The Integration of Measurement and Management for the Treatment of Bipolar Disorder: A STEP-BD Model of Collaborative Care in Psychiatry

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Patients with bipolar disorder are among the most challenging to treat. These patients frequently present with complex mood and other symptoms that change over time, complex psychiatric and medical comorbid conditions, and multiple medications. Clinicians rarely systematically assess or measure all of these factors and instead rely on memory and general impressions. It is imperative that clinicians systematically track and monitor these relevant variables to ensure treatment decisions are based on precise clinical data. By integrating measurement and management, clinicians and patients can collaborate to assess the effectiveness of treatments and to make joint decisions about critical points at which to adjust treatment. This method was shown to be successful in the National Institute of Mental Health (NIMH) Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD). *(J Clin Psychiatry 2006;67[suppl 11]:3–7)*

Blessed be all metrical rules that forbid automatic responses, force us to have second thoughts, free us from the fetters of Self.

—W. H. Auden, *Epistle to a Godson and Other Poems*

Patients with bipolar disorder present with pleomorphic, shifting signs and symptoms that include full *Diagnostic and Statistical Manual of Mental Disorders,* Fourth Edition (DSM-IV) syndromal episodes of recurring manic, hypomanic, and mixed states and major depression; subthreshold symptoms of mania and especially depression[1,2]; episodes of psychosis, or psychotic symptoms with manic or depressive episodes[3]; symptoms from coexisting full syndromal anxiety disorders or anxiety symptoms[4] or other comorbid psychiatric conditions, especially substance abuse disorders[5] and attention-deficit hyperactivity disorder[6]; and comorbid medical conditions.[7,8] To complicate matters further, bipolar patients take multiple concomitant medications[9] associated with adverse side effects,[10,11] including obesity and the metabolic syndrome,[12] as well as with problems of adherence. Clinicians need to identify, track, and manage these phenomena and simultaneously assess if treatments are effective. Without a method to systematically measure the course of bipolar disorder, clinicians risk missing important elements involved in the care of bipolar disorder, much to the detriment of their patients. The purpose of this article is to discuss methods to integrate measurement of the clinical progress of bipolar patients with the management of their care.

HISTORY OF CLINICAL MEASUREMENT IN PSYCHIATRY

Emil Kraepelin (1856–1926), considered the father of modern scientific psychiatry, meticulously measured the course of hospitalized psychiatric patients and used these data to classify mental disorders into dementia praecox, Alzheimer's disease, and manic-depressive psychosis in his *Compendium der Psychiatrie*. The wider community of clinicians never adopted his research methods, but the systematic assessment and recording of the course of his patients have helped to define categories of bipolar disorder to this day. With the dominance of the psychodynamic paradigm for much of the 20th century, psychiatric classification and nosology, and especially measurement of psychiatric symptoms, developed slowly. After the Feighner Criteria[13] and the *Diagnostic and Statistical Manual of Mental Disorders,* Third Edition (DSM-III) were initiated

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in 1972 and 1980, respectively, to improve research communication, most psychiatric residencies started to teach the classification system of DSM-III but did not teach residents to use these guidelines systematically in routine care. Perhaps one of the reasons that systematic classification is disconnected from the clinic is that the instruments (e.g., the Structured Clinical Interview for DSM-III[14]) used to make those diagnoses are generally lengthy and require training for reliability. The Mini-International Neuropsychiatric Interview instrument, for example, is more clinician-friendly but is not generally taught in residencies.[15]

With the advent of randomized clinical trials to prove efficacy for psychiatric interventions, it was necessary to devise methods to diagnose patients and measure clinical outcomes. Scales were developed that included direct observation along with self-report, including the Structured Clinical Interview for DSM,[16] the Hamilton Rating Scale for Depression,[17] the Hamilton Rating Scale for Anxiety,[18] the Brief Psychiatric Rating Scale,[19] the Young Mania Rating Scale,[20] and the Global Assessment of Functioning,[21] to name a few. While these scales are widely used in clinical trials, most clinicians have not adopted them for routine clinical care. Clinicians make diagnoses through general narrative interviews and assess outcomes with gross impressions.

Alvan R. Feinstein (1926–2001), considered to be the father of modern clinical epidemiology, integrated epidemiologic methods into clinical research. Unbeknown to most psychiatrists, Feinstein coined the term *comorbidity*.[22] He meant *comorbidity* to refer to the coexistence of multiple but pathologically distinct disorders, e.g., congestive heart failure and renal cancer. Returning to this definition brings into question psychiatry's use of the term *comorbid condition* as it applies to our categorical diagnostic system that divides up pathologically similar disorders across a spectrum of symptoms and behaviors, all related to brain function.[23] Nevertheless, Feinstein[24] argued that physicians would benefit from using numbers to measure the clinical manifestations of disease, i.e., physicians should be numerate when appropriate. The measurement of clinical phenomena should rest on clear principles and goals that are transparent, sensible, and easily administered.[24] With the exception of the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial[25] and the Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) project,[26] psychiatric researchers have not generally used assessments that have been or could be used in the clinic.

MEASUREMENT: ADVANTAGES AND DISADVANTAGES

To be overly numerate is to ignore the patient and treat numbers on a scale; to be innumerate is to make critical decisions with insufficient data. Avoiding measurement ignores a means of bringing important benefits to clinical care, such as enhanced precision, increased sensitivity to change, opportunities to detect longitudinal patterns, and improved understanding of records and communication with patients and other caregivers. There are some risks to increasing use of standardized measures. When scores become the end rather than a means of examination, excessive data and inappropriate measures can be an obstacle to understanding patients. For instance, severity scores from rating scales are not valid means to diagnose depression or mania. Depression rating scale scores from patients suffering flu are misleading. Furthermore, routine use of formal rating scales can strain rapport and requires time and training. Most clinicians avoid the problems of measurement by avoiding measurements altogether. When clinicians limit measurement and record narratives and general impressions rather than systematically assessing the relevant facets, their ability to track the complex phenomena of bipolar disorder is degraded substantially. Asking general questions is helpful in forming an overall impression but does not lend itself to obtaining precise data to assess if treatments work and to guide changes in treatment.

Table 1. Advantages of a Measurement-Based Collaborative Care Model in Psychiatry

Obtains precise cross-sectional and longitudinal data
Enables clinicians to be systematic and avoid errors of omission
Requires less dependence on memory
Facilitates greater precision by tracking individual symptoms
Enables a blend of clinician authority and patient autonomy
Encourages joint decisions with patient and clinician as an iterative process
Allows patients to be informed and cognizant about full range of symptoms

The advantages of measurement (Table 1) during routine clinical care are many: clinicians can be systematic and reduce errors of omission, a broad range of symptoms can be assessed for severity and scope without relying on memory for completeness, standardized ratings can be recorded efficiently, critical decision points can be made based on cross-sectional and longitudinal data, and assessment of the effectiveness of each intervention can be assessed and shared with patients. If patients decide to try (or will not try) particular interventions, the clinician's and patients' ratings serve to measure the effect of those decisions and provide useful data for joint management decisions. The iterative implementation of this measurement-management process is the guiding principle of collaborative care. Most important, the patient becomes an informed collaborator, cognizant of the full range of relevant symptoms and positioned to examine the change (or lack of change) in his or her symptoms in response to interventions. This is not to suggest that a slavish and overly obsessive attention to measurement should be the sole basis to manage patients, but, instead, that the mea-

surement of clinical phenomena to monitor the effects of treatment of bipolar disorder can be a valuable tool that facilitates care and improves the basis of shared clinical decision-making and collaborative care.[26]

MEASUREMENT AS THE BASIS FOR COLLABORATIVE CARE

Models of patient care have evolved from an authoritarian model in which physicians dictate to patients what their treatment will be to a model in which patients participate in making treatment decisions. The authoritarian model operates on the assumption that the physician knows best. Since patients may be regarded as incapable of making medical decisions, they are not necessarily informed about their illness and may have no participation in treatment decisions.[27] Patients are expected to adhere to instructions and be compliant with physician orders. When we use the terms *adhere* and *comply*, we knowingly or unknowingly invoke the authoritarian model.

On the opposite end of the spectrum, the model of patient autonomy dictates that patients have sole responsibility for all medical decisions, and the physician must, in all cases, defer to those wishes.[27] The physician acts as a guide and teacher but never tells or orders the patient to do anything. In this model, the physician is stripped of all authority and even responsibility for outcomes. As cogently argued by Schneider,[28] extremes of the authority and autonomy models can, in practice, result in suboptimal outcomes. Schneider tells a story of visiting a dentist who refused to give his opinion about whether Schneider needed to have a risky procedure—the dentist inappropriately deferred to the patient to make the decision. Schneider felt that he simply did not have the adequate information or experience to understand the risks and benefits and wanted guidance from someone who did.[28] Absolute physician authority or absolute patient autonomy ignores the opportunity for a meaningful and necessary dialogue of informed consent and shared responsibility.[29]

Alternatives to the authoritarian and autonomy models include models of shared decision-making,[30] relationship-centered care,[31] and collaborative care that blend the authority of the physician (by virtue of superior training, knowledge, and experience) with patient autonomy (informed by patient knowledge, preferences, and values).[32,33] Through a model of shared decision-making, patients become active partners in treatment, take appropriate responsibility for decisions, and are more likely to form a collaborative relationship with their physicians. Through this collaborative model, physicians and patients agree about joint decisions and reach concordance about competing options, taking into account information about the illness and the risks, benefits, and alternatives in treatment decisions (including the decision to refrain from any intervention). The respectful collaborative-care model appears to be what patients with bipolar disorder prefer.[34] Physicians and patients may also find it necessary to shift the balance between the authority model and the collaborative model depending on circumstances,[35] e.g., the physician does not defer to the wishes of suicidal patients to harm themselves.

While the collaborative care model sounds attractive, the model does not specify how busy physicians should implement it. For collaborative care to work, physicians and patients need to make mutually acceptable joint decisions based on shared data. Shared data not only consist of information about the course of illness and expected risks and benefits of treatment and behavior, but also rest on shared measurement of response to treatment. Through shared measurement of clinical progress, the physician and patient talk about the essential ongoing iterative treatment decisions: "Let's look at what we decided together and the outcome of that decision" and "Now let's discuss the next set of options so that you and I can increase the probability that you can be relieved of these specific symptoms acutely in a way that is acceptable to you, helps you to function optimally, and decreases the probability that you will have another mood episode." Alternatively, if a patient declines to try a treatment, by measuring outcomes together, the physician and patient can assess if this strategy worked. We argue that without measurement, this dialogue is not possible.

The collaborative care model has to be flexible enough to meet exigencies that arise in the context of the care of bipolar patients. Emergencies trump collaboration. Specifically, acute suicidal risk, acute severe mania that puts someone at risk of harming themselves or others, or psychosis during depressive or manic episodes that could also result in harm require the clinician to take charge, make decisions, and implement appropriate treatments including involuntary hospitalization. The role of collaboration fits into planning for those exigencies. When patients are more stable, the clinician can discuss what will be done in the patient's best interest when the patient is in danger and formulate a plan that includes the patient's loved ones. It can be helpful to have a written plan and give the patient and his or her family a copy, readily available for emergencies.

MEASUREMENT AS A TOOL TO ACHIEVE REMISSION

An additional advantage of measurement is that clinicians and patients can assess response to treatment with greater precision by tracking individual symptoms and identifying specific residual symptoms for further interventions. Patients with bipolar disorder spend a substantial amount of their lives with subsyndromal symptoms of depression[1,2] associated with decreased psychosocial functioning[36] and increased burden on their caregivers.[37] It is

Table 2. Instruments to Use for Collaborative Care of Bipolar Disorder[26]

The Clinical Monitoring Form (CMF)	The CMF streamlines the process of eliciting and recording basic information during routine follow-up visits from patients suffering from a mood disorder
The Affective Disorders Evaluation (ADE)	The ADE streamlines the process of eliciting and recording patient history information during initial visits or consultation visits with patients suffering from a mood disorder
The Clinical Self-Report Form	The Clinical Self-Report Form was designed to systematically collect information about the symptoms commonly experienced by patients with mood disorders. Collecting information at each visit allows the doctor to better track the course of the patient's symptoms and response to treatment
Mood chart	A mood chart is intended to provide a simple means of generating a graphic representation of a patient's illness over the last month. Mood charting allows patients to systematically bring together important pieces of information such as medication levels, mood state, and major life events to see emerging patterns that otherwise might be difficult to discern
Treatment contract	A treatment contract is a document that the patient writes while feeling euthymic to plan for the times when he or she will be symptomatic. It is written so the patient, as well as the patient's family, friends, and doctors, can recognize his or her symptoms of illness and can comply with the patient's wishes for treatment

possible that for a substantial number of bipolar patients with these symptoms, better recognition would facilitate treatment with the goal of full remission.[38]

Remarkably, the concept of remission, while developed for the treatment of unipolar depression, has not yet been fully defined for bipolar disorder, especially for routine clinical practice.[26] The course of bipolar disorder is characterized by major depressive episodes, manic and hypomanic episodes, and persistent depressive, irritable, and anxious symptoms,[39] along with hypersensitivity to stress and decreased resilience, cognitive dysfunction,[39] and difficulties with overall functioning. Remission of all of these domains would be required to define recovery. To define recovery, though, systematic measurement is required to assess all of these domains.

MEASUREMENT AND MANAGEMENT OF BIPOLAR DISORDER: LESSONS FROM STEP-BD

The Systematic Treatment Enhancement Program for Bipolar Disorder project was designed to establish a system of care and monitoring of a large cohort of participants who would be treated in specialty clinics.[26] Since any patient with any variant of bipolar disorder could be entered, including those with a full range of other psychiatric disorders, the study would be able to determine the outcome of bipolar disorder under conditions of optimal and systematic care—and this had never been done for any psychiatric disorder. Furthermore, randomized clinical trials investigating antidepressants for bipolar depression and the management of treatment-resistant bipolar depression were embedded in STEP-BD; studies of polycystic ovarian syndrome and genetics of the disorder were also included. The principles of measurement and management were easily accessible to clinicians and patients through the thoughtful design of data-gathering instruments used in routine clinical care. Clinicians could both gather objective data for use in clinical research and use that information to guide collaborative care with patients and their families (see Table 2).

Table 3. Useful Web Sites for Clinical Measures to Manage Bipolar Disorder

Massachusetts General Hospital Bipolar Clinic & Research Program	http://www.manicdepressive.org
Mood and Anxiety Disorders Institute (MADI)	http://www.mghmadi.org
Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD)	http://www.stepbd.org

In order to facilitate collaborative care, STEP-BD provided participants with a user-friendly workbook, a self-rating form, and a clinician-administered Clinical Monitoring Form (CMF).[26] The workbook not only provided information about bipolar disorder but it also gave the patients, their families, and their physicians a framework for building a collaborative care team. The self-rating form was filled out in the waiting room prior to clinical visits. The physician would use the self-rating form to assist in completing the CMF. The clinician used the CMF to measure depressive, manic, psychotic, and anxiety symptoms, as well as stressors, medical events, consumptive habits, medications prescribed (and doses missed), medication side effects, and clinical status. Clinical status was determined by assessing the duration of symptoms in the context of the patient's last clinical status. For example, *recovering* is defined by a complete lack of symptoms for one week, and *recovered* is defined as at least 8 weeks of recovering status. These assessments are all reviewed with the patient and form the basis of joint collaborative decision-making. In addition, a self-rated form to monitor mood daily could also be used to augment the CMF. The mood-monitoring form records the greatest levels of mood elevation and depression that a patient felt during the day, as well as sleep, anxiety, and irritability along with any salient events, medications, and side effects. The self-rated waiting-room form, the CMF, and the mood-monitoring form are all readily available to download from www.manicdepressive.org (Table 3).

CONCLUSIONS

Patients with bipolar disorder face considerable hurdles to recover from acute episodes and achieve sustained wellness. Clinicians face substantial obstacles to track and manage the multiple facets of bipolar disorder. We suggest that by integrating measurement and management, patients and clinicians can follow the principles of collaborative care to increase the probability of good outcomes.

Disclosure of off-label usage: The authors have determined that, to the best of their knowledge, no investigational information about pharmaceutical agents that is outside U.S. Food and Drug Administration–approved labeling has been presented in this article.

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