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Depressive symptomatology, patient-provider communication, and patient satisfaction: A multilevel analysis

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Depressive Symptomatology, Patient-Provider Communication, and Patient Satisfaction:

A Multilevel Analysis

by

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A dissertation submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy
College of Nursing
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This dissertation is dedicated to my parents, Mary and Bill, who have unfailingly supported me in every possible way in all of my academic and life pursuits. Their unwavering faith in me motivated me to persist in completing this dissertation when my spirit waned. Thank you for instilling in me the confidence to believe in myself.

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Depressive Symptomatology, Patient-Provider Communication, and Patient Satisfaction:
A Multilevel Analysis

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ABSTRACT

Depression can be a profoundly disabling and costly disorder and is a major

public health concern. Despite the efficacy of treatment options, it is often unrecognized,

under-diagnosed, and inadequately treated in primary care settings. Research on patient-

provider communication supports the connection among the quality of the patient-

provider interaction, patient behavior, and health outcomes. The purpose of this study

was to systematically examine the impact of patients' depressive symptoms on the

patient-provider relationship, patient-provider communication, and patient satisfaction

with the primary care office visit. One hundred twenty three patient-provider encounters

were audiotaped and coded using the Roter Interaction Analysis System (RIAS).   A

$2 \times 2 \times 2$ within-subjects factorial model provided the analytic framework for examining

eight verbal communication behaviors categorized by *speaker* (patient or provider), *type

of utterance* (question or information giving), and *content of utterance* (medical or

psychosocial talk). Hierarchical linear modeling was used to analyze the two-level

nested structure of the data.

Results indicated that depression is associated with, but does not predict,

increased provider-perceived difficulty in the patient-provider relationship. There was no

significant change in either patient or provider communication behavior in relation to the severity of patients' depressive symptoms. Significantly more provider medical information was given during encounters with "difficult" patients and this behavior had a consistent negative effect on patient satisfaction. Patient-provider communication, by itself, does not appear to be a source of depressed patients' oft-reported dissatisfaction with medical care. Additional research is needed to further understand the core processes and structures of primary care practice in relation to the diagnosis and management of depression, their effect on patient outcomes, and to uncover opportunities for enhancing the effectiveness of depression care in primary care.

Introduction

One out of every four adults in the United States experiences a diagnosable

mental disorder each year (Kessler, Chiu, Demler, Merikangas, & Walters, 2005). Based

on 2004 U.S. Census Bureau estimates this figure translates to approximately 57.7

million adults (U.S. Census Bureau, 2005). The true burden of these disorders may be

even greater, as reports from the Global Burden of Disease Study indicate the prevalence

of mental illness is heavily underestimated (Murray & Lopez, 1997a). Researchers

acknowledge that many individuals remain reluctant to discuss their mental health history

because of the stigma associated with mental illness. Stigma, a widespread, powerful,

and often overwhelming barrier to diagnosis and treatment, prevents many individuals

from even acknowledging their own mental health issues, much less disclosing their

concerns with health care professionals. It is estimated that nearly half of all Americans

who experience a *severe* mental illness do not seek any treatment at all (Department of

Health and Human Services [DHHS], 1999).

Mental illness refers collectively to all diagnosable mental disorders (DHHS,

1999). Characterized by alterations in thinking, mood, and/or behavior, mental disorders

are associated with varied levels of emotional distress, impaired functioning, and a wide

range of medical and social consequences.   They can be highly disabling, ranking second

only to cardiovascular conditions as a leading cause of worldwide disability as defined by

the World Health Organization (Murray & Lopez, 1997a). Mental illness affects persons

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of all ages and individuals from all racial, ethnic, religious, educational, and socioeconomic groups. Left untreated, these disorders can be profoundly disabling and costly. The economic burden in the United States is estimated to be over $100 billion annually. (National Alliance on Mental Illness [NAMI], 2006).

Depression is one of the most common and costly mental disorders. The total burden of depression in the U.S., including direct medical, suicide-related mortality, and workplace costs was estimated at $83 billion in 2000 (Greenberg et al., 2003). An illness of substantial public health and economic significance, depression is a leading cause of disability in the United States and is projected to be *the leading cause of disability burden by 2020* (Murray & Lopez, 1997b). Most individuals who seek help for depressive symptoms are evaluated in primary care settings, yet the majority of depressed patients are not diagnosed. Individuals experiencing subthreshold depression are even more likely to go unrecognized and undiagnosed. Of those who are diagnosed, most receive inadequate treatment even after adjusting for demographic, social/behavioral, depression severity, and economic factors (Kessler, Berglund, et al., 2003). Over the past 20 years, these facts have stimulated a multitude of studies aimed at improving provider detection and management of depression. Although many interventions have been shown to improve diagnosis, treatment, and patient outcomes, these improvements are generally short-lived as primary care providers typically return to baseline practice styles within a few months following the intervention (Lin et al., 1997).

Healthy People 2010 (DHHS, 2000) designated mental health as one of the leading health indicators that will be used to measure the health status of the nation at the

end of this decade. Modern treatments for mental disorders are highly effective, with a

variety of treatment options available for most disorders. Despite the efficacy of

treatment options, researchers report the failure of primary care providers to recognize,

diagnose, and effectively treat depression and/or refer patients to mental health specialists

(Spitzer et al., 1994). From a public health perspective, the consequences of untreated or

sub-optimally treated depression are far-reaching and costly. From a personal

perspective, the associated disability is immeasurable and often quite profound.

Continuity of care is a main attribute of primary care and believed to enhance

patient-provider relations and facilitate the disclosure of emotional distress. However, it

has been reported that the continuity of care provided by the primary care provider-

patient relationship is not sufficient to promote the discussion, disclosure, and detection

of psychosocial issues (Wissow et al., 2002). This finding necessitates closer

examination since primary care is the main portal of entry into treatment for mental

disorders for the vast majority of individuals. The role of the primary care provider

demands expertise in communication as numerous studies of patient-provider

communication support the connection among the quality of the patient-provider

interaction, patient behavior, and health outcomes.

Although many barriers to the diagnosis and treatment of depression have been

identified, the contributory affects of both patient *and* provider on the patient-provider

relationship and the medical office encounter require further exploration. In order to

enhance an understanding of the poor performance of primary care clinicians in the

delivery of depression care services, research efforts must first identify all factors that

impede care. As gatekeepers, primary care providers hold the key to improving the mental health of the nation's citizens.

Statement of the Problem

Depression can be a profoundly disabling and costly disorder and is a major public health concern. Despite a multitude of psychometrically sound screening and case-finding instruments, enhanced educational efforts, communication skills training, effective treatment options, and clinical practice guidelines, depression often remains unrecognized, under-diagnosed, and inadequately treated by primary care clinicians. Primary care providers struggle with multiple competing demands in the delivery of care. Yet, diagnosing and treating mental health disorders and providing personal support are part of the responsibilities and tasks that define primary care.

The role of interpersonal communication in the patient-provider relationship has been extensively studied and research findings consistently show that it is central to satisfactory patient-provider relationships and better patient health outcomes. These outcomes include patient satisfaction, patient adherence to treatment recommendations, functional status, symptom resolution, and measures of physiologic status (Brown, Stewart, & Ryan, 2003). However, there is little empirical evidence about how patients' depressive symptoms impact the patient-provider relationship or patient-provider communication during the primary care office visit. Although it is widely documented that depressed patients are generally less satisfied with medical care than individuals who are not depressed, there is no extant research that has identified the communication

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behaviors that are important to this vulnerable group. The purpose of this study was to systematically examine the influence of patients' depressive symptoms on the patient-provider relationship, patient-provider communication, and patient satisfaction with the primary care office visit.

Background

Review of Literature

Depression – Scope of the Problem

Mental disorders are prevalent in society. About half of all Americans will meet criteria for a DSM-IV disorder (American Psychiatric Association, 1994) at some point during their lifetime: one out of five will experience a mood disorder. Mood disorders include major depression (unipolar depression), dysthymia, and bipolar disorder (manic-depression). Major depression is the most common mental disorder in the United States, affecting approximately 14.8 million adults each year (National Institute of Mental Health [NIMH], 2006). Although symptoms can develop at any age, the median age of onset is 32, affecting adults during their most productive years of life (Kessler, Berglund, et al., 2005). Seemingly more prevalent in women than in men (Kessler, Berglund, et al., 2003), the clinical presentation of depression varies among individuals, each of whom experience their own distinct combination of cognitive, affective, somatic and vegetative symptoms.

Depression is associated with significant disability and functional impairment (Lin et al., 2000; McQuaid, Stein, Laffaye, & McCahill, 1999; Wu, Parkerson, & Doraiswamy, 2002). The negative physical impact is comparable to or greater than illnesses such as low back pain, arthritis, diabetes mellitus, and heart disease (Schonfeld et al., 1997). The disabling effects are even more pronounced when depression exists, as

it frequently does, with co-morbid physical or psychiatric illness (McQuaid et al.; Roy-Byrne, 1996; Stein, Cox, Afifi, Belik, & Sareen, 2006; Wu et al., 2002). It is associated with increased costs and utilization of health care services (Callahan et al., 2002; Greenberg & Birnbaum, 2005; Roy-Byrne & Katon, 1997; Shvartzman et al., 2005; Stein et al., 2006), increased hospital length-of-stays (Pearson et al., 1999), non-compliance with prescribed medical regimens (DiMatteo, Lepper, & Croghan, 2000), work absenteeism (Stein et al.) reduced worker productivity (Druss, Schlesinger, & Allen, 2001) and suicide (Harris & Barraclough, 1997). Katon (2003) found depression doubled the medical costs of co-existing medical/physical illness even after controlling the severity of those illnesses. There is also an increasing body of literature suggesting depressive symptoms and major depression may be associated with increased morbidity and mortality from such illnesses as heart disease (Musselman, Evans, & Nemeroff, 1998), diabetes (DeGroot, Anderson, Freedland, Clouse, & Lustman, 2001), and osteoporosis (Robbins, Hirsch, Whitmer, Cauley, & Harris, 2001).

Substantially more individuals suffer milder, but clinically significant depressive symptoms that do not meet DSM-IV criteria for major depression (Brody et al., 1998). Various terms have been used to describe these milder symptoms including subthreshold, subsyndromal, and minor depression. Despite the terminology subthreshold depression is also associated with significant disability, functional impairment, co-morbidity (Lyness, King, Cox, Yoediono, & Caine, 1999), increased costs and utilization of health care services (Pearson et al., 1999), and work absenteeism (Beck & Koenig, 1996). Although watchful waiting may be just as effective as antidepressants for treatment of milder

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symptoms (Kessler, Zhao, Blazer, & Swartz, 1997), many individuals with mild depression develop more serious depressive symptoms (Kessler, Merikangas, et al., 2003) and warrant careful monitoring.

The economic burden of depression is staggering. Using data from the National Comorbidity Survey Replication (NCS-R), Greenberg et al. (2003) estimated the total economic burden of depression in the United States at $83 billion annually. This figure incorporated direct medical (31%), suicide-related mortality (7%), and workplace costs (62%). Unipolar depression, dysthymia, and bipolar disorders were included in their analysis. They also considered the cost of presenteeism (reduced worker productivity) in their assessment. These factors help to explain why their estimated annual cost is significantly greater than the $44 billion frequently cited in the literature.

Diagnosis and Treatment

A variety of efficacious treatment options including pharmacological agents and psychotherapy, alone or in combination, are available to reduce depressive symptoms and assist patients to recovery. Yet, the literature is replete with reports indicating that depression is frequently unrecognized, largely under-diagnosed and inadequately treated. Dwight-Johnson, Sherbourne, Liao, and Wells (2000) noted that the majority of individuals experiencing depressive symptoms desire help. Unutzer et al. (2003) found that individuals are willing to pay up to 9% of their total household income for treatment of depression. Yet, only 20-25% of subjects reported receiving any type of mental health treatment (DHHS, 2000; Kessler, Demler, et al., 2005). The majority of depressed individuals prefer mental health counseling, although desire for treatment and patient

preferences for type of treatment vary by ethnicity, gender, age, income, severity of symptoms, knowledge of treatment options (Brown & Schulberg, 1998; Cooper et al. 2003; Dwight-Johnson et al.; Unutzer et al.), and spirituality (Cooper, Brown, Vu, Ford, & Powe, 2001). Previous experience with antidepressants especially influences older adults who not only fear dependence to drugs, but very often resist acknowledging depression as a true medical illness (Givens et al., 2006).

Depression and the Primary Care Practice

Primary care clinicians address the majority of problems that individuals bring to the health care setting. Although some patient problems require referral, consultation, or hospitalization, the majority of problems are treated and resolved at the primary care level. Hence, primary care is the main portal of entry into treatment for mental disorders and the place where many individuals prefer to receive mental health services (Brody, Khaliq, & Thompson, 1997). The conventional primary care model conceptualizes primary providers as gatekeepers, who are able to identify individuals with mental disorders, initiate and manage treatment, and refer appropriately to mental health specialists. The majority of individuals feel that it is at least somewhat important that their primary care provider attend to their mental health needs (Brody et al.), report being comfortable discussing psychological problems (Spitzer et al., 1994), and welcome the opportunity to address psychosocial concerns during the course of their medical visit (Bertakis, Roter, & Putnam, 1991).

Seventy-five percent of individuals who seek help for depressive symptoms are initially evaluated in primary care settings (Goldman, Nielsen, & Champion, 1999). Yet,

primary care providers fail to recognize or diagnose depression in up to 70% of patients (Callahan et al., 2002; Docherty, 1997; Nuyen et al., 2005). They often defer treating those they do identify, may simply monitor progress in others, and seldom refer patients to mental health specialists (Watts et al., 2002). Individuals experiencing subthreshold depression are even more likely to go unrecognized, undiagnosed, and untreated in primary care (Solberg, Korsen, Oxman, Fischer, & Bartels, 1999; Von Korff & Simon, 1996). Rost et al. (1998) found nearly one-third of primary care patients with major depression remained undetected up to one year despite ongoing office visits. Approximately 50% of those individuals admitted to suicidal ideation during that time.

Greater disability and severity of depressive symptoms increases the chance of being diagnosed (Borowsky et al., 2000; Klinkman, Schwenk, & Coyne, 1997; McQuaid et al., 1999; Simon, Goldberg, Tiemens, & Ustun, 1999). Yet, greater severity of symptoms and diagnosis does not result in improved patient outcomes (Klinkman et al., 1997). Of those who are diagnosed, most receive inadequate treatment even after adjusting for depression severity and demographic, social, behavioral, and economic factors (Kessler, Berglund, et al., 2003). Data from the National Ambulatory Medical Care Surveys (NAMCS) and the Medical Outcomes Study indicate primary care providers are less likely to recognize or diagnose depression in males, the elderly, Medicaid recipients, and African-American patients (Borowsky et al., 2000; Harman, Schulberg, Mullsant, & Reynolds, 2001).

Diagnosing and treating depression in the primary care setting can be effective. A significant public health problem, the U.S. Preventive Services Task Force (USPSTF)

recommends that adults be screened for depression in clinical practices that have systems

in place to assure accurate diagnosis, effective treatment, and follow-up (USPSTF, 2002).

Numerous screening instruments are available to assist primary care providers in

detecting depressive symptoms in their patients. In busy clinical practice settings, asking

patients one or two specific questions about depressed mood and anhedonia may be as

effective as longer screening instruments (Kroenke, Spitzer, & Williams, 2003; Williams

et al., 1999). Patients who screen positive require further diagnostic questioning to

establish an appropriate diagnosis, taking into consideration gender, culture, and the

presence of co-morbid somatic symptoms (Kerr & Kerr, 2001).

Barriers to Diagnosis and Treatment

Numerous barriers to the diagnosis and management of depression in primary

care practice have been identified and detailed in the literature. Despite these barriers,

many patients do attempt to communicate with their primary care providers. Sleath and

Rubin (2002) found that patients were more likely to initiate discussions on depression

than their providers were likely to inquire. Female gender, higher education, poor self-

reported health status (Sleath & Rubin), greater psychological distress (Callahan et al.,

1998) and patient-provider familiarity (Robinson & Roter, 1999) appear to facilitate

disclosure of symptoms. Continuity of care is considered to be a main attribute of

primary care and is widely believed to enhance patient-provider relations and disclosure

of emotional distress. However, continuity appears to vary in its importance to different

subsets of patients (Nutting, Goodwin, Flocke, Zyzanski, & Stange, 2003) and may have

some untoward affects on patient care. Roter (2000) posits there may actually be "some

negative aspects of continuity, such as presumptuousness of familiarity, labeling, and simply the need for a fresh perspective" (p. 13). This may at least partially explain the findings of Wissow et al. (2002) who found that the continuity of care associated with the patient-primary care provider relationship was insufficient to promote the discussion, disclosure, and detection of psychological issues.

Patient presentation and chief complaint can impede a provider's ability to recognize and diagnose depression as the primary reason for a depressed patient visit (Flocke, Frank, & Wenger, 2001). The high prevalence of co-morbid medical and psychiatric disorders is a well-established phenomenon in depressive illness and can mask symptoms and complicate the diagnostic reasoning process. In a secondary analysis of a depression intervention trial, Keeley et al. (2004) found nearly two-thirds of depressed patients presented exclusively with physical symptoms. Somatization is frequently the way that depression presents in primary care in addition to complaints of pain, fatigue, and sleep problems (Aragones, Labad, Pinol, Lucena, & Alonso, 2005; Wittchen, Lieb, Wunderlich, & Schuster, 1999). There are conflicting reports on the impact of somatization and the diagnosis of depression. Barkow et al. (2004) found the presence of somatic symptoms increased the likelihood that depressive symptoms would be detected, but Aragones et al. reported a link between somatization and under-detection of the underlying psychiatric process.

Providers' beliefs and attitudes about depression, knowledge, experience, availability of community resources, and personal level of comfort addressing patients' emotional concerns are additional barriers that affect depression care. Yet, general

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practitioners appear to view barriers to providing effective treatment of depression as being more allied to external issues, particularly patient-centered factors (Nutting et al., 2002) and health system or service provision barriers (Telford, Hutchinson, Jones, Rix, & Howe, 2002) rather than internal factors such as their own knowledge and skills. In a study using focus group and survey methods, Solberg et al. (1999) found primary care physicians cite lack of time as the biggest barrier to the delivery of psychosocial care.

Time management is paramount for primary care providers in today's health care environment. Klinkman (1997) presents a comprehensive discussion of the multiple competing demands that primary care providers face in the delivery of psychosocial care and partially explain the appearance of inadequate depression care. Direct observation reveals primary care visits average only 10 to 19 minutes of direct doctor-patient contact time (Flocke et al., 2001; Stange et al., 1998) although patients bring with them an average of 6 problems to which they need attention (Williams et al., 1999). A linear trend exists between the number of patient problems and length of the encounter and in the vast majority of visits more than one problem is discussed (Flocke et al.). There is also evidence that the discussion of behavioral or emotional concerns, especially when raised during visits not originally identified as a psychological consultation, significantly increases the length of the office visit (Callahan et al., 1998; Cooper, Valleley, Polaha, Begeny, & Evans, 2006; Flocke et al.). Sleath and Rubin (2002) observed talk about depression occurred in only 25% of depressed patient visits adding support to the conclusion of Rost et al. (2000) that the attention patients with depression get during a

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given medical visit is less associated with the severity of the patient's depressive symptoms than with the number or recency of other problems.

The "Difficult" Patient

Typically 10% to 20% of patients provoke a level of physician distress and frustration that transcends the expected and accepted level of difficulty (Hahn, Thompson, Wills, Stern, & Budner, 1994; Hahn et al., 1996). The difficulty is not a property of the patient per se, but is an attribute of the patient-provider relationship as perceived by the provider. This frustration is often expressed through the labeling of such patients with derogatory names. Although the labeling is not a formal diagnosis, it represents a subjective and negative categorization that once applied, is likely to be inscribed in a provider's psyche. Frequently referred to as "heartskink" (O'Dowd, 1988), "problem" (Drossman, 1978), or "difficult" patients in the literature, use of these and similar monikers is widespread in clinical medicine. Groves' (1978) seminal article on the "hateful patient" first legitimized physicians' feelings of frustration and dislike toward certain patients. While it is clear that physicians are responsible for the problem patient designation, McGaghie and Whitenack (1982) carefully noted that they are also responsible for the medical actions that are associated with the labeling process. It is not clear how such feelings manifest during the patient-provider encounter or if providers predictably respond with dislike to specific subsets of patients.

Certain features are common to difficult patients. A strong association with mental disorders, especially depressive and anxiety disorders is well documented (Hahn, 2001; Jackson & Kroenke, 2001; Kroenke, Jackson, & Chamberlin, 1997). Other

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characteristics include an increased number of patient-reported physical symptoms and somatization (Hahn), multiple non-specific complaints (Steinmetz & Tabenkin, 2001), abrasive behavioral style (Schwenk, Marquez, Lefever, & Cohen, 1989), greater functional impairment, higher utilization of health care services, more unmet expectations, lower levels of satisfaction with care (Hahn et al., 1996), more telephone calls to office, and more referral requests to specialists (Linn et al., 1991). Provider characteristics also play a role in defining the difficult patient. A poor provider psychosocial attitude (Jackson & Kroenke, 1999), less practice experience (Steinmetz & Tabenkin), and increased medical uncertainty in the care of the patient (Schwenk et al.) have been found to underlay physicians' perceptions of difficult patients. Using quantitative and qualitative methods Mas Garriga et al. (2003) found physicians believe that the skills and strategies they have to help them manage such patients are limited.

Patient-Provider Relationships

Patients and providers constantly influence each other during the medical encounter. Patient ratings of the patient-provider relationship are increasingly being recognized by health care organizations as a measure of quality of care. Hall, Horgan, Stein, & Roter (2002) studied patients and physicians in established relationships and found patients accurately estimated their physician's liking of them. They also found correlations between patients' liking of their physician and better self-reported health status, affective state following the encounter, better ratings of physician behavior, and increased visit satisfaction.

There is evidence that the quality of the patient-provider relationship affects patient care. Barsky, Wyshak, Latham, and Klerman (1991) found physicians were less aware of symptoms of depression and anxiety in "frustrating" patients than in other patients. The authors suggested that a bad patient-provider relationship might dull a doctor's sensitivity to patients' symptoms. There is also some evidence from the patient perspective that the quality of the relationship affects depression care. O'Malley, Forrest, and Miranda (2003) reported that in their sample of low-income African American women, those who rated their providers as having more respect for them were more likely to report being asked about and treated for depression. In a cross-sectional analysis of 18-month data Meredith, Orlando, Humphrey, Camp, & Sherbourne (2001) found an association between higher patient ratings of the interpersonal relationship and receipt of quality depression care (guideline-concordant care).

Although much has been written about the nature of difficulties in the patient-provider relationship, the literature is mostly descriptive. Researchers grappled with ways to operationalize and measure providers' perceptions of the patient-provider relationship until a valid and reliable instrument became available in recent years. Since then, a review of the literature reveals that although researchers have been able to quantify the degree of provider-perceived difficulty in the patient-provider relationship, the data have primarily been used in efforts to determine patient correlates of difficulty and, to a small extent, examine patient outcomes. Of particular interest is the impact of a provider's negative feelings for his/her patient on the patient-provider encounter. Bensing and Dronkers (1992) analyzed 103 videotaped real-life general practice

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consultations. The authors found providers asked fewer questions, especially

psychosocial questions, in encounters in which the physician appeared to be irritated,

anxious, or nervous.   There is no known research that has measured providers' perceived

difficulty with patients and then observed how that difficulty influences the ensuing

medical encounter. It is possible that a dislike for, or discomfort with, a specific patient

(or subset of patients) has an impact on the dynamics of and challenges inherent in the

delivery of depression care in the primary care environment.

Patient-Provider Communication

Many factors contribute to the evolution of the patient-provider relationship.

However, interpersonal communication is the central element and is fundamental to both

establishing and preserving the partnership. Roter (2000) describes the medical dialog as

"the fundamental vehicle through which the paradigmatic battle of perspectives is waged

and the therapeutic relationship is defined" (p. 5). There is much more to communication

than just spoken words. Brown, Nelson, Bronkesh, and Wood (1993) write "patients

often judge the quality of communication not only by words but by a handshake, eye

contact, and the 'white spaces' when no words are spoken but an emotional or personal

connection is made" (p. 256). Difficulties in the patient-provider relationship are often a

consequence of a breakdown in communication between patient and provider. Levinson,

Stiles, Inui, & Engle (1993) found that physicians often blame patients for the problem.

In their study exploring physicians' perceived communication difficulties in "frustrating"

patient visits, Levinson et al. found physicians' difficulties clustered around six primary

problem areas: (1) lack of trust/agreement, (2) too many [patient] problems, (3) feeling

distressed, (4) lack of understanding, (5) lack of adherence, and (6)

demanding/controlling patient.

Much has been written about the role, content, and structure of interpersonal

communication during the patient-provider relationship. Ong, de Haes, Hoos, & Lammes

(1995) identified three different purposes of communication: (1) creating a good inter-

personal relationship, (2) exchanging information, and (3) making treatment-related

decisions. They also discussed specific communicative behaviors that are displayed

during medical consultations including (1) instrumental (cure oriented) vs. affective (care

oriented), (2) verbal vs. non-verbal, (3) privacy, (4) high vs. low controlling behavior,

and (5) medical vs. everyday language vocabularies. Hall, Roter, & Katz (1988)

collapsed nearly 250 different elements of communication into five categories including

(1) information giving, (2) question asking, (3) partnership-building, (4) rapport-building,

and (5) socioemotional talk. Stewart (1995) and Beck, Daughtridge, and Sloane (2002)

provide comprehensive reviews on physician-patient communication and health

outcomes. Thompson and Parrott (2002) outlined advances that have been made toward

the development of a theory of health communication (p. 708-709).

Communication patterns during the medical encounter have also received much

attention in the literature. Physician communication styles have been described and

defined as affiliation and control (Buller & Buller, 1987), mutuality, paternalism,

consumerism, and default (Emanuel & Emanuel, 1992), patient-centeredness, directing

vs. sharing, and affiliation vs. dominance (Williams, Weinman, & Dale, 1998), and

person-focused, biopsychosocial, biomedical, and high physician control (Flocke, Miller,

& Crabtree, 2002). Roter et al. (1997) found five distinct patterns emerged in their analysis of 537 audiotaped primary care encounters and classified them according to the frequency of both physician and patient questioning and information giving on biomedical and psychosocial issues. They categorized the patterns as narrowly biomedical, expanded biomedical, biopsychosocial, psychosocial, and consumerist. Two-thirds of the visits were characterized as being physician-dominated and narrowly focused on biomedical concerns.

The asymmetrical nature of the patient-provider relationship has been well documented. Accordingly, the medical encounter contains elements of power and control. Thompson and Parrott (2002) note, "Control processes are seen as particularly important within the health care context because of the traditional paternalistic relationship between physicians and patients" (p. 692). Control in relationships is expressed by sending messages that define, direct, or dominate. Techniques that can be used include confrontation, question authority, make assertions, disconfirm, change topics, initiate or terminate interactions (O'Hair, 2003), interruption (Realini, Kalet, & Sparling, 1995), rejecting topics of conversation (Suchman, Markakis, Beckman, & Frankel, 1997), and dominating talk time (Roter et al., 1997).

Physicians can exercise their power to control the content and course of the patient encounter in many ways. Often, that control is exerted by the use of questions (Beckman & Frankel, 1984). Physicians' beliefs about psychosocial care can also influence their communication patterns. Those with more positive attitudes have been found to use more statements of emotion, fewer closed-ended questions, and have more

psychosocial discussions with patients (Levinson & Roter, 1995). Yet, Roter, Lipkin, Stewart, and Stiles (1988) reported that medical encounters that entailed a lot of psychosocial talk and little biomedical talk, although most satisfying to patients, appeared to be the most anxiety-producing pattern of communication for physicians. Their analysis adds support to the earlier findings of Dungal (1978) who found physicians reported more anxiety and frustration, less interest and comfort, and a less satisfactory note when they were dealing with psychosocial problems.

Patients seldom verbalize their emotions directly and spontaneously, tending to offer clues instead. However, there is evidence that physicians' interviewing styles do not change according to patient characteristics such as emotional distress (Del Piccolo, Mazzi, Saltini, & Zimmerman, 2002; Deveugele, Derese, & DeMaeseneer, 2002). In fact, Suchman et al. (1997) found physicians allowed both indirect and direct expressions of emotion to pass without acknowledgement, opting instead to return to the preceding topic, usually the diagnostic exploration of symptoms. Although there is no empirical evidence that patient ordering of concerns is related to medical importance or severity, Beckman and Frankel (1984) found patients were able to complete their opening statement of concern only 23% of the time before being interrupted by their physician within 18 seconds, on average. Physicians gain control of the dialog nearly 80% of the time after they interrupt patients (Realini et al., 1995). These data present a disturbing portrayal of some of the dynamics involved in patient care and highlight significant challenges patients face when seeking treatment for depression in primary care.

The effects of patient characteristics on the patient-provider interaction, such as age, gender, ethnicity/race, culture, socioeconomic status, education, appearance, disability, and health status are well documented in the literature. In a secondary analysis of over 1,300 patient encounters, Hall, Roter, Milburn, and Daltroy (1996) found physicians conveyed negativity in their behaviors with sicker or more emotionally distressed patients and were less likely to engage in social conversation. Patients, in turn, provided more biomedical and psychosocial information, engaged in more emotionally concerned talk, asked more psychosocial questions, and used more submissive voice tone. The authors concluded that the lack of social conversation could reflect the realities of sicker patients' medical care and/or psychological avoidance.

Much of the research that has examined depression and patient-provider communication has focused on the dynamics of the exchange in relation to the physicians' recognition and diagnosis of depression, provider communication skills training, and patient outcomes following various specialized, intensive, or collaborative care depression management programs. Callahan et al. (1996) observed less chatting occurred during depressed patient office visits. There is also some evidence relating aspects of communication during the encounter with the receipt of guideline-concordant depression care and improvement of patients' depressive symptoms (Clever et al., 2006). Little is known, however, about discourse during the medical encounter as it relates to the depressed patient – primary care provider dyad. Historically, researchers have focused on providers' behaviors towards patients. In recent years there has been a shift in emphasis to the patients' experience and individuality. Hall and Visser (2000) noted that

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studying providers has always implied studying patients. "Their behaviors are intertwined…such that the behavior and outcomes of each [depends] on the attitudes, expectancies, skills, and behavior of the other" (p. 115).

In order to fully understand the dynamics of and challenges inherent in the diagnosis and treatment of depression in primary care, it is clear that research must focus on the contributory affects of both patients and providers on the dyadic exchange during the encounter. Previous findings indicate that primary care providers are uncomfortable dealing with patients' psychosocial problems and that physicians exercise power in the relationship to control the content and course of dialog during consultations. Although physicians' most likely use various techniques to control the depressed patient visit agenda, it is reasonable to speculate that their actions serve to direct the discourse toward a more comfortable biomedically focused pattern of communication.

Patient Satisfaction

Patient satisfaction is a legitimate measure of health care quality because of its significant associations with other patient outcomes (Brown et al., 2003). Patients' expectations and requests are central to most theories of patient satisfaction and understanding and responding to patients' needs is an inherent goal of medicine. Yet, adoption of a universal definition is difficult. Brown et al.'s (1993) definition of satisfaction as "what each patient says it is" (p. 9) illustrates that individuals form their own unique opinions of care according to his or her particular needs and experiences. Although patient satisfaction is arguably the most researched outcome of the patient-provider interaction, salient differences in methodologies often confound the ability to

interpret and generalize findings. A cursory scan of the literature is all that is needed to recognize many significant differences in the way patient satisfaction and its various dimensions have been operationalized. Furthermore, comparative studies using different satisfaction instruments, even when measuring similar aspects of care, have been found to yield unreliable and inconsistent results (Cohen, Forbes, & Garraway, 1996; Ross, Steward, & Sinacore, 1995).

There are many dimensions of patient satisfaction. Ware, Snyder, Wright, and Davies' (1983) taxonomy included (1) interpersonal manner, (2) technical quality, (3) accessibility/convenience, (4) finances, (5) efficacy/outcomes, (6) continuity, (7) physical environment, and (8) availability. In a meta-analysis of the patient satisfaction literature Hall and Dornan (1988) categorized aspects of satisfaction with (1) access, (2) cost, (3) overall quality, (4) humaneness, (5) competence, (6) amount of information supplied by the provider, (7) bureaucratic arrangements, (8) physical facilities, (9) provider's attention to psychosocial problems of the patient, (10) continuity of care, (11) outcome of care, and (12) overall satisfaction. The authors found that aspects of satisfaction related to the provider, including overall quality, humaneness, and competence ranked the highest. The position score of satisfaction with attention to psychosocial problems ranked the lowest. They acknowledged the various aspects of satisfaction were measured with very uneven frequencies and expressed concern that, considering the prevalence of unresolved psychosocial problems and their impact on health care utilization, only 3% of studies measured that particular aspect of care.

Many determinants of patient satisfaction with care have been documented. Of these, physician communication, especially when measured immediately after the encounter (Jackson et al., 2001), is widely believed to have the most direct impact on patients' assessments of the quality of care they receive. Yet, patients and physicians do not agree on the relative importance of effective communication (Laine et al., 1996). Buller and Buller (1987) reported nearly 75% of the variance in evaluations of medical care was associated with patient ratings of physicians' communication. Thompson and Parrott (2002) cautiously noted that, at times, the study of patient satisfaction has reflected an "assumed relationship" between patient-provider communication and satisfaction since there has been no direct test of the relationship. Ong, Visser, Lammes, & de Haes (2000) recorded patient visits and found cancer patients' satisfaction was most clearly predicted by the affective quality of the consultation. Interpretation of their findings is somewhat limited, however, since the affective quality of the interaction was not determined by the patients but by third-party coders.

Overall patient satisfaction ratings of varied aspects of medical care are generally favorable. Notwithstanding, the literature is replete with evidence of widespread patient dissatisfaction with what is perhaps the most important quality of care indicator: provider communication during the medical encounter. Any dissatisfaction is a significant issue with which to contend.

Communication and Patient Satisfaction

Different surveys performed in the primary care setting suggest tentative conclusions on the impact of specific communicative behaviors on patient satisfaction.

Williams, Weinman, et al. (1998) provided a comprehensive discussion organized according to the communication behavior categories of (1) information provision by the doctor and/or patient, (2) information-seeking behaviors of doctors and patients, (3) the doctor-patient relationship and expression of negative or positive affect by doctor and patient, and (4) the communication style of the doctor. Brown et al. (2003) reported patient satisfaction positively associated with medical encounters in which patients' perceived their provider as caring, understanding, and competent, and with visits characterized by a balanced inquiry into biomedical, psychological, and sociological concerns. They also noted continuity in the patient-provider relationship and provider awareness of patients' expectations to be key factors impacting satisfaction.

Several studies provide insight to the impact of communication patterns on patient satisfaction. Marvel, Doherty, and Weiner (1998) and Bertakis et al. (1991) found patients reported the greatest satisfaction in visits that encouraged them to talk about psychosocial issues. In a large multi-site collaborative study of primary care visits Roter et al. (1997) also found patient satisfaction with the psychosocial pattern of communication was significantly higher than any other pattern. This pattern was characterized by a balanced amount of physician biomedical and psychosocial talk while patients devoted more than twice their talk to psychosocial (55%) compared to biomedical (25%) topics. Biomedical patterns received the lowest ratings. Flocke, et al. (2002) observed over 2,800 primary care visits and found physicians with a person-focused practice style rated highest on patient satisfaction. They described these physicians as being personable and friendly, receptive to the patients' agenda, willing to

negotiate with patients, and more focused on the patient than the disease. Satisfaction

ratings were lowest for physicians who dominated the encounter and disregarded the

patient's agenda. Buller and Buller (1987) found affiliative styles of communication

were related positively to patient satisfaction, whereas dominant/active styles had a

negative relationship. Other studies also reported an inverse relationship between

provider dominance during the encounter and patient satisfaction (Cecil & Killeen, 1997;

Di Blasi, Harkness, Ernst, Georgiou, & Kleijnen, 2001; Flocke et al., 2002; Roter et al.,

1997).

Communication and satisfaction have been examined in relation to a number of

variables including previous patient-provider interaction experience and number of prior

encounters (Buller & Buller, 1987; Sixma, Spreeuwenberg, & van der Pasch, 1998),

patient expectations (Jackson, Chamberlin, & Kroenke, 2001), gender (Roter, Geller,

Bernhardt, Larson, & Doksum, 1999), age (Callahan et al., 2000), social class (Hall,

Roter, et al., 1988), cultural barriers (Hornberger, Itakura, & Wilson, 1997), education

and income (Weiss, 1988), length of patient visit (Gross, Zyzanski, Borawski, Cebul, &

Stange, 1998), physical disabilities (Kroll, Beatty, & Bingham, 2003), patient self-

efficacy (Zandbelt, Smets, Oort, Godfried, & de Haes, 2004), patient involvement in

decision making (Clever et al., 2006) physician communication skills training (Bredart,

Bouleuc, & Dolbeault, 2005), quality of care (Chang et al., 2006; Flocke et al., 2002),

intention to discontinue care (Federman et al., 2001) and malpractice claims (Beckman,

Markakis, Suchman, & Frankel, 1994).

Patient Health Status and Satisfaction

Certain factors may predispose some individuals toward satisfaction or dissatisfaction with care, including overall life satisfaction, confidence in the medical community, locus of control, and patient health status. Patients who have, or perceive themselves as having, worse physical or mental health are generally less satisfied with their medical care than patients who report better health. At the present time there is no clear understanding of the underpinnings or direction of this association. Patient health status appears to impact communication during the medical encounter, and there is some evidence that it might, in turn, influence patient satisfaction. In a secondary analysis of data, Hall, Milburn, Roter, and Daltroy (1998) explored two explanatory models and found support for a direct hypothesis that poor health reduced satisfaction directly. Causal modeling also supported a "physician mediation hypothesis" and found that physicians' reaction to sicker patients supported an indirect explanation for patient dissatisfaction in the form of curtailed social conversation. Hall, Epstein, DeCiantis, and McNeil (1993), Hall, Milburn, and Epstein (1993), and Like and Zyzanski (1987) have all reported a correlation between physicians' personal feelings about patients and patient satisfaction.

Depression and Satisfaction

It is well documented that individuals with depression are significantly less satisfied with their medical care. One hypothesis is that depressed patients are less satisfied with care due to the adverse effects of depression on mood and cognition. However, little is known about the impact of depression on the patient-provider

encounter. Furthermore, there is limited research to identify the communication

behaviors that are important to this vulnerable group. There is general evidence that

health care providers' interpersonal skills are a very important aspect of care to depressed

patients (Cooper et al., 2000). Some studies have found patient-reported communication

problems associated with depression (Druss et al., 2001; Lerman et al., 1993; van Os et

al., 2005), consistent with a plethora of reports indicating widespread dissatisfaction with

provider communication. Clever et al. (2006) investigated the impact of patient

involvement in decision-making (IDM) on depression care. They found higher patient

IDM ratings associated with significantly greater satisfaction.

In a longitudinal study Orlando and Meredith (2002) found depressed patients

who reported higher satisfaction with care were more likely to receive higher quality

depression care at six months compared to those who were less satisfied. Few studies

have examined depressed patients' satisfaction with medical care in relation to other

outcomes. Solberg, Fischer, Rush, and Wei (2003) found dissatisfied depressed patients

at the index visit continued to be dissatisfied with care and had poorer outcomes during a

three-month follow-up period. Dissatisfied depressed patients have also been found to

likely have persistent depressive symptoms and reduced productivity two years following

initial care (Druss et al., 2001).

The significant association between depression and (dis)satisfaction suggests that

further research is needed to identify the sources of satisfaction for such patients. A

thorough understanding of what depressed patients find important in their care is

necessary in order to improve depression care, patient satisfaction, and its many associated outcomes.

Significance of the Study

Depression is one of the most common mental disorders and a leading cause of disability in the U.S. Left untreated, the personal and societal consequences are pervasive and costly. Despite a multitude of screening instruments and highly effective treatment options, depression is often undiagnosed and inadequately treated by primary care providers. The goal of this study was to develop a better understanding of factors that may impact the diagnosis and effective management of depression in the primary care setting. The purpose of this study was to systematically examine the influence of patients' depressive symptoms on the patient-provider relationship, patient-provider communication, and patient satisfaction with the primary care office visit. It examined the contributory effects of both patients and providers on the dyadic exchange during the medical encounter. It was hypothesized that some communication behaviors during the medical encounter might actually promote patient dissatisfaction and ultimately discourage patients from discussing their mental health issues with their providers. Such a condition, if the case, would function as a barrier to the diagnosis and effective management of depression in the primary care setting. It would be a significant set-back to the current charge to encourage patients to discuss their emotional needs with their primary care provider as part of the overall effort to effectively diagnose and treat depression in primary care.

Specific Aims

The specific aims of this study were to:

1. Determine the influence of patient depressive symptoms on (a) provider perception of difficulty in the patient-provider relationship, (b) patient-provider communication, and (c) patient satisfaction.

2. Determine the influence of provider perception of difficulty in the patient-provider relationship on patient-provider communication during the medical encounter.

3. Explore the potential mediating effect of provider-perceived difficulty in the patient-provider relationship on the association between patient depressive symptoms and patient-provider communication during the medical encounter.

4. Explore the potential mediating effect of patient-provider communication on the association between patient depressive symptoms and patient satisfaction.

5. Identify patient and provider verbal communication behaviors that promote patient satisfaction with the medical encounter.

Theoretical Framework

Emerson's social exchange theory of power-dependence relations was used as a guide to design this study (Emerson, 1962, 1972). The theory focuses attention on the characteristics of the social relationship, whether person-to-person, person-to-group, or group-to-group. Central to the theory is the concept of *power*, explicitly defined as a property of the social relation and not an attribute of a person or group (called "actors").

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As social relations entail ties of mutual dependence between parties, *power* (P) is the function of *dependence* (D) of one actor on another. The degree of dependence of one actor upon another actor is directly proportional to the value the actor places on the resources (or valued behavior) mediated by the other actor and inversely proportional to the availability of those resources (or behaviors) from other sources outside of the relationship. Emerson views power as potential: although it is a component of all interactions, it may or may not be exercised in a given situation. "Power… will be empirically manifest only *if* [actor] A makes some demand, and only *if* this demand runs counter to [actor] B's desires" (Emerson, 1962, p. 33). Understanding his conceptualizations of "exchange relationship" and "transaction" are also important. An *exchange relationship* exists between two parties when they exchange at least occasionally and could be expected to do so, at least occasionally, into the foreseeable future. A *transaction* is a mutually reinforcing or rewarding instance of exchange that can be initiated by either person in the social relation (Emerson, 1972).

Another principal concept in Emerson's theory is the idea that exchange relations can be balanced or imbalanced based on the level of dependency each party has on the other. Unbalanced relations are "unstable" and encourage the use of power. Exercising power opens the door to *cost reduction* and *balancing operations.* To Emerson, the "costs involved are anchored in modifiable attitudes and values" and cost reduction is "a process involving change in values (personal, social, economic) which reduces the pains incurred in meeting the demands of a powerful other" (Emerson, 1962, p. 35). Social exchanges can also be negotiated or reciprocal. In *negotiated exchange*, the terms of the

exchange are negotiated and agreed upon and each party knows what he or she will receive from the transaction. In *reciprocal exchanges*, however, the terms of the exchange are not negotiated and each party chooses behaviors that have consequences for their interaction partners without knowing what the other person will choose to do with them (Smith-Lovin, 2001). Recognizing the reciprocity of social relations, Emerson represents the power-dependence relation as the following pair of equations: *Pab =Dba* (the power of A over B is equal to, and based upon, the dependence of B upon A) and *Pba=Dab* (the power of B over A is equal to, and based upon, the dependence of A upon B) (Emerson, 1962, p. 33).

According to Emerson, actor A, paired with actor B in a social relation, conduct an instance of exchange called a transaction. A initiates behavior X_1 during the transaction that evokes stimulus feedback Y from B. In reciprocity, B delivers help to A if and only if X_1 is rewarding to B. If A's behavior X_1 does not evoke a rewarding behavior from B, then through the conditioned reinforcement of feedback Y, A's behavior will either (a) change to form X_2 which is reciprocated, or (b) the A:B relation will extinguish. While this stimulus consequence defines the temporal boundary of that particular transaction, as a feedback system, it regulates the next transaction. Therefore, each transaction is linked to a history and a future for the actors (Emerson, 1972).

By virtue of their roles, the traditional patient-provider relationship is defined by an imbalance of power. Patients automatically enter into the relationship in a dependent position since they enter into it out of need. Patients require the provider in order to gain access to resources and services to fulfill their needs. Rendering important services or

providing valuable benefits in return confers [the provider] a claim to superior status. Reciprocating denies this claim but [patient] failure to reciprocate validates the claim, thus amplifying the power imbalance in the patient-provider relationship (Blau, 2002).

Applying Emerson's social exchange theory to the patient-provider interaction in general, and to this study in particular, it was hypothesized that the patient (actor A) paired with the provider (actor B) in a social relation meet in an instance of exchange called a transaction (the medical encounter). The patient initiates behavior X_1 (expression of depressive symptoms) during the transaction that evokes stimulus feedback Y (expression of provider difficulty in the patient-provider relationship). If the transaction is to be a mutually rewarding and reinforcing exchange and behavior X_1 (patient expression of depressive symptoms) is not rewarding to the provider, theory would predict that the provider will deliver help to the patient if and only if the patient behavior is rewarding to the provider. If the patient behavior X_1 (expression of depressive symptoms) does not evoke a rewarding behavior from the provider, then through the conditioned reinforcement of feedback Y (expression of provider difficulty in the patient-provider relationship), the patient behavior will either (a) change to a form X_2 which is reciprocated by the provider, or (b) the patient-provider relation will ultimately extinguish. Either way, the patient is likely to be dissatisfied with the transaction (medical encounter) if their behavior is not reinforced and rewarded by the provider and their needs are not met. Since each transaction is linked to a history and a future for the actors, the depressed patient enters into the next patient-provider encounter dissatisfied

and labeled by the provider as "difficult", and the patient-provider relationship is strained.

Definitions

The following definitions are specifically applied to concepts used in this study.

Depressive Symptomatology

The presence and severity of depressive symptoms reported by patients and measured by the Beck Depression Inventory-II (BDI-II).

Primary Care

The provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community (Institute of Medicine, 1996).

Provider-Perceived Difficulty

The presence and intensity of difficulty in the patient-provider relationship as perceived by the provider and measured by the Difficult Doctor-Patient Relationship Questionnaire-10 Item (DDPRQ-10).

Provider Medical Questioning

The proportion of provider talk during the encounter comprised of medical questioning and measured by the Roter Interaction Analysis System (RIAS). It is a composite number derived by totaling the frequencies of (1) closed-ended provider questions directed to the patient about (a) medical condition, and (b) therapeutic regimen

and (2) open-ended provider questions directed to the patient about (a) medical condition, and (b) therapeutic regimen divided by the total number of provider utterances during the encounter.

Patient Medical Questioning

The proportion of patient talk during the encounter comprised of medical questioning and measured by the RIAS. It is a composite number derived by totaling the frequencies of (1) all patient questions directed to the provider about (a) medical condition and (b) therapeutic regimen divided by the total number of patient utterances during the encounter.

Provider Medical Information Giving

The proportion of provider talk during the encounter comprised of medical information giving and measured by the RIAS. It is a composite number derived by totaling the frequencies of provider information giving directed to the patient about (a) medical condition, (b) therapeutic regimen, and (c) counseling medical/therapeutic divided by the total number of provider utterances during the encounter.

Patient Medical Information Giving

The proportion of patient talk during the encounter comprised of medical information giving and measured by the RIAS. It is a composite number derived by totaling the frequencies of patient information giving directed to the provider about (a) medical condition and (b) therapeutic regimen divided by the total number of patient utterances during the encounter.

Provider Psychosocial Questioning

The proportion of provider talk during the encounter comprised of psychosocial questioning and measured by the RIAS. It is a composite number derived by totaling the frequencies of (1) closed-ended provider questions directed to the patient about (a) lifestyle, and (b) psychosocial-feelings and (2) open-ended provider questions directed to the patient about (a) lifestyle, and (b) psychosocial-feelings divided by the total number of provider utterances during the encounter.

Patient Psychosocial Questioning

The proportion of patient talk during the encounter comprised of psychosocial questioning and measured by the RIAS. It is a composite number derived by totaling the frequencies of (1) all patient questions directed to the provider about (a) lifestyle, and (b) psychosocial-feelings divided by the total number of patient utterances during the encounter.

Provider Psychosocial Information Giving

The proportion of provider talk during the encounter comprised of psychosocial information giving and measured by the RIAS. It is a composite number derived by totaling the frequencies of provider information giving directed to the patient about (1) gives information-lifestyle, and (2) counsels-lifestyle/psychosocial divided by the total number of provider utterances during the encounter.

Patient Psychosocial Information Giving

The proportion of patient talk during the encounter comprised of psychosocial information giving and measured by the RIAS. It is a composite number derived by

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totaling the frequencies of patient information giving directed to the provider about (1) gives information-lifestyle, and (2) gives information-psychosocial divided by the total number of patient utterances during the encounter.

Patient Satisfaction

The degree of fulfillment of wishes, expectations, or needs with, or the pleasure derived from, the medical encounter as reported by patients and measured by the patient satisfaction survey.

Hypotheses

This study examined the influence of patient depressive symptomatology on the patient-provider relationship, patient-provider communication, and patient satisfaction with the primary care office visit by testing the following hypotheses:

Hypothesis 1

As the severity of patient depressive symptoms increases, provider perception of difficulty in the patient provider relationship increases.

Hypothesis 2

As the severity of patient depressive symptoms increases, patient satisfaction decreases.

Hypothesis 3

As the severity of patient depressive symptoms increases, provider and patient medical questioning and information giving increases.

Hypothesis 4

As the severity of patient depressive symptoms increases, provider and patient psychosocial questioning and information giving decreases.

Hypothesis 5

As provider perception of difficulty in the patient-provider relationship increases, provider and patient medical questioning and information giving increases.

Hypothesis 6

As provider perception of difficulty in the patient-provider relationship increases, provider and patient psychosocial questioning and information giving decreases.

Hypothesis 7

As provider and patient medical questioning and information giving increases, patient satisfaction decreases.

Hypothesis 8

As provider and patient psychosocial questioning and information giving increases, patient satisfaction increases.

The following chapter describes the methods used in testing these hypotheses.

Method

Pilot Study

A pilot study was conducted to determine the feasibility of the present study. The goals of the pilot study were to (1) evaluate the availability and accessibility of required resources to conduct the study and maintain HIPAA compliance at various practice sites, (2) evaluate the appropriateness, readability, and completion times of the survey questionnaires, (3) evaluate the logistics of audio-recording, and (4) examine the relationships between patient depressive symptoms, difficulty in the patient-provider relationship, patient-provider communication, and patient satisfaction. Four primary care providers from three practice sites in southwest Florida and 26 adult patients participated.

Completion of the pilot study provided the essential data to confirm that the required resources at each practice site were available and accessible, the survey content appropriate, the process of data collection practical, and that the relationships of interest could be explored in the present study. The data were subjected to descriptive, correlation, and regression analyses. Ninety-two percent of patient subjects felt it was "very" or "somewhat" important their primary care provider address their emotional health needs. Findings were consistent with previous research indicating that depressed patients tend to be less satisfied with medical care and that the presence of mental disorders in patients is associated with increased provider-perceived difficulty in the patient-provider relationship. Although the findings lacked statistical significance,

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patient and provider questioning and provider information giving on *psychosocial* issues

was associated with increased patient satisfaction, whereas both patient and provider

questioning and information giving on *medical* issues was associated with lower levels of

satisfaction. Patient information giving on *psychosocial* issues also associated with less

patient satisfaction although interpretation of the data was limited. Scale reliabilities

were acceptable with alpha coefficients ranging from 0.62 to 0.90. Results of the pilot

study provided the essential findings to support continuing with the present research.

The Study

Human Subjects Protection

The present study was reviewed and approved by the University of South Florida

Institutional Review Board –02, protocol #103075. Documents reflecting the approval of

the initial and continuing review applications are located in Appendix A.

Subjects

Sample criteria. Provider subjects were recruited from multiple medical practice

sites that are all part of a large multi-physician multi-specialty practice group in

southwest Florida (Appendix B). All provider participants in this study met the following

criteria:

1. English speaking;

2. Adult age 21 or over;

3. Medical or advanced practice nursing clinical practice in the primary care area
    of Internal Medicine, Family Practice, or Geriatrics;

4. Voluntarily agreed to participate.

Patient subjects were recruited from the same physician practice group as the provider subjects. All patient participants met the following criteria:

1. English speaking;

2. Adult age 21 or over;

3. Presented to the medical office for a medical encounter with their primary care provider;

4. History of at least one previous encounter with the provider (otherwise referred to as an "established patient");

5. Not experiencing an emergent medical need;

6. Did not appear to be in a grossly agitated state, or exhibit gross verbal or physical behavior;

7. No evidence of impaired or questionable cognitive ability;

8. Voluntarily agreed to participate.

Sample size estimate. The pilot study data provided information on the direction and magnitude of the associations between patients' depressive symptoms, provider perception of difficulty in the patient-provider relationship, patient-provider communication, and patient satisfaction. A series of simple and multiple regression equations were used to analyze the pilot study data. The multiple regression of patient satisfaction onto 9 predictor variables, assuming power of .80, $\alpha = .05$, and based on an estimated effect size of $R^2 = .40$, indicated that $N = 60$ was needed for this study. Using the adjusted $R^2 = .067$ for this same regression equation and again assuming power of .80

and α = .05 indicated N = 114 would be sufficient to detect statistical significance.

Tabachnick and Fidell (2001) offer rules of thumb when determining required sample size. They suggest "N ≥ 50 + 8m (where m is the number of independent variables) for testing the multiple correlation and N ≥ 104 + m for testing individual predictors, assuming a medium-size relationship between the independent variables and the dependent variable, α = .05 and β = .20" (p. 117). Their suggestions indicated that N ≥ 122 would be required for stability for testing the multiple regression and N ≥ 113 for testing individual predictors. Considering these four pieces of information, projected costs, pilot study experience, and anticipating a 5% loss of data (due to audio recording failure, etc.), the original protocol sought to enroll 120 patient subjects and 12 provider subjects into this study.

Measures

Provider demographic questionnaire. This 11-item self-report survey documented routine demographic and practice information and self-assessed ratings of the provider's knowledge, ability to diagnose, and ability to treat depression. It asked the provider to rate the impact of several frequently cited barriers to the diagnosis and treatment of depression by primary care providers (Appendix C).

Patient demographic questionnaire. This 14-item self-report survey documented routine demographic information and contained 5 brief questions relating to self-assessed health status, opinion on treatment of emotional health needs in primary care, and opinion on the effect of length of office visit on their perception of care received (Appendix D).

Beck Depression Inventory–Second Edition (BDI-II).   The Beck Depression

Inventory (BDI) is one of the most widely used instruments for evaluating depression.

Like the BDI, the Beck Depression Inventory–Second Edition (BDI-II) is a 21-item self-

report measure designed to assess the presence and intensity of depressive symptoms in

adults and adolescents aged 13 years and older (Beck, Steer, & Brown, 1996). Each item

is a list of four statements arranged in increasing severity about a particular symptom of

depression over the preceding two weeks. The BDI-II has a possible range of 0-63 and is

scored so that a higher value indicates a greater degree of depressive symptomatology.

Reliability of the BDI-II (coefficient $\alpha = 0.92$) is higher than the original BDI (coefficient

$\alpha = 0.86$), and is in alignment with DSM-IV criteria (American Psychiatric Association,

1994). The BDI-II can be self-administered or read aloud by the examiner for individuals

with reading difficulties or sensory deficits. The cut score threshold followed the BDI-II

manual scoring guidelines to maximize sensitivity (Beck et al., 1996) (Appendixes E and

F).

The Difficult Doctor-Patient Relationship Questionnaire (DDPRQ-10).   The

Difficult Doctor-Patient Relationship Questionnaire-10 (DDPRQ-10) is a 10-item self-

report instrument designed to detect and measure difficulties in the doctor-patient

relationship as perceived by the physician. The medical provider completes it after

seeing the patient for the medical encounter. The 10-item DDPRQ was developed for use

in the PRIME-MD 1000 Study (Spitzer et al., 1994). Each item is measured on a six-

point Likert scale and the score is the sum of all 10 items after the values of reversed

items have been corrected for direction. The DDPRQ-10 has a possible range of 10-60.

Scoring for this study was reversed from the original DDPRQ-10 and was scored so that a higher value indicated a greater level of provider-perceived difficulty in the doctor-patient relationship. It has high face validity, and construct validity has established a strong association with the presence of mental disorders, multiple unexplained somatic symptoms, and abrasive personality style with physician-experienced difficulty in the doctor-patient relationship (Hahn, n.d.). The DDPRQ-10 captures 96% of the variance of the original 30-item instrument (DDPRQ-30) and had a Cronbach's $\alpha = 0.88$ in the original sample (Hahn, 2000) (Appendixes G and H).

The Roter Interaction Analysis System (RIAS). The RIAS is a method of coding verbal patient-provider interaction during the medical visit. Derived from social exchange theories related to interpersonal influence, problem solving, and reciprocity, the RIAS is the most widely used system of medical interaction assessment and has been used in over 125 communication studies in a multitude of health care settings (Roter, n.d.). Coding is done directly from audio or video recordings using RIAS software, eliminating the need to transcribe the audio record to written form. Coding is tailored to dyadic exchange specific to the medical encounter. The RIAS is applied to the smallest unit of expression to which a meaningful code can be assigned, defined as an "utterance". All patient and provider dialogue is coded into mutually exclusive and exhaustive categories that reflect the content and context of the routine dialogue between patients and providers during the medical exchange. The RIAS is highly reliable when applied by trained coders and has proved to be clinically meaningful in a number of empirical studies (Sandvik et al., 2002). It has consistently shown an average of 0.85 inter-rater

reliability for both patient and provider categories and clusters. It has demonstrated content and discriminant validity (Roter & Larson, 2002). Roter and colleagues provided the expert coding for the audio recordings collected in this study (Appendixes I and J).

Patient satisfaction survey. The patient satisfaction survey is a 36-item self-report instrument that measured one global satisfaction item and five distinct and reliable aspects of patient satisfaction specific to the immediate medical encounter. It was adapted from the work of Bertakis et al. (1991). Each item is measured on a five-point Likert scale and the score is the sum of all 36 items after the values of reversed items have been corrected for direction. The survey has a possible range of 36-180 and was scored so that a higher value indicated greater satisfaction with the medical encounter. The five subscales revealed by factor analysis are: task-directed skill ($\alpha = 0.90$), interpersonal skill ($\alpha = 0.87$), attentiveness ($\alpha = 0.81$), partnership ($\alpha = 0.76$), and emotional support ($\alpha = 0.71$). The average inter-scale correlation is 0.51 (range 0.29-0.65) (Bertakis et al., 1991). (Appendixes K and L).

Procedure

Recruitment. A recruitment letter describing the study was mailed to all eligible primary care providers within the provider practice group (Appendix M). A telephone call was placed to each provider's office one week after the mailing of the letter seeking to arrange a meeting with the provider to discuss the study in detail. If the provider was interested in hearing more about the study, a telephone or personal meeting was scheduled. During the meeting, the investigator screened the provider for eligibility,

presented all information contained in the informed consent documents, answered any questions, and asked for their voluntary participation.

The intake receptionist at each medical office was asked to distribute a flyer (Appendix N) introducing the study to each adult patient who presented to the office on the day(s) of data collection as they signed in for their office visit. The flyer informed potential patient recruits that the details of the study would be provided to them in privacy once they were escorted back to the examination room. Once the office nurse/medical assistant brought each patient to the private examination room and finished their tasks, she/he then asked each individual if they were interested in learning more about the study. If the patient expressed interest in hearing more about the study, the nurse/medical assistant relayed this information to the investigator. The investigator then entered the examination room, screened each potential patient recruit for eligibility, presented all information contained in the informed consent and HIPAA documents, answered any questions, and asked for their voluntary participation.

Informed consent process. Each provider, who was screened for eligibility and expressed interest in participating in the study, was given a printed copy of the informed consent and consent for audio taping documents to read and sign (Appendix O). The consent documents explained the purpose and plan of the study, benefits and risks of participation, confidentiality of records, voluntary participation, and contact person with telephone number to call with any additional questions. Once informed consent was secured, each provider subject completed the provider demographic questionnaire. Each

provider was then given a copy of his/her signed consent documents and a mutually

agreed upon date(s) for data collection was established.

Each patient, who was screened for eligibility and expressed interest in

participating in the study was given a printed copy of the informed consent, consent for

audiotaping, and HIPAA authorization documents to read and sign (Appendixes P and

Q). The informed consent documents explained the purpose and plan of the study,

benefits and risks of participation, payment for participation, confidentiality of records,

voluntary participation, and contact person with telephone number to call with any

additional questions. Once informed consent was secured, each patient subject was given

a copy of his/her signed documents. Voluntary consent was also required from all third

party individuals who were going to be present in the examination room during the

patient-provider encounter. If a third party individual declined voluntary participation in

the study, the corresponding patient subject was excluded from participation. The

informed consent process for third party individuals mirrored the process used for patient

subjects. All participating third party individuals signed the same informed consent and

consent for audiotaping documents as patients. Each was then given a copy of his/her

signed documents.

Data collection. Patient participants were asked to complete the patient

demographic questionnaire and BDI-II while waiting for the provider to enter the

examination room for the medical encounter. In the event that the subject was unable to

complete the instruments prior to the time the provider entered the examination room,

they were asked to complete them immediately following the patient-provider interaction

and prior to administration of the post-encounter satisfaction survey. Subjects were informed that audio recording was about to begin and the digital voice recorder was turned on. The investigator then left the examination room to photocopy the signed consent documents.

The investigator re-entered the examination room, collected the completed surveys from the subject, provided them with a copy of his/her signed consent documents, and then left the examination room. The BDI-II was scored immediately. Study protocol dictated that patient subjects who admitted to hopelessness and/or suicidal ideation (as measured by items 2 and/or 9 of the BDI-II) with a rating of 2 or 3 were to be withdrawn from further participation (Appendix R) and the provider notified promptly (Appendix S). Otherwise, providers were blinded to the patient's BDI-II results, data collection proceeded and the patient-provider encounter was audio recorded using a digital voice recorder. When it was determined that the patient-provider encounter was finished, the digital voice recorder was turned off. In consultation with the nurse/medical assistant, the feasibility of having the patient subject remain in the examination room to complete the post-encounter questionnaire was determined. If time constraints prohibited the subject from remaining in the examination room, they were escorted to another area within the office to complete the post-encounter satisfaction survey. The subject was instructed to complete the questionnaire and place it in the envelope provided, seal the envelope, and give the envelope to the receptionist upon check out. Each subject was given written notification of his or her BDI-II results in an envelope (Appendix T).

When it was evident the patient-provider encounter was complete and the

provider exited the examination room, the provider was given the provider perception

questionnaire (DDPRQ-10) with instructions to complete as soon as possible that day,

place in the envelope provided, seal the envelope, and return the envelope directly to the

investigator. The provider was given written notification of each patient subject's BDI-II

results (Appendix U) after they returned the completed DDPRQ-10. The investigator

remained at the office site until all questionnaires were returned and a debriefing session

was held with the provider.

Raw Data Management

All survey responses, complete and incomplete, were entered into an SPSS

program database (SPSS 10.0 for Windows, SPSS Inc.) using a personal computer with

password protection to secure confidentiality. Once the data were entered into the

database, the completed surveys were stored in a locked file cabinet. The audio

recordings of the patient-provider encounters, collected by digital voice recorder, were

transferred to the computer, converted to .wav file format using Sony Digital Voice

Editor software (version 2.27, Sony Electronics, Inc.) and saved to CD-R. The voice files

on the digital voice recorder were erased once the records were converted and

successfully stored. The voice files (on CD), were sent in batches of 30 records to Dr.

Roter at The Johns Hopkins University Bloomberg School of Public Health for RIAS

coding throughout the data collection period. The CDs were sent via USPS priority mail

with delivery and signature confirmation. When Dr. Roter and her research staff

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completed coding of the audio files, she forwarded the RIAS data as SPSS data files and returned all CDs via USPS.

Analytic Plan

Statistical analyses to test the proposed hypotheses were guided by Figure 1. A $2 \times 2 \times 2$ within-subjects factorial model provided the analytic framework for examining eight verbal communication behaviors categorized by *speaker* (patient or provider), *type of utterance* (question or information giving), and *content of utterance* (medical or psychosocial talk). The data had a 2-level nested structure; the patient-provider encounters were nested within providers. The hierarchical structure of the hypothesized model revealed the importance of analyzing the data within context in order to elucidate relationships at more than one level. Thus, the data violated the assumption of independence that underlies traditional regression analysis. Multilevel modeling relaxes the independence assumption and allows for correlated error structures (Luke, 2004). This study was designed to examine how patient and provider characteristics influence the patient-provider encounter, providing *theoretical* justification for a multilevel approach to analysis. Because the patient-provider encounters were not independent, were clustered by providers, and were likely to exhibit correlated errors, multilevel modeling was also *statistically* justified.

Results are presented in the following chapter.
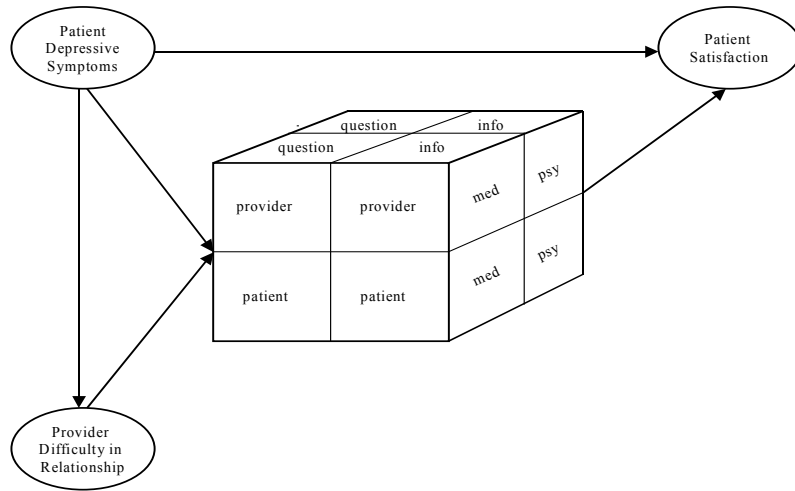
Figure 1. Model depicting the hypothesized relationships between patient depressive symptoms, provider perception of difficulty in the patient-provider relationship, patient-provider communication, and patient satisfaction.

Results

Subjects

Provider Subjects

Recruitment letters were mailed to all potential provider subjects in the multi-physician practice group whose medical or advanced practice nursing clinical practices were in the primary care areas of internal medicine, family practice, or geriatrics (*n*=20). Forty-five percent of the providers did not return telephone messages after the mailing. Eleven providers including six physicians and five advanced registered nurse practitioners (ARNPs) expressed an initial interest in hearing the details of the study during a follow-up telephone inquiry. All 11 providers met eligibility criteria and voluntarily consented to participate. Detailed provider demographic information is presented in Table 1.

The seven males and four females ranged in age from 31 to 62 years with a mean age of 43. All providers had been in practice for at least one year. Eighty-one percent reported having over six years of professional practice experience. They treated an average of 21 patients per day and 50 to 150 patients per week. Physicians and male providers reported more daily (24 and 22 vs. 19 and 18) and weekly (118 and 111 vs. 76 and 76) patient encounters than the ARNPs and female providers. Collectively they estimated that they considered 15% of their patient population as "difficult" (range 5 to 40%).

Table 1

Characteristics of Provider Subjects By Provider Type (N=11)

Variable	MD (n=6)	ARNP (n=5)	%[*]
Gender			
Female	0	4	36
Male	6	1	64
Age			
Mean	38.2	48.4	
Range	31-44	33-62	
Race			
American Indian/Alaskan Native	0	0	0
Asian	0	0	0
Black/African American	0	0	0
Native Hawaiian/Pacific Islander	0	0	0
White	6	5	100
Ethnicity			
Hispanic or Latino	2	0	18
Not Hispanic or Latino	4	5	81
Type of Clinical Practice			
Internal Medicine	1	1	18
Family Practice	3	4	63
Geriatrics	2	0	18
Number of Years in Practice			
Less than one year	0	0	0
1-5 years	1	1	18
6-10 years	3	1	36
11-20 years	2	1	27
Over 20 years	0	2	18

Table 1 (Continued)

Average Number of Patients Seen

Per Day	23.7	18.9
Per Week	117.5	75.5

Note. * Values are rounded and may not total 100%.

The providers rated the impact of various internal (self) and external factors on their ability to diagnose and treat depression in their primary care patients (Table 2). They ranked time constraints and multiple competing demands as having the greatest negative impact on their ability to provide depression care to their patients. Patient reluctance to go to mental health specialists was ranked second.

Table 2

Provider Ratings of Various Aspects of Depression Care Delivery (N=11)

Variable	*M*	Range
Self-Ratings[*]		
Knowledge of depression	8.1	7-10
Ability to diagnose depression	7.7	6-10
Ability to treat depression	7.5	5-10
Influence of Outside Factors[**]		
Time constraints and multiple competing demands	9.0	6-10
Patients don't provide enough information	6.0	3-9
Lack of availability/access to mental health specialists	7.7	5-10
Patient reluctance to go to mental health specialists	8.6	6-10

Note. [*] Based on scale of 0-10 with rating of 10 indicating high proficiency. [**] Based on scale of 0-10 with rating of 10 indicating great influence.

Patient Subjects

One hundred and fifty-two potential patient subjects expressed an interest in hearing details of the study and were subsequently approached directly by the investigator to discuss possible participation. Twenty-nine patients either declined to participate or failed to meet the eligibility criteria for enrollment. The remaining 123 patients met inclusion criteria and voluntarily consented to participate. All patient subjects continued to meet inclusion criteria based upon review of their BDI-II responses and 123 patient-provider encounters were observed. The number of patient encounters per provider ranged from 7-16 with a mean of 11.2. No patient or provider subjects withdrew or were withdrawn from the study during or after data collection.

Detailed patient demographic information is presented in Table 3. The patient subjects were mostly Caucasian (98%) older adults (mean = 63 years, median = 67 years). Seventy-five percent were 50 years of age or older and one-fourth were over the age of 76. Over 40% listed their occupation as professional and reported a college degree or graduate degree as their highest level of education. Slightly more than half of the subjects were retired. According to BDI-II scoring criteria 77% percent reported experiencing minimal depressive symptoms (0-13), 13% mild depression (14-19), 7% moderate depression (20-28), and 3% extreme depression (29-63). The majority of patients (88%) felt that (in general) it was "very" or "somewhat important" that their primary care provider addressed their emotional health needs. Nearly all (96%) indicated that the amount of time they spend with their primary care primary care provider was at least a "somewhat important" factor when evaluating quality of care.

Table 3

Characteristics of Patient Subjects (N=123)

Variable	Female (n=71)	Male (n=52)	%*
Age			
Mean	63.1	62.2	
Range	21-90	21-89	
Race			
American Indian/Alaska Native	1	0	0
Asian	1	0	0
Black/African American	0	2	2
Native Hawaiian/Pacific Islander	0	0	0
White	69	50	98
Ethnicity			
Hispanic or Latino	3	4	6
Not Hispanic or Latino	60	43	84
Occupation			
Professional	23	32	45
Technical	3	6	7
Clerical	17	2	15
Laborer	1	6	6
Housewife	21	1	18
Other	5	5	8
Retired			
Yes	42	26	55
No	25	26	41
Highest Level of Education			
Grade School	1	1	2
High School	31	19	41
Technical School	12	7	15
College Degree	22	17	32
Graduate Degree	5	7	10

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Table 3 (Continued)

Marital Status			
Married	35	32	54
Single	7	7	11
Divorced	9	7	13
Widowed	20	4	20

Note. * Values are rounded and may not total 100%.

Data Management

The data were entered into an SPSS program database. All variables were first

subjected to univariate descriptive analysis with graphic representations and were

examined for accuracy of data entry, out-of-range values, and plausible means and

standard deviations. Suspicious values in data entry were compared to the original data

and corrected.   Means and standard deviations were reasonable. Preliminary BDI-II,

DDPRQ, and satisfaction scores were tabulated for each case by summing individual

scale item responses. The audio recordings of two patient encounters were inaudible and

unusable for analysis and those cases were deleted. Eight composite communication

variables categorized by *speaker* (provider or patient), *type of utterance* (question or

information giving), and *content of utterance* (medical or psychosocial talk) were

computed from the RIAS data file. Suspicious values in data entry were compared to the

original audio records and corrected.

The BDI-II, DDPRQ, and satisfaction scale items were assessed for

multicollinearity and singularity by examining bivariate correlation matrices. The

correlations ranged from $r = .02$ to .70 (BDI-II), $r = .09$ to .75 (DDPRQ), and $r = .00$ to

.79 (satisfaction). The data were examined next to assess the amount and distribution of

missing values. The DDPRQ and RIAS variable data files were complete. Ten of the 21

items on the BDI-II had missing data. Nine of those items were missing one or two

values (0.8 – 1.6%). The tenth item had a total of eight missing values (6.5%). Six

subjects did not answer any items on the satisfaction survey and those six cases were

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deleted, leaving 115 cases for further analysis. Thirty-two of the 36 items on the

satisfaction survey had from 0.8 to 5.2% missing values.

Non-randomly missing values can affect the generalizability of results

(Tabachnick & Fidell, 2001). Therefore, the amount and pattern of missing data were

examined. Independent sample *t*-tests (two-tailed, 95% C.I.) were used to determine if

the patient subjects who failed to respond to at least one of the 21 BDI-II items

($n = 15$) differed from subjects who responded to all items ($n = 100$). No significant

differences were found between the two groups on any of the demographic variables,

practice site, sequence of participation, raw BDI-II or DDPRQ scores. Similar

t-tests were also used to determine if the patient subjects who failed to respond to at least

one of the 36 satisfaction items ($n = 24$) differed from subjects who responded to all

items ($n = 91$). No significant differences were found between the two groups on any of

the demographic variables, practice site, sequence of participation, raw DDPRQ or

satisfaction scores. Because the deletion of all cases with missing values would have

resulted in a substantial loss of subjects, various options were explored to determine the

best method for handling the missing data. Mean item values for the BDI-II and

satisfaction scales were computed for each case based upon the number of scale items the

subject answered. Total BDI-II and satisfaction scores were then tabulated by

multiplying the case mean values by the total number of items in each scale. This

method standardized the survey scores and enabled all cases to be retained for further

analysis.

To improve interpretability of the data, each communication variable (previously defined as a proportion of total utterances) was adjusted to reflect the percentage of either all patient talk or all provider talk. The 11 primary study variables (BDI-II, DDPRQ, provider medical questioning, patient medical questioning, provider medical information giving, patient medical information giving, provider psychosocial questioning, patient psychosocial questioning, provider psychosocial information giving, patient psychosocial information giving, and patient satisfaction) were assessed for univariate and multivariate normality through various SPSS programs. Descriptive statistics are presented in Table 4.

The BDI-II, DDPRQ, patient medical questioning, provider psychosocial questioning, patient psychosocial questioning, provider psychosocial information giving, and patient psychosocial information giving distributions exhibited moderate positive skewness ($2.6 < t < 8.02$, $df = 114$, $p < .01$). Patient satisfaction was moderately negatively skewed ($t = 4.21$, $df = 114$, $p < .01$). BDI-II, DDPRQ, patient medical questioning, provider psychosocial questioning, patient psychosocial questioning, and provider psychosocial information giving distributions were leptokurtic ($t > 2.6$, $df = 114$, $p < .01$).

Four cases with univariate outliers were identified (> 4.0 SDs above the mean). One additional case was identified through Mahalanobis distance as a multivariate outlier with $p < .001$. The cases were examined to verify that they were properly part of the intended sample population as skewed distributions can create problems insofar as they violate the assumption of normality that underlies many other statistical tests. Therefore,

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Table 4

Descriptive Statistics of Study Variables (N=115)

Variable	*M*	*SE*	*Mdn*	*SD*
BDI-II	9.18	0.72	7.35	7.75
DDPRQ	18.46	0.71	17.00	7.62
SAT	159.40	1.79	167.00	19.17
DRMEDQ[*]	9.97	0.50	9.41	5.39
PTMEDQ[*]	2.62	0.23	2.22	2.50
DRMEDINFO[*]	33.41	1.23	33.16	13.16
PTMEDINFO[*]	36.61	1.27	35.90	13.60
DRPSYQ[*]	2.33	0.23	1.79	2.47
PTPSYQ[*]	0.55	0.08	0.00	0.87
DRPSYINFO[*]	5.20	0.51	3.51	5.51
PTPSYINFO[*]	16.81	1.20	14.11	12.83

Note. [*] Variables are reported as percentage of either all provider talk or all patient talk. BDI-II = Beck Depression Inventory-II. DDPRQ = Difficult Doctor-Patient Relationship Questionnaire-10. SAT = patient satisfaction survey. DRMEDQ = provider medical questioning. PTMEDQ = patient medical questioning. DRMEDINFO = provider medical information giving. PTMEDINFO = patient medical information giving. DRPSYQ = provider psychosocial questioning. PTPSYQ = patient psychosocial questioning. DRPSYINFO = provider psychosocial information giving. PTPSYINFO = patient psychosocial information giving.

options for dealing with the non-normality of the variables were explored. Deletion of the outlier cases would reduce statistical power. Retaining the cases would increase the risk of Type I and Type II errors and would limit the generalizability of the results. Transformation of variables when they are skewed to the same moderate extent hinders interpretation of the results, especially when the scale(s) is meaningful or widely used (Tabachnick & Fidell, 2001). Recognizing the potential impact that the outlier cases could have on the interpretation of results, all subsequent analyses of the data were conducted in parallel sets. The data were examined both with (N=115) and without the outlier cases (N=110) and the results were compared. There were no significant differences in results. Therefore, to maintain adequate statistical power and study integrity, these five cases were left in the final analysis. For clarity, the results presented in this chapter refer to the final sample (N=115) unless specified otherwise.

Reliability Analysis of Measures

The BDI-II, DDPRQ, and patient satisfaction scales were evaluated for internal consistency. Scale and subscale reliabilities were acceptable with alpha coefficients ranging from 0.89 to 0.95 (Tables 5 and 6). Analyses were conducted on the raw data and then repeated after missing values were replaced by case mean substitution. Ten percent of the audio records (n=12) were randomly selected and coded by two RIAS experts to assess for errors or bias in coding. Inter-rater reliability estimates were computed for the individual and composite RIAS coded communication variables using Pearson's *r*. Correlation coefficients for the eight composite variables were all positive and ranged from 0.72 to 0.96 (Tables 7 and 8).

Table 5

Reliability Analyses of Scales (N=123)

Scale	Number of Items in Scale	$n^{\#}$	*M*	SD	α	α*
BDI-II	21	100	.3444	.1584	.9131	.9032
DDPRQ-10	10	115	.4660	.1673	.8972	.8972
SAT	36	91	.3611	.1868	.9532	.9483

Note. [#] Listwise deletion. *Cronbach's alpha after missing items replaced using case mean substitution (*N*=115). BDI-II = Beck Depression Inventory-II. DDPRQ = Difficult Patient-Provider Relationship Questionnaire-10. SAT = patient satisfaction survey.

Table 6

Reliability Analysis of Patient Satisfaction Survey Subscales (N=123)

Scale	Number of Items in Scale	$n^{\#}$	M	SD	α	α*
Task-directed skill	10	105	.4828	.1694	.9032	.9006
Interpersonal skill	8	104	.2962	.1788	.7710	.7762
Attentiveness	5	107	.3290	.1140	.7103	.7070
Partnership	9	100	.3957	.1772	.8549	.8497
Emotional support	3	106	.3283	.2557	.5945	.6090

Note. [#] Listwise deletion. * Cronbach's alpha after missing items replaced using case mean substitution (*N*=115).

Table 7

Inter-rater Reliability Estimates of Individual and Composite RIAS Coded Variables (Medical) Using Pearson's r (n=12)

Direction of Speech	Variable Code	Variable Description	*r*
D→P[a]	cmedd	closed question – medical	.91
	ctherd	closed question – therapeutic	.92
	omedd	open question – medical	.70
	otherd	open question – therapeutic	.11[**]
	medqued	composite: question asking - medical	.84[$]
D→P[a]	imedd	gives information – medical	.88
	itherad	gives information – therapeutic	.93
	cnlmdd	counsels – medical/therapeutic	.81
	infomedd	composite: information-giving – medical	.87
P→D[b]	qmedp	all questions – medical	.63[*]
	qtherp	all questions – therapeutic	.81
	medquep	composite: question asking – medical	.81[$]
P→D[b]	imedp	gives information – medical	.99
	itherp	gives information – therapeutic	.89
	infomedp	composite: information-giving – medical	.94

Note. [a] provider talk directed to patient. [b] patient talk directed to provider. [*] mean 1.0-2.0. [**] mean < 1.0. [$] composite value includes only variables with mean > 2.0.

Table 8

Inter-rater Reliability Estimates of Individual and Composite RIAS Coded Variables (Psychosocial) Using Pearson's r (n=12)

Direction of Speech	Variable Code	Variable Description	r
D→P[a]	clsd	closed question – lifestyle	.96
	cpsd	closed question – psychosocial	.87[**]
	olsd	open question – lifestyle	.32[**]
	opsd	open question – psychosocial	.73[**]
	psyqued	composite: question asking – psychosocial	.96[$]
D→P[a]	ilsd	gives information – lifestyle	.72
	cnllsd	counsels – lifestyle/psychosocial	.35[*]
	infopsyd	composite: information-giving – psychosocial	.72[$]
P→D[b]	qlsp	all questions – lifestyle	.41[**]
	qpsp	all questions – psychosocial	.67[**]
	psyquep	composite: question asking – psychosocial	[$]
P→D[b]	ilsp	gives information – lifestyle	.94
	ipsp	gives information – psychosocial	.89
	infopsyp	composite: information-giving – psychosocial	.92[$]

Note. [a] provider talk directed to patient. [b] patient talk directed to provider.
[*] mean 1.0-2.0. [**] mean < 1.0. [$] composite value includes only variables with mean >2.0.

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Preliminary Analysis

The data had a 2-level nested structure with patient-provider encounters (level-1) nested within providers (level-2). According to protocol the data were to be analyzed using hierarchical linear modeling multiple regression. Before the advanced modeling techniques were applied, the data were first subjected to bivariate correlation and standard multiple regression analysis (OLS) to determine if the multilevel relationships proposed in the original hypotheses were present. An alpha level of .05 was used for all statistical tests. The zero-order correlations among the variables are presented in Table 9. Tables 10 and 11 provide a summary of the regression analyses predicting (1) provider perception of difficulty in the patient-provider relationship, (2) patient-provider communication, and (3) patient satisfaction.

Table 9

Intercorrelations Between Communication Variables, Patient Depressive Symptoms, Provider-Perceived Difficulty, and Patient Satisfaction (N=115)

Variable	v1	v2	v3	v4	v5	v6	v7	v8	BDI-II	DDPRQ	SAT
v1	1.00										
v2	-.09	1.00									
v3	.04	.52**	1.00								
v4	.47**	-.04	.18*	1.00							
v5	-.19*	-.19*	-.42**	-.42**	1.00						
v6	-.27**	.14	.03	-.29**	.08	1.00					
v7	-.39**	-.03	-.10	-.43**	.42**	.35**	1.00				
v8	-.32**	-.21*	-.44**	-.56**	.70**	.20*	.38**	1.00			
BDI-II	-.00	-.12	-.21*	-.09	.23*	-.07	-.04	.12	1.00		
DDPRQ	.11	.11	.21*	.11	-.13	-.08	-.13	-.13	.31†	1.00	
SAT	-.19*	-.11	-.30†	-.00	.12	-.05	.17	.09	-.32†	-.41†	1.00

Note. v1 = provider medical questioning. v2 = patient medical questioning.
v3 = provider medical information giving. v4 = patient medical information giving.
v5 = provider psychosocial questioning. v6 = patient psychosocial questioning.
v7 = provider psychosocial information giving. v8 = patient psychosocial information giving.
BDI-II = Beck Depression Inventory-II. DDPRQ = Difficult Doctor-Patient Relationship
Questionnaire – 10. SAT = patient satisfaction.
*p ≤ .05. **p ≤ .005. †p ≤ .001.

Table 10

Summary of OLS Regression Analysis Predicting Provider-Perceived Difficulty and Patient-Provider Communication (N=115)

Predictor	Outcome	*B*	*SE B*	β
BDI-II				
	DDPRQ	0.302**	0.088	0.307**
	Provider medical questioning	-0.025	0.069	-0.035
	Patient medical questioning	-0.056	0.031	-0.174
	Provider medical information	-0.516**	0.157	-0.304**
	Patient medical information	-0.235	0.172	-0.134
	Provider psychosocial questioning	0.095*	0.030	0.297*
	Patient psychosocial questioning	-0.005	0.011	-0.048
	Provider psychosocial information	-0.001	0.070	-0.001
	Patient psychosocial information	0.289	0.161	0.174
DDPRQ				
	Provider medical questioning	0.083	0.070	0.117
	Patient medical questioning	0.054	0.032	0.165
	Provider medical information	0.524**	0.160	0.303**
	Patient medical information	0.263	0.175	0.147
	Provider psychosocial questioning	-0.073*	0.031	-0.224*
	Patient psychosocial questioning	-0.007	0.011	-0.062
	Provider psychosocial information	-0.097	0.071	-0.134
	Patient psychosocial information	-0.303	0.164	-0.180

Note. BDI-II = Beck Depression Inventory-II. DDPRQ = Difficult Doctor-Patient Relationship Questionnaire-10.
* $p < .05$. ** $p \leq .001$.

Table 11

Summary of OLS Regression Analysis Predicting Patient Satisfaction (N=115)

Predictor	*B*	*SE B*	β
BDI-II	-0.979**	0.209	-0.396**
Provider medical questioning	-0.831*	0.337	-0.234*
Patient medical questioning	0.526	0.741	0.069
Provider medical information	-0.635**	0.153	-0.436**
Patient medical information	0.211	0.153	0.150
Provider psychosocial questioning	0.727	0.940	0.094
Patient psychosocial questioning	-2.650	1.960	-0.120
Provider psychosocial information	0.467	0.351	0.134
Patient psychosocial information	-0.182	0.191	-0.122

Note. $^*p < .05.$ $^{**}p < .001.$

Hypothesis 1

   As the severity of patient depressive symptoms increases, provider perception of difficulty in the patient-provider relationship increases. The correlation and regression coefficients revealed a significant positive relationship ($r = .31$, $p = .001$) ($B = 0.302$, $p = .001$), indicating that as the severity of patient depressive symptoms increased, provider perception of difficulty in the patient-provider relationship increased. The results supported Hypothesis 1.

Hypothesis 2

   As the severity of patient depressive symptoms increases, patient satisfaction decreases. The correlation and regression coefficients demonstrated a significant inverse relationship ($r = -.32$, $p = .001$) ($B = -0.979$, $p = .000$), indicating that as the severity of patient depressive symptoms increased, patient satisfaction decreased. The results supported Hypothesis 2.

Hypothesis 3

   As the severity of patient depressive symptoms increases, provider and patient medical questioning and information giving increases. This hypothesis was not supported. Counter to the predicted direction of the relationships, as the severity of patient depressive symptoms increased, provider medical questioning, patient medical questioning, and patient medical information giving decreased although these findings lacked statistical significance. However, as the severity of patient depressive symptoms increased, there was a significant decrease in provider medical information giving

($r = -.21$, $p = .024$) ($B = -0.516$, $p = .001$). This finding disconfirmed one of the

relationships predicted in Hypothesis 3.

Hypothesis 4

 As the severity of patient depressive symptoms increases, provider and patient

psychosocial questioning and information giving decreases. This hypothesis was not

supported. Although lacking statistical significance, as the severity of patient depressive

symptoms increased, patient psychosocial questioning and provider psychosocial

information giving decreased, and, counter to the predicted direction of the relationship,

patient psychosocial information giving increased. However, as the severity of patient

depressive symptoms increased, there was a significant increase in provider psychosocial

questioning ($r = .23$, $p = .014$) ($B = 0.095$, $p = .002$). This finding disconfirmed one of

the relationships predicted in Hypothesis 4.

Hypothesis 5

 As provider perception of difficulty in the patient-provider relationship increases,

provider and patient medical questioning and information giving increases. As

predicted, the correlation and regression coefficients were all positive although the results

supported only one of the hypothesized relationships. As provider perception of

difficulty in the patient-provider relationship increased, provider medical questioning,

patient medical questioning, and patient medical information giving increased although

these results lacked significance. However, as provider perception of difficulty in the

patient-provider relationship increased, provider medical information giving increased

significantly ($r = .21$, $p = .024$) ($B = 0 .524$, $p = .001$). The results partially supported Hypothesis 5.

Hypothesis 6

As provider perception of difficulty in the patient-provider relationship increases, provider and patient psychosocial questioning and information giving decreases. As predicted, the coefficients all demonstrated inverse relationships, indicating that as provider perception of difficulty in the patient-provider relationship increased, provider and patient psychosocial questioning and information giving decreased. Although the bivariate correlation between provider difficulty and provider psychosocial questioning lacked statistical significance ($r = -.13$, $p = .156$), the regression coefficient was significant ($B = -0.073$, $p = .019$). The results partially supported Hypothesis 6.

Hypothesis 7

As provider and patient medical questioning and information giving increases, patient satisfaction decreases. The correlation and regression coefficients were inconsistent with respect to the hypothesized relationships between patient medical questioning and information giving and satisfaction. However, as provider medical questioning ($r = -.19$, $p = .045$) ($B = -0.831$, $p = .015$) and provider medical information giving increased ($r = -.30$, $p = .001$) ($B = -0.635$, $p = .000$), there was a corresponding significant decrease in patient satisfaction. The results partially supported Hypothesis 7.

Hypothesis 8

As provider and patient psychosocial questioning and information giving increases, patient satisfaction increases. These relationships did not reach a level of

significance although the results indicated that as provider psychosocial questioning and provider psychosocial information giving increased, patient satisfaction increased. In addition, and counter to what was predicted, as patient psychosocial questioning increased, patient satisfaction decreased. The correlation and regression coefficients were inconsistent with respect to the hypothesized relationship between patient psychosocial information giving and patient satisfaction. The results failed to support Hypothesis 8.

In addition to testing the proposed hypotheses, this study was designed to also explore (1) the potential mediating effect of provider-perceived difficulty in the patient-provider relationship on the association between patients' depressive symptoms and patient-provider communication during the medical encounter and (2) the potential mediating effect of patient-provider communication on the association between patients' depressive symptoms and patient satisfaction with the medical encounter. In general, a given variable may be said to function as a mediator to the extent that it accounts for the relation between the predictor and the criterion (Baron & Kenny, 1986). To establish mediation, it must be demonstrated that (1) the predictor variable is correlated with the outcome, (2) the predictor variable is correlated with the mediator, and (3) the mediator affects the outcome variable when controlling for the predictor variable in establishing the effect of the mediator on the outcome. The correlation analyses offered preliminary support to consider that (1) provider-perceived difficulty in the patient-provider relationship might function as a mediator between patients' depressive symptoms (predictor variable) and (a) provider medical information giving and (b) provider

psychosocial questioning (outcome variables) and (2) provider medical information giving might mediate the relationship between patients' depressive symptoms (predictor variable) and patient satisfaction (outcome variable).

The data were next examined to assess if the "give and take" dialog between patients and providers was associated with patient satisfaction. Four interaction terms specific to the patient-provider dyadic exchange were computed by centering each of the main effects variables and computing the product of these values: (1) provider medical questioning × patient medical information giving, (2) patient medical questioning × provider medical information giving, (3) provider psychosocial questioning × patient psychosocial information giving, and (4) patient psychosocial questioning × provider psychosocial information giving. Centering the main effects so that each variable had a mean of zero prior to forming the interaction terms reduced potential problems of multicollinearity (Tabachnick & Fidell, 2001). The interaction terms were examined using SPSS correlation and OLS regression. There were no significant correlations between any of the interaction terms and patient satisfaction. Forward entry regression was employed to determine if the addition of the interaction terms improved prediction of patient satisfaction beyond that afforded by BDI-II scores and the eight original communication variables. Addition of the interaction terms to the initial model did not significantly improve R^2. Thus, given that the interaction terms were not included in the originally hypothesized model and failed to enhance the prediction of patient satisfaction, they were dropped from subsequent analysis.

In summary, bivariate correlation and standard regression analysis of the data provided preliminary support for Hypothesis 1 and Hypothesis 2 and partial support for Hypothesis 5, Hypothesis 6, and Hypothesis 7. Hypothesis 3 and Hypothesis 4 were partially disconfirmed. The results failed to demonstrate a need for further examination of the remainder of the originally hypothesized relationships.

Hierarchical Linear Modeling

The simple correlation model demonstrated seven significant predictive relationships among the study variables. However, since traditional OLS regression analysis assumes independent observations, the preliminary results were interpreted with caution. To control for the nested structure of the data, the significant relationships demonstrated in the preliminary OLS regression analysis were subsequently analyzed in Hierarchical Linear Modeling (HLM version 6.02, Scientific Software International, Inc.) using restricted maximum likelihood estimation and an alpha level of .05. This section reviews the multilevel modeling approach used and presents results of these analyses. Level-1 predictors were group mean-centered. The results of the hierarchical analysis are presented in Table 12.

Table 12

Hierarchically Modeled Estimates of Fixed (γ) and Random (µ) Effects (Slopes) (N=115)

Predictor	Outcome	$\gamma^{\dagger}$	$\mu^{\ddagger}$
BDI-II			
	DDPRQ	0.215422	0.04464
	Provider medical information giving	0.366190	0.11127
	Provider psychosocial questioning	0.076276	0.02404[**]
	Patient satisfaction	-1.096203[*]	1.14247[**]
DDPRQ			
	Provider medical information giving	0.504637[*]	0.09080
	Provider psychosocial questioning	-0.050093	0.00200
Provider medical questioning			
	Patient satisfaction	-0.193769	0.20231
Provider medical information giving			
	Patient satisfaction	-0.488496[**]	0.00516

Note. [†] Corresponds to the gamma (γ) coefficients and [‡] corresponds to the mu (µ) estimates in the multilevel modeling equations reported in the text. BDI-II = Beck Depression Inventory-II. DDPRQ = Difficult Doctor-Patient Relationship Questionnaire-10.
* $p < .05$. ** $p \le .005$.

Unconstrained Model (Null)

To measure the proportion of variance in patient satisfaction accounted for by providers (level-2 units), the intraclass correlation coefficient (ICC) was estimated. The unconstrained model, with no level-1 or level-2 predictors was specified by the following equation:

$$\text{SAT}_{ij} = \gamma_{00} + \mu_{0j} + r_{ij.}$$

In this equation, SAT_{ij} = the estimated satisfaction score for a particular patient within a particular provider, γ_{00} = the grand mean of patient satisfaction across all patient subjects, μ_{0j} = variability in patient satisfaction between providers, and r_{ij} = variability in patient satisfaction between patients within providers (random error). The ICC was .26, indicating that 26% of the variance in patient satisfaction was accounted for by providers. This substantial ICC demonstrated a main effect of provider on patient satisfaction in the study sample and provided empirical justification for a multilevel approach to analysis.

Hypothesis 1

As the severity of patient depressive symptoms increases, provider perception of difficulty in the patient-provider relationship increases. This hypothesis was tested by regressing DDPRQ scores onto BDI-II scores. The mixed-effects model was specified by the following equation:

$$\text{DDPRQ}_{ij} = \gamma_{00} + \gamma_{10} \, (\text{BDI-II})_{ij} + \mu_{0j} + \mu_{1j} \, (\text{BDI-II})_{ij} + r_{ij.}$$

In this equation, γ_{00} = the grand mean of DDPRQ scores across all subjects, $\gamma_{10}(\text{BDI-II})_{ij}$ = the effect (slope) of BDI-II scores for the level-2 unit (provider) and $\mu_{1j}(\text{BDI-II})_{ij}$ = between provider variability in the slopes. A non-significant, positive relationship was

observed ($B = 0.215422$, *SE B* $= 0.123324$, $p = 0.111$). In contrast to the OLS regression

analysis findings, the hypothesis that patient depressive symptoms predict provider-

perceived difficulty in the patient-provider relationship was not supported. Modeling

revealed significant variability between providers in terms of their DDPRQ scores ($\chi^2 =$

20.71774, *df* $= 10$, $p = .023$). A graphical summary of the distributions of scores for the

11 providers is displayed in Figure 2. There was no significant difference in slopes

between providers ($\chi^2 = 12.14437$, *df* $= 10$, $p = .275$) (Figure 3). A large random effects

variance component for level-1 (49.17215) demonstrated substantial un-modeled

variability in DDPRQ scores (random error).
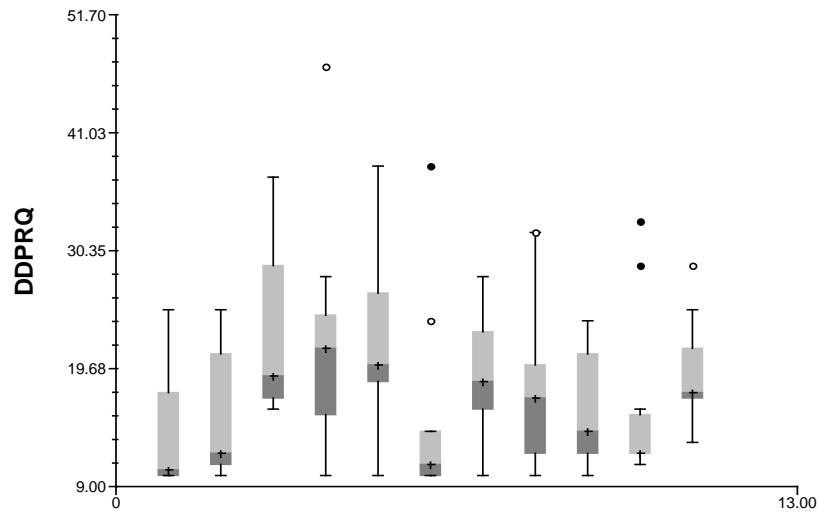
Figure 2. Distributions of provider DDPRQ scores adjusted for patient depressive symptoms.
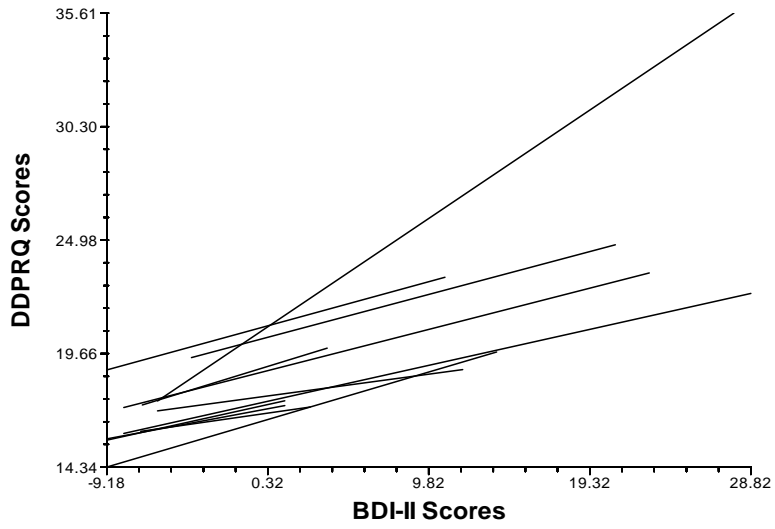
Figure 3. Slopes of provider-perceived difficulty as a function of patient depressive symptoms for each provider.

Hypothesis 2

As the severity of patient depressive symptoms increases, patient satisfaction

decreases. This hypothesis was tested by regressing patient satisfaction onto BDI-II

scores (see also Hypothesis 7). The mixed-effects model was specified by the following

equation:

$$\text{SAT}_{ij} = \gamma_{00} + \gamma_{10} (\text{BDI-II})_{ij} + \gamma_{20} (\text{DRMEDQ})_{ij} + \gamma_{30} (\text{DRMEDINFO})_{ij} + \mu_{0j}$$

$$+ \mu_{1j} (\text{BDI-II})_{ij} + \mu_{2j} (\text{DRMEDQ})_{ij} + \mu_{3j} (\text{DRMEDINFO})_{ij} + r_{ij.}$$

In this equation, $\gamma_{20} (\text{DRMEDQ})_{ij}$ = the effect of provider medical questioning,

$\gamma_{30} (\text{DRMEDINFO})_{ij}$ = the effect of provider medical information giving,

$\mu_{2j} (\text{DRMEDQ})_{ij}$ = variability between providers in the effect of provider medical

questioning, and $\mu_{3j} (\text{DRMEDINFO})_{ij}$ = variability between providers in the effect of

provider medical information giving. A significant, inverse relationship between the

severity of patient depressive symptoms and patient satisfaction was observed

(B = -1.096203, *SE B* = 0.394580, p = .020). The hypothesis that the severity of patient

depressive symptoms predicts patient satisfaction was supported and confirmed the

findings of the OLS regression analysis. There was significant variability between

providers both in terms of their patients' satisfaction (χ^2 = 66.97756, *df* = 10, p = .000)

(Figure 4) and slope of BDI-II (χ^2 = 25.49043, *df* = 10, p = .005) (Figure 5). A large

random effects variance component for level-1 (185.76746) demonstrated substantial un-

modeled variability in patient satisfaction (random error).
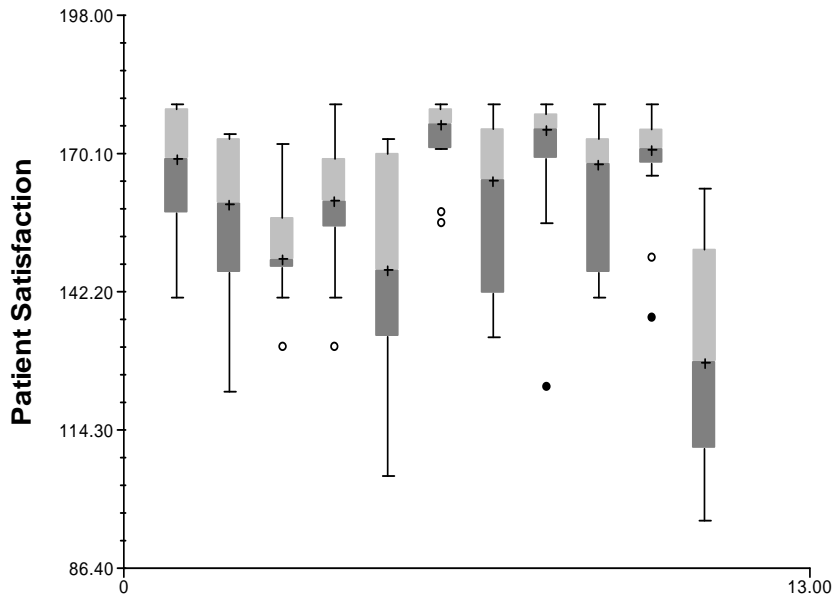
Figure 4. Distributions of patient satisfaction scores adjusted for patient depressive symptoms, provider medical questioning, and provider medical information giving.

Figure 5. Slopes of patient satisfaction as a function of patient depressive symptoms for each provider adjusted for provider medical questioning and provider medical information giving.

Hypothesis 3

As the severity of patient depressive symptoms increases, provider and patient

medical questioning and information giving increases. Preliminary analysis significantly

disconfirmed the hypothesized relationship between patient depressive symptoms and

provider medical information giving. This relationship was further examined by

regressing provider medical information giving onto BDI-II scores (see also Hypothesis

5). The mixed-effects model was specified by the following equation:

$$DRMEDINFO_{ij} = \gamma_{00} + \gamma_{10} (BDI\text{-}II)_{ij} + \gamma_{20} (DDPRQ)_{ij} + \mu_{0j} + \mu_{1j} (BDI\text{-}II)_{ij}$$

$$+ \mu_{2j} (DDPRQ)_{ij} + r_{ij.}$$

In this equation, $DRMEDINFO_{ij}$ = provider medical information giving, $\gamma_{20} (DDPRQ)_{ij}$ =

the effect of provider-perceived difficulty, and $\mu_{2j} (DDPRQ)_{ij}$ = variability between

providers in the effect of provider-perceived difficulty in the patient-provider

relationship. A non-significant, inverse relationship was observed (B = -0.366190, *SE B*

= 0.180610, p = .070). In contrast to the OLS regression analysis findings, the hypothesis

that patient depressive symptoms predict provider medical information giving during the

encounter was not supported. There was significant variability among providers in terms

of medical information giving during the encounter (χ^2 = 65.89477, df = 10, p = .000). A

graphical summary is displayed in Figure 6. There was no significant difference in

slopes between providers (χ^2 = 14.67536, df = 10, p = .144) (Figure 7). A large random

effects variance component for level-1 (102.87816) demonstrated substantial un-modeled

variability in provider medical information giving (random error).
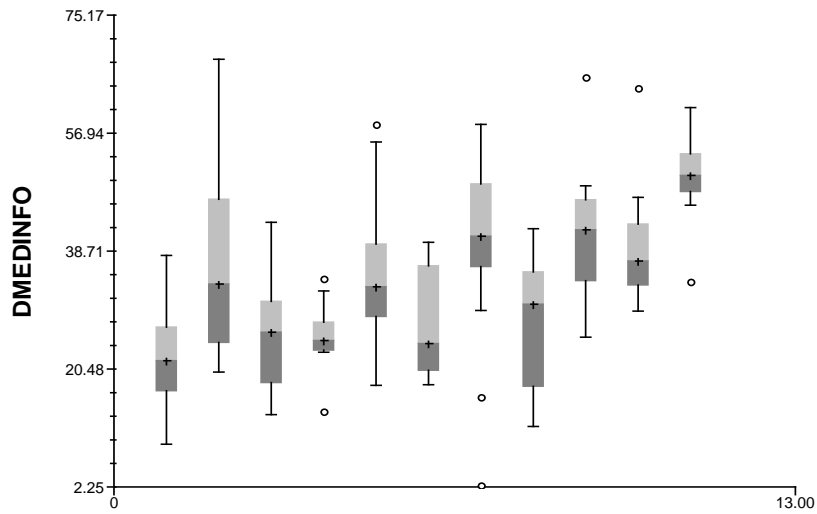
Figure 6. Distributions of provider medical information giving adjusted for patient depressive symptoms and provider-perceived difficulty.

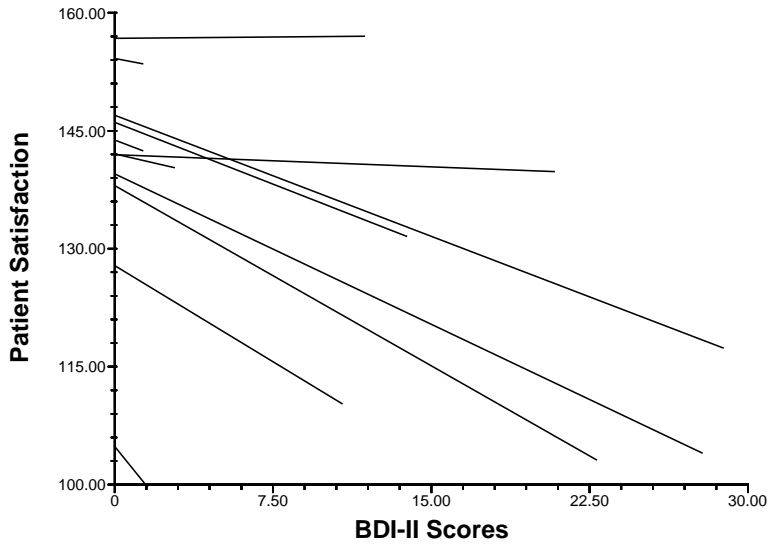*Figure 7.* Slopes of provider medical information giving as a function of patient depressive symptoms for each provider adjusted for provider-perceived difficulty.

Hypothesis 4

As the severity of patient depressive symptoms increases, provider and patient
psychosocial questioning and information giving decreases. Preliminary analysis failed
to support this hypothesis. However, the results significantly disconfirmed the
relationship between patient depressive symptoms and provider psychosocial
questioning. This relationship was further examined by regressing provider psychosocial
questioning onto BDI-II scores (see also Hypothesis 6). The mixed-effects model was
specified by the following equation:

$$\text{DRPSYQ}_{ij} = \gamma_{00} + \gamma_{10}\,(\text{BDI-II})_{ij} + \gamma_{20}\,(\text{DDPRQ})_{ij} + \mu_{0j} + \mu_{1j}\,(\text{BDI-II})_{ij}$$

$$+ \mu_{2j}\,(\text{DDPRQ})_{ij} + r_{ij.}$$

In this equation, DRPSYQ_{ij} = provider psychosocial questioning. A non-significant,
positive relationship was observed ($B = 0.076276$, $SE\ B = 0.059205$, $p = .202$). In
contrast to the OLS regression analysis findings, the hypothesis that patient depressive
symptoms predict provider psychosocial questioning was not supported. However, the
slope of depressive symptoms, as demonstrated in Figure 8, varied significantly among
providers ($\chi^2 = 39.12708$, $df = 10$, $p = .000$). A large random effects variance component
for level-1 (4.44438) demonstrated substantial un-modeled variability in provider
psychosocial questioning (random error).
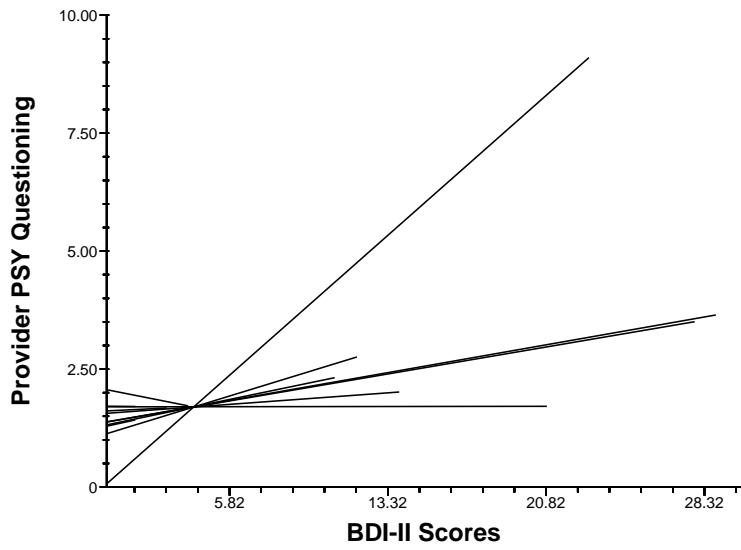
Figure 8. Slopes of provider psychosocial questioning as a function of patient depressive symptoms for each provider adjusted for provider-perceived difficulty.
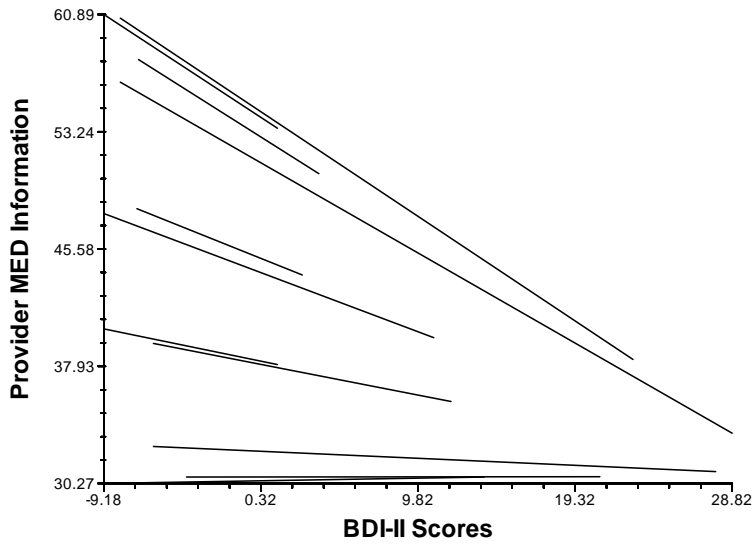
Hypothesis 5

　　As provider perception of difficulty in the patient-provider relationship increases, provider and patient medical questioning and information giving increases. Preliminary analysis supported the relationship between provider perception of difficulty in the patient-provider relationship and provider medical information giving. This relationship was examined by regressing provider medical information giving onto DDPRQ scores (see also Hypothesis 3). The mixed-effects model was specified by the following equation:

$$\text{DRMEDINFO}_{ij} = \gamma_{00} + \gamma_{10}\,(\text{BDI-II})_{ij} + \gamma_{20}\,(\text{DDPRQ})_{ij} + \mu_{0j} + \mu_{1j}\,(\text{BDI-II})_{ij}$$

$$+ \mu_{2j}\,(\text{DDPRQ})_{ij} + r_{ij.}$$

In this equation, DRMEDINFO_{ij} = provider medical information giving. A significant, positive relationship was observed ($B = 0.504637$, $SE\ B = 0.171022$, $p = .015$) (Figure 9) and confirmed the findings of the OLS regression analysis. The hypothesis that provider-perceived difficulty in the relationship predicts provider medical information giving was supported. There was little variation in slopes across providers ($\chi^2 = 16.11970$, $df = 10$, $p = .096$).
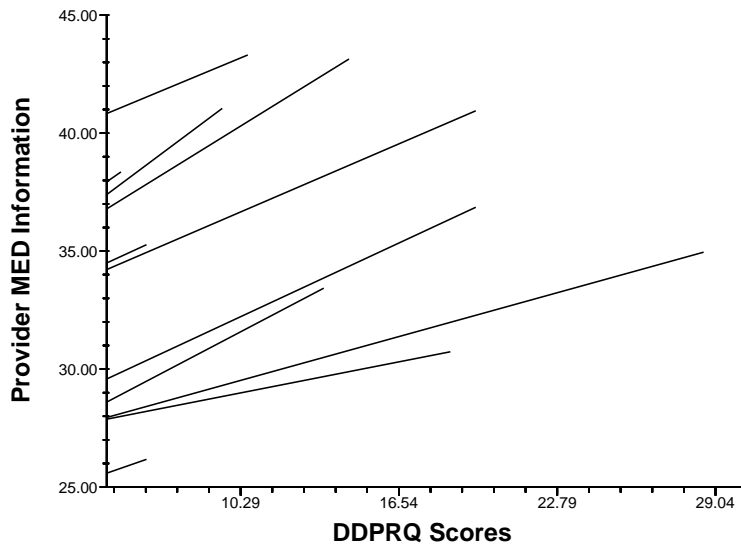
Figure 9. Slopes of provider medical information giving as a function of provider-perceived difficulty for each provider adjusted for patient depressive symptoms.

Hypothesis 6

     As provider perception of difficulty in the patient-provider relationship increases, provider and patient psychosocial questioning and information giving decreases. Preliminary analysis supported the relationship between provider perception of difficulty in the patient-provider relationship and provider psychosocial questioning. This relationship was examined by regressing provider psychosocial questioning onto DDPRQ scores (see also Hypothesis 4). The mixed-effects model was specified by the following equation:

$$\text{DRPSYQ}_{ij} = \gamma_{00} + \gamma_{10}\,(\text{BDI-II})_{ij} + \gamma_{20}\,(\text{DDPRQ})_{ij} + \mu_{0j} + \mu_{1j}\,(\text{BDI-II})_{ij}$$

$$+ \mu_{2j}\,(\text{DDPRQ})_{ij} + r_{ij.}$$

A non-significant, inverse relationship was observed (B = -0.050093, *SE B* = 0.033465, p = .165). In contrast to the OLS regression analysis findings, the hypothesis that provider-perceived difficulty predicts provider psychosocial questioning was not supported. There was no statistically significant difference between providers in terms of amount of psychosocial questioning (χ^2 = 7.52070, *df* = 10, p > .500) or slope of provider-perceived difficulty (χ^2 = 9.24527, *df* = 10, p > .500) (Figure 10).
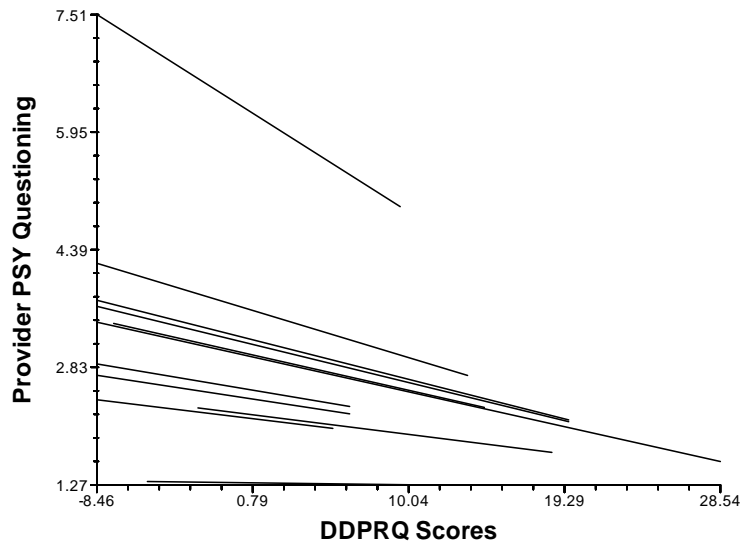
Figure 10. Slopes of provider psychosocial questioning as a function of provider-perceived difficulty for each provider adjusted for patient depressive symptoms.

Hypothesis 7

As provider and patient medical questioning and information giving increases, patient satisfaction decreases. Preliminary analysis supported the relationships between provider medical questioning and provider information giving and patient satisfaction. These relationships were examined by regressing patient satisfaction onto provider medical questioning and provider medical information giving (see also Hypothesis 2). The mixed effects model was specified by the following equation:

$$\text{SAT}_{ij} = \gamma_{00} + \gamma_{10} \text{(BDI-II)}_{ij} + \gamma_{20} \text{(DRMEDQ)}_{ij} + \gamma_{30} \text{(DRMEDINFO)}_{ij} + \mu_{0j}$$

$$+ \mu_{1j} \text{(BDI-II)}_{ij} + \mu_{2j} \text{(DRMEDQ)}_{ij} + \mu_{3j} \text{(DRMEDINFO)}_{ij} + r_{ij.}$$

A non-significant, inverse relationship was observed between provider medical questioning and patient satisfaction ($B = -0.193769$, $SE\ B = 0.307920$, $p = .543$). In contrast to the OLS regression analysis findings, the hypothesis that provider medical questioning predicts patient satisfaction was not supported. The slope of provider medical questioning did not significantly vary across providers ($\chi^2 = 5.77424$, $df = 10$, $p > .500$) (Figure 11).

A significant, inverse relationship was observed between provider medical information giving and patient satisfaction ($B = -0.488496$, $SE\ B = 0.128600$, $p = .004$) (Figure 12) and confirmed the findings of the OLS regression analysis. The slope of provider medical information giving was consistent across providers ($\chi^2 = 6.38846$, $df = 10$, $p > .500$). The hypothesis that provider medical information giving predicts patient satisfaction was supported.
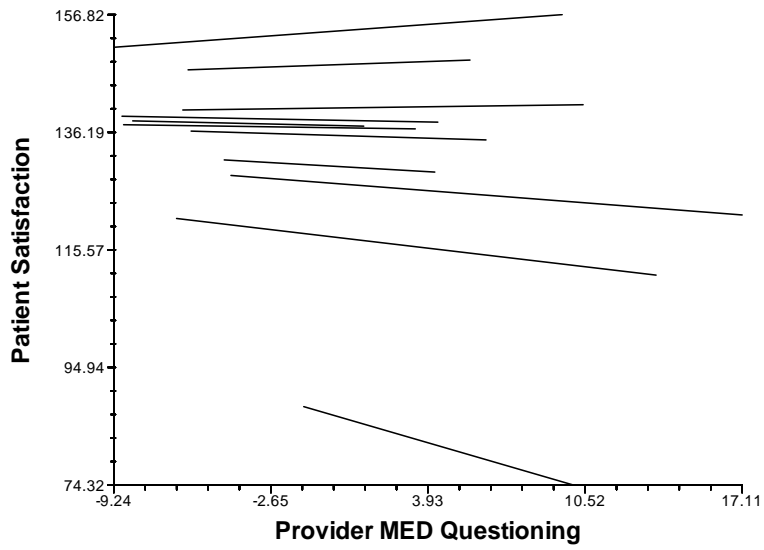
Figure 11. Slopes of patient satisfaction as a function of provider medical questioning for each provider adjusted for patient depressive symptoms and provider medical information giving.
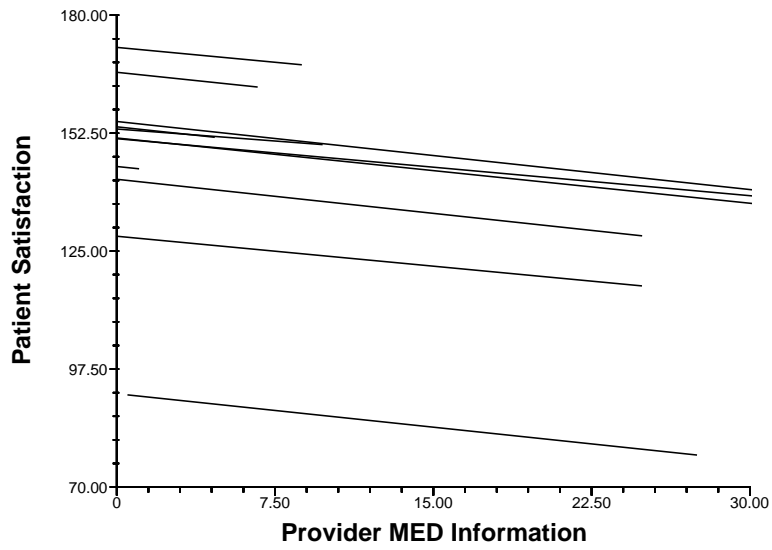
Figure 12. Slopes of patient satisfaction as a function of provider medical information giving for each provider adjusted for patient depressive symptoms and provider medical questioning.

The adequacy of the multilevel modeling at predicting patient satisfaction from BDI-II scores and provider medical information giving was further examined to see how closely the model fit the data. This was tested by comparing the deviance value of the model to the deviance value of the unconstrained (null) model. Deviance, a measure of lack of fit between the data and the model, is distributed as a chi-square statistic with degrees of freedom equal to the difference in the number of parameters estimated in each model (Luke, 2004). The difference between the two deviances was x^2 (5, $N = 115$) = 32.38389, $p = .000$. Adding BDI-II and provider medical information giving as predictors of patient satisfaction provided a significantly better fit to the data than the unconstrained model. Multilevel modeling did not demonstrate the bivariate relationships that would have been required in order to establish a mediation effect of provider-perceived difficulty in the patient-provider relationship, provider medical information giving, or provider psychosocial questioning.

Exploratory Analysis

Hierarchical modeling indicated that the severity of patient depressive symptoms and the amount of provider medical information giving during the medical encounter predict patient satisfaction. However, the analysis failed to support the majority of the hypothesized relationships between the communication variables and patient satisfaction. A large random effects variance component for level-1 (185.76746) demonstrated substantial un-modeled variability in patient satisfaction between patients within providers (random error). In an attempt to further elucidate the underpinnings of patient

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satisfaction with the medical encounter an exploratory analysis was conducted. The RIAS database provided an abundant opportunity for further examination.

Twenty-two additional provider and 19 patient communication variables in the RIAS database were available for review (Table 13). Prior to analysis, the variables were normalized so that the values reflected the proportion of either all provider talk or all patient talk during the encounter and were then adjusted to percentage values to improve interpretability of the data. In addition to the 'utterance by utterance' RIAS coding, the coders also rated the affect of the patient-provider dialogue (i.e., the emotional context) (Table 13). The coders did not directly link these ratings to particular events or utterances during the exchange, but assigned ratings based on their overall affective impressions of the speakers. Ratings were assigned for both provider and patient speech. Inter-rater reliability estimates were computed using Pearson's r. The correlation coefficients were all positive and ranged from .83 to 1.0 (Table 14).

The variables were first examined by a series of SPSS correlations and OLS regressions. Significant bivariate correlations were observed between patient satisfaction and the provider variables of approval-direct ($r = .28$, $p = .002$), back-channels (e.g., indicators of sustained interest, attentive listening, or encouragement) ($r = .20$, $p = .034$), friendliness/warmth ($r = .25$, $p = .007$), sympathetic/empathetic ($r = .21$, $p = .027$), and respectfulness ($r = .19$, $p = .04$), and the patient variables of anger/irritation ($r = -.29$, $p = .002$), interest/attentiveness ($r = .21$, $p = .023$), friendliness/warmth ($r = .28$, $p = .003$), responsiveness/engagement ($r = .26$, $p = .006$), and sympathetic/empathetic ($r = .18$, $p = .054$). The variables were modeled in a forward regression analysis to see if they

Table 13

Additional RIAS Variables Included in Exploratory Analysis

Communication Variables

Provider	Patient
personal remarks	personal remarks
laughs, tells jokes	laughs, tells jokes
approval-direct	approval-direct
compliment-general	compliment-general
disagreement, criticism-direct	disagreement, criticism-direct
disagreement, criticism-general	disagreement, criticism-general
empathy/legitimation statements	empathy/legitimation statements
concern, worry	concern, worry
reassures, optimism	reassures, optimism
partnership statements	gives information-other
self-disclosure	shows agreement, understanding
gives information-other	paraphrase, checks for understanding
shows agreement, understanding	transitions
back-channels	gives orientation, instructions
paraphrase, checks for understanding	all questions-other
transitions	asks for service
gives orientation, instructions	asks for reassurance
open question-other	asks for understanding
asks for opinion	bid for repetition
asks for permission	
asks for reassurance	
bid for repetition	

Global Affect Variables

Provider	Patient
anger/irritation	anger/irritation
anxiety/nervousness	anxiety/nervousness
dominance/assertiveness	depression/sadness
interest/attentiveness	emotional distress/upset
friendliness/warmth	dominance/assertiveness
responsiveness/engagement	interest/attentiveness
sympathetic/empathetic	friendliness/warmth
hurried/rushed	responsiveness/engagement
respectfulness	sympathetic/empathetic
	respectfulness

Table 14

Inter-Coder Reliability Estimates for RIAS Coded Global Affect Variables Using Pearson's r (n=12)

Variable	Coder agreements/ possible agreements	*r*
Provider Affect		
anger/irritation	12/12	1.0
anxiety/nervousness	12/12	1.0
dominance/assertiveness	12/12	1.0
interest/attentiveness	12/12	1.0
friendliness/warmth	11/12	.92
responsiveness/engagement	12/12	1.0
sympathetic/empathetic	11/12	.92
hurried/rushed	11/12	.92
respectfulness	10/12	.83
Patient Affect		
anger/irritation	12/12	1.0
anxiety/nervousness	12/12	1.0
depression/sadness	12/12	1.0
emotional distress/upset	12/12	1.0
dominance/assertiveness	12/12	1.0
interest/attentiveness	12/12	1.0
friendliness/warmth	10/12	.83
responsiveness/engagement	12/12	1.0
sympathetic/empathetic	12/12	1.0
respectfulness	12/12	1.0

improved the prediction of satisfaction above and beyond BDI-II scores and the original eight communication variables. Significant regression coefficients were observed for the provider variables of dominance/assertiveness ($B = 8.062$, $p = .005$), and shows approval-direct ($B = 3.209$, $p = .000$), and the patient variables of friendliness/warmth ($B = 7.000$, $p = .002$), depression/sadness ($B = -9.818$, $p = .016$), and respectfulness ($B = 5.692$, $p = .048$). Adding these variables also significantly improved R^2 of the model (R^2 change $= .020$, $p = .048$).

To evaluate the robustness of these relationships while controlling for the nested structure of the data, the variables were then modeled in HLM to determine if they improved the prediction of patient satisfaction scores beyond that afforded by BDI-II scores and provider medical information giving. A significant, positive relationship was observed between patient friendliness/warmth and patient satisfaction ($B = 6.290095$, $SE\ B = 2.397012$, $p = .026$). This result indicated that the affective quality of a patients' speech, specifically the expression of friendliness/warmth during the medical encounter is a predictor of patient satisfaction. The adequacy of the multilevel modeling at predicting patient satisfaction from BDI-II scores, provider medical information giving, and patient friendliness/warmth was further examined to see how closely the model fit the data. This was tested by comparing model deviance values. The difference between the two deviances was $\chi^2 (4, N = 115) = 16.82947$, $p = .002$. Adding patient friendliness/warmth to BDI-II scores and provider medical information giving as predictors of patient satisfaction provided a significantly better fit to the data.

Characteristics of the patient-provider encounter were examined. A third party

(associated with the patient) participated during 17% of the encounters (n=19). In 12%,

a second provider (provider in-training) participated (n=14). The provider left the

examination room at least once during 46% of visits (n=53) and a staff member

interrupted the patient-provider encounter in 15% (n= 17). The relationships between

these four variables and patient satisfaction were examined using SPSS correlation and

standard regression analysis. The presence of a second provider during the examination

significantly correlated with patient satisfaction (r = -.19, p = .046). There were no other

significant bivariate correlations. Forward entry regression was used to determine if the

addition of these variables improved the variance of patient satisfaction beyond that

afforded by the eight original communication variables and BDI-II scores. None of the

variables were found to be significant predictors of patient satisfaction, nor improve R^2

in the presence of the previously modeled variables using OLS regression.

The data were also explored in an attempt to elucidate the underpinnings of

provider-perceived difficulty in the relationship since multilevel modeling failed to

support the predicted relationship between patient depressive symptoms and provider

difficulty. No significant bivariate correlations were observed between any of the

encounter characteristic variables of third party, second provider, provider left room, or

staff interruption with DDPRQ scores. Forward entry regression was used to determine if

any of these variables predicted DDPRQ scores above and beyond that afforded by BDI-

II scores alone. None of the variables were found to be significant predictors of provider-

perceived difficulty in the patient-provider relationship, nor improve R^2 in the presence of BDI-II scores using OLS regression.

The global affect ratings were re-examined to see if the emotional context of the encounter predicted DDPRQ scores. Significant correlations were demonstrated between DDPRQ scores and provider friendliness/warmth ($r = -.19$, $p = .046$), patient emotional distress/upset ($r = .22$, $p = .018$), patient friendliness/warmth ($r = -.23$, $p = .012$), and patient sympathetic/empathetic ($r = -.34$, $p = .000$). Forward entry regression was used to determine if the any of the provider or patient ratings predicted DDPRQ scores above and beyond that afforded by BDI-II scores alone. The patient global affect variable of sympathetic/apathetic was the only variable that demonstrated a significant relationship with DDPRQ scores in the presence of BDI-II scores ($B = -8.707$, $p = .000$) and also significantly improved R^2 of the model (R^2 change $= .125$, $p = .000$). The robustness of this relationship was then tested in HLM, adjusting for the nested structure of the data. A significant, inverse relationship was observed ($B = -8.525196$, $SE\ B = 2.138115$, $p = .000$). This result indicated that the affective quality of a patient's speech, specifically the expression of sympathy/empathy that is directed toward the provider is a predictor of provider perception of difficulty in the patient-provider relationship. The adequacy of the multilevel modeling at predicting DDPRQ scores from patient sympathy/empathy was examined by comparing the deviance value of the model to the unconstrained (null) model. The difference between the two deviances was x^2 (2, $N = 115$) $= 20.79954$, $p = .000$. Adding patient sympathy/empathy as a predictor of DDPRQ provided a significantly better fit to the data than the unconstrained model.

These findings are discussed in the next chapter.

Discussion

Primary Aims and Hypotheses

Depressive Symptoms and the "Difficult" Patient

A specific aim of this study was to determine if a patient's depressive

symptomatology impacts the patient-provider relationship by increasing the likelihood of

being perceived as a "difficult" or frustrating patient by the provider. The findings

indicate that the prevalence and severity of depressive symptoms in the patient sample

was similar to what has been reported elsewhere. This confirms that substantially more

individuals suffer milder, yet possibly significant, depressive symptoms that do not meet

DSM-IV criteria for major depressive disorder (American Psychiatric Association, 1994).

Subthreshold depression, like major depression, is associated with significant disability,

functional impairment, comorbidity, increased costs and utilization of health care

services, and work absenteeism. These individuals are unlikely to seek treatment for

their depression. Yet the evidence indicates that many individuals with mild symptoms

are likely to develop more serious depressive symptoms. It is critical that primary care

providers recognize, diagnose, and effectively treat depression in their patients in order to

address these problems before significant impairment results.

The DDPRQ was scored and analyzed as a continuous variable. It can also be

used as a dichotomous variable with a cut-point of 30 (Hahn et al., 1996). If used in that

manner, providers would have classified 9% of the patient sample as "difficult". This is

slightly less than what would have been anticipated, as other studies using the DDPRQ typically report that 10% to 20% of patients provoke a level of physician distress and frustration that transcends the expected and accepted level of difficulty (Hahn et al., 1994; Hahn et al., 1996; Jackson & Kroenke, 2001). There are several possible explanations. Provider selection, their interests in and attitudes toward depression care, and a social desirability response set might have biased DDPRQ ratings in this sample. In addition, a patient self-selection bias could have influenced providers' responses. Since previous research has indicated that patients can accurately estimate their physician's liking of them (Hall et al., 2002), patients who had particularly satisfying established relationships with their providers might have been more inclined to participate. Although it is possible that the data underestimate the prevalence of provider perception of difficulty in primary care patients, there is no indication that this sample differed from those of previous studies.

Consistent with previous research, the data demonstrated a significant positive correlation between depressive symptoms and provider-perceived difficulty. However, depressive symptomatology, whether measured by BDI-II scores or implied by the affective tonal quality of patient speech (i.e., sounding depressed, sad, or emotionally distressed), did not predict provider-perceived difficulty in this patient and provider sample after controlling for other predictors. This finding counters the main premise of this study and merits examination.

The association between mental disorders, especially depressive and anxiety disorders is well documented (Hahn et al., 1994; Hahn et al., 1996; Hahn, 2001; Jackson,

2005; Jackson & Kroenke, 2001; Kroenke et al., 1997). Furthermore, many of the

behavioral characteristics associated with and displayed by depressed patients mirror

those that are frequently ascribed to "difficult" patients. However, two distinct

methodological features of this study strengthen the current finding. First, in contrast to

several of the aforementioned studies the providers in this study were blinded to (and

therefore presumably not influenced by) patients' depression screening results during the

encounter. Second, this study sample was limited to established patient-provider pairs.

"New" or "first time" patients who had yet to begin a provider relationship were excluded

from participation. Contrary to a priori speculation this study suggests that providers do

not respond in a predictable way to their depressed patients.

     This nonsignificant finding should not be interpreted as though the null is

unequivocally true however. The data demonstrated an effect size of $r = 0.31$ that is

consistent with the conventional medium effect size of a population r of .30 (Cohen,

1977, p. 60). Hierarchical modeling revealed significant variability between providers in

terms of DDPRQ scores and substantial unexplained differences in scores between

patients within providers (random error). This indicates that either the effect of

depressive symptoms on provider-perceived difficulty, or the study sample size, would

have to be larger to have confidence in detecting it. It is also possible that the outlier

cases impacted the multilevel regression coefficient and solution since extreme cases can

lead to Type I and Type II errors (Tabachnick & Fidell, 2001). This explanation is

partially supported by the observed multilevel regression coefficient p value of 0.07 (95%

C.I. $= 0.18235 – 0.67071$) when the outlier cases were excluded from analysis compared

with $p = 0.11$ (95% C.I. = 0.31097 – 0.82193) when retained. Neither confidence level

contains zero. Therefore, it is possible that providers may have a tendency to respond to

their depressed patients in a predictable way that could not be detected using the

conventional alpha value (.05) in this study.

The relationship between depressive symptoms and provider-perceived difficulty

is likely confounded by other unmeasured variables. Exploratory analysis indicates that

the affective quality of patient speech, specifically the expression of sympathy or

empathy, significantly lowers the likelihood of a patient being considered as a "difficult"

patient. It is interesting to note that the affective quality of provider speech, especially

expressions of anger/irritation or anxiety/nervousness that presumably would reflect

provider frustration with a patient, neither correlate with nor appear to influence provider

ratings of difficulty in the relationship. Future research efforts should explore for

possible interaction effects between patients' depressive symptoms and patient and

provider affective behaviors on provider perception of difficulty. Difficulty may also

arise from a unique combination of particular patient and provider characteristics that

would be difficult to capture in any study.

Depressive Symptoms and Patient-Provider Communication

Depressive symptomatology significantly correlates with provider medical

information giving and provider psychosocial questioning yet it does not appear to have a

significant influence on the verbal content of the encounter. It was hypothesized that

patient and provider communication behaviors, specifically medical and psychosocial

talk, could be predicted based on the severity of patients' depressive symptoms. This

hypothesis was not supported. None of the patient or provider communication variables were predicted by patients' depressive symptoms. Results were consistent whether the depressive symptoms were measured by BDI-II scores or implied by the affective tonal quality of patient speech. This finding is consonant with past research that demonstrated providers' interviewing styles do not change according to patient characteristics such as emotional distress (Del Piccolo et al., 2002; Deveugele et al., 2002; Sleath & Rubin, 2002) and converges with a proposed link between health status and provider behavior (Hall et al., 1996).

Although this finding lacks statistical significance it is clinically meaningful. The majority of patients reported that (in general) it was at least somewhat important that their primary care provider attend to their mental health needs and previous research has shown that patients welcome the opportunity to discuss their psychosocial concerns during the course of the medical visit (Bertakis et al., 1991). Since the majority of individuals with depression are initially evaluated in primary care settings and many rely on a primary care provider for all of their health needs, it is troubling to observe that communication behaviors don't necessarily change in response to patients' depressive symptoms. This finding may reflect some of the dynamics involved in the delivery of depression care. Whether such behavior contributes to the under-diagnosis and sub-optimal treatment of depression in primary care cannot be answered by this study.

Several caveats bear mentioning. First, it is not known exactly how many patients in this study actually desired or had a pre-visit expectation to discuss their depressive symptoms during the observed visit. Less than 3% of patients who responded to the

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question listed depression as their major reason for the appointment on the pre-visit questionnaire. Second, this study provided only a snapshot glimpse into the "black box" of the medical encounter. It did not examine patients' medical or psychosocial history, co-morbid health problems, medication use, recency or content of last office visit, or length of the patient-provider relationship.

Continuity of care is a main attribute of primary care and widely believed to enhance disclosure of symptoms. Perhaps one advantage to familiarity is the ability to "read between the lines". For example, in a well-established relationship one brief patient statement (e.g., "I feel lousy", "not good", "same thing", or even "*you know*") may be all that needs to be said in order for a provider to understand his/her patient's individual situation. Hence, it is possible that verbal coding, which is based on frequency counts, may not adequately reflect the communication process between depressed patients and their providers.

Depressive Symptoms and Patient Satisfaction

It is well documented that individuals with depression are significantly less satisfied with their medical care. This study hypothesized that depressive symptomatology would have a negative impact on patient satisfaction with the medical encounter. The data support this hypothesis and indicate that the more depressed a patient is, the less satisfied he/she is with their care. This finding is not only statistically significant but substantively meaningful as well. Patient satisfaction is a legitimate measure of health care quality and is important not only as a financial investment for

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health care organizations but also because of its significant associations with other patient outcomes including adherence to treatment, physiologic status, and symptom resolution.

Hierarchical modeling revealed significant unexplained variability between providers both in terms of their patients' satisfaction ratings as well as the effect depressive symptoms had on their patients' satisfaction. However, this study cannot untangle nor explain the source(s) of depressed patients' dissatisfaction. Part of it likely stems from the adverse nature of depression itself (i.e., altered mood and cognition). Whether depressive symptoms bias patient assessments of satisfaction, or if these patients receive lower quality of care, as suggested by Orlando and Meredith (2002), cannot be answered by these findings. Further interpretation is also limited by the fact that patients' expectations of the office encounter were not measured. A lack of unmet expectations has been shown to be a powerful predictor of patient satisfaction at various time points (Jackson et al., 2001). Therefore, it is possible that depressed patients in this study were less satisfied than their non-depressed counterparts because their pre-visit expectations may not have been met. A qualitative approach to inquiry, specifically narrative analysis, which focuses on the recounted or observed stories of participants' experiences ("storytelling") would give voice to depressed patients and help to elucidate the underpinnings of their (dis)satisfaction with medical care.

Patient-provider communication does not appear to be a source of depressed patients' (dis)satisfaction as the data failed to demonstrate a "communication mediation hypothesis" between depressive symptoms and patient satisfaction. Two distinct features of this study enhance this finding. First, patient satisfaction was measured immediately

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after the observed visit. Although satisfaction may have been confounded by additional uncontrolled factors (e.g., waiting time, friendliness of the office staff, convenience of appointment, non-verbal communication of the provider, etc.), ratings were not biased by the passage of time (i.e., patient recollection of events). Second, the dyadic exchange during the encounter was examined by direct observation and therefore did not depend on subjects' recollection or interpretation of events.

"Difficulty" and Patient-Provider Communication

The second aim of this study was to determine if provider perception of difficulty in the relationship influences verbal communication, specifically, medical or psychosocial talk, during the encounter. As hypothesized, the results indicate that provider-perceived difficulty predicts at least part of the verbal exchange: provider medical information giving. The more "difficult" or frustrating a patient is, the more medical information they receive during the visit. Providers were strikingly consistent in this behavior. Whether providers give more information in response to patient questions or requests for information, or because of a patient's clinical status, cannot be answered. It could be that providers, when dealing with "difficult" patients, fall back on their professional responsibility to provide medical information and, as a trade-off, subsequently withdraw as social participants during the encounter. Provider perception of difficulty did not predict patient or provider psychosocial questioning or information giving, patient medical questioning or information giving, or provider medical questioning.

Bensing and Dronkers (1992) found providers asked fewer questions, especially psychosocial questions, in encounters in which the physician appeared to be irritated, anxious, or nervous. It is interesting to note two particular trends in the current data despite weak bivariate correlations ($r = -.13$ to $.21$). As difficulty scores increased, there was an across the board increase in patient and provider medical talk and a corresponding decrease in all psychosocial talk. Use of medical and psychosocial talk may indicate subtle ways in which providers tend to dominate consultations. Although interpretation of this observation is limited, this could possibly suggest that providers, when dealing with "difficult" patients, may attempt to control the content and direction of the encounter by using medical jargon. If this is the case, this may be in response to increased uncertainty in the care of difficult patients (Schwenk et al., 1989). It may also be one method providers employ, either consciously or unconsciously, in an attempt to avoid discussing other topics.

The function of provider medical information giving during encounters with "difficult" patients is unclear. To determine if it is an attempt by providers to control the content and direction of the encounter, this could be further examined using a qualitative approach to inquiry, namely discourse analysis. Discourse analysis focuses on how talk within medical (or other) encounters functions to change, establish, or maintain social power relationships (Roter & McNeilis, 2003). Alternatively, the audiotapes of the visits could be coded using a relational control method approach, rooted in relational communication theory. This method examines the exchange of paired sequential messages over time as the basic unit of analysis. Hence, each message is treated as both

a response to the preceding message and a stimulus for the message that follows (Rogers & Farace, 1975).

Patient-Provider Communication and Patient Satisfaction

This study examined the association between medical and psychosocial talk and patient satisfaction immediately after the office visit.   Only one communication behavior had a consistent significant negative effect on patient satisfaction: provider medical information giving during the encounter. The reason for this cannot be explained. However, an overload of information, especially if given too quickly (e.g., due to time constraints) or at a level that the patient does not understand, may result in the patient feeling confused and dissatisfied. Openness to the patient's agenda and willingness to negotiate options may facilitate good communication and convey an understanding of patient preferences and values regarding health. Patients in this study may have felt that they could not ask questions or that their provider did not listen to what they tried to say. Alternatively, this finding may be a function of unmet patient expectations. Once again, a qualitative approach to inquiry, specifically narrative analysis, would give voice to patients and help to elucidate the underpinnings of their (dis)satisfaction with provider medical information giving. Patient satisfaction was not predicted from patient or provider psychosocial questioning or information giving, patient medical questioning or information giving, or from provider medical questioning.

The data suggest an indirect link between provider perception of difficulty and patient (dis)satisfaction in addition to the direct link that has been reported previously (Hahn et al. 1996). The more "difficult" or frustrating a patient is, the more medical

information they receive during the visit. However, this study indicates that the more

medical information given to patients during the encounter, the less satisfied they are

with their care. This offers one possible explanation as to why "difficult" patients report

lower levels of satisfaction, since dissatisfaction has been shown to be associated with a

"high-control" style of provider communication (e.g., domination of the encounter and/or

disregard of the patient's agenda) (Buller & Buller, 1987; Cecil & Killeen, 1997; Di Blasi

et al., 2001; Flocke et al., 2002; Roter et al., 1997). Future research should explore the

potential mediating effect of provider medical information giving on the association

between provider perception of difficulty and patient satisfaction.

Provider communication, especially when measured immediately after the

encounter, is widely believed to have the most direct impact on patient satisfaction

whereas satisfaction ratings 2 weeks and 3 months after the consultation are related to

medical outcome, such as health status (Jackson et al., 2001). However, satisfaction

ratings may reflect something other than the verbal communication and affective

behaviors examined in this study. With the exception of provider medical information

giving ($r = -.30$, $p \leq .001$), all of the other communication variables demonstrated a weak

(or no) bivariate association with satisfaction ($r = -.05$ to $.17$, $p > .05$) *vis a vis* generally

high patient satisfaction ratings. This suggests that patient-provider communication,

especially psychosocial discussion, may not be necessary for patients to be content with

the office visit. If this is the case, then this observation challenges Roter et al. (1988)

who found patients were most satisfied with medical encounters that entailed a lot of

psychosocial talk. High levels of patient satisfaction are a common finding in

satisfaction research and may reflect a ceiling effect of various satisfaction instruments. Patients may also have a tendency to give higher ratings because they are uncomfortable being critical of the person who is responsible for their health care. Yet, it has been posited that satisfaction may more often reflect attitudes (e.g., "they are doing the best they can", or "well, it's not really their job to do" [Williams, Coyle, and Healy, 1998, p. 1358]) and should not be taken to indicate that patients have had or are having good experiences in relation to a particular service.

Multilevel Modeling

The study unequivocally underscores the *importance of context* (grouping of variables) when examining phenomenon of interest to health researchers. Hierarchical linear modeling is a multivariate technique that was theoretically, statistically, and empirically justified for use in this study. Traditional statistical techniques including ordinary least squares regression analysis are not suitable for clustered data with correlated errors, largely because they violate the assumption of independence. Unfortunately, these methods are often inappropriately used in nursing research. In standard regression analysis, the resulting standard errors are smaller than they should be and thereby increase the chance of committing a Type I error (Luke, 2004). This risk is poignantly demonstrated in this study, as many of the significant OLS findings were not replicated once the nested structure of the data was taken into account. Multilevel modeling provided an improved, honest, and substantially different estimate of the

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associations between patient depressive symptoms, provider perception of difficulty, patient-provider communication, and patient satisfaction.

Single level statistical techniques can provide a lot of precision over inferences. However, they limit the ability to evaluate contextual effects. One of the benefits of multilevel modeling is its ability to partition the variance and covariance components among levels (i.e., decomposing the covariation among a set of encounter-level variables [e.g. patient satisfaction] into *within* provider and *between* provider components) (Raudenbush & Bryk, 2002). In this study multilevel modeling identified significant differences between providers (e.g., distributions of DDPRQ scores, effect (slope) of BDI-II scores on patient satisfaction) and within providers (e.g., DDPRQ and patient satisfaction scores) that would not have been detected in a single level analysis. Furthermore, modeling allowed for an improved estimation of effects by estimating separate regression equations for each individual provider. This study was not sufficiently powered to examine the effect of level-2 variables (e.g., provider gender, age, ethnicity, years in professional practice, etc.) on level-1 data (e.g., DDPRQ scores, patient-provider communication, or patient satisfaction). A significantly larger number of groups (providers) would be required to test level-2 estimates.

Hierarchical modeling has one additional significant advantage over traditional statistical methods: its ability to evaluate cross-level effects. However, this study was not sufficiently powered to examine for cross-level interactions. Such analyses would be based on the total number of level-2 units (i.e., providers) rather than on the total sample size. Eleven providers (groups) participated in this study. Kreft and De Leeuw (1998)

discuss studies indicating that at least 30 groups and 30 observations within each group may be needed to detect cross-level interactions. They conclude that "sufficient power… can be obtained when groups are not too small, and the number of groups is larger than 20" (p. 126). Future research should examine for second-level effects as discussed above and for cross-level effects, such as between individual patient characteristics (e.g., gender, age, race, ethnicity, etc.) and provider characteristics (e.g., gender, age, type of provider, years in professional practice, attitude toward depression, etc.) on provider perception of difficulty, patient-provider communication, and patient satisfaction in a larger sample of patients and providers.

Significance to Clinical Practice

Consistent with previous research, this study suggests that primary care providers do not recognize patients' cues and are not responsive to patients' depressive symptoms during the medical encounter. Unequivocally, primary care providers are faced with multiple competing demands in the delivery of depression care. Patients and providers alike face the dilemma of deciding what to discuss during visits, particularly given the many issues that might arise in a primary care visit and the increasing pressure placed on providers to see more patients in less time.

It is important for providers to understand patients' goals and expectations for the visit in order to clarify their own role during the encounter. Without a mutual understanding of goals and expectations, the relationship may come to what has been defined as a dysfunctional standstill or "relationship default" (Roter & McNeilis, 2003).

One way for providers to understand their patients' goals and expectations for the visit is to use a pre-visit patient questionnaire. This may, however, entail a trade-off between conflicting provider goals: trying to improve their response to patient concerns while not significantly increasing the length (and subsequent cost) of the office visit (Hornberger, Thom, & MaCurdy, 1997). Regardless of the time constraints and financial barriers that create complexity and restrictions within care delivery, the role of the primary care provider is to provide comprehensive patient care.

Effective interpersonal communication is crucial to elicit patient concerns. It is also fundamental to establishing and preserving the patient-provider relationship. Primary care providers can be uncomfortable discussing depression with their patients and there is evidence that providers can exhibit increased anxiety during medical encounters that entail a lot of psychosocial talk (Roter et al., 1988). Balint groups can help providers to care for their depressed and/or "difficult" patients. Developed by psychoanalyst Michael Balint, these programs are designed to help general care providers deal with the psychological aspects of their patients' problems by incorporating psychological techniques into general practice (Balint, 1964). The focal point of the seminars is the quality of the patient-provider relationship and the provider's emotional response to his/her patient. Now with an international presence, the groups demonstrate how patients and providers constantly influence each other during the medical encounter. Balint groups help providers gain insight on how their emotional responses to patients impact the course and content of the medical visit, patient outcomes, future patient encounters and health care management, as well as patient and provider levels of

satisfaction. Primary care providers should also take advantage of continuing education offerings, patient-provider communication skills seminars and intensive training programs when available.

Any significant, enduring improvement in the overall treatment of depression by primary care providers will clearly require additional substantive changes in the structure of care delivery above and beyond improving providers' communication skills and receptiveness to depressed patients' needs. Individual clinicians and practice groups should explore local options for integrating mental health services into primary health care, as discussed in the U.S. Surgeon General's report on *The Integration of Mental Health Services and Primary Health Care* (DHHS, 2001). For example, one option is to have a mental health specialist on-site in the primary care provider's office to deliver care and to "bridge" primary and specialty mental health care. Another option may be to utilize case managers to screen patients for depression and to monitor their adherence to prescribed therapy and response to treatment.

This study also has important implications for educators. Graduating primary clinicians often feel ill equipped to deal with the complexities of mental illness in the course of routine practice. Primary care providers report little formal training in the diagnosis and treatment of depression and sparse guidance about what level of severity can be treated effectively in primary care vs. specialty mental health care (DHHS, 2001). There are also few training programs that emphasize the integration of mental health services and primary care (DHHS, 2001). Although many graduate nursing and medical school programs have adopted mental health coursework and communication skills

training into their primary care curricula, there are currently few incentives for educational institutions to step beyond existing training programs. Educators should work in concert with professional associations to develop a set of common core competencies specific to the provision of mental health services for all primary care clinicians.

Limitations

These findings must be interpreted in light of several limitations. A possible selection bias of providers and patients limits the generalizability of these findings to other provider and patient groups. Providers who responded to the initial recruitment letter and agreed to participate may have differed from the providers who chose not to participate. There was limited variation among subjects and a lack of racial and ethnic diversity among patients. All providers were Caucasian and saw patients in a fee-for-service setting in a single urban community.

The data collection and coding methodology impose some limitations. Although the BDI-II is the most widely used instrument for detecting depression symptoms, its reliability is affected by patients' interpretation of its emotional terms and their conception of depression (Kerr & Kerr, 2001). Although each subject was assured of the confidentiality of their survey responses and grip-seal return envelopes were distributed with each BDI-II, DDPRQ, and satisfaction survey, the possibility of a social desirability response set bias might have influenced subjects' responses in a desire to present a

favorable image. Patients and providers could have modified their normal interview behaviors because of the audio recording procedure (Hawthorne effect).

This study observed both the instrumental (cure oriented) and affective (care oriented) verbal communication behaviors that were displayed during the encounter. However, non-verbal behaviors, which are inherently a part of every social interaction and can often "speak louder than words", were not observed. Although the dyadic exchange during the encounter was measured by direct observation, verbal coding (RIAS) is a reliable *representation* of actual medical practice; one cannot read into a patient's head or know what a provider's intentions were when asking certain questions or making particular statements. Verbal coding, which is based on frequency counts, may not adequately reflect the total communication process.

The restricted range in sampling of cases limits interpretation of findings. The majority of patients reported experiencing minimal depressive symptoms, were highly satisfied with their visit, and were not perceived by their providers as very "difficult" patients. Furthermore, five of the eight verbal communication variable distributions were moderately skewed. Therefore, the sample data may not accurately reflect population estimates. The relationships among these variables could be much stronger than shown here.

The study design did not allow for the evaluation of verbal communication behaviors in relation to "how established" a patient was (i.e., length of the patient-provider relationship or number of previous encounters), recency of last office visit, whether the provider recognized a patient's depressive symptomatology, if there was a

past history or current diagnosis of depression in the patient record, if the patient was currently being treated for depression, or the presence of co-morbid psychiatric disorders. Lastly, conclusions drawn from this study are limited by its cross-sectional design, which precludes any inference of causation.

Direction for Future Research

This study supports large body of research indicating that depressed individuals are less satisfied with their medical care. The proposed model did not, however, explain the process or source(s) of depressed patients' dissatisfaction with care. Patient-provider communication, by itself, does not appear to be a contributing factor. Thus, an important priority for future research is to identify sources of satisfaction that are important to this vulnerable group. Methodological triangulation (e.g., using observation, patient interviews, and/or review of medical records) would help to elucidate this problem. In addition, prospective, longitudinal studies that observe patient-provider behaviors over time would help to discern the temporal relationship between these two variables. With the growing body of research demonstrating that patient satisfaction is related to improved patient outcomes, it is imperative that health care organizations and policy makers look beyond the financial incentives related to patient satisfaction and support research efforts to understand and enhance depressed patients' care experiences to improve their quality of life.

Incorporating a pre-visit interview or questionnaire designed to assess patients' expectations in future research will help to illuminate a potential link between health

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status, provider behavior, and satisfaction with care. Likewise, including historical information such patient medical and mental health history, medication use, and length of the patient-provider relationship in future analyses will enhance our understanding of the process of depressed patient care and may add insight to the patient and provider behaviors observed in this study.

This study did not fully examine the verbal or affective behaviors of third parties (such as second providers or accompanying family members) during the encounter. Although their presence did not appear to influence patient satisfaction, their impact on provider perception of difficulty or content of the consultation is not known. Thus, a potential area for future study includes exploring the contributions of other participants during the clinical encounter. Additionally, it would be interesting to examine the dynamics of the office visit by considering patient and third party as one unit (i.e., patient), and provider and second provider as one unit (i.e., provider).

A qualitative analysis of the data would to help disentangle the complexities and subtleties of patient-provider communication during the medical encounter. By more closely examining the verbal dyadic exchange, it would be possible to better understand the relationships of the patients and providers in this study. Therefore, it is important to listen to the audiotapes of the patient encounters in order to get a better idea exactly what was communicated during these visits as well as what that information might mean to each party. Communication patterns could be examined and providers' behaviors in response to patients' psychosocial talk, most notably indicators of depression and direct expressions of depression, could be explored. The dialogue could also be examined for

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various indicators of control during the exchange and would help to characterize the information gained when providers interrupt patients (or patients interrupt providers). In addition, this could help to define the communication strategies that move discourse during the clinical encounter toward (or away from) the traditional medical model approach to patient care.

Finally, an important next step is further analysis of this data to explore for possible interaction effects among the level-1 variables (e.g., What if the patient is depressed *and* angry? What if the patient is deemed a "difficult" patient *and* is assertive, or anxious, or attentive? Does provider medical information giving have the same impact on patient satisfaction if there is *also* a lot of provider reassurance, or laughing, or personal talk during the visit?). The abundant RIAS database provides vast opportunity for further examination.

Conclusions

This study demonstrated that depression is associated with increased provider-perceived difficulty in the patient-provider relationship. Providers do not appear, however, to respond in a predictable way to their depressed patients nor significantly change their interviewing style according to the severity of depressive symptoms. There is significantly more provider medical information given during encounters with "difficult" patients and this behavior has a negative influence on patient satisfaction. In addition, findings indicate that patient-provider communication, by itself, does not appear to be a source of depressed patients' oft-reported dissatisfaction with medical care. The

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sources of and processes contributing to depressed patients' satisfaction remain poorly understood.

Primary care providers are in a position to take a leadership role in improving the quality of life of their patients with depression. Additional analyses of data from this study and others will be needed to further understand the core processes and structures of primary care practice in relation to the diagnosis and management of depression, their effect on patient outcomes, and to uncover opportunities for enhancing the effectiveness of depression care in primary care.

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Appendixes

Appendix A: IRB Approval Letters

USF

Lorraine M. Novosel

UNIVERSITY OF
SOUTH FLORIDA

January 25, 2005

Dear Ms. Novosel:

Your new protocol (**IRB #103075**) entitled, **"Depression and Patient-Provider Communication"** including your Adult Informed Consent Form with the Consent for Audiotaping Form (for patients and third parties) and your Adult Informed Consent Form with the Consent for Audiotaping Form (for providers) was reviewed under expedited review category numbers six and seven (6,7). Having made any required revisions, the approval period for your protocol including your Adult Informed Consent Forms with your Consent for Audiotaping Forms (for patients/third parties and providers) is shown on the stamp below. This information shall be presented to the Institutional Review Board-02 at its next convened meeting on February 18, 2005.

You should take special note of the following:

- Approval is for up to a twelve-month period, *after date of initial review.* A Research Progress Report to request renewed approval must be submitted to this office by the submission deadline in the eleventh month of this approval period. A final report must be submitted if the study was never initiated, or you or the sponsor closed the study.
- **Unless the requirement has been waived by the IRB, documentation of informed consent/assent should be obtained on copies of the attached stamped informed consent/assent document. Please note the form is valid only during the period stamped on the informed consent/assent document.**
- *Based on the new HIPAA Privacy Rule, if the study involves generating, collecting, using, or disclosing 'protected health information' the subject must be given an appropriately approved Authorization form prior to enrolling them into your research study. If the study involves review of medical charts only, please ensure that you have a Waiver of HIPAA Authorization granted by the Privacy Board, prior to commencing the study.*
- Any changes in the above referenced study may not be initiated without IRB approval except in the event of a life-threatening situation where there has not been sufficient time to obtain IRB approval.
- All changes in the protocol or informed consent must be reported to the IRB.
- If there are any adverse events, the Chairperson of the IRB must be notified immediately in writing.
- **Research investigators are required to keep all research related materials, including all IRB correspondence for no less than three (3) years. If at the end of 3 years, the data is no longer needed it should be destroyed. However, if data are kept after 3 years of study completion, please report to the IRB how you will keep data confidential.**

If you have any questions regarding this matter, please do not hesitate to call Angie Reagan at (813) 974-5741 or myself at (813) 974-9343.

Sincerely,

[signature]

Paul G. Stiles, J.D., Ph.D.
Chairperson, IRB-02

PGS: amr

pc: Dr. Judith Karshmer
    FAO (Agency for Healthcare Research and Quality/DHHS)

IRB Approval
FWA 00001669
IRB Number: 103075
From 01-25-2005
Thru 01-24-2006

OFFICE OF RESEARCH • DIVISION OF RESEARCH COMPLIANCE
INSTITUTIONAL REVIEW BOARDS, FWA NO. 00001669
University of South Florida • 12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-5618

USF

UNIVERSITY OF
SOUTH FLORIDA

December 1, 2005

Lorraine M. Novosel

RE: **Approved** <u>Application for Continuing Review</u>
    IRB#: 103075
    Title: *Depression and Patient-Provider Communication*
    Start Approval Period: <u>November 30, 2005</u> to <u>November 29, 2006</u>

Dear Ms. Novosel:

On November 30, 2005, the Institutional Review Board (IRB) reviewed and **APPROVED** your <u>Application for Continuing Review</u> for the afore noted protocol. It was the determination of the IRB that your study qualified for expedited review based on the federal expedited category number six (6) and seven (7). Your Informed Consent Form with the Consent for Audiotaping Form (for Providers) and your Informed Consent Form with the Consent for Audiotaping Form (for Patients and Third Party Individuals) were also approved.

This approval also acknowledges the following: 1) Change in the funding source from AHRQ to American Academy of Nurse Practitioners Foundation, and 2) Increase in the total sample size from 120 subjects to 176 subjects. Approval is granted **for the period indicated above.**

Please note, if applicable, the **enclosed informed consent/assent documents are valid during the period indicated by the official, IRB-Approval stamp located on page one of the form.** Valid consent must be documented on a copy of the most recently IRB-approved consent form. Make copies from the enclosed original.

Please reference the above IRB protocol number in all correspondence regarding this protocol with the IRB or the Division of Research Compliance. In addition, we have enclosed an <u>Institutional Review Board (IRB) Quick Reference Guide</u> providing guidelines and resources to assist you in meeting your responsibilities in the conduct of human subjects research. Please read this brochure carefully. It is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to the Human Research Protections Program. If you have any questions regarding this matter, please call 813-974-9343.

Sincerely,

Paul G Stiles

Paul G. Stiles, J.D., Ph.D.
USF Institutional Review Board

Enclosure(s): (If applicable) IRB-Approved, Stamped Informed Consent/Assent Documents(s)
       <u>IRB Quick Reference Guide</u>
          OFFICE OF RESEARCH • DIVISION OF RESEARCH COMPLIANCE
          INSTITUTIONAL REVIEW BOARDS, FWA NO. 00001669
      University of South Florida • 12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
          (813) 974-5638 • FAX (813) 974-5618

Cc: Angie Reagan, USF IRB Professional Staff
    Dr. Judith Karshmer
    FAO [American Academy of Nurse Practitioners Research Foundation]

CR-AX-05-01

USF

UNIVERSITY OF
SOUTH FLORIDA

November 13, 2006

Lorranie M. Novosel

RE: **Expedited Approval** for Continuing Review
    IRB#: 103075
    Title: *Depression and Patient-Provider Communication*
    Study Approval Period: <u>November 8, 2006</u> to <u>November 7, 2007</u>

Dear Ms. Novosel:

On November 8, 2006, Institutional Review Board (IRB) reviewed and **APPROVED** the above protocol **for the period indicated above.** It was the determination of the IRB that your study qualified for expedited review based on the federal expedited category number 8c.

This approval also acknowledges the addition of Dr. Jason Beckstead as Faculty Advisor for this study.

Please note, if applicable, the **enclosed informed consent/assent documents are valid during the period indicated by the official, IRB-Approval stamp located on page one of the form.** Valid consent must be documented on a copy of the most recently IRB-approved consent form. Make copies from the enclosed original.

Please reference the above IRB protocol number in all correspondence regarding this protocol with the IRB or the Division of Research Integrity and Compliance. In addition, we have enclosed an <u>Institutional Review Board (IRB) Quick Reference Guide</u> providing guidelines and resources to assist you in meeting your responsibilities in the conduction of human participant research. Please read this guide carefully. It is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB.

OFFICE OF RESEARCH • DIVISION OF RESEARCH INTEGRITY & COMPLIANCE
INSTITUTIONAL REVIEW BOARDS, FWA NO. 00001669
University of South Florida • 12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-5618

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We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to the Human Research Protections Program. If you have any questions regarding this matter, please call 813-974-9343.

Sincerely,

Paul G. Stiles, J.D., Ph.D., Chairperson
USF Institutional Review Board

Enclosures: (If applicable) IRB-Approved, Stamped Informed Consent/Assent Documents(s)
IRB Quick Reference Guide

Cc: Angie Reagan, USF IRB Professional Staff
Dr. Jason Beckstead
FAO [American Academy of Nurse Practitioners Research Foundation]

SB-IRB-Approved-EXPEDITED-0601

Appendix B: Site Approval Letter

ANCHOR
HEALTH CENTERS

August 14, 2003

Lorraine M. Novosel, MSN,ARNP,CS
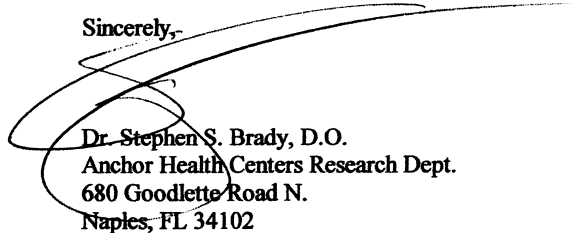
Dear Lorraine:

This letter is to formally support your effort as a University of South Florida doctoral
student to conduct research examining patient-provider communication during the
primary care encounter utilizing Anchor Health Center resources. Anchor Health Centers
is a multi-specialty multi-physician group practice in Naples, Florida whose mission is to
provide quality healthcare in a comprehensive, convenient, and cost-conscious manner.

Your proposed research is appropriate for the clients served by our Family Practice,
Internal Medicine, and Geriatric Divisions. After review and discussion of your research
plan, I acknowledge that our facilities can provide the resources you require to conduct
your research in adherence with HIPAA guidelines and will present minimal disruption to
the daily operations of our facilities. I have reviewed the minimal risks associated with
the research, and note Anchor Health Centers has adequate provisions to handle
appropriately any unanticipated or adverse events that may occur.

Please notify Deborah Chandler, Executive Director when IRB approval is secured and
maintain communication during your study with Karen Sandrick, Director of Clinical
Compliance & Quality Improvement.

Sincerely,

Dr. Stephen S. Brady, D.O.
Anchor Health Centers Research Dept.
680 Goodlette Road N.
Naples, FL 34102
Tel: (239) 262 4556 - Fax: (239) 262 1746

Appendix C: Provider Demographic Questionnaire

Provider Questionnaire

1. What is your gender?   [ ] Female   [ ] Male

2. What is your age? _____ years

3. What is your race?
   [ ] American Indian or Alaskan Native   [ ] Native Hawaiian or Pacific Islander
   [ ] Asian   [ ] White
   [ ] Black or African American

4. What is your ethnicity?
   [ ] Hispanic or Latino   [ ] Not Hispanic or Latino

5. What is your title?   [ ] MD   [ ] DO   [ ] ARNP   [ ] Other _____

6. How would you primarily define your clinical practice?
   [ ] Internal Medicine   [ ] Geriatrics
   [ ] Family Practice   [ ] Other _____

7. How many years have you been in practice?
   [ ] Less than one year   [ ] 6-10 years   [ ] Over 20 years
   [ ] 1-5 years   [ ] 11-20 years

8. On average, how many patients do you see in a typical day? _____ a week? _____

9. What percentage of your patient population would you consider "difficult"? _____%

10. On a scale of 1-to-10 (10 being "most proficient") please rate yourself on the following:

   Your *overall* personal knowledge about depression? _____

   Knowledge and ability to *diagnose* depression in your primary care patients? _____

   Knowledge and ability to *treat* depression in your primary care patients? _____

**11. On a scale of 1-to-10 (10 being "a great deal") to what extent do you feel the following
   <u>negatively affect</u> the care your patients receive for depression:**

   Time constraints and multiple competing demands on providers _____

   Patients don't provide you with enough information _____

   Lack of availability or access to qualified mental health specialists _____

   Patient reluctance to go to mental health specialists _____
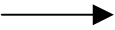
   Other _____

Appendix D: Patient Demographic Questionnaire

Patient Questionnaire
_____

For each question, <u>check</u> the one best answer <u>in the box</u> provided.

1. **Is this the <u>first time</u> you are seeing <u>this</u> doctor or nurse practitioner?**

　　　　[ ] Yes ⟶　　　If you answered 'yes', please **STOP**.
　　　　[ ] No 　　　　　You are not eligible to participate in this study.

2. **What is your gender?**　　[ ] Female　　[ ] Male

3. **What is your age?**　_____ years

4. **What is your race?**
　　　　[ ] American Indian or Alaska Native　　[ ] Native Hawaiian or Pacific Islander
　　　　[ ] Asian　　　　　　　　　　　　　　　[ ] White
　　　　[ ] Black or African American

5. **What is your ethnicity?**
　　　　[ ] Hispanic or Latino
　　　　[ ] Not Hispanic or Latino

6. **What is/was your life's major occupation?**
　　　　[ ] Professional　　　[ ] Laborer
　　　　[ ] Technical　　　　　[ ] Housewife
　　　　[ ] Clerical　　　　　　[ ] Other _____

7. **Are you retired?**　[ ] Yes　　　[ ] No

8. **What is your highest level of education?**
　　　　[ ] Grade School　　　[ ] College Degree
　　　　[ ] High School　　　　[ ] Graduate Degree
　　　　[ ] Technical School

9. **What is your current marital status?**
　　　　[ ] Married　　　　　[ ] Divorced
　　　　[ ] Single　　　　　　[ ] Widowed

10. **Why are you seeing the doctor or nurse practitioner today?**

　　　　_____

11. Did you ask for this appointment today or did your doctor tell you to come in today?
      [ ] I made this appointment
      [ ] My doctor wanted me to come in

12. Have you been told that you have a serious medical problem?
      [ ] No
      [ ] Yes, Please list your diagnosis:

_____

For the following questions, please <u>circle the number</u> that most closely reflects how you feel.

13. Do you think it is important for your doctor (or nurse practitioner) to address your emotional health needs?

Very Important	Somewhat Important	Unsure	Somewhat not Important	Not at all Important
1	2	3	4	5

14. To what extent do you think the amount of time you spend with your doctor (or nurse practitioner) affects the quality of care you receive?

Very Important	Somewhat Important	Unsure	Somewhat not Important	Not at all Important
1	2	3	4	5

Appendix E: BDI-II Invoice (Authorization)

THE PSYCHOLOGICAL CORPORATION®

A Harcourt Assessment Company

INVOICE

Invoice Number	Invoice Date	Account Number
0000510764	8/12/2003	343329
Page		Amount Due
1 of 1		0.00

Bill To:
LORRAINE M NOVOSEL

This invoice is for your information only. The invoice amount of $254.24 has been charged to a credit card and no payment is due at this time. Thank you for your order.

FEIN # 13-1188180

THE PSYCHOLOGICAL CORPORATION®

A Harcourt Assessment Company

INVOICE

Invoice Number	Invoice Date	Account Number
0000510764	8/12/2003	343329
Page		Amount Due
1 of 1		0.00

Send Orders To:	For Inquires Contact:	Return Address
The Psychological Corporation Customer Care Department PO Box 708906 San Antonio, TX 78270-8906	Phone: 1 800-872-1726 Fax: 1 800-232-1223 7:00am to 7:00pm Central Time	To Expedite Return Credit, Please Call Customer Care At The Number Shown For Inquiries

SF Order Number	Order Number 0000439073	Ship To Customer 343329 LORRAINE M NOVOSEL
Purchase Order LORRAINE	Program Code	

Product Code	Quantity	Description	Unit Price	Unit Discount Amount	Amount
0158018389	1	BECK DEPRESSION INVENT-II MNL	$35.00	17.5000	$17.50
0158018486	3	COMBO:BCK DPRSS INVII RCFM-100	$135.00	67.5000	$202.50

This invoice is for your information only. The invoice amount of $254.24 has been charged to a credit card and no payment is due at this time. Thank you for your order.

Merchandise Total	State & Local Sales Tax	Shipping & Handling	Amount Charged
$ 220.00	$ 14.39	$ 19.85	$254.24

0003

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Appendix F: BDI-II Information

The Beck Depression Inventory – II is a registered trademark of The Psychological Corporation, Harcourt Brace & Company, San Antonio, Texas. Purchasing information is available online at http://harcourtassessment.com

Appendix G: DDPRQ Authorization Letter

Date: 4/25/2003 13:44:46 EDT
From: SteveRoost@aol.com
To: lnovosel@hsc.usf.edu
Subject: Re: Request to use DDPRQ-10

Dear Ms Novosel: I am pleased that you wish to use the DDPRQ in your research.
You are free to do so. I only ask that you send me description of your study
when you begin it, and a summary report or reports when it is completed. I
have attached a copy of the DDPRQ manual in case you do not already have one.

Best regards,

Steve Hahn

Steven R. Hahn, MD
Professor of Clinical Medicine
Instructor in Psychiatry
Albert Einstein College of Medicine

Mail Address:
Ambulatory Care Pavilion
Jacobi Medical Center
1400 Pelham Parkway South
Bronx, 10461

Phone: (718) 918-4996
Fax: (718) 918-7701
Page   (917) 897-1885
Cell   (914) 441-6628
Home   (914) 747-8908

****
The HSC AntiVirus Server has scanned this email and attachment(s) for viruses. This
email was found not to be infected. As always, please insure that the antivirus
software on your local machine is kept up to date.
****

Attachment 1

Type: text/html
Filename: Unknown.html   Download
Encoding: quoted-printable

Attachment 2

Type: application/octet-stream
Filename: Ddprqman word.doc Download
Encoding: base64

Neomail does not empty the trash automatically. Please empty your trash before exiting.
Click here for Users'Manual

Appendix H: DDPRQ-10 Questionnaire

PRACTITIONER PERCEPTION QUESTIONNAIRE
(DDPRQ-10)

**Directions: CIRCLE the most appropriate number and <u>SEAL this form in the ENVELOPE</u> provided.
Please return the sealed envelope directly to the study investigator.**

	A Great Deal					**Not At All**
1. How much are you looking forward to this patient's next visit after seeing this patient today?	1	2	3	4	5	6
2. How "frustrating" do you find this patient?	1	2	3	4	5	6
3. How manipulative is this patient?	1	2	3	4	5	6
4. To what extent are you frustrated by this patient's vague complaints?	1	2	3	4	5	6
5. How self-destructive is this patient?	1	2	3	4	5	6
6. Do you find yourself secretly hoping that this patient will not return?	1	2	3	4	5	6
7. How at ease did you feel when you were with this patient today?	1	2	3	4	5	6
8. How time consuming is caring for this patient?	1	2	3	4	5	6
9. How enthusiastic do you feel about caring for this patient?	1	2	3	4	5	6
10. How difficult is it to communicate with this patient?	1	2	3	4	5	6

JOHNS HOPKINS
U N I V E R S I T Y

Bloomberg School of Public Health

Department of Health Policy and Management
624 N. Broadway. 7th Floor
Baltimore MD 21205-1996
410-955-2314 / Fax 410-955-7241

Faculty of Social and Behavioral Sciences
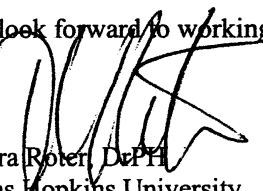
July 2, 2004

Lorraine Novosel, MSN, ARNP, CS
Dr. Judith Karshmer, Major Professor

Dear Ms. Novosel:

As we have discussed, I am happy to work with you on your dissertation research examining depression and patient-provider communication in primary care.

Our research team is willing to provide coding services of audio-recordings obtained as part of this project. Coding of medical exchanges using the Roter Interaction Analysis System (RIAS) provides standardized, reliable and detailed coding of doctor-patient communication, so that useful analysis of the data is possible. Our charge for coding is $75 per visit (for 130-140 visits), with the understanding that visits will be digitized and sent to us on CD.

We look forward to working with you.

Debra Roter DrPH
Johns Hopkins University
Bloomberg School of Public Health
427 N. Broadway
Baltimore, MD 21205

Appendix J: RIAS Information

The Roter Interaction Analysis System (RIAS) is copyright property of Dr. Debra Roter, The Johns Hopkins University, Baltimore, Maryland. Information is available online at http://www.rias.org

Appendix K: Patient Satisfaction Survey Authorization Letter

LORRAINE M. NOVOSEL

February 26, 2003

Klea D. Bertakis, MD
University of California
Davis Medical Center, Department of Family Practice
2221 Stockton Boulevard
Sacramento, CA 95817

Dear Dr. Bertakis:

I am a doctoral student at the University of South Florida College of Nursing in Tampa,
Florida. Last fall I wrote to you requesting a copy of your "visit-specific patient
satisfaction questionnaire" to review for possible use in my doctoral dissertation, which
will explore communication patterns during the patient-provider interaction, depressive
symptomatology, and patient satisfaction in primary care.

I would like to use your questionnaire for my dissertation. At this time I would like to
request written authorization from you, granting permission to reproduce and utilize the
questionnaire for my doctoral dissertation research.

Again, I appreciate your willingness to share your instrument.

Sincerely,

Lorraine Novosel

Lorraine M. Novosel, MSN,ARNP,RN,CS

*You are authorized to use the
questionnaire for your research.*

K Bertakis MD

3/4/03

Appendix L: Patient Satisfaction Survey

Patient Post-Visit Survey

The following statements are things people sometimes say about doctor visits (or nurse practitioner visits – "NP"). This is just asking for your opinion.   There are no right or wrong answers.

Based on your visit TODAY, please **CIRCLE** the answer that best reflects how you feel.

When you are finished, please **put this survey in the envelope**, **SEAL IT**, and **give it to the receptionist before you leave the office today**. Thank you.

		Strongly Agree	Agree	Unsure	Disagree	Strongly Disagree
1.	This was a very satisfying visit.	1	2	3	4	5
2.	My doctor/NP was very careful to check everything when examining me.	1	2	3	4	5
3.	My doctor/NP encouraged me to talk about my worries.	1	2	3	4	5
4.	My doctor/NP interrupted me.	1	2	3	4	5
5.	My doctor/NP is competent and well trained.	1	2	3	4	5
6.	My doctor/NP acted bored at times during my visit today.	1	2	3	4	5
7.	My doctor/NP MISSED important information that I gave him/her.	1	2	3	4	5
8.	My doctor/NP was NOT as thorough as he/she should have been.	1	2	3	4	5
9.	The medical problems I have had in the past were IGNORED during my visit today.	1	2	3	4	5
10.	My doctor/NP and I laughed and joked together during my visit.	1	2	3	4	5
11.	My doctor/NP asked if I understood the information he/she gave me about my condition or treatment.	1	2	3	4	5
12.	My doctor/NP has a good understanding of my past health history.	1	2	3	4	5

	Strongly Agree	Agree	Unsure	Disagree	Strongly Disagree
13. I have great confidence in my doctor/NP.	1	2	3	4	5
14. I'm very satisfied with the medical care I received.	1	2	3	4	5
15. My doctor/NP really seemed to care about me and my health problems.	1	2	3	4	5
16. My doctor/NP explained things in words I could understand.	1	2	3	4	5
17. I depend on my doctor/NP in order to feel better both physically and emotionally.	1	2	3	4	5
18. My doctor/NP told me exactly what he/she planned to do next in my treatment.	1	2	3	4	5
19. My doctor/NP seemed annoyed today.	1	2	3	4	5
20. My doctor/NP told me all I wanted to know about my condition and treatment.	1	2	3	4	5
21. My doctor/NP knew what health problems I wanted to talk about today.	1	2	3	4	5
22. My doctor/NP encouraged me to tell him/her everything I thought was important.	1	2	3	4	5
23. I count on my doctor/NP to set my mind at ease when I am worried.	1	2	3	4	5
24. My doctor/NP had a complete understanding of the things that are wrong with me.	1	2	3	4	5

	Strongly Agree	Agree	Unsure	Disagree	Strongly Disagree
25. My doctor/NP seemed to be in a hurry.	1	2	3	4	5
26. My doctor/NP DID NOT explain my medical problems to me.	1	2	3	4	5
27. I think all the health problems we discussed today were important.	1	2	3	4	5
28. I have health problems which should have been discussed today but were NOT.	1	2	3	4	5
29. My doctor/NP asked for my opinion when trying to decide on the best way to treat my problem.	1	2	3	4	5
30. My doctor/NP seemed nervous today.	1	2	3	4	5
31. My doctor/NP clearly explained why I should do the things he/she asked me to do.	1	2	3	4	5
32. My doctor/NP acted as though he/she were doing me a favor by talking to me.	1	2	3	4	5
33. My doctor/NP tells me if he/she is worried about my condition or how I am doing.	1	2	3	4	5
34. My doctor/NP answered all my questions.	1	2	3	4	5
35. My doctor/NP made me feel important.	1	2	3	4	5
36. My doctor/NP acted bossy and domineering at times during my visit today.	1	2	3	4	5

Thank you for your time.

Please put this survey in the envelope, SEAL IT, and give it to the receptionist before you leave.

Appendix M: Provider Recruitment Letter

[Date]

[Name]
[Address]
[City], [State] [zip]

Dear [Name]:

I have been practicing with Anchor Health Centers as an ARNP for a little over five years now. In addition, I have been pursuing my Ph.D. at the University of South Florida for the past three years. I am now actively working on my doctoral dissertation research and am recruiting and inviting Anchor providers and patients to participate in my study.

I am examining patients' depressive symptoms, the patient-provider relationship, and patient-provider communication during the primary care encounter and am recruiting Family Practice, Internal Medicine, and Geriatric providers and their "established" patients over 21 years of age. ***I have designed the study so that your time commitment would be minimal.*** I would ask you to (1) complete a one-page demographic questionnaire, (2) allow me to audiotape your office encounters with ten of your established patients, and (3) ask you to complete one 10-item questionnaire after seeing each patient that takes *less than one minute* to complete. This study has been has been approved by the University of South Florida Institutional Review Board.

Several Anchor providers participated in a similar pilot study I conducted last year and they reported that participation and data collection resulted in little, if any, interruption to their (or their staff members') daily routine. I would be on-site in your office for all data collection and would ask *only* that (1) your front office staff hand a flyer to each patient upon check-in, and (2) your nurse/medical assistant ask each patient if they are interested in hearing more about the study once they are brought to the exam room. ***Your staff would have no further involvement.***

I would like an opportunity to meet with you at your convenience to discuss the study in detail and answer any questions you may have. I will phone your office early next week and will ask to speak with your office manager [Name]. Successful completion of my dissertation is the final requirement I need to fulfill for my degree. Your participation and support of my research would be so greatly appreciated!

Sincerely,

Lorraine M. Novosel, PhD(c),ARNP,CS
[address]
[City], [State] [zip]
[phone] [pager]

DO YOU FEEL THERE IS ROOM FOR IMPROVEMENT
IN HOW DOCTORS AND NURSE PRACTITIONERS COMMUNICATE
WITH PATIENTS DURING OFFICE VISITS ?

You are invited to participate in a research study today looking at how doctors and nurse practitioners communicate with their patients.

This study is sponsored by the University of South Florida.

To thank you for your participation, you will receive a $10 gift certificate good for breakfast, lunch, or dinner at Mel's Diner!

YOUR PARTICIPATION IS:
* strictly *voluntary*
* will NOT affect the care you receive today
* will require nothing from you beyond today's office visit

Your privacy will be protected and there is **NO COST** to you for participating.

If you are interested in joining this study, please notify the Receptionist or your Nurse/Medical Assistant and details of the study will be provided in privacy once you are in the examination room. However, if you would like to know more about the study while you are here in the waiting room, please ask the Receptionist and she will give you information to read.

Your Participation Would be Greatly Appreciated !

Informed Consent (Provider)

Social and Behavioral Sciences
University of South Florida

IRB Approval
FWA 00001669
IRB Number 103075
From 01-25-2005
Thru 01-24-2006

Information for People Who Take Part in Research Studies

The following information is being presented to help you decide whether or not you want to take part in a minimal risk research study. Please read this carefully. If you do not understand anything, ask the person in charge of the study.

Title of Study: Patient-Provider Communication During the Primary Care Visit

Principal Investigator: Lorraine M. Novosel, PhD(c)

Study Location(s): Anchor Health Centers

Doctors and Nurse Practitioners are being asked to participate if they provider primary care services to adults.

General Information about the Research Study

The purpose of this research study is to examine how patients and primary healthcare providers talk to each other during office visits. How doctors (and nurse practitioners) talk with their patients is very important to the care patients receive. We are interested in finding ways to help doctors (and nurse practitioners) communicate better with their patients, but first we need to get a better understanding of how they talk to each other during routine medical office visits.

Plan of Study

You will be asked to complete a demographic questionnaire that takes less than one minute to complete. You will then be asked to allow the researcher to audiotape your medical office encounters with 10 established patients. After you are finished seeing each patient, you will be asked to complete a 10-item questionnaire that takes less than one minute to complete. Each participating patient subject will be screened for depressive symptoms as part of this study. After you have returned all completed questionnaires to the researcher, you will be notified of the results of each patients' depression screening.

Payment for Participation

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

Benefits of Being a Part of this Research Study

You will not directly benefit from participating in this study. However, by taking part in this study, you may increase our understanding of how patients and their doctors (or nurse practitioners) communicate with each other during routine medical office visits.
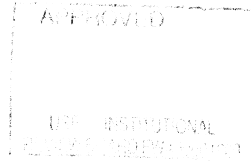
Risks of Being a Part of this Research Study

The risks in this study are minimal. It is possible that some of the questions you will be asked might make you feel a little uncomfortable inside. If you experience any distress during this study speak to the study investigator.

IRB Form: ICadult-LR-SBv17

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Confidentiality of Your Records

Your privacy and research records will be kept confidential to the extent of the law. Authorized research personnel, employees of the Department of Health and Human Services, and the USF Institutional Review Board and its staff, and any other individuals acting on behalf of USF, may inspect the records from this research project.

Information you as a healthcare provider provide will not be shared with your patients.

The results of this study may be published. However, the data obtained from you will be combined with data from others in the publication. The published results will not include your name or any other information that would personally identify you in any way.

Your name will NOT appear on any of the forms you will be asked to complete. A code number will be assigned to you once you enroll in the study, and this code number will be on the forms you complete. The study investigator is the ONLY person who will have access to any information that might identify you, and that information will be securely locked in a file cabinet to ensure your confidentiality. Your audiotapes will be listened to by other trained university researchers out-of-state for coding purposes. Your name will NOT be written on the tapes and no one will be given any other information that might identify you.

Volunteering to Be Part of this Research Study

Your decision to participate (or not to participate) in this research study is completely voluntary and will in no way affect your job status. You are free to participate in this research study or to withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive, if you stop taking part in the study.

Questions and Contacts

- If you have any questions about this research study, contact Lorraine Novosel at the University of South Florida College of Nursing at (813) 974-2191.

- If you have questions about your rights as a person who is taking part in a research study, you may contact the Division of Research Compliance of the University of South Florida at (813) 974-5638.
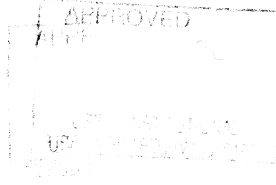
Consent to Take Part in This Research Study

By signing this form I agree that:

- I have fully read or have had read and explained to me this informed consent form describing this research project.

- I have had the opportunity to question one of the persons in charge of this research and have received satisfactory answers.

- I understand that I am being asked to participate in research. I understand the risks and benefits, and I freely give my consent to participate in the research project outlined in this form, under the conditions indicated in it.

- I have been given a signed copy of this informed consent form, which is mine to keep.

_____   _____   _____

Signature of Participant   Printed Name of Participant   Date

Investigator Statement

I have carefully explained to the subject the nature of the above research study. I hereby certify that to the best of my knowledge the subject signing this consent form understands the nature, demands, risks, and benefits involved in participating in this study.

_____   _____   _____

Signature of Investigator   Printed Name of Investigator   Date

Consent for Audiotaping (Provider)

I, _____, agree to be audiotaped as part of the research study "Patient-Provider Communication During the Primary Care Visit". I understand that the researcher in this study will audiotape my conversations with several of my patients in order to gain a better understanding of how patients and providers interact. I have been informed that other university researchers out-of-state will listen to the audiotapes for coding purposes only. At no other time will any other professionals or individuals have access to or listen to the audiotapes.

The audiotapes will be retained by the principal investigator and stored in a locked cabinet for a period of four calendar years after the study is officially closed with the University of South Florida Institutional Review Board. At that time the principal investigator will manually destroy the audio records.

_____   _____
Signature of Subject   Date

_____   _____
Signature of Investigator   Date

IRB Approval
FWA 00001669
IRB Number: 103075
From 01-25-2005
Thru 01-24-2006

Appendix P: Patient Consent Forms

Informed Consent (Patient and Third Party Individuals)

Social and Behavioral Sciences
University of South Florida

Information for People Who Take Part in Research Studies

The following information is being presented to help you decide whether or not you want to take part in a minimal risk research study. Please read this carefully. If you do not understand anything, ask the person in charge of the study.

Title of Study: Patient-Provider Communication During the Primary Care Visit

Principal Investigator: Lorraine M. Novosel, PhD(c)

Study Location(s): Anchor Health Centers

You are being asked to participate because you have a scheduled appointment with a primary healthcare provider today.

General Information about the Research Study

The purpose of this research study is to examine how patients and primary healthcare providers talk to each other during office visits. How doctors (and nurse practitioners) talk with their patients is very important to the care patients receive. We are interested in finding ways to help doctors (and nurse practitioners) communicate better with their patients, but first we need to get a better understanding of how they talk to each other during routine medical office visits.

Plan of Study

If you are the patient: You will only be asked to provide information during today's office visit. If you agree to participate, you will be asked to complete two (2) questionnaires while you sit back in the exam room waiting for your doctor (or nurse practitioner). It should take about 10 minutes for you to fill them out. The questionnaires ask general questions about you (such as your age, marital status, race, ethnicity, etc.) and about symptoms of depression. You will then see your doctor (or nurse practitioner) just like you planned and usually do, except today your visit will be tape-recorded. After you are done seeing your doctor (or nurse practitioner), you will be asked to fill out one more questionnaire before you leave the office today. It should take about 10-15 minutes to answer those questions. After you are finished, you will give the form to the receptionist as you leave the office.

If you are a third party individual who will be in the exam room with the patient: If you agree to participate, you will only be asked to allow your conversation with the patient and/or the doctor (or nurse practitioner) during today's office visit to be tape-recorded.

Payment for Participation

You will not be paid for your participation in this study. However, if you are a patient or a third party individual and you agree to participate, you will receive a $10 gift certificate to a local restaurant. The gift certificate will be yours to keep if you withdraw from the study or if the investigator withdraws you from the study.

IRB Form: ICadult-LR-SBv17

IRB Approval
FWA 00001669
IRB Number: 103075
From 01-25-2005
Thru 01-24-2006

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Benefits of Being a Part of this Research Study

You will not directly benefit from participating in this study. However, by taking part in this study, you may increase our understanding of how patients and their doctors (or nurse practitioners) communicate with each other during routine medical office visits.

Risks of Being a Part of this Research Study

The risks in this study are minimal. It is possible that some of the questions you will be asked might make you feel a little uncomfortable inside. If you become distressed while participating in this study speak with your doctor, nurse practitioner, or the study investigator.

Confidentiality of Your Records

Your privacy and research records will be kept confidential to the extent of the law. Authorized research personnel, employees of the Department of Health and Human Services, and the USF Institutional Review Board and its staff, and any other individuals acting on behalf of USF may inspect the records from this research project.

Some of the questions you will be asked are commonly asked by healthcare providers to help them understand their patient's problems better. The information you provide today about symptoms of depression will be shared with your doctor (or nurse practitioner) since they are very important to your overall health and safety. Information you provide *after* you have seen your doctor (or nurse practitioner) will be shared with your doctor (or nurse practitioner) only as part of a total summary of all patient responses and only after the entire study is completed and only if the provider requests a summary. In this event, your confidentiality will be maintained and there will be *no specific information* given in the summary that could identify you. Since your interaction with your doctor (or nurse practitioner) will be audio recorded, you should try not to mention names of other people you know to protect their identities.

Information healthcare providers provide will not be shared with their patients.

The results of this study may be published. However, the data obtained from you will be combined with data from others in the publication. The published results will not include your name or any other information that would personally identify you in any way.

Your name will NOT appear on any of the forms you will be asked to complete. A code number will be assigned to you once you enroll in the study, and this code number will be on the forms you complete. The study investigator is the ONLY person who will have access to any information that might identify you, and that information will be securely locked in a file cabinet to ensure your confidentiality. Your tape will be listened to by other trained university researchers out-of-state for coding purposes. Your name will NOT be written on the tape and no one will be given any other information that might identify you.
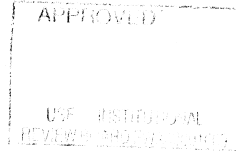
Volunteering to Be Part of this Research Study

Your decision to participate (or not participate) in this research study is completely voluntary and will in no way affect the medical services you receive or are entitled to receive. You are free to participate in this research study or to withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive, if you stop taking part in the study.

APPROVED

Questions and Contacts

- If you have any questions about this research study, contact Lorraine Novosel at the University of South Florida College of Nursing at (813) 974-2191.

- If you have questions about your rights as a person who is taking part in a research study, you may contact the Division of Research Compliance of the University of South Florida at (813) 974-5638.

Consent to Take Part in This Research Study

By signing this form I agree that:

- I have fully read or have had read and explained to me this informed consent form describing this research project.

- I have had the opportunity to question one of the persons in charge of this research and have received satisfactory answers.

- I understand that I am being asked to participate in research. I understand the risks and benefits, and I freely give my consent to participate in the research project outlined in this form, under the conditions indicated in it.

- I have been given a signed copy of this informed consent form, which is mine to keep.

_____   _____   _____

Signature of Participant   Printed Name of Participant   Date

Investigator Statement

I have carefully explained to the subject the nature of the above research study. I hereby certify that to the best of my knowledge the subject signing this consent form understands the nature, demands, risks, and benefits involved in participating in this study.

_____   _____   _____

Signature of Investigator   Printed Name of Investigator   Date

Consent for Audiotaping
(Patient and Third Party Individuals)

I, _____, agree to be audiotaped as part of the research study "Patient-Provider Communication During the Primary Care Visit". I understand that the researcher in this study will audiotape my conversation with the physician (or nurse practitioner) and/or the patient and/or third party individuals who will be present in the exam room today in order to gain a better understanding of how patients and providers interact. I have been informed that other university researchers out-of-state will listen to the audiotape for coding purposes only. At no other time will any other professionals or individuals have access to or listen to the audiotape.
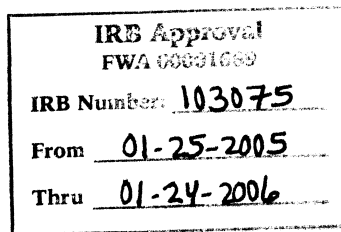
The audiotape will be retained by the principal investigator and stored in a locked cabinet for a period of four calendar years after the study is officially closed with the University of South Florida Institutional Review Board. At that time the principal investigator will manually destroy the audio record.

_____   _____

Signature of Subject   Date

_____   _____

Signature of Investigator   Date

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IRB Approval
FWA 00001669
IRB Number: 103075
From  01-25-2005
Thru  01-24-2006
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Appendix Q: HIPAA Authorization Form

ANCHOR HEALTH CENTERS

REQUEST FOR AUTHORIZATION TO RELEASE
PROTECTED HEALTH INFORMATION TO THIRD PARTIES

By signing this authorization, I authorize Anchor Health Centers (AHC) to use and/or disclose certain protected health information (PHI) about me to, or for, the party, or parties, listed below.

This authorization permits AHC to use or disclose the following individually identifiable health information to:

The Johns Hopkins University, Bloomberg School of Public Health, Department of Health Policy and Management

Person or entity to receive the information
624 North Broadway, Baltimore, Maryland 21205

Address

Specifically describe the information to be released, such as date(s) of service, level of detail to be released, origin of information, purpose of the disclosure etc. using the space below.

The audiotaped recording of today's office visit will be released to researchers at the

above entity for the purpose of having the audiotapes coded.

This authorization pertains only to the event of disclosure. If another disclosure is required, I understand that a second authorization must be signed. I understand that this authorization will expire at the end of the research study.

When my information is used or disclosed pursuant to this authorization, it may be subject to re-disclosure by the recipient and may no longer be protected by the federal HIPAA Privacy Rule. I have the right to revoke this authorization in writing except to the extent that AHC has acted in reliance upon this authorization. My written revocation must be submitted in writing using the reverse of this form.

Signed by: _____   _____
               Signature of Patient or Legal Guardian   Relationship to Patient

            _____   _____
               Print Patient's Name   Date

            _____
               Print Name of Legal Guardian

ANCHOR HEALTH CENTERS

REQUEST FOR AUTHORIZATION TO RELEASE
PROTECTED HEALTH INFORMATION TO THIRD PARTIES

By signing this revocation, I am reversing the authorization that I previously gave Anchor Health Centers (AHC) to use and/or disclose certain protected health information (PHI) about me to or for the party, or parties, listed on the front of this form.

I understand that disclosures made prior to this revocation were made with my authorization and that I must contact those entities who received this information directly if I do not want them to further use or disclose this information.

Signed by: _____   _____
        Signature of Patient or Legal Guardian   Relationship to Patient

        _____   _____
        Print Patient's Name   Date

        _____
        Print Name of Legal Guardian

Appendix R: Patient Notification of Withdrawal from Study

Date: _____

Your answers to the questions you gave earlier show that you have symptoms that

suggest you may be suffering severe depression.   Because this is so important to your

health and safety, you are no longer eligible to be a part of this study and are being

withdrawn immediately. Your doctor or nurse practitioner is being notified of your

results, and you will have your office visit with them as planned.

Thank you for your interest in participating in this study.

Score: _____

Appendix S: Provider Notification of Patient Withdrawal from Study

Date: _____

Dear Dr/ARNP _____:

Your patient, _____, was screened for depression today as part of the study examining patient-provider communication during the primary care visit. In the best interest of this patient's health and safety, it is important to notify you that they responded affirmatively to:

     [   ] Item #2: Pessimism / Hopelessness

     [   ] Item #9: Suicidal Thoughts or Wishes

The Beck Depression Inventory-II Manual indicates such individuals should be closely scrutinized for suicide potential (Beck, et al., 1996). The patient has been given oral and written notification of these findings. In the best interest of their health and safety, they are being withdrawn from the study at this time. The patient is aware that they are no longer eligible to participate in the study and that you are being notified of these results.

_____
Signature of Investigator

Beck, A.T., Steer, R.A., & Brown, G.K. (1996). *Beck Depression Inventory manual* (2nd ed.). San Antonio, TX: The Psychological Corporation.

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Date: _____

Your answers to the questions you gave earlier indicate:

_____ You have symptoms that *may* be due to mild depression. It is recommended that you discuss this or show this paper to your doctor or nurse practitioner. The office staff will be glad to schedule an appointment for you to discuss this in private.

_____ You have symptoms that are *commonly* due to depression. It is highly recommended that you discuss this or show this paper to your doctor or nurse practitioner *as soon as you can*. The office staff will be glad to schedule an appointment for you to discuss this in private.

_____ You have symptoms that suggest you may be suffering severe depression. It is *strongly recommended* that you discuss this or show this paper to your doctor or nurse practitioner *as soon as you can*. The office staff will be glad to schedule an appointment for you to discuss this in private.

Because this is so important to your health and safety, your doctor or nurse practitioner will be notified of this finding.

Score: _____

Date: _____

Dear Dr/ARNP _____:

Your patient, _____, was screened for depression

today as part of the study examining patient-provider communication during the primary

care visit. In the best interest of this patient's health and safety, it is important to notify

you that their score was _____. According to published scoring guidelines, this result

indicates:

      [   ] minimal depressive symptoms (0-13)
      [   ] mild depression (14-19)
      [   ] moderate depression (20-28)
      [   ] extreme depression (29-63)

The patient has been given oral and written notification of the score and it has been

recommended to them that they discuss their score with you as soon as possible. The

patient is aware that this score is being shared with you in the best interest of their health

and safety.

_____
Signature of Investigator

About the Author

Lorraine Marie Novosel, MSN, ARNP, CS, has been in the nursing profession for more than 20 years. She maintains dual national certification as an adult and gerontological nurse practitioner through the ANCC and currently practices internal medicine in Naples, Florida. She holds an A.A.S. from Youngstown State University (1983), B.S. in Nursing from Pennsylvania State University (1992), and M.S.N. majoring as an adult nurse practitioner from Kent State University (1995) where she received the Linnea Henderson Award for Academic Excellence. She will receive her Ph.D. in Nursing from the University of South Florida in 2007.

Ms. Novosel holds professional licensure in Florida, Ohio, and Pennsylvania and is a member of Phi Kappa Phi National Honor Society, Sigma Theta Tau International, American Academy of Nurse Practitioners, American Nurses Association, and the Florida Nurses Association. She is a published author and has presented her research at the state and national levels.