

Running Head: Expanding NP Role in TRMD

Expanding the Nurse Practitioner Role in Treatment Resistant Major Depression

Travis K Svensson, MD, NP, MSN, MPH, PhD, PMHNP-BC, FNP-BC

Abstract

Treatment resistant major depression (TRMD) is a common problem with significant consequences in terms of bio-psycho-social disability and economic impact for the individual, family and community. A 2014 survey of San Francisco bay area community resources confirms that nurse practitioners (NPs) are under represented in the advanced management of TRMD using electroconvulsive therapy (ECT), transcranial magnetic stimulation (TMS) and ketamine infusion therapy (KIT). An expansion in the role of the NP in the management of TRMD is indicated. The purpose of this project was to develop and implement an education course that prepares a cohort of NPs to demonstrate mastery of advanced clinical techniques through direct provision of safe, tolerable and efficacious care to TRMD populations using ECT, TMS and KIT. Five NPs participated in a continuing education program that included four hours of didactic and twelve hours of bedside clinical continuing education in the advanced management of TRMD.

Implementation of this quality improvement project resulted in a high level of satisfaction among NP participants and patient. Upon completion of the training, a considerable increase was evident in self-efficacy in the management of TRMD (95%), ketamine infusion therapy (90%), electroconvulsive therapy (85%), and transcranial magnetic stimulation (80%), relative to pre-training levels. In the 60-day follow-up period, all five NP participants directly managed an average of 8.6 patients with TRMD using advanced techniques. Safety, efficacy and tolerability were comparable to published data for psychiatrist provided services.

Keywords: electroconvulsive therapy (ECT), transcranial magnetic stimulation (TMS), ketamine infusion therapy (KIT), treatment resistant major depression (TRMD)

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Section II: Introduction

Background Knowledge

Major depression is associated with a high rate of mortality and morbidity (Collins et al, 2011) and affects approximately 18 million people at any one time in the United States alone with a lifetime incidence of up to 17% (Cusin and Dougherty, 2012). Psychotherapy or psychopharmacology alone or in combination is the mainstay of treatment for major depression (Lenze, 2002).

Psychotherapy alone is commonly provided by psychologists, marriage and family therapists (MFTs), social workers (LCSWs), and licensed professional counselors (LPCs). Psychopharmacology alone is most commonly provided by: primary care physicians, family nurse practitioners (FNPs), and physician assistants (PAs). Combined psychopharmacology and psychotherapy from a single provider is commonly provided by: psychiatrists, psychiatric nurse practitioners (PMH-NPs), and where available prescribing psychiatric clinical nurse specialists (PMH-CNSs) and the less common prescribing psychologist (Schmidt, 2013). It is estimated that 70% to 80% of cases of major depression will respond to an initial course of psychotherapy and/or psychopharmacology alone or in combination (Cusin and Dougherty, 2012). TRMD is the term that loosely describes those cases of major depression that fail to demonstrate an adequate clinical response to a full treatment course (usually considered to be 12 weeks) of an evidence-based psychotherapy (such as cognitive behavioral therapy or psychodynamic psychotherapy) and two full trials of psychopharmacology from two different antidepressant classes in the current episode (Samuels et al, 2011).

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Local Problem Needs Assessment

In San Francisco and its neighboring counties there are 10 institutions providing ECT and only one of those has an established role/protocol for NPs (Kaiser East Bay). Of the TMS clinics in San Francisco and the surrounding counties, none of the clinics use NPs in the direct patient management of TRMD. Of the KIT clinics in San Francisco and the surrounding counties, NPs are used at one KIT site for pain management (Stanford), but none are involved in the routine management of TRMD.

At Mills Peninsula Health Services (MPHS) in San Mateo the facility provides ECT to approximately 75 patients per year. Of the last approximately 750 patients over the last 10 years treated for TRMD at MPMC using ECT, none have been referred for ECT by an NP and none have had their course of ECT directly managed by an NP. Of the 215 patients treated for TRMD with TMS at the San Francisco TMS Center and the Peninsula TMS Center since 2008, there has been one referral for TMS by an NP and none directly managed by an NP. The Clinical Training and Research Institute (CTRI) located in Burlingame provides KIT for the management of TRMD since 2010. Of the 65 patients that have received KIT since 2010, none were referred or managed by an NP. These statistics suggest that NP involvement in directing and actively managing the care of patients with TRMD using ECT, TMS and KIT is under represented despite the fact that these services are well within the scope of practice for the profession.

Intended Improvement (Purpose of Change)

ECT, TMS, and KIT are all within the scope of practice for knowledgeable and skilled NPs however the ANCC and other NP certifying bodies do not require exposure to these modalities during training for a career that will inevitably include caring for

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patients with TRMD. It is generally presumed that NPs will either pursue post-graduate training in these modalities or refer patients with TRMD to colleagues experienced in the advanced management of TRMD (Jones and Milarik, 2012).

This quality improvement project was developed to improve the knowledge and skill of a cohort of NPs related to the clinical management of TRMD using the advanced techniques of ECT, TMS, and KIT through participation in a continuing education (CE) format that incorporates both didactic and clinical (experiential) learning opportunities. An additional purpose of this project is to demonstrate that ECT, TMS, and KIT services provided by NPs following this continuing education program was comparable in terms of efficacy, safety, tolerability and patient satisfaction to similar services provided by psychiatrists.

Review of the Evidence

A review of the available literature on the current standard of care for treatment resistant major depression using advanced intervention techniques informed the development of this project. PubMed/Medline and CINAHL databases as well as Google Scholar were searched for current evidence using the following keywords and phrases: depression, major depression, treatment resistant depression, treatment resistant major depression, electroconvulsive therapy, transcranial magnetic stimulation, repetitive transcranial magnetic stimulation, ketamine, ketamine and depression, ketamine and suicide, PMHNP, psychiatric mental health nurse practitioner.

Treatment Resistant Major Depression

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TRMD is the term that loosely describes those cases of major depression that fail to demonstrate an adequate clinical response to a full treatment course (usually considered to be 12 weeks) of an evidence-based psychotherapy (such as cognitive behavioral therapy or psychodynamic psychotherapy) and two full trials of psychopharmacology from two different antidepressant classes in the current episode (Samuels et al, 2011). An adequate clinical response is generally considered to be a significant reduction (+/- 50%) in clinical symptoms or a return to near baseline bio-psycho-social functioning (Willes et al, 2012). Some models for TRMD do not specifically require a trial of psychotherapy. Though there are multiple models that try to characterize TRMD in prognostic terms, no one model has emerged as dominant based on the clinical evidence. The commercial insurance industry has typically required documented evidence of TRMD as part of the prior authorization process for ECT or TMS. KIT does not typically require prior authorization as the overhead costs are substantially less than for the other two modalities.

Electroconvulsive Therapy

ECT is typically considered the “gold-standard” intervention for TRMD (Cusin and Dougherty, 2012). ECT provides rapid relief from the symptoms of major depression in 75% to 85% of cases (Willes, 2012). Onset of symptom relief begins as early as day 7-10 (4th to 5th treatment) with relief of most symptoms of depression by the 3rd to 4th week (8th to 12th treatment) (Kellner, 2005). ECT has been available since the late 1930s with evolution in the techniques and practice standards reflecting advances in technology. Current ECT protocols typically prefer unilateral over bilateral treatments and emphasize use of the lowest effective dose of electrical stimulus in an effort to minimize the

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potential for long-term cognitive side effects (Pagnin, Pini, and Cassano, 2004).

Barriers to use of ECT in the management of TRMD include: cost (+/- \$20,000), anesthesia risks/fears, specific cardiac or intra-cerebral contraindications, availability (rural areas), and real or imagined psychosocial stigma.

Transcranial Magnetic Stimulation

TMS research began in the late 1990s and the technology was brought to the consumer markets in Western Europe, Canada and Australia in the early 21st century. The U.S. Food and Drug Administration (FDA) approved the Neurostar TMS device for use in the management of TRMD in 2008 (Horvath, Perez, Forrow, Fregni, and Pascual-Leone, 2010). TMS costs are typically 30% to 50% less than costs associated with ECT (Knapp et al, 2008). A course of TMS typically is composed of 20-30 outpatient sessions that last approximately one hour and are schedule in the outpatient setting five days per week. Symptom relief begins around the 10th treatment (2nd week) with resolution of most symptoms of depression by the 20th session (4th week). Side effects for TMS include a small risk of seizure and the potential for headache early in the course of treatment. The response rate for TRMD to a course of TMS is estimated to be around 50%-60% (Pascual-Leone, Rubio, Pallardó, and Catalá, 1996).

Ketamine Infusion Therapy

Ketamine infusion therapy has emerged in the last 10 years as an evidenced based rapid acting intervention for TRMS (Berman et al, 2000). KIT provides relief of suicidal thinking as early as three hours following the infusion, with peak antidepressant effects at day 3 post infusion lasting for up to 7 days (Larkin, Beautrais, and Lippmann, 2010).

Most KIT protocols provide twice per week treatments for 2-4 weeks with the potential to

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extend into a maintenance protocol similar to maintenance ECT (Otis, 2012). The costs associated with KIT are typically 1-2 times the cost of a combined session of psychotherapy + psychopharmacology with cost variability reflecting the principles of supply and demand in the community. Potential side effects from KIT include dose dependent hypertension, nausea and psychic-dysphoria. The response rate for TRMD to a course of KIT is estimated to be around 50% (Otis, 2012).

Theoretical Framework

Successful expansion of the NP role in management of TRMD using ECT, TMS, and KIT involves enhanced knowledge and skill by the individual practitioner, removal of barriers to change, provision of leadership support, and reinforcement by patients, clinical colleagues, supervising and consulting physicians, and the clinical practice and community environment. Concepts from Prochaska and DiClement's (1984) transtheoretical model (TTM) of change have been successfully applied to quality improvement initiatives to promote individual practice change as well as organization practice change. The TTM represents an integrative framework that can synthesize major approaches to change. Conceptually the stages-of-change dimension has been used to integrate principles and processes of change from divergent models of change.. From a practical perspective, the stages of change dimension has been applied by clinical practice leaders to reduce resistance, increase participation, reduce dropout, and increase change progress among professionals (Prochaska, J, M., Prochaska, J. O, and Levesque, D.A., 2001).

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Core constructs of Prochaska and DiClemente's (1984) TTM include; the processes of change, decisional balance, self-efficacy, and relapse temptation. The model is presented diagrammatically in Appendix B and summarized below:

TTM Processes of Change

- Are both covert and overt activities that are both experiential and behavioral in nature and are used to progress through the stages
- Five Experiential Processes
 - Consciousness Raising (Increasing Awareness)
 - Dramatic Relief (Emotional Arousal)
 - Environmental Reevaluation (Social Reappraisal)
 - Social Liberation (Environmental Opportunities)
 - Self Reevaluation (Self Reappraisal)
- Five Behavioral Processes
 - Stimulus Control (Re-Engineering)
 - Helping Relationship (Supporting)
 - Counter Conditioning (Substituting)
 - Reinforcement Management (Rewarding)
 - Self Liberation (Committing)

Decisional Balance

- Reflects the practitioner's relative weighing of the pros and cons of a change in clinical practice

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- Decisional balance scale involves weighing the importance of the pros and cons

Self-Efficacy

- Represents the situation specific confidence that practitioners have that they can cope with high-risk situations without relapsing to their prior narrower practice patterns

Temptation

- Reflects the intensity of urges to engage in a specific behavior when in the midst of difficult situations (patient crisis, adverse events, clinical practice/environmental pressures)
- Is the converse of self-efficacy

TTM Stages of Change

- Practitioners pass through a series of stages when change occurs
- The five stages of change include:
 - Pre-contemplation (Not ready to change)
 - Contemplation (Thinking of changing)
 - Preparation (Ready to change)
 - Action (Making changes)
 - Maintenance (Staying on track) (Prochaska & DiClemente, 1984)

The sixteen contact hours of continuing education provided to this project's cohort of five NPs was organized and prepared by a psychiatrist with extensive

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experience in ECT, TMS and KIT for the management of TRMD. This same psychiatrist is an experienced clinical educator who has used the TTM model of change in the setting of patient health education, motivational interviewing in primary care, addiction medicine and psychological interventions, CE training for nurses and therapists as well as continuing medical education (CME) coursework for physicians, residents, and medical students. The CE experience in this project was divided into both a didactic and clinical component with the specific intention to allow the participants to move through the stages of change at an individualized pace. Following completion of the formal CE experience, NP participants were supported in the experiential and behavioral processes of clinical practice change through ongoing access to clinical consultation and support with two psychiatrists experienced with ECT, TMS, and KIT and a clinical practice environment at Clinical Training & Research Institute (CTRI), Access Multi-Specialty Clinic (AMSC) and Mills Peninsula Health Services (MPHS) that supports the expansion of the NP role in TRMD using ECT, TMS, and KIT. Experienced supportive mentors and supportive clinical environments are critical to the action and maintenance stages in the transtheoretical model of change.

Section III: Method

Ethical Issues

The University of San Francisco's Committee on Human Research approved this quality improvement project as exempt from Institutional Review Board

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approval. This evidence-based quality improvement project assessed by the DNP committee as exempt from Institutional Review Board approval. In advance, consideration related to respect for persons, beneficence, justice, and informed consent were evaluated. The participants in this project were consenting adult nurse practitioners privileged to provide patient care at Clinical Training & Research Institute, Access Multi-Specialty Clinic, and/or Mills Peninsula Health Services. No issues of confidentiality or privacy for subjects were identified, nor were concerns related to confidentiality or privacy for practitioners or for the patients for whom they provide care. Participation in this DNP training project was voluntary for both providers and the patients for whom care was provided. Participation in this quality improvement project had no impact on employment or academic status or progress. Patients were not part of the didactic training experience. Clinical training for the participants involved observation of the usual practice of mentor psychiatrists experienced in the provision of ECT, TMS and KIT in the management of TRMD. Though NP participants were the direct beneficiaries of the project's training, indirect beneficiaries were patients with TRMD, their family and the community. Social justice and beneficence were served by this project.

Setting

CTRI and AMSC both located in Burlingame, California provide advanced management of TRMD using ECT, TMS, and KIT. Under the supervision of Drs. Travis K. Svensson and Michael U. Levinson these two clinics have consented to participate in this project to provide the knowledge and skills training necessary to expand the role of NPs in the management of TRMD using the modalities of ECT, TMS and KIT (Appendix

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B). Drs. Svensson and Levinson both provide ECT services on an inpatient and outpatient basis at MPHS in San Mateo, California where they train RN students, NP students, medical students and psychiatric residents in the provision of ECT.

Planning the Intervention

Expanding the NP role in the management of TRMS for a cohort of five NPs required access to CE training necessary to increase the skills and knowledge for participants beyond that provided in typical pre-licensure training. This project developed a 16-hour CE course of psychiatrist supervised post-graduate training in ECT, TMS, and KIT in the management of TRMD to enrolled NPs. The underlying assumption of the TTM is that meaningful short-term and long-term practice change is most often met with resistance from within the practitioner and from within the practice setting. Principles from the TTM were used to design a CE course that facilitates change by paying attention to the learning style of the participants, by allowing for individualized progression through the stages of professional practice change and by the provision of a supportive clinical environment both for training and for subsequent implementation of the new skills and knowledge into the participants daily clinical practice.

CTRI and AMSC developed a CE project to provide the skill and knowledge necessary to expand the role of the NP in the use of the modalities of ECT, TMS, and KIT to improve the care of our patients and patients in our community with TRMD. Upon completion of this project's CE training the enrolled NP was expected to increase the rate of recognition of TRMD and successfully expand their use of advanced modalities in its management. Evidence of a successful project was to be demonstrated by:

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- Increase in post-test scores upon completion of CEU training by 50% over pre-course performance
- All NP participants will report enhanced self-efficacy in the direct management of TRMD using the advanced modalities of ECT, TMS, and KIT following completion of this practice improvement project
- All NP participants will embrace an expanded role in the management of TRMD as evidenced by referral and/or management of >3 clients for ECT, TMS or KIT in the 45 days following this practice improvement intervention
- Patients will express confidence in the clinical management of ECT, TMS, and/or KIT by project enrolled NPs as evidenced by a patient satisfaction score in the range of “very satisfied” or “fully satisfied” for services provided in the 90 days following completion of this project’s training
- Clinical efficacy for NP management of ECT, TMS and KIT will be demonstrated by a 50% reduction in PHQ9 scores or return to baseline functioning in 50% of patients managed with TMS or KIT and in 75% of those patients managed with ECT.
- Safety and tolerability of NP managed ECT, TMS and KIT will be demonstrated by the absence of untoward events severe enough to interrupt a course of treatment in the 45 days that follow completion of CEU training.

Potential Barriers

Potential barriers to implementation include:

- Unexpected reduction in referrals for patients with TRMD to CTRI and AMSC during the practice improvement project period

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- Resistance by patients to NP role in the provision of ECT, TMS or KIT
- Resistance to NP training in ECT by MPMC
- Resistance to NP referral for TMS by local TMS clinics
- Resistance to NP management of TRMD by commercial insurance industry

Project Control / Authority / Responsibility

Drs. Travis K Svensson and Michael U. Levinson, board certified psychiatrists will be responsible for clinical supervision of NP engaged in direct management of TRMD with ECT, TMS or KIT. Dr. Travis K Svensson will be responsible for delivery of the didactic training in TRMD, ECT, TMS and KIT and the provision of CEU certificate approved by the California Board of Registered Nursing. Dr. Travis K Svensson is responsible for communication and coordination with DNP project chairperson, Dr. Alexa Curtis and the University of San Francisco's Committee on Human Research.

Implementation of the Project

Work Breakdown Structure

A formal diagram of the work breakdown structure is provided in Appendix C and can be summarized as follows:

- CEU lecture preparation (Pre-testing, post-testing, BRN CEU tracking)
- CEU lecture production (video version of 4 one-hour lectures)
- MD supervised clinical training contact hours (12 hours per NP enrolled)
- Data collection and analysis (patient satisfaction, outcomes data, pre & post CEU testing, NP self efficacy, referral rates)

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- Data presentation (CTRI/AMSC, USF, Publication)

Project Resource Requirements

This project requires a cohort of patients willing to allow the participation of NPs in the management of their TRMD. The project will require a minimum of 3 patients per NP participant. These patients are routinely available at CTRI and AMSC.

This project requires at least one, but is budgeted for two board certified psychiatrists to provide clinical supervision of NP management of TRMD using ECT, TMS and/or KIT. Both psychiatrists hold ECT privileges at MPMC. MPMC routinely allows RN and NP students to participate in clinical training with ECT. Analysis of collected data and presentation of project outcomes will be provided by Travis K Svensson, RN, MD, PhD.

This project requires a minimum of 2 but anticipates a total of 6 NPs to undertake the expansion of their role in the advanced management of TRMD. NP participants may engage in this practice improvement project at either the pre-licensure or post-licensure level of training.

Clerical staff to collect data from patients, patient medical records, and NPs will be provided by CTRI and AMSC. Clerical staff is to be HIPPA trained and have demonstrated HIPPA compliance prior engagement in project related activities.

Information Flow

Patients provide the following information to the NP and medical record for collection by clerical staff: informed consent for TRMD management, PHQ9 data, patient satisfaction data, and reports of untoward and adverse events. The NPs provide the following data to the clerical staff and/or medical records: pre-CEU testing, post-CEU

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testing, assessment of self-efficacy in the management of TRMD, reports of untoward and adverse events and documentation of the use of ECT, TMS or KIT to manage TRMD in the 90 days following completion of CEU training. The Board certified psychiatrists provide the following information to the clerical staff or medical records: untoward and adverse events experienced by patients managed by NPs. The clerical staff gathers the clinical data and presents it to Travis K Svensson, RN, MD, PhD for analysis. Upon completion of the data analysis, Dr. Svensson presents the outcomes for this practice improvement project to CTRI, AMSC, MPMC and University of San Francisco, DNP project Chairperson, Dr. Alexa Curtis and other committee members and prepares a manuscript for publication.

Time and Cost Summary

Assumptions

Detailed assumptions for this practice improvement project are provided in the GANTT chart in Appendix D. It is assumed that patient recruitment, NP recruitment, and NP CEU training can be completed within about 2 weeks. It is assumed that data collection, analysis and presentation will take approximately 2 weeks. It is assumed that enrolled NPs will take less than 45 days to demonstrate independent direct mastery of > 3 patients with TRMD using ECT, TMS or KIT. It is assumed that this practice improvement project will be completed within 90 days.

Constraints (Time, Cost, Performance)

The target date for the completion of this practice improvement project is August, 15, 2015 but no later than the end of the 2015 summer semester at the University of San Francisco. CTRI and AMSC have agreed to provide up to \$3100 to be spent on this

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practice improvement project between April 1, 2015 and August 30, 2015 with a goal to train between 2 and 6 NPs in the advanced management of TRMD using ECT, TMS and/or KIT.

Budget

A formal budget with detailed breakdown of expenses is provided in Appendix D of this prospectus. The total expense is estimated to be \$3,076.80. Of the total expense, \$76.80 will cover clerical expenses involved in data collection. The balance of the expenses incurred is related to psychiatrist costs involved in: CEU preparation (\$120) and production (\$160), supervision of NP clinical training with patients (\$1680), data analysis (\$480) and presentation (\$560). The two host clinics for this project, CTRI and AMSC have committed to provide up to \$4000 total funding for this practice improvement project (Appendix E).

Methods of Evaluation

Reporting Requirements

This project is required to report on the following data:

- Number of NPs enrolled in this practice improvement project
- Number of NPs completing 16 hours of CEU training in the provision of ECT, TMS and KIT in the management of TRMD as part of this practice improvement project
- Pre and Post CEU testing data for enrolled NPs
- Patient satisfaction data for NP management of ECT, TMS and KIT
- Untoward and adverse event data for NP management of ECT, TMS, and KIT

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- Clinical efficacy data for NP management of TRMD using ECT, TMS, and KIT evidence by change in PHQ9 scores or report of return to baseline functioning
- Number patients managed by ECT, TMS or KIT by enrolled in NPs in the 90 days following completion of CEU training

Analysis

Evidence of a successful practice improvement project towards a goal of expanding the role of the NP in care of TRMD using ECT, TMS and/or KIT is provided by the following:

- Completion of 16 hours of CEU training by 2-6 NPs
- 50% improvement in post-CEU testing of NPs compared to pre-CEU test scores
- Patient satisfaction with NP managed ECT, TMS or KIT in the “very satisfied” or “fully satisfied” range
- Absence of untoward or adverse events that interrupt a treatment course of ECT< TMS or KIT
- Clinical efficacy demonstrated by PHQ9 score reduction of 50% or return to baseline mood functioning
- 3 or more patients with TRMD referred for or directly management by NPs using ECT, TMS or KIT in the 45 days following completion of project’s CEU course

Evaluation Timeline

Analysis of project data will be completed within 4 days of the completion of project data collection. Outcome data for the project shall be presented to project funders (CTRI and AMSC), community based TRMD treatment resources (MPMC, local TMS

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and KIT clinics) and USF SONHP within one week of the completion of the data analysis. Data collection, analysis, and presentation will be completed within a 2-week timeframe.

Section IV: Results

Program Evaluation / Outcomes

The goal of this quality improvement project was to produce a change in clinical practice behavior in a small cohort of nurse practitioners using the insights and framework of Prochaska and DiClemente's transtheoretical model. The specific intended change was to increase the NP role in the management of treatment resistant major depression by expanding the clinician's self-efficacy with ECT, TMS and KIT interventions. Pre-contemplation, the first stage of the TTM describes the potential participants as "not ready for change" and involved identification by the project's two psychiatrists of a cohort of nurse practitioners currently practicing in one or more of this project's clinical sites (CTRI, AMSC, MPHS). These three clinical sites represent environments with rich clinical resources available to support the cohort of clinicians that decide to move forward in the project. This first stage involved identification of five NPs professionally active at these three clinical sites who were already providing routine psychopharmacologic and psychotherapeutic management of patients with TRMD.

Contemplation, the second stage of the TTM involved introduction by the two project psychiatrists to the cohort of potential NP project participants of the

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existence of this project, the goals of this project, potential costs to the participants (disruption of usual practice activities, study-time, impact on practice finances, etc.) as well as the potential benefits to the participants (16-hours of CE, acquisition of advanced knowledge and skill in the management of TRMD with ECT, TMS and KIT) and the potential benefits to participant's current and future clients (continuity of care, increased access to services, expanded clinical options, relief of suffering and disability associated with TRMD, etc.). Although participation by the cohort of five NPs was both voluntary and free of charge, it was important for the cohort to recognize the potential costs to the individual participants in terms of study time and temporary disruption to usual practice activities and weigh these against the potential benefits to themselves as clinicians, to their clients and to the community. All five NPs identified as potential participants by the project's two psychiatrists, were eager to move forward and moved quickly through the contemplation phase into the preparation phase.

The preparation stage is marked by readiness for change within the next weeks to month. In this stage of the TTM the five participants cleared space in their professional and personal lives to be actively present for a 16-hour CE experience to include four hours of didactic study focused on evidence based practice with TRMD, ECT, TMS, and KIT. The didactic study was composed of a series of audio-narrated power-point presentation prepared by a board certified psychiatrist experienced with the advanced management of TRMD. The didactic component was to be followed by 12-hours of clinical mentoring with an experienced psychiatrist

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providing ECT, TMS, and KIT related services. All five participants moved through the preparation stage of the TTM within 7-10 days.

The action stage of the TTM (making change) was completed in less than one month by all five of the NP participants. Pre-CE testing and post-CE testing (see Appendix G) was data was collected for each of the four didactic topics (TRMD, ECT, TMS, and KIT) by all NP participants to assess baseline self-efficacy and percent change in self-efficacy following the didactic component. The data is reported in table 1 below and in Appendix F. The average percent increase in self-efficacy for the participants following the didactic component was: TRMD (95%), ECT (90%), TMS (85%), and KIT (80%).

A self assessment of clinical efficacy in the use of ECT, TMS, and KIT in the management of TRMD was completed by all participants following completion of the 12 hours of clinical mentoring with a project psychiatrist. The clinical mentoring component of this CE activity focused on four specific clinical activities:

- Diagnostic criteria for TRMD, case identification and screening
- Detailed informed consent regarding the potential risks and benefits of the management of TRMD with ECT, TMS or KIT
- Pre-Treatment / Pre-Op clearance for ECT, TMS and KIT
- Provision of ECT, TMS, KIT interventions, interval and post-treatment care

The participant's self assessment of clinician efficacy (Appendix G) was reported on a 5 point Likert scale where a score of 5 represents confident in the provision of safe, evidence based protocol driven independent clinical practice with minimal or no input from supervising or consulting psychiatrist. A score of 4 on the Likert scale

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represented confidence with the provision of safe, evidence based protocol driven independent clinical practice in the setting of readily available consultation and supervision with a psychiatrist. A score of 3 on the Likert scale represented confidence with protocol driven evidence based clinical practice under the direct (on-site) clinical supervision of a psychiatrist. A score of 2 on the Likert scale represented confidence assisting a psychiatrist in the provision of evidence based protocol driven clinical services. A score of 1 on the Likert scale represented confidence in the role of trainee or observer of psychiatrist provided evidence based clinical interventions. All participants rated their self-efficacy as clinicians providing ECT, TMS and KIT services at 4 or higher on this Likert scale with an average of 4.6 for the participant cohort at the end of the CE training.

Maintenance is the last stage of Prochaska and DiClemente's TTM. In the stage the cohort of NPs resumed their usual practice activities prepared to offer ECT, TMS, and KIT services to patients with TRMD. In this last stage, the participants provided ECT, TMS, and KIT consultation and treatment services to an average of 8.6 patient encounters (with a range of 4 to 14, for a total of 43 clinical encounters) (see table 1, Appendix F) in the 60 days following completion of the CE training. Chart review of these patient encounters revealed no untoward or adverse events associated ECT, TMS, or KIT services provided by the NP cohort. Patient satisfaction with each ECT, TMS, or KIT encounter provided by the project participants in the 60-day maintenance stage was assessed using a 5-point Likert scales (5 being fully satisfied and 1 being entirely dissatisfied) (see Appendix H) and documented in the medical record. NP participant scores ranged from 4.2 to 4.8 out of 5, with the

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cohort average at 4.6 (see table 1, Appendix F). PHQ-9 scores are routinely used to quantify clinical severity of TRMD in patients at these three clinical sites. A course of treatment with ECT, TMS or KIT was deemed efficacious when the PHQ-9 scores were reduced by 50% or more at the end of a course of treatment or the patient reported a return to baseline functioning and remained at that level on routine follow-up in 2-4 weeks following the last treatment. Individual participant data is reported in table 1 and Appendix F. Clinical efficacy outcomes data for this cohort were reported at 90% for ECT, 70% for TMS, and 80% for KIT.

Table 1: Data

Nurse Practitioner	A	B	C	D	E	NP Cohort Average
Pre-CE TRMD	0	10	10	5	0	5
Post-CE TRMD	100	100	100	100	100	100
% change TRMD	100	90	90	95	100	95%
Pre-CE ECT	10	10	0	5	5	6
Post-CE ECT	90	95	100	95	100	96
% change ECT	80	85	100	90	95	90%
Pre-CE TMS	20	5	15	0	5	9
Post-CE TMS	95	90	95	95	95	94
% change TMS	75	85	80	95	90	85%
Pre-CE KIT	20	20	10	10	5	13
Post-CE KIT	100	95	100	80	90	93
% change KIT	80	75	90	70	85	80%
Self-Efficacy Assessment Post-CE	4	5	4	5	5	4.6
ECT/TMS/KIT in 45 days post CE training	5	4	14	8	12	8.6
Patient Satisfaction	4.3	4.8	4.7	4.2	4.8	4.56
Untoward/Adverse Events	0	0	0	0	0	0
Efficacy/Outcomes ECT	100%	95%	80%	90%	85%	90%
Efficacy/Outcomes TMS	0	60%	80%	0	0	70%
Efficacy/Outcomes KIT	80%	90%	70%	75%	85%	80%

Section V: Discussion

Summary

This quality improvement project identified five NPs at CTRI, AMSC and MPHS currently working with depressed patients and offered this cohort the opportunity to voluntarily participate in a free 16-hour CE project. All five NP participants who began the CE project completed the 16-hours of training and remained active at the three clinical sites in the following 60 days. All participants demonstrated a significant increase in clinical efficacy with the use of ECT, TMS, and KIT in the management of TRMD as evidenced by improvement in post-CE test scores over pre-CE baseline testing. On completion of the CE training, all participants provided a self-assessment of their professional comfort providing ECT, TMS, and KIT related services. All participants reported confidence in their professional self-efficacy with these procedures to independently provide protocol driven services with minimal ongoing supervision with a consulting psychiatrist experienced with these procedures. Following completion of the CE training, this cohort of NP participants participated in 43 patient encounters involving the provision of ECT, TMS and KIT related services over a 60-day follow-up period. This 60-day follow-up period was noted for the absence of adverse and untoward events, patient satisfaction was routinely in the 'satisfied' to 'fully satisfied' range, and clinical outcomes for those patients completing a course of treatment were reported as efficacious for 90% of ECT cases, 80% of KIT cases and 70% of TMS cases. These

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results are consistent with typical outcomes for psychiatrist provided services at these three clinical sites.

Relation to Other Evidence

The safe provision of ECT, TMS, and KIT services has been well established in a variety of clinical settings across the America. This quality improvement project was undertaken in part because nurse practitioners in the San Francisco bay area are under-represented in the management of TRMD with ECT, TMS and KIT despite the fact that management of depression is a routine part of daily practice for many primary care and mental health based NPs. The clinical outcome for patients followed by the NP cohort in the 60-days following completion of the CE training was consistent with national outcomes data for ECT, TMS and KIT (table 2).

Table 2: Outcomes Data

	ECT	TMS	KIT
Efficacy Data commonly reported in the psychiatric literature	75-85%	50-60%	50%
Efficacy Data in the 60-day project follow-up period	90%	70%	80%

Barriers to Implementation / Limitations

Potential barriers to the implementation and completion of this quality improvement project were considered in the planning phase of this project. Potential barriers can be summarized as resistance to an expanded NP role at the clinical sites (CTRI, AMSC, MPHS), resistance to completion of the formal CE training

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by the NP cohort, resistance to incorporating new skills and knowledge into daily practice by the NP cohort in the 60-day follow-up phase, and/or an unexpected drop in referral of TRMD patients to the three clinical sites. None of these potential barriers impacted this project.

This initial small scale, local quality improvement project supports an expanded role for NPs in the management of TRMD involving ECT, TMS, and KIT services at the three clinical sites involved in this project. This project demonstrates that NPs at these three clinical sites, following completion of a 16-hour CE training can provide safe, well tolerated clinically efficacious TRMD treatment involving ECT, TMS, and KIT. Practice protocols for the NPs at CTRI and AMSC will be updated to reflect this expanded NP role in the management of TRMD. Changes to NP practice protocols at a facility the size of MPHS involves a complex inter-departmental process that is estimated to take 6-9 months.

Interpretation

The small size of this project in terms of number of NPs enrolled, number of clinical sites involved, and number of patients involved, limit the clinical interpretation of the data on a larger scale. This quality improvement project is only able to speak to improvements in quality patient care at the three sites involved in the project. Despite the small size and scope of this quality improvement project, the initial data confirms the effectiveness of this 16-hour CE program at raising the clinical self-efficacy of enrolled NPs. It also confirms that following completion of this 16-hour CE training, NP participants provided safe, well-tolerated and clinically efficacious ECT, TMS, and KIT services at least in the initial 60-day follow-up period.

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It is worth noting that for a psychiatrist with no prior ECT experience to add this procedure to his hospital privileges, it typically requires completion of continuing medical education (CME) course in ECT (4-8 contact hours) and proctoring of +/-6 ECT cases by another psychiatrist with ECT privileges at the facility. Outpatient training of a psychiatrist for TMS or KIT typically occurs over a 2-4 hour period at the clinical bedside. The 16-hour CE-training provided in this project well exceeds the community standards for psychiatrists in the community wishing to add these activities as a new clinical privilege.

Conclusions

Prochaska and DiClemente's transtheoretical model of change (1984) was originally presented with five stages (pre-contemplation, contemplation, preparation, action, and maintenance). This quality improvement project was organized and implemented following the original TTM. In the years since the TTM was introduced, a sixth stage titled 'relapse' has often been described in the clinical literature. The final stage of relapse is most often referenced as part of the process of changing health related behaviors such as diet in the setting of diabetes and heart disease or substance use in the setting of tobacco, alcohol and other substances of abuse. This project demonstrates a successful expansion in the role of a cohort of nurse practitioners in the management of TRMD using ECT, TMS, and KIT at three clinical sites through the initial maintenance stage. This project cohort of NPs remain at risk for relapse to prior practice behaviors marked by failure to recognize TRMD and continued efforts to manage TRMD with psychotherapy and traditional

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psychopharmacology despite the patient's repeated failure to respond on this and prior episodes of TRMD. Potential triggers for entry into a relapse stage for this cohort include:

- Loss of access to consulting / supervising psychiatrist with ECT, TMS and/or KIT experience at current clinical practice site
- Change in clinical population served (low incidence of TRMD in pediatric population)
- Financial incentives (high volume psychopharmacology practice may be more financially lucrative than more labor intensive activities such as ECT, TMS and KIT)
- Failure to maintain clinical knowledge and skills as the state of the art care for TRMD evolves over time

Despite the potential for relapse, this quality improvement project successfully demonstrated that the NP role in the management of TRMD using ECT, TMS and KIT services can be successfully expanded without risking patient safety, patient satisfaction, or clinical efficacy.

Section VI: Other Information

Funding

Funding for this project was equally shared by the two outpatient clinical sites (CTRI and AMSC). The costs fell within the proposed budget presented in Appendix E and no additional outside funding was required.

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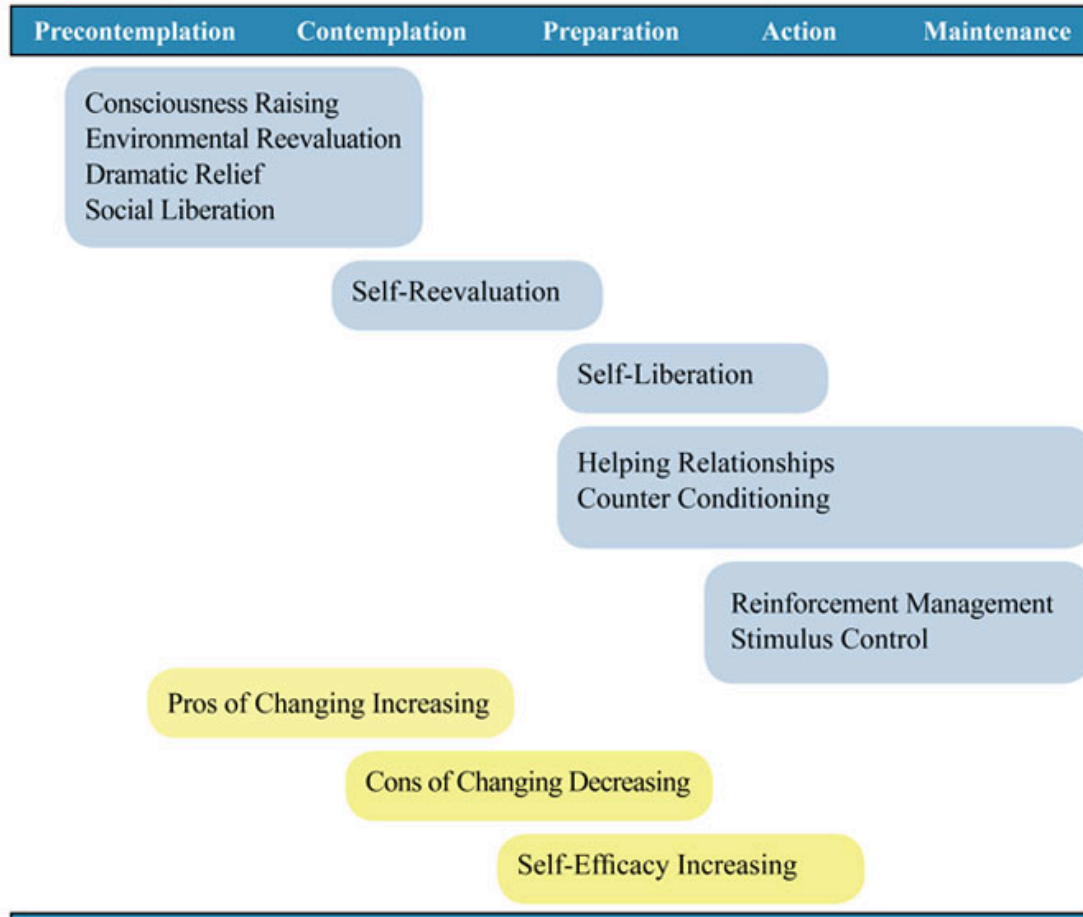
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Appendices

Appendix A: Transtheoretical Model of Change

Stages by Principles and Processes of Change



Expanding NP Role in TRMD

Appendix B: Facility Agreements

Access Multi-Specialty Clinic

Michael U. Levinson, MD, PhD

1838 El Camino Real Suite 130 Burlingame, CA 94010 (415) 596-1151

March 15, 2015

Dear Dr. Svensson,

Our clinic will commit to participate in the "Expanding the Role of the NP in the management of Treatment Resistant Major Depression" project hosted by Clinical Training and Research Institute. We will commit to provide up to 50% of the costs of this project, not to exceed at total of \$1700.

Yours truly,

Michael U. Levinson MD PhD

Michael U. Levinson, MD, PhD

Board Certified Psychiatrist

Burlingame, CA

Expanding NP Role in TRMD

Appendix B- continued

Clinical Training & Research Institute
25 Edward's Court #102, Burlingame, CA 94010
(650) 342-1966 / (650) 348-1515 (fax)

March 15, 2015

Dear Dr. Svensson,

Our clinic will commit to participate in the "Expanding the Role of the NP in the management of Treatment Resistant Major Depression" project under the direction of Dr. Travis K Svensson. We will commit to provide up to 50% of the costs of this project, not to exceed at total of \$1700.

Yours truly,

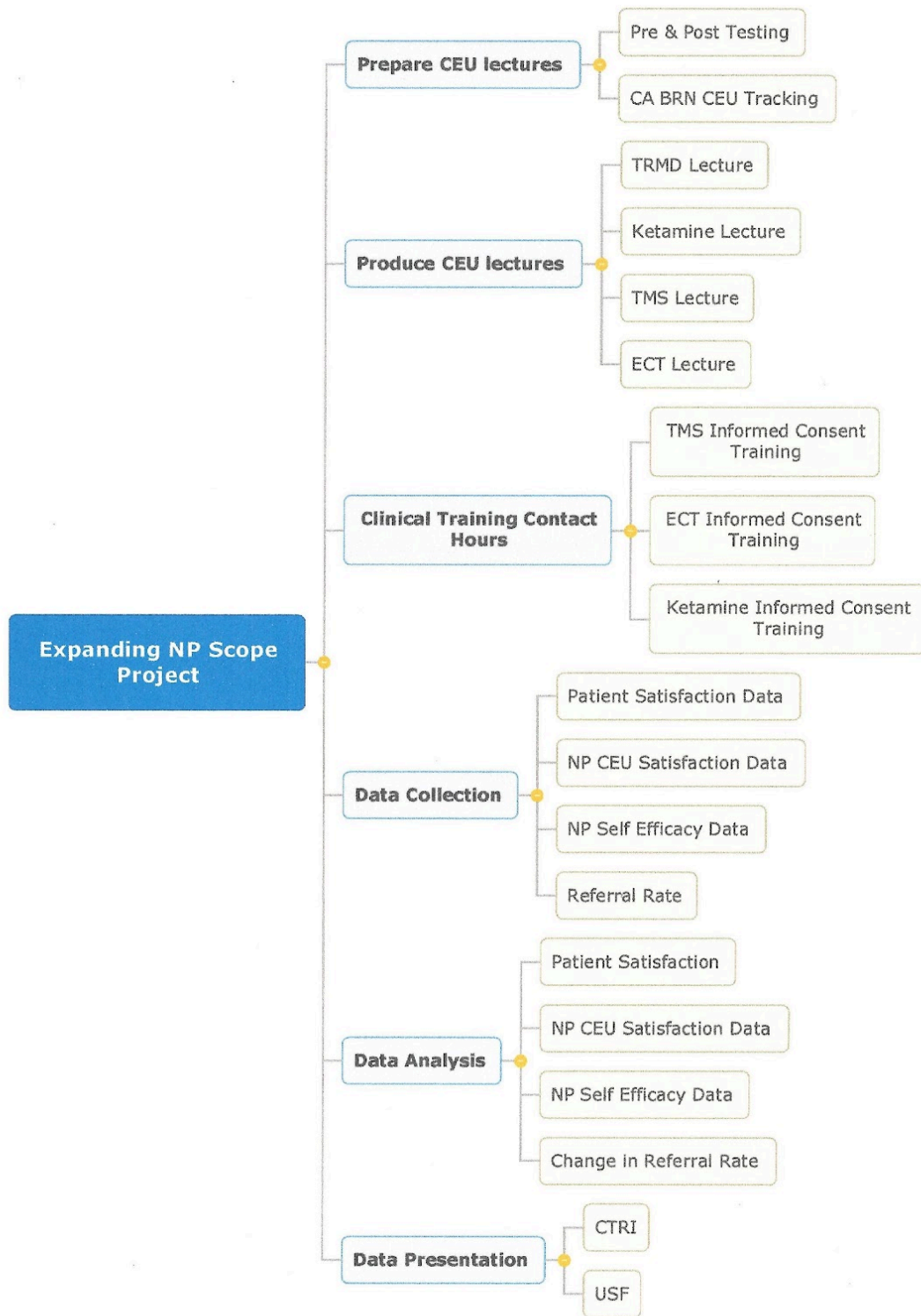
A handwritten signature in black ink, appearing to read "AT Smith III". The signature is fluid and cursive, with the initials "AT" being prominent.

Anthony T. Smith III

Administrator

Clinical Training & Research Institute

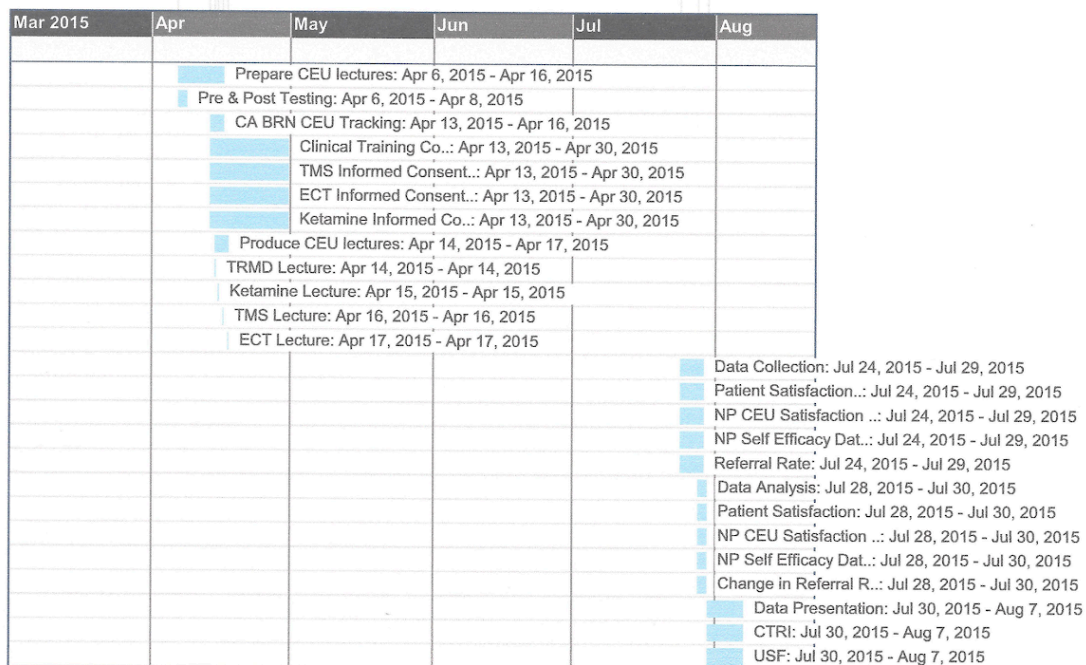
Appendix C: Workflow Breakdown Structure



Expanding NP Role in TRMD

Appendix D: Time and Cost Summary – GANTT

- Prepare CEU lectures
- Pre & Post Testing
 - CA BRN CEU Tracking
 - Clinical Training Contact Hours
 - TMS Informed Consent Training
 - ECT Informed Consent Training
 - Ketamine Informed Consent Training
 - Produce CEU lectures
 - TRMD Lecture
 - Ketamine Lecture
 - TMS Lecture
 - ECT Lecture
- Data Collection
- Patient Satisfaction Data
- NP CEU Satisfaction Data
- NP Self Efficacy Data
- Referral Rate
 - Data Analysis
 - Patient Satisfaction
 - NP CEU Satisfaction Data
 - NP Self Efficacy Data
 - Change in Referral Rate
 - Data Presentation
 - CTRI
 - USF



Expanding NP Role in TRMD

Appendix D – continued

Task No.	Duration	Start	End	Predec.	Compl.	Priority	Resour.	Work	Cost	
1	Expand...	90 days	4/6/2015	6/7/2015	0%	300		638.4 hrs	\$3,076.80	
2	Prepar...	9 days	4/6/2015	4/16/2015	0%	500		56 hrs	\$184.00	
3	Pre S...	3 days	4/6/2015	4/8/2015	0%	500	Physician	24 hrs	\$120.00	
4	CA B...	4 days	4/13/2015	4/16/2015	0%	500	Clerical	32 hrs	\$64.00	
5	Produc...	4 days	4/14/2015	4/17/2015	0%	500		32 hrs	\$160.00	
6	TRMD...	1 day	4/14/2015	4/14/2015	0%	500	Physician	8 hrs	\$40.00	
7	Ketam...	1 day	4/15/2015	4/15/2015	0%	500	Physician	8 hrs	\$40.00	
8	TMS L...	1 day	4/16/2015	4/16/2015	0%	500	Physician	8 hrs	\$40.00	
9	ECT L...	1 day	4/17/2015	4/17/2015	0%	500	Physician	8 hrs	\$40.00	
10	Clinical...	14 days	4/13/2015	4/30/2015	0%	500		336 hrs	\$1,680.00	
11	TMS L...	14 days	4/13/2015	4/30/2015	0%	500	Physician	112 hrs	\$560.00	
12	ECT L...	14 days	4/13/2015	4/30/2015	0%	500	Physician	112 hrs	\$560.00	
13	Ketam...	14 days	4/13/2015	4/30/2015	0%	500	Physician	112 hrs	\$560.00	
14	Data C...	4 days	7/24/2015	7/29/2015	0%	500		6.4 hrs	\$12.80	
15	Pallen...	4 days	7/24/2015	7/29/2015	0%	500	Clerical[...]	1.6 hrs	\$3.20	
16	NP C...	4 days	7/24/2015	7/29/2015	0%	500	Clerical[...]	1.6 hrs	\$3.20	
17	NP Se...	4 days	7/24/2015	7/29/2015	0%	500	Clerical[...]	1.6 hrs	\$3.20	
18	Referr...	4 days	7/24/2015	7/29/2015	0%	500	Clerical[...]	1.6 hrs	\$3.20	
19	Data A...	3 days	7/28/2015	7/30/2015	0%	500		96 hrs	\$480.00	
20	Pallen...	3 days	7/28/2015	7/30/2015	0%	500	Physician	24 hrs	\$120.00	
21	NP C...	3 days	7/28/2015	7/30/2015	0%	500	Physician	24 hrs	\$120.00	
22	NP Se...	3 days	7/28/2015	7/30/2015	0%	500	Physician	24 hrs	\$120.00	
23	Chang...	3 days	7/28/2015	7/30/2015	0%	500	Physician	24 hrs	\$120.00	
24	Data Pr...	7 days	7/30/2015	8/7/2015	0%	500		112 hrs	\$560.00	
25	CTRI	7 days	7/30/2015	8/7/2015	0%	500	Physician	56 hrs	\$280.00	
26	USF	7 days	7/30/2015	8/7/2015	0%	500	Physician	56 hrs	\$280.00	

Expanding NP Role in TRMD

Appendix E: Budget Details

Branch Name	Duration	Start	End	Priority	Completion	Resources	Work	Cost
Expanding NP Scope Project	90 days	4/6/2015	8/7/2015	300	0%		638.4 hrs	\$3,076.80
▣ Prepare CEU lectures	9 days	4/6/2015	4/16/2015	500	0%		56 hrs	\$184.00
Pre & Post Testing	3 days	4/6/2015	4/8/2015	500	0%	Physician	24 hrs	\$120.00
CA BRN CEU Tracking	4 days	4/13/2015	4/16/2015	500	0%	Clerical	32 hrs	\$64.00
▣ Produce CEU lectures	4 days	4/14/2015	4/17/2015	500	0%		32 hrs	\$160.00
TRMD Lecture	1 day	4/14/2015	4/14/2015	500	0%	Physician	8 hrs	\$40.00
Ketamine Lecture	1 day	4/15/2015	4/15/2015	500	0%	Physician	8 hrs	\$40.00
TMS Lecture	1 day	4/16/2015	4/16/2015	500	0%	Physician	8 hrs	\$40.00
ECT Lecture	1 day	4/17/2015	4/17/2015	500	0%	Physician	8 hrs	\$40.00
▣ Clinical Training Contact Hours	14 days	4/13/2015	4/30/2015	500	0%		336 hrs	\$1,680.00
TMS Informed Consent Training	14 days	4/13/2015	4/30/2015	500	0%	Physician	112 hrs	\$560.00
ECT Informed Consent Training	14 days	4/13/2015	4/30/2015	500	0%	Physician	112 hrs	\$560.00
Ketamine Informed Consent Training	14 days	4/13/2015	4/30/2015	500	0%	Physician	112 hrs	\$560.00
▣ Data Collection	4 days	7/24/2015	7/29/2015	500	0%		6.4 hrs	\$12.80
Patient Satisfaction Data	4 days	7/24/2015	7/29/2015	500	0%	Clerical[5%]	1.6 hrs	\$3.20
NP CEU Satisfaction Data	4 days	7/24/2015	7/29/2015	500	0%	Clerical[5%]	1.6 hrs	\$3.20
NP Self Efficacy Data	4 days	7/24/2015	7/29/2015	500	0%	Clerical[5%]	1.6 hrs	\$3.20
Referral Rate	4 days	7/24/2015	7/29/2015	500	0%	Clerical[5%]	1.6 hrs	\$3.20
▣ Data Analysis	3 days	7/28/2015	7/30/2015	500	0%		96 hrs	\$480.00
Patient Satisfaction	3 days	7/28/2015	7/30/2015	500	0%	Physician	24 hrs	\$120.00
NP CEU Satisfaction Data	3 days	7/28/2015	7/30/2015	500	0%	Physician	24 hrs	\$120.00
NP Self Efficacy Data	3 days	7/28/2015	7/30/2015	500	0%	Physician	24 hrs	\$120.00
Change in Referral Rate	3 days	7/28/2015	7/30/2015	500	0%	Physician	24 hrs	\$120.00
▣ Data Presentation	7 days	7/30/2015	8/7/2015	500	0%		112 hrs	\$560.00
CTRI	7 days	7/30/2015	8/7/2015	500	0%	Physician	56 hrs	\$280.00
USF	7 days	7/30/2015	8/7/2015	500	0%	Physician	56 hrs	\$280.00

\$ 3,076.80 Project Funding (from CTRI & AMSC)

\$ 3,076.80 Project Costs

 \$76.80 Clerical Staff Costs (38.4 hours)

 \$3000.00 Physician Costs (600.00 hours)

Expanding NP Role in TRMD

Appendix F: Table 1 Data Collected

Table 1: Data

Nurse Practitioner	A	B	C	D	E	NP Cohort Average
Pre-CE TRMD	0	10	10	5	0	5
Post-CE TRMD	100	100	100	100	100	100
% change TRMD	100	90	90	95	100	95%
Pre-CE ECT	10	10	0	5	5	6
Post-CE ECT	90	95	100	95	100	96
% change ECT	80	85	100	90	95	90%
Pre-CE TMS	20	5	15	0	5	9
Post-CE TMS	95	90	95	95	95	94
% change TMS	75	85	80	95	90	85%
Pre-CE KIT	20	20	10	10	5	13
Post-CE KIT	100	95	100	80	90	93
% change KIT	80	75	90	70	85	80%
Self-Efficacy Assessment Post-CE	4	5	4	5	5	4.6
ECT/TMS/KIT in 45 days post CE training	5	4	14	8	12	8.6
Patient Satisfaction	4.3	4.8	4.7	4.2	4.8	4.56
Untoward/Adverse Events	0	0	0	0	0	0
Efficacy/Outcomes ECT	100%	95%	80%	90%	85%	90%
Efficacy/Outcomes TMS	0	60%	80%	0	0	70%
Efficacy/Outcomes KIT	80%	90%	70%	75%	85%	80%

Appendix G: 5-Point Likert Scale Self Assessment of Clinical Efficacy

Nurse Practitioner Name: _____ Date: _____

Please complete the following self-assessment following completion of the 16-hours of continuing education in the advanced management of treatment resistant depression using electroconvulsive therapy, transcranial magnetic stimulation and ketamine infusions.

Please describe your confidence with providing ECT, TMS, and KIT related services in the management of treatment resistant major depression:

5 Confident that I am well prepared for independent unsupervised protocol driven clinical practice providing ECT, TMS and KIT related services

4 Confident that I am well prepared for minimal physician supervision/consultation with a protocol driven clinical practice providing ECT, TMS, and KIT related services

3 Confident that I am well prepared to provide protocol driven clinical practice with ECT, TMS, and KIT related services with direct supervision from a psychiatrist experienced with the procedures

2 Confident that I am well prepared to assist a psychiatrist in the provision of ECT, TMS and KIT related services

1 Confident that I am well prepared for an ongoing trainee or observational role in the use of ECT, TMS and KIT related services

Appendix H: 5-Point Likert Scale – Patient Satisfaction

Please describe your level of satisfaction with the clinical services provided by the nurse practitioner that you saw today.

Please note that feedback regarding the support staff and clinical facilities will be collected on a different form.

- 5 Fully satisfied with the care provided by my nurse practitioner today
- 4 Somewhat satisfied with the care provided by my nurse practitioner today
- 3 No thoughts / Unmoved by the care provided by my nurse practitioner today
- 2 Somewhat dissatisfied with the care provided by my nurse practitioner today
- 1 Fully dissatisfied with the care provided by my nurse practitioner today