

ABSTRACT

Kristen N. Evans. PREDICTING COMPLIANCE IN VOICE THERAPY USING THE VOICE HANDICAP INDEX. (Under the direction of Kathleen T. Cox, Ph.D.) Department of Communication Sciences and Disorders, May 2010.

Research indicates that it is not uncommon for patients to cancel or postpone scheduled appointments for speech therapy designed to improve the voice, i.e., voice therapy. The purpose of this study is to determine if patient perceptions of their voice and vocal problems will predict which patients exhibit noncompliance with a voice therapy program. The present study also analyzed the effects of demographic variables (i.e. age, gender, occupation, etc.) on patient compliance with voice therapy.

Twenty-five patient participants were included in this study. Before undergoing voice therapy, these participants were asked to complete the Voice Handicap Index (VHI) in order to obtain a subjective measure of how their vocal “problems” have affected their everyday lives: physically, emotionally, and functionally. The VHI is a standardized patient attitude rating scale that has been shown to document similar issues with patient compliance. Prior to this study, however, variables including occupation, type of insurance coverage, and driving distance from the clinic were not included in those analyses. The individual questions of the VHI were also analyzed in comparison to adherence to therapy recommendations.

Descriptive analyses of the data revealed that the VHI scores and responses to individual VHI questions provided no practical significance in predicting patient compliance or noncompliance to voice therapy. In addition, analyses of demographic variables did not offer information that had practical significance regarding patient compliance or noncompliance to therapy.

PREDICTING COMPLIANCE IN VOICE THERAPY
USING THE VOICE HANDICAP INDEX

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the Faculty of the Department of Communication Sciences and Disorders

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of the Requirements for the Degree

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by

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DEDICATION

To Mom, Dad, and the rest of my family.

Thank you for believing in me.

I love you.

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for her guidance and support.

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Table of Contents

LIST OF TABLES	xi
I. REVIEW OF THE LITERATURE	
Introduction.....	1
Risk Factors for Voice Disorders.....	4
Voice Handicap Index.....	8
Time and Adherence to Voice Therapy	10
Rationale for the Study	10
II. METHODOLOGY	
Participants.....	12
Participant Selection	12
Operational Definitions.....	13
Procedures.....	13
Summary of Explanatory Variables.....	16
Data Analysis	17
III. DEPENDENT AND INDEPENDENT VARIABLES AND STATISTICAL TREATMENT OF THE DATA	
Participants' Perceptions of their Voices.....	18
Participants' Responses to VHI Questions	19
Demographic Information and Adherence to Therapy Recommendations	22
Age.....	23
Gender.....	23
Smoking and Reflux	24
Driving Status	24
Distance from the Clinic	25
Insurance and Occupation.....	25
Patient Attendance and Adherence to Therapy Recommendations.....	26
Diagnosis and Adherence	27
Evaluation Dates and Adherence	27
Pearson Correlations and T-tests	29

IV. DISCUSSION

Gender and Age	31
Attendance and Adherence to Voice Therapy	32
VHI Total Scores as Predictor of Adherence and Attendance.....	33
VHI Subtest Scores as Predictor of Adherence and Attendance	34
VHI Individual Questions and Adherence.....	34
Demographic Variables and Adherence	35
Limitations of the Study.....	38
Summary and Conclusions	40
Recommendations for Future Research.....	40
REFERENCES	42
APPENDIX A: VOICE HANDICAP INDEX	46
APPENDIX B: UMCIRB APPROVAL LETTER	48
APPENDIX C: APPROVED INFORMED CONSENT FORM	49
APPENDIX D: UMCIRB HIPPA APPROVAL FORM	53

LIST OF TABLES

1.	VHI Total Score and Subtest Scores.....	19
2.	Comparison of VHI Physical Questions and Adherence.....	20
3.	Comparison of VHI Emotional Questions and Adherence.....	21
4.	Comparison of VHI Functional Questions and Adherence	22
5.	Participant Age in Relation to Adherence	23
6.	Gender Compared with Adherence.....	23
7.	Smoking Status and Reflux Status in Relation to Adherence.....	24
8.	Participant Driving Status and Adherence to Therapy	24
9.	Driving Distance from Greenville in Comparison To Adherence	25
10.	Insurance and Occupation in Relation to Adherence.....	26
11.	Comparison of Diagnosis and Adherence.....	27
12.	Days Between Strobe and Perceptual Evaluation.....	28
13.	Days Between Referral and Stroboscopy Appointment	29
14.	P-values and Pearson Correlation	29

CHAPTER I

REVIEW OF LITERATURE

Speech-language therapy requires active patient participation which often involves practicing target objectives within therapy sessions and at home. Effectiveness of therapy is affected by patient compliance (Hopwood, Creech, Clark, Meagher and More, 2007) in that a patient may not make the desired progress without actively making lifestyle changes and practicing exercises as suggested by a speech-language pathologist (SLP). Patient noncompliance with therapy also impacts “cost-effectiveness” of healthcare (Hopwood et al., 2007; Portone, Johns, and Harper, 2006). Like with many other forms of therapy, patients often demonstrate noncompliance in voice therapy. The noncompliant behaviors may be contributed to factors such as resistance to change and may include a lack of follow-through outside the therapy session (Portone et al., 2008).

Voice therapy is a term that includes a vast array of treatments designed to improve the voice. Voice therapy may contain instruction in vocal hygiene education, phonatory retraining and medical management. Typically, an SLP administers voice therapy tasks including voice exercises, education, and counseling related to the voice disorder. An ENT or other physician oversees medical management which could include the behavioral treatment provided by the SLP, surgical treatments, and medical treatments (i.e., medications).

From the view of an SLP, voice therapy is a form of behavioral intervention that facilitates a patient changing behaviors that cause or contribute to a voice disorder. This may include attempting to improve phonatory functioning despite the etiology of the disorder (i.e., not all voice disorders are caused by inappropriate vocal behavior but can be improved with behavioral voice therapy). Positive therapeutic outcomes for patients have been acknowledged

in many studies regarding voice therapy (Behrman et al., 2008; Blood, 1994; Gordon, Pearson, Paton, & Montgomery, 1997; Gullivan-Murphy, Drinnan, O'Dwyer, Ridha, & Carding, 2006; Lancer, Syder, Jones, & Le Boutillier, 1988; MacKenzie, Millar, Wilson, Sellars, & Deary, 2001; McCrory, 2001; Murry & Woodson, 1992; Sellars, Carding, Deary, MacKenzie, & Wilson, 2002; S. Smith & Thyme, 1976; Speyer, Weineke, Hosseini, Kempen, Kersing, & Dejonckere, 2002; Verdolini-Marston, Burke, Lessac, Glaze, & Caldwell, 1995; Cooper, 1973; Boone, 1971; Brodnitz, 1967). Similar to other healthcare practices, voice therapy is dependent upon active patient participation (van Leer, Hapner, and Connor, 2008). Patient adherence has been shown to be vitally important to outcomes of voice therapy (Behrman, Rutledge, Hembree and Sheridan, 2008). Boone (1974) first attempted to determine the significance of patient adherence to voice therapy with his development of dismissal criteria for termination of therapy with a patient. Boone's criteria were created as an attempt to measure the success of voice therapy in hyperfunctional voice disorders. These dismissal criteria included: (1) improvement of the organic cause of the voice problem, (2) improvement of the patient's voice according to a panel of judges, (3) the patient's self-perception of voice improvement, (4) the patient's perception of no improvement or reduction in vocal performance, or (5) the patient ending the therapy without the SLP's permission. Boone further reported that these criteria may aid the clinician in his or her approach to therapy if he or she focuses on helping the patient attain one or all of the first three criteria and preventing the occurrence of the last two criteria. However, his ideas were not readily accepted because they did not take into consideration that a patient may need to be dismissed for reasons other than noncompliance, having a better feeling of his or her voice, or successfully completing therapy objectives (Henrikson, 1975). Henrikson (1975) argued that patients may experience life changes, such as moving or illness that affect their ability to

complete voice therapy.

The terms 'adherence' and 'compliance' are sometimes used interchangeably. However, the term 'adherence' has been favored by some researchers (Behrman, 2006, p. 216; Lutfey and Wishner, 1999; Miller and Rollnick, 2002) over 'compliance' because of its emphasis on a patient's personal decision to follow through with health-related advice and because it takes into account the multitude of factors that affect patient behavior. Shields, Brawley and Lindover (2005) also considered the term 'adherence' to promote active participation of the individual in making decisions regarding his or her own behavior.

Different views of patient compliance have been advocated over the years. In the 1970s, the term 'compliance' was promoted to take the place of 'recalcitrant' in reference to patients because it was deemed "less judgmental" than the latter (Behrman, 2006, p. 216). At this time, patient compliance was defined as how much a person's behavior correlated with the medical advice of a clinician (Behrman, 2006; Haynes et al., 1979) but some believed that compliance was not an appropriate term because of its exclusion of a patient's personal choice and capacity to change his or her lifestyle. Hapner et al. (2007) considered patient compliance to correlate with voice therapy completion. Their operational definition of voice therapy completion included three possible outcomes: if the patient had accomplished his or her therapeutic goals, if he or she was satisfied with the results of his or her voice, and if the clinician determined that no more progress would be made in therapy (thus, the patient was referred elsewhere). In order for a patient to be considered compliant to voice therapy, he or she must adhere to the recommendations made by an SLP and a laryngologist in addition to attending therapy sessions.

Considering the definition of compliance as advocated by Hapner et al. (2007), noncompliance refers to lack of both attendance and adherence to therapeutic recommendations.

In a study of compliance in HIV-positive patients, “failure to return,” or noncompliance, was defined as individuals who did not return for scheduled medical visits for at least 12 consecutive months. This included deceased patients (Arici, Ripamonti, Maggiolo, Rizzi, Finazzi et al., 2002, p. 52-53). Nonadherence refers to a patient’s unwillingness to follow through with recommendations for treatment. Sometimes, patients may attend scheduled medical sessions but may consistently fail to adhere to the advice given by a clinician; this is an example of patient nonadherence. Hapner, Johns and Portone-Maira (2007) determined that a patient had dropped out of voice therapy when the final therapy note indicated recommendations for further treatment and no additional treatment was recorded or if the patient was dismissed due to failure to follow through with treatment recommendations.

Patient perception of their own disorder may contribute to compliance and adherence, or lack thereof. Voice problems are not negligible nor are they “cosmetic” (Verdolini and Ramig, 2001, p. 37). However, many individuals who are diagnosed with voice disorders do not make the effort to attend voice therapy in order to alleviate the problem. Evidence exists that suggests patient adherence to voice therapy has a more significant impact on therapeutic outcomes than the selection of treatment approaches (Hapner et al., 2007). Despite the role that patient adherence to voice therapy plays in therapeutic outcomes, Portone et al. (2006) found in a study of patient adherence to voice therapy that many of the patients who were referred for voice therapy by their otolaryngologist do not follow through with the referral. In this study, 38% of patients did not comply with a laryngologist’s referral to return for a voice evaluation and 47% who attended a voice evaluation did not attend therapy.

Risk Factors for Voice Disorders: Indicators of Patient Nonadherence

Hapner et al. (2007) presented their first study on attempting to determine variables that

may contribute to patient dropout from voice therapy. In this study, factors including gender, age, race/ethnicity, diagnosis, total Voice Handicap Index (VHI) score, and results of the Consensus Auditory Perceptual Evaluation of Voice (CAPE-V) were assessed to determine their predictor value for patients' completion or withdrawal from voice therapy. Although Hapner et al. (2007) found a 65% voice therapy dropout rate altogether, none of the factors they studied for predictor value were strongly associated with dropout and, therefore, were not predictive of dropout. Suggestions for future research have involved assessing other possible predictor variables such as occupation, insurance coverage, and distance between a patient's home and a voice clinic (Hapner et al., 2007; Portone et al., 2008).

Few studies are available regarding the occupational impact of voice disorders (Herrington-Hall, Lee, Stemple, Niemi, Miller, and McHone, 1988; Roy, Merrill, Gray, and Smith, 2005; Roy, Merrill, Thibeault, Gray, and Smith, 2004). Results of the few studies that have been performed have not been consistent with one another. According to Roy et al. (2005), estimates of voice disorders have been variable (15-65%) in the general population. This wide range may be related to inconsistent sampling procedures. Variable research outcomes may also be due to the fact that a single definition for voice problems has not been agreed upon (Verdolini and Ramig, 2001).

Although not many studies relating to occupational risk factors for voice disorders are available, the existing literature suggests that some occupations are more associated with the development of voice disorders than others, particularly those occupations that require more vocal use (Roy et al., 2005). In the United States, 25% or more of working individuals depend upon their voice as a vital part of their job (Verdolini and Ramig, 2001). There is a high incidence of voice problems among teachers (Roy et al., 2004). A review of the literature by

Verdolini and Ramig (2001) indicated that ‘teacher’ constantly appears as the occupation of those individuals most likely to seek an ENT evaluation for a voice problem. Other frequently occurring occupations presenting to a voice clinic include: singers, counselors, social workers, lawyers, clergy, and keyboard operators. Approximately 40% of teachers in the United States suffer from hoarseness and about the same number indicate that teaching has negative consequences on the voice (Verdolini and Ramig, 2001; Smith et al., 1997). Roy et al (2004) discovered significant differences in the vocal health of teachers versus non-teachers; teachers were more likely to have experienced multiple voice symptoms and signs including hoarseness, discomfort and increased effort using voice; time and again, teachers ascribed these vocal symptoms to their occupation. Also, many indicated that these problems were affecting their work, causing them to have missed more days of work due to these symptoms. Many had considered changing jobs because of these problems (Roy et al, 2004). Although occupation often motivates a patient to seek medical assistance for voice problems, this risk factor for voice disorders has not been studied in terms of its effects on determining patient compliance with voice therapy.

Age may also be a risk factor for voice problems. Voice disorders commonly affect the older population. Using the Quality of Life questionnaire, Verdolini and Ramig (2001) found that elderly participants were “disproportionately affected” by voice disorders as compared to other participants in different age categories. This discrepancy may have been due to the current increase in average life expectancy, better documentation, and health insurance coverage (Herrington-Hall et al., 1988). A strong correlation between age and completion of voice therapy has not been found (Hapner et al., 2007; Portone et al., 2008). However, Portone et al. (2008) found in their study that the age group most likely to attend the first voice therapy session

was the 21-40 year old age group, and the least likely to attend were the 40-64 year olds.

Gender may play a role in an individual's development of a voice disorder. Voice pathologies in general appear more often in females than in males (Herrington-Hall et al., 1988). Psychogenic voice problems are an example of a voice disorder that is more likely to occur in females (Aronson, 1980; Cooper, 1973; Herrington-Hall et al., 1988). Some disorders such as cancer, leukoplakia, and hyperkeratosis have been shown to emerge more in males than in females. This information regarding gender may be partially due to the fact that women seem to be more concerned with health and more likely to seek medical attention than men (Cleary, Mechanic & Greenley, 1977; Hibbard & Pope, 1986; Nathanson, 1977; Herrington-Hall et al., 1988). Anatomical and physiological differences may also cause females more than males to seek medical assistance for voice disorders (Hapner et al., 2007). Gender has not been found to be a predictor of therapy completion or dropout (Hapner et al., 2007; Portone et al., 2008).

Noncompliance with voice therapy may be due to other issues such as financial barriers, change in patient perception of a problem, and inconvenience. According to Portone et al. (2006), the major reasons reported by patients in regards to their noncompliance or nonadherence to the recommendations for voice therapy included denial of insurance coverage, resolution of the problem, and distance from the clinic. Lack of insurance coverage was the chief reason that was reported. A patient's inability to drive or lack of transportation also affects his or her follow-through with therapy (Hapner et al., 2007; Mashima, Birkmire-Peters, Syms, Holtel, Burgess and Peters, 2003). Patients have also reported that a lack of confidence in the treatment was a reason for self-termination of therapy (Hapner et al. 2007). Hapner et al. (2007) coded patients according to their diagnosis of either hypofunctional voice disorder or hyperfunctional voice disorder, but they found no significant difference between these diagnostic categories for

the completion or dropout of voice therapy.

Voice Handicap Index

The Voice Handicap Index (VHI) is a perceptual assessment tool used to obtain a patient's perception of the effects of his or her voice disorder on three aspects of his or her personal life: physical, emotional and functional. The physical component addresses a patient's perception of discomfort and the voice, the emotional sub-scale is used to analyze the patient's emotions regarding the disorder, and the functional aspect evaluates how the disorder is affecting the patient's ability to perform daily tasks (Jacobson, Johnson, Grywalski, Silbergleit, Jacobson, Benninger et al., 1997). The instrument is composed of 30 items which are based on a five-point scale (0 is never, 1 is almost never, 2 is sometimes, 3 is almost always and 4 is always). The total VHI score may range from 0 to 120; 120 is considered to be most severe.

Jacobsen et al (1997) used the World Health Organization's definitions for "disability" and "handicap" when designing the Voice Handicap Index. They applied the definition for disability, which is "a restriction or lack of ability manifested in the performance of daily tasks" to a voice disability which would be a patient's inability to perform a certain vocal task (p. 66). Also, they believed that a voice handicap existed when a patient experienced "a social, economic, or environmental disadvantage" due to his voice disability. Hapner et al. (2007) discovered that the mean pretreatment VHI score for patients who dropped out of voice therapy was actually higher than those who completed it but that this difference was not significant. However, no study has attempted to analyze the use of the VHI subtest scores as predictors of patient adherence or compliance with voice therapy. In addition to demographic variables and patient health status, the present study will examine the significance of patients' scores on the physical, emotional and functional 10-item sub-scales of the Voice Handicap Index. The

present study will also assess whether individual questions on the VHI as well as combinations of questions will predict patient compliance/adherence to voice therapy. These questions will fall under one of the three categories previously mentioned, comprised of physical, functional and emotional items. Due to the evidence suggesting that increased vocal use is associated with occupational risk for voice problems (Roy et al. 2005); the present study will address the relationship between the functional items of the VHI and patient compliance/adherence. Understanding the reasons for patient noncompliance or nonadherence to voice therapy will aid SLPs in providing better healthcare for their voice patients (Portone et al., 2008). The ability to better determine who will adhere to voice therapy may enable clinicians to distribute their services among patients who will benefit most from these services, thus saving time and resources.

Other tools exist to measure patient perception of voice disorders. The World Health Organization has approved a perceptual assessment that consists of 28 items using the International Classification of Impairments, Disabilities, and Handicaps-2 Beta-1 Concept (WHO, 1997). According to Ma and Yiu (2001), this tool allows the patient to report her perception of her voice disorder as well as her “limitation” and “restricted participation” in daily voice activities (p. 511). Ma and Yiu’s (2001) study revealed that, using this perceptual assessment, a group of 40 dysphonic participants reported more severe voice problems, increased limitation in everyday activities and more restricted participation in everyday activities than 40 individuals in the control group. However, this study also showed that the patient’s perception as indicated by this tool was not positively correlated with the clinician’s perception or acoustic measures of the voice disorder. Therefore, the VHI was used for the purposes of this study.

Time and Adherence to Therapy

A recent study completed by Portone-Maira et al (2010) revealed that temporal variables may be indicators of patient dropout or adherence to voice therapy. These variables include: duration between referral by otolaryngologist and initial voice therapy evaluation, duration between voice evaluation and the first follow-up therapy session, the number of sessions attended, the number of cancellations, and the time from the initial to the final therapy session. This study was conducted via retrospective chart review. Results indicated that the mode for number of sessions of those who completed therapy was four sessions. Also, the researchers discovered that fewer days between the otolaryngologist's referral and the initial evaluation with the SLP predicted therapy completion.

Rationale for the Present Study

Many research studies about voice therapy have indicated that patient withdrawal from voice therapy has been a problem. The rate of patient dropout from voice therapy, as previously mentioned, is high and often causes frustration for voice therapists (Hapner et al., 2007). In addition, it negatively impacts costs to healthcare and research outcomes (Portone et al., 2006). Research in the past has attempted to identify predictor variables that may aid clinicians in better identifying patients that are most likely to drop out or be nonadherent to voice therapy. Current and future research regarding this matter should also look into the effects of demographic variables and patient perception on patient compliance and adherence to voice therapy.

This study seeks to discern the relationship between numerous personal variables and patient noncompliance and nonadherence to voice therapy. These variables include: age, gender, driving status, smoking status, diagnosis of acid reflux, diagnosis during voice evaluation, insurance type, occupation, distance from the clinic, and the number of days between the

stroboscopy appointment and the SLP's perceptual voice evaluation. Although no significant relationship was found to exist between the total VHI score and patient noncompliance in the previous study by Hapner et al. (2007), the present study seeks to examine if the sub-scale scores or ratings of individual questions of the VHI correlate with patient noncompliance.

This study aimed to address the following research questions:

- (1) Do VHI scores on individual question items aid in predicting compliance to therapy?
- (2) Do VHI subtest scores (emotional, functional, or physical) aid in predicting compliance to therapy?
- (3) Do personal variables (e.g., age, gender, occupation, etc.) aid in predicting compliance to therapy?
- (4) Does a combination of VHI scores (total and subtests) and personal variables better predict compliance to therapy?

The hypotheses for this study include:

- (1) VHI question items receiving less severe patient ratings (scores of 0, 1 or 2) will aid in predicting patient noncompliance to therapy.
- (2) The VHI subtest of Functional items will have the most predictive value on patient compliance to voice therapy.
- (3) Increased VHI total and subtest scores will aid in predicting those that are more likely to comply.
- (4) Personal variables of driving status, insurance type, and driving distance when paired with VHI overall and subtests scores will best aid in predicting patient compliance.

CHAPTER II

METHODOLOGY

Participants

Twenty-five adult patient-participants were recruited for the present study (6 male and 19 female). Participants were over the age of 18 years old. All participants were first-time patients seen at Eastern Carolina ENT (ECENT) or ECU Speech-Language and Hearing Clinic (ECUSLHC) in Greenville, North Carolina who voluntarily presented to the clinic. All patients over the age of 18 who presented for a first-time voice evaluation at ECENT or ECUSLHC were given the opportunity to participate. All participants whose data was used for this study had never before been diagnosed with a voice disorder nor have had a voice evaluation, and had never seen or used the Voice Handicap Index (Appendix A) prior to this study. Participants were identified only because they were scheduled for a voice evaluation. This means that they were referred from an outside source to evaluate for the presence of a voice disorder. Participants who were subsequently referred for voice therapy after the initial evaluation were followed over the course of their entire treatment in order for the researchers to measure compliance.

Selection of Participants

The participants were informed of this study when they presented to Eastern Carolina ENT or ECUSLHC for a voice evaluation for the first time. Patients interested in becoming participants of this study were required to complete an informed consent document (Appendix B) that was provided by the speech-language pathologist (SLP) or graduate student researcher. The data of those patients who were scheduled to return for an appointment for voice therapy was included in this study. Those who reported a history of voice disorders, received prior voice therapy, or had seen or used the Voice Handicap Index (VHI) before were eliminated from this

study. Patients were not excluded for any reason associated with age, gender, race, ethnicity, occupation, other co-morbid health issues, or smoking status.

Operational Definitions

No solitary definition for voice disorders has been determined (Verdolini and Ramig, 2001). For the purpose of this study, ***voice disorder*** is defined as a voice problem that has been diagnosed by an otorhinolaryngologist (ENT) and has been contributed to an organic, functional or neurological change in the voice that is negatively impacting a patient.

For the purposes of this study, ***voice therapy*** is defined as non-surgical intervention directed by an SLP that may and typically does include vocal exercises and techniques designed to decrease patient discomfort while attempting to increase appropriate use of the voice. Voice therapy may also include education to minimize harmful vocal habits. Typically, voice therapy is individualized to each patient.

The operational definitions for ***compliance*** and ***noncompliance*** for this study are similar to those reported by Hapner et al. (2007). ***Compliance*** is defined as regular attendance to scheduled voice therapy sessions as well as the adherence to voice therapy techniques that are recommended by the SLP. Therefore, 2 different types of compliance measurements have been collected (attendance and adherence). ***Noncompliance*** (or dropout) is considered to be: 1) failure to present for the first voice therapy session, 2) discontinuation of therapy without a clinician's consent, or 3) discontinuation of therapy due to failure to meet therapy objectives (to be determined by the SLPs).

Procedures

Prior to informing a patient of this study, the SLP determined if the patient met the age criteria for participation. Participants were informed that the purpose of this study is to analyze

the individual components of the Voice Handicap Index; however, the participants were not notified that the study will be assessing their compliance with voice therapy as this may have altered the participants' attendance to voice therapy, therefore distorting the data results. The VHI was sent to possible participants via mail. For possible participants who did not receive a VHI in the mail, the VHI was given prior to stroboscopy so they could document their personal perception of their voice before seeing their vocal folds.

Upon completion of participants' voice evaluation, the SLP and ENT determined if voice therapy was an appropriate treatment recommendation for this patient. Patients were seen by an ENT while on-site at ECENT. Patients at ECU were referred to an ENT at the completion of their voice evaluation with the SLP. Once the ENT determined that therapy was appropriate, the patient was then enrolled in voice therapy at ECUSLHC. (The procedures for enrolling patients are slightly different at each clinic; however, at both clinics patients were asked to participate by an SLP or the student researcher, had an ENT recommendation for voice therapy, and were scheduled for therapy as appropriate). The researchers were not a part of this portion of the patient's experience (i.e., the ENT examination); the researchers only distributed the VHI to the patient and then followed the patient's record (i.e. for compliance) if the SLP indicated the patient was enrolled into voice therapy. Participants for whom voice therapy was recommended were included in the present study and the researchers followed their attendance and compliance to treatment via chart reviews. The researchers did not have contact with the participants regarding the study after the initial visit where informed consent was obtained and the VHI was completed. The participants who did not need voice therapy were excluded. The ENT and SLP encouraged patients to attend their first scheduled voice therapy session but this is part of the usual routine of ECENT and ECUSLHC and is not behavior specifically present because of the

present study.

The VHI was scored by the student researcher and the participants were informed of their scores as the SLP deemed appropriate in the course of the patient's treatment. The VHI includes questions regarding patients' perception on how their voice affects their life, physically, emotionally, and functionally. The patient may answer these questions using the following five descriptors: (0) Never, (1) Almost Never, (2) Sometimes, (3) Almost Always, and (4) Always. Questions are divided regarding the type of impairment: physical, emotional, or functional; points for each section were added to reveal subtest (physical, emotional, and functional) scores. The points for all 30 VHI questions were added to receive a total score which was indicative of the perceived level of handicap of the patient participant. The resulting score could indicate no handicap or a mild, moderate, or severe handicap. No handicap/mild handicap is associated with a score of 0 to 30, a moderate handicap is correlated with a score of 31 to 60, and a severe handicap is indicated by a score of 61 to 120.

The use of the VHI in treatment is common and the SLPs used this information as they typically do when treating patients with voice disorders. The data from the VHI as well as demographic information was obtained from the chart by the researchers during a file review after the evaluation was completed and over the course of therapy. This data included the post-evaluation diagnosis, the dates of evaluations, the patient's ZIP code (to determine driving distance), the patient's driving status, smoking status, presence of acid reflux, occupation, age, gender, type of insurance/payment, and the date of dismissal or termination from treatment. The primary investigator rated each patient participant's smoking status, reflux status, occupation, and driving status with a numerical system for each variable. Smoking status was rated as follows: 0= participant never smoked, 1= participant is a former smoker, or 2= participant

continues to smoke. Reflux status was rated using the following scale: 0= participant has never been diagnosed with reflux, 1= participant was formerly diagnosed with reflux, or 2= participant was diagnosed with reflux during today's stroboscopy appointment. Occupation was rated as follows: 0= participant is unemployed or retired, 1= participant works part-time, or 2= participant works full-time. Driving status was divided into: 0= participant is an independent driver, 1= family member or friend drives participant, 2= participants relies on public transportation, or 3= participant relies on medical transportation.

After administration of the VHI, if voice therapy was recommended for the participants, their attendance and adherence to therapy was tracked.

Summary of Explanatory Variables

The explanatory variables for this study included the total score as well as the subtest scores for the VHI. In addition to these data, the following information was collected through the chart reviews: age, gender, driving status, ZIP code, post-evaluation dysphonia diagnosis, presence of reflux, type of insurance/payment, smoking status, occupation, and therapy dates (to count number of sessions attended). Insurance types were categorized into: no insurance, Medicare, Medicaid, private or military. The researchers also reviewed the chart notes to determine the final date the patient was dismissed, terminated, or discontinued therapy as well as the reason for therapy ending. Driving distance was calculated by putting the patient ZIP code and the clinic's ZIP code into an Internet based map service, www.mapquest.com. Lastly, the researchers reviewed the therapy notes to determine if the patient was demonstrating adherence to therapy recommendations.

Adherence was measured by the researcher after the patient completed a treatment session. The number of treatment sessions that each participant attended was recorded by the

investigators. Adherence was rated for each treatment session. Adherence was rated on a 4 point scale by the researchers. A 3 indicated the patient was completely adherent to recommendations, a 2 indicated that the patient was moderately adherent to recommendations, a 1 indicated that the patient was mildly adherent and a 0 indicated the patient was non-compliant in adhering to recommendations. A 0 was given if the patient attended therapy, but did not carry out the therapy assignments as recommended. Participants who did not show for their first treatment session were given a 0 rating for adherence because technically therapy never began. The termination reason was also recorded and categorized according to whether the patient experienced gains from treatment or not (“gains” versus “no gains”). If the patient experienced gains from treatment, a 1 (which indicated “therapy completed, clinician dismissal”) or a 2 (“patient requested dismissal because he/she perceives therapy completed”) was assigned. However, a 3 (indicating “patient experienced no gains, therapy terminated”), a 4 (“patient did not participate/no show for first session”) or a 5 (“patient stopped coming to treatment”) was assigned to participants who did not experience gains from therapy.

Data Analysis

Descriptive statistics were used to describe all explanatory variables. Frequencies, percentages, means, medians, and standard deviations were calculated when appropriate. Due to the limited sample size, inferential analysis was not used to analyze all data. However, Pearson correlation and two-tailed t-tests were used to determine if a statistical difference could be found between adherence rating and the following variables: VHI total and subtest scores, miles from Greenville, and age.

CHAPTER III

DEPENDENT AND INDEPENDENT VARIABLES AND STATISTICAL TREATMENT OF THE DATA

The present study measured the participants' adherence to recommendations for voice therapy in comparison to personal and demographic information, and the patients' perceived handicap related to their voice disorder prior to undergoing stroboscopy. The following explanatory variables were defined: Voice Handicap Index (VHI) total scores and subtest scores, as well as individual VHI questions; demographic information including age, gender, driving status, distance from clinic (using ZIP code), post-evaluation dysphonia diagnosis, presence of reflux, type of insurance or payment, smoking status, occupation, and number of sessions attended; and adherence ratings to therapy recommendations (0= completely nonadherent/did not show for therapy, 1= mildly adherent , 2= moderately adherent, 3= completely adherent).

Due to a lower than expected number of subjects, descriptive statistics were used to account for all explanatory variables. Dependent variables were described with the mean, median, and standard deviations. Adherence ratings to therapy recommendations (values of 0-3) were collapsed into two categories: adherent and nonadherent. Repeated measures two-tailed t-tests were used to determine if there was statistical significance in the correlation between adherence rating and variables such as VHI total and subtest scores, age, and miles from Greenville. A Pearson correlation was applied.

Participants' Perceptions of their Voices

Adherence was compared to the mean and standard deviations of the participants' total VHI scores and subtest scores.

Table 1
VHI Total Score and Subtest Scores

Adherence		VHI Total	VHI Physical	VHI Emotional	VHI Functional
Nonadherent	N	16	17	19	17
	Mean	42.9	18.7	10.6	13.6
	Median	45.0	18.0	11.0	14.0
	Std. Deviation	20.4	8.05	7.04	7.04
Adherent	N	6	6	6	6
	Mean	40.0	19.2	9.3	11.5
	Median	31.0	17.5	6.0	8.0
	Std. Deviation	23.8	5.2	10.5	9.6

Table 1 illustrates the data for the VHI total scores and subtest scores. The mean score for the VHI total score was 42.9 (SD = 20.4) for the nonadherent group and for the adherent group was 40 (SD = 23.8). The mean score on VHI physical subtest score for the nonadherent group was 18.7 (SD = 8.05) and 19.2 (SD of 5.2) for the adherent group. The mean for the nonadherent group's VHI emotional subtest score was 10.6 (SD = 7.04) and 9.3 (SD = 10.5) for the adherent group. The mean for the VHI functional subtest score for the nonadherent group was 13.6 (SD= 7.04) and was 11.5 (SD= 9.6) for the adherent group.

Participant's Responses to VHI Questions

Each of the 30 individual VHI questions was analyzed separately for the mean, median, and standard deviation. Participant responses were divided into two groups: "nonadherent" and "adherent."

Table 2
Comparison of VHI Physical Questions and Adherence

Adherence		Q2	Q4	Q10	Q13	Q14
Nonadherent	N	19	19	18	19	19
	Mean	1.9	1.95	1.92	2.1	2.2
	Median	2.0	2.0	1.2	2.0	2.0
	Std. Dev.	.96	.9		1.3	1.1
Adherent	N	6	6	6	6	6
	Mean	1.8	2.0	2.2	2.2	2.5
	Median	2.0	2.0	2.0	2.5	2.0
	Std. Dev.	.41	1.1	.41	1.2	.84

Adherence		Q17	Q18	Q20	Q21	Q26
Nonadherent	N	19	18	19	18	18
	Mean	.95	1.6	1.8	1.8	2.3
	Median	1.0	2.0	2.0	2.0	2.0
	Std. Dev.	1.1	1.2	1.2	1.2	.89
Adherent	N	6	6	6	6	6
	Mean	1.2	1.5	1.5	2.0	2.5
	Median	1.5	2.0	1.0	2.0	2.0
	Std. Dev.	.98	1.2	1.8	.63	.52

Table 2 outlines the data for the individual scores on the VHI for the adherent and nonadherent groups for questions in the Physical subtest. This included questions 2, 4, 10, 13, 14, 17, 18, 20, 21, and 26.

Table 3
Comparison of VHI Emotional Questions and Adherence

Adherence		Q7	Q9	Q15	Q23	Q24
Nonadherent	N	19	19	19	19	19
	Mean	1.5	1.2	1.9	.74	1.0
	Median	2.0	1.0	2.0	0	1.0
	Std. Deviation	1.2	.90	1.3	1.05	1.16
Adherent	N	5	6	6	6	6
	Mean	1.2	1.6	1.8	.83	.83
	Median	.5	2.0	2.0	.0	.0
	Std. Deviation	1.5	1.1	.98	1.33	1.33

Adherence		Q25	Q27	Q28	Q29	Q30
Nonadherent	N	19	19	19	19	19
	Mean	1.11	.89	.53	.74	1.0
	Median	1.0	1.0	0	0	1.0
	Std. Dev.	.99	.94	.84	1.15	.88
Adherent	N	6	6	6	6	6
	Mean	.67	.5	.5	.5	1.2
	Median	0	0	0	0	1.0
	Std. Dev.	1.2	1.23	1.23	1.23	1.33

Table 3 illustrates the data for the individual scores on the VHI for the adherent and nonadherent groups for questions in the Emotional subtest. This includes questions 7, 9, 15, 23, 24, 25, 27, 28, 29, and 30. Several of the mean scores equal less than 1.0 which is due to the presence of ratings of 0 in the data sample.

Table 4
Comparison of VHI Functional Questions and Adherence

Adherence		Q1	Q3	Q5	Q6	Q8
Nonadherent	N	18	18	19	19	19
	Mean	1.8	2.2	1.5	1.8	1.2
	Median	2.0	2.0	2.0	2.0	1.0
	Std. Deviation	.81	1.1	1.3	1.2	1.02
Adherent	N	6	6	6	6	6
	Mean	2.2	1.8	1.33	1.5	.83
	Median	2.0	2.0	1.0	2.0	.0
	Std. Deviation	.41	.98	1.51	1.23	1.33

Adherence		Q11	Q12	Q16	Q19	Q22
Nonadherent	N	19	19	19	19	19
	Mean	1.1	1.5	.89	1.0	.11
	Median	1.0	2.0	1.0	1.0	0
	Std. Dev.	1.1	.91	.94	1.16	.46
Adherent	N	6	6	6	6	6
	Mean	.83	1.33	.83	.83	0
	Median	0	1.5	0	0	0
	Std. Dev.	1.33	1.2	1.33	1.33	0

Table 4 displays the data for the individual scores on the VHI for the adherent and nonadherent groups for questions in the Functional subtest. This includes questions 1, 3, 5, 6, 8, 11, 12, 16, 19, and 22.

Demographic Information and Adherence to Therapy Recommendations

Tables 5-12 display the data for the explanatory variables and adherence to therapy recommendations.

Age

Table 5
Participant Age in relation to Adherence

		Age
Nonadherent N = 19	Mean	56.4
	Median	59.0
	Std. Deviation	14.9
Adherent N = 6	Mean	58.5
	Median	59.5
	Std. Deviation	9.9

Table 5 displays the following data. The mean age for participants in the nonadherent group was 56.4 years (SD= 14.9 years) and the mean age for participants in the adherent group was 58.5 years (SD= 9.9 years).

Gender

Table 6
Gender Compared with Adherence

		Gender	
		Male	Female
Nonadherent	Frequency (%)	4 (21.1%)	15 (78.9%)
Adherent	Frequency (%)	2 (33.3%)	4 (66.7%)

Table 6 demonstrates the gender breakdowns. Four participants (21.1%) in the nonadherent group were male and 15 (78.9%) were female. In the adherent group, two participants (33.3%) were male and four (66.7%) were female.

Smoking and Reflux

Table 7
Smoking Status and Reflux Status in relation to Adherence

		Smoking			Reflux		
		Never Smoked	Former Smoker	Continues to Smoke	Never Diagnosed	Previously Diagnosed	Diagnosed during Stroboscopy
Nonadherent	Frequency (%)	10(52.6%)	5(26.3%)	4 (21.1%)	3 (15.8%)	12(63.2%)	4 (21.1%)
Adherent	Frequency (%)	3 (50%)	3 (50%)	0	1 (16.7%)	4 (66.7%)	1 (16.7%)

Table 7 illustrates the percentages of nonadherent and adherent participants who fell into the following categories for smoking status: never smoked, former smoker, or continues to smoke. It also demonstrates percentages of participants in the following reflux categories: never diagnosed, previously diagnosed, or diagnosed during stroboscopy.

Driving status

Table 8
Participant Driving Status and Adherence to Therapy

		Driving Status			
		Independent Driver	Family/Friend Drives	Public Transportation	Medical Transport
Nonadherent	Frequency (%)	14 (73.7%)	4 (21.1%)	0	1 (5.3%)
Adherent	Frequency	6 (100%)	0	0	0

Table 8 indicates the driving status of nonadherent and adherent participants.

Distance from the Clinic

Table 9

Driving Distance from Greenville in comparison to Adherence

		Driving Distance
Nonadherent N = 19	Mean	29.2
	Median	39.5
	Std. Deviation	19.6
Adherent N = 6	Mean	44.6
	Median	39.7
	Std. Deviation	23.6

Table 9 illustrates information regarding driving distance from the clinic and participant age. The mean number of miles from Greenville, NC was 29.2 (SD= 19.6) for the nonadherent group and 44.6 (SD= 23.6) for the adherent group.

Insurance and Occupation

The primary investigator reviewed the participant charts for information regarding their primary and secondary insurance, and then rated the types of insurance according to the following: 1= Medicare, 2= Medicaid, 3= Private, 4= self-pay, and 5= Military.

Table 10
Insurance and Occupation in relation to Adherence

		Primary Insurance				
		Medicare	Medicaid	Private	Self-pay	Military
Nonadherent	Frequency (%)	6 (31.6%)	2(10.5%)	10(52.6%)	1 (5.3%)	0
Adherent	Frequency (%)	4 (66.7%)	0	2 (33.3%)	0	0
		Secondary Insurance				
		Medicare	Medicaid	Private	Military	None
Nonadherent	Frequency(%)	1 (5.3%)	0	4 (21.1%)	1 (5.3%)	13(68.4%)
Adherent	Frequency(%)	0	1 (16.7%)	0	0	5(83.3%)
		Occupation				
		Unemployed/ Retired	Part-time Job	Full-time Job		
Nonadherent	Frequency (%)	12 (63.2%)	0	7 (36.8%)		
Adherent	Frequency (%)	5 (83.3%)	1 (16.7%)	0		

Table 10 illustrates the data relating to insurance and occupation.

Patient Attendance and Adherence to Therapy Recommendations

The number of treatment sessions for participants ranged from 0 to 13 sessions. The mean number of sessions for participants in the adherent group was 4 (SD= 4.5) and the mean number of sessions for the nonadherent participants was .42 (SD= .77). The mean adherence rating completed by the SLPs for the nonadherent group was 0 and the mean of 2.5 (SD of .84) was determined for the adherent group. The mean rating for termination reason was 4.1 (SD= .23) for the nonadherent group and the adherent group's mean rating was 2.2 (SD= 1.5).

Diagnosis and Adherence

Patients at the clinic are typically given primary, secondary, and tertiary diagnoses when appropriate. Several participants did not have secondary and/or tertiary diagnoses. All participants involved in the present study received a primary diagnosis at their initial stroboscopy appointment as this was a criterion for inclusion into this study.

Table 11
Comparison of Diagnosis and Adherence

Adherence	Primary		Secondary		Tertiary	
	Frequency	Percent	Frequency	Percent	Frequency	Percent
Nonadherent						
Dysphonia	10	52.6	4	21.1	2	10.5
TVF nodules	3	15.8	1	5.3	0	0
MTD	1	5.3	0	0	0	0
LPR	2	10.5	7	36.8	6	31.6
Myasthenia	3	15.8	3	15.8	1	5.3
Reinke's edema	0	0	1	5.3	0	0
TVF paralysis	0	0	1	5.3	0	0
Chronic Cough	0	0	2	10.5	0	0
Tracheal inflammation	0	0	0	0	1	5.3
Laryngeal tremor	0	0	0	0	1	5.3
No Diagnosis	0	0	0	0	8	42.1
Total	19	100.0	19	100.0	19	100.0
Adherent						
Dysphonia	1	16.7	2	33.3	0	0
LPR	2	33.3	1	16.7	0	0
TVF Polyp	1	16.7	0	0	0	0
TVF nodules	0	0	1	16.7	0	0
SLN weakness	0	0	0	0	1	16.7
CVA	1	16.7	0	0	0	0
MTD	1	16.7	0	0	0	0
No Diagnosis	0	0	2	33.3	5	83.3
Total	6	100.0	6	100.0	6	100.0

Evaluation Dates and Adherence

A scale was used to describe the time between each participant's stroboscopy appointment and perceptual evaluation with the speech-language pathologist (SLP). The following descriptors were used in the scale: 0= patient did not schedule or attend SLP

perceptual evaluation, 1= SLP perceptual evaluation was within 1 week of stroboscopy date, 2= SLP perceptual evaluation was within 2 weeks of stroboscopy date, 3= SLP perceptual evaluation was within 3 weeks of stroboscopy date, and 4= SLP perceptual evaluation was 1 month or more after stroboscopy date.

Table 12
Days between Strobe and Perceptual Evaluation

Nonadherent	N	19
	Mean	1.00
	Median	.00
	Std. Deviation	1.53
Adherent	N	6
	Mean	2.33
	Median	2.00
	Std. Deviation	1.03

Regarding the time between the stroboscopy appointment and the perceptual evaluation, the mean for the nonadherent group was 1.0 week (SD= 1.53) whereas the mean for the adherent group was 2.33 weeks (SD= 1.03). This information is demonstrated in Table 12.

A scale similar to the one used above was also used to describe the time between each participant's appointment with their physician who referred them for stroboscopy and the stroboscopy appointment. The descriptors were modified in the scale to read as follows: 0= no referral date indicated in the chart, 1= stroboscopy appointment was within 1 week of referring physician date, 2= stroboscopy appointment was within 2 weeks of referring physician date, 3= stroboscopy appointment was within 3 weeks of referring physician date, and 4= stroboscopy appointment was 1 month or more after referring physician date.

Table 13
Days between Referral and Stroboscopy Appointment

Nonadherent	N	19
	Mean	.79
	Median	.00
	Std. Deviation	1.4
Adherent	N	6
	Mean	1.7
	Median	1.50
	Std. Deviation	1.9

The mean for the nonadherent group was .79 week (SD= 1.4) and the mean for the adherent group was 1.7 weeks (SD= 1.9). This data is illustrated in Table 13.

Pearson Correlation and T-tests

Table 14
P-values and Pearson Correlation

		Adherence Rating
Age	Pearson Correlation	-.016
	Sig. (2-tailed)	.938
	N	25
Miles from Greenville	Pearson Correlation	.338
	Sig. (2-tailed)	.099
	N	25
VHI Total Score	Pearson Correlation	.031
	Sig. (2-tailed)	.890
	N	22
VHI Physical Subtest Score	Pearson Correlation	.106
	Sig. (2-tailed)	.630
	N	23
VHI Emotional Subtest Score	Pearson Correlation	.032
	Sig. (2-tailed)	.881
	N	25
VHI Functional Subtest Score	Pearson Correlation	-.053
	Sig. (2-tailed)	.809
	N	23

Variables that were expected to demonstrate a trend were further analyzed using Pearson correlation and two-tailed t-tests. Table 14 demonstrates the following data. The correlation between adherence rating and VHI total scores is small (.031) and the p-value is large (.890). Therefore, no correlation was found to exist between these variables. In addition, no correlation was found to exist between adherence rating and VHI subtests scores or age. However, there is a moderate correlation between adherence rating and miles from Greenville.

CHAPTER IV

DISCUSSION

The purpose of the present study was to determine if explanatory variables such as VHI scores, responses to VHI questions, and demographic information would predict patient attendance and/or adherence to recommendations for voice therapy. Prior to data collection, the investigators formed several hypotheses. The first research question was to determine if VHI questions that received less severe patient ratings (scores of 0, 1, or 2) would predict a participant's nonadherence to therapy. The second research question was developed to determine if the VHI Functional subtest would have the most predictive value on patient compliance to voice therapy. The third research question was to determine if more severe VHI total and subtest scores would correlate with participants who received a higher adherence rating. Lastly, it was estimated that explanatory (personal) variables of driving status, insurance type, and driving distance when paired with the VHI total and subtest scores would predict patient compliance.

Gender and Age

Most participants in both the adherent and nonadherent groups were female. This correlates with previous research findings regarding gender of patients who seek medical advice (Cleary, Mechanic & Greenley, 1977; Nathanson, 1977; Hibbard & Pope, 1986; Herrington-Hall et al., 1988) and of those who seek advice for voice disorders (Hapner et al., 2007).

Portone et al. (2008) found that the age group in their study who was most likely to attend the first voice therapy session was the 21-40 year old age group, and the least likely to attend were the 40-64 year olds. In the present study, the mean age for the adherent group was approximately 2 years more than the mean age of the nonadherent group. The ages for the

nonadherent group ranged from 26- 74 years whereas the ages for the adherent group ranged from 42-72 years. This suggests that older individuals may be more likely to comply with recommendations for therapy than a younger population but further research is needed to support this hypothesis.

Attendance and Adherence to Voice Therapy

Portone et al. (2006) found that 38% of patients did not comply with a laryngologist's referral to return for a voice evaluation and 47% who attended a voice evaluation did not attend therapy. The present study had similar outcomes: 12 out of 25 participants (48%) did not return comply with the recommendations to return for a voice evaluation and, of the 13 participants who did return for a voice evaluation, 38% of these participants did not show for the first therapy session. The mean rating for termination reason for the nonadherent group was 4 which indicated that most participants in this group did not even attend the perceptual evaluation. The mean rating for the adherent group was approximately 2 which indicated that most participants in this group discontinued therapy due to personal satisfaction with therapy outcomes. No significant correlation was found to exist between adherence rating and age in the present study. Further research is warranted to find out if there are underlying reasons for lack of patient compliance to voice therapy recommendations.

Although previous studies have measured the amount of patient dropout from therapy, none have measured the amount of time between the initial referral and the stroboscopy appointment. The present study looked at the time between the initial referral and the actual stroboscopy appointment to see if this would be an indicator of therapy adherence/nonadherence. It should be noted that the mean time between these appointments for the nonadherent group was approximately 1 week but it was approximately 2 weeks for the adherent group. It may be

possible that patients who are more likely to attend voice therapy schedule appointments farther in advance than patients who will be nonadherent.

VHI Total Scores as Predictor of Attendance and Adherence

This preliminary study was designed to develop a prospective method for investigating numerous variables about patients and patient care to determine if any predictions can be made about the success of completion of voice therapy. Due to the prospective nature of this study, and several confounding variables with patient recruiting to be discussed later, fewer than expected patients were enrolled in the study. Therefore, inferential statistics were not applied to all variables as the power analysis did not reveal enough strength to allow adequate interpretation of data. However, variables that were suspected of demonstrating a trend were further analyzed using Pearson correlation and two-tailed t-tests.

When inspecting the means of the adherent and nonadherent groups relative to the total VHI scores, it is clear that there is very little practical or statistical difference between the data. Interestingly, the nonadherent participants did rate themselves with less severe handicap in some instances: 3 of the nonadherent participants had a VHI score less than 20 whereas none of the adherent group had a score less than 20. Also, the participant with the highest total VHI score fell into the adherent group. Three participants in the nonadherent group received total VHI scores that fell within the range of no handicap/mild handicap (scores less than 30), whereas the total scores of two participants in the adherent group fell into this range. Nine participants in the nonadherent group received total VHI scores that indicated moderate handicap, whereas the total scores of three participants of the adherent group fell into this scoring range. Four participants of the nonadherent group received severe handicap total VHI scores and one participant in the adherent group obtained a score in the severe handicap range. The mean VHI total score fell

within the category of moderate handicap for both the nonadherent and the adherent groups. Thus, in the present study, the VHI total score did not differentiate the two groups: adherent and nonadherent.

VHI Subtest Scores as Predictor of Attendance and Adherence

Hapner et al. (2007) discovered that the mean pretreatment VHI score for patients who dropped out of voice therapy was actually higher than the score of those who completed therapy but this difference was not significant. In the present study, the mean pretreatment VHI total score for participants who were nonadherent to recommendations for voice therapy was higher than those who were adherent. However, upon inspection of the means, there appears to be no clinical or statistical significance in predicting adherence to therapy. These findings may indicate that patients who are nonadherent may overestimate the severity of their voice disorder prior to viewing their vocal folds via stroboscopy. It may be possible that they become relieved to find out that they do not have a life-threatening condition and do not perceive a need for voice therapy. Further empirical evidence is needed to support this hypothesis.

The means of the VHI Emotional and Physical subtest scores for the nonadherent group were approximately one point higher than for the adherent group. Interestingly, the mean of the VHI Functional subtest scores was approximately two points higher for the nonadherent group than for the adherent group. No significant correlation was found between adherence rating and VHI subtests scores. These results did not support the hypothesis that the VHI Functional subtest score would have more predictive value on patient adherence to voice therapy than the other VHI subtest scores.

VHI Individual Questions and Adherence

No practical difference was found to exist between the two groups' mean responses to

individual questions in the VHI Physical, Emotional, and Functional subtests. Marginal differences, if any, were found to exist between the mean of the responses between the nonadherent group and the adherent group.

Demographic Variables and Adherence

Most participants in the nonadherent group indicated that they never smoked (52.6%) while 26.3% were former smokers and 21.1% were current smokers. In the adherent group, 50% had never smoked and 50% were former smokers. In the nonadherent group, most participants (63.2%) were formerly diagnosed with reflux (prior to their stroboscopy appointment); whereas 15.8% had never been diagnosed with reflux and 21.1% were diagnosed with reflux during the stroboscopy appointment. In the adherent group, most participants were formerly diagnosed with reflux (66.7%), one participant (16.7%) was never diagnosed, and one participant (16.7%) was diagnosed at the stroboscopy appointment. Thus, it appears that these two important organic effects on the vocal folds were present in both groups in a similar degree. Therefore, it would be likely that as participants are added to the population, these two variables may continue not to differentiate the two groups. Although previous studies have researched the benefits of vocal hygiene education, none have explored the effects of smoking status and/or reflux upon patient completion of voice therapy.

In this study, twelve participants (63.2%) in the nonadherent group did not have a job; no participants held a part-time job, and seven (36.8%) held a full-time job. Five participants (83.3%) in the adherent group were unemployed or retired, and one participant (16.7%) held a part-time job. The adherent group did not have any full-time workers whereas the nonadherent group did have seven full time workers. While the lack of statistical analysis prevents strong conclusions, this may be one indicator that individuals with full time employment may have a

more difficult time adhering to a therapy program. However, since most participants in both the nonadherent and the adherent group were unemployed or retired, this data may indicate that those who do not hold a job have difficulty attending therapy (possibly due to financial barriers). Important variables that were explored in the present study were ones that have a direct effect on the ability of patients to even attend therapy – let alone adhere to therapy recommendations by practicing exercises. If participants are not able to physically travel to therapy because they do not have reliable transportation, they may be noncompliant simply because they are unable to make it to the clinic. Similarly, a client could be highly motivated to come to therapy, but without insurance or affordable co-pays for example, the client may be a non-attender because of finances. Thus, in the present study, distance from the clinic and type of insurance were investigated to determine if differences in these variables contributed to adherence.

Most participants (31.6%) in the nonadherent group used a private insurance company for their primary insurance whereas most participants (66.7%) in the adherent group relied on Medicare for primary insurance. Most participants in both groups did not rely on any type of secondary insurance. Of those who did rely on secondary insurance within the nonadherent group, most (21.1%) relied on a private insurance company. The only participant to use secondary insurance in the adherent group used Medicaid. This information suggests that participants who rely on government-funded insurance may participate more in therapy. However, more evidence is needed to confirm this hypothesis.

In the nonadherent group, 14 participants (73.7%) were independent drivers, four (21.1%) depended upon a friend or family member to drive to appointments, and one (5.3%) relied on medical transport for appointments. All six participants (100%) in the adherent group were independent drivers. Most participants in both groups (nonadherent and adherent) were

independent drivers. Therefore, even with a larger participant pool, driving status may not be a strong indicator of patient adherence to therapy. However, the five participants in the nonadherent group who were not independent drivers may have been prevented from attending therapy due to their reliance on other drivers.

Interestingly, the mean number of miles from Greenville was 15 miles more for the adherent group than the nonadherent group. A moderate correlation was found to exist between miles from Greenville and adherence rating. It would seem as though participants who lived further from the clinic would be less likely to adhere to recommendations for therapy due to the driving distance but this was not the case, according to data from this study. Greenville, while technically classified as a city, is a more rural location. There are vast outlying areas where there are no SLP services, let alone a specialized SLP clinic like an ENT office. Thus, it is possible that the patients who were driving greater distances were more motivated to find a specialist because there may not be one in the local area whereas individuals living closer may believe that they can reschedule their appointments more easily because the ENT clinic is simply more accessible.

In a previous study completed by Hapner et al. (2007), diagnosis was divided into “hypofunctional” and “hyperfunctional” categories. Although 29.3% of their participants had “hypofunctional” voice disorders and 70.7% had “hyperfunctional” disorders, these categories were not found to have any significant value in predicting therapy completion or dropout. In the present study, most participants (52.6%) in the nonadherent group were given the primary diagnosis of dysphonia, followed by laryngopharyngeal reflux (15.8%) and true vocal fold nodules (15.8%). Most participants in the adherent group (33.3%) were given the primary diagnosis of laryngopharyngeal reflux. For secondary diagnosis, most participants in the

nonadherent group (36.8%) had laryngopharyngeal reflux whereas most participants in the adherent group had dysphonia (33.3%). Six participants (31.6%) in the nonadherent group presented with laryngopharyngeal reflux as a tertiary diagnosis. The only participant (16.7%) to have a tertiary diagnosis in the adherent group presented with superior laryngeal nerve weakness.

In the present study, results regarding the time between stroboscopy appointments and the SLPs' perceptual evaluations did not agree with results from the study completed by Portone-Maira (2010) who found that less time between initial referral and SLP voice evaluation predicted therapy completion. However, differences in the amount of data collected in each study could contribute to this disparity. For the nonadherent group in the present study, the mean amount of time between these two appointments was approximately 1 week ($SD= 1.53$). For the adherent group, the perceptual evaluation took place approximately 2.33 weeks ($SD= 1.03$) later. One hypothesis to explain the difference in time is that the participants in the adherent group may have looked at their schedules more intently prior to scheduling the perceptual evaluation. This may be an indicator that these participants took the physician/SLP's recommendations for voice therapy more seriously than the participants in the nonadherent group.

Limitations of the Study

Limitations of this study must be considered before this study is replicated. The administration of the VHI on a regular basis was a new practice for the clinic as the office typically used a "hoarseness questionnaire" to obtain patients' perceptions of their voice prior to their appointment. This questionnaire was not a researched, standardized tool. More participants will be included in the population when the VHI becomes standard practice for all new patients. Because the VHI was not a standard form presented to patients at this clinic, missed cases could have occurred because the office staff did not regularly request it from patient's at their first

appointment. A more regular system of administering and collecting the VHI may provide for more consistent patient participation in future studies. The present study was designed to be prospective in nature and the prospective nature of this work is a strength. Further studies should aim to develop the clinical practice patterns that allow for stronger data gathering.

In addition, the data collection for the present study was largely dependent upon patients returning VHIs that were mailed to them. Therefore, patients not only had to agree to complete the VHI but they also had to remember to bring the form to their appointment (*prior* to stroboscopy) in order for the information to be included in the study. If time allows in future studies, it will be beneficial for the investigators to contact the patients who would be possible participants via telephone or similar means to remind them to bring the completed VHI form with them to their stroboscopy appointment (if they would like to participate). This would need to occur should the study remain a prospective one. It may also be advantageous to document the number of possible participants to whom the VHI is sent so that patient attendance or nonattendance to the initial stroboscopy appointment can be measured.

Due to the fast-paced nature of the clinic, many patients who could have been participants in the study were not included because of lack of time between patients to appropriately educate them about the study and obtain ethical informed consent. This contributed to the low number of patient participants and, due to this small number, descriptive statistics were used rather than inferential statistics. In future studies, if possible, it will be beneficial for the primary investigator to devote his/her attention to obtaining patient participation while other clinicians carry out the diagnostics.

Certainly, conducting a retrospective study would also allow more participants to be obtained. This preliminary study identified numerous aspects of the current practice which may

be altered in order to ensure that all new voice patients are provided with the VHI and that it is collected as a part of the intake paperwork. However, the clinic oftentimes treats 200-300 patients per day, many of which are not voice patients. It is likely that there will always be a group of patients who are not identified at intake and thus are not eligible for the study because they did not complete the VHI prior to stroboscopy.

Summary and Conclusions

Data analysis demonstrated that the variables explored in the present study were not clinically or statistically significant in predicting patient adherence or compliance to recommendations to voice therapy. These findings are consistent with those in a study by Hapner et al. (2007) who found that 65% of participants in their studied “dropped out” of voice therapy but that none of the factors they studied for predictor value (such as demographic information) were predictive of dropout.

Recommendations for Future Research

The major contribution of this work compared to the literature was the addition of the adherence and attendance data. Due to the prospective nature of this study, attendance was documented and adherence to therapy recommendations was rated by the clinicians. It will be beneficial for future studies to record adherence and attendance as participants take part (or do not take part) in therapy. In addition, temporal variables should be further assessed for their value in predicting completion of therapy.

A follow-up interview with participants who were completely noncompliant to recommendations for voice therapy (those who received a rating of 4 for “termination reason”) could be conducted as was carried out by Portone et al. (2006). The participants could be asked what they believe is the main reason for their nonadherence to recommendations for voice

therapy. In addition, future studies may use more in-depth inferential statistics to report data, if enough data is collected to do so.

As discussed previously, drop out from various types of therapy is typical and at times as high as 65%. It is imperative that those in the field of these therapies, including SLP, continue to investigate reasons that could be contributing to too few patients receiving the care they need. Future research concerning this matter may aid in reducing unnecessary frustration for clinicians as well as unnecessary costs due to patient nonadherence.

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APPENDIX A

Voice Handicap Index (VHI)

Name: _____

Date: _____

Instructions:

These are statements that many people have used to describe their voices and the effects of their voices on their lives. Make a check in the box that indicates how frequently you have the same experience.

	Never	Almost Never	Sometimes	Almost Always	Always
1. My voice makes it difficult for people to hear me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I run out of air when I talk.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. People have difficulty understanding me in a noisy room.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. The sound of my voice varies throughout the day.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I use the phone less often than I would like.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. My family has difficulty hearing me when I call them throughout the house.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I'm tense when talking with others because of my voice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I tend to avoid groups of people because of my voice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. People seem irritated with my voice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. People ask, "What's wrong with your voice?"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I speak with friends, neighbors, or relatives less often because of my voice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. People ask me to repeat myself when speaking face to face.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- | | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 13. My voice sounds creaky and dry. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. I feel as though I have to strain to produce voice. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. I find other people don't understand my voice problem. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. My voice difficulties restrict my personal and social life. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. The clarity of my voice is unpredictable. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. I try to change my voice to sound different. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. I feel left out of conversations because of my voice. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. I use a great deal of effort to speak. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 21. My voice is worse in the evening. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 22. My voice problem causes me to lose income. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 23. My voice problem upsets me. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 24. I am less outgoing because of my voice problem. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 25. My voice makes me feel handicapped. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 26. My voice "gives out" on me in the middle of speaking. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 27. I feel annoyed when people ask me to repeat. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 28. I feel embarrassed when people ask me to repeat. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 29. My voice makes me feel incompetent. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 30. I'm ashamed of my voice problem. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |



University and Medical Center Institutional Review Board

East Carolina University • Brody School of Medicine

600 Moye Boulevard • Old Health Sciences Library, Room 1L-09 • Greenville, NC 27834

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Chair and Director of Biomedical IRB: L. Wiley Nifong, MD

Chair and Director of Behavioral and Social Science IRB: Susan L. McCammon, PhD

TO: Kristen Evans, 1920 The Exchange Dr., Greenville, NC 27858

FROM: UMCIRB *WLN*

DATE: June 8, 2009

RE: Expedited Category Research Study

TITLE: "Predicting Compliance in Voice Therapy Using the Voice Handicap Index"

UMCIRB #09-0487

This research study has undergone review and approval using expedited review on 6.5.09. This research study is eligible for review under an expedited category because it is a research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.) It is also a research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

The Chairperson (or designee) deemed this **unfunded** study **no more than minimal risk** requiring a continuing review in **12 months**. Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.

The above referenced research study has been given approval for the period of **6.5.09** to **6.4.10**. The approval includes the following items:

- Internal Processing Form
- Informed Consent (dated 3.30.09) (received 6.5.09)
- Methodology
- VHI
- Survey
- Letter of Support (dated 4.20.09)
- Data Collection Form: Participant Number
- COI Disclosure Form (dated 5.20.09)

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

CONSENT DOCUMENT

Title of Research Study: PREDICTING COMPLIANCE IN VOICE THERAPY USING THE VOICE HANDICAP INDEX.

Principal Investigator: Kristen Evans, Graduate Student; Kathleen T. Cox, PhD, Faculty Supervisor

Institution: East Carolina University

Address: Health Sciences Building, Department of Communication Sciences and Disorders, Suite 3310, Greenville, NC 27858

Telephone #: (252) 216-7116

This consent form document may contain words that you do not understand. You should ask the study coordinator to explain any words or information in this consent form that you do not understand.

PURPOSE AND PROCEDURES

The purpose of this research study is to determine which patients may or may not complete a voice therapy program, once enrolled. Voice therapy is non-surgical intervention for voice disorders and typically includes vocal exercises and techniques to improve the voice. You may or may not be enrolled in voice therapy based on your visit today; this will be determined by the physician and speech-language pathologists you are meeting with for your appointment. You are invited to participate in this research study whether or not you are enrolled in voice therapy today.

To participate in this research, you will complete an assessment tool, the Voice Handicap Index (VHI), which is a paper and pencil attitude scale about your voice. You will be asked to rank problems that you are having with your voice by their frequency of occurrence (never, almost never, sometimes, almost always, always). Results of this assessment tool (a score) will be used as data for this research study.

Personal information (demographic information) including your age, gender, occupation, distance from Eastern Carolina ENT or ECU Speech-Language and Hearing Clinic, driving status, voice diagnosis, dates of evaluations and therapy sessions at Eastern Carolina ENT or ECU Speech-Language and Hearing Clinic, type of insurance, smoking status and acid reflux diagnosis will be used in this study. These are the only variables that will be used for the purpose of this study. All information will remain anonymous.

Your active participation will not be necessary after you have filled out the VHI and the necessary demographic information has been collected during this appointment. However, the data collected today and the dates of your voice therapy sessions will be analyzed throughout the course of this year. This study will terminate in year 2010 and data collection will not continue thereafter. Completing this form does not require you to attend voice therapy and your physician may choose not to recommend voice therapy for your course of treatment. Completing this form means you consent to completing the

UMCIRB
 APPROVED
 FROM 6.5.09
 TO 6.4.10

Version date: 3/30/09

- 1 -

Participant's initials

VHI attitude scale and allowing the researchers to collect anonymous demographic information from your medical chart.

POTENTIAL RISKS AND DISCOMFORTS

You may find the following risks or discomforts from participating in this study:

- 1.) Researchers will be accessing personal health information but the identity of participants will remain anonymous.

POTENTIAL BENEFITS

There may be no personal benefit from your participation but the knowledge received may be of value to humanity. This study may aid professionals within the fields of speech-language pathology and ENT in predicting which patients may or may not complete a prescribed voice therapy program.

You may gain personal benefit from this study. By participating in this study, you will be given an assessment tool, the Voice Handicap Index, to complete which may give you insight into the effect your voice has on your everyday life. The results of the VHI will become a part of your medical record at Eastern Carolina ENT or ECU Speech-Language and Hearing Clinic and the professionals at this facility may use this information in your treatment program.

SUBJECT PRIVACY AND CONFIDENTIALITY OF RECORDS

Your privacy and confidentiality will be maintained by Eastern Carolina ENT, ECU Speech-Language and Hearing Clinic as well as the East Carolina University researchers involved in this study. Patient data will remain anonymous.

COSTS OF PARTICIPATION & COMPENSATION

You will not receive any monetary compensation for your participation in this study. Your fees for services at Eastern Carolina ENT will not be waived by your participation in this study. All fees will be charged as they normally would if you were not participating in this study.

VOLUNTARY PARTICIPATION

The investigators are seeking approximately 200 participants for this study. Participating in this study is voluntary. If you decide not to be in this study after it has already started, you may stop at any time without losing benefits that you should normally receive. You may stop at any time you choose without penalty. You will continue to receive the same care from the staff of Eastern Carolina ENT or ECU Speech-Language and Hearing Clinic regardless of your participation in this study.

FROM 6.5.09
 TO 6.4.10
 APPROVED
 UMCI/RB

PERSONS TO CONTACT WITH QUESTIONS

The investigators will be available to answer any questions concerning this research, now or in the future. You may contact the investigators, Kristen Evans or Kathleen T. Cox, PhD at phone numbers 252-744-6085 (days) or (252) 216-7116 (nights and weekends). If you have questions about your rights as a research subject, you may call the Chair of the University and Medical Center Institutional Review Board at phone number 252-744-2914 (days) and/or the ECU Risk Management Office at 252-328-2010. If you would like to report objections to this research study, you may call the ECU Director of Research Compliance at phone number 252-328-9473.

CONFLICTS OF INTEREST

Neither the research site, nor the investigators, Kristen Evans and Kathleen T. Cox, PhD, will receive any financial benefit based on the results of this study.

Research Participant Authorization to Use and Disclose Protected Health Information

The purpose of the information to be gathered for this research study is to better understand patient participation in voice therapy. The individuals who will use or disclose your identifiable health information for research purposes include the primary investigator, Kristen Evans, and the faculty advisor, Kathleen T. Cox. Individuals who will receive your identifiable health information for research purposes include the primary investigator, Kristen Evans; the faculty advisor, Kathleen T. Cox, PhD; and the speech-language pathologists of Eastern Carolina ENT, Dana Gribble, MS, CCC-SLP and Melissa A. Carter, MS, CCC-SLP. The type of information accessed for this research study includes scores on the Voice Handicap Index, gender, age, occupational status, driving status, ZIP code, smoking status, post-evaluation dysphonia diagnosis, presence of reflux, type of insurance/payment, and scheduled therapy appointment dates, including the date of termination of therapy. The information will be used and disclosed in such a way as to protect your identity as much as possible; however, confidentiality cannot be absolutely guaranteed. Someone receiving information collected under this Authorization could potentially re-disclose it, and therefore it would no longer be protected under the HIPAA privacy rules (federal rules that govern the use and disclosure of your health information). There is not an expiration date for this Authorization.

You may not participate in this study if you do not sign this Authorization form. You may revoke (withdraw) this Authorization by submitting a request in writing to Kathleen T. Cox, PhD, Health Sciences Building, Department of Communication Sciences and Disorders, Suite 3310, Greenville, NC 27858. However, the research team will be able to use any and all of the information collected prior to your request to withdraw your Authorization.

FROM 6.5.09
 TO 6.4.10
 APPROVED
 UMCRB

To authorize the use and disclosure of your health information for this study in the way that has been described in this form, please sign below and date when you signed this form. A signed copy of this Authorization will be given to you for your records.

CONSENT TO PARTICIPATE

Title of research study: PREDICTING COMPLIANCE IN VOICE THERAPY USING THE VOICE HANDICAP INDEX.

I have read all of the above information, asked questions and have received satisfactory answers in areas I did not understand. (A copy of this signed and dated consent form will be given to the person signing this form as the participant or as the participant's authorized representative.)

Participant's Name (PRINT)	Signature	Date	Time
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If applicable:

Guardian's Name (PRINT)	Signature	Date	Time
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PERSON ADMINISTERING CONSENT: I have conducted the consent process and orally reviewed the contents of the consent document. I believe the participant understands the research.

Person Obtaining consent (PRINT)	Signature	Date
----------------------------------	-----------	------

Principal Investigator's (PRINT)	Signature	Date
----------------------------------	-----------	------

UMC/IRB
 APPROVED
 FROM 6.5.09
 TO 6.24.10

UMCIRB HIPAA Authorization Checklist/Approval Form

UMCIRB #: 09-0487 PI: Kristen Evans, B.S.

Title of study (full or abbreviated): Predicting Compliance in Voice Therapy Using the Voice Handicap Index

Check one of the boxes below:

- Use of ECU "Research Participant Authorization to Use and Disclose Information for Research"
- Use of a sponsor/granting agency or other alternative HIPAA Patient Authorization
- Use of research informed consent document form with required elements of the HIPAA Patient Authorization

Designated UMCIRB reviewer has reviewed the substitute HIPAA Patient Authorization for Research or proposed research consent form and found that it is written in plain language and contains:

- | Yes | No | |
|-------------------------------------|--------------------------|---|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | A specific and meaningful description of the information to be used or disclosed |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | The name or identification of persons or class of persons authorized to make requested use/disclosure of PHI |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | The name or identification of persons or class or persons who will use PHI for research-related purposes |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | A description of each purpose of the use or disclosure |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | The individual's signature (or that of his/her authorized representative) and the date. |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | An expiration date or event, or a statement "end of research study" or "none" when appropriate |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | A statement that the individual may revoke the authorization in writing; |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Any exceptions to the right to revoke (e.g. researcher may continue to use and disclose, for research integrity and reporting purposes any PHI collected from the individual pursuant to such Authorization before it was revoked). |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | A statement that information disclosed under the Authorization could potentially be re-disclosed by the recipient and would no longer be protected under HIPAA. |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | A statement of the ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization by stating either stating the applicable conditions or the consequences to the individual for refusal to sign the authorization. |
| <input checked="" type="checkbox"/> | | All the above elements are present, HIPAA AUTHORIZATION document is APPROVED |
| <input type="checkbox"/> | | All the above elements are <u>not</u> present; HIPAA AUTHORIZATION document is NOT APPROVED |

Susan McCann
Designated UMCIRB Reviewer

6-5-09
Date

Principal Investigator: Present this signed form at the time PHI is requested from custodians of records. By signing this document, I acknowledge and affirm that all enrolled subjects have signed a valid HIPAA Authorization Form.

Kristen Evans
Principal Investigator

7-1-09
Date

UMCIRB APPROVED
FROM 6-5-09
TO no expiration

UMCIRB HIPAA Authorization Checklist/Approval Form

UMCIRB #: 09-0487 PI: Kristen Evans, B.S.

Title of study (full or abbreviated): Predicting Compliance in Voice Therapy Using the Voice Handicap Index

Check one of the boxes below:

- Use of ECU "Research Participant Authorization to Use and Disclose Information for Research"
- Use of a sponsor/granting agency or other alternative HIPAA Patient Authorization
- Use of research informed consent document form with required elements of the HIPAA Patient Authorization

Designated UMCIRB reviewer has reviewed the substitute HIPAA Patient Authorization for Research or proposed research consent form and found that it is written in plain language and contains:

- | | | |
|-------------------------------------|--------------------------|---|
| Yes | No | |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | A specific and meaningful description of the information to be used or disclosed |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | The name or identification of persons or class of persons authorized to make requested use/disclosure of PHI |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | The name or identification of persons or class or persons who will use PHI for research-related purposes |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | A description of each purpose of the use or disclosure |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | The individual's signature (or that of his/her authorized representative) and the date. |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | An expiration date or event, or a statement "end of research study" or "none" when appropriate |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | A statement that the individual may revoke the authorization in writing; |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Any exceptions to the right to revoke (e.g. researcher may continue to use and disclose, for research integrity and reporting purposes any PHI collected from the individual pursuant to such Authorization before it was revoked). |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | A statement that information disclosed under the Authorization could potentially be re-disclosed by the recipient and would no longer be protected under HIPAA. |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | A statement of the ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization by stating either stating the applicable conditions or the consequences to the individual for refusal to sign the authorization. |
| <input checked="" type="checkbox"/> | | All the above elements are present, HIPAA AUTHORIZATION document is APPROVED |
| <input type="checkbox"/> | | All the above elements are <u>not</u> present; HIPAA AUTHORIZATION document is NOT APPROVED |

Susan McCann
Designated UMCIRB Reviewer

6-5-09
Date

Principal Investigator: Present this signed form at the time PHI is requested from custodians of records. *By signing this document, I acknowledge and affirm that all enrolled subjects have signed a valid HIPAA Authorization Form.*

Principal Investigator

UMCIRB
APPROVED
FROM 6-5-09
TO no expiration

Date