12-14-2018

Use of Antipsychotic and Mood Stabilizing Medication in Pregnancy

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An Independent Study

Submitted to the Graduate Faculty

of the

University of North Dakota

in partial fulfillment of the requirements

for the degree of

Master of Science

Grand Forks, North Dakota

December

2018

Abstract

The case to be explored is a 22 year old female who presented in a psychotic state after stopping her medication to treat symptoms of mania associated with bipolar disorder. Methamphetamine was also being used and contributed to the psychotic state. The patient was found to be pregnant upon assessment. Treating a psychiatric disorder during pregnancy can be difficult, as many antipsychotic and mood stabilizing medications are not well studied during pregnancy and some are known teratogens. The Psychiatric Mental Health Nurse Practitioner (PMHNP) is challenged with treating the patient and her developing fetus, choosing a medication that will cause the least amount of risk to the patient, and also cause the least chance of fetal anomalies related to medication exposure in utero.

Keywords: antipsychotics, mood stabilizing, pregnancy, teratogens, anomalies, fetus, bipolar, psychotic, mania, medication, Psychiatric Mental Health Nurse Practitioner, PMHNP

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Background

Over half of all pregnancies that occur are unplanned. Psychiatric disorders, such as bipolar disorder can cause patients to engage in risky sexual behaviors. The use of illicit drugs can also increase the chance that a patient will engage in risky behaviors that they may not have previously when sober. All of these situations can cause providers to be faced with a challenging case of prescribing antipsychotics and mood stabilizers during pregnancy, whether it be a planned or unplanned pregnancy.

The provider must be confident in treating a psychiatric patient and have education regarding what medications would be the safest for the expectant mother and the developing fetus. A patient encountered during a clinical experience with a history of bipolar disorder and methamphetamine use was found to be pregnant. The patient was unaware of the pregnancy. The patient was not taking her prescribed psychiatric medication and was in a psychotic state where she was having command hallucinations telling her to harm herself and others. This led to the patient needing medication to keep both her and her fetus safe.

Many medications have been identified as being unsafe to use during pregnancy because of the risk of harm and side effects to the fetus. Previously, medications were given a letter grade to identify how safe or risky a medication was to use during pregnancy based on risk to the fetus. As of June 30, 2015, the Federal Drug Administration (FDA) has decided to phase out and remove the letter grading for prescription medications (Stahl, 2017). Prescription drugs will now be labeled according to the Pregnancy and Lactation Labeling Rule (PLLR), which has the goal of creating safer and more effective use of all prescription medications in women who are at child bearing age, lactating, or are pregnant (U.S. Food and Drug Administration, 2018).

When prescribing medication to pregnant, lactating, and even women of child bearing age, the benefits of using the medication must outweigh the risks of not using the medication during this time. There are ethical considerations when using a pregnant woman in a controlled study regarding medication, so there are very limited studies regarding various medications in pregnancy. Data obtained in the literature review often came from various medication registries that were created for providers who could report any defects or anomalies from medications used during pregnancy. This information then educates providers on choosing medications when benefit of using the medication outweighs the risk of no medication used.

Patient Case Report

*Note that some information is intentionally left blank to respect patient privacy.

Identifying Information: S.B. was a 22-year-old Caucasian female who was single and lived in a small rural community with her dad and step-mother infrequently. Many times she was homeless. S.B. was brought to clinic with local law enforcement and Emergency Outpatient Department (EOD) Registered Nurse (RN).

Chief Complaint: "Someone is telling me to cut your throat. I'm going to cut my throat."

History of Present Illness: S.B. was initially diagnosed with Bipolar I Disorder when she was 18-years-old. She has been tried on several medications since the time of diagnosis. S.B. has been unreliable with taking her medication and completing follow-up appointments with the mental health care provider. Early last year, S.B. was brought to the local EOD after displaying erratic and psychotic behaviors. In the EOD, S.B. requested multiple times to leave. She was placed on an emergency hold for the safety others, as well as herself. In the EOD she was given a 'B-52' intramuscular injection of Haloperidol (Haldol) 2 mg, Diphenhydramine (Benadryl) 50 mg, and Lorazepam (Ativan) 2 mg. The medication concoction did calm her down that night in the EOD

and she was able to sleep for a few hours. Blood was drawn and a urine specimen was obtained for testing and it was discovered that she was positive for methamphetamines and tetrahydrocannabinol (THC) at the time. Urinalysis also confirmed a positive pregnancy test; this information was withheld from the patient at the time until she could be assessed by the Psychiatric Mental Health Nurse Practitioner (PMHNP) in the clinic the following Monday morning. Upon an escort from the EOD to the clinic with law enforcement and EOD staff nurse, S.B. was assessed by a PMHNP for emergency hold review and medication recommendations.

Past Psychiatric History: S.B. was hospitalized for inpatient care for one month following overdose on quetiapine (Seroquel) last spring. She had no previous history of self-injury or homicidal thoughts. Previous medication trials include Aripiprazole (Abilify), quetiapine (Seroquel), escitalopram (Lexapro), bupropion (Wellbutrin), olanzapine (Zyprexa), clonazepam (Klonopin). S.B. was started on medication to target depression when she was 16 years old. She complained of side effects including weight gain and was not compliant with taking medications for long periods of time. The effectiveness of the medications were questionable, as S.B. was using methamphetamines since 18 years old, which would cause her to hallucinate. S.B. was vague in regards to a timeline of her past psychiatric medication history.

Substance Use and Addiction: History of methamphetamine misuse since 18 years old and marijuana misuse since 16 years old. No history of chemical dependency treatment. No history of withdrawal symptoms.

Family Psychiatric/Chemical Dependency History: Biological mom diagnosed with Bipolar I Disorder and substance abuse. Biological dad with a history of substance abuse.

Social History: S.B. was born and raised in a small rural community. Parents were divorced and she had been living with her dad and step-mom infrequently. S.B. graduated from high school and did not attend college. She had no issues with meeting developmental milestones. No history of abuse or neglect. Patient is currently homeless when she was not staying with her boyfriend or parents. She has had periods of having her own apartment and paying rent with money she had made selling tickets and working at a concession stand at a recreation area. S.B. is currently employed at the recreation area and has held this part-time job for approximately the last year. She relies on her dad and step-mother for financial support.

Legal History: She has multiple traffic violations with a current open case with charges pending that do not allow her to be hospitalized for psychiatric care across state lines. Legal charges include shoplifting, driving under suspension, and speeding. No history of violent or assault charges.

Current Medications: She is not currently compliant with medication and had last been prescribed olanzapine 10 mg daily by mouth and quetiapine 200 mg daily by mouth. It was unknown when she last took this medications was

Current Labs/Studies: Positive for amphetamines and THC. Positive urine pregnancy test.

Mental Status Exam: Upon assessment by the PMHNP, S.B. was wearing a Post-It note over an eye and a surgical mask over her mouth; appearance is disheveled. She is fidgety and hyperactive during assessment and does not make eye contact during much of the assessment. She was dressed in hospital scrubs. S.B. was oriented to self only. S.B.'s mood was labile. Attention and concentration were scattered and variable. Speech was pressured upon assessment. S.B. presented with paranoid delusions and auditory hallucinations of voices telling her to kill herself by cutting

her throat open. She was homicidal and had auditory hallucinations of voices telling her to cut the throats of others around her to kill them. S.B.'s thoughts were racing and disorganized; associations were loose, which made it difficult to gather full assessment information. S.B. reported that she had stopped taking her medication "months ago". Judgment and insight were poor. S.B. was tearful after being told that she was pregnant.

Impression: S.B. was not stable at this time. She was psychotic and under the influence of amphetamines. She did not know that she was pregnant and cried when she was told the information. It was determined she was a danger to herself and others and required inpatient psychiatric care.

Diagnosis: (F31.2) Bipolar I Disorder, with psychotic features. (F40.10) Generalized Anxiety Disorder. (12.10) Cannabis Use Disorder, mild. (15.20) Stimulant Use Disorder, severe, amphetamine-type stimulant.

Treatment Plan: S.B. continued under the emergency hold and was then transferred to a Minnesota inpatient psychiatric facility under commitment. After review of the most appropriate medication for the treatment of target symptoms present with current pregnancy status, it was determined to treat S.B. with olanzapine 10 mg by mouth daily. This was prescribed for treatment of psychotic symptoms. Lithium 300 mg by mouth BID was prescribed to treat her symptoms of Bipolar I Disorder. Medication risks, benefits, and side effects were reviewed with the patient. There was a plan to check her Lithium level in one week. Prenatal assessment for care of the fetus was provided in the EOD prior to transfer to psychiatric facility. S.B. will follow up with PMHNP in the outpatient clinic after discharge from the inpatient psychiatric hospital.

Literature Review

Mental Illness and Pregnancy

Studies have shown that 8% of women in the United States from ages 15 to 54 years old have a severe mental illness, including, but not limited to bipolar disorder (Allison, 2004). If a woman with a mental illness currently is stabilized on psychotropic medication and she discovers that she is pregnant, stopping the psychotropic medication puts her and the fetus at immediate and long-term risk of re-emergence of psychiatric symptoms. This can include, though are not limited to having hallucinations that command the woman harm herself and/or the fetus, harm others, engaging in risky behaviors, and engaging in drug or alcohol use. Depending on what psychiatric medication is currently being prescribed, continuing the medication could put the fetus at the risk. It is essential for the provider to determine what medication is appropriate for treating the woman's psychiatric disorder, while determining which medication is associated with the least risk of fetal anomalies.

With data that shows that more than half of all pregnancies are unplanned, it is important that the providers educate women about the risks of taking psychotropic medications during pregnancy. Providing medication education when first prescribed to the child-bearing aged woman is best practice (Galbally, Snellen, Walker, & Permezel, 2010; Howland, 2009; Wichman, 2016). Women in the window of reproductive ages who are educated about the risks of medications during pregnancy are better able to make decisions regarding birth control or switching to a different medication with decreased risks of causing fetal anomalies.

Severe mental illness, such as bipolar often require the use of more than one psychotropic medication, including mood stabilizers and antipsychotic medication (Kimmel, et al., 2016). This can make the prescribing of medication during pregnancy more complicated when deciding on the

safest medication to utilize based on side effect profile and efficacy. Women who have been tried, and possibly have failed on multiple mood stabilizers or antipsychotics may have a difficult time deciding on what will be best for their mental health and the health of their unborn child. Empowering women to make the best and most appropriate choice in this situation is essential. A multi-disciplinary approach can be beneficial for women during this time. Psychiatric providers, PMHNPs, and social workers can work together to help women with their ambivalence and specific concerns regarding the use of medication during pregnancy (Bentley, Price, & Cummings, 2014).

Determining the use of Psychotropic Medication in Pregnancy

Women taking psychotropic medications to prevent the relapse of symptoms of a mental illness must make the decision to continue these medications into pregnancy based on their own physical and mental health, as well as the health of their offspring. There can often be contraindications between the two decisions (Allison, 2004). Safety of the mother and the developing fetus must be taken into account by all providers who are assisting in care. Care requires a multidisciplinary approach, including the mental health provider, obstetrical/gynecological provider, and community support services (Galbally, Snellen, Walker, & Permezel, 2010). Toh, et al., (2013) have identified that it is beneficial to both the expectant mother and the developing fetus to treat the mother's psychiatric symptoms during pregnancy. Treatment during pregnancy involves the psychiatric illness, risks and benefits of the psychiatric medication to be used, and the risks or benefits of leaving the psychiatric illness untreated during the pregnancy.

Fetal Anomalies with Psychotropic Medication Use

Whatever medication is chosen to use or continue during pregnancy to prevent relapse of psychiatric symptoms, the lowest dose that is possible to relieve symptoms for the shortest period of time possible should be used (Allison, 2004; Howland, 2009). Smaller doses for shorter periods of time can decrease the risk of malformation of the developing fetus. Allison (2004) has identified that the incidence of anomalies caused by psychotropic medications in general is low, at 2-4%, whereas the baseline of anomalies in the United States, regardless of medication use during pregnancy is 2.5%. Technically, there are no medications that do not cross the placenta and all medications carry the risk of teratogenic effects (Allison, 2004). Behavioral and physical anomalies may be present at birth, but some have been found to manifest later in life (Allison, 2004).

The fetus is exposed to a higher level of the psychotropic medication in utero due to the medication passing through the placenta. This occurs through decreased protein levels, which allows more of the drug to be unbound and enter the fetus. The fetus has a decreased metabolism, immature nervous system, and immature liver enzymes, all of which can be affected by the passage of medication to the fetus (Kulkarni, et al., 2008). With immature development of bodily systems, the fetus is at risk of greater exposure to the psychotropic medication, which can potentiate negative side effects such as future anomalies.

Mood Stabilizer use in Pregnancy

Antiepileptic medications such as Depakote and Tegretol have been used in psychiatric patients as a mood stabilizing medication. There has been research done to support these medications cause cause neural tube deficits, specifically spina bifida, when taken during pregnancy. The risk of this defect is especially high during the first trimester when organs and

limbs are developing. Both of these medications should be avoided in pregnant women requiring the medication for mood stabilization (Allison, 2004; Galbally, Snellen, Walker, & Permezel, 2010; Howland, 2009; Wichman, 2016). Depakote has the highest instance of consistently resulting in an anomaly, at 8.7% (Galbally, Snellen, Walker, & Permezel, 2010; Howland, 2009) and Lamictal has been found to have the lowest risk of anomalies. Lamictal could be used if no other mood stabilizing medications can be used (Howland, 2009; Wichman, 2016).

Lithium has been found to be the safest mood stabilizing medication to use during pregnancy. In studies done on the use of Lithium during pregnancy, there have been no behavioral anomalies present in later life (Allison, 2004; Stahl, 2017). There also have not been any differences in intelligence quotient (IQ) in children exposed in utero to Lithium to those who were not exposed to Lithium in utero (Wichman, 2016). Physical anomalies related to fetal Lithium exposure have been found to include Ebstein's anomaly, neonatal hypothyroidism, goiter, nephrogenic diabetes insipidus, hypoglycemia, increased birth weight, polyhydramnios, and floppy baby syndrome (Allison, 2004; Galbally, Snellen, Walker, & Permezel, 2010; Stahl, 2017; Ward & Zamorski, 2002; Wichman, 2016).

Ebstein's anomaly is the most frequent side effect related directly to intra-utero Lithium exposure. This risk of Ebstein's anomaly is 400 times the normal rate in a fetus exposed to Lithium than one that is not, or 0.05 to 0.1% more likely (Allison, 2004; Galbally, Snellen, Walker, & Permezel, 2010). 1 to 2 infants out of every 1,000 with exposure to Lithium in utero compared to 1 infant out of 20,000 without exposure to Lithium in utero developed Ebstein's anomaly (Ward & Zamorski, 2002; Wichman, 2016).

Ebstein's anomaly is a heart defect where the right atrium is separated from the right ventricle by the tricuspid valve, which allows unoxygenated blood to flow into the body

(Cincinnati Children's Hospital Medical Center, 2018). Ebstein's anomaly can be surgically fixed following delivery and is not considered to be a long term defect (Cincinnati Children's Hospital Medical Center, 2018; Wichman, 2016).

To decrease the incidence of cardiac anomalies, Lithium should not be taken from days 18 to 55 after conception (Allison, 2004). As previously identified, over half of pregnancies are unplanned, making this very difficult to determine (Galbally, Snellen, Walker, & Permezel, 2010; Howland, 2009; Wichman, 2009). Stopping the medication during this 37 day period increases the risk of a relapse of symptoms, thus exposing the fetus to indirect exposure to mental illness and dangerous activities, such as drug use, alcohol use, or self-injurious (Allison, 2004; Howland, 2009). Women with bipolar who stop taking their mood stabilizing medication "are more than twice as likely to relapse in pregnancy (85.5% vs 37%) and are ill for fivefold longer during their pregnancy than those who continue their medications" to treat their mental illness (Galbally, Snellen, Walker, & Permezel, 2010, p. 100).

For the reason that stopping the medication may not be beneficial, or is determined to cause the least amount of harm to the woman and fetus, fetal ultrasounds and echocardiography should be done at 16, 18, 20, and 22 weeks of pregnancy (Allison, 2004; Galbally, Snellen, Walker, & Permezel, 2010). Pregnancy causes many changes to the woman's body, including fluid shifts, increased glomerular filtration rate, and increases in blood volume. All of these bodily changes may lead to sub-therapeutic Lithium levels, so it is important to monitor Lithium levels carefully during the entire pregnancy. At times, higher doses of Lithium may be needed (Allison, 2004; Galbally, Snellen, Walker, Permezel, 2010; Wichman, 2016).

During the third trimester, gastric motility and emptying can decrease. The ability of Lithium's capacity to bind can decrease. Also during the third trimester, fluid volume and hepatic

metabolism increases. Lithium level should be monitored monthly and then weekly at 36 weeks gestation to see if a dosage increase or decrease needs to be made based on the woman's fluid levels (Galbally, Snellen, Walker, & Permezel, 2010).

The most common fetal issue following Ebstein's anomaly is floppy baby syndrome, which is hypotonia, or decreased muscle tone that is present immediately at birth (WebMD, 2015). To prevent floppy baby syndrome, the expectant mother should stop the Lithium 24-48 hours prior to delivery (Galbally, Snellen, Walker, & Permezel, 2010; Stahl, 2017). If the risk of stopping the Lithium prior to delivery outweighs the benefits, it is recommended that the Lithium dosage then be decreased to the dose that was used prior to pregnancy, or decreased by two-thirds of the pre-pregnancy dose (Wichman, 2016). It is important that the expectant woman be hydrated with intravenous fluids consistently during the time of delivery, as well as immediately after delivery (Wichman, 2016). If Lithium toxicity of the infant is suspected, cord blood should be tested to determine the Lithium level in the cord blood (Galbally, Snellen, Walker, & Permezel, 2010). The infant and the mother should be closely monitored following delivery regardless of what medication side effects were or were not present, as side effects and withdrawal symptoms can occur quickly.

Antipsychotic use in Pregnancy

There is conflicting information from studies regarding the safety of antipsychotics use during pregnancy. Some studies have found that there is an increase in congenital malformation, but others have not found a link between antipsychotic use and fetal anomalies (Toh, et al., 2013). Up to date studies have identified there is an increased chance of an infant being stillborn, being larger or smaller for gestational age, or being born prematurely if exposed to antipsychotics in utero (Wisner, Jeong, & Chambers, 2016). Information that is available on the use of

antipsychotics during pregnancy is often limited to atypical antipsychotics (Margulis, Kang, & Hammond, 2014).

While the incidence of fetal malformation related to antipsychotic use in pregnancy is not well studied, a recent study done on 1,341,715 pregnant women found that there was not an increased risk of a congenital anomalies, including cardiac malformation with the use of atypical antipsychotics. Only risperidone was found to have an increased risk of congenital fetal malformations (Huybrechts, et al., 2016; Wisner, Jeong, & Chambers, 2016). According to the study by (Wisner, Jeong, & Chambers, 2016), the increase in the fetal risk of anomalies with risperidone has been linked to the CYP 2D6 pathway for metabolism. Fetal risks associated with risperidone includes abnormal muscle movements and withdrawal following delivery (Stahl, 2017). With this current data and information in mind, the use of aripiprazole, quetiapine, olanzapine, ziprasidone, or clozapine can be used when the small risk of an anomaly outweighs the risk of leaving a psychiatric disorder, such as bipolar, untreated during pregnancy (Huybrechts, et al., 2016; Wichman, 2016).

Atypical antipsychotics are often times added to the medication regimen of someone presenting with bipolar, such as with the patient case example. There are few studies available on the use of antipsychotics during pregnancy and the risks of an anomaly. It has been found that atypical antipsychotics, such as olanzapine are much safer for the fetus than typical antipsychotics during pregnancy (Allison, 2004; Galbally, Snellen, Walker, & Permezel, 2010).

There is the risk of weight gain when taking an antipsychotic. Weight gain can lead to further complications during pregnancy including diabetes, high blood pressure, and high cholesterol (Kulkarni, et al., 2008; Stahl, 2013, 2017). Pregnant women taking atypical antipsychotics, such as olanzapine have a chance of delivering a greater weight baby and

developing gestational diabetes (Galbally, Snellen, Walker, & Permezel, 2010; Gentile, 2008; Kulkarni, et al., 2008). Laboratory tests during pregnancy should include a glucose tolerance test between 14-16 weeks gestation and a glucose challenge test at gestation week 28 to identify a high risk illness during pregnancy (Galbally, Snellen, Walker, & Permezel, 2010). Additional monitoring of the expecting mother should include blood pressure, weight, body mass index, and lipids to identify any high illnesses early during the pregnancy (Wichman, 2016).

Upon delivery, there is a small chance that the infant will have transient extra-pyramidal effects and sedation when exposed to antipsychotics (Galbally, Snellen, Walker, & Permezel, 2010; Ward & Zamorski, 2002). These transient symptoms of extra-pyramidal effects will typically cease after the infant reaches age 10 months (Kulkarni, et al., 2008). There have been some identified cognitive, motor, social, and emotional delays in infants exposed to antipsychotics. These delays have been transient and typically disappear by age 12 months of age (Wichman, 2016).

S.B's Pregnancy and Medications

S.B., a 22 year old female is at the age where the chance of planned or unplanned pregnancy is a possibility, regardless of mental health status. When a diagnosis of bipolar is added into the patient's psychiatric background, there is the risk of increased sexual promiscuity during a manic episode (American Psychiatric Association, 2013). This further increases the risk for an unintended pregnancy.

Psychiatric symptoms take a toll on the woman's emotions, ability to function in daily activities, ability to achieve appropriate prenatal care, and their ability to differentiate between appropriate behaviors and those that are considered dangerous (Ward & Zamorski, 2002). When bipolar disorder is left untreated and without mood stabilizers or antipsychotics during pregnancy,

a woman with bipolar disorder has a greater chance of emerging symptoms that interfere with appropriate prenatal care, use of harmful substances, premature delivery, decreased or increased infant birth weight, infant growth retardation, antepartum hemorrhage, fetal distress, cardiac anomalies, eclampsia, and stillbirth risk (Allison, 2004; Dresner, Byatt, Gopalan, Miller, & Sachdeva, 2015; Galbally, Snellen, Walker, & Permezel, 2010; Gentile, 2010; Wichman, 2016).

In order for a woman to achieve their maximum ability for self-care and care of their developing fetus, the PMHNP should ensure that the patient is being appropriately assessed for what services are needed during the pregnancy. Assessment includes obtaining information from previous psychiatric episodes and the severity of each, which psychiatric medications worked and how well the medication worked for their psychiatric illness (Ward & Zamorski, 2002). "The most important consideration is the patient's past level of function when not taking medications" (Ward & Zamorski, 2002, p.632).

Implications for Practice, Research, and Education

To better provide care for patients who are diagnosed with a psychiatric illness, it is important that PMHNPs are up to date on current research about various diagnoses, treatment options, and medications. Psychiatric patients are a unique group of patients, which can be further complicated when a woman with a psychiatric illness become pregnant. Women of child bearing age should be educated at each visit regarding pregnancy risks, birth control, and the risks that go along with psychiatric medications prescribed for their treatment. PMHNPs should ensure that the safest treatment option is used during a woman's pregnancy. This includes a treatment option that decreases the risk of re-occurring psychiatric symptoms that place the mother and developing fetus at risk, as well as the benefit of using a known teratogenic medication outweighing the risk of. If the patient allows, the PMHNP should also be educating

the family members who are involved in the patient's care. Education should be provided in writing and verbally. Each encounter should include documentation of understanding of the information provided for the treatment plan.

As previously discussed, it would be beneficial to have further data regarding the safety of mood stabilizing and antipsychotic medication use during pregnancy. To educate future and current PMHNPs and providers regarding the risks and benefits of psychiatric medication during pregnancy, the PMHNP could speak at conferences and participate in research. The PMHNP could gather data, perform studies, and complete literature reviews based on this important topic.

The PMHNP should keep in close contact with the patient's obstetric/midwife provider. This ensures that information between the two disciplines is accurate and passed on in a timely fashion. Having other multi-disciplinary staff involved in this process would further benefit the woman and the fetus. Some pregnant women may experience a mental health crisis during their pregnancy and need inpatient hospitalization care. A psychiatrist could be consulted to provide further expertise and direction as to how treatment should be offered. If the woman is at serious risk of harming herself and/or the fetus, the PMHNP may need to collaborate with other disciplines to have the woman committed to an inpatient psychiatric facility for stabilization.

PMHNPs should use the most up to date information when prescribing medications and any side effects or adverse outcomes should be reported. Up to date information can be obtained in reputable publishing materials, such as Stahl's Essential Psychopharmacology Prescriber's Guide or UpToDate. UpToDate is a database that includes evidence based practice treatment guidelines for treatment of patients (UpToDate, Inc., 2018).

PMHNPs are faced with many difficult decisions in how to provide the best treatment for their patients. Patients should be included on the discussion of treatment options, evidence based

practice should be reviewed, and consults to other disciplines should be made when appropriate. It is important to keep in mind that the benefit of treatment or lack of treatment should always outweigh risks involved with a treatment plan or the lack of treatment provided to a patient.

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