Grant Final Report

Grant ID: R18 HS017189

Using Information Technology to Provide Measurement Based Care for Chronic Illness

Inclusive project dates: 09/01/07 - 08/31/10

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Abstract

Purpose: This project was designed to test a method of facilitating measurement based care (MBC) through the use of a clinical decision support system (CDSS) that was integrated into an existing electronic health record (EHR-CDSS).

Scope: Despite the availability of new and effective treatments for MDD evidence continues to demonstrate variable adherence and inadequate antidepressant treatment regimens. An integrated EHR-CDSS model was proposed to provide the tools of MBC and the utilization of evidence-based decision-making at the point of care.

Methods: This EHR-CDSS program was a collaboration between UTSW and the Centerstone Community Mental Health Center, Inc. The EHR-CDSS was instituted in 21 clinics (14 rural/7 urban) and designed to facilitate MBC and improve medication management for patients with MDD, by using information technology (IT) to ensure that clinicians were using standardized measures to monitor three critical response domains: 1) symptom severity, 2) side-effect burden, & 3) treatment adherence.

Results: We analyzed 208 (out of 289) Centerstone employee surveys as part of the Needs Assessment. This assessment primarily revealed concerns that the research would increase the time burden for Centerstone clinicians. With regard to the results of the implementation, no statistical differences were seen between baseline and week 24 with regard to any of the 3 outcome domains. However the pattern of the results is encouraging and symptom decreases were seen early in the course of the study and this follows the pattern of other similar studies.

Key Words: measurement-based care; computer decision support; health information technology; needs assessment

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Final Report

Purpose

This project was designed to test a method of facilitating measurement based care (MBC) in an ambulatory care setting through the use of a clinical decision support system (CDSS) that was integrated into an existing electronic health record (EHR-CDSS). This proposal focused on the use of MBC to improve the quality of care for patients with major depressive disorder (MDD). This EHR-CDSS program was designed to facilitate MBC and improve medication management for patients with MDD, by using information technology (IT) to ensure that clinicians were using standardized measures to monitor three critical response domains: 1) symptom severity, 2) side-effect burden, & 3) treatment adherence.

This was a collaborative project between the University of Texas Southwestern (UTSW) Medical Center and the Centerstone Community Mental Health Center, Inc. Centerstone is a behavioral health services organization that provides mental health treatment throughout the state of Tennessee. The EHR-CDSS facilitating MBC was instituted in 21 clinics (14 rural/7 urban) that treat approximately 8000 patients with MDD. The first part of the project was primarily devoted to: 1) customizing the CDSS to take into account the specific needs of Centerstone and 2) integrating the CDSS with Centerstone's EHR. The second part of the project was designed to implement the EHR-CDSS and intuited MBC for the treatment of MDD. Additionally, the project aimed to assess the effectiveness of the integrated EHR-CDSS to increase the use of MBC principles in medication management by participating clinicians treating patients with MDD.

As a first step, a needs assessment was conducted with representative Centerstone clinical staff members to determine how best to integrate the CDSS and EHR. Subsequently, to fully evaluate the effectiveness of the EHR-CDSS, two research studies were conducted. The first study was designed as a comprehensive, system wide evaluation inclusive of all clinicians using the EHR-CDSS and all of their patients with depression that require a treatment change (either switching medication or dose increase). The second study was designed as an in-depth evaluation of the impact of the EHR-CDSS on a limited sample of physicians and their patients, and directly assessed the use of MBC using a pre-post test design.

Study Objectives

The overall goal for the proposed study is to advance knowledge in integrated EHR/Measurement Based Care for MDD, in both rural and urban ambulatory settings. The aims are as follows:

Aim 1: Integrate a CDSS, facilitating MBC, with physician needs and the EHR at Centerstone. In order to develop an EHR-CDSS that can be used effectively to implement MBC, the project was comprised as a 3-stage process:

- Stage 1: End-User needs assessment—providing information regarding the needs of both the physician and the Centerstone care system;

- Stage 2: Modification of the CDSS based on the information from the needs assessment; and

- Stage 3: Building the CDSS to interface with Centerstone's EHR.

Aim 2: Evaluate EHR-CDSS's successful promotion of MBC in improving medication management. The second aim was designed to evaluate the extent to which implementation of the EHR-CDSS promoted the use of MBC as standard care for depression in both rural and urban settings. Two studies were conducted to evaluate the effects of using an EHR-CDSS to institute MBC. The first study was designed to look at the impact across the entire health care system and the second as an in-depth evaluation of treatment practices and their effects in a sample patients being treated for MDD.

Scope

Background

Despite the high prevalence of major depressive disorder (MDD) and the availability of new and effective treatments over the last 20 years, recent evidence in practice settings continues to demonstrate high rates of inadequate antidepressant medication treatment in terms of dose and duration, as well as low adherence and high drop out rates, all contributing to low rates of remission. Even in guideline-driven practice, clinical treatment of depression varies widely among practitioners. Clinicians often change from one antidepressant to another too quickly or conversely, conduct an unnecessarily prolonged treatment trial with an obviously unsuccessful medication or psychotherapy. Practitioners also differ in how they assess the outcomes of treatment (symptoms, function, side-effect frequency and burden), with global judgments often used instead of specific symptom assessments, even though the former are less accurate. These differences lead to wide variability in treatment implementation and likely also result in wide variations in outcomes in typical practice.

Context

The change in how depression is conceptualized, from that of an episodic, purely psychological disorder to a biologically driven chronic disorder, has also led to the need to fundamentally change treatment practices. To date, such change has not become part of the standard of care. For example, unlike chronic medical disorders like hypertension, diabetes mellitus and asthma, use of standardized measures of symptoms and side effects are currently not routine practice in psychiatric clinical settings. Following from the previous work of the Texas Medication Algorithm Project (TMAP) study, the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial developed the concept of Measurement Based Care (MBC) as a

means of facilitating evidence-based care of depression. Elements of MBC include: 1) Standard assessments of symptoms, function and side effects; 2) Use of critical decision points based on a state-of-the art algorithm for MDD; 3) Consistent patient follow up; and 4) Performance feedback for clinical decision-making.

An MBC approach is essential to clinical decision-making in the treatment of MDD, allowing the physician to individualize decisions about care for the patient based on their progress and their ability to tolerate the medication. The merging of MBC strategies with existing technology should improve quality of care and outcomes of depression by maximizing delivery of appropriate treatment for MDD in ambulatory care settings, making it possible to electronically monitor treatment consistency with effective practices, as well as making MBC strategies accessible and user-friendly for medical providers. The proposed merging of a computerized decision support system (CDSS) for MDD with the electronic health record (i.e. EHR-CDSS) is hypothesized to serve to integrate and evaluate a CDSS that includes MBC into an EHR as it is being implemented in an ambulatory clinic setting.

Settings

This research was designed to test a method of instituting MBC using the CDSS developed from the TMAP algorithm, which was integrated with an EHR in a clinical setting, Centerstone Community Mental Health Centers, Inc. The TMAP algorithm for MDD has previously been tested in the public mental health sector, showing that evidence-based treatments increase the likelihood of achieving full remission. The resulting CDSS was intended to ensure a high degree of adherence to this well-developed and tested pharmacological algorithm for the treatment of MDD. The integration of our CDSS to an EHR was hypothesized to enhance integration of MBC into urban and rural practice settings by requiring information regarding the three primary measures of MBC (i.e., level of symptoms, assessment of side effects, and assessment of adherence) be entered before the clinician can complete the patient visit. Additionally, the EHR-CDSS was hypothesized to further facilitate evidence-based decision-making by providing the clinician with guideline recommendations at the point-of-care, when it is more likely to be adhered to.

Participants

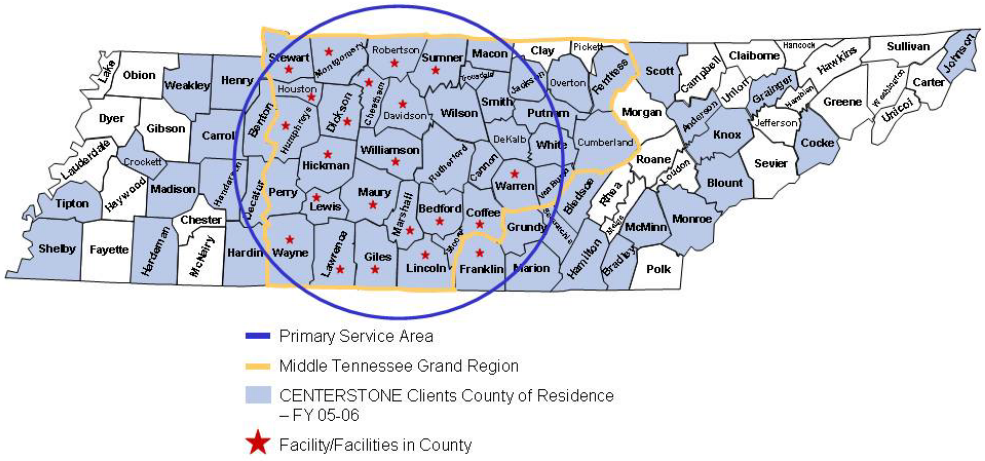
The study site for the proposed research, is a not-for-profit 501(c)(3) community-based, ambulatory behavioral health care organization that at the time of this research operated 66 licensed facilities and/or clinics. These sites serve residents from counties within Middle Tennessee as well as throughout the state as identified in our map.

Centerstone provides behavioral health care to individuals of all ages and their families. With over 50 years of experience, Centerstone provides mental health, substance abuse, co-occurring, and related prevention and educational services for children, adolescents, adults, seniors, and family members in Middle Tennessee. At the time of this study, Centerstone's programs and services reached residents of nearly all of the state's 95 counties, serving over 50,000 individuals and their families annually, making it the largest organization of its kind in Tennessee and the 9th largest in the nation. Also during this time, Centerstone maintained a professional, culturally diverse staff of approximately 1,000 employees consisting of psychiatrists, psychologists, clinical social workers, counselors, case managers, psychological examiners, registered nurses,

nurse practitioners, masters and bachelor level professionals, support staff, and hundreds of volunteers.

For this proposal Centerstone served as the study site, conducting research in 24 clinics, 21 of which (14 rural/7 urban) had the CDSS integrated with their existing EHR.

Figure 1. Centerstone 05-06 service area



Description of Patient Population

The primary patient population was adults (age ≥21 years) being treated for MDD who required a treatment change (either switching medication or dose increase). At the time of this research, Centerstone served over 50,000 individuals of all ages and their families annually. The most prevalent primary diagnoses for Centerstone patients overall are depressive disorders. In fiscal year 2005-06, Centerstone provided nearly 25,000 medical services for adults with depressive disorders, including psychiatric evaluations, medication review and maintenance, etc. At the time of this research over 6,400 Centerstone adult patients were diagnosed with depressive disorder. The study site had a racial/ethnic makeup of 66% White/Caucasian, 22% Black/African American; < 1% Asian or Pacific Islander, <1% American Indian; <1% Alaskan Native; and 3% other. Gender make-up at the site was: 43% males and 56% females, with 1% unlisted.

Methods

Study Design

This research addressed two major aims, the first was designed to develop a model to personalize an existing CDSS to integrate it with an ambulatory clinic's EHR and the second aim then tested the resulting EHR-CDSS for patients with MDD in real-world settings. Below, we present these Study Aims and describe the specific designs that correspond with them.

Aim 1

In order to develop an EHR-CDSS that can be used effectively to implement MBC, Aim 1 comprised a three-stage process:

- Stage 1: End-User need assessment that will provide information regarding the needs of both the physician and the Centerstone Behavioral Health Care Organization;

- Stage 2: Modification/customization of the CDSS based on the information from the needs assessment; and

- Stage 3: Build CDSS to interface with Centerstone's EHR.

Stage 1 Design. An essential element of the research study was to provide extensive training to all participating clinicians since the clinician bears the primary responsibility for treatment and is most familiar with the needs of the Centerstone health care system. To this extent, it is necessary to garner a sense of what employees and clinicians at Centerstone needed with regards to this project. As such a Needs Assessment was conducted in the first year of the project. Following the Needs Assessment a list of required modifications to the system was created.

Following the Needs Assessment an intensive training program was implemented that required training clinical staff in the principles of algorithm-based care, emphasizing how MBC facilitates this process, and instructing the clinical staff in how the CDSS linked to the EHR can be used to provide such care. Planned training included: 1) A one-day training session in the use of the TMAP algorithm for MDD and the CDSS; 2) A trial period using the CDSS to treat patients with MDD—during this test period, clinicians using the CDSS had real-time desktop support for use of the system. Data regarding any problems encountered was collected throughout the course of this trial period; and 3) Regular teleconferences (bi-weekly) were set up as part of ongoing training. Clinicians and other clinic staff had the opportunity to participate and provide feedback as well as receive additional training on specific topics.

Clinician Training. Before beginning the study, clinicians were approached and the background of the study was outlined. All those interested in participating in the study were asked to provide informed consent. Before beginning the study, all participating clinicians received a one-hour lecture reviewing current antidepressant treatment for depression, followed by another two-hour training session focusing on the TMAP algorithm for MDD and the concept of Measurement Based Care (MBC). Additionally, during a separate half-day workshop, clinicians received focused training on the use of the computerized decision support system (CDSS) which is based on the TMAP algorithm for MDD. The CDSS training workshop was videotaped (the videotape of the original training session serves to maintain consistency in training of the clinicians entering later to replace departing clinicians). The CDSS-specific workshop included education on the program and hands-on practice with the CDSS. Simulated visits were created to illustrate how the CDSS was to be used in daily practice. The overall goal of training was to: 1) to assist physicians with becoming familiar with both the depression treatment algorithm and the CDSS, as well as 2) to emphasize the importance of measuring depressive symptoms at each visit. Each clinician was given a copy of the TMAP Manual for MDD. We have extensive experience training and monitoring adherence and fidelity to

algorithm implementation through our recently completed R01 MH-164062-01A1, examining the efficacy of the implementation of a computerized algorithm in tertiary care psychiatric outpatient clinics, compared to a paper and pencil algorithm (PPA-D) and UC-D.

Support Staff Training. While the training of support staff was less extensive than that of the staff providing the primary care to participating patients, to effectively institute system change required that all staff be involved in the process. Centerstone conducts training for all staff twice each year, in the Fall and Spring. To prepare for system wide MBC implementation, all administrative and support staff received training on the principles of MBC, as well as specific instruction on guidelines for administering and entering MBC data. This included any necessary modifications to Centerstone policies and procedures to support MBC implementation. It was our hope, because of repeated use of the MBC system over time that, even after the monitoring system (i.e. the performance feedback and teleconferences) has been discontinued, that the administrative support staff would routinely continue to assess MBC measures and provide them to the clinician *before* patient visits.

Stage 2 Design. As mentioned earlier, the development of the CDSS was originally carried out by the project development team led by the principal investigator (Dr. Trivedi) and co-investigators at UTSW Medical Center, Drs. Rush, Altshuler, and Kern. The guidelines and algorithms, from which the decision support system was developed, were derived from those of the Texas Medication Algorithm Project (TMAP). The design is such that the computer interaction is intended to be efficient and advantageous to the clinician so that clinical decision making for treatment through the computer is a by-product of every day clinical practice.

Aim 1: Data Sources/Collection

The CDSS software program can be loaded on any personal computer with the recommended system requirements. The CDSS consists of three separate parts responsible for user interaction, decision-tree reasoning, and storage of the clinical data. The relationships between these three parts are as follows:

- The user interface: The user interface is an interactive application written for Microsoft Windows platform and developed using Visual Basic programming language. Users can navigate through web-like buttons that provide a user-friendly environment in which to work. It is the only application of the program that is visible to the user.

- The Rules Engine: The clinical algorithms used by TMAP have been translated into specific “rules” by the PI and UTSW computer information systems (CIS) developers and then compiled into a knowledge base and implemented using the industry-standard logical inference engine licensed from Fairslaac Software. The Rules Engine application operates behind the user interface to apply the TMAP algorithms to the current and historical patient data to provide treatment options to the physician via the user interface.

- The CDSS database: All clinical information entered into the CDSS application is securely stored in the back-end SQL server. The database also stores user-specific data (for limiting access to clinical information), and the reference tables for medications and

doses. Because both the reference tables and the rules knowledge base by which the rules engine processes the patient information are stored on a central server, updates to the algorithms can therefore be implemented through the server, without user intervention. The CDSS provides assistance in diagnosis and decision support with appropriate treatment choices, follow-up and preventive care, while at the same time providing access to physician order entry, alert systems, electronic documentation, and information retrieval.

Features of the CDSS

- Diagnosis: For diagnosis, the computer program provides a list of diagnoses for the major psychiatric disorders as categorized in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV-TR). It also provides a link to the American Psychiatric Association Practice Guidelines that provide information on how to perform a diagnostic evaluation. It does not however, provide an expert diagnostic system.

- Measurement Based Care: As mentioned, the CDSS provides measurement tools that can be used to help the clinician monitor symptomatic and functional status over time. Commonly used symptom measures for the evaluation of psychiatric illness are included. In total, the system currently provides over 25 assessment tools, with recommendations for the adequate use of appropriate measurement tools.

- Evidence-Based Decision Support: The clinician is supported in clinical decision(s) by using the interactive tools provided by the CDSS, whereby the program analyzes the pertinent information about the patient that has been provided by the clinician and integrates the patient's information with the rules of the program, which are based on expert knowledge. Refer to Patient Evaluation Screen (Figure 2).

- Follow-up and Preventive Care: The CDSS provides reminders to the clinician via screen prompts so that he or she does not overlook important considerations. For example, if a clinician prescribes a mood stabilizer (e.g., lithium, or some other medication requiring close monitoring of blood levels), he or she will be prompted to order regular blood levels for that medication. The program also recommends and display in how many weeks the patient should return for a visit, based upon the patient's status and stage in the algorithm.

- Computer Physician Order Entry and Error Prevention: In the CDSS software, the clinician initially chooses the psychotropic medication(s) and doses from pull-down menus of the algorithm on the Treatment Selection Screen. The selected medication(s) then appear on the Prescription Screen along with suggested route and frequency. The clinician can choose to adjust the frequency as well as providing specific instructions in the comments section if they desire. On the Prescription Screen the clinician clicks on the check box next to the specific medication the patient needs to be filled and the prescription will be printed for the patient. The medication choices available in the CDSS include primary antidepressant medications and augmenting medications, as well as treatments for associated symptoms and side effects.

- Adverse Drug Event Alert Systems: The CDSS software displays a warning box when medication errors are made. For example, if a physician tries to order two benzodiazepines, a warning box will appear on the screen that notifies the physician that he/she has ordered two medications from the same family of medications. For medications that require a blood level before safely increasing the dose, a warning box will appear on screen that notifies the physician that a blood level is necessary. Similarly, if a physician tries to order two medications that should not be given together or two medications that should only be given together with caution, a warning box will display notifying the physician of the potential problem. The CDSS will also alert the physician if medication blood levels are not in the therapeutic range.

- Electronic Documentation, Record Keeping, and Information Retrieval: All entries to the CDSS are automatically stored, providing electronic documentation and record keeping. In turn, this information is easily available to the clinician at any time, providing easy access to complete patient information. Clinical status and prescription history are presented in easy-to-read graphs for each visit (Figure 2). Additional information (such as patient demographics, blood level, symptom rating scales, and complete progress notes) is also accessible by clicking on the toolbar at the top of the screen in any section of the application. Automatic clinician notes are created and recorded as a by-product of the clinician's actions during a visit; additional notes can be written by using the “slide bar” that is available on the right hand of the screen. The patient’s progress is recorded throughout the course of care as progress notes and is also displayed graphically showing the patient’s status (symptom severity, functional status, and side-effect burden) over time (Figure 2). The medication choices made by the clinician are also recorded in the progress notes, prescription history, as well as graphically. The graphic display presents an “at-a-glance” recording of the patient’s treatment and response over time. The patient’s demographics, history, clinician ratings, mental status examination, symptom scale assessments, and blood levels are all part of the record. Additionally, the program provides links to the Texas Medication Algorithm Project’s manuals and flow charts, the American Psychiatric Association Home Page and Clinical Practice Guidelines, and the CDSS User manual.

Description of the Use of the CDSS

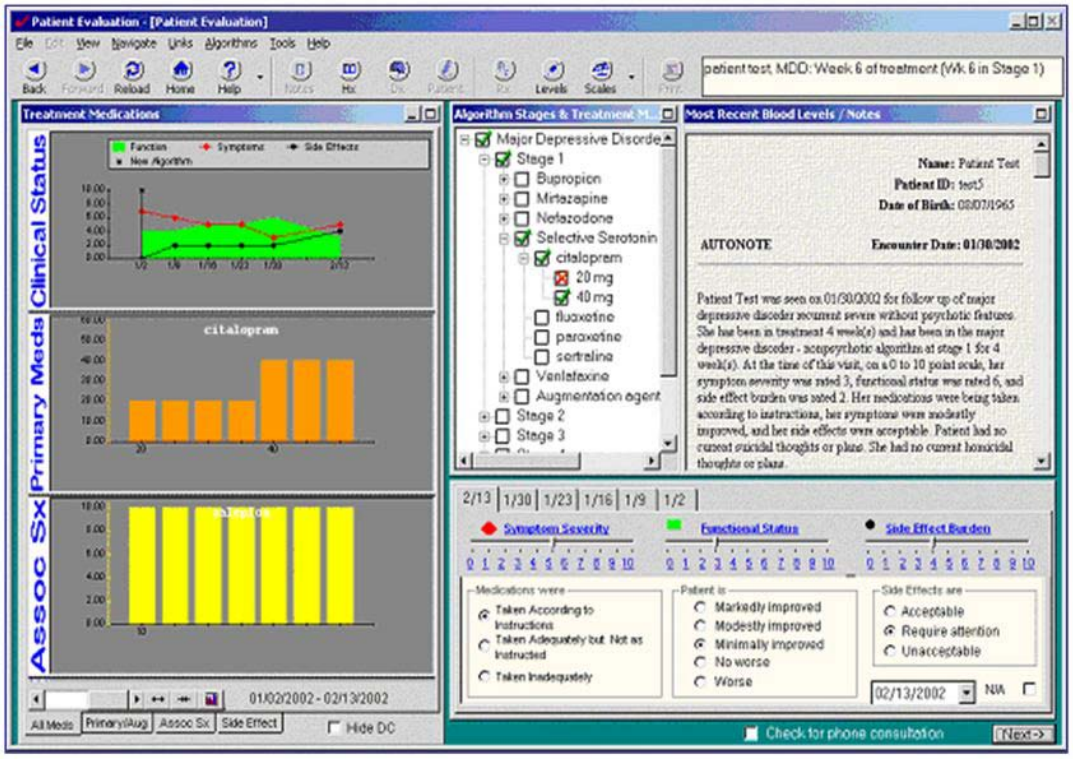
The computerized algorithm application begins with a Sign-on Screen where the user must enter his or her user name and password to access the program. The software utilizes role-related access security, meaning that different levels of access can be granted to individuals depending on their role in the clinic (i.e., only those with prescription rights would be granted access to progress through the algorithm or write prescriptions, but administrative personnel would have access to patient demographic information).

When a clinician signs on with his/her password, the first screen after the Sign-on Screen will be the Patient Selection Screen where a list of patients assigned to that particular clinician will be displayed under his/her name. To access a patient’s record, the clinician simply clicks the patient’s name to display a synopsis of the patient’s care. The next screen is the Diagnosis Screen (for a new patient) and the Patient Evaluation Screen (for a returning patient). On the Diagnosis Screen a clinician can choose the Axis I, II, III, IV, and/or V DSM –IV TR diagnosis

from a cascade of drop-down boxes. Multiple diagnoses can be listed in Axis I, II, or III. Once the specific algorithm and Axis I diagnosis are entered for a new patient, the *next* button will take the clinician to the Patient Evaluation Screen.

For a new patient, the Patient Evaluation Screen (Figure 2) asks the clinician to rate the patient's current level of symptom severity, functional status, and side effects (if applicable) – so facilitating the routine use of measurement based care. A Mental Status Exam (MSE) is also available on this screen, as well as access to scales appropriate for that patient's diagnosis that can assist the clinician in determining the patient's status.

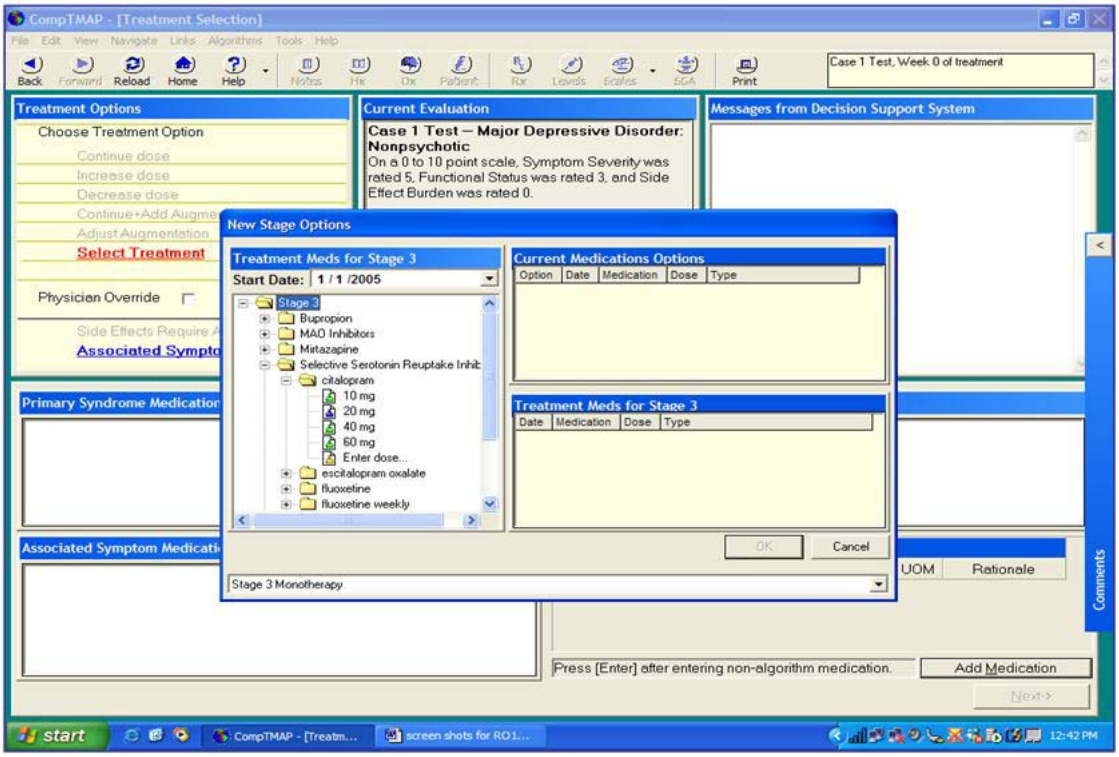
Figure 2. Patient evaluation screen



For a return visit, the Patient Evaluation Screen displays the patient's current stage in the algorithm, current medications (marked with green checks) and discontinued medications (marked in red crosses). The most current progress notes and blood levels are displayed, as well as colored graphs recording the patient's clinical progress (symptom severity, functional status, and side effects) and medications prescribed over time. As with the initial visit, the clinician is asked at each subsequent visit to enter information about the patient's current clinical condition that is necessary for analysis by the treatment algorithm. The required information addresses three aspects of the patient's current status: (1) the patient's compliance (i.e., whether the medication(s) has been taken as directed and/or adequately); (2) the patient's response to treatment (i.e., whether the patient improved markedly, modestly, minimally, not at all, or the conditioned worsened); and (3) side effect burden (i.e., whether side-effects were acceptable, not acceptable, or not significant). Once this information is entered, the "rules engine" of the software is invoked. The rules engine analyzes the new information about the patient that was

entered by the clinician along with several other factors, such as: (1) how long the patient has been on the current treatment, (2) what medication(s) the patient is on, (3) the current dose level, (4) the amount of time at that dose level, (5) the number of dose increases, (6) whether the patient is being augmented with another medication, (7) what the dose is of the augmentation agent, (8) how many dose increases have occurred of the augmentation medication, and (9) medication blood levels (if applicable). After analyzing the information, the computer program will offer the appropriate treatment options(s) with dose options on the next screen, the Treatment Selection Screen (Figure 3).

Figure 3. Treatment selection screen

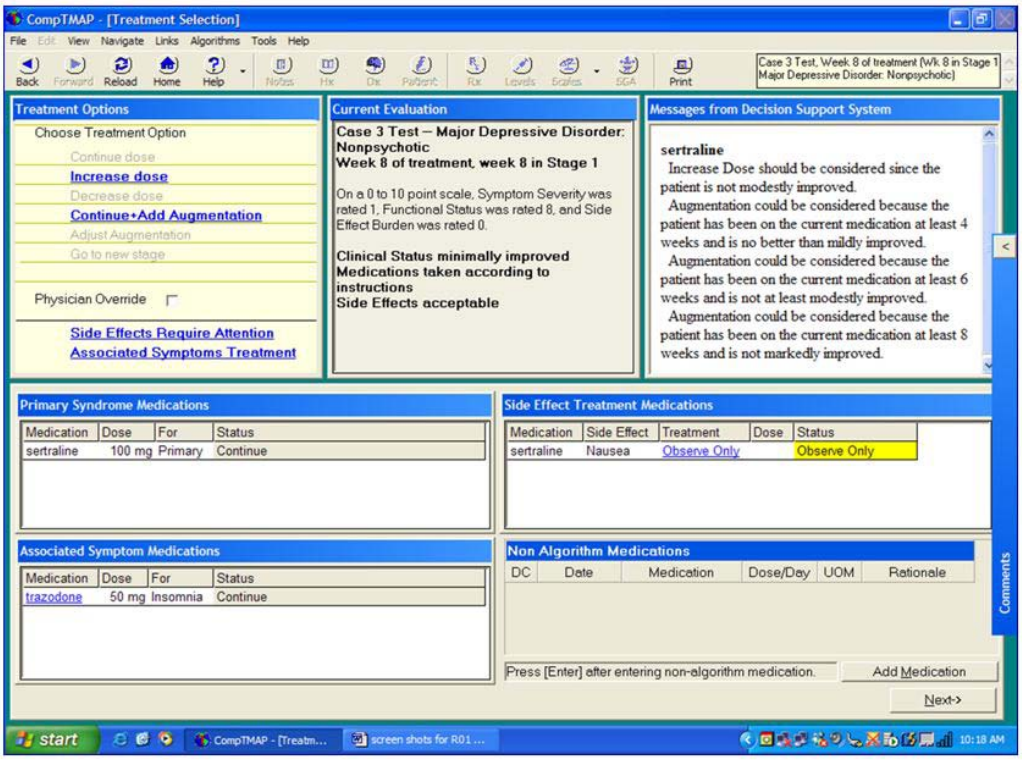


For an initial visit, the treatment options are displayed for the clinician to choose from on the Treatment Selection Screen (Figure 3). To select the recommended option, the clinician simply clicks on the choice and selects the desired medication and dose. The program provides suggestions to assist the clinician in treating the patient with the primary and augmenting medications, and also provides choices for treatments for associated symptoms and side effects. The clinician can click on *side effects require attention* or *associated symptoms treatment* to select the appropriate management of any symptoms. Nonalgorithm medications can also be listed on the screen.

For the return visit, the Treatment Selection Screen (Figure 4) will provide suggestions, such as Continue Dose, Increase Dose, Decrease Dose, Continue and Augment, or Go to Next Stage. Only the blue and underlined options are enabled. Explanations and suggestions are provided in a decision support window on the same screen where the treatment options are displayed. The clinician may override generated suggestions by clicking the *Override* box, which initially

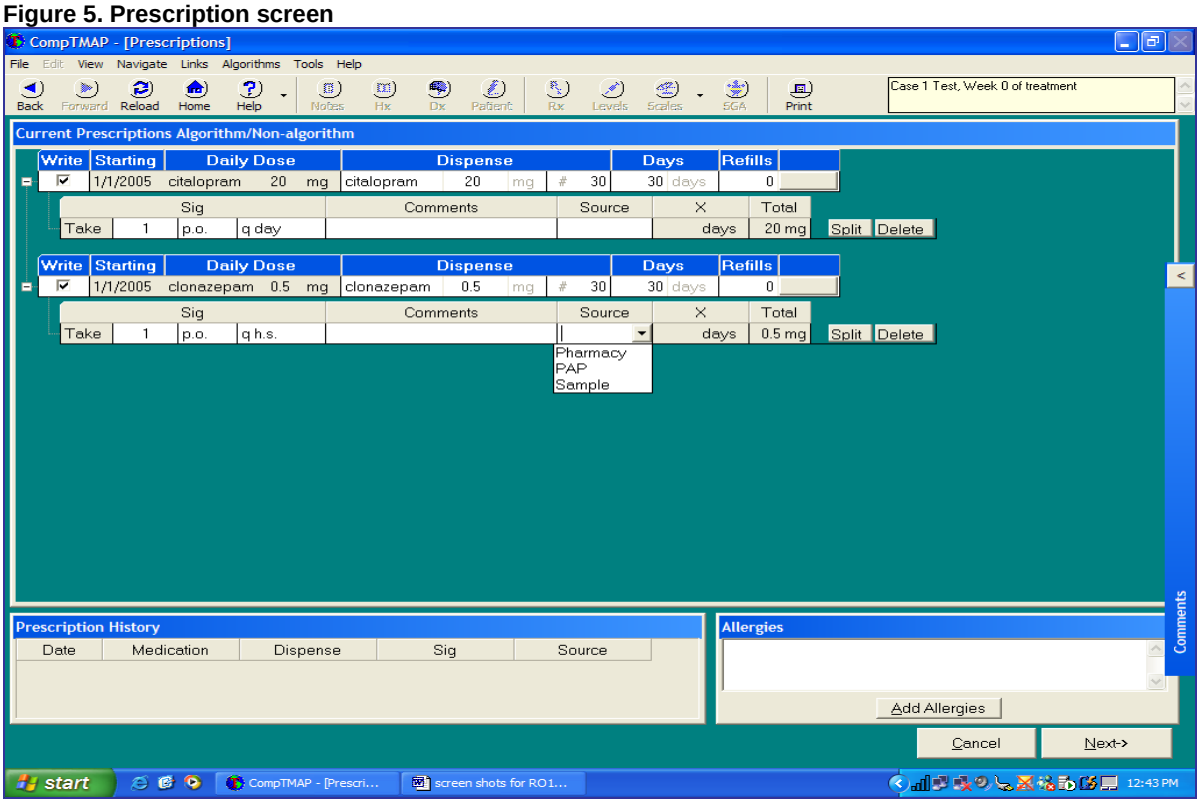
prompts the clinician to record a rationale for the override and then allows the clinician to select the preferred intervention.

Figure 4. Treatment selection screen (revisit)



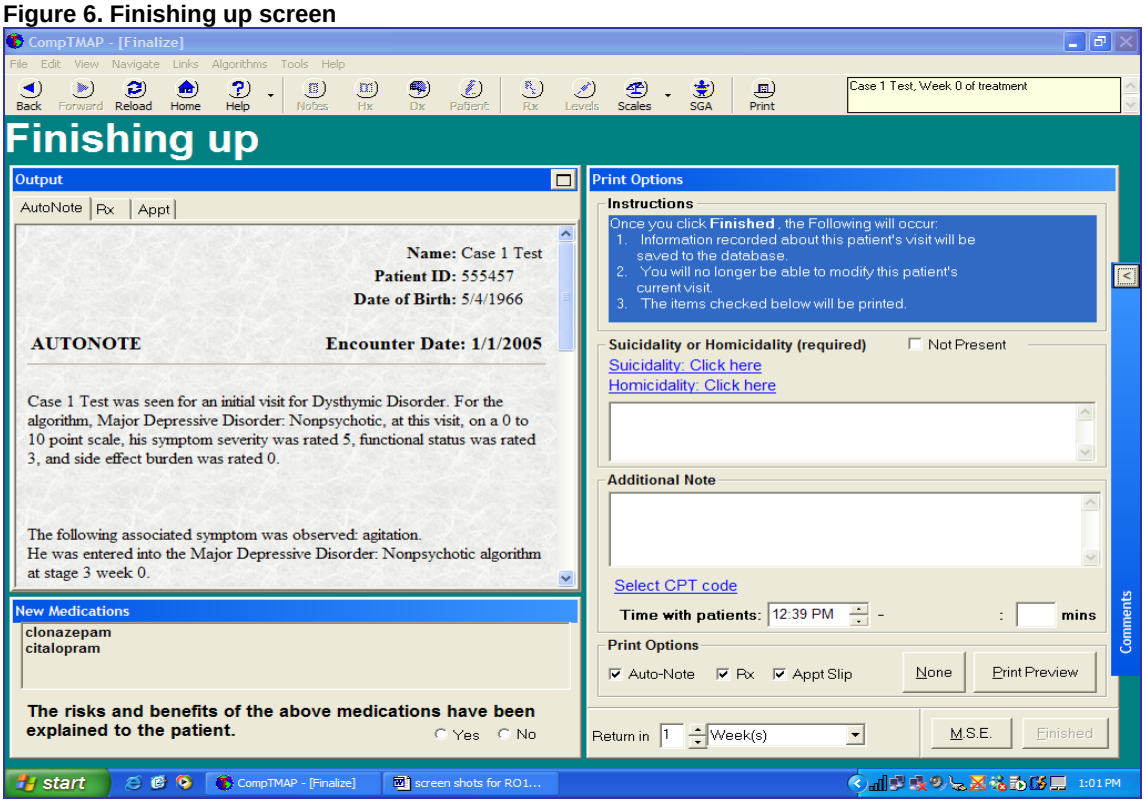
Once selected, the chosen medication(s) will move to the various treatment boxes on the bottom half of the screen and the clinician can then click *"next"* to go to the Prescription Screen (Figure 5). The selected medication(s) then appear on the Prescription Screen along with suggested route and frequency. This includes medication choices for primary medications and augmenting medications, as well as treatments for associated symptoms and side effects, and nonalgorithm medications. The clinician can choose to adjust the frequency as well as type in specific instructions in the comments section if required. The clinician clicks on the check box next to the medication the patient needs and the prescription will be printed for the patient. The clinician can also select whether the medication is prescribed or a sample was given.

Figure 5. Prescription screen



Finally, the clinician can finish the patient's visit by clicking "*next*" to go to the Finishing up Screen (Figure 6). On this screen, the clinician will see the computer-generated progress note, which summarizes the current visit by incorporating the clinical ratings and prescriptions given. On this screen, the application also provides safety-related reminders and documentation. For example, when a new medication is prescribed, the application prompts the clinician to answer whether side effects and benefits of the new medication were explained in order to exit the visit. The automatic progress note documents that the clinician explained the side effects and benefits only if this question is answered "yes" by the clinician on the screen. At this point, the clinician can record any additional notes to be incorporated into the progress notes, select a CPT code or some other billing code from a drop-down menu, record the time spent with the patient (this will automatically record, and can be adjusted), assess suicidal and homicidal ideation, and indicate when the patient should return. Prescriptions and appointment slips for the patient and progress notes for a physical chart are then printed when the note is finished.

Figure 6. Finishing up screen

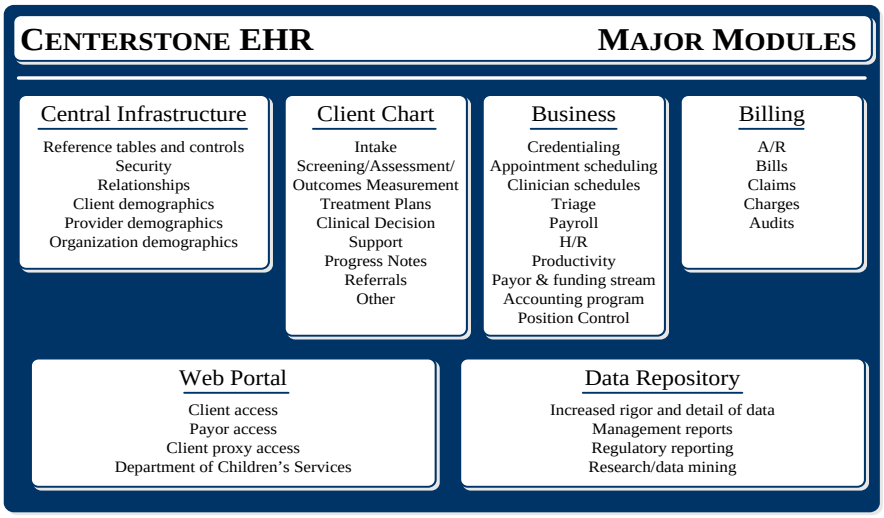


Additional screens in the CDSS, which can be selected during the visit (or anytime) by clicking the appropriate button on the tool bar, include: Blood Level Screen (for recording and viewing blood levels when necessary), Scales Screen (which provides standardized rating scales and charts scores), Notes Screen (a compilation of the progress notes of all visits), and History Screen (full psychiatric history plus a mental status exam).

Centerstone's Current EHR

Centerstone's current EHR is a web-based platform developed explicitly to bring mental health research and practice together. While Centerstone's previous EHR was among the most sophisticated in the mental health sector, Centerstone initiated a complete rewrite of the system two years ago specifically designed to facilitate cross-site research and clinical decision support, comprising the latest technological advances to bridge all elements of science and service. This new system has received national attention and is slated for installation at several leading community behavioral health organizations across the country. One of these organizations recently won the Health Information Management Systems Society (HIMSS) 2006 Davies Award for excellence in the implementation and use of health information technology and is abandoning their award winning system to adopt the Centerstone EHR. The Centerstone EHR manages all major administrative and clinical modules (see chart) and incorporates the following: 1) Screening, consent, inclusion/exclusion criteria, and outcomes; 2) Common data warehouse designed for analysis; 3) Extraordinarily detailed data with opportunity for innovative research questions; and 5) Integrated clinical and research protocols, data collection capacity.

Figure 7. Centerstone EHR major modules



Phase I of EHR development focused on supporting the core clinical and business functions of a large, diverse service provider (e.g., clinical record keeping, scheduling, billing). Centerstone's efforts for this project are based on supporting the delivery of evidence-based practices to improve care and facilitate the transfer of knowledge from research into practice.

Phase II of Centerstone's EHR development focused on the integration of evidence-based practices into the EHR. In the initial stage, which is the subject of this proposal, we integrated a computerized research-based medication algorithm for depression (CDSS). Dr. Trivedi and his team consulted on EHR-CDSS integration to ensure integrity to the TMAP algorithm. This project was hypothesized to add several key components to the Centerstone EHR, including development of a new prescribing interface to support use of the algorithm, to include collection of key clinical indicators required to make evaluation, identification of relevant stage in algorithm, consideration of complicating factors related to stage (e.g., suicide risk, side effects), selection of appropriate medication, dosage, and length of trial, implementation of electronic rating scales to measure progress, and guidance regarding next steps in treatment. It was also hypothesized to provide ongoing analysis of prescribing practices and clinical outcomes to assist in development of evidence base for algorithm refinement.

Integration of the CDSS software into the Centerstone EHR was hypothesized to be accomplished by a few steps of programming to facilitate the bi-directional exchange of data between the two systems' databases. Data are stored in tables within each database. Once the developers determined the specific data elements to be exchanged, the programmers wrote code and created a process that instructed each software application to send and receive data to and from the other. This "bridge" provided code that instructs the Centerstone EHR to send a specific data element from a unique data field in its database to a unique data field in the CDSS database. For example, the Centerstone data field with the title "Last Name" is instructed to send its content, "SMITH", to the data field in CDSS with the title "LN". The CDSS will also need instructions to accept the sent data "SMITH" from the field entitled "Last Name" within the Centerstone EHR and place it in its own data field entitled "LN". The code will also contain instructions for when to send the data. It then remains in the computer's cache memory until it is prompted to be sent. The same process was followed for each exchange of data in a seamless, behind the scenes transfer independent of which software application is used to enter it.

Technical reviews and walkthroughs were designed and implemented as part of the modification process for the Centerstone EHR-CDSS build. This included in-house testing of the software at UTSW Computer Information Services (CIS) to assure modifications made are as specified. In addition to technical reviews of the components, testing also included both standard black box tests (evaluating interfaces, equivalence partitions, etc.) and white box tests (basic path testing, loop tests, etc.). Domain experts (psychiatrists and practitioners) evaluated correctness and usability prior to implementation. Also, at the end of this process, the CDSS was released to the Centerstone users who participated in a trial period to test the modified program prior to the release of the final version. Additional changes were made as needed before the next stage in the project.

Aim 1: Measures/Interventions

An integral component of Aim 1 was to complete a Needs Assessment evaluating the specific needs of Centerstone staff, to ensure integration of the CDSS.

Who was Surveyed. The needs assessment questionnaire was sent to 289 employees in the Centerstone Behavioral Healthcare System (3 employees left Centerstone before the return date), of which 209 questionnaires were returned (73%). One questionnaire was returned blank so all results reported are based on 208 completed questionnaires.

How the Responses were Evaluated. The evaluation of the questionnaire responses can be broken down into two parts: 1) what would be needed to successfully implement MBC for patients with depression and 2) how best to institute the procedures to conduct MBC. In addition to evaluation of the responses as a whole, a second analysis was conducted that included only the respondents that identified themselves as Physicians or Nurse Practitioners (this group will be referred to as Prescribers).

Also as part of Study Aim 1, all clinicians were given the following surveys intended to measure physician satisfaction with the algorithms, including:

Physician Algorithm Evaluation of Ease of Use Survey. The Physician Algorithm Evaluation of Ease of Use Survey (EEOUS) is a study-developed survey that addresses the ease of use of the algorithm (e.g., how easy the algorithm is to learn, understand, and apply to clinical work duties).

Physician Algorithm Evaluation of Usefulness Survey. The Physician Algorithm Evaluation of Usefulness Survey (EOUS) is a study-developed survey that addresses the usefulness of the algorithm (e.g., flexibility, usefulness in everyday workflow, and educational benefits of the application), and the actual frequency of use of the algorithm.

Physician Evaluation of Algorithm Training Survey. The Physician Evaluation of Algorithm Training Survey (EOTS) measures the quality of algorithm training and the completeness of the information provided.

Limitations of Aim 1

The limitations of Study Aim 1 include the following: the results from the Needs Assessment and the process of customizing the system are limited by the fact that it was being conducted for a specific organization and EHR that was developed for that system. As such these results only generalize to the extent to which other systems mirror this one.

Aim 2

The second aim was designed to evaluate the extent to which implementation of this EHR-CDSS promoted the use of MBC as standard care for depression in both rural and urban settings within Centerstone's care system. This included measuring the following during the project:

- The use of standardized and regular assessment procedures;
- The use of guideline-based recommendations at specific points in treatment (critical decision points); and
- Performance feedback by physicians.

The impact of MBC on patient involvement with treatment and satisfaction with care was also assessed.

As mentioned in the design overview, in order to fully evaluate the extent to which implementation of this EHR-CDSS promotes the use of MBC as standard care for depression two research studies were proposed.

Study 1 Design. The first study was a comprehensive system-wide evaluation that included all physicians that used the EHR-CDSS and all of their patients with MDD that require a treatment change (i.e. switching antidepressant or dose increase). The study used a pretest/posttest design (a usual care (UC) baseline, EHR-CDSS use test) and includes data from all patients with a diagnosis of depression that have their treatment changed during a 6-month enrollment period prior to implantation of the EHR-CDSS. Follow-up data was collected for the 6 months after the initial treatment change. This was followed by a second enrollment period and 6-month follow-up after the EHR-CDSS was rolled out. Primary outcomes for this group of patients will include de-identified data that is collected as part of the regular treatment visit (i.e. number of treatment visits, length of time after first treatment visit, length of time patient remains in treatment, frequency of use of standardized assessments, and patient perceptions of care). Patient perception of care was assessed using AHRQ's Consumer Assessment of Healthcare Providers and Systems (CAHPS) Adult Specialty Care Questionnaire which patients will be asked to complete anonymously. Data collection for study 1 was conducted such that all information recorded is not identifiable to the subject and any identifiers that could be linked to the subject will be removed. Thus Study 1 is exempt under 45 CFR 46.101 (b) (4) from all 45 CFR part 46 requirements.

Study 2 Design. The second study used a 2 X 2 design, looking at clinic setting (urban, rural) and type of treatment (UC, EHR- CDSS) and is an in-depth evaluation of the EHR-CDSS impact on a limited sample of physicians and patients by directly assessing the use of MBC. Eligible patients were adults (age $\geq$ 21 years) being treated for MDD who require a treatment change (either switching medication or dose increase). Outcomes data were collected at 6-week intervals by a blinded rater for a total of 6 months after a baseline visit. Primary outcome measures focused on the extent to which treatment is following a state-of-the art medication algorithm for MDD. This included evaluation of the use of standardized assessments as well as an evaluation of impact on patient outcomes (such as changes in the patients symptom severity, quality of life, and satisfaction with care).

Aim 2: Data Sources/Collection

The proposed schedule of visits was designed to allow for treatment to be initiated and optimized, while taking into account symptoms, adherence to medication, and potential side effects. Our experience with STAR*D showed us that adherence to visit frequency was often problematic given time constraints and patient load, so that the desired frequency of visits (every 2 weeks during the acute phase of treatment) was not feasible in real-world clinic settings. Therefore, unlike the visit schedule for STAR*D, clinic visits for EHR-CDSS implemented MBC was designed to occur on weeks 0 (baseline), 2, 4/6, 8/10, and 12. Allowing the flexibility of having the option of a visit at week 4 and or week 6, as well as at week 8 and or week 10 may therefore help facilitate implementation in practice settings.

Table 1.

Week	Visit	Primary Assessment	Primary Visit Task
0	Baseline	Baseline Symptom Severity	Start new treatment
2	Acute visit 1	Side-effects & Treatment Adherence	Address side-effects and Adherence issues
4/6	Acute visit 2	Symptom Severity & Treatment Adherence	Adjust current medication treatment
8/10	Acute visit 3	Symptom Severity & Treatment Adherence	Consider treatment change or Augmentation
12	Acute visit 5	Symptom Severity & Treatment Adherence	Start continuation or Next treatment stage

Note: If the participant moved to the next level at any time during study 2 (i.e. switches to another antidepressant), the schedule starts over with the last visit from the previous level counting as week 0. All patients were expected to be seen during the continuation phase (6 months following acute treatment) on a monthly basis.

Aim 2: Interventions/Measures

For those patients participating in study 2, evaluating the impact of MBC on standard care, the diagnosis of MDD were confirmed by means of a brief diagnostic interview, the Mini International Neuropsychiatric Interview (MINI).

MINI. Mini International Neuropsychiatric Interview (80) – 5th version. This is a brief structured interview for major DSM-IV Axis I disorders. The MINI has been used extensively in psychiatric research in both the United States and Europe since its development in 1997 and takes 15 to 35 minutes to conduct. Studies of reliability and validity comparing the MINI to the Structured Clinical Interview for DSM IV axis I disorders (SCID), produce reliabilities that

range between kappa=.43 and kappa=.92, sensitivities that range between .45 to .96, and specificities that range between .79 and 1.00 for the proposed diagnostic categories.

Measurement Based Care at Study Visits. As discussed earlier, the use of standardized measures of symptoms and side effect burden is currently not part of routine practice in psychiatric practice settings, with practitioners often differing in how they conduct a trial of an antidepressant medication, as well as how they assess treatment outcomes. In order to effectively practice MBC the EHR-CDSS identifies critical decision points for each medication stage. At each critical decision point, the CDSS provides decision support (a recommendation based on the current dose and duration of the current medication together with the degree of symptom change, side-effect burden and treatment adherence) based on the information collected using standardized assessment tools. For each medication, the decision support tools are designed to help to adjust the dosage to reach the maximally tolerated dose within the dose ranges mandated by algorithm, manage side effects adequately so that appropriate dosage increases are possible, and declare treatment failure if remission has not been reached after an adequate dose (maximally tolerated) and duration (up to12 weeks). The clinician can then use this information to drive their clinical treatment, thereby tailoring treatment to the individual patient.

During study 2, clinic visits for MBC were expected to occur on weeks 0 (baseline), 2, 4/6, 8/10, and 12. If the participant moved to the next level (i.e. switches to another antidepressant) at any time during those visits, the schedule was expected to start over with the last visit from the previous level counting as week 0.

Limitations of Aim 2

The limitations of Study Aim 2 include the following: While the first study was designed to include both a comprehensive assessment which involved the vast majority of patients with MDD seen at Centerstone, these assessments were limited in that they only examine the general pattern of treatment visits and not specific treatment outcomes. The second study which did include a detailed assessment of treatment outcomes was restricted to a relatively small sample and therefore may not provide sufficient reflection of a general population. In addition, small samples have significantly less statistical power to detect group differences and thus only give indications when very large between group differences are present. Generally, this project which focused to integrate an existing CDSS with an existing EHR was limited by the realities of today's Health Information Technologies. Namely, Centerstone was required to make substantial modifications to their EHR to comply with organizational needs. Unfortunately, anytime there is restructuring of an EHR any system that is being integrated with that EHR also requires substantial modifications, thus function and reliability suffer, thereby impacting end-users.

Results

The results are presented for the two aims of the study as follows:

Aim 1: Integrate a CDSS facilitating MBC with physician needs to an existing EHR at Centerstone. To address the first aim, Needs Assessment surveys and focus group interviews were conducted.

Aim 2: Evaluate the ability of EHR-CDSS to promote the use of MBC for the treatment of MDD. The evaluation of the impact of the integration of the CDSS into the Centerstone EHR on the development of the use of MBC as a treatment model of depression included two studies; Study 1, a general utilization study, and Study 2, a targeted detailed treatment outcomes study evaluated by blinded raters.

Principal Findings and Outcomes (Needs Assessment Results)

Who was Surveyed. The Needs Assessment questionnaire was sent to 289 employees in the Centerstone Behavioral Healthcare System (3 employees left Centerstone before the return date), of which 209 questionnaires were returned (73%). One questionnaire was returned blank so all results reported are based on 208 completed questionnaires. Details of the return rate by employee position are presented in Table 2.

Table 2. Needs assessment completion by position

Position	Returned	Not Returned
Physician	62%	38%
Nurse Practitioner	79%	21%
Nurse	73%	27%
Therapist	80%	20%
Case Manager	63%	37%
Clinic Director/Manager	72%	28%
Other	92%	8%
Overall Return	**73%**	**27%**

How the Responses were Evaluated. The evaluation of the questionnaire responses can be broken down into two parts: 1) what would be needed to successfully implement MBC for patients with depression, and 2) how best to institute the procedures to conduct MBC. In addition to evaluation of the responses as a whole, a second analysis was conducted that included only the respondents that identified themselves as Physicians or Nurse Practitioners (this group will be referred to as Prescribers). While the results were very similar, differences or additional concerns expressed by the Prescribers group will be specifically noted.

Summary of Findings. With regard to what would be needed to implement MBC, the responses fell into two categories. The first is concern with the possible additional burden that providing this type of care might entail. Examples of these types of responses included “would need more time at treatment visits” and “would need smaller case loads”. The second category

focused on specific changes in current practice procedures. Examples of this type of response included “need to start using standardized assessments”, “need to increase visit frequency”, and “training in the use of depression treatment algorithm”. A specific need expressed by the Prescriber group was that a wider range of medications be availed without having to petition for an exception.

The second part of the questionnaire focused on the specifics of how best to make changes in the clinics necessary to start providing MBC. Several common themes emerged from clinical staff members, which they felt would be necessary to facilitate successful implementation of MBC. This included training in the use of the MDD treatment algorithm and insuring that the standardized assessments were completed. There was not a clear consensus of what type of standardized assessments (self-report versus clinician rated) was preferred, however a clear preference was that the information from the assessments should be integrated into the EHR-CDSS. In terms of visit frequency two-week intervals were seen as not practical without change in case loads and staffing, while visits at 4 week intervals were deemed as possible. It should be noted that higher frequency of visits is only necessary when starting a new treatment stage in the algorithm. Once patients have shown a clear response to treatment, the visit frequency may be reduced.

Discussion and Conclusions (Needs Assessment Results)

The primary concern expressed by clinical staff members is the increased time burden, in terms of both the length of the treatment visit and the number of treatments visits. Based on prior reports (based on physician reports from the STAR*D study and IMPACT studies), the research team expected that providing MBC would initially require more time, but once the system was established the increased visit time would primarily involve the time the patient needed to complete self report assessments. Data from the TMAP study showed that while patients in the algorithm arm of the trial initially were seen at a higher frequency, the total number of visits over a year were similar in both arms of the trial.

Principal Findings and Outcomes (Evaluation Study 1)

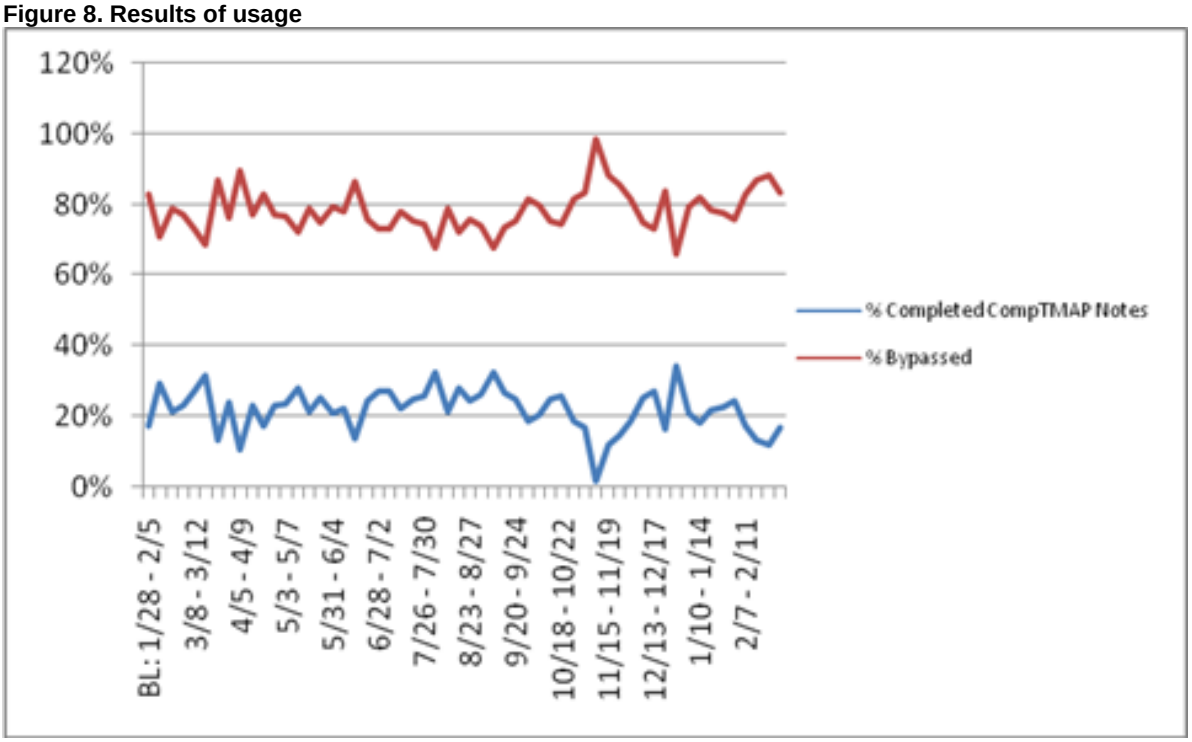
The first study was designed to provide a systematic evaluation of any changes in treatment patterns in the Centerstone System. Data for study 1 was pulled from Centerstone’s EHR and allowed for assessing general changes. These data pulls were conducted in the 6 month period before the start of the program and the 6 month period after the implementation. Note the time periods were matched for the pre and post groups. The data includes all patients treated for a non-psychotic major depressive disorder. During the pre-implementation period there were 1,787 patients seen at 5241 visits and during the post-implementation period 2,194 patients seen at 3288 visits (for details refer to table 3).

Table 2. Number of MDD visits before and after EHR-CDSS implementation

	1 visit	2 visits	3 visits	4 visits	5 visits	6 visits	7 visits	8 visits	9 visits	10 visits	11+ visits
Pre- Implementation	620	408	247	175	113	73	49	32	20	19	31
Post-Implementation	1352	631	176	30	4	1					

As part of the information obtained during the Needs Assessment, and at the request of the Centerstone clinical director an override feature was included to ensure that the use of decision support would be at the discretion of each clinical provider. In order to better understand both when and why decision support was bypassed provider utilization was tracked for one year. Results of usage are presented in the figure below:

Figure 8. Results of usage



Discussion and Conclusions (Evaluation Study 1)

Note there was a significant difference in both the total number of visits as well as the patterns of treatment visits. Additional analyses are ongoing that explore differences based on decision support usages, length of time between visits, and the utilization of MBC assessments during treatment visits.

Principal Findings and Outcomes (Evaluation Study 2)

All patients were approach by Centerstone staff and after they had agreed to participate in the study and signed informed consent they were then contacted and followed by blinded raters at UT Southwestern for all follow-up assessments. The sample was similar to the depressed patient population that is treated in the Centerstone system. Thus, the results of these analyses are likely to be similar to what would be found in the general Centerstone depressed patient population. The demographic details of the sample for the second evaluation study are presented below:

Table 3.

Demographic Variables	Mean (SD) or Percent
Age	47.87 (10.65)
Gender: Male	18%
Gender: Female	82%
Race/ Ethnicity: American Indian	1%
Race/ Ethnicity: African American/ Black	21%
Race/ Ethnicity: Hispanic	1%
Race/ Ethnicity: White	74%
Race/ Ethnicity: Unanswered	4%
Marital Status: Married or Cohabitating	20%
Marital Status: Single Never Married	13%
Marital Status: Divorced or Separated	55%
Marital Status: Widowed	12%
Education (degree completed): None	17%
Education (degree completed): GED	10%
Education (degree completed): High school diploma	37%
Education (degree completed): Associate/Technical degree	20%
Education (degree completed): 4 year College degree	8%
Education (degree completed): Masters degree	6%
Education (degree completed): Unanswered	2%
Education (number years)	12.94 (2.54)
Employment Status: Unemployed, not looking	56%
Employment Status: Unemployed, looking	16%
Employment Status: Full-time employed for pay	11%
Employment Status: Part-time employed for pay	9%
Employment Status: Self-employed for pay	4%
Employment Status: Retired, not working	3%
Employment Status: Unanswered	1%
Annual Income Level: $0 to $24,999	85%
Annual Income Level: $25,000 to $49,9992	13%
Annual Income Level: %50,000 to $74,999	1%
Annual Income Level: Unanswered	1%

It is worth noting that patients who were approached for participation in the study were limited to those that currently needed a change in treatment, and therefore were more likely to be treatment resistant patients. Although the sample reported in TMAP that included patients regardless of their current treatment response status, the majority of patients in TMAP could be identified as treatment resistant, and thus the pattern of response in the current trial looks similar to those seen in TMAP.

The assessment of treatment response included three domains, changes in symptom severity using the HRS-D, changes in quality of life and social function using the Q-LES-Q, and work-related general activities and function using the WPAI. In addition, at week 24 patients were

asked to complete a general self-report rating scale of their perceptions of their care using the PSQ. Results of the means and standards deviation for the three scales are presented below:

Table 4. Results of the means and standards deviation for the three scales

Outcome	Week 0: Mean(SD)	Week 6: Mean(SD)	Week 12: Mean(SD)	Week 18: Mean(SD)	Week 24: Mean(SD)
Symptom Severity (HRS-D): Pre MBC Implementation	22.20(5.45)	21.25(5.91)	20.67(6.15)	20.58(5.66)	18.68(6.52)
Symptom Severity (HRS-D): Post MBC Implementation	22.14(5.45)	20.82(5.34)	19.92(6.54)	18.60(6.63)	18.28(6.61)
Social Functioning (Q-LES-Q): Pre MBC Implementation	2.68(.67)	2.82(.62)	2.78(.78)	2.75(.77)	2.66(.77)
Social Functioning (Q-LES-Q): Post MBC Implementation	2.60(.60)	2.65(.55)	2.64(.63)	2.63(.72)	2.79(.81)
Work Functioning (WPAI): Pre MBC Implementation	6.33(3.16)	6.00(2.75)	6.07(3.22)	5.83(3.23)	5.78(2.76)
Work Functioning (WPAI): Post MBC Implementation	6.56(2.74)	6.52(2.64)	6.32(3.18)	7.00(2.99)	6.76(2.49)

Discussion and Conclusions (Evaluation Study 1)

While there were no statically significant differences between the baseline and week 24 changes in any of the three outcome domains, the pattern of the results are encouraging and match those found in a much larger TMAP study. Specifically, the improvements in symptom severity occur earlier, but are balanced out by the end of the 6 month study period. There was a significant overall decrease in symptom severity scores. This may account for one important factor that needs to be taken into account when evaluating the study results. The number of patients that remained in the study over the entire 24 week period was 14% lower at week 24 while being the same at week 18. The general activities subscale of the Q-LES-Q is reported as a general evaluation of social function, and this measure includes a range of questions about how the current illness impacts a patient's social function, with lower scores indicating less impact. No significant differences between the pre and post groups were found and there were no overall changes regardless of group. The rating reported for the WPAI is for general activity item only, and this item was used since the majority of subjects were not currently working. Lower scores indicate that the patient's medical condition has less interference with activities. The pattern for work function does not match that found for symptom severity, in that while the differences are non-significant, the Pre MBC Implementation group decreases, while the Post MBC Implementation group remains the same.

Significance

An electronic decision support system can be designed that promotes the use of an MBC model for the treatment of a chronic illness. However, utilization of the system will be limited by the extent to which it is made a standard practice in its intended setting. Second, this model does have an advantage in that the same expected resources can be extended to rural practices in the same fashion as a more urban setting.

Implications

Any program that is designed to promote the use of MBC as a general model for treating a chronic disease such as major depression needs to take into account the current practice and resources of the clinical practices. Two factors need to be present to effectively implement MBC, and in a similar fashion CDSS: 1) the system needs to take into account the initial resources needed to implement a change in practice, and 2) there needs to be ongoing support for the decision support system to take into account changes in treatment guidelines. Thus, a web-based system or a centralized system may have advantages over a system integrated into individual EHRs and personal computers.

List of Publications and Products

There are currently three manuscripts in preparation as a result of this grant. The first reports the results of the Needs Assessment and more importantly provides this as a model for assessing organizational needs in the context of implementing MBC and CDSS for chronic diseases. The second manuscript reports the barriers of CDSS implementation as well as the final usage patterns. Lastly, the third manuscript details the findings of Study 2 (as part of Study Aim 2), i.e., the impact of treatment outcomes and patient satisfaction with care.