STABLE

STAndards for BipoLar Excellence

A Performance Measurement
& Quality Improvement Program

STABLE Performance Measures: Field Study Process & Conformance Findings

Field Study Process & Final Measure Acceptance:

- The objective was to determine measure conformance in an appropriate convenience sample
- Measure conformance findings were presented to the STABLE National Coordinating Council (NCC) for final consideration following analysis; 15 measures were accepted.
- Conformance findings are available within this document
- Five STABLE measures were endorsed by the National Quality Forum in December 2006

Field Study Process

IRB Submission:

- A protocol describing a process using redacted records was submitted for IRB review
- IRB review resulted in an exempt determination as redacted records were to be prepared by office staff; therefore, no personal health information was viewable nor would be abstracted.
- If a practice site also required internal IRB review; this process was followed.

Site Recruitment and Participation

- Sites were recruited using a mailed survey of interest and intent to participate.
- Sites were selected if they had at least 10 patients with a new presentation of unipolar disorder or bipolar disorder within the time frame of July 2004 and July of 2006. This time frame was based on the availability of the 2002 Revision: APA Guidelines for the Care of Persons with Bipolar Disorder so that sufficient time for dissemination and uptake was possible.
- Records were selected by clinic/office staff using the case selection criteria provided by the project management team and were redacted prior to abstraction so that no personal health information was viewable by abstractors.

Sample Size

Sample size was computed by considering how many sites and how many records would be required.

- It has been established that if >20% of data values are missing (documentation not supported) for a variable during chart review it should be either dropped or redefined. Using this assumption and that the standard deviation of documentation being present or absent approaches 50% between sites, a minimum of 79 sites was determined to be required for field testing .
- To determine the number of depression and bipolar cases required for field testing the assumption was made that there are a large number of psychiatrists and primary care physicians in the U.S. who manage bipolar disease and/or depression. A conservative estimate of documentation variability was assumed that specification data elements would be present 50% of the time. In addition, a 95% confidence interval was assumed with ±5% precision.
- The resulting desired sample size for each condition was 385 medical records. The goal was to abstract 400 cases of bipolar disorder and approximately 400 cases of unipolar depression.

Field Study Sample:

- Field Study was conducted in 80 sites; 48 Psychiatric Care sites and 32 Primary Care sites
- Sites were from 28 states; 13 West, 30 Midwest, 16 Northwest, 21 Southeast
- Cases; 419 Bipolar Disorder, 383 Unipolar Depression
- Case demographics
  - Bipolar cases: 44% Urban; 41% Suburban; 15% Rural
  - Depression cases: 28% Urban; 37% Suburban; 35% Rural
- Sites included three academic centers and four public clinics

Analysis of Conformance Findings

Measurement algorithms were constructed to calculate each measure's findings. The algorithms were tested using a small sample of charts (five) with comparison to expected results conducted. Discrepancy from expected was studied and as needed, the algorithms were adjusted.

Data was entered into a data base constructed from all abstracts with a sample of cases re-reviewed for data entry accuracy. Tests of reasonableness were conducted.

The measure findings reflect the percent of adherence to the clinical guidelines. Measure findings were provided for all cases; for cases attributed to psychiatrists and to primary care clinicians.

Additional findings were provided from the data collection instrument developed to gather data elements beyond those required to calculate the measure conformance to the specifications, such as;

- The type of screening/assessment tools used; types of coding performed; and types of psychosocial interventions recommended and/or provided.
- Because these additional data elements available, it was possible to provide subsets of data related to each measure criteria set, thus permitting the NCC members to review and accept specification revisions for a small group of measures.

Final Measure Review and Acceptance

Eleven measures were accepted as presented

- 1 measure was accepted with the agreement that specific harmonization wording requested by the NQF-AQA harmonization work group would be included; specifically, educational guidance regarding the APA suggested criteria for a suicide risk assessment.
- Two measures were accepted for use in only specialty (psychiatry) sites, based on the complexity of condition-specific documentation and/or coding required to establish the denominator, which was determined to not be standard documentation in primary care practice.

Four measures were accepted with revisions.

- Monitoring weight gain: Addition of requirement for actual weight
- Provision of condition-specific education: Addition of requirement that medication information alone did not meet the criteria.
- Serum medication level monitoring: Restricted to lithium levels
- Monitoring of change in symptom complex: Addition of requirement that monitoring of change should be assessed and documented using a validated symptom monitoring tool or through the use of a visual flow chart that provides change-over-time information.

One measure was rejected:

- Extremely low level of denominator data feasibility.

National Quality Forum Measure Endorsement:

An opportunity to submit STABLE measures for consideration by the National Quality Forum was available in June of 2006.

- The STABLE National Coordinating Council submitted a subset of the 7 STABLE measures with the most conclusive results from the Pilot Testing Phase and for which the early results from the Field Study Phase were replicated. Note: Field Study was concluded in August of 2006.

- Five measures were endorsed by the NQF in December of 2006:
  - Screening for bipolar mania/hypomania
  - Assessment for risk of suicide
  - Assessment for substance use
  - Screening for hyperglycemia when atypical antipsychotic agent prescribed
  - Monitoring change in level-of-functioning

STABLE PERFORMANCE MEASURES	All Cases	Cases attributed to Psychiatry	Cases attributed to Primary Care
The % of patients presenting with depression who were assessed, prior to initiation of treatment, for the presence of prior or current symptoms and/or behaviors associated with mania or hypomania	47.6%	62.8%	38.4%
The % of patients diagnosed with bipolar disorder who receive an initial assessment that considers the risk of suicide	80.7%	89.6%	39.2%
The % of patients diagnosed with unipolar depression who receive an initial assessment that considers the risk of suicide	61.4%	88.3%	45.0%
The % of patients with bipolar disorder who receive an initial assessment that considers alcohol and chemical substance use	78.3%	87.0%	37.8%
The % of patients with unipolar depression who receive an initial assessment that considers alcohol and chemical substance use	41.0%	78.6%	18.1%
The % of patients with Bipolar I Disorder with mania, hypomania, mixed or cycling symptoms and/or behaviors who have evidence of use of a pharmacotherapy agent with antimanic properties during the first 12 weeks of treatment	Findings reflected small denominators in primary care	78.4%	NCC restricted to specialty-specific measure due to level of diagnostic specificity needed
The % of patients with Bipolar I Disorder with depressive symptoms and/or behaviors with evidence of use of a mood stabilizing or antimanic agent during first 12 weeks of treatment		92.1%	
The % of patients with Bipolar I Disorder who received monotherapy with an antidepressant agent during the first 12 weeks of treatment	0% No cases failed measure	0% No cases failed measure	0% No cases failed measure
The % of patients with bipolar disorder who were monitored for weight gain during the initial 12 weeks of treatment	15.5%	8.4%	48.6%
The % of patients diagnosed with bipolar disorder and treated with an antipsychotic agent who were assessed for the presence of extrapyramidal symptoms twice within the first 24 weeks of treatment	26.0%	30.1%	11.8%
The % of patients diagnosed with bipolar disorder and treated with lithium who have evidence of a serum medication level within 12 weeks of beginning treatment	44.4%	42.9%	60.4%
The % of patients diagnosed with bipolar disorder and treated with an atypical antipsychotic agent with at least one screening for hyperglycemia within the initial 16 weeks of treatment	19.7%	19.4%	20.8%
The % of patients diagnosed with bipolar disorder and treated with an atypical antipsychotic agent with at least one assessment for hyperlipidemia within the initial 16 weeks of treatment	9.2%	10.0%	6.3%
The % of patients diagnosed and treated for bipolar disorder who are provided with education and information about their illness and treatment within the initial 12 weeks of treatment	33.4%	36.9%	17.8%
The % of patients diagnosed and treated for bipolar disorder who are monitored for change in their symptom complex within 12 weeks of initiating treatment	13.1%	15.1%	4.1%
The % of patients with bipolar disorder with a recommendation for an adjunctive psychosocial interventions, including evidence-based therapies, within 12 weeks of initiating treatment.	39.9%	45.2%	16.4%
The % of patients diagnosed and treated for bipolar disorder who are monitored for change in their level-of-functioning within 12 weeks of initiating treatment	41.4%	43.8%	30.6%