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CORRELATES OF ANTIDEPRESSANT MEDICATION COMPLIANCE USE AMONG DEPRESSED WOMEN

by

Pamela Linton

A thesis submitted in partial fulfillment of the requirements for the degree

of

MASTER OF SCIENCE

in

Family and Human Development (Marriage and Family Therapy)

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Correlates of Antidepressant Medication

Compliance Use Among Depressed Women

by

Pamela Linton, Master of Science

Utah State University, 2001

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Department: Family and Human Development

Medication compliance/noncompliance was examined in context of: severity of symptoms; medical side effects; medication education; perceived stigma; and effects on family/social support system. A null hypothesis was formulated for each correlate, stating that those patients who reported a high level of an independent variable (IV) would not be any more likely to discontinue their medication than patients who reported a low level of an IV. To obtain data, a medical usage questionnaire and a depression assessment (OQTM-45.2) were used. Statistical significance was not obtained for any of the hypothesized relationships but trends were consistent with the established literature. The implication points to the efficacy of relational therapy as a conjunct to the medical treatment of depression.

To

Devin, Raelyn, Sierra, Kennedy, Dana, Daniel, Elise, Cheyenne, McHale, Jacob, Kimberly, Sarah, Amanda, Tanya, Samantha, Zachary, Emilee, Tanner, Stephenee, Shaylee, Sydnee . . .

MY JOY!

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CHAPTER I

INTRODUCTION

Physicians report that female patients, diagnosed with depression, often discontinue their antidepressive medications spontaneously, translating into prolonged problems for the women. Noncompliance with the physician's prescription is a problem because the depression returns and the medication process has to start over again (Munizza, Tibaldi, Bollini, Pirfo, & Punzo, 1995). Patients may not be aware that spontaneous discontinuation of antidepressive medication can cause an increase in depression due to reduction of a therapeutic level of medication (Munizza et al.).

The severity of depression acts as a catalyst in medication compliance because of the associated complications of symptoms (Bhatia & Bhatia, 1997). Because depression is a major problem in this country, studies are necessary to understand more about the nature of depression and medication compliance (Coyne, 1987; Hirschfeld, 1994).

Depression of an individual also impacts his or her family. Marriage relationships influence and are influenced by depression (Coyne, 1987). However, the side effects of antidepressant medication may impact the marital relationship if, for example, the woman is dealing with decreased libido or unwanted weight gain (Jensvold, Plaut, Rojansky, Crenshaw, & Halbreich, 1996; Shen & Hsu, 1995) or decreased emotional responsivity. Thus, the immediate side effects of the medication may be a strong deterrent to medication compliance.

Research suggests that medication compliance is low when the patient receives inadequate information about the antidepressant medication from the prescribing doctor

and the pharmacist (Crenshaw & Goldberg, 1996). Many physicians and pharmacists realize that they should take time to educate patients about medication use, pharmacology, and side effects. Research has shown that there are specific ways that those topics can be approached with female patients so that maximum benefit can result (Blechman & Brownell, 1988; Crenshaw & Goldberg, 1996; Jensvold et al., 1996; Sorvaniemi, Joukamaa, Helenius, & Salokangas, 1996). Thus, education about the medication is clearly linked to compliance; that is, compliance is greater when the patient is fully informed about the medication.

Some women report to their primary care physicians that husband and family are concerned about the stigma or the embarrassment of having their wife or mother treated for depression (L. Eskelson, personal communication, March, 5, 1998; R. Wortham, personal communication, December 1, 1998). In addition, many women also worry what others in their larger support system will think of them (M. Gibby, personal communication, May 7, 1998). To alleviate the concerns patients feel about the stigma of having depression, they may discontinue treatment by discontinuing their medication. The concern about stigma may be greater than the concern about medication compliance.

Purpose

The purpose of this study was to investigate compliance or noncompliance (discontinuation) with antidepressant medication prescription in context of severity of symptoms, medical side effects, medication education, perceived stigma, and effects on family/social support system.

Conceptual Framework

To investigate compliance or noncompliance with antidepressant medication prescription in context of selected correlates, an overarching framework of human behavior must be integrated into the study. By broadening the lens of human behavior, assumptions can be made within a framework that accounts for behavior. According to Symbolic Interaction theorists, all meaning comes from interpretations that people attach to their interactions with one another (LaRossa & Reitzes, 1993). Everyday interactions, historical events, culture, and societal norms all influence individuals and prompts their motives and behavior (LaRossa & Reitzes). For some susceptible individuals, negative meaning attached to certain interactions may result in the development of depressive symptoms. Meaning is also derived concerning motivations to stay in compliance with prescribed antidepressant medication or to discontinue medication.

Symbolic interactionism (SI), within the context of general systems theory (GST), merges two dynamic theories to account for much human behavior. The following GST constructs (using the terminology of Gregory Bateson, considered the father of systems theory, and Ludvig von Bertalanffy) delineate ways we may order our world (Goldberg & Goldberg, 1980; Whitechurch & Constantine, 1993). Nonsummativity is another word for synergy, the concept that a system (nations, communities, families, couples, or an individual) is greater than the sum of its parts (Whitechurch & Constantine). This concept underlies the belief that compliance or noncompliance with antidepressant medication must be explored not only on an individual level but in light of interconnections with the family and the social support systems.

Cybernetics theory suggests the idea that systems are self-regulating (Goldberg & Goldberg, 1980; Guttman, 1991). Self-regulation is accomplished through change within the system, which occurs through the process of feedback loops (Goldberg & Goldberg; Guttman). Positive feedback initiates a second order change -- e.g., the individual takes information and processes it to change from the original meaning that he or she had. When the feedback results in a negative feedback loop, the individual will use that information to reinforce previous beliefs (Goldberg & Goldberg; Guttman).

Self-regulation, through the process of feedback loops, is critical to understand in connection with compliance or noncompliance with medication. Medication education and perceived stigma (two of the correlates of compliance or noncompliance with medication) are critically influenced by self-regulation. For a patient to assimilate medical education, a positive feedback loop may have to be processed to stay in compliance with medication prescription. In other words, if patient perception of antidepressant medication does not match the doctor's perception, she must change her way of thinking to stay in compliance with mediation prescription.

Concerning stigma, if patients continue in a negative feedback loop, they may reinforce their previous beliefs about stigma. In other words, if a patient believes there is a stigma attached to antidepressant medication use, she will use that information to reinforce her belief. As an individual communicates with other systems, all information is processed through the unique lens of the individual. The "other systems" of concern in this study are family members, friends, health practitioners, and psychotherapists.

Important parts of communication are the report (actual information) and command

(interpretation) concepts (Guttman, 1991). In any communication one cannot be sure that the information sent to another is interpreted as it was intended.

Communication about each of the correlates of antidepressant compliance or noncompliance is vital. For instance, the information an individual processes about medical side effects and severity of symptoms may result in actions that will either promote compliance or noncompliance with antidepressant medication. It is necessary to communicate with all the appropriate systems to attain as much consensus in meaning as possible (Guttman, 1991). The research focus of this study, compliance or noncompliance with antidepressant medication in the context of the correlates (severity of symptoms, medical side effects, medication education, perceived stigma, and effects on family/social support system) was investigated from the perspective of SI and GST. It is also important to investigate the communication concerning the correlates.

CHAPTER II

REVIEW OF LITERATURE

Although there is no consensus of the definition and cause of depression, there are recognized correlates to the use of antidepressant medication. Five areas of concern are connected to the research on antidepressant medication use among women. First, the severity of the symptoms of depression is a factor that often determines use or nonuse of medication. Second, medication discontinuance may be tied into the dynamics of a woman's family and social support system, which are profoundly impacted by her depression. Third, the negative side effects from use of antidepressant medication vary widely and may be compounded by other medical problems. Fourth, if the patient does not have a basic understanding of the chemistry and function of antidepressant medication, she will not realize the gravity of proper medication use. Finally, the social stigma that is still attached to depression is such a powerful deterrent to acknowledging depression that its role as a correlate in antidepressant use cannot be ignored. Thus, patient cooperation with medication treatment may decrease as risks and side effects increase. Depression and correlates of the use of antidepressant medication are further discussed in the following review.

Depression

Millon and Everly (1985) defined depression as the decompensation of normal personality patterns. Normal personality patterns are the deeply embedded and broadly exhibited cognitive, affective, and overt individual behavioral traits that are constant over

time and are difficult to extinguish (Millon & Everly). The criteria for a major depressive episode, as described in the <u>Diagnostic and Statistical Manual of Mental Disorders</u> (4th edition; <u>DSM-IV</u>), are five or more of the following symptoms that have persisted for a 2-week period and must include either symptom #1 or #2:

- 1. Depressed mood most of the day, nearly every day
- 2. Diminished interest or pleasure in almost all activities nearly every day
- 3. Significant weight loss or gain or decreased or increased appetite nearly daily
- 4. Insomnia or hypersomnia nearly every day
- 5. Psychomotor agitation or retardation nearly every day
- 6. Fatigue or loss of energy nearly every day
- 7. Feelings of worthlessness or excessive or inappropriate guilt nearly every day
- 8. Diminished ability to think or concentrate, or indecisiveness, nearly every day
- Recurrent thought of death, recurrent suicidal ideation, or suicide attempt or specific suicide plan

The symptoms of depression must also include a clinically significant distress or impairment in social, occupational, or other important areas of functioning and the symptoms cannot be attributed to be reavement, namely, recent loss of a loved one (American Psychiatric Association, 1994).

A hallmark symptom of depression that may be manifest in all of the above noted symptoms is cognitive rigidity, or the tendency to focus in an all-or-nothing thought process (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). Cognitive rigidity generally results in distorted thinking, locking thought processes into worst case scenarios—thereby

reinforcing the previously mentioned symptoms.

Blechman and Brownell (1988) noted that several classes of clinical depression included the following factors: genetic, biological, stage of female reproductive cycle, and social/psychological, which include gender roles and cognitive distortion. Given the gender specificity of some of these factors, it is not surprising that more women are diagnosed with depression than men (American Psychiatric Association, 1994; Hansen & Osborne, 1995; Renzetti & Curran, 1995). Williams, Spitzer, Linzer, Kroenke, & Hahn (1995) concluded that (p. 656) "women are much more likely than men to have depressive disorders . . . [f]urther research is needed to determine why women seem to suffer disproportionately from symptoms of depression" Although more women are diagnosed with depression than men, the accepted standard for diagnosing symptoms among both men and women follows the criteria from the DSM-IV (Lesseig, 1996).

Severity of Symptoms

The severity of symptoms can be partially expressed by understanding the complications of depression. When depression is not diagnosed, the client has a greater chance of developing other symptoms such as medical, substance-abuse, academic, and work-related problems (Bhatia & Bhatia, 1997). This is significant considering "the over all national economic burden of mood disorders is approximately \$44 billion" (Bhatia & Bhatia, 1997, p. 1683). Personal and economic problems associated with depression are substantial and may be magnified by the complex and time-consuming process of diagnosis and treatment intervention strategies.

Depression diagnosis must be assessed in the following areas to determine its type and severity and the most appropriate treatment plans: suicidal ideology, secondary depression, bipolar depression, psychotic depression, masked depression, seasonal depression, atypical depression, major depression superimposed on dysthymia, treatment-refractory depression, and adjustment disorder with depressed mood (Bhatia & Bhatia, 1997). A thorough evaluation of the above forms of depression is necessary to prescribe the optimal therapeutic (mental and/or medical) intervention.

The process is further complicated as co-occurring conditions may compound the severity of symptoms (Lesseig, 1996). West, Zarin, and Pincus (1997) stated that "mood disorders constituted the most common principal DSM-IV diagnostic category, affecting 53 percent of the patients in this study [and] the majority [also] had significant psychiatric and general medical co-occurring conditions" (p. 79). Results from a study by Fava et al. (1997) show that "several symptoms characteristic of eating disordered patients are linked to the severity of depressive symptoms" (p. 140). Because the scope of depressive symptoms and coexisting conditions is serious, proper diagnosis is necessary to treat the patient efficaciously. It is common practice for a medical practitioner to monitor patient medications in conjunction with the patient receiving psychotherapy (West et al., 1997). The combination of medication and psychotherapy is efficacious. Hirschfeld (1994) stated that "psychotherapy plays a critical function in the long-term treatment of depression." Patients with depression, especially long-standing or recurrent depression, often have serious marital, familial, social, and occupational problems that have been exacerbated by their illness. In addition, psychotherapy may

help to improve compliance, which helps to prevent relapse" (p. 68).

As noted, there is a clear case for a thorough evaluation and assessment of depression. The severity of depression may render a person less capable of monitoring the very medication that would alleviate the problem. If a patient has a diminished ability to think (one of the criteria for depression), he or she may not be able to follow through with taking the prescribed medication. Secondly, co-occurring problems raise other issues related to compliance in taking medication. The first concern is misdiagnosis, when other symptoms are treated while depressive symptoms are overlooked. The depression may lead the person to feel hopeless and not take the medication to help reduce related symptoms. The second concern with co-occurring problems is related to the cost of multiple medications, which may reduce compliance.

Antidepressant Medication Side Effects

Medical professionals prescribe antidepressant drugs to combat depressive symptoms. The three major classes of drugs are the serotonin selective reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), and the monamine oxidase inhibitors (MAOIs). The SSRIs are less toxic and have milder side effects than the TCAs (Montano, 1994). Li, Hamdy, Sandborn, Chi, and Dyer (1996) suggested that patients taking TCAs and SSRIs can experience "impairment of balance function . . . motor coordination, fine-motor control, postural reflexes, maintaining equilibrium, and reaction time" (p. 191). The MAOI class of antidepressants "can cause sedation [slowing down of physical and mental functioning], heart palpitations [throbbing of the heart], dizziness,

insomnia, sexual dysfunction [normal sexual function disturbed], tachycardia [racing of the heart], constipation, agitation, and edema [swelling of tissues] . . . and the possibility of hypertensive crisis [elevation of hypertension]" (Nemeroff, 1994, p. 5). Long (1998) observed that some antidepressant medications, particularly the tricyclics, have disturbing side effects, such as weight gain and weight loss. Patients using Prozac, Luvox, Paxil, and Zoloft (SSRI class of antidepressants) exhibit anorexia more often in overweight patients, and weight gain in patients after chronic use (Bezchlibnyk-Butler & Jeffries, 1998). Bhatia and Bhatia (1997) reported no weight gain with the use of Prozac, Luvox, Paxil, and Welbutrin. In the tertiary tricyclic class of antidepressants, amitriptyline (Elavil) exhibits a weight gain (over 6 kg) 30% of the time; the next highest incidence is with clomipramine (Anafranil), doxepin (Sineguan), and imipramine (Tofranil), exhibiting weight gain 10% of the time (Bezchlibnyk-Butler & Jeffries, 1998). The secondary tricyclics amoxaprine (Asendin) and nortriptyline (Pamelor) show a low incidence of weight gain (Bhatia & Bhatia, 1997). Weight gain (over 6 kg) reported in the MAOI class of antidepressants is as follows: phenelzine (Nardil), 10%, and tranylcypromine (Parnate), 2% (Bezchlibnyk-Butler & Jeffries, 1998).

Often sexual functioning is affected by medications prescribed for depression (Crenshaw & Goldberg, 1996) through increased libido (Gartrell, 1986) or decreased libido (Crenshaw & Goldberg, 1996) with both being potentially problematic. The antidepressant medications most highly associated with sexual dysfunction are the SSRIs: fluoxetine (Prozac), parocetine (Paxil), sertraline (Zoloft), and fluvoxamine (Luvox); the TCAs: clomipramine (Anafranil), Elavil, Endep, Norpramin, Pertofrane, Adapin,

Sinequan, Tofranil, Aventyl, Pamelor, Vivactil, and Surmontil; and the MAOIs: Marplan, Nardil, and Parnate (Aldrich, Cook, & Pedersen, 1996; Lesseig, 1996). Welbutrin (bupropion), an SSRI, affects sexual dysfunction least (Aldrich et al., 1996; Lesseig, 1996). Antidepressant drugs also have been reported to induce other mental disorders such as rapid cycling of mood change (Oppenheirn, 1982). Thus, the problems with antidepressant medication can range from mild distress to a life-threatening potential.

"Completed suicide is a major risk in depressive illness" (Isometsa, Aro, Henriksson, Heikkinen, & Lonnqvist, 1994, p. 523). The connection between suicide and depression is a complex problem. If depressive symptoms cannot be diminished, then suicidal ideation rises (Isometsa et al., p.78). Prescribed antidepressants, however, have the risk of becoming the means for attempting suicide. When persons in major depression receive medication and become more lucid than they have been in the past, they may have a greater capacity for suicide ideation or even attempt the act (Slaikeu, 1990). After starting an antidepressant drug regimen, mental health professionals recognize the risk of the eminent transition from incapacitating depression to increased functioning that may culminate in a suicide attempt or completion (Slaikeu, 1990). "It is recommended that the practitioner limit the prescription of TCAs (tricyclic antidepressants) to a sublethal dose, particularly early in the course of therapy for depression, since some patients may be more energized to commit suicide as their depression begins to lift" (Lesseig, 1996, p. 78).

Patient cooperation with medication treatment may decrease as risks and side effects increase. A patient may have profound discomfort from a side effect, namely,

dizziness, insomnia, sexual dysfunction, tachycardia, constipation, or edema (Nemeroff, 1994), and discontinue the antidepressant medication. The patient may decide to discontinue the antidepressant medication because of the immediate discomfort it is causing (Long, 1998). Thus, the antidepressant medication may be discontinued before its beneficial effects can take place. Because of the risks and side effects associated with using antidepressant medication, the medical practitioner also acts as a medication manager, monitoring the effects of the drug and changing dosages and/or drugs as necessary.

Medication Education

Management of depression is a growing concern for medical doctors (Bhatia & Bhatia, 1997). Many family practice physicians have a strong commitment to patient education concerning antidepressant medication (Bhatia & Bhatia, 1997; L. Eskelson, personal communication, March 5, 1998; M.Gibby, personal communication, May 7, 1998). Patient education about antidepressant medication needs to come from both the doctor prescribing the medication and the pharmacist. Areas of importance include the pharmacology, indications, contraindications, warnings, precautions, adverse effects, and dosage of the medication along with seasonal influences and alternatives to medication (Long, 1998; Luke, 1998). Knowing the family history of depression and medication use is helpful because "response [to medication] runs in families" (Lesseig, 1996, p. 76). If the patient does not have a basic understanding of the chemistry and function of antidepressant medication, she may not realize the gravity of her recommended

medication use and may discontinue essential treatment.

Perceived Stigma

Stigma is a real concern that interferes with clients reporting depression because they still associate depression with emotional or spiritual weakness (Montano, 1994). Campbell (1996) defined stigma as a label given to people who are mentally disordered, whereby it justifies discrimination against them. In a study by the National Alliance for the Mentally III (Gwirtsman, Blehar, McCullough, Kocsis, & Prien, 1997), family members were asked if they had experienced stigma and most families reported that stigma had a significant effect on the family member with mental illness and family functioning. Montano also reported that "nearly 70% of the respondents in a survey said that stigma was attached to admitting mental illness" (1994, p. 26).

If a patient feels he or she is stigmatized, then other emotions may follow such as shame, guilt, anxiety, fear, or anger. Maxmen and Ward (1995) described shame as an emotion associated with embarrassment, while guilt is an emotion associated with worthlessness. To understand the responses of shame and guilt, Zukerman (1995) applied descriptors to them: burdened, self-condemning, disgraced, devalued, fears rejection/abandonment, failure to attain goals or measure up, and wishes to disappear. Zukerman proposed the following distinction between guilt and shame: shame is associated with a failure of *being* and guilt is associated with a failure of *doing*. According to Erik Erickson's theory of development, humans must resolve the conflict of shame to attain self-control, and the conflict of guilt to develop direction and purpose

(Cole & Cole, 1993). When the depressed individual is experiencing the effects of stigma and associated emotions, the stress it causes may interfere with the patient's ability to act with the necessary degree of direction and self-control to stay in compliance with prescribed antidepressant medication.

Anxiety or fear may be associated with stigma. To understand the responses of anxiety or fear, Zukerman (1995) applied descriptors to them: adrenaline secretion, stomach acid production decrease, loss of bladder/anal sphincter control, nausea, cold sweats/chills, faintness, chest pain, hyperventilation, difficulty breathing, and the fight-or-flight response (a physiological stress or response to fear) which may embody the preceding responses and more. The Diagnostic and Statistical Manual of Mental Disorders (4th edition) defines phobias as persistent fears associated with high levels of anxiety (American Psychiatric Association, 1994). According to Maslow's Hierarchy of Needs (Zukerman, 1995), safety is one of the basic needs that must be met to facilitate self-actualization (the ability to meet ones physical and emotional needs). If an individual is not able to progress toward self-actualization, the associated stress may be over-burdening to the individual, and family/social support system.

It appears that the emotions evoked by stigma may interfere with individual emotional development, which may create or exacerbate problems within the patient's family/social support system. When a patient already is feeling the symptoms of depression, the negative impact it has on the family and social support systems, the side effects of medication, and the difficulty assimilating the precautions associated with

medication use, the added anguish of coping with stigma of depression may be more than the patient can bear.

Effects of Family/Social Support System

Depression is associated with relationship problems. Research suggests that depressed individuals are often treated in ambivalent ways (sympathetic and hostile) and find great difficulty or impossibility in recovering without help (Baucom & Epstein, 1990). Research is needed to investigate depression and relationship interaction, but existing research suggests that the dynamics of relationships are influenced by depression (Coyne, 1987). Some of the problems associated with depression include the fact that individuals often fail to find pleasure in life, suffer from energy loss, cry often, have numerous physical complaints, cannot function optimally, and have suicidal ideation (Coyne, 1987; Lambert & Burlingame, 1996; Lesseig, 1996).

Because of these problems associated with depression, the family/social support system is affected negatively. Coyne (1987) stated that the entire family of a depressed person is at considerable risk for negative outcomes. Coyne also stated that the relationships between depressed persons and their spouses are often conflictual and overtly hostile. Baucom and Epstein (1990) stated that a circular pattern tends to develop in families of depressed individuals "in which negativity and lack of positive responsiveness on the depressed spouse's part elicits hostility and withdrawal from the partner, which in turn elicits anxiety, more depression and demand for reassurance by the depressed person" (p. 114). Baucom and Epstein (1990) further stated that because of the

circular negative communication pattern, couples may require extensive intervention, but the depressed individual may be so depressed that he or she is unable or unwilling to participate in therapy. Fava et al. (1997) reported that the severity of depression may heighten interoceptive awareness or interpersonal distrust, resulting in a sense of alienation and reluctance to form close relationships. From the reports of Coyne (1987), Baucom and Epstein (1990), and Fava et al. (1990), it appears that depression adversely affects the family/social support system.

Research shows that the following factors are associated with depression: biogenetic, family history, family environment, social background, temperament, mood, interpersonal/cognitive abilities, social context, stressors, personal resources, and social resources (Kupfer & Frank, 1998). Kupfer and Frank discussed recent efforts to develop assessment of psychosocial and biological risk factors associated with depression that may develop a more integrated theory to further explain the impact of depression.

Another factor associated with depression that impacts the family/social support system is the fact that medical conditions, chronic illnesses, and other disorders often co-occur with depression (Lesseig, 1996; Fava et al., 1997). Chronic illness such as multiple sclerosis, certain viruses and cancers, and thyroid and/or adrenal disorders co-occur with depression (Lesseig, 1996). There is also evidence linking eating disorders to depression (Fava et al., 1997). It is clear that for a patient and family dealing with depression and co-occurring problems, a significant burden exists.

Once treatment (antidepressant medication) begins, the patient and family find that it takes approximately 4 to 6 weeks for the medication to take effect and relieve some

of the depressive symptoms (Lesseig, 1996). If the medication has to be changed from an SSRI to a MAOI there are washout periods, defined as the time needed between stopping one drug and beginning the other (Lesseig, 1996). The washout period for switching from an SSRI to a MAOI is 2-5 weeks. Thus, the family and patient find that though treatment has begun, they may still be burdened by the effects of depression for another 2-3 months before some symptom alleviation occurs.

Another disturbing situation arises for the family when the late-emerging adverse effects of SSRIs occur. The late-emerging adverse effects, namely, anorexia, anxiety, fatigue, insomnia, and/or sexual dysfunction, can be confusing because the patient and family may think the depression is worsening instead of getting better (Lesseig, 1996).

Summary

The symptoms of depression place a considerable strain on the depressed person and her relationships. Without support from family, friends, and cohorts, the added burden of seeking and following through with treatment may be overwhelming. The severity of the depression alone may be so great that it interferes with her ability to comply with medication prescription. When the pattern of connection among the correlates that contribute to disuse of antidepressant medication is discovered, specific interventions can be used to support the patient in managing her depression.

The specific null hypotheses for this study involve the five contextual issues correlated with medication compliance or noncompliance:

1. Severity of symptoms: Patients who report severe symptoms of depression are

no more likely to discontinue medication treatment than patients who report mild or moderate symptoms.

- Medical side effects: Patients who report adverse medication side effects are
 no more likely to spontaneously discontinue medication treatment than patients who do
 not experience medication side effects.
- 3. Medication education: Patients who can express the properties of the antidepressant medication and their possible side effects are no more likely to continue medication as prescribed than patients who cannot express the properties and effects of an antidepressant medication.
- 4. Perceived stigma: Patients who report a low level of stigma are no more likely to continue antidepressant medications than patients who report a high degree of stigma.
- 5. Effects on family/social support system: Patients who strongly agree that depression has had a negative effect on their family/social support systems are no more likely to discontinue antidepressant medication use than patients who disagree that depression has had a negative effect on their family/social support systems.

CHAPTER III

METHODS

Design

This is a correlational study of the degree of association between the variables being studied. Correlational studies examine relationships between variables without experimental manipulation (Miller, 1986). The variables in this study (severity of symptoms, medical side effects, medication education, perceived stigma, and effects on family/social support system) were not controlled or manipulated but examined ex post facto (after they occurred). A medical usage questionnaire (see Appendix B) was used to gather data about the variables. To strengthen the design, a double-blind study was used, meaning that the women who answered the questionnaire and the persons who administered the questionnaire were not informed about the research questions (null hypotheses).

Sample

Data were collected from September 1999 to March 2000. It was estimated that each provider would see 30 to 40 female patients with depression during the time of the study. Women were chosen as the population for this study rather than men and/or children because the correlates may vary according to gender and age. In addition, studies indicate that depressive episodes occur twice as frequently in women as in men (American Psychiatric Association, 1994).

The sample of women surveyed consisted of 35 women who had been previously prescribed antidepressive medication and who came back into the doctor's office for any reason. The women surveyed were 18 years of age up to age 72, with an average age of 39. On average, respondents had three children, had attended about a year of college, and had a household income of \$46,000 (see Table 1).

Table 1

Demographic Summary of the Sample

Category	<u>n</u>	Minimum	Maximum	Mean	<u>SD</u>
Age	34	18.00	72.00	39.26	11.87
Number of children	34	.00	7.00	3.00	1.92
Total household income (in 1000s)	28	12.00	120.00	46.62	27.94
Years of education completed	34	12.00	19.00	12.82	3.57

Almost three fourths of the sample were not receiving therapy, but of those that were, most reported benefitting (see Table 2). Six women noted they would be interested in receiving information about psychotherapy. The population for this study included the female patients of one psychiatrist ($\underline{n} = 7$); four family practice physicians ($\underline{n} = 12$); and two certified physician assistants ($\underline{n} = 16$) from the Cache Valley region, located in both northern Utah and southern Idaho.

Measurement

The survey included an introductory statement explaining that many women have

found it difficult to stay on their medications. A medical usage questionnaire was devised to gather demographic information; symptoms, social support, side effects, and medication compliance.

Table 2
Sample Resources or Needs Related to the Treatment of Depression

		Yes		No	
Resources/Needs	<u>n</u>	%	(<u>n</u>)	%	(<u>n</u>)
Receiving therapy	33	27.30	(9)	72.70	(24)
Therapy/medication are helping	14	85.70	(12)	14.30	(2)
Need information about therapy	28	21.40	(6)	78.60	(22)

The Outcome Questionnaire (OQtm-45.2; Lambert & Burlingame, 1996) is a 45-item, self-report questionnaire. The assessment is measured on a summated rating scale or Likert-type scale, in which the responses to the questions are answered along a continuum with five possible choices ranging from "never" to "almost always." The questionnaire assessed three areas: symptom distress, interpersonal relationships, and social role. The resulting scores can be more informative if the clinical cutoffs are used rather than using the raw scores. Scores above the clinical cutoffs are indicative of diagnosable problems. The symptom distress subscale consists of 25 questions assessing symptoms of depression, anxiety, and substance abuse. Total scores range from 0-100, with 36 being the clinical cutoff. The interpersonal relationship subscale uses 11 questions to determine distress in marriage and family relations. Scores range from 0-44,

with 15 being the clinical cutoff. Social role distress is a nine-item subscale to determine problems related to work, friends, and society. Scores range from 0-36, with 12 being the clinical cutoff. Each questionnaire area was scored separately and then the three scores were added together for a total score. The cutoff score for the whole measure is 63, with scores above this representing clinically significant symptoms.

The OQ tm- 45.2 is a standardized measure with established reliability and validity. Both the internal consistency and test-retest values have high coefficients. The values are reported in each area with the internal consistency value preceding the test-retest reliability value: symptom distress (.92; .78), interpersonal relationships (.74; .80), social role (.70; .82), and an OQ tm- 45.2 total score (.93; .84; Lambert & Burlingame, 1996).

Concurrent validity was estimated by using the Pearson product-moment correlation coefficients (Cohen, 1988) on the total OQ tm- 45 score and on individual domain scores that correspond to segments in 11 other tests accepted in the field as being valid. The criterion measures were all significant beyond the .01 level of confidence (Lambert & Burlingame, 1996). The counterparts to the OQ tm- 45.2 and their values (the first value is the correlation with the symptom distress component and the second value is for the total OQ tm- 45.2 value) include the General Symptom Index of the Symptom Check List- 90-Revised (SCL-90-R) [.61; .78]; Beck Depression Inventory (BDI) [.63; .80]; Taylor Manifest Anxiety Scale (TMA) [.88; .86]; State-Trait Anxiety Inventory (STAI Y-2) [.65; .80]; Inventory of Interpersonal Problems (IIP) [.62; .54]; Social Adjustment Scale (SAS) [.45; .65]; SF-36 Medical Outcome Questionnaire (SF-36) [.80;

.81]; and the Friedman Well-Being Scale (FW-B) [.77; .81] (Lambert & Burlingame, 1996).

The conclusion is that the OQ tm- 45.2 is valid because the concurrent validity values are significant beyond the .01 level when compared with 11 other tests accepted as valid in the field. The internal consistency and test-retest reliability values in each area are also high, ranging from .70 to .93 (Lambert & Burlingame, 1996). The calculated total reliability score for the OQ tm- 45.2 is .84 (Lambert & Burlingame). The Cronbach's alpha for the present sample was .95 for symptom distress, .89 for interpersonal relationship, .93 for social role, and .94 for the overall measure.

The medical usage questionnaire, consisting of 25 questions, assessed demographic information, the dependent and independent variables, and involvement with psychotherapy. Demographic information assessed included age, number of children, income, education, religiosity, and marital status. Age, number of children, income, and education were determined by write-in questions to determine a specific answer rather than a general category. The write-in questions were designed to increase variability for measurement. Marital status was determined using questions formatted like those used by the United States Census Bureau for the 2000 census: married, divorced, separated, and never been married (U. S. Census Bureau, 1998)

Religiosity was measured to determine the association between religiosity and an objection to taking medication for a psychological condition. Religiosity was measured using questions from the Intrinsic Religious Motivation Scale (IRMS; Hoge, 1972).

Hoge developed the IRMS as a measure of motivation for religious behavior. The IRMS

contains 10 items with a Likert-type scale. Intrinsic religiosity is a strong religious motivation and extrinsic religiosity is the relative absence of religious motivation (Hoge). A reliability coefficient of .90 was achieved by Hoge utilizing the Kuder-Richardson formula 20, and the IRMS also correlated .85 with Feagin's Intrinsic-Extrinsic Scale (Hoge). The Soderson adaptation of the IRMS was used because of the increased scoring choices for the purpose of increasing variability among the scores: strongly agree, moderately agree, slightly agree, slightly disagree, moderately disagree, and strongly disagree (Hoge). Each item was assigned a point value and high scores indicated more intrinsic religious motivation and low scores indicated less intrinsic religious motivation (Hoge). The IRMS assumes that extrinsic religious motivation is the relative absence of intrinsic religious motivation (Hoge). Four questions from the IRMS were deemed appropriate for the survey. The Cronbach's alpha for the four questions used in the present sample was .83, which justifies the appropriateness of the chosen questions.

The next segment of the medical usage questionnaire asked, "Have you discontinued your antidepressant medication on your own?" The yes/no response format was designed to determine if the patient was being compliant or noncompliant in the use of the prescribed medications.

Antidepressant medication side effects were assessed using four Likert-type questions with five possible responses. The questions asked about four common side effects associated with sexual functioning and weight variation. The questions were chosen from information in the current literature concerning antidepressant medication (Aldrich et al., 1996; Bezchlibnyk-Butler & Jeffries, 1998; Crenshaw & Goldberg, 1996;

Gartrell, 1986; Lesseig, 1996; Nemeroff, 1994; Oppenheim, 1982). In addition, the five medical professionals who participated reported the questions had both face and content validity. Internal reliability for these questions had an alpha coefficient of .69.

Medication education was assessed with three Likert-type questions with five possible responses. The questions inquired how informed the patient was about the chemical properties and usage of her medication. The questions were formed from personal communication and by reading the current literature about medical education concerning antidepressant medication (Bhatia & Bhatia, 1997; L. Eskelson, personal communication, March, 1998; M. Gibby, personal communication, May, 1998; Lesseig, 1996; Long, 1998; Luke, 1998). The five medical professionals also reported these questions had face and content validity. The statistical reliability of these questions for the current sample was a Cronbach's alpha of .82.

To assess the presence of stigma, two six point Likert type questions were asked. The questions were taken from the current literature on stigma and depression (Gwirtsman et al., 1997; Montano, 1994). Patients were asked if they felt there was a stigma attached to depression and if someone in their family feels there is a stigma attached to depression. These questions were also reported to have face and content validity by the medical professionals. The internal reliability for these questions was .71.

The final two questions were "yes" or "no" questions to assess the presence and desire for psychotherapy in connection with the patient's depression. Coyne (1987) and Hirschfeld (1994) acknowledge the beneficial effect of psychotherapy in connection with depression. Reference materials were left in the offices of the participating medical

practitioners for the patient who wanted more information from a therapist concerning her depression.

Procedures

Data collection began by contacting health care practitioners who had prescribed antidepressive medication to female patients diagnosed with depression. Each practitioner delineated the methods used to assess depression. The participating practitioners were interviewed concerning the problem of their female patients spontaneously discontinuing their medications. The medical professionals were asked to describe the treatment cycle for depression and their evaluation of that process. It was determined that some women start medication, spontaneously discontinue medication, and then return to the physician's office and begin treatment again (L. Eskelson, personal communication, March 5, 1998; M. Gibby, personal communication, May, 1998).

A packet containing a brief explanatory paragraph to the patient, the OQ tm-45.2, and a medication usage questionnaire was delivered to the practitioners for their approval. It was delivered with a cover letter explaining the research statement: "We are conducting a study to find more about how women use antidepressant medication prescribed by their physician and what influences these decisions." Office personnel who distributed and received the surveys were oriented by the practitioner and trained by the researcher. The packet was then distributed, by the nurse, to patients who the practitioner determined would participate. This was conducted in the doctor's treatment room to promote professionalism and create a convenient private place to answer the questions.

A consent waiver and confidentiality form and two questionnaires were used to collect data. The questionnaires were the OQ tm- 45.2, and a medication usage questionnaire. As patients presented at the physician's office for treatment, a packet containing the forms was given to clients who had previously been prescribed antidepressant medication. This was the standard method of administering the questionnaires. Questions involving the independent variables indicated patient concern in each of the several areas.

The questionnaire was designed to be completed in fifteen minutes. The survey served a two-fold purpose: (1) to provide data for this research and (2) and to provide an indication of patient thought process. The answers were computer coded for statistical analysis. The results were shared with the physicians for use with their patients.

Ethical Considerations

An Institutional Review Board (IRB) review was conducted prior to surveys being distributed. All universities that conduct research with human subjects are mandated by federal guidelines to have an IRB (Leary, 1995). The purpose of the IRB review is to assure protection of human subjects associated with research projects (Leary). A written proposal of the research was submitted to and approved by the IRB (see Appendix A).

The survey given to the women initially began with an informed consent in the introductory paragraph explaining the research. The informed consent included risks,

benefits, confidentiality, and patient rights (see Appendix B). The surveys were anonymous to secure confidentiality of answers and the participants could decline to take the survey.

CHAPTER IV

RESULTS

In this chapter the degree of association is reported between the independent variables and compliance with antidepressant medication as stated in each null hypothesis. The dependent variable (DV) is compliance/noncompliance with medication prescription as stated. There were 19 patients who were in compliance with medication and 15 were not. There is some variance in the number of noncompliant/compliant patients because of missing data for the independent variables. The independent variables (IV) are interval level measures: severity of symptoms, medical side effects, medication education, perceived stigma, and effects on family/social support system.

The appropriate analyses for this study was the <u>t</u> test. A <u>t</u> test was chosen to determine whether mean scores differed for those who discontinued medication, compared with those who remained in compliance. The assumptions for the single-sample <u>t</u> test are (a) there was one random sample of interval scores; (b) the raw score population formed a normal distribution for which the means is the appropriate measure of central tendency; and (c) the standard deviation of the population (patients in medication compliance and those in noncompliance) was estimated to be the same (Heiman, 1996). The dependent variable (DV) was a dichotomous measure (compliance/noncompliance of medication) and the independent variable (IV) is an interval level measure. The <u>t</u> test compares means and from those means, test statistics demonstrate the ability of the data to meet the criteria to show statistical significance.

In addition to the \underline{t} test, it was appropriate to go one step further to report the

effect size. Effect size is a measure of the strength of a relation. Vogt (1993, p. 79) stated that

tests of the null hypothesis only allow you to conclude that a relation is significantly larger than zero, but they do not tell you by how much.

Effect size measures do. Thus the effect size is an estimate of the degree to which a phenomenon is present in a population and/or the extent to which the null hypothesis is false.

Effect size was calculated by subtracting the mean of patients who discontinued medication usage from the mean of patients who continued with medication usage. The difference was then divided by the standard deviation of those who continued medication usage (Durlak, 1995). The scores were then recorded in absolute values. The transformation into effect sizes reflects the relative magnitude of effect in a common term, standard deviations, allowing for meaningful comparisons from one variable to the next. In this study, an effect size of 1.0 would mean that the medication compliance score differed one standard deviation higher or lower than the medication noncompliance score. Durlak reported that "effect sizes of around 0.20 have a small magnitude of effect, those around 0.50 have a medium magnitude of effect, and those around 0.80 have a high magnitude of effect" (p. 328). However, in some areas of research, mean effects of 0.50 may be considered large (Vogt, 1993).

To test hypothesis 1 (severity of symptoms: patients who report severe symptoms of depression are no more likely to discontinue medication treatment than patients who report mild or moderate symptoms) the symptom distress subscale of the OQ tm - 45.2 was

used as an indicator of symptom severity. Medication compliance/noncompliance was the dependent variable. The \underline{t} test for this hypothesis did not reach levels for statistical significance (see Table 3).

Patients who discontinued medication reported more severe symptoms than those who continued medication. It should be noted that the mean scores in the present sample are above the clinical cutoff parameters representing symptom distress for both groups.

The effect size in the present study was .58, which represents a medium to large association.

Table 3

<u>Patients in Noncompliance/Compliance with Antidepressant Medication Paired with Severity of Symptoms</u>

Patients $\underline{\mathbf{n}} = 30$	(Medic	mpliant patients ation ntinuance)	Compliant patients (Medication continuance)		ents		
	<u>M</u>	SD	<u>M</u>	<u>SD</u>	<u>t</u>	р	ES
Severity of symptoms	46.77	17.81	39.32	12.80	1.38	.19	.58

While the two groups (those in medication compliance, and those in noncompliance) were not statistically different, the effect sizes do indicate a strong association in the expected direction. The trend is that patients who were noncompliant with their antidepressant medication prescription had a greater degree of symptom distress. While the trend is noticeable, the differences were not statistically different, and hence the null hypothesis must be accepted.

One possibility for the distress scores being so high is that the underlying

problems are not being treated by the antidepressant medication. To assess this, a frequencies table was done to compare medication noncompliance/compliance and receiving some type of psychotherapy (see Table 4). The <u>n</u> was too low for statistical analysis. The low numbers of women receiving therapy were evenly spread between the medication noncompliant and compliant groups.

Table 4
Frequencies Comparing Medication Noncompliance/Compliance with Receiving Therapy

Groups	Noncompliance (medication discontinuance)	Compliance (medication continuance)	
Receiving therapy	5	4	
No therapy	13	10	
Total	18	14	

To test hypothesis 2 (medical side effects: patients who report medication side effects are no more likely to spontaneously discontinue medication treatment than patients who do not experience the most common medication side effects) four questions concerning side effects were used. The first two questions read, "I have experienced a 10% weight gain since taking my antidepressant," and "I have experienced a 10% weight loss since taking my antidepressant medication," and were answered yes or no. With a dichotomous independent variable, the most appropriate analysis for both weight loss and gain was chi square. The frequencies and analyses are found in Tables 5 and 6. Phi, a measure of association, was also calculated.

Table 5

<u>Frequencies and Chi-Square Analysis Comparing Medication Noncompliance/</u>

Compliance with Weight Gain

		Noncompliant patients (medication discontinuance)	Compliant patients (medication continuance)	
Category		<u>n</u> (%)	<u>n</u> (%)	
Weight gain	Yes	8 (47%)	9 (53%)	
	No	4 (29%)	10 (71%)	
Note. Chi squ	are = 1.11	p = .29 phi = .19		

Table 6

Frequencies and Chi-Square Analysis Comparing Medication Noncompliance/

Compliance with Weight Loss

		(me	compliant patients dication continuance)	Compliant patients (medication continuance)		
Category		<u>n</u>	(%)	<u>n</u>	(%)	
Weight loss	Yes	3	(60%)	2	(40%)	
	No	7	(30%)	16	(70%)	
$\underline{\text{Note}}$. Chi square = 1	.56 <u>p</u> =	.21	phi = .24			

The other questions, "I have problems with my own low sexual interest or desire that seems to be related to antidepressant medication" and "I have problems with sexual functioning that seems to be related to antidepressant medication," were posed as Likert questions and were tested with \underline{t} tests. The results for both questions are found in Table 7. The DV was medication compliance/noncompliance (see Table 7).

Table 7

<u>Patients in Noncompliance/Compliance with Antidepressant Medication Paired with</u>

Medication Side Effects

	Noncomp (medicati discontin		(medic	liant pati cation nuance)	ents		
Patients	M	SD	M	SD	<u>t</u>	Р	ES
Loss of sexual interest ($\underline{n} = 34$)	3.00	2.04	3.53	2.04	.72	.48	.11
Loss of sexual function ($\underline{n} = 34$)	3.23	2.24	3.47	2.06	.70	.75	.11

An examination of the data shows that reducing the data to mean scores loses valuable information. There appears to be a clear curvilinear relationship with the majority of the women being fairly equally represented at both ends of the responses. A frequency table shows the raw scores for the women in the sample (see Table 8).

The null hypothesis stated that patients who reported medication side effects would be no more likely to spontaneously discontinue medication treatment than patients

Table 8
Frequency Rate of Patient Response to Sexual Side Effects

	-	Like	ert choic	ces			
	1	2	3	4	5	6	
Category	Strongly agree					Strongly disagree	
Loss of sexual interest	10	4	3	3	5	9	
Loss of sexual function	9	6	3	1	5	10	

who were not informed about medication side effects. Since none of the analyses were statistically significant, the null hypothesis must be accepted

To test hypothesis 3 (medication education: patients who can express the properties of the antidepressant medication and their possible side effects are no more likely to continue medication as prescribed than patients who cannot express the properties and effects of an antidepressant medication), three questions concerning the IV (medication education) were used: "When you were prescribed antidepressant medication, how well did your physician explain the properties of the medication and what you could expect?"; "When you filled your prescription for antidepressant medication, how well did your pharmacist explain the medication and what you could expect?"; and "Did your physician or pharmacist inform you about the side effects of your medication?" A low score meant the patient received more information. The DV was medication compliance/noncompliance (see Table 9).

An examination of the mean scores shows that the women believed their physicians explained the properties of the medications. The women also thought their pharmacists explained the medications but not as well as their physicians. The explanation on the possible side effects was made clear for the women by both the physicians and pharmacists.

The null hypothesis stated that patients who could identify the properties of the antidepressant medication and their possible side effects would not be more likely to continue medication as prescribed than patients who could not express the properties and effects of an antidepressant medication. None of the statistical analyses were statistically

Table 9

<u>Patients in Noncompliance/Compliance with Antidepressant Medication Paired with</u>

<u>Medication Education</u>

	Noncomp (medicati discontir		(med	oliant p ication tinuanc			
Questions	<u>M</u>	SD	M	<u>SD</u>	<u>t</u>	<u>p</u>	ES
Explanation of properties by physician (<u>n</u> = 30)	1.75	.75	1.94	.80	67	.51	.24
Explanation of properties by pharmacist ($\underline{n} = 29$)	2.58	1.31	2.64	1.00	15	.88	05
Explanation of side effects ($\underline{n} = 31$)	2.31	1.11	2.22	1.17	.21	.84	.07

significant. Since the results were not statistically significant, the null hypothesis was accepted.

To test hypothesis 4 (perceived stigma: patients who report a low degree of stigma are no more likely to discontinue antidepressant medications than patients who report a high degree of stigma), medication compliance/noncompliance was used as the dependent variable: "Have you discontinued your antidepressant medication? The IV was measured three ways. The first component of stigma was a faith measure used to indicate the patient's perception of faith, and indirectly her perception of stigma concerning her relationship with deity. The second component of the stigma measure was patient report that she feels stigma is attached to depression. The final stigma

measure was the patient's report that the family feels there is stigma attached to depression.

The patients who discontinued medication reported virtually the same level of faith as those who continued medication. Both groups reported high degrees of faith, scoring over three fourths of the available responses. Thus in the first component, the women did not report feeling stigmatized by their faith, which is consistent with the null hypothesis (see Table 10). The second and third components of stigma (self-perception of stigma and perception of stigma by others) were also tested and were not statistically different (see Table 10).

The means in all three analyses were not statistically different. An examination of the raw data revealed some interesting trends for stigma from self and others. Over one

Table 10

<u>Patients in Noncompliance/Compliance with Antidepressant Medication Paired with</u>

Perceived Stigma

	(medica	npliant patients ition tinuance)	(medic	iant pati ation nuance)	ents			
Stigma	<u>M</u>	<u>SD</u>	<u>M</u>	SD	<u>t</u>	p	ES	
Religion stigma $(\underline{n} = 33)$	19.38	4.77	19.79	5.25	22	.82	.07	
Stigma of self $(\underline{n} = 32)$	3.46	2.18	3.18	1.74	4.00	.69	.13	
Stigma from others $(\underline{n} = 33)$	2.38	1.56	3.17	1.86	-1.24	.23	.42	

Table 11

<u>Patient's Antidepressant Medication Usage and the Association with Self-Perception of</u>

Stigma

Categories	Noncompliant patients (medication discontinuance)	Compliant patients (medication continuance)	
Strongly agree	5	3	
Moderately agree	3	7	
Slightly agree	2	1	
Slightly disagree	2	1	
Moderately disagree	0	3	
Strongly disagree	1	3	

half of all the women reported feeling moderately or strongly stigmatized. For those who were medication compliant, one third reported not feeling stigmatized (see Table 11).

There was a clear bimodal trend in the women's report of feeling stigmatized by others. One half of the women reported feeling strongly or moderately stigmatized by others. Over a third reported strong or moderate disagreement that they felt stigmatized by others (see Table 12).

In relation to the null hypothesis (patients who report a low degree of stigma are no more likely to discontinue medication treatment than patients who report a high degree of stigma) there were not statistically significant differences. The trend was inconsistent with the null hypothesis, but because the values did not reach statistical significance, the null hypothesis must be retained.

Table 12

<u>Patient's Antidepressant Medication Usage and the Association with</u>

Other's Perception of Stigma

Categories	Noncompliant patients (medication discontinuance)	ts Compliant patients (medication continuance)			
Strongly agree	3	3			
Moderately agree	4	5			
Slightly agree	0	2			
Slightly disagree	0	2			
Moderately disagree	2	3			
Strongly disagree	4	2			

To test hypothesis 5 (effects on family/social support system: Patients who strongly agreed that depression had a negative effect on their family/social support systems are no more likely to discontinue antidepressant medication use than patients who disagree that depression has had a negative effect on their family/social support systems). This analysis was done with tests. There were no statistically significant differences between the medication compliant and noncompliant groups in their family or social support scores (see Table 13).

Patients who discontinued their medication had scores over the cutoff level in both the area of interpersonal relationship and social role. Those who continued their medication had scores below the cutoff level in interpersonal relationship and social role.

The effect size for interpersonal relationship (.57) is considered a medium magnitude of

Table 13

<u>Patients in Noncompliance/Compliance with Antidepressant Medication Paired with</u>

<u>Effects on Family/Social Support System</u>

		Noncom patients (medica discont		Compliants (medican continu				
Category	$(\underline{n} = 32)$	M	SD	$\underline{\mathbf{M}}$	SD	<u>t</u>	p	<u>ES</u> .57
Interpersona	l relationship	17.23	7.25	13.58	6.37	1.51	.14	.57
Social role		12.15	7.23	11.21	3.71	.49	.67	.26

effect, which indicates that there is a relationship between the IV and the DV.

The effect size for social role (.26) is considered a small magnitude of effect, but still indicates a relationship between the IV and DV. Since the groups were not statistically different, the null hypothesis must be retained.

CHAPTER V

DISCUSSION

This chapter consists of several parts. First, the null hypotheses are discussed in the order previously presented. The discussion centers on what the results mean as well as tying each hypothesis to the existing literature. In addition, the discussion addresses the implications this study has for the practice of marriage and family therapy. Limitations of the study are considered, and recommendations are made for future research.

The first hypothesis, addressing severity of symptoms, was posed as a null hypothesis: patients who report severe symptoms of depression are no more likely to discontinue medication treatment than patients who report mild or moderate symptoms. The null hypothesis was accepted because the statistical testing did not reach a level of significance. However, the trend is in the direction found in the literature. An examination of the mean scores for both groups shows that patients reported high levels of symptoms, whether they were medication compliant or not. Because both groups reported symptom distress levels above the cutoff level for the OQ tm - 45.2, this finding is only partially consistent with the literature. The expected trend for patients in compliance with medication would be a subclinical level of symptom distress.

The severity of symptoms can be partially expressed by understanding the complications of depression. When depression is underrated, the client has a greater chance of developing other problems, namely, medical, sustance-abuse, academic, and work related, all of which may reduce medication compliance (Bhatia & Bhatia, 1997).

West et al. (1997) stated that a majority of the patients "had significant psychiatric and general medical co-occurring conditions; 20 percent of the patients had at least three DSM-IV Axis I mental disorders" (p. 79). Thus it may be that if the symptoms of depression are great and other problems develop, the chance for medication compliance is low. However, according to the OO tm- 45.2, the women in this study were still in the clinically significant range of distress, even though many were in medication compliance. There are at least three possible explanations for distress and medication compliance. The first is that individual medications may not be at a therapeutic dosage and therefore not effective. It may also be possible that the prescribed medications do not work for some women. Some patients require psychotherapy in conjunction with medication to stay in medication compliance (Hirschfeld, 1994). West et al. (1997) noted that it is a common practice to couple antidepressant medication treatment with psychotherapy. Further, Hirschfeld stated that it is not only efficacious but critical to include psychotherapy in the treatment of depression. With this recommendation available in the literature, it was surprising that just over a quarter of the women were receiving any type of therapy. It is not known how many women tried therapy or how successful they felt their treatment was. This trend speaks to the need for the doctors and therapists to work together dealing with depressed clients.

The second null hypothesis concerning medical side effects was stated thus: patients who report medication side effects are no more likely to spontaneously discontinue medication treatment than patients who do not experience medication side effects. The side effects included in the survey (sexual functioning, sexual interest,

weight loss, and weight gain) did not show a statistically significant relationship between them and medication compliance. An examination of the data shows that 55% of the women experienced a 10% weight gain. In addition a small number reported a 10% weight loss. There was a slight trend in the side effects related to sex. Women who were not compliant in taking their medications reported more of a concern that their sexual functioning was negatively affected by the medications. None of these trends were statistically significant. However, Dr. Eskelson (personal communication, March 5, 1998) has reported that few women report side effects (because of an assumption that side effects must be endured) when asked how they are responding to the medication. Embarrassment concerning sexual side effects may also be a deterrent to reporting effects. The frequencies of the women's responses for sexual side effects were interesting. The majority of the women strongly agreed or disagreed that the medications affected their sexual desire or functioning. This response set is somewhat unusual for a Likert-type question, indicating the women had clear opinions or experiences. Almost half of the women strongly or moderately agreed that the medications caused sexual problems, which is consistent with the literature. It may be that the other half of the women, who strongly or moderately disagreed, were on medications that did not cause those same sexual side effects.

The patient may decide to discontinue the antidepressant medication because of the immediate discomfort it is causing (Long, 1998). Thus, the antidepressant medication may be discontinued before its beneficial effects can take place. It may be that the degree of distress caused by the medication in conjunction with the degree of distress the patient

has from the depression put some patients at more risk for medication noncompliance. If patients have profound discomfort from side effects, they often discontinue the antidepressant medication (Nemeroff, 1994). The trend of this study is generally consistent with the existing literature; patients who reported a greater degree of distress also tended to discontinue their antidepressant medication.

The third null hypothesis focused on medication education: patients who were informed about the properties of the antidepressant medication and their possible side effects are no more likely to continue medication as prescribed than patients who were not informed. The analyses showed no differences in compliance when compared with explanation of the medication properties or side effects. The means reveal that the women felt their doctors gave very detailed information about the medications. The explanation of drug properties by the pharmacists was rated as detailed. The explanation of the possible side effects from both the doctors and pharmacists was also described as detailed. This is consistent with the doctors' report. All of the health practitioners in this study reported that they include information on how the medications work as well as possible side effects in their patient education (D. Beckstead, personal communication, April, 1998; L. Eskelson, personal communication, March, 1998; M. Gibby, personal communication, May, 1998; P. Jones, personal communication, November, 1998; J. Kirby, personal communication, December, 1998; K. Wade, personal communication, November, 1998; R. Wortham, personal communication, November, 1998). While the doctors all reported providing patient information, an examination of the raw data showed that two women reported their doctors gave no explanation. Eight women

reported their pharmacists did not explain the medication properties. Six women reported neither their doctor nor pharmacist explained the side effects. It is possible that the stress of depression interfered with patient ability to assimilate the physician/patient education process. It is also possible that the medical professionals assumed the patients knew more than they actually did.

Another component of patient education is that it is helpful to know the family history of the patient because type of patient response runs in families (Lesseig, 1996). Thus it is important to know if the patient has a family history of experiencing side effects or habitual medication compliance or noncompliance. Dr. Gibby (personal communication, May, 1998) and Dr. Eskelson (personal communication, March, 1998) also reported that the response of the family to antidepressant medication can have a greater effect on the patient staying in compliance than the education given by the doctor. This is understandable when viewed through the lens of general systems theory. Feedback loops are a major factor in GST (Guttman, 1991). If the family's response is more important to the patient than the practitioner's response, that results in a positive feedback loop, or a reinforcing of the original belief. If the practitioner's information is more valuable to the patient than the family's perception, a negative feedback loop occurs. The negative feedback loop is a deviation from the original belief, or it represents change. In summary, the majority of the women felt informed about the properties and side effects of the medication. It is notable, however, that a sizable number of women reported having little or no information.

The fourth null hypothesis focused on perceived stigma: patients who report a

low degree of stigma are no more likely to continue antidepressant medications than patients who report a high degree of stigma. Three areas of stigma were assessed. For the first area, questions concerning faith were asked to determine if patients feel that God does not approve of them. This was an measure of intrinsic religious motivation, not extrinsic motivation. Thus the deeply held personal convictions about relationship with deity were addressed. The results showed the compliant and noncompliant group means were very similar and statistically nonsignificant. Stigma from God was measured in an indirect manner. It is possible that respondents were responding to religious commitments and not perceived stigma.

Additional questions were asked to determine self-stigmatization and stigmatization by others. Neither of these analyses was statistically significant. An examination of the raw data revealed some interesting trends. In terms of feeling stigmatized by self, the majority of the respondents felt moderately or strongly stigmatized. Compliant patients had a bimodal distribution, with one third of the respondents reporting little or no self-stigma. Given the trends in the data, it is likely that given a larger sample size, the differences would have been more noticeable. The data on feeling stigmatized by others formed an interesting contrast to self-stigma. One half of the respondents moderately or strongly agreed they felt stigmatized by others. For the noncompliant group, there was a group of virtually the same size who moderately to strongly disagreed about feeling stigmatized. This group who did not feel stigmatized is somewhat puzzling. They are not consistent with the literature, which would seem to make them more likely to take their medication.

Montano (1994) reported that stigma is associated with depression. Most families (with a depressed member) report that there is a stigma attached to depression (Montano). In addition, education about depression helps to alleviate stigma. It may be that families in smaller communities have less access to stigma-allaying education. Guilt and shame (the emotions that may follow stigma) are feelings reported by depressed persons. Because guilt and shame responses are debilitating traits (Zukerman, 1995), humans must resolve guilt and shame to develop direction and purpose in life (Cole & Cole, 1993). It may have been that a group of these women had resolved these issues and therefore felt no stigma.

The fifth null hypothesis was: patients who strongly agree that depression has had a negative effect on their family/social support systems are no more likely to discontinue antidepressant medication use than patients who disagree that depression has had a negative effect on their family/social support systems. While statistical significance was not obtained, the trend shows that women who discontinued their medication reported more symptoms in their close relationships and social support than those women who continued their medication. Women who discontinued their medication also scored above the cutoff level on the social role and interpersonal relationships components of the OQ tm- 45.2. The scores above the cutoff level indicate significant levels of problems in these areas. This is consistent with the previous hypotheses that the women were feeling stigmatized. It is reasonable to assume that women who did not take their medication experienced increased negative effects in their family and social support systems.

The results of this study are not statistically different, but the differences are clinically significant (Jacobson & Follette, 1984). Women who did not continue their medication were above the clinical cutoffs for both interpersonal and social role subscales. The cutoff scores can be helpful as they distinguish between distressed and nondistressed people in the areas of measurement. Thus the women in the medication noncompliant group fall in the clinically distressed range, while the women in the medication compliant group would be classified as nondistressed.

The literature clearly indicates that depression is associated with relationship problems. This may occur because depressed people are often treated in ambivalent (sympathetic and hostile) ways (Baucom & Epstein, 1990). The problem is increased by the fact that depressed persons find it difficult or impossible to recover without help (Baucom & Epstein). The depressed person needs support to recover but Coyne (1987) has reported that depressed persons and their spouses are often conflictual and overtly hostile. Baucom and Epstein (1990) added that a circular pattern tends to develop in these families: the negativity of the depressed person elicits hostility/withdrawal from the partner, which causes more depression in the depressed member. This process may be accentuated if the women do not take their medications.

In summary, the women in the sample are distressed whether they continue their medications or not. In addition, most experience side effects and feel stigmatized. The general conclusion is that results were consistent with the literature even though results were not statistically significant.

Implications for Therapy

Although levels of statistical significance were not reached with the null hypotheses, trends from the data present useful information for the practice of marriage and family therapy. The following are implications for the practice of marriage and family therapy: First, the literature suggests that there is a beneficial effect of psychotherapy in connection with depression (Coyne, 1987; Hirschfeld, 1994); thus the combination of medication and psychotherapy is efficacious. The data from this study show that only a small number of the women were receiving psychotherapy. This is critical, as Hirschfeld (1994, p. 337) has stated, "Psychotherapy plays a critical function in the long-term treatment of depression. Patients with depression, especially long-standing or recurrent depression, often have serious marital, familial, social, and occupational problems that have been exacerbated by their illness." In addition, Law and Crane (2000) reported that people receiving marriage and family therapy services are less likely to need health care services. Thus the first recommendation is that therapists and doctors need to be more collaborative when treating depressed clients.

Secondly, the research also acknowledges that compliance with antidepressant medication is a problem and suggests that the combination of psychotherapy and medication is efficacious. An obvious benefit is that the therapist can reinforce the education the doctors and pharmacists provide.

This study showed that patients have and react to severe symptoms of depression, side effects, stigma, and negative effects on family/social support system, despite medication education. It also shows that the patients who were most depressed had the

lowest degree of compliance with medication. The therapists can encourage medication compliance while helping reduce the impact on the family.

A third implication is related to the assessment of depression. This assessment can be expanded by increasing the interaction between practitioner and therapist. The majority of the practitioners in this study want to know what more can be done to help treat depression. David Beckstead, M. D., a referring physician, believes that most patients are not clinically depressed but are suffering from being overwhelmed by life, which is not resolved by antidepressant medication (personal communication, April 7, 1998). Receiving help for life issues falls within the realm of therapy, which can be an excellent resource for not only the health professional but also the patient.

From a medical standpoint, depression is treated in the following ways: The psychiatrist who participated in this study, James Kirby, M.D., evaluates his clients and prescribes medication for depression and the associated side effects. Dr. Kirby continues to monitor patient medication in conjunction with a referral to psychotherapy. His approach combines medication and therapy. The physicians and physician assistants report they are being updated regularly concerning the pharmaceutical aspects of depression. They report a sizeable patient load with depression concerns. Their time is spent diagnosing, prescribing, and monitoring medication for depression and they can benefit from assistance with the concerns psychotherapy addresses. Psychotherapy is designed to address stigma, negative effects on family/support systems, and coping strategies for depression and its side effects. The psychotherapy model advocates integrating the following elements within three areas: (1) basic endowment: biogenetic,

family history, family environment, social background; (2) developmental Processes: social context, interpersonal/cognitive, mood, temperament; and (3) mediators: stressors, personal resources, social resources (Kupfer & Frank, 1998). The ideal alliance is a partnership between physician and therapist. The specific psychotherapy treatment approach suggested by the American Psychiatric Association (2000) is to evaluate for severity of depression to determine any need for medication. With or without medication psychotherapy is recommended for symptom relief.

Limitations

The major limitations of this study are its small and unrepresentative sample. Medical practitioners agreed to gather data for this study to help find ways to alleviate the medication compliance problem. The practitioners and office staff were generous in this offer and anticipated knowing the results of this study. However, it was difficult for the medical office staff to gather data as it appears that they were already functioning at maximum capacity. Each office was given 25 questionnaires and it was anticipated that 150 returned questionnaires could be obtained. Over a 6-month period only 36 questionnaires were returned.

It also should be noted that volunteers who completed questionnaires may be different from the general population suffering from depression. It is possible that women who participated were so distressed they utilized their health care options more than other women, and hence the sample was skewed in a negative or more distressed direction. Conversely, participants might have been less distressed than the general

population. The extent of sample bias cannot be determined and thus it cannot be figured into the study results.

The biggest problems with low \underline{n} are that the sample is not big enough to examine larger patterns and to facilitate effective statistical testing. Thus the low \underline{n} precluded use of more advanced statistical methods to examine how the different factors worked together.

Recommendations

In retrospect, it appears that more data may have been collected if the researcher had collected the data in each medical office. The time spent by the researcher monitoring the data collection over a period of 6 months could have been better spent in concentrated periods gathering data in each office.

There is always a concern with measurement validity. In this case the questionnaire may not be a true reflection of the participant. It may be that the participants do not interpret questions consistently because of interpretation variations or misunderstandings. It may be better to have a trained data collector administer the questionnaire.

In summary, the purpose of this study was to investigate medication compliance or noncompliance in the context of the five variables (severity of symptoms, medical side effects, medication education, perceived stigma, and effects on family/social support system) to add to the body of knowledge concerning depression. Within this purpose was the researcher's goal to raise awareness of the efficacy of using marital and family

therapy as a conjunct to the medical treatment of depression. Within the limited scope of this study, it appears interest and awareness concerning therapy were increased among the medical practitioners and staff who participated.

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APPENDICES

Appendix A. Institutional Review Board Approval

Utah State

VICE PRESIDENT FOR RESEARCH OFFICE Logan UT 84322-1450 Telephone: (435) 797-1180 FAX: (435) 797-1367 INTERNET: [pgerity@champ.usu.edu]

October 27, 1999

MEMORANDUM

TO:

Scot Allgood

Pamela Linton

FROM:

True Rubal, IRB Administrator

SUBJECT: Correlates of Anti-depressant Use Among Women

The above-referenced proposal has been reviewed by this office and is exempt from further review by the Institutional Review Board. The IRB appreciates researchers who recognize the importance of ethical research conduct. While your research project does not require a signed informed consent, you should consider (a) offering a general introduction to your research goals, and (b) informing, in writing or through oral presentation, each participant as to the rights of the subject to confidentiality, privacy or withdrawal at any time from the research activities.

The research activities listed below are exempt from IRB review based on the Department of Health and Human Services (DHHS) regulations for the protection of human research subjects, 45 CFR Part 46, as amended to include provisions of the Federal Policy for the Protection of Human Subjects, June 18, 1991.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through the identifiers linked to the subjects: and (b) any disclosure of 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.

Your research is exempt from further review based on exemption number 2. Please keep the committee advised of any changes, adverse reactions or termination of the study. A yearly review is required of all proposals submitted to the IRB. We request that you advise us when this project is completed, otherwise we will contact you in one year from the date of this letter.

Appendix B. Medical Usage Questionnaire



DEPARTMENT OF FAMILY AND HUMAN DEVELOPMENT College of Family Life 2905 University Blvd Phone: (801) 797-1501 LOSAN UT 84322-2905

FAX: (801) 797-3845

INFORMED CONSENT

- 1	Dat			

CORRELATES OF ANTIDEPRESSANT USE AMONG DEPRESSED WOMEN

Scot M. Allgood, Ph.D and Pamela Linton, B.S., in the Family and Human Development Department at Utah State University are conducting a masters thesis research study to find more about how women use antidepressant medication prescribed by their physician and what influences these decisions. You have been asked to take part in this research because you have been prescribed an antidepressant medication. There will be approximately 40 participants at this site. We will use your answers to help us find ways to decrease the negative consequences associated with antidepressant medication use.

If you agree to be in this study, you will be asked to answer questions about your use of prescribed medication and how you generally get along in life. Please do not put your name on your questionnaire. They will not be kept with your patient file, but will be deposited, by you, in a locked file box, thereby insuring your confidentiality. Participation in this study may involve some psychological discomfort. If you have concerns please talk to your physician about it today during your appointment.

There may or may not be any direct benefit to you from these procedures. The investigator, however, may learn more about how women use antidepressant medication prescribed by their physician, and what things influence that decision. This study may benefit medical/psychological knowledge and others now and in the future.

A member of your physician's office staff has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Professor Scot M. Allgood at (435) 753-5895. Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without any consequence.

Your results will be kept confidential according to federal and state laws. There will be no way to link your name with your questionnaire. Only the investigators will have access to the data, and it will be kept in a locked file cabinet when picked up from your doctor.

The Institutional Review Board (IRB) for the protection of human subjects at Utah State University has reviewed and approved this research project. Your return of this questionnaire implies that you understand the above information and are willing to participate in this project.

Scot M. Allgood, Ph.D. Principal Investigator

Pamela Linton, Student Researcher



Medication Usage Questionnaire

Many women have trouble staying on their antidepressant medications. Please complete the following survey to help us understand why. These two surveys (Medication usage Questionnaire and OQ-45) are confidential so do not put your name on them. They will not be attached to your patient file. Certain issues have been included because they are thought to influence how people use their medication. Please complete the following items by filling in the blank or writing the answer.

C	complete the following	ig items by fillin	ng in the blank or	writing the answer.					
1	. Your age:								
2	2. Number of children ever born:								
3	3. Total annual household income: \$								
	Please circle answe	rs that make th	ne most sense, or a	re the most true for you.					
4	Education: years completed (high school = 12)								
5	5. Your current marital status:								
	Married	Divorced	Separated	Never been married					
6.	. Have you had any problems with finances or medical insurance since you were diagnosed								
	with depression?								
	Yes	No							
7.	. Are you currently seeing a psychologist or therapist for your depression?								
	Yes	No							
8.	If you are seeing a p	sychologist or th	nerapist, is the com	bination of medication and therapy					
	helping you deal wit	h your depression	on related concerns	?					
	Yes	No							
9.	If you are not receiv	ing therapy for y	our depression, wo	uld you like information on available					
	resources?								
	Yes	No							

10. I have experience	d a 10% weight gain	since taking my	antidepressant.	
Yes	No			
11. I have experience	d a 10% weight loss	since taking my	antidepressant.	
Yes	No			
12. How many times	a week do you take y	our antidepress	ant medication?	
Zero One	Two Three	Four Five	Six Seven	
13. When you don't ta	ike your antidepressa	ant medication, v	what is the reason?	
Forget	Cost of refill prescri	ption Side e	ffects Other (p	lease
14. Have you disconti	nued your antidepre	ssant medication	on your own?	
Yes	No	Please explain		
16 H. didd.			-12	
15. How did your doc				
Please explain				
6. Have you had foll	ow-up appointments	with your docto	r for your antidepr	essant medication?
Yes	No			
7. If you are not taking	ng your antidepressa	nt medication se	ven days/week, ho	w are you taking it?
6 days/week	5 days/w	veek	4 days/week	
3 days/week	2 days/w	/eek	1 day/wk	
As needed	Other			
8. When you were pr	escribed antidepress	ant medication.	now well did your	physician explain the
properties of the med				
	-			
Very detailed	Detailed	Not detailed	No explanation	I don't remember
		2		

19.	Whe	n yo	ou fil	led y	our preso	ription for	antidepressant me	edication, how well	did your pharmacist
	exp	lain	the n	nedio	cation and	i what you	could expect?		
		Ver	y de	taile	d Det	ailed	Not detailed	No explanation	I don't remember
2	0. Di	d yo	ur pł	nysic	ian or ph	armacist in	form you about the	e side effects of you	r medication?
		Ver	y de	taile	d Det	ailed	Not detailed	No explanation	I don't remember
2	1. WI	hen	you f	illed	your pre	scription fo	r antidepressant n	nedication, how thor	oughly did you read the
	writ	ten 1	nater	rial a	bout side	effects?			
		Rea	d the	oroug	ghly	Read	pretty well	Read a little	Did not read
		I do	n't re	emen	nber				
F	or ead	ch st	atem	ent t	here are	six (6) poss	ible responses: Si	trongly agree (1); M	oderately agree (2);
S	lightl	y ag	ree (3); S	lightly di	sagree (4);	Moderately disagn	ree (5); and Strongly	disagree (6).
	Plea	se c	ircle	ans	wers tha	t make the	most sense, or an	re most true for you	1.
1	2	3	4	5	6			n my own low sexua o antidepressant me	l interest or desire that dication.
1	2	3	4	5	6			n sexual functioning pressant medication.	that seems to
1	2	3	4	5	6	 Someone in my family feels there is a stigma attached to depression. 			
1	2	3	4	5	6	25. I fe	el there is a stigm	a attached to depres	sion.
1	2	3	4	5	6		depression has h	ad a negative effect	on my family and/or
1	2	3	4	5	6	27. I ai	n satisfied with m	y marriage?	
1	2	3	4	5	6	28. I ar	n satisfied with m	y family?	
1	2	3	4	5	6	29. My	faith involves all	of my life.	

1	2	3	4	5	6	30. One should seek Divine guidance when making every important
	2	2	1	e	6	decision. 31. In my life, I experience the presence of the Divine.
	2					32. My faith sometimes restricts my actions.
1	2	3	4	5	6	33. Although I am a religious person, I refuse to let religious
1	2	3	4	5	6	considerations influence my everyday affairs. 34. My religious beliefs under lay my whole approach to life.
1	2	5	-		O	54. In tengious beliefs under tay my whole approach to me.

^{35.} From your experience what could providers (therapists, doctors, or pharmacists) do that would help people deal with depressive symptoms? (Respond in the space below)