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Mood Charting and Technology: New Approach to Monitoring Patients with Mood Disorders

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Abstract: Bipolar disorder remains a serious public health problem with a significant personal and economic burden. In line with the widespread recognition of the value of active patient involvement in their care, daily mood charting may increase the patient's understanding of their condition and improve adherence with complex medication regimes. Knowledge about the course and pattern of an individual's disorder may also allow earlier recognition of new episodes and help determine the optimal treatment strategy. Mood charting is also an essential tool for longitudinal studies of patient outcomes. Traditionally, patients have used paper-based tools for this daily self-assessment, but these forms are associated with problems of data quality, poor compliance, high costs for data entry, and only provide limited feedback for the patient and physician. As computer technology has gained acceptance by the public worldwide, new options are available to automate monitoring of patients with mood disorders. This article will review mood charting and describe our experience with the development, validation and use of ChronoRecord, an automated instrument for mood charting.

Keywords: Bipolar disorder, mood disorders, longitudinal studies, methodology, self-reporting, mood charting.

INTRODUCTION

Bipolar disorder is an episodic condition that is associated with high morbidity and disability [1], and is the most expensive mental health diagnosis for patients, their insurance companies [2], and employers [3]. The lifetime prevalence of the full bipolar spectrum is estimated to be between 2.6-6.5% of the general population [4]. The severity of symptoms, duration and number of episodes, recovery between episodes and pattern of polarity varies greatly both within individuals and among patients [5-7]. Despite the availability of many new pharmacologic treatments for bipolar disorder, many patients have a poor outcome. Adherence with prescribed treatments is often inadequate, with non-compliance rates reported to be 40-54% [8-10].

Many investigators believe that a collaborative practice approach, which emphasizes patient self-management, patient education and structured interventions, may improve the treatment of chronic mental illness [11,12]. Moreover, patients who have psychosocial problems are likely to be

satisfied with this patient-centered style, and may prefer a partnership approach to medical care [13,14]. A variety of structured interventions that were designed to promote early recognition of mood episodes, increase medication adherence and develop self-management skills have been shown to improve the outcome of patients with unipolar depression [15,16] and bipolar disorder [17-20]. One intervention that is frequently recommended for the treatment of bipolar disorder is daily mood charting. Paper-based self-reporting instruments have been successfully used in clinical practice and in longitudinal research studies to characterize the long-term course of bipolar disorder. We will describe our experience in developing ChronoRecord software to automate mood charting and thus take advantage of the widespread acceptance of computer technology.

PAPER-BASED MOOD CHARTING

Several paper-based data collection instruments for daily recording of mood have been developed for the study of patients with bipolar disorder, including the Life Chart Methodology [21] and the STEP-BP Mood Chart [22]. A third instrument, the ChronoSheet [23], grew out of a simple system of self-reporting developed by Peter Whybrow during the 1980s to follow the clinical course of patients with the rapid-cycling variant of the illness. As with all these instru-

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ments, data collection periods of a day or less are optimal to minimize recall bias with patient self-reporting [24].

BENEFITS OF DAILY MOOD CHARTING

Daily mood charting complements clinician monitoring and provides many benefits for both the patient and clinician. The identification of an individual's pattern of illness may directly impact the specific treatment selection. Daily recording may capture observations that would be missed if data were only collected at clinic visits. One study of patients with bipolar disorder found that weekly clinician ratings captured only 31.4% of days of depression and 14.1% of days of mania recorded by patients completing daily self-ratings [25].

As an educational tool, daily mood charting may help the patient to gain insight into illness patterns, to recognize prodromal symptoms and to learn when to seek professional assistance. Also, the very act of self-recording may serve as a visible reminder that improves patient adherence with prescribed medications [26]. For example, the daily process of charting illness may enhance adherence in patients with bipolar disorder [27, 28] or patients with chronic pain [29].

Daily mood charting instruments are also commonly used in investigational studies of bipolar disorder where longitudinal prospective studies are the optimal approach to understanding the course of illness and evaluating treatment options [21, 30].

PROBLEMS WITH PAPER-BASED MOOD CHARTING

Several significant problems limit the usefulness of a paper-based mood charting instrument. One problem is poor or partial compliance. Patients often complete paper mood charting forms sporadically [31], or just before a clinic visit when the retrospective recall of events may be inaccurate and biased [32]. A review of eight studies comparing entries on paper diaries with the data collected from instrumented devices, such as blood glucose monitors or inhalers, showed that while patients reported an average compliance rate of 88%, the actual compliance rate was 54% [33]. Furthermore, with no time-log of when patient recordings are made, recall errors are often overlooked or ignored [31].

Another problem with paper based mood charting involves transforming the information from paper documents into electronic form for computer analysis. Such data entry is expensive, estimated to constitute 5-10% of the total project cost [34], slow and error prone. Handwritten documents are the most difficult for data entry staff to handle, and require good procedures and intelligent operators. Operators have to determine what is useful in a partially legible, incomplete, ambiguous, or 'noise filled' hand-written document. Another problem is that paper forms cannot prevent contradictory data or request missing data. The high rates of illegible or out-of-range values found in paper-based diaries may limit their usefulness in clinical research [35].

If the data is being collected for longitudinal studies, many data quality problems may exist even when data entry is accurate. Longitudinal data collected from paper-based forms frequently suffers from significant missing values, differential attrition, inconsistent assessment intervals and a

variable number of observations for each participant [36]. Missing data may have a major impact on the analyses, [37-39] especially if there is a relationship between that data and the outcome values [37, 40,41].

COMPUTERS ARE HOUSEHOLD APPLIANCES

Automating daily mood charting became feasible because of the worldwide growth of households with a PC. No longer the province of technology enthusiasts, PCs have become standard household appliances throughout the industrialized world. In 2003, 61.8% of households in the US had at least one computer [42]. By the end of 2004, there were 616 million PCs in the 15 countries with the most computers [43]. One consequence of computers becoming ubiquitous is that patients now expect physicians to use automated tools as part of modern healthcare [44].

To illustrate the acceptance of technology by the general public, electronic diaries have been successfully used in longitudinal studies of patients with a variety of illnesses including chronic pain [29, 45], Parkinson's disease [46], systemic lupus erythematosus [47], asthma [48], substance abuse [49], migraine [50], and diabetes [51]. Several studies have directly compared patient acceptance of computerized and paper-and-pencil assessments, and concluded that computerized versions did not produce anxiety in subjects of different sexes or educational backgrounds [52, 53]. Furthermore, people with disabilities view technology more favorably than those without disabilities, because it provides an opportunity to connect to the outside world including others with similar experiences [54, 55].

Other studies have compared the effectiveness of paper versus electronic diaries. Patients with chronic pain were found to falsify between 75-80% of the date and time entries in paper diaries (backfilled prior to office visits), while the compliance rate with an electronic diary was 94% [56]. In studies that directly compared self-reporting into an electronic versus a paper diary, the use of the electronic diary was preferred by patients with asthma [35], gastroesophageal reflux disease [57], hemophilia [58,59], temporomandibular disorders [60], menstrual disorders [61], and children with chronic pain from headaches or arthritis [62].

DEVELOPING AN AUTOMATED TOOL, CHRONO-RECORD

The rapid incorporation of computer technology into everyday life by the general public provided a unique opportunity to improve the quality of daily mood charting. With this in mind we developed ChronoRecord, an automated version of the self-report ChronoSheet. The patient only needs basic familiarity with a computer to use ChronoRecord, and it takes just a few minutes a day to complete. The ChronoRecord data collection software presents the patient with large, colorful icons for mood, medication and sleep to facilitate data entry. The data that is collected with ChronoRecord is shown in Table 1. For recording mood ChronoRecord uses a 100-unit visual analog scale (VAS) between the extremes of mania and depression that the patient marks proportionately. ChronoRecord uses a slider bar to represent the VAS. The patient moves a knob in the slider bar to select the appropriate mood rating. During the patient's training, personal anchor points were set by the patient describing the most de-

pressed and most manic states they ever experienced. The patient's anchor point for mania, and daily self-ratings of mania or hypomania reflect activation levels for either euphoric or dysphoric mood [63]. Instructions to the patient for mood entry were: 1) Enter a single rating that best describes your overall mood for the prior 24 hours, 2) Carefully review the entire 24-hour period, 3) Try not to let previous day influence how the current day is rated, 4) Calibrate the rating to the anchor points set during enrollment, and 5) Try to enter data at the same time every day. The data collection software is available in English for North America and the U.K., German, Spanish, Polish, Portuguese and Dutch.

Table 1. Data Collected with ChronoRecord

Data Collected	Description	Frequency of Collection
Mood	Overall mood for the prior 24 hours, in relation to extreme anchor points set for patient	Daily
Sleep	Awake, asleep, or in-bed and awake for each hour of the day	Daily
Medications	Name and dosage of all psychiatric medications taken in the prior 24 hours	Daily
Life Events	Patient description of significant life events in the prior 24 hours	Daily
Menstrual Cycle*	Menstrual bleeding over the prior 24 hours (Y/N)	Daily
Weight	Body weight	Weekly

* Only collected from pre-menopausal women.

A validation study described in detail elsewhere [63] compared self-reported ChronoRecord mood ratings from 96 outpatients with clinician mood ratings on the Hamilton Depression Rating Scale (HAMD) [64] and Young Mania Rating Scale (YMRS) [65] and self-reported ratings on the paper-based Beck Depression Inventory (BDI) [66]. To assess concurrent validity, the ratings for the same date at 4 visits over the 3-month study period were evaluated using Pearson correlation, linear regression and general linear mixed model analyses. The Pearson correlation coefficient between HAMD and ChronoRecord was -0.683 ($p < .001$), between BDI and ChronoRecord was -0.673 ($p < .001$) and between YMRS and ChronoRecord was 0.395 ($p < .001$). Both the results of estimating a linear regression and a general linear mixed model that includes a patient factor were significant and consistent. The strong correlation coefficient together with the results of the regression and mixed model showed concurrent validity for HAMD. YMRS was not validated with ChronoRecord in the original study due to insufficient days when clinician YMRS ratings indicated mania in the outpatient sample. Thus an additional validation study was completed using 25 inpatients with mania. ChronoRecord was validated with YMRS for both the inpatients and outpatients (Pearson correlation coefficient 0.709, $p < .001$) and for

the inpatients alone (Pearson correlation coefficient 0.601, $p < .001$) [67].

In the validation study, the mean \pm SD percentage of days missing for mood data was $6.1 \pm 9.3\%$, equivalent to missing 7.3 out of the 114.7 days. The pattern of missing mood data was missing completely at random (MCAR). There was no relationship among the missing data, the patients' demographic characteristics and the patients' mood, including the extremes of mania or depression. At the end of the validation study, 77 (96%) of the 80 patients completed an evaluation questionnaire to rate their comfort with the ChronoRecord software on a 5-point scale (0=not usable, 5=excellent). The mean overall rating was 4.65.

We also investigated if the use of a computer would bias the self-reported data that was collected and found it did not [68]. The gender, ethnicity, diagnosis, age, disability status or years of education did not bias the patient daily mood ratings on the ChronoRecord software. Furthermore, the demographics characteristics of the patients in the validation study were very similar to those reported for patients with bipolar disorder who participated in similar longitudinal studies using paper-based tools [68].

The data collected with ChronoRecord has been used for longitudinal, prospective studies of patients with bipolar disorder, including investigations of the relation between mood and sleep in the prodromal period [69], the differences in the clinical course between the sexes [70], and a comparison of the mood switches to mania in patients taking or not taking antidepressants [71]. ChronoRecord mood charts can be printed on demand (Fig. 1). This immediate feedback and may improve subject motivation to complete a long-term study and may enable the timely use of clinical information captured during a longitudinal study [72]. We have also found that ChronoRecord is well suited as a clinical tool to track individual patient progress [31, 73].

BENEFITS OF AUTOMATING MOOD CHARTING

We found many benefits to automating mood charting. A primary benefit of relates to an improvement in data quality. Since much of the data collected in mood charting is numerical or categorical, it is ideally suited for collection using computer technology [72]. By including error and consistency checks at the time of data entry, out-of-range or internally inconsistent values can be prevented from entering the database [74]. A further benefit of automating data collection is the elimination of the need to transpose the data into an electronic form for analysis.

The ChronoRecord is designed to prevent some data entry errors, and requires the patient correction of others at the time of data collection. For example, ChronoRecord requires that the patient enter weight once a week before the mood data is accepted, requires confirmation before the sleep entry is accepted if the patient enters 0 hours of sleep, and a similar validation before the medication entry is accepted if the patient records a large number of pills being taken. As an added precaution ChronoRecord also prevents modification of previously entered data and of data entry for a future date.

Automating mood charting can help to reduce missing data. Missing data may have a major impact on the analyses, especially if there is a relationship between that data and the

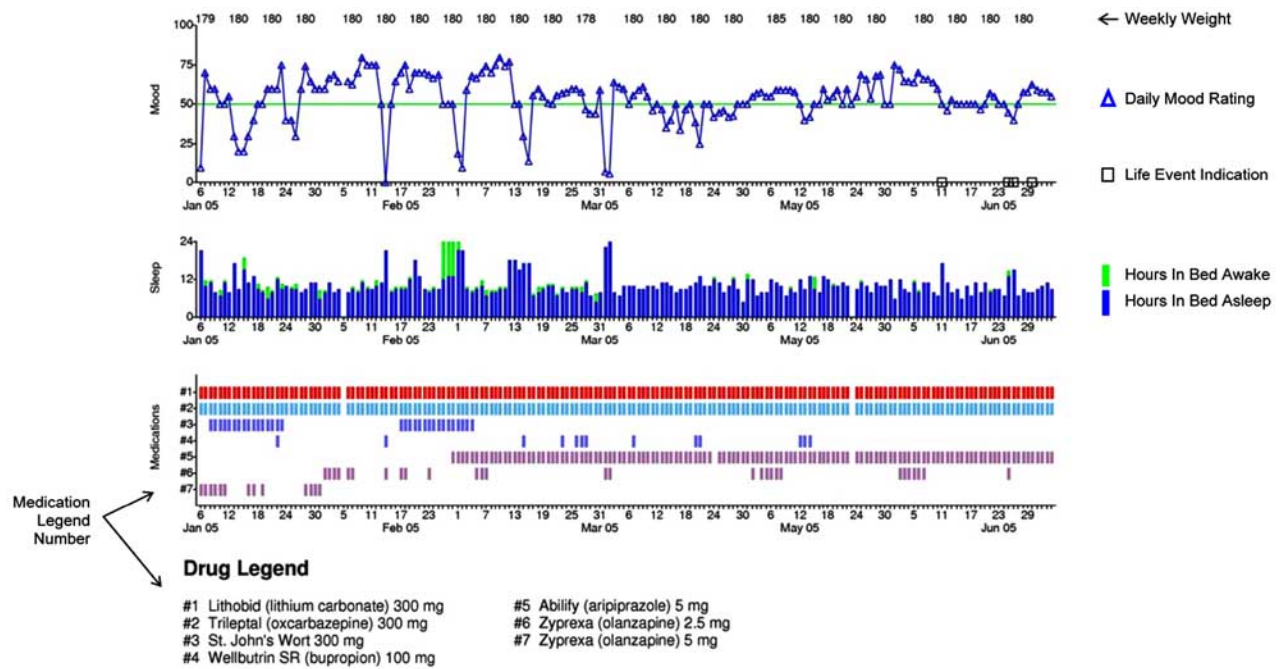


Fig. (1). 180 day mood chart from a 41 year old male with bipolar I disorder.

outcome values [75-77]. Additionally, since both missing values and the strategies used for dealing with missing values can create a potential bias or loss of statistical power [78, 79] and there are no universally applicable methods of handling missing values in clinical trials [80], it is preferable to emphasize techniques, such as automating self-reporting, that can minimize the amount of missing data [79]. In the ChronoRecord validation study in over 80% of patient less than 10% of the daily data were missing [63]. In addition since data can be collected daily, rather than weekly or monthly, a small number of missing values typically have only a minimal impact on the statistical methods used in the analysis.

An automated electronic system can help to standardize data collection in studies at multiple centers, enabling the rapid development of large databases that are consistent and reliable. Automated tools such as ChronoRecord may be used to collect data in open, observational longitudinal studies. Since subjects excluded from randomized controlled trials may participate with this design approach, supplemental information to complement the findings from randomized controlled trials may be obtained [81]. For example, longitudinal data could be collected from patients with bipolar disorder who have multiple comorbidities, a rapid cycling course, medical illnesses or who receive varying complex polypharmacy regimens.

Automated mood charting also provides benefits for the clinician. The graphical illustration provided by ChronoRecord can help the clinician to determine treatment response especially when multiple medications are involved, to assess the patterns of illness over time, and to determine the association between symptoms and events such as hormonal changes, seasonal changes, and psychosocial stressors.

Another benefit of automation is that it can expand the variety of effective psychosocial interventions that are available for the patient and physician. For example, several automated methods (personal computer, Internet, IVR) have been successfully used to deliver cognitive behavioral therapy for patients with depression and anxiety disorders offering 24-hour availability, no appointments and the flexibility to repeat sessions [82]. An automated mood charting system adds a modern approach to daily life charting.

OTHER APPROACHES TO AUTOMATING COLLECTION OF MOOD DATA

Various technological approaches have been successfully implemented to improve on the available paper-based tools used in longitudinal studies of bipolar disorder. Other examples of automated systems for reporting affective symptoms include the use of a palmtop computer to enter life charts [83], employing an interactive voice response system (IVR) over the telephone to administer the HAMD and HAMA scales [84], using a PC to administer a modified version of the HAMD [85], an optical scanning format of the Internal State Scale [86]. The selection of technological approach varies with the patient population, available budget, clinical or study trials situation, and technological skill level of the administrative staff.

CHALLENGES OF AUTOMATING MOOD CHARTING

The primary challenge of implementing ChronoRecord or any automated system for mood charting is that a modification of the daily work routine is required. Clear procedures for clinicians, administrative staff, and patients must define the steps involved in registration, training, data collection, and ongoing technical support. Regardless of the technology involved, both staff and patients must receive adequate train-

ing to use a new technology, adequate budget must be allocated, and a staff member must be assigned overall responsibility for on-going use of the new technology. Table 2 lists the steps that must be addressed for successful implementation and continued use of a new technology.

Table 2. Steps to Ensure Successful Implementation and Continued Use of an Automated Monitoring System

Step	Description
Establish management commitment	Senior management must clearly commit to implementing any new technology.
Document procedures to customize the use of technology for your site	Standardized Operating Procedures (SOPs) and checklists for tasks are essential to maintain consistency over time and across staff and sites.
Select project manager	The project manager has overall responsibility to complete a technology project on time and budget.
Select systems administrator	The systems administrator has overall responsibility for all routine procedures involving a technology, such as training, backup, and data transfer.
Train staff	Staff training is required to successfully incorporate technology into the current work environment.
Train patients	Patient training is required to ensure data reliability and consistency.
Coordinate hardware/software maintenance	Coordinate with software and hardware vendors for on-going support.
Enforce security and privacy policies	Assign responsibility for all security aspects including managing physical access, password control, and remote access.

Table 3. Summary Points

<ul style="list-style-type: none"> Recent approaches to the treatment of bipolar disorder emphasize the role of patient self-management, patient education and structured interventions such as daily mood charting.
<ul style="list-style-type: none"> The widespread worldwide acceptance of computers by the general public allows daily mood charting to be automated.
<ul style="list-style-type: none"> Automated data collection can reduce errors, improve data quality and improve patient compliance.
<ul style="list-style-type: none"> Patients with a wide variety of medical conditions are already using automated data collection tools.
<ul style="list-style-type: none"> Successful implementation of technology projects requires documented procedures and assigned responsibilities.
<ul style="list-style-type: none"> Self-reported data from validated automated mood charting technologies can supplement physician findings in clinical settings and longitudinal studies.

FUTURE DIRECTIONS

In the future, as a variety of validated, automated psychosocial tools become available, physicians will better be able to tailor the interventions and delivery methods to meet patient needs and preferences. Additionally, self-reported patient data will be integrated with other large databases including clinical, investigational and genetic information as the combination of innovative processing systems and low-cost computing power will provide an orderly framework for

the sciences to collect, organize and transform information [87].

CONCLUSION

In conclusion, daily mood charting is a well-established intervention that is compatible with a collaborative practice approach to bipolar disorder. Mood charting can increase patient involvement in their care and provide useful data for clinical practice and longitudinal studies. The widespread acceptance of home-based computer technology can be leveraged to improve daily self-reporting. Automation of data collection may increase patient interest in long-term use, decrease missing data, improve data quality, and expand the number of subjects participating in a standardized protocol across centers. We developed the ChronoRecord, an automated mood charting tool, which has been successfully used in longitudinal studies of patients with bipolar disorder lasting about 6 months. We found that the graphical depiction of mood fluctuations were a useful clinical tool to determine individual medication response and patterns of illness. Automated mood charting can be combined with other psychosocial interventions, delivered by standard or automated methods, to expand the choice of interventions available to patients and clinicians. When implemented with adequate preparation, self-reported data from a validated technology can contribute additional useful information in both clinical and research settings.

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