

STABLE Performance Measures: Development Process & Validity Ratings**Selecting the measure concept statements**

- The National Coordinating Council (NCC) selected the initial measurement concept statements using an adaptation of the RAND Appropriateness Method (Method)
- The selection process utilized the current clinical guidelines for bipolar disorder
- All measures are process-related, as processes are amenable to direct action by clinicians

Operationalizing the measures

- A subset of NCC Members, with content experts in depression and bipolar disorder, identified the numerator and denominator specifications, plus the exclusion and inclusion criteria

Selecting the measure concept statements

The RAND Appropriateness Method (Method) was used to select the key clinical processes for the STABLE measures.

- The rationale for the Method is that randomized clinical trials, the “gold standard” for evidence-based medicine, often cannot provide evidence at a level that applies to the wide range of patients seen in everyday clinical practice. The Method combines the best available scientific evidence with the collective judgment of experts to yield more universally usable statements concerning care.
- The objective of the Method is to determine when and to what extent experts agree rather than to obtain a consensus among them.

To assure appropriate application to real-world settings, RAND recommends that the rating panel should be diverse and comprised of 9-15 members. The recommendation is to include all major clinical disciplines involved in diagnosing and treating the condition(s) under consideration.

- The STABLE project included 13 psychiatrists and primary care physicians with experience in diagnosing and managing bipolar disorder.
- The physicians were from both academic and community practice settings.

The Method is most reliable when there is a scientific foundation of evidence.

- The STABLE Project used the following guidelines plus literature from recent randomized controlled trials:
 - American Psychiatric Association; Practice Guideline for the Treatment of Patients with Bipolar Disorder (2002 Revision)
 - The 2004 Expert Consensus Guideline for Treatment of Bipolar Disorder
 - The Texas implementation of Medication Algorithms (TIMA); 2005 Update
 - The 2005 Canadian Network for Mood and Anxiety Treatments (CANMAT) Guidelines for the Management of Patients with Bipolar Disorder

This STABLE Project followed the recommended steps of the RAND Appropriateness Method:

Prior to the National Coordinating Council Meeting:

1. A systematic review of the current clinical guidelines and clinical literature by project leaders
2. Development of preliminary concept statements by content experts from the project leadership
3. Dissemination of the guidelines and literature to the all NCC members for review
4. Dissemination of the preliminary measurement concept statements to the NCC members with a description of how the statements would be reviewed and rated at the meeting.

The only adaptation of the RAND Method for the STABLE Project involved having both the first and second round of anonymous ratings occur at the same meeting versus having the panelists provide the first rating prior to the meeting and then convening to discuss the results and conduct the second rating.

At the National Coordinating Council Meeting:

5. A face-to-face meeting of the NCC members with a first round of facilitated discussion of the measurement concepts to synthesize and clarify the clinical issues to be considered
6. Additional concept statements could be suggested or revisions made to original concept statements during the discussion process
7. An initial rating of each measurement concept. The rating was conducted using an automated audience response system to maintain confidentiality and to provide immediate results
8. A second round of facilitated discussion to clarify any measurement concepts rejected during the first round followed by a final rating round for these concept statements

Validity Ratings:

Performance measures developed by the RAND Appropriateness Method have been shown to have content validity and face validity based on the use of rigorous clinical evidence. Content validity was rated as to whether the measure concept statement reflected the domain of content, as addressed in current clinical guidelines, well-developed clinical trials, and expert opinion.

Questions rated for content validity: [Rating results available in table below]

- Question 1: This statement relates to an appropriate aspect of care considered important to providing care, according to the current clinical evidence and expert opinion.
- Question 2: This statement relates to an aspect of care where improved clinical process performance is likely to be associated with desired outcomes, according to the current clinical evidence and expert opinion.

Measures developed by the RAND Appropriateness Method have been shown to have face validity due to the involvement of expert panels using a panel/agreement-type development process. Face validity was rated as to whether the measurement concept could be reasonably construed to identify a gap in providing care and focus attention on processes that should be improved to close the gap and improve care.

Questions rated for face validity: [Rating results available in table below]

- Question 1: This statement addresses an aspect of care where current evidence indicates that there is often a gap between actual practice and recommended practice
- Question 2: This statement addresses an aspect of care where improved clinical performance, captured in relation to the recommended practice, could contribute to closing the gap between actual practice and recommended practice and thus improve care.

Operationalizing the STABLE Performance Measures

A sub-group of NCC members, four psychiatric clinical experts in depression and bipolar disorder; two primary care physicians and two physicians with expertise in developing clinical performance measures, operationalized the measurement concept statements

General Inclusions:

- The NCC members stated that the measures would only relate to individuals ≥ 18 years of age due to the lack of current guidelines for younger ages at the time of the meeting
- The NCC members stated that the measures would only relate to patients diagnosed and treated in an out-patient environment

General Exclusions:

It was decided that patients hospitalized during the initial 12 week treatment period should be excluded since the various assessments, monitoring, and therapies might be performed during the hospitalization and may not be available in the out-patient record

Specifications included:

- Data elements needed to populate the denominators and the numerators of the measures
- Codes necessary to identify the cases, as appropriate to the measure
- Types of patient record documentation to be utilized
- Time frames were for inclusion or exclusion for specific measures
- Data dictionary reference information for data collection clarity

<p style="text-align: center;">STABLE Performance Measures Validity Ratings</p> <p style="text-align: center;">Acceptance required a median of ≤ 7.0 with no disagreement on a 9-point scale. Disagreement for panel of 13 members equals \geq of 4 panel members rating 1-3 and 7-9</p>	<p style="text-align: center;">Content Ratings Results</p>	<p style="text-align: center;">Gap Rating Results</p>
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	9.0 9.0	8.0 8.0
The % of patients diagnosed with bipolar disorder or unipolar depression who receive an initial assessment that considers the risk of suicide	9.0 7.0	7.5 8.0
The % of patients with unipolar depression or unipolar depression who receive an initial assessment that considers alcohol and chemical substance use	9.0 8.5	7.0 8.0
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	9.0 9.0	7.5 9.0
The % of patients with Bipolar I Disorder with depressive symptoms and/or behaviors who have evidence of use of a mood stabilizing or antimanic agent during the first 12 weeks of treatment	9.0 9.0	7.5 9.0
The % of patients with Bipolar I Disorder who received monotherapy with an antidepressant agent during the first 12 weeks of treatment	9.0 9.0	7.5 9.0
The % of patients with bipolar disorder who were monitored for weight gain during the initial 12 weeks of treatment	8.5 7.0	8.0 7.5
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	9.0 8.0	8.0 6.5
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	9.0 9.0	7.5 8.5
The % of patients diagnosed with bipolar disorder and treated with an atypical antipsychotic agent who receive at least one screening for hyperglycemia within the initial 16 weeks of treatment	7.5 7.0	7.0 8.0
The % of patients diagnosed with bipolar disorder and treated with an atypical antipsychotic agent who received at least one assessment for hyperlipidemia within the initial 16 week period of treatment	8.0 7.0	8.0 7.5
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	9.0 9.0	8.5 8.5
The % of patients diagnosed and treated for bipolar disorder who are monitored for change in their symptom complex within 12 weeks of initiating treatment	9.0 9.0	8.5 9.0
The % of patients with bipolar disorder who receive a recommendation for an adjunctive psychosocial intervention, including evidence-based therapies, within 12 weeks of initiating treatment.	9.0 9.0	8.0 8.0
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	9.0 8.0	9.0 8.0