Current PSYCHIATRY

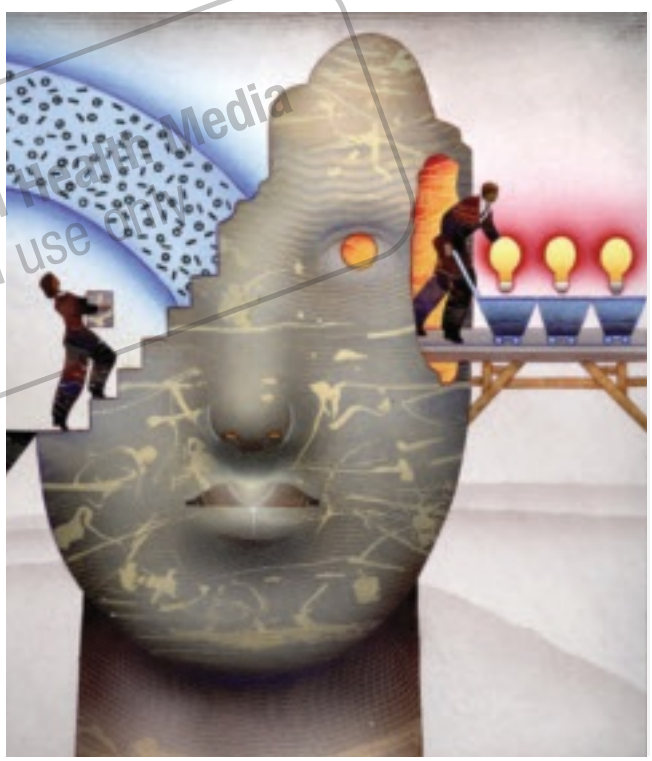
Every patient, every visit: Routine tests yield clinically useful data

Mining your database can reveal response patterns, improve patient outcomes

General psychiatry practitioners such as myself traditionally have relied on writing case reports to describe our clinical experience. One obstacle to getting cases published is that many research journals require submitted articles to include large samples and rating scales as measures of change in the conditions of patients being studied.

I have published articles about my clinical experiences using patient data collected with the Clinical Global Impressions (CGI) scale and other standardized tests. Research instruments such as the CGI can gather empiric data and are easy to use in clinical practice.[1]

This article describes how routine standardized testing provides useful data for research and improves diagnostic accuracy—and patient outcomes—even before I meet my patients for the first time.



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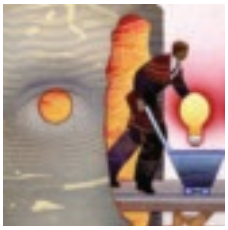
›› To read more about rating scales, see **"Self-rating scales tell you more than the score."** page 110

Why use standardized tests?

Benefits. All my new patients undergo screening before their first face-to-face meeting with a psychiatrist. This registration visit takes about 2 hours, after which they are scheduled for an appointment based on clinical urgency. We charge no fee for the screening visit; the benefits of gathering a comprehensive database before the clinical evaluation outweigh the cost of the tests, software, and staff time.

Along with completing insurance and biographical paperwork, patients perform self-administered psychosocial and medical histories and a battery of



Standardized tests

Clinical Point

Using standardized tests has given our practice a positive image in the community

Box 1

Unipolar or bipolar depression? Mini-SCID can help with diagnosis

Bipolar disorder is difficult to diagnose in patients presenting with depressive symptoms. In a 5-year chart review,[2] we used data from Structured Clinical Interview for DSM-IV (Mini-SCID) screening tests to assess this tool's usefulness in diagnosing depressed patients. Data also included each patient's demographic information, initial clinical diagnosis, current clinical diagnosis, and Symptom Checklist-90 (SCL-90) results.

Among 796 patients who took the Mini-SCID at their initial visit, 256 had a current clinical diagnosis of bipolar disorder and 540 had nonbipolar diagnoses. The Mini-SCID had a sensitivity of 0.58 and specificity of 0.63 in predicting a current diagnosis of bipolarity. This compared with a sensitivity of 0.35 and specificity of 0.98 for the clinician's initial diagnosis. Among patients with bipolar II disorder, the Mini-SCID's sensitivity was 0.55, compared with 0.20 for the clinician's initial diagnosis.

Patients who endorsed mania/hypomania on the Mini-SCID yet had a diagnosis of nonbipolar illness had SCL-90 profiles more like those of bipolar than unipolar patients. Therefore, using the Mini-SCID with the SCL-90 might improve in-office recognition of bipolar illness.

standardized tests. This information allows me to focus on interpersonal issues—rather than fact-finding—during the first interview. It also ensures a comprehensive patient history.

Using standardized tests has given our practice a positive image in the community. Repeated outcome measures also reinforce to patients that our practice provides up-to-date, comprehensive care.

Limitations. One limitation to using rating scales to publish experiences in clinical practice is that clinical need, rather than a research protocol, determines the frequency of visits. Another is that we ask patients to rate symptoms they experience in the week before office visits. Thus, the data do not capture changes that occurred in other weeks.

Standardized tests we use

Except for the Quick Inventory of Depressive Symptomatology (QIDS), I selected the tests I use in the late 1980s because of:

- their ease of use and affordability
- my familiarity with them from my academic work
- their suitability for a mood disorder clinical practice such as mine.

Other tests are available; the point is to select affordable tools for baseline assessment and repeated measurement of change.

Psychosocial history. Patients use an office computer to complete a questionnaire about family and developmental history, financial and employment history, education, health, alcohol and drug history, current stressors, and the presenting problem. Software from Multi-Health Systems (see ***Related Resources, page 48***) allows me to add or remove questions as needed.

To ensure privacy when the next patient uses the computer, each patient's report is deleted after it is printed. I receive the printed report, which details all responses and flags those that may require clarification.

Medical history. A standardized form asks patients about whether they have had most common medical conditions, their present symptoms, and family members' health. An additional form inquires into psychiatric treatment, family history of psychiatric illnesses, and present medications.

Mini-SCID. The Mini-SCID has several advantages over the Structured Clinical Interview for DSM (SCID):

- Patients self-administer the test on a computer at the office.
- For research purposes, Mini-SCID results are protected from clinician biases because patients are interviewed using uniform questions and circumstances.

The clinician receives a printed report that assesses the likelihood of 21 DSM-

Box 2

TEMPS shows value in early detection of bipolar disorder

Being able to identify the bipolar nature of a depressive episode leads to better treatment and outcomes. In our private psychiatric clinic, we used the 39-item Temperament Evaluation of Memphis, Pisa, Paris and San Diego (TEMPS) to screen for temperaments of 783 consecutive mood disorder outpatients. We also examined their demographic information, clinical diagnoses by the treating psychiatrist, and Clinical Global Impressions (CGI) scores to measure response to treatment.[6]

- Patients with bipolar disorder scored significantly higher on cyclothymia, depression, and irritability scales, compared with patients diagnosed with unipolar depression.
- Bipolar II patients scored significantly higher on the same 3 scales than did patients with bipolar I disorder or unipolar depression.

Patients with higher cyclothymia scores tended also to have higher CGI-C scores, indicating greater treatment resistance.

IV diagnoses, including past or current depression, mania, dysthymia, panic disorder, agoraphobia, obsessive-compulsive disorder, social phobia, simple phobia, generalized anxiety disorder, somatoform disorder, delusions, hallucinations, alcohol and substance abuse, anorexia, bulimia, hypochondriasis, posttraumatic stress disorder, and body dysmorphic disorder.

By analyzing Mini-SCID data from >1,000 of our outpatients, we learned that this screening test can improve our diagnosis of bipolar disorder in patients presenting with depressive symptoms (***Box 1***).[2]

Symptom Checklist-90 (SCL-90). This tool adds another layer of support for bipolar illness diagnosis (***Box 1***). It also is useful in conjunction with rating scales specific to other diagnostic categories, such as depression and anxiety.

The SCL-90[3] consists of 90 statements that measure the severity of 9 dimensions of psychopathology: somatization, obsession-compulsion, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism. Using a scale of 0 (not at all) to 4 (a great deal), patients rate how much they are bothered by the feelings expressed in each statement.

In its standard scoring, the SCL-90 returns a score for 9 scales. Hunter et al[4] developed an alternate set of 8 scales that uses SCL-90 questions to screen for depression, mania, schizophrenia, antisocial personality disorder, somatization disorder, obsessive-compulsive disorder, panic disorder, and agoraphobia. These SCL-90 diagnostic scales showed good reliability as an aid to the Mini-SCID in identifying diagnoses among 1,457 adult psychiatric outpatients.

Temperament evaluation. The Temperament Evaluation of Memphis, Pisa, Paris and San Diego (TEMPS) is a 39-item, self-report scale designed to measure 5 different temperaments: cyclothymic, depressive, irritable, hyperthymic, and anxious.[5] It is especially useful for identifying bipolar spectrum patients (***Box 2***).[6]

Clinical Global Impressions scale. The CGI uses a 7-point Likert scale to describe the clinician's impression of change in a patient's condition. This scale:

- transcends symptom checklists by incorporating knowledge of the patient's history, symptoms, and behaviors
- lends itself easily to repeated measures of change and severity of the condition being rated.[1]

I use the CGI-Severity scale for baseline assessment and the CGI-Change when I see patients on follow-up.

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continued

Clinical Point

Mini-SCID data have helped us improve diagnosis of bipolar disorder in patients with depressive symptoms

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Every office visit

At the screening visit and before every office visit, my patients complete 2 depression rating tests to document changes between visits and over time: a visual analog scale (VAS) and the QIDS.

The VAS' 10-cm line with the left side marked "worst ever" and the right side marked "best ever" is a simple tool. It captures patients' subjective impressions of their mood states in answer to the question, "How do you feel today?" I used the VAS as an outcome measure in a study of modafinil augmentation of antidepressant therapy.[7]

The QIDS is a 16-item screen that measures 9 depressive symptoms.[8] It has been validated against the Hamilton Depression Rating Scale (HAM-D)[9] and was used as the outcome measure in the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial.[10] The QIDS-16 is available online for free use in many languages (see ***Related Resources, page 48***).[11]

The QIDS-16 allows you to track the severity of each depressive symptom and provides an overall depression score. It includes 3 questions on insomnia (for early, middle, and late symptoms) and 1 on hypersomnia. Routine use of the QIDS-16 provided data for a poster on the high frequency of persistent insomnia in 145 consecutive outpatients in our practice whose depressive symptoms were in remission.[12]

Until recently, our office performed routine depression screening with the 52-item Carroll Depression Rating Scale (CDRS),[13] a self-administered inventory designed to mirror results from the HAM-D. I published articles using the CDRS as the primary outcome measure in a chart review of long-term effectiveness of antidepressant monotherapy (***Box 3***)[13,14] and in a study of modafinil's effectiveness as adjunctive therapy in patients with unipolar depression.[7]

Box 3

Antidepressant efficacy in unipolar depression

The Carroll Depression Rating Scale (CDRS) is lengthy (52 items), but its self-rating yes/no format makes it easy to administer and score.[13] We used the CDRS as the primary outcome measure in a chart review of long-term effectiveness of antidepressant monotherapy in 346 patients with unipolar depression.[14]

Using baseline and follow-up CDRS scores over 5 years, we examined:

- changes in scores
- which medications most rapidly brought about remission (defined as CDRS score ≤7)
- which medication was most effective in preventing relapse.

We found that sertraline and to a lesser extent paroxetine were more effective than several other antidepressants in achieving remission and preventing relapse.

Logistical concerns

Patient feedback. Although some patients complain about having to complete depression rating scales at every visit, most accept this as equivalent to having routine blood pressure measurements. Many become interested in tracking their improvement by test scores in addition to subjective feelings.

Bottom Line

Consider using standardized tests in routine clinical practice to improve patient outcomes. Choose tests that are easy to administer, affordable, and provide useful data to track patients' progress over time. Mine your database for trends that may contribute to the literature on clinical psychiatric practice.

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Clinical Point

Many patients become very interested in tracking their improvement by test scores in addition to their subjective feelings

Adverse Events with an Incidence ≥1% in Intramuscular Trials—The following treatment-emergent adverse events were reported at an incidence of ≥1% with intramuscular olanzapine for injection (2.5-10 mg/injection) and at incidence greater than placebo in short-term, placebo-controlled trials in agitated patients with schizophrenia or bipolar mania: ***Body as a Whole***—asthenia; ***Cardiovascular***—hypotension, postural hypotension; ***Nervous System***—somnolence, dizziness, tremor.

Dose Dependency of Adverse Events in Short-Term, Placebo-Controlled Trials—Extrapyramidal Symptoms—In an acute-phase controlled clinical trial in schizophrenia, there was no significant difference in ratings scales incidence between any dose of oral olanzapine (5±2.5, 10±2.5, or 15±2.5 mg/d) and placebo for parkinsonism (Simpson-Angus Scale total score >3) or akathisia (Barnes Akathisia global score ≥2). In the same trial, only akathisia events (spontaneously reported COSTART terms akathisia and hyperkinesia) showed a statistically significantly greater adverse events incidence with the 2 higher doses of olanzapine than with placebo. The incidence of patients reporting any extrapyramidal event was significantly greater than placebo only with the highest dose of oral olanzapine (15±2.5 mg/d). In controlled clinical trials of intramuscular olanzapine for injection, there were no statistically significant differences from placebo in occurrence of any treatment-emergent extrapyramidal symptoms, assessed by either rating scales incidence or spontaneously reported adverse events.

Dystonia, Class Effect—Dystonia symptoms (prolonged abnormal contractions of muscle groups) may occur in susceptible individuals during the first few days of treatment. While these symptoms can occur at low doses, the frequency and severity are greater with high potency and at higher doses of first-generation antipsychotics. In general, an elevated risk of acute dystonia may be observed in males and younger age groups receiving antipsychotics; however, dystonic events have been reported infrequently (<1%) with olanzapine.

Other Adverse Events—Dose-relatedness of adverse events was assessed using data from this same clinical trial involving 3 fixed oral dosage ranges (5±2.5, 10±2.5, or 15±2.5 mg/d) compared with placebo. The following treatment-emergent events showed a statistically significant trend: asthenia, dry mouth, nausea, somnolence, tremor.

In an 8-week, randomized, double-blind study in patients with schizophrenia, schizophreniform disorder, or schizoaffective disorder comparing fixed doses of 10, 20, and 40 mg/d, statistically significant differences were seen between doses for the following: baseline to endpoint weight gain, 10 vs 40 mg/d; incidence of treatment-emergent prolactin elevations >24.2 ng/mL (female) or >18.77 ng/mL (male), 10 vs 40 mg/d and 20 vs 40 mg/d; fatigue, 10 vs 40 mg/d and 20 vs 40 mg/d; and dizziness, 20 vs 40 mg/d.

Vital Sign Changes—Oral olanzapine was associated with orthostatic hypotension and tachycardia in clinical trials. Intramuscular olanzapine for injection was associated with bradycardia, hypotension, and tachycardia in clinical trials (*see* PRECAUTIONS).

Laboratory Changes—Olanzapine is associated with asymptomatic increases in SGPT, SGOT, and GGT and with increases in serum prolactin and CPK (*see* PRECAUTIONS). Asymptomatic elevation of eosinophils was reported in 0.3% of olanzapine patients in premarketing trials. There was no indication of a risk of clinically significant neutropenia associated with olanzapine in the premarketing database.

ECG Changes—Analyses of pooled placebo-controlled trials revealed no statistically significant olanzapine/placebo differences in incidence of potentially important changes in ECG parameters, including QT, QTc, and PR intervals. Olanzapine was associated with a mean increase in heart rate of 2.4 BPM compared to no change among placebo patients.

Other Adverse Events Observed During Clinical Trials—The following treatment-emergent events were reported with oral olanzapine at multiple doses ≥1 mg/d in clinical trials (8661 patients, 4165 patient-years of exposure). This list may not include events previously listed elsewhere in labeling, those events for which a drug cause was remote, those terms which were so general as to be uninformative, and those events reported only once or twice which did not have a substantial probability of being acutely life-threatening. *Frequent* events occurred in ≥1/100 patients; *infrequent* events occurred in 1/100 to 1/1000 patients; *rare* events occurred in <1/1000 patients. ***Body as a Whole***—*Frequent:* dental pain, flu syndrome; *Infrequent:* abdomen enlarged, chills, face edema, intentional injury, malaise, moniliasis, neck pain, neck rigidity, pelvic pain, photosensitivity reaction, suicide attempt; *Rare:* chills and fever, hangover effect, sudden death. ***Cardiovascular***—*Frequent:* hypotension; *Infrequent:* atrial fibrillation, bradycardia, cerebrovascular accident, congestive heart failure, heart arrest, hemorrhage, migraine, pallor, palpitation, vasodilatation, ventricular extrasystoles; *Rare:* arteritis, heart failure, pulmonary embolus. ***Digestive***—*Frequent:* flatulence, increased salivation, thirst; *Infrequent:* dysphagia, esophagitis, fecal impaction, fecal incontinence, gastritis, gastroenteritis, gingivitis, hepatitis, melena, mouth ulceration, nausea and vomiting, oral moniliasis, periodontal abscess, rectal hemorrhage, stomatitis, tongue edema, tooth caries; *Rare:* aphthous stomatitis, enteritis, eructation, esophageal ulcer, glossitis, ileus, intestinal obstruction, liver fatty deposit, tongue discoloration. ***Endocrine***—*Infrequent:* diabetes mellitus; *Rare:* diabetic acidosis, goiter. ***Hemic and Lymphatic***—*Infrequent:* anemia, cyanosis, leukocytosis, leukopenia, lymphadenopathy, thrombocytopenia; *Rare:* normocytic anemia, thrombocythemia. ***Metabolic and Nutritional***—*Infrequent:* acidosis, alkaline phosphatase increased, bilirubinemia, dehydration, hypercholesteremia, hyperglycemia, hyperlipemia, hyperuricemia, hypoglycemia, hypokalemia, hyponatremia, lower extremity edema, upper extremity edema; *Rare:* gout, hyperkalemia, hypernatremia, hypoproteinemia, ketosis, water intoxication. ***Musculoskeletal***—*Frequent:* joint stiffness, twitching; *Infrequent:* arthritis, arthrosis, leg cramps, myasthenia; *Rare:* bone pain, bursitis, myopathy, osteoporosis, rheumatoid arthritis. ***Nervous System***—*Frequent:* abnormal dreams, amnesia, delusions, emotional lability, euphoria, manic reaction, paresthesia, schizophrenic reaction; *Infrequent:* akinesia, alcohol misuse, antisocial reaction, ataxia, CNS stimulation, cogwheel rigidity, delirium, dementia, depersonalization, dysarthria, facial paralysis, hypesthesia, hypokinesia, hypotonia, incoordination, libido decreased, libido increased, obsessive compulsive symptoms, phobias, somatization, stimulant misuse, stupor, stuttering, tardive dyskinesia, vertigo, withdrawal syndrome; *Rare:* circumoral paresthesia, coma, encephalopathy, neuralgia, neuropathy, nystagmus, paralysis, subarachnoid hemorrhage, tobacco misuse. ***Respiratory***—*Frequent:* dyspnea; *Infrequent:* apnea, asthma, epistaxis, hemoptysis, hyperventilation, hypoxia, laryngitis, voice alteration; *Rare:* atelectasis, hiccup, hypoventilation, lung edema, stridor. ***Skin and Appendages***—*Frequent:* sweating; *Infrequent:* alopecia, contact dermatitis, dry skin, eczema, maculopapular rash, pruritus, seborrhea, skin discoloration, skin ulcer, urticaria, vesiculobullous rash; *Rare:* hirsutism, pustular rash. ***Special Senses***—*Frequent:* conjunctivitis; *Infrequent:* abnormality of accommodation, blepharitis, cataract, deafness, diplopia, dry eyes, ear pain, eye hemorrhage, eye inflammation, eye pain, ocular muscle abnormality, taste perversion, tinnitus; *Rare:* corneal lesion, glaucoma, keratoconjunctivitis, macular hypopigmentation, miosis, mydriasis, pigment deposits lens. ***Urogenital***—*Frequent:* vaginitis*; *Infrequent:* abnormal ejaculation*, amenorrhea*, breast pain, cystitis, decreased menstruation*, dysuria, female lactation*, glycosuria, gynecomastia, hematuria, impotence*, increased menstruation*, menorrhagia*, metrorrhagia*, polyuria, premenstrual syndrome*, pyuria, urinary frequency, urinary retention, urinary urgency, urination impaired, uterine fibroids enlarged*, vaginal hemorrhage*; *Rare:* albuminuria, breast enlargement, mastitis, oliguria. (*Adjusted for gender.)

The following treatment-emergent events were reported with intramuscular olanzapine for injection at one or more doses ≥2.5 mg/injection in clinical trials (722 patients). This list may not include events previously listed elsewhere in labeling, those events for which a drug cause was remote, those terms which were so general as to be uninformative, and those events reported only once or twice which did not have a substantial probability of being acutely life-threatening. ***Body as a Whole***—*Frequent:* injection site pain; *Infrequent:* abdominal pain, fever. ***Cardiovascular***—*Infrequent:* AV block, heart block, syncope. ***Digestive***—*Infrequent:* diarrhea, nausea. ***Hemic and Lymphatic***—*Infrequent:* anemia. ***Metabolic and Nutritional***—*Infrequent:* creatine phosphokinase increased, dehydration, hyperkalemia. ***Musculoskeletal***—*Infrequent:* twitching. ***Nervous System***—*Infrequent:* abnormal gait, akathisia, articulation impairment, confusion, emotional lability. ***Skin and Appendages***—*Infrequent:* sweating.

Postintroduction Reports—Reported since market introduction and temporally (not necessarily causally) related to olanzapine therapy: allergic reaction (e.g., anaphylactoid reaction, angioedema, pruritus or urticaria), diabetic coma, jaundice, neutropenia, pancreatitis, priapism, rhabdomyolysis, and venous thromboembolic events (including pulmonary embolism and deep venous thrombosis). Random cholesterol levels of ≥240 mg/dL and random triglyceride levels of ≥1000 mg/dL have been reported.

DRUG ABUSE AND DEPENDENCE: Olanzapine is not a controlled substance.

Literature revised March 10, 2008

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Related Resources

- Multi-Health Systems. Publishers of mental health assessment tools. www.mhs.com.
- Inventory of Depressive Symptomatology (IDS) and Quick Inventory of Depressive Symptomatology (QIDS). www.ids-qids.org.

Drug Brand Names

Modafinil • Provigil
Paroxetine • Paxil
Sertraline • Zoloft

Disclosure

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HIPAA. The Health Insurance Portability and Accountability Act (HIPAA) allows publication of large-scale studies that do not identify patients individually. We also obtained permission from the local Institutional Review Board to disseminate non-identifying cumulative data.

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