questions were taken from the Structured Clinical Interview for *DSM-III-R* (SCID),[31] and as in the standard administration of the SCID, the mental health interviewer was specifically encouraged to explore any ambiguous responses. After completing the evaluation for psychopathology, the interviewer asked the patient further questions to determine if the CEG had been administered by their physician. If yes, the telephone interview concluded with two questions: one about how comfortable he or she felt answering the questions asked by their physician as part of the CEG, and a second about how valuable he or she thought the CEG questions were in understanding and determining therapy for their problems.

Missing Data

Approximately 8% of the items on the patient validation study questionnaires and 3% of the CEG nondiagnostic items were not completed. For each SF-20 scale, as recommended by the scale authors, and for the three symptom severity scales, total scores were estimated if information was available for more than 60% of the scale items; this resulted in missing data on 7% to 12% of the subjects for the different scales. Analysis of covariance and partial correlation were used to adjust for initial scores on several variables; only subjects with data on all of those variables were included.

RESULTS

Description of Patients

The mean age of the patients was 55 years (SD, ±16.5 years), with a range of 18 to 91 years; 60% were female, 58% were white, and 28% were college graduates. There was considerable site variability with respect to age (range of means, 43 to 64 years), sex ratio (50% to 73% female), ethnicity (30% to 75% white), and education (4% to 45% college graduates). Site sample sizes varied from 176 to 303 patients. Of the total sample, 77% were established clinic patients; the remainder were seen for the first time. The most common types of physical disorders were hypertension (48%), arthritis (23%), diabetes (17%), heart disease (15%), and pulmonary disease (8%). Within each site, the convenience sample and the consecutive or randomly selected sample did not differ significantly in terms of age, sex, ethnicity, education, functional status, or frequency of PRIME-MD diagnoses.

Diagnostic Results of PRIME-MD Evaluations

Of the 1000 patients, 19% (n=185) were classified as "symptom screen-negative," ie, they acknowledged no or so few items on the PQ that the CEG was not administered (site range, 10% to 28%). An additional 42% (n=419) were "symptom screen-positive, but no psychiatric diagnosis," ie, the CEG was administered but no PRIME-MD diagnosis was made because not enough symptoms were present to justify a diagnosis (site range, 36% to 45%). A further 13% (n=129) were assigned a "subthreshold psychiatric diagnosis," ie, they were given a mental disorder diagnosis that was either subthreshold or probable (site range, 10% to 14%). Finally, 26% (n=257) of the patients were assigned a *DSM-III-R* "threshold psychiatric diagnosis" (site range, 18% to 38%). The prevalence of the 18 psychiatric disorders detected by PRIME-MD is summarized in Table 1. Interestingly, the prevalence of any and of each disorder was unrelated to whether this was a new patient or a patient previously known to the physician.

Co-occurrence of major diagnostic groups was common: of the 386 patients with a psychiatric diagnosis, more than one half (56%) had more than one; nearly one third (29%) had three or more diagnoses. A total of 84% of the patients with an eating disorder also had a diagnosis from one or more of the other four diagnostic modules. The co-occurrence rates for the other modules were also high: anxiety, 82%; somatoform, 73%; mood, 65%; and alcohol, 47%.

Physician Time Administering the CEG

The average amount of time spent by the physician administering the CEG to patients who scored positively on the PQ (n=790) was 8.4 minutes, with 95% of the cases requiring less than 20 minutes. For patients without a PRIME-MD diagnosis (n=413), the average amount of time was 5.6 minutes, with 95% of these cases requiring less than 11 minutes. For patients who were given a PRIME-MD diagnosis (n=377), the average amount of time required for evaluation was 11.4 minutes, with 95% of these cases requiring less than 24 minutes.

Agreement With MHPs

The 431 patients who were reinterviewed by MHPs were, within each site, similar to patients not reinterviewed in terms of demographic profile, functional status, and frequency of psychiatric diagnoses. The MHP interviewers had special training in evaluating psychopathology, and the MHP interview, compared with the CEG, was more like a psychiatric clinical interview (use of several open-ended questions from the SCID and more exploration of ambiguous responses). Therefore, the MHP interview can be regarded as a diagnostic criterion standard for assessing the validity of the PCP's PRIME-MD evaluation. Alternatively, because the PCPs and the MHPs used many of the same CEG questions and diagnostic criteria, agreement between them can be viewed as a demonstration of interrater reliability.

Table 2 presents several indexes of agreement between the diagnoses made by the PCPs using PRIME-MD and those made by the MHP interviewers. To avoid presenting indexes that are likely to be unstable, they are calculated only for those categories that were diagnosed a minimum of 10 times by either evaluator (regardless of their agreement on individual cases).

The first four columns present the sensitivity (proportion of cases given an MHP diagnosis correctly identified by the PCPs), specificity (proportion of MHP cases not given the diagnosis correctly identified by the PCPs), positive predictive value (proportion of cases given the diagnosis by the PCPs that were correctly identified), and overall accuracy rate (proportion of total patients correctly identified by the PCPs as having or not having the diagnosis). Sensitivity was very good for any psychiatric diagnosis and at least satisfactory for the diagnostic modules. For the specific diagnoses, sensitivities ranged from poor (22%) to very good (81%), with subthreshold diagnoses generally having the lowest sensitivities. Specificity was excellent across the diagnostic modules and for specific diagnoses, indicating that the PCPs using PRIME-MD seldom made false-positive diagnoses, ie, ones that were not confirmed by the MHPs. Overall accuracy rates across modules and specific categories were generally excellent.

The fifth column in Table 2 presents κ coefficients,[32] which index agreement between the PCPs and the MHPs for the diagnoses, correcting for agreement due to chance. The agreement for any psychiatric diagnosis was good (0.71). Agree-

Table 2.—Indexes of Agreement Between PRIME-MD Diagnoses Made by Primary Care Physicians (PCPs) and Mental Health Professionals (MHPs) and Their Prevalences (n=431)*

	Sensitivity, %	Specificity, %	Positive Predictive Value, %	Overall Accuracy Rate, %	κ	Prevalence, % PCP	Prevalence, % MHP
Any psychiatric diagnosis†	83	88	80	86	0.71	37	36
Any mood disorder	67	92	78	84	0.61	26	30
Major depressive disorder	57	98	80	92	0.61	10	14
Partial remission or recurrence of major depressive disorder	26	96	41	89	0.26	6	10
Dysthymia	51	96	56	92	0.49	8	9
Minor depressive disorder	22	94	19	89	0.15	7	6
Any anxiety disorder	69	90	60	86	0.55	21	19
Panic disorder	57	99	68	96	0.60	4	5
Generalized anxiety disorder	57	97	55	94	0.52	7	7
Anxiety disorder not otherwise specified	33	91	31	84	0.23	12	11
Probable alcohol abuse/dependence	81	98	65	98	0.71	5	4
Any eating disorder	73	99	80	98	0.73	5	5

*PRIME-MD indicates Primary Care Evaluation of Mental Disorders.
†Includes subthreshold and threshold diagnoses.

Table 3.—Operating Characteristics of the Patient Questionnaire (PQ) Alone

		Criterion Standard: Diagnoses by Primary Care Physician (n=1000)				Criterion Standard: Diagnoses by Mental Health Professional (n=431)			
PQ Screen-Positive Module	No.*	Sensitivity, %†	Specificity, %	Positive Predictive Value, %	Overall Accuracy Rate, %	Sensitivity, %	Specificity, %	Positive Predictive Value, %	Overall Accuracy Rate, %
Any module	805	100	32	48	58	92	48	50	64
Mood	325	100	91	80	94	69	82	62	78
Anxiety	486	100	63	37	59	94	53	31	60
Alcohol	124	100	92	41	93	81	91	27	91
Eating	139	100	89	23	89	86	88	28	88
Somatoform	681	100	37	20	46	...	...	...	...

*Number of subjects from the total sample who screened positive for that module on the PQ.
†Sensitivity is 100% because a primary care physician module diagnosis was made only when the PQ was screen-positive for that module.

ment for the modules was somewhat lower but generally at least satisfactory. Agreement for the specific diagnoses varied greatly but was satisfactory for major depressive disorder (0.61) and panic disorder (0.60), two categories for which there are specific effective treatments.

As can be seen by examining the last two columns of Table 2, the prevalences for PCP and MHP diagnoses were nearly identical, indicating that neither PCPs nor MHPs had a systematic tendency to overdiagnose or underdiagnose any psychiatric disorder.

Operating Characteristics of PQ

Table 3 presents the operating characteristics of the PQ as a screen for identifying which of any CEG modules should be administered, using PCP and MHP diagnoses as outcome criteria. The sensitivity of the PQ for anxiety, eating, and alcohol modules was good to excellent, indicating that relatively few of these disorders were undetected because of a false-negative PQ. The somewhat lower sensitivity of the PQ for mood diagnoses suggests that if there is clinical suspicion of depression, physicians may still want to enter the CEG module even if the PQ is negative. Specificity was similar using PCP and MHP diagnoses and was particularly good for the mood, alcohol, and eating modules. Thus, positive responses on the PQ for these disorders usually indicate a true underlying disorder rather than a false-positive response. Specificity of the PQ was only moderate for the anxiety module and was particularly low for the somatoform module, indicating greater inefficiency of PRIME-MD for these modules (ie, the PQ more frequently prompts entry in the CEG for patients who on further questioning do not qualify for an anxiety or somatoform diagnosis).

Since the Zung Depression Scale has been used in the primary care setting to screen for major depressive disorder, we compared its sensitivity and specificity (using the recommendation of Magruder-Habib and colleagues[33] of a normalized cutoff score of at least 50) with that of the two PQ items that trigger the mood module, using as the criterion the MHP diagnosis of major depressive disorder (n=337 because of some MHP data without Zung Depression Scale data). The sensitivity of both screens was 86%; the specificities were 75% (for the two PQ items) and 74% (for the Zung Depression Scale). Thus, the two PQ depression items compare favorably with the Zung Depression Scale as a screen for major depressive disorder. The PQ also performs well as a general screen for all PRIME-MD mood disorders. In fact, Table 3 demonstrates that the PQ in its entirety functions well as a screen for mental disorders in the primary care setting, but as expected, it does not perform as well as the complete PRIME-MD system.

Relationship of PRIME-MD Results to Functional Status, Health Care Utilization, and Disability Days

Figure 2 shows the mean scores on the six scales of the SF-20 for the four groups of subjects described herein: symptom screen–negative (PQ), symptom screen–positive but no psychiatric diagnosis, subthreshold psychiatric diagnosis, and threshold psychiatric diagnosis. Scores were adjusted by analysis of covariance for number of physical disorders, sex, age, minority status, educational level, and site. On all of the scales the symptom screen–negative group had the highest level of functioning, followed by the symptom screen–positive but no psychiatric diagnosis group, then the subthreshold psychiatric diagnosis group, and finally the group with threshold psychiatric diagnoses. For each SF-20 scale, group main

effects were significant ($P<.001$). All paired comparisons among the four groups were significant at P less than .05, using Bonferroni's correction for type I errors, with the exceptions of the differences between the symptom screen–negative patients and patients with symptom screen–positive but no psychiatric diagnoses on the role and social functioning scales (both $P<.10$).

Table 4 presents the mean values on two indexes of health care utilization and one of disability in the same four groups, with initial scores again adjusted for the variables just noted. Once again, the same pattern among the four groups emerges, and the group main effects were significant (all, $P<.005$). With one exception, paired comparisons, using Bonferroni's correction for type I errors, indicate significant differences ($P<.01$) between the patients with threshold psychiatric diagnoses and each of the remaining groups.

Relationship of PRIME-MD Diagnoses to Symptom Severity Measures

Partial correlation coefficients[34] were calculated between the presence or absence of any diagnosis within a diagnostic module and the scale score on the corresponding symptom severity scale. Initial scores were adjusted for number of physical disorders, sex, age, minority status, educational level, and site.

The partial correlation between scores on the Zung Depression Scale and any PRIME-MD mood disorder diagnosis was 0.58 ($P<.001$; n=820). The partial correlation between scores on the Zung Anxiety Scale and any PRIME-MD anxiety disorder diagnosis was 0.53 ($P<.001$; n=820). Finally, the partial correlation between scores on the Somatic Symptom Inventory and any PRIME-MD somatoform disorder diagnosis was 0.44 ($P<.001$; n=816).

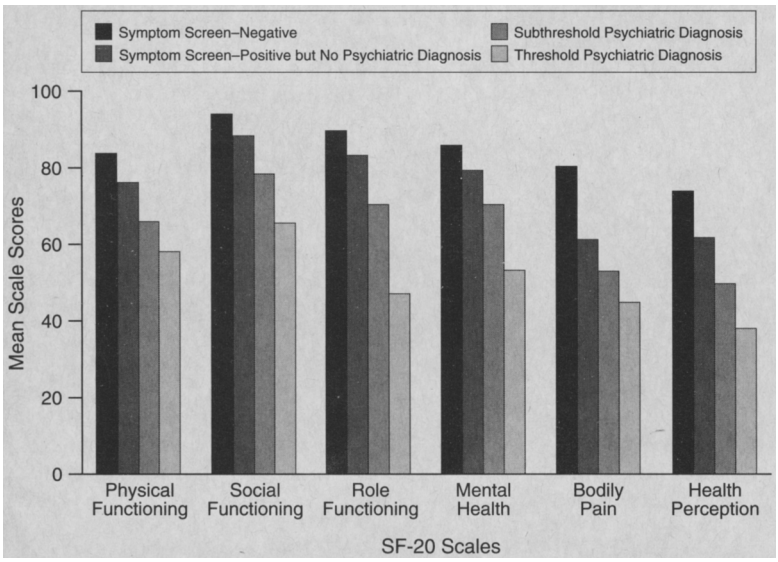


Figure 2.—Relationship of PRIME-MD (Primary Care Evaluation of Mental Disorders) results to functional status. Due to missing data for some patients, the range of numbers of patients across scales was as follows: symptom screen–negative, 155 to 160; symptom screen–positive but no psychiatric diagnosis, 332 to 352; subthreshold psychiatric diagnosis, 105 to 117; and threshold psychiatric diagnosis, 191 to 208. All paired comparisons among the four groups were significant at P less than .05, using Bonferroni's correction for type I errors, with the exceptions of the differences between the symptom screen–negative patients and patients with symptom screen–positive but no psychiatric diagnoses on the role and social functioning scales (both $P<.10$). SF-20 indicates Short-Form General Health Survey.

Recognition of Mental Disorders

Of the 731 patients known "somewhat" or "fairly well" by the physicians before the PRIME-MD evaluation, 287 were given a PRIME-MD diagnosis. Of these 287, 48% (n=138) had not been recognized by their physician as having any diagnosis included in the PRIME-MD system before the administration of the CEG (Table 5). For all of the modules except alcohol, the physician nonrecognition rates were greater than 60%. Nearly identical recognition rates were obtained when the analyses were limited to the 225 patients known "fairly well." Whether the patient was previously known to the physician or not, of 733 patients not known to have a mental disorder before administering the PRIME-MD, 28% (n=209) were given a PRIME-MD diagnosis.

It is possible that some patients had disorders of recent onset that the physician might have recognized even without PRIME-MD. However, even more chronic conditions, such as alcohol, eating, and somatoform disorders, had substantial nonrecognition rates. Therefore, it is likely that most of the cases not previously recognized were being recognized on this visit as a result of the administration of PRIME-MD.

Value of PRIME-MD to Patients and Physicians

Questions about the initiation of a treatment or referral were added midway into the study, and data were collected on 230 of 386 patients with a PRIME-MD diagnosis (Table 6). Before the PRIME-MD evaluation, 125 of these 230 patients were not receiving any therapy and had not been referred to an MHP or self-help

Table 4.—Self-reported Health Care Utilization and Disability Days by PRIME-MD Diagnostic Results*

	Symptom Screen–Negative, Group 1	Symptom Screen–Positive but No Psychiatric Diagnosis, Group 2	Subthreshold Psychiatric Diagnosis, Group 3	Threshold Psychiatric Diagnosis, Group 4	P†
Mean No. in past 3 months of:					
Visits to a physician	1.12 (n=159) (SE, 0.22)	1.52 (n=344) (SE, 0.15)	1.75 (n=115) (SE, 0.26)	2.30 (n=206) (SE, 0.20)	<.005 1 vs 4, <.001 2 vs 4, <.01
Visits to an emergency department	0.09 (n=163) (SE, 0.07)	0.23 (n=354) (SE, 0.05)	0.25 (n=116) (SE, 0.08)	0.57 (n=211) (SE, 0.06)	<.001 1 vs 4, <.001 2 vs 4, <.001 3 vs 4, <.01
Days kept from usual activities because of not feeling well	2.22 (n=162) (SE, 1.11)	3.19 (n=350) (SE, 0.76)	4.31 (n=110) (SE, 1.35)	11.01 (n=186) (SE, 1.04)	<.001 1 vs 4, <.001 2 vs 4, <.001 3 vs 4, <.001

*Scores are adjusted by analysis of covariance for number of physical disorders, sex, age, minority status, educational level, and site. PRIME-MD indicates Primary Care Evaluation of Mental Disorders.
†Nominal significance levels are reported for pairwise differences. Type I errors are controlled for by Bonferroni's criteria.

Table 5.—Frequency of Unrecognized PRIME-MD Psychiatric Diagnoses (n=731)*

	No. of Patients With Diagnosis	Patients Previously Unrecognized, No. (%)
Any PRIME-MD diagnosis	287	138 (48)
Any mood disorder	191	127 (67)
Any anxiety disorder	137	83 (61)
Any somatoform disorder	106	75 (71)
Probable alcohol abuse/dependence	36	15 (42)
Any eating disorder	24	19 (79)

*Only patients known "somewhat" or "fairly well" before the PRIME-MD (Primary Care Evaluation of Mental Disorders) evaluation are included.

Table 6.—New Therapy or Referral Initiated at Index Visit for Patients With a PRIME-MD Diagnosis (n=230)*

	No. of Patients Not Previously Receiving This Therapy or Referral Before PRIME-MD Evaluation	Patients in Whom This Therapy or Referral Was Initiated After PRIME-MD Evaluation, No. (%)
Any therapy or referral	125	78 (62)
Counseling by physician	183	62 (34)
Referral to mental health	198	47 (24)
Reassurance about health	198	42 (21)
Antidepressants	203	21 (10)
Referral to self-help	225	7 (3)
Benzodiazepine/anxiolytic	211	5 (2)

*PRIME-MD indicates Primary Care Evaluation of Mental Disorders.

group. Following the PRIME-MD evaluation, a new treatment or referral was initiated for 62% (n=78). For the patients not already receiving counseling (n=183), counseling was initiated for 34% (n=62). For the patients who had not already been referred to an MHP (n=198), a referral was initiated for 24% (n=47). For the patients who were not already receiving antidepressant medication (n=203), 10% were prescribed an antidepressant following the PRIME-MD evaluation (n=21). This included initiation of an antidepressant in 32% (n=17) of 54 patients with major depressive disorder.

After administering the CEG to a patient, physicians were asked the following question: "Considering the time that you spent doing the CEG, how valuable was the information that you obtained in helping you understand and treat this patient?" The physician found the information to be "very" or "somewhat" valuable for 61% (480/788) of patients given the CEG and for 83% (311/374) of those with a PRIME-MD diagnosis. Rarely did the physician judge the PRIME-MD information to be of no value (among all patients given the CEG, 7%; among all patients with a PRIME-MD diagnosis, 1%).

Reaction of Patients to PRIME-MD

At the completion of the telephone mental health interview, patients were asked if their physician had asked them follow-up questions about problems they had indicated on the PQ. Almost all (96%; n=252) of the patients who indicated that they had been asked CEG questions said they were "very" or "somewhat" comfortable answering these questions. The majority of the patients (90%; n=235) believed that the questions were "very" or "somewhat" valuable in helping their physician better understand or treat the problems that they had been having.

COMMENT

To our knowledge, PRIME-MD is the first psychiatric diagnostic interview schedule designed for PCPs. Numerous self-report screening scales are available for clinical and research use in primary care, but these either focus on a single area of psychopathology (eg, depression[26,35] or anxiety[27]) or on general psychological distress.[36] In addition, these screening scales only suggest the likelihood of a mental disorder, and the physician is not provided with any directions about how to confirm the diagnosis. In contrast, with PRIME-MD, the physician, in a relatively short period of time, actually screens and completes a differential diagnosis of the major classes of mental disorders commonly seen in primary care settings.

The data from this study provide considerable support for the utility and validity of the PRIME-MD system. The prevalence rates of threshold psychiatric disorders (26%) and individual disorders (eg, 12% for major depressive disorder) are comparable with those found in previous research using much more lengthy structured diagnostic interview schedules administered by MHPs.[4,6,37,38]

The agreement between the PRIME-MD diagnoses made by PCPs and the blinded reinterviews by MHPs was modest but approximates the levels of agreement among MHPs using diagnostic interview schedules.[39,40] Similarly, the sensitivities of the PRIME-MD diagnoses were modest using the MHP diagnoses as the standard; however, these were higher than the values obtained in a study in which diagnoses made by lay interviewers using a structured diagnostic interview were compared with diagnoses made by psychiatrists.[41] Furthermore, in evaluating the results of the PRIME-MD 1000 Study, it should be noted that it is particularly difficult to obtain high agreement and sensitivity for mild cases of psychiatric disorder, such as those that tend to be seen in primary care settings.[42] Finally, the high specificities across the CEG diagnostic modules indicate that the PCP, using PRIME-MD, seldom made a psychiatric diagnosis that was not confirmed by the MHP.

The construct validity of the PRIME-MD diagnoses is strongly supported by the findings that patients with PRIME-MD mental disorders have significantly impaired functioning and greater health care utilization, compared with patients without PRIME-MD diagnoses, adjusting for a variety of possible confounding variables, including number of physical disorders. (Unfortunately, we did not have a measure of the severity of physical disorders, which could influence psychiatric symptomatology.) Of special interest, the study provides support for the importance of identifying those patients who have only subthreshold psychiatric disturbances, since these patients were also shown to have impaired functioning and higher rates of health care utilization compared with patients without any psychiatric condition. In addition, the concurrent validity of PRIME-MD is supported by the strong relationship between PRIME-MD diagnoses of mood, anxiety, and somatoform disorders and the corresponding patient self-rated symptom severity scales.

How generalizable are these results to the real world of primary care practice? The physicians who volunteered to participate in this study judged themselves to be more interested in mental disorders than their colleagues. Furthermore, some of them were provided with a modest incentive, such as slightly reduced patient load or reimbursement to their facility, for the additional time it took for them to administer PRIME-MD. How often busy primary care practitioners will be willing to spend the additional time it takes to administer PRIME-MD will undoubtedly depend, at least in part, on the likelihood of third-party reimbursement for their time in conducting the procedure. There are two Current Procedural Terminology[43] codes that are appropriate for requesting reimbursement for administering PRIME-MD as a procedure as well as Evaluation and Management Services codes to bill for time performing this type of patient evaluation; these codes are listed in the CEG. A survey of 200 payers regarding mental health coverage benefits and coding requirements indicated that more than two thirds of payers cover the diagnosis of mental disor-

ders by PCPs and more than half accept evaluation and management codes by nonpsychiatrists or PCPs for a mental health evaluation.[44] Thus, it is likely that in most cases PCPs using PRIME-MD will be reimbursed for the time that they spend performing the evaluation.

The mental disorders diagnosed by PRIME-MD are not only prevalent but are often managed exclusively in the primary care setting where they produce considerable patient suffering and disability as well as increased health care utilization. These factors coupled with the movement toward managed care and health system reform make detection of psychiatric disorders in the primary care setting increasingly important. To this end, the Agency for Health Care Policy and Research[45] has recently published clinical practice guidelines for depression in primary care, and the American Psychiatric Association[46] is developing a primary care version of the *Diagnostic and Statistical Manual of Mental Disorders*. However, time constraints are a critical issue: medical clinic visits are typically much briefer than outpatient appointments with a mental health professional,[14,47] and the need to address other medical problems and issues such as health maintenance further reduces the limited time available to evaluate psychiatric disorders. It is unlikely that any instrument will be useful in primary care unless it balances efficiency with diagnostic accuracy. Our study suggests that PRIME-MD may have these qualities and may therefore be a practical tool for the busy primary care physician.

The development of PRIME-MD was underwritten by an unrestricted educational grant from the Roerig and Pratt Pharmaceuticals divisions of Pfizer Inc, New York, NY. Roger Kathol, MD, Dale Matthews, MD, Mack Lipkin, MD, and Carol Mahon, MD, helped in the initial development of PRIME-MD. Arthur Barsky, MD, Wayne Katon, MD, Herbert C. Schulberg, PhD, G. Richard Smith, MD, Junius Gonzales, MD, Kenneth Wells, MD, and Michael Von Korff, MD, were valuable consultants to the project. Miriam Gibbon, MSW, assisted in data collection, Amy Lazev coordinated data collection, and Mark Davies, MS, and Jacob Cohen, PhD, assisted in statistical analysis.

For a complimentary copy of PRIME-MD materials (revised for compatibility with the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*), write Dr Spitzer at Biometrics Research Department, Unit 74, New York State Psychiatric Institute, 722 W 168 St, New York, NY 10032.

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