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Pregnancy Bridge Program for Psychiatric Patients

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PREGNANCY BRIDGE PROGRAM FOR PSYCHIATRIC PATIENTS

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Adam Barnett

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Abstract

The National Institute of Mental Health (2017) estimates that 9.2 million people age 18 years and older are diagnosed with bipolar disorder in the United States. Research has shown pregnancies in women with mental health problems have higher rates of poor outcomes and complications (Epstein et al., 2014; Freeman, 2007; Rusner et al., 2016; Scrandis, 2017). **Aim.** The purpose of this scholarly project is to provide standardized patient education, increase urine human chorionic gonadotropin screening rates, and to set up a gynecologic care bridge for patients considering pregnancy and are diagnosed with bipolar disorder. **Evidence.** The Centers for Disease Control and Prevention (2019b) estimates 51% of pregnancies are unplanned and recommends planning for pregnancy ahead of time. The American College of Obstetricians and Gynecologists (2019) recommends a multidisciplinary care team for patients that plan on pregnancy. Mood-stabilizing and anti-psychotic medications are known human teratogens (Bodén et al., 2012; Mittal et al., 2015; Stahl, 2017). **Method.** Female patients with bipolar disorder, ages 18-65 years, received standardized medication and contraception education. These patients were screened for pregnancy intentions or human chorionic gonadotropin. Patients that met criteria were connected with a gynecologic provider. **Results.** 158 patients were screened for pregnancy and offered education over ten weeks. 37 patients had recent pregnancy tests. 50 patients were indicated for follow up. Implications. Medication safety is of paramount importance for this high-risk population. Data captured during this project provides a snapshot. This process should be continuous and championed by health care organizations.

Keywords: medication, safety, pregnancy, mood-stabilizers, psychotropics, evidence-based practice change

Pregnancy Bridge Program for Psychiatric Patients

Supporting Background Information

Of the 9.2 million people age 18 and older with bipolar disorder, females in this group have been shown to have higher rates of complications and poor pregnancy outcomes (Epstein et al., 2014; Freeman, 2007; National Institute of Mental Health [NIH], 2017; Rusner et al., 2016; Scrandis, 2017). Planning for pregnancy needs to occur ahead of time as approximately 51% of pregnancies are unplanned and this percentage is likely higher in those with mental health disorders (Centers for Disease Control and Prevention [CDC], 2019b; Rusner et al., 2016; Yonkers et al., 2004). It is critical to include medication planning for patients that are thinking about pregnancy. Research has shown that most mood-stabilizing medications are human teratogens (American College of Obstetricians and Gynecologists [ACOG], 2008; Bodén et al., 2012; Stahl, 2017). In order to alleviate this issue, the ACOG (2018) recommends patients have a multidisciplinary care team if they are planning to become pregnant. Preventing complications and poor pregnancy outcomes in the mental health population is paramount for patient safety and to alleviate the already tremendous burden on the healthcare system.

A care gap for both providers and patients regarding the complications associated with medications and psychiatric illness related to pregnancy outcomes exists in the proposed project site. The ACOG (2008) describes guidelines on psychiatric medication use during pregnancy and lactation with the purpose of reducing complications and adverse fetal effects. These guidelines are critical for mental health care institutions because they align with patient safety goals and mission principles. The ACOG highlights scientific evidence that demonstrates potential adverse health effects from the administration of many mood stabilizers. Medications such as lithium carbonate and valproic acid, as well as atypical and typical antipsychotics are used for mood stabilization. Birth defects effects occur in the fetus exposed to these drugs, including neural tube

and cranio-facial malformations (Epstein et al., 2014; Stahl, 2017). Scrandis (2017) notes that providers should weigh risks and benefits found in current evidence regarding the effects of these medications. In some cases, women should continue their medications that may increase risk to pregnancy outcomes.

Irrespective of mental health, unplanned pregnancy rates range from 45%-75% depending on age (CDC, 2019b; Yonkers et al., 2004). On top of this, research indicates women with BPD have higher rates and poorer pregnancy outcomes (Rusner et al., 2016). The ACOG (2019) and the CDC (2019a) discuss the importance of pre-pregnancy counseling and education in order to reduce complications. These institutions call for a multidisciplinary approach to pregnancy, with the patient at the center. Patients need concrete counseling and screening prior to pregnancy. If a patient becomes pregnant, they should be under the care of an obstetrician and gynecologist (OBGYN) or other women's health care provider in addition to their mental health provider.

Problem Statement

Many psychotropic medications pose a threat to the development of newborns in female patients receiving mental health treatment (ACOG, 2008; Bodén et al., 2012). This is especially important if special considerations are not made with respect to side effects, dosage, or the patient's care is mismanaged. For instance, bipolar disorder is a chronic and severe mental health disorder that requires continuous mood stabilizing to lower suicide risk (Bodén et al., 2012). One-third of all women who become pregnant in the United States are potentially exposed to psychotropic medication at some point during pregnancy (ACOG, 2008).

Moreover, simply being diagnosed at some point with a mental health condition such as bipolar disorder or schizophrenia has been associated with an increased risk of negative

pregnancy effects. In women with mental health diagnoses, there is increased prevalence of poor reproductive health and knowledge, and a tendency to have more sexual partners and sexually transmitted diseases (Epstein et al., 2014; Dinc et al., 2019). Lack of education and proper support for these patients can cause an increase in adverse pregnancy outcomes. Although the Food and Drug Administration (FDA) is stopping the use of pregnancy categories in the United States, the previous category ratings of most mood stabilizers were category D, meaning there was positive evidence of risk to the fetus. Most typical and atypical antipsychotics are category C, meaning risk cannot be ruled out (Epstein et al., 2014). Additionally, Haskey and Galbally (2017) found supporting evidence of adverse fetal outcomes in their systematic review of studies on medications in these categories.

In this outpatient mental health clinic (OMHC) setting, no standardized education was being provided to potential mothers on the teratogenic effects of many commonly prescribed mood stabilizers and antipsychotics. Three providers were noted to give patients on-the-spot pregnancy education counseling by their provider. The OMHC also performs pregnancy screening either via verbal attestation or by urine or serum human chorionic gonadotropin (hCG) test at sporadic intervals and at the least yearly. Often, this is after the patient is exposed to potentially harmful medication. This process is also disjointed, as the licensed vocational nurse (LVN) or registered nurse (RN) questions the patient about their pregnancy intentions during their review of systems (ROS). They do not educate patients and are limited to questioning and drawing labs if the provider orders an hCG. The psychiatric-mental health nurse practitioner (PMHNP) conduct medication consent for psychotropic and on the spot, discretionary education. Female patients between ages 18-65 are tested for pregnancy depending on how they respond to LVN/RN questions.

There are alternative treatments that have efficacy during pregnancy. Substantial evidence supports psychotherapies for managing bipolar depression, which can prevent relapse in some patients. “Bipolar-specific cognitive behavioral therapies, family-focused therapy, interpersonal and social rhythm therapy, group psycho-education, and systematic care management” have demonstrated effectiveness in BPD treatment (Epstein et al., 2014, p. 13). The proposed project site does not provide sessions with trained psychotherapists nor do they provide services by an OBGYN.

Needs Assessment

Identification of the problem included several steps: The first step was to consider the patient population of the OMHC. The majority of the patients at this OMHC are diagnosed with major depressive disorder, bipolar disorder, or schizophrenia. Next, medication prescriptions for mood stabilizers were evaluated. Between November 1, 2019 and January 31, 2020, 240 patients with one of the diagnosis codes for bipolar disorder were identified as having active an average of 2.1 active prescriptions. The majority of these patients are on active prescriptions for one of the sodium channel modulators (14.6% of prescriptions; such as valproate or lithium) or typical or atypical antipsychotics (85% of prescriptions; such as lurasidone or aripiprazole). These patients are prime candidates for education regarding pregnancy, due to generally low socio-economic and educational status and poor insight associated with many mental health conditions and associated poor pregnancy outcomes (ACOG, 2008; Epstein et al., 2014). Providing an intervention related to the needs of the community and the practicing clinicians in this OMHC will advance the organization and provide a much-needed client service with positive holistic outcomes.

One of the primary measures that the organization wishes to achieve is safety of care. The first step in achieving this goal is education. Education for patients regarding this proposal in the OMHC is currently left to provider discretion. Sporadic chart reviews demonstrated providers commonly documented one sentence on pregnancy risk education in their notes. Other forms such as medication consent were sporadically completed. The medication consent listed that risks and benefits of medications were discussed with the patient. To better achieve patient safety, patients should receive standardized contraceptive counseling before taking psychotropic medications. Additional information regarding medication safety will aid the health care organization achieve its goals and improve outcomes for its childbearing age healthcare population.

Another large part of process change to better adhere to guidelines is screening for pregnancy. LVNs or RNs accomplish reviews of systems (ROS) during patient intake. These staff members are supposed to ask patients about pregnancy planning during their ROS on each patient visit. However, many patients are unaware of their current pregnancy status or are not sure if they plan to become pregnant. As mentioned previously, rates of unintentional pregnancy are higher in the mental health population. Ideally, all patients will be pregnancy tested if appropriate during their visit.

Finally, there is no follow up in place for patients that are found to be pregnant or plan to become pregnant. This OMHC does not provide OBGYN staff care which both the ACOG (2019) and the CDC (2019a) outline as part of pregnancy planning. Therefore, part of the process change is to implement a care bridge involving providers specialized in caring for expecting mothers. To close the care gap, this subpopulation of patients be linked with community providers that specialize in obstetric and gynecologic service.

Readiness for Change

The DNP mentor and student accomplished initial conception for this project by considering the population and organizational needs. Assessment of the staff in the fall of 2019 and spring of 2020 demonstrated they are open to participate in the process change. The organization's readiness for change and success of this DNP proposal depend on how the stakeholders engage in the project. The promotion of a safe working environment is a serious goal and requires leadership and staff involvement.

Involvement of Agency Stakeholders

Program implementation required formation of a team to accomplish this DNP project. The DNP mentor and advisor were crucial in program proposal and development. During the early phases of needs assessment and throughout the planning stage in the fall of 2019, stakeholders were identified at the local and organizational levels. The Chief Medical Officer (CMO) and Treatment Care Council (TCC) for the organization were invaluable by providing frequent feedback and ideas for this process change.

The proposed plan, intervention and outcomes were provided to the TCC on December 11, 2019. The CMO, clinic & organizational leadership and various PMHNP providers were present and voted to proceed with the pilot intervention with guided supervision (see appendix W). Further follow up regarding this process change was communicated with both the local clinic staff and the organizational leadership throughout the planning, implementation and evaluation phases.

For the first 5 weeks of the implementation period (February 17, 2020 through March 20, 2020), the LVN and provider staff of the organization were regularly assessed for proper project procedures. Initially, several staff stated they were not comfortable with completing the checklist

or other basic tasks until a supervisor approved it. Time is a huge issue for all nursing staff and was regularly mentioned by 2 of the LVNs and by the case management (CM) identified to participate mid-way through the project. During the day, all staff see patients during business hours so adding a checklist to their to-do list caused noticeable anxiety and resistance to process change.

Project Identification

The IOWA model provides a simple and straightforward approach to systems change. The framework provides a clear feedback loop and process to guide clinical practice evaluation. The IOWA model dictates knowledge-focused triggers, such as implementation of organizational guidelines, guide evidence-based practice changes. For this project, guidelines provided by the ACOG (2008) and highlighted by the CDC (2019a) are the templates for this QI project intervention. Before implementation, the process change was in line with the proposed organization's goals. These goals are to promote a comprehensive, safe, and collaborative care for its patients.

With the indication of these needs, a project team was formed. A DNP project mentor was identified at the proposed site to provide oversight at the location. During the project development and before implementation, this project was presented to two tiers of leadership, including organizational and the local site. Faculty from the University of the Incarnate Word provided oversight of the DNP student. Literature regarding this QI project was identified by the DNP student and synthesized for supporting evidence. The accumulated and synthesized research supports an evidence based clinical practice pilot change on select units.

Purpose

The purpose of this project was to implement a three-part simultaneous process change governed primarily by ACOG (2008; 2019) guidelines and supported by the CDC (2019) and

March of Dimes (2017) in the proposed site. The three parts are:

- Standardized education for patients regarding medication risk and contraceptive use.
- Screening for early pregnancy detection in all females.
- Follow up collaborative care for patients planning on pregnancy.

Standardized educational, hCG urine screenings and collaborative care with OBGYNs has been shown to reduce adverse pregnancy outcomes, allow for providers to document more comprehensively, and reduce potential liability of the organization. The long-term goal of this practice improvement project was to increase safe and effective care for female bipolar patients in the psychiatric outpatient community setting.

Aims and Objectives

This project's focus was on primary prevention as this problem and population are admittedly difficult to capture. Education regarding the prevention of possible complications with pregnancy in the mental health population is the first step towards better outcomes. To meet this goal, it was necessary to review and discuss what is currently known about mood stabilizers. Mood stabilizing medications consist of voltage sensitive sodium channel modulators and antipsychotic medications, which are often used off label for this purpose (Jones & Jones, 2017; Stahl, 2017). The majority of the patients at this OMHC are taking one of these types of medications for treatment. Between November 1, 2019 and January 31, of 2020, a sample of 240 patients revealed that 12% were on active prescriptions for Lamictal, Lithium, Depakote or Carbamazepine. Most prescriptions for this population in this setting were for one form of Abilify (31%) or Latuda (17%).

The objective of this project was to increase positive outcomes for pregnant female patients with bipolar disorder through a three-part process implementation. This evidence-based project aimed to implement guidelines by ACOG and the CDC on top of the highest quality studies regarding psychotropic medications and pregnancy. The goal was to provide standardized education, improve pre-conception screening of females between the ages of 18 and 65, and set up a pregnancy care bridge for this outpatient setting. The process begins when a patient enters treatment as an outpatient in the psychiatric and mental health clinic setting and the process of pregnancy outcome education ends when the patient is discharged to home or another facility. By modifying the education, screening and the follow-up process, the short-term objective was to assess changes in these areas for the female patient receiving psychopharmacologic treatment. The long-term objective is to increase psychotropic pregnancy outcomes for patients and providers.

The first goal of this project is to provide standardized education to female patients regarding risks of psychotropic medication and their effects during pregnancy. In the OMHC, education was accomplished in the narrow time window the individual provider had with the patient during their appointment. The providers of this OMHC educated patients on the fly regarding risks of mood stabilizing and antipsychotic medication during pregnancy. The OMHC used a consent form where providers noted when they gave psychotropic medication education regarding pregnancy risks. Standardized medication and contraceptive specific, pregnancy trifold (see appendix A & B) were provided to all female patients ages 18-65 years with bipolar disorder. The goal was to provide this education to 100% of these patients from February 17,

2020 to April 24, 2020. Creation of a more objective and defined policy for education will also allow and facilitate provider documentation and discussion with patients regarding the risk of psychotropic medications.

Along with specific education, all patients were screened for pregnancy via the one question initiative (ACOG, 2016). When applicable, blood or urine hCG pregnancy tests were supposed to be ordered by providers. Often, pregnancy testing was not conducted until after the patient has been prescribed medication. In order to better capture and prevent possible problems regarding pregnancy and medication teratogenicity, it is proposed that all females ages 18 to 65 with bipolar disorder be screened and that urine or blood hCG be ordered when needed. The goal was to achieve a screening rate of 100% of females in this age group with bipolar disorder regardless of their response to the “one key question” (Oregon Foundation for Reproductive health, n.d.).

Finally, the third goal was to refer patients for follow up care that meet criteria for education and screen positive for blood or urine hCG. Those patients that were pregnant or planning on pregnancy needed to be connected with an OBGYN according to literature review and guidelines (CDC, 2019a; ACOG, 2018). Establishing a collaborative bridge for pregnant patients by connecting them with providers that specialize in pregnancy care is the most important piece of this project. Therefore, 100% of patients that screen positive for pregnancy or plans on pregnancy should be set up with an OBGYN specialized provider to facilitate perinatal outcome. This was documented on the same checklist by the PMHNP provider.

The expected outcome was to achieve 100% patient education for these patients, complete 100% pregnancy screening via urine or serum testing when the patient indicates it was needed, and involve gynecologic service for patients with bipolar disorder that wish to become

pregnant when applicable. Preconception health care is the first step to improve outcomes in the psychiatric outpatient population (CDC, 2019a). Secondly, screening for pregnancy needs to be accomplished on all female patients for prophylactic planning purposes. Finally, patients should be connected with OBGYN service for pre-pregnancy counseling and care (ACOG, 2019). These three interventions of pre-pregnancy education, pregnancy screening and follow up care in this OMHC will create an environment that promotes safety and positive outcomes for mothers and their children.

Summary and Strength of Evidence

Literature for this project was found using CINAHL, PubMed, and Google Scholar databases. Randomized controlled trials (RCT) and literature reviews that include them have been conducted to study psychotropic medications and their effects on pregnancy outcomes. The highest evidence shows clear adverse effect of many psychiatric medications and fetal exposure during pregnancy. Literature reviews support strict use of mood stabilizer use and avoidance of certain drugs during pregnancy (Jones & Jones, 2017; Scrandis, 2017; Stahl, 2017). Furthermore, Epstein et al. (2014) found few controlled studies prove medication effectiveness for pregnant women with bipolar disorder.

There are ethical issues when it comes to conducting prospective randomized controlled trails on this type of population for obvious reasons. Administering potentially harmful medications to test teratogenic effects would no doubt be catastrophic (Jones & Jones 2017; Poels et al., 2018). Twelve articles for this project were at least level IV evidence, which primarily consisted of literature reviews including retrospective cohort studies or case reports. The committee opinions by the ACOG included the highest possible tiers of literature, but lacked of prospective research with randomized samples for aforementioned reasons. Nineteen articles

were between levels 5 and 7, meaning evidence for these studies were descriptive or qualitative in nature, again lacking randomization of sample cohorts, comparative analysis or controlled groups.

On top of the issue with prescription medications, several other problems present with the psychiatric population and pregnancy. Women with bipolar disorder have often been found to smoke, be overweight, and misuse alcohol or other substances more than women without bipolar disorder (Bodén et al., 2012; March of Dimes, 2016). Along with these comorbidities, another major problem with the psychiatric population is street drug use. About one in twenty women use street drugs during pregnancy, which can lead to many of the same immediate complications with the fetus and labor, such as problems with the placenta or malformations such heart or other birth defects (March of Dimes, 2016).

Research regarding pregnancy, mood stabilizers and antipsychotics is consistent and the evidence proposes a team approach to medication during pregnancy. As with most clinical problems, there is need for additional research (ACOG, 2008; Rusner et al., 2016; Yonkers et al., 2004). Many studies claim medications need more randomized controlled trials in specific populations, but prospective research on bipolar pregnant females will always be hard to conduct. It is understandable that data would be lacking in this area, as the population is naturally evasive, non-compliant and it is hard to study medication-associated risk on expecting females (Epstein et al., 2014; Haskey & Galbally, 2017).

Method

Practice guideline number 92 by the ACOG (2008) centers on risk to the developing fetus safety to meet the standards of care. The ACOG and the CDC outline a standard of care when it comes to pregnancy recommendations for patients on mood stabilizing drugs. Over the course of

project implementation, staff were educated regarding their role and participation in the process change. Implementation of the project requires careful attention and engagement from all team members at the OMHC. As the intervention rolled out, daily follow was conducted to ensure the process is being completed properly. Front desk personnel, medical assistance and clerical staff were not used in this pilot program. Inclusion of the nursing (primarily LVN) staff and the mental health prescribers are the key professionals to perform as a team in this quality improvement (QI) project. Ideally, there would be a committee to chair this QI project in the future. The DNP student served as the primary coordinator for this project for at least 10 weeks of data collection.

Clinical Setting

The clinical setting for the intervention is an OMHC located in a large metropolitan area in south Texas. This site is located in the central city with supporting facilities for the disadvantaged mental health patient in close vicinity. The OMHC consists of the following healthcare (non-administrative) personnel: Numerous patient care specialists (PCSs) and medical assistants (MAs), seven LVNs, two RNs, four case managers (CMs), two psychiatrists, and four PMHNPs as well as multiple primary health care staff and providers. Health care personnel work 8-hour shifts from 8:00 a.m. to 5:00 p.m. The OMHC is open Monday through Friday and closed on federal holidays. The managerial staff host meetings for the healthcare staff every week, and report to the board of directors at least once a month.

A small number of staff were selected for pilot of this process change for many reasons. This OMHC contains three primary patient process areas, and each patient goes through up to four types of different patient care staff (for example, MA, LVN, PMHNP, & CM). This project was easier to pilot with a small selection of staff. Also, timeframe for implementation is limited

and there are likely improvements in process and checklist that can be made going forward. For these reasons, four prescribers and two associated LVNs were used for this pilot QI process initially. After March 20, 2020, most patients were from one provider due to changes at the clinic from COVID19. Five weeks of data were collected using two LVNs and the four associated prescribing staff. For the last 5 weeks, data was collected from home using remote access due to necessary social distancing measures implemented at the clinic.

Timeframe

The proposed interventions were implemented over ten weeks, from February 17, 2020 through April 24, 2020. The intervention consisted of three changes implemented at the same time: (a) Standardized patient education, (b) various screening methods to encompass all female patients ages 18-65, and (c) collaborative care referral involving OBGYN service and medication list for patients planning to become pregnant. Staff tasks and patient information were tallied via a comprehensive checklist and data collected was kept in a password secured SPSS (statistical package for the social sciences) data set for easy analysis. Results were compiled and data disseminated to leadership at the OMHC once analyzed and at their request.

Project Intervention

The ACOG (2016) describes the use of checklists and proper procedures for implementation, revision and evaluation. The simplest method to pilot change in this organization was the implementation of a checklist regarding the aforementioned goals. Other methods might be more desirable in the future, but are outside the scope of this project (see barriers). There were three primary sections in this checklist where staff are able to notate the following:

- Dissemination of mood stabilizer risk, contraceptive information, and community pregnancy resources.
- Pregnancy screening.
- Description of collaborative care follow up with an OBGYN if a patient is planning to be pregnant or is found to be pregnant through screening (Appendix Y).

Each intervention is described in detail below.

Evidence Based Patient Education

The first step in improving pregnancy outcomes is patient counseling. The proposed educational material contains a summary of the evidence that described in multiple high-quality literature samples. Educational materials adhere to the recommended guidelines by the ACOG (2008), CDC (2019a), and relevant cited literature. An educational tri-fold was developed to serve as a practical guide for both patients and providers (Appendix A and B). Pamphlets were given to female patients, ages 18-65 years with any form of bipolar disorder, and consisted of three sections. The front part of the pamphlet included a summary of evidence regarding pre-natal counseling, containing advisory information regarding mood stabilizing medications and the need for pregnancy risk assessment with the patient's providers. The middle section included recommendations for common contraceptive use, with detailed methods and effectiveness. Finally, the backside contained community women's health resources, a medication-tracking card, and follow up procedures for women during pregnancy. The educational tri-folds were given to LVNs that complete the ROS for each patient and the PMHNP providers that provide medication management and counseling. Chart reviews were used to evaluate documentation and education given to this patient population. The checklist allowed for notation of the standardized

psychotropic medication and pregnancy recommendations. Access to the educational tri-fold was provided in both English and Spanish, as a large portion of this OMHC population speak Spanish. Tri-folds were emailed to patients when applicable by providers once social distancing was mandated by the local government at the project site.

Human Chorionic Gonadotropin Screening

Blood or urine hCG tests need to be done on all female patients when applicable. The OMHC currently screens patients depending on how they respond to reproductive health questions, primarily the question, “do you plan on becoming pregnant,” by LVNs or RNs. Providers also ask patients about their pregnancy plans and document lab reviews in their evaluation and management note. Chart review revealed baseline hCG screening rates were approximately 97% percent prior to project start. The purpose of this project is to increase the screening rates to 100% by serving as a reminder to screen patients. The goal is to improve capture of the expecting or unplanned pregnant patient. Urine hCG screenings are administered by the RN or LVN staff before seeing the provider. The clinic has a policy of at least yearly laboratory draws and as needed hCG urine or serum testing. More data regarding pre and post-invention screening is discussed in the results section. Both prescribers and LVNs are able to document on the checklist regarding screening. When social distancing was implemented, data were obtained via organization electronic health record (EHR) and analyzed in SPSS.

Obstetrician Collaborative Care

The OMHC does not provide OBGYN services and follow up care for women’s health is not tracked by any OMHC staff. ACOG (2019) guidelines and evidence-based literature dictate all patients planning to become pregnant should be under the care of an OBGYN. Pre-conception planning for patients with bipolar disorder should be a team effort and include the patient,

psychiatric provider and a women's health specialist. The goal is to connect 100% of these patients with an OBGYN provider. Trends regarding pre-intervention rates were compiled via retrospective chart review. Post-invention referrals and collaborative care were documented on the one stop checklist by PMHNPs and CMs to determine effectiveness of intervention.

This OMHC provides care to clients that are from the local zip code. Therefore, three clinics were identified in close proximity to the area to provide for follow up care if needed. There are exceptions for this, including patients that already have an OBGYN provider or do not live in the local area. For the purpose of this project, several local clinics specializing in low income, obstetric and gynecologic care were identified during planning. All three clinics were contacted via email or phone to assess for the type of service they provide and the type of funding. These clinics normally service similar client types as those that receive care at the project site. These clinics are local to the city and are independent clinics that provide women's health services. Patients identified for follow up were presented to a case manager for follow up.

Ethical Considerations and IRB

This project upholds ethical considerations by avoiding collection of sensitive personal information, remaining focused on process improvement based, and allowing for patient right of refusal at any step in this process. Internal Review Board (IRB) approval is not required for the implementation of this QI project. Therefore, a DNP statement of non-research is included (Appendix X). Leadership at the OMHC provided a letter of support for implementation of the project at their location (Appendix W). The DNP student complied with the Health Insurance Portability and Accountability Act in conducting QI activities.

Patients were allowed to refuse any part of this process. Just as well, it is unethical for a health care provider to dictate pregnancy needs of their patients. Pregnancy planning and

contraceptive choices are for patients to decide. Lack of human randomized controlled trials will continue in the future. Testing the teratogenicity of medications in mothers with developing fetuses is an ethical concern, especially considering these medications are known to be harmful.

Evaluation Plan

To assess effectiveness of this QI project, three primary measures are of interest. For all parts of the process change, percent calculations of pre and post-intervention statistics can be compiled. Provision and documentation statistics of pre-conception counseling, number of patients that are screened for urine or blood hCG, and collaborative care referrals for pregnant patients or patients wishing to become pregnant was tracked via the checklist. A checklist is the simplest method to immediately implement this process and measure changes. The checklist outlined process changes and allow for multiple staff to document whether or not steps are completed and why.

The first step for the checklist is to document how many patients receive the standardized tri-fold of educational materials. It is expected that all female patients ages 18-65 years with bipolar disorder are educated for all four of the staff providers. Providers are expected to disseminate the standardized tri-fold. Provider documentation was reviewed throughout the process change to areas for improvement. The number of patients provided standardized education can be documented by LVNs and providers. Education rates and documentation were tracked pre and post-intervention. Pre and post-intervention screening changes were measured in addition to changes in OBGYN referral and collaboration rates. Data trends and changes were disseminated to leadership in the OMHC and at the organizational level.

Secondly, space on the checklist was be dedicated to pregnancy screenings. Both verbal screening and quantitative testing were included. Both the “one key question” and blood or urine

hCG screening documentation was accomplished by provider or LVN staff. Although the LVNs are the primarily responsible for tracking initial screening, additional details can be added by the providers. Often times the providers have to order blood hCG depending on how the patient responds to pregnancy questioning during individual counseling. The LVNs complete focus reviews of systems for their patients.

Finally, follow up care was evaluated pre and post-intervention via chart review. Providers and CMs are responsible for patient connection with OBGYN care. The checklist included an area to document care bridge care set up. Providers and case managers were able to track the number of times patients needed to connect this population with community OBGYN care. The goal is that all female patients ages 18-65 with bipolar disorder receive proper pregnancy counseling when indicated. Associated metrics were tallied for each category pre and post intervention (see results).

Results

A total of 158 patient samples were collected over a total of 10 weeks from, 17 February through 24 April 2020. Descriptive statistics and frequencies were used to analyze all data in this project. 100% of patients were screened for pregnancy plan and offered the standardized educational material compared to 97% before implementation of this intervention. Table 1 and 2 specify patients by diagnoses and demographics of the sample.

Table 1*Patients by Diagnosis*

Diagnosis	<i>n</i> = 158
Schizophrenia/schizoaffective	29
Bipolar I	86
Bipolar II	12
Bipolar Disorder, Unspecified	20
Major Depressive Disorder	11

Note. Major depressive disorder and schizophrenia were included due to the use of similar medications being used to treat these patients.

Table 2*Patients by Age and Race*

Demographics	<i>n</i> = 158
Age	
18-29	30
30-39	41
40-49	49
50-59	34
60-79	6
Race	
Hispanic	85
Caucasian	48
African American	20
Mixed/Other	5

Table 3 outlines reasons that patients did not need additional follow up. The most common causes were menopause (20.9%), followed by hysterectomy (9.5%), then tubal ligation (7%), and birth control (8.2%). Nine patients refused further questioning. Two sets of eight patients each stated they had the same sex partner or were abstinent from sex. In total, 68% of

patients screened did not need follow up women's health care. The primary screenings were accomplished in the ROS section of the EHR by the two LVN project staff and follow up need was indicated by four provider staff. 39 of the 158 patients had urine or serum hCG lab tests within the last few months. Some of the sample patients refused screening procedure due to personal circumstances (single, not sexually active, etc.). However, this was unclear because documentation did not require providers specify these reasons and lack of access to first-hand provider-patient counseling. One primary reason many of the providers reported was that many patients already had children and families and said they did not plan to have more. In order to understand why certain patients did not receive testing or screening, further investigation could be done. There were likely reasons provided during the patients visit with the provider that testing was not needed.

Table 3

Reasons That Patient did not Need Follow-Up

Reason	<i>n</i> = 158
Post menopause	33
Surgical hysterectomy	15
Using birth control	13
Surgical tubal ligation	11
Currently menstruating	10
Refused program need	9
Abstinence from sex	8
Same sex partner	5
Irregular menses	3
Polycystic ovarian syndrome	1

Note. Patients currently menstruating were excluded from follow up. Birth control in this table was counted as using prescription methods from a provider.

Out of the 158-patient sample, 50 patients were identified as needing follow up. These 50 patients were forwarded to CM for follow up purposes via email or telephone that was provided by the organization's EHR. CM was able to reach 39 of these 50 via phone or email to find out their pregnancy plans for the future. Eleven patients reported they were not sexually active. Nine patients stated they used other birth control methods with their partners. Six patients reported they have same sex partners. Three reported seeing or having an OBGYN care provider already. One patient reported they were unable to have children but did not know why. Three clients stated they did not have an intimate partner. Two patients stated they adopted their children and did not plan to have their own children. Four patients were noted to need an OBGYN provider and were referred to one of the local clinics outlined in the educational tri-fold.

Discussion

The most important part of this QI project was the implementation of a pregnancy bridge program for patients. The major practice change for female psychiatric patients was the recommended inclusion of OBGYN health care. The project site did not offer this type of service previously. The provider staff were able to screen a large sample of patients over 10 weeks and provided important education and follow up as needed. These patients had the option to connect with pre-conception services in the community if indicated. The primary practice change at the microsystem level was utilization of a checklist to remind providers to screen for pregnancy intention. Ordering labs was accomplished per institution policy and at the discretion of provider counseling. From pre and post analysis, these rates showed an increase from data that was gathered prior to this intervention. Patients who did not have a recent pregnancy test were identified for follow up as long as they did not have some other reason (such as hysterectomy or tubal ligation). The core of this project was adherence to recommendations of the CDC and

ACOG and the highest levels of evidence found relating to process change. Literature focusing on patients with bipolar disorder involving a pregnancy care bridge was not found despite the clear evidence of this problem in research. Other studies primarily focus on depression and how it relates to pregnancy outcome.

Barriers and Limitations

Staff participation and adherence to methods was required for project success. The LVN staff was responsible for initiating the checklist on identified patients after they check in to the OMHC. Usually, the LVNs were responsible for tracking and accomplishing screening procedures, including one key question, and possibly either blood or urine hCG screenings on female patients. Finally, one CM was used to track and follow up with patients regarding OBGYN care. Accurate patient data for this project is required to provide useful information for the organization and nursing practice. Another barrier is the patients' right to refuse any part of the process by the LVNs or mental health care prescribers regarding pregnancy recommendations. In order to ensure process is maintained, weekly follow up and the DNP student gave feedback to staff even when social distancing was mandated.

Local clinic leadership was hesitant to sign off on project details and steps until higher tiers of the organization had approved. Even after the organizational leadership at their treatment team meeting approved the project, there was clear disconnection between the higher and lower levels of leadership. Only some staff at the local clinic were present for the TCC presentation. Most of the staff that participated in this project were not at the TCC presentation.

Time constraints for providers and project timeline for this project were a big barrier. Additional time would be optimal to capture more patients and work out kinks in the process as well as further clarify the project checklist. Many staff were resistant to using the checklist when

it came to implementation time. One of the LVNs stated, “I don’t have time for all that.” This LVN was subsequently dropped from the project and another prescriber was picked up for implementation. This LVN along with one of the provider staff gave the impression they did not have enough time to fill out the checklist.

The QI project site was a large, multi-tiered organization with many different departments and leadership chains. Implementation of anything outside a checklist would not be feasible due to time constraints. In order for something as simple as the addition of a prompt in the electronic health record (EHR) change would likely take months to pilot and eventually implement with this project site’s structural barriers. Ultimately, the addition of something in the EHR would possibly facilitate some aspects of the process change in the future.

Project staff required constant education and orientation to the goal of the project and use of the checklist and educational material. All providers had trouble understanding process changes and the goals of the project for several weeks. Most providers are scheduled with a patient every 30 minutes or hour during the day, making it difficult to follow up frequently. The checklist proved to be cumbersome and could continue being revised. One primary revision to the list was made to ease use for the providers (Appendix V). The checklist was simplified by creating common items so that providers could circle them and blank space and columns were reduced. Unfortunately, this new list was sent out right before the clinic changed its processes due to COVID19. In late March, provider guidance was no longer face-to-face throughout the week.

Another problem was provider turnover or absence. One of the initial providers went on pregnancy leave near the first week of implementation, so another prescriber staff was added in her place. Another provider went on vacation during the COVID19 outbreak and was unable to

return due to travel restrictions. Several staff also took paid time off during implementation of the project. Rotating schedules of providers and absenteeism affected the workflow and caused difficulty in accurate patient count. During the project, some of the project staff took paid time off or went on leave. One of the providers initially selected had to go on maternal leave. Another provider was out of town when travel restrictions went into place for COVID19. Staff selected for the project were regularly out of direct care at the clinic after the pandemic forced the organization to implement safety protocols. For these reasons, it is almost impossible to determine what an accurate count should be for this project.

Patient selection related to diagnosis codes were problematic and caused confusion among providers. Diagnoses such as schizophrenia, bipolar type (ICD-10 diagnosis code 25.0), were not anticipated as being part of the project but were included. Several patient checklists were filled out with diagnosis code of depression as well (ICD-10 diagnosis code 33.X). These patients should be included in future data collection as the educational material is applicable to all patients. There is a lot of gray area and overlap when it comes to psychiatric diagnoses, and many patients have symptoms of multiple disorders. Nonetheless, these patients should be included as additional education, screening, and provider collaboration still applies.

Obtaining data for this project was met with organizational resistance and large time requirements. Data requests to the organization's information technology (IT) department had to be approved by higher levels of leadership. The initial IT report requested took 2 months to receive. Even with this report, there were limitations on the data that was generated by IT. The center was only able to report boxes checked or very concrete data. Details in the notes of providers for patients included in the project were not able to be collected. Even with this report,

it was difficult to tell if primary diagnoses were captured, as patients often had many more than one.

The organization imposed regulation regarding student computer access. Computer and EHR permissions were limited due to student/non-essential staff status. This meant some functions were not available to the DNP student for data gathering. With computer access, retrieving EHR information was very tedious. After March 20, 2020, the DNP student collected data by going through one patient record at a time, viewing the ROS and provider evaluation notes. Many patients were unable to be contacted. Distinguishing how relevant cancelations, no shows, and other factors for data collection skew project data are difficult to discern.

There are hard to identify gaps in the data collected for this project due to inability to be present for provider counseling. A large portion of patients that did not have lab testing even though they met theoretical criteria. Likely, the information supplied by the patient to the provider indicated the patient did not need follow up for pregnancy plan. Providers often did not order hCG testing on their patients and it was unclear without further investigation and talking with the provider about the patient why this occurred. There are likely other reasons for why patients were not requiring testing, such as the patient not being sexually active. This type of information was not reflected in the patient chart. However, it is impossible to know all reasons without being present for every patient screening and visit. This setting had its own standardized window for lab testing, which was every year and sooner if indicated by the patient.

The Novel Coronavirus 2019

The novel coronavirus (COVID19) had tremendous implications in this project. The pandemic hit hard around mid-March in the United States, with most Texas cities shutting down large public gatherings. The outbreak caused most medical facilities, including this project site,

to focus on changing structure and taking safety precautions to avoid spread of the virus. Leadership of this organization first called for limitation of student in house hours and internships starting on March 20, 2020 (see Appendix Q). After this point, contact with the project site and project staff was conducted through email and phone since most staff were teleworking from home. Furthermore, staff roles were changed as described below.

At this OMHC, a screening tent was set up at the front of the building to screen patients for the symptomatology related to COVID19. Starting the week 6 of implementation (March 23, 2020), both of the LVN and RN staff selected and spearheading the ROS/screening part of the project had to take turns sitting in this tent to do screening for the new virus. From then on, both project staff were only doing vital signs for patients and told by clinic leadership not to perform patient focused ROS. Initially, the LVN staff would screen the patient and do any lab collection needed. As of the 23, these staff reported only doing vital signs for patients and outdoor COVID19 screening.

Clinic prescribers were transitioned to tele-health only. On March 23, 2020, all providers started seeing patients via phone or video call. The providers were also rotating shifts; one week they would be in clinic and the next they would be at home conducting patient interviews via telehealth. The complete absence of face-to-face time made giving patients meant predesigned educational material had to be emailed to patients. In addition, provider caseloads were able to be determined via remote access EHR starting March 23, 2020 for this project. Some patients did not have emails in the EHR for providers. The clinic staff was able to adapt to send information to people without face-to-face contact. Access to phone or email for some patients was also problematic during the pandemic. Some patients were not able to obtain or receive education or counseling as they did not answer their phones or provide email addresses.

The primary issue with the pandemic was lack of person-to-person contact. Verbal counseling and in person services are no doubt better for patient outcomes. Services such as blood draws and injections were accomplished for those patients that absolutely needed to come into the clinic. Due to the clinic's changes, the project was transitioned to online only after March 20, 2020. All patient data was gathered from with one or two providers after this date, as the DNP student was able to contact all providers via phone and email. Updates for the project staff were conducted via phone and email primarily. Brief follow up in person at the OMHC was allowed from time to time.

Recommendations

Capturing this highly specific population of expecting mothers struggling with mental disorders remains elusive. This is in large part due to the nature of pregnancy planning by the public. This project made it clear these clients will always be difficult cohort to study. Meeting goals for this process change require continued testing and reevaluation to determine effectiveness and best implementation. To continue implementation of this project, the organization must continue to promote the project resources and make them easily accessible for staff and patients. Another full-time employee could conduct care coordination and proper follow up. Furthermore, provider completion rates depend on consistent education and involvement from all levels of leadership.

The checklist used in this project was updated once and could be further refined in the future. Unfortunately, time constraints and retraining staff make this difficult. With additional time and organizational buy in from all levels, it would be ideal to implement this project as part of the EHR. Changes in the clinic's EHR would streamline this process change. However, before piloting implementations and revising the process over time, it would be unclear how to

implement a change in the EHR. Data specialists, the EHR, and the organization would have to confer. More data and time would aid in determining whether this type of change is indicated and how best to accomplish these goals. There would be lengthy time and testing requirements outside of the scope of the timeframe for this process change. A standing order set would be required for all patients to have blood or urine pregnancy testing. However, this is clearly not necessary for most patients. Testing and follow up is left to interaction between the patient and provider and without witnessing all that happens during counseling, it is very difficult to determine appropriate follow of these patients.

This project demonstrated how difficult it is to establish and capture patients for this type of following for many reasons. Firstly, appointments tend to be every month or more. It is possible that women will become pregnant in between appointments. The data collected here provides a single snapshot, while effective follow up need to be continuous. Therefore, it would be difficult to ensure these patients receive proper care at one point in time. Even if testing and follow up was done at the time of this project, things could easily change for the patient in the future. Much responsibility lies on the individual, as healthcare providers spend so relatively little time with their patients. Covering all patient needs will always be difficult.

All patients, regardless of age and diagnosis, should be interviewed for pregnancy plan. By no means, should only patients with a certain diagnosis receive pre-pregnancy counseling. Both men and women should be educated and followed for risk. The more patients that are educated regarding the known risks of medications, the better the community outcomes will be for this community. Research has shown that many medications are transported in body fluids (Grover & Avasthi, 2015; Stahl, 2017) and affect fetal outcomes.

Pre-intervention, medication consent forms were accomplished on 97% of patients. The purpose of this form is to serve as proof the patient gave consent to take medications which may cause harm to the fetus. The consent information is in accordance with guidelines by the ACOG, is meant to advise patients of the risk of medications, and recommends future mothers find a primary care provider for women's health purposes.

The sustainability of this DNP project is dependent on the staff and organization overcoming barriers and refining the process. The pilot program results suggest the importance of refining the process and regular staff training. It is critical that staff understand how to use new materials and the goal of new processes. Further staff teaching about the importance of depression screening, the impact on patient outcomes, and meeting national accreditation guidelines and recommendations may further improve the likelihood of project sustainability. Continuous assessment of staff adherence towards new interventions can further succeed completion rates of the GDS. Additionally, developing ready-made admission and discharge packets to include the GDS and depression education handouts may improve the rate of completion by nursing staff upon patient admission and discharge.

Implications for Practice

Due to the nature of mental illness and its ramifications, this population remains elusive when it comes to pregnancy plan and ease of follow up. Many patients with mental health disorders are homeless or in another living situation which prevents effective planning and or follow up. Hypersexuality and unplanned pregnancy and is a frequent characteristic of bipolar disorder and is likely part of the problem resulting in high unplanned pregnancy rates (Dinc et al., 2019).

Revision of checklists is critical and described by the ACOG (2016) in order to improve and streamline processes in development. Several changes to the checklist could be made to decrease provider workload and confusion. Design changes such as including more options for providers to circle and write would reduce workload and improve ease of use for project staff. There were also several useful data points that were originally omitted from the checklist for this project that were obtained through lookup in the organization's EHR. This included, age, ethnicity, and gender that were added to the checklist revision.

Originally, the idea was to conduct urine hCG tests on all females for pregnancy. This would require a standing order set as providers ordered tests depending on patient history and interview responses to pregnancy planning questions. Results from this project show that hCG positive rates would be very low on a large sample. After a few weeks of data collection for this project, it was evident that urine screening for most patients is not necessary. Even when hCG testing was accomplished, it is hard to say what a sufficient window of time is. Patients tested the day of appointment could become pregnant tomorrow. The data from this project provides a screenshot of data, whereas these patients should be continuously followed. A larger sample would result in more patients needing follow up and planning care.

This organization could hire one full time employee to conduct follow up for pregnancy planning for their patients. Only four providers were selected for this pilot, so following all patients from all providers would result in many times the sample amount in this DNP project. Tracking and following up properly with all of the patients that come through this clinic would at least require another full-time employee. It is clear a select few patients need further monitoring. Therefore, process change in the future is still appropriate, due to the lack of a pregnancy care bridge at this project site. However, as outline previously, there are many ways to improve the

methodology. At the very least, this project encourages providers to provide more comprehensive pre-pregnancy planning.

This project is a good example of where the DNP degree fits into real applications. The DNP is beneficial for organizations that wish to increase patient health and have clinically focused problem solvers. DNP prepared nurses can look critically at practices that need change, identify gaps in knowledge, and work to bridge these chasms to improve organization flow and health outcomes. This requires nurses be familiar with clinical care, examine the highest tiers of literature, and identify those guidelines that need to be integrated into routine.

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Appendix A

Standardized Tri-Fold (Front)



Pregnancy Planning

It is critical to let your provider know if you plan on becoming pregnant, are sexually active, or are pregnant. Many medications used to treat mood disorders can cause problems for a developing fetus.

The most important thing to do is to tell your mental health provider. An individualized approach to pregnancy is critical.

Along with mental health specialty care, obtaining an OB/GYN specialist is best practice. Please ask your health care provider or case manager for help obtaining care from a specialist in maternal care if needed!

MEDICATION SAFETY

Please get in contact with an **OBGYN** if you happen to become pregnant or become sexually active! **Local centers** that provide this care are located in this tri-fold.

Many commonly prescribed medications might be harmful during pregnancy. Please ensure that you and your mental health provider review your **medication consent**.

Common medications to treat **bipolar disorder** include:

- Abilify—Depakote—Geodon**
- Lithium—Lamictal—Latuda**
- Rexulti—Risperdal—Seroquel**
- Tegretol—Vraylar—Zyprexa**



COMMON METHODS OF CONTRACEPTION

Barrier Methods

Diaphragm or cervical cap— placed inside the vagina.

Sponge—Contains spermicide and is placed in the vagina where it fits over the cervix.

Male condom—Worn by the man, a male condom keeps sperm from getting into a woman's body.

Female condom—Worn by the woman, the female condom helps keeps sperm from getting into her body.

Spermicides— Foam, gel, cream, or film that kill sperm and come in several forms—foam, gel, cream, film, suppository, or tablet in the vagina before intercourse.

Other methods are more effective on average, such as **tubal ligation** or **regular hormonal controls**.

Emergency contraceptives should only be used as last resort!

Please see the **Centers for Disease Control and Prevention** Website for more reproductive health & contraception methods including

Appendix C

Original Project Checklist

PROJECT CHECKLIST			Case number: _____	Provider: _____
Staff, please provide for all female pts age 18-65 with Bipolar Disorder (F31.X)			Date	
			Time	
TASK	RN/LVN	PROVIDER	CASE MANAGER	Comments
All female patients 18-65 with dx code of F31.X need the educational tri-fold.				
Provided tri-fold	YES / NO	YES / NO		
Any questions from pt?				
Pt refused; please explain				
All female patients 18-65 with dx code of F31.X need a screen for pregnancy.				
One Key Question	YES / NO	YES / NO		
Urine hCG				
Blood hCG				
Pt refused; please explain				
All female patients 18-65 with dx code of F31.X need a pregnancy plan and OBGYN.				
Communicare Medical Center				
The Source SA				
Metropolitan Women's Campus				
Other				Patient already has OBGYN, etc.
Follow up completed				Pt was contacted after visit r/t pregnancy follow

Appendix D

Revised Project Checklist

PROJECT CHECKLIST (V2) For female patients age 18-65 with Bipolar Disorder F31.0 - F31.9	Date: _____
	Case # _____
	Provider: _____
	Pt Age: _____
	Pt Ethn: Cauc AA Hisp Other
	ICD-10 Code: F31. _____
Question	Response
1) Does pt need pregnancy counseling?	Please circle: Abstant Birth Control Hysterectomy IUD Menopause Tubal Ligation Other reason:
Provide patient with educational material!	Stop! Proceed to (2) if none of the above circled!
2) Does the pt need screening?	Please circle: Blood hcG Urine hcG Test date:
In addition to the ROS/one key question	Stop! Proceed to (3) If the pt needs at test, please order!
3) Does pt need follow up?	Please circle: Communicare (Med center) The Source (SA) Metropolitan Women's Campus Pt already has OBGYN Other:
	Pt needs case managment r/t pregnancy follow-up!

Appendix E
Letter of Support



Where hope and healing begin.

Date: January 24, 2020

BOARD OF TRUSTEES

To Whom It May Concern;

Daniel T. Barrett
Chairman

Adam Barnett, University of Incarnate Word DNP student, has presented a proposal to the Center for Health Care Services Treatment & Care Council to complete a quality improvement project titled "Pre-pregnancy Education, hCG Screening and OBGYN Bridge QI Initiative."

Mary Rose Brown
Vice Chairman

Student has provided a letter indicating this project does not meet federal regulatory requirements for human subject research and does not require approval via the IRB process. This project is deemed to be not regulated research and no identifiable or personal health information will be shared.

Donnie Windham Whited
Secretary

Margaret A. Kelley, M.D.
Treasurer

Required approvals have been met for Adam Barnett to proceed with this project.

Graciela A. Cigarroa
Hon. Laura L. Parker
Hon. Polly Jackson Spencer
Richard P. Usatine, M.D.
Margaret M. Vera

Sincerely,

Sam Williams, Jr.
Member Emeritus

Rene L. Olvera, M.D., M.P.H.
Chief Medical Officer
The Center for Health Care Services
Professor and Vice-Chairman for Community Psychiatry
UT Health San Antonio
Ph. (210) 261-1007

Ira Smith, Jr.
Member Emeritus

Jelynn LeBlanc Burley
President
Chief Executive Officer

Appendix F**Statement of Non-Research**

11/13/2019

Project Lead: Adam Barnett

Project title: Pre-pregnancy education, hCG screening and OBGYN bridge QI initiative

Adam:

Your project titled Pre-pregnancy education, hCG screening and OBGYN bridge QI initiative was deemed to be **Not Regulated Research**.

Your proposed project was reviewed and found to not meet federal regulatory requirements for human subject research and does not require approval via the IRB process. Please use the IRB number **NRR [19051]** when inquiring about or referencing this determination.

No further review of the project as proposed is required. Should you determine at any point you wish to add additional elements to the project, please contact us before initiating those components, as this may impact the determination.

For information regarding the IRB or the review process, please contact me at (210) 805-5885.

Sincerely,

[Ana Hagendorf, PhD, CPRA](#)

Ana Hagendorf, PhD, CPRA

Director, Office of Research and Sponsored Projects Operations

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