Full Research Protocol

Overview of SUSTAIN and Clinical Procedures
FULL RESEARCH PROTOCOL

The PACE/PACENET Behavioral Health Laboratory Project: Evaluation of a Clinical Management Program among Older Adults Newly Prescribed Medication for Behavioral Health Issues

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I. INTRODUCTION AND PURPOSE

Despite advances in the assessment and treatment of behavioral health disorders among older adults, such disorders remain inadequately diagnosed and managed in later life. This is troubling in light of the fact that behavioral health issues often serve as the catalyst for a variety of negative psychosocial and physical health outcomes in later life, including changes in social network functioning, physical disability and morbidity, loss of independence, and institutionalization. Factors such as limited provider resources for conducting frequent monitoring, variability in patient preferences and symptom severity, patients’ lack of treatment acceptance and engagement, low medication adherence, formal and informal social support and aid, and logistic issues (e.g., transportation, finances, etc.) all work in concert to influence patient identification and disease management. Yet, these factors are difficult to address when managing conditions using traditional mental health (MH) care delivery models that rely primarily on referrals to specialty care and/or face-to-face contact.

Recognizing that traditional MH care delivery models and treatment strategies do not address both practice- and patient-level logistical issues that are particularly relevant in behavioral health care, where frequent clinical visits for monitoring and therapeutic contact are key components in the successful treatment of patients, we have adopted a strategy of delivering disease management by way of telephone assessments. The Behavioral Health Laboratory (BHL) is a flexible and dynamic telephone-based clinical service designed to help identify and manage behavioral health issues. The Philadelphia Veterans Affairs Medical Center (PVAMC) and the University of Pennsylvania are the development and founding sites of the BHL. Within the Department of Veterans Affairs, the BHL has been recognized as a “Best Practice” for identification and early intervention of MH and substance abuse (SA) symptoms in primary care patients. Over 10,000 patients have been assessed since the BHL’s inception. The principles of the program include: MH as a key component to overall physical health; the need to make early MH screening, assessment, and referral to services a part of common practice; the value in utilizing technology in accessing and delivering MH care; and the importance of research- and evidence-based practice.

Given our organizational capacity and expertise, we have been able to successfully implement the BHL program at our clinics. Preliminary findings from our VA site suggest that the program is both feasible and acceptable to patients; in the year 2007 alone, of 2,471 identified patients, approximately 80% agreed to an initial assessment, which includes measures for behavioral health issues such as depression, anxiety, cognition, and psychosis. When needed, follow-up appointments in MH specialty care were coordinated and telephone-based disease management was enacted successfully. Moreover, approximately 83% of patients who recently had initiated antidepressant use completed at least 2 follow-up telephone assessments designed to monitor their depression symptoms, antidepressant adherence, and side effects.

An untoward outcome of the efforts to improve rates of treatment is the increased and sometimes inappropriate use of psychotropic medication. Among the general population, the use of psychotropic medication and rates of psychotropic polypharmacy continue to rise, with increased use of medication for both anxiety and depression in both primary care and specialty care. The rates of use have raised concerns regarding inappropriate prescribing among the elderly. One study looking specifically at psychotropic prescribing among the elderly found that elderly patients were prescribed a psychotropic agent in 8.7% of all visits, with potentially inappropriate agents prescribed in 27.2% of these visits.

Concerns about excessive prescribing of medications are highlighted by recent meta-analyses questioning the efficacy of antidepressants in mild or subsyndromal depression. Findings from a study of subsyndromal depression found that the majority of symptoms resolve with close monitoring and education, with only a fraction of patients needing treatment. There is similar literature questioning the long term efficacy of anxiolytics for anxiety or sleep disorders.

Results from our initial program of care management services for PACE/PACENET cardholders support the above concerns related to psychotropic medication prescription in the elderly and also raise additional questions about off-label or inappropriate prescribing. The program results indicate that the PACE/PACENET population is mostly female with a mean age of 78.1 years (SD 7.0), and an SF-12 Physical Component Score of 41.6. The
average PHQ-9 score for those on antidepressants was 6.1 (5.4), with no statistically significant difference between medication groups \( F(2.436)=2.14, p=0.12 \); just 9 (6.3%) of those receiving anxiolytics met criteria for an anxiety disorder, which was not significantly different than other medication classes \( x^2(2)=1.77, p=0.41 \). Overall, 208 (47.4%) participants in the sample did not meet criteria for any mental health disorder, including 80 (55.9%) of those receiving anxiolytics.

Thus, the purpose of the current project—*The PACE/PACENET Behavioral Health Laboratory Project: Evaluation of a Clinical Management Program for Older Adults Newly Prescribed Medication for Behavioral Health Issues*—is to evaluate the impact of the PACE/PACENET BHL clinical program (from this point on referred to as the **S**Upporting **S**eniors **R**eceiving **T**reatment **A**nd **I**ntervention (SUSTAIN) Program) on older Pennsylvanians and to evaluate the feasibility and impact of enhancements to the current clinical program.

**II. RESEARCH OBJECTIVES**

In collaboration with our partners in the PACE/PACENET programs, we propose to evaluate the SUSTAIN being provided to PACE/PACENET enrollees. In order to meet this objective, the following primary questions will be addressed in the current project:

- Is the SUSTAIN Program associated with improvements in behavioral health outcomes among older adults newly prescribed an antidepressant, antipsychotic, or anxiolytic?
- Is the SUSTAIN Program associated with improved access to and delivery of evidence-based care?
- Is the Care Management (CM) arm of the SUSTAIN Program associated with better outcomes than the Monitoring Alone (MA) arm of the SUSTAIN Program?

Secondary question:

- Do caregivers of individuals with cognitive impairment benefit from engaging in the PACE/PACENET BHL programs?
- Are medication type and/or baseline symptom severity related to differential group outcomes?

**III. BACKGROUND & SIGNIFICANCE**

Mental health (MH) conditions, such as depression, anxiety, and dementia, are prevalent in later life and lead to significant morbidity and disability, thereby contributing to increased medical and nursing home service utilization and mortality\(^1-5\). For example, according to epidemiological, community-based studies, major depression occurs in approximately 1-3% of the general elderly population, with 8-16% of older adults experiencing clinically significant depressive symptoms\(^6\). The prevalence of depression appears to be even higher in primary care settings; while 5-10% of older adults in primary care have major depression or dysthymia, 11-29% exhibit depressive symptoms\(^6-7\). Given high rates of mental health disorders among older primary care patients, it is not surprising that most older adults seek or receive treatment for depression while in primary care\(^8\). In fact, due to a variety of factors such as insufficient insurance coverage and perceived stigma associated with mental illness and mental health treatment, older persons are less likely to be referred to or utilize services from specialty mental health clinics\(^8\). It has been estimated, for example, that 64% of all outpatient visits for older adults with depression occur in primary care\(^9\). Moreover, nearly half of all antidepressants, sedatives, and hypnotics, as well as approximately 20% of all antipsychotics, are prescribed by primary care providers\(^10\).

Thus, primary care settings serve as valuable vehicles for the delivery of care to those who are depressed. Nevertheless, despite advances in the assessment and treatment of behavioral health disorders among older adults, underdiagnosis and undertreatment of such disorders remain major public health concerns. For example, as little as 23.5% of individuals with moderate to severe dementia are identified by their primary care providers as having a dementia syndrome\(^11\). With respect to individuals needing treatment for depression, treatment is initiated in less than 50% of cases. Moreover, less than 20% of patients treated for major depression are seen monthly for the first 3 months, and they often do not achieve remission. Factors such as limited provider resources for conducting frequent monitoring, assessing comorbidity of multiple MH conditions and symptoms, and patients’ lack of acceptance of treatment, low medication adherence, and logistic considerations involving transportation, daily schedules, and finances, pose additional barriers to successful treatment outcomes.

To address these issues, a number of initiatives have sought to design and develop care models that not only increase the detection of mental health disorders, but also improve rates of guideline adherent care and treatment outcomes. Our group in the Department of Psychiatry at the University of Pennsylvania School of Medicine has considerable experience in the development, implementation, and evaluation of integrated, or collaborative, disease management models for behavioral health issues among older adults. Recent findings from our clinical trials suggest that integrated care models that include frequent patient contact, ongoing monitoring of treatment adherence and assessment of symptomatic outcomes, patient and provider
feedback, and modification of treatment when needed, result in greater treatment engagement, and improved treatment outcomes (12-15).

For example, in the Primary Care Research in Substance Abuse and Mental Health for the Elderly (PRISM-E) study, older adults with behavioral health issues (e.g., depression, anxiety, substance abuse), were randomized to one of two treatment arms-integrated (i.e., collaborative) care or enhanced referral care (12-14). In the integrated care arm, patients screening positive for mental health issues received MH services in the primary care clinic from a licensed mental health provider. Thus, the delivery of all services (e.g., assessment, counseling, education, care management, psychotherapy and pharmacological treatment) took place in the primary care clinic, enabling mental health and primary care clinicians to communicate about the evaluation and treatment plan for each patient. Older adults assigned to the enhanced specialty referral model of care received MH services (both assessment and treatment) from licensed mental health professionals in a specialty setting that was physically separate from the primary care office and specifically designated as a mental health clinic. Within two to four weeks of the primary care visit, eligible patients were referred to an appointment with the specialty mental health care provider. Additional features of the enhanced referral arm included follow-up with patients who missed their first scheduled specialty visit, ensuring that transportation was available for those who were in need, and the availability of consults in the event of an emergency. Results from this clinical trial suggest that individuals in the integrated care arm were significantly more likely to engage in treatment with a mental health specialist, and that both integrated and enhanced referral mental health service models were effective in reducing rates of depressive disorder and at-risk drinking behavior among older primary care patients (12-14).

Thus, facilitating the management of behavioral health issues and engaging patients who do not seek out treatment on their own, have difficulty adhering to treatment, and/or have logistic considerations that preclude their ability to engage in treatment, appear to be key factors in treatment outcomes. In order to address potential logistic issues that might serve as barriers to frequent clinical visits for monitoring and therapeutic contact, such as lack of transportation and limited access to behavioral health care for patients in smaller clinics or rural settings, our group examined the efficacy of a telephone-based disease management program for the acute management of depression and/or at-risk drinking among Veterans in primary care (15). Patients screening positive for depression or at-risk drinking received either the Telephone Disease Management (TDM) program or usual care. The TDM program consisted of regular contacts with each patient by a behavioral health specialist (BHS). BHS’s assisted in patient assessment, education, support, and treatment planning. Four month follow-up analyses of patients in this trial demonstrated that overall response rates favored those assigned to TDM compared with those assigned to usual care (39.1% responded vs. 17.6%, p= 0.022) (15). Moreover, response rates within the separate diagnostic groups (i.e., depression, at-risk drinking) also favored TDM, but this was only significant for depressive disorders.

Taking results from these prior trials into account, we have adopted a strategy of screening for behavioral health issues and delivering disease management by way of telephone assessments. The Behavioral Health Laboratory (BHL) is an evidence-based clinical service administered via telephone and designed to help identify and manage behavioral health issues. The conceptual framework underlying the BHL program, which is based on over 15 years of research within our network of primary care providers, can be found in Figure 1. The BHL views behavioral health problems as chronic and relapsing, and therefore recognizes the need for more flexible and extended treatment intervention models that better address the characteristics of these disorders (16). One such approach is the Chronic Care Model (17), which specifies regular and extended contact between patients and service providers, interventions to increase patient confidence and skills to manage chronic conditions (e.g., goal setting, identification of barriers to reaching goals, development of plans to overcome barriers), links to community resources, the use of accurate and timely patient data to monitor progress and guide interventions, and provision of support to facilitate self-management. The benefits of regularly recording symptom severity and behaviors on health outcomes also has been stressed by other investigators (18, 19), possibly because it serves as a prompt to maintain behavior change efforts. Thus, the BHL model aims to complement the services available in high quality specialty MH/SA care settings with an integrated care model.
Thus, the BHL program represents a novel and flexible clinical service that overcomes some of the barriers that hinder treatment outcomes for MH problems. The BHL facilitates care for patients with lower perceived need of care, those with preferences for care outside of specialty care, and for those with privacy concerns or preferences for non-group participation. Given the fact that the program provides assessment, monitoring, early intervention, disease management, and referral management, the program can be tailored to each individual’s specific needs. The BHL program also overcomes logistical barriers such as the necessity of frequent face-to-face contact in specialty programs, and thus can enhance existing specialty care programs by reducing wait times and “no-show” rates.

Furthermore, the BHL addresses the importance of quantifying the degree of impairment, and recognizes the value in assessing comorbid psychiatric disorders and the availability of personal and community resources needed to manage mental health issues. For example, the program provides support for cognitive impairment, dementia, depression, alcohol, and anxiety problems. Within each disorder, the program addresses a broad spectrum of severity, from subsyndromal symptoms to referral management to specialty care and/or community resources for the most complex or severely affected individuals. As a result, the BHL has the potential to result in higher patient satisfaction, improved health, and, accordingly, greater independent functioning.

As previously mentioned, the BHL was developed and first implemented at the Philadelphia Veterans Affairs Medical Center (PVAMC), and has been recognized as a “Best Practice” for identification and early intervention of MH and substance abuse (SA) symptoms in primary care patients. The program is well received by both providers and patients; data from our VA site show that in 2007 alone, approximately 80% of the 2,471 referred patients agreed to an initial Core assessment. With respect to older adults, approximately 85% of individuals over the age of 60 referred to the program by their physicians for depression completed the Core assessment, while 84% of individuals who were identified by pharmaceutical records agreed to an initial telephone assessment. Moreover, among individuals in the Depression Monitoring Module of the BHL, which includes patients identified via pharmacy-based casefinder searches as having newly been prescribed an antidepressant, approximately 83% completed the initial Core assessment and at least 2 follow-up telephone assessments. During these assessments, depressive symptoms, medication adherence, and side effects were monitored. Preliminary analyses of data from the Depression Monitoring Module demonstrate that not only does the BHL program help providers meet the Health Plan Employer Data and Information Set (HEDIS) performance measure of 3 contacts in 84 days after starting an antidepressant, but also that patients appear to improve over the course of monitoring. For example, 74% of patients in the Depression Monitoring Module reported treatment adherence and 53% evidenced a remission in depressive symptoms over the course of the 9-week monitoring period. Furthermore, there was a significant (p<.001) decline in mean depressive symptoms at each follow-up monitoring call (e.g., 2, 6, and 9 weeks) relative to baseline.

Finally, data from the Watchful Waiting Module of the BHL, which is designed to prospectively monitor depressive
symptoms among patients presenting with minor depression or distress, suggest that patients randomly assigned to Watchful Waiting evidence both improved mental health and physical functioning.

In addition to aiding in the identification, assessment, and monitoring of individuals with behavioral health issues, the BHL also provides disease and referral management services. Preliminary data from the BHL suggest that where appropriate, follow-up appointments in MH specialty care have been successfully coordinated and telephone-based disease and referral management successfully enacted. Discussed in more detail below, Care Management is algorithm-driven care for conditions such as depression, panic disorder, and generalized anxiety disorder, and is delivered by a Behavioral Health Provider (BHP) as an adjunct to primary care.

IV. STUDY SAMPLE

A. Sample Characteristics

1. SUSTAIN Program Enrollees
   a. Clinical sample participating in the current SUSTAIN Program: The clinical contract for services targets PACE/PACENET beneficiaries who have been newly prescribed an antidepressant, antipsychotic, and/or anxiolytic, and, where appropriate, their caregivers. The current clinical program is being offered to enrollees and caregivers over the course of 12 months. In order to obtain a representative sample of PACE/PACENET enrollees, the PACE/PACENET program uses a stratified sampling method for the identification and referral of eligible beneficiaries to the SUSTAIN Program. Stratification is conducted with respect to two variables--county (Philadelphia area, Allegheny area, Other) and medication type (antidepressant, antipsychotic, anxiolytic), with individuals randomly selected from each strata. Both rural counties as well as antipsychotic medications are oversampled relative in order to allow for balanced subsamples of beneficiaries when conducting subsequent analyses. It is important to note that the current SUSTAIN Program is funded by PACE/PACENET. Thus, current clinical participants are not being sampled or contacted specifically for research purposes. The research portion of this project relates only to the evaluation of those enrolled in the clinical program and to the delivery and evaluation of the enhancements to the current program.

   The PACE/PACENET program provides SUSTAIN with protected health information for each potential enrollee via a business associate agreement with First Health Services Corporation (see Appendix I), a group that manages the pharmacy benefit program for PACE/PACENET. We also have business associate and data use agreements with PACE/PACENET (see Appendix I).

2. SUSTAIN Research Participants
   a. Care Management (CM) Participants: Upon completion of the initial SUSTAIN Program interview, we will randomly select a subset of enrollees for the CM intervention and invite them to participate in the CM arm. If the enrollee is not able to complete the full initial SUSTAIN interview due to cognitive impairment (either as identified by cognitive screening or caregiver report), their caregiver may be invited to participate in the caregiver component of the SUSTAIN Program, the Telehealth Education Program (TEP) Module. The CM arm of the SUSTAIN Program is described in more detail below (refer to Study Design and Study Procedures).

   b. Evaluation Participants: 1. SUSTAIN Program Evaluations: Participants recruited for the evaluation component of the SUSTAIN Programs (Monitoring Alone and Care Management) will fall into the following categories:
      a. Evaluation of SUSTAIN Clinical Data: In order to examine factors such as participant clinical and sociodemographic characteristics, process of care, prescription refills, and use of services, we will ask enrollees for permission to use the clinical data collected during their SUSTAIN interviews. To accomplish this component of the evaluation, we will orally consent all individuals who at least begin a baseline interview to allow use of their clinical data for research purposes. Participants do not need to consent to use of their clinical data as a prerequisite to participating in the clinical program. The clinical data will include their prescription data supplied by the PACE/PACENET program.

      b. 3/6 Month Outcome Evaluation: In order to examine long-term outcomes, participants (i.e., enrollees or their caregivers) who complete an initial clinical interview will be offered participation in an outcome evaluation at 3 and 6 months (i.e., “3/6 Month Outcome Evaluation”).
B. Key Inclusion Criteria

1. To be eligible for the Care Management arm of the SUSTAIN Program, the only inclusion criterion is to have participated in an initial telephone assessment as part of the current SUSTAIN Program. If a patient cannot complete a full assessment due to cognitive, hearing, or speech impairment, they may identify a caregiver to complete the Caregiver Interview. To be eligible for the TEP (caregiver support group) component of Care Management, the enrollee must exhibit cognitive impairment; if only the Caregiver Interview was completed, responses from the caregiver regarding the enrollee’s cognition (score of 2 or greater on “AD-8 Dementia Screening Interview” and/or a dementia diagnosis) will be used as an indication of impairment in lieu of the enrollee’s BOMC score.

2. Similarly, to be eligible for the SUSTAIN Program Evaluations (i.e., SUSTAIN Clinical Data Evaluation, 3/6 Month Outcome Evaluation), the inclusion criterion is to have participated in an initial telephone assessment as part of the current SUSTAIN Program. As above, enrollees who do not complete the initial assessment are still eligible if a caregiver is available to complete the Caregiver Interview.

3. Enrollment in the current SUSTAIN Program. Though not part of the research program, we note that the current program targets older, community-dwelling adults (i.e., 65 years and older) enrolled in the PACE/PACENET programs, who have filled at least one new prescription for an antidepressant, antipsychotic, and/or anxiolytic medication. The SUSTAIN program does require the basic ability to communicate by telephone; either the enrollee or an identified caregiver must meet this criterion for participation in the SUSTAIN Clinical Program.

C. Key Exclusion Criteria

Exclusion criteria for participation in the Care Management arm of the SUSTAIN Program and the 3/6 Month Outcome Evaluation are 1) having severe cognitive impairment (BOMC score 14 or greater) in the absence of a caregiver, and/or 2) endorsement of psychosis or mania during the initial clinical interview, and/or 3) a PHQ score of 25 or greater, and/or 4) positive drug abuse screen, and/or 5) alcohol dependence. Enrollees endorsing any of above mentioned exclusions will be offered assistance with referral to community specialty-care resources as part of the SUSTAIN Program.

Exclusion criteria for caregiver participation in the TEP component of Care Management is lack of report of cognitive impairment when only the Caregiver interview was completed.

D. Subject Recruitment and Screening

1. SUSTAIN Clinical Data Evaluation: Following completion of the initial SUSTAIN clinical assessment (i.e., “Core assessment”), all enrollees will be asked for their permission to use the clinical data collected during their interviews. Enrollees who complete only partial Core assessments due to significant cognitive impairment (see “Conducting SUSTAIN Core Clinical Assessments” for details) will also be asked for permission to use their clinical data. We will orally consent all individuals to allow use of their clinical data for research purposes. Recruitment and consent for the use of the interview data will follow the attached script and consent will be documented using response form (see Appendix III.A).

2. Care Management Program Recruitment: Following completion of the initial SUSTAIN clinical assessment (i.e., “Core assessment”), a subset of enrollees will be asked if they would agree to participate in the Care Management Program. Randomization to the Care Management Program will occur within strata as determined by index medication type (i.e., antidepressant, anxiolytic, or antipsychotic) and Core interview assessment outcome (i.e., clinically significant depression and/or anxiety symptoms, no clinically significant symptoms, cognitive impairment). After obtaining informed consent, a separate simple randomization protocol will be followed within each substratum of enrollees. For each substratum every other participant will be offered participation in the Care Management Program. In cases where caregivers complete the initial caregiver clinical assessment (i.e., “Caregiver Interview”) caregivers who endorse cognitive impairment in their care-recipient enrollee will be randomized to participation in the Care Management TEP Program. SUSTAIN staff will follow the attached scripts and complete the consent documentation forms when recruiting and consenting enrollees (see Appendix III.B) or caregivers (see Appendix III.C).

3. 3/6 Month Outcome Evaluation Recruitment: Following completion of the initial SUSTAIN clinical assessments and agreement to participation in the Care Management Program or our Monitoring Alone Program, enrollees or their caregivers will be asked to participate in an evaluation of the SUSTAIN program at 3 and 6 months from the initial SUSTAIN core clinical interview. Recruitment and consent for use of the interview data
will follow the attached scripts and consent will be documented using response forms (see Appendix III.D & Appendix III.E).

4. Enrollment in the current SUSTAIN Clinical Program: Again, though not part of the research project, we will provide information on how enrollees are initially approached for participation in the current, SUSTAIN Program. Prior to commencement of the current SUSTAIN Clinical Program, all referred PACE/PACENET program enrollees are sent preliminary letters introducing them to the SUSTAIN program. These letters explain the purpose of SUSTAIN and serve as notice that they will be receiving a call from a staff member (HT/BHS) to conduct an evaluation, and that their participation in the clinical service is voluntary and confidential. Copies of our current materials are attached (Appendix IV.A.1 & Appendix IV.A.2). These have been reviewed and approved by the Department of Public Welfare and PACE/PACENET administrators.

E. Early Withdrawal of Subjects
PACE/PACENET enrollees and/or caregivers will be informed that they may withdraw from the two clinical programs (Monitoring Alone or Care Management) or the evaluation program at any time without any penalty or loss with respect to their health care or prescription drug coverage. PACE/PACENET enrollees and/or caregivers will be informed that they do not have to take part in any component of this study, and that their refusal to participate will involve no penalty or loss of rights to which they are entitled. Enrollees/caregivers need only provide verbal notice of refusal/withdrawal.

F. Vulnerable Populations
Children, pregnant women, fetuses, neonates, or prisoners are not included in this research study.

G. Populations vulnerable to undue influence or coercion
This research study will include those with cognitive impairment. The initial clinical assessment is designed to identify individuals with moderate-severe cognitive impairment through use of the Blessed Orientation Memory Concentration test (BOMC). In these cases, a caregiver is also contacted, with the enrollee’s assent, to participate in the program by providing collateral information.

V. STUDY DESIGN
We describe the care delivered in the current SUSTAIN Clinical Program and the proposed enhancements to this program (Sections A and B) as well as the evaluation component (Section C). The following diagrams provide an overview of the proposed modification in the project’s design.
A. The SUSTAIN Monitoring Alone Program

SUSTAIN is divided into several core services. Each service is evidence-based and manualized with a specific training program. Current SUSTAIN program services are provided by Health Technicians (HTs) and Behavioral Health Providers (BHPs).

Enrollment and participation in the current SUSTAIN Program occurs on a rolling basis. Over the course of 12 months, the PACE/PACENET programs identify and refer a sample of enrollees who have been newly prescribed an antidepressant, antipsychotic, or anxiolytic to the SUSTAIN Program.

The SUSTAIN Monitoring Alone Program is a clinical service and includes an initial Core assessment and 1-4 brief follow-up assessments during which time medication adherence, side-effects, and symptoms are monitored. In cases where enrollees are experiencing hearing, speech, or moderate to severe cognitive impairment, caregivers are asked to complete a brief interview. The components of the program are outlined below:

1. Initial Telephone Assessment: Enrollee Core Interview and Needs Assessment

The Core assessment of the SUSTAIN program is a structured telephone interview that takes, on average, 20-40 minutes to complete. The interview is conducted by HTs or BHPs and is completed by direct entry of clinical data in a computer program designed for ease of use with simple entry screens (see Appendix VI.A for a copy of clinical assessments). The domains assessed during the Core interview include demographic variables, financial status, social support, new/current psychotropic medication use, past depression treatment, alcohol use (using a 7-day follow-back method) and use of other illicit substances, depression history, pain, sleep, and symptoms of agitation/irritability. Specific, standardized, well-known scales administered include the Blessed Orientation-Memory-Concentration (BOMC), Mini International Neuropsychiatric Interview (includes Psychosis, Mania, Generalized Anxiety Disorder, Panic Disorder, and Alcohol Abuse/Dependence modules), Patient Health Questionnaire-9 (PHQ-9; a brief depression severity measure), the 5-item Paykel Scale for suicide ideation, Medical Outcomes Survey (SF-12), and the GAD-7. Enrollees are also asked about any resources/services that they need and about service utilization during the prior three months.

Upon completion of the Core assessment, a lab report summarizing the enrollees’ outcomes is generated for each individual’s prescribing clinician (see Appendix V.A for a sample clinical report). Enrollees are mailed educational materials regarding specific reported symptoms (see Appendix V.B for a sample enrollee letter).

2. Initial Telephone Assessment: Caregiver Core Interview and Needs Assessment

If an enrollee scores 14 or greater on the BOMC, s/he is asked for permission to speak with a caregiver/loved one (heretofore referred to as “caregiver”) (see Appendix II.A). If the enrollee is not able to complete an interview due to hearing or speech impairment based on the report of a caregiver, that individual is asked if s/he is willing to complete an interview about the enrollee. In the BHL Caregiver Core Interview (see Appendix VI.B), caregivers are asked about care recipients’ behavioral, psychological, and cognitive symptoms and level of physical functioning (Functional Activities Questionnaire). The interview also assesses caregiver burden, safety concerns and entails a resource and needs assessment highlighting additional services that the caregiver might need.

A brief written summary of the caregiver’s responses to questions regarding the enrollee also is incorporated into the clinical note sent to the prescribing clinician.

3. Follow-up Monitoring

The Monitoring Alone Module is a service designed to help provide evidence-based care for individuals receiving new antidepressant, anxiolytic, or antipsychotic prescriptions. Monitoring consists of up to 4 brief (5-10 minutes), structured assessments following the Core assessment. These follow-up contacts are conducted over the telephone by the HT/BHS and take place during the initial 12 weeks of pharmaceutical treatment (e.g., 2, 6, 9, and 12 weeks). These brief interviews monitor adherence, side effects, and response to treatment. A progress report is provided to the prescribing clinician following each interview to help in treatment planning and to alert the clinician of special issues.

The Monitoring Module interview (Appendix VI.C) includes the PHQ-9, the GAD-7, and questions regarding sleep, agitation/irritability and medication side effects and adherence.

4. Semi-structured follow-up assessment

This assessment is administered by a BHP or HT to any enrollees who complete an initial interview and report minimal to no mental health symptoms (see Appendix VI.D). Given that all patients contacted for this program have been prescribed a psychotropic medication, the aim of this assessment is to gain an understanding of why some patients do not endorse at least moderate depression, anxiety, or other mental health symptoms. The assessment focuses primarily on patients’ perception of the medication’s impact on their symptoms, as well as past episodes and treatment of depression or anxiety.

5. Referral Management
For participants who report severe mental health symptoms during the initial core interview (such as mania, psychosis, PHQ score 25 or greater, drug abuse, alcohol dependence, etc.), SUSTAIN makes recommendations for scheduling in Mental Health specialty care. Recommendations are based on available resources in the enrollees’ communities and individuals are provided with contact information. The BHP will work with the enrollee to encourage attendance to the specialty care appointment.

6. Needs Follow-up

For every enrollee or caregiver that completes an initial interview, the participant will be provided with community resources for needs that were identified during the SUSTAIN Core assessment. This assistance can be provided through informational materials sent in the mail or may take place during a follow-up call.

B. The SUSTAIN Care Management Program

Upon completion of the Core interview, a subset of enrollees will be randomly selected to participate in the Care Management Program (i.e., Enhanced Monitoring Module or Care Management Module).

For enrollees who do not report clinically significant mental health symptoms the Care Management Program consists of the Monitoring Alone Program enhanced with a discussion of continuing versus discontinuing the medication. The BHP will follow-up with the enrollee after 6 weeks to discuss continuing versus discontinuing the medication.

For enrollees who report clinically significant depression, anxiety, and/or pain symptoms the Care Management Program consists of Care Management, which is designed for the management of individuals who are actively enrolled in primary or medical subspecialty care. The model incorporates the use of a BHP who has expertise in mental health assessment and is well versed in the delivery of algorithm-based management strategies for disorders such as depression and anxiety. The role of the BHP is to facilitate treatment and provide informal psychosocial therapy, using motivational interviewing techniques in a manner that is consistent with the Agency for Health Care Policy and Research (AHCPR) guidelines. The BHP monitors and encourages patient acceptance and adherence to treatment recommendations through support, education, and motivational engagement. The BHP initiates care management when enrollees are not responding to the initial treatment or as clinically needed based on the initial Core interview and needs assessment. The BHP also uses problem solving therapy to assist patients. The frequency and number of contacts for each individual will vary, but our experience suggests that individuals typically engage in 1-2 contacts per month for several months. Written updates are provided to the prescribing clinician, as clinically indicated.

In cases where caregivers complete an initial interview (i.e., enrollees score 14 or greater on the BOMC and allow the staff to speak with a caregiver, or the enrollee is not able to speak on the phone at all), and endorse cognitive impairment in their care-recipient enrollee, a random sample of caregivers will be offered participation in the Telehealth Education Program (TEP). TEP is an existing, manualized program developed and validated with caregivers of veterans with moderate to severe dementia. Although this program has been delivered in a group format in other settings, in the current project the BHP will work individually with each caregiver. The program consists of various modules which seek to provide both education and psychosocial support for individuals caring for older adults with moderate to severe cognitive impairment. Based on the responses from the Caregiver Core Interview and participant preference, the BHP and caregiver will determine which TEP modules will be covered over the course of TEP. If no modules are identified as relevant (or the caregiver declines all modules), the BHS will still follow-up with the caregiver, offering unstructured supportive phone calls.

The inclusion of education, emotion and problem focused coping skills, and support in TEP is based on well-established and widely used principles of interventions with older adults. Delivering the program over the telephone allows access to education and support without having to manage the difficulties of getting the enrollee out of the house or finding supervision for him/her in order to attend face-to-face sessions.

If selected for the Care Management program modules, oral consent will be obtained by the HT or BHP, who will review all elements of consent (see Appendix III.B & Appendix III.C for enrollee and caregiver versions, respectively). We will document the oral consent process on a case-by-case basis. For enrollees and caregivers who provide consent, we will mail a letter that reiterates the information and extends an invitation to call for further clarification of the Care Management modules (Appendix IV.B or Appendix IV.I & Appendix IV.C or Appendix IV.J). Both the oral script and the written material will include statements that indicate that participating in the Care Management program modules is voluntary and that individuals can drop out at any time without any impact on their or their loved one’s care or PACE/PACENET enrollment. Individuals who refuse the Care Management Program can still participate in the 3/6 Month Outcome Evaluation component of the project.
C. Evaluation Component
We propose a pretest-posttest design in order to examine outcomes among individuals in the Monitoring Alone and Care Management arms of the SUSTAIN Program.

1. SUSTAIN Program Evaluations
   a. Evaluation of Clinical Data: For all participants, clinical data collected during the SUSTAIN Clinical interview (both enrollee and caregiver versions) will be evaluated in order to examine factors such as participant clinical and sociodemographic characteristics, process of care, and use of services. Moreover, for all participants, we will examine utilization and prescription data provided by the PACE/PACENET program. The data available will include prescription coverage for a year prior to SUSTAIN program enrollment and a year after enrollment. For this component of the evaluation, we also will include a random sample of enrollees in the PACE/PACENET programs not selected for the SUSTAIN Clinical Program. Thus, we will have de-identified administrative data on enrollees referred and enrolled in the current SUSTAIN Monitoring Alone Program, the Care Management Program, and a group of enrollees not referred to the current program but who would have otherwise met the criteria for referral (i.e., new medication, age 65 or older). The provision of this data from PACE/PACENET is covered under a business associate agreement. PACE/PACENET also intends to assist in the acquisition of Medicaid Data (e.g., placement in long-term care) for enrollees that are part of the evaluation component.

   b. 3/6 Month Outcome Evaluation: Secondly, in order to evaluate individual-level outcomes and rates of clinical improvement at 3 and 6 months, we will attempt to collect follow-up data from all enrollees/caregivers who have completed the initial SUSTAIN Clinical Program assessment. Using data extracted from the enrollee follow-up assessments, we will examine psychological, behavioral, and cognitive symptoms, physical disability, health care utilization, and access to community resources. Using data extracted from caregiver follow-up assessments, we will be able to evaluate care recipients’ behavioral, psychological, and cognitive symptoms and level of physical functioning, in addition to caregiver burden and safety concerns.

   All components of the SUSTAIN programs will be administered via telephone and conducted by research staff located in the SUSTAIN research office at the University of Pennsylvania. The 3/6 Month evaluation also will be completed by telephone.

VI. STUDY METHODS

A. Clinical and Study Instruments
   1. SUSTAIN Clinical Core Assessments:
      All assessments for clinical status and diagnosis are conducted via telephone by HTs/BHPs, and responses are directly entered into the computer program (please refer to Appendices VI.A, VI.B, VI.D for paper copies of all assessments). The domains assessed during the SUSTAIN Enrollee Core Interview include:
      - Demographic Variables
      - Medication Information
      - Current Care (i.e., whether followed in mental health, location of primary care)
      - Financial Status
      - Social Support
      - Blessed Orientation-Memory-Concentration (BOMC)
      - Mini International Neuropsychiatric Interview (includes Psychosis, Mania, Generalized Anxiety Disorder (GAD), Panic Disorder, Alcohol Abuse/Dependence)
      - GAD-7 (a brief measure of anxiety symptoms and severity)
      - Patient Health Questionnaire-9 (PHQ-9; a brief depression severity measure)
      - Past/Current Antidepressant Medications
      - 5-item Paykel Scale for suicide ideation
      - Alcohol use, using a 7-day follow-back method
      - Use of Other Illicit Substances
      - Depression History
      - Medical Outcomes (SF-12)
      - Sleep and Pain Symptoms
      - Enrollee Needs Assessment
      - Service Utilization
Agitation/Irritability Symptoms
- Semi-structured questionnaire (only for enrollees with minimal to no mental health symptoms)

In the SUSTAIN Caregiver Core Interview, we will assess:
- Caregiver reports of care recipients’ physical functioning (Functional Activities Questionnaire)
- Sensory/communication and cognitive deficits, and behavioral and psychological symptoms
- Caregivers’ safety concerns, perceived burden, and a needs assessment

2. 3/6 Month Outcome Evaluation:
The instruments used in the 3 and 6 month follow-up assessments will mirror the initial Enrollee and Caregiver Core assessments (Appendix VI.A & Appendix VI.B); the only difference is that the follow-up interviews assess help received to address needs, rather than including a needs assessment.

Thus, for enrollees, the domains assessed will include social support, past/current medication use, alcohol use (using a 7-day follow-back method), depression history, pain, sleep, agitation/irritability, and service utilization. Specific, standardized, well-known scales will include the BOMC, PHQ-9, 5-item Paykel Scale for suicide ideation, and the Medical Outcomes Survey (SF-12).

Caregivers will be asked about care recipients’ behavioral, psychological, and cognitive symptoms and level of physical functioning (Functional Activities Questionnaire). They also will be asked about caregiver burden and safety concerns.

B. Clinical and Study Procedures
Details of the procedures followed by both HTs and BHPs can be found in the SUSTAIN “Manual of Operations”. Below, we describe the current procedures followed in the SUSTAIN Monitoring Alone Program (1.A), as well as the proposed procedures for the Care Management Program modules (1.B & 1.C) and SUSTAIN program evaluations (1.D). We would like to reiterate that the Clinical program is not being proposed as part of the research project. Nevertheless, in order to understand all of the elements of the Care Management Program as well as the evaluation component of the proposed research, we have included detailed procedures below.

1. Current SUSTAIN Monitoring Alone Program Procedures

SUSTAIN Clinical Core Interview
Contacting Enrollees for the Initial SUSTAIN Clinical Core Interview
- On a weekly basis, the PACE/PACENET program mails two introductory letters explaining the SUSTAIN program to those enrollees identified using the sampling method described previously. The letter from SUSTAIN explains the purpose of the program and informs the enrollee that they will be receiving a phone call from SUSTAIN staff; the letter from PACE explains the relationship between PACE and SUSTAIN and gives enrollees the opportunity to “opt out.” One of two available SUSTAIN letters is selected for mailing to the enrollee based on the index medication—antidepressant/anxiolytic medication or antipsychotic medication (see Appendix IV.A.1 & Appendix IV.A.2). Using a secure data transfer program, enrollee names, addresses, phone numbers, and prescription filling details (e.g., name of medication, date filled, dosage) are sent from the PACE/PACENET program to SUSTAIN. Approximately 3 business days after the letters have been sent, the HT/BHP will attempt to contact the enrollees in order to conduct the initial Core interview.
- The HT/BHP aims to contact enrollees within approximately one week of their referral date. Upon entry of the enrollee information, the SUSTAIN software program automatically assigns each case a “window” (i.e., time frame) during which time enrollees will be considered “active” cases.
- A “Call Log Book” is used to organize PACE/PACENET referrals and to track when to call patients.
- The HT/BHP calls the referred enrollee by phone.
- Calls are made at various times throughout the day, with calls made on evenings for those who are difficult to reach.
- An enrollee is considered Unable to Contact (UTC) once five call attempts have been made (including one late night call and one early morning call) or if there is no accurate contact information available (including wrong and disconnected numbers).
The Project Coordinator generates an “Active Patient Report” from the SUSTAIN program periodically to ensure that referrals are being responded to in a prompt manner.

Prior to starting the interview, the HT/BHP asks enrollees if they are willing to participate in the assessment.

The HT/BHP encourages all enrollees to complete the interviews.

- When an enrollee is reluctant to start or complete the interview, the HT/BHP uses one of a number of scripts to encourage participation.
  - Nevertheless, during the interview, if the enrollee decides, for whatever reason, that s/he does not wish to complete the interview, the HT/BHP terminates the interview.
  - If the enrollee wishes to stop an interview, but is willing to continue at a future time, the HT/BHP terminates the interview, and conducts the interview at a more convenient time.

- If an enrollee is unable to complete a telephone interview due to hearing, speech, or other communication difficulties (such as a language barrier), the person will be asked about their willingness to participate in the Caregiver Interview.
  - If the person who speaks to the SUSTAIN staff reports that the enrollee has cognitive impairment, the HT/BHP will inform them that a cognitive assessment occurs early in the phone interview, and that the interview would be discontinued if severe impairment were identified. If the informant still prefers that the SUSTAIN staff not speak with the enrollee, the HT/BHP will ask the informant of their willingness to participate in the Caregiver Interview.

Conducting SUSTAIN Core Clinical Assessments

- Enrollees are assessed in various domains of symptom logic to determine clinical status and diagnosis.
  - Assessments are conducted using the questionnaires in the SUSTAIN computer program or, when needed, on a back-up paper version. Paper versions of all interviews can be generated from the software program.
  - Paper copies are coded with an ID, de-identified from any personally identifiable information, and are accessible to study staff only. Paper copies of all questionnaires and participant data are stored and secured within a locking file cabinet in the SUSTAIN office. Electronic data are stored on a password protected server.
  - Upon completion of the Blessed Orientation Memory Concentration Test, the SUSTAIN program automatically scores the enrollee’s impairment level based on his/her responses.
    - Enrollees who score 0-13 on the BOMC complete the Enrollee Core interview without caregiver involvement.
    - If the score is 14 or greater, the interview terminates. At this time, enrollees are asked if it would be possible to speak to a caregiver.
      - If the enrollee agrees, the caregiver will be asked for their verbal consent and the SUSTAIN Caregiver Core Interview will commence.

- In order to ensure data quality, an HT/BHP user cannot go backwards within the interview, which means that once the HT/BHP has completed a page and moved on to the next, there is no way to access the previous page. Furthermore, the program is set up so as to not allow an HT/BHP to proceed from one question to the next without answering each question.
  - Each HT/BHP should be sure that s/he has several paper copies of the Core Assessments and each module assessment available. During an interview, it is common for an individual to change his/her mind regarding an earlier response or clarify his/her response in a way that may change the answer. Furthermore, it is possible that the computer program may be down for a period of time (errors, updates, etc.).
  - If such errors occur, the HT/BHP will generate a “Database Correction Form” after the interview is completed and give it to the Project Coordinator to correct the error.

Completing the SUSTAIN Core Assessments and Generating Reports

- If the enrollee has completed a full SUSTAIN Core Assessment, the HT/BHP informs the enrollee about the approximate time frame for next clinical follow-up phone call they will be receiving, which will vary based on the type of service (approximately 2 weeks for Monitoring Alone, 1-3 days for Referral Management). The
HT/BHP then reminds the participant that they will be receiving additional phone calls designed to monitor their medication adherence, side effects, and symptoms.

- The HT/BHP enrolls individuals in the appropriate clinical module, which creates windows/time frames within which individuals should be contacted. Prior to enrollment, an HT might consult with a BHP to determine which service the patient should receive (Medication Monitoring or Referral Management, depending upon the severity of the enrollee’s symptoms).

- Once the Core assessment is completed, the HT will generate the clinical report based on the enrollee’s responses. This report will be sent to the prescribing clinician, along with a cover letter describing the services of SUSTAIN and explaining the clinical report. Enrollees will also be mailed a follow-up letter including educational material.

- Should the enrollee/caregiver report needs for community services, the HT/BHP will attempt to find resources in their area to assist the participant with the identified needs. The HT/BHP will send informational materials in the mail and possibly attempt to follow-up with the participant over the phone as appropriate.

2. Care Management Program Procedures: Monitoring Alone with discussion of medication discontinuation

- If the enrollee is offered and agrees to the Monitoring Alone arm with discussion of medication discontinuation component at the 6-week monitoring call s/he will be invited to discuss the risk/benefit of medication discontinuation with a BHP.
  - If the enrollee decides to continue on the medication, the HT will resume Monitoring for the 9- and 12-week monitoring calls
  - If the enrollee decides to discontinue the medication, the BHP is available at the enrollee’s request to call the prescribing clinician to discuss possible discontinuation reporting back to the enrollee the results of the call. The HT will attempt to make two additional calls to the enrollee at the 9- and 12-week points to follow-up on clinical symptoms.

3. Care Management Procedures

For enrollees agreeing to participation in the Care Management arm of the SUSTAIN program, the BHP follows up with telephone assessments at appropriate, individualized time points based on clinical status, and domains similar to the Monitoring Alone Module (e.g., adherence, side effects, symptoms) are assessed.

Preparing for the Baseline Assessment

- Prior to the first Care Management call, the following information is reviewed and pertinent details recorded on a Baseline Progress Note:
  1. The SUSTAIN Core Assessment report
  2. List of current medications, including dosages and durations

- The BHP documents each phone call and all pertinent information. If keeping a paper record for each enrollee, the BHP includes all relevant documentation, including case details, handwritten notes, copies of reports sent to providers, contact information, etc. These records are kept in locked files in the SUSTAIN laboratory.

Conducting the Baseline Assessment

- During the baseline contact, the BHPs:
  ▪ Begin to establish rapport with the enrollee in order to build a supportive relationship.
  ▪ Review the purpose of the phone call and the reasons for follow-up. Confirm the screening results that led to referral.
  ▪ Obtain medical and psychiatric history/current medications/past psychotropic medication use history from the enrollee.
  ▪ Conduct a semi-structured clinical interview with the enrollee in order to learn the enrollee’s perception of his or her problem.
  ▪ Complete any or all of the following (depending on clinical need and judgment): PHQ-9, GAD-7 (for those with an anxiety diagnosis or report of significant anxiety symptoms during the semi-structured interview), questions about pain, MINI Psychosis assessment (where appropriate), agitation/irritability assessment, side effects inquiry, and the assessment of alcohol use.
• Ask the enrollee if s/he would like educational materials on depression/anxiety and a list of symptoms of depression/anxiety mailed to him/her. BHPs check to see if these materials have already been sent to the enrollee by the HT/BHP after the Core interview.
• Complete a Baseline Progress Note.
• Send a written summary to the prescribing clinician that summarizes the BHP’s contact with the enrollee, as appropriate.

Follow-Up Assessments
• Over the course of monitoring, if the enrollee is not responding to treatment and/or the BHP feels that intervention is clinically appropriate, the BHP consults with the SUSTAIN Medical Director. Based on that consultation, a written report is sent to the prescribing clinician that summarizes the pertinent assessment findings and informs him/her of any recommendations.
• Enrollees who are asymptomatic or minimally symptomatic are monitored by the BHP for up to six months to assess adequacy of response. At the end of participation in Care Management, a summary report is sent to the prescribing clinician. Reports to the prescribing clinician also include any recommendations made to the enrollee.
• During all contacts, BHPs seek to foster trust and engage/motivate enrollee for treatment, if ambivalence or resistance to treatment recommendations is present.

4. Care Management: TEP Module Procedures
• Prior to contacting the caregiver to initiate TEP, the BHP will review the responses from the Caregiver Core interview to determine which modules appear to be appropriate given the enrollee’s level of impairment.
• During the initial session, the BHP will introduce him/herself and provide a general overview of the format, content, and goals of the TEP program. In addition, the BHP will review the available/recommended subject areas and, along with feedback from the caregiver, will finalize the list of TEP modules to be covered throughout the course of the program.
• Sessions will occur approximately once per week, depending upon the availability and preference of the participant. The total number of contacts will depend upon the number of topics to be covered.
• Each session will include reviewing a different education topic (e.g., disease symptoms and stages, behavior management, etc.). The remainder of the session involves coaching the participant on emotion-focused and problem-focused coping strategies, as well as methods of stress reduction. These coping strategies will be taught and practiced during each session. The BHP will discuss problem solving with the participant to reinforce the action plan and the educational component of the intervention. The BHP will also use this time to check in with the caregiver on areas that they had discussed during previous calls.
• The development of a weekly action plan related to problem solving discussions will be encouraged at each session and caregivers will complete workbooks, which they will get to keep, prior to the next session.
• If a caregiver declines all of modules of the program, the BHP will still attempt to contact them at least three times for general support and follow-up.

5. SUSTAIN Program Research Consent and Evaluation Procedures
• Prior to concluding the initial clinical assessment phone call, the HT/BHP will ask each enrollee if they consent to the use of their clinical data for research purposes.
  ▪ HT/BHPs will complete the “Use of Enrollee Core Interview and Clinical Data” form (Appendix III.A).
• A subset of enrollees, or their caregiver, if applicable, will be asked if they are willing to participate in the Care Management arm.
  ▪ Again, HT/BHPs will document participants’ consent/response on the appropriate documentation forms (Appendices III.B & III.C).
  ▪ Every enrollee/caregiver completing an initial interview and agreeing to further participation in the program will be asked to participate in the 3/6 Month Outcome Evaluations.
  ▪ HT/BHPs will document participants’ consent/response on the appropriate documentation forms (Appendices III.D & III.E).
  ▪ Enrollees/caregivers who agree to randomization will be sent a letter explaining the details of their program (Appendices IV.B, & IV.C, IV.D & IV.E, or IV.I & IV.J).
- Enrollees who agree to randomization also will be sent the “University of Pennsylvania Health System and School of Medicine Research Subject HIPAA Authorization.” (Appendix IV.H)
- Enrollees or caregivers providing verbal consent to participate in the 3/6 Month Outcome Evaluations will be called again at 3 and 6 months following the date of the initial contact. At each of these follow-up calls, assessments will be conducted that mirror the initial Core assessments.
- Enrollees/caregivers who are considered Unable to Contact (see page 13, Contacting Enrollees for the Initial SUSTAIN Clinical Core Interview) will be sent a 3/6 Month Outcome Evaluation UTC letter (Appendices IV.F & IV.G).

6. Summary & General Procedures

All follow-up assessments for individuals providing oral consent will occur via telephone. In order to ensure that individuals are contacted within the appropriate time frames, the SUSTAIN computer program will suggest “window” dates. These window dates will be set for a prespecified length of time from the Core assessment. After this time period expires, the health tech/BHP will close the window. This procedure will ensure that individuals are contacted within a reasonable time period. In the case of enrollee or caregiver attrition, we will treat incomplete assessment visits as “missing”. Given that hospitalization and placement in long term care remain outcomes of interest, we will document these occurrences in the data set.

The caregiver TEP sessions range from a few to approximately 30 minutes; the total number of sessions will vary by caregiver, but BHPs will aim to complete at least 3. The 3/6 Month Outcome Evaluation will take approximately 20-30 minutes to complete.

7. Emergency Procedures

There are numerous, detailed emergency procedures in place for dealing with special cases (e.g., suicidal, hostile, inebriated individuals). SUSTAIN has an emergency contact list, starting with the primary contact (i.e., Medical Director) and followed by the subsequent backup (the P.I.). These contacts are listed in order, from the primary contact to secondary and so on. The HT contacts the Medical Director/P.I. using an Emergency Pager. The BHP will facilitate this communication. The supervising clinician (i.e., Medical Director) ensures that all individuals on the emergency contact list are trained to respond to emergency pages and take appropriate actions.

C. Data Management

Data collection and management for the research project will mirror the procedures used by the current SUSTAIN Clinical Program. Data will be collected using direct data entry into a Microsoft C++ based program. Each entry has been created with range checks and primary keys to reduce errors and to prompt queries of questionable responses. As a check on data integrity, exported data files will be checked by the investigator, project coordinator, and relevant research technicians against the raw data and any discrepancies will be resolved. Data also will be collected electronically on a password-protected website run by the University of Pennsylvania’s Data Management Unit and stored on the DMU network. The DMU is a closed and password protected data entry system has been designed so that only the responsible data entry person and the DMU supervisor can enter and/or edit data and this can be done only be using the programs and/or utilities available on the menu system. Data and user stamping are used to create an audit trail. Range checks, review screens, and various error trapping routines are built into the system as quality control procedures. All possible relevant information on the forms is pre-coded and field-validated. All specific instructions and choices are provided for all data forms. All errors on source documents must be initialed and dated. The DMU director will be responsible for working with the project staff to ensure the integrity of the data entry process. The investigator or study research staff can request the data at any point during the study so that audits of the study’s current data input can be conducted and the data’s integrity assessed. With respect to data available to the clinician, the “laboratory” reports generated from the SUSTAIN evaluations will be sent to clinicians in order to facilitate communication with the PCP (Appendix V.A). This will include general recommendations for enrollee follow-up, the enrollee’s willingness to consent and participate in the Care Management program (where appropriate), and whether referral for face-to-face evaluation was necessary and made. Letters to enrollees highlight reported symptoms and suggestions for self-directed care (Appendix V.B).

Procedures designed to maintain confidentiality include both formal training sessions for all health technicians in the importance of procedures to be followed as well as formal mechanisms for limiting access to all information that can link data to individual subjects. All research personnel will maintain current POR training throughout the project period. Participant identifying information provided by PACE/PACENET (i.e., names, addresses, phone numbers, date of birth), as well as data from all telephone-based assessments, will be maintained
on a single host computer and accessible only to SUSTAIN staff via password protected files. In addition, the research office area will be accessible to a limited number of staff.

At the point of conducting research on the SUSTAIN database, a separate research database will be created, de-identified, and kept in separate password protected files on a single computer in the research office area. To facilitate tracking, the PI and staff will maintain, under a limited password, a unique ID number for each individual in the research data base, assigned at the time of the SUSTAIN assessment. This unique number can be used to link the research database to the clinical database in the event that identification of the individual is necessary. Access to the research database will be limited to Dr. Oslin or his designee and access to this data will be tracked.

Finally, a data sharing agreement between the University of Pennsylvania and PACE/PACENET has been created and approved by all parties (see Appendix I). This agreement enables the University of Pennsylvania to have access to the names and contact information generated by PACE/PACENET. The data generated by the SUSTAIN is the property of the University of Pennsylvania but can be shared with PACE/PACENET per agreement of the principals.

D. Data Analysis

Statistical analysis procedures will depend on each individual research objective being addressed. Prior to conducting analyses, we will run descriptive analyses, including univariate statistics such as percentiles and means, and graphs such as histograms, box and whisker plots, scatter plots, and Q-Q plots. Such analyses will allow us to examine overall trends, as well as identify outliers or potential data entry errors.

In the case of missing data, where needed, we will employ multiple imputation of missing covariates to maintain sample sizes for various sets of analyses. In cases where multiple imputation is not needed, we will use random effects models, which assume missing at random (MAR) and are especially robust to the presence of missing values. Moreover, for all longitudinal analyses, we will conduct attrition analyses in order to examine whether there are any significant group differences between those with complete vs. incomplete data.

1. To determine the range of behavioral health issues present in our sample and whether individuals are successfully assessed by the SUSTAIN Program, we will use descriptive statistics (e.g., percentages, crosstabs, chi-square tests) to evaluate:
   a. The proportion of older adults assessed by SUSTAIN who meet diagnostic criteria for conditions that can be managed via collaborative care (e.g., major depression, minor depression, anxiety, panic disorder).
   b. The proportion of older adults assessed by SUSTAIN who meet diagnostic criteria for conditions that are optimally managed by mental health specialists (e.g., mania, bipolar disorder, alcohol dependence, co-occurring mental health problems, suicide ideation, or illicit drug abuse problems).
   c. The proportion of referred older adults who are 1) contacted and 2) assessed by SUSTAIN; and
   d. Whether rates of contact/assessment vary by medication type and/or behavioral health issue.

2. To examine the extent to which the Monitoring Alone and Care Management SUSTAIN Programs predict changes in enrollee-level (e.g., symptoms, adherence, functioning) and/or caregiver-level (e.g., access to resources, perceived burden) factors, differences between the Monitoring Alone and Care Management groups will be estimated using random effects logistic (for binary outcomes) and linear (for continuous outcomes) regression models. For the 3 and 6 month follow-up interviews, we will again use random effects analyses to model longitudinal changes in both continuous (using SAS PROC MIXED) and binary outcomes (using SAS PROC NLMIXED). These procedures allow for estimation of regression coefficients accounting for both within- and between-individual variance. Population-averaged models without random effects will be conducted using Generalized Estimating Equations (GEE) in SAS PROC GENMOD.

Primary analyses will be conducted separately for those with clinically significant baseline symptoms (in order to compare longitudinal outcomes between those receiving Monitoring Alone vs. Care Management) and low baseline symptom severity (in order to compare longitudinal outcomes between those receiving Monitoring Alone vs. monitoring + discussion regarding continuation/discontinuation of medicine). Secondary analyses will involve stratifying the sample based on index medication type (anxiolytic, antidepressant) and, where appropriate, baseline symptom severity score.

3. Univariate and cross-sectional analyses (e.g., t-tests, ANOVAs, chi-square tests) will be used to evaluate:
   a. Provider satisfaction
   b. Differences in rates of older adults maintaining continuous use of medication among those referred to SUSTAIN vs. those who are not.
VII. RISK/BENEFIT ASSESSMENT

A. Risks

There are no significant risks associated with participation in the Care Management Program or SUSTAIN Program Evaluations. Nevertheless, individuals may become distressed from discussions about mental health issues. To ensure minimal risk, we will continue following the procedures that are currently in place for the SUSTAIN Clinical Program. The direct contact staff consist of professionals, primarily nurses or social workers, with clinical and/or research experience in conducting behavioral health interviews, and managing behavioral issues. Additionally, direct contact staff are selected for their role specifically considering their interpersonal expertise. At all times, providing a positive experience for enrollees and their caregivers is of overriding importance. Should distress arise that cannot be effectively managed by the direct contact staff, consultation with the SUSTAIN Medical Director is available to all SUSTAIN staff. In addition, a psychiatrist is available on call to review any urgent issues that arise, to conduct additional enrollee evaluations, when necessary, and to facilitate treatment.

Enrollees who are offered the Monitoring Alone Program in which the telephone contact is with a health technician, rather than a licensed program clinician (BHP), will be immediately referred to the study doctor for follow-up in the event that the enrollee reports clinically significant symptom worsening or demonstrates a positive suicide screen at any contact.

Caregivers experiencing depressed mood will be encouraged to discuss these feelings with their primary health care provider, and will be provided with information regarding local resources that may be of assistance to them.

Procedures designed to protect participants from the risk of loss of confidentiality include: 1. formal training sessions for all research staff emphasizing the importance of confidentiality; 2. specific procedures developed to protect enrollees’/caregivers’ confidentiality, and 3. formal mechanisms limiting access to information that can link data to individual respondents. As is currently the case, data forms that include identifying information will be kept in locked cabinets. Only the unique ID number, assigned by the HTs at the time of initial contact, will represent enrollees/caregivers during data entry, data transfer, data analysis, or other file management procedures. To facilitate tracking, a password-protected computer file will be maintained containing the identity of enrollees/caregivers, their ID numbers, and information about how they can be reached. This file, however, will contain no clinical data.

All data will be stored in a securely locked area accessible only to authorized research personnel. The Principal Investigator will allow trial-related monitoring, audits, IRB review, and regulatory inspection by providing direct access to source documents. The IRB and other regulatory authorities will also have access to source documents. We inform individuals of this access in the informed consent process.

B. Benefits

The Care Management arm of the SUSTAIN Program includes participation in a telephone-based clinical service designed to help identify and manage behavioral health issues and communicate important assessment findings and recommendations for treatment to prescribing clinicians. Caregiver participation in a psychoeducational support program can address caregiver burden and provide linkage to community-based services to promote successful management of the enrollee at home. Both of these features are considered to be an enhancement of the current program that may directly benefit enrollees. Expected individual benefits include early recognition of treatment-emergent issues and treatment response, increased knowledge about behavioral health issues and local resources, increased personal resources such as coping skills and stress management, and increased engagement in treatment recommendations. More generally, participation in the Care Management program and/or follow-up evaluation component may benefit society by increasing what providers know about the treatment of behavioral health issues.

C. Investigator’s Risk/Benefit Assessment

The risks of study participation are minimal. With respect to benefits, individuals newly prescribed a medication for behavioral health issues have an opportunity to benefit from enhanced evaluation and care management. Caregivers of individuals with moderate to severe cognition problems also may benefit from participation in psychoeducational sessions. Thus, the risk/benefit ratio of study participation appears acceptable.
D. Subject Confidentiality

Procedures designed to maintain confidentiality in the Care Management arm of the SUSTAIN Program and SUSTAIN Program Evaluations will parallel those currently used in the SUSTAIN Clinical Program. We will hold formal training sessions for all health technicians in the importance of procedures to be followed as well as formal mechanisms for limiting access to all information that can link data to individual subjects. Furthermore, data from all telephone-based assessments will be maintained on a single host computer and accessible only to SUSTAIN staff via password protected files. In addition, the research office area will be accessible to a limited number of staff.

The participants’ responses and all documentation involved in this program that reveal enrollees’/caregivers’ identity will remain confidential. Research forms to be used for program evaluation will be coded with a numerical ID, de-identified from any personally identifiable information, and will be accessible to study staff only, except in the case where the IRB and other federal regulatory agencies request access for auditing purposes. Paper copies of all questionnaires and participant data will be stored and secured within a locking file in the research office. All electronic data will be stored on a password protected server located in the research office at the University of Pennsylvania.

At the point of conducting research on the SUSTAIN database, a separate research database will be created, de-identified, and kept in separate password protected files on a single computer in the research office area. To facilitate tracking, the PI and staff will maintain, under a limited password, a unique ID number for each individual in the research data base, assigned at the time of the SUSTAIN assessment. This unique number can be used to link the research database to the clinical database in the event that identification of the individual enrollees is necessary. Access to the research database will be limited to Dr. Oslin or his designee and access to this data will also be tracked.

In order to protect participants’ privacy and confidentiality, we will follow the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws when handling participants’ data. Protocol deviations, serious adverse events, and breaches of confidentiality will be communicated to the University of Pennsylvania as required by their Institutional Review Board guidelines.

All data that reveals enrollee/caregiver identity will remain confidential and be retained for a minimum of 5 years following completion of the study, after which all records will be shredded. Electronic data will be permanently deleted from the password protected server.

E. Subject Privacy/Protected Health Information

For the current clinical program, protected health information regarding enrollees is provided by the PACE/PACENET program and includes the following: a) first, middle, and last name; b) addresses and phone numbers, c) date of birth, and d) PACE/PACENET ID numbers. All personal identifying information is stored on a secure computer under password protection. For the Monitoring Alone or Care Management Programs, outcomes of assessments performed by the study staff will be communicated only to the prescribing provider; otherwise, all information will be kept confidential except as required by law.

F. Compensation

Participants will not be compensated for their participation in this research study.

G. Data and Safety Monitoring

Again, the data and safety monitoring procedures for the Care Management Program and SUSTAIN Program Evaluations will parallel those currently in place for the SUSTAIN Clinical Program. Given the high importance accorded to data and patient safety monitoring, Dr. Joel Streim, the Medical Director, and other members of the University of Pennsylvania, Department of Psychiatry will be asked to provide on an ad hoc basis consultation regarding: 1) consent procedures, 2) data collection issues, 3) risks associated with disclosure of confidential information, 4) communication among the program staff and clinicians, and 5) ongoing monitoring of participant progress, especially regarding potential adverse events. Team meetings associated with monitoring data and patient safety monitoring will occur every three weeks during the conduct of the program to discuss the issues above, with ad hoc meetings more frequently as required.

Protocol deviations, serious adverse events, and breaches of confidentiality will be communicated as required by the University of Pennsylvania Institutional Review Board guidelines. All serious adverse events and non-serious unexpected events will be reported to the PI and IRB in accordance with Good Clinical Practice Guidelines and IRB Regulations. Severe adverse events (SAEs) (e.g., hospitalization, death), will be reported to the PI within 24 hours and to the IRB as appropriate per IRB reporting requirements. Minor adverse events and anticipated adverse events and problems will be logged. A summary of adverse, expected, and non-serious events
will be prepared as part of the annual review process. The PI will comment on the implications for future participants and the need for changing the risk to benefit ratio of participating in the trial.

VIII. INFORMED CONSENT

A. Consent Process

We are requesting a waiver of written informed consent for the current project. Oral consent for use of clinical data and additional follow-up contact will be obtained by the HT, who will review all elements of consent with enrollees (see Appendix III.A). We will document the oral consent process on a case-by-case basis. For those who provide consent and enter the Care Management Program and/or SUSTAIN Program Evaluation, we will mail a letter that reiterates the information and extends an invitation to call for further clarification of the Care Management Program/SUSTAIN Program Evaluation. Both the oral script and the written material will include statements that indicate that participating in the Care Management Program/SUSTAIN Program Evaluation is voluntary and that individuals can drop out at any time without any impact on their care or PACE/PACENET enrollment.

B. Waiver of Informed Consent and HIPAA waiver

Meaningful assessments of individuals starting a new medication must occur within well-defined time periods in order to be clinically relevant. Therefore, it is necessary to design the enrollment and consent processes for the Care Management Program so as not to preclude necessary enrollee observations and BHP contacts with prescribing clinicians. Administering assessments via telephone is ideally suited to timely and prompt enrollment and evaluations. Obtaining informed consent from individuals also requires prompt action. A written consent process would involve sending enrollees consent forms by mail, and asking that they return them to us by mail. Our experience with other studies suggests that while many individuals wish to participate, they often are unable to send the signed consent form within the narrow time period allotted. This process often takes 14 days or more which then defeats the purpose of timely support and assessment. In light of the fact that our goal for the Care Management Program is to enroll individuals starting a new medication within 1 week of their prescription fill date, we are particularly concerned that written consent represents a significant barrier to the conduct of the research. Further the participants will be geographically dispersed across the state of Pennsylvania making a face to face interaction impossible. The proposed program cannot practically be conducted with written informed consent, and thus we are requesting a process to allow oral informed consent to allow timely entry of representative subjects. We are also requesting a waiver of HIPAA notification but will be mailing the HIPAA Authorization form to the individual. We will not, however, request a return of the authorization form.
References

I. Brief Description: The SUSTAIN Program

The SUpporting Seniors Receiving Treatment And INtervention (SUSTAIN) program is an evidence-based clinical service delivered by telephone to help in the identification and early intervention of mental health and substance abuse symptoms in primary care patients. Since 2008, the Commonwealth of Pennsylvania’s Pharmaceutical Assistance Contract for the Elderly (PACE) has contracted with SUSTAIN to provide clinical services to older adults in Pennsylvania who have been newly-prescribed an antidepressant, anxiolytic, or antipsychotic medication. Referred beneficiaries are contacted to complete an initial baseline interview. Following the baseline interview, beneficiary participation in the program occurs over the span of up to six months, with the number of calls based upon clinical need (described in the procedures below). Following each interview, a clinical report based on the beneficiary’s responses is sent to the prescribing clinician. This report includes information about specific symptoms and medication adherence and side effects.

II. Beneficiary Recruitment and Enrollment

The SUSTAIN Program targets PACE/PACENET beneficiaries who have been newly prescribed an antidepressant, antipsychotic, and/or anxiolytic medication. In order to obtain a representative sample of PACE/PACENET beneficiaries, the PACE/PACENET program uses a stratified sampling method for the identification and referral of eligible beneficiaries to the PACE/PACENET BHL Clinical Program. Stratification is conducted with respect to two variables--county (Philadelphia area, Allegheny area, Other) and medication type (antidepressant, antipsychotic, anxiolytic), with individuals randomly selected from each strata. Both rural counties as well as antipsychotic medications are oversampled in order to allow for balanced subsamples of beneficiaries when conducting subsequent analyses.

The PACE/PACENET program provides SUSTAIN with protected health information for each potential beneficiary via a business associate agreement with First Health Services Corporation, a group that manages the pharmacy benefit program for PACE/PACENET. We also have business associate and data use agreements with PACE/PACENET.

Key inclusion/exclusion criteria for clinical program enrollment and participation

Key inclusion criteria
- Per PACE/PACENET pharmaceutical records, the beneficiary is recently prescribed an antidepressant, anxiolytic, or antipsychotic medication.
- Beneficiary is community dwelling or living in an assisted living facility.

Key exclusion criteria
- The BHL program does require the basic ability to communicate by telephone; the beneficiary must meet this criterion for participation in the BHL Clinical Program.
- Not meeting the inclusion criteria listed above.

III. Clinical Procedures

The BHL Clinical Program starts with an initial baseline assessment; following the baseline assessment, it is then divided into several core services. Each service is evidence-based and manualized with a specific training program. Current BHL program services are provided by Health Technicians (HTs) and Behavioral Health Providers (BHPs). Details of the procedures followed by both HTs and BHPs can be found in the BHL “Manual of Operations”.

1. Initial Telephone Assessment: Beneficiary Baseline Interview and Needs Assessment

A. Contacting Beneficiaries for the Initial Beneficiary Baseline Interview
- On a weekly basis, the PACE/PACENET program mails two introductory letters explaining the BHL program to those beneficiaries identified using the sampling method described previously. The letter from the BHL explains the purpose of the program and informs the beneficiary that they will be receiving a phone call from SUSTAIN staff; the letter from PACE explains the relationship between PACE and SUSTAIN and gives beneficiaries the opportunity to “opt out.” Approximately 3 business days after the letters have been sent, the HT/BHP will attempt to contact the beneficiaries in order to conduct the initial baseline interview.
The HT/BHP aims to contact beneficiaries within approximately one week of their referral date. Upon entry of the beneficiary information, the BHL software program automatically assigns each case a “window” (i.e., time frame) during which time beneficiaries will be considered “active” cases.

A “Call Log Book” is used to organize PACE/PACENET referrals and to track when to call patients. The HT/BHP calls the referred beneficiary by phone. Calls are made at various times throughout the day, with calls made on evenings for those who are difficult to reach. A beneficiary is considered Unable to Contact (UTC) once five call attempts have been made (including one late night call and one early morning call) or if there is no accurate contact information available (including wrong and disconnected numbers).

The Project Coordinator generates an “Active Patient Report” from the BHL program periodically to ensure that referrals are being responded to in a prompt manner.

Prior to starting the interview, the HT/BHP asks beneficiaries if they are willing to participate in the assessment. The HT/BHP encourages all beneficiaries to complete the interviews. When a beneficiary is reluctant to start or complete the interview, the HT/BHP uses one of a number of scripts to encourage participation. Nevertheless, during the interview, if the beneficiary decides, for whatever reason, that s/he does not wish to complete the interview, the HT/BHP terminates the interview. If the beneficiary wishes to stop an interview, but is willing to continue at a future time, the HT/BHP terminates the interview, and conducts the interview at a more convenient time.

B. Conducting Beneficiary Baseline Interview

The Beneficiary Baseline interview is a structured telephone interview that takes, on average, 20-40 minutes to complete. The interview is conducted by HTs or BHPs and is completed by direct entry of clinical data in a computer program designed for ease of use with simple entry screens.

When needed, the interview can be completed on a back-up paper version which can be generated from the software program. Paper copies are coded with an ID, de-identified from any personally identifiable information, and are accessible to SUSTAIN staff only. Paper copies of all questionnaires are stored and secured within a locking file cabinet in the SUSTAIN office. Electronic information is stored on a password protected server.

The domains assessed during the baseline interview include demographic variables, financial status, social support, new/current psychotropic medication use, past depression treatment, alcohol use (using a 7-day follow-back method) and use of other illicit substances, depression history, pain, sleep, and symptoms of agitation/irritability. Specific, standardized, well-known scales administered include the Blessed Orientation-Memory-Concentration (BOMC), Mini International Neuropsychiatric Interview (includes Psychosis, Mania, Generalized Anxiety Disorder, Panic Disorder, and Alcohol Abuse/Dependence modules), Patient Health Questionnaire-9 (PHQ-9; a brief depression severity measure), the 5-item Paykel Scale for suicide ideation, Medical Outcomes Survey (SF-12), and the GAD-7. Beneficiaries are also asked about any resources/services that they need and about service utilization during the prior three months. Beneficiaries who report minimal to no mental health symptoms are asked a semi-structured assessment about their perception of the medication’s impact on their symptoms, as well as past episodes and treatment of depression or anxiety.

Upon completion of the Blessed Orientation Memory Concentration Test, the BHL program scores the beneficiary’s impairment level based on his/her responses.
- If beneficiary scores 14 or greater on the BOMC, the interview terminates.

In order to ensure data quality, an HT/BHP user cannot go backwards within the interview, which means that once the HT/BHP has completed a page and moved on to the next, there is no way to access the previous page. Furthermore, the program is set up so as to not allow an HT/BHP to proceed from one question to the next without answering each question. If an error occurs, the HT/BHP will generate a “Database Correction Form” after the interview is completed and give it to the Project Coordinator to correct the error.

C. Completing the Beneficiary Baseline Interview and Generating Reports

Following completion of the baseline assessment, the HT/BHP discusses with the beneficiary the next clinically appropriate steps, which are based on symptom logic that is built into the BHL software program. During this discussion, the HT/BHP informs the beneficiary about the approximate time frame for next clinical follow-up phone call they will be receiving, which will vary based on the type of service.
The HT/BHP enrolls individuals in the appropriate clinical module in the BHL software, which creates windows/time frames within which individuals should be contacted. Once the baseline assessment is completed, the HT will generate the clinical report based on the beneficiary’s responses. This report will be sent to the prescribing clinician, along with a cover letter describing the services of the BHL and explaining the clinical report. Beneficiaries will also be mailed a follow-up letter including educational materials regarding specific reported symptoms (see Appendix B for examples of clinical letters).

2. Needs Follow-up
   For every beneficiary who completes an initial interview, s/he will be provided with community resources for needs that were identified during the Beneficiary Baseline interview. This assistance can be provided through informational materials sent in the mail or may take place during a follow-up call.

3. Referral Management
   For beneficiaries who report severe mental health symptoms during the initial baseline interview (such as mania, psychosis, PHQ score 25 or greater, drug abuse, alcohol dependence, etc.), the BHL makes recommendations for scheduling in Mental Health specialty care. Recommendations are based on available resources in the beneficiaries’ communities and individuals are provided with contact information. The BHP will work with the beneficiary to encourage attendance to the specialty care appointment.

4. Follow-up Monitoring Module
   The Standard Clinical Follow-up Monitoring Module is a service designed to help provide evidence-based care for individuals receiving antidepressant, anxiolytic, or antipsychotic prescriptions. Follow-up Monitoring consists of up to 4 brief (5-10 minutes), structured assessments following the baseline assessment. These follow-up contacts are conducted over the telephone by the HT/BHP and take place during the initial 12 weeks of pharmaceutical treatment (e.g., 2, 6, 9, and 12 weeks). These brief interviews monitor adherence, side effects, and response to treatment. A progress report is provided to the prescribing clinician following each interview to help in treatment planning and to alert the clinician of special issues. The Follow-up Monitoring Module interview includes the PHQ-9, the GAD-7, and questions regarding sleep, agitation/irritability and medication side effects and adherence.

5. Follow-up Care Management
   Beneficiaries who report clinically significant depression, anxiety, and/or pain symptoms the Enhanced Program consists of Care Management, which is designed for the management of individuals who are actively enrolled in primary or medical subspecialty care. The model incorporates the use of a BHP who has expertise in mental health assessment and is well versed in the delivery of algorithm-based management strategies for disorders such as depression and anxiety. The role of the BHP is to facilitate treatment and provide informal psychosocial therapy, using motivational interviewing techniques, in a manner that is consistent with the Agency for Health Care Policy and Research (AHCPR) guidelines. The BHP monitors and encourages patient acceptance and adherence to treatment recommendations through support, education, and motivational engagement. The BHP initiates care management when beneficiaries are not responding to the initial treatment or as clinically needed based on the initial baseline interview and needs assessment. The BHP also uses problem solving therapy to assist patients. Based on the needs assessment, the BHP also helps connect beneficiaries with non-mental health community resources and services. The frequency and number of contacts for each individual will vary, but our experience suggests that individuals typically engage in 1-2 contacts per month for several months. Written updates are provided to the prescribing clinician, as clinically indicated.

A. Preparing for the Care Management Baseline Assessment
   Prior to the first Care Management call, the following information is reviewed and pertinent details recorded on a Baseline Progress Note:
   - The BHL Baseline Assessment report
   - List of current medications, including dosages and durations
   - The BHP documents each phone call and all pertinent information. If keeping a paper record for each beneficiary, the BHP includes all relevant documentation, including case details, handwritten notes, copies of reports sent to providers, contact information, etc. These records are kept in locked files in the BHL laboratory.
B. Conducting the Baseline Assessment

- During the baseline contact, the BHPs:
  - Begin to establish rapport with the beneficiary in order to build a supportive relationship.
  - Review the purpose of the phone call and the reasons for follow-up. Confirm the screening results that led to referral.
  - Obtain medical and psychiatric history/current medications/past psychotropic medication use history from the beneficiary.
  - Conduct a semi-structured clinical interview with the beneficiary in order to learn the beneficiary’s perception of his or her problem.
  - Complete any or all of the following (depending on clinical need and judgment): PHQ-9, GAD-7 (for those with an anxiety diagnosis or report of significant anxiety symptoms during the semi-structured interview), questions about pain, MINI Psychosis assessment (where appropriate), agitation/irritability assessment, side effects inquiry, and the assessment of alcohol use.
  - Ask the beneficiary if s/he would like educational materials on depression/anxiety and a list of symptoms of depression/anxiety mailed to him/her. BHPs check to see if these materials have already been sent to the beneficiary by the HT/BHP after the baseline interview.
  - Complete a Baseline Progress Note.
  - Send a written summary to the prescribing clinician that summarizes the BHP’s contact with the beneficiary, as appropriate.

C. Follow-Up Assessments

- Over the course of monitoring, if the beneficiary is not responding to treatment and/or the BHP feels that intervention is clinically appropriate, the BHP consults with the BHL Medical Director. Based on that consultation, a written report is sent to the prescribing clinician that summarizes the pertinent assessment findings and informs him/her of any recommendations.
- Beneficiaries who are asymptomatic or minimally symptomatic are monitored by the BHP for up to six months to assess adequacy of response. At the end of participation in Care Management, a summary report is sent to the prescribing clinician. Reports to the prescribing clinician also include any recommendations made to the beneficiary.
- During all contacts, BHPs seek to foster trust and engage/motivate beneficiary for treatment, if ambivalence or resistance to treatment recommendations is present.

6. Emergency Procedures

There are numerous, detailed emergency procedures in place for dealing with special cases (e.g., suicidal, hostile, inebriated individuals). The BHL has an emergency contact list, starting with the primary contact (i.e., Medical Director) and followed by the subsequent backup (the P.I.). These contacts are listed in order, from the primary contact to secondary and so on. The HT contacts the Medical Director/P.I. using an Emergency Pager. The BHP will facilitate this communication. The supervising clinician (i.e., Medical Director) ensures that all individuals on the emergency contact list are trained to respond to emergency pages and take appropriate actions.

7. Weekly Supervision Procedures

Supervision is scheduled weekly with the SUSTAIN Medical Director, a Geriatric Psychiatrist, to allow discussion and supervision related to the BHP’s cases including Care Management, Referral Management, and suicide follow-ups. If an urgent issue is identified which is judged not appropriate to wait for a formal supervision session, the BHP or the HT is expected to contact the Medical Director or his proxy for ad hoc clinical supervision, with follow-up discussion in the next planned supervision. It is expected that all BHP enrollee contacts made since the last individual BHP supervision will be presented. Supervision also allows a platform for discussing how the program is progressing, monitoring workload, ensuring fidelity to the program, and providing opportunity for problem-solving and product-detailing among all stakeholders.

In addition to providing supervision to the BHP role, HTs are encouraged to attend weekly supervision to facilitate learning and to allow discussion of challenges/clinical issues that arise in the course of their contact with enrollees.

In order to make effective use of supervision time, the following guidelines have been developed for the presentation of BHP cases:

1. Type of call
2. Index medication, dose, reason patient is taking medication, and if medication is used PRN how often a patient actually takes the medication

3. Any other psychotropic medications that the patient is taking (including dose and reason for taking other meds)

4. Enrollee’s baseline scores at referral to BHP

5. (Baseline Care Management:) All other current medications/salient medical history/issues; initial impression possible Care Management goals

6. Follow-Up CM contacts
   a. Patient’s current scores.
   b. Progress toward Care Management goals
   c. Updates, highlights, questions

7. Referral Management contacts
   a. Details of HT Psychosis/Mania/Substance dependence assessment
   b. Summary outcome of contact and plan
   c. Need for further Contacts