Exploring Mental Health in the Prenatal Genetic Counseling Setting

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Exploring Mental Health in the Prenatal Genetic Counseling Setting

THESIS

submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

in Genetic Counseling

by

Rachel Anne Peralta

Thesis Committee:

Professor Maureen Bocian, MD, Chair
Professor Kathryn Steinhaus French, MS, LCGC
Professor Julianne Toohey, MD

2015
DEDICATION

To my parents...

I’m not quite sure how I ended up your daughter, but I cannot explain how grateful I am for it. Both of you have showed me what it means to be successful in life. Mom, you showed me from a young age that helping others is always the right thing to do. Dad, you instilled in me resilience and determination that continue to drive me today; I’ll always be a Youngblood because of it. Thank you both for supporting me every step of the way.

To my Gramma Edi,

I know you had something to do with my being here. Without your support, I wouldn’t be where I am today. I love and miss you every day.

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TABLE OF CONTENTS

LIST OF FIGURES vi
LIST OF TABLES vii
ACKNOWLEDGMENTS viii
ABSTRACT OF THE THESIS x

1: INTRODUCTION 1
1.1 Depression and Anxiety Prevalence 1
1.2 Diagnosing Depression and Anxiety 1
1.3 Mental Health Disorders in Pregnancy 2
1.4 Current Screening Methods for Depression & Anxiety during Pregnancy 4
1.5 Genetic Counseling in the Prenatal Setting 4
1.6 Genetic Counseling for Psychiatric and Mental Health Disorders 6
1.7 A need for Depression and Anxiety Screening in the Genetic Counseling Setting 8
1.8 Study Objectives & Hypothesis 10

2: RESEARCH DESIGN AND METHODS 10
2.1 Study Population 10
2.2 Recruitment 11
2.3 Data Collection 13
   2.3.1 Data Collection Tools – Survey and PROMIS Instruments 13
   2.3.2 Assessment of Data Collection Tools 14
   2.3.3 Revised Survey and Study Information Sheet – Spanish 15
2.4 Data Analysis 15
   2.4.1 Survey Transcription and Demographic Assessment 15
   2.4.2 Assessment of PROMIS Score 16
2.5 Statistical Analysis 17
2.6 Ethical Considerations 17
2.6.1 Resources for Depression and Anxiety

3: RESULTS

3.1 Descriptive Analysis of Participation Rate at Each Site
3.2 Descriptive Analysis of Maternal Age at Delivery of Participant Population
3.3 Descriptive Analysis of Race/Ethnicity of the Participant Population
3.4 Descriptive Analysis of the Combined Household Income of the Participant Population
3.5 Descriptive Analysis of Individuals Present at the Genetic Counseling Appointment
3.6 Descriptive Analysis of Genetic Counseling History of the Participant Population
3.7 Descriptive Analysis of the Reported Reason for Genetic Counseling of the Participant Population
3.8 Descriptive Analysis of the Stoppage of Medication in the Participant Population
3.9 Descriptive Analysis of the Reason for Stopping Medication in the Participant Population
3.10 Descriptive Analysis of When Participants Stopped Taking Their Medication
3.11 Descriptive Analysis of the Depression Prevalence in the UCI Participant Population
3.12 Descriptive Analysis of the Depression Prevalence in the SJMC Participant Population
3.13 Descriptive Analysis of the Overall Depression Prevalence in the Participant Population
3.14 Descriptive Analysis of the Anxiety Prevalence in the UCI Participant Population
3.15 Descriptive Analysis of the Anxiety Prevalence in the SJMC Participant Population
3.16 Descriptive Analysis of the Overall Anxiety Prevalence in the Participant Population
Participant Population 31

3.17 Descriptive Analysis of Statistically Significant Findings Relating to Depression T-score 32

3.18 Descriptive Analysis of Statistically Significant Findings Relating to Anxiety T-score 35

3.19 Descriptive Analysis of Mean Depression and Anxiety in the Participant Population 37

4: DISCUSSION 41

References 53

APPENDIX A: UCI IRB Approval Letter 55

APPENDIX B: UCI IRB Electronic Modification Approval Letter 57

APPENDIX C: UCI Study Information Sheet 58

APPENDIX D: UCI Study Information Sheet – Modified 61

APPENDIX E: UCI Study Information Sheet – Spanish Translation 63

APPENDIX F: SJMC IRB Approval Letter 66

APPENDIX G: SJMC Study Information Sheet 67

APPENDIX H: Survey – English 69

APPENDIX I: Survey – Spanish Translation 71
# LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 1</td>
<td>Age Distribution of Participant Population by Site</td>
<td>22</td>
</tr>
<tr>
<td>Figure 2</td>
<td>Race/Ethnicity Distribution of the Participant Population</td>
<td>24</td>
</tr>
<tr>
<td>Figure 3</td>
<td>Household Income of the Participant Population</td>
<td>25</td>
</tr>
<tr>
<td>Figure 4</td>
<td>Participant-Reported Reason for Genetic Counseling Referral</td>
<td>27</td>
</tr>
<tr>
<td>Figure 5</td>
<td>Medication Stopped in the Participant Population</td>
<td>29</td>
</tr>
</tbody>
</table>
LIST OF TABLES

Table 1: Demographic Summary of Participant Population 20
Table 2a: Depression Prevalence in the Participant Population 32
Table 2b: Anxiety Prevalence in the Participant Population 32
Table 3: Demographic/Historical Information Relating to Depression T-score 34
Table 4: Demographic/Historical Information Relating to Anxiety T-score 36
Table 5: Mean Depression and Anxiety by Demographic Information 38
Table 6: Mean Depression and Anxiety by Personal History Information 39
Table 7: Mean Depression and Anxiety by Referral Indication 40
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ABSTRACT OF THE THESIS

Exploring Mental Health in the Prenatal Genetic Counseling Setting

By

Rachel Anne Peralta

Master of Science in Genetic Counseling

University of California, Irvine, 2015

Professor Maureen Bocian, MD, Chair

This study was designed to determine if any specific demographic or historical factors could be correlated with depression and anxiety among patients who were being seen for prenatal genetic counseling. Prior to seeing the genetic counselor, participants were given an anonymous 32-question survey that assessed demographics, pregnancy history, genetic counseling referral indication and mental health history, followed by an 8-question PROMIS screen for depression and an 8-question PROMIS screen for anxiety. In total, 122 women participated in the study. Overall, 14.8% of participants screened positive for depression, and 24.6% of participants screened positive for anxiety. We were able to determine 7 demographic/historical factors that correlated with participants’ depression status and 7 demographic/historical factors that correlated with participants’ anxiety status. The only two factors that were statistically significant for both a positive depression and a positive anxiety screen were the historical questions regarding whether a patient had a prior history of depression and whether there was a personal history of anxiety.
The results of the study support the idea that a mental health history assessment is a logical and beneficial extension of the risk assessment that is already performed within the prenatal counseling session. At a minimum, we recommend that a brief mental health history assessment be made through direct questioning of patients in the prenatal genetic counseling setting to identify those who might be at risk for either recurrence or new onset of a mental health disorder during pregnancy or in the post-partum period.
1: INTRODUCTION

1.1 Depression & Anxiety Prevalence

Mental health disorders are believed to affect one in four adults, making them one of the most prevalent disorders in the United States[1]. Major Depressive Disorder affects approximately 7% of the population, with women affected more often than men[1]. Anxiety disorders are seen in approximately 18% of the population, and those who are affected are often affected with a depressive disorder as well[2]. Although depression and anxiety are both common, they are often not considered “real” health concerns because of the low prevalence of associated physical symptoms. Almost 90% of those affected by major depressive disorder reported social impairment as a result of their depression, sometimes so severe that it impacted daily function or the ability to work[2]. Unfortunately, because of stigma, absence of physical symptoms, or lack of access to resources, many affected individuals are not getting the care that they need.

1.2 Diagnosing Depression and Anxiety

There are strict criteria that govern what qualifies as clinical depression and anxiety. In order for individuals to be diagnosed with clinical depression, they must display the following symptoms, as determined by a psychiatric professional, for greater than two weeks: depressed mood, reduced interest in activities that used to be enjoyed, change in appetite or weight increase/decrease, sleep disturbances, feeling agitated or slowed down, fatigue or loss of energy, feeling worthless or excessive guilt, difficulty thinking or concentrating, difficulty making decisions, and/or having suicidal thoughts or intentions[3]. To be diagnosed with a clinical anxiety disorder, a preliminary evaluation by
a medical doctor is necessary. Because many of the symptoms of anxiety disorders can also occur with various medical conditions, a doctor is needed to rule out any medical condition, other disorder, or substance abuse that could account for the symptoms of anxiety. Once medical disorders or other mental health disorders such as depression have been ruled out, a doctor can recommend evaluation by a psychiatrist to have clinical anxiety diagnosed. There are many different types of specific anxiety disorders, and in order to determine the exact sub-type that a person may have, evaluation by a psychiatric professional is necessary. It is important to remember that whereas screening for mental health disorders can be done by other health professionals, only psychiatric professionals can diagnose mental health disorders.

1.3 Mental Health Disorders in Pregnancy

It has been shown that women are particularly vulnerable to mental health disorders during pregnancy. According to the American Congress of Obstetricians and Gynecologists (ACOG), “between 14 percent and 23 percent of pregnant women will experience depressive symptoms while pregnant”[4]. In addition, many studies show that depression can have adverse effects on the health of the pregnancy[5], fetal brain development [6], and general adverse outcomes in infancy[7, 8]. The combination of the relatively high frequency of mental health disorders in pregnancy and the resulting potential for adverse outcomes indicates that there would be great benefit in identifying cases of mental health disorders during pregnancy so that appropriate referrals can be made.
Identifying women who might be susceptible to developing a prenatal mental health disorder can be difficult. The presence of a prenatal mental health disorder can “arise for the first time during the perinatal period or may represent a relapse of a preexisting condition”[9]. We cannot assume that a past history of a mental health disorder will mean a relapse during pregnancy, and equally, we cannot assume that a negative history of a mental health disorder means that a woman is precluded from the possibility of developing a mental health disorder during pregnancy.

There is a broad range of psychiatric disorders that can be present within the prenatal setting, many of which have overlapping symptoms. Common perinatal mental health disorders include eating disorders, mood disorders, anxiety disorders, psychotic disorders, postpartum psychosis, substance-use disorders, and personality disorders. Each of these categories has its own subset of specific mental health disorders, along with specific risk factors linked to their development. Some of the risk factors that are commonly associated with more than one disorder include past history of a mental health disorder, an unplanned pregnancy, insufficient emotional or social support, unfavorable obstetric or neonatal outcomes, and low socioeconomic status[10].

One very real concern is that women who are being treated for a psychiatric disorder might stop taking their medication(s) during pregnancy because of concern regarding its possible effects on the fetus. In a study of women who had a past history of major depression it was found that those who stopped their medication because of a pregnancy were more likely to have a relapse than those who continued to take medication, although depressive symptoms persisted for some who continued their
medication[11]. Many women may not understand the high potential for relapse during pregnancy and the postnatal period, or may assume that it would be safer for their baby if they discontinued medication during the pregnancy, or may consider pregnancy to be a “protective period” against mental health disorders, meaning that they believe they will no longer have symptoms. It is unclear how often women are told by a healthcare provider to stop taking medication, and how often women stop taking medication of their own accord. For these reasons, excellent prenatal care is necessary to screen women early in pregnancy to identify those at risk and should include a discussion by their healthcare providers of potential mental health disorders and the risk factors for these disorders that could be associated with pregnancy.

1.4 Current Screening Methods for Depression & Anxiety during Pregnancy

Routine screening for antepartum and postpartum depression has been addressed by the American Congress of Obstetricians and Gynecologists (ACOG). ACOG Committee Opinion 630, which was released in 2015, states: “Although definitive evidence of benefit is limited, the American College of Obstetricians and Gynecologists recommends that clinicians screen patients at least once during the perinatal period for depression and anxiety symptoms using a standardized, validated tool”[12]. However, since screening is not mandated, it is unclear how often pregnant women are screened in everyday obstetrical practice.

1.5 Genetic Counseling in the Prenatal Setting

Although the term “genetic counseling” was first introduced in 1947 by Reed, genetic counseling as a profession was not established until the 1970’s[13]. The first
definition of genetic counseling given by the American Society of Human Genetics in 1975 put strong emphasis on the utility of genetic counseling—specifically for the process of identifying reproductive risk[14]. Although both the role of genetic counselor and the definition of genetic counseling have expanded over the years, the foundation of providing genetic counseling specifically for reproductive risk has remained an important component of modern genetic counseling in the prenatal setting.

Since the 1970’s, prenatal genetic counseling has undergone many changes, especially when it comes to the types of testing that counselors offer to patients. One of the most prevalent and historic testing procedures is to screen pregnancies noninvasively for abnormalities using maternal biochemical blood markers. Noninvasive prenatal screening programs have been in place since the 1980’s. The California Prenatal Screening Program (CPSP) was established in 1986 and currently uses a combination of maternal serum analyte levels and an ultrasound measurement of the fetal nuchal translucency to give risk estimates for trisomy 18, trisomy 21, neural tube defects, ventral wall defects, and an autosomal recessive disorder called Smith-Lemli-Opitz Syndrome; other congenital anomalies and fetal demise may also be detected[15]. Diagnostic invasive procedures, which come with a small risk of pregnancy loss, also exist. Amniocentesis has been clinically available since the 1970’s[16, 17], and chorionic villus sampling (CVS) has been clinically available since the 1980’s[13]; percutaneous fetal blood sampling and fetal skin and other biopsies have been used much less often and are used rarely now if at all[18]. Non-invasive screening and diagnostic amniocentesis and CVS are available to women of all ages, depending on the specific risk factor(s) and indication(s) for testing. In 2012, the use of noninvasive prenatal screening using cell-free fetal DNA found in maternal blood was
recommended by ACOG for use in high-risk pregnancies to screen for three chromosomal abnormalities: trisomies 13, 18 and 21[19].

Ideally, prenatal genetic counselors see women of advanced maternal age (AMA) in the first trimester so that they have the opportunity to choose between all screening and diagnostic testing options available to them. Women referred for other indications may be seen for genetic counseling for different risk factors or because they have tested “screen positive” for one of the disorders that can be detected by maternal screening. Other referral indications can include a personal history of genetic disease or of a disorder or factor that may adversely affect the fetus, a history of infertility or recurrent miscarriage, a family history of genetic disease, a fetal ultrasound abnormality, history of a previous child affected with a genetic disorder, and others. Although most patients who are seen are already pregnant, some patients seek counseling prior to conception.

Women who see a genetic counselor in the prenatal setting are generally referred because they are at increased risk in some way and are usually seen at facilities or offices where high-resolution fetal ultrasound and high-risk obstetric consultation are available. Regardless of age or even pregnancy status, there are various factors that could influence the mental health of a woman who is seeing a genetic counselor.

1.6 Genetic Counseling for Psychiatric and Mental Health Disorders

Psychiatric illness and mental health disorders are not common reasons for referral to a typical clinical genetics or genetic counseling service. There are many genetic disorders that can have associated psychiatric manifestations; however, these are usually not the primary reason for the referral. In general genetics clinics, a personal or family history of
psychiatric and/or mental health disorders is revealed fairly frequently when a family history is taken from patients who are being seen for a completely different indication. Because psychiatric and mental health disorders generally do not follow typical Mendelian inheritance patterns, we consider them to be inherited in a multifactorial manner, meaning that both genetic and environmental factors are likely playing a role in the development of these diseases[20]. For this reason, when mental health disorders are encountered in a patient or in their family history, the genetic counselor may ask if there is interest in knowing more about the heritability of psychiatric disorders. This is similar, for example, to having a family history of cancer revealed during a routine prenatal genetics evaluation– it may not be the reason that the patient was referred, but the genetic counselor usually explains the inheritance of that disorder and what testing, screening, and preventative options are available and/or may refer the patient to a genetic counselor who specializes in comprehensive cancer genetic risk assessment. Encountering a family history of psychiatric illness, on the other hand, is somewhat different in that there may not be an available mental health clinic, genetic counselor specializing in mental health disorders, or specific genetic testing that can be offered to patients in the way that there often is for a family history of cancer or other genetic disorders.

The idea of genetic counseling specifically for a history of psychiatric or mental health disorders is a fairly recent concept. The development and availability of genetic testing are growing rapidly, and our ability to detect genetic causes of psychiatric disorders and mental illness will continue to improve, arguing that genetic counselors will be needed to help interpret such findings to patients[21]. In 2008, a pilot study was introduced to determine the effectiveness of providing genetic counseling to parents who
have children with psychiatric disorders[22]. The pilot study postulated that genetic counseling for psychiatric disorders is actually quite beneficial to such families and concluded that genetic counselors were extremely effective in counseling for psychiatric disorders, including explaining the multifactorial etiology of psychiatric illness, discussing protective environmental factors that families may be able to influence to decrease risk, and utilizing empiric data and, in some cases, limited available genetic testing to assess risk.

As of May 2015, the University of British Columbia, where the 2008 pilot study was conducted, has the only center in the world devoted solely to psychiatric genetic counseling. There are also some genetic counselors who specialize in providing psychiatric genetic counseling, either in private practice or within a general genetics/genetic counseling clinic, in San Francisco, Germany, and the United Kingdom. Many counselors have visited the clinic in British Columbia to observe or to spend a period of study, so that they can learn about and develop clinical tools and practices[23].

1.7 A Need for Depression and Anxiety Screening in the Genetic Counseling Setting

This study will help to provide information about whether it is useful to screen all women who are seeing a prenatal genetic counselor, regardless of their referral indication, for depression and anxiety to increase early detection, thereby allowing for more effective intervention. It has already been shown that genetic counselors find it difficult to identify women who may be depressed simply on the basis of their interaction during an appointment[24]. In many or most practices, an intake questionnaire including demographic information, pregnancy history, and personal and family histories is given to
patients in the waiting room prior to their appointments. Routine screening using a standardized measure should be easy to implement as part of the intake questionnaire. By screening all women for depression and anxiety in addition to their prenatal genetic risk assessment, there is the potential to identify those women who could benefit from a referral for mental health evaluation and, if indicated, treatment.

Women seeing a prenatal genetic counselor are more likely to have a high-risk pregnancy, which could increase their risk for being depressed or anxious. It has been shown, understandably, that women who have received an abnormal prenatal screen result for a chromosomal anomaly are more likely to be depressed than those who have not[25]. Although not all women coming to see a genetic counselor have received an abnormal prenatal screen result, there are many other factors that could possibly contribute to their potential to be depressed or anxious, such as advanced age or other referral indication, past pregnancy history, psychosocial stressors, education level, and income[10].

The population of patients within the prenatal genetic counseling setting is quite diverse, spans a wide range of ages and socioeconomic classes, and includes high-risk pregnancies. These factors combine to provide a population that is ideal for the assessment of maternal depression and anxiety. We were particularly interested in investigating the incidence of a positive depression and anxiety screen within a culturally diverse population of Southern California, which has a very large Latina community. There are differences among minority groups in terms of what types of depressive disorders may affect them and what their beliefs are about seeking treatment and help for those disorders[26]. In addition, Latinas who are depressed “do not consider themselves to be ill, but instead
understand their symptoms as a normal reaction to a high level of stress” and “are most likely to recognize depression based on suicidal ideation or severe symptomatology”[27]. There should be a way to identify women at risk, including those of minority backgrounds, before such severe symptoms occur.

1.8 Study Objectives & Hypothesis

We hope that by learning the incidence of positive depression and/or anxiety screens among our prenatal patients, we can provide them with earlier access to resources for appropriate mental health care. Our hypothesis is:

H₁: After screening using a standardized PROMIS screen, depression and/or anxiety WILL be correlated with a factor(s) from the patient’s background and/or medical history

The results of this study will be valuable not only to genetic counselors but to all healthcare professionals. By understanding the incidence of positive depression and/or anxiety screens within a diverse prenatal population, we hope to increase awareness among healthcare providers regarding which signs and symptoms to look for, when help should be offered, and possibly how to modify or avoid some of the factors that predispose these women to depression or anxiety.

2: RESEARCH DESIGN AND METHODS

2.1 Study Population

The study population comprises adult women who saw a genetic counselor during the study period in the prenatal setting at the University of California Irvine Center for
Fetal Evaluation (UCI) or at the St. Jude Medical Center Fetal Diagnostic Center (SJMC), where UCI genetic counselors also see patients in the prenatal setting. Any woman over the age of 18 was eligible to participate if she was being seen by a prenatal genetic counselor. Adult women of all ages 18 and over were included to avoid any age-based bias that might complicate an association between a demographic or personal history factor and the participants’ answers to the mental health survey. We required that participants be over 18 so that they would be able to consent to participation in our optional survey. The only other criterion was that participants could read the survey in either English or Spanish and could verbally consent to participation.

2.2 Recruitment

Participants were recruited from October 2014 to March 2015. Recruitment was done at UCI and at SJMC. Recruitment days were chosen at random. At UCI, participants were recruited by approaching them when they returned their waiting-room questionnaires. Patients were told that because they were seeing a prenatal genetic counselor, they were eligible to participate in an optional, anonymous survey to better understand emotional health in our patient population. To protect patient privacy, we said, “Because you are seeing a genetic counselor today, you are eligible to participate in an optional anonymous survey for a research project investigating emotional health, including depression and anxiety, in pregnancy. Your responses will be anonymous, but they have the potential to make the experiences of women seeing a counselor in the future better. Would you like to hear more about the survey?”
If the patient wanted to hear more about the survey, we used the approved UCI study information sheet (Appendix D) to explain the risks and benefits of the study and to obtain the patient’s informed verbal consent; signed informed consent was not required by the IRB. If the patient decided to participate, the study questionnaire was completed by the patient in the waiting area. Completed surveys were placed in a locked box that was kept visible on the front desk in the waiting room.

At SJMC, participants were recruited in the private check-in office of the Fetal Diagnostic Center. Participants were given all check-in information and paperwork by a nurse and then were introduced to the lead researcher, who explained the study using the same script that was used at UCI. If there was interest in participation, the study information sheet approved by SJMC (Appendix G) was reviewed with them, and their verbal consent was obtained. Participants filled out the survey together with their intake paperwork in the private waiting room, returned it with their completed paperwork, and placed it in the locked box in the check-in office. The locked box was removed by the lead researcher after each recruitment day and emptied at the end of each week. If recruitment was to take place at the other site before the week ended, surveys were removed prior to the end of the week to avoid mixing surveys between the two sites. Surveys were transported to our academic offices in Orange and were placed in a locked drawer.

If a participant’s preferred spoken language was Spanish, an employee of each respective medical center introduced the research study using a translation of the same script that was used for English-speaking patients. The lead researcher was present for the
verbal consent and was able to answer any questions that arose regarding study participation and specifics of the questionnaire.

2.3 Data Collection

2.3.1 Data Collection Tools – Survey and PROMIS Screens

The anonymous survey that was distributed to participants comprised of 32 questions that included a combination of demographic and history questions followed by the two validated PROMIS screens used to assess depression and anxiety (Appendix H). The demographic questions assessed race/ethnicity, education level, socioeconomic status, household size, age at anticipated delivery date, marital status, pregnancy history, reason for referral to a prenatal genetic counselor, and questions assessing personal experience with depression and anxiety.

The PROMIS (Patient Reported Outcomes Measurement Information System) short-form depression and anxiety screens contain eight questions each. The PROMIS screen is an inclusive, validated instrument that was created by the National Institutes of Health, and has been normalized to easily identify a score that is either above or below the “normal” limit[28]. Each of the two PROMIS screens used in this study asked how often within the past seven days participants felt various reactions in response to specific emotions or statements. For example, in the depression screen, participants were asked,

“In the past seven days... (1) I felt worthless, (2) I felt helpless, (3) I felt depressed, (4) I felt hopeless, (5) I felt like a failure, (6) I felt unhappy, (7) I felt I had nothing to look forward to, (8) I felt that nothing could cheer me up.”
In the anxiety screen, participants were asked,

“In the past seven days... (1) I felt fearful, (2) I found it hard to focus on anything other than my anxiety, (3) My worries overwhelmed me, (4) I felt uneasy, (5) I felt nervous (6) I felt like I needed help for my anxiety, (7) I felt anxious, (8) I felt tense.”

There were five answer choices for each of the eight questions, and each was assigned a point value. The choices were: never, rarely, sometimes, often, or always. The minimum score for each screen was 8, and the maximum possible score for each screen was 40. In this study, we used “PROMIS Short Form Depression – v1.0 Depression 8a,” and “PROMIS Short Form Anxiety – v1.0 8a.”

The validated depression and anxiety screens were available in Spanish, which was necessary since one of our main goals was to assess a diverse population, and many of the patients we see at our two clinical sites are Spanish-speaking only.

2.3.2 Assessment of Data Collection Tools

The assessment of the data collection tools was done by other current genetic counseling graduate students in our program. Because the PROMIS screens are validated, we did not feel it was necessary to do a pilot study to assess responses to the questions within the PROMIS screen. Instead, 10 of the current genetic counseling graduate students took the entire survey, including demographic/history questions and both PROMIS short forms, to determine how long the survey would take and whether the demographic and history questions were well-worded. Based on observations and comments from the students who participated in the trial, certain personal history questions were re-phrased
in more simple language to make the questions more understandable by a general audience.

2.3.3 Revised Survey and Study Information Sheet – Spanish Translation

In order to assess our entire patient population, it was necessary to offer our survey in Spanish as well as English. In November 2014 the approved survey and study information sheet were translated into Spanish by a fluent Spanish-speaker who was not a member of the study team. The survey was then reviewed by a second fluent Spanish-speaker, also not associated with the study team. Members of the study team who speak Spanish read and approved the final translation. A modification request was submitted to the UCI IRB for approval of the new Spanish translation in January 2015 and was approved on February 4th, 2015. A copy of the approved translation can be found in Appendix I.

2.4 Data Analysis

2.4.1 Survey Transcription and Demographic Assessment

Completed surveys were brought to our academic offices in Orange to be electronically transcribed. All possible question options for the demographic information were given numerical scores and entered into an Excel worksheet. Total scores for each of the individual mental health measures were calculated and entered into the spreadsheet. Surveys that were incomplete for certain demographic questions were included, but surveys in which at least one entire validated PROMIS measure had not been completed were discarded. In order to reduce data entry error, data was entered twice, with an error rate of .002%. For demographic information, any individual who provided an ethnicity
within the blank for the “other” category was re-coded; Filipino was recoded to Asian, Lebanese was re-coded to White/Caucasian. If “other” was selected but no nationality or ethnicity was provided, the response remained as “other.”

2.4.2 Assessment of PROMIS Score

Raw PROMIS scores could only be generated for participants who complete more than 50% of each measure. If more than four questions on a measure were left blank, that measure was not used for analysis. For participants who did not complete the measure but who answered four or more items for that measure, their pro-rated raw scores could be determined by calculating the raw sum multiplied by the number of items on the measure, divided by the number of items that were actually answered. If their pro-rated raw score was a fraction, their score was rounded up to the nearest whole number.

Based on the PROMIS validation study, raw scores could be directly translated to a T-score, which indicates a person’s score relative to the standardized population norm. A T-score of 50 is considered normal, with a standard deviation of 10 points. A T-score of 40 indicates that a participant was one standard deviation below the general population; patient scores below the norm indicate that they have fewer depressive or anxious symptoms. A T-score of 60 indicates that a person is one standard deviation above the general population and is, therefore, one standard deviation worse in terms of his/her depressive or anxious symptoms. Half a standard deviation is considered significant for the PROMIS measure, meaning that anyone who has a T-score of 55 or greater shows evidence of clinical depression or anxiety. The PROMIS Scoring Guide shows the complete range of possible raw scores and their respective T-scores and Standard Errors[29].
For our participant population, anyone who had a T-score of ≤50 was considered to be the “Normal” population. All participants with a T-score of >50 to <55 (i.e., 50.1 to 54.9) were grouped into the “At Risk” category. Participants who had a T-score of ≥55 were grouped into the “Positive Screen” category.

2.5 Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics version 21 (International Business Machine Corporation, 2012). This research project was looking for associations between a woman’s mental health status and her demographics, personal history and pregnancy history. Statistical analysis was performed to determine if an association was significant between any specific personal history characteristic, aspect of pregnancy history, or demographic and the reports of depressive or anxious behaviors or symptoms.

2.6 Ethical Considerations

This research study was approved by the University of California, Irvine Internal Review Board (UCI IRB) as HS#2014-1378 on August 27th 2014 and was classified as “Exempt Review, Category 2.” IRB review ensured that participants were giving informed consent, that anonymity was upheld, and that protections were in place to reduce the risk of a breach of confidentiality. The UCI IRB found that the procedures outlined by the research team met the requirements for appropriate use of human subjects within the research setting. A copy of the letter of approval from the UCI IRB can be found in Appendix A.
On October 31st, 2014, this research was approved by St. Joseph Health, which oversees St. Jude Medical Center. This research was approved as SJH Reference #14-080 by the Human Research Protection Program (HRPP) as exempt from Human Subjects Regulation. The St. Joseph HRPP determined that informed consent of patients was required and that the research must be conducted in accordance with the ethical principles outlined in the Belmont Report. A copy of the letter of approval from St. Joseph Health can be found in Appendix F.

2.6.1 Resources for Depression and Anxiety

During the study design phase, a concern was raised regarding participants who might score very high on either the depression or the anxiety screen, including those who might report that they had strong feelings of hopelessness or that they felt they needed help for their anxiety. Because the surveys are anonymous and we would not be able to connect any participant’s responses to her personal identifiable information, we would have no way to reach out to participants who could benefit from additional help. For this reason, we attached a list of local depression and anxiety resources to the study information sheet that were either free-of-charge or available at a low cost for those in financial need. The list included support groups, group therapy, individual therapy, and general information that could be found online about depression and anxiety. Multi-lingual resources were provided in the list, including resources in Spanish, Vietnamese, Korean and Japanese. See Appendices D and G for a copy of the respective study information sheets, which include the list of patient resources.
In addition to being given the patient resource information sheet, participants were told during the consenting process that they should feel free to discuss any questions or concerns that arose from the survey with their genetic counselor; if they were having an ultrasound that day, they could also speak with the perinatologist. We clearly stated that speaking to their healthcare professionals about their survey was optional and that they could still participate without discussing their survey with anyone. No personal identifiable information such as name or date of birth was collected.

3: RESULTS

There was a total of 123 participants from the two sites between October 2014 and March 2015. Participants completed a 32-item survey, which included questions about demographics, pregnancy and mental health history, and two 8-question validated screening measures by PROMIS – one for depression and one for anxiety. Demographic information that was collected about participants included ethnicity, marital status, and socioeconomic status. A summary of the demographic and historical information collected is presented in Table 1.

One of the 123 participants one had to be excluded because she did not finish either the depression or anxiety screen, leaving 122 usable participants. In total, 10 out of the 122 (8.2%) usable responses were completed in Spanish.
### Table 1: Demographic Summary of Participant Population

<table>
<thead>
<tr>
<th>Demographic Information</th>
<th>Total</th>
<th>UCI</th>
<th>SJMC</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td>122</td>
<td>100</td>
<td>52</td>
<td>43%</td>
</tr>
<tr>
<td><strong>Age of Participant</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;25 years</td>
<td>9</td>
<td>7%</td>
<td>7</td>
<td>15%</td>
</tr>
<tr>
<td>25-29 years</td>
<td>8</td>
<td>7%</td>
<td>7</td>
<td>15%</td>
</tr>
<tr>
<td>30-34 years</td>
<td>18</td>
<td>15%</td>
<td>10</td>
<td>21%</td>
</tr>
<tr>
<td>35-39 years</td>
<td>65</td>
<td>53%</td>
<td>21</td>
<td>44%</td>
</tr>
<tr>
<td>≥40 years</td>
<td>15</td>
<td>12%</td>
<td>3</td>
<td>6%</td>
</tr>
<tr>
<td>Did Not Respond</td>
<td>7</td>
<td>6%</td>
<td>4</td>
<td>8%</td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latina</td>
<td>43</td>
<td>35%</td>
<td>24</td>
<td>46%</td>
</tr>
<tr>
<td>African American</td>
<td>3</td>
<td>2%</td>
<td>3</td>
<td>6%</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>33</td>
<td>27%</td>
<td>8</td>
<td>15%</td>
</tr>
<tr>
<td>Caucasian</td>
<td>32</td>
<td>26%</td>
<td>12</td>
<td>23%</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>1%</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Multiple Ethnicities Selected</td>
<td>10</td>
<td>8%</td>
<td>4</td>
<td>8%</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High School or less</td>
<td>21</td>
<td>17%</td>
<td>17</td>
<td>33%</td>
</tr>
<tr>
<td>Some College/Associate Degree/Trade</td>
<td>38</td>
<td>31%</td>
<td>22</td>
<td>42%</td>
</tr>
<tr>
<td>Bachelor's, Master's or Doctorate</td>
<td>63</td>
<td>52%</td>
<td>13</td>
<td>25%</td>
</tr>
<tr>
<td><strong>Household Income</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; $50,000</td>
<td>37</td>
<td>30%</td>
<td>29</td>
<td>58%</td>
</tr>
<tr>
<td>$50,000-99,999</td>
<td>31</td>
<td>25%</td>
<td>11</td>
<td>22%</td>
</tr>
<tr>
<td>$100,000-149,999</td>
<td>32</td>
<td>26%</td>
<td>6</td>
<td>12%</td>
</tr>
<tr>
<td>≥$150,000</td>
<td>19</td>
<td>16%</td>
<td>4</td>
<td>8%</td>
</tr>
<tr>
<td>Did Not Respond</td>
<td>3</td>
<td>2%</td>
<td>2</td>
<td>4%</td>
</tr>
<tr>
<td><strong>Household Size</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-2 people</td>
<td>43</td>
<td>35%</td>
<td>21</td>
<td>41%</td>
</tr>
<tr>
<td>3-5 people</td>
<td>64</td>
<td>52%</td>
<td>25</td>
<td>49%</td>
</tr>
<tr>
<td>&gt;6 people</td>
<td>9</td>
<td>7%</td>
<td>5</td>
<td>10%</td>
</tr>
<tr>
<td>Did Not Respond</td>
<td>6</td>
<td>5%</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single, Never Married</td>
<td>13</td>
<td>11%</td>
<td>8</td>
<td>15%</td>
</tr>
<tr>
<td>Married/Domestic Partnership</td>
<td>100</td>
<td>82%</td>
<td>38</td>
<td>73%</td>
</tr>
<tr>
<td>Divorced</td>
<td>7</td>
<td>6%</td>
<td>4</td>
<td>8%</td>
</tr>
<tr>
<td>Separated</td>
<td>2</td>
<td>2%</td>
<td>2</td>
<td>4%</td>
</tr>
<tr>
<td><strong>Persons Present at GC Visit</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Husband or Father of Pregnancy</td>
<td>72</td>
<td>59%</td>
<td>30</td>
<td>58%</td>
</tr>
<tr>
<td>Participant came alone</td>
<td>38</td>
<td>31%</td>
<td>14</td>
<td>27%</td>
</tr>
<tr>
<td>Other (Parent, Sibling, Friend)</td>
<td>12</td>
<td>10%</td>
<td>8</td>
<td>15%</td>
</tr>
</tbody>
</table>

* = significant p-value for Chi-squared Analysis  ^ = significant p-value for Fisher's Exact Test

\(a\) = statistically significant p-value for ANOVA analysis
3.1 Descriptive Analysis of Participation Rate at Each Site

At St. Jude Medical Center (SJMC), a total of 70 patients participated out of the 76 approached, for a participation rate of 92%. At UCI Medical Center (UCI), a total of 53 patients participated out of the 64 approached, for a participation rate of 83%. When the two centers were combined, there were a total of 123 participants out of 140 patients who were approached, for a total participation rate of 88%.

3.2 Descriptive Analysis of Maternal Age at Delivery of the Participant Population

In total, 115 out of 122 women provided their age at the anticipated delivery date on their surveys, and seven participants declined to answer. The age at delivery ranged from 19 to 44 years, and the average age at delivery was 34.76 years. A majority of the participants (53%) fell between the ages of 35-39, which fits with Advanced Maternal Age (35 years or greater at expected delivery) being the most common indication for referral to prenatal genetic counseling. At SJMC the mean age at delivery was 36.60 with a standard deviation of 4.19. At UCI the mean age at delivery was 32.19 with a standard deviation of 5.60. There was a statistically significant difference in the mean age at delivery between the two sites (p=0.000004).
Figure 1: Age Distribution of Participant Population by Site
3.3 Descriptive Analysis of Race/Ethnicity of the Participant Population

The total participant population was 35% Hispanic/Latina, 27% Asian/Pacific Islander, 26% Caucasian, 3% African American, 1% Other, and 8% of participants chose multiple ethnicities. The patient populations at UCI and SJMC were significantly different (p=0.02). At UCI, the participant population was predominantly Hispanic/Latina (46%), with 23% being Caucasian, 15% Asian/Pacific Islander, 8% selected multiple ethnicities, 6% African American, and 2% Other. At SJMC, the participant population was predominantly Asian/Pacific Islander (36%), 29% Caucasian, 27% Hispanic/Latina, and 8% selected multiple ethnicities.
Figure 2: Race/Ethnicity Distribution of the Participant Population

Total Participant Population

- Hispanic/Latina: 27%
- African American: 8%
- Asian/Pacific Islander: 3%
- Caucasian: 35%
- Other: 1%
- Multiple Ethnicities Selected: 26%

UCI

- Hispanic/Latina: 46%
- African American: 8%
- Asian/Pacific Islander: 6%
- Caucasian: 23%
- Other: 2%
- Multiple Ethnicities Selected: 15%

SJMC

- Hispanic/Latina: 0%
- African American: 8%
- Asian/Pacific Islander: 0%
- Caucasian: 27%
- Other: 29%
- Multiple Ethnicities Selected: 36%
3.4 Descriptive Analysis of the Combined Household Income of the Participant Population

The most common income level for participants overall was less than $50,000. At SJMC, the most common income level was between $100,000 and $150,000. At UCI the most common income level was below $50,000. There was a significant difference between the two sites in terms of their income level distributions (p=0.0001).

Figure 3: Household Income of the Participant Population

3.5 Descriptive Analysis of Individuals Present at the Genetic Counseling Appointment

In total, 59% of the participants brought their spouse/reproductive partner to the genetic counseling visit, 31% came alone, and 10% came with a parent, sibling, friend, or parent and friend.
3.6 Descriptive Analysis of Genetic Counseling History of the Participant Population

Of the 122 participants, 23 (19%) had seen a genetic counselor in the past, 98 (80%) were seeing a genetic counselor for the first time, and one participant did not respond. The question on the survey asked if the participant had seen a genetic counselor in the past, either for a previous pregnancy or if they had already seen a genetic counselor during their current pregnancy. Participants were not excluded if they had already seen a genetic counselor, but they were excluded if they had already taken the survey.

3.7 Descriptive Analysis of the Reported Reason for Genetic Counseling of the Participant Population

Participants were able to select multiple reasons for their visit with a genetic counselor. Of the 122 participants, 120 participants answered the question, and 18 of them (15%) indicated multiple reasons for seeing the genetic counselor. Of those 18, three participants indicated three different reasons for seeing a genetic counselor, and 15 participants indicated two different reasons for seeing a genetic counselor. In general, UCI had more reports of multiple indications for referral: 15 of the 18 who reported multiple referral indications were from UCI. Only three participants from SJMC indicated multiple reasons for referral. Two out of the three individuals who indicated three reasons for referral were from UCI. A summary of the referral indication for the participant population can be found in Figure 4.
3.8 Descriptive Analysis of the Medication Stopped in the Participant Population

Among our participant population, 16 participants (13%) indicated that they had stopped taking medications because of the pregnancy. Ten out of the 16 women stopped taking medication for a mental health disorder—either depression, anxiety or both. Three out of 16 stopped taking medication that was for their own personal health or maternal medical condition, such as seizures or high blood pressure. One participant stopped taking medication for both her mental health disorder and her maternal medical condition. Three stopped taking over-the-counter pain or allergy medicine, and one participant had stopped taking hormonal treatments. A summary of the medication stopped can be found in Figure 5.
3.9 Descriptive Analysis of the Reason for Stopping Medication in the Participant Population

In total, nine out of the sixteen participants who indicated that they stopped taking medication(s) reported that their doctor recommended discontinuing their medication(s). One participant stopped taking medication because a friend or a family member told her that she should stop. In total, four selected “other” as their reason for stopping.

Of the ten participants who indicated that they stopped taking a medication for a mental health disorder, seven indicated the reason that they stopped. Four participants stopped taking their depression or anxiety medicine because a doctor told them to. The remaining three chose “other” as their reason for stopping their medications; their reasons included “to have a healthy pregnancy,” “because I was pregnant,” and “I only took the medication as needed.”

3.10 Descriptive Analysis of When Participants Stopped Taking Their Medication

Of the sixteen women who reported stopping medication because of their pregnancy, eleven participants reported whether they stopped before they got pregnant or after they found out they were pregnant. Five participants stopped taking the medication before becoming pregnant, and six stopped after they learned that they were pregnant.

Of the ten participants who stopped taking a medication that had been prescribed for a mental health disorder, seven indicated when they stopped taking the medication. Of those seven, four stopped before getting pregnant, and three stopped after getting pregnant.
Figure 5: Medication Stopped in the Participant Population

Medication That Was Stopped Because Of Pregnancy
- Medication for Mental Health Disorder
- Medication for Maternal Disorder
- Hormonal Treatment
- Over The Counter Medication

Why Was Medication Stopped?
- My Doctor Told Me To Stop
- Other
- Did Not Respond

When Was Medication Stopped?
- Before I got Pregnant
- After I Found Out I Was Pregnant
3.11 Descriptive Analysis of the Depression Prevalence in the UCI Participant Population

The 52 UCI participants were placed into the three risk groups based on their depression screen T-score. Of the 52 participants, 31 (59.6%) were in the “Normal” group, 11 (21.2%) were in the “At Risk” group, and 10 (19.2%) were in the “Depression Positive Screen” group. Among the UCI participants, the mean depression T-score was 47.65 with a standard deviation of 8.91.

3.12 Descriptive Analysis of the Depression Prevalence in the SJMC Participant Population

The 70 SJMC participants were placed into the three risk groups based on their depression screen T-score. Of the 70 participants, 52 (74.3%) were in the “Normal” group, 10 (14.3%) were in the “At Risk” group, and 8 (11.4%) were in the “Depression Positive Screen” group. Among the SJMC participants, the mean depression T-score was 44.90 with a standard deviation of 6.96.

3.13 Descriptive Analysis of the Overall Depression Prevalence in the Participant Population

Depression scores were calculated for each site and were then combined for the overall depression prevalence of the entire participant population. There was no statistical difference in the prevalence of depression between the two sites. Of the 122 total participants, 83 (68%) were in the “Normal” group, 21 (17.2%) were in the “At Risk” group, and 18 (14.8%) were in the “Depression Positive Screen” group. The overall mean
depression T-score for the participant population was 46.07 with a standard deviation of 7.93. There was no statistical difference between the mean depression scores from the two sites (p=0.059), (Table 2a).

3.14 Descriptive Analysis of the Anxiety Prevalence in the UCI Participant Population

The 52 UCI participants were placed into three risk groups based on their anxiety screen T-score. Of the 52 participants, 27 (51.9%) were in the “Normal” group, 12 (23.1%) were in the “At Risk” group, and 13 (25.0%) were in the “Anxiety Positive Screen” group. The mean anxiety T-score among the UCI participants was 49.51 with a standard deviation of 10.53.

3.15 Descriptive Analysis of the Anxiety Prevalence in the SJMC Participant Population

The 70 SJMC participants were placed into three risk categories based on their anxiety screen T-score. Of the 70 participants, 40 (57.1%) were in the “Normal” group, 13 (18.6%) were in the “At Risk” group, and 17 (24.3%) were in the “Anxiety Positive Screen” group. The mean anxiety T-score for the SJMC participants was 47.84 with a standard deviation of 8.46.

3.16 Descriptive Analysis of the Overall Anxiety Prevalence in the Participant Population

Anxiety scores were calculated for each site and were then combined for the overall anxiety prevalence of the entire participant population. There was no statistical difference in the prevalence of anxiety between the two sites. Of the 122 total participants, 67
(54.9%) were in the “Normal” group, 25 (20.5%) were in the “At Risk” group, and 30 (24.6%) were in the “Anxiety Positive Screen” group. The overall mean anxiety T-score for the participant population was 48.55 with a standard deviation of 9.39. There was no statistical difference between the mean anxiety scores at the two sites (p=0.355), (Table 2b).

**Table 2a: Depression Prevalence in the Participant Population**

<table>
<thead>
<tr>
<th>Site</th>
<th>Mean Depression Score Mean</th>
<th>St Dev</th>
<th>p-value</th>
<th>Normal T-score ≤50 N</th>
<th>%</th>
<th>At Risk T-score &gt;50-&lt;55 N</th>
<th>%</th>
<th>Screen Positive Depression T-score ≥55 N</th>
<th>%</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCI</td>
<td>47.65</td>
<td>8.91</td>
<td>0.059</td>
<td>31</td>
<td>59.6</td>
<td>11</td>
<td>21.2</td>
<td>10</td>
<td>19.2</td>
<td>0.224</td>
</tr>
<tr>
<td>SJMC</td>
<td>44.9</td>
<td>6.96</td>
<td></td>
<td>52</td>
<td>74.3</td>
<td>10</td>
<td>14.3</td>
<td>8</td>
<td>11.4</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>46.07</td>
<td>7.93</td>
<td></td>
<td>83</td>
<td>68</td>
<td>21</td>
<td>17.2</td>
<td>18</td>
<td>14.8</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2b: Anxiety Prevalence in the Participant Population**

<table>
<thead>
<tr>
<th>Site</th>
<th>Mean Anxiety Score Mean</th>
<th>St Dev</th>
<th>p-value</th>
<th>Normal T-score ≤50 N</th>
<th>%</th>
<th>At Risk T-score &gt;50-&lt;55 N</th>
<th>%</th>
<th>Screen Positive Anxiety T-score ≥55 N</th>
<th>%</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCI</td>
<td>49.51</td>
<td>10.53</td>
<td>0.335</td>
<td>27</td>
<td>51.9</td>
<td>12</td>
<td>23.1</td>
<td>13</td>
<td>25</td>
<td>0.779</td>
</tr>
<tr>
<td>SJMC</td>
<td>47.84</td>
<td>8.46</td>
<td></td>
<td>40</td>
<td>57.1</td>
<td>13</td>
<td>18.6</td>
<td>17</td>
<td>24.3</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>48.55</td>
<td>9.39</td>
<td></td>
<td>67</td>
<td>54.9</td>
<td>25</td>
<td>20.5</td>
<td>30</td>
<td>24.6</td>
<td></td>
</tr>
</tbody>
</table>

3.17 Descriptive Analysis of Statistically Significant Findings Relating to Depression

**T-score**

Participants were either placed in the “Normal”, “At Risk”, or “Depression Positive Screen” group based on their depression screen T-scores. In total, seven factors from the
demographic or personal history were found to be statistically significant in their relationship to participants’ depression T-scores: combined household income level (p=0.042, 0.046), seeing a genetic counselor for carrier screening/being a known carrier of a genetic disorder (p=0.004, 0.020), age at delivery (p=0.011, 0.013), seeing a genetic counselor for multiple indications (p=0.049), whether or not the participant had a history of depression (p=<0.0005, <0.0005), whether or not the participant had a history of anxiety (p=0.013, 0.016), and, if the participant did have anxiety, whether or not it was related to a pregnancy (p=0.028, 0.026), (Table 3).
Table 3: Demographic/Historical Information Relating to Depression T-score

<table>
<thead>
<tr>
<th>Factors Associated With Depression</th>
<th>Normal T-score ≤50 N</th>
<th>At Risk T-score &gt;50-&lt;55 N</th>
<th>Screen Positive Depression T-score ≥55 N</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is your combined household income?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50,000</td>
<td>21</td>
<td>7</td>
<td>9</td>
<td>0.042*</td>
</tr>
<tr>
<td>50-99,999</td>
<td>17</td>
<td>9</td>
<td>5</td>
<td>0.046^</td>
</tr>
<tr>
<td>100-149,999</td>
<td>28</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>≥150,000</td>
<td>15</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Are you seeing a Genetic Counselor today for carrier screening, or because you are a known carrier of a genetic disorder?</td>
<td></td>
<td></td>
<td></td>
<td>0.004*</td>
</tr>
<tr>
<td>Yes</td>
<td>2</td>
<td>4**</td>
<td>0</td>
<td>0.020^</td>
</tr>
<tr>
<td>No</td>
<td>81</td>
<td>17</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Are you seeing a Genetic Counselor today because you will 35 years or older at delivery?</td>
<td></td>
<td></td>
<td></td>
<td>0.011*</td>
</tr>
<tr>
<td>Yes</td>
<td>57</td>
<td>7</td>
<td>12</td>
<td>0.013*</td>
</tr>
<tr>
<td>No</td>
<td>26</td>
<td>14**</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Do you have more than one reason for seeing a Genetic Counselor today?</td>
<td></td>
<td></td>
<td></td>
<td>0.049^</td>
</tr>
<tr>
<td>Yes</td>
<td>8</td>
<td>6</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>75</td>
<td>15</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Has there ever been a time in your life that you thought you were depressed?</td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td>Yes</td>
<td>26</td>
<td>16**</td>
<td>11</td>
<td>&lt;0.0005^</td>
</tr>
<tr>
<td>No</td>
<td>57</td>
<td>5**</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Has there ever been a time in your life that you thought your anxiety was unhealthy?</td>
<td></td>
<td></td>
<td></td>
<td>0.013*</td>
</tr>
<tr>
<td>Yes</td>
<td>25</td>
<td>7</td>
<td>12**</td>
<td>0.016^</td>
</tr>
<tr>
<td>No</td>
<td>58</td>
<td>14</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>If you have a history of anxiety, was it related to a pregnancy?</td>
<td></td>
<td></td>
<td></td>
<td>0.028*</td>
</tr>
<tr>
<td>Yes</td>
<td>7</td>
<td>0</td>
<td>7</td>
<td>0.026^</td>
</tr>
<tr>
<td>No</td>
<td>17</td>
<td>7</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

* = statistically significant Chi-squared p-value  ^ = statistically significant Fisher’s Exact p-value

**=cell value which contributes to statistically significant difference
3.18 Descriptive Analysis of Statistically Significant Findings Relating to Anxiety T-score

Participants were placed in either the “Normal”, “At Risk”, or “Anxiety Positive Screen” group based on their anxiety screen T-scores. In total, seven factors from the demographic or personal history were found to be statistically significant in their relationship to the participants’ anxiety T-scores: if they were seeing a genetic counselor because they had a positive screen on the California Prenatal Screening Program (p=0.008, 0.006), seeing a genetic counselor for multiple indications (p=0.009, 0.006), whether or not the participant had a history of depression (p=0.005, 0.005), whether or not the participant had a history of anxiety (p=<0.0005, <0.0005), whether or not the participant had ever been treated for anxiety (p=0.001, 0.001), whether or not the participant was currently taking medication for depression (p=0.004, 0.002), and whether or not the participant was currently taking medication for anxiety (p=<0.0005, <0.0005), (Table 4).
Table 4: Demographic/Historical Information Relating to Anxiety T-score

<table>
<thead>
<tr>
<th>Factors Associated With Anxiety</th>
<th>Normal T-score ≤50 N</th>
<th>At Risk T-score &gt;50-&lt;55 N</th>
<th>Screen Positive Anxiety T-score ≥55 N</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you seeing a Genetic Counselor today because you screened positive in the California Prenatal Screening Program?</td>
<td></td>
<td></td>
<td></td>
<td>0.008*</td>
</tr>
<tr>
<td>Yes</td>
<td>6</td>
<td>7</td>
<td>10</td>
<td>0.006^</td>
</tr>
<tr>
<td>No</td>
<td>61</td>
<td>18</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Do you have more than one reason for seeing a Genetic Counselor today?</td>
<td></td>
<td></td>
<td></td>
<td>0.009*</td>
</tr>
<tr>
<td>Yes</td>
<td>4</td>
<td>7</td>
<td>7</td>
<td>0.006^</td>
</tr>
<tr>
<td>No</td>
<td>63</td>
<td>18</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Has there ever been a time in your life that you thought you were depressed?</td>
<td></td>
<td></td>
<td></td>
<td>0.005*</td>
</tr>
<tr>
<td>Yes</td>
<td>21</td>
<td>12</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>46</td>
<td>13</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Are you currently taking medication for depression?</td>
<td></td>
<td></td>
<td></td>
<td>0.004*</td>
</tr>
<tr>
<td>Yes</td>
<td>0</td>
<td>2</td>
<td>5**</td>
<td>0.002^</td>
</tr>
<tr>
<td>No</td>
<td>66</td>
<td>23</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Has there ever been a time in your life that you thought your anxiety was unhealthy?</td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td>Yes</td>
<td>14**</td>
<td>11</td>
<td>19**</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>53</td>
<td>14</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Have you ever been treated for anxiety?</td>
<td></td>
<td></td>
<td></td>
<td>0.001*</td>
</tr>
<tr>
<td>Yes</td>
<td>7</td>
<td>6</td>
<td>13**</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>59</td>
<td>19</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Are you currently taking medication for anxiety?</td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.0005*</td>
</tr>
<tr>
<td>Yes</td>
<td>0</td>
<td>0</td>
<td>6**</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>66</td>
<td>23</td>
<td>22</td>
<td></td>
</tr>
</tbody>
</table>

* = statistically significant Chi-squared p-value  ^ = statistically significant Fisher’s Exact p-value  
** = cell value which contributes to statistically significant difference
3.19 Descriptive Analysis of Mean Depression and Anxiety in the Participant Population

Mean depression and anxiety scores were calculated by individual demographic and historical factors. Mean scores for depression and anxiety organized by demographic information are presented in Table 5, mean scores for depression and anxiety organized by personal history information are presented in Table 6, and mean scores for depression and anxiety organized by referral indication are presented in Table 7. Mean scores of above 50 are bolded, except in cases where a group consisted of only one individual.

One demographic factor was associated with a mean of above 55 for anxiety: not being currently pregnant. It was the only factor that had a statistically significant confidence interval (95%). One historical factor was associated with a mean of above 55 for anxiety: currently taking medication for anxiety. It was the only factor that had a statistically significant confidence interval (95%). There were no factors among the referral indications that had a statistically significant confidence interval for the mean depression or anxiety score.
## Table 5: Mean Depression and Anxiety by Demographic Information

<table>
<thead>
<tr>
<th>Demographic Factors</th>
<th>N</th>
<th>Mean Depression T-Score</th>
<th>St Dev</th>
<th>p-value</th>
<th>Mean Anxiety T-Score</th>
<th>St Dev</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>What race/ethnicity do you identify with?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latina</td>
<td>43</td>
<td>45.86</td>
<td>8.83</td>
<td>0.158</td>
<td>47.52</td>
<td>9.07</td>
<td></td>
</tr>
<tr>
<td>Black/African American</td>
<td>3</td>
<td>43.50</td>
<td>9.18</td>
<td></td>
<td>47.77</td>
<td>9.52</td>
<td></td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>33</td>
<td>46.33</td>
<td>7.74</td>
<td></td>
<td>49.23</td>
<td>9.35</td>
<td></td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>32</td>
<td>45.93</td>
<td>6.96</td>
<td></td>
<td>49.33</td>
<td>8.71</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>67.70</td>
<td>n/a</td>
<td></td>
<td>83.10</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Multiple ethnicities selected</td>
<td>10</td>
<td>45.21</td>
<td>5.30</td>
<td></td>
<td>45.07</td>
<td>7.42</td>
<td></td>
</tr>
<tr>
<td>What is the highest level of education you have achieved?</td>
<td></td>
<td></td>
<td></td>
<td>0.917</td>
<td></td>
<td></td>
<td>0.792</td>
</tr>
<tr>
<td>High school or less</td>
<td>21</td>
<td>45.54</td>
<td>8.13</td>
<td></td>
<td>48.14</td>
<td>8.15</td>
<td></td>
</tr>
<tr>
<td>Associate degree / trade school / some college</td>
<td>38</td>
<td>45.93</td>
<td>6.83</td>
<td></td>
<td>47.86</td>
<td>8.05</td>
<td></td>
</tr>
<tr>
<td>Bachelor’s / Master’s / Doctorate</td>
<td>63</td>
<td>46.34</td>
<td>8.57</td>
<td></td>
<td>49.11</td>
<td>10.56</td>
<td></td>
</tr>
<tr>
<td>What is your combined household income?</td>
<td></td>
<td></td>
<td></td>
<td>0.19</td>
<td></td>
<td></td>
<td>0.822</td>
</tr>
<tr>
<td>&lt;$50,000</td>
<td>37</td>
<td>47.62</td>
<td>8.25</td>
<td></td>
<td>48.15</td>
<td>9.05</td>
<td></td>
</tr>
<tr>
<td>$50-99,999</td>
<td>31</td>
<td>47.03</td>
<td>7.54</td>
<td></td>
<td>48.56</td>
<td>9.95</td>
<td></td>
</tr>
<tr>
<td>$100-149,999</td>
<td>32</td>
<td>43.72</td>
<td>8.61</td>
<td></td>
<td>47.59</td>
<td>10.56</td>
<td></td>
</tr>
<tr>
<td>≥$150,000</td>
<td>19</td>
<td>45.38</td>
<td>6.44</td>
<td></td>
<td>50.17</td>
<td>7.92</td>
<td></td>
</tr>
<tr>
<td>How many people live in your household?</td>
<td></td>
<td></td>
<td></td>
<td>0.638</td>
<td></td>
<td></td>
<td>0.295</td>
</tr>
<tr>
<td>1-2 people</td>
<td>43</td>
<td>46.60</td>
<td>8.51</td>
<td></td>
<td>50.01</td>
<td>9.18</td>
<td></td>
</tr>
<tr>
<td>3-5 people</td>
<td>64</td>
<td>46.25</td>
<td>7.64</td>
<td></td>
<td>48.13</td>
<td>9.73</td>
<td></td>
</tr>
<tr>
<td>6+ people</td>
<td>9</td>
<td>43.81</td>
<td>8.43</td>
<td></td>
<td>44.97</td>
<td>7.85</td>
<td></td>
</tr>
<tr>
<td>How old will you be at your due date?</td>
<td></td>
<td></td>
<td></td>
<td>0.125</td>
<td></td>
<td></td>
<td>0.54</td>
</tr>
<tr>
<td>&lt;25 years</td>
<td>9</td>
<td>43.38</td>
<td>5.74</td>
<td></td>
<td>45.17</td>
<td>6.69</td>
<td></td>
</tr>
<tr>
<td>25-29 years</td>
<td>8</td>
<td>50.53</td>
<td>5.85</td>
<td></td>
<td>51.03</td>
<td>6.36</td>
<td></td>
</tr>
<tr>
<td>30-34 years</td>
<td>18</td>
<td>47.35</td>
<td>7.64</td>
<td></td>
<td>47.23</td>
<td>12.46</td>
<td></td>
</tr>
<tr>
<td>35-39 years</td>
<td>65</td>
<td>45.65</td>
<td>8.59</td>
<td></td>
<td>48.93</td>
<td>8.85</td>
<td></td>
</tr>
<tr>
<td>40+ years</td>
<td>15</td>
<td>42.46</td>
<td>5.02</td>
<td></td>
<td>45.98</td>
<td>9.56</td>
<td></td>
</tr>
<tr>
<td>Who came with you to the genetic counseling session?</td>
<td></td>
<td></td>
<td></td>
<td>0.249</td>
<td></td>
<td></td>
<td>0.193</td>
</tr>
<tr>
<td>Husband or Father of Pregnancy</td>
<td>72</td>
<td>46.12</td>
<td>7.24</td>
<td></td>
<td>48.42</td>
<td>8.29</td>
<td></td>
</tr>
<tr>
<td>Parent, Sibling or Friend</td>
<td>12</td>
<td>49.34</td>
<td>12.62</td>
<td></td>
<td>53.02</td>
<td>14.34</td>
<td></td>
</tr>
<tr>
<td>I came to the session alone</td>
<td>38</td>
<td>44.96</td>
<td>7.29</td>
<td></td>
<td>47.39</td>
<td>9.37</td>
<td></td>
</tr>
<tr>
<td>Have you ever seen a genetic counselor?</td>
<td></td>
<td></td>
<td></td>
<td>0.921</td>
<td></td>
<td></td>
<td>0.65</td>
</tr>
<tr>
<td>Yes</td>
<td>23</td>
<td>46.29</td>
<td>8.53</td>
<td></td>
<td>49.30</td>
<td>12.23</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>98</td>
<td>46.10</td>
<td>7.83</td>
<td></td>
<td>48.30</td>
<td>8.68</td>
<td></td>
</tr>
<tr>
<td>Did you get pregnant naturally?</td>
<td></td>
<td></td>
<td></td>
<td>0.046</td>
<td></td>
<td></td>
<td>0.094</td>
</tr>
<tr>
<td>Yes</td>
<td>114</td>
<td>45.99</td>
<td>7.88</td>
<td></td>
<td>48.48</td>
<td>9.30</td>
<td></td>
</tr>
<tr>
<td>No, I used IVF (In-Vitro Fertilization)</td>
<td>6</td>
<td>43.27</td>
<td>5.92</td>
<td></td>
<td>45.48</td>
<td>9.77</td>
<td></td>
</tr>
<tr>
<td>I am not currently pregnant</td>
<td>2</td>
<td>59.05</td>
<td>5.59</td>
<td></td>
<td>61.95</td>
<td>2.19**</td>
<td></td>
</tr>
</tbody>
</table>

* = statistically significant ANOVA p-value when comparing groups  ** = statistically significant confidence interval
Table 6: Mean Depression and Anxiety by Personal History Information

<table>
<thead>
<tr>
<th>Historical Factors</th>
<th>N</th>
<th>Mean Depression T-Score</th>
<th>St Dev</th>
<th>p-value</th>
<th>Mean Anxiety T-Score</th>
<th>St Dev</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has there ever been a time in your life that you thought you were depressed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>53</td>
<td>49.30</td>
<td>8.19</td>
<td>&lt;0.0005</td>
<td>51.97</td>
<td>8.97</td>
<td>0.0003</td>
</tr>
<tr>
<td>No</td>
<td>69</td>
<td>43.60</td>
<td>6.80</td>
<td></td>
<td>45.93</td>
<td>8.91</td>
<td></td>
</tr>
<tr>
<td>If you have had depression, was it related to a pregnancy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>20</td>
<td>51.72</td>
<td>10.52</td>
<td>0.094</td>
<td>53.18</td>
<td>12.29</td>
<td>0.449</td>
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<tr>
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<td>33</td>
<td>47.83</td>
<td>6.13</td>
<td></td>
<td>51.23</td>
<td>6.30</td>
<td></td>
</tr>
<tr>
<td>Have you ever been treated for depression?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>24</td>
<td>48.83</td>
<td>9.03</td>
<td>0.063</td>
<td>52.76</td>
<td>7.83</td>
<td>0.012</td>
</tr>
<tr>
<td>No</td>
<td>97</td>
<td>45.47</td>
<td>7.54</td>
<td></td>
<td>47.43</td>
<td>9.50</td>
<td></td>
</tr>
<tr>
<td>Are you currently taking medication for depression?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>7</td>
<td>52.19</td>
<td>6.74</td>
<td>0.037</td>
<td>55.56</td>
<td>3.29</td>
<td>0.042</td>
</tr>
<tr>
<td>No</td>
<td>113</td>
<td>45.74</td>
<td>7.90</td>
<td></td>
<td>48.15</td>
<td>9.48</td>
<td></td>
</tr>
<tr>
<td>Has there ever been a time in your life that you thought your anxiety was unhealthy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>44</td>
<td>49.30</td>
<td>8.67</td>
<td>&lt;0.001</td>
<td>53.67</td>
<td>9.87</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>78</td>
<td>44.25</td>
<td>6.90</td>
<td></td>
<td>45.67</td>
<td>7.80</td>
<td></td>
</tr>
<tr>
<td>If you have had anxiety, was it related to a pregnancy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>14</td>
<td>52.93</td>
<td>11.03</td>
<td>0.066</td>
<td>56.45</td>
<td>14.09</td>
<td>0.263</td>
</tr>
<tr>
<td>No</td>
<td>29</td>
<td>47.71</td>
<td>6.99</td>
<td></td>
<td>52.90</td>
<td>6.58</td>
<td></td>
</tr>
<tr>
<td>Have you ever been treated for anxiety?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>26</td>
<td>48.25</td>
<td>7.94</td>
<td>0.13</td>
<td>54.16</td>
<td>7.60</td>
<td>0.0005</td>
</tr>
<tr>
<td>No</td>
<td>94</td>
<td>45.57</td>
<td>7.92</td>
<td></td>
<td>47.04</td>
<td>9.28</td>
<td></td>
</tr>
<tr>
<td>Are you currently taking medication for anxiety?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6</td>
<td>52.02</td>
<td>7.44</td>
<td>0.058</td>
<td>58.40</td>
<td>2.00</td>
<td>0.008</td>
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<tr>
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<td>111</td>
<td>45.70</td>
<td>7.87</td>
<td></td>
<td>47.94</td>
<td>9.43</td>
<td></td>
</tr>
</tbody>
</table>

*a = statistically significant ANOVA p-value when comparing the two groups*  
** = statistically significant confidence interval
## Table 7: Mean Depression and Anxiety by Referral Indication

<table>
<thead>
<tr>
<th>Referral Indications</th>
<th>N</th>
<th>Mean Depression</th>
<th>St Dev</th>
<th>p-value</th>
<th>Mean Anxiety</th>
<th>T-Score</th>
<th>St Dev</th>
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* = statistically significant ANOVA p-value when comparing the two groups
4: DISCUSSION

Pregnancies are likely to be thought of as joyous occasions, despite the fact that many women have pregnancies that are at risk for potential complications and that many women are affected by mental health disorders during pregnancy and in the post-partum period. Mental health disorders are not typical topics of discussion during the prenatal genetic counseling session. In general, prenatal genetic counselors see women who are at high risk to have pregnancy complications due to maternal factors or who have an increased risk to have offspring with a genetic disorder, such as a chromosome abnormality. The goal of this study was to identify specific aspects of demographics or personal history that could be associated with having either depression or anxiety among the population of patients who are seeing a genetic counselor in the prenatal setting. We hypothesized that a specific factor or factors would be correlated with a depressed or anxious score when using a validated screening tool. We discovered that specific factors from patients’ personal histories or demographics were associated with their being either depressed, anxious, in a high risk group, or at the normal population level.

The two sites at which UCI prenatal genetic counselors see patients, UCI Medical Center and St. Jude Medical Center, had slightly different patient populations. In total, we had 122 participants between the two populations, with 88% of patients who were approached choosing to participate in the survey. The two populations were statistically different with respect to age, race/ethnicity, education level, and household income. In general, participants at St. Jude Medical Center tended to be older, had more evenly distributed ethnic backgrounds, were more highly educated, with 71% having four-year
college degrees or higher, and had higher household incomes, with the majority of participants indicating a combined household income of above $100,000. At UCI Medical Center, participants were younger, were mostly Hispanic/Latina (46%), tended to be less educated, with a majority of participants selecting “some college, associate degree or vocational training,” and had lower household incomes, with a majority of participants indicating that their combined household income was less than $50,000. The two sites did not differ significantly in their household size, marital status or with respect to whom they brought to the counseling visit. Although their demographic histories may have been different, when the groups were combined, we were able to show that demographic factors in general were not good predictors of participants’ depression or anxiety status.

In total, we discovered that 14.8% of our participants were clinically depressed, and 24.6% of our participants were clinically anxious. Eleven participants (9%) screened positive for both depression and anxiety. When a random sampling of over nine thousand Americans was performed, 26% of the population was affected with a DSM-IV mental health disorder based on regular assessments that occurred over a 12-month period[1]; however, the rate of comorbidity identified within the national study was much higher, with 22% of participants meeting criteria for two mental health disorders. Our rate of 14.8% of participants screening positive for clinical depression is higher than what has been reported previously for pregnant women: in 2010 the University of Washington assessed 1,888 women receiving ongoing prenatal care and found that 9.9% met criteria for depressive disorders, with 4.8% meeting minor criteria, and 5.1% meeting criteria for probable major depression[30]. Our number also is consistent with the reported 14-23% of pregnancies affected by depression that is described by ACOG[4].
We discovered that seven factors from the participants’ personal histories could be associated with their depression status. This supports our hypothesis, which stated that certain historical or demographic information could be associated with depression. The income of the participant was associated with an unequal distribution among the three categories: Normal, At Risk and Depressed, with those of lower income being over-represented in the depressed category. Reporting that there was a past history of depression was highly associated with being in the “At Risk” group, meaning that these individuals could be highly susceptible to recurrence of their mental health disorders, either during their pregnancy or in the post-partum period. Reporting that there was a past history of anxiety was highly associated with currently being depressed (p=0.013, 0.016) indicating that mental health disorders are not necessarily mutually exclusive and that having a past history of one mental health disorder does not limit one to being at risk for only that specific disorder. Having a past history of anxiety related to a pregnancy was associated with currently being depressed. There were more participants who were currently depressed and also had a past history of anxiety related to a pregnancy than were expected, based on a Chi-squared statistical assessment and a Fisher’s Exact Test (p=0.028, 0.026). Women who were seeing a genetic counselor for genetic disorder carrier screening or because they were known carriers of a genetic disorder were significantly more likely to be within the “At Risk” group for their depression status. Having more than one reason for seeing the genetic counselor was also statistically significant in the unequal distribution among the three possible groups (p=0.049). Women who were seeing a genetic counselor for their age 35 or above were less likely to be depressed or in the “At Risk” group than women who were younger than 35, which contradicts one of the fundamental assumptions.
that might be made about genetic counseling—that women who are 35 or older might be more likely to experience symptoms of a mental health disorder during pregnancy because they are at a higher risk for fetal chromosomal abnormalities. This finding is consistent with other studies that have investigated the incidence of depression during pregnancy[30]. Our data shows that although depression is clearly common in our population, we cannot always associate depression with a specific causative factor.

We discovered seven factors from the participants’ personal histories that could be associated with their anxiety status. This supports our hypothesis that certain factors from a patient’s background and/or medical history can be correlated with her anxiety. Having a referral indication of a positive screen on the California Prenatal Screening Program was associated with an unequal distribution among the three categories: Normal, At Risk and Anxious (p=0.008, 0.006), with an overrepresentation of participants being anxious and having a positive screen. Seeing a genetic counselor for multiple indications was also associated with an unequal distribution among the three categories, with more women who reported multiple indications being in the anxious group than was expected. Reporting that there was a history of ever being depressed was associated with being anxious. Again, this indicates that regardless of the specific past mental health disorder, there was an association with having symptoms of a current mental health disorder. In addition, reporting that the participant was currently taking medicine for depression was highly associated with being anxious. It is unclear if currently taking medication for depression increases the risk for anxiety because of the potential risks of continuing medications for mental health disorders or if it simply increases the risk to be anxious for other reasons. In addition, having a past history of anxiety was highly associated with currently being
anxious (p=<0.0005). We discovered an association between ever having been treated for anxiety and screening positive for anxiety (p=0.001), which shows that mental health disorders can recur. In addition, we found that currently taking medication for anxiety was associated with screening positive for anxiety (p=<0.0005), which shows that taking medication during a pregnancy does not completely protect against symptoms of a mental health disorder.

Our study supported the hypothesis that certain factors from a participant’s demographic or personal history could, in fact, be correlated to her current depression or anxiety. Out of the 14 factors that were significant in their association, eight were related to mental health history, five were related to the reason for referral to see a genetic counselor, and one was a demographic factor. In particular, having a past history of anxiety was a predictor for currently being depressed, and having a past history of depression and/or taking medication for depression was a predictor for currently being anxious. This indicates that having a past history for a particular mental health disorder does not mean that one is only at risk for that same disorder. Although having a past history of anxiety was a predictor for currently being anxious, having a past history of depression was more highly associated with being in the “At Risk” group for depression, which could indicate that there are other factors that might be influencing a woman’s risk of recurrence during pregnancy. For this reason, knowing the mental health history of the prenatal genetic counseling patient population is very important in understanding that they might be at risk for recurrence of that disorder or to develop a different mental health disorder.
We were particularly interested in knowing what proportion of our population had stopped taking medication for a mental health disorder because of their pregnancy. Since pregnancy is often thought of as a “protective” time, and mental health medications are often assumed to place the fetus at risk, we asked our population to report (1) if they stopped taking any medication, (2) if so, why had they stopped, and (3) at what point during their pregnancy they had stopped. In total, 10 participants indicated that they had stopped taking medication for a mental health disorder because of their current pregnancy. Of those 10, four indicated that their doctor told them to stop, three gave other reasons for stopping, and three did not respond. Although we know that their doctors recommended stopping medication, we do not know the context of their recommendation. It could be that the medications were known to be associated with birth defects or other pregnancy complications, or the doctors may not have been knowledgeable about teratogenic drugs and may have assumed that it would be safer for the woman to stop. It is also likely that there are medical professionals who fear liability and who, to be safe, simply recommend stopping all medications without understanding the risk-benefit information about the drugs. Ideally, pregnant (or preconceptional) women should be referred to a genetic counselor or clinical geneticist who is trained to evaluate the teratogenic potential of each drug and can discuss the potential risks and benefits of continuing versus discontinuing medication in the context of the women’s medical histories.

Mean depression and anxiety scores were calculated for demographic and historical factors and referral indications. When mean scores were calculated, standard deviations were observed to determine if any groups had a mean score with the entire first standard deviation above 55, indicating that a majority of the group was significantly depressed or
anxious. Based on demographic information from the participant population, only one factor—not currently being pregnant—had a mean score whose entire first standard deviation was completely above the cut-off score of 55. Although it was statistically significant, there were only two participants in this group, which could potentially bias this calculation. Based on historical information, only one factor—currently taking medication for anxiety—had a mean anxiety score whose entire first standard deviation was completely above the cut-off score of 55. Although there were only six participants who fell within this group, the statistical significance of this finding was confirmed. Again, our data indicates that continuing to take medication for anxiety during a pregnancy does not necessarily prevent symptoms from recurring or continuing. As for referral indications, there were no specific factors that had mean scores above 55 with statistically significant confidence intervals. In total, eight factors had mean depression scores above 50, and 18 factors had mean anxiety scores above 50, all of which are bolded within their respective tables (Table 5, Table 6 and Table 7). Although a mean score of above 50 does not indicate clinical depression or anxiety for any of these groups as a whole, these numbers could indicate that the individuals in these groups are at higher risk for depression or anxiety, since on average their scores were closer to a clinically significant cut-off value of a mean score of 55.

In the introduction of this paper, we addressed previous work that had been done to assess the depression prevalence among women who were referred to a genetic counselor because of a positive maternal screen based on abnormal or suspicious fetal ultrasound findings or on a positive maternal serum screen for chromosomal aneuploidy or spina bifida[25]. The study assessed two groups within their population – those who had
positive screen, and those who were pregnant and did not have a positive screen and did not see a genetic counselor. In addition, they assessed pregnant women who were currently taking medication for depression as a means for comparison. Their study population was given the Edinburgh Postnatal Depression Scale (EDPS), and 35% of participants with a positive screen had a score that was above the threshold for depressive symptoms, 2.4% of their control group had a score above the threshold, and 52.4% of individuals taking medication for depression had a score above the threshold. In comparison, we found in our study that among women who were referred either for a positive maternal serum screen or for an ultrasound finding, 4.9% screened positive for depression using the PROMIS scale, and 9.8% screened positive for anxiety using the PROMIS scale. In our study, those currently taking medication for depression were not more likely to screen positive for depression, but they were more likely to be clinically anxious, with 19.6% screening positive for clinical anxiety. In addition, our participants who were currently taking medication for anxiety were also more likely to be anxious, with 18% screening positive for clinical anxiety. Although it might not be a surprise that those who have clinically diagnosed anxiety have anxious symptoms, it is important to note that almost one out of five who are taking medication are still having severe enough symptoms to screen positive, which supports the need to communicate regularly about severity of symptoms so that medication dosage can be optimized. It is important to note that our population differed significantly from the population in the above-mentioned study, both in demographic factors and in the reason for their genetic counseling appointments. The goal of this study was not to be able to compare the two populations directly; however we believe that the findings from both studies indicate that there is a need in the field of
genetic counseling to continue to assess mental health disorders within various populations.

This study had many limitations, the main one being the small size of our participant population. In addition, both of the sites that we assessed were located relatively close to each other in the same county, which could have created bias in our data. In order to have more statistical power and predictive ability, our study would have had to be done in multiple geographic areas across the state or country and include more participants. In addition, although we had a fairly broad range of ethnic backgrounds when the two sites were combined, women of African American heritage were poorly represented in our population. There were many aspects of patients’ backgrounds or histories that appeared to have the potential to be significant, such as having a pregnancy conceived with in-vitro fertilization or not being pregnant at the time of the appointment. However, due to the low number of participants in these groups, it was not possible to confirm these associations statistically. A possible limitation of this study is that a majority of participants were accompanied by another person at their visits, most of the time their spouse or the father of their pregnancy. It is possible that participants were not as honest in the depression and anxiety screen because there was someone present who could have seen their answers to the screening questions. Another limitation to the study was the ability to contact participants whom we thought might be at significant risk for either depression or anxiety. Although the anonymity of the study was likely a motivating factor for participation, we were concerned that there might be opportunities missed to connect participants with resources. For this reason, we attached a list of local resources—many of which were free or low-cost, and multi-lingual—to the study-information sheet.
Although a prenatal genetic counseling session is not focused on establishing the mental health status of a patient, it has already been determined that genetic counselors have a unique ability to connect with patients, especially about topics that are often thought of as taboo, such as domestic violence[29]. Mental health disorders may also be unacceptable topics, especially when associated with pregnancy, which is typically seen in mainstream society as being an overly joyous and positive experience that does not include mental health disruptions. Having a past history of a mental health disorder proved to be strongly associated with being currently depressed or anxious. Although mental health might be considered a prohibited topic in the context of pregnancy, our study shows that 88% of women were willing to take the survey knowing that it would ask about their current and past history of mental health disorders, including depression and anxiety. Women seem open to talking about mental health in the prenatal setting, and we would argue that a genetic counseling session is the perfect opportunity to assess mental health history and concerns and then to address them through interdisciplinary teamwork with other healthcare providers.

There are fundamental aspects of a prenatal genetic counseling session that provide excellent opportunities to act as a checkpoint for mental health concerns. Prenatal genetic counseling begins with taking a highly detailed family and pregnancy history. During this assessment, genetic counselors often learn information that might be lost to other specialists simply because of the lack of time within a standard obstetrical or other medical appointment. By providing such detailed historical information, a patient might disclose a history of post-partum depression or of a mental health disorder that required hospitalization, medication, or other therapies. Genetic counseling sessions typically occur
in the late first trimester or early second trimester of a pregnancy. During this time, many women who stopped taking their medications before pregnancy might still be free of symptoms but may be at risk for symptoms to recur during their pregnancy. Genetic counselors should be aware that the risk of recurrence in the perinatal period is as high as 68% when women stop taking medication for mental health disorders during pregnancy[11]. In addition, clinical anxiety during pregnancy is one of the top risk factors for post-partum depression, regardless of a past history of mental health disorder. Another advantage that genetic counselors have is their ability to counsel patients about complicated, and often emotional, topics. The complex counseling skills that genetic counselors have makes them well qualified to assess patients’ mental health history and current needs. Obstetricians might not have the time or training to go into depth about these disorders, and they should see genetic counselors as a resource and team-member in helping to assess their patients. In order for patients to get the most from their prenatal care, we believe that obstetricians, perinatologists, genetic counselors and psychologists/psychiatrists should work in an interdisciplinary manner to assess, counsel, and recommend the best treatment plan for each patient.

We believe that genetic counselors have a unique opportunity to screen their patients for mental health disorders by asking if they have any past history of depression or anxiety, regardless of whether they ever were given a clinical diagnosis. We recommend that all prenatal genetic counselors assess their patients’ past history of mental health disorders by asking, “Has there ever been a time in your life when you were depressed or thought that your anxiety was unhealthy?” In being asked about her past history, a woman is not directly challenged to admit that she currently may have symptoms of a mental
health disorder. Asking this one question could serve to initiate a conversation about what we know about the risk of recurrence of a mental health disorder during pregnancy or in the post-partum period, along with the benefits that can come from early intervention, such as medication, or individual therapy. In addition, screening using a standardized measure could easily be incorporated into the waiting-room questionnaire and could provide additional assurance that all reasonable steps have been taken to assess each patient. Although ideally we would recommend using a combination of a mental health screen and direct questioning of the patient, we believe that the direct assessment of their past mental health history would provide an accurate assessment of their risk and could provide more potential benefit because it opens the door for dialogue. If any woman reports that she does, in fact, have a history of a mental health disorder, we can assess her current status, educate her about the chance of recurrence of symptoms, contact her obstetrician (with her permission), and provide her with resources that she can use as needed.

As the roles of genetic counselors expand, we expect that issues regarding mental health disorders will continue to arise in genetic counseling sessions. We believe that the information gleaned from this study supports the idea that there is value in mental health screening in pregnancy and that genetic counselors have a particularly unique opportunity to become part of an interdisciplinary team to assess and assist in the mental health of their patients.
REFERENCES


CONFIRMATION OF EXEMPT RESEARCH REGISTRATION

August 27, 2014

RACHEL YOUNGBLOOD
PEDIATRICS

RE: HS# 2014-1378  "Exploring Mental Health in Prenatal Genetic Counseling"

The human subjects research project referenced above has been registered with the UC Irvine Institutional Review Board (UCI IRB) as Exempt from Federal regulations in accordance with 45 CFR 46.101. This exemption is limited to the described activities in the registered UCI IRB Protocol Narrative and extends to the performance of such activities at the sites identified in your UCI IRB Protocol Application. Informed consent from subjects must be obtained unless otherwise indicated below. UCI IRB conditions for the conduct of this research are included on the attached sheet.

Information provided to prospective subjects to obtain their informed consent should, at a minimum, consist of the following information: the subject is being asked to participate in research, what his/her participation will involve, all foreseeable risks and benefits, the extent to which privacy and confidentiality will be protected, that participation in research is voluntary and the subject may refuse to participate or withdraw at any time without prejudice.

Questions concerning registration of this study may be directed to the UC Irvine Office of Research, 5171 Calafia Avenue, Suite 150, Irvine CA 92697-7600; 949-824-6000 or 949-824-2125 (biomedical committee) or 949-824-6862 (social-behavioral committee).

Level of Review:
Exempt Review, Category 2

Ruth A. Muhrnd, DNSc, RN, CNRN, CIP, FAAN
Vice Chair, Institutional Review Board

Registration valid from 08/27/2014 to 08/29/2017
UCI (FWA) 90004071. Approved: January 31, 2003

Informed Consent Requirements:
1. Signed Informed Consent Not Required
   a. Study Information Sheet Required
2. Use of Translated Language Consent

1 In order to consent subjects who are unable to read and speak English, the English version of the consent form must be translated into appropriate languages once IRB approval is granted. Submit the translated version of the consent form to the IRB for stamping. FWA# 00004071 to use.

UNIVERSITY OF CALIFORNIA
UCI RESEARCH POLICIES:
All individuals engaged in human-subjects research are responsible for compliance with all applicable UCI Research Policies (http://www.research.ucir.edu/compliance/human-research-protection/irb-policy-library/human-policies.html). The Lead Investigator of the study is ultimately responsible for assuring all study team members adhere to applicable policies for the conduct of human-subjects research.

LEAD RESEARCHER RECORDKEEPING RESPONSIBILITIES:
Lead Researchers are responsible for the retention of protocol-related records. The following web pages should be reviewed for more information about the Lead Researcher's recordkeeping responsibilities for the preparation and maintenance of research files: http://www.research.ucir.edu/compliance/human-research-protection/researchers/lead-researcher-recordkeeping-responsibilities.html

PROTOCOL EXPIRATION:
The UCI IRB expiration date is provided on the exempt registration letter. All exempt protocols are registered for a maximum period of 3 years. If the study will continue beyond 3 years, a new Application for IRB review is required. No annual continuing renewals are required.

MODIFICATIONS & AMENDMENTS:
No changes are to be made to the registered protocol or the approved, stamped consent form without the prior review and approval of the UCI IRB. All changes (e.g., a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and confirmed by the IRB before they are implemented.

APPROVED VERSIONS OF CONSENT DOCUMENTS, INCLUDING STUDY INFORMATION SHEETS:
Unless a waiver of informed consent is granted by the IRB, the consent documents (consent form, study information sheet) with the UCI IRB approval stamp must be used for consenting all human subjects entered into this study. Only the current approved version of the consent documents may be used to consent subjects. Approved consent documents are not to be used beyond their expiration date.

ADVERSE EVENT & UNANTICIPATED PROBLEMS REPORTING:
All unanticipated problems involving risk to subjects or others or serious adverse events must be reported to the UCI IRB in accordance with Federal regulations and UCI policy. See http://www.research.ucir.edu/compliance/human-research-protection/researchers/reporting-of-adverse-events-unanticipated-problems-and-violations.html for complete details.

CHANGES IN FINANCIAL INTEREST:
Any changes in the financial relationship between the study sponsor and any of the investigators on the study and/or any new potential conflicts of interest must be reported immediately to the UCI Conflict of Interest Oversight Committee (COCI). If these changes affect the conduct of the study or result in a change in the required wording of the approved informed consent document, then these changes must also be reported to the UCI IRB via a modification request.

CLOSING REPORT:
An electronic closing report should be filed with the UCI IRB when the research concludes. See http://www.research.ucir.edu/compliance/human-research-protection/researchers/closing-a-protocol.html for complete details.
APPENDIX B: UCI IRB Electronic Modification Approval Letter

November 25, 2014

RACHEL YOUNGBLOOD  
PEDIATRICS

RE: HS# 2014-1378  Exploring Mental Health in Prenatal Genetic Counseling

Electronic Modification Request # 16268

The following modification(s) for the human subjects research protocol referenced above has/have been approved by the UC Irvine Institutional Review Board (UC IRB). Below is a summary of the approved changes requested via e-modification request number 16268**:

Change Sample Size:
Change Sample Size: Increase allocation by 300 to 600
IRB Approved Sample Size: 300

Change Sample Size: Increase allocation by 300 to 600
IRB Approved Sample Size: 300
Reason: Because I am adding recruitment at a second location, the potential number of participants approached will increase. I was approved for survey distribution for 300 patients at St. Jude Medical Center.

Change in Performance Sites:
Add: St. Jude Medical Center in Fullerton
Reason: I have added St. Jude Medical Center in Fullerton as another location to distribute my survey because UC Irvine genetic counselors see patients there as well. This way I am able to capture a more broad population range within my participants.

Other Changes:
I have changed my name because of marriage.
Reason: I am requesting a modified stamped study information sheet with my correct name so that I can use it to consent patients.

**The IRB may not have approved all changes proposed in the e-modification request. Review the above summary of approved changes and any revised documents provided with this letter. If a requested change does not appear in the summary or in the revised documents, the IRB did not approve that change. Please consult with an IRB Administrator for further information.

Changes to approved protocols may not be made without prior approval by the IRB.

Note: If the approved modification(s) includes changes to the informed consent document, the approved stamped consent form is enclosed with this letter. Please discontinue use of any previous versions of the informed consent document and use only the most updated version for enrollment of all new subjects. Questions concerning approval of this study may be directed to the UC Irvine Office of Research, 5171 California Avenue, Suite 150, Irvine, CA 92697-7600; 949-824-6086 or 949-824-2125 (biomedical committee) or 949-824-6662 (social-behavioral committee).


Ruth A. Mulnard, DNSc, RN, CNRN, CIP, FAAN  
Vice Chair, Institutional Review Board

Approval Issued: 11/25/2014  
(FWA) 00004071, Approved: January 31, 2003

UNIVERSITY OF CALIFORNIA
APPENDIX C: UCI Study Information Sheet

University of California, Irvine
Study Information Sheet

Exploring Mental Health in the Prenatal Genetic Counseling Setting

Lead Researcher
Rachel Youngblood, Genetic Counseling Intern
Pediatrics, Division of Genetic and Genomic Medicine
714-456-5837 | ryoungbl@uci.edu

Faculty Sponsor
Kathryn Steinhaus French, LGCC
Pediatrics, Division of Genetic and Genomic Medicine
714-456-6883 | kasteinh@uci.edu

Other Researchers
Julianne Toohey, M.D.,
Obstetrics and Gynecology, Division of Maternal Fetal Medicine
714-456-6118 | jtoohey@uci.edu

Maureen Bocian, M.D., FAACP FACMG,
Pediatrics, Division of Genetic and Genomic Medicine
714-456-5791 | mbocian@uci.edu

Meredith Jones, LGCC
Pediatrics, Division of Genetic and Genomic Medicine
714-456-5796 | merjones@uci.edu

- You are being asked to participate in a research study to better understand mental health during pregnancy.
- You are eligible to participate in this study if you are a woman over 18 years of age and are seeing a genetic counselor at your appointment today.
- The research procedures involve a 5-10 minute 32 question anonymous survey. No identifiable information will be collected. The survey will NOT become a part of your medical record.
- Possible risks/discomforts associated with the study are psychological stress caused by reading the questions of the survey, or bringing up memories of past medical history events that could have been traumatizing.
- There are no direct benefits from participation in the study. However, this study may explain how we can better identify women who are in need of additional mental health resources during pregnancy.
- You will not be compensated for your participation in this research study.
- All research data collected will be stored securely and confidentially. There will be no identifiable information gathered that could be traced back to you.

Confirmed as Exempt on: 0827714

HS# 2014-1376

eAPP# 8211

1 of 3
The research team, authorized UCI personnel, and regulatory entities may have access to your study records to protect your safety and welfare. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law.

If you have any comments, concerns, or questions regarding the conduct of this research please contact the researchers listed at the top of this form.

Please contact UCI's Office of Research by phone, (949) 824-6662, by e-mail at IRB@research.uci.edu or at 5171 California Avenue, Suite 150, Irvine, CA 92617 if you are unable to reach the researchers listed at the top of the form and have general questions; have concerns or complaints about the research; have questions about your rights as a research subject; or have general comments or suggestions.

Participation in this study is voluntary. There is no cost to you for participating. You may choose to skip a question or a study procedure. You may refuse to participate or discontinue your involvement at any time without penalty. You are free to withdraw from this study at any time. If you decide to withdraw from this study you must notify the research team before placing your survey in the locked box.

Local Depression and Anxiety Resources:
Depression and Bipolar Association of Orange County - www.dbaoac.org
Free meetings at multiple locations

Share Our Selves (S.O.S.)
1500 Superior Ave.
Costa Mesa, CA 92627
For OC residents
(949) 270-2150
Free services for low income

Human Options Counseling Center (Corbin Family Resource Center)
221 S. McFadden Ave., Ste. G
Santa Ana, 92704
(714) 480-3737
Sliding scale fee. Provides services to adults & children affected by domestic violence, individual & group therapy. Provide services in English & Spanish

Korean Community Services (3 locations)
12531 Harbor Blvd, Ste. G
Garden Grove, 92840
(714) 638-5058
Provide counseling services for adults & children on a sliding scale. Individual, marriage, and family counseling services are available by licensed clinicians at a sliding fee scale. Provides services in Korean, Spanish, Vietnamese, and Japanese

Interval House
(951) 594-9492
Counseling, support groups, advocacy, PEP groups. Some services are free.

Straight Talk Clinic
5712 Camp St.
Cypress
(714) 428-2000
Provides services to adults & children on a sliding scale. Specializes in behavioral problems, grief and loss issues. Services can be provided in Spanish

The Center Orange County
1600 N. Spurgeon
Santa Ana, 92701
Confirmed as Exempt on: 08/27/14

HS# 2014-1378

IRB USE ONLY - DO NOT ALTER THIS FOOTER

eAPPI 5211

2 of 3
Sliding scale fee, primarily serves the LGBT community. Daytime & evening hours available, free services to HIV positive individuals, groups

MOMS Orange County - www.momsorangecounty.org
Depression screening and general wellness programs for low income pregnant women

Mental Health Association of Orange County - www.mhaooc.org

National Depression & Anxiety Resources:
National Institute of Mental Health – www.nimh.nih.org
University of California, Irvine
Study Information Sheet

Exploring Mental Health in the Prenatal Genetic Counseling Setting

Lead Researcher
Rachel Peralta, Genetic Counseling Intern
Pediatrics, Division of Genetic and Genomic Medicine
714-456-5837 | ryoungbl@uci.edu

Faculty Sponsor
Kathryn Steinhaus French, LCRC
Pediatrics, Division of Genetic and Genomic Medicine
714-456-6883 | kasteinh@uci.edu

Other Researchers
Julianne Toohey, M.D.,
Obstetrics and Gynecology, Division of Maternal Fetal Medicine
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Maureen Bocian, M.D., FAAFP FACMG,
Pediatrics, Division of Genetic and Genomic Medicine
714-456-5791 | mebocian@uci.edu

Meredith Jones, LCGC
Pediatrics, Division of Genetic and Genomic Medicine
714-456-5796 | merjones@uci.edu

- You are being asked to participate in a research study to better understand mental health during pregnancy.

- You are eligible to participate in this study if you are a woman over 18 years of age and are seeing a genetic counselor at your appointment today.

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- Possible risks/discomforts associated with the study are psychological stress caused by reading the questions of the survey, or bringing up memories of past medical history events that could have been traumatizing.

- There are no direct benefits from participation in the study. However, this study may explain how we can better identify women who are in need of additional mental health resources during pregnancy.

- You will not be compensated for your participation in this research study.

- All research data collected will be stored securely and confidentially. There will be no identifiable information gathered that could be traced back to you.

- The research team, authorized UCI personnel, and regulatory entities may have access to your study records to protect your safety and welfare. Any information derived from this research project that

Approved by IRB on: 11/25/14

HS#: 2014-1378
personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law.

- If you have any comments, concerns, or questions regarding the conduct of this research please contact the researchers listed at the top of this form.

- Please contact UCI’s Office of Research by phone, (949) 824-6662, by e-mail at IRB@research.uci.edu or at 5171 California Avenue, Suite 150, Irvine, CA 92617 if you are unable to reach the researchers listed at the top of the form and have general questions; have concerns or complaints about the research; have questions about your rights as a research subject; or have general comments or suggestions.

- Participation in this study is voluntary. There is no cost to you for participating. You may choose to skip a question or a study procedure. You may refuse to participate or discontinue your involvement at any time without penalty. You are free to withdraw from this study at any time. If you decide to withdraw from this study you must notify the research team before placing your survey in the locked box.

Local Depression and Anxiety Resources:

Shore Our Selves (S.O.S.)
1503 Superior Ave.
Costa Mesa, CA 92627
For OC residents (949) 270-2160 - Free services for low income

Human Options Counseling Center (Corbin Family Resource Center)
2215 W. McFadden Ave., Ste. G
Santa Ana, 92704
(714) 480-3737 - Sliding scale fee, provides services to adults & children affected by domestic violence, individual & group therapy. Provide services in English & Spanish

Korean Community Services (3 locations)
12331 Harbor Blvd, Ste. G
Garden Grove, 92840
(714) 639-5000 - Provides counseling services for adults & children on a sliding scale. Individual, marriage, and family counseling services are available by licensed clinicians at a sliding scale rate. Provides services in Korean, Spanish, Vietnamese, and Japanese

Interval House
(562) 594-9482 - Counseling, support groups, advocacy, PEP groups. Some services are free.

Straight Talk Clinic
5712 Camino St.
Cypress
(714) 629-2800 - Provides services to adults & children on a sliding scale. Specializes in behavioral problems, grief & loss issues. Services can be provided in Spanish

The Center Orange County
1605 S. Sparragon
Santa Ana, 92701
(714) 953-5429, ext. 330 - Sliding scale fee, primarily serves the LGBT community. Daytime & evening hours available, free services to HIV positive individuals, groups

MOMS Orange County - www.momsorangecounty.org - Depression screening and general wellness programs for low income pregnant women

Mental Health Association of Orange County - www.mhassoc.org

National Depression & Anxiety Resources:
National Alliance on Mental Illness – www.nami.org

National Institute of Mental Health – www.nimh.nih.gov

Approved by IRB on: 11/25/14

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eMod# 10268
Universidad de California, Irvine
Formulario de información sobre el estudio

Explorando la salud mental en el ambiente de asesoramiento genético prenatal

Investigadora principal
Rachel Peralta, Consejera genética en práctica
Pediatrics, Division of Genetic and Genomic Medicine
714-456-5837 | ryoungbl@uci.edu

Patrocinadora del profesorado
Kathryn Steinhaus French, LCGC
Pediatrics, Division of Genetic and Genomic Medicine
714-456-6883 | kasteinh@uci.edu

Otros investigadores
Julianne Toohey, M.D.
Obstetrics and Gynecology, Division of Maternal Fetal Medicine
714-456-6118 | jtoohey@uci.edu

Maureen Bocian, M.D., FAACP FACMG
Pediatrics, Division of Genetic and Genomic Medicine
714-456-5791 | mebocian@uci.edu

Meredith Jones, LCGC
Pediatrics, Division of Genetic and Genomic Medicine
714-456-5796 | merjones@uci.edu

- Se solicita que usted participe en un estudio de investigación para entender mejor la salud mental durante el embarazo.
- Ud. es elegible para participar en el estudio si es una mujer mayor de 18 años de edad que visite a una consejera genética en su cita de hoy.
- Participar en el estudio consiste en contestar una encuesta anónima de 32 preguntas con duración de unos 5-10 minutos. No se recolecta nada de información con la que se pueda identificarla. La encuesta completada se archivará en su registro médico personal.
- Los posibles riesgos y molestias asociados con el estudio son estrés psicológico debido a leer las preguntas de la encuesta, o recordarle de eventos médicos pasados que pudieran ser traumáticos.
- No hay ningún beneficio directo a usted por participar en el estudio. No obstante, es posible que este estudio nos ayude a identificar más efectivamente a las mujeres que necesitan apoyo adicional para cuidar la salud mental durante el embarazo.
- Usted no recibirá dinero por su participación en este estudio de investigación.
- Todos los datos recolectados se mantendrán seguros y confidenciales. No se pide nada de información personal que lo identifique a usted.
• El estudio personal está autorizado por UCI y entidades regulatorias. UCI tiene acceso a sus datos con el propósito de proteger su seguridad y bienestar. Estas entidades no divulgarán nada de información que indentifique a usted personalmente sin su consentimiento separado, excepto por petición legal.

• Si usted tiene cualquier comentario, preocupación o pregunta relacionada con la manera en que se ha hecho la investigación, favor de comunicarse con los investigadores arriba mencionados en este formulario.

• Si no puede comunicarse con los investigadores mencionados en este formulario y tiene preguntas generales, preocupaciones o quejas relacionadas con la investigación, preguntas acerca de sus derechos como sujeto de investigación o comentarios o sugerencias generales, favor de comunicarse con la Oficina de Investigación (Office of Research) por teléfono a (949) 824-6662, por e-mail a IRB@research.uci.edu o en persona a 5171 California Avenue, Suite 160, Irvine, CA 92617.

• Su participación en este estudio es voluntaria. Participar no le cuesta nada. Ud. puede saltar cualquier pregunta o procedimiento del estudio. Usted puede retirar su participación o descontinuar su conexión con el estudio en cualquier momento sin castigo. Usted está libre a retirarse de este estudio en cualquier momento. Si decide retirarse del estudio, debe notificar a un miembro del equipo de investigación antes de entregar su encuesta en la caja cerrada.

Recursos locales: la depresión y la ansiedad
Depression and Bipolar Association of Orange County - www.dbuoc.org
Reuniones sin costo en varios lugares

Share Our Selves (S.O.S.)
1550 Superior Ave.
Costa Mesa, CA 92627
Para residentes del condado de Orange
(949) 270-2100
Servicios sin costo en caso de bajos ingresos

Human Options Counseling Center (Corbin Family Resource Center)
2216 W. McFadden Ave., Ste. G
Santa Ana, 92704
(714) 459-3737
Pagos por escala móvil, provee servicios para adultos y niños afectados por la violencia doméstica.
Terapia individual y en grupo. Servicios en inglés y español.

Korean Community Services (3 locations)
12351 Harbor Blvd, Ste. G
Garden Grove, 92840
(714) 638-5008
Provee servicios de terapia para adultos y niños. Consejería individual, matrimonial o para la familia es disponible con terapeutas clínicos licenciados; pagos determinados por escala móvil. Servicios en coreano, español, vietnamita y japonés.

Interval House
(562) 594-9492
Terapia, grupos de apoyo, defensa, grupos de PEP (programa de apoyo para padres y madres). Algunos servicios son gratuitos.

Straight Talk Clinic
5712 Camp St.
Cypress
(714) 828-2000
Provee servicios para adultos y niños, pagos por escala móvil. Especialista en problemas de comportamiento y asuntos del dolor y la pérdida. Servicios disponibles en español.

The Center Orange County
1055 N. Spurgeon
Santa Ana, 92701
(714)953-5439, ext. 330
Pagos por escala móvil, sirve primariamente a la comunidad LGBT. Horas de servicio extendidas, servicios gratis a individuos VIH positivos.

MCMS Orange County - www.mcmsonearcogency.org
Evaluaciones y diagnósticos de la depresión y programas de bienestar general para mujeres de bajos ingresos.

Approved by IRB on: 02/04/15
HS# 2014-1376

eMod# 16288
Recursos nacionales: la depresión y la ansiedad:

National Institute of Mental Health – www.nimh.nih.org
APPENDIX F: SJMC IRB Approval Letter

October 31, 2014

SJH Reference # 14-080
Protocol Title: Exploring Mental Health in the Prenatal Genetic Counseling Setting

Dear Ms. Rachel Peralta:

This is to advise you that the above referenced research project has been presented to the St. Joseph Health System Human Research Protection Program (HRPP) Office for review, and the following action was taken with the explanation provided below:

Study Status: Exempt from IRB Review: 10/31/2014
Description: The SJH HRPP Office reviewed the above-referenced submission and determined that the study qualifies for Exemption from 45 CFR 46 regulations governing human subjects research in accordance with 45 CFR 46.101(b) under Category 2 (Research involving the use of survey procedures, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation).

The following materials are approved:
- Application "Exploring Mental Health in the Prenatal Genetic Counseling Setting"
- Participant Information Sheet dated 20Oc2014
- Survey Side 1 and 2

Please note:
Although this study is exempt from Human Subjects Regulations found at 45 CFR 46, this project must be conducted in accordance with the Ethical Principles outlined in the Belmont Report.

If the study design or procedures change, please submit the changes to the HRPP Office. Please be aware that significant study changes may nullify the exemption and require IRB review and approval.

Please inform the HRPP Office via email or letter when you have completed your study.

Sincerely,

Stuart O'Brien, CIP
IRB Manager
APPENDIX G: SJMC Study Information Sheet

Participant Information Sheet

Exploring Mental Health in the Prenatal Genetic Counseling Setting
You are invited to participate in a research study that utilizes information collected through an anonymous survey. The purpose of this study is to determine the overall status of emotional and mental health during pregnancy within the population of women who are being seen by a genetic counselor.

What will happen during this study?
If you choose to participate in this study, you will take an anonymous 32-question survey which asks questions about your demographics, past pregnancy history, reason for seeing a genetic counselor today, and then questions about depression and anxiety.

Your involvement in this study will last for the time it takes you to fill out the survey/questionnaire, which for most people is less than 10 minutes.

You will not be compensated for your participation in this study.

You can stop participating in this study at any time without penalty to you or loss of benefits to which you are normally entitled. As this is an anonymous survey, if you choose to withdraw your participation, please do not place your survey within the lock box.

What are the risks and benefits to me while participating in this study?
There may be the potential for loss of confidentiality. In addition, there may be unknown risks, or risks that we did not anticipate. For more information about potential risks with participating in this study, talk to your study investigator.

There are questions within the survey about past pregnancy history, depression, and anxiety, which could cause discomfort for some people.

You may not directly benefit from participating in this study. However, the benefit of this research is that we hope to learn about how to better meet the needs of our patient population.

What alternatives are there to participating in this study?
The alternative to this study is to not participate.

Your participation in this study is completely voluntary. There will be no penalty to you or loss of benefits to which you are normally entitled if you choose not to participate in this study.

What measures are taken to ensure privacy and confidentiality?
This is an anonymous survey, which collects no identifiable information. If there are any questions that you think will compromise your confidentiality, you can choose to not answer them. Completed surveys are kept within a locked box while the research team is enrolling participants. At the end of each day, the box leaves the facility with the research team and the surveys are taken to a locked office. Surveys will be transcribed to a digital format with no identifiers at the end of each week until enrollment ends. By entering data at the end of the week,
the participants' identity is further protected from the research team, as there will be a weeks
worth of surveys within each box, making it unlikely that the researchers would be able to
connect a survey with a specific participant. Paper copies of the surveys will be kept in a locked
area as a back-up to the digital format. At the conclusion of this research study, all paper copies
of the surveys will be destroyed.

Who can answer questions about this study?
If you have any questions about this study or decide to discontinue participation, please contact
Rachel Peralta at 714-456-5837 or ryoungbl@uci.edu.

For questions about your rights while taking part in this study, or if you have any questions or
concerns, you may contact your study investigator or St. Joseph Health Human Research
Protection Program (HRPP) Office at 949-381-4907.

Local Depression and Anxiety Resources:
Depression and Bipolar Association of Orange County - www.dabaoc.org - Free meetings at multiple locations
Share Our Selves (S.O.S.)
1550 Superior Ave.
Costa Mesa, CA 92627
For OC residents
(949) 270-2100 - Free services for low income

Human Options Counseling Center (Corbin Family Resource Center)
2216 W. McFadden Ave., Ste. G
Santa Ana, 92704
(714) 480-3737 - Sliding scale fee, provides services to adults & children affected by domestic violence, individual & group therapy.
Provide services in English & Spanish

Korean Community Services (3 locations)
17551 Harbor Blvd, Ste. G
Garden Grove, 92840
(714) 638-5088 - Provide counseling services for adults & children on a sliding scale. Individual, marriage, and family counseling
services are available by licensed clinicians at a sliding fee scale. Provides services in Korean, Spanish, Vietnamese, and
Japanese

Interval House
(562) 594-9492 - Counseling, support groups, advocacy, PEP groups. Some services are free.

Straight Talk Clinic
5712 Camp St.
Cypress
(714) 828-2001 - Provides services to adults & children on a sliding scale. Specializes in behavioral problems, grief and loss issues.
Services can be provided in Spanish

The Center Orange County
1666 N. Sprague
Santa Ana, 92701
(714)953-5428, ext. 330 - Sliding scale fee, primarily serves the LGBT community. Daytime & evening hours available, free services
to HIV positive individuals, groups

MOMS Orange County - www.momsorangecounty.org - Depression screening and general wellness programs for low income
pregnant women

Mental Health Association of Orange County - www.mhaoc.org

National Depression & Anxiety Resources:
National Alliance on Mental Illness - www.namiorganization.org OR www.nami.org
National Institute of Mental Health - www.nimh.nih.gov

Info Sheet Template Version 4/11/2013
APPENDIX H: Survey – English

1. What is your race/ethnicity? (Check all that apply)
   □ Hispanic or Latino
   □ Black or African American
   □ Asian or Pacific Islander
   □ Native American or American Indian
   □ White/Caucasian
   □ Other: ____________________________

2. What is the highest degree or level of school you have completed?
   □ Grade 1-8
   □ Some High School
   □ High School Diploma
   □ Trade/Technical/Vocational Training
   □ Some College
   □ Associate Degree
   □ Bachelor’s Degree
   □ Master’s Degree
   □ Doctorate Degree

3. What is your total household income?
   □ Less than $25,000
   □ $25,000-$49,999
   □ $50,000-$74,999
   □ $75,000-$99,999
   □ $100,000-$124,999
   □ $125,000-$149,999
   □ Above $150,000

4. How many people live in your household (including yourself)?

5. What is your marital status?
   □ Single, never married
   □ Married or Domestic Partnership
   □ Widowed
   □ Divorced
   □ Separated

6. How old will you be when your baby is born?

7. Did anyone come to this appointment with you?
   □ Spouse/Parent of pregnancy
   □ Parent
   □ Brother or Sister
   □ Friend
   □ I came to the session alone

8. Before today, have you ever had an appointment with a Genetic Counselor? (either for a previous pregnancy, or previously during your current pregnancy?)
   □ Yes
   □ No

9. What is your reason for seeing a Genetic Counselor today? (Check all that apply)
   □ My age (over 35 years)
   □ Positive California Prenatal Screen result
   □ Abnormal ultrasound finding
   □ Carrier testing/know carrier of a genetic disorder
   □ Recurrent Pregnancy Loss/Miscarriages
   □ Problems with a previous pregnancy/child
   □ My medical condition (diabetes, seizures, etc.)
   □ To get information before I get pregnant
   □ I don’t know

10. Did you get pregnant naturally?
   □ Yes
   □ No, I used In-Vitro Fertilization (IVF)
   □ I am not pregnant at this time

11. Has there ever been a time in your life that you thought you were depressed?
   □ Yes
   □ No

12. If YES, was it related to a pregnancy (either during or right after a pregnancy)?
   □ Yes
   □ No

13. Have you ever been treated for depression?
   □ Yes
   □ No

14. Has there ever been a time in your life that you thought your anxiety was unhealthy?
   □ Yes
   □ No

15. If YES, was it related to a pregnancy (either during or right after a pregnancy)?
   □ Yes
   □ No

16. Have you ever been treated for anxiety?
   □ Yes
   □ No

17. Because of this pregnancy, have you stopped taking any medicine?
   □ Yes
   □ No

18. If YES, what is the name of the medicine and/or what was it taken for?

19. If YES, why did you stop taking the medicine?
   □ Doctor’s recommendation (Primary Care/OB-GYN)
   □ I read on the Internet that I should stop
   □ I was told by a friend or family member I should stop
   □ Other:

20. If YES, when did you stop taking the medication?
   □ Before I got pregnant
   □ After I found out I was pregnant

PLEASE CONTINUE THE SURVEY ON THE BACK OF THIS PAGE
### In the past 7 days...

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<th></th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
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</thead>
<tbody>
<tr>
<td>I felt worthless</td>
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<tr>
<td>I felt helpless</td>
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<td>I felt depressed</td>
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<td>I felt hopeless</td>
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<td>I felt like a failure</td>
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<td>I felt unhappy</td>
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<tr>
<td>I felt that I had nothing to look forward to</td>
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<tr>
<td>I felt that nothing could cheer me up</td>
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</table>

### In the past 7 days...

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>I felt fearful</td>
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<tr>
<td>I found it hard to focus on anything other than my anxiety</td>
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<tr>
<td>My worries overwhelmed me</td>
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<td>I felt uneasy</td>
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<td>I felt nervous</td>
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<tr>
<td>I felt like I needed help for my anxiety</td>
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<tr>
<td>I felt anxious</td>
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<tr>
<td>I felt tense</td>
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THANK YOU FOR YOUR PARTICIPATION!

PLEASE LEAVE YOUR SURVEY IN THE LOCKED DROP BOX
APPENDIX I: Survey – Spanish Translation

1. ¿Cuál es tu raza o grupo étnico? (Marque todas las respuestas que correspondan)
   □ Raza Negra o afroamericano
   □ Indígena americano/Indio de las Américas
   □ Africano Americano
   □ Asia o de las Islas del Pacífico
   □ Otro:

2. ¿Cuál es el nivel de educación más alto que usted ha terminado?
   □ Menos de 8
   □ 8-10
   □ 11-12
   □ 13-15
   □ 16+  años

3. ¿Cuáles son los ingresos anuales de todos los miembros de su casa en total?
   □ Menos de $25,000
   □ $25,000-$49,999
   □ $50,000-$74,999
   □ $75,000-$99,999
   □ $100,000-$124,999
   □ $125,000-$149,999
   □ Más de $150,000

4. ¿Cuántas personas viven en su casa (incluyendo usted mismo)?

5. ¿Cuál es su estado civil?
   □ Soltero, nunca casado
   □ Casado o en pareja de hecho
   □ Viudo/a
   □ Divorciado/a
   □ Viviendo con otros

6. ¿Cuántos años tendrá en el momento en que nazca su hijo?

7. ¿Alguna otra persona la acompaña a la cita de hoy?
   □ Mi esposa/el padrastro
   □ Mi madre o padre
   □ Mi hermano/a
   □ Mi amigo/a
   □ Otro:

8. Antes del día de hoy, ¿alguna vez ha consultado a un consejero genético? (Eso podría ser por razón de un embarazo previo, o anteriormente durante el embarazo actual.)
   □ Sí
   □ No

9. ¿Por qué consultas hoy al asesor genético? (Marque todas las respuestas que correspondan.
   □ Resultados positivos en la revisión prenatal del estado de California (CaPNS)
   □ Resultado negativo en la ecografía/ultrasonido
   □ Prueba de portador/Portadora conocida de una enfermedad genética
   □ Múltiples pérdidas de embarazo/molares abortos espontáneos (Las respuestas posibles continúan en la columna que sigue.)

   □ Problemas previos con un embarazo/hijo
   □ Mi afectación médica (diabetes, enfermedad convulsiva, etc.)
   □ Para recibir información antes de quedarme embarazada
   □ Otro:

10. ¿Usted se quedó embarazada naturalmente?
    □ Sí
    □ No

11. ¿Ha habido algún momento de su vida en que tuviera la depresión?
    □ Sí
    □ No

12. ¿Ha recibido tratamiento para la depresión?
    □ Si
    □ No

13. ¿Ha habido algún momento de su vida en que pensara que su salud no era saludable?
    □ Sí
    □ No

14. ¿Ha habido algún momento de su vida en que estuviera deprimida?
    □ Sí
    □ No

15. ¿Ha habido algún momento de su vida en que estuviera deprimida?
    □ Sí
    □ No

16. ¿Ha dejado de tomar algún medicamento a causa de este embarazo?
    □ Sí
    □ No

17. ¿Por qué dejó de tomar el medicamento?
    □ Mi médico me ha recomendado que no lo toma (médico de cabecera o obstetra ginecólogo (OB-GYN))
    □ Leí en el internet que no debería tomarlo
    □ Me dijo un amigo o familiar que no debía tomarlo
    □ Otro motivo:

18. ¿Cuándo dejó de tomar el medicamento?
    □ Antes de quedarme embarazada
    □ Después de que entarame de que estaba embarazada

POR FAVOR CONTINUE ESTA ENCUESTA EN EL DORSO DE LA PÁGINA
<table>
<thead>
<tr>
<th>En los últimos 7 días...</th>
<th>Nunca</th>
<th>Rara vez</th>
<th>Algunas veces</th>
<th>A menudo</th>
<th>Siempre</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Senti que no valía nada</td>
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<td>2. Me sentí indefenso/a (que no podía hacer nada para ayudarme)</td>
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<td>3. Me sentí deprimido/a</td>
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<td>4. Me sentí desesperanzado/a</td>
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<td>5. Me sentí fracasado/a</td>
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<td>6. Me sentí descontento/a</td>
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<td>7. Senti que nada me ilusionaba</td>
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<td>8. Senti que nada me podía animar</td>
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<td>En los últimos 7 días...</td>
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<td>Algunas veces</td>
<td>A menudo</td>
<td>Siempre</td>
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<tr>
<td>1. Senti miedo</td>
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<tr>
<td>2. Tuve dificultad para concentrarme en otra cosa que no fuera mi ansiedad</td>
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<tr>
<td>3. Mis inquietudes fueron demasiado para mi</td>
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<td>4. Me sentí intranquilo/a</td>
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<td>5. Me sentí nervioso/a</td>
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<td>6. Senti que necesitaba ayuda para mi ansiedad</td>
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<td>7. Senti ansiedad</td>
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<td>8. Me sentí tenso/a</td>
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