IMPROVING KNOWLEDGE, EVALUATING OPINIONS, AND ASCERTAINING THE ACCEPTANCE OF GENETIC COUNSELING FOR BIPOLAR DISORDER: ANALYSIS OF RESPONSES IN THE UNITED STATES AND INDIA

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Bipolar disorder (BPD) is a serious mood disorder that affects about 1% of the population of the United States. Twin, family, and adoption studies have shown evidence for a genetic component of BPD, but monozygotic twin concordance is less than one, indicating that BPD is a multi-factorial disorder. First-degree relatives of an individual with BPD have approximately a 5-30% risk of developing BPD because of shared genes and environment. No strong susceptibility loci for BPD have been located, although some areas of interest are currently being evaluated. With increasing genetic information, demand for genetic counseling for BPD and other psychiatric disorders are increasing.

This study used anonymous surveys for individuals with BPD and their first-degree relatives to assess knowledge, opinions, and acceptance of genetic counseling. The Health Belief Model was used to assess current health beliefs relating to BPD. Additionally, using a brief educational session, the effect of education on knowledge and health beliefs was assessed.

A similar study was conducted by Dr. Triptish Bhatia in India and she has provided her unpublished results so that they could be included in this document for comparative purposes.

Data show that the perceived severity of BPD and perceived barriers of testing were high in both populations. Data show that the perceived susceptibility, benefit, and knowledge of BPD in affected individuals were higher in the US population than in the Indian population.

Ascertainment criteria and the evaluation procedures for the samples were different in both countries and they cannot be considered to be representative of the respective ‘populations’. The public health significance includes: the creation of public health programs in which clients can learn more about their condition, how BPD is related to genomics and what the risk is to their offspring.

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1.0 INTRODUCTION

The project was created to determine the current health beliefs of individuals diagnosed with Bipolar Disorder (BPD), the current health beliefs of their first-degree relatives in response to disease course, treatment, and genetic information, and knowledge of BPD. Researchers anticipate that the demand for genetic counseling services for psychiatric disorders will increase in the future, on the basis of a lack of knowledge among individuals diagnosed with BPD.

A modified Health Belief model (HBM) was implemented to assess quantitative variables in the data set. The survey was designed to measure familiarity with, and interest in, genetic counseling, knowledge of bipolar disorder, and health beliefs. A five-point scale response system assessed perceived susceptibility, perceived seriousness, perceived benefit of testing, and perceived barriers to testing for BPD.

The Master's Thesis project was originally designed for fifty or more participants in each country. To date, 62 participants have completed the survey and 6 have completed the education session and follow-up survey. The data has been analyzed and interpreted to this point (April 2009), and it is expected interpretations of the data may be higher with more participants added.

A final set of questions, five open-ended questions encouraging a discussion of the causes of bipolar disorder and the likelihood that there is a genetic component were analyzed looking for similar responses. These open-ended questions were analyzed to find themes and differences in responses to the questions.

1.1 SPECIFIC AIM 1

Knowledge of Bipolar Disorder and the Health Belief Model:

Specific Aim: To determine the current health beliefs of individuals diagnosed with Bipolar Disorder (BPD), the current health beliefs of their first-degree relatives in response to disease course, treatment, and genetic information, and knowledge of BPD.

Hypothesis: Participants in a voluntary survey will have a high level of perceived severity of BPD, a low level of knowledge about cause of mental illness, a low level of perceived susceptibility, a moderate level of perceived benefit to testing, and a low level of perceived barriers to testing. The perceived susceptibility, benefit, and knowledge of BPD will be higher in the US population than in the Indian population.

Plan: Utilizing anonymous surveys among individuals diagnosed with BPD, and their first-degree relatives, the following topics were analyzed: the current state of knowledge of disease cause, course, treatment, and genetic information. Assessment of knowledge of

psychiatric genetic risks was studied to determine if there is a correlation among health beliefs of the disorder.

1.2 SPECIFIC AIM 2

Knowledge of Bipolar Disorder and Acceptance of Genetic Testing and Counseling:

Specific Aim: To assess patient's knowledge of genetic counseling, and to assess acceptance of and interest in genetic counseling services and genetic testing.

Hypothesis: US and Indian data will show that the perceived severity of BPD and perceived barriers of testing will be high in both populations.

Plan: Utilizing anonymous surveys in individuals diagnosed with BPD and their first-degree relatives, the current state of knowledge of genetic testing and genetic counseling, and acceptance of genetic counseling services were ascertained.

2.0 BACKGROUND AND SIGNIFICANCE

The overall goal of this project was to learn more about the needs of the populations diagnosed with BPD, anticipating that the demand for genetic counseling services for psychiatric disorders will increase in the future. In order to address these issues, it was necessary to review the incidence and natural history of BPD, the current treatment and molecular genetics of psychiatric conditions, and published studies that have examined opinions of the BPD population to date. An extensive literature review of BPD is referenced in E. James' thesis (2007)[1].

2.1 BIPOLAR DISORDER (BPD) EPIDEMIOLOGY

2.1.1 Incidence and Prevalence of BPD

Approximately one percent of the US population will be diagnosed with bipolar disorder in their lifetime. The average age-at-onset of BPD ranges from 18 years in the United States to 27 years in Puerto Rico. While the first symptoms of BPD can appear at almost

any age, there appears to be a peak period of onset between 15 and 19 years of age in the United States and affects men and women equally[2].

Earlier age of onset indicate increased risk for relatives. [3] Risk to first-degree relatives to develop BPD is between 5% and 30%[3]. Bipolar I disorder, bipolar II disorder, and bipolar disorder not otherwise specified are discussed as separate diagnoses only when the distinction is clear; in this document, bipolar disorder or BPD includes the entire bipolar disorder spectrum, with no distinction made between subtypes.

2.1.2 Natural History of BPD

Bipolar disorder, or manic depression, is a condition that causes extreme shifts in mood, energy, and functioning. These changes may be subtle or dramatic and typically vary greatly over the course of a person's life as well as among individuals. Over 10 million people in America have bipolar disorder, and the condition affects men and women equally.[4]

Symptoms of mania and depression constitute a diagnosis of BPD. Mania is described as one phase of BPD and includes symptoms of: elated or happy mood, increased physical and mental energy, racing thoughts, flight of ideas and grandiose plans, impulsive activity (spending, alcohol or drug use) or decreased sleep. Depression is described as a second phase of BPD. Symptoms of depression include: loss of energy, prolonged sadness, inability to concentrate, loss of interest or enjoyment in activities that are normally enjoyable, feeling of guilt or thoughts of suicide.

Sometimes, individuals may experience an increased frequency of episodes. When four or more episodes of illness occur within a year's time, the individual is said to have BPD with rapid cycling. Rapid cycling is more commonly associated in women than men because of hormone fluctuation.

The exact cause of BPD is not known, although most scientists believe that it is a collection of multiple factors that lead to a chemical imbalance in the brain. Those factors may encompass life events in combination with genetic factors, or each by itself. BPD often runs in families and research studies are currently assessing genetic loci involved.

2.1.3 Treatment of BPD

Treatment of BPD has been established and published in the Expert Consensus Guidelines in 2000. Use of a mood stabilizer is recommended in all phases of treatment. Divalproex (DEPAKOTE®) and lithium are the primary mood stabilizers for both acute and preventive treatment of mania. If monotherapy fails, the next recommended intervention is to combine them. The combination of lithium and divalproex can then serve as the foundation to which other medications are added if needed. Carbamazepine is the leading alternative mood stabilizer for mania in individuals who are unable to take lithium or divalproex[5-7].

Additional medications may be indicated during depressive episodes. Antidepressants including, bupropion (Wellbutrin and Zyban), serotonin reuptake inhibitors (SSRIs), and venlafaxine (Effexor®) are preferred treatments for mild to severe depression. Antidepressants should be tapered 2-6 months after remission of depressive

symptoms. New mood stabilizers have been approved by the Food and Drug Administration for the treatment and prevention of BPD, including but not limited to, Abilify, Celexa, Lamictal and Seroquel[4; 5].

Unfortunately, current treatments are not effective in all individuals with BPD. Often, multiple combinations of mood stabilizers are necessary to find the right balance for the change of emotions seen in individuals with BPD. Side effects of mood stabilizers may include nausea, weight gain, increased thirst and urination, drowsiness, unpleasant or metallic taste in mouth or changes in thyroid or kidney function.

Electroconvulsive therapy (ECT) is a non-drug treatment for bipolar disorder and other mental disorders, such as severe depression. ECT can be beneficial for patients who need immediate stabilization of their condition and who cannot wait for medications to work. Individuals who benefit for ECT include: most patients with mania -- especially elderly patients with severe mania, patients who suffer suicidal thoughts and guilt during the depressive phase, patients who cannot tolerate drug treatments, patients with certain types of heart problems, and young patients[8]. In a review of studies, about 80% of ECT-treated patients experienced improvement, and for some, it is the only treatment that works. ECT may help by causing changes in the brain's physiology. For example, ECT may increase the permeability of the blood-brain barrier, produce an antiseizure effect (similar to the effects of antiseizure drugs used as mood stabilizers), and reduce blood flow in parts of the brain associated with improved mood. It also causes various hormonal changes, particularly with thyroid-related hormones. ECT has been found to balance dopamine levels. This brain chemical plays an important role in bipolar disorder as well as other conditions for which ECT is sometimes recommended, including

delusional depression. Lastly, ECT can stimulate growth of neurons in the hippocampus (the area in the brain responsible for memory) [7; 9; 10].

2.1.4 Risk Factors for BPD

A risk factor is a variable associated with an increased chance of disease. Aside from genetic susceptibility, gender and age increase an individuals' risk for BPD. Bipolar disorder affects both sexes equally, but there is a higher incidence of rapid cycling, mixed states, and cyclothymia in women. On the other hand, early-onset bipolar disorder tends to occur more frequently in men and it is associated with a more severe condition. Manic phases usually begin in adolescence or young adulthood, with an average age of onset being 18 years, while depressive phases usually begin by age 21.

Higher incidences of comorbidities (accompanying conditions that include panic disorder, conduct disorder, substance abuse, suicidal behavior, and psychotic symptoms) are increased in individuals with BPD. Young patients are at higher risk for these complications. BPD is often more severe in children than in adult patients, with a higher risk of mixed mania, multiple and frequent cycles, and a longer duration of illness without well periods.

Symptoms of bipolar disorder in children are often confused with attention-deficit hyperactivity disorder (ADHD). Furthermore, the two conditions can coincide. In one study, 65% of adolescents with bipolar disorder met criteria for ADHD. Yet another study indicated that close to 25% of children diagnosed with ADHD either already had bipolar disorder or go on to develop it. The risk for both diagnoses is highest in

Caucasian males. In some cases, ADHD in children or adolescents may be a marker for an emerging bipolar disorder.

Miscellaneous factors that may increase an individual's risk for BPD include: change of seasons, socioeconomic status, and the loss of a parent. A higher incidence of bipolar disorder occurs in people who were born in the winter and in those who had experienced complications around the time of birth. The time of the year appears to play a role in the risk for specific episodes. Mania is more likely to occur in the summer and depressive episodes from October through May (which is different from seasonal affective disorder, a depressive disorder that only occurs in darker months). Bipolar disorder is more prevalent among people with a higher socioeconomic status. The rate of the disorder is estimated to be 10 to 20 times higher among people in the creative arts than in the general population. Thirdly, children who lose a parent early in life also appear to be more likely to develop bipolar disorder when they become adults.

2.1.5 Molecular Genetics of BPD

Family, twin, and adoption studies provide evidence for a heritable component to BPD[11-13]. Family studies can determine if a condition occurs in multiple members of a family; however, it is difficult to separate genetic and environmental factors because families share common lifestyles. Twin and adoption studies are used in genetics to study individual differences by highlighting the role of environmental and genetic factors of a condition. Modern twin studies have shown that almost all traits are in part influenced by genetic differences, with some characteristics showing a strong influence (e.g. height),

others an intermediate level (e.g. IQ) and some more complex heritability, with evidence for different genes affecting different elements of the trait – such as BPD. Researchers found the heritability of BPD to be 80-90%[13]. Monozygotic and dizygotic twin concordance rates are 45-70% and 20%, respectively. These rates suggest that BPD is a multi-factorial inherited condition, affected by both genetics and environmental factors.

An empiric risk is a risk estimate that is given for the chance of occurrence or recurrence of a particular condition in an individual based on the observation of other families with that condition. The Psychiatric Special Interest Group of the National Society of Genetic Counselors (NSGC) reviewed empiric risk literature for BPD in 2006[3]. The results are reported in Table 1.

Table 1: Empiric Risks, reviewed by NSGC Psychiatric Genetics Special Interest Group[3]

Relationship to affected individual	Empiric Risk
Any first degree relative	5-30%
Parent	10%
Sibling	13%
Child (one parent affected)	15-30%
Child (one parent affected) AND one sibling affected	20%
Child (both parents affected)	50-60%
Second degree relative	5%

Bipolar disorder has been shown to have a strong genetic component, thus, the next step is to evaluate the disorder at the molecular level. Linkage analysis and genome-

wide association studies have identified stretches of the genome with a likely susceptibility to causing BPD. Studies have reported significant chromosomal locations contributing to this susceptibility. The results are reported in Table 2.

Table 2: Chromosomal Locations of Candidate Genes for BPD[13-16]

Chromosomal Region	Gene
1q42	*DISC1*
2p13-14	*ASCT1*
6q22.3	*DTNBP1*
8p12	*NRG1*
13p; 13q	?
22q12.3	*TOM1/HMG2L1*

2.1.6 Direct to Consumer Testing

Direct to consumer (DTC) marketing strategies have been implemented in the general population with regards to cancer genetics. Myriad Genetics© has implemented BRAC*Analysis*® to assesses a woman's risk of developing breast or ovarian cancer based on detection of mutations in the *BRCA1* and *BRCA2* genes. This test has become the standard of care in identification of individuals with hereditary breast and ovarian cancer. The biopharmaceutical company has also made advances in genetic testing for hereditary colorectal and endometrial cancer, pancreatic cancer, and melanoma[17]. Companies such as 23andme© and Navigenics© offer comprehensive genetic testing and personal DNA analysis, in hopes of making personalized health care a reality for consumers. Currently,

such companies do not offer genetic testing for psychiatric disorders because recent research into the genetic risk markers has yielded inconsistent results.

Difficulty arises in researchers' ability to apply DTC to mental health genetics. Progress is being made to remove the stigma of mental illness in mental health disorders. Stigma, by definition, is a mark of disgrace or shame. Stigma has four components: labeling someone with a condition, stereotyping people who have that condition, creating a division — a superior "us" group and a devalued "them" group, resulting in loss of status in the community, and discriminating against someone on the basis of their label[18; 19].

For individuals with a mental illness, the consequences of stigma can be devastating — in some cases, worse than the illness itself. Some of the harmful effects of stigma include: trying to pretend nothing is wrong, refusal to seek treatment, rejection by family and friends, work problems or discrimination, being subjected to physical violence or harassment, or inadequate health insurance coverage of mental illnesses. Incorporating results from studies like this will enable public health professions to create a DTC marketing plan that is culturally sensitive and responsive to the needs of families with bipolar disorder[20].

Concerns arise when creating a DTC marketing plan, for any patient population. It will be important to provide accurate and proper informed consent for all consumers of DTC testing services, so they understand what results and interpretation are possible from testing. Currently, there is little governmental regulation for DTC testing and in fact, for many types of genetic tests. There are also concerns related to interpretation of results for

genetic tests in the BPD population. As we do not know a single gene cause for BPD, the interpretation of results must accurately reflect research of the genes being tested[19; 20].

2.1.7 Health Belief Model

The Health Belief Model (HBM) was initially developed in the 1950's by a group of social psychologists at the U.S. Public Health Service in an effort to explain the widespread failure of people to participate in programs to prevent or to detect disease. Later, the model was extended to apply to people's responses to symptoms and to their behavior in response to diagnosed illness and compliance with medical regimens. Health screening behavior was determined to be driven by a combination of: 1) the individual's perceived susceptibility to the condition, 2) the individual's perceived seriousness of the condition, 3) the individual's perceived benefit of the specific behavior, and 4) the individual' perceived barriers to the behavior[21] (Table 3). Variables and descriptions which are in bold and italics were applied to the project. HBM statements regarding BPD are located in Table 4 below.

Table 3: Health Belief Model Components

Variable	Description
Perceived threat	
Perceived severity	***Feelings concerning the seriousness of developing a condition or leaving it untreated (medical and social consequences)***
Perceived susceptibility	***Subjective perception of risk***
Perceived benefits	***The believed effectiveness of strategies used to reduce the burden of disease***
Perceived barriers	***Negative consequences that may occur if a particular health action is taken (physical, psychological, or financial)***
Cues to action	Bodily or environmental events that motivate an individual to take action
Other variables	Indirect effects of sociopsychological, ***demographic,*** and structural factors
Self-efficacy	The individual's belief that they can successfully execute the behavior

Use of the Health Belief Model has been successful in assessing and motivating health belief change among African Americans in regards to genetic information and utilization of health care resources for sickle cell patients[22]. The HBM has been used in the assessment of health care facilities by sickle cell patients, suggesting the health beliefs pose modifiable psychosocial variables that could be used in development of interventions to reduce health care costs and provide additional education[23].

Table 4: Health Belief Model Statements

Severity
Bipolar disorder is a serious disease.
Having a child with bipolar disorder would be very scary.
My life would change if my child had bipolar disorder.

Benefit
It is useful to know if I have genes that make bipolar disorder more likely.
It is useful to know if my partner has genes that make bipolar disorder more likely.
Knowing the risk of having a child with bipolar disorder would change my plans about a future pregnancy.

Susceptibility	Barriers
My children are at risk for bipolar disorder.	Genetic testing for bipolar disorder is painful and difficult.
Bipolar disorder could happen in my family.	My partner would be hard to convince to have genetic testing.
My partner may be a carrier of genes for bipolar disorder.	I would not want to pay for genetic testing.

3.0 MATERIALS AND METHODS

3.1 DESIGN AND RATIONALE

The overall goal of this project was to learn more about the needs of the US population diagnosed with BPD, anticipating that the demand for genetic counseling services for psychiatric disorders will increase in the future. Components of this study, including the knowledge and health belief surveys, were given to the participants in the US as part of the genetic counseling component. A study being conducted in India by Dr. Bhatia titled, "Neurological Endophenotypes in Psychiatric Genetic Research in India " is collecting similar data and she shared her unpublished data so that comparative analyses could be made. This comparison helps to elucidate whether the needs of both groups of participants are similar. Data was collected from Indian participants by Dr. Bhatia and IRB-equivalent approval was obtained from Indian Council for Medical Research. Particularly of interest, the results of this study will be compared to the results in India to determine whether the needs and findings differ for the two patient populations[24].

3.2 PARTICIPANTS

Participants were recruited through public notification. A flyer was approved by the University of Pittsburgh IRB (Appendix E). Initially participants were recruited through the University of Pittsburgh and Western Psychiatric Institute and Clinic (WPIC); however, the response was less than desired. Research participants came from many sources across Pennsylvania, and Ohio, from centers partnered with WPIC and the flyers posted at these sites and throughout the University of Pittsburgh. Informed consent was obtained from all participants by verbal telephone script (US) or personal interview (India)

Study criteria included: (1) age 18 years or above and (2) self-reported diagnosis of bipolar disorder or first-degree relative of an individual with a self-reported diagnosis of bipolar disorder. The racial, ethnic, and gender characteristics of the proposed study population reflect the demographics of the regions from which participants were drawn (Pennsylvania and Ohio, India). No exclusion was made based on race, ethnicity or gender.

3.3 EXPERIMENTAL DESIGN

The University of Pittsburgh Institutional Review Board (IRB) under IRB number 0610128 in 2007-2009 (Appendix A) approved the experimental design for this study. An anonymous survey (Appendix C) was administered to each participant after verbal

informed consent (Appendix B) was given and documented. All contact with participants was over the telephone in the US and by personal interview in India. Research in India was a duplicated study.

The survey was designed to measure familiarity with, and interest in, genetic counseling, knowledge of bipolar disorder, and health beliefs. The survey also ascertained demographic information and a brief psychiatric history. Knowledge of BPD was assessed using eight multiple-choice questions. The knowledge survey was modeled after a survey administered to school-age children and women of childbearing age to assess knowledge of sickle cell disorder. The health belief survey was modeled after a survey administered to women of childbearing age to assess health beliefs regarding sickle cell disease and sickle cell trait[22]. Both the knowledge and health belief surveys were adjusted to apply to bipolar disorder for the study "Neurological Endophenotypes in Psychiatric Genetic Research in India". The health belief survey used a five-point scale response system to assess perceived susceptibility, perceived seriousness, perceived benefit of testing, and perceived barriers to testing. A score of one corresponded to "strongly disagree" and a score of five corresponded with "strongly agree" as recommended by Champion[21]. The final set of questions was a set of five open-ended questions encouraging a discussion of the causes of bipolar disorder and the likelihood that there is a genetic component.

Every other individual who completed the survey was offered participation in a brief educational session followed by an identical survey. The rationale behind this approach was that the first data set provides information on the patient population among the general population. The second data set would allow comparative analysis of the data

to see if knowledge, health beliefs, or opinions changed after the educational intervention.

The educational session was a brief semi-structured discussion of genetic counseling, genetics, multifactorial inheritance, empiric risk for bipolar disorder, and general information about BPD.

Telephone interviews were selected as the data collection technique because it allowed inclusion of participants who would not have otherwise been able to attend a face-to-face interview or focus group (e.g. those living in rural areas or living a great distance away). An additional benefit of this method is that some participants may perceive a greater degree of anonymity, thus increasing the validity of their responses[25].

Alternatives to the telephone interviews in the US would include face-to-face interviews, which would have allowed for observation of non-verbal cues and responses and may have built more trust with the interviewer.

The Indian participants are required to have face-to-face interviews either at home or at the RML hospital. Telephone access is often limited in India, especially in the population served by RML Hospital.

3.4 DATA ANALYSIS

3.4.1 Quantitative Analysis

Data from affected individuals and first-degree relatives were analyzed to determine if there was a significant difference in knowledge, health beliefs, and acceptance of genetic counseling for psychiatric disorders between the US and Indian populations.. Answers to the knowledge questions were coded into variables, with correct answers coded as one and incorrect answers coded as zero. The maximum possible score for knowledge questions of BPD was eight. On the five-point scale, the population mean for perceived severity of BPD, susceptibility, benefits of testing, and perceived barriers to testing were calculated, including a score for each component and a cumulative score for each category. Values were categorized as low (0-3.0), moderate (3-4) or high (4-5) risk. Statistical significance was measured for each score, involving a 95% confidence interval. The difference between means was assessed using a t-score and p-values were documented. P-values less than 0.05 were considered statistically significant.

3.4.2 Analysis of Responses to Open-Ended Questions

Answers to the open-ended questions were analyzed to identify similarities and differences among responses. The goal was to find themes and differences in responses to the questions. Each individual's answer to a question was compared to all other answers to that question, and themes were identified and described. A theme or pattern in answers

can be defined as a common topic, view or feeling. The themes generated from the open-ended questions for this study were compared to the themes found in the semi-structured interviews conducted in India. This comparison allows similarities and differences between the two populations to be described.

4.0 RESULTS

4.1 DEMOGRAPHICS

To date, 31 individuals have participated in this US study. The population surveyed was primarily over the age of 45 (48%), single (54%) and had no children (35%). The average years of schooling for participants were 11 years ± 3.40 years. To date the participant population is 73% female and 27% male.

From the unpublished data shared by Dr. Bhatia, 31 individuals have participated in the Indian study. The population surveyed was primarily over the age of 30, married (68%) and had no children (35%). The average years of schooling for participants were 14 years ± 3 years.

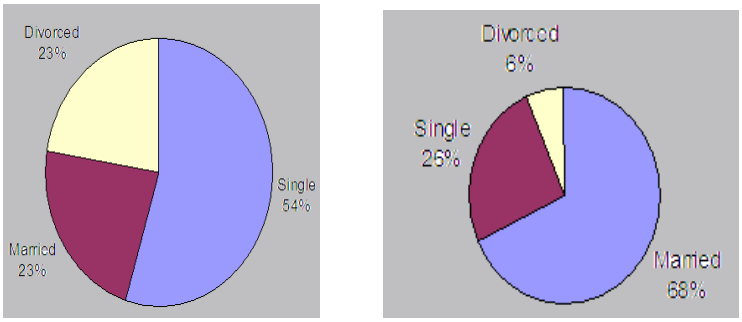

Figure 1: Marital Status of Survey Participants, Lt: US, Rt: India

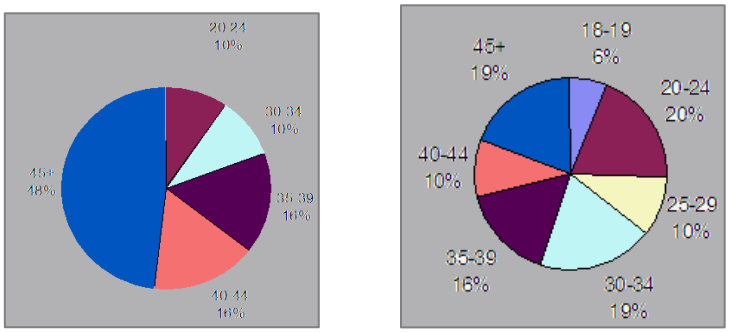

Figure 2: Age Distribution of Survey Participants, Lt: US, Rt: India

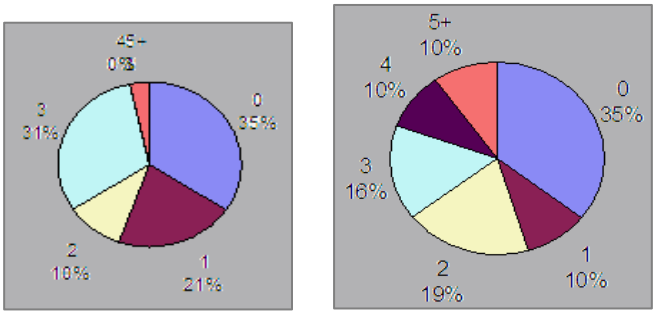

Figure 3: Number of Children of Survey Participants, Lt: US, Rt: India

4.2 SPECIFIC AIM 1

Thirty-one individuals diagnosed with BPD have been surveyed in Pittsburgh. The cumulative perceived severity of BPD was high at 4.35 (±0.86), the cumulative perceived susceptibility to BPD was high at 3.90 (±1.06), the cumulative perceived benefit to genetic information was moderate at 3.82 (±0.82), and the cumulative perceived barriers to genetic testing were low at 2.60 (±1.07) (Tables 5-8).

Thirty-one individuals diagnosed with BPD have been interviewed in India. The cumulative perceived severity of BPD was moderate to high at 3.34±1.72, the cumulative perceived susceptibility to BPD was low at 2.60 ±1.59, the cumulative perceived benefit to genetic information was low at 2.60±1.69, and the cumulative perceived barriers to genetic testing were moderate to high at 3.38 ±3.15 (Tables 5-8).

Table 5: Summary of Health Beliefs: Severity

Severity	India Mean±SD	US Mean±SD	t(p value)
Bipolar disorder is a serious disease.	4.44 ±1.04	4.77±0.80	1.35(NS)
Having a child with bipolar disorder would be very scary.	3.60±1.63	4.23±1.14	1.68(NS)
My life would change if my child had bipolar disorder.	4.23±1.1.33	4.06±1.41	-0.45(NS)
***Severity Cumulative**	***3.34±1.72***	***4.35±0.86***	***2.91(0.005)***

The US cumulative perceived severity of BPD was high at 4.35 (±0.86) and moderate to high at 3.34±1.72 in the Indian population. Individual questions did not show statistical significance (Table 5).

Table 6: Summary of Health Beliefs: Susceptibility

Susceptibility	India Mean±SD	US Mean±SD	t(p value)
My children are at risk for bipolar disorder. ** p<0.05	***3.15 ±1.76***	***4.00 ±1.29***	***2.09(0.04)***
Bipolar disorder could happen in my family. **p<0.05	***3.28 ±1.59***	***4.48 ±0.81***	***3.66(0.001)***
My partner may be a carrier of genes for bipolar disorder.	3.00 ±1.62	3.33 ±1.65	0.76(0.45)
***Susceptibility Cumulative**	***2.60 ±1.59***	***3.90 ±1.06***	***3.78(<0.001)***

The US cumulative perceived susceptibility to BPD was high at 3.90 (±1.06), and was low at 2.60 ±1.59 in the Indian population. Also noted of significance are two individual

statements highlighted in pink. The first statement was ‘my children are at risk for bipolar disorder; the second statement was ‘bipolar disorder may happen in my family’ (Table 6).

Table 7: Summary of Health Beliefs: Benefit

Benefit	India Mean±SD	US Mean±SD	t(p value)
It is useful to know if I have genes that make bipolar disorder more likely.	***3.56±1.68***	***4.65±0.71***	***3.25(0.002)***
It is useful to know if my partner has genes that make bipolar disorder more likely.	***3.32±1.73***	***4.47±1.04***	***2.98(0.004)***
Knowing the risk of having a child with Bipolar disorder would change my plans about a future pregnancy.	***3.48±1.73***	***2.48±1.41***	***-2.33(0.02)***
***Benefit Cumulative**	***2.60±1.69***	***3.82±0.82***	***3.58(0.001)***

The US cumulative perceived benefit to genetic information was moderate at 3.82 (±0.82), and was low at 2.60±1.69 in the Indian population. All three statements yielded results of statistical significance (Table 7).

Table 8: Summary of Health Beliefs: Barriers

Barriers	India Mean±SD	US Mean±SD	t(p value)
Genetic testing for Bipolar disorder is painful and difficult.	**2.61 ±1.69**	**1.97 ±1.33**	-1.556(NS)
My partner would be hard to convince to have genetic testing.	**2.83 ±1.61**	**2.79 ±1.72**	-0.07(NS)
I would not want to pay for genetic testing.	**2.90 ±1.92**	**3.23 ±1.54**	0.667(NS)
***Barriers Cumulative**	**3.38 ±3.15**	**2.60 ±1.07**	-1.29(NS)

The US cumulative perceived barriers to genetic testing were low at 2.60 (±1.07), and moderate to high at 3.38 ±3.15 in the Indian population. None of the statements or cumulative results was of statistical significance (Table 8).

Data show that the knowledge of BPD in US individuals is high, with an average score of 6.19 correct (±1.51) out of a possible 8 questions. The lowest score to date is 2 correct and the highest score is 8 correct. Data are insufficient to determine if there is a significant difference in knowledge of BPD or in acceptance of genetic counseling before and after the education session. Many individuals chose not to participate in the education session after the preliminary interview for unknown reasons. Data show that the knowledge of BPD in Indian participants is low, with an average score of 2.68 correct (±1.62) out of a possible 8 questions. After the educational session given to Indian participants, data showed Indians had less knowledge about testing and counseling prior to learning the new information than after.

Analyzing the data in correlation with demographic factors showed that participants in the Indian population have little knowledge about their diagnosis of BPD. This may be culturally related, as mental illness may not be as accepted in India when compared to the United States[24;

[28]. Research conducted in India about the stigma of mental illness revealed that depressive symptoms were perceived as socially disadvantageous as these may affect marriage, social status, and employment[28].

Answers to the open-ended questions were analyzed to identify themes. Analysis revealed four common responses to the first question, “when you first heard about mental illness in your family, what did you think caused it?” (Table 9) Most participants in the US attributed their diagnosis of BPD as a combination of factors: life-triggering event and genetic causes. On the other hand, Indian participants attributed their diagnosis to bad eating habits, a chemical imbalance and stress (Table 10).

Table 9: Common Responses to Open-ended Question 1, US Data.

When you first heard about mental illness in your family, what do you think caused it?
"An imbalance of chemicals in my brain."
"In my family, I would say events, life-changing events happened."
"Well, I guess I had felt that mine was related to stress and, like, maybe a predisposition to feel depressed and melancholy in certain situations. When I was under a lot of stress I began to experience more symptoms, so like, when I had some breakdowns and was hospitalized I relate them to stressful circumstances. But, I feel like I had a predisposition."
"My life was a triggering event - a combination of factors. It is genetic made worse by people not understanding. Self medication is destructive. I think it is caused by genetics. The degree depends on the environment."

Table 10: Common Responses to Open-ended Question 1, India Data.

When you first heard about mental illness in your family, what do you think caused it?
"When I came to know about myself that, I personally was at the verge of (being in the grip of mental illness), I was completely shocked & really it was totally surprising. "
"How did it happened to me and how will I maintain my employment"

4.3 SPECIFIC AIM 2

The second specific aim was designed to assess participants' knowledge of genetic counseling, as well as the interest and acceptance of genetic counseling sessions and the possibility of genetic testing in the future.

Thirty-one US participants with a diagnosis or family history of BPD have been surveyed. Data show that the knowledge of genetic counseling is low, with only 30% of participants stating that they have heard of genetic counseling or know what it is, prior to an education session. Twelve of 31 individuals (39%) stated that they did not know if genetic counseling would be useful to them. Results from Indian participants were not available as of March 2009.

5.0 DISCUSSION

This study examined the health beliefs, level of knowledge and acceptance of genetic counseling in individuals with BPD and their first-degree relatives. The demand for genetic counseling is growing in the medical profession, specifically in the area of psychiatric genetics[29]. As medical professionals it is important to determine the needs of this patient population and offer new services accordingly. The study was designed to look at whether an educational session can improve or change acceptance of genetic counseling or health beliefs. It is important to provide evidence that education is a good intervention to offer more information to this patient population, with goals of furthering psychiatric genetic counseling. Determining possible changes in acceptance of genetic counseling after the education session has the potential to show that interest in genetic counseling services increases with just a short discussion of the multifactorial pattern of inheritance and current research regarding genetic influences of BPD.

5.1 SPECIFIC AIM 1

The first aim was to determine the current health beliefs of those who have been diagnosed or who have a family history of bipolar disorder (BPD) with regard to course, treatment, and genetic information. It was hypothesized that participants would have a low level

of knowledge of BPD, and this was, in fact, not supported by the data. Data show that participants have high background knowledge of their condition. In addition, it was hypothesized that participants would have a high level of perceived severity, a high level of perceived susceptibility, a moderate level of perceived benefit to testing and a low level of perceived barriers to testing. Data reveal that participants in the US had perceptions of high severity, susceptibility and knowledge of BPD, perceptions of moderate benefit to testing, and perceptions to barriers of testing. High severity of BPD indicates that many participants felt that BPD is a serious disease and having a child with BPD would impact their life in significant ways. High perceived susceptibility indicates that there is a concern of risk to other family members. Of note, two of the questions that asked about susceptibility had statistical significance with p-values <0.05. Moderate benefit to genetic information indicates that participants are interested in genetic information. A low level of concern regarding barriers to genetic testing indicates US participants are not worried about the testing procedures itself. Future studies aimed at educating individuals with BPD about severity and susceptibility could potentially ease anxiety about their condition.

In comparing the data collected from Indian participants, data reveal perceptions of moderate severity, and barriers to testing, and perceptions of low susceptibility, benefit to genetic information and knowledge of BPD. These results differ from the US participants' perceptions and may be due to different perceptions of mental illness in the Indian population[24; 28; 30]. Low susceptibility indicates that there is the notion that there is not an increased risk to other family members. Low concern regarding benefit of genetic information indicates individuals are not interested in receiving genetic information. These participants are concerned about the seriousness of the disorder, but do not believe BPD has a genetic component. Moderate severity

of BPD indicates that many participants felt that BPD is a serious disease and having a child with BPD would impact their life in significant ways. Moderate barriers to genetic testing indicate that participants have an increased level of concern regarding testing procedures.

The analysis of the open-ended questions provides valuable information for future studies regarding BPD genetics. In a more detailed examination in comparing answers of the knowledge questions to views stated in the open-ended questions, it was striking that some individuals chose answers based on a genetic component to BPD, yet stated that BPD is mainly environmental in the open-ended questions. Those same participants then stated there is a high probability of passing the condition onto their children. If individuals have a strong belief about the cause of their disorder (i.e. environmental vs. genetic), it may be a barrier to accurately assessing a family history in a genetic counseling session. This is an important theme to examine, in the future, by creating an educational support group for members of the BPD community and their family members to learn more about their condition and for genetic counselors to record an accurate family history for better risk assessment.

5.2 SPECIFIC AIM 2

The second specific aim of the study was to assess participants' knowledge of genetic counseling, and to assess acceptance of and interest in genetic counseling services and the future of genetic testing.

Identifying the status of knowledge and acceptance of genetic counseling will determine areas of education that might lead to increase knowledge and acceptance. Data show moderate

benefit of genetic information, which indicates that most individuals diagnosed or with a family history of BPD would like to know if they or their partners have genes that make bipolar disorder more likely to occur. In looking at US data on susceptibility, data from one statement, “My children are at risk for bipolar disorder” has a statistical significant score of 3.9 (±1.06) out of a possible 5 (using a t-value of 3.78 and a p-value <0.01). Data on the question, “Knowing the risk of having a child with Bipolar disorder would change my plans about a future pregnancy” has a statistical significant score of 2.48 (±1.42) out of possible 5 (using a t-value of 2.33 and a p-value of 0.02), indicating that genetic information may not be used for reproductive purposes. In looking at the Indian data on susceptibility, the data suggest these participants are not as worried about an inheritable component for BPD. Indian participants felt BPD is less likely to occur in the family, less likely to have children with BPD, and not as concerned about their partner’s carrier status as compared to the US population.

The US cumulative perceived barriers to testing were low. However, on average, participants disagreed with the statement that genetic testing is painful and difficult with a score of 1.97 (±1.33). The strongest perceived barrier included convincing their partners to have genetic testing. The Indian cumulative perceived barriers to testing were moderate to high. On average, participants felt that genetic testing could be painful and difficult, and would not be interested in paying for genetic testing. Conclusions suggest that participants do not have knowledge of how genetic testing is completed, the cost of testing, or possible testing interpretations.

Studying the correlations between demographic factors and knowledge, health beliefs, and acceptance of genetic counseling will aid in properly serving this patient population and giving clients the information they are seeking. Additional analysis between knowledge of BPD

and health beliefs may show some affect on severity, susceptibility, benefits and barriers to genetics testing for BPD.

Data bias can not be eliminated from the individuals surveyed because attitudes of the populations studied have not been altered. Attitudes influencing results include: religious preference, political issues, tolerance of mental health, and general cultural beliefs. Bias that has been eliminated includes: participants were recruited for this study only. Participants gathered in the beginning of the study (2007) were gathered through another study of BPD in Pittsburgh. The original data could be skewed, knowing those individuals would have additional exposure to learning more about BPD and genetics because they were apart of a BPD genetics support group.

One final limitation of the study: all contact with US participants was over the telephone, including a self-report of diagnosis. Telephone interviews do not allow for patient/counselor interaction and may affect any rapport that could be established between individuals facilitating communication. In regards to the education session, it was modeled after a genetic counseling session in which the interviewer is trained when trying to detect non-verbal cues to assess how much of the material the patient understood.

Genetic counselors can help patients understand the complexities of genetic information and testing by providing insights into a test's benefits, risks, and implications before an individual takes the test. Counselors also help patients interpret the results and consider management steps, if necessary. Finally, they may help individuals deal with their genetic risk, something that may be necessary whether the testing outcome is positive or negative, since the test "may change long-held beliefs about disease risk." This type of work could be problematic if completed over the telephone, because counselors often use additional visual materials to aid individuals who adapt best to visual learning. For example, genetic counselors often use visual

aids to assist in the learning process of genetic information and genetic testing. Some individuals may learn more easily when presented with information in a visual form.

6.0 CONCLUSION

This study was successful in eliciting health beliefs and knowledge from individuals diagnosed with bipolar disorder. The information gained from the study could be used to develop an educational model for individuals with BPD and their families.

Characterization of the current state of health beliefs of the BPD population is still in progress, as participant recruitment continues. According to the data at this point, the results show high level of severity, susceptibility and knowledge of BPD, moderate benefit of genetic information and low level of concern to barriers of genetic testing in the US population. Results of the Indian population show moderate level of concern to severity and barriers of genetic information, and low levels of concern to susceptibility, benefit of genetic information and knowledge of BPD. Similarity among both countries is found in the level of severity of BPD; both countries believe it is a severe condition. Differences between both countries can be seen in regards to benefit to genetic information: US participants want to know the information, whereas Indian participants do not feel a need for the information because they believe BPD is not genetic. Differences are also noted with regards to susceptibility to BPD: US participants know their children and family members are at risk for BPD, while the Indian participants do not feel other family members are at-risk to develop BPD. Finally, the US and Indian participants differ

when talking about barriers to genetic testing: US participants are not as concerned about testing procedures, while Indian participants have a high level of concern.

Aside from the results of the Health Belief Model, researchers gained insight into other areas of BPD. Participants in both countries had different viewpoints in regards to BPD predisposition: Americans felt there is a mix of genetic and environmental factors, while Indians felt it was caused by stress, environmental factors or poor eating habits. This difference may be a result of how BPD is discussed in these countries. BPD has a stigma in both countries, but the stigma is much worse for Indians. Indian participants were most concerned how BPD would affect their employment, marital and social status.

Much was learned throughout the process of implementing this study. First of all, the success of this project would only occur with an open and active participation of all parties involved. Without the support of the Graduate School of Public Health (GSPH) and Western Psychiatric Institute and Clinic (WPIC), participation would have been limited. This may have also added some limitations to our study by supplying participants who are already in a heightened state of awareness of the importance of knowledge of BPD. These participants have actively pursued to learn more information about their condition and so may already be open to health care information and the future of genetic testing.

Our study hopes to continue gathering participants and assessing their beliefs about BPD as they consider the value of knowledge and genetic counseling for mental health disorders. As the data from India highlights, future developments of the study and educational interventions that are developed based on the results should take into account unique beliefs and cultural aspects of the community at risk. Recognizing the different ways in which cultural background can influence perceptions is important in addressing the needs of a particular community. .

Focus can then be directed to providing more information regarding susceptibility, testing, and severity of BPD, as well as benefits and limitations to psychiatric genetic counseling in a culturally sensitive manner.

APPENDIX A: IRB REVIEW LETTERS

INSTITUTIONAL REVIEW BOARD (IRB) REVIEW LETTERS

University of Pittsburgh

Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1146 (fax)

MEMORANDUM:

TO: Ms. Emily M. James

FROM: Christopher Ryan, Ph.D., Vice Chair

DATE: January 22, 2007

SUBJECT: IRB# 0610128: Improving Knowledge, Evaluating Opinions, and Ascertaining the Acceptance of Genetic Counseling for Bipolar Disorder

The above-referenced proposal has received expedited review and approval from the Institutional Review Board under 45 CFR 46.110 (7).

Please Note:

- ***The advertisement that was submitted for review has been approved as written.***
- ***The waiver for the requirement to obtain a written informed consent for telephone screening has been approved.***

If applicable, please include the following information in the upper right-hand corner of all pages of the consent form:

Approval Date: January 22, 2007
Renewal Date: January 21, 2008
University of Pittsburgh
Institutional Review Board
IRB# 0610128

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. The IRB Reference Manual (Chapter 3, Section 3.3) describes the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Event Coordinator at 412-383-1504.

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month prior** to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

CR:kh

University of Pittsburgh

Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)

MEMORANDUM

TO: Elizabeth Gettig, MS

FROM: Christopher Ryan, PhD, Vice Chair

DATE: January 15, 2008

SUBJECT: IRB #0610128: Improving Knowledge, Evaluating Opinions, and Ascertaining the Acceptance of Genetic Counseling for Bipolar Disorder

---

Your renewal with modifications of the above-referenced proposal has received expedited review and approval by the Institutional Review Board under 45 CFR 46.110 (7).

Please include the following information in the upper right-hand corner of all pages of the consent form(s).

Approval Date: January 15, 2008
Renewal Date: January 21, 2009
University of Pittsburgh
Institutional Review Board
IRB #0610128

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. The IRB Reference Manual (Chapter 3, Section 3.3) describes the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Event Coordinator at 412-383-1504.

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month prior** to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

CR:kh

University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
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http://www.irb.pitt.edu

Memorandum

To: Elizabeth Gettig PHD

From: Christopher Ryan PHD , Vice Chair

Date: 2/6/2009

IRB#: IRB0610128

Subject: TITLE: Improving knowledge, evaluating opinions, and ascertaining the acceptance of genetic counseling for bipolar disorder.

Your renewal for the approved referenced study has received expedited review and approval from the University of Pittsburgh Institutional Review Board under:
45 CFR 46.110.(7) characteristics/behaviors

Please note the following information:

Approval Date: 2/6/2009

Expiration Date: 2/5/2010

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. The IRB Reference Manual (Chapter 3, Section 3.3) describes the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

Jagrish Bhatia Ph.D
Psychiatric Epidemiology & Genetic Counselor
Training Program for Psychiatric Genetics in India
Program: NIH Project
Dept. of Psychiatry
Dr Ram Manohar Lohia Hospital
New Delhi 110001
India
Phone: 91-11-23404365
bhatiajagrish@yahoo.co.in

To
Prof. Elizabeth Anne Oetting.
Associate Professor Human Genetics
Co-Director Genetic Counseling Program
Graduate School of Public Health
University of Pittsburgh
Pittsburgh, PA 15261

Subject: Ethics approval for my Attitude of

Dear Madam,
I have ethics committee permission for the above project titled "Assessing Genetic Counseling Potential in Bipolar Disorder in India dated 27.1.07 for one year. Co-principal investigator was Dr S N Deshpande. During this period the data was collected used in the present study. The copy of the ethics approval is enclosed.
Thank you.
Sincerely,

Jagrish Bhatia

Government of India

डा. राम मनोहर लोहिया अस्पताल, नई दिल्ली

Dr. RAM MANOHAR LOHIA HOSPITAL, NEW DELHI

OFFICE MEMORANDUM

Subject:- "Assessing Genetic Conspelling Potential in Bipolar Disorder in India"- Dr. S.N. Deshpande, Sr. Psychiatrist & HOD.

With reference to her application dated 10th April 2007 on the above-cited subject, Dr. (Mrs) S.N. Deshpande, Sr. Psychiatrist & HOD Psychiatry informed that the Ethics Committee has approved the above said project.

26/04/07

(Dr. (Mrs.) Meenakshi Bhardwaj)
Sr. Pathologist & Member-Secretary
Ethics Committee.

Dr. S.N. Deshpande
Sr. Psychiatrist & HOD Psy deptt.
Dr. R.M.L. Hospital,
New Delhi

APPENDIX B: CONSENT FORM

CONSENT FORM

_____

Participant's Name

"I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed."

_____	_____
Printed name of Person Obtaining Consent	Role in Study
_____	_____
Signature of Person Obtaining Consent	Date

After completion of the informed consent, the survey will be administered. At the conclusion of the survey, every other participant will be asked if they would like to participate in the individual educational session, using the following script:

"As I mentioned earlier, some people who complete the first interview are asked to participate in the second phase of the study. This can be done immediately or at a time convenient for you. This part of the study, also over the telephone, will include an educational interview about bipolar disorder, family history, the science behind inheritance and recurrence in a family, and a discussion about genetic testing and its impact. This session will also conclude with an interview including multiple choice and opened ended questions. Participants completing this phase and follow-up survey will be given an additional $25 Giant Eagle gift card. Your participation in this part of the study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time. Do you have any questions? Do you think you might be interested in participating in that study?"

If yes, begin the individual educational session. If no, thank you for participating in our study.

APPENDIX C: SURVEY

SURVEY

C.1 DEMOGRAPHIC AND PSYCHIATRIC HISTORY QUESTIONAIRRE

1. How old are you?

2. What is your marital status?

    - Single
    - Married
    - Divorced
    - Widowed

3. How many children do you have?

    - 0
    - 1
    - 2
    - 3
    - 4
    - 5+

4. Do you live with your partner?

    - Yes
    - No
    - I don’t have a partner

5. What is the highest level of education you finished?

    - Some high school
    - High school graduate
    - Some college
    - College graduate
    - Graduate/Doctoral/Professional School

6. Do you have, or have you had, bipolar disorder?

    - Yes
    - No

7. Do you have a relative who has been diagnosed with Bipolar Disorder?

    - Yes
    - No

    7b. If yes, which family member or family members have bipolar disorder? (all that apply)

        - Myself
        - Mother
        - Father
        - Child
        - Adopted child
        - Brother
        - Sister
        - Grandparent
        - Aunt/Uncle (blood relation)
        - Cousin
        - Other (please specify)

Follow-up questions for “affected subject with no affected first-degree relatives” and “affected subject with one or more affected first-degree relatives”:

1. How long ago were you diagnosed?

    - In the last 6 months

- 6-12 months ago
- 1-2 years
- 3-5 years
- 5+ years
- Other

2. When did you last actively have symptoms?

    - Currently in an active phase
    - In the last 6 months
    - 6-12 months ago
    - 1-2 years ago
    - 3-5 years ago
    - 5+ years
    - Other

3. Are you currently being treated for Bipolar Disorder?

    - Yes
    - No

    3b. If yes, what type of treatment? (all that apply)

        - Taking medication
        - In day therapy
        - In residential therapy (hospital)
        - Other

4. Do you have any other psychiatric diagnoses?

    - Yes
    - No
    - Do not know

    4b. If yes, what is the diagnosis?

        - Personality disorder
        - Manic depression

- Depression
- Schizophrenia or schizoaffective disorder
- Other
- Do not know

C.2 GENETIC COUNSELING QUESTIONAIRRE

13. Have you heard of genetic counseling?

- Yes
- No

14. Do you know what genetic counseling is?

- Yes
- No

15. Have you ever had genetic counseling?

- Yes
- No

16. If yes, was it due to a family or personal history of bipolar disorder?

- Yes
- No

17. Do you think genetic counseling would be useful to you?

- Yes
- No

Comments:

C.3 KNOWLEDGE QUESTIONAIRRE

Following are some questions about bipolar disorder. I will read each question to you, along with five possible answers. Please select the one best answer for each question.

1. Bipolar disorder is caused by

    a. Dirty needles
    b. A virus
    c. Inheriting genes from parents
    d. The exact cause is unknown currently
    e. none of the above

2. How many genes must someone inherit to have Bipolar disorder?

    a. zero, it is not caused by genes
    b. one from their mom
    c. two, one from their mom, and one from their dad
    d. the number of genes is not presently known
    e. none of the above

3. Bipolar disorder can cause

    a. euphoria, feeling 'high'
    b. racing thoughts, talkativeness
    c. drug or alcohol use
    d. inability to concentrate well
    e. all of the above

4. Bipolar disorder is most likely caused by

    a. genes

b. the environment such as a major life event
c. a combination of genes and environment such as a major life event
d. radiation
e. none of the above

5. Bipolar disorder is a serious condition that causes shifts in

a. mood
b. energy
c. functioning
d. all of the above
e. none of the above

6. Bipolar disorder is present

a. more in poor people
b. more in rich people
c. same across all ethnic and economic group
d. more in some ethnic groups
e. more in some regions

7. Bipolar disorder is treated by

a. medications known as mood stabilizers
b. liver transplant
c. rest
d. blood transfusions
e. none of the above

8. How can you tell if someone carries genes for Bipolar disorder?

a. they look sick
b. they will eventually have Bipolar disorder
c. with a simple blood test
d. there is no way of knowing
e. none of the above

C.4 HEALTH BELIEF ASSESSEMENT

Please rate your level of agreement with each of the following statements on a 5-point scale where 1 means “strongly disagree” and 5 means “strongly agree”.

C.4.1 Severity

1. Bipolar disorder is a serious disease.

Strongly disagree 1 2 3 4 5 Strongly Agree

2. Having a child with bipolar disorder would be very scary.

Strongly disagree 1 2 3 4 5 Strongly Agree

3. My life would change if my child had bipolar disorder.

Strongly disagree 1 2 3 4 5 Strongly Agree

C.4.2 Susceptibility

4. My children are at risk for bipolar disorder.

Strongly disagree 1 2 3 4 5 Strongly Agree

5. Bipolar disorder could happen in my family.

Strongly disagree 1 2 3 4 5 Strongly Agree

6. My partner may be a carrier of genes for bipolar disorder.

Strongly disagree 1 2 3 4 5 Strongly Agree

C.4.3 Benefit

7. It is useful to know if I have genes that make bipolar disorder more likely.

Strongly disagree 1 2 3 4 5 Strongly Agree

8. It is useful to know if my partner has genes that make bipolar disorder more likely.

Strongly disagree 1 2 3 4 5 Strongly Agree

9. Knowing the risk of having a child with bipolar disorder would change my plans about a future pregnancy.

Strongly disagree 1 2 3 4 5 Strongly Agree

C.4.4 Barriers

10. Genetic testing for bipolar disorder is painful and difficult.

Strongly disagree 1 2 3 4 5 Strongly Agree

11. My partner would be hard to convince to have genetic testing.

Strongly disagree 1 2 3 4 5 Strongly Agree

12. I would not want to pay for genetic testing.

Strongly disagree 1 2 3 4 5 Strongly Agree

C.4.5 Open-ended Questions

13. When you first heard about mental illness in your family, what did you think caused it? How do you think it happened or occurred?

14. When we say a condition might be inherited, what does that mean to you?

15. How do you think a hereditary condition would affect your family now and in the future?

16. Do you think bipolar condition is hereditary?

    If response is Yes and you have bipolar disorder – what do you think your risk is for passing it on to a child?

    If response is Yes and you do not have bipolar disorder – what do you think your risk is for developing the condition?

17. Do you have any other comments you would like to share?

APPENDIX D: EDUCATIONAL SESSION OUTLINE

EDUCATIONAL SESSION OUTLINE

a) Contracting: In this education session we will discuss what is known and what is not known about the genetics and effects of bipolar disorder. Please feel free to ask any questions that you may have. This will be similar to a genetic counseling session.

b) What is genetic counseling?

i) Genetic counseling is a discussion of the genetic causes for a disorder, the chance that other family members will show signs and symptoms of the disorder, how the diagnosis may affect the family, and where people can go for more information.

c) Genetic counseling usually involves a brief discussion of genetics.

i) Genetics is the study of DNA. You may have heard of DNA before. DNA is like an instructional manual for the body. We each have our own, unique DNA code, but we also share some of that code with our family members.

(1)We know that changes in the DNA can put people at risk for developing certain conditions.

(a) For bipolar disorder, the exact causes are not completely understood, but at present time it seems that both genetic and environmental factors may increase the risk for BPD.

(b) The number and exact locations of the predisposing genes are not known.

(c) If you have one first-degree relative with BPD, your risk of about 3-15%, although some studies say the risk is as high as 24%.

ii) At present, there is no way to tell if a person carries genes that make them more susceptible to BPD. You cannot tell by looking at someone, by a physical exam, or with genetic testing.

d) What are the effects of BPD?

i) BPD can affect moods, energy levels and functioning.

e) Who does BPD affect?

i) BPD affects about 1% of the population. Current evidence suggests that it affects men and women equally, and the rate is equal across ethnic groups.

f) Treatment

i) Most individuals affected with BPD are treated with mood stabilizers. Sometimes antidepressants are also prescribed. Doctors work with their patients to find the best possible management.

APPENDIX E: RECRUITMENT FLYER

RECRUITMENT FLYER

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