

APPROVAL SHEET

Title of Thesis: "Patterns of diagnostic care in nonspecific low back pain:
Relation to patient satisfaction and perceived health"

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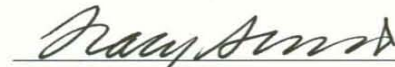
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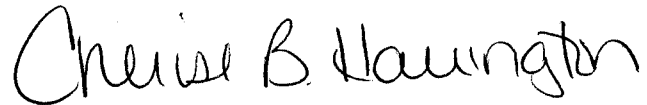
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A handwritten signature in black ink that reads "Cherise B. Harrington". The signature is written in a cursive, flowing style.

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ABSTRACT

Title of Thesis: “Patterns of diagnostic care in nonspecific low back pain:
Relation to patient satisfaction and perceived health”

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Research focused on identifying the best diagnostic approaches for nonspecific back pain establishes that physical and neurological exams are sufficient and that a secondary specialty evaluation does not add to the diagnosis or management of this condition. However, despite evidence based recommendations, these techniques continue to be used. Some reasons for this discrepancy are attributed to avoidance of litigation, financial incentives, adhering to patient wishes, improving perceived health, and overall patient satisfaction. The relationship between diagnostic procedures, patient satisfaction, and perceived health were investigated within the MHS health system, where the threat of litigation is minimal and financial incentives for such diagnostic procedures are absent. This study employed a cross-sectional design using health services and patient survey data on 15,789 individuals with nonspecific acute low back pain. Results indicate that when these secondary specialty procedures were used they either had no impact or were associated with lower levels of patient satisfaction and perceived health.

Running head: Diagnostic Procedures for Nonspecific LBP

Patterns of diagnostic care in nonspecific low back pain:
Relation to patient satisfaction and perceived health

Cherise B. Harrington, B.A.

Master's Thesis

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INTRODUCTION

Nonspecific back pain is a major public health problem and affects an estimated 49% to 70% of adults in a lifetime (Cherkin, Deyo, Loeser, Bush, & Waddell, 1994; Koes, van Tulder, & Thomas, 2006). Nonspecific back pain for which there is no known etiology (Frank et al., 1996; Koes et al., 2006) is the fifth most common reason for physician visits (Feuerstein, Marcus, & Huang, 2004; Hart, Deyo, & Cherkin, 1995; Patel & Ogle, 2000) and is the focus of considerable research aimed at epidemiology, diagnosis, and treatment. While research and clinical efforts continue to work toward identifying the most effective ways to diagnosis and treat back pain, back pain continues to represent a costly health problem physically, mentally, and financially. Previous research indicates that diagnostic procedures extending beyond the basic exploratory physical and neurological examination do not add any useful information in nonspecific low back pain (Bratton, 1999; Koes et al., 2006; Patel et al., 2000). While most cases of back pain are nonspecific and self-limiting, many diagnostic procedures and interventions shown to be inappropriate continue to be widely used in practice (Koes et al., 2006).

It has been suggested that higher levels of patient satisfaction with care and perceived health may help to account for the continued use of various diagnostic procedures and care that have been shown to have no utility in the management of low back pain (Curtis et al., 2000; Soloman, Bates, Panush, & Katz, 1997). Subjective measures of general health (i.e., perceived health) and adequacy of health care (i.e., patient satisfaction) are important to pain management because of their positive association with health-related behaviors including compliance and the use of medical services (Weiss, 1988).

Patient satisfaction is defined as attitudes about care or aspects of care (Jenkinson, Coulter, Bruster, Richards, & Chandola, 2002). Many factors can impact satisfaction and perceived health in patients with back pain including sociodemographic factors (Weiss, 1988), patient expectations (Hazard, Haugh, Green, & Jones, 1994), physician-patient relationship (Pulliam, Gatchel, & Robinson, 2003), physician communication skills (Deyo & Diehl, 1986), and confidence in physician abilities (Pulliam et al., 2003). Typically, the literature on patient satisfaction focuses on aspects of care, the care setting, and physician-specific factors. Although varying in condition and treatment type, several studies on treatment and clinical outcomes show that patterns of care are associated with measures of patient satisfaction and perceived health (Avidan, Drenger, & Ginosar, 2003; Thomas et al., 2006). Research also indicates that patient and physician agreement regarding the diagnosis and treatment plan is associated with higher levels of patient satisfaction and perceived health in cases of back pain (Staiger, Jarvik, & Deyo, 2005). Also, perceived health has been associated with variations in health services received (Goldstein, Siegel, & Boyer, 1984) and appears not to be related to daily functioning or episode duration (Van den Hoogen, Koes, Van Ejik, Bouter, & Deville, 1997). This area of literature suggests that previous measures of perceived health have been related to care received, and less affected by episodic fluctuations in health. Overall, research on back pain suggests that a relationship between patient satisfaction and perceived health may be related to type of service provided (Curtis et al., 2000; Soloman et al., 1997).

Ninety percent of all back pain is nonspecific, or has an unknown origin (Cherkin et al., 1994; Koes et al., 2006). Diagnosis of nonspecific back pain is based on the exclusion of specific pathophysiology (Koes et al., 2006). A medical visit for the

diagnosis of back pain usually consists of a general medical history, a back specific medical history, a physical examination, and a neurological examination (Bratton, 1999; Patel et al., 2000). From these examinations, a physician can determine if a case of low back pain has a specific or nonspecific etiology. In cases of specific low back pain, imaging or other specialty procedures are used to confirm the physician's diagnosis. In cases of nonspecific low back pain, these same procedures are not recommended because the physician has already determined that the pain cannot be related to any physical source. Despite this recommendation, the use of imaging and other specialty procedures are continually used, inspiring considerable debate on the usefulness of these procedures for nonspecific back pain. The association between the occurrence of non-specific back pain and abnormalities in X-rays and magnetic resonance imaging (MRI) is weak (Koes et al., 2006; van Tulder, Assendelft, Koes, & Bouter, 1997). The same abnormalities are present in individuals with and without back pain (Koes et al., 2006; Weiner, Young-Sin, Bonino, & Wang, 2006). In addition, many people with back pain show no abnormalities on imaging. These observations have lead many to recommend the restriction of imaging referrals for individuals with nonspecific back pain (Kendrick, Fielding, & Bentley, 2001; Koes et al., 2006). However, despite the research questioning its appropriateness, high technology or specialty consultations continue to be used with nonspecific low back pain. In addition, a population health study of outpatient care for nonspecific back pain in the U.S. observed that these procedures actually increased in the years from 1987 to 1997 (Feuerstein et al., 2004). Reasons for the continued use despite evidence to the contrary may be attributed to the avoidance of litigation and the expectation among providers that their use improves patient satisfaction (Feuerstein et al., 2004; Little et al., 1998). In

most cases, an imaging diagnostic examination is conducted to confirm a physician's hypothesis about the nature of the problem in specific back pain cases. These procedures should not be used nor are they useful as exploratory measures, and thus are inappropriate for cases of nonspecific back pain. However, lay knowledge of imaging and other specialty techniques within the general population may contribute to an individual's expectation of care, and ultimately ratings of patient satisfaction. For example, patients who believe that they are not receiving the best available care may have lower levels of patient satisfaction and may be more likely to seek litigation. The continued use of these approaches is further complicated by the fact that the evaluation of back pain lacks definitive diagnostic procedures (Kerr et al., 2001). Evidence-based clinical practice guidelines attempt to correct this problem and other similar problems in the diagnosis and management of acute low back pain (Bratton, 1999).

The Department of Defense (DoD) with TRICARE developed and implemented clinical practice guidelines (CPGs) for acute low back pain (LBP) (Cretin, Farley, & Dolter, 2001). Among the evidence-based recommendations, these guidelines restrict the use of high technology and specialty evaluations for nonspecific acute low back pain (Cretin et al., 2001). A previous study has shown that adherence to the guideline is generally associated with enhanced patient satisfaction, better self-reported health status, increased function, and lower health care cost (Feuerstein, Hartzell, Rogers, & Marcus, 2006). Additionally, when compliance increased outcomes were more favorable (Feuerstein, Hartzell et al., 2006). This work highlighted the observation that the factors that impact physician adherence to clinical guidelines are unknown. The U.S. DoD health care system represents a unique health care system to investigate patterns of care

and outcomes because the fear of litigation and financial incentives for the use of such procedures are absent from the care process. Also, there is presumed equal access to care across participants within the system.

Given the evidence that supports the restriction of specialty and high technology evaluations in nonspecific back pain guidelines, the question remains why such evaluations continue to be part of care for these cases? By directly comparing differences between individuals who received these diagnostic procedures and those who did not, it is possible to determine whether differences in patient satisfaction and perceived health may help to account for the use of such procedures. The present study investigates the relationship among the use of MRI, X-rays, multiple diagnostic procedures, blood work, and specialist consults with patient satisfaction and perceived health, within a health care system where clinical practice guidelines that do not recommend the use of these procedures are expected to be implemented.

HYPOTHESES

1. Receiving a non-guideline supported diagnostic procedure will be associated with higher levels of patient satisfaction compared to the no-evaluation group accounting for pain condition severity.
2. Receiving a non-guideline supported diagnostic procedure will be associated with higher levels of perceived health compared to the no-evaluation group accounting for pain condition severity.

The rationale for these hypotheses is based on the premise the more care one receives the more positive they will feel about their health and care.

A model was developed to represent the hypothesized relation between diagnostic care and patient satisfaction and perceived health (see Figure 1). The model depicts the non-recommended pathway of the use of exploratory/confirmatory procedures for nonspecific low back pain. It also includes factors suggested in the literature that contribute to a physician's usage of these non-recommended procedures for nonspecific low back pain.

METHODS

Case Definition

The sample was extracted from the administrative databases maintained by the Department of Defense (DoD). Outpatient direct care visit records were obtained from the Standard Ambulatory Data Record (SADR). Outpatient purchased care visit records were obtained from the Health Care Service Record (HCSR). Both of these records were linked to a database containing information from the Health Care Survey of DOD Beneficiaries (see <http://www.TRICARE.osd.mil/survey/hcsurvey/> for more information), an annual healthcare satisfaction questionnaire that is sent to a random sample of military health services (MHS) beneficiaries four times a year for years 1998-2002.

Inclusion Criteria

Data were extracted from records of enrolled MHS beneficiaries aged 18 to 65 that completed a questionnaire (DUA 06-348 acquired January 2006). All enrollees were recipients of MHS healthcare services within the continental United States, between fiscal years 1998 and 2002. All claims for people who visited a provider for acute low back pain (LBP) were extracted. Diagnoses for low back pain were those included in the DOD/VA LBP Clinical Practice Guideline. These diagnoses included the following International Classification of Diseases, 9th Revision (ICD-9) codes: 307.89, 344.60, 355.0, 716.98, 729.0, 729.1, 720-724, 729.2, 732.0, 732.8, 733.00, 733.13, 846, 847.1, 847.2, 847.3, 847.4, and 847.9 (see Table 1 for descriptions).

Exclusion Criteria

A total of 17,983 cases of LBP were initially extracted for analysis. Cases were excluded from analysis if they did not meet criteria for a new case of low back pain or if there was evidence of a specific etiology to their back pain (i.e., as characterized by “red flags”). Diagnoses commonly associated with “red flags” in low back pain indicate the need for more specialized care (ICD-9 diagnosis codes of 720, 721, 355.0, 723.0, 724.4, 729.2, 732.0, 732.8, 344.60, and 733.13: see Table 1 for descriptions). After these exclusions, the total number of cases available for analysis was 15,789.

Care Received for LBP

This research examined all diagnostic related care delivered within 166 days (less than 6 months) from the initial visit because the existence of pain six months after the initial onset is characteristic of chronic or episodic pain (Bratton, 1999). Diagnostic services associated with LBP care during the 166 days were obtained from the provider specialty codes for office visits and Current Procedural Terminology (CPT) codes in each record. The provider specialty codes that described office visits for LBP were divided into 10 general categories (general practitioner, specialist, surgeon, chiropractor, anesthesiologist, mental health provider (psychologist, psychiatrist, social worker) physical therapist, and occupational therapist, miscellaneous, and unknown). This procedure was done based on the DoD Clinical practice guidelines that describe the type of care recommended during 166 days following an onset of back pain. CPT codes were classified into four service type categories Lab work, X-ray, MRI/CT, and specialty diagnostic test, based on the incidence of these type of services in cases of low back pain (Patel et al., 2000). The data were set up such that individuals received one of three types

of primary treatment for their nonspecific low back: medical visit only, medical visit with follow-up or medical visit with follow-up and physical therapy. The data were organized to assess the impact of receiving one of the four diagnostic procedures, multiple procedures, or no diagnostic evaluation in addition to a primary treatment.

Outcome Measures

Patient Satisfaction

Patient satisfaction data were obtained from the Health Care Survey database. The measure of patient satisfaction was comprised of 17 questions, which covers topics such as overall rating of the healthcare plan, problems receiving needed care, difficulties obtaining referrals to a specialist, treatment delays that hinder care, obtaining the help required, promptness of care, doctor's ability to listen and explain things clearly, and whether the doctor spends enough time with the patient (Feuerstein, Hartzell et al., 2006). Each variable was either measured on or converted to a scale of 1-10 (1=low satisfaction, 10=high satisfaction). The scores available for each case were then averaged to compute a satisfaction score. (For questions from survey year 2001 see Appendix A: Questions 17 – 45.)

Perceived General Health

Data regarding perceived general health also were obtained from the Health Care Survey of DOD Beneficiaries. The participant was asked to rate his/her health over the past 4 weeks. Responses were converted to a scale ranging from 1 –5 (1-2 = Fair/Poor, 3-5 = Good/Excellent). (For questions from survey year 2001 see Appendix A: Question 93.)

Functional Outcome

The health care provider assessed functional outcome at each visit using a disposition code as part of the outpatient direct care visit record (SADR: Standard Ambulatory Data Record database). Responses were dichotomized into either: (1) always released without limitations, or (2) released with work duty limitations, sick at home/quarters, immediate referral, or admitted at any visit during the treatment episode. The measure was used as a proxy for severity, because it was assumed that the more severe the back pain the greater the functional limitations (Gross & Battie, 2005).

Institutional Review Board (IRB) Approval/Human Use

This project received expedited review under IRB approval contract #C172HT for April 2006 through April 2007. All Human use guidelines were adhered. There was no personal identifiable information within the data extraction.

Data Analysis

Participant Characteristics:

Demographic data were assessed using Chi-Square analysis to accommodate the categorical characteristics of the variables. The sample was organized by type of diagnostic procedure received (Lab Work, N = 201, 1.3%; X-ray, N = 876, 5.5%; MRI, N = 708, 4.5%; specialist consultation, N = 185, 1.2%; multiple evaluations, N = 632, 4.0%; no specialty evaluation, N = 13187, 83.5%). The groups were then compared by demographic data including age, race, education level, marital status, and service.

Because of the large number of individuals in the no specialty evaluation group, a randomized sample was taken (N = 1000) from this group and used for analysis. Using

chi-square analysis, it was determined that the stratified sample was demographically representative of the full non-evaluation sample on all demographic variables except non-minority versus minority status ($\chi^2_{(2, N=10803)} = 6.30, p < .05$). The full sample had 78.5% non-minority and 21.5% minority. The stratified sample had 74.7% non-minority and 25.3% minority. It is estimated that the clinical relevance of the minority and non-minority representation is minimal due to the consistency between the relative racial make-ups of the groups. In addition, these demographic variables are accounted for in the logistic regression analysis.

Non-guideline recommended diagnostic procedures and outcome

Analysis of Variances (ANOVAs) were conducted to assess whether type of diagnostic procedure received differed on patient satisfaction and perceived health. Post hoc analyses for these data were run using Tukey HSD (Honestly Significant Difference).

Multivariate logistic regressions were conducted to determine whether receipt of a non-guideline diagnostic procedure was associated with patient satisfaction and/or perceived health. For this analysis, patient satisfaction and perceived health were dichotomized using a median split. Dichotomizing the variables was done for two reasons. First, an objective of this project was to establish a simple discrimination within patient satisfaction and perceived health using an arbitrary cut-off (i.e., median split). Second, the median split was used to make the information more easily interpretable for clinical application. Categorizing the outcome variables allowed for the identification of factors that contribute differentially to high and low levels of patient satisfaction and perceived health. The logistic regression analysis was used based on the goal of identifying the factors that impact patient satisfaction and perceived health. Evaluation

groups (Lab Work, X-ray, MRI, Specialist Consults, and Multiple Evaluations) for this analysis were compared to the No Secondary Evaluation Group. In the regression analysis demographic variables were entered first into the model and include age, gender, race, education, marital status, and service. The physician rated disability/function score was entered, as a proxy measure of severity, followed by the diagnostic procedures. The hierarchical entry method was conducted to account for demographic variables and severity, in order to assess the relationship between type of secondary diagnostic procedure received and patient satisfaction and perceived health. Data analysis was conducted using SPSS 12.0.1 (Chicago, IL).

RESULTS

Participant Characteristics:

Demographic data were analyzed. The sample was grouped by secondary diagnostic tests received (Lab work, X-ray, MRI, Specialist Diagnosis, Multiple evaluations, No Secondary Diagnostic Evaluations).

The diagnostic groups differed significantly with regard to age ($\chi^2_{(10, N=3602)} = 302.42, p < .001$), gender ($\chi^2_{(5, N=3602)} = 268.04, p < .001$), race ($\chi^2_{(5, N=2480)} = 34.64, p < .001$), education ($\chi^2_{(5, N=3551)} = 58.90, p < .001$), and type of service ($\chi^2_{(20, N=3602)} = 59.70, p < .001$). The groups were also significantly different on physician rating of disability/function ($\chi^2_{(5, N=3602)} = 178.67, p < .001$). The groups did not differ significantly on marital status ($\chi^2_{(5, N=1696)} = 10.00, p = .075$). The values are depicted in Table 2. These factors were accounted for in the logistic regression model.

Outcomes across diagnostic procedures

Patient Satisfaction

The ANOVA to assess univariate differences in patient satisfaction by non-guideline recommended diagnostic procedure showed a significant difference ($F_{(5, 2403)} = 3.92, p < .01$: See Figure 2). Post hoc analysis revealed that individuals who received X-rays ($M = 7.52$) had higher levels of satisfaction compared to the MRI and Multiple evaluation groups (TUKEY HSD: MRI, $M = 7.16, p < .05$, multiple evaluations, $M = 7.08, p < .01$). The group that did not receive any secondary specialty evaluation did not differ significantly on patient satisfaction compared to all other groups.

Perceived Health

The ANOVA used to assess univariate differences in perceived health by diagnostic procedures showed that the groups significantly differed ($F_{(5, 3125)} = 10.36, p < .001$: See Figure 3). Test of the assumption of homogeneity of variance was violated ($F_{(5, 3119)} = 2.69, p < .05$). Violation of this assumption may lead to an inflated F statistic. After reviewing the standard deviations for this sample, which ranged from .93 to 1.00, it is apparent that no substantive differences exist between the groups despite a significant Levene's test. The large sample size increases power and, therefore, increases power for the Levene's test of homogeneity of variance (Field, 2005). Post hoc analysis revealed that individuals who received a Specialist Consultation ($M = 2.99$) had lower levels of perceived health compared to the Lab Work Group, X-ray group, MRI group, and No Secondary Evaluation group (TUKEY HSD: Lab Work, $M = 3.32, p < .05$; X-ray, $M = 3.27, p < .05$; MRI, $M = 3.24, p < .05$; No Evaluation, $M = 3.13, p < .001$). The group that received no specialty diagnostic procedure ($M = 3.44$) had higher levels of perceived health compared to all specialty/high tech evaluation groups except Lab Work (TUKEY HSD: X-ray, $M = 3.27, p < .01$; MRI, $M = 3.24, p < .01$; Specialist Consultation, $M = 2.99, p < .001$; Multiple Evaluations, $M = 3.13, p < .001$).

Factors associated with use of non guideline diagnostic procedures

Multivariable logistic regressions were conducted to determine whether receipt of a non-guideline evaluation was associated with patient satisfaction and perceived health. The model included age, race, gender, education, marital status, service, function rating (severity proxy), and specific diagnostic procedure. To control for any influence associated with the diversity of demographic characteristics between the groups,

demographic characteristics were entered first into the regression model to account for their influence.

Patient Satisfaction

The analysis for patient satisfaction reveals several significant predictors. Compared to the group of individuals who did not receive any of these specialty diagnostic procedures, receiving a Specialist Consult ($OR = .676, p < .055, CI: 95\% = .453 - 1.008$) and receiving multiple evaluations ($OR = .727, p < .05, CI: 95\% = .561 - .943$) were significantly associated with lower levels of patient satisfaction when disability/severity was controlled. Some demographic characteristics also were associated with higher levels of patient satisfaction; increased age ($OR = 1.029, p < .001, CI: 95\% = 1.021 - 1.037$), being high school educated ($OR = 1.377, p = .001, CI: 95\% = 1.130 - 1.676$), and reporting high function ($OR = 1.544, p < .01, CI: 95\% = 1.157 - 2.061$); see values in Table 2 and Figure 2.

Perceived Health

The analysis of perceived health demonstrated several significant associations. Individuals receiving an MRI ($OR = .780, p < .05, CI: 95\% = .630 - .967$), specialist diagnostic workup ($OR = .506, p < .001, CI: 95\% = .506 - .349$), or multiple evaluations ($OR = .663, p < .001, CI: 95\% = .527 - .833$) were more likely to report a low rating of overall perceived health again accounting for disability.

There were also a number of demographic associations with perceived health. Age was significantly associated ($OR = .991, p < .05, CI: 95\% = .984 - .998$) in that younger age was associated of higher levels of perceived health. Race had a moderately significant association with perceived health, such that Non-Minorities were 1.2 times

more likely than minorities to report high levels of perceived health ($OR = 1.167, p = .056, CI: 95\% = .996 - 1.368$). Being high school educated was associated with lower levels of perceived health ($OR = .545, p < .001, CI: 95\% = .457 - .651$): See Table 3 and Figure 3.

DISCUSSION

The use of the non-recommended secondary diagnostic procedures was not related to higher levels of patient satisfaction or perceived health and in some cases was associated with poorer outcomes. The pattern was present even after accounting for functional severity of back pain. These findings support the existing literature that indicates no additive direct effect or indirect association with patient satisfaction or perceived health as indicated in the present study of these procedures (e.g., MRI, X-ray) in the management of nonspecific back pain. It is surprising that these procedures continue to be used and that use has even increased over a decade when efforts were initiated to reduce their use (Feuerstein et al., 2004). The motivation behind the use of these procedures in cases of nonspecific low back pain is still unclear. The literature suggests that physician determination of diagnostic procedure appropriateness is possibly heavily influenced by psychosocial factors including patient satisfaction and reassurance (Jenkinson et al., 2002; Little et al., 1998). However, the results of this study do not support a relationship between the use of these procedures and increased levels of patient satisfaction and perceived health.

The present findings are meaningful in the context of the health care system in which it was studied (i.e., Military health system). The military health system (MHS) is unique because it is assumed that fear of litigation, financial incentive, and overly responsive provider response to patient requests for inappropriate evaluations are either nonexistent or modest. While these diagnostic procedures were used infrequently, as compared to the non-MHS private fee for service health care (Weiner et al., 2006),

research is needed to determine the specific driving forces behind the use of imaging and specialty referrals for cases of nonspecific back pain in both MHS and civilian systems.

The literature consistently indicates that these secondary diagnostic procedures are not appropriate for cases of nonspecific back pain (Koes, 2006). Univariate analysis showed that for patient satisfaction, groups overall appeared satisfied with care. Further, individuals who did not receive additional diagnostic testing did not differ from the groups that received them. This finding may be a product of the population used in the analysis (i.e., Military). Another possibility is that an inverse relationship exists between patient satisfaction and patterns of care, where trait satisfaction with overall health care impacts the physician's decision to refer for additional services. Patient satisfaction controlling for severity using functional severity as a proxy, was actually lower among the group with multiple evaluations. Interestingly, receiving Lab work, X-ray or MRI did not impact these outcomes in comparison to the group who received no specialty evaluation at all. Univariate analysis for perceived health also demonstrated a relatively positive perception of health for all groups; however, the group who did not receive any additional non-recommended procedure had significantly higher levels of perceived health compared to all other groups except the Lab Work group. Unexpectedly, factoring in severity of function related to the back pain episode, lower levels of perceived health were associated with receipt of an MRI, Specialist consult, or multiple evaluations.

It is notable that the groups overall did significantly differ with respect to demographic characteristics. Perhaps most problematic is that the sub-sample of individuals taken from the full sample of those who did not received a secondary specialty evaluation were younger overall compared to the other evaluation groups. As

with race, gender, marital status, and education, age was entered in the logistic regression model to account for differences and confounder influence. The results from this study suggest that the use of these secondary diagnostic procedures is not related to better subjective or patient evaluations of health or care (See Figure 1 and Figure 2). The evidence based explanation for the use of these approaches must await further research.

The relatively infrequent use of these evaluation procedures within this health system is supported by the data. The data provide support for clinical practice guidelines as they relate to evaluations for nonspecific low back pain. Given the design of the present study the directionality of this relationship can not be determined. Actual prospective studies are needed to identify factors that trigger the use of these diagnostic tests and the outcomes of such tests in terms of other measures of processes of care and outcome in nonspecific low back pain.

It is important to note that clinical practice guidelines work from the premise that in most health care settings and with most illnesses, the more severe the case, the more services received. We attempted to account for severity by including the physician rating of disability/function as a proxy measure for severity. While there is no gold standard for severity of nonspecific back pain, other measures that may have been useful as well such a pain severity score were not available. However, the literature does acknowledge a complex relationship between pain severity and disability in low back pain (Gross et al., 2005). Because of the nature of the database (i.e., administrative data) we were limited in the range of variables we could consider which is a limitation of this study. Future research needs to measure other potential factors that could motivate use of these procedures in actual practice, such as provider expectations (Little et al., 1998),

patient distress (Feuerstein, Harrington, Lopez, & Haufler, 2006), pain severity, and patient expectations (Hazard et al., 1994; Verbeek, Sengers, Riemens, & Haafkens, 2004). We also were unable to determine if the assessment of satisfaction in this database was adequate to assess the association between patterns of care and impressions of care directly related to the nonspecific low back pain episode. The fact that the measures of satisfaction and perceived health were generic was a consequence of using the existing health care system database. In addition, measures not specific to the care for back pain also may have influenced the findings. It may be the case that these global measures were neither sensitive nor specific enough to investigate the association between back pain care and patient satisfaction or perceived health and merely reflects a perception of overall care in the system. In addition, these cases may have had other comorbid health problems which is common for individuals with nonspecific low back pain (Hagen, Svensen, Eriksen, Ihlebaek, & Ursin, 2006). However, given that the majority of these cases were between the ages of 19 and 50, and given that this was an initial pain complaint, the likelihood of comorbid illnesses is diminished (Gallagher, 2003). Future research should attempt to assess patient satisfaction with care directly related to diagnosis and management of nonspecific low back pain.

Despite limitations in the methodology of this study because of the use of the existing administrative data bases, the results provide further support for the restricted use of some specialty diagnostic procedures in the management of non specific low back pain. This study adds to the current literature base by suggesting that in addition to its limited influence on the management of nonspecific low back pain, the use of these non-recommended diagnostic procedures also do not impact measures of generic patient

satisfaction and overall general health in comparison to individuals who do not receive a non-guideline recommended diagnostic procedure. Within this sample, approximately 17% of the population received these evaluations. It remains unclear the motivations of physicians who recommend these procedures. This research highlights the continued need for investigations into the actual use of evidence-based practices in preventing, diagnosing, and treating cases of nonspecific back pain. It is only through such research that we can modify guidelines to consider actual processes in practice and improve their clinical validity, adherence, and ideally, patient outcomes.

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TABLES

Table 1. ICD-9 Codes Used for Data Extraction

International Classification of Diseases 9 th Revision (ICD-9)	
Back Pain Diagnosis codes	
307.89	Other pain disorder related to Psychological factors
344.60*	Cauda Equina Syndrome w/ Neurogenic Bladder
355.0*	Lesion of Sciatic Nerve
716.0	Other and unspecified arthropathies
720*	Ankylosing spondylitis and other inflammatory spondylopathies
721*	Spondylosis and other allied disorders
722	Intervertebral disc disorders
723*	Other disorders of cervical region
724	Other and unspecified disorders of the back
724.0	Spinal Stenosis, other than cervical
724.1	Pain in thoracic Spine
724.2	Lumbago
724.3	Sciatica
724.4*	Back pain with radiation, unspecified
729.0	Other disorders of soft tissue
729.1	Fibromyositis
729.2*	Neuralgia, radiculitis
732.0*	Osteochondropathies
732.8*	Other specified forms of osteochondropathy
733.00	Osteoporosis
733.13*	Pathologic fracture
846	Sprains & strains of sacroiliac region
847.1	Thoracic sprain
847.2	Lumbar sprain
847.3	Sprain of sacrum
847.4	Sprain of coccyx
847.9	Sprain of unspecified site of back

*Red Flag Diagnoses

Table 2. Participant Demographics by Diagnostic Procedure

	Lab Work 201(1.3%)	X-ray 876 (5.5%)	MRI 708 (4.5%)	Specialist Consultation 185 (1.2%)	Multiple Evaluations 632 (4.0%)	+No Specialty Evaluation 1000 (13187; 83.5%)
Age*						
19-35	29.4	14.4	17.5	16.8	15.3	32.2
36-50	40.3	29.8	49.7	48.1	41.0	48.1
51-65	30.3	55.8	32.8	35.1	43.7	21.2
Race*						
Non-Minority	80.6	83.3	86.3	76.7	83.5	74.7
Minority	19.4	16.7	13.7	23.3	16.5	25.3
Gender*						
Male	24.9	26.9	51.0	33.5	38.9	51.1
Female	75.1	73.1	49.0	66.5	61.1	48.9
Education*						
HS	32.2	34.0	21.3	31.5	30.5	21.1
College	67.8	66.0	78.7	68.5	69.5	78.9
Marital Status						
Married	86.0	85.1	84.1	81.7	87.2	79.6
Not-Married	14.0	14.9	15.9	18.3	12.8	20.4
Service*						
Army	28.4	29.2	30.1	29.2	30.4	33.4
Air Force	31.3	39.6	45.9	35.1	41.1	43.0
Navy	27.9	20.2	16.1	28.1	19.5	17.4
Marine	9.5	7.4	5.9	6.5	6.5	5.3
Other	3.0	3.5	2.0	1.1	2.5	.9

+1000 individuals were randomly sampled from the N = 13187 for analysis.

*Chi-Squared analysis demonstrated that all demographic variables except for marital status were significantly different among the evaluation groups; values expressed as percentages

Note: N's refer to treatment received excluding other Evaluations (Lab Work, X-ray, MRI, and Specialist Diagnostics).

Table 3. Factors Associated with Patient Satisfaction

Patient Satisfaction			
Variable	Odds	B	CI 95%
Age (Continuous)	1.029***	.029	1.021 – 1.037
Gender			
Male vs. Female	1.071	.069	.827 – 1.389
Race			
Non-Minority vs. Minority	.869	-.140	.726 - 1.041
Education			
High School vs. College	1.377**	.320	1.130 – 1.676
Marital Status			
Married vs. Not Married	1.219	.198	.939 – 1.583
Service Group			
Army	.916	-.087	.528 – 1.591
Air Force	.920	-.084	.533 – 1.585
Navy	.990	-.010	.564 – 1.737
Marine	.851	-.162	.455 – 1.592
Function (Severity Proxy: Continuous)	1.544**	.434	1.157 – 2.061
Diagnostic Procedure			
Lab Work vs. No Secondary Evaluation	.894	-.112	.596 – 1.342
X-ray vs. No Secondary Evaluation	.991	-.009	.772 – 1.273
MRI vs. No Secondary Evaluation	.918	-.085	.719 – 1.173
Specialist Consult vs. No Secondary Evaluation	.676	-.391	.453 – 1.008
Multiple vs. No Secondary Evaluation	.727**	-.319	.561 - .943

N = 2403: Note: * p < 0.05, ** p < 0.01, *** p < 0.001

Table 4. Factors Associated with Perceived Health

	Perceived Health		
Variable	Odds	B	CI 95%
Age (Continuous)	.991**	-.009	.984 - .998
Gender			
Male vs. Female	1.196	.179	.947 – 1.510
Race			
Non-Minority vs. Minority	1.167	.155	.996 – 1.368
Education			
High School vs. College	.545***	-.606	.457 – .651
Marital Status			
Married vs. Not Married	.894	-.112	.706 – 1.132
Service Group			
Army	.657	-.420	.385 – 1.121
Air Force	.754	-.282	.445 – 1.278
Navy	.826	-.191	.481 – 1.420
Marine	1.193	.177	.662 – 2.150
Function (Severity Proxy: Continuous)	1.078	.075	.855 – 1.360
Diagnostic Procedure			
Lab Work vs. No Secondary Evaluation	.916	-.088	.657 – 1.275
X-ray vs. No Secondary Evaluation	.920	-.083	.744 – 1.137
MRI vs. No Secondary Evaluation	.780**	-.248	.630 – .967
Specialist Consult vs. No Secondary Evaluation	.506***	-.681	.349 – .733
Multiple vs. No Secondary Evaluation	.663***	-.412	.527 - .833

N = 3125: Note: * p < 0.05, ** p < 0.01, *** p < 0.001

FIGURES

Figure 1. Factors Related to the Non-recommended Use of Diagnostic Procedures for Acute Nonspecific Low Back Pain

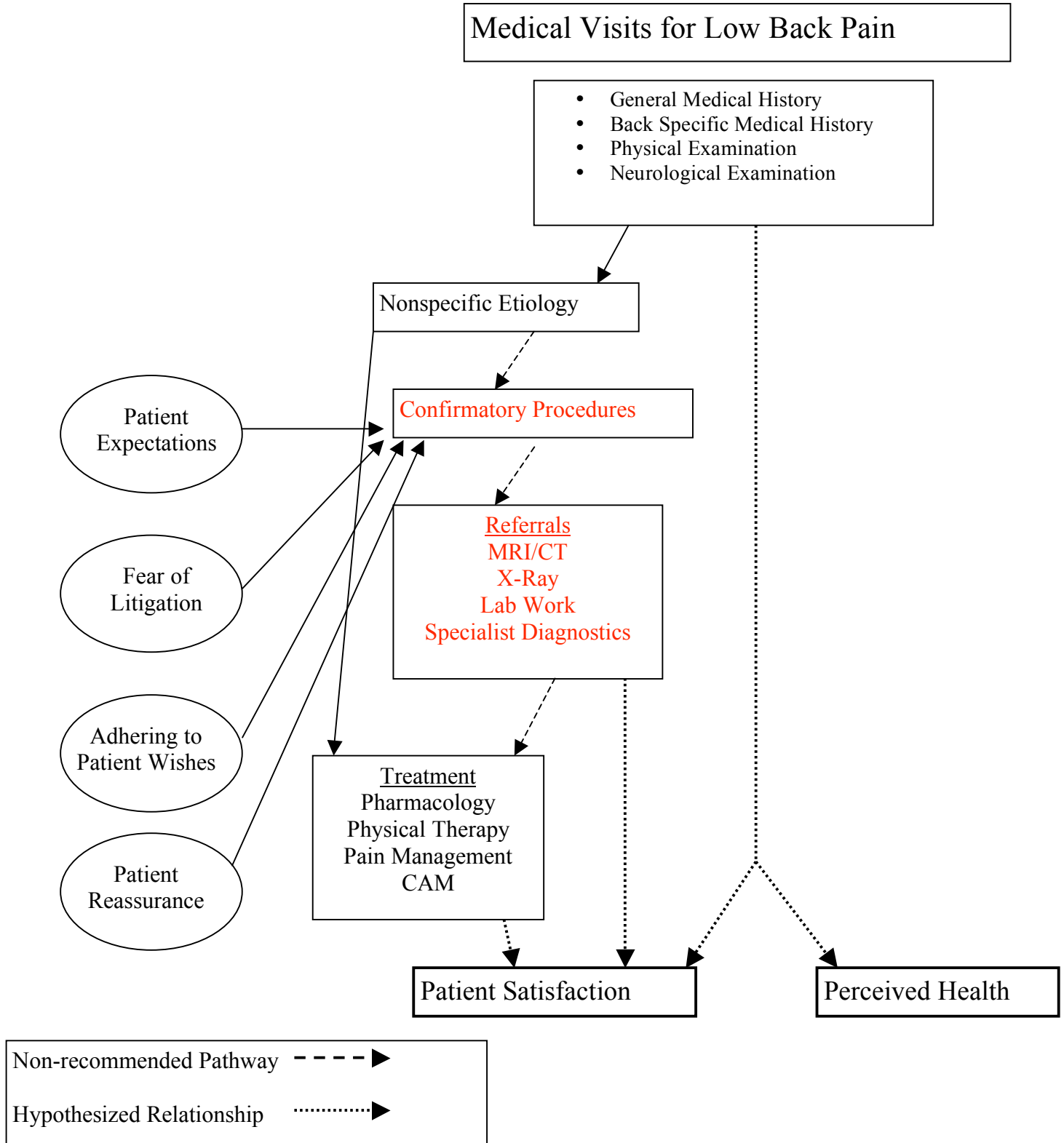


Figure 2. Patient Satisfaction & Diagnostic Procedure

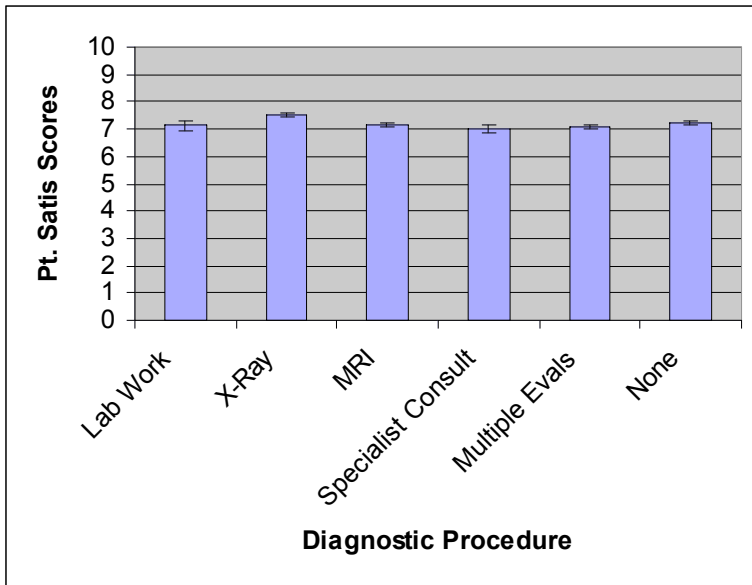
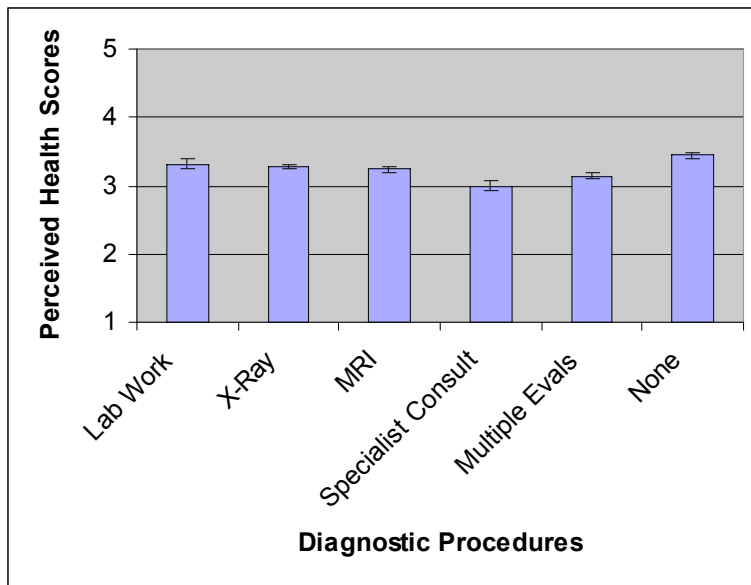


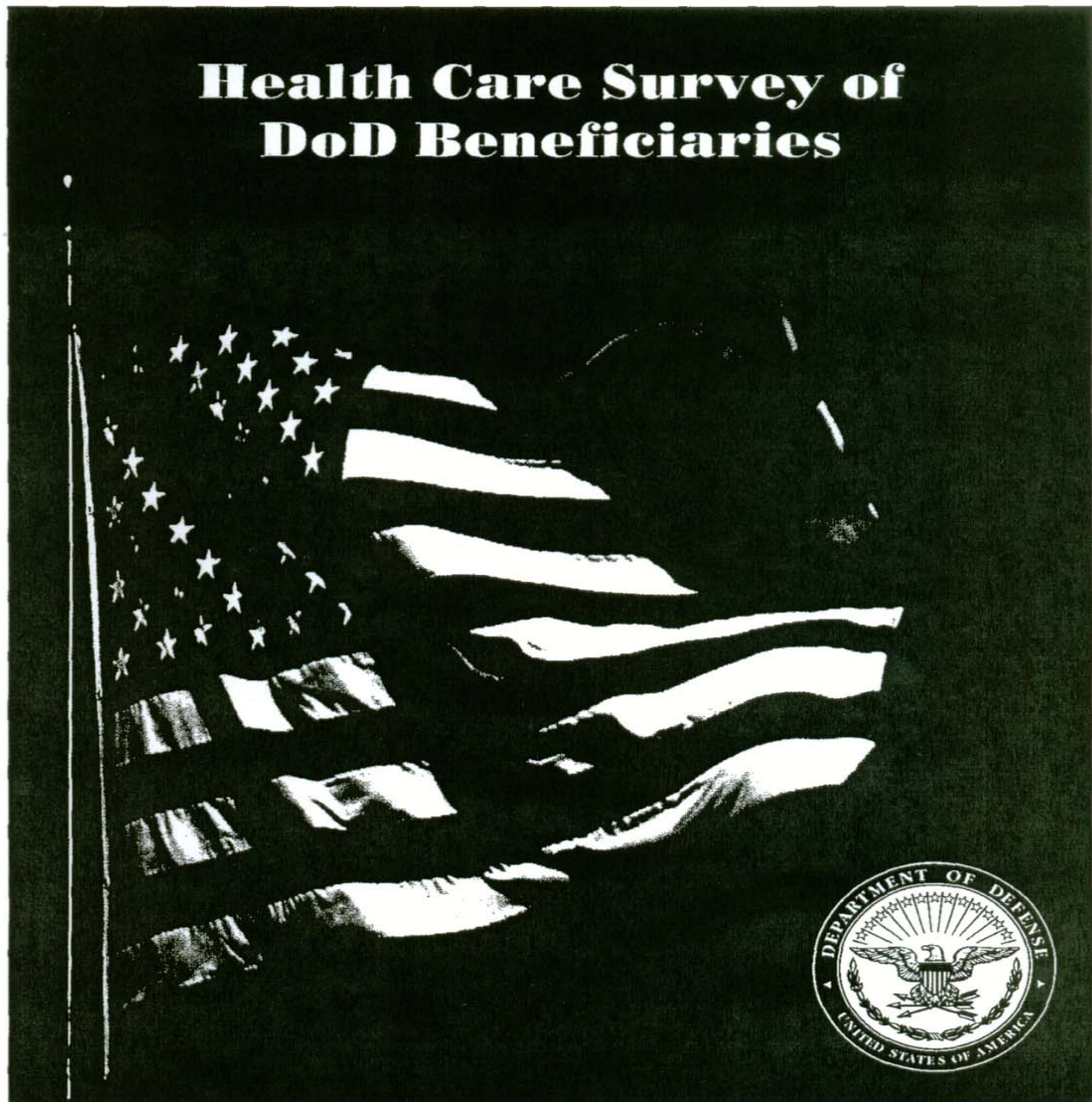
Figure 3. Perceived Health & Diagnostic Procedure



APPENDICES

- A. Health Care Survey of DoD Beneficiaries: Example of patient satisfaction and perceived health survey questions (January 2001 Survey)

RCS: DD-HA(A) 1942
Expires: 09/12/03



UHC Survey No. 00-0001
01007037

January 2001

16. Do you know your PCM's name?

- 1 Yes 2 No

H00012
See Note 5

-----GETTING HEALTHCARE FROM A SPECIALIST-----

When you answer the next questions, do not include dental visits.

17. **Specialists** are doctors like surgeons, heart doctors, allergy doctors, skin doctors, and others who specialize in one area of healthcare.

In the last 12 months, did you or a doctor or nurse think you needed to see a specialist?

- 1 Yes 2 No Go to Question 19

H00013
See Note 6

18. In the last 12 months, how much of a problem, if any, was it to get a referral to a specialist that you needed to see?

- 1 A big problem 3 Not a problem
2 A small problem -6 I didn't need to see a specialist in the last 12 months.

H00014
See Note 6

19. In the last 12 months, did you see a specialist?

- 1 Yes 2 No Go to Question 23

H00015
See Note 7

20. In the last 12 months, how many times did you go to a specialists for care for yourself?

- 1 None Go to Question 23
2 1
3 2
4 3
5 4
6 5 to 9
7 10 or more

S00C05
See Notes 7 and 8

21. We want to know your rating of the specialist you saw most often in the last 12 months, including a personal doctor if he or she was a specialist.

Use any number from 0 to 10 where 0 is the worst specialist possible, and 10 is the best specialist possible. How would you rate the specialist?

- 0 Worst specialist possible
 1
 2
 3
 4
 5
 6
 7
 8
 9
 10 Best specialist possible
-6 I didn't see a specialist in the last 12 months.

H00016
See Notes 7 and 8

22. In the last 12 months, was the specialist you saw most often the same doctor as your personal doctor?

- 1 Yes 2 No -6 I don't have a personal doctor or I didn't see a specialist in the last 12 months.

H00017

See Notes 7 and 8

-----CALLING DOCTORS' OFFICES-----

23. In the last 12 months, did you call a doctor's office or clinic during regular office hours to get help or advice for yourself?

- 1 Yes 2 No Go to Question 25

H00018

See Note 9

24. In the last 12 months, when you called during regular office hours, how often did you get the help or advice you needed?

- 1 Never 4 Always
2 Sometimes -6 I didn't call for help or advice during regular office hours in the last 12 months.
3 Usually

H00019

See Note 9

-----YOUR HEALTHCARE IN THE LAST 12 MONTHS-----

25. A health provider could be a general doctor, a specialist doctor, a nurse practitioner, a physician assistant, a nurse, or anyone else you would see for healthcare.

In the last 12 months, did you make any appointments with a doctor or other health provider for regular or routine healthcare?

- 1 Yes 2 No Go to Question 28

H00020

See Note 10

26. In the last 12 months, how often did you get an appointment for regular or routine healthcare as soon as you wanted?

- 1 Never 4 Always
2 Sometimes -6 I didn't need an appointment for regular or routine care in the last 12 months.
3 Usually

H00021

See Note 10

27. In the last 12 months, how many days did you usually have to wait between making an appointment for regular or routine care and actually seeing a provider?

- 1 Same day 6 15-30 days
2 1 day 7 31 days or longer
3 2-3 days 8 I tried but could not get an appointment.
4 4-7 days -6 I didn't need an appointment for regular or routine care in the last 12 months.
5 8-14 days

H00022

See Note 10

28. In the last 12 months, did you have an illness or injury that needed care right away from a doctor's office, clinic, or emergency room?

- 1 Yes 2 No Go to Question 31

H00023

See Note 11



00LL1C8I
01007040



29. In the last 12 months, when you needed care right away for an illness or injury, how often did you get care as soon as you wanted?

H00024

- 1 Never 3 Usually -6 I didn't need care right away for an illness or injury in last 12 months.
2 Sometimes 4 Always

See Note 11

30. In the last 12 months, how long did you usually have to wait between trying to get care and actually seeing a provider for an illness or injury?

H00025

- 1 Same day 5 4-7 days
2 1 day 6 8-14 days
3 2 days 7 15 days or longer
4 3 days -6 I didn't need care right away for an illness or injury in the last 12 months.

See Note 11

31. In the last 12 months, how many times did you go to an emergency room to get care for yourself?

H00026

- 1 None 2 1 3 2-3 4 4-6 5 More than 6

32. In the last 12 months (not counting times you went to an emergency room), how many times did you go to a doctor's office or clinic to get care for yourself?

H00027

- 1 None Go to Question 46 2 1 3 2 4 3 5 4 6 5 to 9 7 10 or more

See Note 12

33. In the last 12 months, how much of a problem, if any, was it to get the care you or a doctor believed necessary?

H00028

- 1 A big problem 2 A small problem 3 Not a problem -6 I had no visits in the last 12 months

See Note 12

34. In the last 12 months, how much of a problem, if any, were delays in healthcare while you waited for approval from your health plan?

H00029

- 1 A big problem 2 A small problem 3 Not a problem -6 I had no visits in the last 12 months.

See Note 12

35. In the last 12 months, how often did you wait in the doctor's office or clinic more than 15 minutes past your appointment time to see the person you went to see?

H00030

- 1 Never 2 Sometimes 3 Usually 4 Always -6 I had no visits in the last 12 months.

See Note 12

36. In the last 12 months, how often did office staff at a doctor's office or clinic treat you with courtesy and respect?

H00031

- 1 Never 2 Sometimes 3 Usually 4 Always -6 I had no visits in the last 12 months.

See Note 12

37. In the last 12 months, how often were office staff at a doctor's office or clinic as helpful as you thought they should be?

H00032

- 1 Never 2 Sometimes 3 Usually 4 Always -6 I had no visits in the last 12 months.

See Note 12

38. In the last 12 months, how often did doctors or other health providers listen carefully to you?

H00033

- 1 Never 2 Sometimes 3 Usually 4 Always -6 I had no visits in the last 12 months.

See Note 12

39. In the last 12 months, how often did doctors or other health providers explain things in a way you could understand?

- 1 Never 2 Sometimes 3 Usually 4 Always -6 I had no visits in the last 12 months.

H00034

See Note 12

40. In the last 12 months, how often did doctors or other health providers show respect for what you had to say?

- 1 Never 2 Sometimes 3 Usually 4 Always -6 I had no visits in the last 12 months.

H00035

See Note 12

41. In the last 12 months, how often did doctors or other health providers spend enough time with you?

- 1 Never 2 Sometimes 3 Usually 4 Always -6 I had no visits in the last 12 months.

H00036

See Note 12

42. We want to know how you, your doctors, and other health providers make decisions about your healthcare.

In the last 12 months, were any decisions made about your healthcare?

- 1 Yes 2 No Go to Question 45

S00C06

See Notes 12 and 13

43. In the last 12 months, how often were you involved as much as you wanted in these decisions about your healthcare?

- 1 Never 3 Usually -6 No decisions were made about my healthcare in the last 12 months.
2 Sometimes 4 Always

S00C07

See Notes 12 and 13

44. In the last 12 months, how much of a problem, if any, was it to get your doctors or other health providers to agree with you on the best way to manage your health conditions or problems?

- 1 A big problem 3 Not a problem
2 A small problem -6 No decisions were made about my healthcare in the last 12 months

S00C08

See Notes 12 and 13

45. We want to know your rating of all your healthcare in the last 12 months from all doctors and other health providers.

Use any number from 0 to 10 where 0 is the worst healthcare possible, and 10 is the best healthcare possible. How would you rate all your healthcare?

- 0 Worst healthcare possible
 1
 2
 3
 4
 5
 6
 7
 8
 9
 10 Best healthcare possible
-6 I had no visits in the last 12 months.

H00037

See Note 12



"DOLL1K8S"
01007048



87. Are you under age 40?

- 1 Yes **Go to Question 90** 2 No

H00073A

See Notes 3 (Part C) and 24

88. When was the last time your breasts were checked by mammography?

- 5 Within the last 12 months 3 3 years to 5 years ago 1 Never had a mammogram
4 1 to 2 years ago 2 More than 5 years ago

H00073B

See Note 23 (Part C)

89. When was the last time you had a breast exam by a healthcare professional?

- 5 Within the last 12 months 3 2 years to less than 5 years ago 1 Never had a breast exam
4 1 to 2 years ago 2 5 or more years ago

H00074

See Note 23 (Part C)

90. Have you been pregnant in the last 12 months or are you pregnant now?

- 1 Yes, I am currently pregnant **Go to Question 91**
2 No, I am not currently pregnant, but have been in the past 12 months **Go to Question 92**
3 No, I am not currently pregnant, and have not been pregnant in the past 12 months **Go to Question 93**

H00075

See Notes 23 (Part C) and 25

91. In what trimester is your pregnancy?

- 1 First trimester 2 Second trimester 3 Third trimester

H00076A

See Notes 23 (Part C) and 25

92. In which trimester did you first receive prenatal care?

- 4 First trimester 3 Second trimester 2 Third trimester 1 Did not receive prenatal care

H00076B

See Notes 23 (Part C) and 25

-----ABOUT YOU-----

93. In general, how would you rate your overall health now?

- 5 Excellent 4 Very Good 3 Good 2 Fair 1 Poor

H00077

94. Because of any impairment or health problem, do you need the help of other persons with your personal care needs, such as eating, dressing, or getting around the house?

- 1 Yes 2 No

S00C15

95. Because of any impairment or health problem, do you need help with your routine needs, such as everyday household chores, doing necessary business, shopping, or getting around for other purposes?

- 1 Yes 2 No

S00C16

96. Do you have a physical or medical condition that seriously interferes with your independence, participation in the community, or quality of life?

- 1 Yes 2 No

S00C17



00LL023.
01007027



B. Institutional Review Board Approval Form



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
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BETHESDA, MARYLAND 20814-4712
www.usuhs.mil



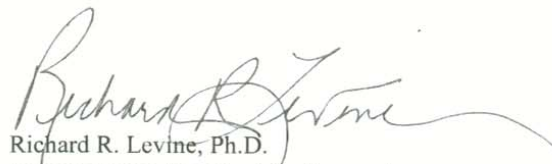
May 25, 2006

MEMORANDUM FOR MS. CHERISE B HARRINGTON, , MEDICAL AND CLINICAL PSYCHOLOGY

SUBJECT: IRB Exemption of Study (DoD Assurance No. P60001 and FWA # 00001628)

1. Your research protocol G172HT entitled, "DoD/VA Treatment Guidelines: Impacts of Patterns of Care on Patient Satisfaction, Functional and Health Outcomes and Healthcare Costs," was reviewed and approved for execution on May 25, 2006 as an EXEMPT human use study under the provisions of 32 CFR 219.101(b)(4).
2. An exempt study signifies that you will not be required to submit renewal applications for full Board review **as long as that portion of your project involving human subjects remains unchanged**. If during the course of your project, you intend to make changes which may significantly affect the human subjects involved, you should contact the IRB office for guidance prior to implementing these changes.
3. The aim of this study is to examine the influence of treatment type on outcomes for patients with lower back pain. The information for this study will be extracted from records that were transferred from a DOD/TriCare database under a data use agreement for Dr. Michael Feuerstein's approved protocol, CO72FT. The PI is a co-investigator on Dr. Feuerstein's study. The data extracted for this protocol contains no identifying information.
4. Any unanticipated problems related to your use of human subjects in this project must be promptly reported to the full Board through this office. This is required so that the IRB can institute or update protective measures for human subjects as necessary.
5. Exemption is granted with the understanding that no further changes or additions will be made to the procedures followed or investigators involved without the knowledge and approval of the IRB.
6. You are required to keep all research-related documents in a permanent file in an area designated for that purpose that is accessible to your chain of command and inspectors of official audit agencies. Your study and its documentation are subject to inspection at any time. You must maintain your records to facilitate such inspections. **You are to notify the USU IRB Office upon completion of the study.**
7. If you have questions regarding specific issues on your protocol, or questions of a more general nature concerning human subjects protection, please contact me at 301-295-3303/9534 or rlevine@usuhs.mil

Director, Research Administration
Chair, MPS


Richard R. Levine, Ph.D.
Assistant Vice-President for Research
and Executive Secretary, IRB